A Reference Architecture for Pharma, Healthcare & Life Sciences

A Framework for Using Digital Technology

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Abstract: This paper contributes to the digitalization research by proposing a digitalization reference architecture (RA) for the pharma, healthcare and the life sciences domain in the context of the overall healthcare landscape from a business and information technology (IT) perspective. The RA fills the gap created by the existing siloed, non-interoperable standards. The RA comprises three main components – therapeutic segments, pharma-specific functions, and generic functions. Horizontal slices – following the widespread TOGAF framework layers – characterize the RA to support a seamless view from capability to technology. The paper aims to provide a holistic RA along examples of how this architecture can be used in general and in the oncology sector – one of the largest pharma markets. The proposed RA can help companies interested in evaluating the value of digital technologies, their alignment with business models, or the impacts of regulations or other legal requirements in light of these digital technologies.

Keywords: Pharma, Healthcare, Life Science, Reference Architecture, Digital Technology

1 Introduction

Digitalization is disrupting and reshaping industries. Digitalization creates not only serious competitive threats, but also significant competitive opportunities, and it is perceived as an imperative for enterprise viability [Ha10]. Digitalization technologies have already proven to be an essential value enabler in many areas. One well-known example is the cost-cutting potential of cloud computing [Ca16]. Although many companies across a variety of industries are interested in digitalization, the degree of maturity differs significantly among industries and countries. For example, the German pharmaceutical and healthcare domain is characterized by an early stage in terms of digitalization strategy [De16]. To exploit the potential of digitalization for public health, federal agencies as well as political and economic institutions are intensively promoting its development and adoption [Di18, In15, Th14]. New regulatory requirements and legislation are laying the foundation for further integration of digital technologies in everyday practices [CSS17]. However, the three related sectors – pharma (drug and

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medical device manufacturing), healthcare (healthcare provision) and life sciences (research and development for healthcare applications) - are highly regulated and knowledge-intensive, and they form a complex ecosystem. The adoption of digital technologies within this ecosystem comes along with great differences in risks and expectations among various players. Consequently, understanding the influences of new technologies on existing companies and their underlying business architectures is important for all ecosystem participants, who become stakeholders in the digital technology implemented for their industry and for the entire ecosystem.

This paper contributes to the digitalization research by proposing a digitalization reference architecture (RA) for the pharma, healthcare and life sciences domain in the context of the overall healthcare landscape from a business and information technology (IT) perspective. The business perspective describes the functions and the solutions which are exposed to the market, such as drugs and medical devices. The underlying IT architecture describes available technological solutions which can leverage digitalization principles. By providing comprehensive information on the pharma, healthcare and life sciences domain and the associated value creation (from business functions to solutions with their underlying technological structure), this RA provides a reference tool for industry participants as well as a building block for future research. For example, companies and researchers can use this RA to evaluate alignment to new business models, extensions to legal regulations, or value of adopting to new technologies, among others.

The RA proposed in this paper adds to the growing body of literature on reference architectures developed for specific domains. An RA for the aviation industry has been proposed in order to promote industry standards and increase the efficiency and effectiveness of companies adopting the RA [Su16]. An RA for the maritime industry has been introduced in order to guide the development of new systems in heterogeneous technology, organizational, governance, and usage environments [WHN16]. An RA for the pharmaceutical industry has been developed in order to help companies engage in digital transformation using emerging technologies such as the Internet of Things, cognitive computing, and augmented reality [CSS17]. On a more technical level, architectures for complex powertrain systems and service robotic systems have been proposed to improve software development quality and showcase best practices that can support future architectural developments [Lu14, Ve17].

2 The existing pharma, healthcare and life sciences ecosystem

The pharma, healthcare and life sciences ecosystem is composed of multiple actors who interact with each other through the exchange of value - information, physical goods (drugs and medical devices), services, and payments. The main actors are the pharma industry (pharmaceutical companies), other life sciences companies (such as biotechnology companies or medical device manufacturers), healthcare providers,

solution suppliers, governments, payers (private or government-owned), and last but not least patients. The exchange of value can be exemplified with the provision of healthcare services for the treatment of patients or regulations imposed by the government to support public health. In this paper, we develop an RA from the perspective of a main actor in this ecosystem – the pharma industry, whose primary role is to provide drugs or medical devices to the overall healthcare landscape. Therefore, the use of the word value in the following sections will be based on the pharma industry value definition - as an analogy for drugs and medical devices.

In order to successfully deploy digital technology applications for pharma, healthcare and life sciences, it is necessary to consolidate the variety of standards in this domain. However, existing standards complement and partially overlap each other and no integrated end-to-end standard or interoperability scheme exist. This is partly due to the complexity of the domain, and the different types of regulations (sometimes very extensive) that exist in different countries. This results in a very heterogeneous market, which encourages the development of siloed architectural solutions. At present, it is unclear if standardized interfaces exist and if interoperability of these siloed solutions is possible.

Examples of these existing, non-interoperable standards are summarized in Table 1 below.

Architectural Solution	**Source**	**Features**	**RA Gap to be Addressed**
The caBIG® Life Science Business Architecture Model	[Bo11]	Shared taxonomy (shared understanding of the vocabulary, goals and processes that are common in the business of life sciences research)	• Only based on use cases • Does not capture information about the problem • Needs to be mapped to concrete system solutions • No relationship between business and technology • Every actor has its own detailed process (so the model is more like a checklist)
IBM Reference Architecture for Genomics	[Le15]	End-to-end, unified solution for genomics research	• Technology solution only
Healthcare Enterprise Reference Architecture	[He18]	A framework for developing an RA for any healthcare company	• A cognitive map • Unclear taxonomy • Process step recommendations

(HERA)			• Examples for solutions only (both an advantage and disadvantage)
Software Ecosystems (SECO) for the Life Sciences Application Domains	[TS15]	A collection of common systems and actors focused on developing software applications for life sciences domain	• Unidirectional only (from technology to the life sciences domain area, but no details for other players such as software vendors) • No solutions provided
National Health Information Network	[Pu09, Na10]	Set of standards, services and policies that enable secure health information exchange	• Focus on underlying concept of information exchange • Capabilities of digital solutions are out of scope
Connected Health Reference Architecture	[Co18]	RA for improving clinical care protocols.	• Technology-specific for electronic health data
Pharma Industrial Internet Reference Architecture	[Ke16]	RA for a 5G infrastructure	• Technology-specific and pharma manufacturing only
IT Reference Architecture for Healthcare by Atos	[IT11]	Description of a digital hospital based on Enterprise Architecture	• High-level framework
Healthcare Reference Architecture for Mobile Access by Aerohive Networks	[He12]	Static model to support the access of mobile solutions	• Technology-specific for mobile access • Not considering healthcare processes

Tab. 1: Existing pharma, healthcare and life sciences standards

As shown in Table 1, most of the RAs provide very specific technology solutions. However, this does not allow for a seamless, holistic approach for the ecosystem as a whole. The various solutions would need to be integrated into different processes specific to each organization adopting them and its context. Although the majority of the

RAs are built upon common standards, they are not vendor neutral. Looking back to the rise of ERP systems in Europe and the emergence of only one major player, one should be very careful about building solutions dependent on a vendor's architectures. Indeed, many customers became dissatisfied with the business models of ERP vendors – i.e. lock in customers by providing only basic customization for enterprise-wide processes and a low degree of interoperability. This led to unwieldly integration with other systems. In general, a highly interoperable solution would be preferred in order to maintain the power on the side of the adopting organizations (rather than on the side of the vendor). Furthermore, most of the existing architectures do not consider the pharma, healthcare and life sciences supply chain as a whole. In our previous work on an RA for digitalization in the pharmaceutical industry [CSS17] we presented an integrated view on potential digital solutions that can be used to support business capabilities. Such an integrated view becomes even more important as agencies such as Centers for Disease Control and Prevention (CDC) in the United States and the European Medicines Agency (EMA) in the European Union are promoting an integrated, multi-disciplinary, multi-sector view, named "One Health". To fully realize the potential of this concept, it is not enough to focus on specific players – instead, the supply chain needs to be analyzed from a holistic perspective.

To fill the lack of coherent standards – what one may call a standards interoperability gap - we construct a holistic view of the pharma, healthcare and life sciences domain from a digital technology architectural perspective. Focusing the resulting RA on this specific domain allows for the development of a more concrete solution that can be readily used by actors of the domain who are trying to create value based on digital technologies [BSC17]. Our motivation is to create an RA that encompasses all areas of pharma, healthcare and life sciences – detailing them into subdomains, uncovering relations between them, mapping the business capabilities to the domains, illustrating which applications (software solutions) cover these capabilities, and highlighting which technologies enable these applications. Since many connections between areas (and their capabilities) exist, the applications that cover these capabilities are connected as well (in an ideal case by an interface).

3 Concept development

The values exchanged by actors in the pharma, healthcare and life sciences ecosystem are drugs and medical devices that come along with various requirements and regulations. Companies operating in this ecosystem rely on a highly specialized and sophisticated internal structure for a sustainable management of their activities. Therefore, the logic of the RA for this industry has to describe the internal structure as well as a classification of the values, defined as therapeutic segments. The internal structure is composed of two parts – the industry-specific domain (in our case the pharma-specific domain) and the general domain. The former comprises functions that are highly specialized based on the nature of the industry, and the latter describes

functions that are performed in a similar way across industries. Therefore, the basic structure of the RA contains three parts – the general domain, the pharma-specific domain, and the therapeutic segments. In this paper, we focus on explaining the highly specialized components of the RA – the pharma-specific domain and the therapeutic segments. The resulting RA structure is depicted in Figure 1 and described in detail below.

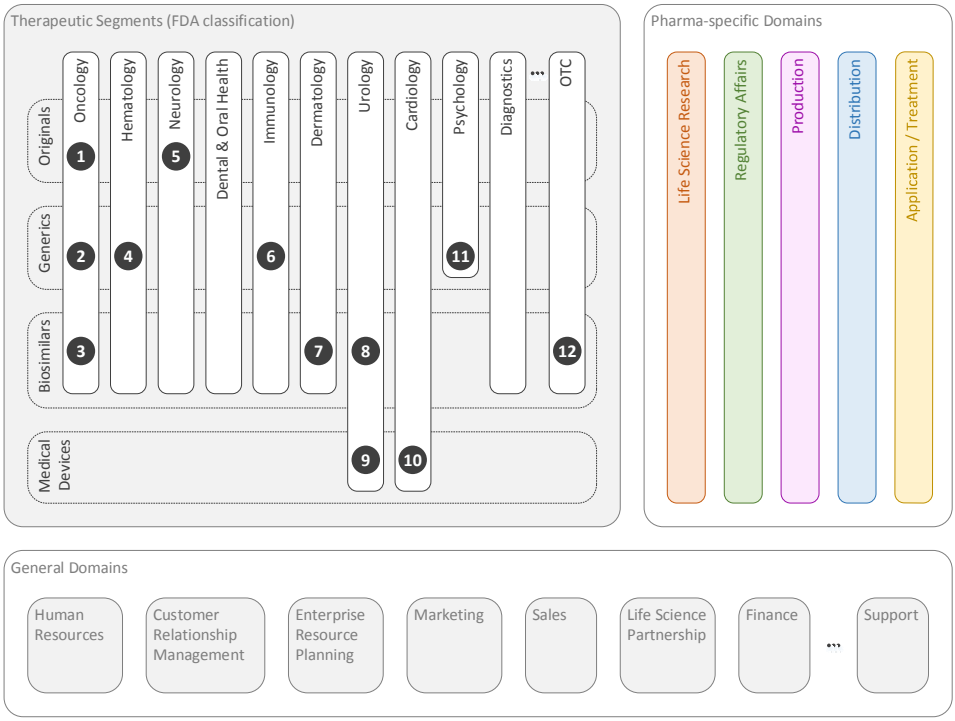

Fig. 1: The structure of the pharma RA

The top right section of Figure 1 shows the pharma-specific domain. It describes the functions of Life-Sciences Research (also called R&D, or Research and Development), Regulatory Affairs (laws and regulations specific to the industry), Production (drug or device manufacturing), Distribution (logistics and wholesale) and Application/Treatment (use of drugs or devices in hospitals, clinics, nursing homes, home care, and pharmacies). These functions differ significantly from other industries in terms of capabilities, requirements and processes. For example, in 2017, the European Commission revised their legislation regarding significant technological and scientific progress to increase both the safety and the level of health for its citizens [Re18]. Regulatory agencies – such as the Food and Drug Administration (FDA) in the United States or the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) in Germany - enforce laws and regulations

related to all steps of the pharma supply chain. Consequently, the Regulatory Affairs function in pharma companies needs to ensure that relevant legislation is incorporated in an enterprise's architecture - for example, in the quality management activities of laboratories or manufacturing facilities. The pharma-specific functions are also strongly correlated - for example, the Life Sciences Research function correlates strongly with Regulatory Affairs, as drug research and development requires significant regulatory oversight. The Distribution function is highly regulated as well - for example, companies need to monitor conditions and prove that they have complied with requirements during storage and transportation of the drugs, as in cold chain logistics. A detailed explanation of the pharma-specific domains and its layers is provided in section 4.

The top left of Figure 1 shows the therapeutic segments model. It can describe a complete list of drugs or devices as solutions for a patient's treatment. The RA classifies these solutions according to their treatment area (vertical slices such as oncology, hematology, etc.) and solution type (horizontal slices describing the type of drug or device). First, the treatment area is aligned to the therapeutic areas for drugs that are approved by regulatory agencies such as the FDA [FD18]. This allows for a standard and comprehensive classification of relevant solutions. Second, there are multiple solutions (or treatments) for each therapeutic area, denoted as four horizontal slices: Originals, Generics, and Biosimilars (for drug-based solutions) and Medical Devices.

4 Applying the concept

In the preceding section, we introduced the fundamental concepts of the RA by describing a first level of abstraction and showing a high-level view of the RA for one major actor – the pharma industry. In this section, we describe concrete solutions and show how they are applied to the corresponding RA elements.

4.1 Therapeutic segments

The therapeutic segments model includes the disease areas and the corresponding solutions that are provided by the pharma actor to its environment. Drug-based solutions include originals, generics, and biosimilars. Originals are drugs that have been developed first and are subject to a patent by the company that developed them (usually for 20 years in many countries). When patents expire, generics and biosimilars can be developed as copies of the original drug by other companies. Generics describe drugs with less than 500 molecules, while biosimilars consist of more than 500 molecules. Although the generics and biosimilars do not need to go through the whole approval process compared to the original medication, companies need to prove biosimilarity for biosimilar drugs (by providing evidence of highly similar structure and function as well as results from animal and clinical studies testing the biosimilar's effects) and quality by design (focusing on, among others, the active ingredient(s), correctness and consistency of the manufacturing process, safety of the design, etc.) for generics. However, due to

the shortened regulatory process, these drugs receive a competitive edge regarding the development costs. In addition, these types of drugs differ in their effect, as generics are less complicated and they work more precisely than biosimilars.

Mobile devices such as heart pacemakers are another separate treatment option. With the increasing role of medical devices for the treatment of patients, their characteristics are getting closer to those of regulated drugs, and they are increasingly incorporated in legislations by regulatory bodies such as the FDA or the European Commission. Therefore, the medical devices category is included in our RA as another solution type.

To illustrate how solutions fit in each therapeutic segment, twelve examples of solutions of various types (denoted by numbers on the therapeutic segments grid in Figure 1) are listed in Table 2 in the Appendix as concrete solution objects. For example, the therapeutic segment (vertical slice) of oncology includes three illustrative examples of drug-based solutions (denoted by the active substance followed by the respective tradename in brackets): 1 - Bevacizumab (Avastin), 2 - Gemcitabin (Gemzar), and 3 - Rituximab (MabThera). Avastin is an original medication used to treat a number of cancers, while Gemzar and MabThera are examples of drugs with generic and biosimilar copies, respectively. As Roche's Avastin patent is set to expire in 2019 in the US and a few years later in Europe, competitors such as Amgen are trying to copy its structure and create biosimilars that have the same treatment effects on patients.

4.2 Pharma-specific domains

To further define the structure of the RA, it is important to note that organizations use different layers of architectures to describe their business in a comprehensive way. This RA makes use of the layering convention from TOGAF, a commonly accepted architectural framework for the design, planning, implementation, and maintenance of enterprise architectures. The pharma-specific domain in Figure 1 can be further described with TOGAF layers which define the business capabilities, the structure of data assets, the applications used, as well as the underlying technological environment. Subsequently, specific capabilities (e.g. software solutions) with regard to the function and layer can be assigned to the grid. Given this layering convention, the RA ensures that for each pharma-specific function, the requirements - such as new legislation for safety and quality - will be incorporated not only in the business architecture, but also in the underlying architectures for data, applications and technologies used. Note that the pharma-specific layers (horizontal slices) are independent from the therapeutic segments solution slices (horizontal slices).

Figure 2 provides more details on the different layers for each pharma-specific domain – namely the capabilities, the data and the applications that cover these capabilities, and the technologies that are backing the applications. For example, data collected during the research and development process or clinical trials supports the pharma intelligence capability (including clinical trials management, regulatory affairs management, and

marketing screening) and applications such as the *Informa Pharma Intelligence Platform* or *MaxisIT CTRenaissance*. Supporting technologies include a variety of on-premises or cloud databases such as *Veeva R&D Cloud*.

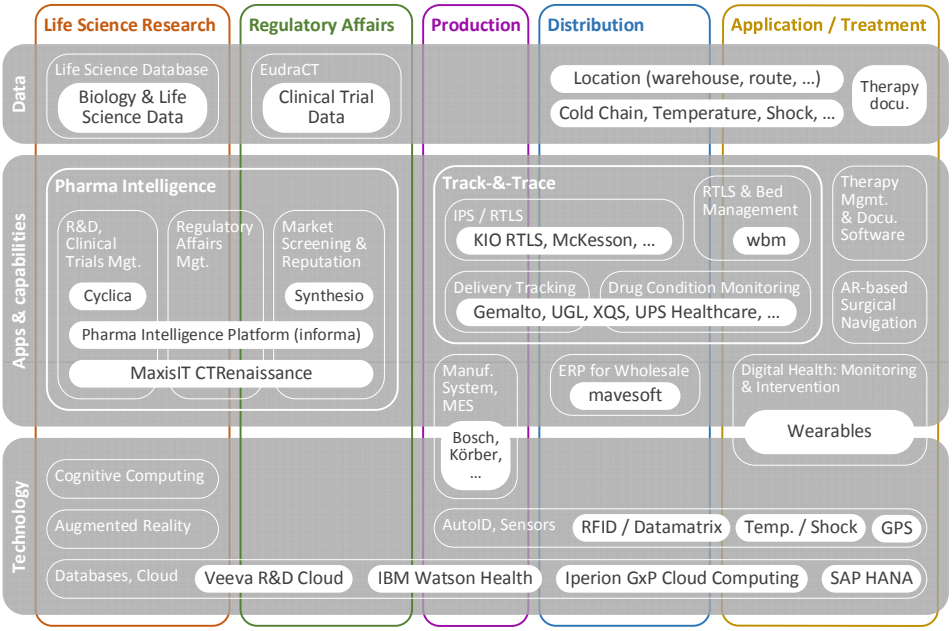

Fig. 2: General pharma capabilities map

Augmented Reality (AR) is increasingly becoming important in surgery. AR's potential in this area was pinpointed in early 2000's [Sh04], but the technology has only recently started to reach its promises: integrating a variety of data (including preoperative imaging such as MRIs or real-time imaging) into AR applications that support and enhance surgical processes through better, more complete, and even real-time visualization of the surgical site. In addition, AR can be combined with Cognitive Computing technologies to develop real-time insights from pattern analysis of the visualizations. For example, the recently-developed AR-based surgical navigation integrates real-time surface images and X-rays to create 3D views that help surgeons perform image-guided open and minimally-invasive spine surgery [Ph17]. Minimally-invasive surgery – which is only possible with adequate imaging - minimizes the extent of incisions which in turn speeds up the patient's healing process, freeing beds in hospitals (because of shorter hospital stays) and creating direct value for healthcare providers.

Cognitive computing technologies – sometimes combined with AR as well – can offer significant benefits to R&D processes. For example, providers such as *Cyclica* are using cognitive computing technologies to analyze how drugs under development interact with

the proteins in a patient's body and what effects may occur as a result of these interactions. The company offers a platform for the creation of drugs that supports teams and individual users (for different aspects of the R&D process), incorporates analytics in the form of predictive modelling of successful molecular structures, and allows for real-time manipulation of the models to reveal optimal structures for a protein's intended activity. Thus, the system can suggest not just potential uses for the drugs but also potential harmful effects – well in advance of expensive clinical trials [En18].

Another very interesting capability for pharma, healthcare and life sciences companies is understanding their market reputation. Technologies like those provided by *Synthesio* enable "social listening" by tracking the social media sentiment in key markets and demographics and monitoring brand satisfaction to spot business opportunities. The company provides automated sentiment analysis to identify positive, negative and high-priority conversations for a brand's individual products and services [So18].

The RA developed in this paper helps companies describe a whole functional area of the pharma domain with regard to its existing digital solutions. As an example, let us consider the distribution. Drug distribution is the process where the internal created value (the drug) is transmitted to a healthcare stakeholder (e.g. a pharmacy or hospital). The distribution process of a drug is highly regulated, because drug quality is very much dependent of how processing, transportation and delivery take place. For example, a constant temperature needs to be maintained in order to preserve quality during the transportation. The distributor is taking on a vital role between the drug manufacturer and the healthcare provider – and it needs to abide by the existing regulations in order to ensure the safety of the drug distribution process.

The distribution vertical slice in Figure 2 describes this process from the serialization and labeling to the final monitoring of a drug. With a digital technology solution, drugs coming from the production line are labeled with an auto generated ID (a serial number), encoded using an RFID chip or a simpler optical label (such as Datamatrix). Electronic tags such as RFID (and the supporting tag reading infrastructure) are now capable of tracking the drug during the distribution process using pre-defined stations (for example, at the manufacturer's transportation dock, in the transportation truck, at the distributor's receiving dock, etc.). The condition of the drugs (temperature, humidity, movement, etc.) as well as their location can be recorded and the relevant data can be stored in the cloud. In case of any non-conformance, all the drugs that trigger an alert regarding inconsistencies in the data or the process can be investigated further. The RA describes the related capabilities (Track and Trace), data (location, temperature / cold chain characteristics, shock, etc.), applications (*XQS*, *Gemalto*, etc.), and technologies (RFID, Datamatrix, various sensors, GPS systems, etc.). From a cross-functional perspective, the Distribution process provides relevant insights for other functions, such as Regulatory Affairs and identifies the relevant point of actions, such as Good Distribution Practices (GDP). Furthermore, relevant data can be evaluated retrospectively and analyses can be conducted by various patient segments. This might create valuable insights for targeting activities in the Life Science Research function to specific patient problems. Therefore,

our RA is capable of describing concrete, end-to-end digital technology solutions that are relevant for various actors in the healthcare system. Each actor can set up priorities and requirements with regard to digital technologies, and use the RA to develop a custom solution for their situation.

A benefit of our RA is that it can describe an entire value chain composed of different industries such as pharma, healthcare, life sciences and related support industries such as logistics based on a common framework – the TOGAF layers. To take advantage of business synergies across different organizations in different industries, describing different industry perspectives is necessary [CSS17]. From an organizational point of view, the vertical slices represent a static description of elements that organizations require for value creation. For example, the distribution function is required to transport the drugs developed by one organization to the respective stakeholders. It is the definition of vertical slices in our RA that is helping to capture different industry perspectives. This allows us to describe individual participants in the context of the value chain as a whole, by extending the vertical slices with the vertical slices of partner industries. The vertical slices can overlap with other industries when values are exchanged. Consequently, by connecting different industries with digital technology will provide a cross-industry perspective. Figure 2 presents the extension of the dimensions elaborated in [CSS17]. In addition, describing the vertical slices with regard to the interrelated digital technologies allows software vendors to recognize synergies across industries. This can be exemplified with the data layer: the inter-industry connection makes the data exchange of applications - and therefore the underlying interactions and integrations of applications across industries - visible [CSS17].

Figure 3 presents a specific example of the capabilities map for the oncology area. It should be noted that the solutions covering the capabilities are only examples – many more solutions exist and can be added to the RA in order to use it in practice. We are only providing representative solutions in this paper in order to illustrate the solution categories. Capabilities include plant design and optimization (for the production function), tracking and tracing (for production and distribution), and treatment planning and documentation. Because different solutions cover different oncology sub-segments, such as surgical oncology, radiation oncology, medical oncology, immune oncology, and so on, the applications and technologies will be sub-segment specific. Tools such *J-MED* or *megaMANAGER* are covering requirements calculation of optimal therapy plans and therapy documentation in medical oncology. *Varian* software and hardware are focused on radiation treatment and thus cover the capabilities in radiation oncology. Software for preparation of cytotoxic drugs is used in conjunction with special equipment such as gravimetric and volumetric measurement devices and cytotoxic isolators. In addition to these applications, oncology-specific Life Science Research software platforms also exist. Examples are *ThermoFischer's Oncomine Platform* (a bioinformatics discovery platform for cancer researchers), *PDS Life Sciences' Ascentos* software suite (for managing and analyzing data from preclinical research laboratories and monitoring good laboratory practices (GLP)), and *Exploristics* (which offers cloud-based data analysis solutions for pharma and healthcare companies).

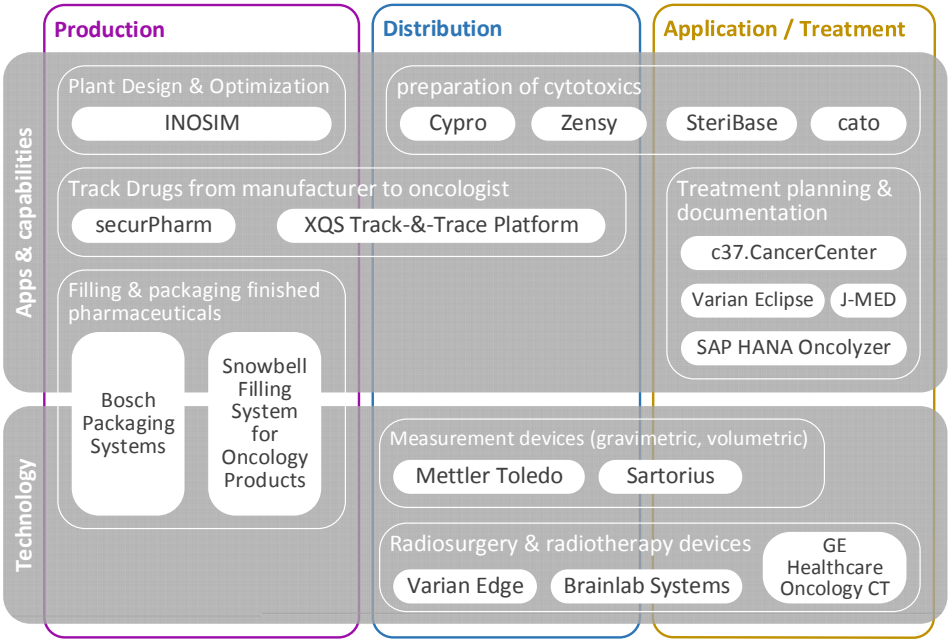

Fig. 3: Oncology capabilities map

5 Conclusions and outlook

The rapid pace of technology development today indicates a huge potential for the improvement of our society in all areas, including healthcare systems. Companies and governmental institutions in many countries are actively promoting these developments, hoping for widespread benefits. As a consequence, enhancing the healthcare system with digital technologies is becoming a fundamental value enabler. To derive the full value of digital technologies, however, a holistic view of the healthcare system - and its interacting parts - is needed. This paper addresses this need by developing a reference architecture for all actors of the healthcare system that shows them where digital solutions exist and how they can be related to the actors' capabilities. The RA is characterized by three components – therapeutic segments, pharma-specific functions, and generic functions. In addition, the RA is characterized by horizontal slices - following the widespread TOGAF framework layers - to support a seamless view from capability to technology. In this paper, we describe the holistic RA and give examples of how the architecture can be used in general. We also provided an exemplary model for the oncology sector – one of the largest pharma markets.

The most compelling benefit of this RA is that it structures three interdependent areas - pharma, life sciences, and healthcare - into one integrated enterprise architecture which

includes a consistent way of classifying capabilities, related applications that cover these capabilities, the data processed by these applications, and the technologies backing the applications. This is especially important for today's organizations, which have to manage flexible, rapidly changing IT architectures. As software release cycles are getting shorter, there is a need for a holistic view on how software applications interact with each other. Such a view can help identify the impacts of particular applications on the value chain as a whole in an effective, efficient, and consistent way. Therefore, another benefit of our RA would be to create heat maps of the impacts [BS16]. Furthermore, architects or companies that are new to the industry can use the information embedded in the RA to better understand the complexity of the industry and achieve greater productivity in a shorter period of time [Su16]. In addition, the RA enables actors in a value chain to share a common language when designing solutions that are beyond one functional area [Su16]. Using our RA as a knowledge base, the participants across a value chain are able to create values based on a common reference. These statements are especially important if one considers the strategic goals of governmental institutions such as the European Union and their objective of unifying the healthcare market based on digital solutions. In our opinion, access to the healthcare market should not be limited by industry entry barriers and to existing players who already have this holistic view as an internal knowledge asset. Our RA can be a knowledge base to any company or individual interested in how the digital assets and the participants in the healthcare value chain interact. This allows new entrants to succeed.

One limitation of this paper is that it only provides representative solutions. There are many therapeutic segments – all with their own characteristics, requirements, processes and hence with their own solutions. Covering all of them is not possible in the space allotted for this paper; however, the existing framework can be used to develop models for each one of these segments, resulting in a final complete RA. We aim to build models for additional areas in future research. Another limitation of the RA presented in this paper is that the interfaces among applications and the types of data exchanged are not specified. Future work will describe the connections between applications, which will be detailed through interface models. An additional limitation of the paper is that we do not detail processes in the RA. In future releases of this RA we will introduce a process-oriented view showing the processes that are performed by applications, the artifacts generated as a result, and how they will used by other applications in the process steps that follow. Based on an initial evaluation, a possible way to achieve this is by using the cognitive map of the HERA model [He18]. For example, the HERA model builds upon plan, build, and run cycles. By extending our model with the healthcare specific cycles of the HERA model, we could create a new view on our model that is encompassing a process perspective.

Ultimately, we hope that the RA presented in this paper will prove to be a useful reference tool for companies interested in evaluating the value of digital technologies, their alignment with business models, or the impacts of regulations or other legal requirements in light of these digital technologies.

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Appendix

We present in Table 2 twelve examples of solutions for the therapeutic segments mentioned in Figure 1. The table includes the example number, the drug-based solution name (the substance) or the medical device name, and the official trade name (in parentheses, if applicable), and the type of solution.

Example	Representative (Object)	Type
1	Bevacizumab (Avastin)	Original
2	Gemcitabin (Gemzar)	Generic
3	Rituximab (MabThera)	Biosimilar
4	Fondaparinux (Arixtra)	Generic
5	Almotriptan (Malate)	Original
6	Ceftibuten (Cedax)	Generic
7	LaViv (Azficel-T)	Biosimilar
8	Sipuleucel-T (Provenge)	Biosimilar
9	Urodynamic Systems	Medical Device
10	Cardiac Pacemaker	Medical Device
11	Adderall XR	Generic
12	Flublok (seasonal influenza vaccine)	Biosimilar

Tab. 2: Examples of solutions for different therapeutic segments (also see Figure 1)