

MASTER'S THESIS

The role of Enterprise Architecture in the strategic planning process An exploratory study in the preclinical domain

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Award date:
2023

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The role of Enterprise Architecture in the strategic planning process

An exploratory study in the preclinical domain



Opleiding: Open Universiteit, faculteit Betawetenschappen
Masteropleiding Business Process Management & IT

Degree programme: Open University of the Netherlands, Faculty Science
Master of Science Business Process Management & IT

Course: IM0602 BPMIT Graduation Assignment Preparation
IM9806 Business Process Management and IT Graduation Assignment

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Date: 07 February 2023

Thesis supervisor: Dr. ir. Karel Lemmen

Assessor: Drs. Pien Walraven

Version number: 1.0

Status: Definitive

Abstract

Research and development of new drugs is a very challenging job in a highly changing environment where digital transformations are crucial to stay an innovative company. It is critical that all departments' business processes and IT align on that strategy. However, it can be a lengthy process to align IT with Business goals if it is not happening on a strategic level. This research is investigating what EA artefacts that exist in literature are used in the preclinical area that can attribute to the strategic planning process. Findings show that from the 17 EA artefacts that Grave, van de Wetering, and Kusters (2021a, 2021b) published in literature, almost all of them were traced back, with the exception of guidelines & principles that aid in the decision making part of the strategic planning process. We see that both IT and Business stakeholders confirm that certain artefacts from the adjusting/creating strategy part of the strategic planning process are combined into one document, and both the business case and roadmap are considered as the most important ones, and other EA artefacts are considered as derivatives. This opens the question to research further on the effectiveness of EA artefacts.

Key terms

EA artefacts; digital transformation; strategic planning process

Summary

When a pharmaceutical company is directing a strategy to transform into a digital, innovative company it is critical that all departments' business processes and IT align on that strategy, if not business will die in the next 10 years if they are unable to transform themselves in light of new technologies (Ross, 2015). EA describes an organization from an integrated IT and business perspective in EA artefacts which can be used to bridge the gap between IT and Business (Kotusev, 2018, 2019).

Therefore, we want to know *“When researching an EA model supporting strategic planning in a preclinical context: what are the findings regarding the applicability of the model?”*. To research this, we first conducted an extensive Critical Literature Review. From literature we know that 17 EA artefacts can contribute to the strategic planning process of an enterprise (Grave et al., 2021a, 2021b). So, the research question evolved to ***“Can Enterprise Architecture Artefacts contribute to the strategic planning process in a preclinical context?”***.

We developed 3 theorems from the article where Grave et al. (2021a, 2021b) identified 17 EA artefacts that contribute to the strategic planning process.

Theorem 1: When a preclinical research department senses a disruption or encounters new challenges, we expect to find EA artifacts evidence of **1)** a SWOT analysis and **2)** a Technology and skills forecast model that describe the surveillance, technology, and business watch which sensed the disruption or new challenges.

Theorem 2: When a preclinical research department is creating or adjusting their strategy, we expect to find EA artifacts evidence of **3)** a business function development plan, **4)** an operating model, **5)** a high-level operational concept, **6)** an impact and risk assessment, **7)** a strategic plan to transform, **8)** a business case that describe the EA impact and simulations practice process.

Theorem 3: When the preclinical research department is undergoing a transformation, we expect to find EA artifacts evidence of **9)** a conceptual data model, **10)** an enterprise portfolio, **11)** a governance structure, **12)** principles and guidelines, **13)** a roadmap, **14)** a security and privacy plan, **15)** services and products overview, **16)** a stakeholder communication plan, **17)** and technology standards that describe the decision-making facilitation EA practice process.

A single case study was conducted in a pharmaceutical company within the preclinical department. The presence and use of EA artefacts was researched in a real-life setting. We interviewed 9 people, both from IT and Business high and lower level. Prior to the interviews an online survey was conducted to validate the conceptual model and confirm the problem statement.

We found evidence of all artefacts except for the guidelines and principles artefact that can support in the decision-making process. This artefact was very limited evidenced. What is striking is that both IT and Business stakeholder consider the business case and roadmap as the most important EA artefacts, and the other EA artefacts related to the creating/adjusting strategy part are more seen as 'derivatives of'. This opens the door to research in a follow up study the effectiveness of EA artefacts. As the preclinical area senses that IT and Business are not enough connected, they moved to the concept of High Performing Teams, which are part of strategic meetings, and where departments, such as the preclinical department, are considered as the product. Describing the human objectives is a new artefact that within the preclinical department is considered as extremely important during strategy setting for transformational initiatives. This needs more investigation as well.

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Glossary

Concept	Definition
AIM	Accelerated Implementation Methodology: flexible, but business-disciplined framework for managing organizational changes, including transformational change, through to full Return on Investment. It's an integrated system of operationalized principles, strategies, tactics, measurement analytics and tools
ATLAS.ti	computer program that helps with the analysis of, among other things qualitative research data. Coding is one of the core functionalities of ATLAS.ti and helps with data organization and data analysis
Digital Transformation	process where digital technologies create disruptions that triggers the need for strategic responses from organizations
Enterprise Architecture	methodology that describes an organization from an integrated IT and business perspective where according to a specific EA framework an enterprise is described as its current state, future state, and the migration roadmap
EA artefacts	documents that describe an organization from an integrated business and IT perspective in its current, transition or future state
EA framework	logical structure to classify, organize, manage, and communicate EA
EMA	European Medicines Agency
FDA	US based Food and Drug Administration
HPT	High Performing Teams: concept within organizational development that refers to teams, in this case IT teams, that are highly focused on their goals and achieve superior business results
Preclinical Research	part of drug development process that investigates the safety before to proceed to first in human tests
Strategic planning	organizational management process to 'deliberative, discipline efforts to produce fundamental decisions and actions that shape and guide what an organization is, what it does and why

1. Introduction

1.1. Background

Discovering and developing drugs has come a long way: during the 19th century isolating natural medicinal plant compounds were used. During the post war period this provided the pharmaceutical industry with a 'golden age' of productivity driven by random screening of synthetic molecules called 'molecular roulette'. Later, drug receptor target knowledge became crucial, and this led to an increased industrialization in biopharmaceuticals in the 1980s and 1990s which could be seen as the start of the biotechnology era where new technologies emerged such as for example the high throughput screening assays (Hopkins, Martin, Nightingale, Kraft, & Mahdi, 2007).

This resulted in innovation in various new biotech-based techniques where Information Systems (IS) play a big role. As described by Korhonen and Halén (2017) companies need to be able to adapt quickly to the change that new technologies and innovations bring to a company. This requires adaptive capabilities and dynamic skills.

When a pharmaceutical company is directing a strategy to transform into a digital, innovative company it is critical that all departments' business processes and IT align on that strategy. The extent to which strategic decision-makers are supported with pertinent and high-quality information and advice about an organization's current and planned business systems at the right time contribute to this goal (Tamm, Seddon, Shanks, Reynolds, & Frampton, 2015).

Strategic planning is an organizational management activity to set the priorities of an enterprise. It defines what an organization is, what it does and why and when in the (near) future it wants to achieve these goals (Bryson, 2018).

Therefore, strategic planning is of uttermost importance if a company wants to stay abreast as according to Cisco CEO John Chambers, 40% of business will die in the next 10 years if they are unable to transform themselves in light of new technologies (Ross, 2015).

1.2. Exploration of the topic

Strategic planning can be described as an organizational management process to deliberate, discipline effort to produce fundamental decisions and actions that shape and guide what an organization is, what it does and why (Bryson, 2018) and sets out its priorities (Azevedo, Ferreira Pires, Almeida, & Van Sinderen, 2015). This strategic planning will positively influence an organization's performance and creates coherence in the ability to adapt to the internal and external environmental challenges (Al-Shammari & Hussein, 2007; Bryson, 2018; Miller & Cardinal, 1994).

Digital transformation signifies the transformational implication of digital technologies for business: think about the creation of new business models, new types of products/services made possible through digitization. (Nambisan, Wright, & Feldman, 2019). (Vial, 2019) describes digital transformation as a "process where digital technologies create disruptions that triggers the need for strategic responses from organizations." These strategic responses will affect the enterprise as a

whole as it will have downstream implications on the products and services that the enterprise delivers and especially how they are delivered inside the organization (Azevedo et al., 2015). Therefore, digital transformation is an example of an internal and even external environmental challenge that should be incorporated into the strategic planning of an enterprise.

Enterprise Architecture (EA) aims to have the complete enterprise aligned and integrated. EA describes an organization from an integrated IT and business perspective where according to a specific EA framework an enterprise is described as its current state, future state, and the migration roadmap (Kotusev, 2018, 2019). EA is an approach to provide insight and generates overview to manage the complexity of an enterprise and to aid strategic decision making (Blomqvist, Halen, & Helenius, 2015). A lot of EA frameworks exist such as the Zachman or TOGAF-framework. EA practices, in the strategic planning phase of Enterprise Architecture Management (EAM), such as EA analysis and/or documentation play an important part to ensure the development of the EA for the future and business/IT alignment (Ahleman, Stettiner, Messerschmidt, & Legner, 2012). The various EA artifacts with different stakeholders, their use, complex interrelationships, and life cycles together actually form a description of the EA.

1.3. Problem statement

The need for a proper drug development strategy is crucial to avoid uncertainties and complete preclinical work in time with quality data. Every newly discovered drug has its unique pathway to reach the market. Many factors vary from product to product, such as type of product, the category it belongs to, disease prevalence, study design, regulatory pathway, phases of trials need to conduct.

The large amount of (new) IT systems, new types of digital data (AI derived data, digital pathology, etc.), and processes involved in the preclinical area is enormous and expanding every day together with the involvement of new regulatory demands from U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA).

EA frameworks can seem quite rigid as traditionally it is focused on process standardization and integration instead of continuous adaptation to the changing business and technological landscape (Korhonen & Halén, 2017). These EA frameworks give little insight in what EA information is critical for strategic planning. Little is known about EA best practices, how well they fit strategic goals, what the challenges are and how stakeholders act in successful EA practice of the day-to-day business (Azevedo et al., 2015; Kotusev, 2019; van de Wetering, Kurnia, & Kotusev, 2020). There is research conducted to close the gap between EA and strategy planning, but little empirical evidence has been published (Blomqvist et al., 2015; Kotusev, 2019).

Having and using the right information on time is crucial for the process of strategic planning for (digital) transformation within preclinical research. With this study, we want to gain insight in the gap between EA and a (digital) transformation strategy planning process and want to add to the empirical evidence.

1.4. Research objective and questions

This study responds to the question if EA is connected to strategic planning of digital transformation. We want to investigate based on the theoretical findings therefore “Can EA help in the strategic planning process?”

For this we will investigate following:

Literature questions:

1. *What is Enterprise architecture?*
2. *What is a strategic planning process?*
3. *What are current strategic planning models?*
4. *How can EA support the strategic planning process and are there any models available to give substance to this?*
5. *What theories exist selecting a purposeful stakeholder sample?*

Empirical research question:

6. *When researching an EA model supporting strategic planning in a preclinical context: what are the findings regarding the applicability of the model?*
7. *Which stakeholders are of relevance in the case study?*
8. *What are the conclusions of the research conducted and how can this relate to literature?*

1.5. Motivation/relevance

From literature, we see that EA can support the strategic planning process of digital transformation (Azevedo et al., 2015; Blomqvist et al., 2015; Labusch, Aier, & Winter, 2014). However, it is not clear exactly what EA artifacts can contribute to the strategic planning process. This will give the practitioner the necessary insights to plan for strategic transformation and help to adapt more quickly to new digital opportunities.

1.6. Main lines of approach

The research focuses if EA can support the strategic planning process. With a case study approach, we want to find the answer to the research question. A case study has the capacity to generate insights from in-depth research into the study of a phenomenon in its real-life context, leading to empirical descriptions and the development of theory as described by Saunders, Lewis, and Thronhill (2016).

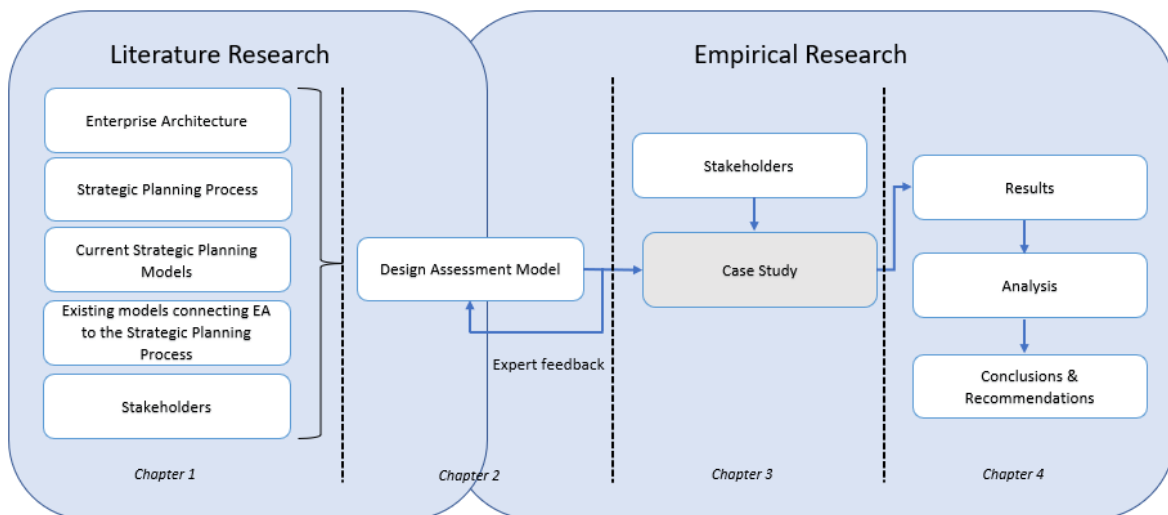


Figure 1 Research Approach

In the first phase of the research model, seen in **figure 1**, literature research is conducted around key questions (Chapter 1). Using this literature, we will design an assessment model in chapter 2. This model will be validated by subject matter experts. The assessment model is the cornerstone for the empirical research done at the case organisation in Chapter 3. After that, results are gathered, and an analysis will lead to conclusions and recommendations.

2. Theoretical framework

2.1. Research approach

The literature research was executed to find answers within scientific grounded literature to start from a common understanding, to place the main research question in context and to find evidence of the literature research questions. As described in (Saunders et al., 2016), the critical literature review (**figure 2**) should be a critical analysis that shows a clear argument what the current literature published knows and not knows about the research question related to the problem statement and provide answers.



Figure 2 The critical literature review process (Saunders et al., 2016)

2.1.1. Search Terms

To find the relevant literature we translated the literature questions in combination with the main research model (*figure 1*) to find suitable search terms (*figure 3*). By using specific search terminology and relate the literature questions to the parts of the main research model, we want to increase the relevance of the literature research result.

Literature Question	Search Terminology
A1	Enterprise Architecture
A2	Strategic planning process
A3	Strategic planning process model
A4	Enterprise Architecture & strategic planning
A5	Purposeful Stakeholder sample/analysis

Figure 3 Search terms in relation to literature question

2.1.2. Critical Literature Review

Using the search terms and the procedure described in *figure 4* resulted in 111 articles (full list of references can be found in *Appendix 1*) as highlighted in *table 1*.

From this longlist an assessment was done by using criteria as described in 2.2.2 which ultimately resulted in a short list of 15 articles that will be used to work further with.

1. Search engine used: Google Scholar – For reproduction purposes and transparency google scholar is used as this search engine is freely accessible to everyone.
2. Article Language: English – most research related to the subject is written in English and can provide the researcher a good knowledge of the concept which could be different in other languages. Other languages will be excluded.
3. Year of publication >2017 – to have not too many ‘outdated articles’ or >2005 – if not many publications were present
4. Search term in title: to make a narrower search, this filter considers articles where the term is present in the title of the article
5. Search term in article: see this filter makes a first selection of articles by content based on the presence of the term in the article text
6. Review article: yes/no – as there are a lot of publications for EA, I decided to focus on review articles only
7. Number of citations : number of citations of a publication gives an rating for the quality of the publication ((LUMC), 2014).
8. Criteria: the results of the literature search were assessed for the content. Even though the article appears in the list, it could be the case that it is not relevant for the research question. When articles refer to other relevant articles, these are added to the selected list of publication after they have been assessed on the content (snowball method)
9. Critical Literature Overview: combining a good search methodology, using the right search terms, filtering, and assessing the results should ensure a relevant set of articles that is suitable for this thesis. The final selection of the articles forms the critical literature review based on which conclusions and recommendations can be make.

Figure 4: procedure for literature review

2.1.3. Processing

Transparency for reproduction is important to see whether sufficient and correct data is available for the selected set of literature. Saunders et al. (2016) list bibliographic details that are relevant. For all articles used, the search URL is stored in Google Scholar as well in **table 1** the URL is present.

2.2. Implementation

2.2.1. Search Process for Literature Review Longlist in Google Scholar

question	Search terminology	search terms in article/title	Date of publication	Review articles	Date of search	Number of results	Search URL	Comments
A1	Enterprise Architecture	Title	>2017	no	1-4-2022	2000	link	
		Title	>2017	yes	1-4-2022	73	link	
A2	Strategic planning	Exact phrase	>2017	no	1-4-2022	4410	link	
	Strategic planning - management	exact phrase – with all the words	>2017	no	1-4-2022	378	link	
	Strategic planning – management process	exact phrase – with all the words	>2017	no	1-4-2022	20	link	
A3	Strategic planning process model							See remark A3
A4	strategic planning & enterprise architecture	Allintitle	>2005	no	1-4-2022	13	link	
A5	Purposeful Stakeholder sample/analysis	With all the words – exact phrase	>2017	no	1-4-2022	5	link	See remark A5

Table 1: Overview search criteria and number of results with link to search URL that results in the long list of 111 articles derived from the CLR in table 1

Remark question A3: During the search it became clear that there were not that many relevant articles in google scholar that provided models for strategic planning from 2017 on.

Considering earlier years gave a lot of articles, however, we want to have the more 'recent thinking' in relation to some established proved thinking. For strategic planning and strategic planning models, it was decided to use the book of (David, 2007) as well.

Remark question A5: For purposeful sampling, we will use as well the literature handed by the thesis tutor around this topic (Mitchell, Agle, & Wood, 1997).

2.2.2. Assessment of search results: from longlist to shortlist

From this total of 111 articles, **a selection to come to a shortlist was made by using the following set of criteria**

- Excluding irrelevant articles after analysis of title
- Excluding irrelevant articles or articles that were not in English after analysis of the abstract, introduction and conclusions
- Articles are part of top 5 cited articles
- Exclusion of article if no full version was found

This resulted in a total of 15 articles which will be used to answer the questions. The selection of these articles can be found in **figure 5**. For full reference, please find in **Appendix 1** per search question a table that shows which all articles indicated with left out/kept in using the criteria described above. The selected articles contribute to answering the theoretical research questions. The other ones are less relevant to the research.

Enterprise Architecture		
<i>Authors</i>	<i>Title</i>	<i>Number of citations</i>
DD Dang, S Pekkola	Systematic literature review on enterprise architecture in the public sector	98
Gampfer, Fabian; Jürgens, Andreas; Müller, Markus; Buchkremer, Rüdiger;	Past, current and future trends in enterprise architecture—A view beyond the horizon	75
Zhang, Mengmeng; Chen, Honghui; Luo, Aimin;	A systematic review of business-IT alignment research with enterprise architecture	53
Kotusev, Svyatoslav;	Enterprise architecture: what did we study?	43
Kitsios, Fotis; Kamariotou, Maria;	Business strategy modelling based on enterprise architecture: A state of the art review	40
Strategic planning process		
Rentes, Victor Cattani; de Pádua, Silvia Inês Dallavalle; Coelho, Eduardo Barbosa; Cintra, Monica Akissue de Camargo Teixeira; Ilana, Gabriela Gimenez Faustino; Rozenfeld, Henrique;	Implementation of a strategic planning process oriented towards promoting business process management (BPM) at a clinical research centre (CRC)	13
Asobee, Marc Salama;	Exploring the importance of strategic thinking to strategic planning in the strategic management process	4
David, F.R.	Strategic Management: Concepts and cases 13 th e.d.	See remark
EA & strategic planning		
Bernard, Scott;	Using enterprise architecture to integrate strategic, business, and technology planning	51
Azevedo, Carlos LB; Sinderen, Marten van; Pires, Luís Ferreira; Almeida, João Paulo A;	Aligning enterprise architecture with strategic planning	19
Blomqvist, Sixten; Halén, Marco; Helenius, Mika;	Connecting enterprise architecture with strategic planning processes: Case study of a large nordic finance organization	17
Riku, Marianus Omba; Setyohadi, Djoko Budiyanto;	Strategic plan with enterprise architecture planning for applying information system at PT. Bestonindo Central Lestari	15
Vaniya, Nilesh; Bernus, Peter;	Strategic planning to build transformational preparedness: an application of enterprise architecture practice	4
Grave, Frank; van de Wetering, Rogier; Kusters, RJ;	Enterprise architecture artifacts facilitating digital transformations' strategic planning process	3
Stakeholder Enterprise Architecture		
Kurnia, Sherah; Kotusev, Svyatoslav; Shanks, Graeme; Dilnutt, Rod; Milton, Simon;	Stakeholder engagement in enterprise architecture practice: What inhibitors are there?	7

Figure 5: End Result of the critical literature research

2.3. Results and conclusions from Literature Review

In the section below you will find an analysis of the literature articles.

2.3.1. Literature question 1: What is Enterprise Architecture?

According to (Dang & Pekkola, 2017) there is no globally accepted definition for Enterprise Architecture as the term refers to an approach or a methodology that holistically describes an organization's structures, business environments, and information systems, and can therefore facilitate the integration of strategy, personnel, business, data, and IT. This approach describes the current situation of the organization, conceptualize its future vision, and provide a transition plan for how to reach the future vision" as stated by Dang and Pekkola (2017).

One of the most well-known frameworks are the TOGAF framework and the Zachman Framework. These frameworks consider "EA as a discipline that manages the fundamentals of an enterprise which is embodied in its components i.e., Business architecture, Application Architecture, Data Architecture and Technology Architecture (which is considered as the 'narrow view')." According to Gampfer, Jürgens, Müller, and Buchkremer (2018) EA relies as well on various architecture subdomains such as Information Systems (IS) and Information Technology (IT) (which is considered the 'extended view') and therefore one of the biggest goals of EA is to integrate the various domains on which it depends, this is seen in **figure 6**.

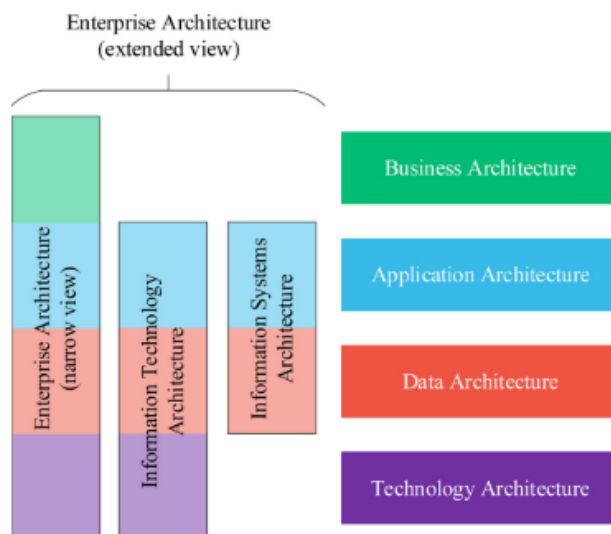


Figure 6 : Extended and narrow view of EA according to Gampfer et al. (2018). Narrow view described the 4 EA layers, the extended view shows the various subdomains that EA relates to. It shows that EA is grounded in Business and IT architecture and thus can provide an integrated view of the whole enterprise.

2.3.2. Literature question 2 & 3: What is a strategic planning process and what are current models?

Strategic planning is developed in the 1950s when organizations realized the need to “plan for success”. Strategic planning can be described as an organizational management process to ‘deliberative, discipline efforts to produce fundamental decisions and actions that shape and guide what an organization is, what it does and why (Bryson, 2018). (Azevedo et al., 2015) explains the prescription theory where there is a clear distinction between the design of the plan and the implementation. In the design part, the strategy is completely defined that fits the enterprise best. After this design phase and poured into strategy goals, when and how and communicated to the enterprise, the defined plan is implemented. Further in this article we discover the most used strategic planning model which is the Goal-Based or also called Vision-based model. This model starts with the enterprise mission, vision, and its planned goals. The organization needs to describe which operations are needed to fulfil the goals, what required capabilities are needed. Also, the strategic planning is separately performed into different departments as well into different levels of the organization.

More often, this key concept is even more generalized by the strategic planning process model described by Blomqvist et al. (2015) and is divided in simply three phases or pillars: strategy formulation, strategy implementation and strategy evaluation (Blomqvist et al., 2015; David, 2007; Simon, Fischbach, & Schoder, 2013) where each phase consists of certain subphases as seen in **figure 7**:



Figure 7: The strategic planning process model (Blomqvist et al., 2015) which shows the 3 pillars for strategy planning: first a formulation of the strategy phase, then the strategy needs to be implemented and the strategy needs to be evaluated as well. Each of these pillars consists of several subphases.

2.3.3. Literature Question 4: How can EA support the strategic planning process and are there any models available to give substance to this?

Simon et al. (2013) describes possible EA application scenarios mapped to strategic management stages which can be seen in **figure 8**.

Stage of strategic management	EA application scenario	
Strategy formation	Strategic analyses	
	Strategic choice	
	Business execution design	Business transformation readiness assessment
Strategy programming/implementation	Strategy implementation planning	
	Strategy review	
Strategy evaluation/control	Strategic governance	

Figure 8 EA application scenarios mapped to stages of strategic management according to Simon et al (2013). The figure shows where EA possibly can contribute to the stage of strategic planning.

Simon et al. (2013) describe in their article that EA takes a facilitating role in strategic management.

The facilitating role of EA is especially true in the formulation phase and the implementation phase as it breaks down the strategy into business models, processes, and organizational structures.

Grave et al. (2021a) make the link between EA artefacts and strategic planning as “EA artefacts are documents that describe an organization from an integrated business and IT perspective in it’s current, transition or future state” (Grave et al., 2021a). In their article they describe 15 artefact that facilitate the digital transformation (DT) strategic planning process. DT is the umbrella term for the changes that organizations go through which are driven using digital technologies and should be incorporated into the strategic process of organizations because the ability to use DTs in achieving an organizational vision assures a competitive advantage (Vial, 2019). The 15 artifacts can be seen in **figure 9**. This table describes what the EA artefact is about and what the purpose is in an organization.

EA artefact	What is it?	Why is it needed?	Based upon article
Technology & skills forecast	Serves as input for SWOT-analysis	Facilitates reduction of dependence on legacy systems and technologies	(Grave et al., 2021a)
Swot analysis	Provides strengths, weaknesses and opportunities that form the foundation of the strategic plan	determines internal and external factors where enterprise should focus on	(Grave et al., 2021a)
Strategic plan	mission, vision, and goals of organization	Serves as an input for the operational and business development plan	(Grave et al., 2021a)
High-level operational concept	One-page picture with high-level view of processes, data, and technologies	Serves to plan implementation of new solutions and their integration in current environment	(Grave et al., 2021a)
Business function development plan	Structured view of all organization business capabilities on a single page	Facilitate alignment of strategic business goals with priorities for IT	(Grave et al., 2021a)
Operating Model	To determine the necessary level of business process integration and standardization for delivering goods and services	Provides a more actionable view of the company than strategy	(Grave et al., 2021a)
Enterprise portfolio	Provides information about the architecture as a whole including relationships between components	Aims to align developments	(Grave et al., 2021a)
Conceptual data model	Provides the main data entities	Aims to achieve better global data consistency and uniformed handling of information in all IT systems	(Grave et al., 2021a)
Principles and guidelines	High-level global guidelines for decision making in planning in an organization and IT-specific implementation prescriptions	Facilitates reuse of proven best practices and reduces general technical complexity of the IT landscape	(Grave et al., 2021a)
Security and privacy plan	Plan that contains physical data, personnel and operational security elements and procedure	Provides information of the security program throughout the enterprise	(Grave et al., 2021a)
Stakeholder communication plan	Plan that elaborates the 'what, when, how, and by whom' relating communicating	Aims to foster effective communication to the right stakeholders at the right time	(Grave et al., 2021a)
Technology standards list	List of all technologies used in an organization	Aims to reduce complexity of IT landscape	(Grave et al., 2021a)
Impact and risk assessment	Artefact that assesses current EA to identify changes that should be made to initial EA	Identifies new facts that can invalidate existing aspects of architecture	(Grave et al., 2021a)
Governance structure document	Describes decision rights and accountabilities to encourage desired behavior	Aims to be transparent on whom is responsible for what	(Grave et al., 2021a)
Services and products overview	Map of lifecycle of services and or products of the organization	Allows enterprise to see where vertical and horizontal crosscutting are located and helps to define ownership of those processes	(Grave et al., 2021a)
Business Case	Justification for an initiative, supported by data, such as a cost benefit	Determines what, why. Sort of 1-pager for funding, stakeholder convention	(Grave et al., 2021b)
Roadmap	Visual plan containing deliverables and when to deliver	Serves to have overall project milestones in 1 place with deliverable dates	(Grave et al., 2021b)

Figure 9 shows the 15 EA artefact identified by Grave et al. (2021a) that facilitate the strategic planning process. 2 Artefacts are added based upon (Grave et al., 2021b) ending up with a total of 17 artefacts

As this article is very interesting, we noticed a follow up article published in July of that year of (Grave et al., 2021b). After discussion with the thesis tutor, we decided to incorporate this into our Literature research. This article (Grave et al., 2021b) dives deeper into the strategic planning process and maps the EA artefacts and their EA practice process or EA routines as it is called in this article to the strategic planning process as seen in **figure 10**. This figure shows the three pillars of the strategic planning process (in this case for DT), the EA routines that belong to the pillar of strategic planning and then the EA artefacts as has been detailed out in table 3 are mapped to the EA routines and Strategy planning process. Upon reading, it is notable that 2 new artifacts were added. These 2 artefacts, business case and a roadmap, where initially not included but research in 4 case organizations led to the incorporation of these EA artifacts as all 4 case organizations used it.

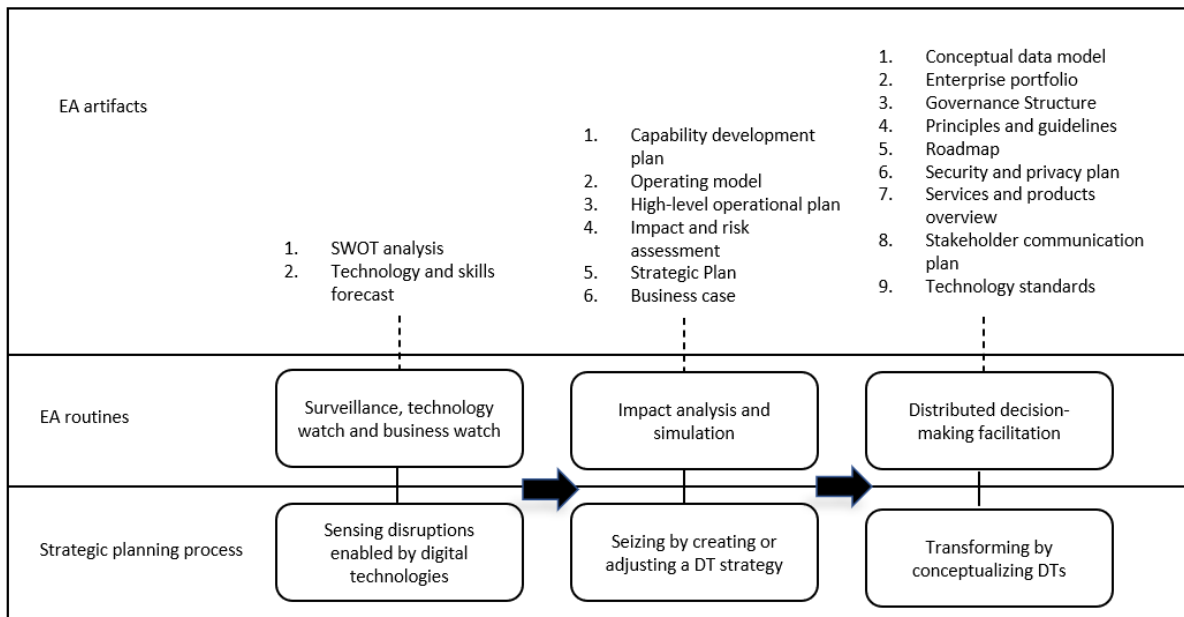


Figure 10: EA practice processes/routines related to the EA artifacts they produce per strategic planning process phase according to (Grave et al., 2021a)

2.3.4. Literature Question 5: What theories exist selecting a purposeful stakeholder sample?

What is very important in the research is to have a purposeful sample. According to (Mitchell et al., 1997) purposeful stakeholders need to have a combination of three critical attributes: power, legitimacy and urgency. There are 7 stakeholder types, which can be seen in **figure 11** below. This model is known as the ‘Saliency model’ and divides stakeholders amongst three categories or aspects.

Looking at **figure 11** one can see that the first aspect ‘Power’ describes the power that a stakeholder contains to influence the organization, project, or program. The second aspect ‘Legitimacy’ describes the legitimacy that a stakeholder must act, and the third aspect describes the ‘Urgency’ that a stakeholder can exert when carrying out actions. These aspects represent 8 types of stakeholders. Stakeholders that represent all three aspects are considered high priority stakeholders, when stakeholders represent two aspects then they are considered as medium priority stakeholders and when representing only one aspect they are considered as low priority stakeholder. Evidently, having no aspects then these stakeholders are considered as non-stakeholders (Mitchell et al., 1997).

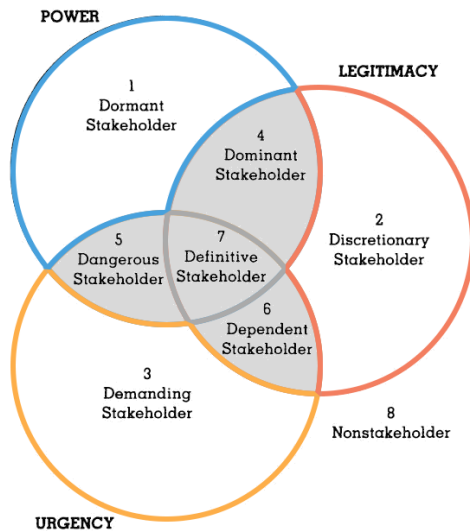


Figure 11 shows 7 typologies of stakeholders. According to Mitchell et al. (1997) one or more of three relationship attributes are needed to have a good stakeholder representation that can attribute to the case studies.

Saunders et al. (2016) also explicitly explains the importance of defining the research population clearly as the “sample selected should be related to the population highlighted in the research question”. Therefore, having a representative purposeful sample for conducting the research is critical. According to (Kurnia, Kotusev, Shanks, Dilnutt, & Milton, 2021), EA Artifacts can be placed in the middle and are surrounded by different stakeholder groups using them. All EA stakeholders can be grouped according to their specialization into Business and IT stakeholders and separated into two organizational levels i.e., Higher-level stakeholders (such as corporate or division level) and lower-level stakeholders (such as department or project level) as seen in **figure 12**.

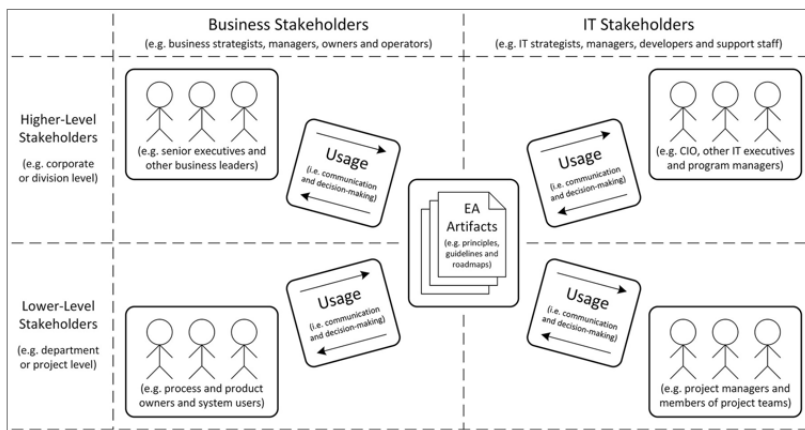


Figure 12: EA Stakeholder overview of the different functional areas and the organizational structures surrounding EA Artifacts.

2.4. Conclusion literature review

Insights from literature show that EA is a methodology that can provide the organization an integrated view of its business process evolution, application architecture, data architecture and IT technology-stack landscape. It is a mean to combine strategy with business goals between those four layers to come from a current state to a future state and remain competitive. It is documented in EA artifacts.

Strategic planning is of uttermost importance to an enterprise as it “plans for success”. There are several strategic planning models of which the ‘Goal-Based model’ is most widely used. This model consists of 3 major pillars - strategy formulation, strategy implementation and strategy evaluation. Each phase consists of certain subphases that are key pillars of the strategic planning (explained in *figure 7*).

From literature, it is shown that EA mainly contributes to the formulation of the strategy and the implementation since it can be used as an intermediate or a tool to break down the strategy into business models, processes, and organizational structures. Most of the current EA frameworks lack a true strategy planning perspective or the EA modelling language should be extended with it.

The model from (Grave et al., 2021a) relates Strategic planning and EA practice processes to the EA artifacts they produce. *Figure 1* highlights the criteria that will be used to conduct research in the domain of preclinical research with regards to the strategic planning process and will contribute to answering the research question.

Based on the findings in literature, we can sharpen our research question as formulated in **section 1.4.1** “When researching an EA model supporting strategic planning in a preclinical context: what are the findings regarding the applicability of the model?” into

“Can Enterprise Architecture Artefacts contribute to the strategic planning process in a preclinical context?”

Based on the EA artefacts evidence we can answer the research question. This leads to the conceptual model as seen in *figure 13*.

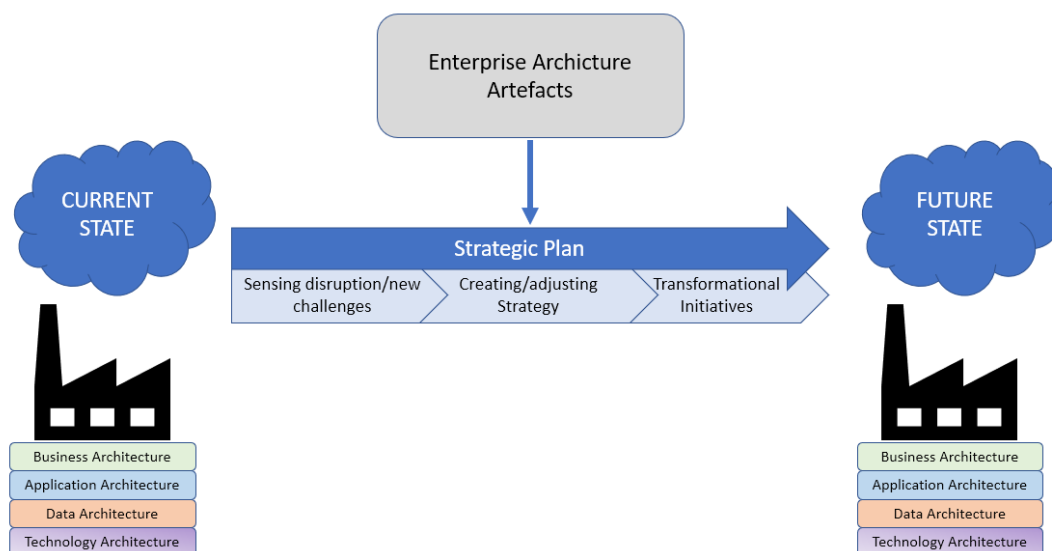


Figure 13 Conceptual model for EA Artefacts supporting the strategic planning process.

As seen in the conceptual model in **figure 13**, a strategic plan will bring an enterprise from a current state to a future state. The enterprise is captured in EA artefacts describing the business, application, data, and the technology architecture. The strategic plan consists of 3 phases where it starts with sensing disruption or new challenges. Next a strategy creation or adjustment to react and give direction to the new challenges will take place while in the final strategic planning phase, the transformation will happen according to the (adjusted) strategy. Therefore, it is evidenced from literature that EA artefacts have the potential to contribute to the strategic planning phases. In this research, we will seek evidence from the EA artifacts described by (Grave et al., 2021a, 2021b) in a preclinical pharmaceutical context.

From the conceptual model (**figure 13**) and from the EA practice processes/EA artifacts model (seen in **figure 10**) by Grave et al. (2021a); (Grave et al., 2021b) we can derive **3 theorems** which are based upon literature and will be the foundation for our research within the preclinical pharmaceutical development context.

Theorem 1:

When a preclinical research department senses a disruption or encounters new challenges, we expect to find EA artifacts evidence of

- 1) a SWOT (Strength, Weakness, Opportunity, and Threat) analysis
- 2) a Technology and skills forecast model

that describe the surveillance, technology, and business watch which sensed the disruption or new challenges.

Theorem 2:

When a preclinical research department is creating or adjusting their strategy, we expect to find EA artifacts evidence of

- 3) a business function development plan,
- 4) an operating model,
- 5) a high-level operational concept,
- 6) an impact and risk assessment
- 7) a strategic plan to transform
- 8) a business case

that describe the EA impact and simulations practice process.

Theorem 3:

When the preclinical research department is undergoing a transformation, we expect to find EA artifacts evidence of

- 9) a conceptual data model,
- 10) an enterprise portfolio,
- 11) a governance structure,
- 12) principles and guidelines,
- 13) a roadmap
- 14) a security and privacy plan,
- 15) services and products overview,
- 16) a stakeholder communication plan
- 17) and technology standards

that describe the decision-making facilitation EA practice process.

2.5. Objective of the follow-up research

Literature shows uncertainty to what strategic phase EA can contribute to and how it exactly correlates to the overall strategic planning process. The comparison of connecting the strategic planning phases with EA is rather limited. Therefore, it is still valuable to investigate empirically if EA can contribute to strategic planning and to what phase it has its most value.

3. Methodology

This chapter will describe the justification for the empirical research. It will start with describing the conceptual design, the technical design, the data analysis and ends with the discussion.

3.1. Conceptual design: select the research method(s)

The empirical research will be conducted in the preclinical research department of a pharmaceutical company. This preclinical department consists of a multitude of subdepartments that researches the safety from a new promising drug and consists of around 700 people. Numerous (digital) transformations are taking place to make the department more efficient and incorporate new ways of working to ensure high-quality and competitiveness of preclinical safety.

In this section there will be two main parts: first, identify relevant stakeholders from the case organisation for gathering empirical data; second, gather the data needed to answer the empirical research questions.

Saunders et al. (2016) describe the different methods for conducting research as seen in **figure 14**, a distinction is made based on deductive vs inductive and quantitative vs qualitative research.

Method	Research Approach	Quantitative/Qualitative
Case study	Inductive/deductive	Qualitative
Experiment	Inductive	Quantitative
Survey	Deductive	Quantitative
Grounded Theory	Inductive	Qualitative
Ethnography	Inductive	Qualitative
Archival and Documentary	Inductive/Deductive	Qualitative
Narrative inquiry	Inductive	Qualitative

Figure 14 – Research Methods according to (Saunders et al., 2016) distinguished deductive from inductive and quantitative from qualitative research.

If research starts with a theory, often derived from a literature review and you use a research strategy to test the theory, this is a **deductive approach**. Controversly, if your strategy starts with collecting data and generate or build a theory on it this is an **inductive approach**.

In this research, we will verify the model from (Grave et al., 2021a) in a preclinical domain and thus start from theory and test that theory in this particular domain and thus we will be using a deductive method which is qualitative in nature. However, during the interviews, we will check if other artefacts are used. Because of time limitation of the empirical research, we will focus on testing the theorems from existing theory. The choice for a qualitative research is based upon the selection of a single case study method to gain a deep understanding of the role of EA on strategy planning in a preclinical context.

This case study will probe in-depth the real-life business topic in an organizational setting where the domain boundaries are not completely clear in its natural environment and gathers information from multiple sources i.e. people or documents (Saunders et al., 2016; Yin, 2003). The case in a case study research may refer to a persons, a group, an organisation, an event as well as many other types of case subject (Saunders et al., 2016). Because the research will focus solely on the organization as

a whole – the preclinical research department, hence we are treating the organisation as a **holistic case study** instead of looking at different departments within the organisation (subdepartments of preclinical research. Department level differentiation would call for an embedded case study instead (Saunders et al., 2016).

Based on the characteristics of the research’s problem domain, it will be classified as an **exploratory case study**: likely to use a deductive approach, using theoretical propositions to test their applicability in the case study, to build and verify an explanation as explained in (Saunders et al., 2016).

For data collection, a primary source of information will be conducting interviews within the case organization. **Figure 15** shows that for an explanatory casestudy a semistructured interview is most appropriate to understand the relationship between the variables (Saunders et al., 2016). Advantage of semi-structured interview is firstly, a guide can be prepared based on the theoretical literature findings and second interviewees have the possibility to explain their answers which can lead to areas that were not defined in the interview guide but could be important for understanding and help answer the research question.

	Exploratory	Descriptive	Explanatory	Evaluative
Structured		xx	x	x
Sem-Structured	x		xx	xx
Unstructured	xx			x

Figure 15 - Uses of different types of interview for each research purpose. Xx= more frequent ; x = less frequent (Saunders et al., 2016)

As a secondary source of data collection is document research by requesting interviewees to provide examples of the artifacts found. This way, we can triangulate answer we got from the interviews. This second data collection method is based on secondary data analysis (i.e., data initially collected for some other purpose) and provides additional knowledge, interpretations or conclusions (Bulmer, Sturgis, & Allum, 2009) and will help create the chain of evidence. Advantage of documents research is that there is no unconscious bias, which can happen when conducting interviews. Documents arise and exist without owners realizing it might be used in research. This way socially desirable behaviour is avoided. With these two data collection methods we can do triangulation: having two independent sources of data will ensure that the data are telling what we think it is telling us. It can be seen as cross-reference checking.

We will use within the semi-structured interview a mixed method design, this will help to validate themes that have emerged from the use of a questionnaire (Saunders et al., 2016). One section of the interview will be composed with some preset answers (yes/no) while the other section will use semi-structured questions to elicit robust responses. To make sure that relevant information can be gathered during the interviews, a stakeholder analysis will be done. Those stakeholders will be mapped to the ranking based on stakeholder typology of Mitchell et al. (1997) as seen in **figure 11** and the EA stakeholder mapping of (Kurnia et al., 2021) .

3.2. Technical design: elaboration of the method

With the semi structured interview technique, a broad context can be given to the interviewees, also we can adjust the interview along the road. New questions may derive, and it offers interviewees the possibility to add their own opinions (derived from respective subject matter expertise). All this supports the qualitative data collection (Saunders et al., 2016). Prior to the interviews, as Enterprise Architecture might not be well known by all stakeholders within the case organisation, a session will be organized to explain what EA is to enhance internal validity.

Finally, authorization to record the interview was asked as well as reaching out after the interview if this was needed to validate or clarify any items. With this agreement, the interviewees had the trust they could speak freely as all data collected falls within this confidentiality agreement.

The interviews will be transcribed with Amberscript (<https://www.amberscript.com>). With Amberscript, audio- and video recordings can be converted to text. These text documents will be revised for semantic correctness and integrity.

3.2.1. Identification of Stakeholders

Based on the EA stakeholder selection by Kurnia et al. (2021) where a distinction is made between business and IT and high and lower level, all relevant stakeholders are then selected and classified using the ranking of Mitchell et al. (1997), which can be seen in **figure 15**. Based upon if a stakeholder is a high-level ranked manager, there is power present but also legitimacy and urgency. If lower level: there is no power but a need for legitimacy and urgency.

Number	Function	Actor - Kotusev and Kurnia (2021)	Ranking - Mitchell et al. (1997)
1	Vice President Preclinical Safety Toxicology	Business Higher-Level Stakeholder	Power- yes Legitimacy- yes Urgency- yes
2	Capability Manager	Business Low-Level Stakeholder	Power- no Legitimacy- yes Urgency- yes
3	IT manager	IT Higher-Level Stakeholder	Power- no Legitimacy- yes Urgency- yes
4	Head of Data Science	IT Higher-Level Stakeholder	Power- yes Legitimacy- yes Urgency- yes
5	IT Project Lead & Application owner	IT Lower-Level Stakeholder	Power- no Legitimacy- yes Urgency- yes
6	Head of Resource & Business Analytics	Business Lower-Level Stakeholder	Power- no Legitimacy- yes Urgency- no

Figure 15: Selection and ranking of stakeholders in the case organization: if a stakeholder is a high-level ranked manager, there is power present but also legitimacy and urgency. If lower level: there is no power but a need for legitimacy and urgency.

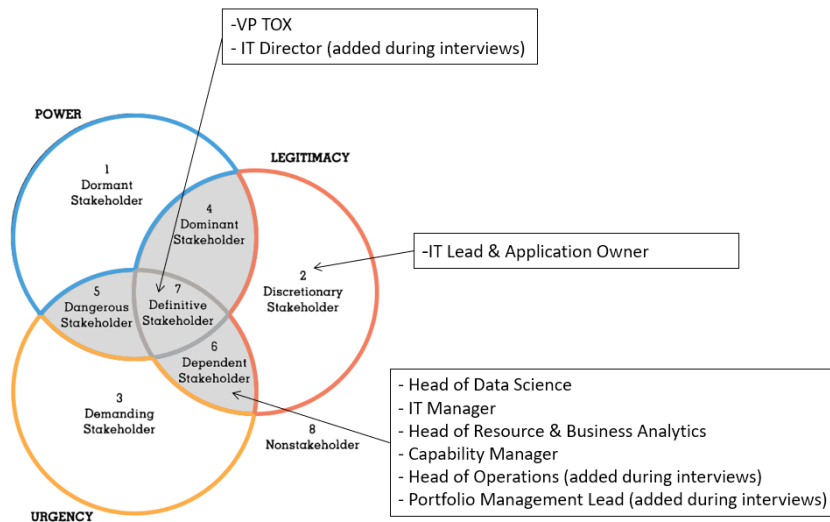


Figure 16 Stakeholder typology mapping of selected functions/roles selected within the case organisation according to (Mitchell et al., 1997)

The list of stakeholders to interview and their EA stakeholders' place according to Kurnia et al. (2021) are listed in **figure 17**.

All stakeholders contain at least 2 attributes based on the typology from Mitchell et al. (1997) and therefore are considered as important stakeholders within the case organisation. Next to that, all 4 groups from the approach of (Kurnia et al., 2021) are covered so that the data from different stakeholders perspectives can be gathered. Based on these 2 selection criteria we have a representative sample that increases the internal and external validity of the research conducted.

Function Title	IT role	Business role	Reason for selection
VP TOX		x	Head of department that lays out strategy
Head of Data Science	x		IT team within preclinical that lays out strategy
IT manager	x		Manager of IT
IT Lead & application owner	x		Application owner
Head of Resource & Business Analytics		x	Bridge between portfolio planning and IT systems within preclinical department
Capability manager		x	Bridge between enterprise IT and business
IT Director	x		Director of IT <i>(added during interviews)</i>
Head of Operations		x	Lead of Operations withing preclinical department <i>(added during interviews)</i>
Portfolio management lead		x	Lead of Portfolio management <i>(added during interviews)</i>

Figure 17: list of stakeholders to interview. Note: during interviews extra stakeholders were added as described in section 4.1

3.2.2. Operationalization of the research goals

As discussed in the conclusion of the literature review, we will use the model the of Grave et al. (2021a, 2021b) within a preclinical context of a pharmaceutical organization to gain more insight into EA artifacts that facilitate strategic planning. The research approach as depicted in **figure 1** shows that Expert Feedback will be asked about the assessment model and shows the operationalization as seen in **figure 18** based on the conceptual model that exists of

- a video around EA to enhance internal validity – creating common understanding of EA, providing **figures 9 and 10**
- an Online Survey to validate the conceptual model and enhancing the internal validity and to gain understanding of the preclinical environment
- Interviews to research the Theorems

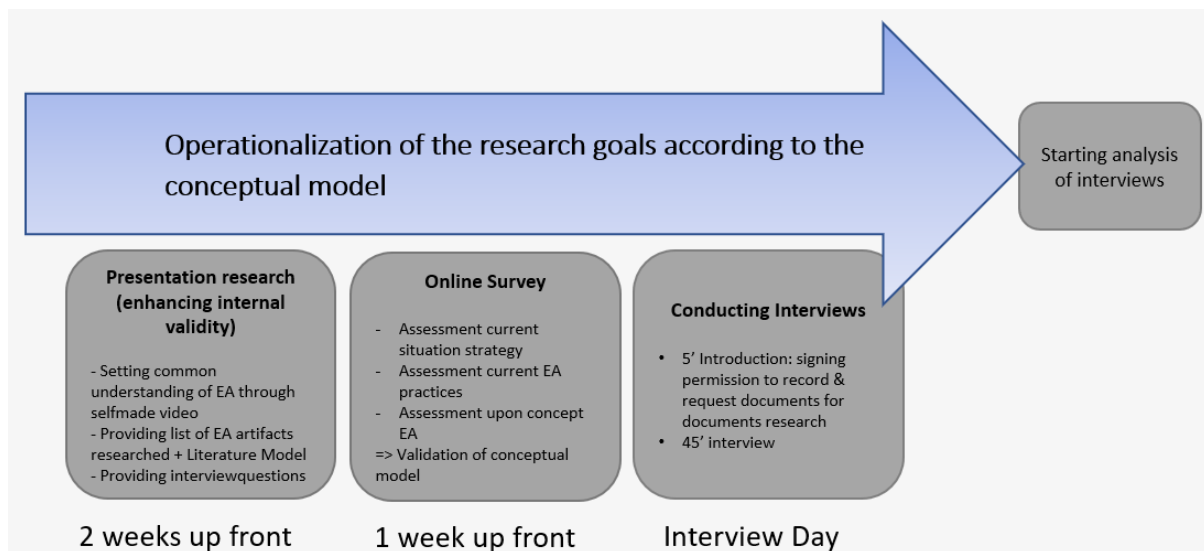


Figure 18: Operationalization of the research goals – practical approach + timing

3.2.3. Identification of artifacts that facilitate strategic planning

(Grave et al., 2021a, 2021b) identified 17 EA artifacts that can be used as a guideline to facilitate strategic planning as discussed in **figure 10** where we see the relationships between EA artifacts, EA practice process/EA routines and the strategic planning process linking all three areas together.

The interview questions are formulated to proof the theorems that are presented in section 2.4. Per EA practice process are several EA artifacts acknowledged as seen in and described by (Grave et al., 2021a, 2021b) that fit a specific strategy planning phase. **Goal of the interviews is to find evidence of these EA artifacts in the preclinical context.**

3.2.4. Expert Validation

Two expert members, Head of Data Science, and the Head of Resource & Business Analytics, within the case organization provided expert feedback. Main remarks are that EA might not be very well known by business members but could be more known to the IT members of the organization. Small adjustments were made to the text to make it more business understandable, but experts agreed with the proposed assessment model.

3.2.5. Backbone of Interview questions

Saunders et al. (2016) describe very well how to conduct a research interview and use the different types of question that exist such as open questions, probing questions, or specific and closed questions but also how to behave during an interview. Based on these guidelines, an interview guide has been developed which can be found in **Appendix 2. The theorems developed need to be 'translated' into interview questions.** In **figure 19**, the relation between the backbone interview questions and the theorems developed from literature are shown.

To have a smoother interview and make it more visual, two documents will be given upfront as seen in **figure 18**: the first one is the list of 17 EA artifacts with a detailed explanation of each artifact as seen in **table 3**, the second is **figure 10** which shows the strategic planning process, the relation to the EA practice process/EA routines and the EA artifacts they produce and their relationships.

Also, a video will be made available about what EA is which will increase the internal validity. An Online Survey will be conducted before the interview to validate the conceptual model and confirm the problem statement as can be seen in **figure 18**. We will also check during the interview if the organization is using artefacts which are not included in the model of (Grave et al., 2021a, 2021b).

# of Theorem	Theorem (based upon section 2.4)	Interview questions to research theorem
1	<p>Based on the EA artifacts defined in the article of (Grave et al., 2021b) that describe the surveillance, technology watch and business watch EA practice process, we expect to find evidence of</p> <ol style="list-style-type: none"> 1. a SWOT analysis and 2. a technology and skills forecast which senses disruption or new challenges 	<ol style="list-style-type: none"> a) How is (DT) transformation triggered in the organisation? b) Is it part of the strategic business plan? c) Is it part of the IT plan? d) Does it go hand in hand, or can it start simply in 1 of the two area's and then flow down? e) What is the timeframe? Small changes opposed to large? f)What exactly is your role in the organization? g)In your role, how familiar are you with EA? h)And EA artifacts? i)Are EA artefacts described in your process? j)Is there a structure/standard available so that for each transformation you have a framework? k) when new challenges arise, how is this sensed in the organization? l)In your opinion, can you relate to the surveillance, technology watch and business watch EA practice process that goes hand in hand with the strategic planning process? m) Do you use a SWOT analysis and forecast for skills and technology as seen in table 7?
2	<p>Based on the EA artifacts defined in the article of (Grave et al., 2021b) that describe the impact analysis and simulations EA practice process, we expect these EA artifacts to facilitate the strategic planning process in a preclinical context . Finding evidence of</p> <ol style="list-style-type: none"> 1. a business function development plan, 2. operating model, 3. high-level operational concept, 4. impact and risk assessment, 5. case a strategic plan 6. a business will facilitate the strategic planning process 	<ol style="list-style-type: none"> a) When looking at creating or adjusting current strategy, can you relate to and explain how you do the impact analysis and simulate EA practice process? b) Are you using any of the following EA artifact and what is the most relevant in your opinion? business function development plan, operating model, high-level operational concept, impact and risk assessment, business case, a strategic plan. c) Are you missing items?
3	<p>Based on the EA artifacts defined in the article of (Grave et al., 2021b) that describe the distributed decision making facilitation EA practice process, we expect these EA artifacts to facilitate the strategic planning process in a preclinical context . Finding evidence of</p> <ol style="list-style-type: none"> 1. a conceptual data model, 2. enterprise portfolio, 3. governance structure, 4. principles and guidelines, 5. roadmap 6. security and privacy plan, 7. services and products overview, 8. stakeholder communication plan and 9. technology standards will facilitate the strategic 	<ol style="list-style-type: none"> a) When looking at the actual transformation, can you relate to it as the distributed decision-making facilitation EA practice process? b) Do you make use of the following EA artifacts? conceptual data model, enterprise portfolio, governance structure, principles and guidelines, security and privacy plan, services and products overview, stakeholder communication plan and technology standards? c) Are you missing items?

Figure 19 backbone of interview questions related to the theorems

3.3. Data analysis & Coding

In qualitative research, meanings are derived mainly from words and images and not numbers. Since words and images may have multiple meanings and interpretation dependant, it is necessary to handle with care. The quality of qualitative research depends on the interaction between data collection and data analysis to allow meanings to be explored and clarified (Saunders et al., 2016). Data obtained is a non-standardized set requiring classification into categories.

Thematic analysis is a generic approach for the analysis of qualitative data. It involves coding the data to identify themes or patterns for further investigation related to the research question. It's a logic and orderly approach that starts with becoming familiar with your data, code the data, search for themes and recognize relations, refine themes and test the propositions (Saunders et al., 2016). In our deductive approach, the themes will be linked to existing theory - being the model of Grave et al. (2021b). As we are looking to see which of the 17 artefacts exist in the case organisation, it means that the semi-structured quantitative interviews already have "categories" and "codes".

For this the recordings of the semi structured interviews will be converted to text document using Amberscript. Once converted, it will be coded by using another software, ATLAST.TI which helps to analyse qualitative research data. Coding is one of the core functionalities of ATLAST.TI and helps to organise the date and to analyse the data.

3.3.1. Document Analysis

As a secondary data source, we will look for document research. However, we need to keep in mind that these documents are considered 'secondary' because they were created for a different purpose and therefore were not originally created for a research purpose. Because of this, great care needs to be taken into assessing the quality of the documents to overcome threats to reliability and validity. Also, as these documents were created for a different purpose, we need to consider that the data can give a distorted picture of reality (Saunders et al., 2016).

3.4. Reflection w.r.t. validity, reliability, and ethical aspects

As case study research is based on the need to understand a real-life phenomenon in a rich contextual setting (Saunders et al., 2016) it is essential to make sure the research was done with the correct quality. For improving the quality of our research, we followed the guidelines of Riege (2003) and Yin (2003).

3.4.1. Construct validity

To maximize construct validity thus that our questions measure the constructs we intended to measure we used multiple sources of evidence e.g., several key persons and document research, and second, we established a chain of evidence in our data collection phase i.e., use of interview notes and transcripts during the interviews which allowed us to have sufficient citations and cross checks sources of evidence. To validate our research model, we also gathered expert feedback on our assessment model as seen in **figure 1**.

3.4.2. Internal Validity

For maximizing our internal validity i.e. that our research demonstrates a causal relationship between variables, we made sure that 1) we assure internal coherence by cross-checking our results by several key persons and in document research (triangulation of the findings of the interviews) and 2) we interviewed several key persons with a different background/function, 3) we made sure to

have a self-made video that explains what EA is so interviewees can put the questions of the interview in context and 4) assess the current situation, EA practices and concept of EA in the online survey that should be filled before conducting the actual interview.

3.4.3. External Validity

External validity is the extent to which research results from a particular study can be generalized to all relevant contexts (Saunders et al., 2016). As this is a single case study, generalization is rather limited, however theory can help support the external validity. Our literature research in chapter 2 supports our findings of other relevant settings different than a preclinical context. Also conducting a stakeholder analysis based on proven theory from (Mitchell et al., 1997) will increase external validity.

3.4.4. Reliability

For maximizing reliability and thus the extent to which data collection techniques will give consistent findings we made sure that we 1) have a semi-structured interview protocol, 2) record the interviews, and 3) reduced respondent bias by interviewing multiple key persons. Also, we need to be aware of the interviewer bias that can exist.

Finally, authorization to record the interview was asked as well as reaching out after the interview if this was needed to validate or clarify any items. With this agreement, the interviewees had the trust they could speak freely as all data collected falls within this confidentiality agreement.

3.4.5. Ethics

Research ethics is extremely important and refers to the standards of behaviour that guides the research in relation to the rights of those who become the subject of the research or are affected by it. Therefore, we will take great consideration for the following aspects:

- Voluntary nature of participation and right to withdraw
- Responsibility in the analysis of data and reporting of findings
- Shared data and information will be used solely for research purposes
- Integrity and objectivity of the researcher
- No compensation to obtain research data
- Ensuring confidentiality of data and anonymity of those taking part

4. Results

4.1. Implementation of the empirical research

Figure 20 shows schematically the implementation of the empirical research. In this chapter we will explain the different steps of the research conducted. Results will be discussed and compared to literature.

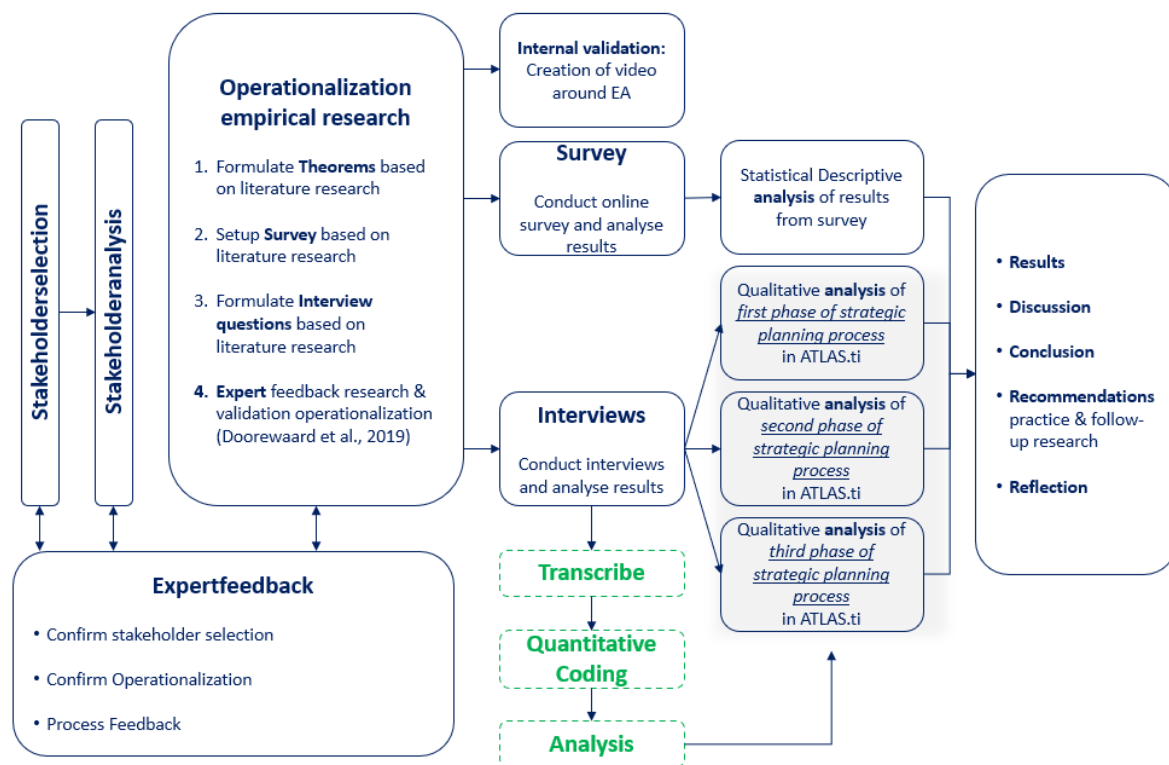


Figure 20 Empirical research methodology

Before interviews were conducted, another Expert on EA Artefacts and Strategy was consulted during a meeting. Frank Grave, PhD Candidate went over the conceptual model and discussed the interview questions. Small additions were done, but no questions were altered.

Respondents got informed about the research approach upfront: an email was sent as seen in **Appendix 3** with a self-made video around EA, explanation of thesis research, the list of artefacts with their explanation, the link to the online survey and additional articles.

Interviews were conducted either face to face in Dutch or when the interviewee was US based, the interview was held in English and Microsoft Teams was used while having a camera on. All interviews were digitally recorded and transcribed using Amberscript. Transcripts were checked and corrected if needed. Transcripts were uploaded in ATLAS.ti and can be found in **Appendix 4**. Transcripts for verification were sent to the interviewees. None of them had remarks.

Within the transcripts, excerpts were marked with a code per category and topic as described in section 3.3. All coded results per topic per respondent were assembled. Due to the nature of the theorems, researching if certain EA artefacts can be found within the case organization, gives a yes/no answer, it was decided to use quantitative coding (Dingemanse, 2021, 26 oktober). By using

the semi-structured interview methodology, we could gather more insight into why a certain artefact was or was not used as seen in **Appendix 4**.

During the interviews, the Vice President of Toxicology advised extra stakeholders, which after analysis, were fit to interview as well. This included the new appointed IT Director of Preclinical which is considered as a Definitive stakeholder while the Portfolio Manager and Head of Operations were considered as Dependent stakeholders. All three of them do take part in strategy setting.

The online survey was built in Microsoft Forms and can be found in **Appendix 5**. Results were exported into excel and the BI visualization tool Tableau was used to create visuals.

4.2. Results

First, we will discuss the Online Survey where results were gathered using Microsoft Forms and exported to Microsoft Excel and Tableau software was used as a BI Tool to create visuals. Next, we will discuss the results gathered from the interviews where we used Microsoft Excel to create visuals. A full table of the results can be found in **Appendix 5**.

4.2.1. Results: Validation of the conceptual model

Our main research question is ***“Can Enterprise Architecture Artefacts contribute to the strategic planning process in a preclinical context?”***.

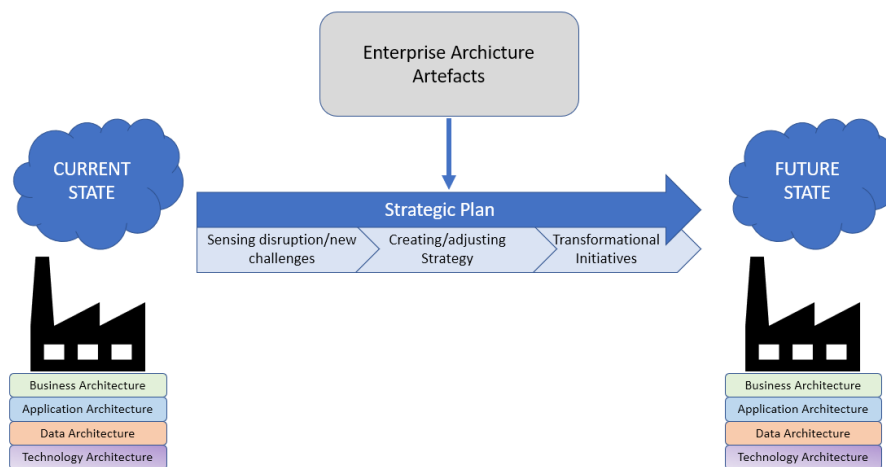


Figure 21 Conceptual model for EA Artefacts supporting the strategic planning process.

The Online Survey was used to validate the conceptual model: it researches if there is a clear **strategic plan** present as this is the foundation for the research conducted as well if **EA is known** within the organization and to **confirm the problem statement**.

The online survey will provide more background to the environment where the research was conducted and increases the internal validity of the research.

Results in **figure 22** shows first an overall results view of both IT and Business. It seems that overall, there is a clear mission and vision formulated for all interviewees and their role in that strategy is

clear. When looking into detail to the two different stakeholder groups, it is remarkable that within IT their role in this strategy is less clear than opposed to the Business.

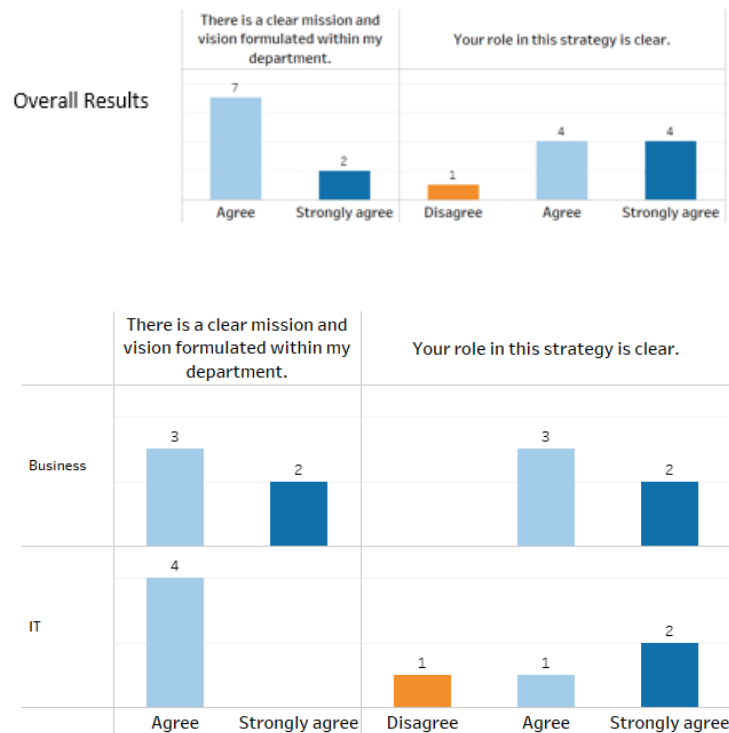


Figure 22 Results of presence of strategic plan and role in strategic plan. First figure shows overall results, second figure is detailed to IT and Business stakeholders' level.

Second part of the conceptual model is that EA can help strategic planning. In the online survey we assessed the **familiarity with EA and the current presence of EA** in the case organization.

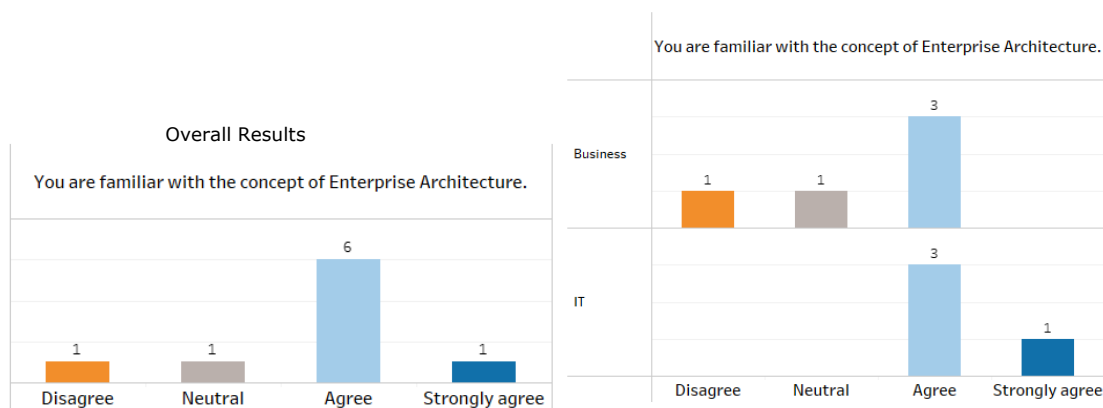


Figure 23 Results of presence of strategic plan and role in strategic plan. First figure shows overall results, second figure is detailed to IT and Business stakeholders' level.

From **figure 23** we can see clearly that EA is known to the case organization and looking at the stakeholder level detail we can see that IT there is more familiar with EA than the Business.

The online survey is also looking into more detail **how EA is handled within the case organization** and shows one part of the problem statement: having all EA layers present.

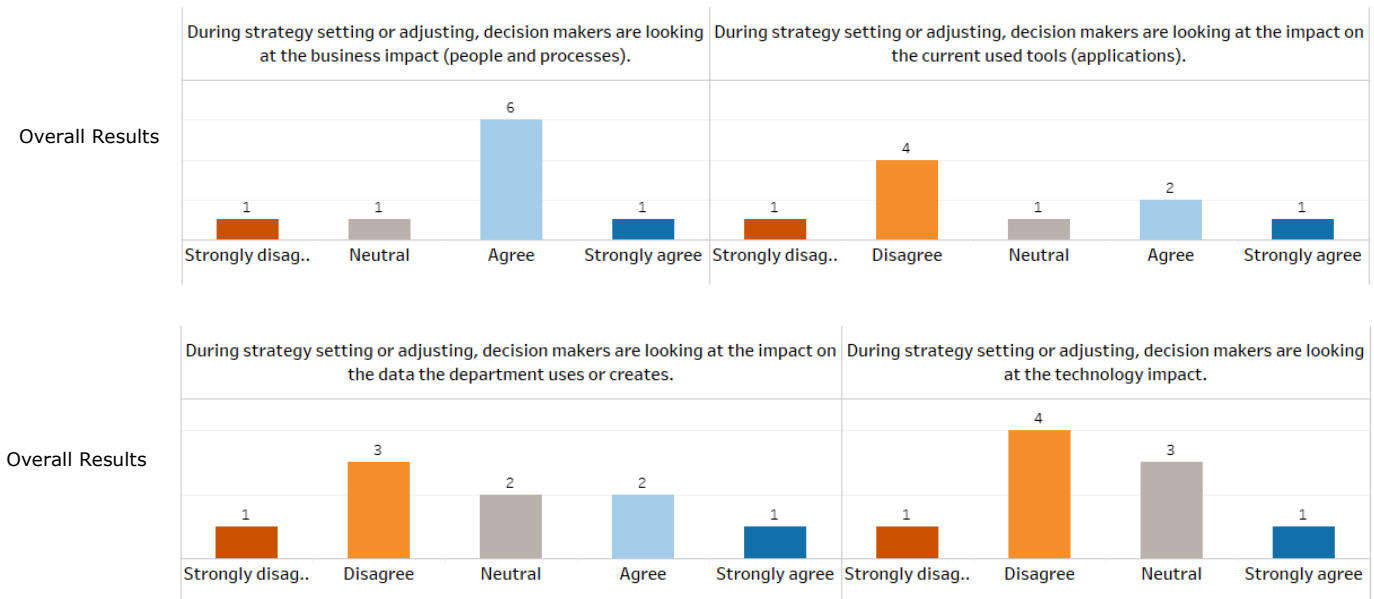


Figure 24a Overall results survey question 4-7 that looks at the four different layers of EA.

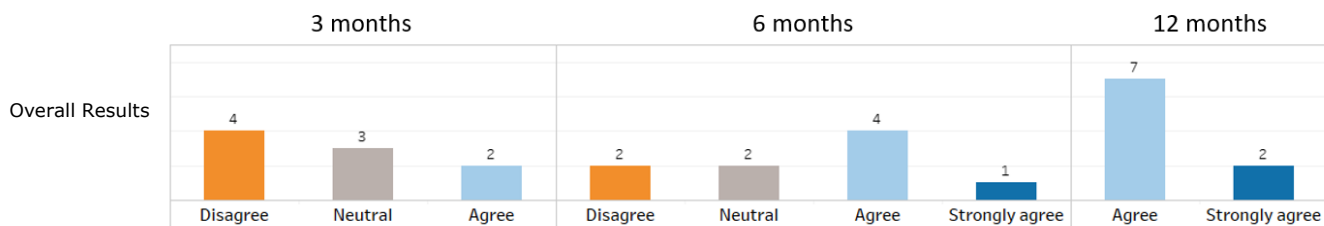


Figure 24b Results detailed to IT and Business stakeholders' level of survey question 4-7 that looks at the four different layers of EA.

We can see from the results in **figure 24a and figure 24b** that currently, the focus is more on the business and application impact than on the data and technology and that IT even has a more negative perception of it. This could be because IT is not present at the table during executive strategic discussions of the Business.

A second part of the problem statement is that adaptation to changes need to occur quite fast and thus having the right information on time is crucial. The online survey did check how fast the case organization is able to adapt to larger (digital) changes. From **figure 25** we can see that this can take up to 12 months. No remarkable difference between the stakeholder groups were observed.

When challenges arise, that comprise a multitude of cross functional groups and systems, strategy is adjusted within



When challenges arise, that comprise a multitude of cross functional groups and systems, strategy is adjusted within

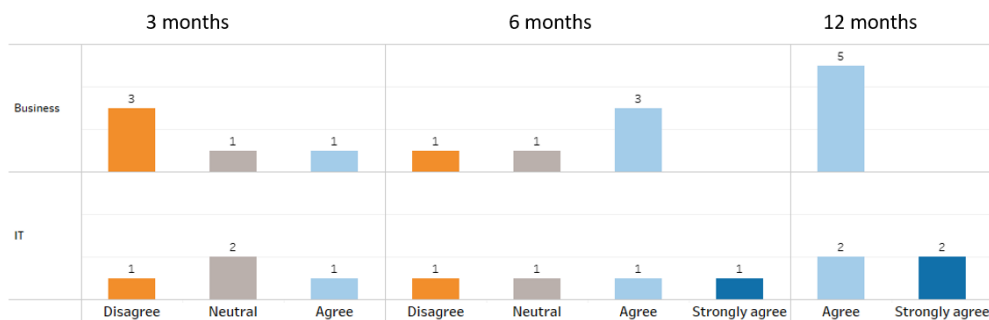


Figure 25 Results survey question 8-10 that looks how fast strategic decisions are implemented. First figure shows overall results, second figure is detailed to IT and Business stakeholders' level.

In summary, we can see that

- There is a clear mission and vision
- Role is clear to both Business and IT
- During strategic setting, decision takers are looking mostly on the impact on Business processes and in a lesser degree on applications, data, and technology
- IT and Business seem not always to be aligned: this could have an impact on the theorems and must be taken into consideration in the internal validity

4.2.1. Results Theorem 1 - Sensing disruption/new challenges phase

In the interview part we were able to dig deeper into the details of the strategic plan that consists of three phases as seen in the conceptual model in **figure 21**. For each phase we assessed the presence of the EA artefacts that helps strategic planning based upon the article of (Grave et al., 2021b). We will discuss the findings per theorem developed in chapter 3.

Theorem 1	<i>When a preclinical research department senses a disruption or encounters new challenges, we expect to find EA artifacts evidence of 1) a SWOT (Strength, Weakness, Opportunity, and Threat) analysis 2) a Technology and skills forecast model</i>
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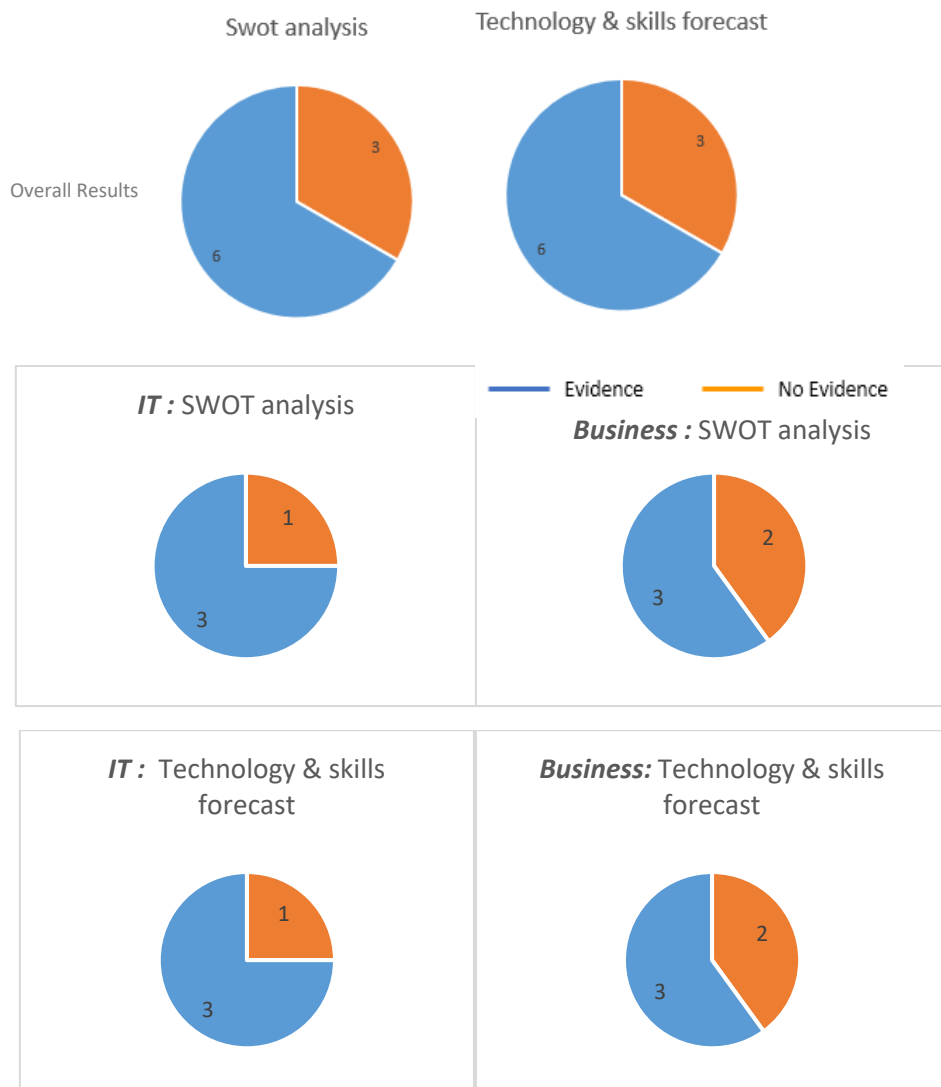


Figure 26 Results of evidence per EA artefacts for sensing disruption in pie-charts. First two figures show overall results, second set of figures are detailed to IT and Business stakeholders' level.

From the pie charts seen in **figure 26** we can see that overall majority tends to use both artefacts with a slight difference between IT vs. Business.

For SWOT analysis: Opinions are more variable. Both stakeholder groups confirm they do an analysis, but not always a SWOT analysis plus depending on the size of the change. Here we can see that the 'fit for purpose' principle is used. Also, the analysis is most of the times done within the Business Case.

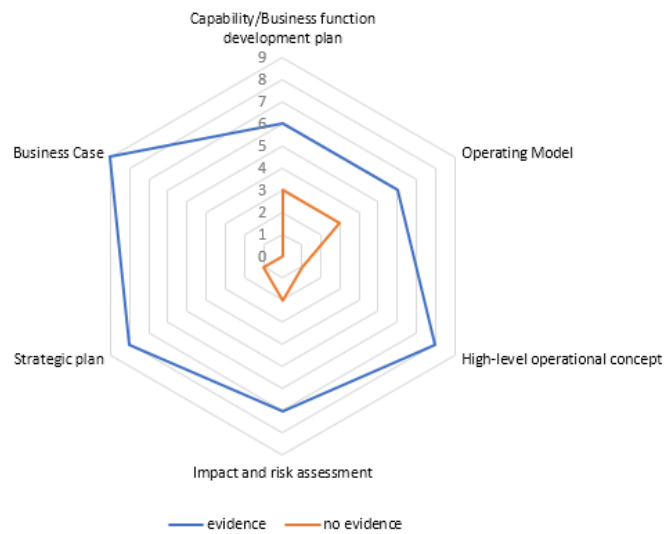
For the Technology & skills forecast: When looking from an **IT perspective**, according to the Head of Data Science *"impact analysis on those legacy systems, and then also it impacts the skills, whether we have the skills to absorb the new technology and integrate with existing legacy system. That impact analysis is again small, medium, large or it is severe impact. That helps us determine what level of transformation it is going to be."* **Business** is looking at this in a different way: the Vice President of Toxicology argues that it is not used as it should within the business as *"people tend to start already with a solution in mind"*.

These findings are answering **Theorem 1**: despite understanding the importance of the EA practice of describing the surveillance, technology, and business watch there is a rather small difference in how the preclinical area is documenting and using these artefacts as opposed to the findings in literature (Grave et al., 2021a, 2021b): not per se a SWOT analysis is done, but an impact analysis based on the fit-for-purpose principle.

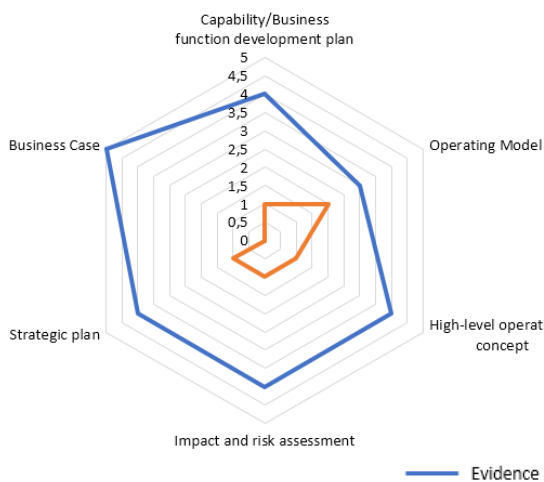
4.2.2. Results Theorem 2 - Creating/adjusting strategy phase

Theorem 2	<p><i>When a preclinical research department is creating or adjusting their strategy, we expect to find EA artifacts evidence of 3) Capability/Business function development plan, 4) Operating model, 5) High-level operational concept, 6) Impact and Risk Assessment, 7) Strategic Plan, 8) Business Case</i></p>
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Overall Results : Existence of EA artefacts for creating/adjusting Strategy



Existence of EA artefact for creating/adjusting Strategy according to **Business**



Existence of EA artefacts for creating/adjusting Strategy according to **IT**

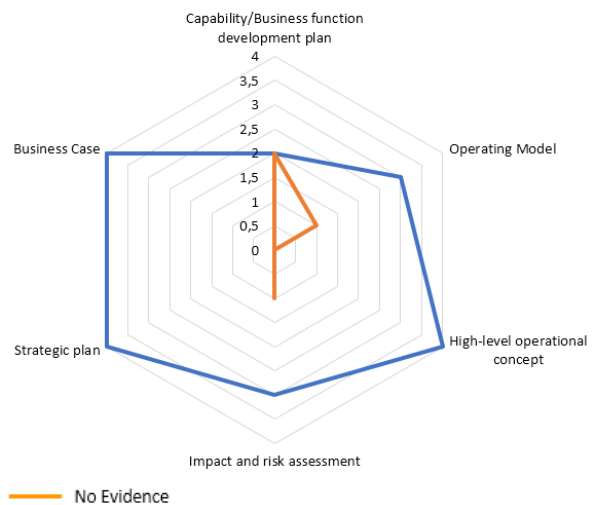


Figure 27 Results of evidence of EA artefacts for creating/adjusting strategy phase in spider-chart. First figure shows overall results, the two others show results from IT and Business perspective.

How to read the spiderwebs: the higher the number on the blue line, the more interviewees confirm the evidence of the artefact. For example: Business Case **is evidenced** according to all 9 interviewees as seen with the blue line, while Operating Model shows **no evidence** according to 3 interviewees as seen with the orange line.

Results in **figure 27** show that overall, artefacts are traced back. Especially Business Case, Strategic plan and the High-Level operational concept, less present is the Operating model and the capability/business function development plan. Looking more detailed we can see that the Business case is most used from both an IT and Business perspective, followed by the strategic plan/High-level operational plan, capability/business development is least present by IT. The IT director points out: *“The only one that matters, the only! All of the others, are derivatives of number six (note: being the business case)”*.

Some interesting remarks:

IT perspective:

- **several artefacts are combined in 1 document** as can be seen in the detailed table in **Appendix 6**
- according to the Head of Data Sciences the Capability/Business function development plan, the Operating Model, and the High-Level operational concept feed into each other
- also confirmed by the IT Director where it is taken even a step further where **the Business case drives all other artefacts which are all combined**

Business perspective:

- similar trend of combining of EA artefacts:
 - according to the Capability Mgr. the Capability/Business function development plan and the operating model are combined
 - according to the Head of Business Analytics true documents for Capability/Business function development plan, Operating model and the High-level operation concept do not exist.

These findings are answering Theorem 2: the EA artefacts are present but not always in the form as described by (Grave et al., 2021b). It seems that the case organization is using the basis, and forming, according to their specific needs, their specific usage of EA artefacts. It is very clear from the interviews that the gap between IT and Business is large, and they are in the process of reorganizing that to improve the current way of working.

4.2.3. Results Theorem 3 - Transformational Initiative Phase

Theorem 3	<p><i>When a preclinical research department decides on a transformational initiative, we expect to find EA artifacts evidence of 9) a conceptual data model, 10) an enterprise portfolio, 11) a governance structure, 12) principles and guidelines, 13) a roadmap, 14) a security and privacy plan, 15) services and product overview, 16) a stakeholder communication plan and 17) technology standards that describe the decision making</i></p>
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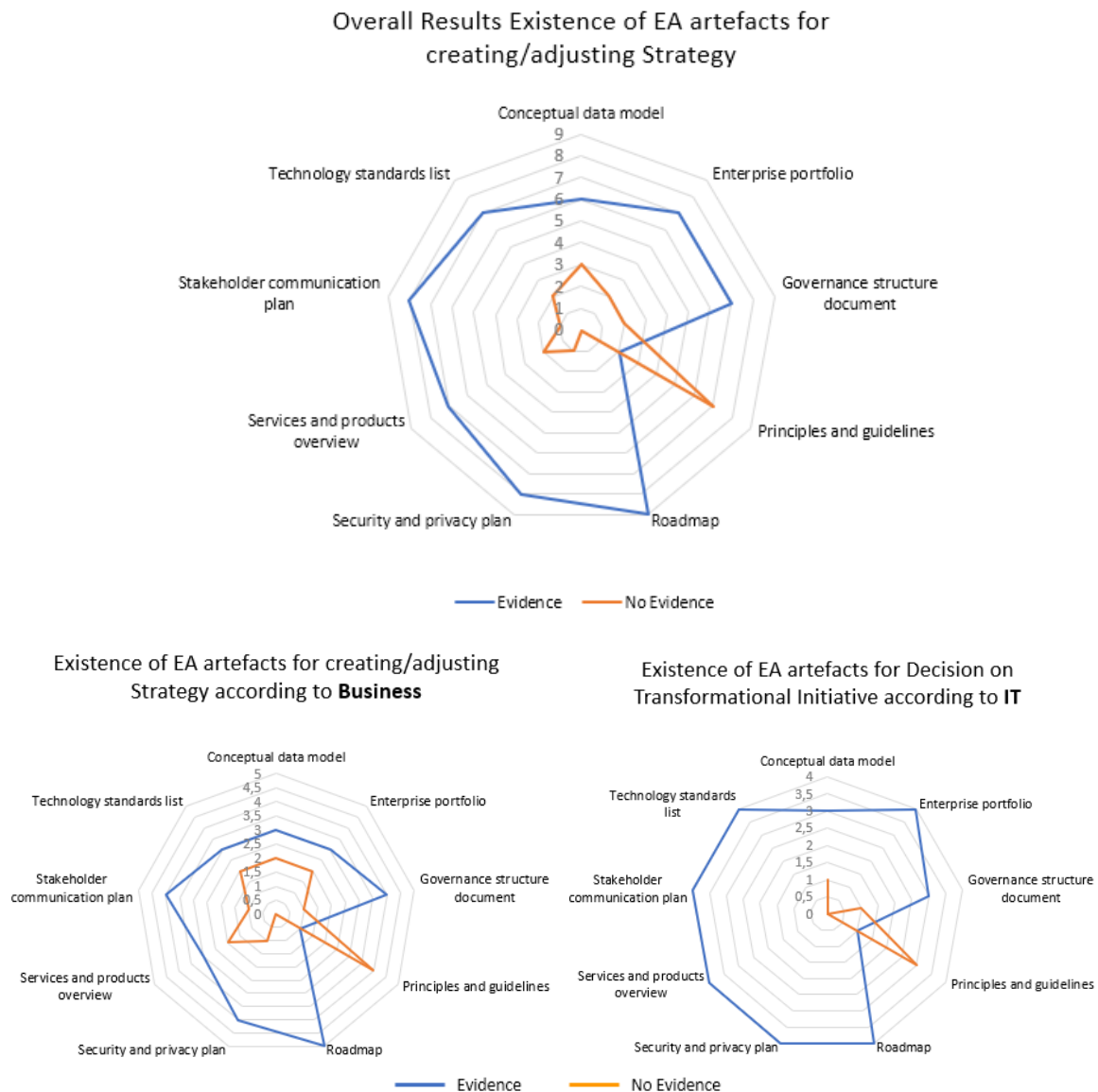


Figure 28 Results evidence of EA artefacts for transformational initiative phase in spider-chart from IT and Business perspective. First figure shows overall results, the two other figure show results by stakeholder group.

The EA artefact the least present for both IT and Business is obviously the principles and guidelines as seen in **figure 28**. According to the VP Toxicology "decision making is related to either cost profit, resource profit, time profit", head of Data Science takes it even a step further by claiming "it's all through word-of-mouth and a common understanding through emails". This view gets confirmed as well by the Head of Operations who claims that "this is a function of business acumen and functional

acumen on how and what to do are the principles. I would say that's part of the experience that comes with it."

IT Perspective:

- 7 out of 9 artefacts are present by all respondents
- Principles and guidelines almost not present

Business Perspective:

- Roadmap most frequent used artefact: can be due to the fact this artefact is the more 'actionable' one that integrates both Business and IT and what happens when for whom
- More scattered view
- Principles and guidelines almost not present

Several times the comment from Business was: "I think that is something for IT". From the results we can see this getting confirmed, however it also shows that there is a lack of holistic view on this strategic planning phase and both stakeholders are operating in a more silo form and thus are not together around the table when it comes to these strategic discussions.

These findings are answering **Theorem 3**: the EA artefacts are present except for the Principles and Guidelines. Also, there is a bigger discord between the two stakeholder groups.

When asking both stakeholder groups if they use **other EA artefact than mentioned in the list, Business came up with a new one: Human Objectives**. According to the VP Toxicology "*Success is not just rolling out a process or implementing a system, but ultimately how people use it and that's also where systems have failed in this department, because we just didn't have enough adoption and not enough enforcement to use the new system.*"

4.3. Summary of the results

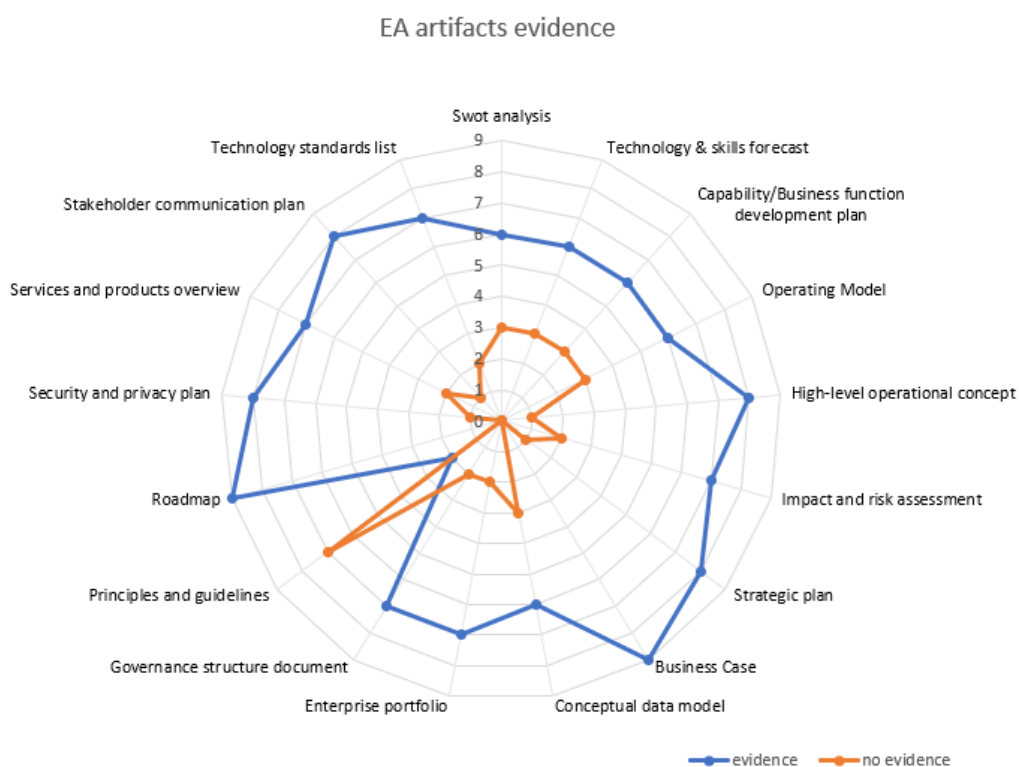


Figure 29 Summary of all Results that show the evidence of EA artefacts within a preclinical context

The conceptual model was validated by the online survey. From this survey we learn that there is a strategic plan and that respondents' roles are clear in the case organization. EA is well known to the organization, mostly to IT which is logic as EA architects are more of an IT function. The problem statement was also confirmed: EA is not holistically used and not all 4 layers are well defined as well does it take quite some time to get large (digital) transformations implemented.

A strategic plan consists of three phases. Each theorem is looking into the evidence of the EA artefacts contributing to the specific strategic planning phase. **The results of the theorems, the evidence of the EA artefacts described in the theorems, contribute to answering the main research question.** A summary of all results can be seen in **figure 29**.

For the **strategic planning phase that senses disruptions or challenges**, both artefacts are present and found useful. However, not always a SWOT analysis is done, but 'some sort of analysis': how detailed is dependent on the 'just enough, just in time' principle and based on how large the disruptions are. Technology & skills forecast is partially present within the Business.

For the **strategic planning phase that creates or adjusts the strategy**, we can see that both the Business Case and Strategic plan are most used for both stakeholder groups. What is striking is that, especially for IT, artefacts are combined and even perceived as derivatives from the Business Case. The Business started using the AIM methodology last year which also combines a lot of the artefacts into 1 document, again according the 'just enough, just in time' principle detailed. Recently, a redesign of the IT landscape occurred: EA is reformed to High Performing Teams with the sole

purpose to bring IT closer to the business on a strategic level as a department is now considered as 'the Product'.

For the final **strategic planning phase where transformational initiatives** are rolled out the EA artifacts contributing to this phase are almost all present in a high degree for IT, while for the business this is more scattered view as several artefacts such as the Enterprise Portfolio, Services and Products overview, Technology standards and Conceptual Data Mode are seen as 'part of IT'. Strikingly, for both stakeholders the Principles and Guidelines artefact was almost not present that could help facilitate the decision making. Within the case organization, an artefact is being used that is **not on the list** of the model in literature: **human objectives**. This artefact is not seen as a change management item, but a true artefact as it plans for success.

5. Discussion, conclusions and recommendations

5.1. Discussion – reflection

Having and using the right information on time is crucial for strategic planning for (digital) transformation within preclinical research. When a pharmaceutical company is directing a strategy to transform into a digital, innovative company it is critical that all departments' business processes and IT align on that strategy. EA has the capacity to do so. Therefore, main research question was: *"Can Enterprise Architecture Artefacts contribute to the strategic planning process in a preclinical context?"*. To answer this question a theoretical model from literature research was used to research in practice in the case organization (Grave et al., 2021a, 2021b).

Theorems 1, 2 and 3 were studied using semi-structured interviews for both high- and lower-level IT and Business stakeholders and showed that from the 17 artefacts, we found evidence of almost all of them except for principles & guidelines. For both stakeholders, the business case and roadmap are considered as the most important artefacts and others are more seen as a derivative and are created or used according to the 'fit-for-purpose' principle. Recently, EA architecture disappeared as a discipline and the High Performing Teams were introduced that brings IT much closer to the Business. The concept of these HPT is that it considers the case organization as a product.

A new artefact was identified: describing the Human Objectives. The case organization takes this into account already early in the strategic planning process as it means to "plan for success" and "success" means that people adopt the change, it is not considered as a change management item. Large transformations failed in the past because no attention was given to this in an early planning phase and only came into play once the transformation was implemented.

Concluding, we can say that EA artefacts do play a crucial role in strategic planning of transformation in a preclinical context. All theorems confirm the evidence of the EA artefacts as described by (Grave et al., 2021a, 2021b) for strategic planning except for the principles and guidelines artefact.

5.1.1. Items that improve the quality of the research

In section 3.4 we reflected in theory to the items that improve the quality of a research. The below table is giving more details how we improved the constructs in our case study.

Quality construct of Research	Usage to improve
construct validity	<ul style="list-style-type: none"> - Expert Reviews - Triangulation of results with document research
internal/impression validity	<ul style="list-style-type: none"> - Interview with several key persons with a different background/function - Setting benchmark of EA with self-made video that explains what EA is so interviewees can put the questions of the interview in context - Asses the current situation, EA practices and concept of EA in the online survey that should be filled before conducting the actual interview: from here we can see a difference in responses IT vs. Business: we need to be aware that this can impact internal validity - Transcripts were sent to interviewies but due to christmas holiday, very limited feedback was received. However, we assume, if there were large discrepancies, feedback would have been provided. - Usage of peer-reviewed articles to validate research with the conclusions in existing literature
external validity	<ul style="list-style-type: none"> -Due to the chosen research strategy, the degree of generalizability is limited, however theory can help support the external validity. Our literature research in chapter 2 supports our findings of other relevant settings different than a preclinical context. - Conducting a stakeholder analysis based on proven theory from (Mitchell et al., 1997) will increase external validity. <p>The research involves a goal-oriented, homogeneous, role-based sample, which selects respondents who correspond to 'typical' members of the population. It seems plausible that the results also apply to the rest of the study population, which should be demonstrated by additional research.</p>
reliability	<p>For maximizing reliability and thus the extent to which data collection techniques will give consistent findings we made sure that we</p> <ul style="list-style-type: none"> - have a semi-structured interview protocol - record the interviews - reduced respondent bias by interviewing multiple key persons - we need to be aware of the interviewer bias that can exist <p>All transcripts, documents, data and results are to be found in the appendix to provide a chain of evidence and maximize transparency.</p>
Ethical aspects	As discussed in section 3,4,5 were discussed with respondents. No one objected.

Figure 30 Items that are important to maximize the quality of the research and how we improved it as discussed as well in section 3.4

5.2. Conclusions

In chapter 2 current EA literature consist of several studies identifying and explaining the value of EA artefacts in the strategic planning process and the stakeholders involved. The findings of the empirical research are aimed to deepen our understanding of the role of EA artifacts in practice. To be able to answer the research question we developed 3 theorems:

Theorem 1:

When a preclinical research department senses a disruption or encounters new challenges, we expect to find EA artifacts evidence of **1)** a SWOT analysis and **2)** a Technology and skills forecast model that describe the surveillance, technology, and business watch which sensed the disruption or new challenges.

Theorem 2:

When a preclinical research department is creating or adjusting their strategy, we expect to find EA artifacts evidence of **3)** a business function development plan, **4)** an operating model, **5)** a high-level operational concept, **6)** an impact and risk assessment, **7)** a strategic plan to transform, **8)** a business case that describe the EA impact and simulations practice process.

Theorem 3:

When the preclinical research department is undergoing a transformation, we expect to find EA artifacts evidence of **9)** a conceptual data model, **10)** an enterprise portfolio, **11)** a governance structure, **12)** principles and guidelines, **13)** a roadmap, **14)** a security and privacy plan, **15)** services and products overview, **16)** a stakeholder communication plan, **17)** and technology standards that describe the decision-making facilitation EA practice process.

Finding evidence of the above-described artefacts, will help to answer the research question: ***“Can Enterprise Architecture Artefacts contribute to the strategic planning process in a preclinical context?”***.

Our research was able to find evidence of almost all artefacts. However, what is interesting is that both IT and Business stakeholder groups identify **the Business Case and the Roadmap** from the creating or adjusting planning phase as **most important** and even argue that the **other artefacts** are more detailed **derivatives**. The artefact **almost not present** is the **principles and guidelines document** and seems not relevant for the decision making as this is mostly done by business acumen and based upon experience or profit (in cost, time, resources).

One **new EA artefact** came to light which is even documented in the Business Case is the **Human Objectives**: this gained remarkable interest over the last year as it was exactly the point where transformational initiatives failed in the past: when this is not formulated upfront (defining success) and not backed up by management and through stakeholder enforcement, then transformational initiatives tend to fail. One can argue that this is change management, however the preclinical organization sees this as an integral part of the strategic planning process.

What are the conclusions of the research conducted and how can this relate to literature?

The research confirms the evidence of EA artifacts during the strategic planning process as described by (Grave et al., 2021a, 2021b). Some interesting things are seen within the case organization: the business plan and roadmap are considered most important and other artefacts are mostly derivatives of it. Also, the ***'just enough, just in time'*** approach as described by (Ahleman et al., 2012) is used, meaning the EA artefacts are documented that are needed to achieve the business goals. Even though respondents recognized the relevance of documenting all EA artefacts as this can bring value in a later phase. Especially Business is concerned with the lack of integration of IT and both stakeholder groups can feel as they are operating in silos. Just very recently, the introduction of the ***High Performing Teams (HPT)*** was implemented which aims to integrate IT with Business in a much higher capacity.

5.3. Recommendations for practice

The use of artefacts for the business is centralized amongst the business case and the roadmap. By using the AIM methodology, a more structured approach has already been reached, however, it might be an opportunity to incorporate the layers of technology, applications, and data into that Business Case of AIM. When forming teams around it, a representation of IT is a must as both stakeholders admit that closer collaboration on strategic level is needed. What could help, is the introduction of some Key Performance Indicators (KPI) for transformational changes: we identified the "core" artefacts, but it is a matter of bringing these from both IT and Business perspective together and align on an integrated approach. Questions like who should be on the team, what template documents do we use for every transformational change, when is documenting considered 'good', identification of the correct team members and make sure enough IT weight is present to ask the right questions about technology, application and data are ways to improve current EA.

5.4. Contribution to the field and recommendations for further research

The research is contributing to the field as it confirms the use of EA artefacts for strategic planning as stipulated by Grave et al. (2021a, 2021b). However, as we found that certain artefacts are considered as "core artefacts" and other ones as "derivatives" it would be interesting to investigate the effectiveness of the EA artefacts. The gap between EA artifacts that can contribute to strategic planning in theory and the findings in practice calls for further research. A multi-case research around the 'core EA artefacts' at similar organizations is needed.

From the results one can see that there is a rather limited integration between IT and Business. With the new setup of the HPT, this could be bridged. Interesting would be how in practice that would work: how much will HPT involved in strategic decisions and what artefacts are used? This calls for further research as well.

5.5. Reflection

This research was a real journey: searching for a good research question, keeping it small and to not think too big as time was limited was very challenging. During my years in preclinical research, I was so many times confronted with the fact that systems, applications, and data always seem to lag when strategic decisions that have an impact on the organization structure (and thus on the systems in the departments) were taken. As EA is a methodology that I am passionate about, I really wanted to combine those areas. I am extremely grateful for the participation of preclinical and what is most striking, that in the last 6 months changes are really happening that bridges that gap, or at least the intent is there. It is very interesting to see where this new approach is taken the preclinical department to.

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