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Health Informatics — Methodology for analysis of business and information needs of health enterprises to support standards based architectures

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National foreword

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Healthcare organizations need to have coordinated and systematic methodologies for business management, quality management and information management. These methodologies also support creating of a coherent business and information architectures as one of the prerequisites for achieving semantic interoperability in both the healthcare enterprises and their information and communications technology (ICT).

Healthcare is a business sector where high quality information is crucial for the quality of the services delivered. In healthcare it is critical to be able to share information between different healthcare providers regionally, nationally and sometimes also internationally. Therefore, business and information architectures should be coherent and based on standards. To achieve this, an appropriate methodology should be used for creation of such architectures.

This document describes the methodology for analysis of business and information needs of health enterprises to support standards based architectures, BIA methodology. The purpose of the methodology is to provide an efficient business and information needs analysis for an optimal healthcare enterprise description in order to create a standards based business and information architectures.

The BIA methodology starts with describing of the organization's mission and vision.

The organization's mission defines the type of business to be conducted and its extent. A defined business always has a purpose to state why it exists.

The business vision drives the business forward, stating the direction for streamlining and thereby development of the business.

There should be a comprehensive holistic overview that describes the current state and the target state of the business and its information management, as well as how to move from the current state to the target state, thereby allowing the vision to be more easily achieved.

The BIA methodology is used for the analysis and descriptions of a defined business. The resultant descriptions comprise the basis for decisions made for different purposes, ranging from the production of a holistic overview as a basis for the business development, information supply, ICT strategies as well as ICT requirements-setting.

The methodology consists of several steps that analyse and describe different aspects of a business. It also defines how these aspects relate to each other in order to achieve an effective and lean analysis of the business and its information needs. The analysis results in descriptions of:

— Goals - long-term, strategic, wider goal, not precisely quantifiable

— Objectives - more short-term, on operational level, specific measurable

— Stakeholders - roles/actors/target groups that directly interact in the business or have an interest that business is operative

— Concepts - the concepts that are fundamental and anchored in the business

— Process from value processing perspective - patterns for action that shall ensure that the objectives are achieved

— Process from a collaboration perspective - crystallizing of the processing perspective that shows the business roles in collaboration

— Information needs – what type of information that business roles are needed in their collaboration

— Information structure - a comprehensive and structured description of the type of information managed by the different roles in the process

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— Codes, classifications and terminologies - agreed and predefined values which describe a certain type of information related to a specific attribute in the information structure

Using an established and specific for healthcare system methodology ensures that the result is fit for its purpose, maintaining quality at a high level. It also increases opportunities for comparing and re-using different analytical results as well as producing an optimal business description which can be used for different purposes.

The BIA methodology also points out a number of International Standards to use as reference models in development of the standards based coherent business and information architectures.

This document is targeted at experts working with strategic issues such as devising a business goals, objectives and strategies as well as those working with the production of industry frameworks, creating of standards based business and information architectures, business and information analyses, information structuring and requirements setting for ICT or their information supply.

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TECHNICAL SPECIFICATION **ISO/TS 22272:2021**

Health Informatics — Methodology for analysis of business and information needs of health enterprises to support standards based architectures

1 Scope

This document presents a methodology which supports and enables the development of standards based business and information architectures that contribute to good quality of healthcare and patient safety. The methodology is used to develop descriptions of healthcare enterprises from different aspects. Those aspects are covering what, how, where, who, when, why[1] and are based on standards.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 13940, *Health informatics — System of concepts to support continuity of care*

EN 15224, *Quality management systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO 13940, and EN 15224 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
business mission
purpose and scope of a business

3.2
business vision
future or ideal goals that a business strives to achieve

3.3
holistic view of the business
description of the business current state, the target state and how to move from the current to the target state

3.4
time dimension
view of the business in the current state or the target state

3.5
strategy for transition to the target state
overall description for displacement of business from current state to target state

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3.6
action plan
concrete activities intended to achieve the target state

3.7
current state
description of way in which the business and its support operate, for example information management and information and communications technology

3.8
target state
description of desired way in which the business and its support should operate, for example information management and information and communications technology

3.9
business aspect
type of business analysis from a certain point of view in order to create a deeper understanding of the business and its information management

3.10
set of information
the information managed by the activities in the process

3.11
stakeholder
role, actor or target group who directly interact with the business or who have an interest in the outcomes of that business

3.12
process from a value processing perspective
patterns for action that ensure that the objectives are achieved

3.13
process from a collaborative perspective
crystallizing of the processing perspective that shows the business roles in collaboration

3.14
concept
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087:2019, 3.2.7, modified — Notes removed.]

4 Why the BIA methodology is useful in healthcare

The structure and standardization of information handled in electronic systems in the healthcare has been attempted over several decades in many different countries. It became clear that there was a need to first define the concepts which are the basis for this information before structuring could commence.

Concepts and information structures by themselves are insufficient to create the preconditions for the information to be unambiguously defined. Users should therefore understand the context in which this information is created and handled.

Healthcare is an information-intensive industry, that is both knowledge- and evidence-based. Figure 1 illustrates that many different professions and roles work together in the patient care. For clarification and the maintenance of patient safety, those roles shall understand the clinical context in which the information was created. In addition, it is important that information is retained in such a way that it can be reused in order to meet the needs of different stakeholders.

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As healthcare information shall be handled over many years, it is necessary that structures are backwards compatible. Information structures and related regulations should be stable over time and based on a predefined conceptual structure.

Business and information analysis methodology takes those aspects characteristic of healthcare into account:

— many professions

— many specialties with their own development needs

— interaction with others

  — to understand each other in the same way

  — to protect patient safety

— information-intensive

— traceability and an audit trail of information management

— based on knowledge and evidence

— the need for follow-up

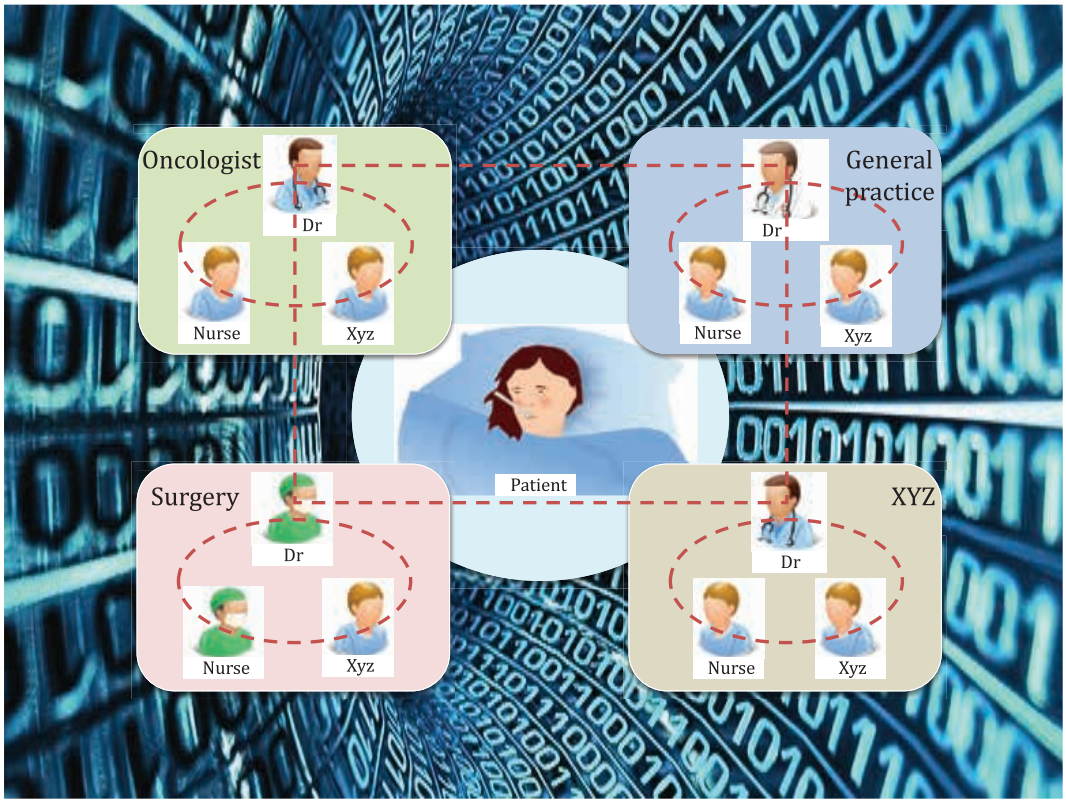

Figure 1 — Managing of a large amount of information

Healthcare professionals should focus their time and resources on patients. At the same time, it is necessary to streamline healthcare enterprises, their information management and ICT. Healthcare usually has a need to pass through this with quite limited resources and under the short periods of time without disturbing the core enterprise. Therefore, enterprises should use methodologies in change work that meets these requirements.

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The BIA is such a methodology that characterizes:

— well-demarcated methodology and with limited scope

— easy to understand, relatively quick to learn and get started to use

— can be used in its entirety or in less delimited parts

— enable to involve healthcare professionals in analysis

— healthcare professionals are the driving factor in analysis

— analysts play the role as help and support in analysis work

Historically, healthcare professionals were very poorly involved in business and information analysis. ICT professionals conducted analysis with very minimalist involvement of healthcare professionals. Such analysis was ICT-driven.

A fundamental advantage of the BIA methodology is that it is the healthcare professionals who "owns" analysis and are at the focus in the analysis work. Analysts are seen as the help and support in this work and stands for the structural perspective. Through agreement and consensus in analysis work, healthcare professionals create different models. Analysts, on the other hand, help keep the focus in the discussion in order to come to a common understanding of areas of analysis.

To be able to involve healthcare professionals in analysis, the methodology should to be easily understood. Healthcare professionals also need to see how each step in analysis work contributes to a qualitative end result.

Because the BIA methodology is clearly defined and made easy to understand, opportunities are created for healthcare professionals to be the driving force in analysis work. The purpose of the BIA methodology is to conduct business-driven analysis.

5 Efforts to achieve the business vision

5.1 The business mission, vision, holistic view and strategies

A mission defines the type of business that is to be conducted and the extent of this business. A defined business always has a specific purpose which justifies its existence.

The vision drives the business forward, stating a direction for streamlining and thereby its development as it shows in Figure 2. A business should have a common, agreed and established vision why it exists. A vision doesn't have to be measurable or even completely realistic; it serves to point out the direction of the business' future.

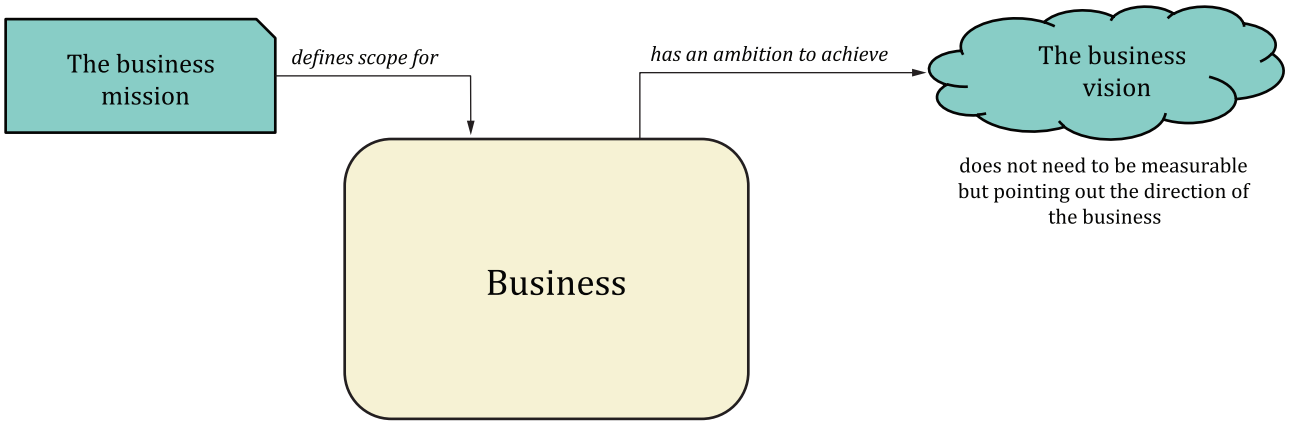

Figure 2 — Business vision

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Sometimes a business is not sufficiently effective enough to achieve its vision at the present time; there should be a holistic view of the business that describes its current state, how it is viewed and perceived the way it works today. The target state of the business, that is another part of the holistic view, describes the desired state of how it will function in the future. Figure 3 illustrate the relationship between business vision, current state, target state and strategy for transition. A gap analysis handles the difference between the current state and the target state.

In reality, it can be difficult to directly change the business if major operational changes are involved. However, rather than compromising the vision, the strategic plan allows it to be reached in steps with the added benefit of continuously evaluating the relevance of the target state to ensure it retains its viability.

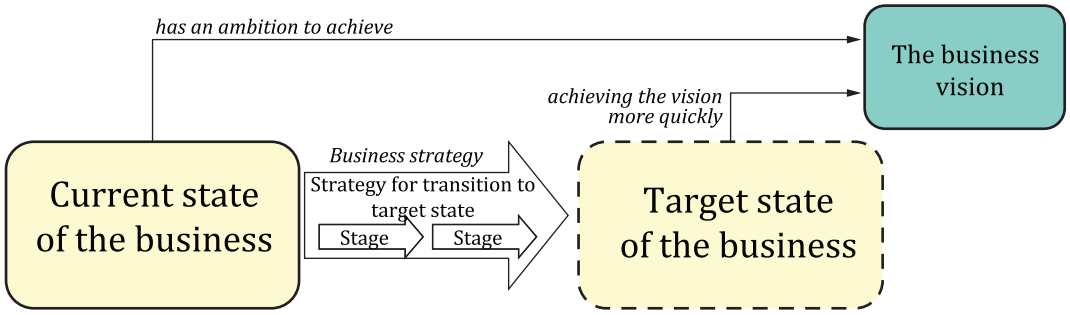

Figure 3 — Business vision and strategy for transition

The business' target state should be clear before the tools which support it, such as information and communications technology, are devised.

Just as the business can perceive its current state as insufficient to achieve the vision, ICT tools can also have shortcomings.

However, the business and its ICT still have to operate as usual on a daily basis. Therefore, short-term measures which describe how to make minor and limited changes should be identified in order to allow the business to continue to function. Figure 4 shows the movement of the business from the current state to the target state should be synchronized with an ICT strategy.

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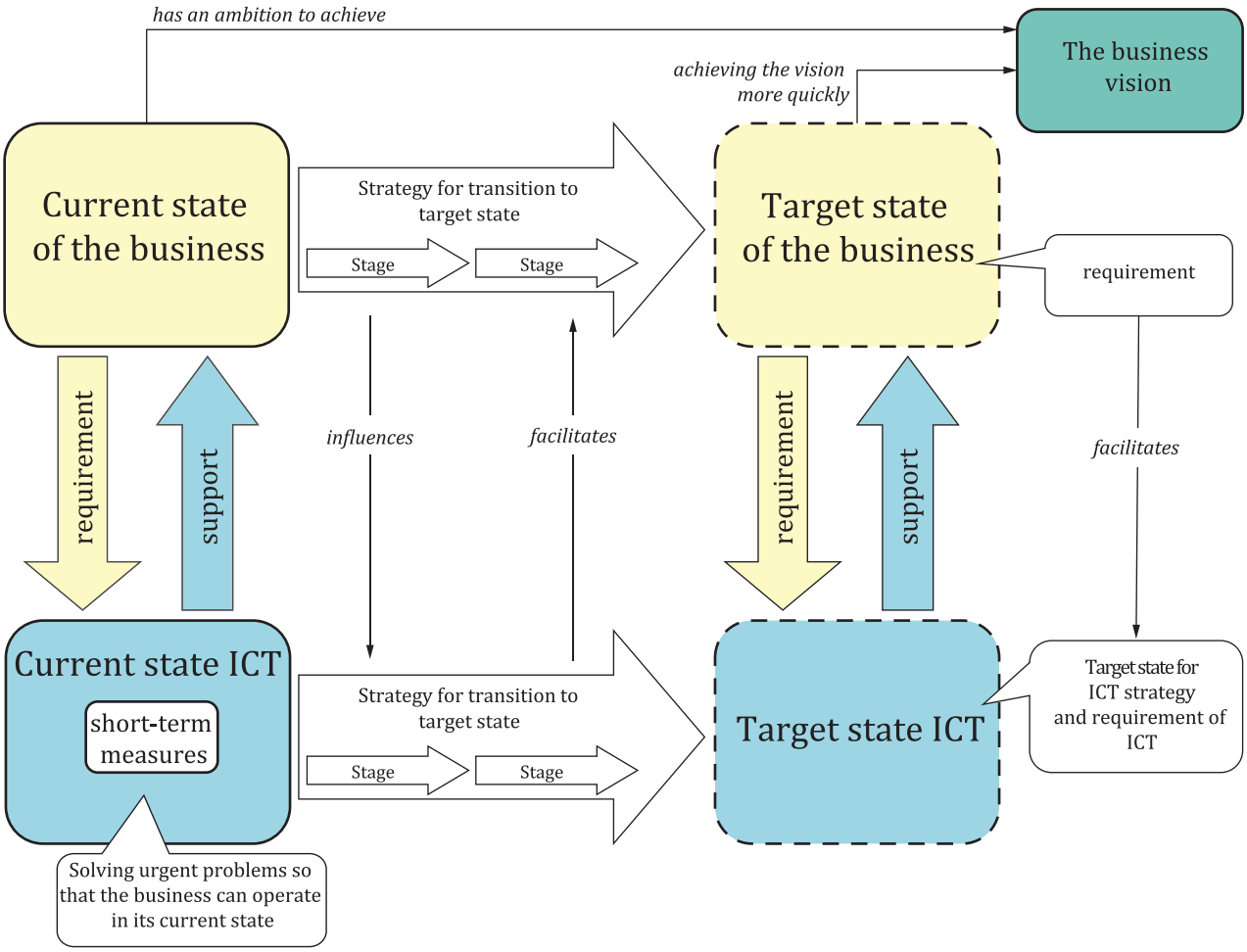

Figure 4 — Synchronization between different perspectives

Streamlining the business and developing an effective ICT alone are insufficient to effectively achieve the vision. Nowadays, the supply of business information plays a decisive role in the enterprise. Effective information management is central to creating the optimum conditions to achieve the business' target state and thereby its vision. Therefore, the current state, target state and strategy for transition to the target state within information management is central to achieving the business vision.

In summary, the holistic view of the business includes the descriptions of the current state of the business, information management as well as the ICT. The strategies for transition to the target state facilitate achievement of the vision as it is shown at Figure 5.

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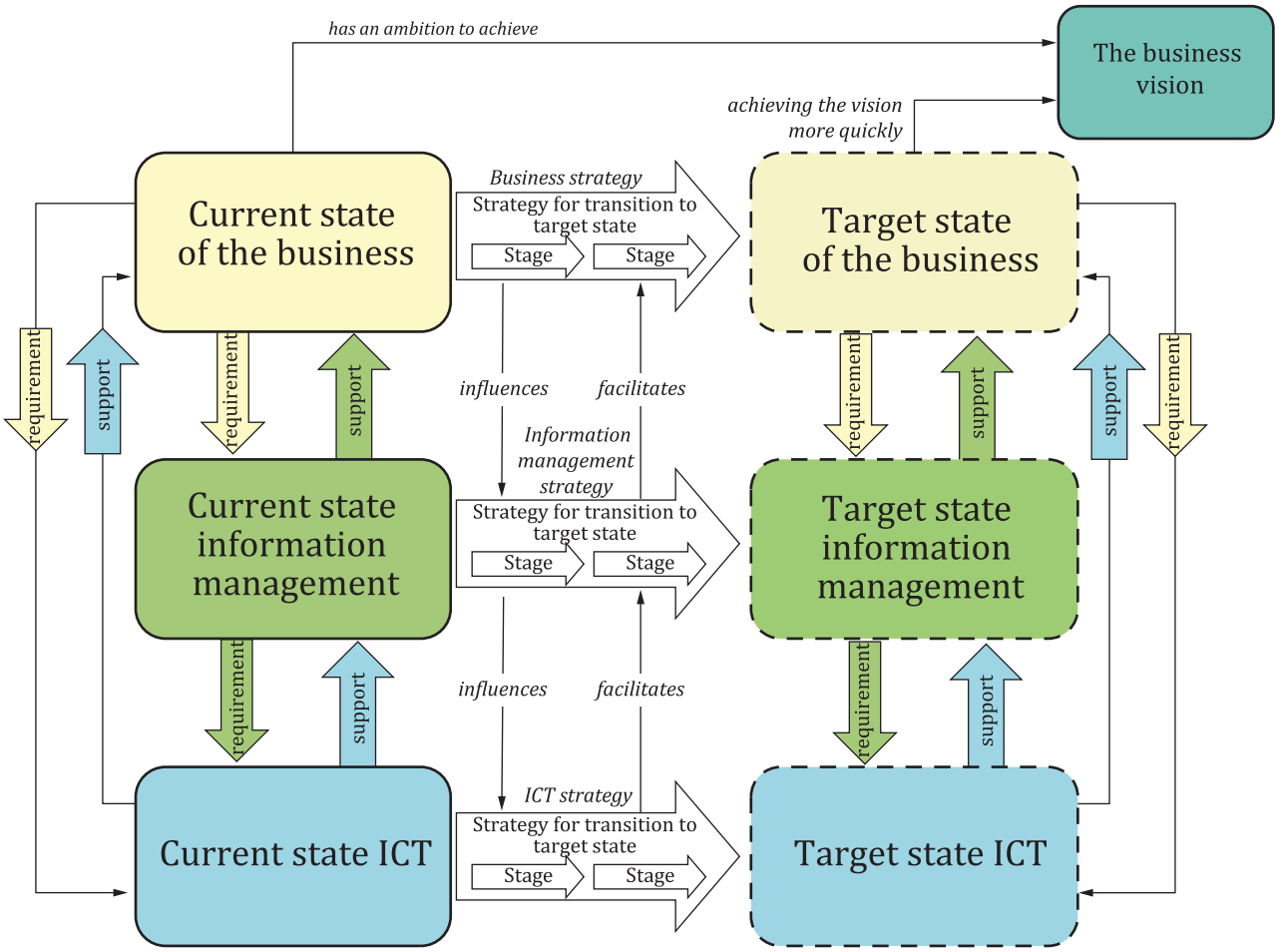

Figure 5 — Holistic view of the business

5.2 Different steps in analysis work and change management

Figure 6 illustrates several important steps in the analysis work and change management. The gap analysis identifies which business areas should be streamlined and improved. Using this as base for decision, a business strategy is then devised, which describes the route to achieve the target state. Stipulating which business areas should be prioritized for commencing the change work allows the definition of action plans for the change.

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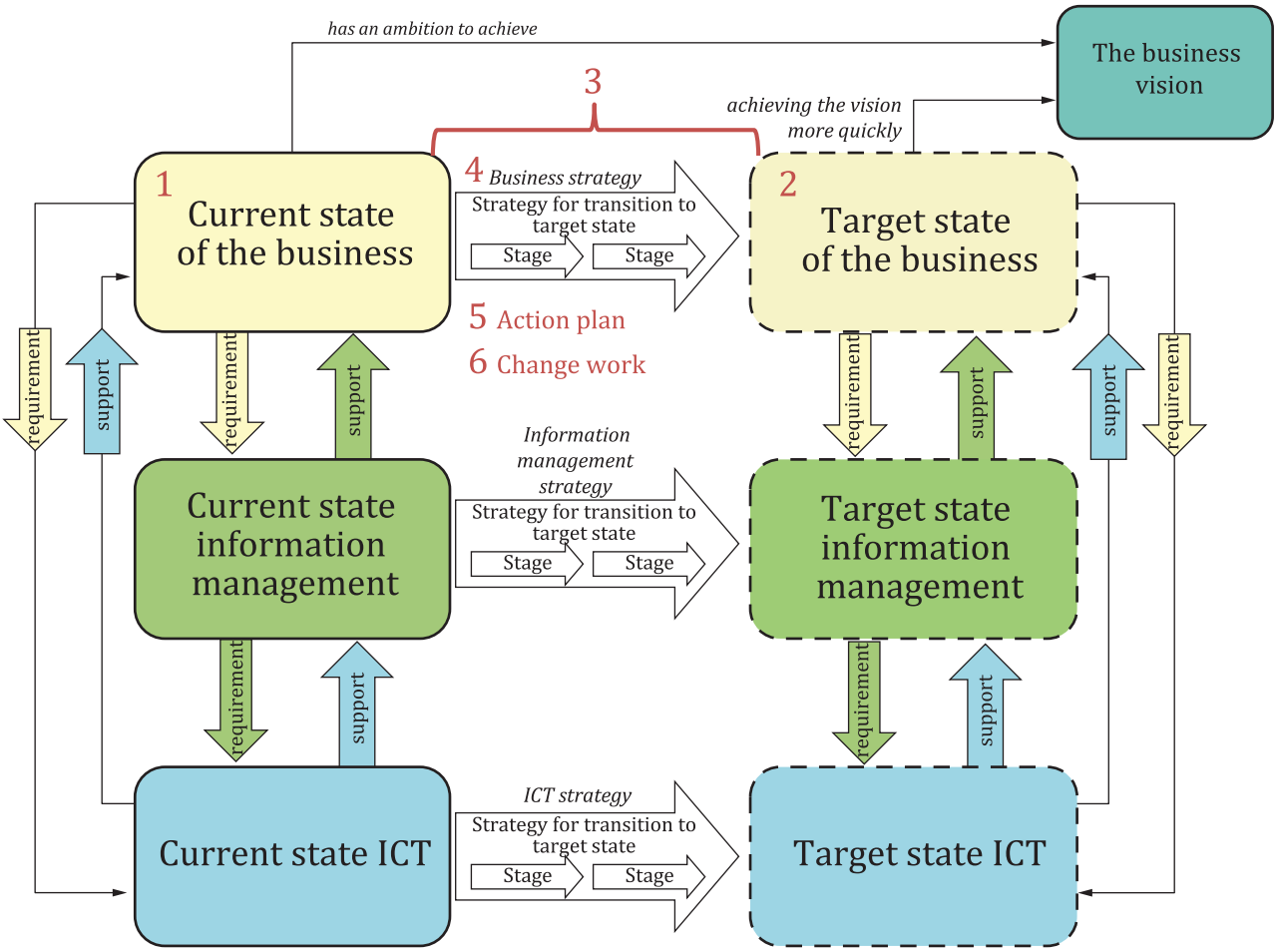

Figure 6 — Different steps in analysis work and change management

The planning of all change work should start from the holistic view of the business and its vision. The same principles apply at an overall level within all three perspectives, i.e. business, information management and ICT. It is very important that the changes within these three perspectives are coordinated and take place on a collaborative basis, see Figure 7.

Discrepancies between the descriptions of the current and target states forms the basis for devising the strategies for business development and its information supply, thereby creating the base for decision for devising the ICT strategy.

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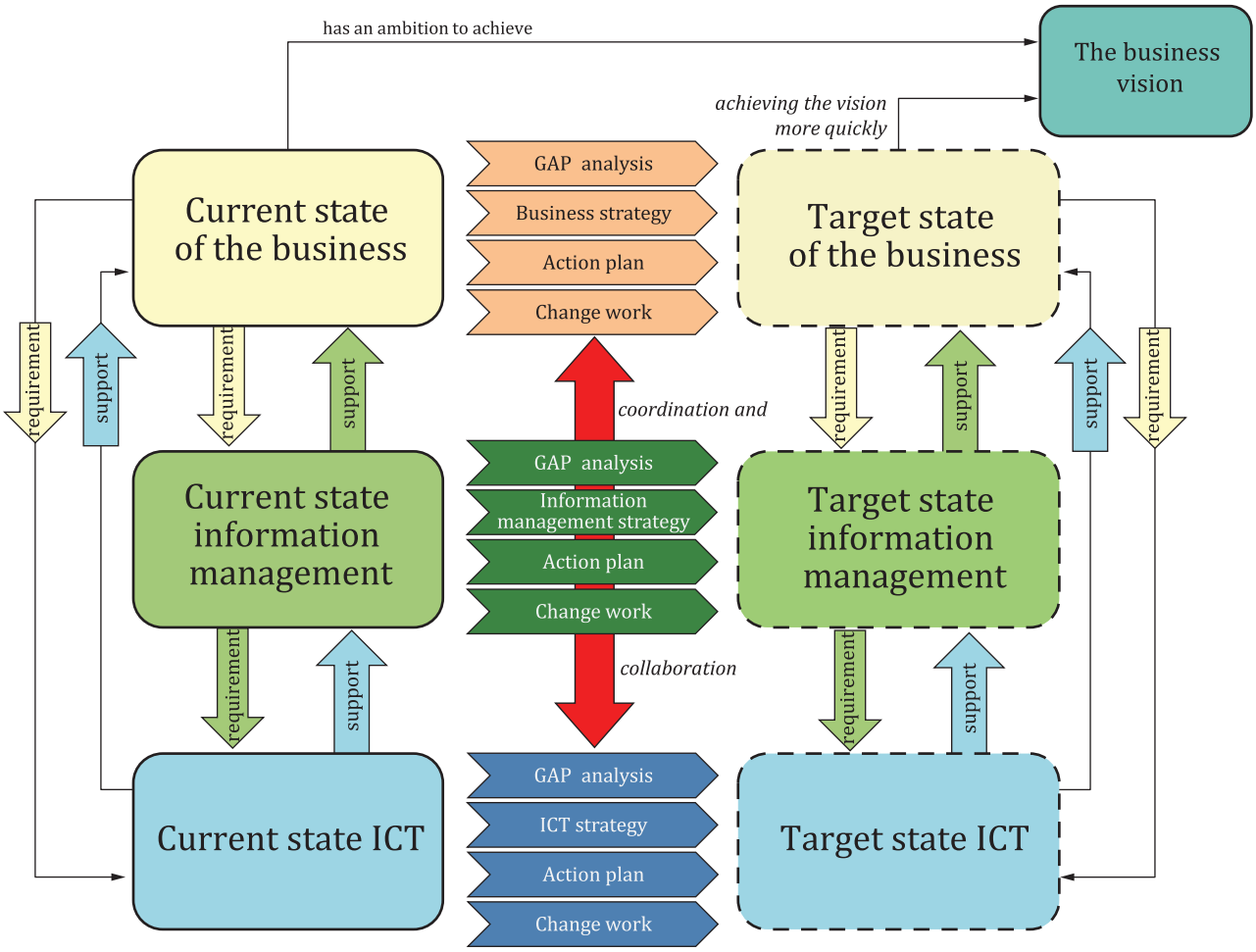

Figure 7 — Coordination and collaboration between different perspectives in change work

Within each perspective, strategies for transition to the target state (business strategy, information management strategy and ICT strategy) shall be outlined and coordinated. Change management should be planned and implemented in collaboration between these perspectives.

Without an overall picture, it is difficult to describe effective processes within the business that will deliver the results, which in turn contribute to the achievement of objectives. For example, if there is no description of the target state and strategy for transition within information management then there is a risk that the information is not traceable and that siloed sets of information which are not compatible are created. By the same token, it is difficult to devise a business-based and realistic ICT strategy without a description of the target state and strategy for transition for the business and its information supply.

5.3 Fundamental areas within healthcare as a system

Management of healthcare is divided into strategic and operational levels. The strategic level sets goals for the core business and is responsible for the implementation of governance within healthcare. The operational level is responsible for ensuring that the core business delivers the patient care. In addition, healthcare is dependent upon regulations, laws, constitutions, knowledge bases and ethical values as it shows in Figure 8.

When starting a business and information needs analysis, it is important to identify which fundamental area(s) will be covered. These areas are grouped into:

— core business

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— leading and governing the core business

— support and resource allocation for the core business

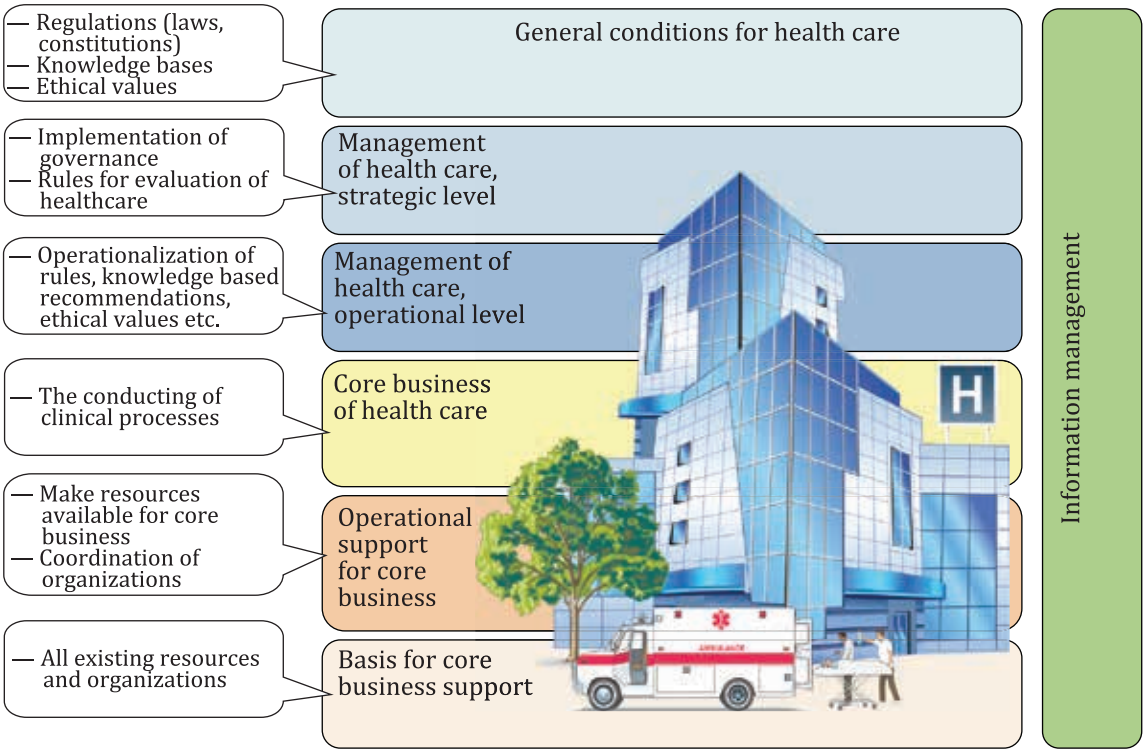

Figure 8 — The fundamental areas within healthcare as a system

5.4 Time dimensions in the BIA methodology

The first step in the analysis work, according BIA methodology, is to describe the business from a high-level perspective including how different parts of the business are related to each other and the mutual dependences which exist between them. It is important to identify which level within fundamental areas that business belongs to and how it relates to other levels.

The next step is to provide descriptions of the holistic view of the business that consists of the current and the target states of the business. These descriptions cover different business aspects.

Often the current state will highlight inefficient processes or a waste of time and resources.

Sometimes it can be difficult to achieve a sustainable common description of the current state of the business due to the lack of a common view or perception. However, the description of the current state should be done even if only at high level. Otherwise it would be impossible to define a strategy for reaching a target state and an action plan for transition if the starting point is unknown.

Figure 9 illustrates the connection between the fundamental areas and the description of the holistic view of the business.

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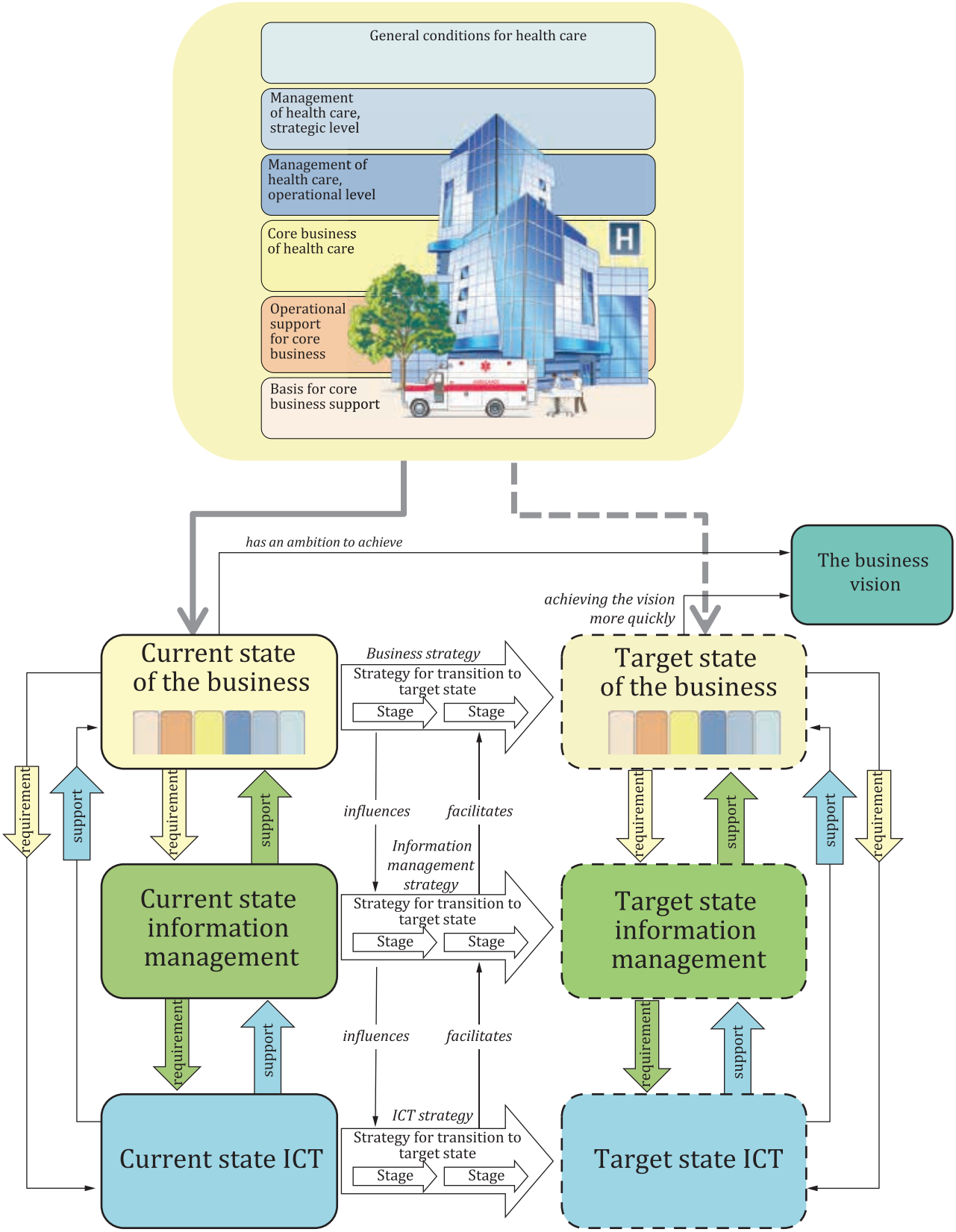

Figure 9 — The fundamental areas of healthcare and the holistic view of the business

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5.5 Focus of the BIA methodology and business aspects

Figure 10 illustrates the focus of BIA methodology that supports analysis for creating of the business and information architectures.

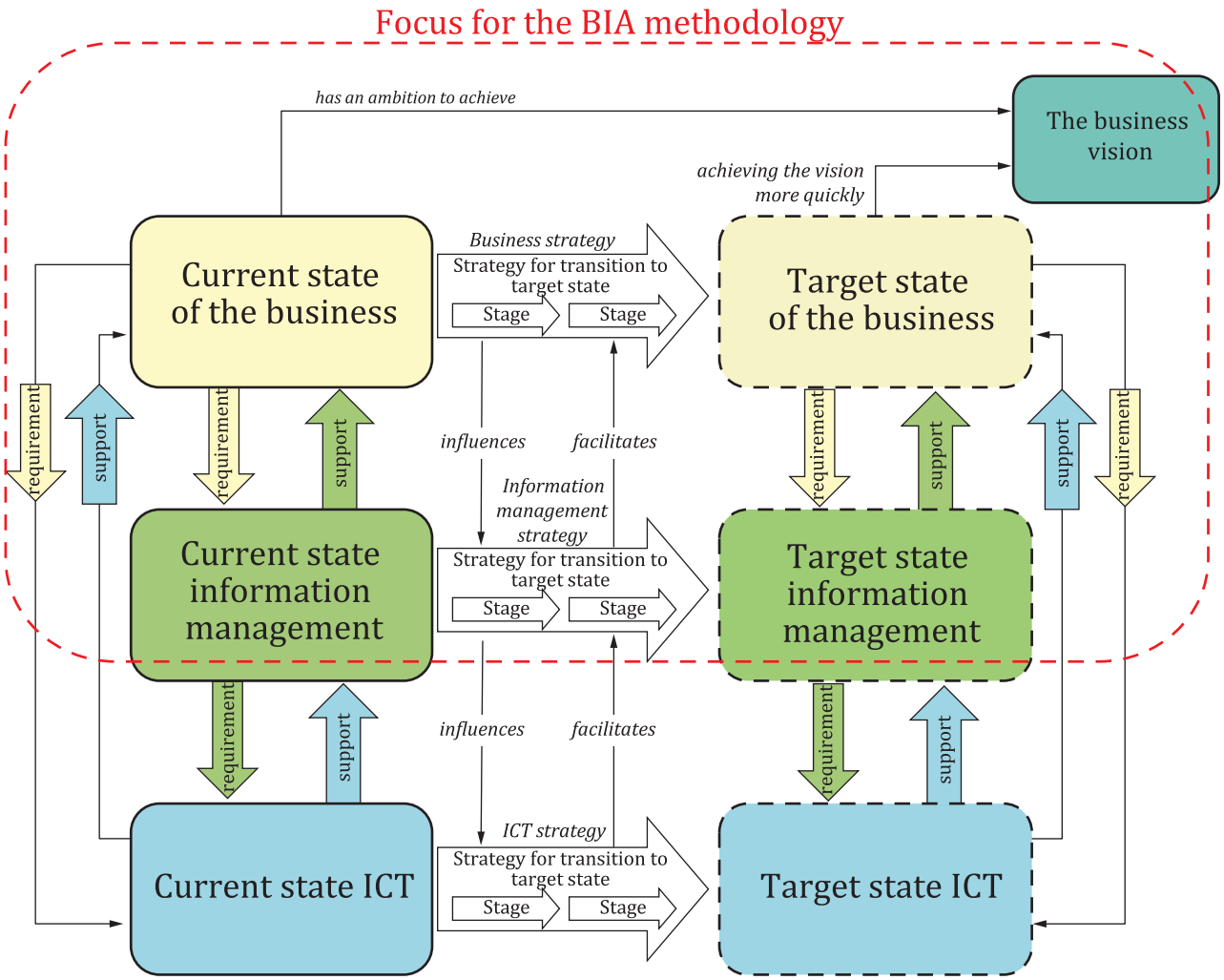

Figure 10 — The BIA methodology focus

The results of these analysis provide a deep and an aggregate understanding of the business and its information management. Figure 11 shows how a business and its information management are described from various business aspects.

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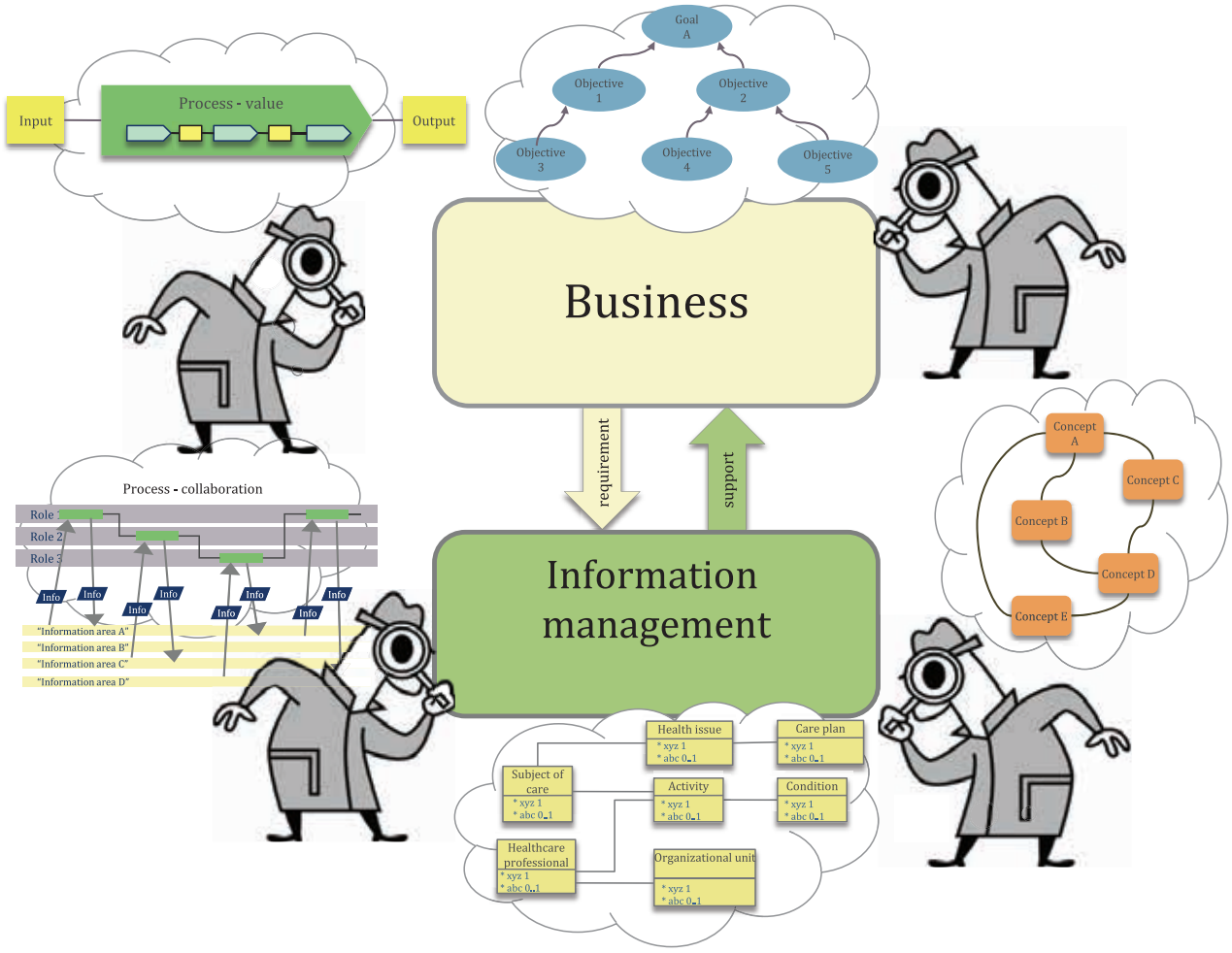

Figure 11 — Business aspects in BIA methodology

For both current and target states, the following business aspects should be identified as it shows in Figure 12:

— Analysis of the purpose of the business, its goals and objectives. The intended purpose of the business and what should be achieved. Goals – long-term, strategic, wider goal, not precisely quantifiable. Objectives – more short-term, on operational level, specific measurable. Normally structured in an **objectives** model.

— Analysis of stakeholders – those who have an interest in the outcomes and the objectives which can be linked to them. It can be roles/actors/target groups that directly interact in the business or have an interest that the business is operative. Normally described using a **stakeholder** model.

— Concepts – the concepts that are fundamental and anchored in the business so that the roles can collaborate in an effective way. Normally described using **concept** model.

— The processes which have been implemented in the business and those which should be analysed and described. Processes from a value processing perspective – patterns for action that shall ensure that the objectives are achieved. Normally described using a **process** model.

— Processes from a collaborative perspective – crystallizing of the processing perspective that shows the business roles in collaboration. Normally described using a **process** model.

— The kind of information managed in these processes and how the information is structured. Information needs – what type of information that business roles are needed in their collaboration. Normally described as a **set of information** in the form of templates, forms, checklists, etc.

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— Information structure – a comprehensive and structured description of the type of information managed by the different roles in the process formulated in a "logical and solution-neutral" **information** model. Among other things, this means that the model does not describe how, for example, a database should be structured in practice but how information is perceived to "link together" in a logical way.

— Coding systems, classifications and terminologies – agreed and predefined values which describe a certain type of information related to specific attribute in the information structure.

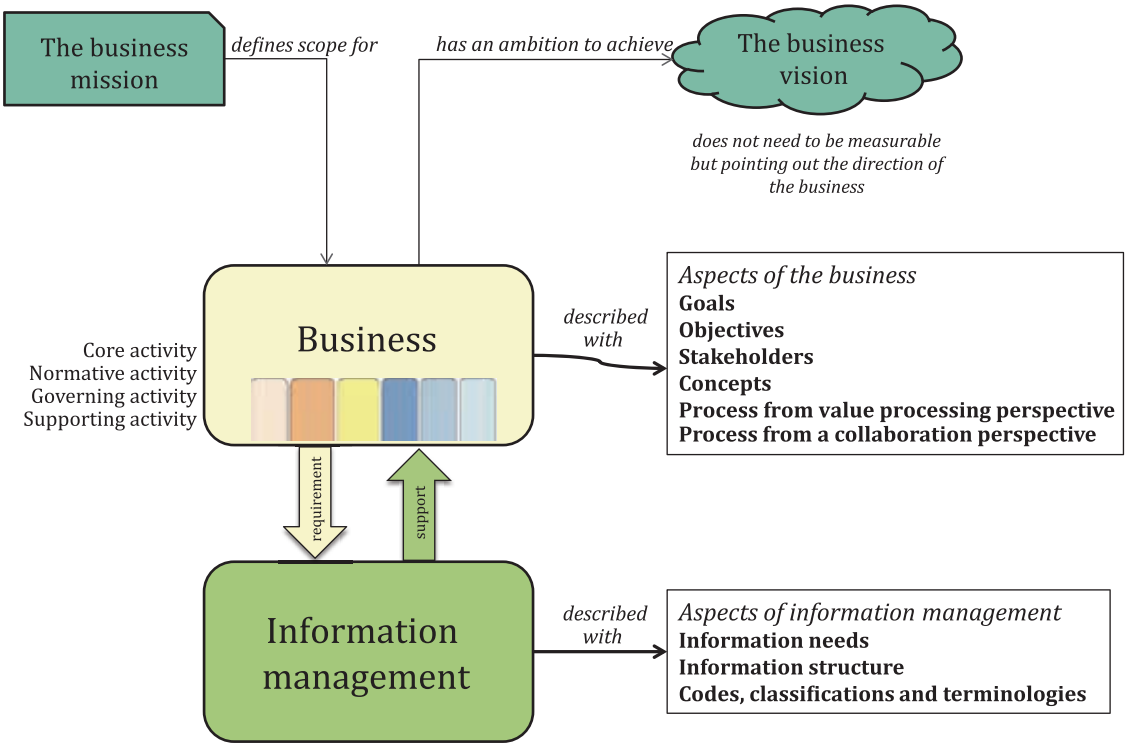

Figure 12 — Different aspects of the business and its information management

5.6 The basic concepts in the BIA methodology

Figure 13 illustrates the connections between the basic concepts in the BIA methodology.

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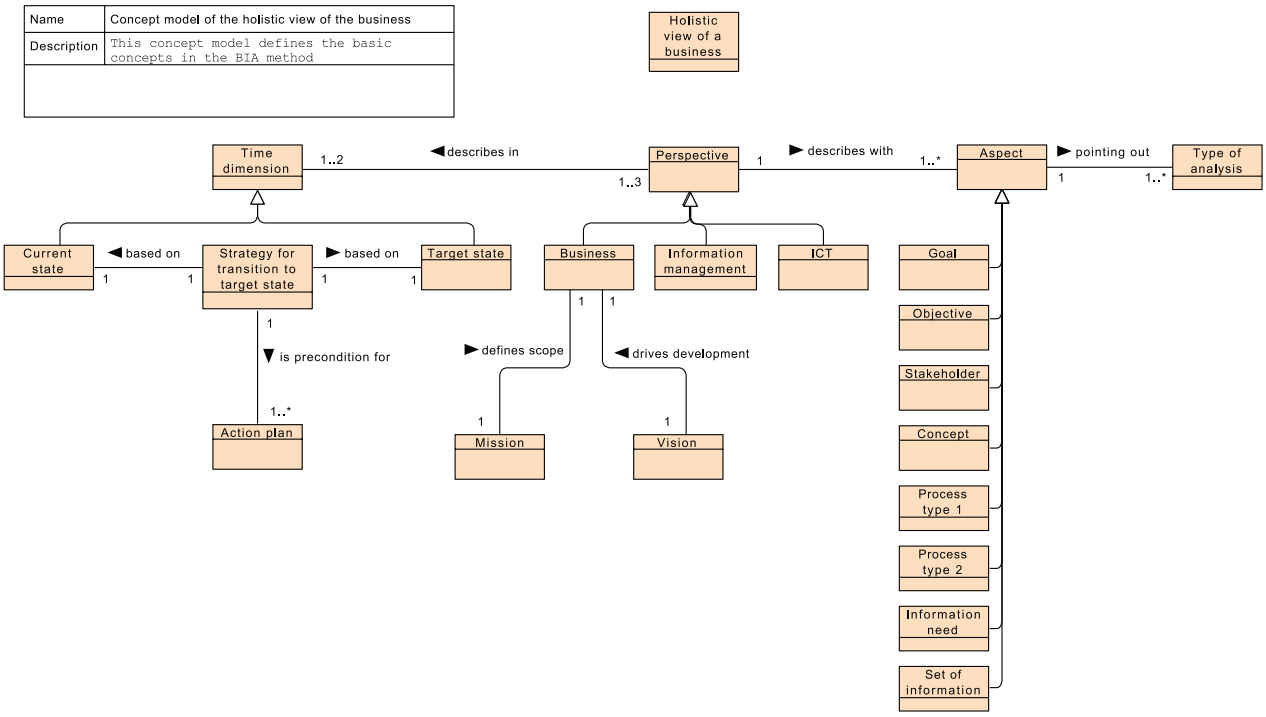

Figure 13 — Concept model of the BIA methodology

6 The route to semantic interoperability

6.1 A mutual understanding of the business

A common and agreed understanding of the business is the basis for semantic interoperability.

Semantic interoperability means that both the sender and receiver of information used in a given context within a given period of time have a common understanding of the content. This applies regardless of whether information is communicated orally or through technology.

The route to creating an effective collaboration between individuals is to ensure they have a common view and understanding. Whilst this can sound self-evident, often different perspectives exist. The reasons can include their work duties, education and experience, however this “non-common business view” can become apparent following reorganization, mergers of companies/organizations, acquiring new partners or undergoing process reengineering. All these factors have an effect on how the concepts are connected and what words or terms are used.

Consensus on these views can be achieved through the results of business analysis. However, these results should be documented as a record of decisions made or actions taken. This is where the technique of modelling comes in: all participants are given the opportunity to “see” what is being discussed and thus make the discussion easier to follow.

In addition, using models to focus on a description of the business results in a more objective outcome whereby different options for change can be tested prior to implementation.

The models shall be supplemented with textual descriptions written in a clear and precise manner in order to form an unambiguous and common perception and description of the business. The fundamental prerequisites for the ICT to work are:

— those who are setting requirements, i.e. the business representatives, are united in their view/perception of their business

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— those who are setting requirements can describe and explain their business to the designers in an unambiguous way

— those who are setting requirements can explain what kind of information they need and in which format

— the designers understand the business and its information needs descriptions then design the ICT accordingly

In order to be able to interact in an efficient and effective way, it shall be well-functioning technology which suits the business described. However, the fundamental prerequisite is that there is a common and agreed business and its information needs description. The business is responsible for describing the business and its information needs. Selecting a suitable technical solution for this is the responsibility of the ICT designers.

6.2 Prerequisites for a semantic interoperability

Each person perceives and interprets situations differently, based on knowledge and past experiences. The situation can be of a concrete nature, for example measurement results, or have a more abstract dimension such as feelings like joy, sorrow, melancholy. Should this be a new situation for an individual, (s)he will try to interpret it through association to concepts which are familiar to him / her.

Concepts can be communicated in symbols in addition to words. In this context, symbols can mean signs, gestures, images, icons, but also those items in a coding system. Whichever is used, there shall be agreement about what is meant.

In Figure 14, *xyz* is an example of a symbol. Someone perceives something in his/her "reality" and interprets this as *xyz*. This is registered and stored in a database. Sometime later, someone else, or the same person, sees this information and interprets *xyz*. How *xyz* is interpreted depends on the knowledge this person has about the "reality" from which the information originated. If we have the same frames of reference and knowledge about the "reality" then there is less risk of misinterpretation than if we have a completely different view and experience of this "reality".

The basic condition has nothing to do with the technology chosen for the transfer of information. Parties will understand each other better if they talk directly to each other as any misunderstanding can be handled immediately. More indirect communication in the form of electronic or paper documents increases the risk of misunderstanding. The basic premise is that all parties shall have a common view on and knowledge of "reality" and thus business.

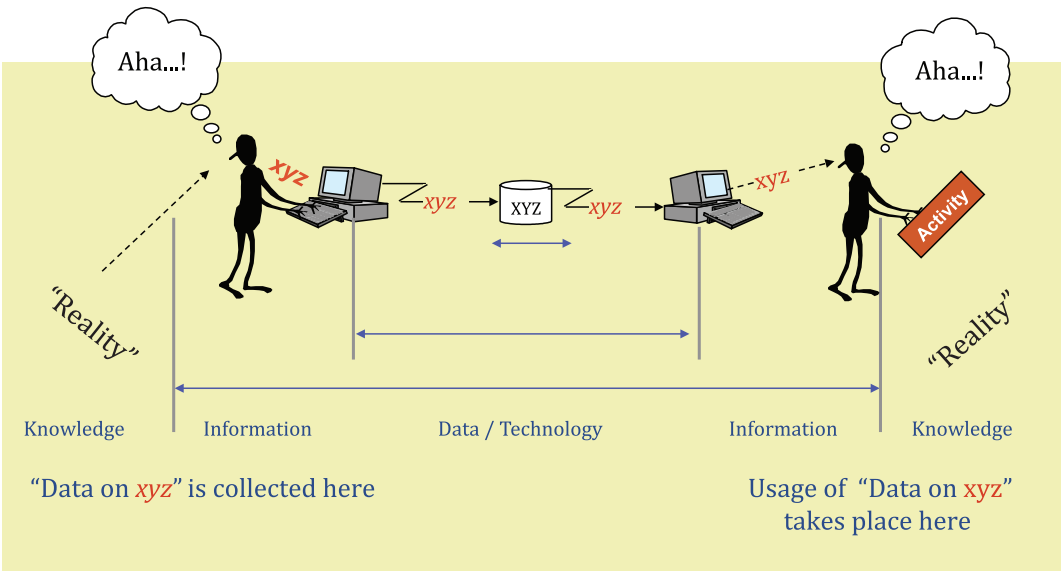

Figure 14 — A mutual understanding of information

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