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Intelligent data utilisation against supply bottlenecks

A data-centred solution to prevent supply bottlenecks through trust-based data collaboration

Intelligent data usage to combat supply bottlenecks – A data-centric solution for preventing supply bottlenecks through trusted data collaboration

Continuous availability of medications poses a significant challenge in healthcare. When essential drugs are not in stock for patients, it can lead to severe consequences for those affected. It is suggested that digitalization along the supply chain, as well as mutual information sharing, could contribute to making supply chains more transparent and efficient, improving the forecasting of potential supply shortages, and thereby directly influencing supply planning. However, there is little intrinsic motivation among supply chain participants to exchange data. Through multipart workshops and focus groups with subject matter experts, the barriers to data exchange within the supply chain have been identified, and it has been explored whether a collaborative data space with a data trustee can resolve these obstacles. In the project »HealthTrack-X«, it is evident that ensuring trust, data sovereignty, and availability from a technical standpoint can be an effective approach. This allows companies to obtain the necessary supply chain data to identify shortages early and take corrective actions. A data space combined with a data trustee can help overcome barriers to data sharing for companies in the healthcare sector.

Keywords

supply shortages, data space, data trustee, healthcare, medications, pharmaceuticals

Ensuring the continuous availability of medicines is crucial in healthcare, and supply shortages are a growing problem [1]. These are caused by global supply chain disruptions, production issues and increasing demand [2], which can lead to significant supply issues and jeopardise patient care. Known methods of inventory management and forecasting often reach their limits. According to the Federal Institute for Drugs and Medical Devices (BfArM), a supply shortage is an 'interruption of a delivery in the usual scope for more than two weeks or a significantly increased demand that cannot be adequately met [1]. It becomes relevant for patients if the prescribed medicine or an alternative medicine is not in stock and cannot be ordered promptly from wholesalers. This would correspond to a supply bottleneck. Legislation already addresses this problem in the Pharmacy Operating Ordinance, which stipulates: '[E]ach pharmacy must keep in stock medicinal products and pharmacy-only medical devices that correspond to at least the average requirement for one week' (Section 15 ApBetrO). Furthermore, AMG Section 52b (1) stipulates: 'Pharmaceutical companies and operators of wholesale distributors of medicinal products [...] shall ensure an adequate and continuous supply of the medicinal product to meet the needs of patients within the scope of this Act.'

>> The European Medicines Agency (EMA), the highest medicines authority in Europe, has issued ten recommendations for action to avoid supply bottlenecks. Many of the recommendations, which go beyond existing regulatory measures, have in common that data and information should be shared within the supply chain in order to jointly counteract supply bottlenecks [6]. Despite these initiatives and recommendations for action, companies from the healthcare industry have shown little willingness to provide data [7]. In order to prevent future supply bottlenecks, the BMWE-funded research project 'HealthTrack-X[2] is aiming for a standardised exchange of information via a data room to make it easier for companies to provide data. The project is also analysing why companies have generally not provided data to date. In order to identify barriers to data sharing and to research an innovative option for low-threshold and secure data sharing, the team of authors is investigating the following research questions (Q):

Q1: What hurdles exist for companies in the healthcare industry with regard to data sharing to effectively counteract drug shortages?

Q2: Is a data room with a connected data trust suitable for overcoming the identified hurdles?

The following section explains the basics of combating supply bottlenecks, data rooms and data trustees. The method used to answer the research questions is then described. The results are presented in the subsequent section. A discussion with an outlook concludes this article.

Fundamentals

Regulatory measures to **combat supply bottlenecks** exist at both federal and European level. In Germany, the Act to Combat Supply Shortages and Improve Supply (ALBVVG) came into force on 27 July 2023. Among other things, it includes the relaxation of pricing rules for paediatric medicines, preferential consideration of EU-produced antibiotics, a reduction in the co-payment exemption limit, simplified exchange regulations for pharmacies, flexible pricing instruments in the event of market shortages, increased stockpiling obligations and incentives for the development of new reserve antibiotics. In addition, the BfArM maintains a supply bottleneck list for supply-critical medicines and an 'urgent list of paediatric medicines' and the Paul Ehrlich Institute maintains a corresponding vaccine list. The supply bottleneck list maintained by the BfArM contains around 500 medicines. In 2024, a total

1: https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/_artikel.html, abgerufen am 03.07.2025
2: https://www.healthtrack-x.de/, abgerufen am 04.06.2025

of 892 different prescription medicines were reported as supply shortages[3]. Since 2022, the Federal Ministry of Health (BMG) has declared a total of seven supply shortages that lasted until 2025, including folinic acid, salbutamol and sodium chloride[4].

For eight out of ten (82.8%) pharmacy teams, supply bottlenecks are one of the biggest annoyances in their day-to-day work - a figure that has remained high for years [3]. Most pharmacy teams in Germany spend 20 to 30 hours (average: 23.7) per week managing bottlenecks with doctors, wholesalers and patients [3]. This is twice as much time as the European average (10.6 hours per week) [4]. Pharmacies document so-called unavailability in around 20 million cases per year [5]. The BfArM's early warning system also plays a central role in combating supply bottlenecks, which is intended to identify impending shortages at an early stage. At European level, the EMA's mandate was strengthened by EU Regulation 2022/123. This regulation creates the legal basis for coordinated crisis management in the pharmaceutical sector. The central instrument for this is the European Shortages Monitoring Platform (ESMP), through which pharmaceutical companies and national authorities report data on availability, demand and supply shortages[5].

Data rooms could offer an opportunity to strengthen the willingness to share data and thus prevent supply shortages. Data rooms are decentralised, federated information systems in which secure and sovereign cross-company data exchange takes place [8]. Selected data is exchanged between stakeholders on the basis of digital identities and access and usage conditions, with the data-providing organisations defining the conditions themselves. In this way, a data space addresses the tension between data sovereignty and data economy [9]. In accordance with the FAIR principles (findability, accessibility, interoperability and reuse) [10], secure data transactions take place that comply with European standards and values. It is particularly important to emphasise that the data initially remains in the system of the provider and only reaches the data user directly when a specific agreement is reached (peer-to-peer) [8].

If data is to be aggregated before use by the actual data users or the source is to be made unrecognisable, **data trustees** can take on this task. Specifically, a data trustee can be defined as 'a natural or legal person or a partnership that mediates access to data provided or held by data custodians in accordance with contractually agreed or legally prescribed data governance regulations (also) in the interest of third parties' [21]. In the healthcare sector in particular, there are various forms of data trustee models, such as intermediary, processing, aggregation or custodian trustees [22], so that both responsibilities and processing can be assigned. In addition, Steinert and Altendeitering (2024) [23] have already shown that the concepts of data trustees can be seamlessly integrated into the architectures of data spaces. A data trust therefore appears to be a useful addition to the data room if the peer-to-peer paradigm is to be broken up. This occurs when companies want to transfer processing, storage, responsibilities or decisions to a neutral entity.

Method

Collaborative workshops based on the principles of participatory health research and co-creation approaches were used as a central methodological element [11]. Both approaches are theoretical and conceptual frameworks that see users not only as objects of information and study, but also allow them to participate in decision-making processes by means of a weighted voice [12, 13]. By involving various experts (n = 8) from the pharmaceutical sector, the data room context, health sciences and consulting in the healthcare and pharmaceutical market, the workshops aimed to analyse the topic of supply bottlenecks in a practical manner and to jointly develop possible innovative solutions. This interdisciplinary composition of participants, consisting of players along the entire industrial healthcare value chain, made it possible to incorporate different perspectives, experiences, requirements and (latent) knowledge.

At the beginning, a collaborative face-to-face workshop served to identify the fundamental challenges of the pharmaceutical market and the reasons for avoiding data sharing. In addition, the participants discussed the suitability of a data room as an innovative solution approach and identified relevant data sources and data flows. In subsequent online follow-up workshops, these findings were explored in greater depth, specific requirements for a corresponding data room and the associated data trust were derived and a possible solution architecture was designed and evaluated. The workshops were continuously documented and results were validated in feedback loops with other participants. This iterative design enabled continuous reflection on the research process and ongoing adaptation of the methodology to the needs of the participants. This collaborative methodology not only strengthens the acceptance of the emerging ecosystem, but also makes a significant contribution to building trust with regard to secure and sovereign data exchange - and at the same time creates the basis for broad connectivity and sustainable scalability across industry boundaries.

Results

Thanks to the methodical approach and the combination of face-to-face and online workshops, practical and consensus-based results were achieved. Table 1 shows an overview of the identified hurdles (see F1) as well as the corresponding resolution through a data room with connected data trust (see F2). The results of the collaborative workshops in combination with current literature show that the obstacles for companies to share their data are multi-layered and can be attributed to a complex interplay of several factors. The following six (1-6) overarching obstacles were identified.

A central problem is the (1) lack of transparency across the supply chain, as information on stocks, planned deliveries or production downtimes is often not available promptly and across all sectors. As a result, later links in the supply chain cannot make any

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3: https://anwendungen.pharmnet-bund.de/lieferengpassmeldungen/faces/public/meldungen.xhtml, abgerufen am 30.06.2025

4: https://www.bfarm.de/DE/Arzneimittel/_FAQ/Arzneimittelinformationen/Lieferengpaesse/faq-liste.html, abgerufen am 30.06.2025

5: https://www.ema.europa.eu/en/news/european-shortages-monitoring-platform-fully-operational-monitoring-shortages-eu, abgerufen am 30.06.2025

statements about previous processes and therefore cannot provide any data that covers the supply chain in advance. However, companies would be able to share the data they generate and thus ensure transparency for their customers. A data room would have the corresponding function of enabling the connected companies to share their data via a common channel.

data via a common channel. If all players in the supply chain are represented in the data room, the lack of transparency is broken. The data room makes it possible to digitally map the supply chain and make it traceable.

Another hurdle addresses the (2) complexity of supply chains. The healthcare industry is characterised by a strong global dependency. The relocation of the production of special goods has led to a large proportion of active ingredient production and key preliminary products being outsourced to a few countries outside Europe. This means that the supply chain consists of a large number of different players, manufacturers, suppliers, logistics partners, wholesalers, pharmacies and authorities, and in different countries. The industry is faced with the challenge of a lack of uniform standards and definitions to make this complexity manageable. This is where a data room comes in, the inherent aim of which is to facilitate integration and collaboration through standardised interfaces and data formats. A data trust can also be a vehicle for uniting several companies under one trust centre, thereby reducing complexity.

Obstacles and overcoming them		
	Identifizierte Hürden (F1)	**Datenraum u. Datentreuhand zur Überwindung (F2)**
1	Fehlende Transparenz über die Lieferkette	Jedes Unternehmen wird befähigt, Daten zu teilen, wodurch die Lieferkette digital abbildbar wird.
2	Komplexität der Lieferkette und fehlende Standards	Standardisierte Schnittstellen und Datenformate erleichtern die Integration und Zusammenarbeit.
3	Geschäftsgeheimnis	Unternehmen wählen selbstbestimmt, welche Daten unter welchen Bedingungen geteilt werden.
4	Geschäftsinteresse	Sicherung der eigenen Geschäftsinteressen durch bspw. Datenverschleierung.
5	Angst vor Sanktionen	Klare Governance und gemeinsame sowie transparente Regeln.
6	Kostenintensive IT und Sicherheit	Bereitgestellte Infrastruktur ermöglicht einfache Anbindung und sichere Datenaustäusche.

Tab. 1: Obstacles and overcoming them. Own representation.

There has also been a lack of willingness to share data or a reluctance to share data among companies because data on inventories, supply chains and sales are considered (3) trade secrets [14]. Their disclosure could give competitors insights into market strategies, pricing or supply bottlenecks and is therefore considered strategically important information. Companies often see no direct benefit in sharing their data, especially if there are no clear economic (or regulatory) advantages [15, 16]. If companies cannot understand how their data contributes to improving security of supply, they are less willing to co-operate [17]. To ensure that business secrets are protected, companies within a data room can decide for themselves which data should be shared and under what conditions. A data trust also follows this approach, which is why the concepts complement each other very well. Furthermore, a data trust can take over decisions and process steps on behalf of a company, for which the company would otherwise be responsible itself.

If companies see an advantage in sharing data, this is often focussed on the data user and not the data provider. Therefore, (4) business interests can also ensure that data is not shared. This may be due to fears that information about the company, stocks and activities will be used for deliveries or negotiations, for example, resulting in actions by business partners that could have a negative impact on the company's own profitability. This hurdle can be overcome by a data trust. Safeguarding one's own business interests can be achieved, for example, by concealing data. Data can be made available to an official body by the trust, but the origin of the data is concealed so that it cannot be traced back directly to a company. Companies retain full data sovereignty and can decide which data is shared with whom.

Another hurdle is the fear that shared data could lead to (5) sanctions or other regulatory measures [18, 19]. The legal obligation to share data is often not clearly regulated or is interpreted differently. This leads to a defensive attitude towards voluntary disclosure [20]. Furthermore, competition law sets limits on which data may be shared with other companies. A system with clearly defined process models can be found in a data room. The data room establishes clear governance and defines common and transparent rules for each other. The data room operator is responsible for ensuring that the standardised processes comply with applicable regulations and provides recommendations for the companies. A data trustee can also ensure that a standardised process is followed when data is requested or viewed.

Companies often do not have the necessary infrastructure or resources to provide data in a suitable form [21, 22]. Proprietary IT systems, a lack of interoperability and fragmented data silos prevent a consistent flow of data between the stakeholders involved. The integration of a large number of data interfaces, standardisation and quality assurance is considered to be particularly complex [15, 23]. Consequently, the (6) cost-intensive IT (infrastructure, software and personnel) was identified as a further obstacle to sharing data. Companies also expressed uncertainty as to whether the security of the data is sufficiently guaranteed and whether data is not unintentionally passed on to third parties or even made public [24]. In addition to the governance level already mentioned, a data room also forms a technical basis. The decentralised infrastructure makes it easy to connect companies and exchange data securely with each other. The scalable solution saves costs as the technical interfaces are interoperable and there is no need for customised software solutions. Communications between companies

always take place directly, unless a data trust function is required. Both technologies follow the current gold standards for IT security and create trust between the parties involved.

Trust plays a key role in all six of the hurdles mentioned. Companies expect that their data will only end up in trustworthy hands, that it will be treated confidentially and will not be misused to the detriment of the company. As trust is above all of the categories mentioned, it is not considered a hurdle in its own right. Nevertheless, a data room with data trust also offers a mechanism to strengthen trust at this point. The technical and legal structure ensures that data is only released in self-defined cases.

Discussion and outlook

The availability of medicines is a fundamental factor in safeguarding the health of our society. Nevertheless, there are regular supply bottlenecks in Germany, which complicate therapies and treatments for patients. The team of authors agrees that some of the challenges posed by supply bottlenecks could be reduced or avoided altogether if digital information were handled with trust. Nevertheless, there is little interest on the part of companies in the domain to digitise the supply chain and exchange important data. For example, supply chains are highly complex, meaning that individual digital solutions are built between individual players that do not scale and are therefore cost-intensive. Our identified hurdles are not exhaustive due to our methodology and concentrated expertise, but certainly give a good indication of the issues companies face. Nevertheless, an appropriate technical and legal system could break down these barriers. A data room with a connected data trust enables standardised communication and helps to improve data availability. Overall, however, a rethink within the industry is essential in order to realise the potential and identify supply bottlenecks earlier and more accurately. The hurdles identified certainly also apply in other contexts and domains. The competitive pressure in the economy can lead to an elbow mentality, but joint collaborations between companies would be enormously valuable for society, especially in the healthcare industry, as a bottleneck, for example, harms all participants in the supply chain and it is in everyone's own interest to create more transparency in the supply chain while preserving data sovereignty.

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The team of authors therefore recommends that policymakers demonstrate and promote precisely this potential of collaborative cooperation to companies. However, we also address the corporate decision-makers who need to engage with the technology and frameworks of data rooms and data trustees. These concepts can be used to create transparency and trust. Within the 'HealthTrack-X' research project, we want to drive digitalisation along the supply chain in the healthcare industry and are building a data room that includes a data trust to ensure additional trust among companies and create a neutral authority. In conclusion, it can be said that all the hurdles identified can be overcome through a data room in combination with a data trust, so that better healthcare must be strived for. With our work, we want to show that there are indeed opportunities for companies to share data and thus create win-win-win situations; advantages for data-providing companies, for data-using companies and for patients. <<

Author's declaration

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