WHITEPAPER

Model-Driven Digital Health

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The vision

Imagine a world where health information is available when and where needed, across systems, space, and time; where person-centered digital services help improve health and well-being at lower cost.

Healthcare systems around the world are searching for new and better ways to meet the changing demand for care. Digital health promises to transform the way we receive health services by leveraging the rapidly growing network of sensors, wearables, and mobile devices, along with internet-based technologies in connected care environments.

Can the industry deliver on this promise?

A model-driven approach to digital health helps organizations plan, build, and operate digital health solutions in the environment of care. Using industry standards and best-practices, Model-Driven Digital Health (MDDH) is an enabler to establish a culture of quality and organizational excellence within and across organizations and make the vision of digital health a reality.

Why we must act

Digital health is achieving widespread market acceptance and adoption, with multiple vendors offering digital health platforms and solutions. However, the industry lacks common frameworks, use models, and best-practices. This leads to inefficiencies, lack of collaboration among stakeholders, and ultimately reduces quality and increases cost.

Model-Driven Digital Health is an enabler and important driver to establish the required standardization to make digital health a success.

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Value Proposition

At the heart of digital health is the person journey, our journey, through the healthcare system. On this journey, many actors work together to deliver services, provide, and use devices, software, vaccines, and medicinal products, and generate and consume data. Model-driven digital health provides value to each actor and their interactions across the health ecosystem:
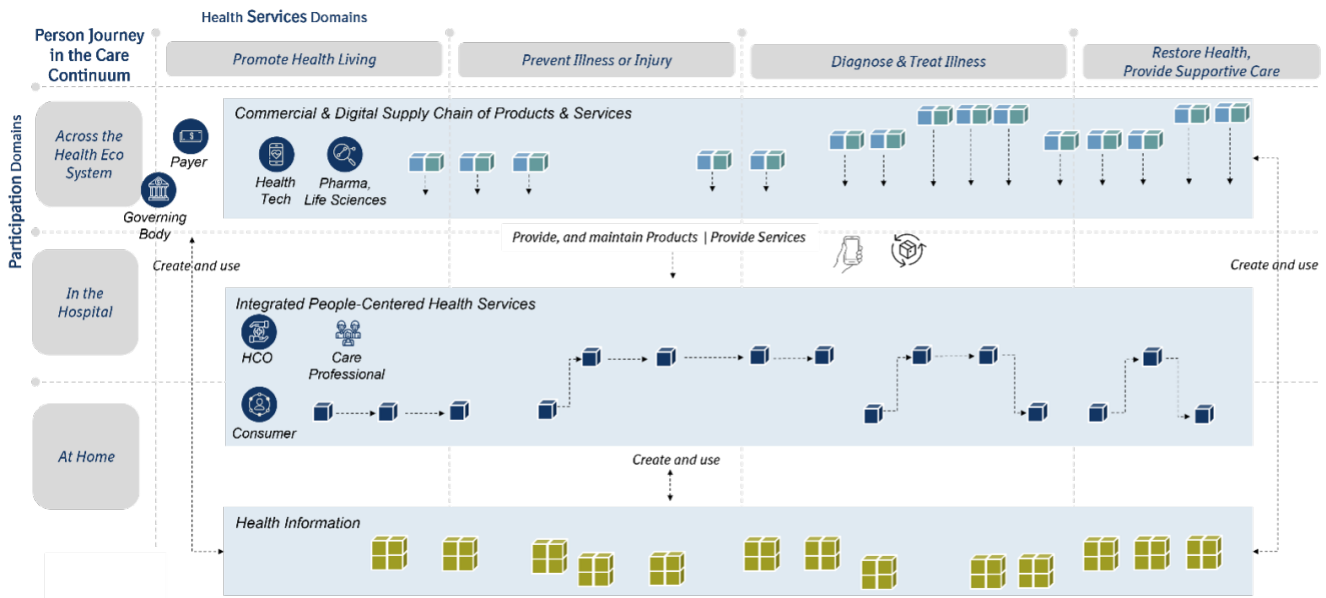
Patient | Health Worker

Patients and health workers can rely on common use models, consistent service offerings, shared health information, and a common supply chain 'way of working', driven by standardization and the use of best practices, promoted by MDDH.

Provider | Payer

Providers and payer organizations can rely on models, approaches, and offerings that share commonalities across different technologies.

Digital Health Providers

Digital health solution providers can reduce cost and time to market by leveraging established models, methodologies, and tools to drive consist-ency across their portfolio and supply chain.
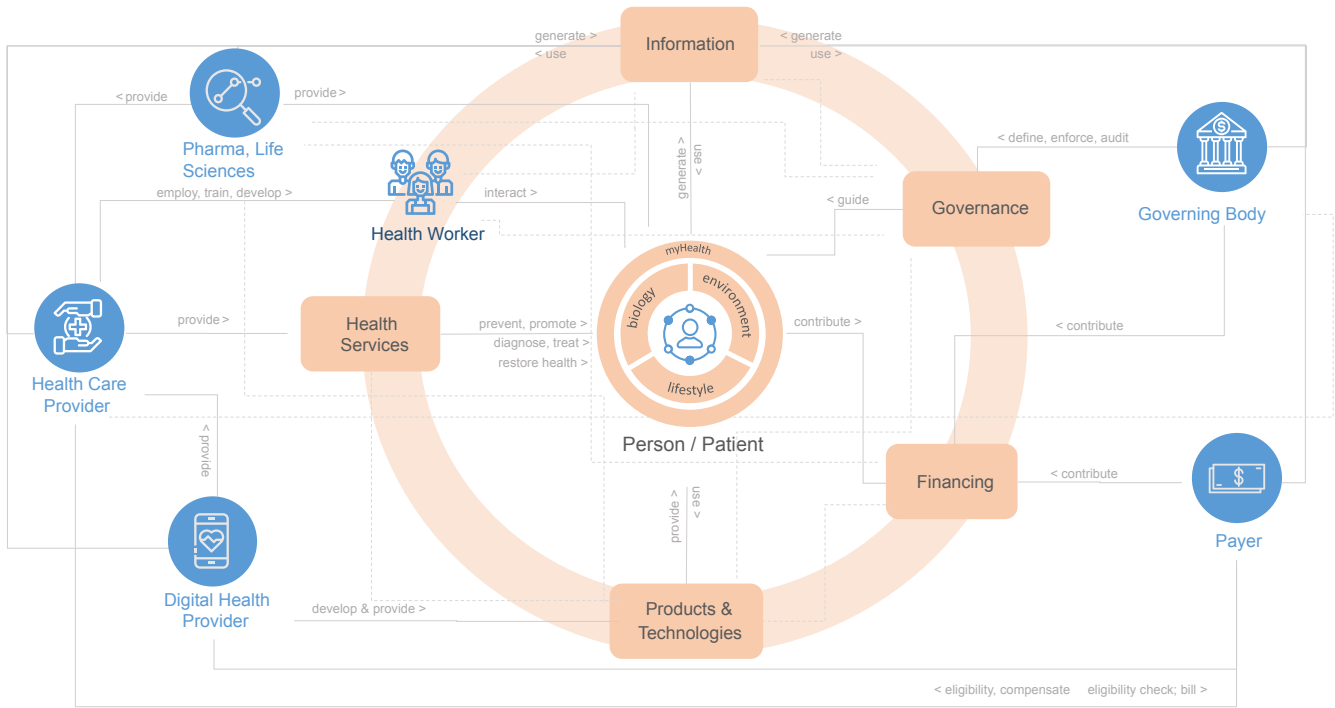
Governing Body

Governing bodies can drive standardization in the healthcare ecosystem through the adoption and application of Model-Driven Digital Health.

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Usage Scenario

Users and beneficiaries of digital health are diverse, ranging from consumers to healthcare providers, payers, technology/service providers, and governing bodies.

Let's explore the power of Model-Driven Digital Health using the fictional example of Curis, a multi-hospital group, and CDS+, the maker of a micro-services-based clinical decision support solution.

In this scenario, Curis enters into an agreement with CDS+ to use their digital solution. Curis plans for a hybrid deployment, with selected microservices hosted and operated by the hospital in its private cloud environment. The hospital group's QMS requires the qualification of the software for its intended use.

The scenario begins with John, the CDS+ validation manager, and his team. John uses the manufacturer's application lifecycle management tool to validate and verify software releases based on the CDS architecture model in UML®. He uses VVML, a domain-specific language (DSL), to describe validation and verification activities.
Anna, the CDS+ solution architect, interacts with Frederique, the IT architect and validation manager of Curis.
Anna takes various approved models from the CDS+ model repository and

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shares them with Frederique, who uses them as input to qualify the CDS solution and plan its deployment. In parallel, John, the CDS+ validation manager, delivers the VVML validation and verification scripts, which significantly reduces Frederique's effort and time to qualify the CDS solution.

After the qualification, Ajay, the Curis IT system owner, deploys the CDS+ solution in its cloud environment. Ajay uses a configuration management database to establish an up-to-date model of the deployed configuration items (CIs). The deployed CIs are exchanged with the operational model of the CDS+ hosting environment in a federated CMDB that is used by both organizations to maintain and service the CDS solution.

Scope

Digital health solutions combine software, hardware, services, and data into a coherent offering to solve a healthcare-related problem. They require a supporting supply chain to deliver these elements. MDDH must reflect the complexity of digital health solutions and provide a framework and reference models that integrate individual elements into a unified lifecycle.
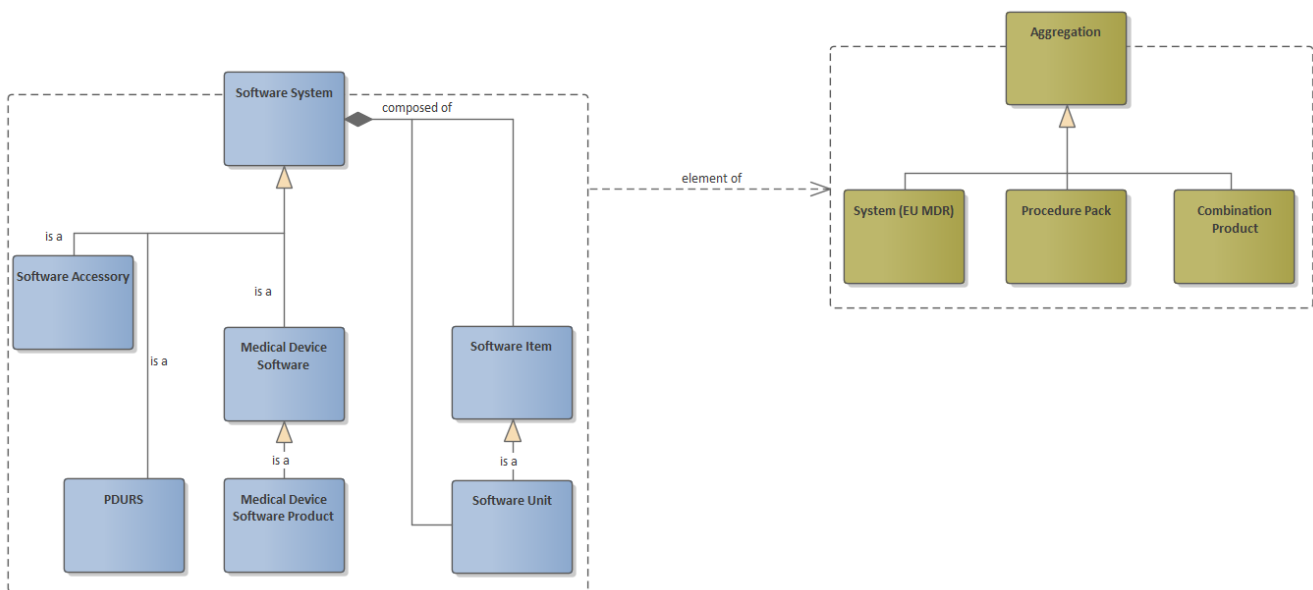
Digital Health Solutions

Product

MDDH must cover individual products, as well as the aggregation or grouping of products, as shown for software products:
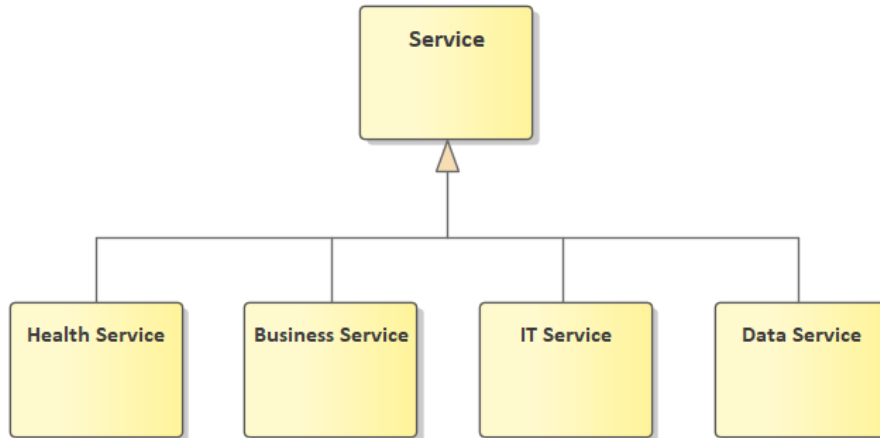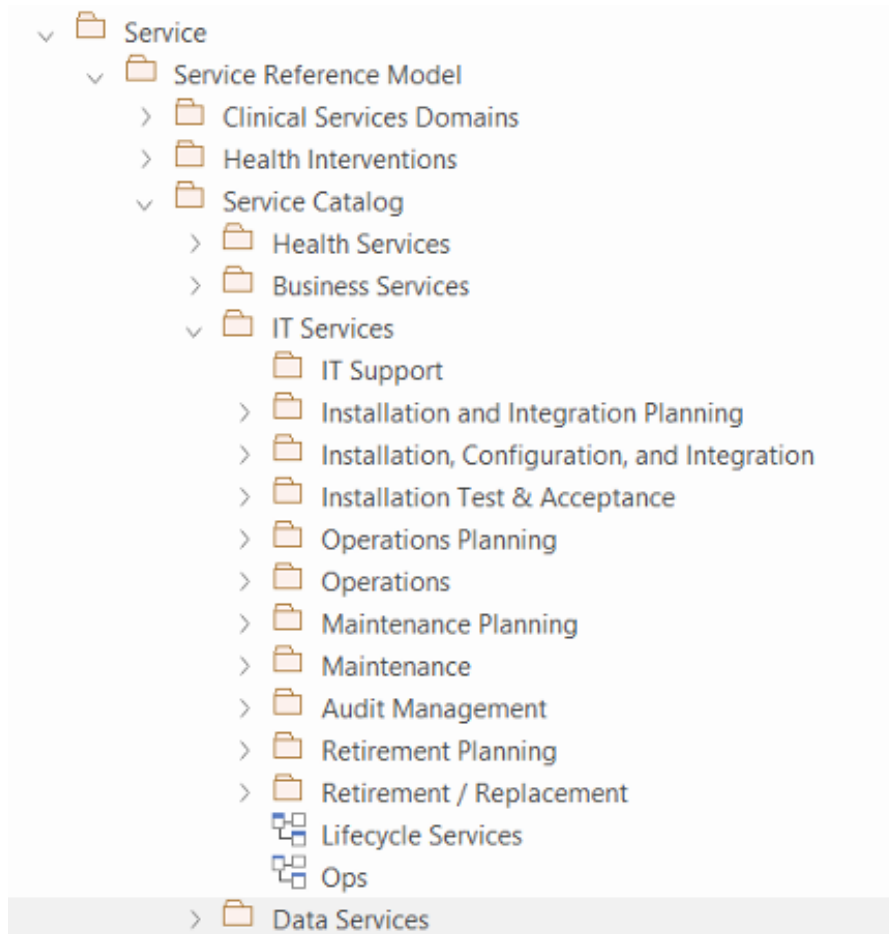
Service

MDDH may cover several categories of services, summarized in the following diagram:

For each category, MDDH must specify reference service models, as shown in the following example for IT services:
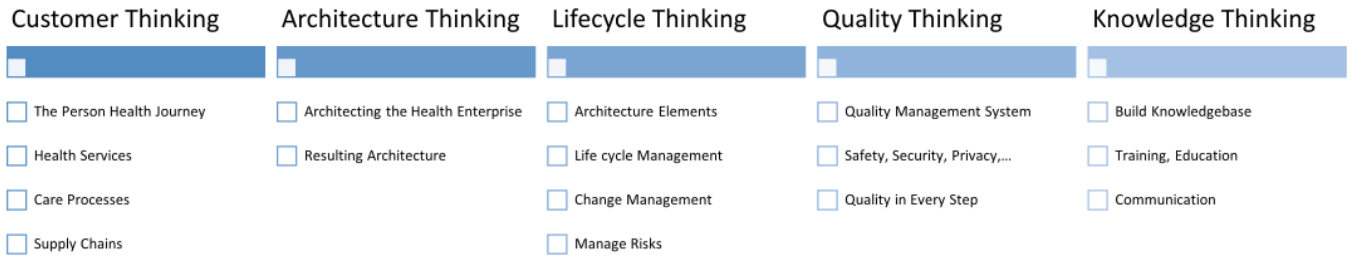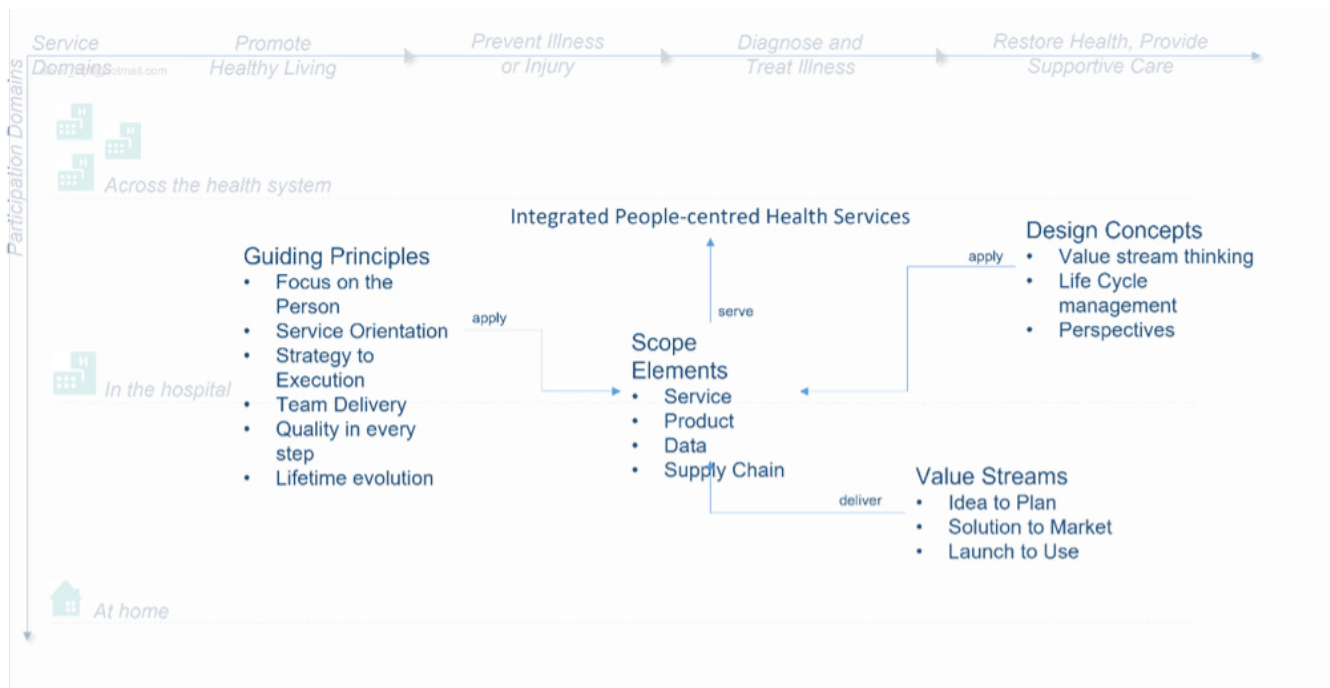

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The Approach

Model-driven for healthcare starts with a way of thinking that is specific to an industry where 'do no harm' is paramount:

| Customer Thinking	Architecture Thinking	Lifecycle Thinking	Quality Thinking	Knowledge Thinking
☐ The Person Health Journey	☐ Architecting the Health Enterprise	☐ Architecture Elements	☐ Quality Management System	☐ Build Knowledgebase
☐ Health Services	☐ Resulting Architecture	☐ Life cycle Management	☐ Safety, Security, Privacy,...	☐ Training, Education
☐ Care Processes		☐ Change Management	☐ Quality in Every Step	☐ Communication
☐ Supply Chains		☐ Manage Risks		

In support of integrated People-Centered Health Services, MDDH has to manage the life cycle of digital health solutions from Idea to Customer:

The required outcome is a set of methodologies, languages, and tools that provide the necessary models in the design, development, and operations domain:
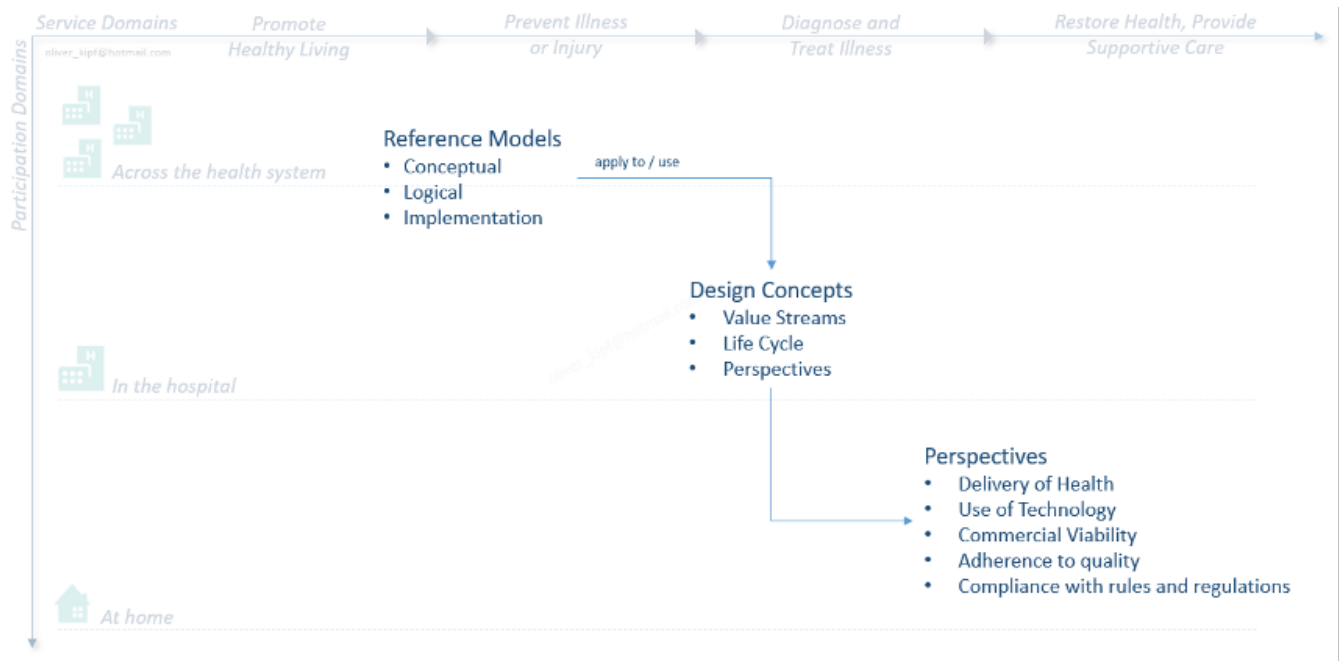
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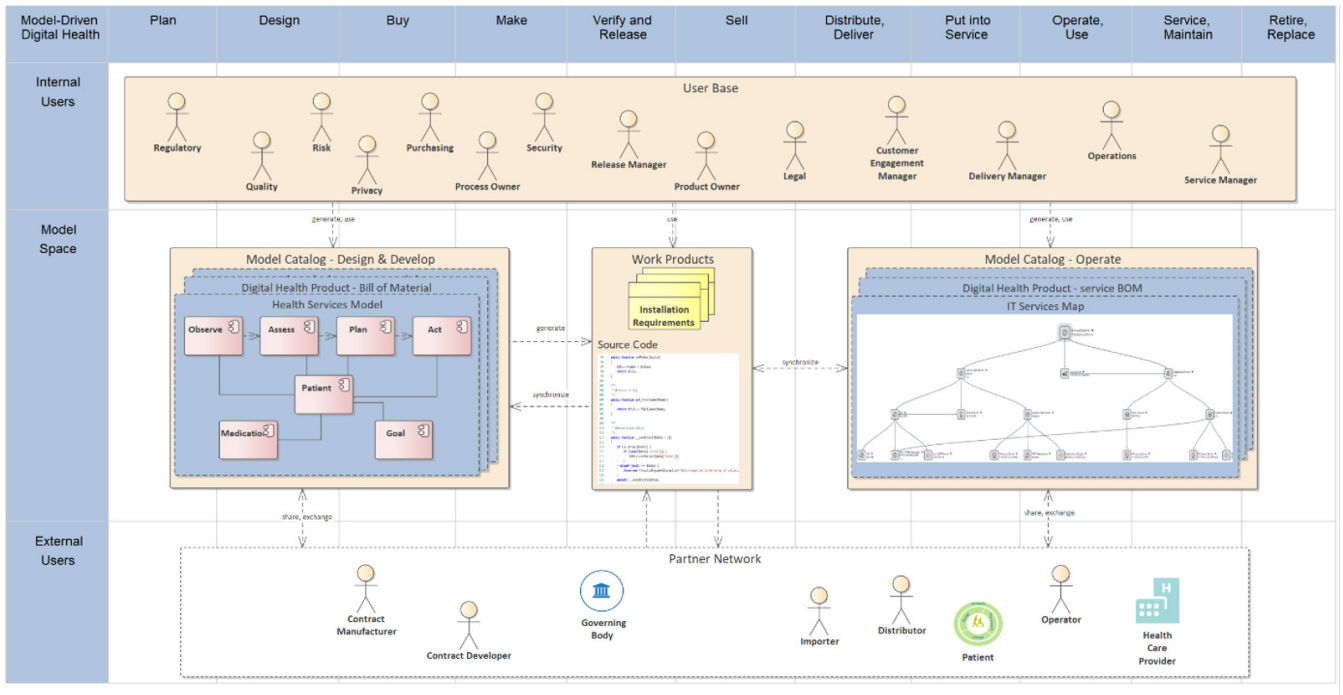
Methodology

MDDH must provide a set of reference models and perspectives to help manage value streams and the lifecycle of digital health solutions:

Special attention must be paid to control the commercial and digital supply chain and the flow of objects, as shown in the following overview:

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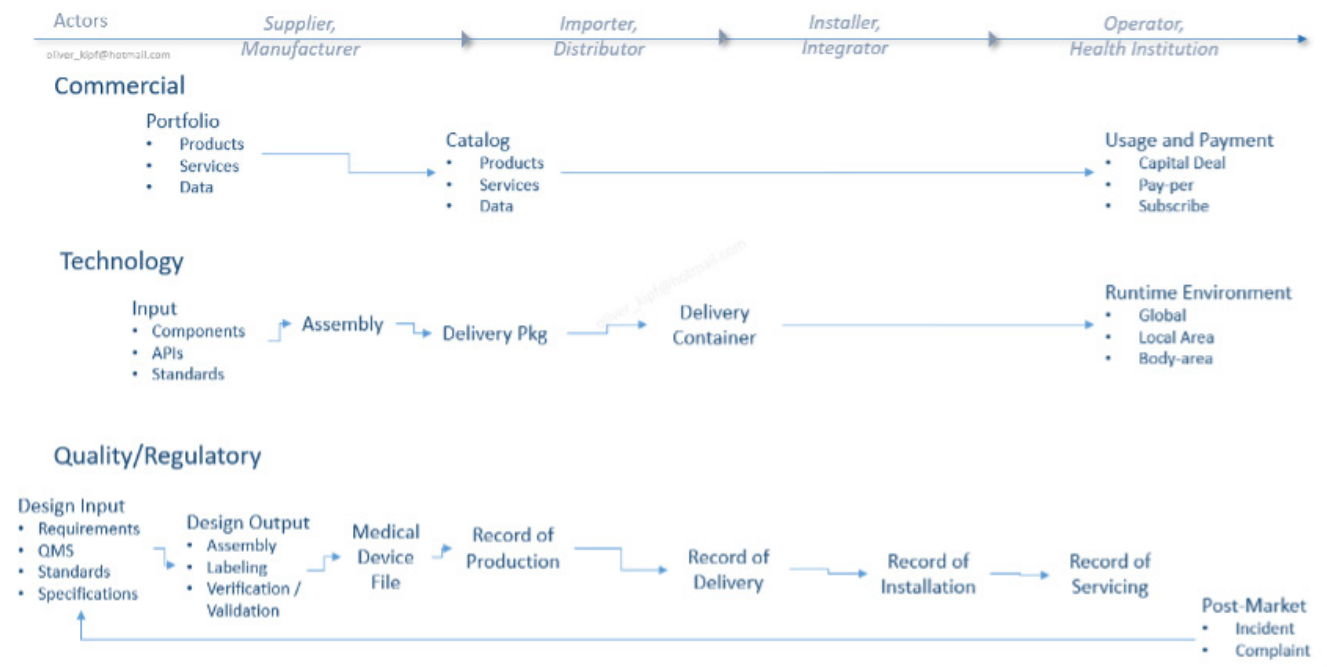
Language

Model-Driven Digital Health needs to include different modeling languages, such as Archimate®, UML®, BPMN™, or DMN™, according to their intended use into a coherent framework.

Tools

MDDH requires a tool chain that includes application lifecycle management in the design space, such as Enterprise Architect, and the operations and servicing space, such as ServiceNow®, to provide a complete picture from design to implementation.

Standards

To help organizations meet their regulatory obligations and promote standardization, MDDH requires the inclusion of standards related to products, data; and services, as shown in the following diagram:
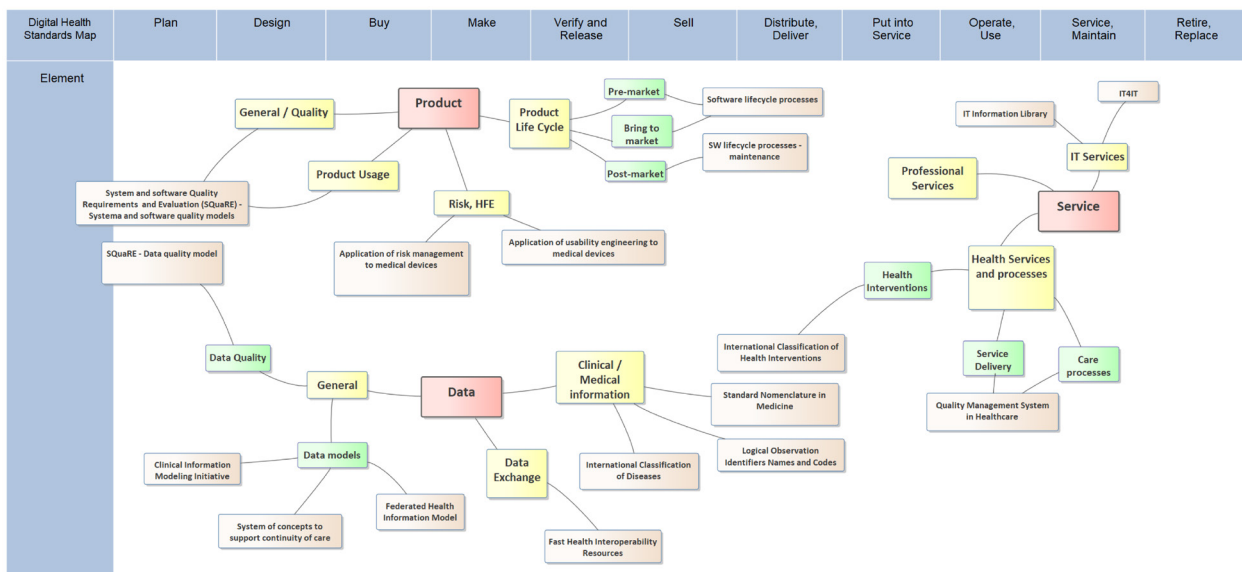
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<u>Supplements</u>

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Terms and Abbreviations
This paper uses the following terms and abbreviations:

Term	Meaning	Reference
ALM	Single Payer	
CDS	Beveridge model, Semashko model	
CI	National Health Insurance	
CMDB	Configuration Management Database	
Digital Health	Digital health is the application of information and communication technology in the health sector to help manage diseases and support wellness through data, images, and other forms of digital information	[WHO Digital Health Platform Handbook](#)
DHS	A Digital Health Solution (DHS) is the combination of hardware, software, services, and data to solve a health-related problem, and the supply chain to provide the solution and its elements	
DSL	Domain-specific language	
FDA	U.S. Food and Drug Administration	
Health System	A health system consists of all organizations, people, and actions whose primary intent is to promote, restore or maintain health.	[Health system - Wikipedia](#)
IMDRF	International Medical Device Regulatory Forum	
MDDH	Model-driven digital health (MDDH) is an approach using standardized models, languages, methods, and tools, to plan, build, and run a Digital Health Solution	
PDURS	Prescription Drug Use Related Software (PDURS)	
QMS	Quality Management System	
SaMD	Software as a Medical Device	
UML	Unified Modeling Language	

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