



Handelshøyskolen BI

GRA 19703 Master Thesis

Thesis Master of Science 100% - W

Predefinert informasjon

Startdato:	16-01-2022 09:00	Termin:	202210
Sluttdato:	01-07-2022 12:00	Vurderingsform:	Norsk 6-trinns skala (A-F)
Eksamensform:	T		
Flowkode:	202210 10936 IN00 W T		
Intern sensor:	(Anonymisert)		

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Informasjon fra deltaker

Tittel *: How can Blockchain Technology be used to support SCRM in Drug Supply Chains?

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Inneholder besvarelsen Nei Kan besvarelsen Ja
konfidensielt offentliggjøres?:

Gruppe

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Master Thesis

**How can Blockchain Technology be used
to support Supply Chain Risk Management
in Drug Supply Chains?**



Hand-in date:
01.07.2022

Supervisor:
Marianne Jahre

Examination Code:
GRA 19703 Master Thesis

Program:
Master of Science in Business
Logistics, Operations and Supply Chain Management

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Abstract

Purpose – Drug shortages and drug counterfeiting continue to pose a severe threat to human health, both in low-income and high-income countries. Supply chain risk management is becoming more important in the fight against these two issues. New emerging technologies, such as blockchain technology, might offer new methods and tools to support supply chain risk management in that task. The use of blockchain technology in supply chain risk management is new, but also field with limited academic literature. Subsequently, the purpose of this master thesis was to explore how blockchain technology may support supply chain risk management in drug supply chains. Thus, the research objective of this study was to; (i) provide insights into how (practically) blockchain technology can be used to support supply chain risk management in drug supply chains, (ii) assess the value of using a blockchain in drug supply chains for supply chain risk management, and (iii) identify blockchain implementation barriers in drug supply chains.

Design/Methodology/Approach – A qualitative approach with an embedded case study design was followed. The case was a general drug supply chain. Both primary data, collected in semi-structured interviews, and secondary data, such as corporate records, were analyzed. A total of 14 interviews with institutional, blockchain, and drug supply chain professionals and experts were conducted.

Findings – The study shows that blockchain technology is of great value not just to supply chain management in general, but also to supply chain risk management. Risks related to counterfeiting, product integrity, and even drug shortages can be mitigated as supply chain transparency can be increased. Supply chain risk management may also be made more efficient, as risks are easier identified, the information flow facilitated, and supply chain risk management enabled to be more proactive. The findings, however, also show that blockchain technology is not a *silver bullet*, and the value of blockchain for a company is highly dependent on (i) the use case, with track and trace being the most attractive among the four identified use cases, and (ii) the specific company situation and business problem.

Nonetheless, the results show that the value of blockchain technology in drug supply chains is greater than in other supply chains as the value proposition is different; (i) drug supply chains decide about life or death, (ii) transparency in drug supply chains is lower than in other supply chains, and (iii) trust among drug supply

chain actors is especially low, making a blockchain solution even more valuable. However, there is currently no full-scale supply chain blockchain business case in drug supply chains up and running. The study identified 17 barriers that must be overcome to fully capitalize on the potential of blockchain technology in drug supply chains, ranging from a reluctance to share data and collaborate to technological barriers. As a result, the thesis team urges that additional research is conducted to confirm and expand the initial results in the field, and cross-disciplinary efforts are made to further detail the identified enablers as well as identify additional key success factors for blockchain deployment.

Finally, the findings suggest that blockchain technology in drug supply chains is unlikely to achieve a commercial breakthrough within the next one or two years. However, the study identified that the track and trace use case is of high value for supply chain risk management and that this, in the eyes of the thesis team, makes the long journey to overcome the identified implementation barriers worthwhile – worthwhile for the well-being of all patients, the end-customer of all drug supply chains, and our society as a whole.

Research Limitations/Implications – The most important limitations of this study are (i) a small sample size, which limits generalizability, (ii) findings that are not backed up by literature on all points, (iii) a strong industry focus, which limits generalizability to other industries, (iv) no distinction between supply chains of patented and generic drugs, and (v) practical implications that need to be detailed.

Originality/Value – This study is the first that focuses on the intersection of blockchain technology, supply chain risk management and drug supply chains and so is an important first step in bridging the existing literature gap. This study proved that, if used in the right use case, blockchain technology is highly valuable for supply chain risk management in drug supply chains. These initial findings also serve as a stepping stone for future research. However, more research in the area will be needed, to (i) validate and extend initial findings, (ii) further detail blockchain-enabled track and trace systems, and (iii) make identified blockchain enablers for blockchain deployment in drug supply chains more actionable.

Keywords – Supply chain risk management, Drug supply chains, Medical supply chains, Blockchain technology, Supply chain risks, Drug shortages, Counterfeits, Product integrity, Trust, Transparency, Provenance, Traceability, Track and trace

Acknowledgements

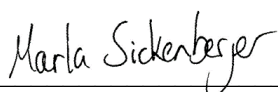
First and foremost, we owe our gratitude to Marianne Jahre, our supervisor at BI Norwegian Business School, for her unwavering support and inspirational lectures during our master's program. Without your constructive, honest, and encouraging feedback and support at all times, our work would not be where it is now. Thanks also for creating an easy and productive work environment, in which no question was *too stupid to ask* and for trusting us to choose a topic that was in parts new to all of us. We would also like to thank the other BI professors for their great lectures, lively discussions, and valuable insights. Further, we owe gratitude to our fellow students; the fellowship despite the pandemic has been wonderful.

We would also like to express our gratitude to all 14 research participants. The conversations were insightful, the discussions inspiring, and the laughs plentiful. Further, there would have been no answer to our research question, nor a complete master thesis, without your theoretical and practical expertise in blockchain technology, supply chain risk management, and drug supply chains. Your contribution has been invaluable.

A special gratitude we want to say to our families and good friends who have supported and motivated us at all stages during our thesis. Your cheering on the sideline, patience, and encouragement, particularly as we approached the finish line, have been priceless.

Writing this thesis has been one of, if not the most, difficult challenge of our bachelor's and master's studies and we could not have done that without each other. Therefore, we want to thank each other. Thank you, Amalie/Marla, for always being flexible, understanding, positive, and holding each other's back in a time with many challenges. Thanks for the *great teamwork, honesty, trust, and beautiful friendship*. We are excited and proud to submit our results, but we are even more grateful for the experience and lessons learned along the way.

BI Norwegian Business School, July 1st, 2022



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List of Abbreviations

AI – Artificial Intelligence
BC – Blockchain
BCT – Blockchain Technology
DB – Database
DSCSA – Drug Supply Chain Security Act
EEA – European Economic Area
EMA – European Medicines Agency
EU – European Union
FDA – Food & Drug Administration
FMCG – Fast-Moving Consumer Goods
FMD – Falsified Medicines Directive
GDPR – General Data Protection Regulation
GPS – Global Positioning System
HMA – Heads of Medicines Agencies
IoT – Internet of Things
IP – Intellectual Property
KSF – Key Success Factor
NSD – Norsk Senter for Forskningsdata
PoW – Proof of Work
P2P – Peer-to-Peer
RFID – Radio-frequency Identification
SC – Supply Chain
SCM – Supply Chain Management
SCRM – Supply Chain Risk Management
US – United States
WHO – World Health Organization
3PL – Third-Party Logistics Provider

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1.0 Introduction

This master thesis elaborates on the use of blockchain technology (BCT) in supply chain risk management (SCRM) with a focus on drug supply chains (SCs). The introduction introduces the thesis motivation, background, research question, as well as the research justification.

1.1 Motivation

Covid-19 disrupted global SCs in an unprecedented manner, causing shortages of critical pharmaceuticals such as cancer, heart disease, and even Covid-19 drugs (Reno, 2021). For example, by October 2021, as many as 100 different drugs were out of stock in the United States (US) due to SC disruptions (FDA, 2021a). The pandemic highlighted and amplified the problem of drug shortages, bringing it to the forefront of the news and our minds. However, the problem is not new; its old. And the problem is severe. Any SC interruption, no matter how small or large, normal or abnormal, can have a major impact on drug SCs and, as a result, human life. According to a European Union (EU) report on drug shortages, there is no substitute available for about 25% of all missing drugs (EU, 2021). As a result, it's not a surprise that the European Commission and the Food and Drug Administration (FDA) have declared the situation an urgent health crisis and a threat to patients' safety, care, and lives (EU, 2021; Strassmann, 2021).

As the pandemic brutally demonstrated, the industry is still in the process of identifying the root causes of shortages, developing countermeasures, and implementing solutions. The lack of transparency and traceability in drug SCs is certainly one factor impeding effective and timely proactive and reactive SCRM in drug SCs. To efficiently manage complex and costly drug SCs, it appears that knowing where the drugs are at all times is critical. What other way is there to ensure that the right medication reaches the right patient at the right time and in the right condition? However, today, that level of transparency is often not given.

Ahmad et al. (2021) claim that BCT could be one approach to improve drug SCs through decentralization, traceability, transparency, and security, as opposed to drug SCs that are today often centralized with limited traceability. Falasca et al. (2021) recommend using a combination of authentication technology, SC collaboration and BCT, to avoid counterfeiting and boost traceability in drug SCs. BCT, an emerging new technology, is frequently referred to in the literature as a

possible game changer in Supply Chain Management (SCM). Today, however, BCT use cases in drug SCs are very rare. The untapped value that BCT might offer to the industry as well as the severity of operational difficulties in drug SCs makes it crucial for researchers and practitioners, as well as the thesis team, to investigate BCT's potential to support SCRM. Furthermore, benefits, use cases, implementation barriers, and enablers of BCT in drug SCs must be identified.

1.2 Background

Drug SCs, providing vital services for society, are particularly difficult to govern as they span across multiple geographic and organizational boundaries. Moreover, as a special type of healthcare SCs, drug SCs are exposed to unique risks such as counterfeiting, transparency, on-time delivery, and maintaining optimal drug conditions (Musamih et al., 2021). The introduction of the Falsified Medicines Directive (FMD) in the EU and the European Economic Area (EEA) was one legislative initiative to address these challenges (European Parliament, 2011). The purpose of the legislation, as with any other measure implemented to decrease risk in drug supply chains, is to eliminate counterfeits in the market and thus to save lives. The FMD requires that prescription drugs must be checked for authenticity before being dispensed to the patient. The system, however, is not a full-fledged track and trace system. Furthermore, the legislation establishes regulations for physical product packaging as well as central data depositories. The FDA has introduced similar legislation in the US called the Drug Supply Chain Security Act (DSCSA) which seeks to identify and trace prescription drugs and detect fake drugs (FDA, 2016). Even though certain nations and regions have enacted new legislation to minimize counterfeits and promote transparency, both problems remain serious.

BCT is often referred to be a game changer when it comes to decreasing counterfeits and enhancing transparency. To most people BCT, however, is the technology that underpins the cryptocurrency Bitcoin. What is less well known is that BCT, since its beginnings in 2008, has seen significant technological advancement and has been applied in an increasing number of use cases, with healthcare and SCM being only two of the industries and sectors where BCT has taken hold. De Beers, for example, uses unique BC codes to verify the authenticity of diamonds on their path from mines to end users (Staff, 2018; Tracr, 2020). Besides applications in SCM, researchers point to several potential BCT benefits in healthcare, including (i) improved data security and privacy, (ii) transparency and trust, (iii) data

verifiability, (iv) robustness and resiliency of data, and (v) decentralized health data management giving all stakeholders equal access to health records (Agbo et al., 2019). It is no surprise that BCT is expected to have a substantial influence on the healthcare industry (Agbo et al., 2019). SC experts, according to Partida (2018), even believe that BCT will give firms a competitive advantage in the future.

BCT in healthcare has two broad application fields; (i) the physical drug SCs and (ii) service logistics. The physical drug SC denotes the flow of drugs from point A to point B. In this case, BCT may be utilized as a database (DB) to track drugs from the manufacturer of the active pharmaceutical ingredients (APIs) to the end user. Further, due to special encryption it is impossible to amend data once recorded on the BC, such as order or drug condition history. Both features make BCT a great potential instrument to increase transparency in a SC. In addition, information on the BC can be utilized to meet legal obligations. But BCT has another potential, special use case in drug SCs, compared to other SCs. The World Health Organization (WHO) estimates that 10% of all medical products in low- and middle-income countries are below standards or even falsified (WHO, 2018). BCT might have the potential to be a game changer here, since the technology allows for greater traceability and secure tracking in drug SCs, allowing for the detection of counterfeits before they reach patients (ConsenSys, 2021). Blockverify is an anti-counterfeit BC solution used to identify counterfeits in the pharmaceutical sector (Blockverify, 2016). A simple tag on each product allows pharmacies to validate the drug's legitimacy and trace back its history along the SC.

The second application field of BCT in healthcare is service logistics, which addresses the flow and management of information connected to patient data. Patient data might include information regarding a patient's current and past health, treatment, and insurance coverage. That sensitive data might be securely exchanged between the patient, doctors, pharmacies, and other stakeholders with the use of a BC. For instance, DIPS AS, a leading e-health system provider in Norway, employs BCT to manage patient data (DIPS 2021). Although both areas are important, we will concentrate our research on the use of BCT in physical drug SCs rather than service logistics. We do so to provide more thorough findings and because we believe physical SCs are a more interesting and relevant topic.

As the vulnerability of SCs escalates, SCRM with the goal to prevent or reduce SC

risks is of increasing importance (Norrman & Jansson, 2004). SCRM has also become increasingly important for pharma drug SCs as a result of increased globalization and more frequent disruptive events like natural disasters (Coppola, 2020). To meet these demands, the SCRM toolset must be updated, for example, by leveraging new technologies. In today's time, it is more important than ever to have full transparency of drug SCs and map SCs, including supplier, manufacturer, distributed and end user (Musamih et al., 2021). BCT might be a useful tool to aid SCM and SCRM in this work, and thus BCT is the focus of our thesis.

1.3 Research Area and Problem Statement

The overall objective of this master's thesis is to provide insight into how BCT may support SCRM. The pharmaceutical industry was chosen because of the aforementioned unique characteristics of drug SCs. SCRM was chosen as a focus topic within SCM, because it is the field within SCM that has as a key goal to ensure that drugs are at the right time in the right quantity and quality at the right place, in short, to prevent drug shortages. Furthermore, SCRM is becoming increasingly relevant today, not just as a result of Covid-19, but also because new technologies allow to expand the toolbox of SCRM. To assess the potential of BCT as a game changer in drug SCs, in-depth knowledge about BCT is key for our thesis. The use of BCT in SCM is covered in recent scholarly literature. However, the combination of BCT and SCRM is a subject largely devoid by academic literature and research.

Thus, we aim to investigate what benefits BCT could have for drug SCs, specifically how different a) SCRM activities, such as identifying or mitigating risks b) variables, such as transparency or security and c) SC risks, such as counterfeit or product integrity, are influenced using BCT. The lack of large-scale use cases of BCT in drug SCs, however, demonstrates that deploying BCT in drug SCs can be difficult. As a result, it is also critical to analyze and investigate the challenges and barriers of BCT implementation for various SC actors. Then, enablers and best practices can be identified, and recommendations can be made. Overall, today's academic and practical insights into the subject are insufficient. As a result, our master's thesis project seeks to provide a response to the research question:

“How can Blockchain Technology be used to support Supply Chain Risk Management in Drug Supply Chains?”

We have conducted an embedded case study, with various drug SCs as our case,

and collected primary data in semi-structured interviews to answer our research question. We interviewed experts within both BCT and drug SCs. Further, we want to emphasize that we approached our research question from two angles; First, we looked at the status quo of BCT in drug SCs and how existing use cases support SCRM. Second, we identified BC use cases that are more conceptual ideas than yet applied in practice, as well as their expected influence on SCRM.

1.4 Research Justification

To ensure the significance of the research, a research question needs to fulfil three requirements. The research question is (i) of general interest, with meaningful practical implications for key stakeholders, (ii) aims to add new insights to academic knowledge and (iii) is sustained by the researcher's personal motivation. In the following, we evaluate our research question along the three dimensions.

Practical Relevance

The purpose of a drug SC is to ensure drug availability, in other words, that drugs are available in sufficient quantity and quality at the right location and time. That task, however, is far from simple. Consequences of drug shortages or counterfeits are brutal; human life is jeopardized, or secondary health damages are risked, as the end user of any drug SC is a patient with unique needs. Drug SC customers are more vulnerable than other service customers (Betcheva et al., 2020). That is precisely what our work addresses. This thesis seeks to add practical value and assist relevant stakeholders by (i) providing an overview of what BCT is and how the technology works, (ii) providing insights into how BCT can improve SCRM in drug SCs, and thus benefit the pharma industry, and (iii) identifying barriers of BCT implementation and identifying enablers to address these challenges.

BCT has the potential to reform typical SCM tasks and urge practitioners to rethink how SCs are managed (Saber et al., 2019; Wang et al., 2019). Academic research predicts that different drug SC players, such as drug makers or transportation providers, may be able to increase the efficiency of their SCs or improve data security, traceability, and risk management (Wang et al., 2019). No question, BCT will transform SCM in the coming years. However, early adoption and the best possible use of BCT by all actors can only be ensured if practical research is done. We aim to contribute to that collaborative effort. Numerous scholars agree that BCT has a large untapped potential to improve drug SCs in practice (Alkhudary et al.,

2020; Francisco & Swanson, 2018; Kshetri, 2018; Saberi et al., 2019; Wang et al., 2019). Therefore, this thesis aims to provide insights into how BCT might be used and benefit drug SC actors. In addition, our thesis can add value to Non-Governmental Organizations and institutions that also have an interest to learn about new ways for reducing risk in drug SCs and ensuring a consistent supply of drugs to their customers or citizens.

We also seek to identify barriers to BCT implementation and adoption. This provides valuable insights to BCT experts and corporations, fostering mutual understanding and, ultimately, allowing BCT companies to address specific concerns of drug SC actors. Lastly, this thesis will ideally present various best practice examples of how BCT is applied in drug SCs, allowing us to formulate practical implications and recommendations that ensure the best possible use of BCT in SCRM. To summarize, securing a reliable supply of drugs is one of today's most pressing societal challenges - our thesis provides instant, practical value for stakeholders to address this life or death challenge.

Theoretical Contribution

To answer the research question, we will look into the three areas that comprise our research question; drug SCs, SCRM, and BCT, as well as their intersections. By connecting the three areas, we provide insights into an as-yet untapped academic field. It is fair to say that not only is BCT adoption in industries other than the financial industry in its early stage, but also BCT as a research area. Over the last ten years, there has been an increase in the academic literature on a variety of BCT-related themes, including BCT governance, adoption, and new business models. Furthermore, the use of BCT in SCM has received some attention in recent scientific literature. The majority of the research, however, has focused on the link between the BCT and SC visibility (Saberi et al., 2019; Wang et al., 2019). According to Alkhudary et al. (2020), the combination of BCT and SCRM is a field largely devoid of academic theory and research on BCT and SCRM is deemed limited, with minor publications. Thus, our thesis responds to that demand by studying the combination of BCT and SCRM. To conclude, our master's thesis seeks to add to theoretical knowledge in three ways. First, review earlier research in the three areas comprising our research question as well as their intersections. Second, contribute to the identified literature gap concerning BCT and SCRM by creating new insights in the form of a conceptual framework for how BCT might

support SCRM and identifying implementation barriers. Further, we hope that our findings will be partially generalizable to other industries or serve as a stepping stone. Third, incorporate our findings into current knowledge, therefore adding to the bigger picture and providing the basis for future research in the field.

Personal Interest

As outlined, our research question, like any good research question, is of practical relevance and aims to add to existing academic knowledge. However, this is not enough; there must also be personal motivation. According to Watson “*one has to locate a key issue which is fascinating enough to sustain the researcher's interest through the slog which is to come*” (1994, p. 79). Personal interest is a key prerequisite for completing a time-consuming research project. Therefore, we would like to emphasize two points; (i) as new technologies become more prevalent in our personal and professional lives, it is in our best interests to have a deeper understanding of them and critically reflect on them, and (ii) by focusing our efforts on the healthcare industry, we can assure that our time and efforts benefit not just the company’s bottom line or academic knowledge, but also, and most importantly, the well-being of our family, friends, and society as a whole.

1.5 Thesis Structure

Our master thesis is structured into seven chapters. Following the introduction, proposing a research question and briefly motivating the research topic, chapter two presents key literature identified in a narrative literature review. Relevant concepts and theories are highlighted. A theoretical framework is constructed based on the literature review in chapter three to guide the research design and concretize the desired research output. Chapter four outlines the author's methodological choices for answering the research question as well as documents the thesis team's research process. The data analysis and empirical findings are presented in chapter five. Chapter six covers the discussion of the findings and answers the research question. The last chapter draws a conclusion referring back to our research question and outlines practical and theoretical limitations, as well as research recommendations.

2.0 Literature Review

The literature review aims to specify what we want to write about by presenting theories, models and concepts academics have developed. To build a basis for our research, we have searched, read, and evaluated academic literature that is relevant

for the three areas (i) drug SCs, (ii) SCRM and (iii) BCT as well as the combination and intersection of the three fields (Figure 1). The 15 most important identified articles in the literature review are summarized in [Appendix 1](#).

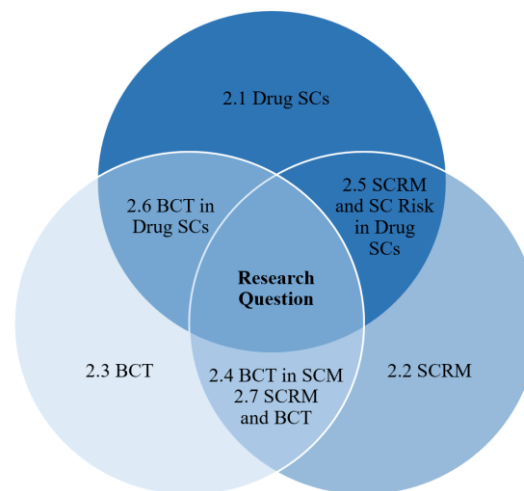


Figure 1. Structure of Literature Review

2.1 Drug SCs

As stated by Kapoor et al. (2018) there is limited research available when it comes to drug SCs. A drug or pharmaceutical SC, according to Mendoza (2021, p. 689), is “*the means through which prescription medicines are manufactured, stocked, and delivered to customers*”. In general, one can differentiate between two types of drugs; (i) patented drugs and (ii) generic drugs. Unlike patented drugs, which can only be manufactured by the company that holds the intellectual property rights, generic drugs can be manufactured by any company as long as they meet other regulatory requirements, as they are no longer protected by patents. However, as a patent on average last for 15 to 20 years, in most nations, the great majority of drugs today are generic. Drug SCs are distinctive in numerous ways: they bring together a vast range of actors and interests, operate in a highly regulated environment, and face specific transportation requirements.

2.1.1 Drug SC Actors

The five basic actors in a physical drug SCs are according to Mendoza (2021) (i) the *pharmaceutical companies*, who produce the drugs, (ii) the *wholesale distributors*, who purchase the drugs from the manufacturers and distribute them to pharmacies or hospitals, (iii) the *pharmacy benefit manager*, who work as manager and middlemen between manufacturers and insurer, negotiating with both parties to get the drug listed and to set its price, (iv) the *pharmacies*, where retailers decide

on the stock of drugs and provide information and safety about the drugs to consumers, and (v) the *consumers* such as patients, physician offices and hospitals, who purchase the drugs from the pharmacies. However, even though there is no fixed definition of where a drug SC officially starts, in most cases is desirable to also consider raw material and API suppliers, when talking about drug SCs. API suppliers supply the basic components that pharmaceutical companies require to manufacture the drug. Furthermore, Kapoor et al. (2018) emphasize the need to include public and government institutions, research organizations, and regulatory authorities as key stakeholders. Regulatory agencies such as the FDA and the European Patent Office are particularly important when a new medicine is introduced (Kapoor et al., 2018). A large number of stakeholders with their divergent interests make drug SCs very complex to manage and vulnerable to SC disruptions. In addition, often the more upstream the drug SC, the lower the level of transparency. As a result, the literature highlights the need for collaboration between all stakeholders to achieve high drug traceability, on-time delivery, counterfeit and bribery prevention, and safe drug storage and handling (Friday et al., 2017; O'Hagan & Garlington, 2018; Musamih, 2021).

2.1.2 Drug SC Characteristics

The literature review reveals that drug SCs differ significantly from other SCs in multiple dimensions. First and foremost, patients are the end-users of drug SCs and as their health and life are at stake, drug SC customers are more vulnerable than customers of other services (Betcheva et al., 2020). Another dimension is the vulnerability of the product itself, which necessitates specific transportation requirements. According to Musamih et al. (2021), some drugs require very specific conditions, such as a specific humidity and temperature, while shipped, distributed, and sold. Further, drug SCs are often global and span across boundaries, posing further complications. However, there is a lack of research on cold-chain management, drug tracking, and drug visibility, according to Dixit et al. (2019).

In addition, drug SCs differ from other SCs in that product shortages have serious repercussions. Not just in low-income countries, but also in high-income ones, drug shortages are a common phenomenon (EU, 2021). Academics emphasize that SCM and, in particular, SCRM insights, as well as validated SCRM practices, can help to reduce drug shortages (de Vries et al., 2021). However, our examination of the literature reveals that academic literature is scarce on the causes of drug shortages

and that identifying the causes of drug shortages is still often difficult or impossible (de Vries et al., 2021). In that context, disruptive SC events or situations are referred to as causes. Pandemics and other external events are examples of abnormal causes. Normal causes, such as demand changes, manufacturing problems, or distribution delays, happen on a more regular basis and usually originate inside the supply chain (Ho et al., 2015; Sodhi and Tang, 2012). SCRM strategies are further distinguished in academic literature along two dimensions; (i) who is taking action – a corporation or a policymaker, and (ii) whether measures are taken before or during the disruption (Ahlqvist et al., 2022; de Vries et al., 2021). Examples of government interventions that have a high potential to reduce drug shortages but still require more academic research and empirical insights, are; (i) establishing strategic stocks, (ii) nearshoring drug manufacturing, and (iii) revising pricing, tendering, and reimbursement practices (de Vries et al., 2021).

Furthermore, as the pharmaceutical industry is heavily regulated, drug SCs are subject to many regulations. As previously stated, EU/EEA countries must comply with the FMD, whereas the US must comply with the DSCSA (DSCSA, 2021). Both regulations strive to keep counterfeit drugs off the market. The goal is to safeguard customers from counterfeit, contaminated, or stolen drugs, as well as to detect and remove counterfeit drugs. High legal standards, such as the FMD or DSCSA, make drug SCs more trustworthy and counterfeits less probable (European Parliament, 2011). Nonetheless, the regulations place restrictions on operations. In countries where there are no particular laws, fraud and bribery are more widespread, increasing the likelihood of counterfeiting.

Finally, Betcheva et al. (2020) point out that, unlike other SCs, drug SCs rely on third-party financing and external decision-making, making them more vulnerable. Further, drug SCs are often characterized by a lack of transparency, inaccurate information, and lack of data provenance (Musamih et al., 2021). Musamih et al. (2021) emphasize the great need of mapping the different actors and the whole SC. Overall, the implementation of more advanced SCM practices is needed to achieve higher operational efficiency in drug SCs.

2.2 SCRM

2.2.1 SC Risk and SCRM Definition and Processes

Ho et al. (2015, p. 5035) define SC risk as “*the likelihood and impact of unexpected*

macro and/or micro-level events or conditions that adversely influence any part of a supply chain leading to operational, tactical, or strategic level failures or irregularities” and SCRM as “an inter-organizational collaborative endeavour utilizing quantitative and qualitative risk management methodologies to identify, evaluate, mitigate and monitor unexpected macro and micro-level events or conditions, which might adversely impact any part of a supply chain”.

As the vulnerability of SCs escalates, SCRM is becoming increasingly critical for many businesses, with any link in the SC potentially affecting all others. Sodhi and Tang (2012) propose the so-called *Butterfly Model* as a framework to analyze key risks. They emphasize four key activities in SCRM; (i) *identifying* risks, such as supply, demand, process, and corporate-level risks to determine local and global causes, (ii) *assessing* risks, to determine where a risk incident might occur, (iii) *mitigating* risks, by using well-founded and relevant strategies to reduce the likelihood or impact of the risks identified, and (iv) *responding* to risks. Furthermore, some experts suggest *recovery* to be another important SCRM activity. In addition to the four risk types proposed by Sodhi and Tang (2012), supply, demand, process and corporate level risk, Christopher et al. (2011) include environmental and sustainable risks in their framework on global sourcing risks. Moreover, there are macro risks to consider when assessing a company's SC risk, including natural disasters, wars, terrorism, political and regional instabilities, legislation, and social and cultural grievances (Ho et al., 2015).

Once all SC risks are identified, Sodhi and Tang (2012) suggest cataloguing them in a risk register. In the next step, scholars emphasize the necessity of prioritizing. The relative importance of a SC risk must be assessed, and a risk-mapping exercise must be performed (Choi et al., 2020; Norrman & Jansson, 2004). When all possible SC risk sources are mapped, the different risks should be categorized to distinguish between causes and effects, delays and disruptions, drivers and consequences and normal and abnormal risks (Sodhi & Tang, 2012). The underlying rationale is that by identifying and mapping risks, risk awareness increases, enabling and empowering proactive SCRM. In addition, Manuj and Mentzer (2008) believe that identifying possible losses that may occur from unforeseen events is key for successful risk mitigation. They also emphasize the need of having a risk mitigation strategy in place, which includes back-up service providers. As SCs get more globalized and complex, SC risks do as well, calling for new, innovative ways to

manage risks (Manuj & Mentzer, 2008). New technologies could be one way to address that challenge.

2.2.2 SC Collaboration and Transparency in SCRM

According to Mendoza (2021), the challenges and risks that drug SCs faced during the Covid-19 pandemic, and still face, must be better understood, assessed, and SCs reshaped accordingly to be more resilient in the future. In a multi-case study, Christopher et al. (2011), however, found that most firms lack a systematic SCRM and mitigation approach. Only a few companies adopted successful network-based strategies like agility, and network-based collaboration among global sourcing partners was entirely absent. The need for closer SC collaboration in SCRM is obvious, and many scholars agree (Christopher et al., 2011; Friday et al., 2017; Ho et al., 2015; Norrman & Jansson, 2004). The main reason for collaboration is, according to Christopher et al. (2011), that it benefits all stakeholders in a SC, including the end-consumer, and that they together create a better outcome than if they compete with each other. Moreover, Friday et al. (2017) explicitly state that companies will gain from implementing a holistic collaborative approach in SCRM. Hence, collaboration is the key to successful SCRM.

Besides SC collaboration, transparency plays an important role in SCRM. According to Bai and Sarkis (2020, p. 2145), “*transparency in a supply chain context, refers to information readily available to end-customers and companies within a supply chain*”. Covid-19 showed once again that organizations that were proactive in mapping their SC before the interruption had better SC transparency and hence knew exactly which SC links or products are at risk (Choi et al., 2020). Hence, companies that invest in SC transparency and traceability may successfully minimize SC risk while also performing a more efficient and resilient SCRM. Furthermore, a lack of SC transparency makes it difficult to validate product information such as origin and ingredients, which makes SCRM actions such as product recalls more difficult (Chang et al., 2020). Chang et al. (2020) propose the usage of BCT as a possible solution to support SCRM and increase transparency.

2.3 BCT

BCT is a new technology that is still in its early stages. Clarke's words perfectly describe the hype around BCT; “*Any sufficiently advanced technology is indistinguishable from magic*” (Clarke, 1977, p. 39). However, by definition, magic

is something we do not understand. As a result, it is in both the researcher's and the reader's best interests to develop a comprehensive understanding of how BCT works before focusing on its use in SCM (chapter 2.4). Chapter 2.3, therefore, explains key terms that comprise the functioning of a BC, as well as the key properties of the BCT and its different BC types and use cases. Due to the thesis's page constraint, the thesis team included a short overview of the history of BCT ([Appendix 2](#)) and a detailed description of the functionality of BCT ([Appendix 3](#)) in the appendix.

2.3.1 Definition

BCT is a peer-to-peer (P2P) distributed ledger technology (Zheng et al., 2018). The basic idea of BCT is that a community of users can document and track transactions using a distributed DB, also called a ledger, in which no transaction can be altered once it is published. A universally accepted definition of BCT has not yet been codified in the literature. Different definitions emphasize different characteristics of BCT. For example, Zheng et al. (2018, p. 354) define BCT as “*a public ledger, in which all committed transactions are stored in a chain of blocks*”, highlighting a BC's transparency properties. Seebacher and Schüritz (2017, p. 14) emphasize the distributed, decentralized nature of a BC by defining a BC as a “*database, which is shared among and agreed upon a peer-to-peer network*”. Before providing a short introduction to the BCT architecture, and explaining how a BC works, it is necessary to define some basic terminology.

BCT vs. Distributed Ledger Technology

The terms distributed ledger technology and BCT are sometimes used interchangeably. But that is incorrect; there are important differences. Both terms are explained in detail in [Appendix 4](#).

2.3.2 Functionality

To understand the unique properties of a BC and all potential use cases, a basic understanding of the BCT architecture and how a BC works is of crucial importance for someone new to the field. Scholars describe BC's architecture or infrastructures in layers or interconnected mechanisms. Lu (2019) differentiates between six layers of a BC; data, network, consensus, contract, service, and application layer. Each layer is associated with various components and mechanisms that, when combined, provide the functionality of the BC. Lu's framework serves as a framework for

explaining how a BC works and is explained in detail in [Appendix 3](#).

2.3.3 Characteristics

Based on the developed understanding of how BCT works, the fundamental properties of the BCT can be examined. In a structured review of peer-reviewed literature, Seebacher and Schüritz (2017) identify a distinct set of eight key BCT characteristics. All characteristics are intertwined and reinforce one another (Figure 2). Trust and decentralization are recognized as the two principal characteristics of BCT in the scientific literature (Seebacher & Schüritz, 2017).

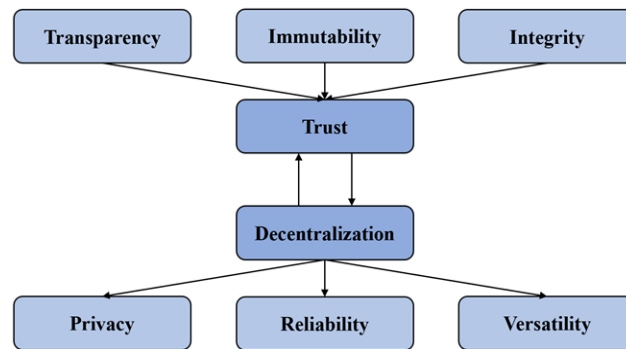


Figure 2. BC Characteristics according to Seebacher and Schüritz, 2017

Trust

Participants in traditional business networks that do not trust each other require the help of a third party, an intermediary, who is trusted by all parties, to engage in transactions (Lu, 2019). Trust in a BC network, on the other hand, is established through trust in the system, the BC, itself, which ensures information integrity inside the BC (Francisco & Swanson, 2018; Lu, 2019; Swan, 2015). BCT's trust-enabling notion is backed and established by various BC characteristics such as transparency, integrity, and immutability of data, all of which are linked to the BC architecture and outlined in the following (Seebacher & Schüritz, 2017).

Transparency - Transparency is attained by a “*shared and public view on occurring transactions throughout the peer-to-peer network*” (Seebacher & Schüritz, 2017, p. 15). All participants keep synchronized copies of the BC, which results in great data accessibility and a shared, transparent view of all shared data (Niranjanamurthy et al., 2019; Swan, 2015). Furthermore, the encryption used in BCs allows participants to keep track of every transaction and “*enables the traceability and precise positioning of blockchain data*” (Yuan & Wang, 2016, p. 2665).

Immutability - Data immutability is a key property of BCs that causes high trust in

the BCT (Abeyratne & Monfared, 2016; Casino et al., 2019; Zheng et al., 2017). A transaction published to the BC cannot be modified. Cryptographic hashing and the consensus mechanism, as outlined in [Appendix 3](#), are the underlying mechanisms that ensure such property. Cryptographic hashing ensures that if data in a block is changed, the hash in the next block no longer matches. The consensus process ensures that one would need to control 51% of the nodes, to approve changes in the BC, which is practically impossible. Furthermore, all transactions are stored on various nodes of the distributed network. As a result, users are assured of the “*highest degree of confidence that the chain of data is unaltered and accurate*” (Abeyratne & Monfared, 2016, p. 3).

Integrity - The integrity of data, also referred to as credibility, is a property that is closely related to the property of immutability (Lu, 2019; Seebacher & Schürütz, 2017). Because data cannot be altered in the aftermath, there is only one version of the BC that is shared across the distributed network and a single source of truth at all times (Francisco & Swanson, 2018; Natarajan et al., 2017).

Decentralization

Decentralization is BCs other principal characteristic. The decentralization feature of a BC has two aspects; first, because the BC is distributed throughout a network of nodes, each node holds a copy of the BC. Second, rather than being controlled by a single central authority, such as a bank or government, the P2P network uses a decentralized consensus process to determine what information is added to the BC (Natarajan et al., 2017). This characteristic eliminates the need for a trusted third party to validate transactions (Seebacher & Schürütz, 2017; Zheng et al., 2017).

According to Seebacher and Schürütz (2017, p. 15) “*decentralization facilitates the creation of a private, reliable and versatile environment*”. According to Nakamoto (2008), anonymous public keys, a cryptographic feature used in BCs, ensure a node's anonymity. But academics controversially discussed that statement. Some scholars argue that there is no true anonymity, just pseudonymity, as pseudonyms may be tracked back to IP address (Hurlburt, 2016; Zheng et al., 2018). However, as identities are covered by pseudonyms, a high degree of privacy is ensured (Hull et al., 2016; Lu, 2019). Decentralization promotes a reliable environment because (i) information is kept throughout the network rather than at a single point and (ii) smart contracts can automate processes, reducing human mistakes and biases (Guo

& Liang, 2016). Lastly, decentralization creates a versatile environment, in which participants may actively participate in the development of the BC structure.

Trust and Decentralization

Trust and decentralization reinforce each other (Seebacher and Schüritz, 2017). Transparency, integrity, and immutability, as well as trust in the BCT, are necessary to construct a decentralized network in which transactions can take place without the intervention of a trusted third party. In turn, decentralization motivates users to engage in the BC network, allowing the consensus mechanism to function and replacing trust in a third party with trust in the BC itself.

2.3.4 BC Types

As BCT has evolved, different types of BC architectures with distinct properties have emerged. BCs may be classified in two dimensions (Figure 3); first, a BC can be categorized as public or private depending on whether the ledgers can be accessed by anyone or only by a trusted group of network participants (Natarajan et al., 2017). It is vital to note that not all data in a public BC is public, but the platform is open to everybody to join. Second, a BC, as a type of distributed ledger, can be categorized as permissioned or permissionless, depending on whether nodes require permission from any central entity or consortium to make modifications to the BC (Azzi et al., 2019; Natarajan et al., 2017). The second quadrant is inapplicable since a BC cannot be open for everyone to make modifications (permissionless) when access is restricted (private). Scientific literature distinguishes three BC types, which may be assigned to the matrix's quadrants (Buterin, 2015; Lu, 2019; Zheng et al., 2017). The three different BC types are described in detail in [Appendix 5](#).

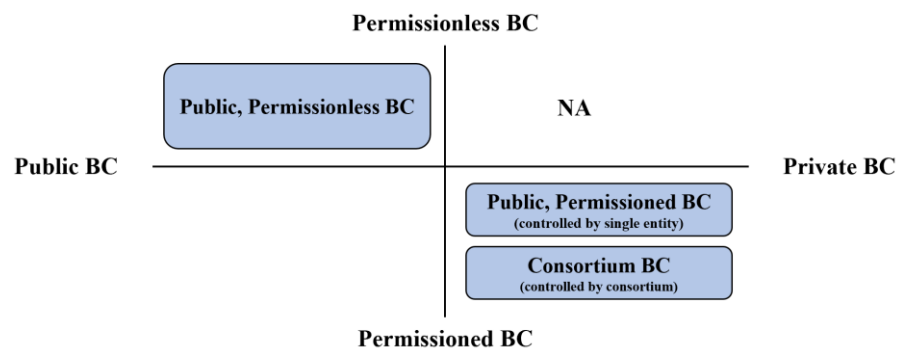


Figure 3. Types of Blockchains

All properties outlined in chapter 2.3.3 apply to a public, permissionless BC. Zheng et al. (2017) describe the differences between the three BC types (Table 1). The

application layer and the desired functionality decide the optimal BC. According to Kshetri, (2017), the choice is influenced by the number of participants, the asset value, and the importance of authorizing nodes with varying credentials.

Property	Public, permissionless BC	Consortium BC	Private, Permissioned BC
Census determination	All miners	Selected set of nodes	One organization
Read permission	Public	Could be public or restricted	Could be public or restricted
Immutability	Nearly impossible to tamper	Could be tampered	Could be tampered
Efficiency	Low	High	High
Centralized	No	Yes	Partial
Consensus process	Permissionless	Permissioned	Permissioned

Table 1. Properties of BC Types according to Zheng et al., 2017

2.3.5 Use Cases

Most people nowadays associate BCT with the technology that powers cryptocurrency. However, cryptocurrencies were only the beginning of the BCT hype. Tapscott and Tapscott (2018, p. 76) define BCT as a technology that “*can be programmed to record virtually everything of value and importance to humankind*”. The BCT’s distinct properties have the potential to assist businesses in a wide range of industries, and technological innovations are projected to provide even more use cases, resulting in new business opportunities. Hughes et al. (2019) mention just a few domains, where BCT can be applied beneficial, such as accounting and assurance, peer review, voting, and transport and logistics. Another often mentioned use in the literature is the verification of digital signatures. SCM has been highlighted as a high potential sector in numerous studies of BC application areas (Hughes et al., 2019). Scholars even assert that the numerous uses of BCT in SCM have the potential to provide organizations with a competitive advantage in the future (Alkhudary et al., 2020; Francisco & Swanson, 2018). As a result, the following three chapters, chapters 2.4, 2.6 and 2.7, will investigate BCT and SCM, BCT in drug SCs, and BCT and SCRM.

2.4 BCT in SCM

Practical and successful use cases of BCT in SCM are rare, and adoption rates are low (Queiroz & Fosso Wamba, 2019). Most BCT deployment projects in SCM are still in the pilot stage “*with no evidence of large-scale adoption within the SC*” (Wang et al., 2019, p. 65). Widespread adoption could take decades. However, in

recent years, academic research on BCT in SCM has gained traction, providing new insights into advanced BCT use cases. Nonetheless, studies that provide a comprehensive cost-benefit analysis or a ranking of different BCT use cases in SCM, as well as insights backed up by empirical evidence and case studies, are still sparse. According to Hald and Kinra (2019), the literature on BC in SCM lacks theoretical foundation and substance. Overall, most researchers agree that the technology has the potential to cause a paradigm shift and massive disruptions in SCM, but they also point out several challenges (Alkhudary et al., 2020; Francisco & Swanson, 2018; Kshetri, 2018; Saberi et al., 2019; Wang et al., 2019). Some critical voices, contrary believe that BCT is overhyped. This chapter examines academic research on (i) how to incorporate BCT in SCs, (ii) what BCT use cases exist in SCM, and (iii) what are identified adoption barriers.

2.4.1 BCT Integration in SCs

Saberi et al. (2019) claim that SCs will need to undergo significant change to realize the benefits of BC. Which changes are required, and what are key success factors (KSFs)? How such a transformation might look like, and which actors are crucial to involve are outlined in detail in [Appendix 6](#).

2.4.2 BCT Use Cases and Value Drivers in SCM

BCT has a wide range of use cases in SCM, which have been extensively researched over the past five years. BCT's value to SCM is closely linked to its use cases and the literature rarely distinguishes between value drivers, use cases, and benefits. Through a systematic review of academic literature, Wang et al. (2019) provide a good, if not exhaustive, overview of BCT's potential use cases in SCM. BCT might provide significant value to SCM through; (i) extended transparency and traceability, (ii) SC digitalization and disintermediation, (iii) improved data security and (iv) smart contracts (Wang et al., 2019). In the following, this framework will be used to present the findings of important scholars in the field.

Extended Transparency and Traceability

When reviewing the literature on BCT's use in SCM, the most frequently cited and discussed benefit of BCT for SCM is the increased transparency and traceability, which allows for enhanced product traceability (Chang et al., 2019; Saberi et al., 2019; Wang et al., 2019). Wang et al. (2019, p. 71) predict that “*product traceability will likely be the point at which the blockchain sees large-scale*

deployment". Increased transparency and traceability, according to the literature, will mostly benefit complex, multi-tiered SCs that operate in a highly regulated environment, since those SCs require a greater level of visibility.

Scholars agree that by combining BCT with the Internet of Things (IoT), the value of BCT for SCM could be even higher and enhance information and product flow (Hackius & Petersen, 2017; Kumar et al., 2021; Tijan et al., 2019; Zheng et al., 2017). When BCT and IoT are combined, timestamping allows for real-time tracking (Wang et al., 2019). The IoT is a system of interconnected devices that can interact and be monitored remotely. By adding sensors to assets like radio-frequency identification (RFID) or Global Positioning System (GPS) tags, the IoT may be used to track asset location, temperature, and other product-specific data. The transmitted sensor data can then be registered, verified, and stored on the BC. Changes in ownership, SC actors engaged, origin, authenticity, or environmental data, such as a shipment's energy use, might all be documented (Abeyratne & Monfared, 2016). Thus, the BC creates a decentralized and immutable record detailing the who, when, and where of a shipment's journey - a product's digital footprint. As a result, the BC serves as a single source of truth for all SC actors, increasing product visibility and allowing for better product traceability.

Enhanced end-to-end SC visibility and transparency not only improve product traceability but are also tied to an SC's general performance and, in particular, SCRM. Furthermore, customers today place a high value on the production and distribution information of a product (Francisco & Swanson, 2018). Customers, for instance, increasingly demand proof that fish is not caught using illegal netting practices. According to Francisco and Swanson (2018), meeting this demand with today's SCM tools is costly and difficult. BCT is expected to address all these issues, according to academics. Some of the benefits of increased SC visibility achieved by deploying BCT in SCM will be discussed in the following.

Tracking - A benefit of employing BCT in SCM that is widely noted in academic literature is improved product traceability, enabled through increased SC visibility (Chang et al., 2019; Hald & Kinra, 2019; Wang et al., 2019). SC actors can track the location and status of their shipments in real-time. Because data stored in the BC is immutable, SC actors can be assured of the data's credibility and authenticity. Hence, the BCT's properties are perfect to develop traceability systems such as BC-

based tracking systems (Francisco & Swanson, 2018; Tian, 2017).

Product Provenance - One of the most frequently studied use cases of BCT in SCM is enhanced product provenance due to the increased traceability (Cole et al., 2019; Kshetri, 2018; Lu, 2019; Wang et al., 2019). As every transaction on a BC is fully auditable, BC data can be used to locate the origin of a product or the production side of ingredients (Tian, 2017). End customers, authorities, and other SC parties can be provided with verifiable and immutable records of product provenance in the form of digital certificates (Chang et al., 2019). It is therefore made possible to track an asset all the way back to its origin. Furthermore, by using tokens, BCT allows each individual product to be tracked rather than a palette or box of items. “A token is a representation of a digital asset”, and each token is tied to a unique physical asset (Natarajan et al., 2017, p. iv). If an asset is delivered, the recipient can use the BC data to validate the token, and thereby verify the item's authenticity and origin (Francisco & Swanson, 2018). The BCT ensures that no SC actor can alter the data, hence improving product safety and quality.

Advantages of Improved Tracking and Product Provenance - The benefits of improved traceability and product provenance through the use of BCT in SCM are many and well-documented in the literature. We have compiled a summary of the most important advantages in Table 2.

Advantage	Advantage Description
Commercial Benefits	Commercial benefits, such as increased willingness to pay a higher price, consumer loyalty, and trust in the product and brand as a result of transparent product origin and shipment information (Abeyratne & Monfared, 2016; Cole et al., 2019; Laaper et al., 2017; Wang et al., 2019).
Efficient Recalls	More efficiently, and less expensive product recalls (Cole et al., 2019; Kshetri, 2018; Saberi et al., 2019, 2019; Tian, 2017; Wang et al., 2019)
Cost Savings	Cost savings result from faster and more accurate data sharing, and schedule optimization (Laaper et al., 2017; Seebacher & Schüritz, 2017).
Product Integrity	Higher product safety and quality through better traceability (Azzi et al., 2019).
Reduction of Counterfeit Products	When goods and documentation move from one SC to another, they are subject to counterfeiting or theft. Counterfeit items in a BC-enabled SC can be caught and hence reduced due to better SC visibility and product authenticity (Cole et al., 2019; Wang et al., 2019). This might be critical for food, luxury goods and drug SCs. Revenue losses and health risks from black or grey market items can be reduced.
Improved	Today's firms must comply with a plethora of regulations, including

Compliance	product safety, and social and environmental responsibilities (Chang et al., 2020). Failure to comply with these rules might have serious regulatory or reputational ramifications. BC-enabled traceability systems enable businesses to provide adequate proof of compliance to authorities and product conformity could be improved (Chang et al., 2020). Besides businesses, governments and other authorities can benefit from BC-based traceability systems. Regulators, like other SC members, might be BC nodes with access to the BC system (Tian, 2017). The data stored on the BC, such as the origin and treatments of products, may then be verified, audited, and compliances checked (Tian, 2017).
Increased Trust	Increased trust and curbed opportunism among strategic partners of a SC, through the BCs immutability (Chang et al., 2020; Schnellbacher & Weise, 2020; Wang et al., 2019).

Table 2. Advantages of Improved Traceability and Product Provenance

According to Wang et al. (2019, p. 72), the food, diamond, and pharmaceutical industries may benefit the most from the BCT since they “*carry a sense of urgency for reliable traceability and product provenance*”. For example, Tian (2017) combines RFID and BC to develop a traceability system for agri-food SCs.

SC Digitalization and Disintermediation

Deploying BCT in SCM allows to digitize paper-based documentation and “*establish an immutable, shared record of all transactions among network participants*” (Wang et al., 2019, p. 72). Hence, processes can be speeded up and the risk of lost and manipulated documents reduced (Francisco & Swanson, 2018; Wang et al., 2019). It's also possible to employ BCT to decentralize administration. Because of the distributed consensus process, the need for a centralized authority can be reduced, if not removed (Cole et al., 2019). Intermediary functions like transaction validation, contracting, and payment setup are subsequently taken up by BC nodes, SC actors, or the general public. Transparency and immutability, two BC properties, enable the change. Researchers believe that removing intermediaries in BC-based SCs can result in (i) enhanced SC interaction, (ii) reduced global SC complexity, (iii) reduced corruption, and (iv) lower transaction costs (Abeyratne & Monfared, 2016; Min, 2019; Wang et al., 2019) Intermediaries in freight forwarding, customer clearing, and fourth-party logistics services may be phased out (Wang et al., 2019). While BCT may make certain SCM actors obsolete, Treiblmaier (2019) contends that it also offers the chance to develop new business models or extend the service offerings of existing SC players.

Improved Data Security

Information stored in a centralized DB can be corrupted (Tian, 2017). Data saved in a BC, on the other hand, is immutable and secure against fraud and cybercrime (Abeyratne & Monfared, 2016; Wang et al., 2019; Zheng et al., 2017). Actors in a BC-enabled SC could encrypt sensitive data and control access to it (Zheng et al., 2017). Hence, BCT can improve data security, which is critical in SCM as transactions frequently contain sensitive business data (Azzi et al., 2019; Francisco & Swanson, 2018; Wang et al., 2019). Data in a BC is of high quality, according to Niranjnamurthy et al. (2019) because of its completeness, consistency, timeliness, accuracy and wide availability. Ultimately, Wang et al. (2019, p. 72) argue that “*increased data security would lead to increased confidence and trust of transactions between supply chain partners and end-consumers*”.

Smart Contracts

Smart contracts have the potential to automate many SC processes (Lu, 2019). Smart contracts are digital, self-executing contracts that may be designed to automatically execute the terms and conditions of a contract upon a BC (Morabito, 2017; Wang et al., 2019). The delivery of a product is a simple example; when the buyer registers the delivery of a product in the BC, a smart contract immediately transmits the money. The benefits of smart contracts in SCM are; that processes can be automated, speeded up, costs reduced and because a BC is distributed, a single SC actor cannot force the contract to be executed; instead, the contract is only executed when all criteria are satisfied (Niranjnamurthy et al., 2019; Swan, 2015; Wang et al., 2019). Furthermore, Omar et al. (2021) show that the use of smart contracts to automate the complex purchasing process in healthcare SCs promotes transparency, and data provenance, and is economically feasible. Scholars caution, however, that the use of smart contracts profoundly alters SC structures and governance, and that it might take decades for smart contracts to become the standard in SCM (Wang et al., 2019).

Other BCT Use Cases in SCM

The deployment of BCT is also discussed in relation to other SCM fields, such as (i) SC Finance (Min, 2019), (ii) Purchasing (Schnellbacher & Weise, 2020; Tönnissen & Teuteberg, 2018) and (iii) Sustainable SCM, where academics focus on the potential of BCT to enforce sustainability standards in developing countries or the concept of circular economy (Cole et al., 2019; Kshetri, 2021; Nandi et al., 2021). These fields, however, only play a secondary role in our research.

2.4.3 Barriers BC Deployment in Drug SCs

Aside from the numerous identified use cases of BCT in SCM, researchers outline several challenges and barriers that may limit the impact of BCT in SCM. The fact that only a handful of companies employ BCT in their SCM processes underscores the fact that both academics and SC practitioners are unsure about BCT's true potential in SCM. Academics emphasize that despite the growing interest in BC's use in SCM, there remain major concerns and challenges towards organizational adoption. Companies, together with their SC partners, must recognize and understand these challenges, according to Saberi et al. (2019). Saberi et al. (2019) and Lohmer and Lasch (2020) developed a framework to classify the barriers to BCT implementation and adoption in SCs into four categories; (i) intra-organizational, (ii) inter-organizational, (iii) system-related, and (iv) external barriers. While some barriers are unique to SCM, others apply to all BCT use cases. The most discussed barriers will be reviewed in the following.

Intra-organizational Barriers

Intra-organizational hurdles, according to Saberi et al. (2019), are related to internal organizational activities and an insufficient organizational environment. Identified barriers on an individual level are related to personal reluctance, often driven by the fear of losing one's job or of cultural and procedural change (Hald & Kinra, 2019; Wang et al., 2019), or a lack of technical know-how and capacities (Saberi et al., 2019; Wang et al., 2019). Furthermore, Kamble et al. (2019) discovered that people's perceptions of the technology's use, attitudes toward change, and subjective norms all have an impact on their intention to use BC-based solutions. Scholars also have identified barriers that are specific to an organization. Examples include; (i) a high upfront investment with a long pay-back period (Saberi et al., 2019), (ii) a lack of top management awareness and commitment (Lohmer & Lasch, 2020; Saberi et al., 2019), (iii) the fear of losing an existing revenue stream (Wang et al., 2019) and (iv) the difficulty in effectively communicating provenance information to customers (Montecchi et al., 2019). Furthermore, according to a survey done by Hackius and Petersen (2017), the benefits of BCT in logistics are unclear to 40% of respondents, indicating a lack of best-practice examples.

Inter-organizational Barriers

Inter-organizational barriers refer to barriers related to the collaboration of different SC actors. Challenges mentioned in the literature are related to either a lack of (i)

SC collaboration or (ii) standardization (Lohmer & Lasch, 2020; Saberi et al., 2019). One of the key problems of BCT in SCM is getting every relevant SC actor to join the BC network and share information utilizing the BC (Kshetri, 2018). Hackius and Petersen (2017) even found that getting “*different parties joining forces*” is the second most recognized obstacle to BC implementation in the logistics industry. Interestingly, Kshetri (2018) found that SCs in industries with a small number of suppliers had a significantly higher adoption rate. In addition, the reluctance to share information with SC partners may hinder the successful implementation of BC in SCM (Saberi et al., 2019; Wang et al., 2019). BCT allows companies to share data efficiently, however, companies often store data in different formats. That makes system integration difficult and prevents BC participants from cooperating efficiently. Moreover, Seebacher and Schüritz (2017) state that industry data standards, such as data sharing norms and procedures, are necessary for assuring data transfers between firms, but are often missing.

System-related Barriers

The system-related barriers, also known as technological barriers, are diverse and are not always SCM-specific. Nonetheless, in a survey conducted by Hackius & Petersen (2017), 49% of respondents noted a lack of technological maturity as a barrier to BCT implementation in logistics. Why? Technological challenges and, hence, barriers can be grouped into four primary themes; (i) integration, (ii) capacity and scalability, (iii) security and (iv) resources. Some of the most often raised issues and concerns are summarized in Table 3. However, as our master thesis does not focus on the technical aspects the chapter is kept short.

Barrier	Barrier Description
Integration	Implementing BC-based solutions requires companies to link diverse IT- and ERP systems and people to exchange and share data. The interoperability between different IT- and ERP systems is a challenge within organizations and between different entities.
Capacity and Scalability	In comparison to centralized DBs, BCT is frequently criticized for its restricted throughput capacity, which results in low processing speed and latency, as well as limited storage capacity (Chang et al., 2019; Saberi et al., 2019; Tijan et al., 2019). These factors limit BCT's scalability. Moreover, as the BC grows in size with each transaction, the cost increases and the processing speed decreases.
Security	Scholars frequently raise security concerns for a variety of reasons. Security concerns related to the guarantee of pseudonymity, physical

	product tampering, a hostile majority – or minority attack (51% attacks) and data integrity (Kshetri, 2018; Wang et al., 2019; Yuan & Wang, 2016). Details are beyond the scope of our thesis.
Resources	The resources required to run BC-based solutions are another aspect that may limit BCT's efficiency in SCM. Running a blockchain-based network that validates thousands of transactions per second consumes a lot of energy (Niranjanamurthy et al., 2019). The energy requirements have a significant environmental impact and must be financed (Cole et al., 2019; Wang et al., 2019). In addition, hardware must be purchased, and installation and maintenance costs covered.

Table 3. System-related Barriers

External Barriers

The category of external barriers summarizes barriers related to external stakeholders, such as industries, institutions, and governments (Lohmer & Lasch, 2020; Saberi et al., 2019). The literature points to two key roadblocks; (i) a lack of legislation governing the use of BCT, and (ii) a lack of technical BC standards. According to Hackius & Petersen (2017), regulatory uncertainties are the largest perceived barrier to BC adoption in the logistics industry. As a newly emerging technology BCT faces a *law leg*, which means that rules have not yet been developed for or adjusted to the technology, nor have they been standardized across countries (Niranjanamurthy et al., 2019). Scholars claim that the *law leg* leaves SC actors with significant uncertainty (Tijan et al., 2019). The literature indicates that the use of BCT in SCM in relation to data protection, compliance, general data protection regulations (GDPR), tokenization, as well as importer and exporter disclosure obligations, requires immediate legislative guidance (Upadhyay, 2020). Scholars across the board call for the development of a worldwide consistent legislative framework to resolve the current uncertainties surrounding the use of BC, but acknowledge the difficulties (Lohmer & Lasch, 2020; Niranjanamurthy et al., 2019; Saberi et al., 2019). Lichtenstein is a rare, good example of a country that proactively set a clear framework for BC usage. Furthermore, researchers urge the development of commonly agreed-on technical standards to minimize data format discrepancies and compatibility problems between SC actors (Tijan et al., 2019).

2.5 SCRM and SC Risk in Drug SCs

2.5.1 SCRM in Drug SCs

Overall, academic literature calls for more research on effective SCRM measures and strategies in drug SCs backed up by empirical findings (Ahlqvist et al., 2022;

de Vries et al., 2021). Senna et al. (2021) found in an extensive literature review that there is a lack of empirical studies concerning SCRM in healthcare and drug SCs. The limited relevant literature found by the thesis team on the topic is presented in the following.

In general, SCRM refers to “*supply chain solutions that ensure supply continues to meet the demand in case of a disruption or soon after the occurrence of such a disruption*”, according to Sodhi and Tang (2012, p. 304). They structure SCRM into four activities; (i) identifying risk, (ii) assessing risk, (iii) mitigating risk, and (iv) responding to risk. Hopp et al. (2022), further, suggests distinguishing between preparedness, reducing consequences, and mitigation SCRM strategies, reducing occurrence. Academics stress that to be able to mitigate risk, especially in drug SCs, it is crucial to identify risks such as counterfeit risk or risks of improper drug conditions as early on as possible (Musamih et al., 2021; Sodhi & Tang, 2012). Moreover, it is helpful to perform a risk mapping to then perform a proactive SCRM in drug SCs (Choi et al., 2020; Norrman & Jansson, 2004; Senna et al., 2021). Bishara et al. (2020) emphasize the complex global, temperature-sensitive drug SCs, and call for a more complete, accurate mapping process to identify all entities handling a drug on its way to the end customer. As stated by Enyinda et al. (2010), to manage and mitigate risks effectively companies need to rank and prioritize risk, which is challenging in drug SCs.

Besides a structured SCRM process, literature is highlighting the importance of collaboration for an efficient SCRM. Some academics even consider SC collaboration as a standalone strategy (Ho et al., 2015). Also, the WHO (2017) strongly encourages its member countries to collaborate to fight substandard and falsified drugs, make drug SCs safer and reduce socioeconomic costs and damage to health. Falasca et al. (2021) highlight the importance of collaboration within drug SCs and encourage the use of BCT to increase traceability, hence, tracking the drug's location at all times. Yaroson et al. (2021), further, proposed two SCRM strategies for drug SCs, both building on a collaborative approach: recovery, requiring cooperative decision-making and flexibility, and resistance, requiring to pool resources. Chitre et al. (2019), further emphasize that drug SCs become more vulnerable to infiltration of counterfeit drugs when there is a lack of collaboration. As drug SCs differ from other SCs largely because the vulnerability of human

health; well-being and life are at stake, SCRM is even more important in these SCs than in others (Betcheva et al., 2020). Covid-19 caused drug SC disruptions, showing that drug SCs are on a large scale. Without any doubt, Covid-19 has been the largest test to SCRM strategies and practices in drug SCs implemented ahead of Covid-19 in recent years. But not only did Covid-19 test the SCRM strategies in place, but it also required drug SC actors to take new measures and adjust existing SCRM strategies. Research has discovered that SCRM strategies implemented before a disruption or during a disruption are not necessarily different but are imposed to achieve a different goal (Ahlqvist et al., 2022).

The role of public decision-makers in SCRM is increasingly being recognized in academic literature, as they are identified as having a critical role in preparing for and responding to disruptions (Ahlqvist et al., 2022; Ho et al., 2015). Policymakers can either leverage their position to incentivize drug SC actors to adopt certain SCRM preparedness and mitigation actions, or they can take active measures themselves, such as establishing drug safety stocks (Ahlqvist et al., 2022). Scholars however point out that good policymakers' interventions are not always straightforward to identify since (i) drug SCs are often global, involving a variety of policymakers, (ii) SC transparency is low, making interventions more challenging, and (iii) the industry is highly regulated. In a multiple case study, assessing the paracetamol SC in seven countries, researchers, however, found that policymakers did adopt a variety of successful SCRM strategies – during Covid-19, with an emphasis on collaborative strategies, but also, though to a lesser extent, before the pandemic (Ahlqvist et al., 2022). The study also found that during abnormal times, such as Covid-19, policymakers (i) intensified established SCRM strategies, (ii) adopted new strategies or (iii) implement pre-pandemic prepared strategies (Ahlqvist et al., 2022). Nevertheless, literature calls for policymakers to intensify efforts to ensure drug availability, and that academics further should look into which SCRM strategies or combinations of SCRM strategies in drug SC are most successful in normal and abnormal times.

Moreover, drug SCs bring together many actors such as API suppliers, distributors, regulators, pharmacies, hospitals, and patients, and require an effective traceability system, to determine past and present product ownerships (Uddin et al., 2021). Until today, there was no legislation requiring you to know where a drug came from in many EU states. New legislations have been enacted across Europe to address the

risks involved with this, such as counterfeiting. The Norwegian Transparency Act, for example, will take effect in July 2022, forcing drug manufacturers to document how they plan to respond to potential poor working conditions along their whole supply chain, from raw materials to final drug (NTA, 2022). The new law requires a new level of collaboration, information sharing and transparency in drug SCs.

Finally, to secure proper drug conditions such as the right temperature or humidity, and perform on-time delivery, Musamih et al. (2021) highlight the importance of transparency in drug SCs. However, according to Sahoo et al. (2020), there is often improper monitoring and management of drug SCs. They call for an improvement in SCRM, to increase traceability and visibility and to make drug SCs more robust, resilient, transparent, and trustworthy.

2.5.2 SC Risk in Drug SCs

Disruptions such as natural disasters, geopolitical events, and supplier bankruptcy, can be classified as generic SC risks and could lead to direct deaths if occurring in drug SCs. However, while many SC risks in drug SCs are risks to SCs in general, there are some risks that are very unique to drug SCs. For instance, some people act in an antisocial or anti-established manner to harm others by producing and selling counterfeit drugs or trying to make money without caring if people get hurt (Coppola, 2020). According to Jaberidoost et al. (2013), the majority of drug SC risks are internal due to people, processes, functions mismanagement and people. In the following drug shortages and counterfeit risks will be highlighted as two very unique risks in drug SCs.

Drug Shortages

Drug shortage is an increasing challenge not only in developing countries but also for many EU and EEA countries, presenting major problems for SC continuity and quality of patient care (EU, 2021). Vulnerabilities in drug SCs have also been demonstrated during Covid-19. Due to different definitions of a drug shortage in EU countries, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) agreed on the following definition of a shortage (HMA/EMA, 2019, p. 2); "*A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level*". According to a EU report (2021), shortages may arise for all kinds of drugs, but oncology, anti-infectives, anti-hypertensives, and pain relief medication are those with the highest risk.

Further, research shows that there has been a substantial increase in especially generic, hence, off-patent drug shortages in recent years (DiPiro et al. 2021).

One of the problems is, according to the report on drug shortages (EU, 2021), that none of the actors within a drug SC has full insights on where the drugs are in the SC at which time. There is a lack of transparency. Thus, they call for greater transparency, and therefore, data-sharing between different actors of the SC is increasingly important (EU, 2021). A lack of standardization is, however, often hindering information sharing between countries (HMA/EMA, 2019). Also, a lack of transparency makes it difficult to get an overview and full understanding of the drug shortages as well as exact numbers on how big the problem is (EU, 2021).

Counterfeit Risk

Among unexpected events, such as natural disasters, pandemics, and economic downturns, counterfeiting is a less obvious risk as it is not immediately obvious, or even intentionally hidden (Falasca et al., 2021). Coppola (2020) highlights that drug SCs are especially exposed to man-made risks such as counterfeiting. Counterfeit drugs are defined as “*deliberately and fraudulently mislabeled with respect to identity and/or source*” (Uddin et al., p. 2), and might contain wrong or insufficient active ingredients, absence of active ingredients or fraudulent packaging.

According to the WHO (2017), falsified or substandard antibiotics were registered in every region of the world, hence, counterfeits are a global problem. The WHO has estimated that 10% of all global pharmaceutical commerce, representing a worth of 21 billion dollars, involves counterfeit drugs, especially in low- and middle-income countries (WHO, 2018). In low-income countries, customers tend to buy drugs from small local shops, where it is difficult to validate the authenticity of drugs (Chitre et al., 2019). The Philippines is an example from the Asian continent, where an inspection of drug stores in 2003 showed that 30% of all stores had “*falsely labeled or counterfeit*”, leading to a health and economic burden both for the government and the population (Sylim et al., 2018). But counterfeiting is also a problem in developed countries. In the US, it is estimated that approximately 1% of all sold drugs are counterfeits, mostly purchased online, some even through the infiltration of legitimate SCs (DSCSA, 2013; FDA, 2021a). Thus, due to the risk to the patient’s life, the counterfeit risk puts an extra demand and challenge on drug SCs compared to other SCs.

The EU tries to reduce counterfeits entering the market through the FMD law, however, counterfeiting is still a problem in Europe and people are dying from falsified drugs (European Parliament, 2011). Both the European Parliament and FDA try to strengthen their legal framework in Europe and the US, with the FMD and DSCSA, respectively. To prevent falsified drugs from entering drug SCs, the European Directive 2011/62/EU requires that all prescription drugs have safety labels and a unique serial number on it, allowing for verification checks throughout the whole SC (EU, 2011). By doing this, falsified and counterfeit drugs can be identified and safely withdrawn (Chiacchio et al., 2019). Moreover, the Anti-Counterfeiting Trade Agreement between Japan, Australia, New Zealand, Singapore, South Korea, Morocco, Mexico, Canada, the US, the EU, and Switzerland is another international framework building on collaboration to reduce counterfeits (ACTA, 2011; DSCSA, 2013; European Parliament, 2011). Despite all these regulations globally, the counterfeit problem remains a serious threat to human health. Hence, the need for better SCRM in drug SCs is pressing.

According to Botcha et al. (2019), fewer involved parties in a SC, reduce the chance of someone injecting a falsified drug into the SCs. Also, more links in a SC increase the risk of delays, causes storage problems and keeping the drugs at the right temperature is harder (Dixit et al., 2019). According to Chiacchio et al. (2019), SC risks may be managed by the serialization of drugs. Bansal et al. (2013) highlight the use of anti-counterfeit technologies such as; (i) tamper-resistant packing, (ii) product authenticating and (iii) tracking and tracing, to reduce counterfeits. As a result, increasing transparency in drug SCs can fight counterfeits and save lives.

2.6 BCT in Drug SCs

2.6.1 Use Cases and Value Drivers

In chapter 2.4.2 four main use cases and value drivers of BCT in SCM have been described. The use of BCT in drug SCs is one specific case of BCT in SCM, one specific industry case. Literature specific to drug SCs highlights the value of BCT in drug SCs for; (i) improved data security, and (ii) extended transparency and traceability, hence, two of the four value drivers of BCT in SCM are identified in chapter 2.4.2. The benefit of removing intermediaries, SC disintermediation, is also discussed in the literature. Hölbl et al. (2018), for example, emphasize the benefit of conducting transactions between entities in a SC without the need for a third party whose trustworthiness and dependability may be questioned. In addition to

those to value drivers identified in chapter 2.4.2 Agbo et al. (2019) highlight three additional benefits of using BCT in drug SCs; (i) *data verifiability* is high, which is important in drug SC management due to different legal requirements of records verification very, (ii) the data stored on BC is *robust and resilient* against data corruption, losses or security attacks and (iii) BCT allows for a *decentralized* data management, which makes collaboration within drug SCs easier. As the two value drivers, improved data security and extended visibility and traceability, are mentioned the most often we emphasize the two in the following.

Improved data security - Radanovic and Likic (2018) state that BCT is a technology that has a great potential for reducing costs in drug SCs and keeping sensitive data secure. Similarly, Hölbl et al. (2018) claim that BCT has a great potential for securing sensitive data on drug SC operations.

Extended transparency and traceability - As outlined in chapter 2.4.2, extended visibility and traceability enable the tracing of a product back to its origin and the reduction of counterfeits. These two benefits of BCT are often highlighted by literature specific to drug SCs. Because of BCT's immutability, each drug can be traced back to its origin, allowing users to verify that the drug was manufactured by a genuine entity (Raj et al., 2018). Hence, using BCT in drug SCs can make drug SCs more reliable and secure. Furthermore, according to Raj et al. (2018), RFID has been used to prevent counterfeiting in drug SCs for over a decade, but because RFID tags may be cloned, the drug identity cannot be 100% guaranteed and the system can be cheated. They argue that contrarily if in addition to the use of RFID a BC is used, data recorded once is unchangeable. Hölbl et al. (2018) have made a systematic review of using BCT in healthcare and drug SCs and conclude similarly that BCT is fairly new in the fields but has tremendous potential, especially for anti-counterfeiting drugs. As the use of BCT in drug SCs to prevent counterfeit is so prevalent in the literature, chapter 2.6.2 is focused only on that topic.

2.6.2 BCT to Prevent Counterfeiting

As outlined in chapter 2.5.2, the growing problem of counterfeits in drug SCs is a major source of concern not just for the end user, and the patient, but also for other stakeholders in the SC such as pharmaceutical companies and pharmacists (Falasca et al., 2021). Counterfeits could lead to a loss in reputation and revenue, expensive recalls, and broken trust relationships between stakeholders in drug SCs.

To address the problem two main approaches have been followed. First, different *physical anti-counterfeiting technologies*, such as embedded codes, images and dyes, holograms and color shifting inks have been utilized by different pharmaceutical companies, to assure legitimate product delivery in drug SCs (Chambliss et al., 2012). Second, different anti-counterfeiting techniques have been suggested to track and trace drugs building on a centralized data repository (Kumar & Tripathi, 2019). However, Kumar and Tripathi (2019) claim that these strategies have shown insufficient results. Yiu (2021) emphasizes the vulnerability of centralized anti-counterfeiting systems owing to the possibility of system attacks by dishonest SC actors or external SC actors inflicting system threats or physical tag threats on the system. Moreover, using third-party logistic providers (3PLs) may make drug SCs more vulnerable facing the challenge of a lack of transparency and limited knowledge about the data origin (Betcheva et al., 2020; Musamih et al. 2021). Despite all of these measures, including increased legislative efforts and private anti-counterfeiting initiatives, counterfeiting remains a severe danger to humanity and people's health across the world.

Kumar and Tripathi (2019) highlight the importance of knowing how and where drugs are made. They claim that this knowledge is essential for detecting counterfeits in the first place, managing recalls, and so improving drug safety and patient health, and in the worst-case scenario, even preventing death. However, tracking components and drugs as they go through the SC is very difficult (Kumar & Tripathi, 2019). To address the problem and ensure drug security and producer legitimacy, Kumar and Tripathi (2019) suggest a secure BC-based infrastructure for drug SCs that eliminates potentially untrustworthy third parties. Similarly, Sylim et al. (2018) developed and tested a pharma surveillance BC system that connects producers, wholesalers, retailers, the Philippine FDA, and the consumer allowing for information exchange along the drug SC. Although the initiative they propose is disruptive, they plan to work with the Philippine FDA to develop implementation strategies and procedures that would make adoption easier.

According to Ahmad et al. (2021), BCT has the potential to improve drug SCs due to its decentralized character, and its property of transparency, traceability, security, and truthfulness. As mentioned in chapter 2.4.2, BCT has the potential to increase visibility and traceability in SCs. BCT is found to be of great value in drug SCs, as the technology allows to set up a system for drug traceability from producer to end-

customer. This might be especially useful in drug SCs to reduce counterfeits, as tracking and provenance are critical in detecting counterfeits in drug SCs (Wang et al., 2019). Drug SCs are projected to progressively use BCT in the future because of their unique risk profile and significant vulnerability to counterfeit, fraud, and corruption (Radanovic & Likic, 2018). And literature shows that BCT has a great potential for detecting, reducing, and eliminating counterfeit drugs.

2.6.3 Challenges and Limitations

Uddin et al. (2021) and Musamih et al. (2021) are among few researchers, to the best of our knowledge, that look at challenges that may hinder the successful implementation of a BCT solution to trace drugs in a drug SC. Such identified challenges are listed in Table 4.

Challenge	Challenge Description
Stakeholders' Agreement	Drug SC stakeholders within the BC network may be reluctant to lose their advantage of competition since multiple competitors are included in the same drug SC with joint agreements.
Interoperability	BC-based solutions, similar to other drug traceability solutions, lack full interoperability due to missing standardized solutions to make adaptability, integration and implementation easier.
Implementation Costs	Implementation and energy costs are the main cost drivers for a BCT-based solution in drug SCs and designing a cost-optimal and cost-attractive BC use case is still under development.
Attacks and Vulnerabilities	Several security risks have been highlighted in cyber security reports, such as man-in-the-middle-attacks and bad actors (McAfee, 2020).
Lack of Standardized Regulations	Due to the complexity of BCT, legal guidance in terms of legal boundaries and the role of regulatory agencies become more relevant but is today often insufficient. According to Uddin et al. (2021), when a new transaction is recorded on the BC, it is difficult to clearly state the correct legal obligation for each node in the BC network.

Table 4. Challenges Using BCT in Drug SCs

Similar to Uddin et al. (2021), Musamih et al. (2021) point out interoperability as a BCT limitation in drug SCs, in addition to immutability, data privacy, scalability, and efficiency. Although immutability is frequently cited as one of the key benefits of employing BCT in drug SCs, it potentially contradicts with regulations, such as GDPR. Moreover, manual human errors, such as when adding data, are irreversible and might have serious consequences for the end customer. Because transactions in drug SCs are numerous and must be completed within milliseconds, proper coding of BC features such as smart contracts is challenging (Musamih et al., 2021).

2.7 SCRM and BCT

As of today, there is only one study, that of Lai et al. (2021), that adequately addresses the intersection of BCT and SCRM. The study by Lai et al. (2021), however, is limited to Taiwan's manufacturing sector. To the best of our knowledge and based on extensive research, there is not a single study that covers the interface of BCT and SCRM across industries or, what would be the best case, specifically in drug SCs. In line with our findings, scholars acknowledge that there is a substantial literature gap (Alkhudary et al., 2020; Etemadi et al., 2021; Lai et al., 2021; Saberi et al., 2019). Etemadi et al. (2021, p. 2), for instance, state that “*there is still a need for clarity about whether blockchain (...) can manage and predict disruptions and lead to more resilience and robustness of the supply chain*”. The literature gap is explained frequently by the novelty of the research field of BCT in SCM, as well as the scarcity of real-life BCT use cases in SCRM (Min, 2019).

Nevertheless, if one is actively searching for it, academics after 2018 mention the potential of BCT to support SCRM in general or specific or singular SC risks that may be reduced. In 2018, Kshsteri (2018) was one of the first to highlight *risk reduction* as one of six SC performance dimensions enhanced by BCT, together with cost, quality, speed, dependability, sustainability, and flexibility. Other researchers agree that BCT has the potential to enhance SCRM, even if they do not explicitly discuss the topic in their studies (Alkhudary et al., 2020; Etemadi et al., 2021; Lai et al., 2021; Layaq et al., 2019). For example, Layaq et al. (2019, p. 57) indicate that BCT “*can be a tool to mitigate risk,*” and Etemadi et al. (2021, pp. 2, 13) state that BCT “*has a potential benefit for exploring and controlling supply chain risks*” and “*lead to resilience and robustness of the supply chain*”.

All reviewed papers relate the potential of BCT in SCRM to the distinctive BCT qualities outlined in chapter 2.3.3, such as transparency (Vishnubhotla et al., 2020). One may argue that many aspects of SCRM are addressed indirectly by academics in their studies. For example, the literature indicates that BCT improves SC visibility; hence, one may logically conclude that improved SC visibility reduces the likelihood of counterfeits. Alternatively, one may claim that BCT enhances data security and so reduces SC cyber risk. But scholars only occasionally make that *next step* in their reasoning, and if then only with singular, designated SC risks. Layaq et al. (2019, p. 55), for instance, state that “*traceability is directly related to supply risk*” or Kshsteri (2018) claims that SC cybersecurity risks may be minimized

in permissioned BCs as actors must be mutually accepted before engaging in transactions. However, as indicated before, no study has yet established an explicit, direct relationship between BCT and SCRM from a holistic SC risk perspective.

2.7.1 BC-enabled SCRM

There isn't sufficient research on how BCT can support SCRM. According to Alkhudary et al. (2020) and Etemadi et al. (2021), BCT can help to identify and mitigate SC risks, hence, supporting two of the four SCRM activities. To our knowledge, Min (2019) is the only one who has defined BC-enabled SCRM in more detail. He claims that, compared to traditional SCRM, BC-enabled SCRM can be (i) more preventive and proactive, (ii) is based on the information and risk sharing, rather than buffering and hedging, (iii) can identify intangible risks, such as cyberattacks, miscommunication, or contract frauds, and (iv) allows for multiple layered security measures (Min, 2019). Ivanov et al. (2019) add, that besides proactive SCRM, BCT might support reactive SCRM by allowing for faster tracking of disruption sources or improved short- and mid-term stabilization and recovery actions. Further, Etemadi et al. (2021) identify cyber and disruption SCRM as two streams of how BCT might support SCRM. Tian (2017) investigate one concrete use case of BCT in SCRM, claiming that BCT combined with the Hazard Analysis and Critical Control Points approach in SCRM minimize the safety risk in food SCs. Also, by mapping all parts of a drug SC and omitting unnecessary third parties, drug SCs might be less vulnerable and more transparent, according to Musamih et al. (2021).

2.7.2 SC Risk Reduced by BCT

Besides the agreed-upon potential of BCT to support SCRM, academics point out specific SC risks that can be mitigated or reduced. As previously noted, the study of Lai et al. (2021), which focuses on the Taiwanese manufacturing industry, is the most advanced in the field. They identify 19 adoption enablers for lowering SC risk through a literature review and interviews and rate their relative importance through a survey. According to their results, BCT is mostly used in the manufacturing industry to reduce the risk of (i) unknown supply sources, (ii) counterfeit and shoddy products and (iii) contract fraud (Lai et al., 2021). The criterion that is found most important is supply source clarity, since BCT's “*anti-hacking, anti-tampering, traceability, and immutability*” properties can help identify potentially risky links or processes (Lai et al., 2021, p. 1105). The reduction of counterfeit products is

ranked second in the study and explained by the property of a BC as a “*publicly viewable ledger, permanently tracking the relevant records of specific assets for the SCM*” (Lai et al., 2021, p. 1106). The reduction of contract fraud is ranked third and explained by smart contracts, which allow for transparent and conflict-free transactions as well as the elimination of middlemen.

Alkhudary et al. (2020) also try to present a holistic picture by providing a framework for how BCT might lower specific SC risks (Figure 4). The thesis team, however, deems their findings to be fairly shallow for two reasons; First, the identified risks that may be mitigated by BCT are rather generic, such as lean production, outsourcing, or external events. Second, the findings do not seem to be sufficiently backed up by literature or empirical evidence.

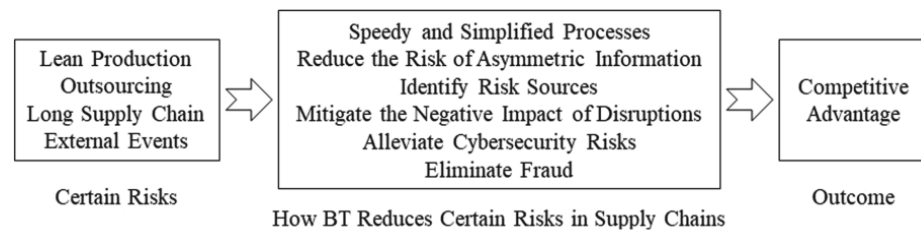


Figure 4. Relation of BCT and SCRM by Alkhudary et al., 2020

Authors, other than Lai et al. (2021) and Alkhudary et al. (2020), only occasionally mention specific, single SC risks that might be reduced through the use of BCT. The SC risks mentioned in the thesis team's reviewed literature are summarized in Table 5. The SC risks highlighted by various authors range from a reduced data security risk to a lower risk of contractual dispute or lower transactional risk.

SC Risk	SC Risk Reduction through BCT	Literature Reference
Data Security Risk	Lower risk of hacking and cyberattacks due to immutability and decentralization of data, Reduced risk of a single point of access failure	Alkhudary et al., 2020; Etemadi et al., 2021; Kshetri, 2018; Lai et al., 2021; Lu, 2019; Min, 2019; Tijan et al., 2019; Wang et al., 2019
Relational Risk	Common accessible single source of truth and mutually accepted BC participants increase trust in SC, Reduced information asymmetry and incompleteness, Reduction of intermediary risk	Etemadi et al., 2021; Fu & Zhu, 2019; Kshetri, 2018; Morabito, 2017; Treiblmaier, 2019; Wang et al., 2019; Wang et al., 2020
Counterfeit Risk	Easier identification and traceability of counterfeit products and their provenance, Easier verification of authenticity	Cole et al., 2019; Etemadi et al., 2021; Lai et al., 2021; Layaq et al., 2019; Min, 2019; Saberi et al., 2019
Information and Data	Real-time and efficient information sharing (e.g., lower risk of stockouts or	Alkhudary et al., 2020; Etemadi et al., 2021; Hald & Kinra, 2019;

Quality Risk	overproduction), Lower risk of data manipulation, Fewer inconsistencies and fulfilment errors	Ivanov et al., 2019; Layaq et al., 2019; Min, 2019; Vishnubhotla et al., 2020
Contractual Dispute Risk	Reduced contractual fraud or misunderstanding of contract fulfilment using smart contracts	Lai et al., 2021; Layaq et al., 2019; Min, 2019; Vishnubhotla et al., 2020
Product Integrity (Transport)	Easier traceability and recall of bad products (e.g., contaminated food) and their provenance, Reduce the risk of loss and damage during transit	Etemadi et al., 2021; Kamilaris et al., 2019; Layaq et al., 2019; Min, 2019;
Document-ation Risk	Lower risk of lost or altered SC documentation, Reduced paper processing errors	Cole et al., 2019; Lai et al., 2021; Layaq et al., 2019; Saberi et al., 2019

Table 5. Overview of Reduced SC Risk by BCT

Contrary to the many authors that only name specific risks, Layaq et al. (2019) are the only ones that state that BCT can improve all types of supply risks, distinguishing between supply, procurement, business, environmental, demand, and economic risks. Nonetheless, Treiblmaier (2019, p. 4) also highlights that the use of BCT might bring new SC risks resulting from “*increased transparency, the immutability of records, as well as the necessity for wide adoption and standard implementation*”. Overall, it is evident that no holistic picture of BCT in SCRM exists, either in terms of how SCRM can be supported, or which risks can be reduced. Clearly, there is a substantial literature gap that demands attention by academic research, or to put it in the words of Saberi et al. (2019, p. 14), “*the issue that blockchain technology can improve supply chain risk and resiliency requires further investigation*”.

3.0 Theoretical Framework

3.1 Literature Gap and Research Objective

Reviewing the literature on the three areas that comprise our research question, as well as their intersections, we discovered a lack of theory on how BCT may be utilized to support SCRM. There is substantial work done on how BCT can be used in SCM and how BCT can be used to combat counterfeit. However, to the best of our knowledge, no systematic and comprehensive study of how BCT could support SCRM exists. Alkhudary et al. (2020) even claim that there is a sufficient literature gap. Hence, a systematic study of the research question “*How can BCT be used to support SCRM in drug SCs?*” is required given the fragmented state of the literature. Our work provides a starting point for bridging that literature gap. Accordingly, our research objective is threefold;

- (i) provide insights into how (practically) BCT can be used to support SCRM in drug SCs
- (ii) assess the value of using BCT in drug SCs for SCRM
- (iii) identify implementation barriers and challenges of BCT in drug SCs

3.2 Conceptual Framework and Desired Research Output

This chapter introduces our developed conceptual framework (Figure 5). The framework, which contains key concepts and theories identified in the literature review, illustrates what we intended to investigate in further depth and guided the development of our research design, interview guide and data analysis.

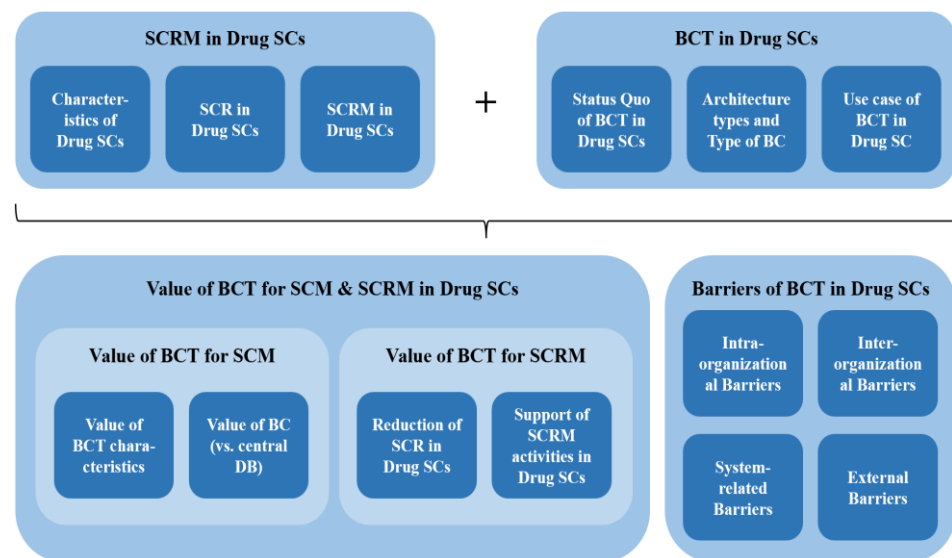


Figure 5. Theoretical Framework - The Impact of BCT on SCRM

SCRM in Drug SCs - A robust base of knowledge about drug SCs is required to accomplish the intended research outcome. Thus, we want to identify the unique characteristics of drug SCs, as well as SC risk and SCRM practices in drug SCs.

BCT in Drug SCs – To achieve the first research objective, BCT use cases in drug SCs will be identified. We would want to address the research question from two perspectives; first, determine which BCT use cases are already in use to get an as-it-is view and second, what other conceptual notions of BCT use cases might be viable. Furthermore, we intend to determine which architecture and BC type are viable possibilities, as well as which is most suited for the use in drug SCs.

Value of BCT for SCM and SCRM in Drug SCs – To assess the value of BCT in drug SCs, we intend to analyze the value of the specified BC characteristics (chapter 2.3.3.) for SCM as well as compare the value of employing a BC instead of a central DB, before specifically assessing the value of BCT for SCRM in drug SCs. The

purpose of the next part is to identify which of the four SCRM activities (chapter 2.2.1) can be supported by effective BCT use, as well as how and which types of drug SC risk might be reduced or eliminated.

Barriers of BCT in Drug SCs - Furthermore, as the framework suggests, assessing the challenges and implementation barriers to BCT encountered by diverse SC players is crucial. The framework developed by Saberi et al. (2019) and Lohmer and Lasch (2020) introduced in chapter 2.4.3 will be used to classify and structure identified barriers.

4.0 Research Methodology

In this part, we present a thorough description and justification of how we went about answering our research question - our methodological approach. In the words of Watson (1994, p. 80), what is the investigative style and approach we applied for gathering and analyzing data, and therefore what was the research set-up of our master thesis? Appendix 7 summarizes all methodological choices. The chapter consists of five parts; research strategy, design, data collection, data analysis, and assessment of the scientific quality and methodological limitations of our research.

4.1 Research Strategy

According to Bell et al. (2019, p. 35), a research strategy is defined as “*a general orientation to the conduct of business research*”, which guides researchers through the planning and execution of a study.

4.1.1 Scientific Approach

There are two research methods; (i) qualitative research, which favors an inductive approach, and (ii) quantitative research, which favors a deductive approach (Bell et al., 2019). The inductive approach aims to generate theories from data and specific observations, while the deductive approach is characterized by hypotheses derived from existing theories (O’Reilly, 2012). In addition, Dubois and Gadde (2002) suggest a third approach; systematic combining, often known as the abductive approach. They characterize the approach as a process in which empirical and theoretical frameworks co-evolve. The systematic combining entails a continuous back and forth between data and theory in a “*hermeneutic circle*” (Bell et al., 2019, p. 24). According to Dubois and Gadde (2002), the abductive approach is similar to the inductive approach, and it is a form of iterative strategy in which data collection and analysis are done concurrently. The approach allows researchers to make

changes to the framework while collecting and evaluating data. We followed an abductive approach in our research project, as it was ideal for our research question since we followed a continuous interplay between empirical data and theory (Figure 6). Further, the method allowed us to adjust our developed theory and framework in response to new data, hence, during the data analysis process.

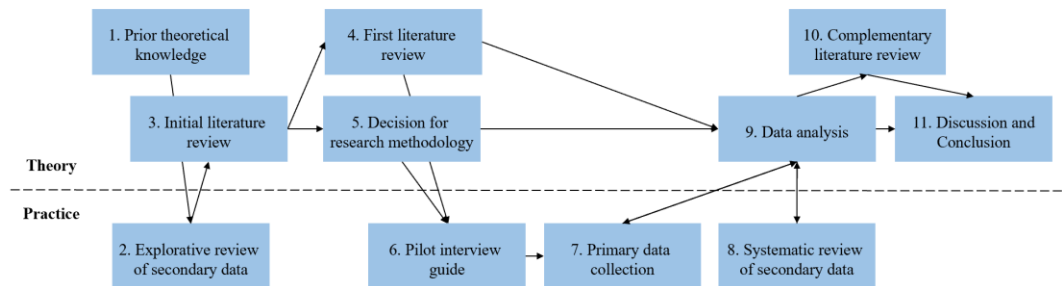


Figure 6. Abductive Research Design

4.1.2 Research Method

A research method, according to Bell et al. (2019), is a technique for data collection, which can be used in combination with different research designs. Hence, one needs to differentiate between research method and design. However, the research method adopted has an impact on the research design, data collection, and analysis. According to Håkansson (2013), there are three research methods; (i) quantitative, (ii) qualitative and (iii) mixed methods. We decided on a qualitative research method, which is best when dealing with complex issues, according to Wheeldon and Ahlberg (2012). Qualitative research places a great focus on language and meaning (Bell et al., 2019). Furthermore, it allows researchers to address questions that are not accessible with a quantitative approach (Sale & Thielke, 2018). We found the method appropriate since we aimed to develop theory rather than test hypotheses. Moreover, it enabled us to explore the nature of a novel phenomenon, such as the use of BCT in drug SCs and SCRM (Khan, 2014). In addition, because the wealth of qualitative data that was obtained and analyzed, a qualitative research method was more likely to provide more insights (Bell et al., 2019). Despite criticism from quantitative researchers, such as the researcher's subjectivity, generalization problems, or a lack of transparency, we believe the qualitative method was the best method to answer our research question (Bell et al., 2019).

4.2 Research Design

A research design is the “*plan for relating the conceptual research problem to relevant and practicable empirical research*” (Ghauri et al., 2020, p. 61). In other

words, the research design provides a framework that guides researchers through the data collection, analysis, and interpretation, and explains how the empirical study will be led in detail (Sreejesh et al., 2014). Further, it reveals the type of research and the level of analysis (Ghauri et al., 2020).

4.2.1 Type of Research

Ghauri et al. (2020) list three types of research designs; exploratory, descriptive, and causal. The three types are not mutually exclusive. Conducting our research, we followed an exploratory design. Exploratory research aims at understanding the topic in focus and is conducted to discover new ideas and often involves qualitative research, as it is often associated with theory generation, and a relatively unstructured research process (Sreejesh et al., 2014). Applied to our research question we aim to (i) provide insights into how (practically) BCT can support SCRM in drug SCs, hence, what are use cases and architecture types, and (ii) assess the value of using BCT in drug SCs, and (iii) identify implementation barriers and challenges of BCT in drug SCs, all research objectives that require an explorative research design. Following that line of argumentation, the aim of our research is to generalize findings to a larger group of drug SCs.

4.2.2 Level of Analysis

The following addresses the issue of the primary unit of analysis, the concept of level. Individuals, groups, organizations, and societies are all common levels of analysis, according to Bell et al. (2019). Again, some research designs draw on samples that combine multiple levels. But none of these levels fit our research question. In SCM research levels of analysis, such as the internal or external SC, dyadic relationships, or inter-business networks are common (Croom et al., 2000; Harland, 1996; Wolf (2008) warns that the inter-business network as the level of analysis can be very complex and analysis superficial. Therefore, we consider a general drug SC, drug SCs of patented and generic drugs, as the best level of analysis for our research, as we wanted to understand how BCT support SCRM in drug SCs in more general.

4.2.3 Embedded Case Study Design

Turning to the practical research setup, Bell et al. (2019) distinguish between five main research designs; (i) experimental, (ii) cross-sectional, (iii) longitudinal, (iv) comparative and (v) case study design. To answer our research question, we chose

an embedded case study, a sub-category of the classic case study. We chose a general drug SC as our case, rather than one specific drug SC. The decision was made because as we expected that many of the BCT use cases and implementation barriers apply to more than one drug SC. Further, speaking with all actors in a particular drug SC would be practically impossible and very time-consuming. This method enabled us to examine data from several drug SCs, SCs of patented as well as generic drugs, which aided the construction of a comprehensive picture of how BCT can support SCRM in drug SCs. Moreover, the odds of generalizing findings were higher with a large sample size, hence, when covering different drug SCs.

Our overall research objective was to generate an overview of how BCT can support SCRM in drug SCs in general. The aim was to generate findings that were applicable independent of a specific context, such as company, drug, time or place. An embedded case study entails the collection of data on more than one unit, or object of analysis, compared to a single-case study (Scholz & Tietje, 2002; Yin, 2014). Hence, it is more likely to make different observations and may be easier to generalize findings later. Further, it is unlikely that the whole range of BCT use cases is employed in a single drug SC, making the general drug SC the only plausible *case* for our research question. Further, if a phenomenon is studied in sub-units to comprehend "*the various salient aspects of the case*", it is best understood as an embedded case study, if the focus is on the "*cases and their unique contexts*", it is better viewed as a multiple-case study (Bell et al., 2019, p. 67; Scholz & Tietje, 2002, p. 10). The phenomenon we want to study is the use of BCT in drug SCs. The use of BCT to support SCRM was the case, and the different aspects of the case were the different BCT use cases in different drug SCs.

4.3 Data Collection

4.3.1 Primary Data

Our collection of the primary data followed a three-step process; decision phase (phase A), interview preparation and planning phase (phase B) and execution phase (phase C). Figure 7 depicts the detailed, systematic process we followed.

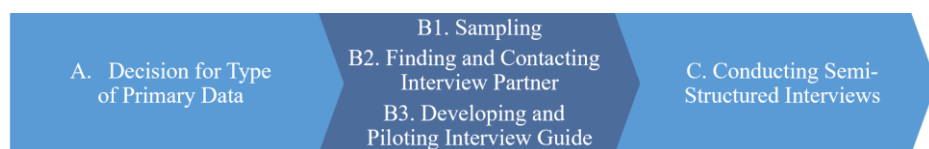


Figure 7. Process of Primary Data Collection

A. Type of Primary Data

We chose to conduct semi-structured interviews due to the flexibility they provide and the possibility to ask follow-up questions (Bell et al., 2019; Yin, 2014). Hence, semi-structured interviews are good for discovering and exploring new concepts and theories. We decided against structured interviews and questionnaires due to their focus on predefined topics and questions, and against unstructured interviews, since they are too open for our research question (Bell et al., 2019).

B1. Sampling

According to Bell et al. (2019, p. 188), a sample is “*the segment of the population that is selected for investigation*”. Thus, sampling is the process of identifying people who should be approached for data collection. Scholars distinguish between probability and non-probability approaches. The non-probability approach implies that certain units in the population have a higher chance of being chosen than others (Bell et al., 2019). Samples in qualitative research should be chosen based on their relevance to the research objective, according to Bell et al. (2019). As a result, they argue for purposive sampling, a non-probability method. Participants in this method are chosen strategically rather than at random, based on the researchers' judgment of their relevance to the research question (Saunders et al., 2012). Purposive sampling, also known as judgmental sampling, is widely used to identify particularly informative cases (Neuman, 2005). Scholars stress that human judgment might be biased. Eisenhardt (1989, p. 537), however, points out that sometimes a “*random selection is neither necessary, nor even preferable*”. Further, it is critical for our research that participants meet certain criteria, such as an understanding of BCT and drug SCs. Hence, purposive sampling, or more specifically the sub-category of criterion sampling, was ideal for our research.

We defined two basic criteria for our interviewees; (i) BCT knowledge (technical knowledge) and (ii) drug SC expertise (focus topic and industry knowledge). These criteria resulted in three participants' target groups relevant to our research question; (i) BCT experts working with SCM, preferably with drug SCs, (ii) drug SC practitioners, and (iii) institutional representatives dealing with drug SCs and counterfeits. However, during the sampling process, we decided to add a fourth target group; (iv) BCT and drug SCs experts, as we discovered that there are experts who are competent in both domains and cannot be placed in target group one or two. We also included a fifth group, (v) alternative to BC experts, because we felt it would be very valuable to interview companies who try to combat counterfeits but

do not explicitly use BCT. As a result, we ended up with five target groups (Figure 9), each with a goal of two interviewees, totaling a goal of ten interviews.

B2. Finding and Contacting Interview Partner

Cold calls via E-Mail or LinkedIn, contact from BI representatives, and our professional and private network were used to identify interview partners that fit into one of the five target groups. We used a snowballing tactic to find and contact appropriate potential interview partners (Figure 8.) According to Bell et. al. (2019, p. 396), it is a technique “in which the researcher samples initially a small group of people relevant to the research questions, and these sampled participants propose other participants who have had the experience or characteristics relevant to the research. These participants will then suggest others and so on”.

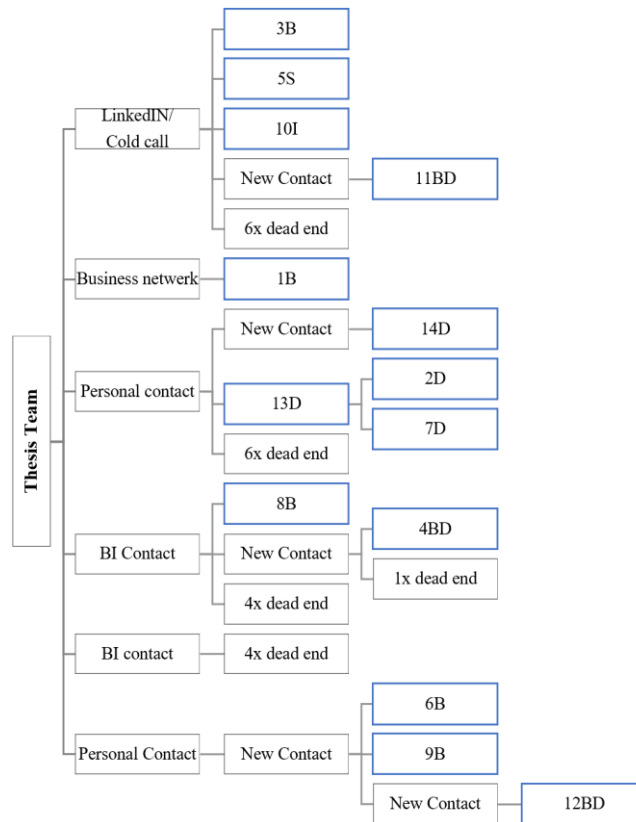


Figure 8. Finding Interview Partner; Snowballing Tactic

We developed a One-Pager and attached it whenever contacting new contacts to provide them with the most important information about our thesis (Appendix 8). In addition, six Get2Knows were arranged to introduce our thesis to potential interviewees. We reached out to 35 potential interview partners in January and February 2022 and ended up conducting 14 interviews in March 2022 (Figure 9). Three more interviews were unfortunately cancelled on short notice. Even though we sent a minimum of two follow-up E-mails, the remaining contacted people did

not answer our request. As a result, we attained a success rate of 40%.

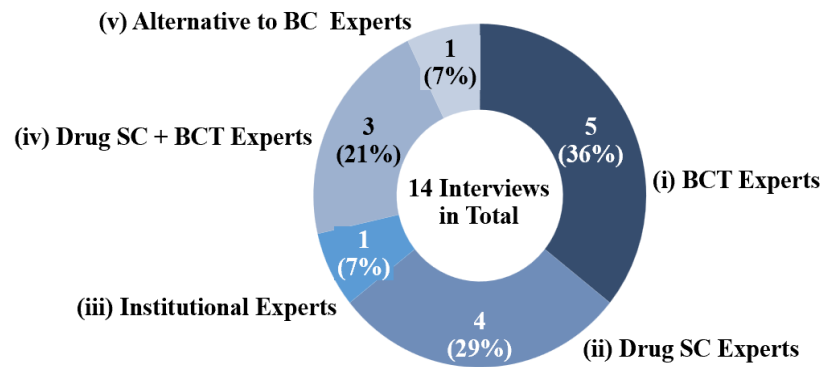


Figure 9. Overview of Conducted Interviews per Target Group

B3. Developing and Piloting of Interview Guide

While contacting the interview partners, we developed a custom interview guide for each of the five target groups based on our research question, theoretical framework, and literature review ([Appendix 9](#)). Furthermore, we piloted the interview guides before the actual interviews to (i) familiarize ourselves with the interview setting and questions, and (ii) identify any possibly problematic questions (Bell et al., 2019). As a result, several questions were modified. We learned valuable lessons from the pilot, such as the necessity to repeat questions, and the leaving some time in the end for an open discussion.

C. Conducting Semi-structured Interviews

Three steps were involved in the actual interview process;

1. *E-Mail Information* - In preparation for the interview we sent out interview details, the interview guide, as well as the consent and information form from the Norsk Senter for Forskningsdata (NSD) to the interviewees by E-Mail.

2. *Interview Preparation* – We met for about 30 minutes before each interview to prepare ourselves by going over the interviewee's background, preceding E-Mail correspondence, dividing questions, and adjusting and adding interview questions based on the person interviewed and the organization they represent.

3. *Interviews* - Due to location differences and pandemic constraints, the interviews were conducted using the platform Zoom, except for one in-person interview. All interviews were held in English. Each interview lasted between 40 and 60 minutes (Table 6). One lasted for only 20 minutes due to a busy schedule. We used an audio recorder during the interviews to simplify the transcription later and thereby ensure the accuracy of the data. Making an audio recording instead of taking

notes allowed us to be more present during the conversation. Furthermore, while conducting interviews, we ensured to respect both GDPR and NSD guidelines.

Interview ID*	Date	Target Group	Company	Company Role	Length
1B	04.03.22	BCT	IBM	BC Consultancy	45 min.
2D	07.03.22	Drug SC	Merck	Drug Manufacturer	40 min.
3B	07.03.22	BCT	Unitsot	BC Service Provider	50 min.
4BD	08.03.22	BCT/Drug SC	Deloitte	Consultancy	46 min.
5S	08.03.22	Special case	Kezzler	Serialization Provider	55 min.
6B	08.03.22	BCT	IBM	BC Consultancy	55 min.
7D	09.03.22	Drug SC	Merck	Drug Manufacturer	60 min.
8B	14.03.22	BCT	EY	Consultancy	50 min.
9B	16.03.22	BCT	IBM	BC Consultancy	55 min.
10I	17.03.22	Institution	NOMVEC	FMD Execution	50 min.
11BD	18.03.22	BCT/Drug SC	Bayer	Drug Manufacturer	40 min.
12BD	21.03.22	BCT/Drug SC	Equideum	BC Provider	20 min.
13D	23.03.22	Drug SC	Merck	Drug Manufacturer	50 min.
14D	25.03.22	Drug SC	Sanofi	Drug Manufacturer	50 min.

Table 6. Detailed Interview Schedule

The main challenge in the interviews was to remain flexible because many of the participants had already touched on or even answered the next question in an earlier question. As a result, we had to either skip the questions or ask for more explanation. Furthermore, not everyone was able to respond to all of the questions. Two of the interviews involved two interviewees, which we thought in advance would be challenging. Fortunately, we experienced that it worked out fine. However, we found the concept of semi-structured interviews to be very valuable because it allowed us to bring up and discuss ideas discussed in earlier interviews in subsequent interviews. That allowed us to get more perspectives on key ideas.

4.3.2 Secondary Data

We used two publications in addition to primary data; (i) the *Kezzler Pfizer Viagra Case Study* (Kezzler, 2020), which was referred to in the Kezzler Get2Know and (ii) the *FDA DSCSA Blockchain Interoperability Pilot Project Report* (FDA, 2020), the BC pilot which was discussed extensively in interviews. We also used several additional online resources, such as company websites. The main advantage of

using these data is that its collection is less time-consuming as the data was already collected (Bell et al., 2019). However, to ensure a high quality of data we always validated the information with interviews or a second data source.

4.4 Data Analysis

Thematic analysis and grounded theory are the two widely used qualitative data analysis methods, according to Bell et al. (2019). To analyze the data collected during the semi-structured interviews, we employed the thematic analysis method. The thematic analysis is, according to Braun and Clarke (2006, p. 79), defined as “a method for identifying, analyzing and reporting patterns (themes) within data”. A theme is, therefore “a category identified by the analyst through his/her data; (...) and provides the researcher with the basis for a theoretical understanding of his/her data” (Bell et al., 2019, p. 519). They also emphasize that repetition in one or across data sources is “one of the most common criteria for establishing a pattern”, but that “repetition per se is an insufficient criterion for something to warrant being labeled a theme” (Bell et al., 2019, p. 519). In our thematic analysis, we followed the six-phase process proposed by Braun and Clarke (2006, p. 87) (Figure 10).

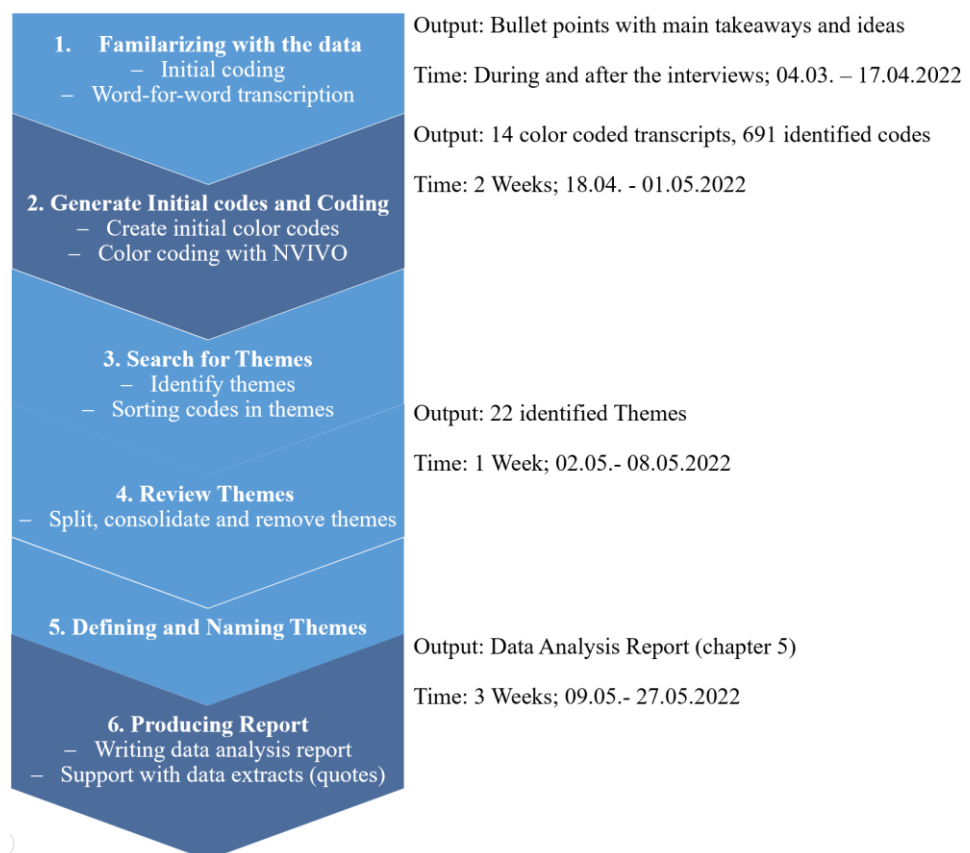


Figure 10. Thesis Thematic Analysis according to Braun & Clarke, 2006

The structured six-phase process can help researchers find relevant patterns and themes more systematically and easily (Braun & Clarke, 2020). The thematic analysis is by nature recursive and iterative, as it permits the researcher to move back and forth between the different phases, hence it is not a linear process (Braun & Clarke, 2020). This back and forth requires flexibility and iterations of earlier phases and might lead to new data interpretations. By using the six-phase process, we were able to (i) identify patterns and (ii) see if themes from our data correlated with themes from our literature review and theoretical framework. Following are detailed descriptions of what we did in each phase.

Phase 1. Familiarizing with the data – We went through two steps to familiarize ourselves with the data, and the interview content. First, immediately after each interview, we sat down for 10-15 minutes to note down the most important ideas and takeaways, to (i) be able to address them in subsequent interviews, (ii) get ideas for a skeleton of our data analysis and (iii) gather insights relevant to our discussion. Second, we first transcribed our interviews word-for-word. According to Bell et al. (2019), “it is best to allow around five to six hours for transcription for every hour of speech”. Eleven hours of audio recordings took us the respective transcription time. However, according to Braun and Clarke (2020), the process of transcription is necessary to be able to identify information relevant to one's research question. Braun and Clarke (2020, p. 87), state that “while it may seem time-consuming, frustrating, and at times boring, (it) can be an excellent way to start familiarizing yourself with the data”. When all interviews were transcribed, we read the transcripts that the others had prepared. Further, we highly valued transcribing in later phases because it allowed us to quickly code data and extract quotes.

Phase 2. Generate initial codes / Coding – In phase two, we started off with creating initial color codes, based on the insights gained in phase one, as well as our research question and objectives, resulting in a preliminary structure of our data analysis. The outcome was a long list of color codes, such as various shades of blue for SC risk in drug SCs or pink for nice quotes.

After compiling initial color codes, we coded the data by going through the transcripts target group by target group. Braun and Clarke (2020, p. 89) describe the step as “identify interesting aspects in the data items that may form the basis of repeated patterns (themes) across the data set”. Even though it took more time,

we noticed that doing the actual coding together was very valuable as it allowed us to consult with one another, discuss ideas immediately, and document findings. This also allowed us to strengthen our shared understanding of the data.

We began by manually coding the data in Word, but soon realized that certain text sections qualified for multiple codes. As a result, we decided to use the software NVIVO. Apart from being able to drag and drop text sections into color codes, thus, increasing efficiency, NVIVO was valuable for our work in several other ways; (i) we could generate an unlimited number of codes, whereas Word has a limited number of colors, (ii) once all transcripts were coded, we were able to extract all text sections coded in the same color with one click, and (iii) NVIVO allows us to generate an audit trail of our data analysis, such as a codebook ([Appendix 10](#)), hence, increase the credibility of our work.

Phase 3. Search for themes – When all data were coded, we identified themes, where “*the codes (were) the basic building blocks of the upcoming themes*” (Braun & Clarke, 2020). According to Braun and Clarke (2006, p. 89), this phase entails “*sorting the different codes into potential themes and collating all the relevant coded data extracts within the identified themes*”. Thus, we sorted our codes into identified themes and sub-themes. We want to emphasize that we were aware of the potential for bias in overseeing themes that did not match our own ideas and actively tried to remind us about that bias.

Phase 4 and 5. Reviewing themes, Defining, and Naming Themes - When reviewing the themes, it became clear that some of them need to be split into two, are not truly themes or must be condensed. Our final codebook included 22 themes ([Appendix 10](#)). In addition, the Appendix contains a graphic depicting the frequency of various codes, as well as an overview of the themes and codes identified in each interview ([Appendix 11, 12](#)). Finally, we were establishing and naming themes, which Braun and Clarke (2006, p. 92) define as “*identifying the ‘essence’ of what each theme is about (as well as the themes overall)*”. The identified themes helped us to find meaningful answers to our research question. The result of phase five was a final thematic map, which is illustrated exemplary for the theme *barriers of BCT adoption* in drug SCs in Figure 11.

Phase 6. Producing report – The last step was to write up our empirical findings and present a “*concise, coherent, logical, non-repetitive and interesting account of*

the story the data tell, within and across themes” (Braun & Clarke, 2006, p. 93), as well as data extracts to support it. While writing up the data analysis we made sure to already collect and note ideas and important insights for the discussion part.

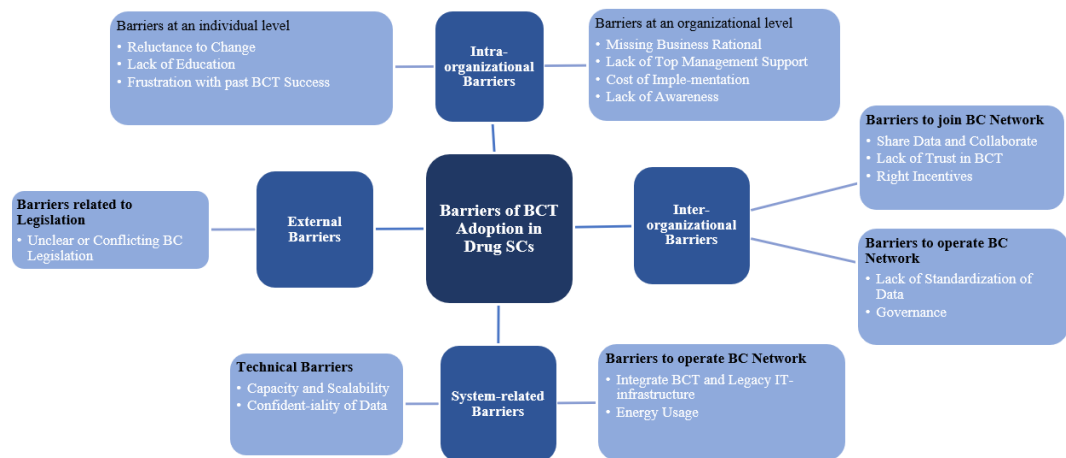


Figure 11. Exemplary Thematic Map for one Theme

4.5 Scientific Quality and Methodological Limitations

This chapter focuses on assessing the trustworthiness and authenticity of our research. Unlike reliability and validity, these two quality criteria are specifically designed and suited to assess the scientific quality of qualitative research, and hence are relevant to our research (Guba & Lincoln, 1994; Shenton, 2004). Qualitative research methods, according to Bell et al. (2019), have four major methodological limitations; (i) researcher subjectivity (confirmability) (ii) difficulty replicating qualitative studies (dependability), (iii) generalization problems due to small sample sizes (transferability), and (iv) lack of transparency (related to dependability). In the following, we will assess our research's trustworthiness and authenticity, as well as each sub-criteria, from two perspectives; (i) what did we do to avoid these pitfalls and (ii) how we assess the scientific quality of each criterion.

4.5.1 Trustworthiness

Trustworthiness is the key quality measure in qualitative research and encompasses four interconnected characteristics; (i) confirmability, (ii) dependability, (iii) transferability and (iv) credibility (Bell et al., 2019; Shenton, 2004). Whereas credibility and transferability are equivalent to internal and external validity, respectively, and dependability to reliability in quantitative research (Yin, 2014).

Confirmability – This criterion pertains to the data interpretation's objectivity. Due to the impossibility of being entirely objective (Bell et al., 2019), confirmability is concerned with how much the researchers have integrated their own beliefs and

values into the research processes and therefore distorting the findings. It is critical for confirmability that the data accurately reflect the information presented, that the interpretations are not based on the inquirer's imagination and that the findings reflect the participant's voice rather than the researcher's perspective. Quantitative researchers frequently criticize qualitative researchers for their subjectivity, claiming that their findings are based on a subjective, non-systematic assessment of which findings are relevant and which are not (Bell et al., 2019). They also claim that qualitative researchers often use relatives as informants. We took four measures to ensure confirmability and objectivity; (i) we deliberately and frequently reminded ourselves of our biases, (ii) we finished the transcription process before discussing findings, (iii) no relatives or acquaintances were interviewed, and (iv) both of us were present during each interview. Overall, we assess our research to have a high degree of confirmability.

Dependability – This criterion refers to the stability of data over time and conditions, whereas stability refers to the degree to which similar results are obtained on two separate occasions (Bell et al., 2019). According to Bell et al. (2019), the unstructured nature of qualitative studies and often missing standard procedures makes replication difficult, if not impossible. Closely tied to a study's dependability is the level of transparency researchers disclose in their work. “*It is sometimes difficult to establish from qualitative research what the researcher actually did and how they arrived at the study's conclusions*” (Bell et al., 2019, p. 375). For instance, it is often unclear how interviewees are selected or data is analyzed. We ensured dependability and tried to make our work as transparent as possible by (i) writing word-for-word transcripts, (ii) following a structured and proven data analysis process (chapter 4.4), (iii) using the software NVIVO for the data analysis to create an audit trail of our work, and (iv) thoroughly documenting our research process in this chapter. For a qualitative study, we assess our research as having a medium to a high level of dependability.

Transferability – This criterion pertains to the generalizability of research results, hence, the ability to apply findings to other contexts and times (Guba & Lincoln, 1994; Shenton, 2004). For us, as for many qualitative studies, a challenge was the sample size, which could be too small to generate generalizable results. We, thus, tried to conduct as many interviews as possible while also trying to interview people with diverse organizational backgrounds. As a result, 14 interviews were conducted

with 16 individuals from ten different organizations. Because of the unique character and complexity of drug SCs, we believe that our findings may not be fully generalizable or relevant to all drug SCs but provide a good indication of how BCT can support SCRM in drug SCs for other drug SCs. Some findings are unquestionably firm-specific, but they may still be useful to other organizations. Furthermore, we assess the generalizability to other industries as possible, but not perfect. Overall, we assess the transferability of our findings as moderate.

Credibility – A study's credibility is determined by the trustworthiness of the collected data, which is greatly influenced by the data collection process (Yin, 2014). As suggested by Shenton (2004), we used semi-structured interviews as our data collection method, a proven and successful research method within qualitative research. To further enhance the credibility of our work and increase the probability of honest responses, we informed and emphasized to participants about their voluntary participation in the interviews and that withdrawal is possible at any time. Overall, we assess our research with a high level of credibility.

4.5.2 Authenticity

Authenticity refers to the “*wider social and political impact of research*” (Bell et al., 2019, p. 365). Further, they add that “*authenticity places responsibility on the researcher to fairly represent different viewpoints within a social setting*”. To assure the authenticity and fairness of our research, we included individuals from a variety of organizations and educational backgrounds. We also tried to conduct our research in a way that helps various stakeholders, hence, various drug SC actors in improving operations and, as a result, patient health and life.

4.5.3 Legal Requirements

Apart from scientific quality criteria, laws and regulations must be adhered to achieve high-quality research (Bell et al., 2019). We applied to the NSD in January 2022 and were granted permission to collect and store dedicated data legally in February 2022. Throughout the thesis, we made sure that our work and activities complied with both GDPR and NSD standards. For example, before conducting interviews, we always obtained written consent from participants to gather personal data, record interviews, and anonymized participants.

5.0 Data Analysis and Empirical Findings

We conducted an embedded case study to answer our research question; “*How can*

Blockchain Technology be used to support Supply Chain Risk Management in Drug Supply Chains?”. The interviewees' responses to the question ranged from; in drug SCs “there is not one option to where I am convinced” (7D) to BC “is the perfect solution for drug supply chains” (3B) and “can bring instant value” (8B). To be able to answer our research question in a coherent, well-founded, and transparent manner, the consecutive chapter presents the empirical findings of our thematic analysis. In the thematic analysis, we analyzed the collected primary and secondary data. This chapter follows the structure of our developed theoretical framework presented in chapter 3.1 and includes four parts; (i) SC risk and SCRM in drug SCs, (ii) current state, architecture and use cases of BCT in drug SCs, (iii) value of BCT in drug SCs and (iv) barriers and challenges of BC deployment in drug SCs.

5.1 SC Risk and SCRM in Drug SCs

To be able to answer our research question and accomplish the desired research outcome we consider it important to have a strong foundation of knowledge regarding drug SCs. Thus, the findings of our analysis on (i) special characteristics of drug SCs, (ii) unique drug SC risk, and (iii) SCRM practices and pain points in drug SCs, are presented in this chapter. We would also want to point out at that point that our findings don't distinguish between proprietary and generic drugs.

5.1.1 Special Characteristics of Drug SCs

When asked what distinguishes a drug SC from other SCs such as automotive or fast-moving consumer goods (FMCG) SCs, the informants cited various characteristics such as a lack of information sharing and unique transportation requirements. Overall, our thematic analysis revealed a total of nine distinct drug SC characteristics (Figure 12). Low information sharing was stated the most frequently among all of the identified special qualities, followed by a lack of trust. 11 of the 14 interviewees cited at least one unique drug SC characteristic.

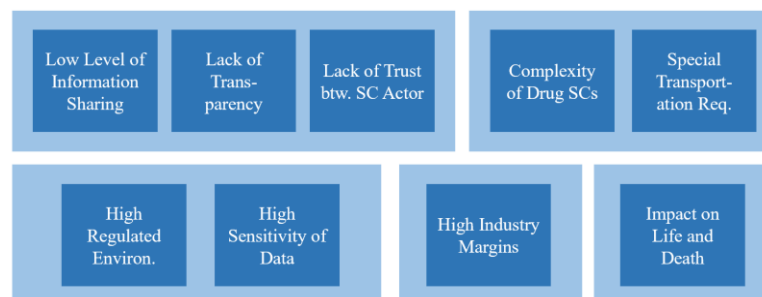


Figure 12. Special Characteristics of Drug SC compared to other SCs

1. *Low Level of Information Sharing* – Our data analysis reveals that information

sharing within drug SCs is rather low and that many businesses operate independently. One interviewee even stated, *“information sharing is always bad. Everywhere where people need to talk to each other is a risk. Full stop. And that's neither bad nor good, it's just how it is”* (13D). According to one interviewee, different actors in drug SCs historically have been *“creating information moats around themselves”* (9B), to ensure their profits. These actors have no interest to share information as *“sharing sort of let you cross the moats”* (9B). Surprisingly, interviewees described not just external, but also internal information sharing as limited. Furthermore, our analysis revealed that drug SC experts rate information sharing more often as adequate than BC experts, with one interviewee stating, *“I think most of the critical data is known to the people who should know it”* (7D).
“Today we’re only connected to some health authorities, may some 3PLs.” (7D)
“Pharmacies are reluctant to share data for free, they share data but not with us there are companies that collect data on drugs. (...) Then these organizations sell this data back to pharma companies (us) in fancy reports.” (7D)

We identified five causes for the low level of information exchange in drug SCs that were cited in the interviews. First, drug SCs must maintain a high level of data confidentiality. Because 3PLs are frequently involved in drug SCs, there are not only many parties involved, but also sometimes unknown parties who cannot be trusted with confidential data. Second, competition in the pharma industry is fierce, making companies reluctant of sharing information since *“pharmacies, wholesalers, and manufacturers, don't share an interest - they are competing for the same pieces of the same pie”* (10I). Third, for many years there was no legal obligation to disclose the provenance of a drug or ingredients, and therefore to share the relevant data. Fourth, numerous interviews noted a mental barrier, resistance, wrong mindset, or even fear of sharing information in the industry. Fifth, interviewees mention a lack of trust among drug SCs actors, which we treat as a separate characteristic as it was mentioned multiple times.

“So, if I'm a pharma company, I don't wanna share information, I'm not used to sharing any information. To do that scares me. If I'm a distributor, I certainly don't wanna do this.” (9B)

“The challenge for our industry is to find a way to collect and manage data and share it with the right level of confidentiality with the 3PLs.” (14D)

Nonetheless, a few respondents stress the need and value of data sharing and collaboration, arguing that it might be a win-win scenario for everyone. *“Sometimes*

you have to share the data in order to get something back” (7D), one drug SC expert acknowledged. Interestingly, one source was stating that he strongly believes that pharma companies 20 to 30 years from now will be quite different from today as “they will have to share information” (9B).

2. *Lack of Transparency* – Because of the lack of information sharing, drug SCs often have a poor level of transparency. According to one source, the lack of transparency causes \$100 billion in annual inefficiencies in drug SCs.

“Drugmakers know far less about their products once it leaves the factory than an FMCG company. Procter and Gamble, making toilet paper, pretty much knows where each roll of toilet paper is going. Pfizer does not know that.” (9B)

3. *Lack of Trust between Drug SC Actors* – The lack of data sharing, and thus transparency is explained by many interviews by a lack of trust amongst drug SC actors. However, drug SC experts also stress that they see the need of building trust between external and internal stakeholders. They have noticed a shift, with firms gradually starting to trust each other, which means they are moving away from being hesitant to share data and competing with one another, realizing that cooperation is beneficial and information sharing *“is very powerful” (7D).*

“If I am sharing data, I’m actually giving things away. Can I trust that this is not misused or used against me or something? That is the level of trust.” (13D)

“Pharma firms don’t trust each other; they even don’t like each other.” (9B)

4. *Complexity of Drug SCs* – Drug SCs are also more complex than other SCs, according to interviewees, because (i) they involve a large number of actors, (ii) the manufacturing process is getting more complex as the industry moves away from basic chemistry and toward living products, (iii) they are often global crossing many borders, and (iv) they have a high level of sourcing dependency. In addition, our research revealed a trend in drug SC that further complicates drug SCs. There is a shift from campaign manufacturing towards personalized medicine, especially in the US and EU. Personalized medicine requires direct-to-patient delivery. According to one responder, individualized cancer treatments such as CAR T-cell therapies require *“millions of n=1 shipments per day” (9D)*, showing the need for a one-to-one vein-to-vein (V-to-V) SC. Although personalized medicine is a great opportunity, respondents name two barriers; (i) from an ethical standpoint personalized medicine is most likely only to take off in wealthy countries, and (ii) the *“supply chain up today is simply not equipped to handle that at any scale” (9B).*

“Manufactured in Brazil or India, then they go to a factory maybe in New Zealand. Then it is shipped somewhere else and finally gets into Europe.” (10I)

5. *Special Transport Requirements* – Special transport requirements, which were often mentioned by interviewees, are another factor complicating drug SCs. *“More and more new medicines need to be temperature controlled”* (8B), according to a drug SC expert. Because of the temperature sensitivity of many drugs, each stop in the SC must have cold-chain capabilities with precise temperature control to guarantee that the products' integrity is maintained.

6. *High Sensitivity of Data* – As stated before, interviewees repeatedly highlighted the high level of confidentiality that is required in drug SCs compared to other SCs. Different data and parameters, such as for instance temperature, size, ingredients, or origin not only require extensive documentation with a high level of confidentiality but also are subject to GDPR or intellectual property (IP) rights.

7. *High Regulated Environment* – The pharma industry, and thus drug SCs, is a *“heavily legislated industry”* (10I) due to regulations such as the FMD in Europe, the DSCSA in the US or IP rights. Regulators *“require you to submit your protocols for how to exchange products for drugs”* (12B), which is not the case for toys or consumer products, one BC expert states. One respondent even refers to the pharma industry as a *“kind of a captive market, with the regulations”* (14D), referring to patent rights. Furthermore, drug manufacturers are obliged to serialize their products in many countries. Overall, compliance with regulations, according to drug SC specialists, often influences operations and is a top priority.

“In the drug use case, regulations are more important than in other SCs.” (1B)

“Every health authority has their requirements and there is no discussion around that, so you always have to fulfill those needs.” (2D)

8. *High Margins for Patented Drugs* – Drug SCs experts also point out that the pharma industry is traditionally an industry with high margins, among other reasons owing to patent rights that often last 15 to 20 years. According to one interviewee, the industry is *“flushed with margins”* (9B). We also commonly heard that low levels of digitization, low efficiency, and lack of transparency in drug SCs are due to large profits and lack of competition due to patent rights, similar to *“why spend money when you don't have any competition?”* (14D). However, we must emphasize that high margins are a unique drug SC characteristic seen exclusively

for patented drugs. Once the patent expires profits are often very low since the price usually drops when a patent expires.

9. *Impact on Life and Death* – Compared to other SCs disruptions of any kind in drug SCs can have a direct and severe impact on a patient's health. *"There's always a patient behind"* (2D) who is dependent on the product. Thus, many informants highlight the importance of drug availability and integrity as the main differences between drug SCs and, say, automotive SCs.

"If you have a lack of cars, nobody cares, but if you don't have a medicine on time, in the right quantity, form or quality, we are talking about death." (14D)

5.1.2 SC Risk in Drug SCs

To assess how BCT might support SCRM in drug SCs it is crucial to assess which SC risks in drug SCs are prevalent. When asked about SC risks, several drug SC specialists stated that it is difficult to define risk and draw the boundary between daily operations and risks in practice. We also want to emphasize that the listed SC risks are not meant to be a complete list of drug SC risks, but rather an overview of often cited and for our research relevant drug SC risks, with an emphasis on supply risk. Supply risks are mentioned most frequently by interviewees, while demand, process, and corporate-level risks are mentioned less frequently (Figure 13).

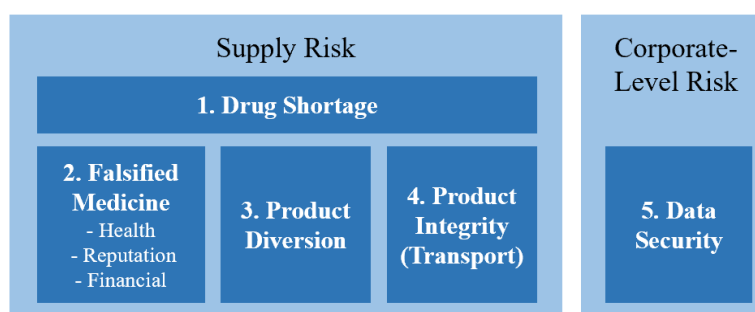


Figure 13. SC Risk in Drug SCs relevant to Research Question

1. *Drug Shortage* – An out-of-stock, non-availability or drug shortage situation immediately affects the end customer, the patient. As a result, any disruptions in drug SCs can have a significant impact on life and health. Drug non-availability was not just the most often mentioned risk, but also the most important to combat since it impacts patients' well-being. According to our research, drug shortages may be caused by a variety of factors, including counterfeit medicine, product diversion, and improper transportation, all of which are listed as three separate risks below.

"Yet we have more drugs in chronic short supply than ever." (6B)

"The concept of out-of-stock doesn't work in pharma. It's the main risk." (14D)

“It’s all about continuity. I mean it’s called “chain” because there are so many things coming together. That we find a weak part that you can’t solve immediately. That’s the biggest risk.” (2D)

2. *Falsified Medicine* – Falsified drugs are another frequently mentioned risk, however, interviewees point out significant local differences. According to the respondents, the problem is still a global issue, but it is most acute in Asia, Africa, and Latin America, as well as in Southern and Eastern Europe. The problem is considered modest in Norway, due to the National Competent Authority, which regulates and authorizes drugs. Our analysis also revealed two types of falsified medicine; (i) products that are manufactured as fake products and (ii) stolen products that are removed from the legal SC and then sold back to it. The reason for the second type is stated to be a lack of transparency and control over where the drug was stored or transported. Further, falsified drugs have two consequences for patient health; (i) you may get sick or even die or (ii) obtain a non-optimal medicine for your disease as the initial drug was falsified and thus did not work.

“I know a case where insulin was sold with the same box even, without any insulin in the vials. It’s a massive risk.” (13D)

“There’s this high-level estimate that about 30% of products in less developed countries are counterfeits and it is something like 2% of worldwide drugs.” (7D)

“It’s a very marginal problem in Norway. But 2016 we had an incident.” (10I)

According to our findings, there are two risks at the corporate level associated with the risk of counterfeits for patients. First, buying fake drugs can result in a significant financial loss for a wholesaler or distributor since products cannot be resold. Second, if a drug manufacturer's fake products enter the market and are detected, the brand and company image is at risk, posing a *“significant reputation risk for the manufacturers”* (10I). One example provided was Pfizer's Viagra brand, which saw fraudulent versions enter the market through mail orders.

3. *Product Diversion* – Another risk mentioned was product diversion, which occurs when unauthorized individuals sell drugs outside the regulated distribution channels or when drugs end up are sold in markets where they were not intended.

4. *Product Integrity (Transport)* – Drug SCs often have special transportation needs, such as cold-chain capabilities, as indicated in chapter 5.1.1. As a result, getting drugs to their final destination in perfect condition is a significant challenge and hence a risk. The products may travel overseas and through many means of

transportation, including sea, air, train, and road, making maintaining a consistent temperature, humidity, and little physical movement difficult. For example, the Pfizer Covid-19 vaccine must be stored and transported at minus 17 degrees.

“When we are shipping there are many stops along the chain. Doing all these stops we need to be sure we are keeping the integrity of the products.” (14D)

“From a logistics perspective, it was a nightmare, you don’t have that many cold-chain capabilities along the supply chain.” (14D)

5. Data Security – Drug SCs must ensure a high level of confidentiality, as stated in chapter 5.1.1. It can be challenging to maintain data confidentiality in complex drug SCs, especially as personalized medicine becomes more popular, causing more fragmented direct-to-patient shipments.

5.1.3 SCRM in Drug SCs

After having identified relevant risks in drug SCs, we consider it important to assess what the practical issue with these risks is - is it a problem to identify these risks early enough, assess their impact or actually mitigate them? Hence, this chapter summarizes our findings on; (i) how an SCRM process in drug SCs looks like, (ii) which SCRM activities are seen to be the most difficult, and (iii) which corporate measures are currently in place to manage the identified SC risk in chapter 5.1.2.

SCRM Process and SCRM Activities

SCRM and the actions undertaken in drug SCs, according to our analysis, are highly dependent on the company culture and hence cannot be generalized. However, one interviewee stated, *“the more mature you become as an organization the more you try to evaluate all risks”* (13D), implying the more mature you become as an organization, the more mature your SCRM gets. Furthermore, our data reveal that reactive SCRM still dominates proactive SCRM. Drug SC experts, on the other hand, realize the need to be proactive and utilize the pareto principle, rather than trying to eliminate all risks. Overall, today SCRM seem more like a reactive task which is performed in response to an urgent SC disruption.

In addition, drug SC experts were asked which of the four SCRM activities outlined in the literature review, namely; (i) identifying, (ii) assessing, (iii) mitigating, and (iv) responding to risk, had the most improvement potential in their organization, and hence is the greatest pain point. Identifying risk was cited by 75% of the respondents as the SCRM activity with the most improvement potential, mitigating risk was ranked second. No interviewee stated assessing and responding to risk.

“Identify risk is definitely the place where I would like to improve.” (13D)

“That’s the problem, the identification. How do you identify risk?” (2D)

SCRM Measures in Drug SCs

When discussing risk mitigation, drug SC experts mentioned a variety of measures in use today. Serialization and track and trace were the measures named most and are described in detail below. Six additional measures were named; (i) a high level of documentation concerning quality requirements, to prove compliance with regulations, (ii) qualifying a second source for each API, or even packaging components to avoid production stops, (iii) implementing quality checks along the SC, (iv) use anti-tempering devices to seal packages, (v) use security personnel to guard shipments to reduce counterfeits or (vi) have high levels of safety stock.

“Due to supply chain disruptions, there is a need to always have a plan B. You need to ensure that you have a backup site for a specific market.” (2D)

“Contracts are something that is helping us to have a preventive measurement, like having contracts with several sides.” (2D)

“Safety stock is definitely something to mitigate this kind of risk.” (2D)

Serialization – Serialization describes the practice of assigning a unique number to a drug, a unique identifier. Each product becomes uniquely identifiable and traceable. According to one respondent, 70% of Merck products are serialized due to regulations. Serialization has been an effective method for fighting counterfeiting as well as detecting product diversions. For example, Kezzler, a firm whose representatives we interviewed, established a track and trace system for Pfizer Viagra using serialization and a central DB (Kezzler, 2020). The system allows pharmacists and customers to scan a barcode, which served as the product's unique identity and therefore verifies the drug's authenticity. This resulted in a 40% reduction of falsified drugs in Hong Kong within 12 months. Overall, serialization is an old, proven and very successful method for preventing counterfeiting. Furthermore, serialization is the basis of every track and trace system and thereby, one measure to reduce or mitigate risk in drug SCs.

Track and Trace – A track and trace system based on serialization was the second most frequent mentioned SCRM measure. A drug can be traced throughout the SC if it is serialized. As a result, you may “*verify the authenticity of a product within a fraction of a second*” (10I). Tracing is also possible at the unit level rather than at the batch level. “*The priority for pharma risk is track and trace to limit any risk*

along the chain” (14D). However, our results show that not all drug manufacturers track their products along the whole SC with their own system, but only do as much as legally required by laws, such as the FMD.

Our thematic analysis revealed three regulatory approaches to reduce counterfeits. The first approach is the EU approach, *“where you have serial numbers, you store them in a European database and just check drugs in the end with that database”* (7D). The approach is constituted in the FMD, presented in chapter 2.1.2, and is mandatory in EU countries. The EU central DB today connects 4000 drug manufactures, 110.000 pharmacies and 10.000 wholesalers from 29 countries. Our results however show two apparent FMD weaknesses; First, drugs can only be scanned at the end of the SC, when given out to the patient. From the patient's standpoint, this enables the detection of all counterfeits before delivery. However, as no scans are performed along the SC, it is impossible to determine how fake drugs entered the SC. Further, according to interviewees, scanning along the SC is not only prohibited but also would be very *“work-intensive”* (7D) and thus costly. Second, drug SC actors who do not have direct patient contact, such as pharmacists, are not granted access to the DB or serial numbers. As a result, the DB is a passive DB, and a drug maker is unable to determine where his drugs wind up. The second approach is the US approach, detailed in the DSCSA (chapter 2.1.2), *“where there is no national database (...) firms have to set up a system to exchange data with their partners”* (7D). The third approach is a full track and trace, where *“you have scans at different steps in the process, so you can have a full track and trace of all the product”* (7D).

5.2 Current Status, Architecture and Use Cases of BCT in Drug SCs

The second part of our analysis covers three main topics; (i) what is the current state of BCT use cases in drug SCs, and what developments do BCT and drug SC experts see in the future, (ii) what practical options are there to apply BCT in drug SCs, and thus which architecture and type of BC are possible and likely to be adopted in the future, and (iii) what are practical use cases of BCT in drug SCs.

5.2.1 Status Quo and Future Outlook

Lack of Full-scale Use Cases of BCT in Drug SCs today

The thesis team wanted to get a sense of the present state of BCT use cases in drug SCs before evaluating how BCT may support SCRM in drug SCs. As a result,

specific questions were posed. The results are sobering. None of the four drug SC specialists interviewed could give a single full-scale example of BCT usage in drug SCs in their firm or industry. But single initiatives, driven by either (i) industry consortiums, or (ii) technology companies such as IBM or Equideum, have been cited by others. Nevertheless, for big pharma companies like Merck and Sanofi, BCT appears to be more of a remote phenomenon than an actively employed technology in SCM, or SCRM.

“Nobody talks about blockchain.” (14D)

“It was considered already somewhere, but no, we don’t use it right now.” (2D)

“So far, I have not seen one use case up and running with blockchain.” (7D)

Three phases of BCT usage were mentioned in the interviews; (i) proof of concept, (ii) pilot and (iii) production. A proof of concept is a very simplified version of the end product that is *“minimized down to maybe two or three transactions with one or two players”* (4BD) and is used to *“prove the actual concept or value”* (4BD) of using BCT. The pilot then takes the proof of concept model a step further by adding more participants and using real-life data. The production phase is entered when the BC use case is up and running.

Our findings indicate that there are many proof of concept and small-scale pilots of BCT in drug SCs. However, the industry is just now beginning to *“think about how they can implement use case”* or *“scale the solutions”* (1B), hence, entering the third phase. According to BC experts, there is no full-scale example of BCT in drug SCs. Also, our respondents verified that neither Merck nor Sanofi employs BCT in their SCs. Merck employees mentioned three main reasons why BCT is not employed today; (i) *“It’s not maybe mature enough for what we need”* (13D), (ii) *“the level of understanding of what it is, is not there”* (13D) and (iii) the use case and business needs are not clear. Further identified barriers to BCT adoption in drug SCs are outlined in chapter 5.4. In addition, there were no government-led projects mentioned in the interviews. When we asked about BCT being considered for the FMD, we were told that *“it has never been brought up”* (10I). An interview partner from Merck, however, told us that the discussion of using BCT was just picked up again recently, after four to six years of silence, since there was *“some interest from the CEO or higher management to start thinking about blockchain”* (7D). Overall, the use of BCT in drug SCs appears to be minimal today, although it is gradually gaining traction.

“I think we've seen quite a journey in the blockchain space. When we started it was very much “what is blockchain” and we still have some of that, (...) but now there's less what is it, but more trying to define “how they would implement it” or “strategically where it should go.” (4BD)

“I haven't seen any live production use case.” (4BD)

Promising BCT Initiatives in Drug SCs

Although our study found no full-scale examples of BCT in drug SCs in use, we want to highlight two initiatives that were frequently referenced as very promising. Both initiatives are documented in full using primary data and secondary sources; however, due to page constraints, the descriptions are placed in [Appendix 13](#).

Positive Future Outlook of BCT in Drug SCs

BCT in drug SCs has a future, sooner or later, in one form or another, according to BC experts and, to our surprise, drug SC experts. However, drug SC professionals are still unsure regarding the actual application or use case of BCT in drug SCs. Overall, BCT as a commercial and mainstream application is a feasible prospect for drug SC experts, but something that lies more far in the future and is less clear for them than for BC experts.

“I actually believe in it – even if it is just maybe for certain specific process steps, maybe not for the whole SC, may specifically for risks mitigation.” (2D)

“I think there's huge value. But a couple of challenges as to when.” (4BD)

“Today everything is run well. We make our business, we ship. But it doesn't mean that we can't do it better or more efficient.” (2D)

The speed of adoption, according to the interviews, will be determined by; (i) how the industry itself evolves in the coming years, such as toward direct-to-patient delivery or lower margins, and (ii) how quickly the industry is willing and able to radically change *“how companies cooperate and compete with each other”* (6B) and (iii) how quickly other practical and technical obstacles are overcome.

There are commercially available BCT solutions in SCM, but not in drug SCs, to the best of our knowledge and based on the interviews. When asked if and when BCT use in drug SCs will become mainstream, the answer was almost consistently yes, but usually with the condition that it would take time and *“it doesn't happen overnight”* (4BD). Interviewees often refer to other technologies, such as the Cloud business or artificial intelligence (AI), which also took time to go from hype to mass adoption. Another compelling argument was made by an IBM partner (9B), who

stated that today's pharma companies selling patented drugs are “*flushed with margins*”, giving them “*little reason to use blockchain*”, but that this will change in the future and pharma companies will invest more in efficiency and transparency, making BCT more appealing for them. When asked about a precise time frame, BC and drug SC experts varied largely from two to twenty years.

“But to think of this in the future, where again a drug company 20, 30 years from now is very different than the drug company of today, they will have to share information. So, it's a question of how they position themselves. But today again pharmaceutical company profits enormous, being super efficient is not really something that bothers them today.” (9B)

“May we're talking more of a three to five-year timeline, (...) I think there are still things that need to be ironed out before people gonna mass adopt it.” (4BD)

“You want me to put a date on it? Come back in 20 years.” (9B)

Surprisingly, the drug SC experts we spoke to believe in the future of BCT in drug SCs, even seeing BCT as part of the “*next generation of supply chain*” (13D). They repeatedly mentioned the potential of BCT regarding (i) enhanced transparency, (ii) counterfeit reduction and (iii) SCRM. Only one interview partner was quite skeptical about the future of BCT in drug SCs, saying “*Personally I am still struggling, what would be the real potential. Sometimes I think we try to find use cases where we can apply blockchain, instead of the other way around*” (7D).

“Blockchain is addressing the pain points of a supply chain, especially if it comes to transparency, even predicting risks (...).” (13D)

“I don't see it right now how to implement it, but I am sure there is room for improvement when it comes to transparency.” (2D)

“In some cases, you want to be the leader, in some, you want to be the smart follower, (...). May we are not the leader in this, but we want to watch the market to see what was happening.” (7D)

It is also worth noting that respondents did not claim that BCT is the answer to all drug SC problems and that they do not “*think everything will be shared on a blockchain*” (12BD). Furthermore, when asked if BCT may be a feasible alternative for executing the FMD in the future, the NOMVEC representative did not rule it out and stated that BCT “*could be the next generation*” (10I) of technology, when the current technology expires in 2029. Other use cases of BCT in drug SCs that were mentioned are outlined in chapter 5.2.3, as are the barriers that need to be overcome to make BCT in drug SCs mainstream in chapter 5.4.

5.2.2 BC Architectures and Types

To answer the question of how BCT might support SCRM in drug SCs, it's essential to consider the various options for how BCT can be used in terms of; (i) architecture, such as whether a BC is implemented at the individual SC level or the industry level, (ii) who has access to the BC and what data is stored on it, and (iii) what type of BC is used, such as a private, public or hybrid BC. The following chapter summarizes the options identified for the three aspects, as well as their qualitative assessment based on the interviews.

Four BC Architectures in Drug SCs

“There are three different kinds of blockchains” (1B) according to one respondent; (i) the *Founder BC*, (ii) the *Industry BC* and (iii) the *Cross-industry BC*. However, other interviews revealed that there are two types of industry BCs, which are distinguished by access rights and data stored on the BC. As a result, we distinguish four alternative BC architectures in drug SCs in the following (Figure 14).

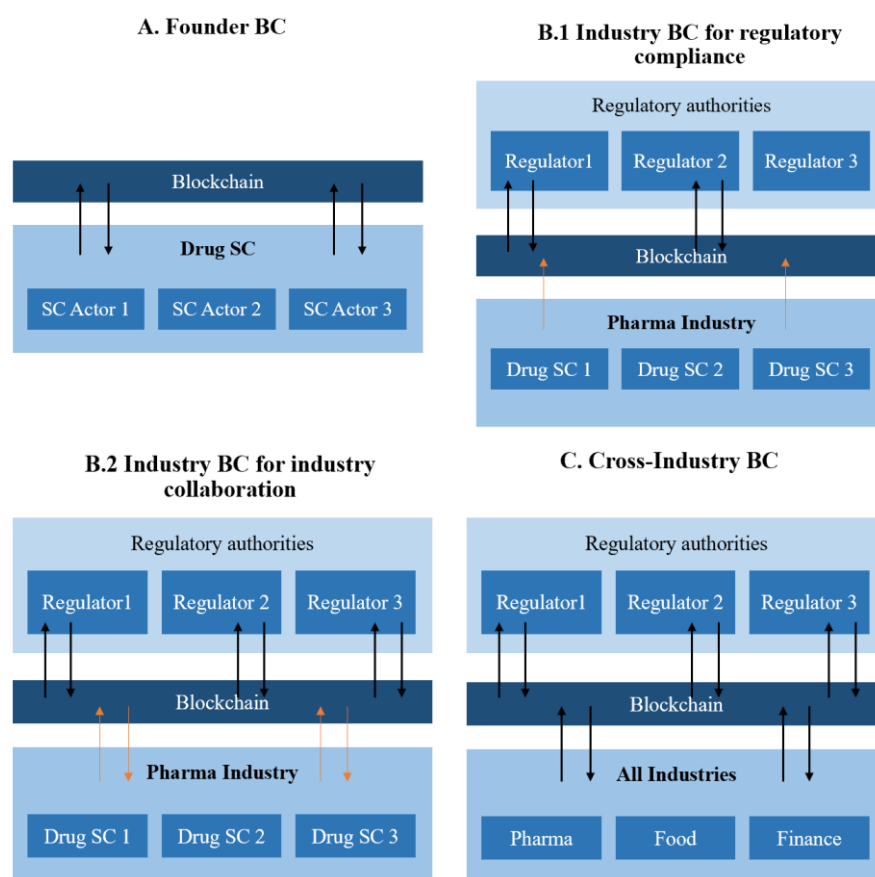


Figure 14. Four BC Architectures in Drug SCs

Before explaining the four BC architectures identified, two remarks should be made. First, it was emphasized that BCT is a good tool for connecting parties who engage with one another and benefit from data sharing, whether at the SC or

industry level. Second, it was stressed that BCT is not a replacement for existing IT infrastructure, but a technology that must be integrated with legacy IT architecture.

“It's a great tool for setting up a business network, between participants that really interact with each other.” (11BD)

“I think it's also important to understand that a blockchain is not a standalone magic sparkling solution that you get a separate desktop icon on your computer (..). It's just a protocol. It means that it's just a layer that lays in your existing ERP system.” (8B)

Founder BC for One SC – The first BC architecture describes a BC that is implemented at a SC level. All actors in a single drug SC, such as paracetamol, are connected to the BC and share operational data such as order amounts, order status, drug conditions, and forecasts with one another.

“The founder BC, that is one big company, and they obligate the other participants to be in the blockchain network.” (1B)

Industry BC for Regulatory Compliance – The second architecture refers to a BC that is implemented across the whole pharma industry, like in Europe or the US, but whose sole purpose is to demonstrate regulatory compliance of SCs actors. Different SC actors upload or export data into the BC, while regulatory entities have their own node in the BC network to access and validate data. Some interviewees also described that setting as an audit layer. In that case, the track and trace activities would still be handled by a central DB. The benefit stated in interviews is that; (i) drug SCs are heavily regulated, thus audits and legal compliance is the daily business and (ii) the regulators can be “*sure that the data is true*” (1B) in a BC.

“There may be an application, where you have an overarching layer, with distributed nodes that check information, as an overarching repository.” (5S)

“You're gonna retain a centralized database to perform tracking and trace operations and data aggregation and then you might export from that information to a blockchain for regulatory purposes.” (5S)

Industry BC for Industry Collaboration - The third architecture describes a BC that is implemented across the whole pharma industry but also functions as a data repository for all drug SC actors to share relevant data in addition to regulatory compliance. The set-up is similar to the *Industry BC for regulatory compliance*, but SCs actors can actively tap into the DB to share and access data, exactly like the *Founder BC*, but for the whole industry. As a result, unlike in the founding BC setting, a distributor connects to only one industry-wide BC rather than many BCs.

BC, as well as drug SC specialists, emphasized the value of such a setup, which provides high transparency and a single source of truth. However, respondents also stated that such a setup would require a fundamental industry change and that the pharma industry may not be ready for such a transparent setting.

“Indeed, if you go one layer further to the pharmacists and hospital, then, of course, you are going to be connected to much more industry partners and then indeed blockchain might be one of the options.” (7D)

“I'm not sure if the pharma industry is already ready for that.” (7D)

Cross-Industry BC - The third architecture describes a BC that is implemented across industries; for example, banks and food SC actors are linked to the BC. What was interesting was that one BC specialist was certain that there would only be one ultimate BC in the end, while others were certain that there would not be one.

“I believe that there will only be one global main public blockchain because blockchain is also a timestamping service, it's a global clock and you only have one global clock like the UTC time, all the time connect to that one.” (3B)

“I can already say, I don't think there's one blockchain to rule them all.” (6B)

BC Types

To assess the different options of how BCT might be used in drug SCs, it is necessary to determine not only at which level BCT should be used, hence, which architecture, but also which qualities the BC should have, hence, which BC type. Our findings are based on the theory of the three main BC types described in the literature review: private, public, and consortium (hybrid) BC. The responses to the question “*what type of BC do you believe SC participants and/or regulators will adopt in the future?*” were not clear-cut. The majority of respondents believe that public BCs will be the future, while a small proportion believes that a mix of private, public, and consortium BCs will be employed. As of today, only private and consortium BCs are in use in SCM, and no public BCs (Figure 15).

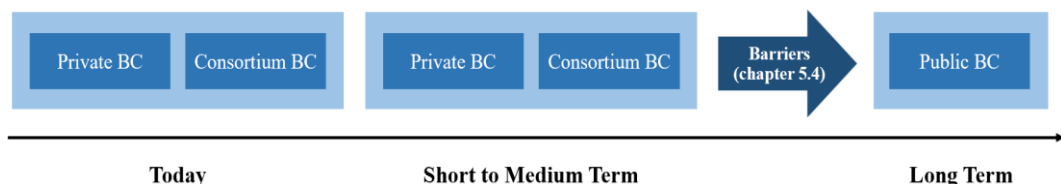


Figure 15. BC Types in the Future

Before going into detail about how different respondents see the future, we would like to emphasize four points that are critical to the practical deployment of the three BC types. First, a private BC varies little from a central DB in the eyes of

a BC expert. A private BC is run by a single entity, much like a central DB, with the exception that the underlying technology is different. Second, practitioners do not distinguish between a consortium and a hybrid BC. Third, a common misperception about public BCs is that “*everyone can see everything, but that's not the case*” (9B). There are means to create a “*private secure space for transactions on a public BC*” and to even “*fully encrypt or protect the privacy of that data*” (9B). Fourth, private and consortium BCs are not necessarily private; it all depends on how the BC is set up. A consortium BC, for example, might be set up so that “*all the different participants have similar rights, and they maintain their infrastructure themselves*” (3B). Thus, a clear distinction between the different BC types is not always possible, further complicating the discussion.

“There is no such a thing as a private blockchain - so I won't even say it. A private distributed ledger, is just a database.” (3B)

“Just because you have a public blockchain, doesn't mean the information is public. (...) You can control who's get access to the information.” (6B)

“I think even our words like private and public and all that gotta change some. So, if it's a consortium it doesn't necessarily mean private. You could have a consortium of pharmaceutical companies come together and still have the data be largely accessible because they're going to share it fairly openly.” (6B)

Only private and consortium BCs, not public BCs, will be employed in SCM in the short to medium term, according to respondents. Why? The top three reasons given for why SCM has not yet adopted public BCs are; (i) there is still “*some anxiousness of this idea of opening up publicly*” (4BD), (ii) the “*technology is still intendancy and still maturing*” (4BD), and (iii) the BCT and “*decentralized operations are very difficult for people right now to understand*” (8B). More details on these challenges, as well as additional hurdles to the adoption of public BCs in drug SCs, can be found in chapter 5.4.

“I think where we're playing at the moment is probably the hybrid space, (...) that's probably what we are playing for in a little while. (...) but I think the intent as the technology matures as an understanding of the technology and its capabilities matures, that we will look more towards public.” (4BD)

In the long run, 75% of respondents believe public BCs will be the future, while 25% believe there will be a mix of private, hybrid, and public BCs. What was interesting was that two IBM partners from the US independently declared that their views on which BC type will be the future had fundamentally changed over

the last years. They used to believe in consortium BCs, but now they believe public BCs are the way to go.

“I’m 200% sure that it’s only public blockchain that will survive.” (3B)

“I think that’s a very difficult question because I don’t see that there will be either one. I see in the future that there will still be public blockchains and still be private blockchains.” (11BD)

“A few years ago, when I started this, I would have said consortium blockchains. (...) Roll the tape and what we’ve seen is that those networks are very hard to incubate. (...) Along the way, the public blockchain networks have progressed itself. (...) I think more and more it seems like public networks, with these private network cargos, will be the way that things emerge.” (9D)

According to BC experts, consortium BCs are not the future for practical rather than technical reasons, such as; First, setting up a working governance mechanism, which includes deciding and agreeing with all consortium members on who can join the network, and who cannot, what kind of data is shared, and so on, is difficult because different actors have very different interests. One interviewee stated that *“when it’s one or 20 parties, we can probably figure it out. But when it’s 50 or 100, it gets hard. Then it’s not just the pharma companies that have a say in this, you need shippers, pharmacies, dispensers - it becomes 1000 different business interests, (...) they don’t really want to play nice together” (6B)*. In a public BC, however, they claim that token and a well-constructed economic model, rather than an agreed-upon legal contract, is the motivation factor. Second, a consortium BC requires that all BC participants trust the consortium, which some BC experts doubt to be possible. In a public BC, people must *only* trust the technology, not other participants. Third, the cost of funding and running a physical IT infrastructure is high, particularly as the BC scales, and the time it takes to become profitable is long. *“Looking at the prices on the market today it gets way too expensive” (3B)*. In a public BC, however, *“you’re just connecting to the available network” (3B)*, and the *“physical infrastructure is already there” (9B)*.

“I think the problem with consortiums, I don’t think the industry agrees with me yet, but after doing this for three years and looking at how slow the progress is going, I think consortium models are going to be very difficult to scale.” (6B)

“I spend a lot of time working with kind of consortiums and setting up governance - and it’s hard. I actually think the technology is the easiest part because it does what it says it will do. People are the hardest part.” (4BD)

It is also worth noting that the interview partners stated, that the right BC type, and

therefore characteristics, are determined by (i) the willingness to collaborate and exchange data, as well as (ii) the use case. If the BCT use case, such as track and trace, requires a fast transaction speed, one BC type is preferable to another. Therefore, the next chapter presents the most promising BC use cases in SCM and SCRM, as determined from our data.

5.2.3 Use Cases of BCT in Drug SCs

BC and drug SCs experts agree, as indicated in chapter 5.2.1, that BCT is of high value in drug SCs for both businesses and patients, in some form or another. *“The possibilities are huge and it's gonna have a massive impact on patients, but also on the efficiency of the entire supply chain”* (4BD). However, our findings reveal that the pharma industry is still trying to *“demystify the technology”* (13D), with drug SC experts asking themselves what the actual use case of BCT in drug SCs might look like. One Merck drug SCs specialist even said that he sometimes thinks they *“try to find used cases where you could apply BC, instead of the other way around”* and that they are *“still struggling to find really use cases where they (we) can apply blockchain technology”* (7D). Our findings suggest that, while drug SCs experts believe BCT has value for them, they are unsure about the specific use case, thus how and where to apply BCT. As a result, BC experts were particularly questioned regarding BCT use cases in drug SCs. Although the responses were frequently vague and multiple use cases were mentioned at once, our analysis revealed four clusters of use cases, which are presented in Figure 16.

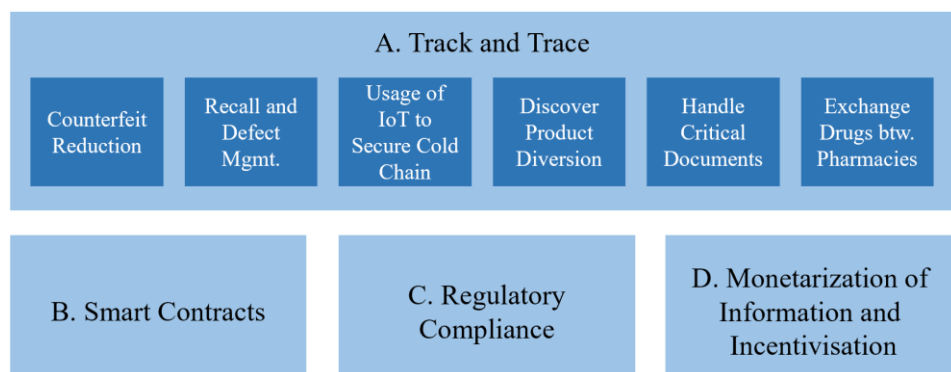


Figure 16. Uses Cases of BCT in Drug SCs

Before outlining the identified use cases, we want to highlight four points of general importance; First, from a quantitative standpoint, the track and trace use case, as well as its several sub-use cases, was by far the most cited. Second, as indicated in chapter 5.2.1, none of the use cases is in production today, hence, the use cases are either (i) similar to use cases of other SCs or industries, or (ii) ideas and concepts.

Third, our questions and findings focused on BCT use cases in physical drug SCs rather than service logistics. Fourth, BC experts emphasize that BCT is not an application or “*standalone magic sparkling solution that you get a separate desktop icon on your computer*” (8B), but rather an “*underlying foundation*” or “*anchor*” (4BD) that (i) must be integrated with the existing company IT-infrastructure and (ii) is “*really really powerful*” (4BD) when combined with other technologies like AI or IoT. An interviewee, for example, emphasized that data on a BC is approved by all actors and therefore of high quality, making it an ideal data source for AI. The interviewee states, “*AI can then come up with amazing predictions about the status of the supply chain, and its vulnerabilities*” (9B).

A. Track and Trace

The most often named use case for BCT is to set up a BC-based track and trace system. The idea is to tag a single drug and trace it through the SC all the way from the API manufacturer to the patient. Here it is advantageous, that drugs are often already serialized, hence have a unique identifier, due to legal requirements. The drug is then scanned by each SC actor handling it using technologies like RFID, and the data is exported to a BC, where each drug's unique track record is kept (Figure 17). In chapter 2.4.2 further detail on the technicalities of this and other use cases discussed in this chapter are outlined. One interviewee gave an interesting example of the distribution of drugs with a short shelf life once produced, such as radioactive drugs for cancer treatment or vaccine vials. He stressed the benefit of being able to track these drugs with precise timestamps as well as their condition. Further, it was mentioned that the pharma industry's V-to-V SC trend, which requires round-trip logistics and exact monitoring of who will receive which treatment, might be substantially eased by a BC-enabled track and trace system.

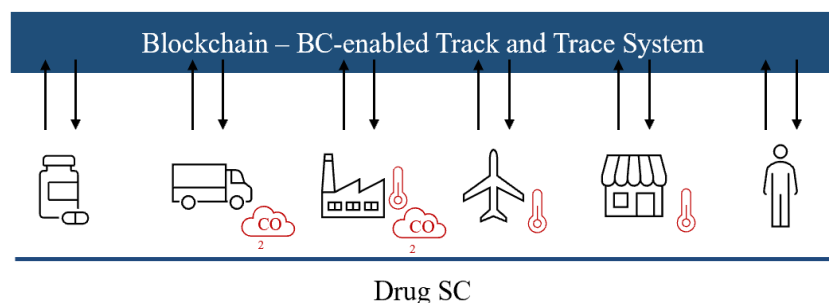


Figure 17. BC-enabled Track and Trace System

“You could see the history of a drug in time and space - from when it left the manufacturer until it gets to, let's say the hospital. And if we do this real large, suddenly we have tremendous visibility into the disposition of drugs.” (9B)

“Blockchain is a great way to keep track of stuff, especially when the stuff crosses boundaries. (...) be those boundaries, geographic boundaries, organizational boundaries, or tracking things across time.” (9B)

BC experts highlight that using BCT for track and trace purposes provides a single source of truth that allows all SC actors to see a drug's history across time and space, giving a *“tremendous visibility into the disposition of drugs”* and an *“end-to-end view”* (9B). Because this chapter focuses on the use case, the benefits of increased visibility and traceability, as well as the benefits of other use cases, are presented in chapter 5.3. Table 7 summarizes all identified use cases that leverage a BC-based track and trace system for a specific purpose, such as counterfeit reduction.

Use Case	Use Case Description
Identify Counterfeit Drugs	As a BC provides a single source of truth about a drug's history, it's feasible to <i>“verify which drugs where batches of drugs shipped from a specific manufacturer”</i> (12BD), and thus identify counterfeits or prove authenticity. Scanning drugs along the SC, allows SC actors to determine where and how fake drugs entered the SC. This allows SC actors to not only remove the counterfeits before they reach the patient and cause harm but also to take proactive measures against counterfeiters. Although neither the FMD nor the DSCSA requires drug SC actors to use a BC-based track and trace system to prevent counterfeits, interviewees stated that it might be an option.
Recall and Defect Management	Track and trace data stored on a BC may also allow for improved recall management. <i>“If there was an issue with one drug, you'd be able to trace it back and see where that issue happened in the chain or what warehouse it came from”</i> (4BD). One example given was if, for instance, one truck got stuck in traffic and thus the drugs went out of the temperature window, just the few hundred drugs transported with that truck would need to be recalled from pharmacies, rather than the thousands, or ten-thousand units in the batch. The <i>FDA DSCSA Blockchain Interoperability Pilot</i> was an initiative aimed at just that use case.
Usage of IoT to Secure Cold Chains	A combination of a BC-enabled track and trace system and IoT devices was another commonly suggested use case. Drug SCs, such as the Pfizer Covid vaccine, have extreme cold storage and transportation requirements, with -70°C. According to respondents, you may add a temperature log to the BC to monitor if the drug is kept at the right temperature over time. Further, it was stressed that <i>“with the IoT-based blockchain system you (...) do not have to rely on the company that is reporting that information”</i> and therefore <i>“it has better data integrity”</i> (12BD).
Discover Product Diversion	Product diversions are one risk identified in drug SCs (chapter 5.1.2). According to interviewees, a BC-enabled track and trace system enables SC actors to not only detect large-scale product diversions, such as when

	thousands of drugs produced for the European market end up in Brazil, but also to pinpoint where they were redirected.
Ease Paperwork	BCT allows for the safe exchange of important documentation such as cargo letters, invoices, or custom declarations, according to BC experts.
Exchange Drugs between Pharmacies	Drug exchanges between pharmacists in the EU and the US are forbidden due to security concerns. For instance, if a pharmacy has <i>“too much of something and you need it, that transaction is not allowed, it is forbidden by law to happen”</i> (9B). <i>“Which is completely insane, because it prevents the system from self-optimizing”</i> (9B). Interviewees emphasized that BC allows for a safe and controlled drug exchange, allowing <i>“the network to be more self-optimized”</i> (9B)

Table 7. Track and Trace Sub-Use Cases

B. Smart Contracts

Several BC specialists discussed the use case of smart contracts, some in relation to a track and trace system, but not all. The two most common examples were; First, payment automation, in which a smart contract could automatically transfer money if a shipment is registered in the system, and (ii) SCRM, where in case an order did not arrive or a shipment went out of its designated temperature window, the system could *“act on those risk if they appear in a very fast manner”* (11BD) by *“automatically triggering some event to substitute that product”* (9B).

C. Regulatory Compliance

The use of BCT in drug SCs is frequently referenced in regard to demonstrating compliance to regulatory authorities, as detailed in chapter 5.2.2. It is said to be a great solution for SC actors to ease compliance work because data recorded on the BC cannot be altered and authorities can easily connect to the BC. One respondent further advocates BC as the perfect solution for increasing EU legislation, such as Germany's *Lieferkettenschutzgesetz*, which mandates businesses to provide *“some kind of traceability”* (3B). Another example offered was supplier qualification, in which the BC serves as a trusted source for validating supplier data and certificates.

D. Monetization of Information and Incentivisation

We increasingly got statements like *“blockchains have the potential to change the economics about how companies cooperate and compete”* (6B), *“the most interesting work that's going to happen in blockchain over the next years, is going to come from economists, (...) because you've got to construct the right framework for companies to use this vehicle in a way”* (6B) or *“blockchain is a way of*

incentivizing people to share information” (6B). All of these remarks refer to the ability to sell and buy information from other BC participants in a BC network using tokens. The technical details of how a token-based economic model in a public BC works will not be covered here.

As noted in chapter 5.1.1, the degree of information sharing in drug SCs is low. Often data is only shared with one upstream and one downstream party, or even sold to external parties, who then resell the information back to other SC actors. Therefore, experts stress the importance of information monetarization and hence *“incentivization of different participants along the supply chain”* (11BD) in this context. All SC actors, whether pharmacies, manufacturers, or even customers, *“get an incentive to sell their information to other SC actors. So now they have an incentive to share information, because they make money”* (3B). Convincing SC actors to join a BC network, such as a BC-enabled track and trace system, is difficult. According to BC experts, a monetary reward for sharing information could be a strong motivator for SC actors to join the BC. Further, according to experts, an incentive for pharmacies and manufacturers to share sales data on new drugs might be very beneficial to patients, as production and distribution can be optimized.

5.3 Value of BCT in SCM and SCRM

Chapter 5.1 and 5.2 provide the knowledge foundation to answer our research question as they present identified SC risk and SCRM practices in drug SCs, as well as BCT use cases and architecture types. The findings on the perceived value of BCT for SCM and, more particularly, for SCRM in drug SC are presented in this chapter and build on chapter 5.1 and 5.2. As a result, this chapter analyzes which BC characteristics are beneficial for SCM, how the identified use cases might benefit SC risk and SCRM practices, the advantages of a BC over a central DB, and if the value proposition of BCT in drug SCs differs from that of other SCs.

5.3.1 Value of BCT in SCM

According to our findings, BCT can add value to SCM in drug SCs in four ways; (i) BCT might improve the information exchange between drug SC actors, (ii) increase transparency in drug SCs, (iii) allow drug SC actors to trust the BC rather than other SC actors and (iv) is more secure than a central DB and it is easier to connect many drug SC actors to a BC rather than a central DB.

Information, Product and Money Flow of SCM

In SCM it is often differentiated between product, information and money flow. When we asked which type of *flow* BCT is most valuable for in drug SCs, the majority of participants said information flow, followed by product and money flow. They did say, though, that it also depends on the specific BC use case. In the track and trace use case, for instance, they state that transparency and data exchange is increased and hence, the information flow is facilitated. Furthermore, respondents say that as the information flow improves, so does the product flow.

Beneficial BCT Characteristics for SCM in Drug SCs

When asked which of the BCT characteristics presented in chapter 2.3.3, is most valuable for SCM, interviewees did not name a single one. Overall, SC transparency was cited the most, and as a result, was recognized as the most valuable for SCM, followed by trust and immutability. Decentralization related characteristics like privacy, reliability, and versatility were deemed less beneficial for SCM.

Transparency – Referring to the track and trace use case, interviewees state that implementing a BC-enabled track and trace system significantly improves SC transparency. That in turn has multiple benefits such as reduced SC risk (chapter 5.3.2) and efficiency and effectiveness gains.

Trust – Another benefit that was often emphasized was trust. Respondents stressed that with a BC solution “*you can trust the system and you don't have to trust the other actors*” (3B). This is said to be especially important in industries where trust between players is poor, such as the pharma industry. They go on to say that BCT is a simple way of “*establishing consensus and aligning interests of parties that might not trust or know each other*” (6B). Respondents also emphasize how the three properties of immutability, transparency, and trust are interconnected and mutually reinforcing. According to one reply, transparency and immutability are the basis on which trust in the BC is formed.

“Blockchain allows for stakeholders that don't trust each other, to trust the data that they generate along the entire chain of custody of an asset.” (12BD)

“With a blockchain you have one universal source of truth, that everybody can trust.” (3B)

Immutability and Integrity – Immutability is another feature frequently considered beneficial for SCM in drug SCs. You can trust the data since it is “*updated in a secure manner*” (11BD) and has not been tampered with. As a result, the data integrity is high. Data integrity and variability are of considerable value for SC

operations, especially in an environment where there is a lack of trust amongst SC actors. Furthermore, BC is described as “*the most secure time-stamping system in the world*” (3B), guaranteeing high data confidentiality.

Decentralization – The decentralized feature of a BC is mentioned less frequently by respondents. However, interviewees claim that because every SC actor has a copy of the BC, everyone can monitor all transactions in real-time which increases transparency. They also emphasized that “*you can share information without the need of an intermediary*” (4BD), such as 3PLs. As a result, the danger of engaging un-trustable intermediaries is lowered.

“Blockchain enables the creation of decentralized, synchronized databases, which help to minimize or reduce the dependency on intermediaries.” (11BD)

BC versus Central DB

Drug SC practitioners frequently questioned why they should use a BC if they could use a central DB. “*Personally, I do think that centralized services don't really have any drawbacks relative to a blockchain – but of course, it depends on the application*” (5S), one respondent says. However, our analysis of BC specialists’ interviews revealed three advantages of a BC over a central DB, all of which are strongly tied to BC characteristics. First, a central DB must always be administered by one entity, which decides who has access to which data and has the power to decide on the level of transparency. Therefore, information sharing is often lower compared to a BC network. BC specialists emphasize that there may be “*some level of mistrust from each other because there are external participants*” (4BD), making a single ruling entity difficult. Further, because a decentralized BC provides a copy of the ledger to each SC player, transparency is ensured. Second, as the central DB is controlled by one entity, data can be modified without the other parties’ knowledge or consent. Hence, a BC is more trustworthy than a centralized DB. Third, the interoperability of a central DB is said to be lower. A BC is designed to allow many participants to join it but connecting a large number of actors to a central DB becomes difficult and very costly.

5.3.2 Value of BCT in SCRM

According to our findings, BCT can add value to SCRM in drug SCs in four ways; (i) BCT can help to identify SC risk in drug SCs, (ii) reduce counterfeits, (iii) help to identify product diversion, and (iv) assure product integrity. As a result, BCT has the potential to help alleviate drug shortages.

BCT and SCRM Activities

When drug SC practitioners were asked which of the four SCRM activities had the greatest potential for improvement in their firm, 75% said *identifying risk*, with *mitigating risk* coming in second (chapter 5.1.3). Interestingly, most respondents from BCT and the combination of BCT and drug SC also answered *identifying risk* when asked which of the SCRM activities they believe BCT is most valuable for. They cite enhanced transparency, as well as the fact that everyone has a copy of the BC, the single source of truth, as reasons why risk can be identified better and earlier. However, the interviewees stressed that BCT is valuable for all four SCRM activities, not only risk identification.

“I would say all of the above. But if I had to pick one, identifying risks.” (9B)

“I guess from the top of my head I would say that BC could provide benefits for all of these activities.” (11BD)

Drug SC Risks Mitigated or Reduced by BCT

After asking for specific SC risks in drug SCs in general, we explicitly asked which of these SC risks in drug SCs, presented in chapter 5.1.2, respondents believe BCT can mitigate or reduce. The findings indicate that BCT can address all five risks to some extent, with the counterfeit risk being the risk that can be addressed best. Additionally, respondents were asked to rank the four primary risk types, namely supply, demand, process, and corporate-level risks, in the order in which BCT has the potential to address them. The majority ranked *supply risk* first or second, followed by *corporate-level* and *process risk*. As indicated in chapter 5.1.2, the majority of identified specific drug SC risks fall within the *supply risk* category. BCT, according to our results, can mitigate these risks. The potential of BCT to reduce or mitigate the identified risks in chapter 5.1.2, is next assessed one by one.

1. Drug Shortage – BCT was not mentioned in any of the interviews as having the ability to directly eliminate or reduce drug shortages. However, our research reveals that while there is no direct link between BCT and a drug shortages reduction, BCT might indirectly address the issue by, for instance, reducing counterfeits and product diversions.

2. Falsified Medicine – Almost all respondents cited the use case of *Identify Counterfeit Drugs*, described in chapter 5.2.3, and hence the potential of BCT to identify and thereby minimize drug counterfeits as a risk BCT can reduce. According to our findings, a BC-enabled track and trace system combined with drug

serialization is a good and very effective way of detecting counterfeit drugs. According to our interview partners, the counterfeit risk, which is unique to drug SCs and highly destructive if not caught early on, may be effectively minimized, if not completely removed, with the use of BC.

“I guess that there could also be other solutions for setting up an anti-counterfeiting solution apart from blockchain, but I guess blockchain provides a great means to do that.” (11BD)

“Counterfeit risk is something that is a high risk in this setting and is definitely something where blockchain, could be used and make a difference.” (11BD)

3. *Product Diversion* – Similarly to the drug shortage risk, the reduction of product diversions was not mentioned as a direct benefit of BCT. However, because a BC-enabled track and trace system can detect where a specific drug is delivered, by whom, or when a shipment's track record ends, product diversions can be identified using BCT, according to our findings.

“Blockchain has a potential to verify where batches of drugs were shipped from a specific manufacturer and can track the entire supply chain.” (12BD)

4. *Product Integrity (Transport)* – Interviewees note that BCT can help companies to track and control various shipment conditions, such as humidity and temperature, with the use of IoT and BCT. Having full transparency about the history of these conditions not only allows companies to take mitigation actions but also allows patients to authenticate the validity of a drug they purchased at a drugstore or online.

5. *Data Security* – In our interviews, no one addressed BCT's ability to mitigate the data security risk, which is high in drug SC due to the high data confidentiality. However, BC specialists emphasized that even in a public BC, data can be shared selectively with SC actors or authorities, and is therefore as safe as in a central DB.

Other Risks – Our findings show that, in addition to the five risks outlined in chapter 5.1.2, BCT may be able to reduce or mitigate other SC risks. BCT may reduce the risk of over- or under-stocking since more data from upstream and downstream SC actors are shared, and forecasts are more accurate. Moreover, one location may have an excess of certain medicine in stock, while other locations may experience drug shortages. BCT might provide a secure platform for these two locations to exchange drugs, which today is prohibited. This would allow the network to be “*more self-optimized*” (9B). Furthermore, because a BC-enabled track and trace system let you see where single APIs originate from and how it has been processed, “*you generally*

get a higher product security” (3B). Hence, the product security risk is lowered.

Unique Value Proposition of BCT in Drug SCs

While some interviewees said that the value proposition of BCT in drug SCs “is the same more or less” (3B), others argued that the value proposition is profoundly different from other SCs. The majority of practitioners, though, think that the value proposition is different, emphasizing the unique quality of an *Impact on Life and Death* as a reason. Not only is the risk of a product shortage, counterfeiting, or product diversion larger, but consequently so the value of eliminating these risks using BCT, they argue. To conclude, they agree that “the stakes are higher on drug supply chains” (9B), resulting in a unique value proposition.

“If you don’t have the medicine on time, in the right quantities, in the right form or quality, we are talking about death.” (14D)

5.4 Barriers to BC Deployment in Drug SCs

Our findings in chapter 5.2.1 reveal that not one active usage of BCT in drug SCs has been documented as of yet. On the other hand, BC and drug SCs experts are confident that BCT will play an important role in the future and recognize BCT's value in drug SCs (chapter 5.3). To determine why BCT is not utilized today and what roadblocks are in the way of quick adoption, we posed open questions about barriers, as well as questions about specific challenges, to all target groups. The barriers described were numerous; on average, each interviewee mentioned five barriers, and many of them were interconnected, making it difficult to draw a clear line between them. Nevertheless, our analysis identified 17 barriers (Figure 18).

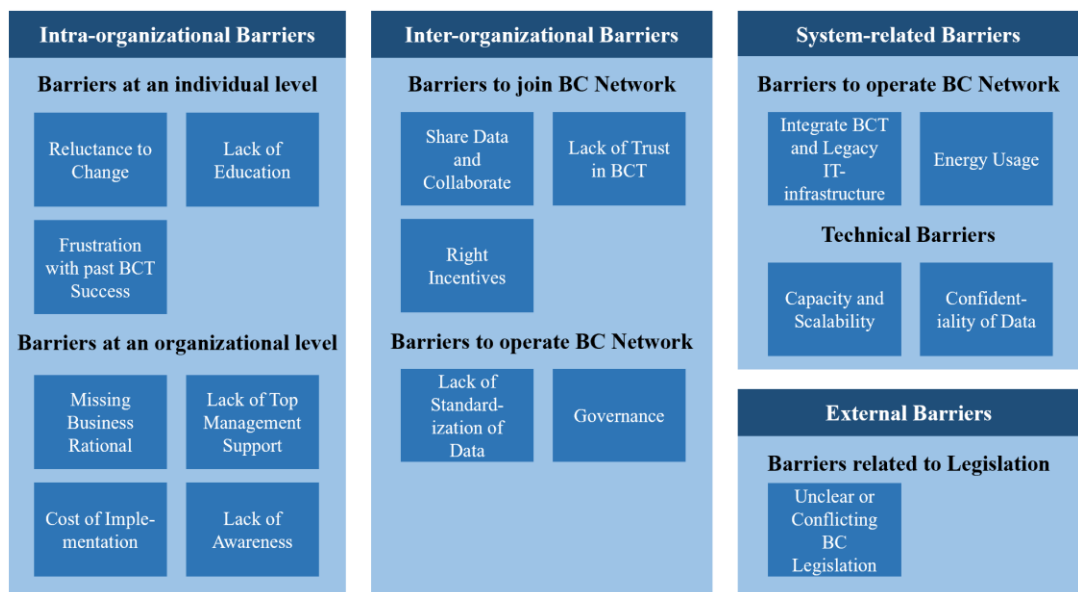


Figure 18. Barriers to BC Deployment in Drug SCs

Further, we classified the 17 barriers into the four categories of the framework developed by Saberi et al. (2019) and Lohmer and Lasch (2020), introduced in chapter 2.4.3. From a quantitative aspect, intra- and inter-organizational barriers were stated the most, with 28 and 21 references, respectively.

“We looked into it with my experts. It's not that it's not good - that's not the point. It's not mature enough for what we need, on one hand, on the other hand, I see also the level of understanding of what it is, is not there.” (I3D)

Because everyone's response to the question *“what do you consider the biggest barrier?”* differed, we analyzed how frequently barriers were stated (Figure 19). The barrier of reluctance to change was mentioned the most often, with nine out of fourteen interviewees citing it. Second and third most often mentioned were capacity and scalability constraints and reluctance to collaborate and share data in a BC-network. It is also worth noting that the majority of barriers were cited by both BCT and drug SCs experts. Only the lack of sufficient incentives and the education barrier were indicated more frequently by BC experts, whereas drug SC experts mentioned capacity and scalability constraints more frequent.

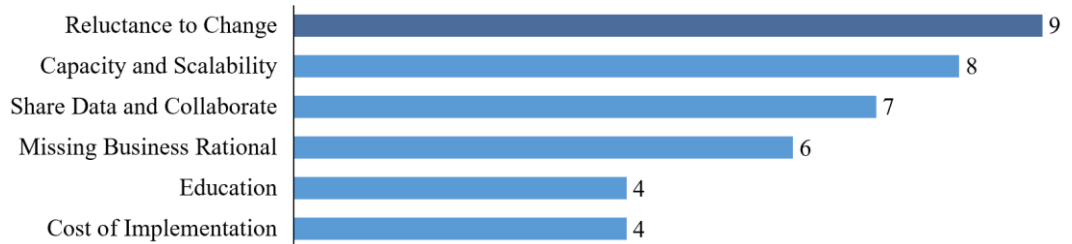


Figure 19. Top 6 Barriers

Before elaborating on the different barriers, it is important to note that they all apply to only public and consortium BCs and their respective characteristics. They do not apply to private BCs as a private BC is essentially a central DB with a different underlying technology. Also, for consortium BCs, three additional barriers could be identified; (i) establishing a governance mechanism, (ii) trust in consortia, and (iii) funding and running a physical IT infrastructure, as detailed in chapter 5.2.2.

5.4.1 Intra-organizational Barriers

Intra-organizational barriers dominate both in terms of total barriers and references, according to our findings. To fit the framework of barriers in chapter 2.4.3 and to provide some structure, we classified the seven barriers into two sub-categories.

Barriers at an Individual Level

Reluctance to Change – Reluctance to change, or reluctance to change the status

quo and adopt BCT as a new technology, was the most often stated barrier. Not only did interviewees note “*a certain resistance to use new technologies and engage in them*” (11BD), but they also highlighted three additional factors that often provoke hesitancy and skepticism. First, if an existing working system or process is being considered for replacement. The auditing process was an example of a functioning system that might be altered if a BC is used. Drug SC experts underlined that they are not willing to replace existing processes, but that BCT “*will be on top of*” (7D) existing solutions rather than replace them. A lack of vision was also mentioned by one respondent, stating “*technologies are only enablers*” (13D) and good change management is needed to overcome the reluctance.

“I think that changing the status quo is really one of the hardest things to do in this space. (...) They have a system already set up. Using blockchain and changing that system, would be reform everything they've been doing in the past. I think there's hesitation to do that.” (12DB)

“I think you have to be careful that you not replacing a working process.” (7D)

“They feel they need to replace all their legacy systems with blockchain.” (4BD)

“You will have a period where things not run as smooth as they should.” (8B)

Lack of Education – Another frequently cited barrier is the lack of education. According to BC specialists, companies do not need to learn how to program a smart contract or run proxy nodes, nor do they need to set up a “*whole department of programmers*” (3B). However, knowledge of BCs characteristics, architectures, types, and use cases is critical, but often lacking. Further, BC experts noted that there are many misconceptions about BCs. One common misunderstanding of public BCs, as indicated in chapter 5.2.2, is that everyone can see everything.

“It's about enabling people to understand more what it is and what not.” (13D)

“The main challenges for blockchain adoption in general, regardless of the supply chains, is that no one at the CEO level actually understands it.” (8B)

Frustration with past BCT Success – Lastly, the fact that BCT has been around for a long time but “*hasn't delivered quite yet*” (4BD), is commonly cited as a reason why people are skeptical and hesitant.

Barriers at an Organizational Level

Missing Business Rational – Drug SCs experts frequently stated that they do not see a clear business reason or case for using BCT or where it should be used. For them, the added value is unclear. Our analysis identified two reasons for this; (i)

many organizations do not know how BCT might be utilized, and consequently what potential use cases and architectures are (chapter 5.2) and (ii) the technology's benefit is unclear because there are no best-practice examples in the drug SC space.

“We need some demonstration of the benefit of the blockchain.” (14D)

“May it’s a kind of mental barrier, you speak a lot about proof of concept, about pilots. So far, I have not seen one use case up and running with BC.” (7D)

“It should give added value, not replace an existing process.” (7D)

Lack of Top Management Support – It was stated that the C-suite support or buy-in is often lacking or too weak and that it is critical that BC is “*part of the company strategy*” and “*fit into what the company is trying to achieve*” (4BD).

Cost of Implementation and Lack of Awareness – The BC integration with existing IT infrastructure, as well as the required hardware and staff, demands significant resources, which could be a barrier, “*even though the pharma industry is not a poor industry*” (14D), according to interviewees. Our research revealed that initial investments, as well as running costs, also play a role in the reluctance to change. Finally, it became clear from the interviews that BCT is not always a top-of-mind technology in drug SC operations.

“Companies will not say let’s do something completely different regardless of whether there is a benefit or not. There is a cost, that has gone into that investment and so it’s unlikely they’re gonna rip it out.” (5S)

“Today, when we are discussing with 3PL, when we for instance are setting up a new relationship or developing an interface, etc., I have never heard about blockchain. I can tell you - Nobody talks about blockchain.” (14D)

5.4.2 Inter-organizational Barriers

Our research identified two types of inter-organizational barriers; barriers to join and to operate a BC network. *Barriers to join a BC network* was by far the most often mentioned sub-category, with 11 out of 14 interviewees expressing a barrier linked to joining a BC network.

“Create a solution is easy. But later you need to convince all the participants to adopt the solution. This is something that is complex.” (1B)

Barriers to Join a BC Network

Share Data and Collaborate – Seven interviewees listed data sharing and collaboration with other SC actors as barriers to BCT in drug SC. If you do not want to share information, you do not need a BC. BC professionals stressed that while

BCT allows for greater transparency in drug SCs, it ultimately comes down to “*what the different participants are willing to share*” (11BD). Our study, however, reveals that drug SCs are characterized by a low level of cooperation and data sharing. When asked directly, drug SC professionals confirm that the industry is not yet ready to collaborate so closely and share data with so many entities. According to BC specialists, a lack of trust between parties in a drug SC is often the reason for reluctance to share data. They underline that the barrier is mostly a *people challenge*, requiring a company to realize that data sharing is beneficial rather than inherently harmful. One BC/drug SC expert expressed it as a mindset shift that must occur. He also claims that network effects, such as greater SC transparency in drug SCs, cannot be leveraged, without a *network mindset*, which includes to “*be more open and share information*” or “*be aware of what the other participants need*” (11BD). Respondents, however, note that this mindset shift is challenging since it requires companies to “*really give up some of their power*” (11BD).

“I’m not sure if the pharma industry is already ready for that. I think maybe it is still a traditional industry and we are not there yet to share everything.” (7D)

“So, if I’m a pharma company, I don’t wanna share information, I’m not used to sharing any information. To do that scares me. If I’m a distributor, I certainly don’t wanna do it.” (9B)

“There is the notion of setting up a network, that is useful for all participants. So being aware of what the other participants need. So, you are aware that working together you might get rid of some of your power, but you gain other capabilities, better data access, etc., which should be more valuable than maintaining your power position. So, it is a network mindset that’s needed.” (11BD)

Lack of Trust in BCT – Another aspect that has been noted as contributing to the reluctance to join a BC network is a lack of trust in BCT. Participants must no longer trust one another when using a BC DB; but they must trust the technology. We could identify three factors that nurture that barrier; (i) trusting a technology, and hence a code or protocol, is fundamentally different from trusting an organization or direct contact person, (ii) data recorded on a BC may still contain manual human errors, and some interviewees even argue that “*nothing tells me the information that you have entered is the true information*” (5S), and (iii) trusting a BC to execute key processes, means trusting a medium that is not totally within one's control. This is frequently regarded as risky in terms of business continuity, which is critical, especially for drug SCs.

“It's a social issue. It requires these companies to interact with each other in ways that is totally foreign to them. These companies in the pharmaceutical space, they don't trust each other. They even do not like each other right.” (9B)

Right Incentives - Interviewees also said that other SC actors often do not have a strong reason or are offered good incentives to join a BC network, set up by another drug SC actor. BC experts stress that is still a challenge for companies and in general to (i) “*construct the right framework and economic model for companies to use this vehicle*” and (ii) to “*figure out how to build incentives*” (6B).

Barriers to Operate BC Network

Lack of Standardization of Data – Because all BCT use cases in drug SCs involve many SC actors, interviewees emphasize the importance of industry standards such as uniform data formats, data exchange norms, and procedures. One BC expert points out that “*BC is only as good as the data it gets, so even though it's immutable, if you're gonna put in garbage you're gonna have garbage immutable*” (4BD). However, those data standards are often missing, resulting in companies having data in various formats.

“With blockchain it will come more data, so you need to find the smart way to integrate it and take something out of it.” (2D)

Governance – Even though “*the governance issues are a little bit less weighty*” (9B) in a public BC than in a consortium BC, governance mechanisms must be set up. Technical details are not discussed here. However, decision as to who is authorized to see which data must be made and are described to be difficult.

5.4.3 System-related Barriers

Although technical aspects of BCT are not the focus of our thesis, it is crucial to note that technical limitations were noted in our interviews, with the most common being limited capacity and scalability. However, our results also reveal that both BC and drug SC specialists believe that these challenges will be effectively solved in the near future. For the time being, though, barriers and uncertainties remain.

“I think there are new protocols or new advances of protocols that exist that are already trying to manage these challenges.” (4BD)

“I think the engineering problems are rapidly being solved and even for the unsolved ones, (...) we got three or four ways we can solve them, it's a question which one we align around. I think we're well past engineering problems.” (6B)

Barriers to Operate BC Network

Integrate BCT and Legacy IT-infrastructure and Resource Usage – It was stated in interviews that “*doing the blockchain project itself is a challenge, but also integrating that into the own organization is another challenge*” (11BD), emphasizing the difficulty of integrating BCT and legacy IT-systems, as well as the high energy needed to run a full-scale BC network.

Technical Barriers

Capacity and Scalability – The BCT's Achilles heel, according to drug SCs, is its capacity and scalability. The most frequently expressed points were that a BC (i) is not fast enough in terms of transactions per second to handle and process the data volume required in a drug SC, and (ii) has insufficient file storage. Interviewees stressed the importance of speed and instant data availability for use cases like validating the legitimacy of a drug, recalls, or tracking shipments on a unit-level. BC specialists, on the other hand, disagree and rarely view it as a problem, or if they do, they are certain that it will be fixed soon.

“One of the problems if we were to use blockchain, you need a very fast response. You don't want the pharmacist when giving out a drug go like hang on, find yourself a seat, while you wait and see what happens.” (10I)

Confidentiality of Data - Drug SC experts say that drug SCs deal with sensitive data, such as IP and personal data, that requires high confidentiality and is protected by patents or GDPR, which they are unsure can be guaranteed in a BC network.

“It's also a question of privacy, and data confidentiality, there is transaction data for all pharmacies and all packs, that's very valuable information.” (10I)

5.4.4 External Barriers

Unclear or Conflicting BC Legislation – Respondents claim that legislation is inadequate, in the sense that it (i) contradicts BC deployment or (ii) leaves SC actors unsure whether BCT is a legally accepted alternative. They also claim that the *law leg* increases the risk of investing in BCT, reducing the technology's attractiveness.

“It's not so much that there's a regulation against it. It's that the regulations don't clearly allow for it.” (9B)

Nobody wants to do anything that gets ahead of a regulator and then be told by the FDA or the EU equivalent that this blockchain system they put in place not sufficient. So, regulators could do more by encouraging innovation.” (9B)

5.4.5 Barriers of BC Deployment in Drug SCs vs. Other SCs

We asked the eight BC and BC/drug SC specialists if they believe the barriers to

BC deployment in DSCs are different from those in other SCs. The majority of respondents said, yes. Five people indicated the barriers are different and tend to be higher rather than lower, one said there is not much of a difference, and two said there is no difference. When respondents said barriers are higher, they referred to two barriers (Figure 20); First, because drug SCs are heavily regulated, firms may be hesitant to implement a BC system for fear of “*then be told by the FDA or EU equivalent that the system they put in place is not sufficient and they have to pull it out*” (9B). As a result, the unclear or conflicting BC legislation is thought to be more severe. Because drug SCs involve a large number of actors, sharing data and collaborating with each other is considered a greater challenge. Second, data about drugs and patients are regarded as very sensitive, respondents conclude that sharing data and collaborating in drug SCs is more difficult than in other SCs.

“There’s probably a Venn-diagram, where some are unique to drug supply chains, some are unique to other industries, and there’s a lot that overlap.” (6B)

“No, in terms of the implementation process, that doesn’t matter at all.” (8B)

“Data is probably more sensitive, so people may do not want share that across the network - that’s a specific challenge for drug supply chains over other supply chains.” (4BD)

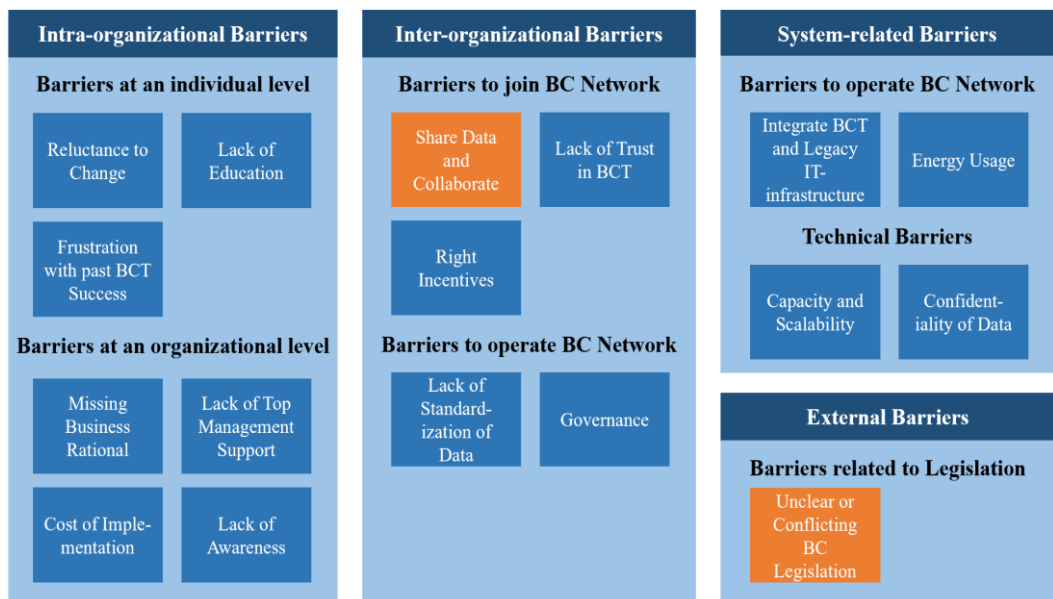


Figure 20. Barriers of BC Deployment in Drug SCs vs. other SCs

6.0 Discussion

A *missing business rationale* was one of the most important identified barriers to BC deployment in drug SCs. A *missing business rationale*, however, just means that drug SC practitioners do not know if or how to apply BCT in SCRM in drug SCs. They are essentially asking the same question as we are; “*How can Blockchain*

Technology be used to support Supply Chain Risk Management in Drug Supply Chains?” We, therefore, assess the two basic questions in this chapter; (i) is there any value in employing BCT in SCRM in drug SCs at all, or is it just a hype?, and (ii) if there is any value, how can companies and, thus society, leverage that value? To answer these questions the chapter is divided in three parts; First, which of our research findings are backed-up by academic literature, and which are perhaps contradictory? Second, how can we answer our research question with help of the data and empirical findings presented in chapter 5.0? Here we want to point out that in this chapter, we discuss and interpret our findings in the light of our research question, whereas in chapter 5.0 these findings are only presented in a structured way without interpretation. And third, what are implementation enablers for turning BC promising BC business cases from concept into production, hence, how to overcome the identified implementation barriers?

6.1 Empirical Findings in Comparison to Academic Literature

In the following, we will discuss our empirical findings, presented in chapter 5.0, in comparison to the relevant academic literature, presented in chapter 2.0. However, only the most important parallels and discrepancies are highlighted.

6.1.1 Drug SCs and Drug SC Risks

Characteristics of Drug SCs – Our research revealed nine distinct special characteristics of drug SCs, all of which are found in the literature as well. The low level of information sharing and transparency in drug SCs were two characteristics that were extensively stressed in both, the literature, and our interviews. The resistance to share information is said to have a long, deeply rooted tradition in drug SCs. There are, however, drug SCs experts that acknowledge that information sharing is valuable and necessary to survive as a firm in the future. Something that is also extensively demanded by academics.

Drug SC Risks – In comparison to the relevant academic literature, our research did not reveal any entirely new drug SC risks. However, we were able to get a clear picture of which SC risks are very special to drug SCs and hence, have greater relevance in drug SCs than in other SCs. Our research confirmed that the counterfeit and product integrity risks in drug SCs are two serious and unique risks. The risk of product diversion, on the other hand, was mentioned more frequently in our interviews than in the academic literature.

6.1.2 BCT Usage in Drug SCs

BC Use Cases in Drug SCs – While academic literature has emphasized the value of BCT in drug SCs for (i) an increased SC transparency, and (ii) improved data security (chapter 2.6.1), our research revealed four distinct use cases with a clear priority; the track and trace use case is the most promising. As a result, the ability of BCT to increase SC transparency in a SC through a BC-enabled track and trace system has been identified as key. The two sub-use cases of counterfeit reduction and the use of IoT to secure cold chains, in particular, were often mentioned. Further, we discovered new use cases that, to our knowledge, have not been highlighted in the literature. These use cases include product diversion, drug exchange between pharmacies, and information monetarization. Moreover, the use case of smart contracts was found to be less relevant as compared to the literature.

BC Architecture – The question of how to set up a BC, at what level and with which actors, is rarely addressed in academic literature, particularly in regard to drug SCs. However, it became evident throughout our work that the BC architecture is highly important not just for the value a BC use case may provide to a firm, but it also has a significant impact on the BC implementation barriers. In our study, we discovered four BC architectures in drug SCs (chapter 5.2.2). Academic literature, on the other hand, typically assumes that a *Founder BC* is being used or fails to distinguish between these types at all.

BC Types – During our literature review, we discovered that BCs may be divided into three types; the *public, permissionless BC*, the *private, permissioned BC* and the *consortium BC*. However, according to our research, the only distinction made in reality is between a *private, public, and consortium BC*. As a result, the second dimension – permission or permissionless – indicated as a differentiation criterion in chapter 2.3.4 (Figure 3) is not recognized as very relevant in practice.

6.1.3 Value of BCT in SCRM

SC Risk Reduced by BCT – “*The issue that blockchain technology can improve supply chain risk and resiliency requires further investigation*” (Saberli et al., 2019, p. 14), which nicely summarizes our literature review findings. We found that there is currently no comprehensive overview of risk reduction by BCT in drug SCs available, just single publications that indicate one or two SC risks that can be reduced or mitigated but do not address the topic directly. Only Lai et al. (2021)

and Alkhudary et al. (2020) address the topic more directly. Nonetheless, Lai et al. (2021) findings are confined to the Taiwanese manufacturing industry, and Alkhudary et al. (2020) framework lacks empirical evidence, is very generic, and not well supported by academic literature. Chapter 2.7.2 (Table 3) summarizes the few SC risks addressed by BCT that were discovered in our literature review from various papers. In chapter 2.6.2, the potential of BCT to mitigate counterfeit risk is discussed in detail. Nonetheless, there is no overall picture of which SC risks BCT can alleviate in SCRM, not even to speak of the specific drug SC context.

We were able to identify five drug SC specific risks that can be addressed by BCT in our research (chapter 5.3.2). Our findings confirm that BCT can mitigate the counterfeit and product integrity risk, as well as the health, financial, and reputational risks associated with counterfeiting. However, we identified product diversion as a new risk, and several of the risks discussed in Chapter 2.7.2, such as relational and contract dispute risks, are not supported by our results.

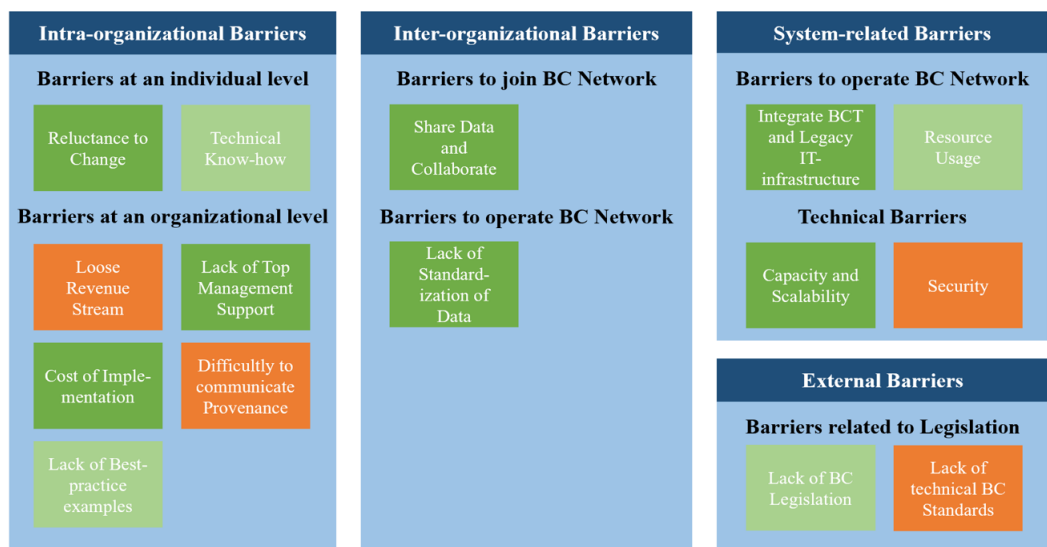
Value of BCT in Drug SCs – BCT is valuable for drug SCs for two reasons, according to academic literature; (i) improving data security and (ii) visibility and traceability. Both are confirmed by our research as being of great value for drug SCs (chapter 5.3). However, our empirical data show that the benefit of increased visibility and traceability is dominating and hence, the main value BCT can provide to SCRM. The track and trace use case, build on a BC-enabled track and trace system, was regarded as the most promising. Through the BC-enabled track and trace system, SC transparency and hence SC visibility and traceability can be increased. According to our research, this allows SC practitioners to increase information sharing along the SC and reduce risks such as counterfeiting, product diversion, and product integrity risk.

6.1.4 Barriers of BCT Deployment in Drug SCs

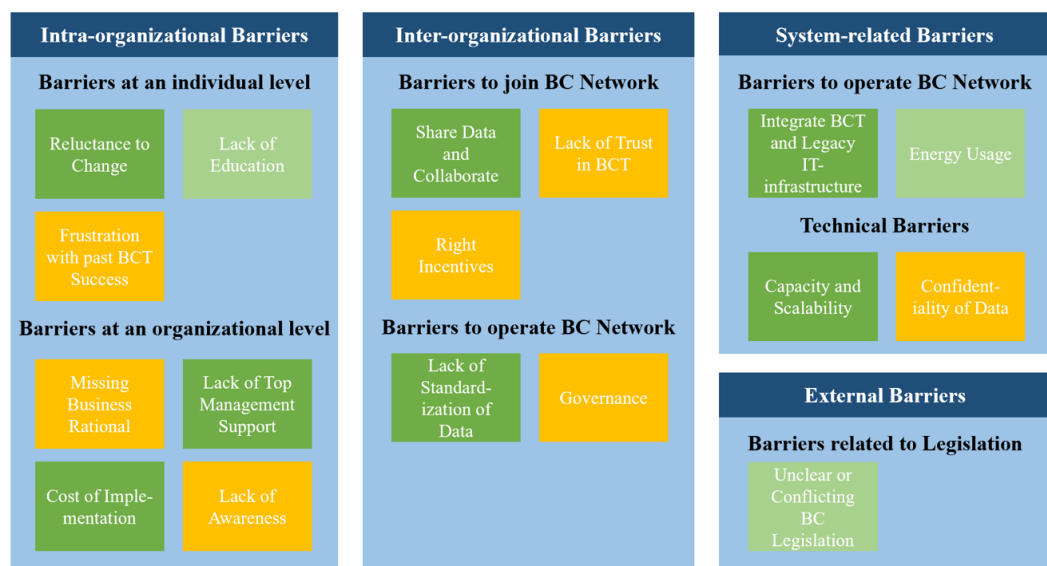
Our literature review identified several general challenges of BC deployment in SCM, categorized into intra- and inter- organizational, system-related and external barriers (chapter 2.4.3). Further, Uddin et al. (2021) and Musamih et al. (2021), identify drug SC specific challenges that may hinder BC deployment such as interoperability or a lack of standardized regulations (chapter 2.6.3). Our research identified a total of 17 drug SC specific implementation barriers. While some barriers described in the literature were not supported by our findings, other barriers

identified in our study were found to be new and not backed up by the literature (Figure 21). The top three barriers identified by our research, namely reluctance to change, capacity and scalability as well as the reluctance of sharing data, were all also noted as highly crucial important in the literature (dark green). However, also we discovered new barriers that were not discussed in the literature, such as a lack of business rationale, ranked fourth in the list of major barriers, or a lack of right incentives, or governance (yellow). Further, several barriers identified in the literature were either not confirmed by our research (orange) or were found in a slightly different way (light green).

Barriers identified in Literature Review



Barriers identified in our Research



- Barrier confirmed by Research
- Barrier not confirmed by Research
- Similar Barrier confirmed by Research
- New Barrier identified by Research

Figure 21. BCT Barriers identified in Literature vs. our Research

6.2 Research Question

After systematically comparing academic literature and our research findings, this chapter seeks to answer our research question “*How can BCT be used to support SCRM in drug SCs?*”. However, in addition to determining how BCT may be employed in SCRM in drug SCs, hence identifying use cases, our research question encompasses a number of important related questions. First, which of the use cases makes the most sense and, as a result, is the best business case? Second, do we truly need BCT as a solution to solve today's problem of SCRM in drug SCs, or may an already commercially used central DB suffice? And third, what existing roadblocks must be overcome to actually turn BCT use cases from theory into production?

6.2.1 Transparency and Trust Problem of SCRM in Drug SCs

Our findings reveal three key problems in today's drug SCs (chapter 5.1); (i) *identifying risks* early on is difficult, (ii) SCRM is still a reactive rather than a proactive task, and (iii) there are five risks identified as being prevalent in drug SCs; drug shortages, falsified medicine, product diversion, product integrity, and data security risks. It is obvious that there is an urgent need to address these challenges, not just for drug SC practitioners, but also for academics. However, to address these problems, it is crucial to assess the underlying root cause of why these risks occur and are difficult to identify and hence mitigate.

Our findings show that a lack of transparency is one reason, if not the main root cause, for four of the five drug SC risks identified in chapter 5.1.2. Due to a lack of transparency, counterfeit drugs can enter the market undetected, drugs can go out of their set temperature window or products can wind up somewhere they aren't supposed to, resulting in drug shortages. As a result, one may reasonably conclude that the lack of transparency in drug SCs contributes significantly to these risks, or that increased transparency would reduce these risks. Furthermore, a lack of transparency not only increases SC risks, which might determine a patient's life or death, but it also makes early risk identification more difficult, if not impossible. It is also fair to conclude that a lack of transparency is caused by a lack of information sharing, another characteristic common to drug SCs.

But why is there a lack of information sharing in drug SCs today? Our research revealed five reasons, but only one stands out; there is a lack of trust among drug SC actors (Figure 22). Other reasons might be technical barriers to exchange data

or the fact that drug SC practitioners do not see the added value of sharing data. None of these reasons is supported by our data. But our findings clearly indicate a lack of trust, which results in a mental barrier, resistance, or even fear of sharing information in the industry. Taking our root cause analysis to a head, one might ask why there is a lack of trust among drug SC actors. Even though that question is beyond the scope of our thesis, our findings suggest that several factors contribute to it including (i) complex SCs with many players, (ii) a high degree of data sensitivity, and (iii) a historic and well-rooted practice in the pharma industry of competing rather than cooperating with other SC actors.



Figure 22. SCRM Problem in Drug SCs based on Drug SC Characteristics

As indicated in chapter 5.1.3, one of the most common SCRM measures used to address the five identified SC risks in drug SCs is a track and trace system based on serialization using a central DB. However, our findings show that pharma companies often only do what is required by law, such as the FMD. Because the FMD employs a passive DB, it does not provide SC transparency to SC actors, only to regulators. As a result, while that solution may address the transparency issue for the regulatory agencies, the trust issue remains unresolved. Thus, our findings leave us with one clear conclusion; **A tool or platform that allows all drug SC actors to share data in a trusted and safe manner would be needed** to address the identified root cause of SC risk in drug SCs and allow for a more efficient SCRM.

6.2.2 BCT as one Solution to Reduce SC Risk in Drug SCs

Is BCT capable of resolving the identified issue of drug SC transparency and trust? According to our research, the answer is yes. BCT is unquestionably one option for increasing transparency in drug SCs in a secure and trusted manner. But is BC really the solution or the even only solution? And is a BC really needed to increase transparency and trust in drug SCs, or may a central DB do the job as well? These questions are addressed in this chapter. In addition, this chapter examines how BCT can support SCRM in practical terms, hence, what is the best business case, and which architecture type and BC type is to be used best in this case.

Where to use BCT in SCM in Drug SCs?

Our findings identified the track and trace use case as most promising and thus

as the best use case of BCT in drug SCs. Our findings show that a BC-enabled track and trace system has the potential to solve both identified problems in DSCs; First, a BC-enabled track and trace system increases transparency in drug SCs by allowing data to be shared across the entire SC and ensuring that everyone holds a copy of the BC. Second, and perhaps even more important, the data exchange using a BC is safe and trusted. The trust issue is solved by the BC itself, or more specifically by its unique characteristics (chapter 5.3.1); (i) the decentralized nature of a BC network ensures that no entity controls or owns the BC; thus, drug SC actors no longer need to trust one another if they can trust the technology and (ii) the immutability feature of a BC ensures that no data may be manipulated.

Our research also identified one specific business case for the track and trace use case; interviewees from all target groups agreed that a BC-enabled track and trace system is a viable option for enforcing the DSCSA, the US anti-counterfeiting statute. Two reasons are obvious why a BC-enabled track and trace system would be a good solution in this environment. First, a BC pilot was already successfully tested for that purpose ([Appendix 13](#)). Second, because there is currently no national DB in the US, all drug SCs actors exchange data with their SC partners using different systems. That means there is not an existing system that must be replaced. The FMD in the EU, however, uses a central DB, and thus the change of status quo if a BC-enabled track and trace system is introduced is much larger.

Finally, we want to emphasize that, while the track and trace use case has been recognized as the best use case, it is not necessarily the best business case for all companies. The best business case is the one that addresses a drug SC's pain points best. But because our analysis shows that transparency and trust are frequently problems in drug SCs, the track and trace use case is likely to be a compelling business case. However, it is possible that regulatory compliance is a bigger issue, and thus that the regulatory compliance use case is the better business case.

Why use BCT in SCRM in Drug SCs?

How can BCT, or a BC-enabled track and trace system, support SCRM in drug SCs? **A BC-enabled track and trace system can significantly increase SC transparency for all SC actors, regulatory authorities, and even end-customers, the patients,** if adopted by all SC actors. Knowledge of where a drug “comes from, where it's been moved, how long it's been handled, how long it's been

stored” (10I) is extremely valuable, particularly in drug SCs characterized by low transparency. Transparency enables (i) pharmacies to determine “*whether or not a delivery was transported*” (8B), or (ii) pharmaceutical companies to determine “*how much inventory is actually out on the shelf of a pharmacist for all of its products*” (9B) and (iii) which SC nodes and deliveries are affected by a SC disruption, such as an airport closure. Now that companies have all that information at hand in real-time, they can (i) plan and forecast more accurately, (ii) identify potential over or understock scenarios early and begin mitigation actions, and (iii) start thinking about how to route shipments around disasters with minimal disruption to other activities. As a result, BCT in the track and trace field could help SCRM by reducing risk in warehouse operations, planning, forecasting, and disruption management, or, as one respondent put it, “*you have a better understanding of where the product is and therefore of your supply-side risk*” (6B).

Furthermore, increased transparency makes it easier to *identify risks*, a task that many respondents see as difficult. Our findings show that, when compared to the other four SCRM activities, BCT is the most useful for *identifying risk*, and that, in general, BCT may considerably improve the *information flow* in SCs. Overall, increased transparency enables not only better risk identification, but also a more proactive rather than reactive SCRM, which is still very common in drug SCs.

Which Drug SC Risk can BCT Reduce or Mitigate?

According to our findings, different BCT use cases reduce or mitigate distinct SC risks to varying degrees (Appendix 14). The five risks identified in chapter 5.1.2 are in focus in the following. According to our findings, **the track and trace use case is the only one that touches all five risks and hence has the potential to mitigate or reduce all five risks, although to varying degrees** (Figure 23).

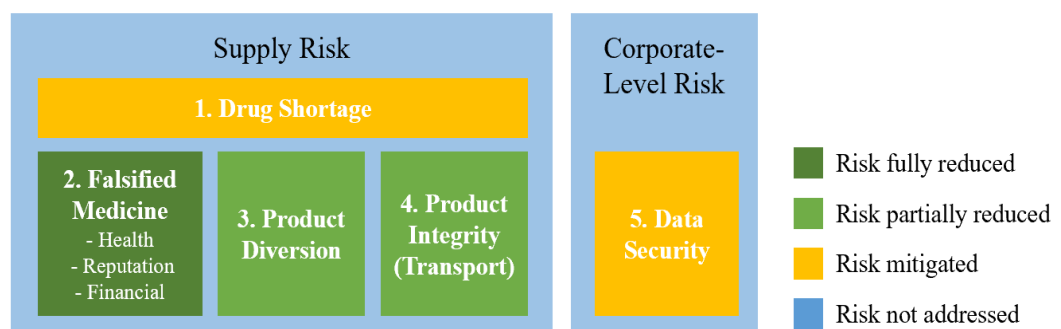


Figure 23. Drug SC Risk addressed by BC-enabled Track and Trace System

A BC-enabled track and trace system increases SC transparency, allowing drug SC actors to detect counterfeits early and remove them from the SC. Our findings

suggest that the risk of counterfeit drugs may be entirely removed. Furthermore, increased transparency allows the detection of product diversions, which is the first step in mitigating this risk. A BC-enabled track and trace system can also mitigate the risk of product safety or integrity during transportation as the technology provides the option to control and verify transit conditions such as temperature and humidity. Although the risk of a drug going out of its designated temperature window may not be reduced, the odds of that drug being given to a patient can be reduced. Hence, the risk can be mitigated. Transparency also allows improved planning, forecasting, SC disruption countermeasures, and possibly even drug exchanges between pharmacies, reducing the likelihood of drug shortages. Finally, because data recorded on a BC is per se immutable, our findings imply that even in public BCs, the data security risk can be mitigated.

How to use BCT in Drug SCs?

To turn a BC use case into production two practical decisions on the BC set-up must be taken (chapter 5.2.2); (i) at which level should the BC be implemented, thus which BC architecture should be used, and (ii) which BC type should be applied. Our findings suggest that the ideal solution for both elements is highly dependent on the use case and that both aspects must be evaluated together.

Nonetheless, our findings show that in the track and trace use case, **there is a clear preference for one architecture type; an *Industry BC for Industry Collaboration***. The identified arguments in support of an *Industry BC* are also arguments against the other two architecture types and will be presented in that manner. In the track and trace space, a *Founder BC* has two major disadvantages; First, establishing a BC or a BC-enabled track and trace system at the drug SC level would necessitate each drug SC actor, such as an API manufacturer, to connect to a thousand different BCs. From an organizational perspective, this is neither practical nor realistic. Having a single BC for all drug SCs could solve that problem. Second, regulatory agencies lack the manpower to verify that each of these *Founder BCs* meets all of the requirements for compliance reporting. This is a lot easier with an *Industry BC*. A *Cross-industry BC* is not ideal either as different industries have very different BC needs that can be difficult to align. Although interviewees recognize that aligning the interests of all drug SC actors is more difficult in an *Industry* than in a *Founder BC*, our findings show that the disadvantages of a *Founder BC* outweigh the benefits. Hence, an *Industry BC for*

Industry Collaboration is preferable in the track and trace use case.

In terms of BC type, our analysis did not directly reveal one superior BC type for the track and trace use case. However, taking into account different data points and findings, **a public BC seems to be the best option for the track and trace use case.** The reason for this is threefold; First, in a private or consortium BC, the BC network is controlled by one company or a consortium of companies. As a result, all drug SC actors must trust this party or group of parties and therefore, these BC types will not alleviate the trust issue identified in chapter 6.2.1. Second, even in a public BC, data may be shared selectively, which is crucial in drug SCs with a high level of data confidentiality. Third, our findings suggest that, despite their lack of widespread usage today, public BCs will be the future. Nonetheless, we want to stress again that our data imply that distinguishing between the three types might be difficult at times, as private BCs are not always fully private and public BCs are not always fully public; it all depends on the detailed technical set-up.

Is a BC really needed for track and trace?

Our findings show that BCT, when used in a BC-enabled track and trace system, is one solution for SCRM in drug SCs, addressing the lack of transparency and trust discussed in chapter 6.2.1. Is a BC, however, the best or only way to do so? This question was omnipresent in our interviews, with drug SC practitioners repeatedly inquiring about the *value-add* of a BC versus a track and trace system based on a central DB. Table 8 compares the use of a BC versus a central DB as the base of a track and trace system along six dimensions based on our empirical findings. We also want to point out, that the assessment only covers the dimensions identified as very important for a company when deciding between a BC and a central DB, and it does not cover all criteria that may be considered.

Assessment criteria	BC	Central DB
Degree of Adoption	Low	Very high
Ease of Implementation	Low	High
Interoperability	High interoperability	Lower interoperability
Cost for IT-infrastructure	Low	High
Transparency Problem in Drug SCs	Problem solved	Solves problem
Trust Problem in Drug SCs	Problem solved	Problem not solved

Table 8. BC versus Central DB in the Track and Trace Context

While a central DB is widely used today, for instance by the FMD, and hence easier to implement, our study found that connecting a large number of drug SC actors to a BC rather than a central DB is easier and cheaper. A BC's interoperability is higher. As we see a trend towards personalized medicine and eventually V-to-V SCs, more patients may want to connect to the track and trace system, so the number of stakeholders is likely to grow substantially. Another advantage of a BC is that the costs of maintaining the required IT-infrastructure are lower. Valuing each dimension equally, BC and a central DB both prevail in two dimensions.

We, therefore, considered whether a BC or a central DB better solve the transparency and the trust problem, which are the two main issues in today's drug SCs when it comes to SCRM. A BC-enabled track and trace system, as well as a central DB-based track and trace system, both improve SC transparency. However, only a BC can successfully overcome the trust problem. Turning both above-cited reasons for why a BC can solve the trust issue around directly reveals why a central DB cannot. A central DB is not decentralized; hence, it is controlled by one entity or a group of entities. Second, data stored in the central DB is not immutable, and the ruling entity or group of entities can modify data, perhaps even without being recognized by other SC actors.

Considering all six dimensions, our data indicate that a BC has a slight but not negligible advantage over a central DB in the track and trace context. However, our results also show that BCT is not the only solution and that a central DB has its own set of benefits. To summarize, while a central DB may be *easier* to be implemented, a lack of trust among SC actors remains a problem. Also, according to our findings, a lack of trust is particularly troublesome in drug SCs.

6.2.3 Roadblocks to Use BCT in Drug SC

As identified in chapter 6.2.2, there are two distinct disadvantages to employing a BC for track and trace as opposed to a central DB; (i) BC adoption today is very limited, and (ii) BCT implementation in the SC is perceived as difficult. Furthermore, our empirical findings revealed 17 distinct barriers to BC adoption in drug SCs, regardless of the use case (chapter 5.4). The most often cited barrier was reluctance to change, followed by capacity and scalability constraints and reluctance to collaborate and share data in a BC network. Overall, based on the data collected, it is obvious that there are several, and sometimes very unique,

roadblocks to the rapid adoption of BCT in drug SCs, whether they are inter-company, intra-company, or technological in nature. Also, widespread BCT usage in drug SCs is unlikely to occur in the next two years. Even more important is then to identify strategies for companies to address these barriers. As a result, we suggest some practical measures and enablers for companies to overcome the most important identified barriers, based on our research in the next chapter.

6.3 BC Implementation Enablers

After answering our research question, we want to conclude with some practical implications for drug SCs practitioners to turn our findings from theoretical knowledge into practical and executable next steps. This chapter, therefore; First, discusses how to overcome the identified roadblocks to BCT deployment in drug SCs, as outlined in chapters 5.4 and 6.2.1, and measures a company can take or what capability they can develop to create an environment enabling a fast and successful BC adoption. In short, what are BC enablers? Second, identifies further prerequisites or KSFs for a successful BC adoption in drug SCs. We identified eight enablers based on our primary and secondary data (Figure 24). Three enablers are associated with the firm's environment, whereas the remainder of the enablers is related to the specific company undertaking a BC project. The *network mindset* was the most often mentioned, hence is determined to be the most important enabler.

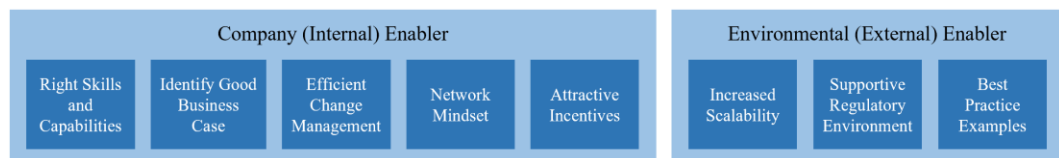


Figure 24. Company and Environmental Enablers of BCT in Drug SCs

6.3.1 Company (Internal) Enablers

Right Skills and Capabilities – This enabler refers to experts who claim that one barrier to implementing BCT in drug SCs is a *lack of education*. To address this barrier, personnel with the right skills and capabilities must be hired or current employees trained. It is also a good idea to map out every employee's skill level to see whether there are any knowledge gaps. Further, our results show that deep technical expertise, such as coding, is not necessarily needed, but employees must understand what the most attractive use cases of BCT in drug SCs are and what business problems BCT can solve. Our work here serves as the first stepping stone (chapter 5.2.3). Staff must have the required skills and capabilities to (i) first consider BC as a solution to specific business problems, (ii) manage BC projects,

and (iii) reduce the reluctance to change, another BC barrier.

Identify Good Business Case – Our findings imply that, while drug SCs experts believe in the future of BCT in drug SCs, they are unsure about the specific use case, and therefore how and where to employ BCT. They *lack a business rationale* for implementing BCT. Not knowing which BC use cases exist, prevents drug SC practitioners to consider BC as a solution for a specific business problem. As a result, no good BC business case can be developed, and BCT cannot be leveraged to the company's advantage. To tackle the problem, we propose four steps; First, *identify a business problem*, such as a drug SC risk or an SCM process issue. Second, *familiarize yourself with attractive BC use cases* (enabler one). Third, bring together steps one and two and *assess whether BC and the specific BC use case, is the best solution* for the identified specific business problem. Hence, critically evaluate the specific company situation and provide clear-cut business reasons why BC makes sense or why not in that context. And fourth, phrase the problem as a business problem and clearly formulate the BC project's *value-add*.

Efficient Change Management – This enabler directly addresses the *reluctance to change*, the barrier identified as most prevalent. Employees are often hesitant to change, particularly to replace existing and well-functioning processes or systems, for a variety of reasons. Reasons are; (i) they do not see the need to do so, (ii) are too comfortable to do so, or (iii) can have an emotional attachment to the old way of working, since they, for example, built up the existing processes themselves. To convince employees of the *value-add* of BC we suggest different change management measures. First, get top management support. Second, explain to employees why a BC project is carried out, hence, make the business problem, business case (enabler two), as well as the business rationale for BC deployment, clear and easy to understand. Third, keep workers informed about the project's timeline, and actively seek their feedback on key decisions.

Network Mindset – This enabler relates to the *reluctance to share and collaborate*, one of the most important identified barriers. Our findings reinforce an old and well-known problem in SCM; SC actors within one SC often compete rather than collaborate. As a result, information exchange is limited, which was identified as a key characteristic of drug SCs. But literature highlights that cooperating rather than competing benefits all actors. Further, the use of BCT, such as a BC-enabled track

and trace system, necessitates extensive collaboration and data sharing. For a long time, academics have attempted to address this. Companies must comprehend that collaborating and sharing data is preferable to competing alone. As a result, a mindset shift is required to adopt a *network mindset*.

Attractive Incentives – This enabler refers to the *right incentive* to join a BC network barrier. Our findings demonstrate that scaling BC solutions and convincing other SC members to join the BC network is generally challenging. SC actors may be unable or unwilling to adopt BC-based solutions, making SC actor buy-in a huge challenge. An attractive incentive system is closely tied to a network mindset. It is possible that the benefit of a BC solution is greater for one drug SC actor than it is for the other. Having a *network mindset* involves putting yourself in the shoes of other drug SC actors and considering what could be in it for them. You might even actively create incentives for them to join your BC network.

Incentives can take many forms; for example, a company creating a BC network may simply explain how other parties can benefit from the BC network. The starting party of a BC-enabled track and trace system, for instance, may explain to other SC actors that they, too, receive valuable data that they are used to improve their forecast or customer relations. Other incentives might include monetary rewards or tokens, which were often mentioned in our interviews. In a token-based economic model, the BC essentially serves as a platform for BC participants to sell and buy information (chapter 5.2.3). As a result, all drug SC actors and potential BC participants are incentivized to share information and join the BC network. However, regardless of which incentive is best, for a BC business to be successful, there needs to be a strong business reason and hence an incentive for drug SC actors to join a BC network. If no natural reason to join the BC network exists, that reason or incentive must be created in one form or the other.

6.3.2 Environmental (External) Enablers

Increased Scalability – Our study indicates that a BC must be able to manage enormous volumes of data, particularly when utilized in SCM with its many transactions, but that the technology is not yet there. Our study also reveals that both BCT and drug SC specialists are optimistic about solving this technical problem in the foreseeable future. Some even claim that a public BC can handle the required data volume already. However, scalability remains a key enabler. The

technical challenge must be overcome by BC developers, for example, by using new consensus mechanisms like *Proof of Stake*. Drug SC actors can only wait, closely monitor market developments and react quickly if a sufficient number of transactions per second is achieved.

Supportive Regulatory Environment – This enabler addresses the barrier of *unclear or conflicting BC legislation*. Our findings suggest that BC legislation is insufficient, as no BCT guidelines have been developed or revised, and no international standards have been established. Moreover, since drug SC players question if BCT is a legally acceptable alternative, the *law leg* makes BCT investment less attractive. BC and drug SC specialists believe that more should be done to support BC deployment. Regulatory authorities, such as the government, tax authority, or the national pharmacy association, must draft new laws or revise existing ones in order to set clear legal guidelines. In addition, global BC standards must be established. The country of Lichtenstein is a rare example of a state that has proactively developed a clear framework for the use of BC.

Best Practice Examples – This enabler does not directly address one of the stated barriers, but it might be used to address the issue of a *lacking business rationale*. Our data reveals that many drug SC practitioners often do not know where and how to use BCT. In addition to the previously indicated increased education and a systematic approach (enabler one and two), it is best to provide drug SC practitioners with concrete, in the best-case successful examples. However, established BC solutions in drug SC do not yet exist, as chapter 5.2.1 reveals. Hence, we advise practitioners to (i) learn from other industries, such as food SCs, and (ii) have the courage to take the first steps, learn from their own and others' mistakes, and try different approaches.

7.0 Conclusion

7.1 Research Question

The aim of our thesis was to explore how BCT can support SCRM in drug SCs. The study's three research objectives were to; (i) provide insights into how (practically) BCT can be used to support SCRM in drug SCs, (ii) assess the value of using BCT in drug SCs for SCRM, and (iii) identify implementation barriers of BCT in drug SCs. During our research, we also realized that it is important to discuss the *value-add* of a BC versus a central DB, hence, if a BC is truly needed or if a commercial

central DB can also do the job. The research question was investigated using a theoretical framework developed for the research question, which enabled us to; (i) obtain a comprehensive picture of our research field by breaking down our research question into sub-topics, and (ii) answer our research questions in a structured manner using an embedded case study and semi-structured interviews.

Theoretical Contribution – Overall, our findings do not contradict the rather limited literature on BCT in SCRM and BCT in drug SCs; in fact, they are consistent with previous publications. However, because our work, to the best of our knowledge, is the first to combine BCT, SCRM and drug SCs, our findings are in several aspects more detailed and present a more comprehensive picture of an as-yet untapped academic field than earlier papers. Our work also starts to fill in the identified literature gap and serves as a first stepping stone for future research. For example, this study is the first, to our best knowledge, to offer an overview of drug SC risks BCT can mitigate, as well as what are the specific implementation barriers of BCT.

Value of BCT for SCRM – Overall, our findings show that BCT has a great potential for SCRM in drug SCs and may support it in several different ways; First, using BCT in the context of track and trace can considerably improve transparency and visibility, which is often an issue in drug SCs. Increased transparency makes it easier and faster for drug SC professionals to identify risks like counterfeiting and product diversions. Second, because risks might be identified earlier, immediate mitigation actions can be taken to eliminate counterfeits, avoid product diversion and improve product integrity and safety. Overall, mitigating these risks can help drug SC actors and therefore society in general in reducing drug shortages, which are still a major issue across the world. Third, by providing a trusted platform for all SC actors to share data, BCT not only facilitates information flow among SC actors but also lays the basis for more proactive SCRM.

Unique Value of BCT vs. Central DB – After determining the value of BCT in drug SCs for SCRM, one question frequently asked by practitioners remains: Is BCT the best solution for addressing the two major problems of SCRM in drug SCs, as there are transparency and trust, or would a track and trace system based on a central DB solve these problems equally well? In short, a track and trace system based on a central DB solves the transparency problem, but not the problem of trust. The identified unique selling point of a BC, on the other hand, is that the trust required

in other drug SCs actors is substituted by trusting a secure, independent, and non-human medium, the BC itself. Hence, the trust problem is solved! And because a lack of trust has been identified as the main reason for the low level of information sharing and transparency in drug SCs, a BC-enabled track and trace system may not be the only solution, “*but it's definitely a good one*” (11BD). One interviewee nicely summarizes, that if “*things are tracked across boundaries, be those, geographic, or organizational boundaries, or if we want to establish the provenance of something and when there's an inherent lack of trust between actors*” (9B), there is a great chance that BC could be a good business case.

Attractive BC Use Case – However, we must also stress that, while BC may be beneficial in some situations, it is not a *one size fits all solution* that will fix every problem. According to our findings, the track and trace use case is the most attractive one and very likely a great business case. Our analysis also identified that an *Industry BC* is most suited for that use case since it allows BC's full transparency potential to be realized. However, whether a BC makes sense or is better than a central DB in a given situation is heavily reliant on two company-specific factors; (i) what is the company's actual business problem, and (ii) to what extent and at what costs does the BC solve the specific business problem.

Current Roadblocks to Use BCT in Drug SCs – Nonetheless, examining the status quo of BCT deployment in drug SCs, we discovered that as of today no full-scale BC solution in drug SCs is up and running. In addition, our analysis reveals that, when compared to a central DB, the degree of adoption and ease of implementation for BCT is very low. Both these factors are, without doubt, interconnected. Due to the difficulty of implementation, adoption is low, especially when compared to a today widely commercially used central DB. But why is the implementation difficult? Our research identified 17 distinct barriers to why BC deployment is perceived as difficult. Some of these identified barriers are more drug SC-specific than others. According to our research, drug SCs show a higher level of reluctance to share data and collaborate than other SCs, but reluctance to change and a missing business rationale are also substantial barriers to BC adoption in drug SCs.

Unique Value Proposition of BCT in Drug SCs – Nonetheless, our findings clearly show that particular in drug SCs, it is worthwhile to push BC usage as the value proposition is distinct from that of other SCs. Not only can the issue of transparency

and trust be addressed, but the risk of a product shortage, counterfeiting, or product diversion is higher in drug SCs, and consequently the value of eliminating these risks using BCT. One may even argue that the value of BCT in drug SCs is larger than in other SCs, and therefore the motivation to address the identified barriers is greater for companies, given the specific business case is good.

Practical Implications and BC Enablers – For companies to overcome the most important barriers, we provide suggestions for initial strategies or enablers in chapter 6.3. A *network mindset* and *effective change management* are two of the key BC enablers identified. Adopting a *network mindset* requires businesses to recognize that data sharing and cooperating may be beneficial to all parties involved. No BC solution, such as a BC-enabled track and trace system, can scale without that *network mindset* or the full potential of BCT be leveraged. However, our findings show that, even if drug SC actors work hard to put these enablers in place, it will take time for BC to become a commercialized solution in drug SCs.

Summary – To conclude, our research shows that BCT is of great value not just to SCM in general, but also to SCRM. Risks related to counterfeiting, product integrity, and even drug shortages can be mitigated. SCRM may also be made more efficient and effective, as risks are easier identified, the information flow among SC actors is facilitated and SCRM is enabled to be more proactive. Our findings, however, also show that BCT is not a *silver bullet*, and the value of BC for a company is highly dependent on (i) the use case, with track and trace being the most attractive use case, and (ii) the specific company situation and business problem.

Nonetheless, our findings show that the value of BCT in drug SCs is greater than in other SCs because the value proposition is different; (i) drug SCs decide about life or death, (ii) transparency in drug SCs is lower than in other SCs, and (iii) trust among drug SC actors is especially low, making a BC solution even more valuable. However, there is currently no full-scale BC business case in drug SCs up and running. We identified several reasons and barriers that must be overcome to fully capitalize on the potential of BCT in drug SCs, ranging from a reluctance to share data and collaborate to technological issues. As a result, we urge that (i) additional research is conducted to confirm and expand our initial results in the field, and (ii) cross-disciplinary efforts are made to further detail the identified enablers as well as identify additional KSFs for a successful BC deployment.

Finally, our findings suggest that BCT in drug SC is unlikely to achieve a commercial breakthrough within the next one or two years. However, our study identified that the track and trace use case is of high value for SCM and SCRM and that this, in the eyes of the thesis team, makes the long journey to overcome the identified implementation barriers worthwhile – worthwhile for the well-being of all patients, the end-customer of all drug SCs, and our society as a whole.

7.2 Research Limitations

There is no such thing as perfect research. When performing scientific research, three types of limitations must be assessed and documented; (i) methodological limitations (ii) theoretical limitations, and (iii) practical limitations.

Methodological Limitations – We detailed our study's methodological limitations in chapter 4.5, therefore this chapter just highlights and repeats the most relevant ones. The limited time and resources of our master thesis were a general restriction of our research, impacting data collection and the quantity of our collected primary data. Therefore, the small sample size of our study is the most significant methodological limitation. In total 14 interviews were conducted. Per target group, the number of interviewees ranged from only three to five. Especially for the target group of BCT *and* drug SCs experts, identifying these persons and convincing them to participate was difficult, as only a few fulfilled our selection criteria. More time and a larger sample size would be preferable to improve our findings generalizability and transferability. Nevertheless, we believe that our findings provide interesting and first relevant insights into our research question, even though there may not be fully generalizable to all drug SCs.

Aside from the small sample size, the selection of our interview partners may not be completely objective. We conducted purposive sampling and used the snowballing tactic to identify potential appropriate interview partners. Purposive sampling, as described in chapter 4.3.1, is based on the researcher's assessment of *how useful* a person is for their research. We believe that by doing our research in a team of two, we reduced the level of subjectivity in our interviewee selection to an acceptable level. Nevertheless, other researchers may have selected differently.

Theoretical Limitations – According to Alkhudary et al. (2020), the combination of BCT and SCRM is a field largely devoid by academic theory and research is deemed very limited. Thus, this thesis is the first of its kind, to the best of our

knowledge, to combine the three fields; BCT, SCRM and drug SCs. Even though our research contributes to the identified literature gap, it has several theoretical limitations related to the exploration of that new field; First, because the existing literature in the field is so limited, it has been difficult to establish a solid and rich theoretical foundation for our research (chapter 2.6, 2.7). Thus, our findings are not backed-up or supported by literature on all points. Second, as our research investigates an un-tapped field our finding's level of detail is not as high as it is desirable. Moreover, we have limited our research to drug SCs, resulting in a strong industry focus. Hence, due to the special characteristics of drug SCs our findings may not be generalized to other industries, but they can be used as an orientation.

Practical Limitations – To what degree do our findings help drug SC practitioners in determining if BCT is a good option for improving their SCRM? First, we must emphasize that we did not distinguish between different types of drugs in our study. For many SC practitioners and SCRM decisions, the distinction between patented and generic drugs is essential. A generic drug is often manufactured by several suppliers, but a patented drug is only produced by one supplier, and the repercussions are more severe if that one supplier fails to deliver that drug. As a result, SCRM plays a very different role, and thus the value of BCT may be assessed differently by a generic drug manufacturer versus a patented drug manufacturer.

Furthermore, according to our findings, many drug SC professionals are unsure about how and when to use BCT. We therefore in chapter 6.3 outlined practical implications and BC enablers to turn our findings from theoretical knowledge into more actionable steps on how to overcome barriers to BCT deployment. Nevertheless, identifying enablers is just a start. Cross-disciplinary efforts are needed to further detail these enablers and make them more actionable, as stated in chapter 7.3. Furthermore, we believe that best practice examples are the most effective way for drug SC practitioners to (i) recognize the value of BCT for drug SCs and (ii) to learn how to implement a BC. However, there aren't many good examples right now, and also our research won't be able to meet that need. We, therefore, advise drug SC practitioners to (i) learn from other industries that use BCT for track and trace purposes, such as the food industry, and (ii) get started, learn from their own or other's mistakes, as one respondent stated; “*it doesn't mature if we don't start it*” (13D).

Overall, our research has a number of limitations, most of which can be attributed to the short amount of time available. The most important limitations are; (i) a small sample size, which limits generalizability, (ii) findings that are not fully supported by literature on all points, (iii) a strong industry focus, which limits generalizability to other industries, (iv) no made distinction between SCs of patented and generic drugs, and (v) practical implications that need to be further detailed. Our thesis, however, is the first that focuses on the intersection of BCT, SCRM and drug SCs and so is an important first step in bridging the literature gap. Our findings also serve as a stepping stone for future research. Still, we stress that more research in the area will be needed, to for instance validate our initial findings.

7.3 Future Research

As our research is the first that focuses on the intersection of BCT, SCRM and drug SCs, further research is needed. We, therefore, have compiled a list of three interesting opportunities for further research. To summarize, further research is needed to (i) validate and extend our initial findings, (ii) further detail BC-enabled track and trace systems, and (iii) to make identified BC enablers for BC deployment in drug SCs more actionable.

First, we first and foremost suggest taking a similar approach to this study to validate our findings and increase generalizability, but with a larger sample size and a distinction made between patented and generic drugs. It also would be highly beneficial to validate our findings with empirical evidence by doing a single case study on an existing full-scale BC use case in drug SC with the focus to support SCRM. Further, we consider it interesting to conduct a longitudinal study to determine the long-term effect of BCT usage on SCRM performance. In addition, our taken qualitative approach fails to quantify benefits or implementation costs from a financial perspective. However, a business case must be profitable before a company decides to pursue a BC project. Hence, a quantitative approach to our research question conducting a cost-benefit analysis would be of high added value.

Second, we suggest future research should focus on two specific areas; (i) the track and trace use case, which our study found to be the most promising, and (ii) the usage of a BC solution, such as a BC-enabled track and trace system, to support different SCRM strategies. Moreover, it may be worthwhile to look into whether BCT can meet the increasing compliance and documentation requirements in the

EU, such as the Norwegian Transparency Act or German *Lieferkettenschutzgesetz*. These laws may be a compelling reason for regulatory bodies to evaluate BCT as a solution to increase SC transparency.

Third, as indicated in chapter 7.2, we encourage researchers from different disciplines to join efforts to further develop the eight identified BC enablers and make them more actionable. Academic efforts from only SCRM or SCM are not sufficient in this case. For example, insights scholars working with leadership and change are extremely highly valuable in describing what effective change management looks like. Further, we encourage drug SC practitioners to learn from other industries that already successfully use BCT, such as finance.

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Appendices

Appendix 1 – Top 15 Articles of Literature Review

Article	Literature Review Chapter	Content
Mendoza (2021)	2.1.1 Drug SC Actors	Five actors in a physical drug SCs
Musamih et al. (2021)	2.1.2 Drug SC Characteristics	Drug SC Characteristics
Sodhi and Tang (2012)	2.2 SCRM	Butterfly model; four key activities in SCRM
Lu (2019)	2.3.2 Functionality of BCT	Six architectural layers of a BC
Seebacher and Schüritz (2017)	2.3.3 Characteristics of BCT	Set of key BCT characteristics
Zheng et al. (2017)	2.3.4 BC Types	Terminology of BC Types
Kshetri (2018)	2.4 BCT in SCM	BC's roles in meeting key SCM objectives
Wang et al. (2019)	2.4.2 BC use cases and Value Drivers in SCM	BCT use cases in SCM
Saberi (2019)	2.4.3 Barriers for BCT Adoption in SCs	Barriers to BCT implementation in SCs
EU (2021)	2.5.2 SC Risk in Drug SCs	Drug shortage in the EU
Hölbl et al. (2018)	2.6.1 Potential of Using BCT to Improve Drug SCs	Systematic review of using BCT in healthcare
Uddin et al. (2021)	2.6.3 Challenges and Limitations Using BCT in Drug SCs	Challenges in adopting BCT in Drug SCs
Min (2019)	2.7.1 BC-enabled SCRM	Characteristics of BC-enabled SCRM
Lai et al. (2021)	2.7.2 SC Risk Reduced by BCT	SC risk reduced through BCT
Alkhudary et al. (2020)	2.7.2 SC Risk Reduced by BCT	Framework of how BCT can lower specific SC risks

Appendix 2 – History of BCT

Blockchain was successfully applied for the first time in 2008 as the technology behind the cryptocurrency Bitcoin (Nakamoto, 2008). A still unknown individual using the pseudonym Satoshi Nakamoto was the first to describe how BCT could be used to transfer money in the form of Bitcoins in a P2P manner, thereby overcoming the *double-spending problem* (Nakamoto, 2008; Natarajan et al., 2017). Many other digital, BC-based crypto-currencies, such as Ethereum and Litecoin, followed. However, BCT's story did not end with cryptocurrency.

According to the literature, there are three phases in the development of BCT (Agbo et al., 2019; Lu, 2019; Swan, 2015). The technology's embryo stage, known as Blockchain 1.0, was centered on its most well-known use case, cryptocurrency (Swan, 2015). The second phase, termed Blockchain 2.0, began in 2013 and introduced new features like smart properties and contracts, as well as the possibility of cross-industry collaboration (Agbo et al., 2019; Lu, 2019). The third phase, Blockchain 3.0, is characterized by BCT use cases that are not tied to the financial industry. Governments, science, contract management, insurances, SCM, and healthcare are examples of those BCT use cases (Agbo et al., 2019; Swan, 2015). Richards (2019) even discusses a fourth generation of BCT, which is marked by the integration of the IoT into the BC.

Appendix 3 – Detailed Functionality of BCT

Data Layer

As the name implies, a BC “stores and transmits data in packages called blocks that are connected to each other in a digital ‘chain’” (Natarajan et al., 2017, p. iv). A BC is created. Starting with the first block, the genesis block, new data blocks are added to the chain structure. Each data block contains the same three components (Figure below) (Kamilaris et al., 2019):

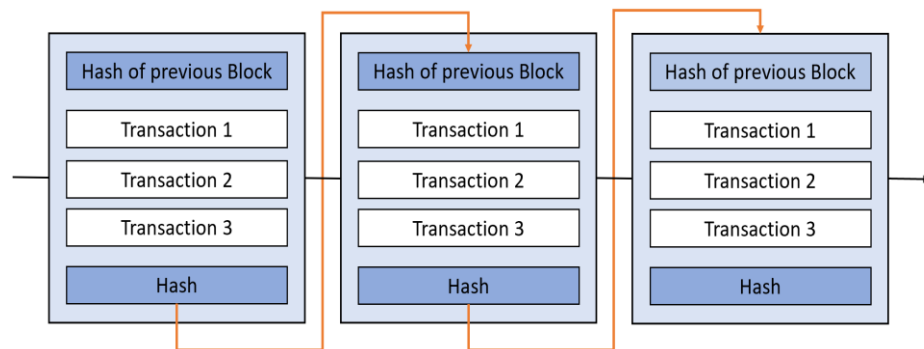


Figure. Data Layer of BC

Transactions (Data) - The data stored on the BC is referred to as transaction data or simply transactions. What type of data is stored on a block depends on the purpose of the BC, the application layer. For example, the Bitcoin BC holds transaction data such as the sender, receiver, and number of Bitcoins.

Hash - A hash is a unique digital identifier. A hash, like a human fingerprint, uniquely identifies a block and its data. Once a block is created, its hash is computed in a process known as hashing using cryptography. Manipulation of the data in the block changes the hash, resulting in a different block *fingerprint*.

Hash of Previous Block - Each block contains the hash of the previous block. This hash acts as a cryptographic link to the preceding block in the BC, linking two blocks to a BC. If recorded data in a block is altered, the hash of the block is updated, and the cryptographic link to the preceding block is no longer valid, resulting in the BC being disconnected.

Network and Consensus Layer

If a member of a public BC wants to store new information on the BC a new block containing the encrypted data is created. That block, however, is not immediately added to the BC; the data must first be authorized. As a distributed ledger technology, BCT is a decentralized network; hence, there is no central entity that controls the chain and approves new information to the BC. The task is completed by the decentralized network. When new transactions are documented, the new block is broadcast to all participants in the P2P network, also known as nodes. The nodes then collectively decide on the validity and authenticity of the data stored in the new block (Natarajan et al., 2017). The block is added to the BC only if there is consensus that the transactions in the block are valid; otherwise, the block is rejected. Each change to BC is replicated across the entire P2P network and each network member has a full, identical copy of the entire ledger at any point in time.

A pre-defined algorithmic validation method, referred to as the consensus mechanism, guides the process of reaching a consensus. Nguyen and Kim (2018) describe a consensus mechanism as an agreement that regulates who among P2P members is allowed to add proposed blocks to the chain. A consensus method specifies how nodes interact with one another and how to get an agreement on what the ultimate truth is. There are several methods for achieving consensus in a BC network. Proof of Work (PoW) was the first technical solution that allowed for

decentralized consensus, and it is still the most extensively used consensus method today (Nakamoto, 2008; Tschorsch & Scheuermann, 2016). Other mechanisms have since been introduced, including *Proof of Stake* and *Proof of Authority*. All consensus algorithms have benefits and drawbacks and should be applied following the system's purpose.

The consensus process is also vital for BC's security. When the data in a block change, so does the hash, and therefore the block itself. In principle, computers could quickly recalculate hundreds of hashes while keeping the BC intact. All new blocks and cryptographic linkages, however, must go through the consensus process again. Other nodes will reject the modified block. Thus, to change one block, you must tamper with all blocks in the chain, redo the PoW for each block, and gain control of the majority of the P2P network, also referred to as 51% attack. Only then the modified block is added to the BC. This is practically impossible. In addition, the consensus mechanism slows down the creation of new blocks. Calculating the PoW to add a new block, for example, takes roughly 10 minutes in the Bitcoin BC. This makes data manipulation in BC very difficult because changing one block requires recalculating the PoW for all subsequent blocks, which requires an infinite amount of processing time and capacity.

Contract Layer

The contract layer, also known as the compute interface, provides advanced, optional BC functions. A BC, for example, may “*store complex states which are updated dynamically*”, allowing states to “*shift from one to another once specific criteria are met*” (Casino et al., 2019, p. 57). Smart contracts and incentive mechanisms have emerged as a result of these functions (Lu, 2019).

Service and Application Layer

The “*service and application layers implement blockchain-based activities into practice*” (Lu, 2019, p. 81). The service layer, referred to as the governance layer by Casino et al. (2019, p. 57), “*extends the blockchain architecture to cover the human interactions*”. The layer merely represents the platform on which the BC operates, such as Ethereum, or Hyperledger, as well as the BC protocols linked to the BC (Casino et al., 2019). The application layer represents the context in which the BC is used, which can be cryptocurrency, healthcare, or SCM.

Appendix 4 – BCT vs. Distributed Ledger Technology

Although our thesis is focused entirely on BCT, it is critical to distinguish between the two terms. Distributed ledger technology, according to Natarajan et al. (2017, p. iv) is an “*approach to recording and sharing data across multiple data stores (or ledgers)*”, allowing “*for transactions and data to be recorded, shared, and synchronized across a distributed network of different network participants*”. A distributed ledger is thus a DB that is spread across multiple locations or participants, commonly known as a P2P network. A BC is a specific type of distributed ledger. Thus, while all BC are distributed ledgers, not all distributed ledgers are BCs. This property explains why a BC is sometimes referred to as a distributed data structure, DB, or decentralized network (Figure below). Natarajan et al. (2017, p. iv) definition of a BC as “*append-only data structure that takes the form of a chain of so-called ‘transaction blocks’*”, indicated two key differences between the two concepts; first, whereas a BC organizes data in blocks, data in a distributed ledger may be organized differently. Second, blocks in a BC have a sequential linear order, a distributed ledger does not require a certain data sequence.

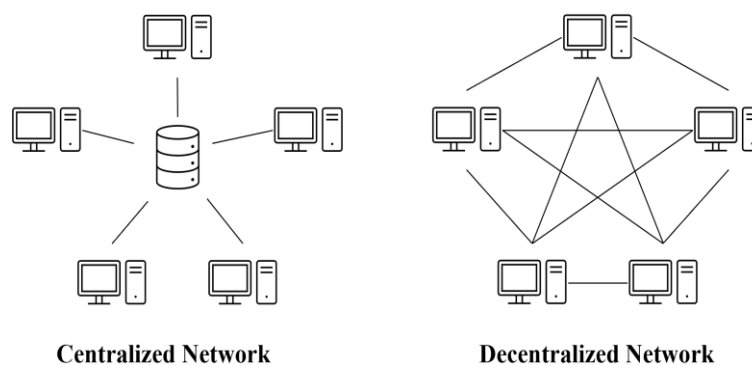


Figure. Centralized vs. Decentralized Network

Appendix 5 – BC Types

Public, Permissionless BC - Public, permissionless chains were the first to appear and are spread to many disciplines. Because a public, permissionless BC is open to anyone, there are no restrictions on who may join as a user or validator (Yaga et al., 2018). The type of BC is a fully decentralized BC as every node in the distributed system can participate in the data reading, writing, and verification (Zheng et al., 2017). The consensus mechanism replaces centralized trust. Bitcoin and Ethereum are two of the most well-known public BCs.

Private, Permissioned BC - A private BC, on the other hand, restricts who may access the BC and participate in transactions and validation. A single, centralized

authority selects which nodes have access to the data and selectively grants reading permissions (Zheng et al., 2017). Access to the BC, for example, may be restricted to a small number of individuals or organizations.

According to Girasa (2018, p. 32), the key benefits of this type of BC are “*security from external attack, low cost, sole control over who may access data*”. Because reading rights may be restricted, privacy concerns are alleviated. Zheng et al. (2017) further contend that a private BC is more efficient since transactions involve fewer validators. However, many of the benefits of public BCs are lost in such design. Because only one entity controls access and read rights, the private (permissioned) chain cannot be considered decentralized, but rather a controlled, centralized network (Zheng et al., 2017). As a result, trust must be established in the organization administering the BC. Another point made by Zheng et al. (2017) is that private BC can be reversed or tampered with since one entity controls all nodes. The property of immutability is lost. This type of BC, on the other hand, is frequently regarded as more valuable for firms that do not want sensitive data made public. The most common uses are DB management and auditing.

Consortium BC - The consortium BC, a hybrid, is situated between the two other types. Because the BC is administered by a group, a so-called consortium, rather than a single entity the BC is partially distributed (Zheng et al., 2017). To participate in the consensus process, one node must first be authorized by the consortium (Zheng et al., 2017). Thus, certain nodes may control the consensus procedure, while other nodes can only access the data on the BC to which they are entitled. The Hyperledger Project is an example of a hybrid BC that focuses on organizational solutions (Lu, 2019). Consortium BCs are relevant to companies that want to share information internally but not with the rest of the world. They can maintain transactions on a consortium BC, and because the system is distributed, no member can modify the transaction history. Thus, they do not need the help of a trusted third party.

Appendix 6 – BCT Integration in SCs

Cole et al. (2019) identify four phases in the process of implementing BCT in SCs; development, evaluation, implementation, and integration. In the first stage, the technology is tailored to the specific needs of each SC, while the second and third phases are concerned with the evaluation and decision to adopt the BCT, as well as

the actual implementation. BCT should only be adopted after a detailed value analysis, according to Wang et al. (2019). Additionally, Kshetri (2018) stresses the need for SC collaboration.

Finally, the BCT must be integrated with other legacy enterprise systems, and existing processes may be adjusted. Enterprise systems are "*large-scale application software packages that support business processes, information flows, reporting, and data analytics in complex organizations*" (Morabito, 2017, p. 125). These systems connect all business processes inside a company and across SCs. Enterprise systems comprise enterprise resource planning, warehouse, and customer relationship management systems. The literature cites several organizational benefits for the integration of BCT and enterprise systems, such as decentralized business-to-business audits, smart contracts for automated purchasing, and centralized data archiving (Morabito, 2017). However, integrating IT systems is one of the most named challenges when using BCT in SCM (Wang et al., 2019).

Saberi (2019) projects four actors to play a key role in SCs incorporating BCT; (i) institutions, which define standards and legislation, (ii) registrars, who provide users with unique identities, (iii) certifiers, which grant participation rights, and (iv) actors, such as suppliers, manufacturers, and customers. Aside from new players, academics argue that combining BCT with other technologies can make it significantly more effective. Often BCT in SCM is discussed in relation to tracking technologies such as RFID, or other IoT devices (Hackius & Petersen, 2017; Kshetri, 2018; Wang et al., 2019). Recently also the use of digital tokens is discussed increasingly (Francisco & Swanson, 2018).

The literature agrees that SC networks based on BCT are likely to be permissioned, with restricted access (Saberi et al., 2019). One frequently cited argument is that public, permissionless BCs are impractical due to the huge computational power required, particularly in the logistics context and are easier to hack (Wang et al., 2019). Permissioned BCs have also been used in recent BC projects, such as the Maersk IBM project (Kshetri, 2018). The scholars that argue that permissionless SCs could also play a role are a minority.

Appendix 7 – Research Methodology – Research Set-up

Decision Variable	Methodological Choice
1. Research Strategy	
Scientific Approach	Abductive Approach/Systematic Combining
Research Method	Qualitative Research
2. Research Design	
Type of Research Design	Explorative
Level of Analysis	Drug Supply Chains (Patented & Generic Drugs)
Research Design	Embedded Case Study
3. Data Collection	
Primary Data Collection Method	Semi-Structured Interviews
Secondary Data Collection Method	Document Analysis
4. Data Analysis	
Data Analysis Method	Thematic Analysis
5. Scientific Quality of Research	
Assessed Quality Criteria	Validity (Confirmability, Dependability, Transferability, Credibility) Authenticity Legal Requirements

One-Pager - Master Thesis

How can Blockchain Technology be used to support Supply Chain Risk Management in Drug Supply Chains?

University:
BI Norwegian Business School

Programme:
MSc. Business - Major in Logistics, Operations & Supply Chain Management

Thesis Team:
Anna Amalie Julsvoll
Marla Sickenberger

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A. Research Question:

How can Blockchain Technology be used to support Supply Chain Risk Management in Drug Supply Chains?

B. Research Method:

Data Collection Method: Semi-structured Interviews with three target groups:
i) SCM Practitioners/ Experts in drug supply chains (pharmaceutical companies, distributors, etc.)
ii) Blockchain Experts
iii) Institution Representatives (e.g. NOMVO)

Research Design: Embedded case study; look at supply chains of different drugs

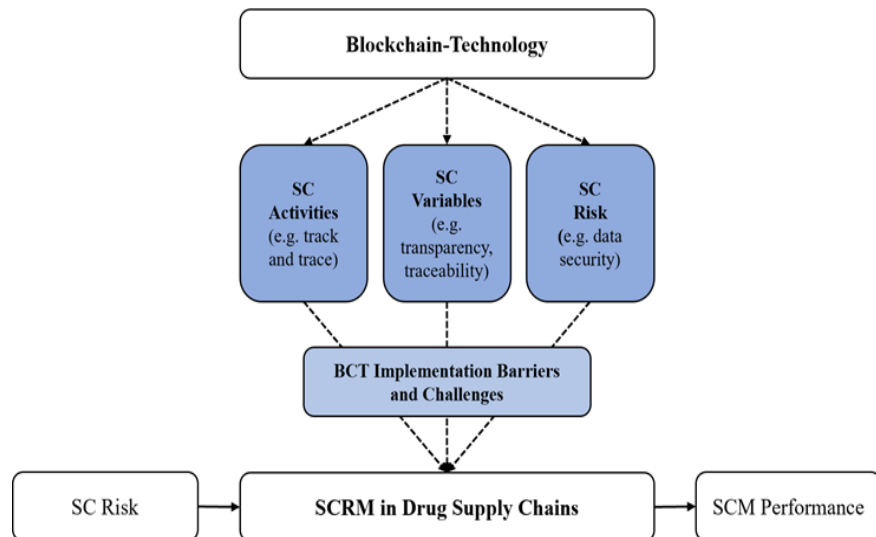
C. Proposed Research Output including Theoretical Framework:

Proposed Research Output:



¹ See Theoretical framework

Theoretical Framework (old framework; status 05.01.2022):



For questions or further information feel free to reach out to us, we are happy about any support of our thesis

Appendix 9 – Interview Guides

Introduction to Master Thesis and Interview:

We are here today to get your perspective on the question, “*How can Blockchain Technology be used to support Supply Chain Risk Management in Drug Supply Chains?*”. We believe that, in the future, BCT will greatly benefit supply chain management by increasing SC transparency and visibility. We further believe that there is a large untapped potential of BCT to support SCRM. However, academic literature is lacking sufficient knowledge in this area. We want to change this by generating insights that may be used as a first stepping stone for further research. The purpose of the interview is to learn more about how BCT might help SCRM – with a focus on drug supply chains, as well as what challenges and barriers there may be when using BCT.

Our Research Question:

How can Blockchain Technology be used to support Supply Chain Risk Management in Drug Supply Chains?

A. Interviewee Background

1. Currently, you are working at XX. What is your professional experience, regarding BCT and/or drug SCs?

B. Target Group Specific Question

B1. Blockchain Technology Expert

B1.1. Blockchain Technology

1. What is BCT? Please limit your response to two sentences.
2. Why, in your opinion, should a company use BCT to e.g. track supply chain transactions, rather than a central (e.g. cloud-based) DB?
3. What type of BC (private, public or hybrid) do you believe SC participants and/or regulatory organizations will most likely adopt in the future?

B1.2 Blockchain in Supply Chain Risk Management

4. SCRM can be structured into four activities: (i) identifying risk, (ii) assessing risk, (iii) mitigating risk, and (iv) responding to risk. Which activity of SCRM do you think BCT can be most valuable for?
 - a. *Follow-up:* Are there any relevant examples/ use cases you could name here?
5. What type of risk in the SC do you believe BCT could eliminate or reduce?

-
- a. *Follow-up*: SC risk is often categorized into (i) demand risk, (ii) supply risk, (iii) process risk, (iv) corporate-level risk. In which order do you rank the four risk categories in terms of the potential of BCT to remove or mitigate them, and why?
 6. What characteristics of BCT do you believe are most beneficial for SCM specifically, such as transparency, immutability, trust, and decentralization? And why?
 7. SCM is often classified into managing (i) product flow, (ii) information flow and (iii) money flow. What do you believe BC is most valuable for? Pick only one.
 8. Do you believe BCT will become a commercial application in SCM in the future? And, if so, when?
 - a. Do you also believe BCT will become mainstream in the future?

B1.3 Blockchain Technology in Drug Supply Chains

Drug SCs have a different risk profile than other SCs, e.g., counterfeit risk, stringent regulatory requirements, and a safe cold chain, among other things.

9. Do you believe there are any additional SC risks that BCT could eliminate or reduce in drug SCs, apart from the ones already discussed?
10. Would you think that the value proposition of BC for SCRM in drug SCs differs from that of other industries?
11. (IBM specific question): We were reading about the BCT pilot IBM did together with Merck, KPMG and Walmart in the US to simplify drug recalls. If you read the white paper the pilot sounds very successful. Can you tell us more about it? And what is done today?

B1.4 Blockchain Technology Adoption and Challenges

12. What do you think are the main implementation barriers and challenges for the adoption of BCT in SCs?
 - a. *Follow-up*: Do you believe that implementation challenges in drug SCs differ from those in other SCs?
13. Billions of transactions each second must be processed in SCM. Do you believe BCT will be able to manage that volume of data (scalability)?
14. What are the most significant success factors for successful BCT deployment, in your opinion?

B2. Drug Supply Chain Experts

B2.1 Supply Chain Risks and SCRM in Drug SCs

-
1. What do you believe is the main difference in managing a drug SC, compared to another SC, such as an automotive, or FMCGs SC?
 2. What does SCRM in the drug SC include for you? Please limit your response to two sentences.
 3. What do you consider the highest SC risks in drug SCs?
 - a. *Follow-up:* How big of a problem is counterfeit in drug SCs (in the EU vs. elsewhere)?
 4. What are your current measures to reduce the risk mentioned above?
 5. SCRM can be structured into four activities: (i) identifying risk, (ii) assessing risk, (iii) mitigating risk, and (iv) responding to risk. Which step do you believe has the most improvement potential for your company?
 6. How would you describe the level of information-sharing between different parties in drug SCs?
 - a. *Follow-up:* How do you share information (technology, rules) and to what extent (degree of transparency, type of shared information)?
 7. Besides the FMD law that is in place in the EU, which mandates that a product's validity be checked before it is given to a patient, how do you track drugs in your SCs?

B2.2 Blockchain technology in Drug Supply Chains

8. Do you use BCT in SCRM? Or did you ever consider using it?
 - a. If yes – In which context, did you use it/ for which purpose?
 - b. If not - Why did you decide against it?
 - i. *Follow-up:* What do you think are the main implementation barriers and challenges for the adoption of BCT in drug SCs?
9. We were reading about the BCT pilot IBM did together with Merck, KPMG and Walmart in the US to simplify drug recalls. If you read the white paper the pilot sounds very successful. Can you tell us more about it? And what is done today?
10. Can you think of any other industry example where BCT is being used in the drug SC?

B2.3 Blockchain technology in Supply Chain Risk Management

11. What do you think is the value proposition of BCT for SCRM in drug SCs?
12. What type of risk in the SC do you believe BCT could eliminate or reduce?
 - a. *Follow-up:* SC risk is often categorized into (i) demand risk, (ii) supply risk, (iii) process risk, (iv) corporate-level risk. What type of risk do you believe BCT can remove or mitigate?

-
13. SCRM can be structured into four activities: (i) identifying risk, (ii) assessing risks, (iii) mitigating risk, and (iv) responding to risk. Which activity do you think BCT can be most valuable for?

B3. Blockchain Technology and Drug Supply Chains Expert

B3.1. Blockchain Technology

1. What is BCT? Please limit your response to two sentences.
2. Why, in your opinion, should a company use BCT to e.g. track SC transactions, rather than a central (e.g. cloud-based) DB?
3. What type of BC (private, public or hybrid) do you believe SC participants and/or regulatory organizations will most likely adopt in the future?

B3.2 Blockchain in Supply Chain Risk Management

4. SCRM can be structured into four activities: (i) identifying risk, (ii) assessing risk, (iii) mitigating risk, and (iv) responding to risk. Which activity of SCRM do you think BCT can be most valuable for?
 - a. *Follow-up:* Are there any relevant examples/ use cases you could name here?
5. What type of risk in the SC do you believe BCT could eliminate or reduce?
 - a. *Follow-up:* SC risk is often categorized into (i) demand risk, (ii) supply risk, (iii) process risk, (iv) corporate-level risk. In which order do you rank the four risk categories in terms of the potential of BCT to remove or mitigate them, and why?
6. What characteristics of BCT do you believe are most beneficial for SCM specifically, such as transparency, immutability, trust, and decentralization? And why?
7. Do you believe BCT will become a commercial application in SCM in the future? And, if so, when?
 - a. Do you also believe BCT will become mainstream in the future?

B3.3 Blockchain Technology in Drug Supply Chains

Drug SCs have a different risk profile than other SCs, e.g. counterfeit risk, stringent regulatory requirements, and a safe cold chain, among other things.

8. What do you consider the highest SC risks in drug SCs?
 - a. *Follow-up:* How big of a problem is counterfeit in drug SCs (in the EU vs. elsewhere)?
9. Do you believe there are any additional SC risks that BCT could eliminate or reduce in drug SCs, apart from the ones already discussed?

-
10. Would you think that the value proposition of BC for SCRM in drug SCs differs from that of other industries?

B3.4 Blockchain Technology Adoption and Challenges

11. What do you think are the main implementation barriers and challenges for the adoption of BCT in SCs?
 - a. *Follow-up:* Do you believe that implementation challenges in drug SCs differ from those in other SCs?
12. Billions of transactions each second must be processed in SCM. Do you believe BCT will be able to manage that volume of data (scalability)?
13. What are the most significant success factors for successful BCT deployment, in your opinion?

B4. Institutional Experts

B4.1 Context - Counterfeits and Falsified Medicines Directive (FMD)

1. How big of a problem is counterfeit in drug SCs (Norway vs. EU vs. other parts of the world)?
 - a. *Follow-up:* How do fake products end up in the SC? What are common tactics?
2. What do you think the main SC risks in physical drug SCs are, aside from the danger of counterfeits?
3. In 2011, the FMD was implemented in the EU to combat counterfeiting. Can you summarize the FMD's idea in a few words?
 - a. *Follow-up:* Was the implementation successful? Did it reduce counterfeit as much as we hoped to?
4. In 2013, the DSCSA was introduced in the US. The DSCSA is comparable to the EU directive. What are the main differences?
5. What are common methods and tools for detecting and reducing counterfeits in areas not covered by the regulations stated above (private sector initiatives)?

B4.2 Current Technical Solution to execute Falsified Medicines Directive (FMD)

6. As we understood today, the validity of (almost) all¹ prescription medicines must be validated before given to a patient in the EU, that is done by retrieving information from the EU central DB. Can you explain how the existing system works and which technologies are currently in use in more detail?

-
- a. *Follow-up:* We know that the FMD requires that the drug is only checked at the end, why is it not checked along the SC? (Because then you are better able to identify where and how the fake product entered the SC)
 7. Is it possible to determine how and where counterfeit items entered the supply chain using the present FMD system?
 8. No system is perfect - What are the system's existing flaws of the FMD law in your opinion?

B4.3 The use of Blockchain Technology to Reduce Counterfeits

9. Currently, the anti-counterfeiting system relies on a centrally controlled, EU-wide DB. Have you thought of using BCT in that context?
 - a. *Follow-up:* For what purpose did you consider employing it?
 - b. *Follow-up:* What were the reasons to decide against it?
10. If you had to make that decision for or against BCT today, would you think differently?
 - a. *Follow-up:* What do you think are the main implementation barriers and challenges for the adoption of BCT in SCs?
11. We were reading about the BCT pilot IBM did together with Merck, KPMG and Walmart in the US to simplify drug recalls. If you read the white paper the pilot sounds very successful. Can you tell us more about it? And what is done today?
12. Over the next several years, the use of BCT in SCM is expected to grow. Do you think BCT has a future in (i) preventing counterfeits in the context of executing the FMD/ DSCSA or (ii) in the private sector (pharmaceutical industry)?

B5. Special Interview guide (Alternative to BCT)

B5.1. Track & Trace in Drug Supply Chains

Drug SCs have a different risk profile than other SCs, e.g., counterfeit risk, stringent regulatory requirements, and a safe cold chain, among other things.

1. What do you consider the highest SC risks in drug SCs?
 - a. *Follow-up:* How big of a problem is counterfeit in drug SCs (in the EU vs. elsewhere)?
2. Your company is working with serialization, f.e. for drugs, we were reading on the Pfizer, Viagra study. Why was that project done, in the first place?
 - a. *Follow-up:* Which IT solution is used for the Track & Trace system (central DB)

-
- b. *Follow-up*: What are the weaknesses of the system? e.g. how do you ensure data is not modified? Who controls the DB?

B5.2 Blockchain Technology

3. How would you explain BCT in two sentences?
4. Why, in your opinion, should a company use or not use a BC to e.g. track SC transactions rather than a normal central DB?
 - a. *Follow-up*: Why is your company not using it? Did you ever consider it?
5. Can you think of any industry example where BCT is being used in the drug SC?
6. Do you believe BCT will become a commercial application in SCM in the future? And, if so, when?
 - a. *Follow-up*: Do you also believe BCT will become mainstream in the future?

B5.3 Blockchain Technology Adoption and Challenges

7. What do you think are the main implementation barriers and challenges for the adoption of BCT in SCs?
 - a. *Follow-up*: Do you believe that implementation challenges in drug SCs differ from those in other SCs?

C. Concluding questions

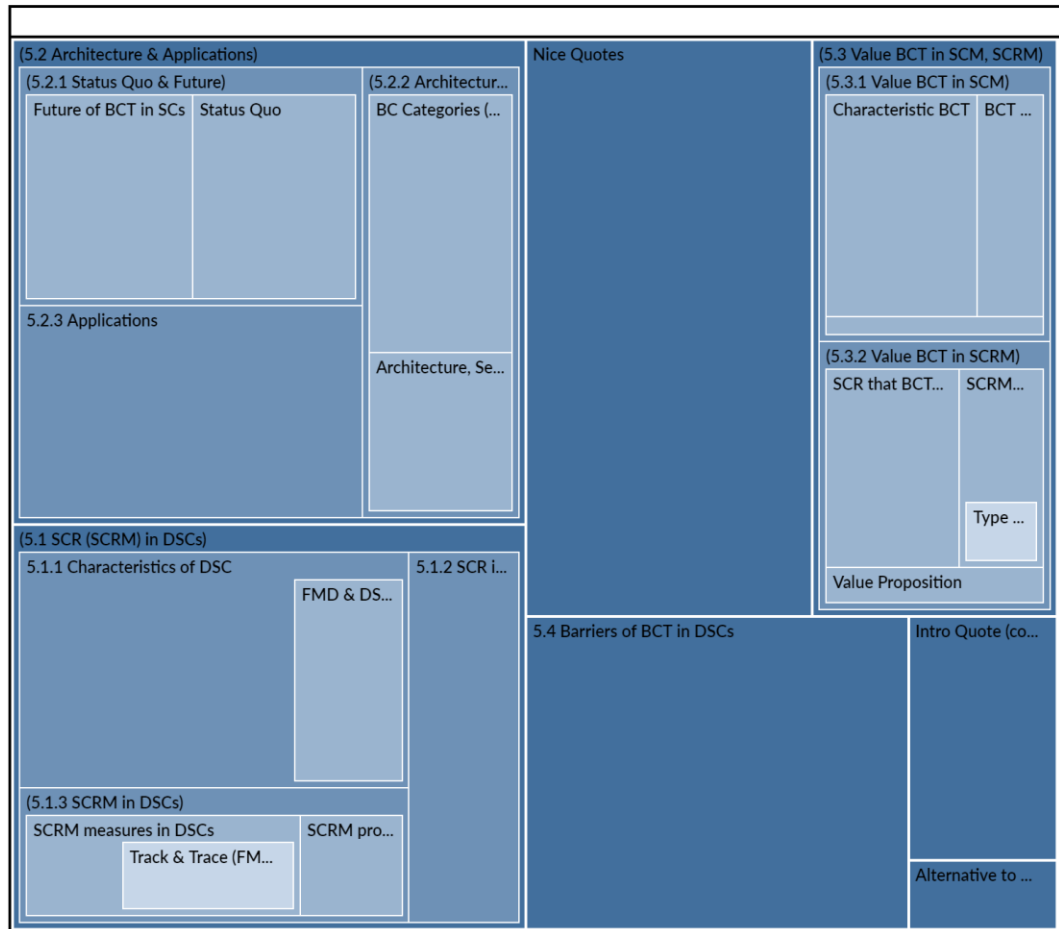
1. Is there anything else you want to talk about that we haven't already discussed?
2. Is it possible to contact you again if further information or clarification is needed?
3. Is there anyone else you suggest us to talk to?
4. Do you have any questions that you would want to ask us?

That's all from us for now. We will revert to you with a transcription of the interview and now only can say a big thank you for making time for us and supporting our research, we really appreciate that!

Appendix 10 – Final Codebook; Number of References per Code

Theme	# Interviews	# References/Codes
SCRM Measures in Drug SCs	4	11
Track and Trace (FMD), Serialization	6	21
SCRM process + 4 SCRM Activities	4	12
Characteristics of Drug SC	11	55
FMD & DSCA	4	22
SC Risk in Drug SCs	10	34
Future of BCT in Drug SCs	13	34
Status Quo	14	33
BCT Architecture Types	10	22
BC Types (private, public, hybrid)	8	36
BC Use Cases	12	60
4 Flows in SCM	4	4
BCT vs. Central DB	8	15
Characteristic BCT	11	34
SC Risk BCT can eliminate, reduce	9	27
SCRM Activity BCT most valuable for	8	11
Type of SC Risk (4 types)	5	6
Value Proposition	6	8
Barriers of BCT in Drug SCs	14	89
Alternative to BCT to Fight Counterfeit	1	7
Intro Quotes	13	27
Nice Quotes	14	123

Appendix 11 – Hierarchy Chart (NVIVO) – Frequency of Codes



Appendix 12 – Number of Codes and References per Interview

Interview ID	# Different Themes in Interview	# References/Codes in Interview
1B	14	36
2D	12	40
3B	15	48
4BD	15	71
5S	12	38
6B	17	74
7D	13	55
8B	13	53
9B	18	67
10I	12	68
11BD	12	38
12BD	13	30
13D	13	39
14D	10	34

Appendix 13 – Promising BCT Initiatives in Drug SCs

PharmaLedger – PharmaLedger is a consortium of 12 global pharmaceutical corporations, including Novartis, Bayer, and Pfizer, and 17 public and private entities, including technical, legal, regulatory, and academic and research institutions (PharmaLedger, 2022). The project's three-year goal is to design a scalable, sustainable, and beyond-state-of-the-art blockchain platform that benefits the whole ecosystem, from manufacturers to patients, by December 2022 (PharmaLedger, 2022). The focus of the pilot is on the use of BCT for drug SCs, in addition to health data exchange and clinical trials. BCT is one of the most promising and efficient monitoring, verification, and authentication technologies for reducing counterfeits, according to the report. *“It is not live, and not in production yet”* (4DB), but the fact that they *“really have the whole bandwidth of the entire supply chain”* (11DB) together at a table is noted in the interviews as a key benefit of the initiative and a strong indication that they will provide relevant results in the near future.

FDA DSCSA Blockchain Interoperability Pilot – In 2019, the FDA developed a BCT pilot focused on traceability and enhancing recall capabilities of fake drugs in collaboration with IBM, Merck Sharp & Dohme, Walmart, and KPMG. The purpose was to demonstrate how BCT may be used to comply with the DSCSA's track and trace requirements (FDA, 2020). The project team also looked at using BCT for purposes other than compliance, but to show a financial value. The objective of the pilot was to; (i) demonstrate that BC can provide a shared record of product movement by securely linking different organizations and systems to meet DSCSA requirements, and (ii) improve patient safety by triggering alerts and increasing visibility to relevant SC partners in the event of a recall (FDA, 2020). The report states that the pilot was successful in both objectives and that BCT is *“able to address the foundational requirement of track and trace for DSCSA in addition to establishing trust between trading partners”* (FDA, 2020, pp. 5).

Although the project report is very favorable about the project's success, it does not specify the next steps. Also, through our interviews and secondary data screening, the team was unable to determine what, if any, steps were taken in response to the pilot. The report itself states that *“an interoperable solution that will track and trace pharmaceutical products between trading partners will require a fundamental consideration for governance”*. The report proposes an *“egalitarian, inclusive,*

open-sourced commercial solution” to spur industry adoption but warns that “uniting the industry around this concept is a formidable challenge” that requires collaboration (FDA, 2020, p. 3). Similarly, one involved IBM partner stated that “trying to get people to adopt this social change is really proven to be, at least for the moment, almost insurmountable” (9B). Another IBM employee highlighted the difficulty of funding such a large undertaking.

“The project worked, the technology worked. It’s a social issue. It requires these companies to interact with each other in ways that are totally foreign to them. These companies in the pharmaceutical space don’t trust each other. They even do not like each other.” (9B)

“So to my knowledge, I mean may I am incredibly wrong here, I think it led to nowhere.” (5S)

We like to highlight two additional examples that are not directly related to drug SCs as they demonstrate how BCT has already advanced in closely adjacent fields. The Excelsior Pass, which is used by 10 million people, is one commercially available BCT solution in the health and life sciences domain. With the aid of BCT, people can prove they have been vaccinated by verifying that the state of New York granted that proof of vaccination. TradeLens, which focuses on tracking container shipments with BCT, is another example of a successful BCT SCM solution.

Appendix 14 – Drug SC Risk Reduced by BCT

Use case (Chapter 5.2.3)	Drug SC Risk (Chapter 5.1.2)	Risk Reduction Score of Use Case*	Total Risk Reduction Score of Use Case
Track and Trace (BC-enabled track and trace system)	Drug Shortage	1	9
	Falsified Medicine	3	
	Product Diversion	2	
	Product Integrity	1	
	Data Security	2	
Smart Contracts	Drug Shortage	0	1
	Falsified Medicine	0	
	Product Diversion	0	
	Product Integrity	0	
	Data Security	1	
Regulatory Compliance	Drug Shortage	1	5
	Falsified Medicine	2	
	Product Diversion	1	
	Product Integrity	1	
	Data Security	0	
Monetarization of Information and Incentiv- isation	Drug Shortage	1	4
	Falsified Medicine	1	
	Product Diversion	1	
	Product Integrity	1	
	Data Security	0	

* 3 = Risk fully reduced, 2 = Risk partially reduced, 1 = Risk mitigated, 0 = Risk not addressed