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Standards and Principles to Enable Interoperability and Integration of 5P Medicine Ecosystems

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Abstract. Health and social care ecosystems are currently a matter of foundational organizational, methodological and technological paradigm changes towards personalized, preventive, predictive, participative precision (5P) medicine. For designing and implementing such advanced ecosystems, an understanding and correct representation of structure, function and relations of their components is inevitable. To guarantee consistent and conformant processes and outcomes, the specifications and principles must be internationally standardized. Summarizing the first author's Keynotes over the last 15 years of pHealth conferences, the paper discusses concepts, standards and principles of 5P medicine ecosystems including their design and implementation. Furthermore, a guidance to find and to deploy corresponding international standards in practical projects is provided.

Keywords. 5P medicine, ecosystem. System architecture, knowledge representation, knowledge management, modeling, integration, interoperability

Introduction

Health and social care around the globe undergo a transformation into advanced health ecosystems. An ecosystem is a system or network of living and nonliving interconnecting and interacting elements to meet specific objectives. The transformation is bound to fundamental organizational, methodological and technological paradigm changes. Organizationally, the systems move from organization-centered local services through cross-organizational local services, distributed local and remote services to ubiquitous care. Methodologically, they transform health from empirical, phenomenological medicine with one solution fitting all, through evidence-based medicine with domain-specific services for decease-specifically defined groups, person-centered medicine, and personalized medicine, up to 5P medicine. 5P medicine, i.e., personalized, preventive, predictive, participative precision medicine or systems medicine considers the individual

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in its personal, environmental, social, occupational, and behavioral context, thereby deploying life sciences, social sciences, and engineering sciences, but also specialties such as the bunch of omics disciplines and others. The actors' community expands from regulated professionals through regulated and non-regulated professionals up to the inclusion of laymen and technical systems. Interoperability advances thereby from signal sharing through data sharing, information sharing, knowledge sharing at IT-concept level, knowledge sharing at business concept level, knowledge sharing at domain level (cross-domain cooperation), up to skills-based knowledge sharing (moderated end-user collaboration). Such transformation must be supported by appropriate technologies from mobile devices through wearable and implantable sensors and actuators, pervasive sensors, actuators and network connectivity, up to micro, molecular, and quantum level. By combining the advancements in societies, sciences including data sciences, and technologies, health and social care systems are transformed into 5P medicine ecosystems. The outcome of the process enables early identification, proactive intervention and full understanding of the course of disease, i.e., its pathology and its effective treatment. It allows for health service provision everywhere anytime, thereby individualizing the system according to status, context, needs, expectations, wishes, etc., of the subject of health and social care. More details can be found at [1].

Table 1 summarizes the organizational paradigm changes in transformed health and social care ecosystems.

Table 1. Organizational paradigm changes in transformed health and social care

Care Type	Organization, Service Provision	Actors	Services	Target
Phenomenological medicine	Organization-centered - Local services	Regulated professionals	Domain-specific general services – one solution fits all	Humanity
Evidence-based medicine	Organization-centered - Local services	Regulated professionals	Domain-specific, group specific services	Disease-specifically defined group
Person-centered medicine	Cross-organizational - Local services	Regulated professionals	Multiple domains' services	Individual
Personalized medicine	Distributed - Local and remote services	Reg. and non-reg. professionals, laymen, technical systems	Multiple domains' services - Telemedicine	Individual in personal disposition
Systems medicine - 5P Medicine	Distributed cross-domain services, Smart healthcare	Reg. and non-reg. professionals, laymen, technical systems	Cross-domain services - Consumerism, Telemedicine	Individual in personal, environmental, social, occupational. and behavioral context
Ubiquitous personal health	Ubiquitous autonomous and intelligent services	Reg. and non-reg. professionals, laymen, technical systems	Integrated services - Consumerism, Ubiquitous medicine	Individual under comprehensive focus

Table 2 highlights the methodological and technological paradigm changes as well as related requirements for standards in transformed health and social care ecosystems. The column addressing the standardization just focuses on the representation and specification of the real-world business systems. The specification for designing and implementing information and communication technology (ICT) solutions requires of course other standards and specifications, also discussed in this paper.

Table 2. Methodological, technological and standardization paradigm change in transformed health and social care

Care Paradigm	Justification	Way of Practicing	Representation Style	Electronic Comm./ Cooperation	Standards
Phenomenological Medicine	Pattern recognition	Observation	Data	Local data repository; Inside the unit	Data standards
Evidence-Based Medicine	Statistical justification of group-specific treatment outcome	Observation with objective evaluation	Information	Central data repositories	Information standards
Person-Centered Medicine	Process mgmt.; Best medical practice guidelines	Managed care	Agreed terminology, DMP Best Practice Guidelines	Cross-organizational Business Process	Terminology standards; Process standards
Personalized Medicine	Clinically justified individual status and context	Considering the pathology of disease	Disciplinary concepts in situational context	Knowledge management	Domain ontology standards
5P Medicine	Scientifically justified individual status	Understanding the pathology of disease	Multidisciplinary concepts in comprehensive context	Knowledge Space management	Multiple ontologies guided by Top Level Ontologies standards

Table 2 clearly demonstrates that the advancement in health and social care paradigms must be accompanied by related advancements in the standards world. Healthcare transformation must be supported through appropriate technologies. Table 3 presents the objectives of 5P medicine, the requirements for enabling those objectives as well as the methodologies and technologies to realize them [2, 3].

In Section 1, we will provide a comprehensive and scientifically sound representation of 5P medicine ecosystems as well as the standards for defining, modeling and implementing the related system elements.

Table 3. 5P medicine objectives, characteristics and methodologies/technologies to meet objectives (after [2], changed)

Objective	Characteristics	Methodologies/Technologies
Provision of health services everywhere anytime	• Openness • Distribution • Mobility • Pervasiveness • Ubiquity	• Wearable and implantable sensors and actuators • Pervasive sensor, actuator and network connectivity • Embedded intelligence • Context awareness
Individualization of the system according to status, context, needs, expectations, wishes, environments, etc., of the subject of care	• Flexibility • Scalability • Cognition • Affect and Behavior • Autonomy • Adaptability • Self-organization • Subject of care involvement • Subject of care centration	• Personal and environmental data integration and analytics • Service integration • Context awareness • Knowledge integration • Process and decision intelligence • Presentation layer for all actors
Integration of different actors from different disciplines/domains (incl. the participation/ empowerment of the subject of care), using their own languages, methodologies, terminologies, ontologies, thereby meeting any behavioral aspects, rules and regulations	• Architectural framework • End-user interoperability • Management and harmonization of multiple domains including policy domains	• Advanced systems architecture • Terminology and ontology management and harmonization • Knowledge harmonization • Language transformation/ translation
Usability and acceptability of 5P Medicine solutions	• Preparedness of the individual subject of care - Security, privacy, trust and ethics framework • Consumerization • Subject of care empowerment • Subject of care as manager • Information based assessment and selection of services, service quality and safety as well as trustworthiness • Lifestyle improvement and Ambient Assisted Living (AAL) services	• Tool-based ontology management • Individual terminologies • Individual ontologies • Tool-based enhancement of individual knowledge and skills • Human Centered Design of solutions • User Experience Evaluation • Individual, context-sensitive Privacy Agreements • Trust calculation services

1. Representation of 5P Medicine Ecosystems

To represent 5P medicine ecosystems, all domains involved, specific objectives and contexts, but also all steps in the development process represented as system views must be considered, thereby strictly following the good modeling best practices [4].

P5 medicine requires communication and cooperation of actors from multiple disciplines with specific perspectives, contexts, and objectives, using their special methodologies, languages, knowledge and skills to name and define the business use case concepts and relations for correctly deriving the system requirements. The challenge

of P5 medicine ecosystems is the proper representation, mapping and matching of their domain-specific knowledge at any representation level. The different representation levels or viewpoints range from the real-world business system defined by domain ontologies through the Enterprise View of the ICT system to manage the business process, the Information View and the Computational View representing the semantic interpretation of data to information, and finally the Engineering and Technology Views representing the implementable solution and its maintenance. The last five views are defined using corresponding ICT ontologies. Their according to the Chomski grammar hierarchy more and more constrained representation languages start with domain-specific or natural languages to represent the business system by domain experts. At next level, business process modeling languages like BPML and BPML+, followed by information representation languages such as vocabularies, thesauri, taxonomies, glossaries, data dictionaries, or information models, and finally data representation languages such as data/meta-data definitions, database management system (DBMS) schemes, or programming languages are used. In their data modeling hierarchy, Hoberman et al. [5] call the aforementioned representation levels as very high level, high level, logical level, and physical level, respectively. The corresponding representation of a multi-domain, ontology-based, policy-driven P5 ecosystems using the model and framework of the ISO 23903 Interoperability and Integration Reference Architecture [6], discussed in the next section, is shown in Figure 1.

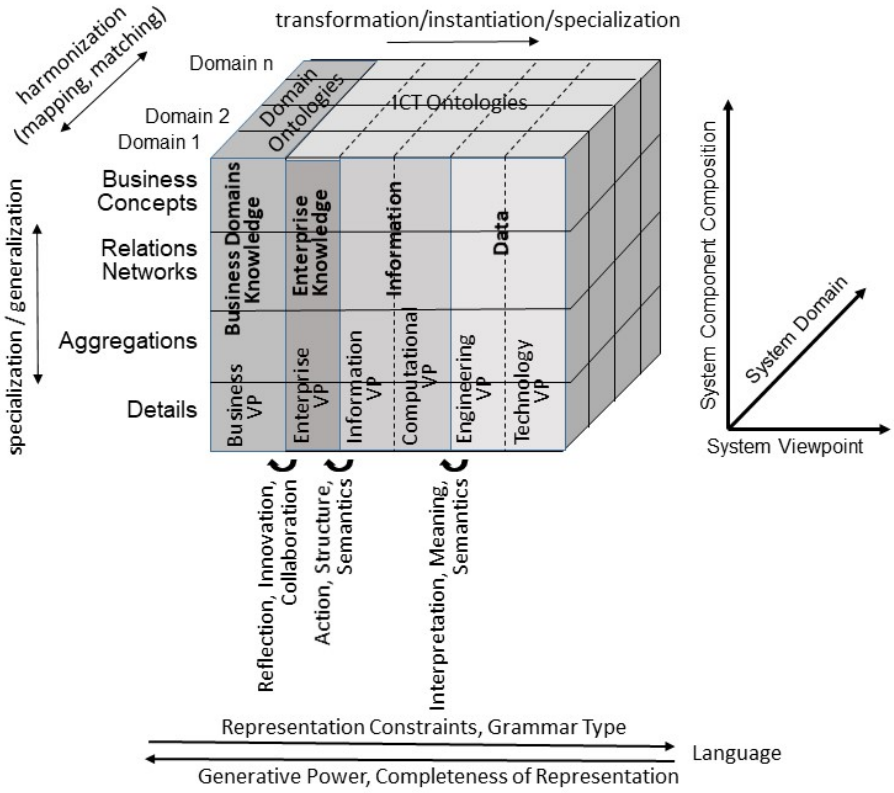

Figure 1. Model and framework for representing multi-domain, knowledge-based, ontology-based, policy-driven ecosystems.

The mapping between elements from different domains or different viewpoints can only be performed at horizontal level, i.e., at the same level of granularity. To get there, components must be specialized or generalized, respectively.

For designing, developing and implementing P5 medicine ecosystems, we must generically model the system architecture and the unified process around. Thereafter, we have to represent formally the domains involved in the use case of the business system considered. Then, we have to represent the different views in the contexts and under the perspectives of the domain experts participating in the business use case. A domain controlling the business system behavior and therefore being relevant across all specific use cases is, e.g., the policy domain, covering legal, administrative, security, privacy and trustworthiness as well as ethical aspects.

For managing organizations to meet their objectives, interests and needs, strategic, operational and tactical aspects must be considered. In that context, related standards and procedures have to be established beside policies to create a strong governance structure. Security and privacy policies addresses the operational needs [7].

Consequently, we need architecture standards, knowledge representation and management standards including ontology standards and terminology standards, policy standards, business process modeling standards, information standards and data standards to model and implement the 5P medicine ecosystem in a compliant and conformant way. Each standards family will be discussed and exemplified in some detail in the next sections.

2. Standards for Modeling 5P Medicine Ecosystems

The solution for designing, managing and implementing the intended ecosystem is a system-theoretical white box, architecture-centric, ontology-based and policy-controlled approach, meanwhile standardized as ISO 23903 Interoperability and Integration Reference Architecture – Model and Framework and re-used by many international Standards Developing Organizations (SDOs) such as ISO, CEN, IEC, IEEE, OMG, but also HL7. Beside the definition of the modeling and system development process, ISO 23903 also covers challenges such as domain-specific knowledge representation and management at epistemological level as well as its harmonization. In that context, it supports ontology development and harmonization, but also the implementation of good modeling best practices.

2.1. Architecture Standards

Regarding the architectural approach, ISO 23903 builds on ISO/IEC/IEEE 42010:2011 Systems and Software Engineering – Architecture Description[2] [8] and ISO/IEC/IEEE 42020:2019 Software, Systems and Enterprise – Architecture Processes [9]. On that basis, ISO/IEC 10746 Open Distributed Processing [10] has been widely introduced, which is a family of international standards for describing and developing distributed systems and applications. Regarding the system development process, ISO 23903 refers to ISO/IEC 10746 and the Rational Unified Process (RUP) [11]. Another architectural approach, reusing the Reference Model of Open Distributing Processing (RM-ODP) is the HL7

[2] ISO/IEC/IEEE 42010 is originally based on ANSI/IEEE 1471-2000 Recommended Practice for Architectural Description of Software-Intensive Systems.

Version 3 Development Framework (HDF), advancing the messaging approach HL7 started with.

Almost all architecture standards focus on the ICT perspective and ignore the importance of real-world communication and cooperation between the domain experts, which is however crucial for all ecosystems and especially for the 5P medicine ecosystems. ISO 23903 extended the aforementioned standards by the business view represented by domain experts. Contrary to those standards, ISO 23903 introduced a three-dimensional model with the additional domain perspective dimension to represent multiple domains involved in the ecosystem's specific use cases and with the component composition dimension, thereby re-using the OMG Model Driven Architecture hierarchy [12]. The latter starts with the computation independent model (CIM) or requirement model defining the system in its environment. CIM is transformed into the platform independent model (PIM) or analysis and design model defining the system's architecture. PIM is then transformed into the platform specific model (PSM) or realization model defining how the system is built. At the end, the code of the system and configuration artifacts is generated [13]. An overview on architecture standards and approaches including their relations to ISO 23903 is provided in [14]. Table 4 compares those data model levels as well as the dimensions of modeling with the model and framework of ISO 23903 and ISO/IEC 10746.

Table 4. Comparing Data Model Levels and Dimensions of Modeling with ISO 23903 and ISO 10746

Data Model Level	**Modeling Actors**	**Model Scope**	**Dimension of Modeling**	**Interop. Reference Architecture**	**Examples**		
Very-high-level data model	Business domains stake-holders	Scope, requirements and related basic concepts of business case	Knowledge space	Business View			ISO 23903 Interoperability and Integration Reference Architecture
High-level data model	Business domains stake-holders	Relevant in-formation and representation & relation-ships of basic concepts	Knowledge	Enterprise View	DCM, CSO	ISO 10746 ODP-RM	
Logical data model	Data modelers and analysts	Layout & types of data and object relationships	Information	Information View	HL7 V3 (CMETs), HL7 CIMI, openEHR Archetypes, FHIM		
				Computational View	HL7 FHIR		
Physical data model	Data modelers and develo-pers	Implementati on-related and platform-specific aspects	Data	Engineering View			

2.2. Knowledge Representation and Knowledge Management Standards

Regarding the business system representation from the perspective and context of the domain experts involved by formally representing their knowledge, we deploy the related domain ontologies. An ontology provides an explicit specification of a conceptualization [15]. It is a collection of terms, relational expressions and associated natural-language definitions in combination with formal theories [16] to represent that knowledge.

Medical/clinical domain terminologies and ontologies for 5P medicine ecosystems are, e.g., the Unified Medical Language System (UMLS) [17], the SNOMED International products Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) and Systematized Nomenclature of Medicine Clinical Term Ontology (SCTO) [18], ISO 25720 Genomic Sequence Variation Markup Language [19], Human Phenotype Ontology (HPO) [20], Infectious Diseases Ontology (IDO) [21], Epilepsy and Seizures Ontology (EPSO) [22], Alzheimer's Disease Ontology (ADO) [23], or the Gene Ontology (GO) [24].

2.3. The Policy Domain

A policy defines a set of legal, regulatory, ethical, and contextual requirements and obligations for communication and cooperation including privacy and trustworthiness. That way controlling the intended behavior of business systems, a policy domain representing policy knowledge, concepts and relations is crucial for defining, designing and running any type of ecosystems. Using the ISO 23903 model and framework, Figure 2 demonstrates the specialization of the policy domain into the sub-policy domains relevant for P5 medicine ecosystems. The user policy domain – sometimes also called personal policy domain or individual's policy domains – represents the intentions, expectations, wishes, etc., of the individual engaged in the business case such as a patient.

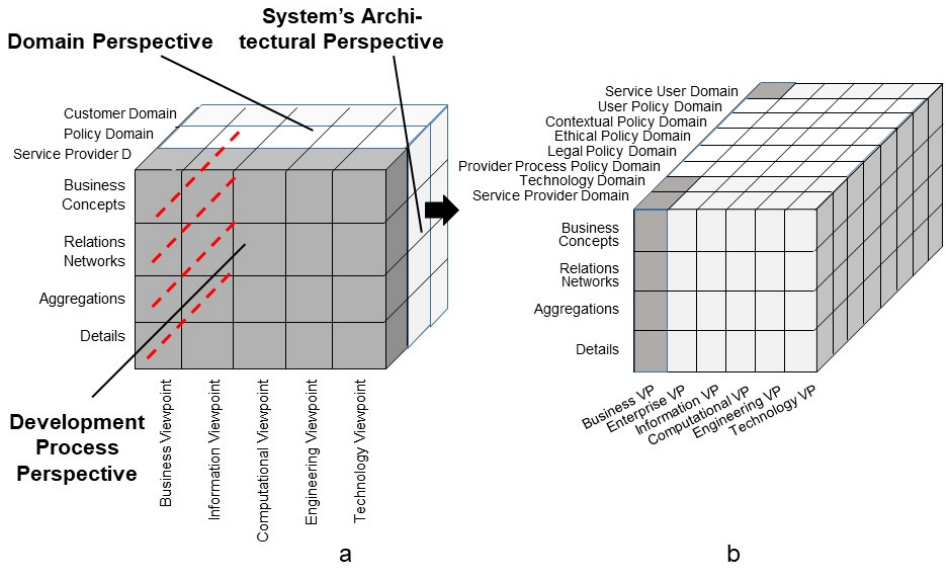

Figure 2. Specialization of the policy domain into sub-policy domains relevant for P5 medicine ecosystems (after [25], changed)

An example for a provider process policy domain instance are best practice clinical guidelines. All sub-policy domains must be represented using related ontologies.

Based on the Ponder Language specification [26], a policy ontology to formalize the rules and constraints controlling the behavior of a business system has been provided by ISO 22600 [27], instantiated for the security and privacy domain (Figure 3).

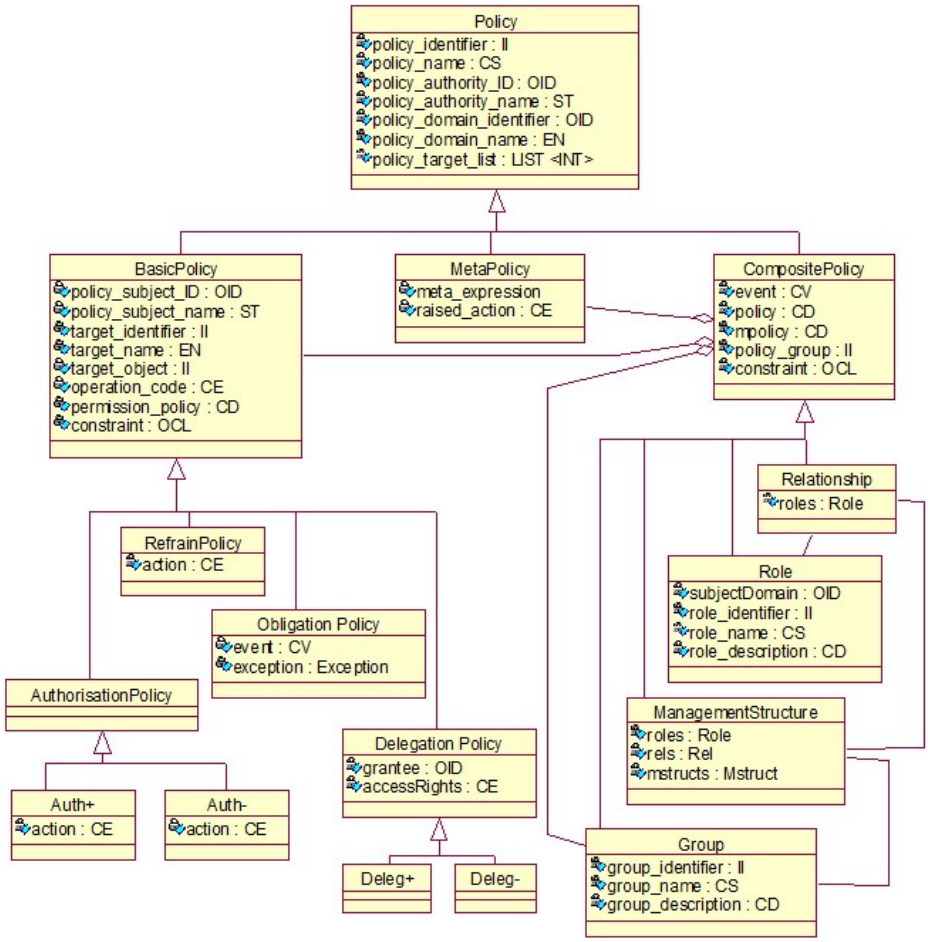

Figure 3. Policy domain components according to ISO 22600-2 [27]

The integration of that policy ontology in an ecosystem for managing security and privacy, using ISO 23903, has been performed in the HL7 Privacy and Security Logical Data Model, Release 1, June 2021 [28] (Figure 4).

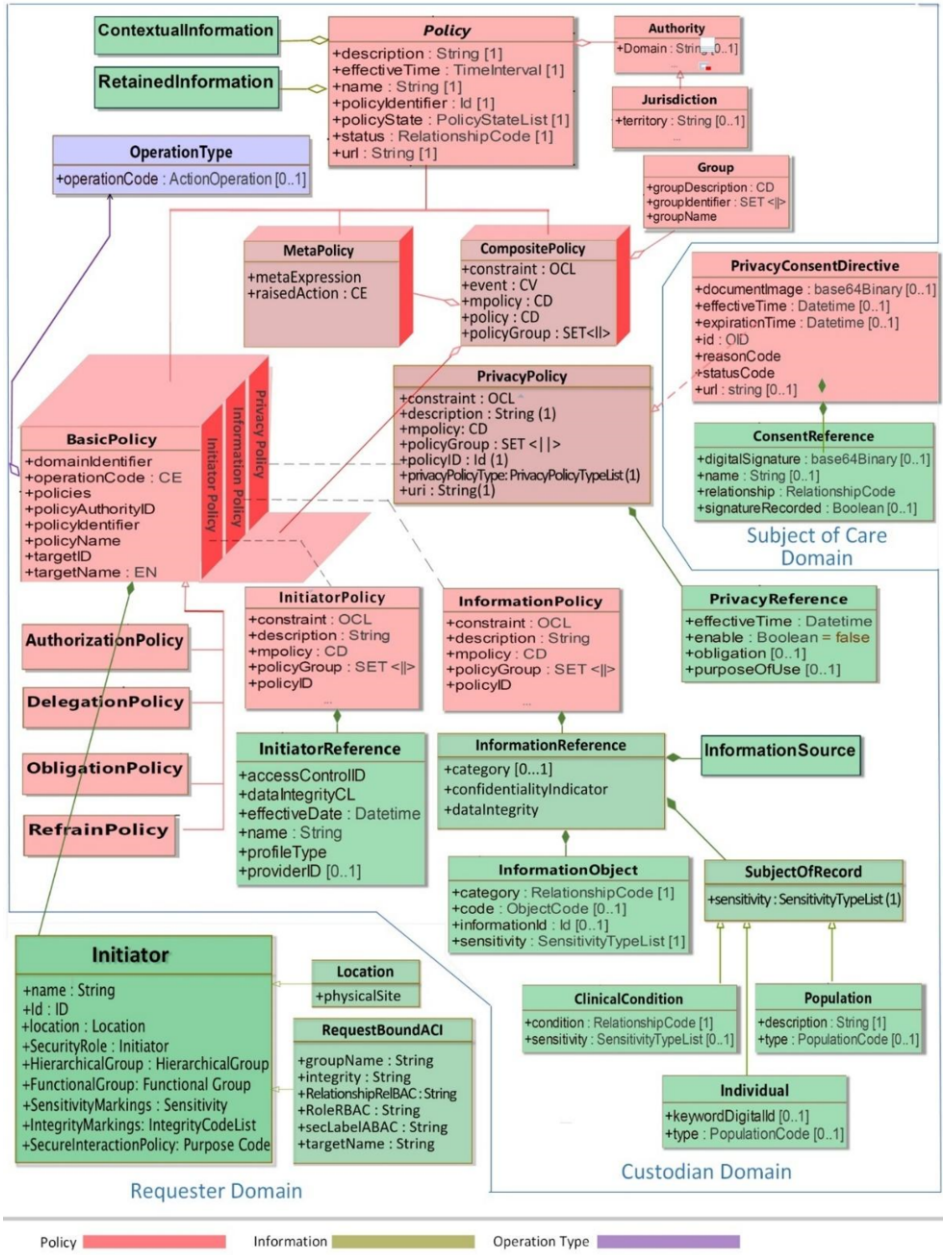

Figure 4. HL7 Privacy and Security Logical Data Model, Release 1, June 2021 [28]

The integration of ethical and trust aspects of autonomous and intelligent 5P medicine ecosystems has been developed at IEEE with a first global ontological standard for ethically driven robotics and automation systems (ERAS) [29].

For mapping and matching different ontologies to enable cross-domain communication and collaboration, the ontologies have to be represented or re-

engineered, respectively, as formal entities including their contexts, constraints and relationships by using attributes and relations according to ISO/IEC 21838:2021 Information Technology – Top Level Ontologies [16] (Figure 5).

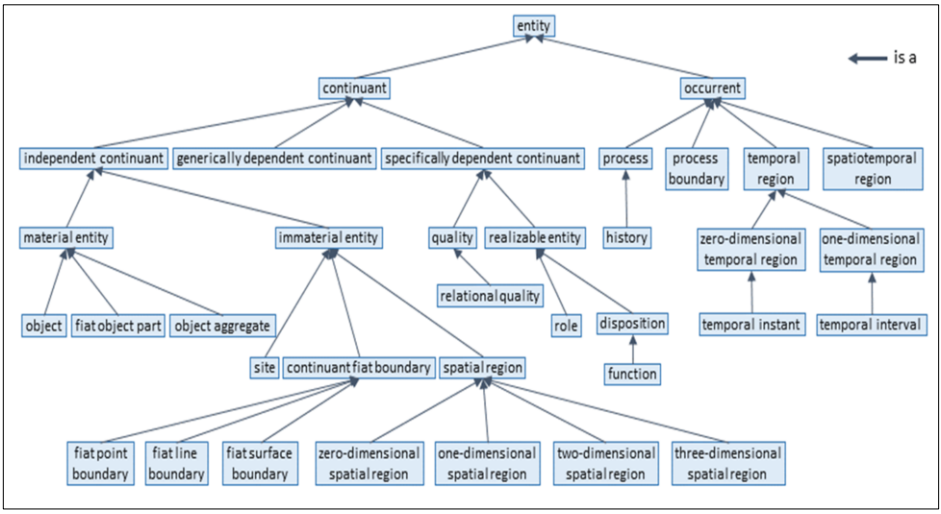

Figure 5. Basic Formal Ontology (BFO) is-a Hierarchy (after ISO/IEC 21838:2020) [16]

3. A Short Overview on Standards Classes and Related Specifications

Following, we present for the standards classes Architecture standards, Modeling standards, Terminology and ontology standards, Communication standards, Policy, security and privacy standards, Safety standards, and Identifier and identification standards some international specifications relevant in the context of P5 medicine ecosystems. Of course, the presented standards type and examples list is not intended to be complete.

Table 5. Standards Classifications and Related International Standards Examples

Standards Classification	Examples
Architecture standards	HL7 versions 2.x/3, OMG CORBA, OMG MDA, ISO 12967 Health informatics – Service architecture (HISA), ISO 7498-2:1989, Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture, ISO 13407:1999 Human-centred design processes for interactive systems
Modelling standards	OMG Unified Modeling Language (UML), ISO/IEC 19505-2:2012 Unified Modeling Language (UML), CEN 15300 CEN Report: Framework for formal modelling of healthcare security policies
Terminology and ontology standards	UMLS, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), Systematized Nomenclature of Medicine Clinical Term Ontology (SCTO), ISO 25720 Genomic sequence variation markup language, ISO/IEC 2382-8:1998 Information technology — Vocabulary — Part 8: Security, CEN-ENV 13608-1:2000 Health informatics — Security for healthcare communication — Part 1: Concepts and terminology, ISO 13940:2015 Health informatics — System of concepts to support continuity of care

Communication standards	HL7 v2.x/3, X12 EDI, UN EDIFACT, Odette FTP, CEN 13606 Electronic healthcare record communication, ISO/ IEEE 11073 Health informatics -- Point-of-care medical device communication, ISO 17113 Health informatics – Exchange of information between healthcare information systems – Development of messages, CDISC and DICOM specifications
Policy, security and privacy standards	ISO/IEC 2700 Information security management, ISO 22600:2014 Health informatics – Privilege management and access control, ISO 17090 Public key infrastructure, ETSI TS 101733 Electronic Signature Formats, ASTM E1987-98 Standard guide for individual rights regarding health information, CEN 13608 Security for healthcare communication, CEN 13729 Secure user identification - Strong authentication using microprocessor cards, ISO 25237:2017 Health informatics — Pseudonymization, ISO/IEC PDTS Pseudonymisation Practices for the Protection of Personal Health Information and Health Related Services, ISO/IEC 27018:2019 Information technology — Security techniques — Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors, ISO/IEC 29151:2017 Information technology — Security techniques — Code of practice for personally identifiable information protection, ISO 21298:2017 Health informatics – Functional and structural roles, ISO/IEC 9594-8:2008, Information technology — Open Systems Interconnection — The Directory: Public-key and attribute certificate frameworks, ISO/IEC 9798-3:1998, Information technology — Security techniques — Entity authentication — Part 3: Mechanisms using digital signature techniques, ISO/IEC 10181-1:1996, Information technology — Open Systems Interconnection — Security frameworks for open systems: Overview, ISO/TS 17090-1:2013 Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services, ENV 13729:1999, Health informatics — Secure user identification for healthcare strong authentication using microprocessor cards, ISO 21091:2013 Health informatics — Directory services for healthcare providers, subjects of care and other entities, ISO/IEC 15408-1:2009 Information technology — Security techniques — Evaluation criteria for IT security — Part 1: Introduction and general model
Identifier and identification standards	LOINC, ASTM E1714-00 Standard guide for properties of a Universal Healthcare Identifier
Safety standards	CEN 13694 CEN Report: Safety and security related software quality standards for healthcare, ISO/DTS 25238 Classification of Safety Risks

4. Managing the Modeling and Development Process of 5P Medicine Ecosystems

4.1. Representation of 5P Medicine Ecosystems through Standards

When modeling and developing 5P medicine ecosystems, we have first to solve the mapping between the involved domains represented by domain ontologies to correctly and formally represent the considered multi-disciplinary business system use case. Thereafter, we have to perform the transformation into the ICT-specific views from the enterprise viewpoint down to the engineering viewpoint representing the implementable artifacts. Thereby, we have to deploy the related ICT ontologies from business process modeling through information modeling up to data modeling domain. While this process including the representation styles is clearly specified for the ICT domain perspective by using ISO/IEC 10746 Open Distributed Processing [10] and related specifications, the ontologies and representation styles in health informatics may be healthcare-specific and changing over the time. Healthcare-specific standards for representing domain-specific

business views are, e.g., the HL7 Domain Analysis Models or the ISO or CEN Health Informatics Functional Models (FM) or Services Functional Models (SFM). An example for the first group is the HL7 Composite Security and Privacy Domain Analysis Model (CSP-DAM), meanwhile replaced by the aforementioned HL7 Privacy and Security Logical Data Model, R1. Examples for the latter group are the HL7 EHR-System Functional Model, R2 (HL7 EHR-S FM), the HL7 PHR-System Functional Model, R2 (HL7 PHR-S FM), or the HL7 Service Functional Models like the HL7 Common Terminology Services 2 Functional Model or the HL7 Version 3 Standard Identification Service R1. Also, ISO 13940 System of Concepts to Support Continuity of Care [30] must be mentioned here. A newer example for representing health enterprise view components are clinical information models according to ISO 139722 Clinical Information Models [31] or the openEHR [32] and ISO 13606 Electronic Health Record Communication [33, 34] archetypes. Thereby, also some aspects of the business view as well as the informational representation (information view) are covered. Standards for healthcare-specific information view representations have been established in the HL7 Clinical Document Architecture (HL7 CDA) series [35]. Computational view representation examples are HL7 Implementable Technology Specifications (ITS), but also the meanwhile globally pushed HL7 Fast Healthcare Interoperability Resources (HL7 FHIR) [36]. Figures 6 and 7 represent the different standards and representation styles in the ISO 23903 Interoperability and Integration Reference Architecture model and framework. Regarding FHIR, starting as implementable resource as expressed in Figure 7, 5 levels are meanwhile supported. The highest Level 5 covers knowledge-related aspects such as clinical reasoning, Level 4 process-related aspects, Level 3 semantic interpretations, Level 2 service implementations, and Level 1 technical representations.

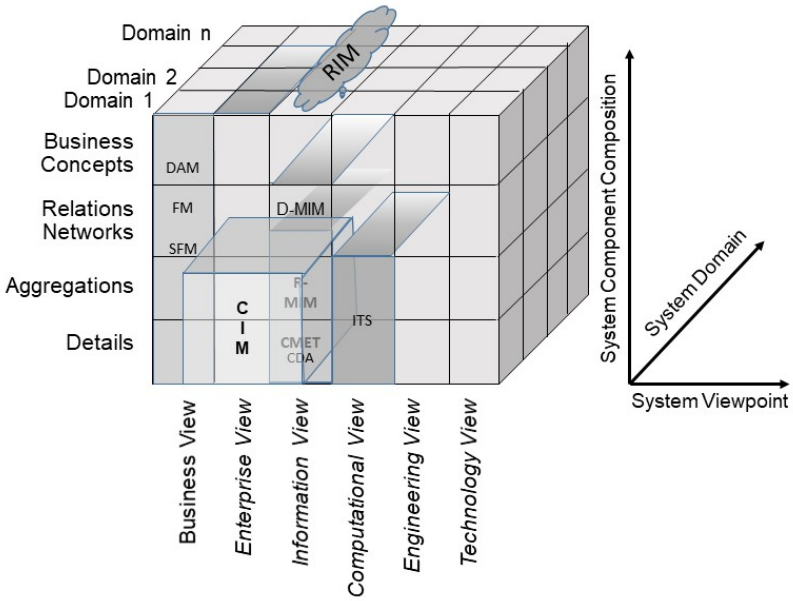

Figure 6. Healthcare-specific representations for different ISO 23903 views

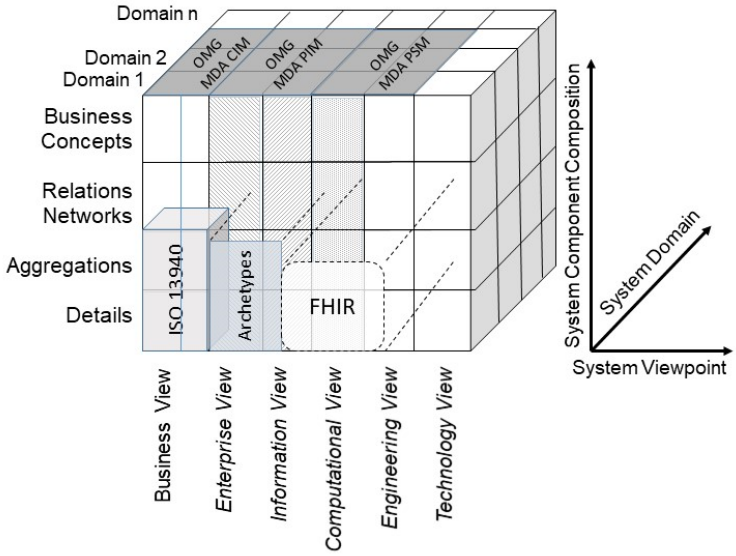

Figure 7. Healthcare-specific representations for different ISO 23903 views

4.2. Integrating Existing Standards in 5P Medicine Ecosystems

After discussing in some detail modeling and development of 5P medicine ecosystems, we will now address the challenge of mapping/matching or integrating existing specifications and artifacts using the model and framework of the ISO 23903 Interoperability an Integration Reference Architecture. For meeting this challenge, we have to understand perspectives, objectives, concepts, contexts, etc., the designer and developer of the component had in mind. Without that knowledge, any integration, mapping, or matching is not decidable. Therefore, we must re-engineer that missing knowledge. As the aforementioned conditions might change from use case to use case, the provided interoperability and integration outcome is specific for the considered use case or related classes of use cases, and the procedure has to be performed again for any new settings and contexts.

In the first step, components in question must be correctly placed into the ISO 23903 model regarding the domain, the granularity level and the represented development process viewpoint. Thereafter, the concepts represented by the considered components must be formally modeled in the business view using the corresponding domain ontologies as well as top-level ontologies for interrelating them. The concepts must be completed to correctly and operationally represent the real-world business system and business processes for the use case to be enabled or supported. The resulting business system representation must then be transformed into the views according to the development process up to the considered components' view. This includes a re-engineering of the components and relationships, i.e., classes, attributes, operations and relations needed to represent the full business use case must be added or modified. Figure 8 represents the described procedure.

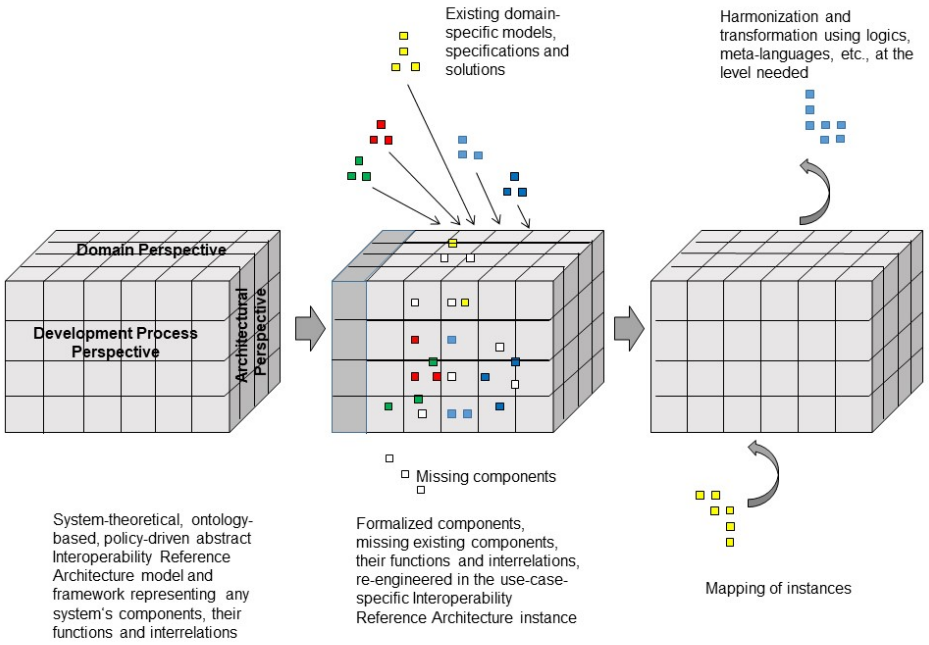

Figure 8. Integration of standards and specifications using the ISO 23903 Reference Architecture model and framework.

5. Discussion

Building on many years of work in health care with responsibilities for designing, implementing and using related information systems including necessary infrastructure services for interoperability, security, privacy, etc., but also for advancing health with telemedicine, pHealth and eHealth, the paper presents a model and framework for comprehensively and consistently representing and managing 5P medicine ecosystems using ISO 23903. The Generic Component Model (GCM), setting the basis for the approach dates from the early nineties of the last century and has successfully evolved over the time. Meanwhile, the Health Informatics TCs of ISO and CEN mandated the use of ISO 23903 for any project covering multiple aspects or domains, acknowledging the limitation of the data focus for specifying ecosystems. The described limitations of constraint representation language results in the need to advance from data sharing interoperability to knowledge sharing interoperability in dynamic and complex intercultural, interdisciplinary and inter-jurisdictional environments. By the way, this was the driving factor for replacing the EU Data Protection Directive [37] by the EU General Data Protection Regulation (GDPR) [38], i.e., advancing from a privacy-related data classification towards the detailed consideration of processes and contexts of creating, collecting, using, and sharing personally identifiable information (PII) [39]. Projects such as the European Health Data Space [40] are therefore more than questionable (see e.g. [3]). The nature of 5P medicine requires a concept- and context-based approach also for issues such as accompanying privacy and ethical aspects.

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