ISSN 1846-6168 (Print), ISSN 1848-5588 (Online)
https://doi.org/10.31803/tg-20230504144856

Preliminary communication
Received: 2023-05-04, Accepted: 2023-05-08

A Returnable Transport Item to Integrate Logistics 4.0 and Circular Economy in Pharma Supply Chains

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Abstract: Recent global events, such as the COVID-19 pandemic, the war in Ukraine and the climate crisis, force the pharma logistics sector to rapidly improve their processes and establish more resilient and sustainable medical supply chains. For this purpose, the pharma logistics sector needs to catch up in Industry 4.0 adoption and establish circular economies. In the context of the applied research project DigiPharmaLogNet, a prototypic returnable transport item (RTI) is enhanced with communication technology and piloted in pharma-specific use-cases. The results will build the base for developing business models and roadmaps towards sustainable pharma logistics networks. This article describes the technological developments and economical evaluations of potential business models.

Keywords: Circular Economy; Industry 4.0; Pharma Logistics; Pharma Supply Chain; Reverse Logistics; Sustainable Development Goals

1 INTRODUCTION

1.1 Circular Economies for the Reduction of Packaging Waste in Pharma Logistics

Recent shortages in medical supply illustrate the importance of resilient pharma logistics networks [1, 2]. The pharmaceutical industry puts high requirements on its supply chains; most notably temperature monitoring and traceability of medicinal products are a priority in order to warrant product functionality or avoid distribution of counterfeit drugs, respectively [3].

In pharma logistics, carboard-based transport items are most commonly in use for delivery of medical products from manufacturers to the point of administration. The life cycle of such one-way transport solutions entails a considerable footprint [4, 5]. Even though paper waste can be recycled to manufacture new transport items, the quality of the recycled fibers limits the number of reuse cycles (Fig. 1A). Besides, transportation of paper waste to package manufacturing plants is necessary, which further contributes to an increase of the environmental footprint.

As a consequence of the objective to reach the global sustainable development goals (SDG), the European Green Deal proposes a policy framework for handling packaging waste that triggers more sustainable business innovations. The introduced directive will also set new standards in logistics, since transport crates rely heavily on one-way solutions for packaging and filling materials [6].

In order to advance the European Green Deal and move towards a circular economy the usage of returnable transport items (RTI) seems very promising. RTIs eliminate a required package manufacturer as intermediary, thus allowing shorter circulation routes. In addition, higher numbers of reuse cycles compared to cardboard-based transport items are expected (Fig. 1B) [5].

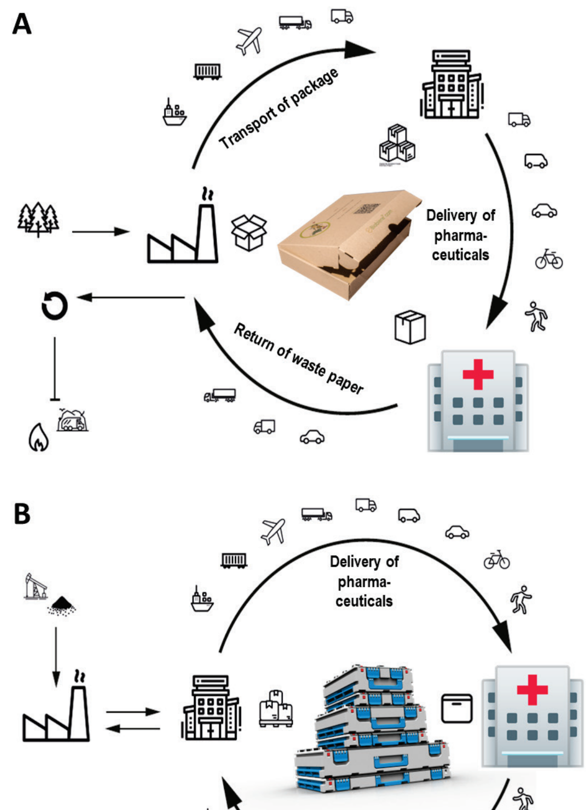

Figure 1 Circular economies based on RTIs are expected to result in ecological and economic advantages over the recycling process of fibers from cardboard-based boxes. (A) Life cycle of fibers devoted for cardboard-based transport items. Packages are fabricated and transported to pharmaceutical manufacturers utilizing cardboard-based boxes for delivery purposes. Once shipped pharmaceuticals reach the customers (e.g., hospitals or pharmacies), fibers of package material are either recycled in package factories or incinerated. (B) Life cycle of material devoted for RTIs. Once fabricated, pharmaceutical manufacturers may repeatedly utilize returned RTIs for delivery purposes. Package material may be eventually recycled after RTIs become damaged or unemployable.

1.2 Organization of the Article

Section 2 summarizes current challenges and technical opportunities in establishing circular economies in pharma logistics. Section 3 introducing the applied research project DigiPharmaLogNet that aims at evaluating the feasibility of implementing RTI solutions as enablers of logistics 4.0 and circular economies. Section 4 presents the last results of DigiPharmaLogNet. The conclusion in section 5 provides an overview of remaining gaps to be addressed by research.

2 LITERATURE REVIEW

2.1 The Challenges in Integrating Circular Economies with Logistics 4.0 Technologies

The advent of the Industry 4.0 not only triggered new technical innovations and paradigms in the manufacturing industry, but also led to the emergence of new business models and processes [7]. As part of Industry 4.0 in a wider sense, this equally applies to Logistics 4.0, the next generation of logistics, which also aims to solve pressing problems in the area of sustainability [8].

Due to the nature of (pharma) supply chains, the establishment of circular economies relies on the consent of multiple business stakeholders willing to transform their processes with RTI solutions, amongst others wholesalers and other intermediaries [9]. As economic players, their readiness strongly depends on the applicability and long-term profitability of the RTI solution in their specific field. Driven by the European Green Deal policy, the question therefore arises how a practically applicable RTI solution in the context of (pharma) Logistics 4.0 can be designed that creates a technical solution capable of achieving sustainability goals in line with profitable, long-term business models.

In order to build circular economy concepts based on Logistic 4.0, specific use cases and business models are needed to provide quantifiable evidence on the potential of novel technical solutions. In this paper, we aim to contribute to the specific research field of circular economies in pharma logistics by exploring a new technology solution of reusable containers, examine its economic feasibility in two use cases, and explore potential business models designed for implementation of the RTI solution.

2.2 Current Work on Circular Economies in Pharma Logistics Sector

RTIs have been used in the pharmaceutical sector in closed intra-logistics systems or between pharma wholesalers and pharmacies, where there are several deliveries a day and the return logistics of the empty RTIs is done at little or no extra cost [10, 11]. In addition, digitization of supply chains and widespread use of Internet of Things (IoT)-technology, that allow tracking and tracing of shipments suggest increased reliability of RTI-based circular logistics systems [12]. In particular, there are very promising applications of blockchain technology [13] as well as robotics and drone solutions that could streamline reverse logistics and cold chain processes [14, 15].

3 THE RESEARCH PROJECT DIGI-PHARMA-LOG-NET

DigiPharmaLogNet is a consortium project for the development of a returnable transport item solution applicable for the establishment of circular economies within pharma supply chains (Fig. 2). The Institute for Digital Transformation and Strategy of the University of Applied Sciences for Management and Communication in Vienna leads and conducts the project in partnership with non-profit research institutions, start-up companies, and industrial partners involved in Austria’s pharma supply chains. The partners provide the process resources needed for the analysis of possible business cases [16].

The project addresses the following research questions:

- What are the organizational requirements for the establishment of circular economies in pharma logistics?
- What are the technical requirements for an RTI solution that enables the integration of logistics 4.0 and reverse logistics?
- What are the potential economic impacts of implementing an RTI solution?
- How to evaluate sustainability aspects of RTI solutions?

In order to achieve the objectives, the project follows an exploratory, incremental design approach, in which a proof-of-concept demonstrator is designed and applied to selected use cases for first feasibility evaluations. According to the chosen approach, the development of the proof-of-concept demonstrator is carried out in four phases:

1) Flare and Focus Phase: in this phase, the initial designs for the proof-of-concept demonstrator were established.
2) Design and Development Phase: in this phase the initial design was refined, and a physical prototype built, including the digital control systems.
3) Demonstration phase: here, feasible use cases from the partner companies were selected and test-settings derived. The proof-of-concept demonstrator was then adopted in these test-use-cases.
4) Business model derivation phase: in the final phase, the findings from the previous tests were combined to develop possible future business models.

This particular project approach not only allowed to utilize the insights from the practical application to be used as a basis for redesigning the initial RTI prototype, but also provided valuable insights for designing possible future business models.

The core technology developed in DigiPharmaLogNet is an RTI designed by BOOXit, which is intended for circular logistic chains. In its current developmental stage, the RTI is made of a durable plastic-based material that allows a high number of reuse cycles (Fig. 1).

Moreover, its design is optimally suited for an application in pharma logistics. It offers opportunities for enhancement with Industry 4.0 sensor and communication technologies and enables temperature monitoring and tracking functionalities which are some of the most discussed problems in pharma logistics [9]. With a multitude of additional hard- and software add-ons it strives to provide an

Internet of Things (IoT) ecosystem in logistics with the RTI as the central component and enabler of value-added services.

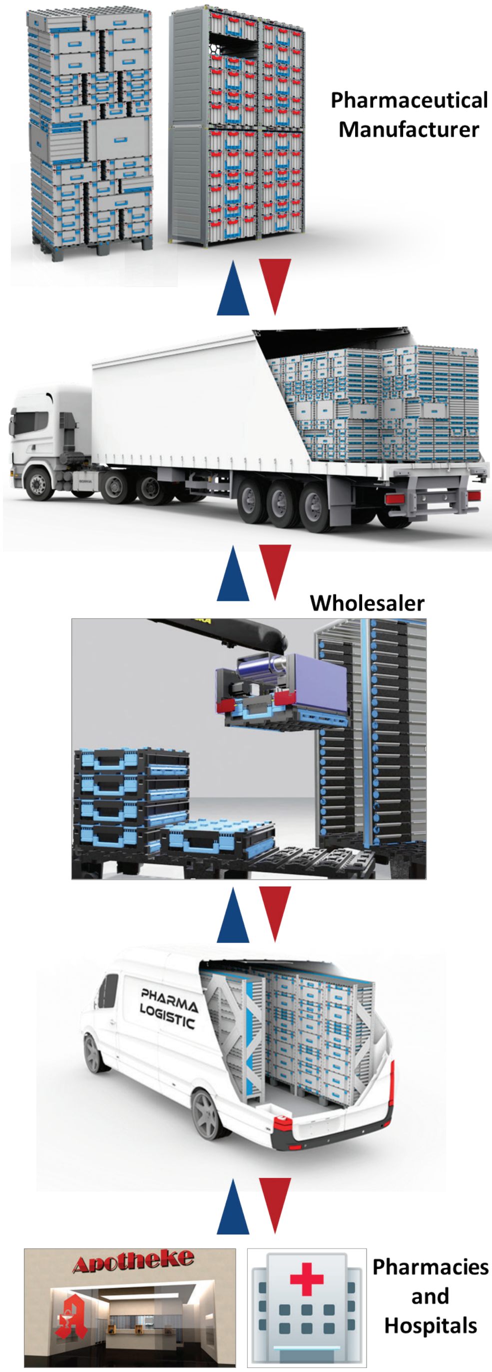

Figure 2 The vision of DigiPharmaLogNet. The RTI solution to be developed by the project team has a modularity mechanism incorporated, which allows stacking boxes with different sizes. Its compatibility with a robotic system enables automation of warehouse processes. Since RTIs are intended for reuse, circular logistic chains could be established in pharma logistics. RTI, returnable transport item.

The design solution includes an integrated grid mechanism that allows stacking boxes of different sizes, comparable to Lego® bricks (Fig. 3A-C). Furthermore, the grid mechanism enables horizontal displacement of boxes placed one upon the other. This allows utilization of individual boxes as drawers in dedicated racks (Fig. 3D), dubbed as "one-shot loading" of multiple boxes on or off delivery systems, such as trucks or trains, becomes possible. In view of the goal to eliminate cardboard-based boxes in supply chains [6], a grid mechanism poses an advantage, since cardboard-based boxes need to be managed single-handedly and demand extra transport security measures like belts or cellophane wrapping.

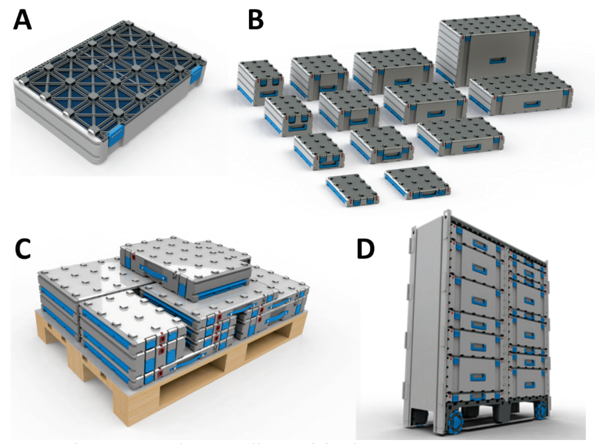

Figure 3 Grid system of the RTI (from BOOXit) that serves as core technology of DigiPharmaLogNet. The integrated grid mechanism (A) allows modular applications of boxes with different sizes (B), i.e., “stackability” (C) or usage as drawers in a proprietary rack (D).

The grid mechanism and overall design of the core technology also offers potential for semi- or full automation of RTI inventory management processes in warehouses. In addition, the RTIs are compatible with a robot arm. Together with the "one-shot load" feature of a specialized rack on wheels the overall RTI system will thus reduce ergonomic problems of the logistics industry.

The ultimate objective of DigiPharmaLogNet is the evaluation of usability and economic feasibility in terms of economic efficiency and reduced CO_2 emissions, that are expected due to a high number of reuse cycles (Fig. 1B). For this purpose, potential use cases were selected based on their improvement potential but also on accessibility to pharma supply processes of the industrial partners.

4 RESULTS

To date, the research and development project delivered several outcomes, which are presented in this section. The primary outcome is a proof-of-concept (PoC) demonstrator that identifies technical benefits and challenges of the new RTI concept. With the limitations that a demonstrator poses, two real-world use cases in pharma logistics could be identified. Those use-cases were analyzed with respect to their economic potential when implementing the new RTI system. Vice versa, the considerations during implementation also led to adjustments and improvements of the PoC demonstrator itself. Based on the data from the use cases, a hypothetical business model was created for the start-up company BOOXit, which develops and commercializes the new RTI system.

4.1 The Proof-of-Concept Demonstrator

A major objective of DigiPharmaLogNet is the development of an Industry 4.0-based RTI solution that meets the specific demands of the pharma logistics industry, such as temperature monitoring and location tracking. This necessitates the integration of electronic components for automatic communication with an inventory system software program.

The prototypic rack controller, which is conceived as the basic electronics unit of the rack, automatically reads data from a near frequency communication (NFC) chip (as part of a box), such as RTI identification number, content (pharmaceuticals) in the RTI, or current position (slot) in the rack. The prototypic firmware also has writing functionalities for data stored on the NFC.

In addition, a first configuration of an RTI controller was applied to communicate with sensor technologies (e.g., temperature sensor) that might be incorporated in the box. In order to support delivery personnel with drawing boxes from racks or warehouse personnel with putting boxes into racks (of trucks), the firmware has pick-by-light or put-by-light functionalities, respectively.

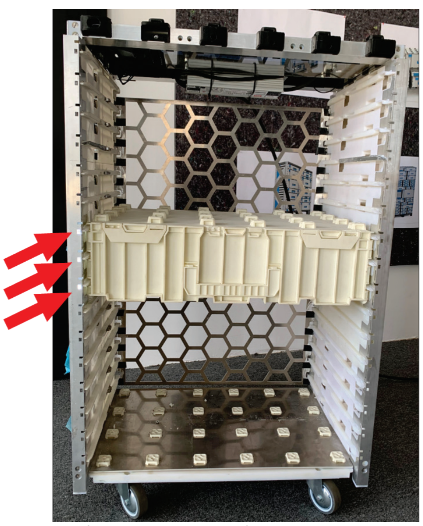

Figure 4 Put-by-light / pick-by-light signal functionality integrated in the PoC demonstrator rack. The flashing LED lights (red arrows) indicate that the respective slot is unlocked, thus ready for removing the box it holds or accepting a box. Once the LED lights turn out, the slot is locked, thus the box is fixed in the slot or the slot is not ready for accepting a box. PoC, proof-of-concept; LED, light-emitting diode.

The rack and RTI controller units were integrated with the first PoC demonstrator rack. In its current developmental stage, the rack controller can be manually triggered to control the lock mechanism of the rack. If the light-emitting diode signals are flashing, the corresponding locks of the slots are ready to accept or release single or stacked boxes (Fig. 4). In combination with the box inventory system, RTI movements can be managed. A prototypic smartphone app for supporting the RTI handling has already been developed (Fig. 5).

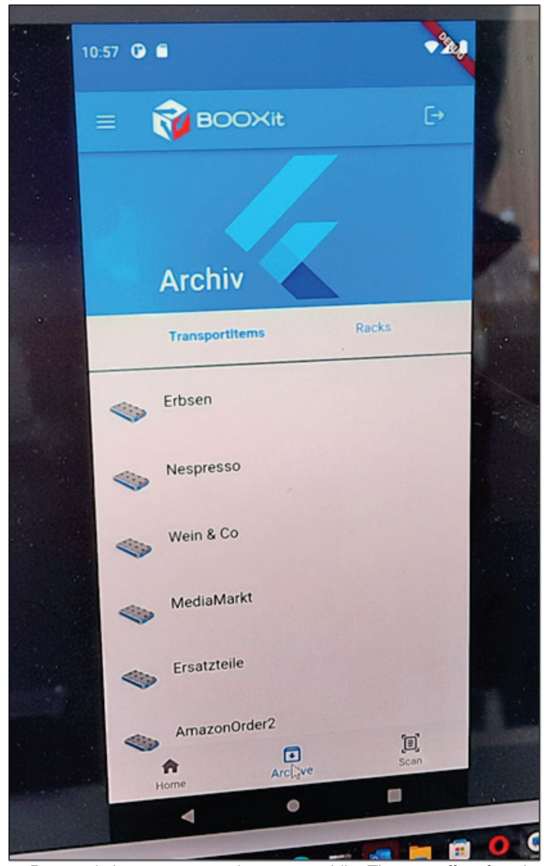

Figure 5 Prototypic inventory control system mobile. The app offers functionalities for RTI management, such as receipts or initiations of shipments, or identifications of RTIs in racks. RTI, returnable transport item.

Later process analysis of the milk run use case (see 4.2.1) revealed that some pharmaceuticals might still need manual loading into boxes. Therefore, the lock mechanism of the core technology was advanced for simplification of the opening of the box to enable subsequent automation. To further facilitate manual loading, the PoC demonstrator box was equipped with an additional mechanism that allows removal of the entire lid. At present, the box supports one-sided lid opening (Fig. 6A) and complete lid removal (Fig. 6B).

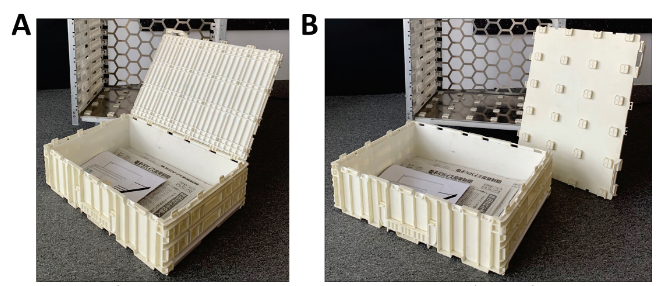

Figure 6 PoC demonstrator box opening mechanism. The first PoC demonstrator of the RTI has an integrated hinge mechanism for one-sided opening (A) or complete detachment of the lid (B). PoC, proof-of-concept.

4.2 Identification and Analysis of Two Potential Use Cases

In order to estimate the logistical improvement potential of the proposed RTI solution, two possible use cases for deployment were identified together with one industry partner from the pharmaceutical wholesale area and one partner from the shipping sector:

- a wholesaler's pharmacy delivery milk run and
- an international carrier's airfreight shipment of pharmaceuticals that need cooling (pallet shipper).

The use cases were chosen according to the alternative transport containers utilized in each case. Each container represents an ideal target for substitution through either parts or the whole prototypic RTI system.

4.2.1 The Wholesale Milk Run

The wholesale milk run case describes the wholesale supply of pharmaceuticals to local pharmacies, which order various pharmaceuticals for humans and animals, but also goods such as animal feed and other specialty products for animal care. Two types of plastic boxes (standard RTIs and passively cooled polystyrene-based boxes as shown in Fig. 7) are filled in a highly automated picking system and then loaded according to the respective tours.

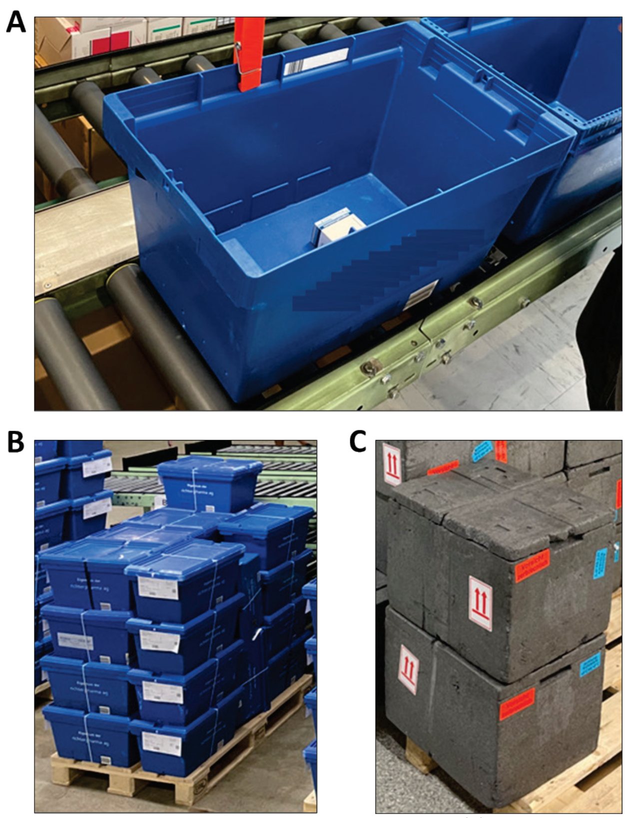

Figure 7 Transport items currently in use by the wholesaler. (A) An RTI with the lid removed. These types of RTIs are used for transportation of drugs that need no cooling. (B) Stacked RTIs. (C) Polystyrene-based cooling boxes to be filled with dry ice for cold chain delivery. RTI, returnable transport item.

Truck drivers sort the boxes corresponding to the stops on their routes and load them into their trucks in reverse order. Each driver then completes his tour and delivers the boxes to the pharmacies on that tour. In the process, the driver also picks up the empty boxes from the pharmacies and returns them to the warehouse at the end of his tour.

While feed bags or bulk packs seem to be less suitable for substitution, the standard box used in the delivery process represents an ideal target for substitution by the proposed prototype. Since the prototype RTI can also be equipped with refrigerated panels, an exchange of the cooled box variant is also conceivable. However, due to simplicity, first calculations were only made with the standard variant. Regarding the economic potential of this use case, the packaging process already seems to be largely automated. However, the sorting and delivery runs are almost entirely carried out manually, thus showing the greatest potential for logistical improvements in terms of cost savings.

4.2.2 The Pallet Shipper

The pallet shipper use case, represents the scenario of a carrier's international pharmaceutical shipping service, specialized to the needs and requirements of specific pharmaceutical business sectors that need temperature control, e.g., manufacture of vaccines or other biotechnology-based products. The process analyzed in this use case thereby consists of arranging the transport from its original destination to the clearing center at the airport and booking the airfreight transportation. Since many goods in the pharmaceutical sector require low temperatures and strict compliance with the cold chain, the means of transportation used in this case is a special isolated pallet shipper, equipped with cooling elements and a temperature logger. Beside the organizational duties mentioned earlier, the carrier is also responsible for providing and assembling the pallet shipper for the customer.

In this use case the pallet shipper represents the means of transport that is to be replaced by the prototype rack. The juxtaposition in Fig. 8 shows the apparent similarities between both systems.

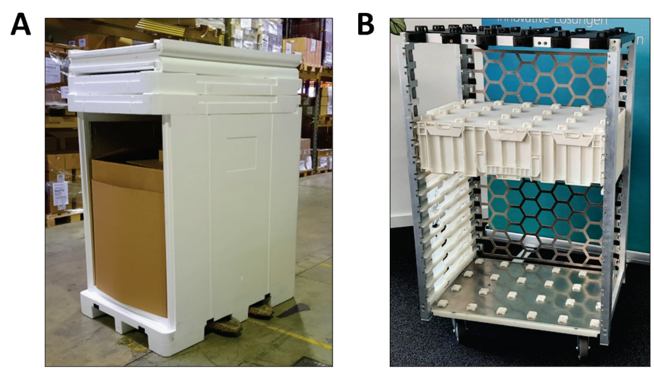

Figure 8 Juxtaposition of a pallet shipper and a rack compatible with the RTI solution. (A) Pallet as currently utilized for international shipments of pharmaceuticals. (B) A first PoC demonstrator designed for the RTI solution to be technically advanced for pharma logistics purposes according to the project objectives. PoC, proof-of-concept; RTI, returnable transport item.

Initial economic considerations of this process suggested that the expense of assembling the pallet shipper, as well as temperature monitoring, could be simplified by the new reusable prototype. However, the current pallet shipper system is designed as a single-use container and return transport is not currently included in the process. Installing a return transport regimen is an organizational challenge and under current framework conditions will result in considerable additional costs.

In order to evaluate the economic potential of the two use cases (pallet shipper and milk run), actual business process data was exhibited for extrapolating potential cost reduction opportunities from hypothetical implementations of the RTI solution in these cases.

4.3 Logistical Improvements of the Use Cases

Finally, estimating the respective logistical improvement potentials was achieved through the comparison of actual and future cost models, which were derived from underlying business processes and improvement data from expert experiences, pre-tests and videos of the prototypical solution. The potential logistical improvements of those two cases are presented in the following two sections.

4.3.1 Improvements of the Milk Run

For the milk run use case, the team chose to investigate the process section starting after the boxes have left the fully automated picking unit and wait for sorting and delivery till final delivery at the customers as the most promising area for implementation. The primary source for potential savings is time savings during sorting and delivery. The RTI technology facilitates automated or non-automated pre-sorting of filled boxes into the racks directly at the end of the conveyor belt. Thus, staff is not required to manually carry the individual boxes to the assigned truck. Trucks can be equipped with transportation locks that assure the racks are secured in the freight hold. Thus, the racks work as handling aids and load securing device at the same time.

When unloading the boxes at the customers, the RTI system also promises significant time savings. The pick-by light system precludes time-consuming search for the right RTI. Currently, on average a truck driver abides about three minutes at a single customer. With the new technology, this time should be reduced by 38 seconds.

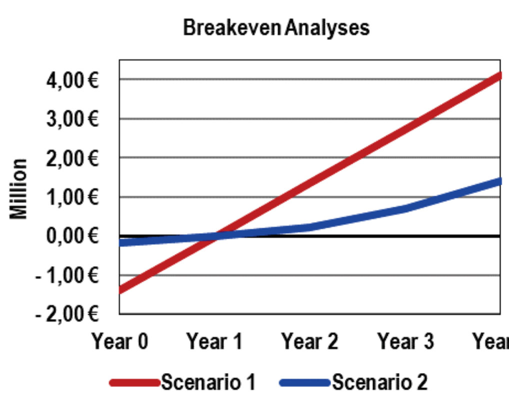

Figure 9 Breakeven analyses for the milk run use case. Scenario 1 assumes full replacement in the first year. Scenario 2 assumes rolling replacement of old boxes with the BOOXit boxes. The x-intercept signifies the year of reaching the breakeven point.

The overall time savings for one tour (currently on average 9.4 hours) sum up to roughly 1.28 hours. Assuming that the company is able to fully utilize the achieved time savings, the calculations show a yearly cost reduction of €1.3 million per year.

Based on the process analysis and optimization a static break-even analysis of two different scenarios was performed. Scenario 1 assumes that all existing boxes are replaced at year 0. Scenario 2 assumes a rolling replacement of old boxes. Under this scenario, complete replacement is achieved after 5.83 years. Irrespective of the scenario, however, the break-even point is reached after almost exactly 1 year (Fig. 9).

4.3.2 Improvements of the Pallet Shipper

Unlike the milk run use case where one RTI technology should be replaced with another RTI technology, the pallet shipper use case investigates the replacement of a single-use system with the RTI and rack system. The pallet shipper use case was selected because of the apparent similarities of the existing pallet shipper and the RTI and rack system (Fig. 8). The RTI system's main advantage in this case is not based on more efficient handling but simply on the cost advantage of reusing the transport boxes. The purchase price of the existing single-use pallet shipper amounts to €1.400. The estimated purchase price of the entire rack with comparable shipping volume is €2,360. The rack should sustain 100 cycles and the boxes 250 cycles. This results in depreciations of €101.12 per cycle.

However, the challenge of this use case is the establishment of a functional return shipment of the boxes. In its current mode of operation, the pallet shipper is primarily used for airfreight, where drugs are sent in irregular intervals and accompanied with individual services. Returning racks with empty boxes over long distances on a low-volume basis proved to be inefficient, both from an economic and an environmental point of view. The calculation yielded an estimated cost increase of 18.4%.

Our obtained insights from investigating the use case are in line with recent literature that highlights transportation distance, delivery frequency, volume, and number of active players as determining factors of the establishment of a return system [17, 18]. At present, these requirements cannot be met by the medium-sized family-owned company in this particular use case. A long-term solution might be the establishment of a circular system with local partners based on frequent orders and stepwise expansion of the system to other businesses.

4.4 A Business Model for the Milk Run Use Case

Based on the preliminary data, a potential business model for time-to-market expedition was derived. The scope of these business models for reaching market entry was set to one or two years after project completion. The business idea builds on a combination of a selling and service model addressing pharma wholesalers and pharmacies as primary (initial) customer segments, who plan to establish circular economy processes.

The major sources of income are the regular selling of the RTI system (RTIs, racks, IT-infrastructure) and single updates of the global database that supports the box inventory management system. Customers initiate an update each time an RTI enters or exits a rack, which requires updates of its current location and content (e.g., removal of delivered drugs). Additional updates of the database are required by the real-time temperature monitoring feature (if ordered by the customer). Since customers pay per use, single (periodical or manual) inquires of box properties (location, content, temperature log, etc.) will generate income as well.

Next to that core business, the business model also includes service provisions, involving maintenance of the box system and the entire IT-infrastructure. The different building blocks of the initial business model are summarized by the business model canvas according to Osterwalder and Pigneur depicted in Fig. 10 [19].

<table>
<tr><th>Key Partners</th><th>Key Activities</th><th>Value Proposition</th><th>Customer relationships</th><th>Customer segments</th></tr>
<tr><td rowspan="3">• Box manufacturer
• Tool designer
• Developer of a passive cooling system for isolated transport items
• Developer and manufacturer of the electronic equipment
• Developer of the inventory control system
• Box deliverer
• Rack deliverer
• System integrator
• Box cleaning service provider</td><td>• Box selling
• Service provision
• Electronic box management with the inventory control system program software
• Continuous technical and software development</td><td rowspan="3">• Reduction of investment costs
• Reduction of box depletion
• Tracking and tracing of boxes
• Elimination of polystyrene-based cooling boxes
• Elimination of the need to use dry ice for cooling medical products
• Real-time temperature monitoring
• Support of delivery- and warehousemen</td><td>• Business Development
• Customer Service
• Equipment delivery
• Take over of old equipment for recycling purposes</td><td rowspan="3">• Pharma wholesaler
• Pharmacies</td></tr>
<tr><th>Key Resources</th><th>Channels</th></tr>
<tr><td>• Box
• Rack
• Box warehouse
• IT-infrastructure</td><td>• Direct sales and distribution
• Direct marketing
• Website
• Service points</td></tr>
<tr><th colspan="2">Cost Structure</th><th colspan="3">Revenue Streams</th></tr>
<tr><td colspan="2">• Production per box - scale effect (high initial costs)
• Delivery costs - scale effect (high initial costs)
• Consultancy with and/or execution of the integration of the IT-infrastructure and box technology with existing IT-systems
• Maintenance of boxes and the IT-infrastructure
• Box storage
• Provision of IT resources and access to core data</td><td colspan="3">• Sale of boxes
• Sale of racks
• Sale of IT-resources
• Pay per use - fixed fees for each update of and access to the core data bank
• Temperature monitoring
• Service fees</td></tr>
</table>

Figure 10 Business model canvas of an initial business model

5 CONCLUSION

The preliminary results of the DigiPharmaLogNet project presented in this paper demonstrate self-organizing RTI that are digitally enhanced can substantially foster automation and thus the optimization of the supply chain in pharma logistics. The technological, logistical and economical potential of the novel RTI ecosystem developed by the projects company partners. The two use cases showed that economic feasibility is highly dependent on the specific process and its boundary conditions. While one use case shows a very high return on investment with a break-even after about one year, the second use case is likely harder to implement in a profitable manner, even though it is theoretically feasible. Especially the establishment of the reverse logistics for airfreights seems highly complex and expensive. This coincides with observations from other sectors of the economy (e.g., transportation of milk or other drinks with glass bottles, or RTIs for machine parts), where reverse logistics is only possible, if empty transport capacity is used for the backhaul of the RTIs [11]. In the context of pharma logistics, the presented milk run use case already provides this backhaul opportunity and hence an actual implementation seems promising.

Acknowledgements

The authors would like to thank Andreas Holzleithner and Peter Entenfellner from BOOXit for providing the photo material and the team of DigiPharmaLogNet for sharing their expertise.

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