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# A PLM based approach for supporting collaboration and knowledge management in the medical domain : Application to the treatment process requiring prosthesis implantation

Thanh Nghi Ngo

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# THESE DE DOCTORAT DE

L'ÉCOLE CENTRALE DE NANTES  
COMUE UNIVERSITE BRETAGNE LOIRE

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Sciences pour l'Ingénieur  
Spécialité : Génie Mécanique, Productique, Transport

Par

**Thanh Nghi NGO**

**Une approche PLM pour supporter les collaborations et le partage des connaissances dans le secteur médical: Application aux processus de soins par implantation de prothèses**

Thèse présentée et soutenue à Nantes, le 27 juin 2018

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# Contents

<b>Main Introduction .....</b>	<b>8</b>
<b>Introduction générale .....</b>	<b>12</b>
<b>Chapter 1 Research context and related problematics .....</b>	<b>16</b>
1.1 Introduction to medical domain requiring prosthesis .....	17
1.2 Diversity of medical data.....	20
1.2.1 Introduction to medical imaging .....	21
1.2.2 Data acquisition methods .....	22
1.2.3 Medical scan data .....	24
1.2.4 Diversity of data related to variety of prosthesis .....	24
1.3 Data exchange and collaboration issues .....	25
1.4 Synthesis and problematics of medical treatment requiring prosthesis .....	29
<b>Chapter 2 Literature survey on PLM and KM approaches.....</b>	<b>31</b>
2.1 Introduction .....	32
2.2 The concept of knowledge in enterprise.....	33
2.2.1 Definitions of data, information and knowledge .....	33
2.2.2 Main pillars of knowledge management in modern enterprises .....	35
2.3 Knowledge representation and sharing .....	37
2.3.1 Knowledge representation languages and tools .....	39
2.3.2 Ontology as a support for knowledge classification .....	41
2.4 Knowledge modeling frameworks .....	45
2.5 Product lifecycle management approach.....	50
2.5.1 Introduction to product lifecycle.....	50
2.5.2 Product lifecycle management approach .....	51
2.5.3 PLM functions.....	54
2.6 PLM applications.....	57
2.6.1 Applications in industrial domain .....	57
2.6.2 Applications in medical domain .....	59
2.7 Synthesis and research questions.....	63

<b>Chapter 3 A conceptual approach for connecting medical and engineering processes .....</b>	<b>66</b>
3.1 Introduction and research method .....	67
3.2 Process modeling framework for medical sector .....	69
3.3 Lifecycles Analysis Framework .....	74
3.3.1 Prosthesis and disease Lifecycle .....	75
3.3.2 The five pillar analysis model of lifecycle stages connections analysis .....	79
3.4 Ontology-based modeling of the target medical domain .....	83
3.5 Conclusion .....	91
<b>Chapter 4 Implementation of the proposed framework in AUDROS PLM tool ..</b>	<b>93</b>
4.1 Introduction .....	94
4.2 Implementation strategy .....	95
4.2.1 Global architecture within AUDROS tool .....	95
4.2.2 Implementation scenario and related PLM functionalities .....	96
4.3 Implementation of main use cases in AUDROS .....	100
4.3.1 Prosthesis project management with the Flowboard module .....	101
4.3.2 Scenario of disease knowledge update.....	102
4.3.3 Scenario of functional requirement creation and update .....	105
4.3.4 Scenario of prosthesis design .....	108
4.4 Administration issues: Construct the workflows.....	111
4.4.1 Medical data workflow .....	112
4.4.2 Disease workflow.....	113
4.4.3 Requirement workflow .....	113
4.4.4 Prosthesis workflow .....	114
4.5 Conclusion .....	114
<b>Final Conclusion and Future Perspectives.....</b>	<b>116</b>
<b>Scientific Valorization .....</b>	<b>119</b>
<b>REFERENCES .....</b>	<b>120</b>
<b>Appendix A AUDROS PLM TOOL.....</b>	<b>132</b>
A.1 Main commercial PLM tools .....	132

A.2 AUDROS PLM tool .....	133
A.2.1 ModelShape.....	133
A.2.2 View Designer.....	134
A.2.3 SE Manager .....	134
A.2.4 AWS .....	135
A.2.5 AUDROS Addons.....	135
A.2.6 AWS creation .....	136
A.2.7 AUDROS Applet .....	136



# LIST OF FIGURES

Figure 0.1 - Organization of the manuscript .....	11
Figure 1.1 - Domain Reference Model for Hospitals (Ziekenhuis et al., 2012).....	17
Figure 1.2 - The treatment process requiring prosthesis .....	19
Figure 1.3 - Variety of models in the realization of prosthesis (Zdravković et al., 2012a) .....	21
Figure 1.4 - CT Scan machine .....	23
Figure 1.5 - IT structure for medical treatment process requiring prosthesis (Zdravković et al., 2012a).....	26
Figure 2.1 - Hierarchy of data, information and knowledge (Chaffey and White, 2010) .....	34
Figure 2.2 - Interdisciplinary constraints concept (Kleiner et al., 2003).....	38
Figure 2.3 - An inheritance-style semantic network (Davis et al., 1993).....	39
Figure 2.4 - Example of conceptual graph (Sowa, 1992).....	40
Figure 2.5 - An example of ontology (Nadoveza and Kiritsis, 2014) .....	43
Figure 2.6 - User interface of Protégé tool. ....	45
Figure 2.7 - UML class diagram of the FBS-PPRE model (Labrousse et al., 2004) ....	46
Figure 2.8 - PPR meta-model (Le Duigou et al., 2009) .....	47
Figure 2.9 - Top layers ontology in Bio-Imaging (Pham et al., 2016).....	49
Figure 2.10 - Product lifecycle phases (Terzi et al., 2010).....	51
Figure 2.11 - Fundamental elements of PLM (Terzi et al., 2010).....	52
Figure 2.12 - Basic components of the PLM approach (Abramovici, 2007) .....	53
Figure 2.13 - PLM and business approach (Le Duigou et al., 2011) .....	54
Figure 2.14 - Change management in PLM .....	55
Figure 2.15 - PLM functions in each phase of the product lifecycle (Stark, 2015) .....	56
Figure 2.16 - PLM framework focusing on supplier integration (Tang and Qian, 2008) .....	57
Figure 2.17 - Management of BMI study in Teamcenter (Allanic et al., 2014) .....	59
Figure 2.18 - BMI-LM data model schema (Allanic et al., 2014) .....	60

Figure 2.19 - KM-PLM based tool supporting information queries (Pham et al., 2015)	61
Figure 2.20 - Collaborative platform in pharmaceutical processes (Jadhav, 2011)	61
Figure 2.21 - Quality System Inspection Techniques (QSIT) Pillars within medical PLM (Oracle Medical PLM)	62
Figure 3.1 – The PLM as a hub connecting disease and prosthesis data	68
Figure 3.2 - General diagram of the treatment process	70
Figure 3.3 - Patient data analysis process	71
Figure 3.4 - Prosthesis realization process	72
Figure 3.5 - Surgery preparation process	72
Figure 3.6 - Treatment achievement process	73
Figure 3.7 - Two lifecycles in the treatment process requiring prosthesis	75
Figure 3.8 - Three possible cases of prosthesis after recovery process	76
Figure 3.9 - Linking between disease lifecycle and prosthesis lifecycle	78
Figure 3.10 - Main concepts in the treatment process	79
Figure 3.11 – Description of Link 1	80
Figure 3.12 - Linking between disease checking and requirement analysis stage	81
Figure 3.13 - Linking between treatment definition and requirement analysis stage	81
Figure 3.14 - Linking between treatment realization and prosthesis design stage	82
Figure 3.15 - Linking between treatment realization and prosthesis design stage	82
Figure 3.16 - Linking between Usage and Health problem stages	83
Figure 3.17 - Knowledge repository concept	84
Figure 3.18 - Global semantic model for the treatment process	85
Figure 3.19 – Ontology construction process	86
Figure 3.20 - Flow taxonomy	87
Figure 3.21 - Patient pathology classification	88
Figure 3.22 – Prosthesis taxonomy	88
Figure 3.23 - Requirement taxonomy	89
Figure 3.24 - Process taxonomy	90
Figure 3.25 - Tool taxonomy	90

Figure 3.26 - Stakeholder taxonomy .....	91
Figure 4.1 – Implementation strategy within the AUDROS PLM tool.....	96
Figure 4.2 - Use case diagram .....	100
Figure 4.3 – Creation of the project prosthesis.....	102
Figure 4.4 - Scenario of disease knowledge update .....	103
Figure 4.5 - Main interface of PLM object “DISEASE” .....	103
Figure 4.6 - List of symptoms .....	103
Figure 4.7 - Identify pathology of patient from symptoms. ....	104
Figure 4.8 - Patient disease defined with pathology .....	104
Figure 4.9 - Notify results to surgeon.....	104
Figure 4.10 - Surgeon receives the notification from medical doctor.....	105
Figure 4.11 - Scenario of functional requirement creation .....	106
Figure 4.12 - Main interface of PLM object “REQUIREMENT” .....	106
Figure 4.13 - Identify prosthesis type from descriptions.....	106
Figure 4.14 - Descriptions of prosthesis types .....	107
Figure 4.15 - Requirement defined with type of prosthesis .....	107
Figure 4.16 - Functional requirement attachment. ....	107
Figure 4.17 - Verify and send notification to prosthetist .....	108
Figure 4.18 - Scenario of prosthesis design.....	109
Figure 4.19 - Main interface of PLM object “PROSTHESIS” .....	109
Figure 4.20 - 3D design drawing attachment .....	110
Figure 4.21 - Prosthesis CAD model validation.....	110
Figure 4.22 - Notify the completion to producer.....	110
Figure 4.23 - Roles of the medical doctor in the system. ....	111
Figure 4.24 - Workflow of medical data .....	112
Figure 4.25 - Workflow of disease .....	113
Figure 4.26 - Workflow of requirement .....	113
Figure 4.27 - Workflow of prosthesis creation and validation.....	114
Figure A.1- User interface of AUDROS Model Shape.....	134
Figure A.2 - User interface of View Designer module .....	134

Figure A.3 - User interface of AUDROS SE Manager .....	135
Figure A.4 - User interface of AUDROS AWS Creation .....	136
Figure A.5 - User interface of AUDROS Apple .....	137

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## **LIST OF TABLES**

Table 1.1 - Comparative advantages and disadvantages of data acquisition methods..	24
Table 1.2 - List of software used to convert DICOM to STL .....	27
Table 1.3 - Popular 3D File Formats (Farahani et al., 2017) .....	28
Table 2.1 - Definitions of data, information and knowledge .....	34
Table 2.2 - Logical axioms table in medical domain (Zeshan and Mohamad, 2012) ..	44
Table 2.3 - The role of PLM in different life stages (Saaksvuori and Immonen, 2008b) .....	56
Table 4.1 - Scenario of the implementation process in AUDROS.....	98
Table A.1 - List of PLM software .....	132

**English Title:** A PLM based approach for supporting collaboration and knowledge management in the medical domain: Application to the treatment process requiring prosthesis implantation

## **Main Introduction**

During the past few decades, large varieties of technological developments are supporting the human being by proposing new ways for working, consuming and communicating. As stated by the large variety of research works (BIOSTEC, 2017), medical and healthcare are critical domains where the application of technology is challenging at both technical and societal dimensions. This is because the medical devices have to interact with humans in various sensitive and risky situations. The realization and the usage of such devices are strongly regulated by standard policies. In addition, every patient should be considered as a unique case study even if he/she suffers from a common pathology and the patient data is covered by confidentiality. This second specificity also makes difficult to assess the real performance of the devices during their usage stage and, consequently, to guarantee the completeness and the accuracy of the related requirements.

This assumption is particularly important in the case of medical devices implanted in human body where the behavior of the implanted device is linked to the health status and the daily activities of the patient. Prosthesis can be standard or customized and could be implanted for a permanent or temporal usage. However, in all case, the prosthesis should be suitable to the patient morphology and guaranty a maximum of flexibility and safety for him throughout his different life situations. Thus, the accuracy and completion of the device requirement have a strong influence on the success of the whole treatment process. For example, considering handling constraints in the design of the prosthesis reduces the risk of incidents during surgery process. Post-treatment and related costs can be also reduced if the geometry of the prosthesis is perfectly adapted to the patient morphology. Consequently, the patient will be recovered quickly after surgery in this case (Zdravković et al., 2012b).

To obtain such results, a strong collaboration between various stakeholders is required. The list of stakeholders includes patient, medical doctors, designers, engineers and all other professionals that could interact with the patient during his

recovery. Focusing on the design and realization stages, medical doctors have to share their knowledge in a comprehensible way so that the engineers can start designing the prosthesis based on accurate requirements. Conversely, the medical doctor has to learn about the capacity and constraints of each type of prosthesis when deciding the right treatment for a given patient pathology. In case of emergency situation, the decision should be taken collectively in a very short time and thus, high reactivity is expected from the involved actors.

As a consequence, technology is not the unique way for improving the medical treatment process with prosthesis implantation. This could be also possible through an efficient assistance to actors for knowledge reuse, data sharing and collaborative activities. The new generation of information and communication technology (ICT) systems might foster better consideration of these aspects by supporting the management and the traceability of relevant data and information. It might facilitate stakeholders' collaboration among the whole product lifecycle in a context of virtual organizations (Belkadi et al., 2017). From these categories of ICT, Product Lifecycle Management (PLM) approach are distinguished by their capacity to manage in a consistent way all product-related information and processes through the entire lifecycle, from the initial idea to end-of-life (Saaksvuori and Immonen, 2008a, Terzi et al., 2010). It also provides the support for the interoperability between heterogeneous information systems and computer aided applications (CAX, X of design engineering, etc.) in the company (Schuh et al., 2008). Thanks to its integration capacities, PLM approach can be adapted from industrial domain to support the medical treatment processes and, similarly, the connection of these processes with prosthesis related engineering processes. Furthermore, as a common repository of shared information in the organization, PLM system can be also used for the management of useful knowledge and its capitalization in a consistent format.

These assumptions are at the aim of this research work, where the entire treatment process requiring prosthesis is studied in detail. The main limitations in terms of data sharing, knowledge reuse, collaboration between organizations and different stakeholders are then highlighted. The key advantages of PLM and knowledge management approaches to improve these issues are discussed. Based on this, a global solution is defined and implemented in the industrial PLM software named AUDROS to support data sharing and knowledge reuse along the medical treatment process requiring prosthesis. The idea is that all disease data, prosthesis data, stakeholders and tools involved in the treatment process will be connected through a PLM hub. With this proposal, actors can, on one a hand, share data and knowledge with each other. On

the other hand, they can monitor the progress of the treatment plan. As a result, the performance of the recovery process in terms of accuracy and completion time will be significantly improved.

To do so, a conceptual approach is developed to analyze the connections between the patient disease and the prosthesis lifecycles. As part of this conceptual framework, a formal description of the treatment process using IDEF0 formalism that is an extension of SADT (Structured Analysis and Design Technique) language is achieved. This diagram describes the order of sub-processes/activities and indicates information, material flows, stakeholders, tools and software involved in the process.

This analysis conducts to the formal representation of shared knowledge at every life stage following the Product-Process-Resource perspectives (Le Duigou et al., 2009). Collaborative and knowledge-based assistance functionalities are then derived as operational solutions to implement the connection between the above mentioned lifecycles. A semantic meta-model is proposed covering main concepts to structure the common repository in charge of storing and managing shared data between all stakeholders. Ontology model for a medical sector requiring prosthesis is built as an extension of the semantic met-model to support the structuring and easy reuse of shared knowledge. The exploitation of the developed data and process models is made possible through the definition of a set of data and knowledge management functions as well as collaborative workflows.

These operational elements are implemented for the test and verification in the AUDROS PLM following a nominal treatment scenario. The remaining of the manuscript is organized in four chapters as follows. The links between these chapters is described in Figure 0.1.

Chapter 1 presents a general description about the medical sector. The patient treatment process requiring prosthesis is detailed as the scope of the present research work. All actors, tools and knowledge involved in the treatment process are identified and clarified. From this analysis, the main problems of collaboration and knowledge management in such domains are described as an introduction to the problem statement.

Chapter 2 summarizes the literature review on knowledge management, knowledge modeling and ontology as well as computer supported collaborative work (CSCW) and product lifecycle management (PLM) systems. Based on the state of the art provided in chapters 1 and 2, the research problem of this PhD work is stated.

These elements will be used as a basis for the development of the proposed KM-PLM based Framework.

Chapter 3 set-ups the main foundations of the conceptual approach to cope with the research problematic identified in Chapter 2. As indicated above, the conceptual framework consists on: A formal IDEF0 models; medical and engineering lifecycles connections in terms of flows, stakeholders, tools, processes and requirements; and ontological models describing medical and prosthesis shared knowledge.

Chapter 4 deals with the implementation issues of the proposed approach. Useful modules of the AUDROS PLM software are identified and configured to implement a set of designed functions and collaborative workflows. The graphical user interface is constructed based on AUDROS facilities to shows the interactions between stakeholders and the tool throughout a nominal treatment scenario.

Finally, the conclusion discusses the contributions of the research work and the validation of the obtained results. It also indicates the future works and summarizes the scientific impact of the proposition.

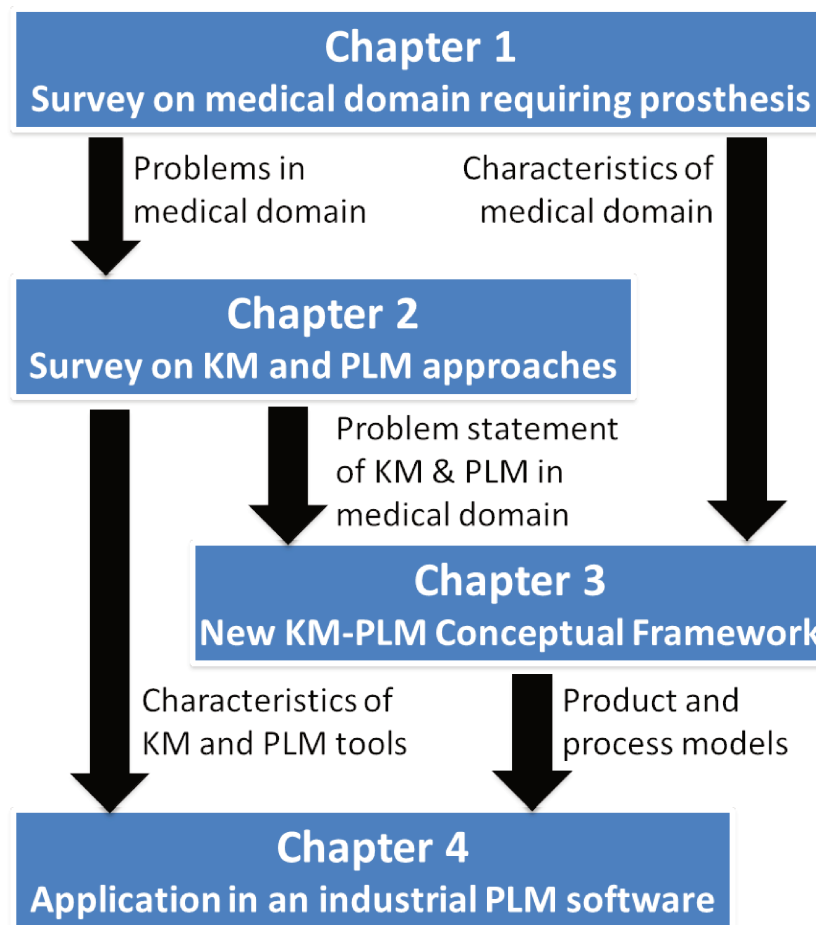


Figure 0.1 - Organization of the manuscript



# Introduction générale

Durant les dernières décennies, beaucoup de développements technologiques ont été réalisés pour améliorer le bien-être des humains à travers de nouveaux modes de travail, de consommation et de communication. Comme l'atteste la large variété de travaux de recherche (BIOSTEC, 2017), le secteur de la santé est l'un des domaines critiques dans lesquels l'application de la technologie présente des grands challenges aussi bien sur la dimension technique que sociétale. Ceci est dû au fait que les dispositifs médicaux doivent interagir avec les humains dans des diverses situations souvent très sensibles et présentant un haut niveau de risque. La réalisation et l'utilisation de ces dispositifs sont fortement règlementées par des normes strictes. De plus, chaque patient doit être considéré comme un cas unique même si la pathologie de sa maladie semble similaire à d'autres cas. Les données du patient sont couvertes par les règles de confidentialité. Cette spécificité rend difficile l'évaluation de la performance réelle des dispositifs durant leur phase d'utilisation et par conséquent, garantir la complétude et la précision des exigences associées.

Ceci est particulièrement plus important dans le cas de dispositifs médicaux implantés dans le corps du patient où le comportement du dispositif implanté est lié à l'état de santé et les activités quotidiennes du patient. La prothèse peut être standard ou personnalisée et peut être implantée d'une façon temporaire ou permanente. Cependant, dans tous les cas, la prothèse doit être adaptée à la morphologie du patient et lui garantir un maximum de flexibilité et de sécurité pour toute situation de vie. Par conséquent, l'exactitude et la complétude des exigences du dispositif médical ont un impact direct sur le succès de processus de soins médicaux. Par exemple, la considération des contraintes de manipulation durant la conception de la prothèse réduisent les risques d'incidents durant l'opération chirurgicale. Les coûts relatifs au post-traitement peuvent aussi contribuer à la réduction des coûts si la géométrie de la prothèse est parfaitement adaptée à la morphologie du patient. Par conséquent, le patient va se rétablir plus rapidement après la chirurgie (Zdravković et al., 2012b).

Pour obtenir ces résultats, un grand effort de collaboration est nécessaire de la part des parties prenantes. La liste des parties prenantes inclues le patient, les médecins, les chirurgiens, les concepteurs, les ingénieurs, ainsi que toute autre professionnel qui interagit avec le patient durant la période de convalescence. En se focalisant sur la phase de conception de réalisation, les médecins doivent partager leurs connaissances

d'une façon compréhensible afin de permettre aux ingénieurs de faire la conception sur la base d'une définition claire et précises des exigences. Inversement, le médecin doit prendre conscience des capacités et contraintes d'utilisations propres à chaque type de prothèse afin de décider le bon traitement pour une pathologie donnée. Dans le cas de situation d'urgence, la décision doit être prise d'une façon collective dans des délais très courts et un haut niveau de réactivité est attendu de la part des acteurs impliqués dans le processus.

Par conséquent, la technologie n'est pas le seul moyen pour améliorer la performance du processus de soins médicaux nécessitant une prothèse. Ceci peut être possible à travers une assistance efficace aux acteurs pour la réutilisation des connaissances, le partage des données et la réalisation des activités collaboratives. Les nouvelles générations des technologies de l'information et de communication (TIC) peuvent considérer ces aspects à travers le support de la gestion et de la traçabilité des données et des informations. Ces systèmes peuvent faciliter la collaboration entre les acteurs tout au long du cycle de vie du produit dans un contexte d'organisation virtuelle (Belkadi et al., 2017). Parmi ces catégories des TIC, les approches de gestion du cycle de vie (ou PLM en anglais) sont connus pour leur capacité à gérer d'une façon consistantes toutes les informations relatives au produit et processus tout au long du cycle de vie, depuis l'idée initiale jusqu'à la fin de vie (Saaksvuori and Immonen, 2008a, Terzi et al., 2010). Ces approches proposent également l'interopérabilité entre les différents systèmes d'information hétérogènes et les applications métier assistées par ordinateur (XAO, X pour conception, ingénierie, etc.) disponibles en entreprise (Schuh et al., 2008). Grâce aux capacités d'intégration offertes par les approches PLM, ces applications peuvent être adaptées du secteur industriel pour supporter le processus de traitement médical et assurer le lien entre ce processus avec les processus d'ingénierie des prothèses. De plus, autant que référentiel partagé dans l'entreprise, le PLM peut aussi être utilisé pour la gestion des connaissances utiles ainsi que leur capitalisation et leur partage.

Ce constat est à la base de ce travail de recherche, dans lequel le processus de traitement médical nécessitant une prothèse est étudié en détail. Un focus est mis sur les problématiques rencontrées dans ce processus en lien avec la réutilisation des connaissances, la collaboration entre organisations et parties prenantes. Les avantages majeurs des approches PLM et de gestion des connaissances pour répondre à ce type de problématiques seront également discutés. Sur cette base, une solution globale est définie et implémentée dans un logiciel PLM du marché nommé AUDROS pour

supporter le partage des données et la réutilisation des connaissances tout au long du processus de soins médicaux.

Pour ce faire, une approche conceptuelle est développée permettant d'analyser les connections entre le cycle de vie d'une maladie et celui de la prothèse. Dans ce cadre conceptuel, les modèles du processus de traitement médical nécessitant une prothèse sont décrits avec le langage de modélisation qui est une extension du langage SADT (Structured Analysis and Design Technique). Les diagrammes IDEF0 permettent de représenter l'ordre des sous-processus/activités et d'indiquer les flux d'information et de matière échangés entre ces blocs opérationnels ainsi que les parties prenantes et autres outils et logiciels impliqués dans ces processus.

Cette analyse a conduit à la représentation formelle des connaissances partagées à chaque phase de vie selon les trois perspectives Produit-Processus-Ressources (Le Duigou et al., 2009). Des fonctions d'assistance à base de connaissances et des supports de collaborations sont ainsi dérivées comme éléments de la solution opérationnelle pour implémenter la connexion entre les cycles de vie mentionnés précédemment. Un méta modèle sémantique est proposé pour couvrir les principaux concepts du domaine et les structurer dans le référentiel partagé. Un modèle ontologique pour le secteur médical nécessitant une prothèse est ensuite construit comme une extension du méta-modèle global afin de faciliter la structuration et l'utilisation des connaissances partagées. L'exploitation de ces modèles de connaissances est possible à travers un ensemble de fonctions de gestion des connaissances et des workflows collaboratifs.

Ces éléments opérationnels sont implémentés pour test et vérification dans l'outil PLM AUDROS en respectant un scénario nominal de traitement. La suite de ce manuscrit est organisé dans quatre chapitres comme suit. Les liens entre les différents chapitres sont décrits dans la Figure 0.2.

Le chapitre 1 présente une description générale du secteur médical. Le processus de traitement médical nécessitant une prothèse est détaillé comme étant le sujet principal de ce travail de recherche. Tous les acteurs et les composants impliqués dans le processus de traitement sont identifiés et expliqués. De cette analyse les principaux problèmes de gestion des connaissances et de collaboration dans ce domaine médical sont décrits en préambule de la problématique de recherche.

Le chapitre 2 résume la revue de la littérature sur les méthodes de gestion des connaissances, de modélisation et de construction des ontologies ainsi que les systèmes d'aide au travail collaboratif et le PLM. Sur la base des éléments de la

littérature des chapitres 1 et 2, les problématiques de recherche de cette thèse sont établies. Ces éléments serviront de base pour la proposition d'une approche mixte KM-PLM en réponse à ces problématiques.

Le chapitre 3 présente les fondements de base de l'approche conceptuelle proposée pour répondre aux problématiques de recherche identifiées dans le chapitre 2. Comme indiqué précédemment, le cadre conceptuel inclut les modèles IDEF0 ; les connections entre les cycles de vie de la maladie et de la prothèse en termes de flux, acteurs, outils, processus et exigences ; le modèle d'ontologie pour la description des connaissances partagées entre secteur médical et ingénierie de la prothèse.

Le chapitre 4 s'intéresse à l'implémentation de l'approche proposée. Les différents modules utiles de l'outil AUDROS sont identifiés et configurés pour la mise en œuvre d'un ensemble de fonctions d'assistances et de workflows collaboratifs. L'interface utilisateur graphique est conçue en utilisant les modules prédéfinis d'AUDROS pour montrer les interactions entre les parties prenantes et l'outil tout au long du scénario nominal d'expérimentation.

Finalement, la conclusion discute les contributions du travail de recherche et la validation des résultats obtenus. Les travaux futurs sont également annoncés ainsi que l'impact scientifique des propositions.

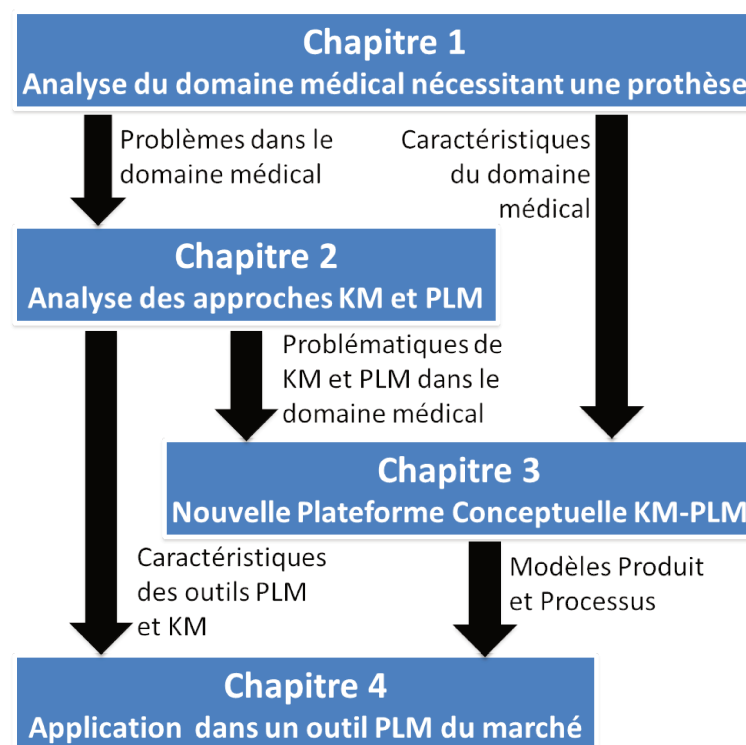


Figure 0.2 - Organization du manuscrit

# Chapter 1

## Research context and related problematics

### Contents

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1.1 Introduction to medical domain requiring prosthesis.....	17
1.2 Diversity of medical data.....	20
1.2.1 Introduction to medical imaging.....	21
1.2.2 Data acquisition methods.....	22
1.2.2.1 CT scan (Computed Tomography).....	22
1.2.2.2 MRI scan (Magnetic Resonance Imaging).....	23
1.2.3 Medical scan data.....	24
1.2.4 Diversity of data related to variety of prosthesis.....	24
1.3 Data exchange and collaboration issues.....	25
1.4 Synthesis and problematics of medical treatment requiring prosthesis.....	29

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## 1.1 Introduction to medical domain requiring prosthesis

Nowadays, standard of living and quality of life are in constant improvement. Therefore, the medical sector is one of the most interesting and challenging in the current society. This is the reason why improving efficiency in medical field has become a critical issue. To describe main business activities and information objects, a domain reference model for hospitals has been proposed by Ziekenhuis et al. (2012). On the initiative of the Netherlands Association of Hospitals (NVZ), the I-Ziekenhuis program started in 2009 with the aim to set up and maintain a framework to support the information technology organization and knowledge exchanged within hospitals in the Netherlands. Figure 1.1 shows the main common processes identified in medical domain based on the analysis of the organization of numerous hospitals. Nine (09) categories of business processes are identified in this model covering the whole disease lifecycle, from the identification to the recovery.

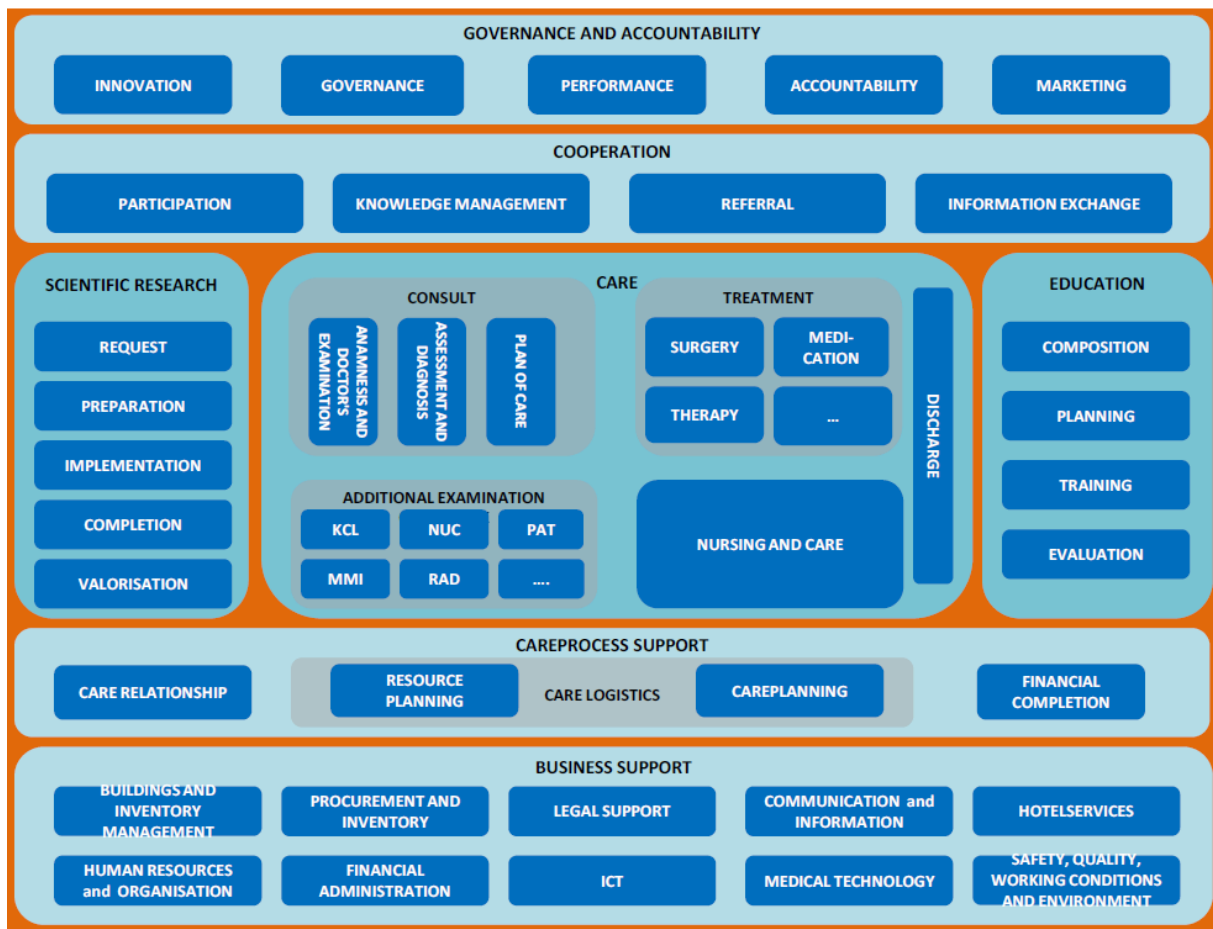


Figure 1.1 - Domain Reference Model for Hospitals (Ziekenhuis et al., 2012)

- The first category includes the core processes that are directly involved into the disease life stages: medical consultation for diagnosis and analysis of diseases, additional exams required by specific pathologies, treatment processes with or without surgery, nursing and care during hospitalization and after care processes. The diagnostic service includes blood tests, X-ray, blood pressure measurement, CT/MRI scan, etc. The treatment service includes: surgery, prescribing a medicine or only getting an advice from a doctor, etc.
- Governance and administrative processes that focus on the definition and management of the strategy as well as the evaluation of the whole performance.
- Cooperation processes are interested to the relationships between different services and experts in various medical fields in order to preserve the core competencies of the actors and the referral knowledge of the hospital in terms of rules and procedures.
- Care support process focuses on internal resource planning and the planning of operational care activities. It also concerns the relationships with the patient and suppliers for example the patient registration and related costs.
- Business support processes are necessary to maintain the realization of daily activities in good conditions. This includes the maintenance of buildings, information and communication tools to store and share the basic data through various services in the hospital, the hotel services, etc.
- Scientific research processes in charge of the realization and the valorization of new experimentations and medical protocols to develop new treatment processes for particular pathologies. These processes are connected to the education processes concerned by the training of students.

From the large variety of treatment processes, the topic of this research work focuses only on processes requiring prosthesis. These processes are very important and complex in the medical domain because they include many activities with the participation of various stakeholders (Bibb et al., 2015d). Especially, the particularity of this domain is the connection of two separate business areas: medical and engineering. This section presents an overview of the related activities as described in the literature survey and the current practices.

An overview of the main steps is described as Figure 1.2. Generally, this process starts by patient interview and initial exams allowing the medical doctor to create a preliminary opinion on the patient pathology. After which, the radiologist will scan the concerned part of body. Medical imaging can be provided with several mechanisms depending on the identified symptoms. These methods can produce sets of two-

dimensional (2D) images and three-dimensional (3D) reconstructions for interpretation (Kim et al., 2012, Udupa and Herman, 1999).. Currently, CT and MRI are the two most popular methods for producing computerized images of patients (Tukuru et al., 2008). CT and MRI provide pixel-based images in a series of slices.

For the analysis of the collected data, 3D Medical Image Processing software became important tools for supporting medical images analysis and diagnosis purposes (Mahmoudi et al., 2010). Such kind of software reduced cost and quality problems associated to conventional radiology, where doctors and secretary lost lot of time and money for the printing, reading and archiving in good conditions huge quantity of documents (S. Suri et al., 2002). The 3D Medical Image Processing (3DMIP) software applies various automatic analysis and processing algorithms to accurately segment and visualize the data described on the 2D/3D images (Chabat et al., 2000).

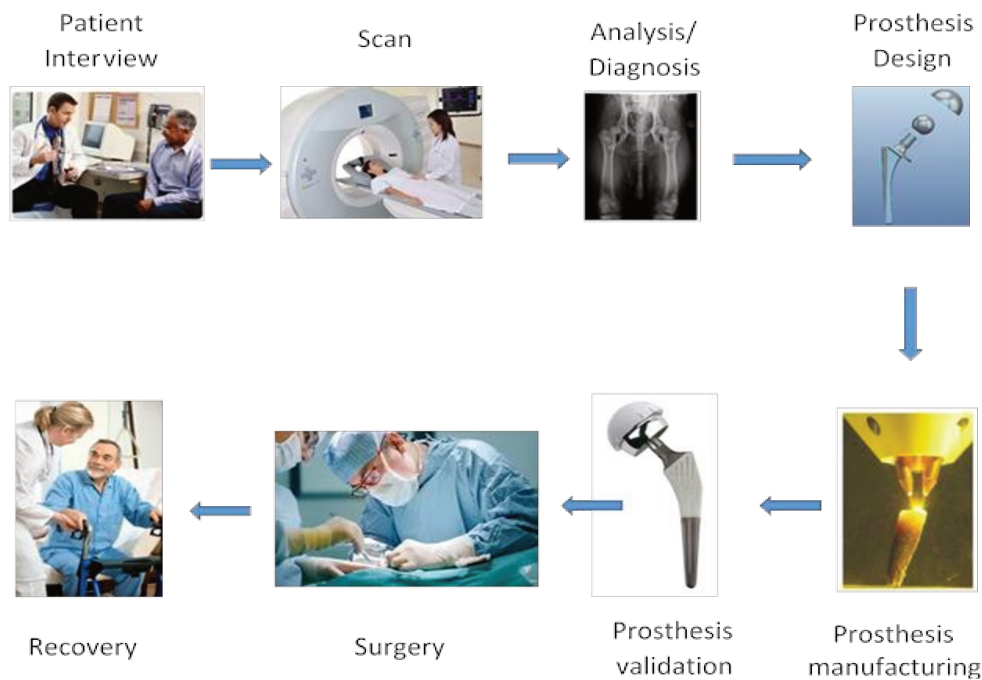


Figure 1.2 - The treatment process requiring prosthesis

DICOM (Digital Imaging and Communications in Medicine) is a standard that allows the exchange, sharing and processing of medical images information easily. It could be generated by scanners and supported by 3DMIP viewers (Bibb et al., 2015b, Varma, 2012). In medical applications, DICOM is the leading standard for storage and transfer of image data (Mildenberger et al., 2002). This standard provides a protocol for sharing across many different medical devices and systems. It is widely used in hospitals to represent the output forma of medical imaging devices such as MRI, ultrasound, X-rays and CT scans. The DICOM file exists as a series of many hundreds of cross-sectional slices taken through an area of the patient’s body via CT/MRI scan.



After the analysis of medical images obtained from the scan, the realization of the needed prosthesis is achieved. 3DMIP tools like MIMICS software (Materialise's Interactive Medical Image Control System) propose the conversion of the scanning data from DICOM format into the highest possible quality STL (STereoLithography) data or VRML (Virtual Reality Modeling Language) files. STL files are easily imported into the CAD software (Bibb et al., 2009, Jardini et al., 2014, Truscott et al., 2007) to start the conception of the prosthesis based on an accurate image of the body morphology. The (semi-)automatic representation of bone morphology proposed by this file provides the designers by a set of technical specifications that are completed by additional manipulation requirements from the surgeon. The same type of files can be used to accelerate the prosthesis manufacturing, which is the next step of the treatment process. Nowadays, several technologies are currently used for the manufacturing of the prosthesis depending on its type and material. It can be fabricated by using conventional CNC (Computer Numeric Control) machines, or more recently, using additive manufacturing through 3D printing machines (Azari and Nikzad, 2009, Subburaj et al., 2007). The final step before implanting the prosthesis on the patient's body is the quality approval realized collaboratively by engineers, medical doctors and surgeons (Tukuru et al., 2008). The last process after implantation is then rehabilitation and recovery. During the treatment process as described above, we can identify the necessary of medical image data from the patient.

Based on this analysis, the next sections of this chapter are dedicated to describe the main characteristics of the treatment process requiring prosthesis in order to identify the main problems in this domain. Particularly, the diversity of data, tasks, tools and stakeholders through the medical treatment process requiring prosthesis is introduced to identify the main problems in this domain.

### **1.2 Diversity of medical data**

The custom orthopedic implants manufacturing is based on a multi-level computer model of human osteoarticular (bone & joint) system, consisting of design, behavior and production perspective. As shown in Figure 1.3, the model of certain level is used to solve specific problems and it is associated with the appropriate tools for its creation and use. The models represent the different views to the orthopedic implant products. They aim at enabling the representation of the relevant knowledge and inference in the field of decision support in treatment and pre-operation planning.

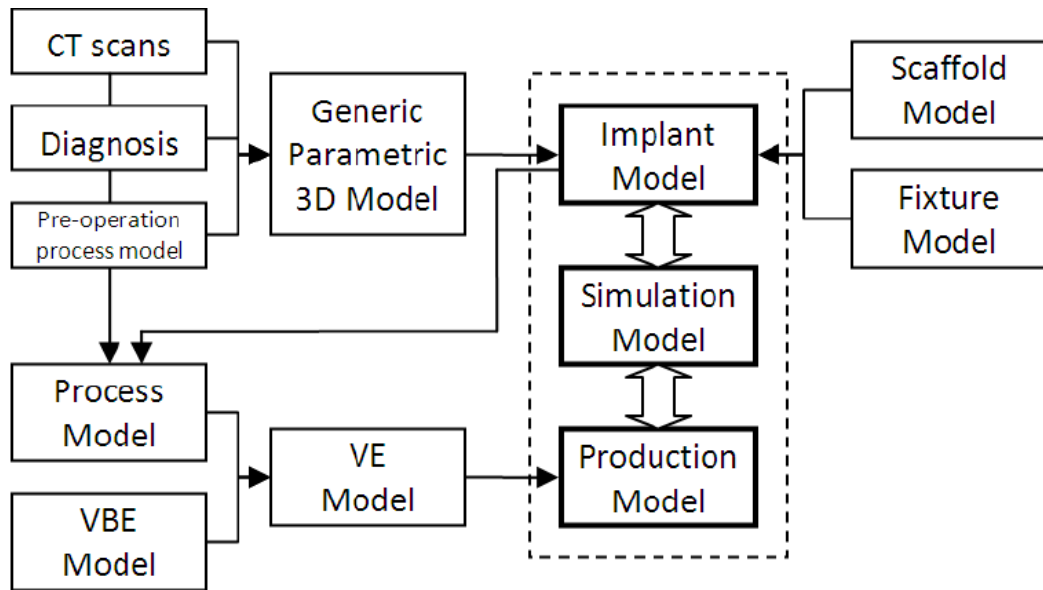


Figure 1.3 - Variety of models in the realization of prosthesis (Zdravković *et al.*, 2012a)

Medical image is one of the important data for variety of processes such as: prosthesis design, prosthesis manufacturing and surgery. This section will introduce medical imaging, the common technologies to collect medical images from patient. Then methods of data acquisition are also introduced in this section.

### 1.2.1 Introduction to medical imaging

Medical imaging is visual representations of the interior of body parts, tissues or organs for uses in clinical diagnosis, treatment and disease monitoring. In the medical domain, virtual or physical models of any human anatomy are produced based on medical images. These images are made by scanning a patient. A number of scanning modalities can be used, ranging from hospital facilities found in radiology departments to laboratory or clinic.

There are many different methods to obtain the medical images from patients such as: computed tomography (CT), magnetic resonance imaging (MRI), X-ray, ultrasound imaging, positron emission tomography, thermography and different types of microscopy (Jardini *et al.*, 2014, Splinter, 2010). Among these methods, CT and MRI are currently the two most popular methods for producing computerized images of patients (Tukuru *et al.*, 2008). Globally, the methods to collect images from patients could be divided into two main groups: scan the whole patient body (both inside and outside) and scan only the outside.

In the first group, we have techniques such as CT and MRI. A patient will lie on a table, and the scanner will operate and collect the whole picture. The cross-sectional

images are arranged in a specific order so that the computer can construct a three-dimensional (3D) data set of this patient. By using computer software, the image data will be reconstructed to describe parts of the patient's body accurately.

For the second group, only scan the patient's external surface, some tools can be used to collect 3D images of the external surface. There are many types of surface scanner available for this purpose. But in general it can be divided into two categories: contact scanners and non-contact scanners (Curless, 1999). Contact scanners are useful for industrial reverse-engineering applications that precision is the most important factor. Noncontact methods that are widely used in medical domain obtaining 3D images faster and more simple than contact scanners (Farahani et al., 2017).

This research will only focus on the first group that scans the whole patient. In the next section, we will introduce some methods of image acquisition from the patient.

### **1.2.2 Data acquisition methods**

In order to provide patients' tomography data in 3D form to support the diagnosis and treatment process, a suitable data acquisition method must be used on patient depending on the position and type of disease. Nowadays, many different methods and techniques are existing but two popular methods are Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) (Paterson et al., 2010).

#### **1.2.2.1 CT scan (Computed Tomography)**

Computed Tomography (CT) scans widely are used for diagnostics and surgical planning to collect images from the internal organs as well as external organs of the patient. Especially, it is great to look at the bones. CT scans machine (Figure 1.4) can produce detailed images of many structures inside the body, including the internal organs, blood vessels and bones. While traditional X-rays image organs in two dimensions, CT scans allow for a more three-dimensional effect (Bibb et al., 2015a).

A CT Scan is best suited for viewing bone injuries, diagnosing lung and chest problems, and detecting cancers. CT scans are widely used in emergency rooms because each scan takes less than 5 minutes. However, it has a limitation that CT scan delivers a high dose of unwanted radiation to the patient (Chandra et al., 2005).



Figure 1.4 - CT Scan machine<sup>1</sup>

There are two components, a table where the patient lies down and a hollow tube within which the CT images are acquired and the camera in CT machine moves around inside and takes pictures. The computer collects the scan results and translates them into images that look like a “slice” of a person (Tran, 2012). Measurements are taken from various angles to produce a series of axial slices, and are illustrated in grey scale to demonstrate different densities within the body, ranging from black to represent air, and white to represent the densest bone (Bibb et al., 2015d).

### 1.2.2.2 MRI scan (Magnetic Resonance Imaging)

Magnetic Resonance Imaging (MRI) scans are used for looking at soft tissue. The MRI scans use magnetic and radio waves, there is no exposure to X-rays or any other damaging forms of radiation. In the magnetic field, the effects of radio waves through the body cause body’s tissue to resonate and take high-resolution pictures of your bones and soft tissues. One of the great advantages of MRI is the ability to change the contrast of the images. Moreover, unlike CT, by altering the direction of the radio waves used, MRI is able to change the imaging plane without moving the patient, MRI machines can produce images in any planes, any angle (Chang et al., 1987).

An MRI is suited for examining soft tissue in ligament and tendon injuries, spinal cord injuries, brain tumors, etc. An MRI can take up to 30 minutes. It is accurate and reproducible but very expensive (Chandra et al., 2005). Table 1.1 gives a comparative analysis of advantages and limits of data acquisition methods (Bibb et al., 2015a).

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<sup>1</sup> <https://www.amberusa.com>

Table 1.1 - Comparative advantages and disadvantages of data acquisition methods

Data capture method					
Ideal characteristics	CT/MRI	Anthropometry	Direct 3D laser scanning	Indirect 3D laser scanning (support jig)	Indirect 3D laser scanning (plaster cast)
No trained specialists required	×	✓	✓	✓	✓
Affordable for low budget projects	×	✓	✓	✓	✓
Quick, easy access	×	✓	✓	✓	✓
Low/no waiting times	×	✓	✓	✓	✓
Minimum preparation time	✓	✓	✓	×	✓
Quick data collection	MRI = × CT = ✓	×	✓	✓	✓
Low/no discomfort for patients	✓	✓	✓	✓	✓
No health/safety risks to patients	×	✓	✓	✓	✓
Low risk of data capture error	✓	×	×	Dependent on suitability of jig	✓
Suitable accuracy	✓	✓	✓	✓	✓
Suitable resolution	✓	✓	✓	✓	✓
Data capture unaffected by movement	MRI = × CT = ✓	×	×	Dependent on suitability of jig	✓
No line of sight limitations	✓	✓	×	×	×
Little/no concern over positioning	✓	×	×	×	✓
Reliable repeatability	✓	×	×	Dependent on suitability of jig	✓
Direct export into 3D CAD software	✓	×	✓	✓	✓

### 1.2.3 Medical scan data

Medical scanners such as CT and MRI produce pixel-based images in a series of slices. Normally, the output of these scanners usually is DICOM format. (Bibb et al., 2015a, Varma, 2012). DICOM (Digital Imaging and Communications in Medicine) is a standard format which allows the exchange, sharing and processing of medical images information easily.

In medical applications, DICOM is the leading standard for storage and transfer of image data (Mildenberger et al., 2002). This standard format provides a protocol for sharing across many different medical devices and systems. It is widely used in hospitals as well as the output format of medical imaging devices such as MRI, ultrasound, X-rays and CT scans.

DICOM stands for Digital Imaging and Communications in Medicine and is a standard for handling, storing, printing and transmitting information in medical imaging. The DICOM file exists as a series of many hundreds of cross-sectional slices taken through an area of the patient’s body via a CT scan, MRI scan.

### 1.2.4 Diversity of data related to variety of prosthesis

Prosthesis is an artificial device supporting functionalities of some biological structures. It can be placed either inside or on the surface of the body (Bartolo et al., 2012). It can be divided into two types of implants: permanent implants and temporary

implants. Permanent implants are placing devices on a patient over one year such as stents and hip implants. Temporary implants are commonly used in sports and medical surgeries, especially in shoulder and knee surgery. They are usually made of biodegradable polymers like screws, suture threads and plates.

Using customized orthopedic implants in surgery has important advantages: it is designed to be suitable for a specific patient; it helps surgeons performing surgical operations easier; with a customized orthopedic implant, it reduces the duration of the surgery operation and increases the reliability (Zdravković et al., 2012a). Thus it reduces post-treatments and related costs, and patient will be recovered quicker after surgery (Zdravković and Trajanović, 2011, Zdravković et al., 2012b).

Nevertheless, it spends more time to design and fabricate. For a customized orthopedic implant, design technicians may need up to three months of lead time (Christensen and Chen, 2008), but standard implants can be used instantly. The standard implants can be made by mass production, and stored in stock in advance; so their costs are lower and there is no waiting time for manufacturing.

Some types of prosthesis which play an important role in supporting human organs' functionalities are hip prosthesis, shoulder prosthesis, wrist joint prosthesis, elbow prosthesis, finger prosthesis, toe prosthesis, humeral prosthesis, etc. (Greenwald et al., 1978, Hood et al., 1994). In this work limitation, the research only focuses on the customized prosthesis. It includes all processes from collecting data, converting data to suitable format, modifying, reconstructing 3D model and finally fabricating the final prosthesis.

### 1.3 Data exchange and collaboration issues

Zdravković et al. (2012a) propose an interesting information system structure to classify the variety of tools in medical treatment requiring prosthesis and to identify the relations between them. The proposed IT structure is dedicated to support the design and manufacturing of customized orthopedic prosthesis. The IT structure is composed by three categories of systems covering the development stage of orthopedic prosthesis: clinical information system, system for pre-operation planning and system for implant design (Figure 1.5).

**The Clinical Information Systems (CIS)** is defined as an integrated suite of IT tools dedicated to manage medical, administrative, financial and legal aspects of healthcare provision. Relevant subsystems of CIS are Radiology Information System (RIS) and Picture Archiving and Communication System (PACS). **The System for**

**pre-operation planning (PRE-OP-Sys)** is used for making the most important decisions, with regard to significant features of the customized implant. Based on CT scan, namely bone and joint system and interpreted features of trauma, PRE-OP-Sys should be capable to suggest relevant indicators to help realizing the surgery. **The System for implant design (IMPL-D-Sys)** concerns the software applications, used by stakeholders to support the design of product topology. It includes facilitation of the decisions on geometric features and the associated services.

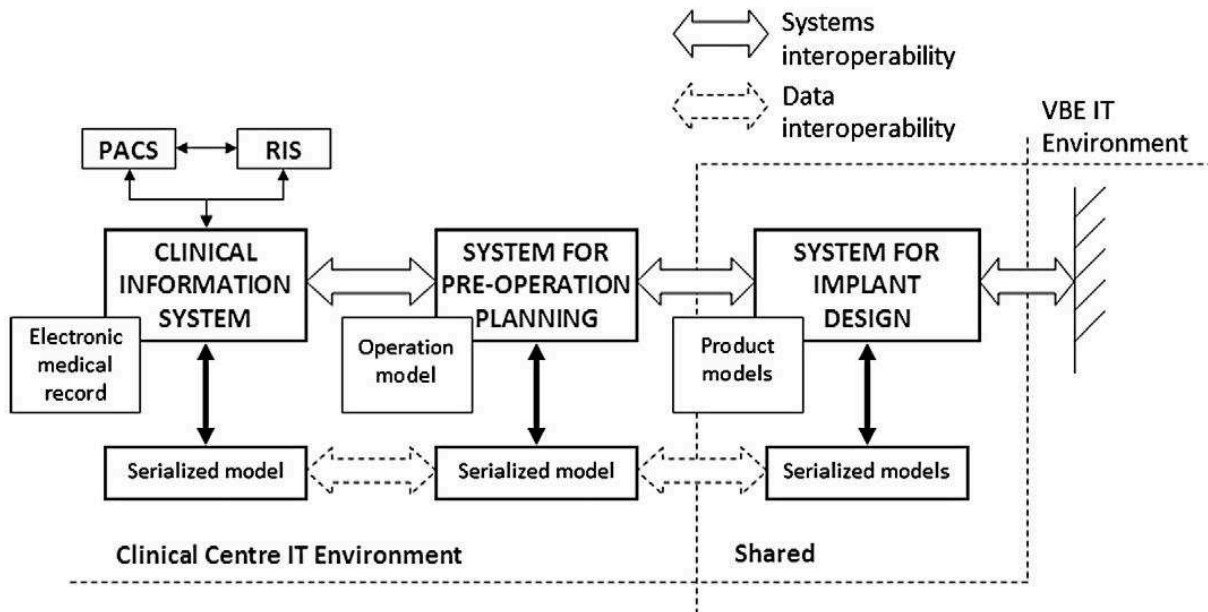


Figure 1.5 - IT structure for medical treatment process requiring prosthesis (Zdravković et al., 2012a)

Concretely, to produce prosthesis from DICOM files (obtained from patient scan process: CT, MRI, etc.), medical images (saved in DICOM format) are converted to STL format by using software. From this format, it is possible to produce the model on any commercially available 3D printing or additive manufacturing system. This format also allows users to integrate with most existing CAD systems. Users can easily use CAD software to view, modify and design prosthesis and implants which may in turn also be produced through additive layer manufacturing techniques (Bibb et al., 2015b).

Nowadays, there are many software that can convert DICOM file to STL (Table 1.2). Among them the most popular software package is MIMICS (Materialise Interactive Medical Image Control System). This is the software for reading in CT/MRI data and outputting 3D CAD for integration in other software or RP technologies. The most common input format is DICOM, but other input formats can be used such as TIFF, JPEG, RAW and BMP. The common output file format is

Stereo Lithography (STL) format that defines 3D volumes in faceted triangles. Other 3D output formats are VRML, PLY and DXF. (Kumta et al., 2015).

Table 1.2 - List of software used to convert DICOM to STL

Software name	Company	Website
3D slicer	Slicer Community	<a href="https://www.slicer.org">https://www.slicer.org</a>
3D Doctor	Able	<a href="http://www.ablesw.com">http://www.ablesw.com</a>
Amira	FEI+ZIB	<a href="http://amira.zib.de">http://amira.zib.de</a>
Analyze	Mayo Clinic	<a href="http://www.analyzedirect.com">http://www.analyzedirect.com</a>
BioBuild	Anatomics	<a href="http://www.anatomics.com">http://www.anatomics.com</a>
Mimics	Materialise	<a href="http://www.materialise.com">http://www.materialise.com</a>
SliceOmatic	TomoVision	<a href="http://www.tomovision.com">http://www.tomovision.com</a>
Simpleware	Simpleware	<a href="https://www.simpleware.com">https://www.simpleware.com</a>
PyFormex	Verhegghe	<a href="http://www.nongnu.org">http://www.nongnu.org</a>
Democratiz3D	Embodi3d	<a href="https://www.embodi3d.com">https://www.embodi3d.com</a>

The variety of data used in the medical domain implies the problematic of data exchange and interoperability between tools (Zdravković et al., 2012b). After data is converted from DICOM to 3D format, 3D modeling and computer-aided design software such as: Freeform (Williams et al., 2006) can be used to view and modify the prosthesis model; then this model is formatted into any of 3D file formats that are compatible with 3D printers or commercial 3D printing vendors. Table 1.3 lists some types of 3D format, description in details and 3D features supported: Geometry, colors and textures. For example, STL format only supports geometric features (Farahani et al., 2017). Health Level Seven (HL7<sup>2</sup>) standard is also used to improve the operational workflow efficiency in radiology (Mabotuwana and Hall, 2017). HL7 messaging standard is arguably the most widely implemented standard for interoperability in healthcare across the world and allows the exchange of clinical data between disparate systems.

<sup>2</sup> <http://www.hl7.org>



Table 1.3 - Popular 3D File Formats (Farahani et al., 2017)

Extension	Name	Description	Supported 3D Features		
			Geometry	Colors	Textures
.stl	Stereolithography	A popular 3D file format, initially developed by 3D Systems, which describes mesh surfaces as lists of geometric features; information can be stored either in plain text or binary form, the later is used more often as it is a more efficient storage	✓		
.mb	Maya Scene	The primary format of Autodesk's Maya software. Highly prevalent in the in the film and gaming industries	✓	✓ <sup>1</sup>	✓ <sup>1</sup>
.3ds	3D Studio Max Scene	The primary format of AutoDesk's 3ds Max software; a binary format consisting of chunks that hold various pieces of information; chunks contain an identification indicating what information is stored there and the offset to the next chunk	✓	✓ <sup>1</sup>	✓ <sup>1</sup>
.obj	Wavefront OBJ	The most popular 3D file format. It is a text based, open file format developed by Wavefront Technologies; has been widely adopted by other 3D graphics applications vendors and can be imported/exported by a number of them; consists of a number of lines each containing a key and various values; the key on each line indicates the type information to follow	✓	✓ <sup>2</sup>	✓ <sup>2</sup>
.iges	Initial 2D/3D Graphics Exchange Specification	Initial Graphics Exchange Specification format, published by the National Bureau of Standards in 1980, is a popular neutral format for digital the exchange of CAD information; format is designed to store both 2D and 3D data	✓		
.ply	Stanford PLY	Designed for the purpose of being both a flexible and portable 3D file format; has both an ASCII and a binary version; binary version includes information to make it machine independent; also allows for user defined types allowing it to be extensible to the needs of future 3D data	✓	✓	
.stp	Standard for the Exchange for Product Data	A plain text format that deals with named objects rather than just raw geometric information; developed as a successor to the .iges format; like the .iges file format it relies on solid modeling, which is convenient for CAD developers	✓		
.u3d	Universal 3D	Developed by the 3D Industry Forum which consisted of companies such as Intel, Boeing, Adobe and HP; intended to be a universal standard for 3D data of all kinds that would facilitate exchange with a focus on promoting 3D graphics development in manufacturing, construction and various other industries	✓	✓	✓
.amf	Additive Manufacturing File	An open standard for describing objects for additive manufacturing processes such as 3D printing. XML-based format designed to allow any computer-aided design software to describe the shape and composition of any 3D object to be fabricated on any 3D printer. Unlike its predecessor STL format, AMF has native support for color, materials, lattices, and constellations	✓	✓	✓

Similar to any other medical process, the actors of the treatment process requiring prosthesis has to interact with other decision centers such as hospitalization services, logistic or compatibility. Thus, additional specific files and data also have to be considered as a part of the global digital chain to be managed by information systems.

Thus, variety of tools and data formats conducts to the complex problem of interoperability (Penciuc et al., 2014). Domains (conceptual) interoperability concerns the semantic connection between the domain of surgery and manufacturing, affecting models interoperability. Data interoperability issues are related to exchange of different file formats between different systems. These exchanges occur between clinical information and pre-operation planning systems on one side, and between pre-operation planning and implant design systems on the other side. Organizational

interoperability issues affect administrative procedures and relationships between non-technical information systems.

#### 1.4 Synthesis and problematics of medical treatment requiring prosthesis

Medical sector is a dynamic domain that needs continuous improvement of its business processes. In the specific case when a prosthesis implant is needed, the treatment process of a patient includes many sub-processes such as: the patient data acquisition, prosthesis design, manufacturing, surgery and recovery. The accuracy and completion time of these sub-processes have a strong influence on the success of the treatment process. For instance: with better quality of the prosthesis, it reduces the incidents may occur during surgery process. Post-treatment and related costs can be also reduced if the geometry of the prosthesis is completely adapted to the patient morphology. The patient will be recovered after surgery quickly in this case (Zdravković and Trajanović, 2011, Zdravković et al., 2012b).

During the above process, several types of data and knowledge are created and shared between stakeholders. This data concerns: medical reports and other patient data, surgery procedures, medical images and prosthesis data among others. However, there are many factors influencing the accuracy and the completion time of the patient treatment process (Bibb et al., 2015c). These factors and practices usually lead to potential errors and delays that can be summarized as follow:

- **Data reading and interpretation:** The size data manipulated in the treatment process is generally very large (up to 300 MB) and several technical and human factors are influencing the accuracy, the completion and the exploitation of the generated data. Therefore, the problems linked to corrupted or incomplete data are very important because of the low capacity of data structuring and searching as well as the high risk of losing details in the big mass of data, especially when it is shared via ad-hoc networks.
- **Communication methods:** Actually, there are no optimum methods to achieve the efficient collaboration between actors. They often use the ad-hoc network, email to share the data together or even the data is archived to a CD/DVD, then supply for related sub-processes. In addition, the cultural barriers due to the variety of business fields make the communication and the mutual understanding difficult.
- **Interoperability issue:** because of the variety of standards and tools, several problems of data exchange can occur during the import/export of files in/from tools. This increases the impacts of communication failure between organizations.

Domain, data and organization currently are the three main interoperability types identified in medical domain requiring prosthesis.

- **Delays:** The stakeholders in one sub-process want to receive the data from another sub-process. They must send a request and wait for accepting from another stakeholder. The data is then sent by the internet or saved to a CD/DVD. This method is not optimal. It causes delay in the data exchange between the sub-processes. Consequently, the completion time of the whole process is lengthened.
- **Data sharing through the prosthesis lifecycle:** the surgeons always want to monitor, check information and the data of the prosthesis and patient. Based on the data acquired, he can effect, adjust the prosthesis design process or modify the manufacturing and implantation processes.
- **Knowledge capitalization failure:** doctors and engineers generally focus their interaction on the descriptive data for the current medical treatment of a patient and the prosthesis under development. Less interest is given to the capitalization and the sharing of decision taken and respective business rules. This results in time loosing for future cases.

In such context, there is the need to provide stakeholders by: (1) common standards for data structuring and easier communication, (2) interactive workflows for easier collaboration, (3) knowledge-based supports for decision-making and (4) robust finding mechanisms to make easier the exploitation of saved knowledge. Therefore, enhancing the accuracy of all sub-processes in the patient treatment process and shortening the development time of the prosthesis are emergency problems that can find new solutions by using new generation of ICT (Information and Communications Technology). These elements are among the most important development pillars within the information perspective and should be considered as part of a global framework in order to ensure the consistency of the whole medical treatment process requiring prosthesis.

The next chapter presents a literature survey related to the domains of knowledge management and product lifecycle management as complementary pillars for dealing with the problems of knowledge sharing and collaboration. Current practices and recent development in medical sectors within these pillars is also discussed to show the limits and to refine the research problem of this PhD thesis.

# Chapter 2

## Literature survey on PLM and KM approaches

### Contents

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2.1 Introduction .....	32
2.2 The concept of knowledge in enterprise.....	33
2.2.1 Definitions of data, information and knowledge .....	33
2.2.2 Main pillars of knowledge management in modern enterprises .....	35
2.3 Knowledge representation and sharing .....	37
2.3.1 Knowledge representation languages and tools .....	39
2.3.2 Ontology as a support for knowledge classification .....	41
2.3.2.1 Definition of ontology.....	42
2.3.2.2 Tools for designing Ontologies.....	44
2.4 Knowledge modeling frameworks .....	45
2.5 Product lifecycle management approach.....	50
2.5.1 Introduction to product lifecycle.....	50
2.5.2 Product lifecycle management approach .....	51
2.5.3 PLM functions.....	54
2.6 PLM applications.....	57
2.6.1 Applications in industrial domain .....	57
2.6.2 Applications in medical domain .....	59
2.7 Synthesis and research questions.....	63

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## 2.1 Introduction

Because of the increasing complexity of systems, their variability, and constant evolution of customer needs, business activities has become more and more challenging and requires the collaboration between heterogeneous teams holding expertise in specific tasks. For instance, the outcomes of each expert field have to be put together without affecting the global integrity of the whole project. In context of medical treatment requiring prosthesis, the design and manufacturing of the prosthesis needs more than technical knowledge and involves stakeholders from medical and healthcare domains. In order to control the consistency of data and information produced and used during the design process, concurrent engineering methods are required. To do so, there is the need to develop integrated approaches where a knowledge model representative of the product in a multiple-view is the reference for each expert to refer throughout the whole project lifecycle.

Knowledge engineering and management communities provide a set of interactive processes and best practices to support the whole knowledge lifecycle in the enterprise, from the creation to the exploitation and archival (Liao, 2003, Studer et al., 1998). Knowledge engineering provides conceptual frameworks and exploitable formal knowledge representations (Matta, 2004). Sainter et al. (2000) distinguished six steps for the knowledge management process from knowledge identification to knowledge reuse. Each of them involves several actors coming from various fields. At the operational level, the achievement of the above steps requires the development of modeling and methodological frameworks for the representation and manipulation of knowledge. Numerous systems and methodologies are developed with the aim to support knowledge modelling, storage and reuse (Liao, 2003). Regarding industry needs, knowledge-based systems can be presented as dedicated databases, documents, reports, etc.

On another side, new generation of IS could offer large capabilities to manage information representing the explicit part of expert knowledge. One of the most judicious solutions is to use these capabilities for the building of the knowledge-based module. As part of the modern Information and Communication Technology (ICT) systems in industrial companies, the product lifecycle management (PLM) approach might have great advantages to implement the above needs since it provides interesting mechanisms for supporting different levels of inter-enterprise collaboration (Ming et al., 2005) and associated data sharing (Van Wijk et al., 2008).

The following sections present a literature survey on the concept of knowledge and existing knowledge management methods in the enterprise. The question of how data and knowledge are structured in enterprise information systems is also discussed through a review of PLM system foundations. Some applications of such KM and PLM tools on industry and medical domains are presented to clarify the key functions and characteristics of these systems in context of extended organization.

Based on this literature survey, the problem statement of this PhD work is refined and formulated as a set of research questions. First, the concepts of data, information and knowledge are clarified. The role and classification of this immaterial capital in the company are highlighted. Second, methods and tools for knowledge representation are described relying on most important and standard modeling frameworks. A focus is made on ontology paradigm as a key tool for semantic modeling. In the second part of this chapter, the description of PLM systems, their main characteristics and applications in the industrial domain are detailed. Synthesis and research questions are proposed in the final section.

## **2.2 The concept of knowledge in enterprise**

The complexity generated by the concept of knowledge along its lifecycle implies several problematics related to its acquisition, representation, exploitation and management in the enterprise. The following sections discuss the main issues within the concept of knowledge.

### **2.2.1 Definitions of data, information and knowledge**

The distinction between "data", "information" and "knowledge" is commonly discussed in the literature. According to Ackoff (1989), data are symbols that represent the properties of objects and events, data has no meaning or value because it is without context and interpretation. They represent a fact or statement of an event without any relation to other data.

Information is contained in descriptions. It provides answers to "who", "what", "where", "why", or "when" questions. Information is inferred from data to which meaning is attributed in a defined context. Information for one person may remain a given for other people who do not have access to its meaning because of a lack of context or a reading tool (Keller and Tergan, 2005).

Unlike data and information, knowledge is more difficult to define since it is associated to cognitive resources and expert activity (Grundstein, 2000). Indeed,

according to Guerra-Zubiaga et al. (2006), data relate solely to words or numbers, which meaning is dependent on the context where it is used. Information is structured data used to provide a meaning within a given context. Several definitions of knowledge exists in the literature (Belkadi, 2006). The most known definitions argue that the knowledge results from the acquisition of information and its interpretation in a given operational context (Prax, 2000).

The Hierarchy of data, information and knowledge are described in Figure 2.1 (Chaffey and White, 2010). According to this figure, knowledge has the highest value and meaning comparing to information and data. It is also the most difficult on the ability to program and create algorithms.

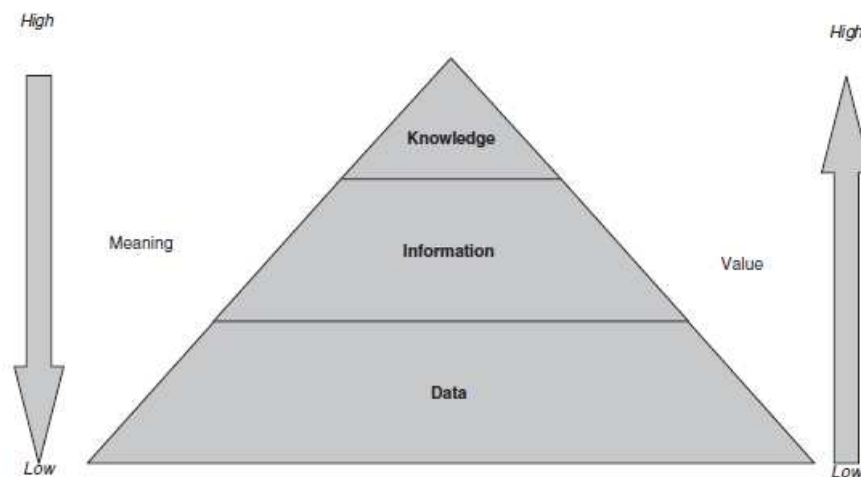


Figure 2.1 - Hierarchy of data, information and knowledge (Chaffey and White, 2010)

Another clarification of the concepts of data, information and knowledge is given by Zeleny (1987) as shown in Table 2.1. In this table, it is also compared with the definitions of Ackoff (1989).

Table 2.1 - Definitions of data, information and knowledge

	<b>Ackoff (1989)</b>	<b>Zeleny (1987)</b>
Data	Symbols	Know nothing
Information	Data that are processed to be useful; provides answers to who, what, where and when questions	Know what
Knowledge	Application of data and information; answers how questions	Know how

Focusing on the knowledge dimension, it is commonly agreed that knowledge exists when the user within that specific context recognizes useful data relationships, or when the user is able to derivate those relationships from raw, but structured information database. One of the major properties of knowledge is the capacity to

generate a new kind of knowledge from existing one, by using data stored in engineering systems and mapping methods (Gordon, 2000, Studer et al., 1998). Knowledge can be obtained by transmission from another person or by extracting it from experience (Keller and Tergan, 2005). Generally, two major forms knowledge are distinguished in the literature: explicit and tacit (Nonaka and Takeuchi, 1995).

- Explicit knowledge represents the rational dimension that can be expressible in formal language and transmissible from one individual to another. This knowledge is observable, measurable and therefore easily captured and storable in formal documents and digital files such as texts, tables, formulas, diagrams and product specifications. This kind of knowledge exists in symbolic or written form and a representation of this knowledge can be recorded in information systems (Bocij et al., 2008).
- Tacit knowledge represents the subjective dimension that cannot be easily articulated neither verified. It is personal, intuitive, difficult to formalize in speech and often linked to a particular context. Because of this, it is difficult to communicate and to transfer it (Lam, 2000). Tacit knowledge is a part of the human mind that cannot be recorded in any system. (Bocij et al., 2008).

### 2.2.2 Main pillars of knowledge management in modern enterprises

Knowledge influence on the enterprise performance is often proved (Lopes et al., 2017). As stated by Dewulf (2013), in innovation process, knowledge about the final solution increased progressively while engaged costs decrease along the different stages of the project. Experience from past projects will support decision-making and contribute to increase knowledge about the current solution. Commonly called “lessons learned”, this term defines the practice of learning from successful and unsuccessful past events to reduce failure risks in the future projects. The likelihood of reusing “lessons learned” depends on their applicability to future projects and the similarity between projects.

Looking to the increasing value of this human heritage, companies have been adopting managerial and technological solutions for several years in order to preserve and structure their know-how. Knowledge management is a research discipline that has emerged as a key to answering this problem, aiming at proposing methodological and organizational approaches in order to capitalize on knowledge and reinforce its added value in the life of organizations.



In France, the model of Grundstein (2000) is a benchmark work that identifies four key facets of the knowledge management process. The first facet deals with the location of crucial knowledge in the company that is necessary for decision-making and the realization of core processes. This is the kernel of the immaterial capital of the company that is necessary to identify, characterize, estimate the added value and prioritize according to the strategy. The second facet concerns the preservation of the located knowledge through the actions of acquisition, formalization and conservation. The third facet is the continuous valorization of the acquired knowledge so as to make them already accessible and ready to exploit in the business processes. This facet includes the actions of dissemination, sharing, usage and combination for the creation of new knowledge. The last facet concerns the actualization of the capitalized knowledge to follow-up the evolutions of the company. This is achieved through a set of appraising, updating, standardizing and enriching mechanisms along the whole life of the knowledge (Grundstein and Rosenthal-Sabroux, 2003).

In industry, three main categories of knowledge are generally distinguished: product engineering knowledge, manufacturing process knowledge and organizational knowledge. Product knowledge refers to different types of characteristics describing the functional, behavior and structural views as well as geometry (Gero and Kannengiesser, 2004). Process knowledge refers to the concept of activity which allows creating the link between products, resources (facilities, humans...) and their characteristics (rules, sequences, tasks, etc.). It concerns the process scheduling, the set of resources (human resources, machines, tools and tooling), the organization of the production unit (work centers) and the manufacturing know-how (Fortin and Huet, 2007). In addition, information about decisions taken during the project, their justifications and their context of consideration are another important type of knowledge necessary to achieve reasoning. This leads to the activity of traceability that is usually associated with project memory. Project memory captures project histories that can subsequently be retrieved and applied to current problems (Kwan and Balasubramanian, 2003). A modelling framework of a traceability system is used to structure and capture the history of design (Brandt et al., 2006) which concerns relevant information, about the product, its different evolutions, activities, resources, tools, events, and the organization of these elements during the project progress. Various methods, generally associated to KM systems have been developed to meet the need for traceability (Ramesh et al., 2001).

For an efficient exploitation of company knowledge, expert systems propose to users a set of tools to help structuring, reasoning on and manipulating knowledge for

decision making perspective. A knowledge-based expert system consists of a knowledge repository, an inference engine and a user interface (Kiritsis, 1995). According to its architecture, such a system would be able to deduce a result from input (forward chaining) or to find inputs corresponding to given results (backward chaining), or even both of them. The inference engine can be based on a set of logical rules, a semantic description or ontology, a stochastic approach or a fuzzy logic engine. Thus, the system reuses knowledge to explain results or to give advice.

The information acquisition stage in these methods is frequently based on analysis of data and on interviews of experts. However, the key issue for an optimal exploitation of the collected knowledge is still the structuration and the representation of this knowledge in a consistent format.

### **2.3 Knowledge representation and sharing**

Independently of the type of knowledge, the question of the knowledge representation in practice is critical. As stated by Ganascia (1996), knowledge is a part of the cognitive resources for one person and cannot exist out of his memory. In fact, all physical and digital sources store and manipulate a representation of the expert knowledge (Belkadi, 2006). Knowledge is often hidden behind the set of data and information and must be "unveiled" to become usable (Bertschi et al., 2013). Knowledge representation is a sub-domain of Artificial Intelligence that studies computer models, languages, and systems that can explicitly represent or reason about knowledge (Chein et al., 2013). According to Shapiro (2006), knowledge representation is responsible for designing and implementing ways of representing information in machines so that programs can use it: To derive information that is implied by it; To converse with people in natural languages; To plan future activities; and To solve problems in areas that normally requires human expertise.

Knowledge sharing is one of the main implications of knowledge representations. It consists on the activities of transferring or disseminating knowledge from one person, group or organization to another (Lee, 2001). Between two types of knowledge, Ipe (2003) points out that sharing of explicit knowledge is easier than sharing of tacit knowledge. Researchers indicate that knowledge sharing among actors plays a very important role between members inside or outside of an organization. This sharing provides the information to make the right and quick decisions. In addition, knowledge sharing improves communication among employees, enhances the process of ideas, experiences and expertise (Haas and Hansen, 2007). Knowledge sharing also helps actors reuse experiences to solve the problem in the best way.

In design projects for example, the concept of shared representation is often linked to the development and handling of many halfway objects and models. As a result, the integration of such variety of viewpoints is one of the main challenges. This variety of viewpoints implies the development of methods and tools promoting knowledge integration upstream the product design process (Ouamer-Ali et al., 2017). Experts collaborate among the whole product lifecycle and use different supports to share exchange and build new knowledge. A survey of the topic pointed out the existence of various product models, which aim to provide a representation of the product knowledge in terms of its functional and physical description (structural and geometrical) as well as behavioral representation used in simulation. In addition, the experts can apply their own perspective on a common object based on their business expertise. Kleiner et al. (2003) assume that one of the major sources of data consistency provide from the diversity of interdisciplinary constraints generated during the development process (Figure 2.2). The concept of interdisciplinary constraints aims to map the constraints of each business point of view back to the product model. It allows the inter-connection of various business design constraints by mapping them to intrinsic product information in order to enhance the management of conflicts.

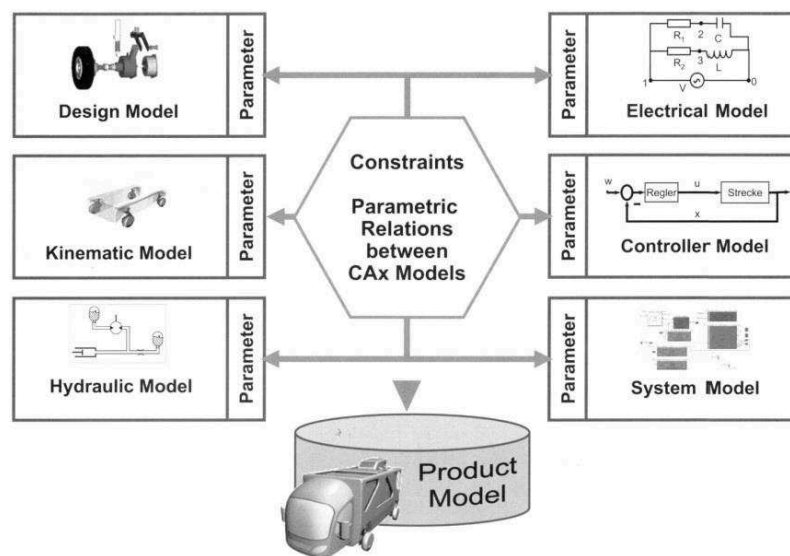


Figure 2.2 - Interdisciplinary constraints concept (Kleiner et al., 2003)

In industry, several works are interested to knowledge formalization (Bernard et al., 2009). As a kind of mechanical system, the design and manufacturing of the prosthesis should respect the same steps of industrial design processes and could be subject to the similar problematics of knowledge representation and formalization. In addition to mechanical engineers, the specificity is that other actors from the medical domain are also needed making the problem of interdisciplinary constraints more

complex. The complexity of knowledge representation increases for other medical devices which include additional electronic and electric components.

The knowledge sharing is constructed according to a set of cognitive and organizational processes, from the aggregation of different data and information defined in separate repositories, organized according to specific models and manipulated by different tools and actors. In the medical domain, this issue is more complex because of the communication barriers between medical and engineering domains. Due to the heterogeneity of the business culture of each expertise field and the variety of software supports, the same knowledge might be represented with different semantics (mechanical simulation, manufacturing, etc.). Standard models are critical to support the shared knowledge and should be based on robust formalisms and languages. The next section presents an overview of the main modeling languages and tools currently used to represent business knowledge in a standard way.

### 2.3.1 Knowledge representation languages and tools

An important role of knowledge representation is to provide support for human expression and communication (Davis et al., 1993). The most common medium of such type is natural language because of its expressive. However, natural language is often ambiguous, inconsistent and difficult to model. Therefore, it is not appropriate for the knowledge representation and its manipulation. For this reason, the more suitable formalisms with computer are used in the information system. For instance: semantic networks, frames, description logics, conceptual graphs and fuzzy logic (Jakus et al., 2013) among others.

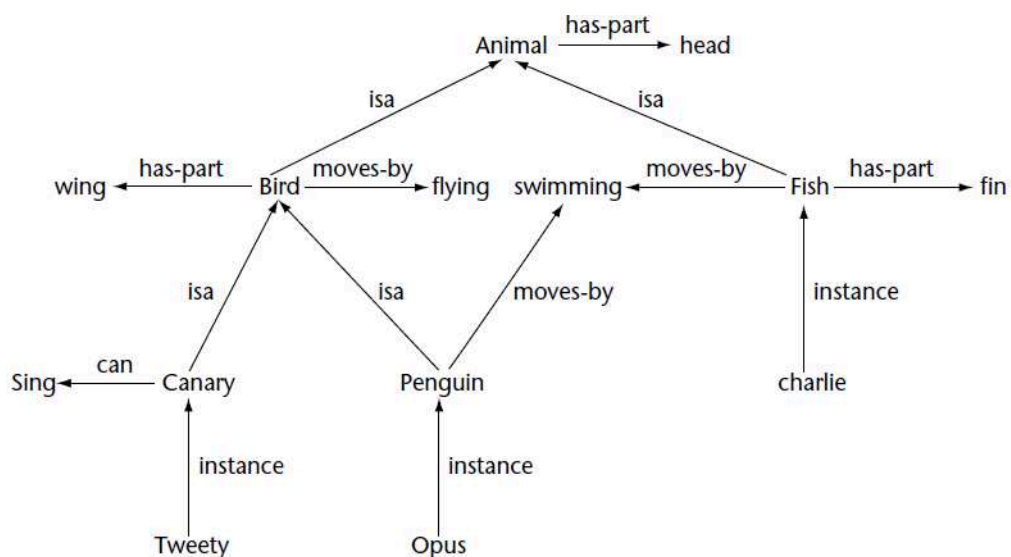


Figure 2.3 - An inheritance-style semantic network (Davis et al., 1993)

**Semantic networks:** The semantic network, introduced by Quillian (1968), are a set of nodes and arcs (nodes: objects, concepts or events, arcs: relations between the nodes they connect). There are two kind of semantic networks: inheritance networks (Figure 2.3) and propositional semantic networks (Shapiro, 2006). The relationships are often used such as: “is-a”, “has part”, “one-type-of”, “can be” etc. The graphic representation is a great advantage of the semantic network, which makes knowledge representation easier to understand. However, the semantic network can be difficult to interpret when the number of nodes and arcs becomes too large.

**Frames:** Semantic networks evolved into frames in the 70s and 80s (Minsky, 1974). A frame is the central object in the model. It represents an entity as a set of slots that contain the attributes and relationships of the frame. A slot has one or more facets to describe the characteristics of the relationship. There are three main frame types: class frames represent sets of entities, slot frames which represent binary relations, and individual frames which represent single entities (Klein, 2004).

**Description logics** is a knowledge representation language used to represent a domain of application through logical semantics based on logic (Baader, 2003). A strong point of logical description is the reasoning ability. A kind of inference (in addition to abduction, deduction and induction) is the automatic classification: The new description can be placed automatically in the right place in the hierarchy of predefined objects.

**Conceptual graphs** was firstly introduced by Sowa (1984) as knowledge representation based on existential graphs and the semantic network. Conceptual graphs are a diagrammatic system of logic (Sowa, 1992). It includes two kinds of nodes: concepts and conceptual relations. Figure 2.4 shows an example of a conceptual graph in which concepts are presented by rectangles, and conceptual relations are presented by circles.

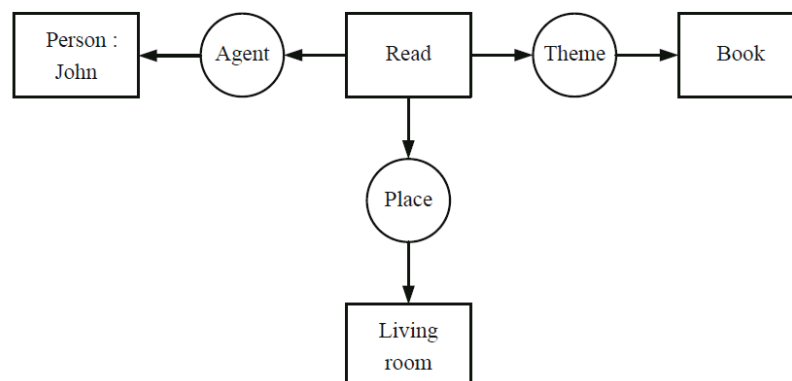


Figure 2.4 - Example of conceptual graph (Sowa, 1992)

From a standardization perspective, the OMG<sup>3</sup> (Object Management Group) is created as an international, open membership, not-for-profit technology standards consortium. OMG Task Forces develop the enterprise integration standards for a wide range of technologies and an even wider range of industries. This organism proposes several standardization languages to support knowledge representation. BPMN (Business Process Model Notation) and UML (Unified Modelling language) are among the most known languages proposed by this organization. UML is a tool for describing all kinds of object-oriented artifacts (Booch et al., 1999). In order to allow other similar languages to be defined as well, the OMG uses a general framework based on the MOF (Meta-Object Facility) (OMG, 2013). Following this couple of standards, UML meta-model allows defining generic concepts to be used in a UML models. A given UML model describes a set of specific concepts and their relations as an abstraction of the real world (Chapurlat, 2007). The development of Models and Meta-models became an important challenge for the success of the interoperability strategy at the semantic and organization levels. This makes possible the communication between varieties of information systems and the consistency of shared knowledge between experts (Belkadi et al., 2012).

Process models are also used for supporting inter-enterprise collaboration (Li et al., 2015). Service-oriented approaches (SOA) can be used to implement business processes (BPs) in a very flexible way so that business changes can rapidly be considered in given information system solutions (Hachani et al., 2013). Business process modelling is often considered as an essential stage for the analysis of any business domain, such as the medical sector (Augusto and Xie, 2014), administration (Gottschalk et al., 2009) or the financial sector (Weiss and Winkelmann, 2011) by using different modelling languages such as Business Process Modelling Notation (BPMN), and IDEF3 of the ICAM Definition (IDEF) method (where 'ICAM' is an acronym for Integrated Computer-Aided Manufacturing).

### 2.3.2 Ontology as a support for knowledge classification

Ontology-based modeling is a well-known approach to support knowledge representation (Tursi et al., 2009) as well as interoperability between IT systems during the collaborative business process (Barbau et al., 2012). They are used to formalize the knowledge of a domain and thus add a semantic layer to computer systems and applications. Ontologies make it possible to explicitly represent domain

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<sup>3</sup> <https://www.omg.org/>

knowledge using a formal language so that it can be manipulated and shared easily. Their use is widespread in a variety of research areas such as knowledge representation (Hoehndorf et al., 2014) information retrieval (Castells et al., 2007) and information integration (Wache et al., 2001).

In this section, we present the definition of ontology. The components, types and application of ontology are also discussed.

### 2.3.2.1 Definition of ontology

Ontology is an explicit specification of a conceptualization (Gruber, 1993b). It is a system of fundamental concepts set up to model, represent and describe a specific domain in terms of axiomatic definitions and taxonomic structures (Chandrasegaran et al., 2013). Based on data models, ontologies give sense to data. Concepts are usually defined to build a common taxonomy and improve collaborative works by easily sharing knowledge. In other words, they provide the vocabulary for a domain and use simple languages to build complex models (Nadoveza and Kiritsis, 2014, Wojtusiak et al., 2016). They include many applications such as data integration, knowledge management, and decision support (Bodenreider, 2008).

Advantages of Ontology models for context modeling are high expressive power which is very important in building complex models, and facilitation in sharing and reusing formal represented knowledge among users (Nadoveza and Kiritsis, 2014). In other words, the main purpose of the ontology is to produce a shareable and reusable set of information elements to be used by people and computer systems (Fitzpatrick et al., 2012).

Ontology proposes graphical and constraint based modeling tools to represent variety of knowledge. The main components of ontology are concepts/classes, relations, functions, axioms and instances. (Gómez-Pérez, 1999, Gruber, 1993a):

- **Concepts:** also called classes or types are a core component of most ontology. A concept represents a set of objects and their common properties. It can represent a material object, an event, a notion or an idea (Uschold and King, 1995). A concept may be a sub-concept of another concept. For example, concept "computer" has two sub-concepts: "laptop" and "desktop PC". In addition, concepts may also share relationships between each other.
- **Relations:** describe the way that all individuals relate to each other. It can be relationships between individuals or between concepts. Relationships indicate the interaction among the concepts in the domain. They are defined by the properties

and by the attributes that characterize the classes in the domain. Figure 2.5 shows (sub-)classes and the relationship between them (Nadoveza and Kiritsis, 2014).

- Functions: are a particular type of relations that can be used in place of an individual term in a statement
- Axioms: represent assertions formulated in a logical form that together comprise the core knowledge that the ontology describes in its domain of application. Axioms are used to design an explicit way of expression that is always true. An interesting list of axioms commonly identified in the medical domain is proposed by Zeshan and Mohamad (2012). An example of this axiom list is shown in Table 2.2.
- Instances: are individuals or particulars that model concrete objects and represent the base components of ontology.

Three types of ontology can be distinguished: Global ontologies, domain ontologies and application ontologies (Guarino, 1998). **Global ontologies** (Top-Level Ontology) propose formal representation with a high level of generality and abstraction. They are the result of a systematic, consensual and rigorous development that allow sharing knowledge and transferring one context to another. They are dedicated to a very general use and serve as a basis for the development of local ontologies to given domains. **Domain ontologies** are limited to a representation of the concepts of given domains (geography, medicine, etc.). They have a lower level of abstraction than global ontologies. In general, they bring a specialization of the general concepts of a global ontology. **Application ontologies** describe the concepts relating to a particular application for a specific domain. It has a high degree of specificity. Application ontology specifies domain ontology or global ontology.

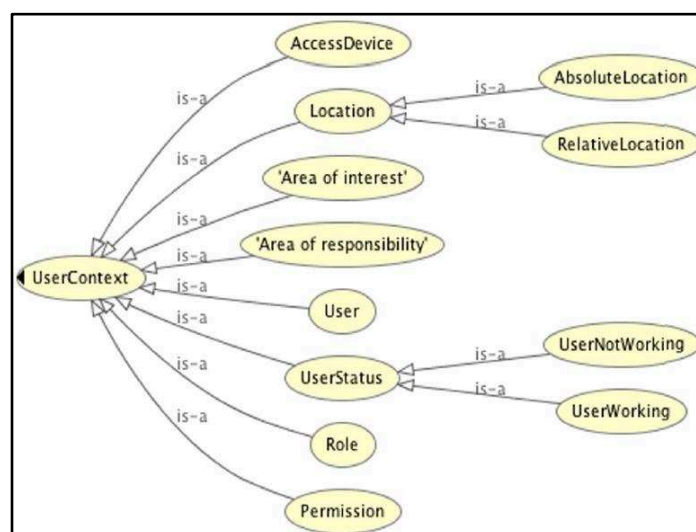


Figure 2.5 - An example of ontology (Nadoveza and Kiritsis, 2014)



Table 2.2 - Logical axioms table in medical domain (Zeshan and Mohamad, 2012)

Concept name	Axiom description	Logical expression
Staff	Person who is a member of hospital and has staff id, name and designation	$\forall X, \text{Staff}(X) \Rightarrow (\exists \text{HospitalID.String}) \text{ and } (\exists \text{Name.String}) \text{ and } (\exists \text{Designation.String})$
Nurse	Person who is a staff member and cares for the patient and helps the doctor to examine the patient and wears a white uniform	$\forall X, \text{Nurse}(X) \Rightarrow \text{Staff}(X) \text{ and } (\exists \text{Duty.String} = \text{'Patient Care'}) \text{ and } (\exists \text{Dress.String} = \text{'White'})$
Paramedics	Person who is not a doctor but can examine and treat patients without the help of a doctor A person who is trained to give emergency medical treatment	$\forall X, \text{Paramedics}(X) \Rightarrow \text{Staff}(X) \text{ and } (\exists \text{Duty.String} = \text{'Patient Treatment in Ambulance'}) \text{ and } (\exists \text{Ddegree.String} \neq \text{MBBS})$
Doctor	Person who is a staff member and has an MBBS degree and can examine patients	$\forall X, \text{Doctor}(X) \Rightarrow \text{Staff}(X) \text{ and } (\exists \text{Degree.String} = \text{MBBS})$
Surgeon	Person who is a doctor and specializes in surgery	$\forall X, \text{Surgeon}(X) \Rightarrow \text{Staff}(X) \text{ and } \text{Doctor}(X) \text{ and } (\exists \text{Duty.String} = \text{Surgery})$
Physician	Person who is a doctor and is in charge of a patient and cannot perform surgery	$\forall X, \text{Physician}(X) \Rightarrow \text{Staff}(X) \text{ and } \text{Doctor}(X) \text{ and } (\exists \text{Duty.String} \neq \text{Surgery}) \text{ and } (\exists \text{Responsibility.String} = \text{Patient in-charge})$
Patient	Person who receives medical treatment One who receives medical attention, care or treatment	$\forall X, \text{Patient}(X) \Rightarrow (\exists \text{Name.String}) \text{ and } (\exists \text{Condition.String} = \text{'injured'})$

### 2.3.2.2 Tools for designing Ontologies

Ontologies are widely used in many domains such as knowledge engineering, artificial intelligence and computer science, applications related to knowledge management, natural language processing, e-commerce, intelligent integration information, information retrieval, database design and integration, bio-informatics, education, and in new emerging fields like the Semantic Web. In these domains, the usage of ontology is proved to be extremely useful (Meenachi and Baba, 2012).

To do so, many ontology tools use a variety of formalisms and offer different features. All of these tools provide support for creating ontologies. The most popular tools such as Protégé, DOE, Ontolingua and OntoEdit are described as follows:

**DOE** (Differential Ontology Editor) (Troncy and Isaac, 2002) offers the possibility of constructing the hierarchies of concepts and relations by using the differential principles, then adding the referential concepts. The semantics of relations is then specified by constraints.

**Ontolingua**: provides users with the ability to browse, create, edit, share and reuse ontologies stored on an ontology server.

**OntoEdit** (Ontology Editor) is a development environment for ontology design and maintenance. It allows the editing of hierarchies of concepts and relations. Graphic tools dedicated to the visualization of ontologies are included in the environment. It is

widely used in the biomedical field. OntoEdit integrates a server for editing ontology by several users. Consistency checking of the ontology is ensured through the management of the publishing orders.

**Protégé** is a modular interface for editing, visualization, control (checking constraints) ontologies (Noy et al., 2000), and semi-automatic ontologies fusion using the Prompt plugin (Noy and Musen, 2000). The underlying knowledge model for protégé is derived from the frames model and contains classes (concepts), slots (properties) and facets (values and constraints), as well as class instances and properties. It allows the definition of meta-classes, whose instances are classes, which creates its own model of knowledge before building the ontology. Protégé proposes a graphical interface very pleasant and simple to use (Figure 2.6) to create classes and instances as well as relationships and properties in the ontology.

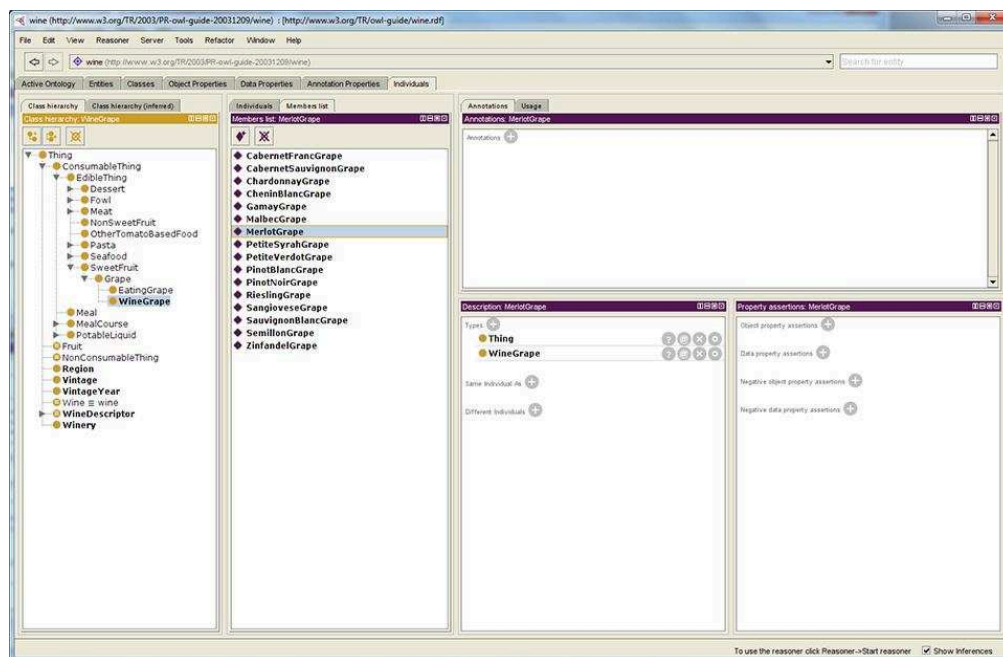


Figure 2.6 - User interface of Protégé tool.

## 2.4 Knowledge modeling frameworks

Several modeling frameworks and methods already exist in the literature. Some of them are generic offering guidelines and semantic to describe heterogeneous business domains and other ones are specific for supporting some applications. For instance, the collaborative aided design framework proposed in (Nowak et al., 2004) is based on the concepts of Product, Process and Organization as main modeling axis for engineering process. The commonly accepted approach for structuring product knowledge has been through the construction of Product Models (Stokes, 2001). Product model

consists of the definition of the functional, structural and behavioral dimensions of the product, while process model focuses on the various activities around the product. An example of such models is the Core Product Model (CPM) proposed by the NIST (National Institute of Standards and Technology) (Sudarsan et al., 2005). The organization model is interested to the resources and their roles in the process.

Similar concepts are used in the P4LM methodology (Danesi et al., 2008), where the product data are conjointly managed with process and project as well as proceeds. Project dimension includes the organization of resources as well. FBS-PPRE (Function, Behavior, Structure – Process, Product, Resource, External) is another modeling framework proposed by Labrousse et al. (2004). It extends the FBS (Function Behavior Structure) model proposed in the work of Gero (1990) in order to offer a better genericity and completeness. FBS-PPRE wants to be unified in order to ensure dynamic management of the company's knowledge. This model is based on the assumption that all information concerning an enterprise object is organized according to three basic classes: function, behavior and structure. Figure 2.7 illustrates the concepts used in the FBS-PPRE model.

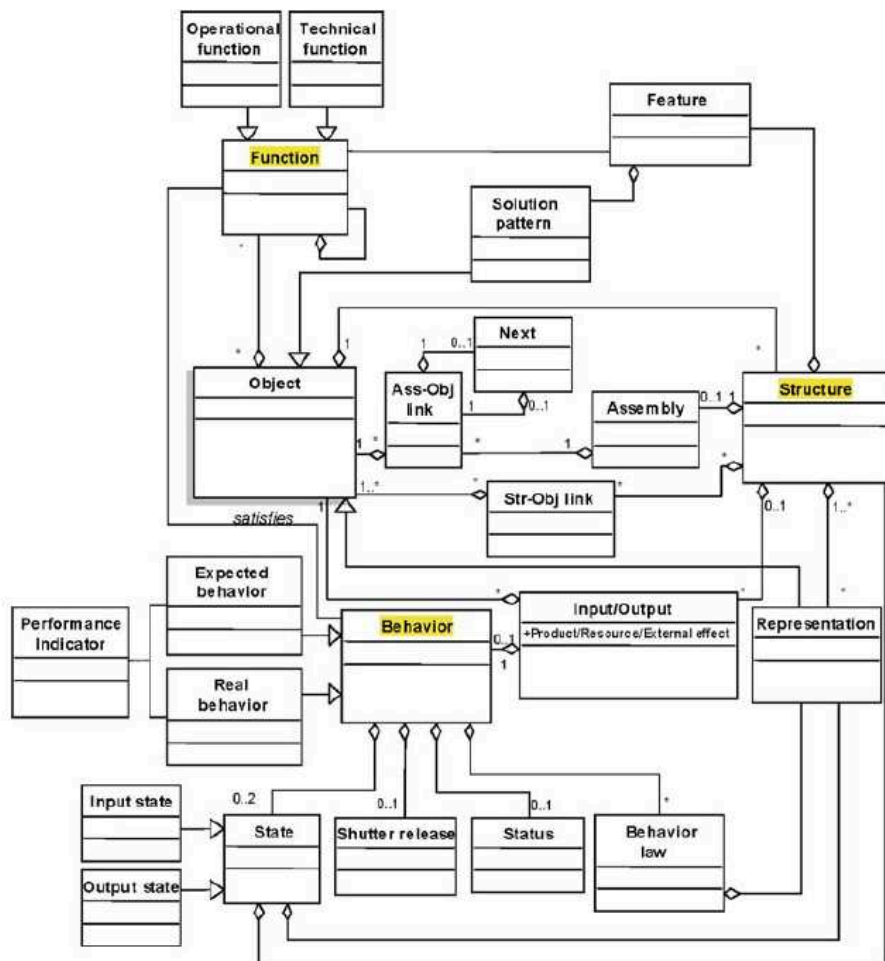


Figure 2.7 - UML class diagram of the FBS-PPRE model (Labrousse et al., 2004)

The PPO (Product, Process, Organization) meta-model is another modeling framework proposed by Frédéric and Roucoules (2008) according to 3 levels: product model, process, and organization. This model is dedicated to the development phase of new products and provides efficient assistance to collaboration during innovative design project. Based on these models, Le Duigou et al. (2009) propose the PPRO (Product-Process-Resource-Organization) meta-model for the specification of PLM systems dedicated to SMEs (Small and Medium Enterprises) in the field of mechanical engineering as shown in Figure 2.8.

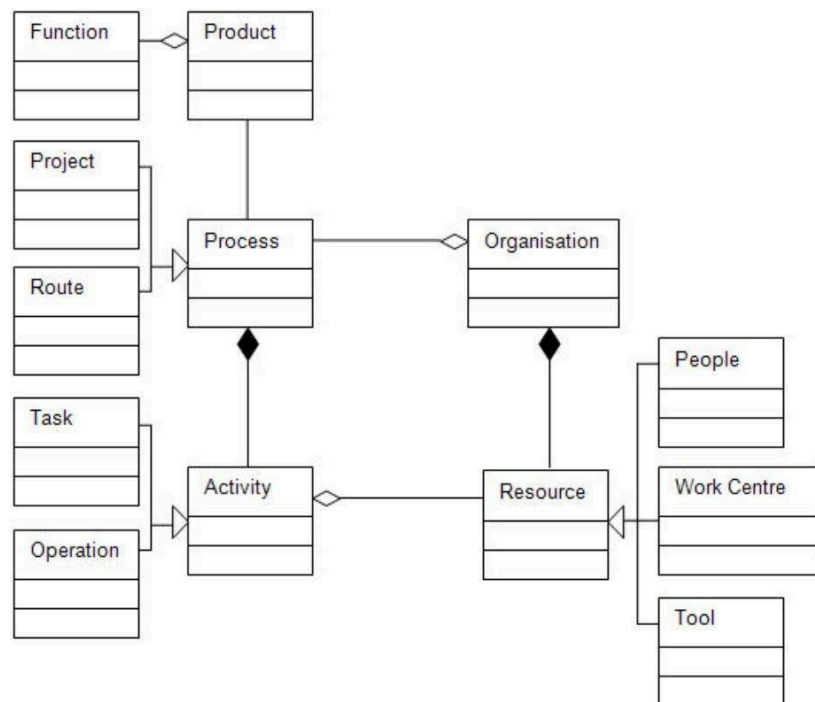


Figure 2.8 - PPR meta-model (Le Duigou et al., 2009)

Similarly, ontology is often used to represent expert knowledge. In the early 1990s, researchers in the knowledge acquisition community used ontologies to capture, preserve, and represent knowledge (Staab and Studer, 2010). Occasionally, ontologies have been the subject of research in other disciplines such as: natural language processing, knowledge management, e-commerce, etc. The notion of ontology is becoming widespread in areas such as the intelligent integration of information, cooperative information systems, retrieval of information, etc. (Tursi et al., 2009).

In the industrial domain, Fiorentini et al. (2007) translated the NIST's core product model and proposed ontology for the Open Assembly Model (OAM) implementing several OWL (Ontology Web Language) capabilities. In the same perspective, Tursi et al. (2009) have proposed a product ontology framework that aims

to formalize all technical data and concepts contributing to the definition of a Product Ontology, embedded into the product itself and making it interoperable with applications, minimizing loss of semantics. Assouroko et al. (2014) proposed an ontology covering requirement engineering, mechanical design and numerical simulation. This ontology supports data capitalization; data reuse and decision-making by representing dynamically relationships between different engineering entities (e.g. link between a specific design and its associated simulations). Maleki et al. (2017) proposed and developed a new sensor ontology that structures the domain knowledge, covering both theoretical and experimental sensor attributes. This ontology is developed as an OWL file and implemented in a common repository to facilitate knowledge reuse and reasoning when searching optimal sensor kits to integrate in a given industrial product-service system.

In medical domain, several applications of ontology are proposed including data integration, knowledge management, and decision support (Bodenreider, 2008). The ontology in western medicine includes several knowledge categories such: organic, diagnostic, disease and chemic (Binfeng et al., 2007). An application of ontology is proposed by Dramé (2014) to support knowledge representation for an information retrieval system used in biomedical domain. Medical ontology could be also used for computer assisted clinical decision support as shown in the patent proposed by Martin et al. (2011). According to this patent, the proposed medical ontology indicates semantic groupings of features that help, through a learning process, to identify at least one similar patient record from existing patient records. Examples of knowledge implemented in the ontology to realize the decision-making process: Clinical (including patient information, physical exams and laboratory tests); imaging (Magnetic Resonance and ultrasound) and genetics (describing gene expression and sequences).

A review of interesting applications in biomedical research was reported by Wojtusiak et al. (2016). The most popular biomedical ontologies identified in this review includes Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT), International Classification of Diseases (ICD), Logical Observation Identifiers Names and Codes (LOINC), Gene Ontology (GO), Medical Subject Headings (MeSH), RxNorm, Foundational Model of Anatomy (FMA) and Medical Dictionary for Regulatory Activities (MedDRA). Other ontologies are also proposed as a solution for the management of heterogeneous and distributed Bio-Imaging data (Pham et al., 2016). Figure 2.9 gives an overview of the top layers of this ontology which proposed to classify the Bio-Imaging domain knowledge according to four main categories of

concepts: Tool, Data, Process and Investigator. In the same domain, Gibaud et al. (2014) propose an application ontology to support the annotation of models integrated in the Virtual Imaging Platform (VIP). VIP aims at setting up a common repository to facilitate models sharing and reuse, based on a comprehensive conceptualization of those models, suitable for main types of imaging modalities and simulators.

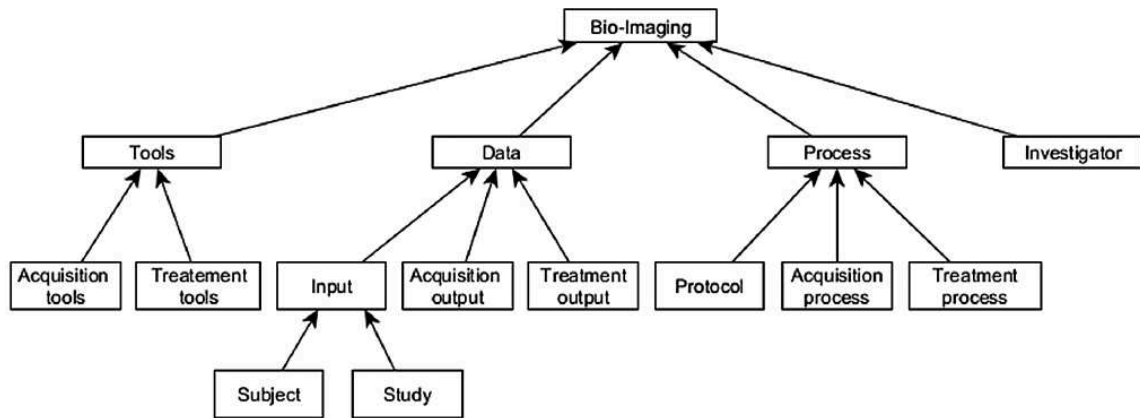


Figure 2.9 - Top layers ontology in Bio-Imaging (Pham et al., 2016)

In order to solve communication barriers due to the variety of ontologies and data models, the Unified Medical Language System (UMLS) was developed by the National Library of Medicine (NLM) in 1986 (Lindberg, 1990) that is permanently updated. The UMLS has three knowledge sources: Metathesaurus, Semantic Network, and Specialist Lexicon. The UMLS contains more than 3.25 million concepts, 22 million relationships among those concepts, and 12 million unique concept names from over 170 source vocabularies. The mappings between various Bio-Ontologies are obtained by assigning a concept unique identifier (CUI) in the Metathesaurus to terms from various source ontologies that have the same meaning (Wojtusiak et al., 2016). The mappings among these vocabularies allow computer systems to translate data among the various information systems. According to Bodenreider (2008), the rich relationships in the UMLS give interesting support for browsing medical knowledge and perform reasoning in this corpus. It also allows natural language processing, and value sets for Clinical Quality Measures (CQMs).

As a synthesis, ontologies can be used not only to structure the immaterial capital of the company but also to: help communication between humans; ensure interoperability between different systems and improve the capacity of information systems to manage with the same semantic large variety of data and information (Jasper and Uschold, 1999). In this work, the ontology is used as a conceptual background to improve the data and information representation structuration in an information system dedicated to connect medical and engineering domains.

Specifically, this research work is interested to study the potential of using product lifecycle tools as a collaborative knowledge based framework dedicated to medical domain requiring mechatronic or mechanic devices like prosthesis. The next section gives a presentation of Product Lifecycle approaches and associated tools, technologies.

### **2.5 Product lifecycle management approach**

Product data management (PDM) systems are claimed as capable of speeding up the process of distributing engineering information and knowledge, while centralizing management of the overall product development process. This category of systems is used to manage the engineering Bill of Material (eBOM) that is composed of components, parts and sub-parts. The corresponding product's structure for manufacturing view (mBOM) is stored in the enterprise resource planning (ERP) system. More conventional database tools in the industry are related with configuration management systems in order to integrate other categories of product and process data. Recently, the enterprise information systems were developed in an integrated way as part of a whole product life cycle approach that consists more than a connection of heterogeneous software. The next sections describe the different issues related to PLM approach. A focus on the functions of PLM as a tool is also detailed. Before this, the first question is to explain what the concept of product lifecycle means.

#### **2.5.1 Introduction to product lifecycle**

A product system's life cycle includes all stages from inception, through engineering design and manufacture, to service and disposal. According to Boujut and Blanco (2003), the product considerably evolves and matures throughout its life cycle. Ducellier (2008) divides this maturity into four stages: the virtual product (definition of product requirements), the evolving product (product design and manufacture), the mature product (product distribution and use) and the product decline (stop using product). One of the common definitions from Kiritsis et al. (2003), product lifecycle is divided into three main phases: Beginning of Life, Middle of Life and End of life:

- Beginning of Life (BOL) includes concept development, product design, prototyping, testing, process planning, supply chain planning and production (Fatallah et al., 2008). Design and manufacturing teams collaborate to define the product and also to plan production tools and supplies.

- Middle of Life (MOL) includes delivery, installation, maintenance and other services to customers. In this phase, the product is reached the final customers. Products are distributed, used and supported by customers and/or service providers.
- End of life (EOL) includes removal, disposal and recycling. The product is removed from service for recycling or replacement. The information of product (components, materials ...) is collected to ensure its recycling or reuse.

Three phases of product lifecycle are composed by several stages and sub-stages as it summarized in Figure 2.10 (Terzi et al., 2010). In each stage, the characteristics of the product and its level of maturity is changed and coupled with the generation of several requirements and constraints that implies several processes and practices.

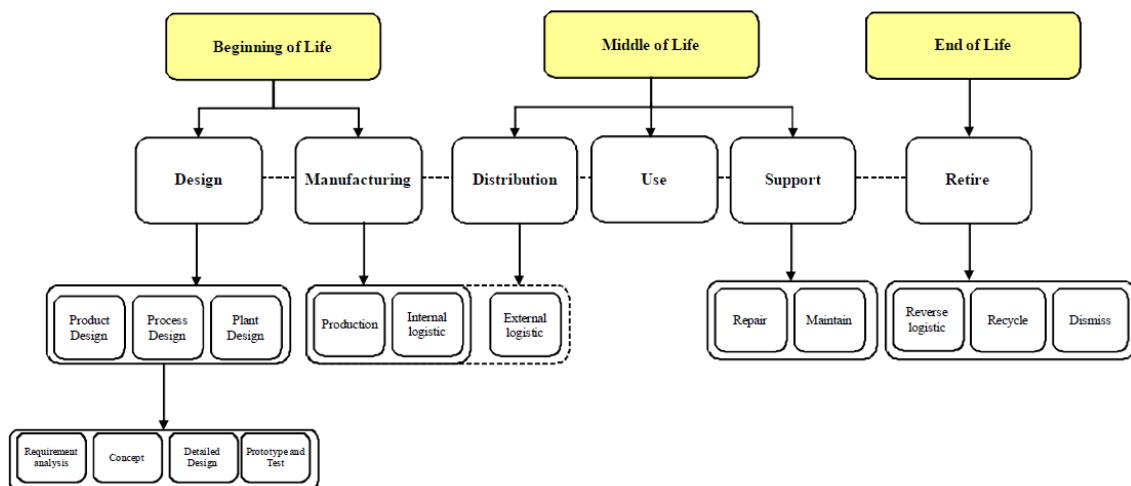


Figure 2.10 - Product lifecycle phases (Terzi et al., 2010)

The variety of life stages for a system lifecycle implies the need to manage variety of processes and knowledge within different perspectives from heterogeneous actors. The next section gives an overview on the existing methods and tools dedicated to the management of product lifecycles in different business domains.

### 2.5.2 Product lifecycle management approach

PLM systems began to emerge in the late 1990s. It was an integrated approach to product design management in automotive and aerospace industries (Konstantinov, 1988). The complexity of the products developed in these areas, as well as the increased competition caused by globalization, has compelled to find a solution to manage product data systems effectively (Ming et al., 2005). The main objective of PLM is to control the complexity that characterizes the development and monitoring of products. More than a simple tool, the PLM approach provides a global collaborative



environment that aims to integrate all actors involved during the product lifecycle and manage all related processes. This is part of corporate strategy that contributes to save resources and cost, time to the market and increase product quality (Paviot, 2010).

As for any enterprise information system the main objective of PLM is to provide the right information to the right users in the right context and at the right time throughout the product lifecycle in order to reduce costs linked to information finding and data consistency (Ameri and Dutta, 2005). As a new paradigm, the challenge is not only to manage the product technical data but also to manage all concepts associated with the product (Stark, 2004).

PLM has been widely accepted and defined by various communities with a little different definition depending on the point of view of the authors. There is no common definition accepted by the entire community (Abramovici, 2007, Liu et al., 2009) but there are some popular PLM definitions can be found in the literature. PLM is defined as a systematic concept for the integrated management of all product-related information and processes through the entire lifecycle, from the initial idea to end-of-life (CIMdata, 2002, Saaksvuori and Immonen, 2008b). PLM also can be defined as a life-cycle-oriented development model as shown in Figure 2.11 (Terzi et al., 2010). According to the authors, there are three fundamentals of PLM that are involved along the lifecycle phases of the product: Methodologies, Processes and ICT. The product data is shared among these fundamentals along three phases of product lifecycle.

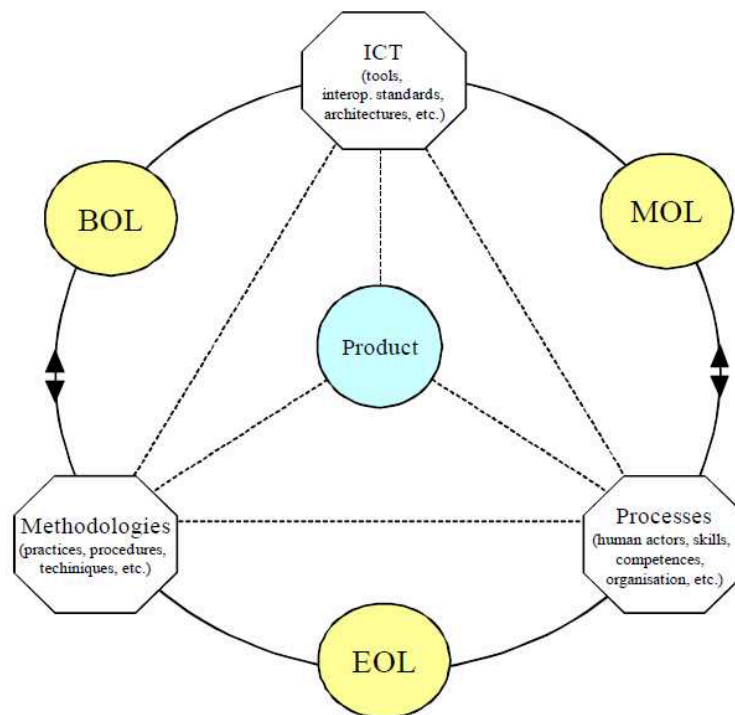


Figure 2.11 - Fundamental elements of PLM (Terzi et al., 2010)

Another definition of PLM is from Abramovici (2007). PLM is an integrated approach managing all product information, engineering processes and applications along the different phases of product lifecycle. The PLM approach has the ambition to covers all product lifecycle stages as shown in Figure 2.12. PLM methods and tools can be classified into three groups:

- Information management for identifying, structuring, classifying, retrieving and sharing product, process and project related data.
- Process management for structuring, planning, operating and controlling all internal processes of a company or those supporting inter-enterprise collaboration.
- Application integration to manage interfaces between various tools and data bases distributed in the different services of the enterprise.

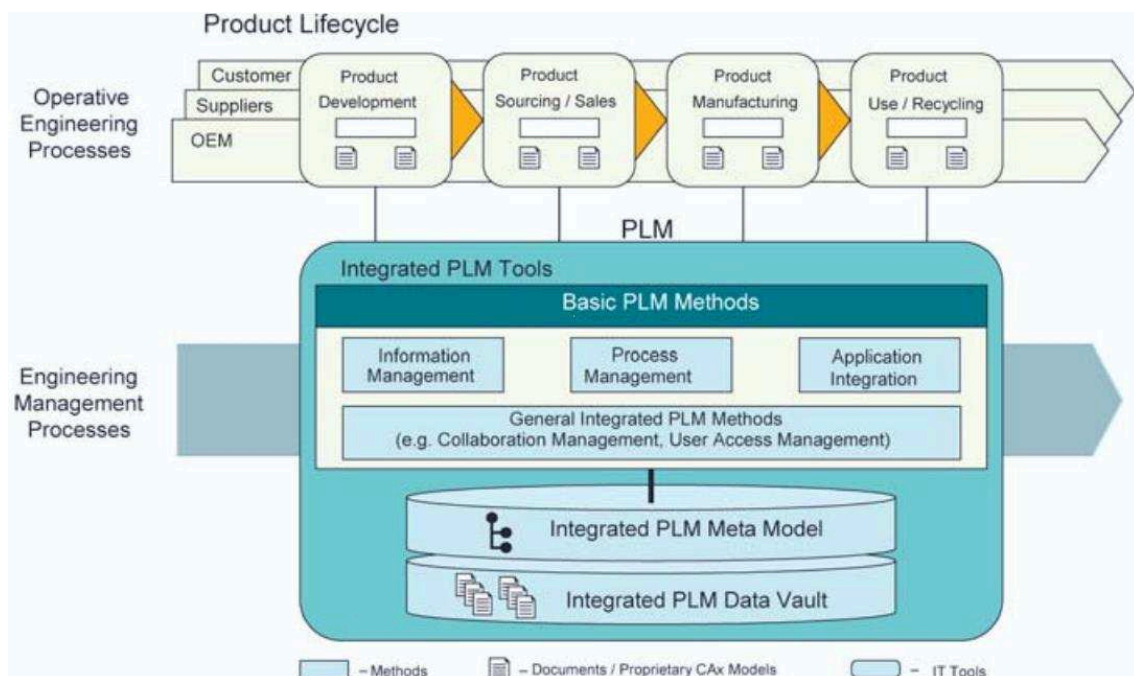


Figure 2.12 - Basic components of the PLM approach (Abramovici, 2007)

As shown in Figure 2.13, the PLM, as an approach, results from the integration of PDM/PLM tools with other types of business software, such as: Computer Aided Design (CAD), Computer Aided Manufacturing (CAM), Enterprise Resource Planning (ERP), Knowledge Based Systems (KBS), Supply Chain management (SCM) and other simulation tools, etc. (Le Duigou et al., 2011). By integrating a set of connectors, the PLM as a tool can be considered as a hub that supports information exchange between various tools including in the whole process.

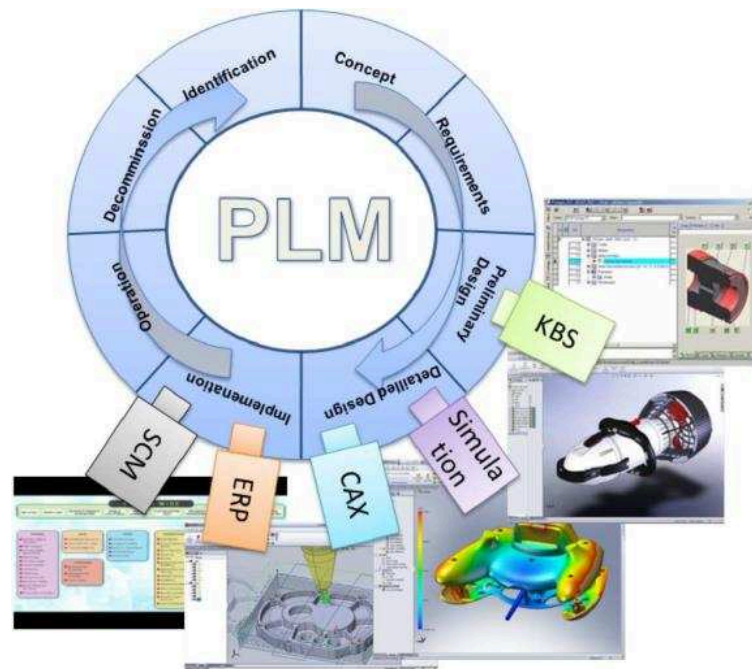


Figure 2.13 - PLM and business approach (Le Duigou et al., 2011)

### 2.5.3 PLM functions

Using a PLM system to manage product data and project processes, companies are strongly supported to develop innovative products with a shortened time to market. This contributes to reduce risks and costs, drive innovation, accelerate revenue growth, increase productivity, and improve the quality of products and procedures. (Rudeck, 2015). PLM has various functions throughout the product lifecycle. Synthesized from Abramovici and Sieg (2002), Liu et al. (2009), Saaksvuori and Immonen (2008a), Borul Sawan (2012), some key functions of PLM is listed as follows:

- Traceability: keeps track and instances of data over time. All initial information and change processes are stored in the system. Therefore, it helps the user manage the information and data easily.
- Document/File Management: The system controls the information on the item and the status of the item as well as processes related to the creation and maintenance of items.
- BOM (Bill of materials) Management: Product structure management allows you to manage BOMs from various points of view.
- Configuration Management: It allows products to be customized according to customer requirements. Moreover, it plans and controls the versions, structure, and relation between information from different sources. This is important for developing complex product. Configuration management supports to identify, control and verify product components.

- **Workflow Management:** is one of the fundamental and important functions of PLM, the series and sequences of works as well as the users can be shown through the workflow.
- **Collaboration:** The teams of a company or a factory (sales, marketing, design office, manufacturing, customer and maintenance service, etc.) are often geographically distant. Collaborative function allows these teams work in collaboration. Various users can share and update data easiest in the same system at different locations.
- **Information retrieval:** is one of the main functions of PLM. PLM systems intensify and facilitate the retrieval of information so that it is possible to utilize existing information to create new information that is better than the old one.
- **Visualization** allows quick access and preview of documents in a variety of formats including CAD format.
- **Data vault management:** the system also includes a file vault, or storage place for files. It is the place where files are recorded.
- **Change management** controls modified data by using principle “check-in/check-out”. The principle is shown in Figure 2.14. When users want to modify data from the system, they will check-out the data and then do the modification. If a new revision is created, it will be reviewed and approved by an administrator before check-in to the system. With this function, the system can be used by various users without conflicts
- There are also Portfolio Management, Program Management, Project Management, Resource Management, Quality Management, Requirements Management, Content Management, Manufacturing Process Management, and Sourcing & Supply Chain Management.

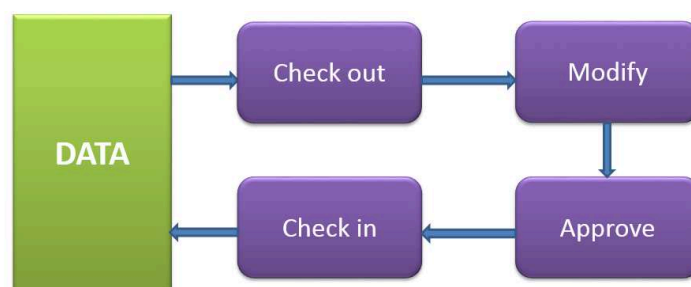


Figure 2.14 - Change management in PLM

Corresponding to each lifecycle phase, Saaksvuori and Immonen (2008b) pointed out the different functions of PLM as shown in Table 2.3. The connection of PLM functions to different lifecycle phases clarifies the role of PLM in each industrial business process and which department are using which function of the PLM.

Table 2.3 - The role of PLM in different life stages (Saaksvuori and Immonen, 2008b)

Lifecycle phase	Concept planning design and engineering	Launch ramp up and volume production		Service, support, maintain	
PLM role	Design data mgmt	Productizing	Production change mgmt	After sales	Support
• PLM functions	<ul style="list-style-type: none"> <li>• Item mgmt</li> <li>• Structure mgmt</li> <li>• Document mgmt</li> <li>• Interfaces to design tools</li> <li>• Support for workflow mgmt</li> <li>• Support for change mgmt</li> <li>• Design collaboration</li> <li>• Sourcing</li> </ul>	<ul style="list-style-type: none"> <li>• Item mgmt</li> <li>• Structure mgmt</li> <li>• Document mgmt</li> <li>• Integration to ERP</li> <li>• Change mgmt</li> <li>• Sourcing</li> <li>• Support product transfer to other/multiple sites</li> <li>• Support for program mgmt</li> </ul>	<ul style="list-style-type: none"> <li>• Integration to ERP</li> <li>• Change mgmt</li> <li>• Document vault</li> <li>• Component mgmt</li> <li>• Approved supplier mgmt</li> <li>• SCM</li> <li>• Version mgmt</li> <li>• Collaboration</li> </ul>	<ul style="list-style-type: none"> <li>• Document vault</li> <li>• Item mgmt (spares, etc.)</li> <li>• Structure mgmt</li> <li>• Data retrieval</li> <li>• Re-use of components</li> <li>• Maintenance</li> <li>• After sales services support</li> <li>• Change mgmt</li> </ul>	<ul style="list-style-type: none"> <li>• Document vault</li> <li>• Item mgmt (spares, etc.)</li> <li>• Structure mgmt</li> <li>• Document mgmt</li> <li>• Data retrieval</li> <li>• Support for product mgmt in all lifecycle phases</li> <li>• Provides easy access to all information to all concerned</li> </ul>

Another research categorizes the functions of PLM depending on each stage of the product lifecycle: product design, product manufacturing and product use as described in Figure 2.15 (Stark, 2015).

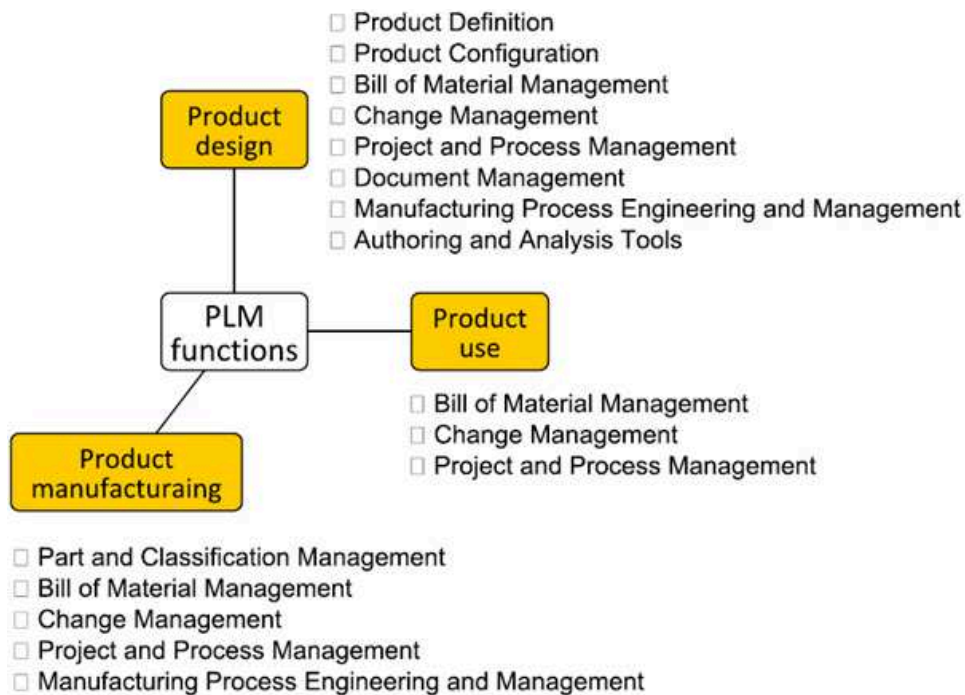


Figure 2.15 - PLM functions in each phase of the product lifecycle (Stark, 2015)

In general, PLM is used in all sizes of companies, ranging from large corporations to small and medium enterprises. It is applied across a wide range of industrial sectors such as in automotive and aerospace industry, as well as in research, education, medical, military and other governmental organizations (CIMdata, 2002). The next section gives an overview of PLM applications in both industrial and medical sectors.

## 2.6 PLM applications

### 2.6.1 Applications in industrial domain

PLM technology is primarily used in automotive and aerospace industry, because the products of these areas have long lifecycles, high complexity and nearly no possibility of physical prototyping. Whereas, PLM still has fewer applications in high tech/electronic and heavy construction industries due to its short lifecycles and minor product complexity (Abramovici and Sieg, 2002).

Several applications of PLM approach can be found in the literature. For example, Tang and Qian (2008) proposed a PLM framework to connect Automotive OEM and supplier in collaboration (Figure 2.16). Authors presented an automotive case study to illustrate the PLM implementation (Nanjing-Fiat, an automotive company, Products are designed in Italy while the manufacture and assembly are performed in China).

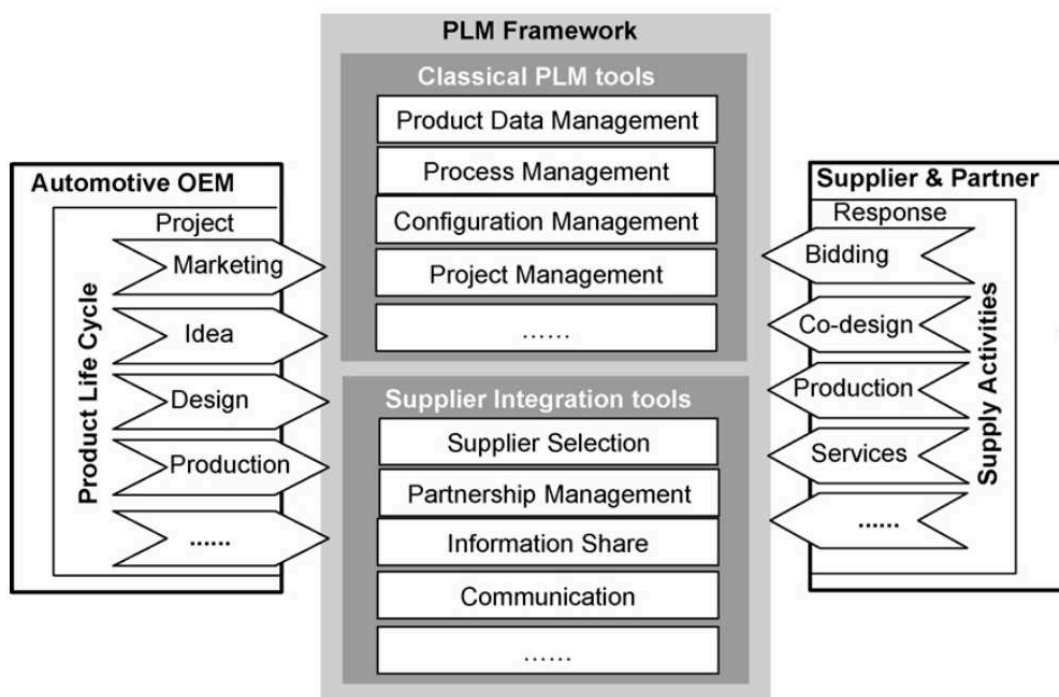


Figure 2.16 - PLM framework focusing on supplier integration (Tang and Qian, 2008)

Another application of the in SMEs (Small and medium-sized enterprises) is proposed by Le Duigou et al. (2010) who pointed-out some difficulties to apply PLM tools in such business sector. The authors proposed a PLM meta-model that suitable to the characteristics of SMEs business. The main function of the general data model within the proposed PLM: externally, to facilitate the information integration and exchange between different enterprises with different modeling frameworks;

internally, to realize the information integration and exchange between PLM and other information systems such as CAD, ERP.

Regarding to the problematic to integrate knowledge management practices within PLM approach, many research works are proposed in the literature to support the capitalization of product engineering and manufacturing process knowledge (Xu et al., 2014). For example, Bissay et al. (2008) have proposed a methodological approach to capitalize knowledge in PLM systems. The proposed approaches integrate the knowledge generated by a business process into PLM based on two main phases: process integration and knowledge integration. Similarly, the work of Bertin et al. (2011) aimed to integrate a lessons learnt system (REx) into PLM. The authors demonstrated how to couple PLM-REx in order to enhance the capacity of PLM in knowledge capitalization.

Within the multi-agent-based approach, Monticolo et al. (2006) developed a knowledge engineering module integrated into a PLM system with the aim of capturing knowledge and technical data related to design projects. In the same perspective, Mahdjoub et al. (2010) proposed a knowledge engineering system embedded in a PLM environment in order to capture knowledge from information generated during collaborative activities carried out by the designers. The authors apply the captured knowledge to a virtual reality system in order to help the designers in their daily tasks.

Based on KM methods, Bosch-Mauchand et al. (2013) have used PLM capabilities to achieve semi-automated capitalization of heterogeneous knowledge from various enterprise information systems (EISs). The authors used this set of knowledge in order to assess the manufacturing process performance. The authors developed a framework to support this manufacturing process assessment based on three main modules: knowledge capture, knowledge structuring and performance assessment. Kiritsis et al. (2008) introduced the concept of a closed-loop PLM, a system that enable all people who play a role during the life cycle of a product to track, control and manage product information.

The work of Young et al. (2009) proposed a conceptual framework showing how to extend information sharing to a richer knowledge base supporting the capture, sharing, and verification of multiple sources of manufacturing knowledge among PLM and other ICT systems in the factory. This work can be considered as one of the few works that took into account the interoperability issue when dealing with data and information transfer between PLM and other knowledge-based systems. The literature

review shows that using KM techniques together with the PLM approach, knowledge is not necessarily centralized in one repository but is distributed within interconnected knowledge repertoires associated with EIS like Guerra-Zubiaga et al. (2006).

### 2.6.2 Applications in medical domain

PLM has now been widely adopted by the whole manufacturing industry world (Fielding et al., 2014). Nevertheless, it has not widely set up in medical sector (Allanic et al., 2013). As one of the rare applications in the medical domain from a research point of view, Allanic et al. (2014) constructed a data model for PLM in bio-medical imaging (BMI). BMI can be viewed as a four-step process: study specification, data acquisition (raw data), data processing (derived data), and publication of data (published data). This process can also be modeled as a lifecycle. This means that the published data may provide a basis for the following studies.

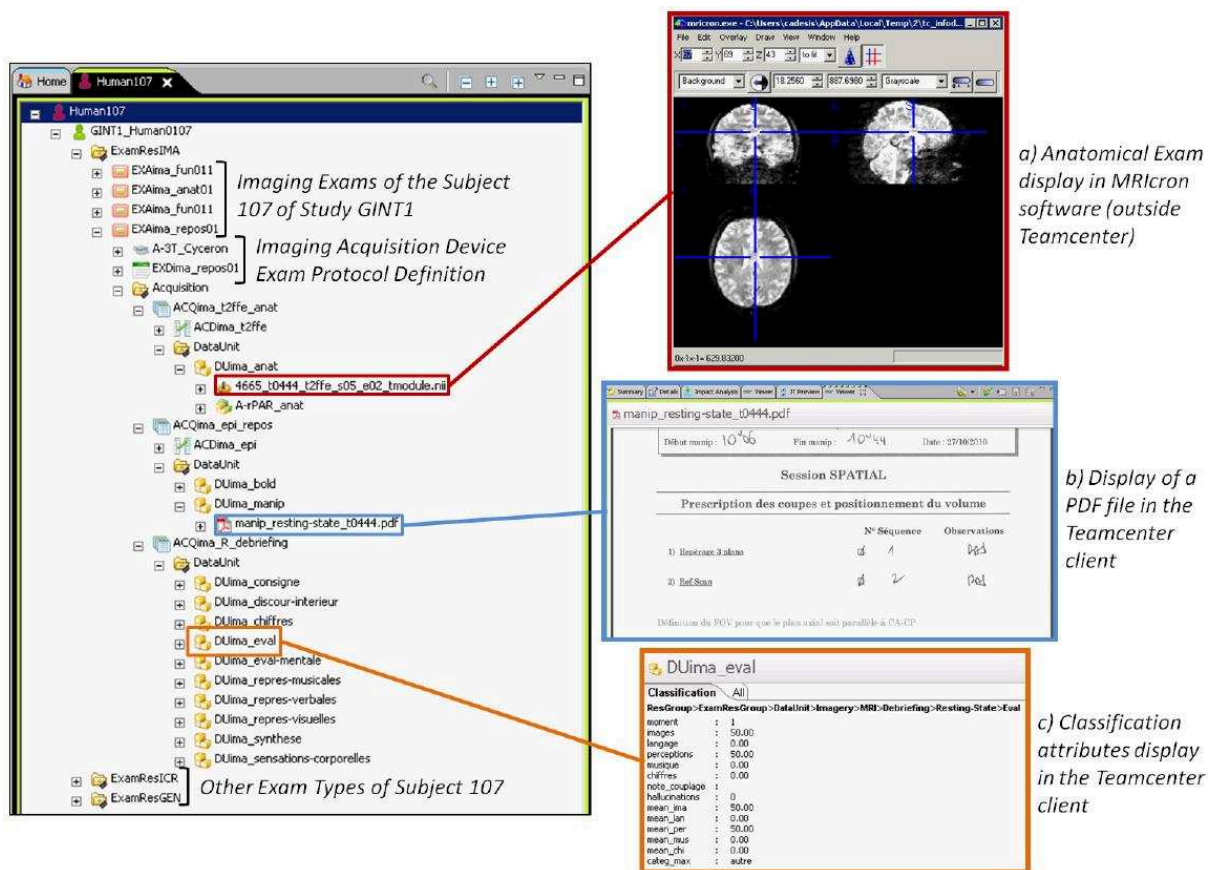


Figure 2.17 - Management of BMI study in Teamcenter (Allanic et al., 2014)

From this point of view, Allanic et al. (2014) propose a PLM based solution to manipulate complex research studies in Neuroimaging. This solution is implemented in Siemens Teamcenter 9.1 PLM software (Figure 2.17). Many components and concepts of Teamcenter software have been used such as dataset, revision workflows



and classification. An integrated workflow has been designed and implemented using Teamcenter workflow management module to manage the processing of BMI data. This PLM implementation is deployed to enable the acquisition, access, processing, validation, analysis and publication of laboratory data. The aim is to manage the data of the entire BMI lifecycle, share data among all researchers, manage data access, and enable data recovery and reuse.

To achieve these goals, the authors proposed a data model called Biomedical Imaging Lifecycle Management (BMI-LM) (Figure 2.18) covering the four stages of BMI, it can store and manage all BMI data from specification study phase to published result phase. For the implementation perspective, a class of Teamcenter objet is created for each business of the BMI-LM model, so that the four stages of a BMI study are supported. The business objects instances in the tool contain the metadata and are linked between them, which constitute the provenance.

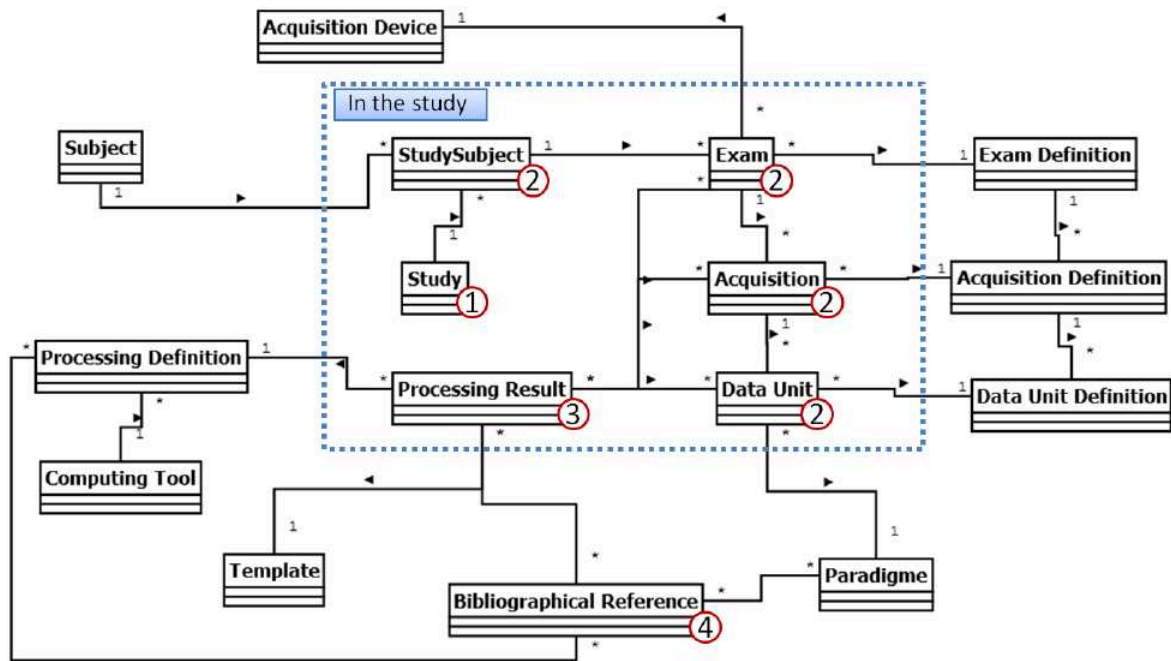


Figure 2.18 - BMI-LM data model schema (Allanic et al., 2014)

By adapting their ontology to the BMI-LM model and considering the connection specificities of the TeamCenter PLM database, Pham et al. (2015) developed a semantic query system to help users to easily find the requested information in a shared database. The dependencies among data and the evolution of data resources challenge users (especially for non-technician users) in querying the right data. Ontology can be used to share the users' understanding about data relationships to all community as well as to trace the database evolution (Figure 2.19).

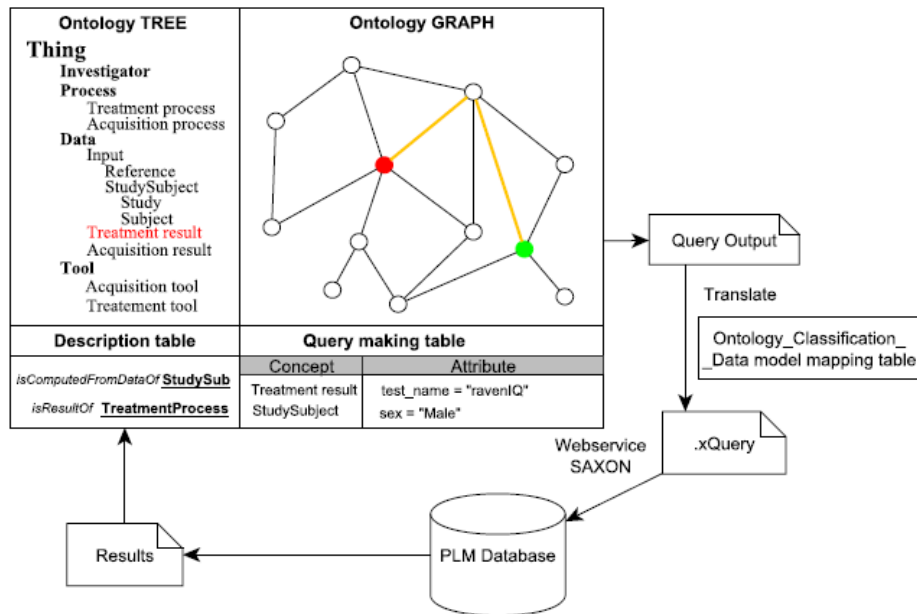


Figure 2.19 - KM-PLM based tool supporting information queries (Pham et al., 2015)

Another application in the medical sector, Jadhav (2011) illustrated some applications of PLM in pharmaceutical domain. According to the author, various important stakeholders get involved in the drug development process, from drug discovery to retiring and extension, such as pharmaceutical scientist, engineer, change analyst and manufacturer. In order to achieve the common goal, they can work with multiple protocols, processes together but with different roles. Therefore, the stakeholders have different access rights depending on the objectives and nature of every development stage. The access rights concern the reading, writing, storage, control and usage of sensitive data. Figure 2.20 depicts the collaborative platform connecting stakeholders, drug data and files along their whole lifecycle.

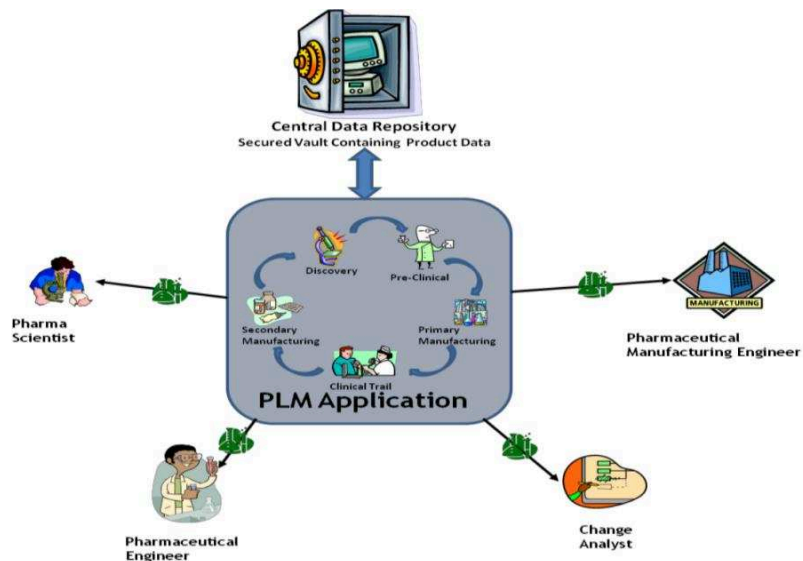


Figure 2.20 - Collaborative platform in pharmaceutical processes (Jadhav, 2011)

Looking to commercial PLM solutions, most of editors become aware of the importance to develop specific tools for medical industry. For example, Arena PLM software proposes interesting functionalities for medical actors as does for any other industry or business (Arena medical PLM). The key functionalities is the quality control of medical devices. PTC, one of the most important PLM editors, has extended its core Windchill product lifecycle management capabilities into a suite of offerings designed to help medical device manufacturers streamline, simplify and gain greater value from their medical device quality investments (PTC Medical PLM). The PTC solutions for medical device innovators drive business results and continuous innovation by transforming engineering practices and product designs through variety of PLM modules such as: intelligent workflows, medical device quality management, requirement management, document control, etc. Oracle<sup>4</sup> PLM for the Medical Device Industry is another commercial application that shows the increased interest given by big PLM editors to medical domain.

Similar to other PLM solutions, the Oracle PLM supports medical device companies by a set of tools to effectively and economically ensure the compliance of the developed device. Oracle PLM allows companies to manage a compliant data set consisting of all documents, decisions and activities to address all pillars of the Quality System Inspection Techniques (QSIT) (Figure 2.21). It supports document authoring and change management (Oracle Medical PLM). The synchronization of this information across each information system improves the business performance and the compliance integrity of the whole digital chain behind the medical domain.

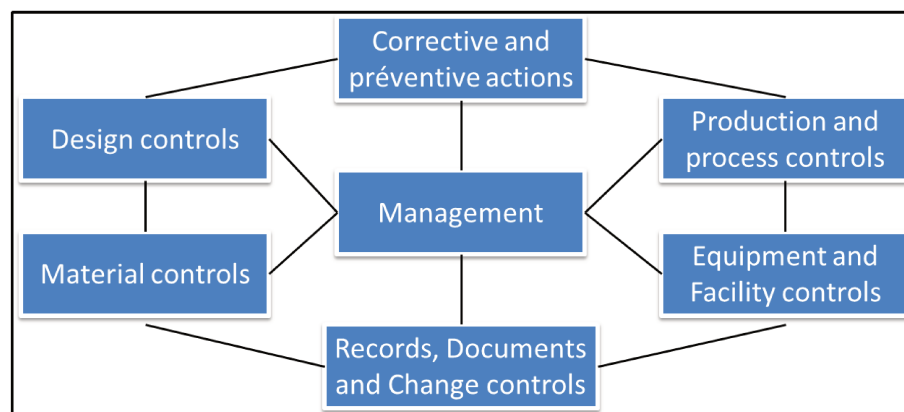


Figure 2.21 - Quality System Inspection Techniques (QSIT) Pillars within medical PLM (Oracle Medical PLM)

However, despite this variety of PLM solutions that claim covering the medical domain needs, it is to highlight that their real applications deal principally with the

<sup>4</sup> <https://www.oracle.com/>

engineering processes of medical devices. The idea is to support the development process of such products which can be considered as a kind of mechatronic systems.

### 2.7 Synthesis and research questions

The concept of lifecycle is connected to the concept of system that refers to a collection of things that work together to perform a useful purpose that none of them can do alone. This concept is applicable with the same meaning to several categories of systems: physical, organizational or mixed like product-service systems (PSS) (Maleki et al., 2018). The medical domain requiring prosthesis could be considered as a kind of PSS since the final user (the patient) will get added value from the integration of physical product functions (the prosthesis) and service units (coming from the treatment process).

The state of the art shows the growing interest to apply technology in medical sectors. Various software applications and technical devices are proposed to assist heterogeneous categories of actors involved in the medical domain. However, majority of these solutions deal with one specific applications and there is no concrete initiative that aim to cover the global lifecycle of the disease.

An interesting analysis of existing solutions in biomedical imaging is realized by Allanic (2015). The drawbacks of existing solutions identified in this thesis are easily extended to other medical-dedicated software applications. Additional limits can be also cited in the particular case of treatment requiring prosthesis.

- Failure of current tools to support the management of all data with a common strategy along a whole medical process. Majority of systems provide database solutions with simple storage facilities of data but there is no robust models to manage all concepts and relations between them.
- The existing solutions are implemented as specific databases but there are no real integrated file management mechanisms such as for PLM tools to make easier the collaboration between actors around a unified files repository. Some local databases contain metadata only, and the data are reachable via a link to the file that is stored outside the database.
- This failure conducts to another big issue of data retrieval, as nothing guarantee that the repository contain the latest version of the files and these files are conserved in the correct location. Engineering files of the prosthesis are concrete examples because of their variety of versions and iterations as well as their disconnection with patient data files (generally stored in other databases).

- Because that prosthesis files and medical data are stored in separate places, it is difficult to reuse the prosthesis models when repairing the existing prosthesis or when new prosthesis is needed to cure a patient that presents similar symptoms and characteristics.
- Access management mechanisms are very limited in the current tools and this problem is more complex in case of medical treatment involving stakeholders coming from heterogeneous services and external companies.
- Data inconsistency is a direct consequence of the multiplicity of data sources and the heterogeneity of models used for the structuration of the disparate data. Few tools propose the traceability of data provenance and the validation of completeness of data description.

The situation is critical in medical processes requiring a prosthesis because there are no real tools fully dedicated to the management of the whole process and the connection of medical and prosthesis lifecycles in a common platform. Despite the existence of some initiatives of commercial PLM that claim supporting medical domain, it is evident that the focus of these systems is the support of medical devices as kind of mechatronic products. These commercial tools propose to extend the classical PLM modules (workflows, data access, user rights, etc.) but there is no effective proposition to consider the connection between the medical device and the disease lifecycles.

Another very important aspect that is not yet well addressed by the technological development for medical domain concerns knowledge management and reuse for decision making perspective. In case of medical treatment requiring customized prosthesis, this aspect is very important because that every prosthesis is specific to one patient. Even if it is evident that some developed approaches have succeeded in the knowledge integration process, PLM systems are not yet considered as knowledge-based systems and the integrated knowledge set is partially reused.

Nowadays, thanks to the advanced development made on PLM integrated modules, this system can incorporate not only the geometry and the shape of the product but also a higher level of product information and other process information required to support decisions in the manufacturing or maintenance phase of the product development. Indeed, because of their distributed and multi IS connections properties (Abramovici and Sieg, 2002) as well as interoperability mechanisms (Penciuc et al., 2014), PLM approach gives more advantages to support the knowledge extraction and capitalization.

As indicated in chapter 1, the research problem concerns to data sharing and knowledge reuse in the treatment process requiring prosthesis. This conducts to set-up the following research questions:

- Is the current PLM approach able to manage in an integrated way all processes of medical treatment requiring prosthesis? This question leads to the following issues:
  - Capacities of the PLM approach to manage variety of data and to ensure their traceability and their connection with data sources.
  - Capacities of the PLM approach to manage the links between disease and prosthesis lifecycles
- Is the PLM approach able to support collaboration between medical and engineering actors? This question leads to the following issues:
  - Right access and sharing management strategy
  - Types and characteristics of interactive workflows models.
- Is the PLM approach able to support knowledge management and reuse? This question leads to the following issues:
  - Robust models for knowledge representation.
  - Categories of medical knowledge to be (re)used in engineering domain and vice versa.

To answer to these questions, there is a need to develop a conceptual framework for the analysis of all aspects of medical processes requiring a prosthesis. The next chapter presents the main foundations of the proposed approach.

# Chapter 3

## A conceptual approach for connecting medical and engineering processes

### Contents

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3.1 Introduction and research method .....	67
3.2 Process modeling framework for medical sector .....	69
3.3 Lifecycles Analysis Framework .....	74
3.3.1 Prosthesis and disease Lifecycle .....	75
3.3.2 The five pillar analysis model of lifecycle stages connections analysis .....	79
3.4 Ontology-based modeling of the target medical domain .....	83
3.5 Conclusion .....	91

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### **3.1 Introduction and research method**

The development of the prosthesis follows the classical steps of design and manufacturing processes of mechanical products. However, due to the specificity of this kind of devices in the medical domain, there are two separate lifecycles, disease and prosthesis representing respectively medical and engineering domains. As it will be demonstrated later, the processes supporting these lifecycles are independent but always connected through the need of data and knowledge exchange between the involved actors and tools. Thus, the prosthesis lifecycle is strongly linked to the disease lifecycle. The management of these two lifecycles should be managed in a concurrent way so that the consistency of the medical and engineering dimensions of the treatment process is conserved. Indeed,

In order to perform the sub-process behind the above lifecycles, it is necessary to refer and collect the data, information, knowledge from other sub-processes. This sharing plays an important role for enhancing the accuracy, quality, decision making and also shorten completion time of the entire process. For example, the surgeon has to collaborate to share geometric requirements and handling constraints useful to design and manufacture the appropriate prosthesis. Moreover, from the data collected, he can comment and adjust the designed prosthesis as suitable as possible. This improves the final quality of prosthesis and makes the surgery operation more comfortable.

From the problems identified in chapters 1 and 2, the proposition is that using PLM approach to enhance efficiency of collaboration, information and, knowledge sharing between stakeholders related. The idea is that all disease data, prosthesis data, actors, tools of both sub-processes inside hospital (interview patient, do exam, do surgery, etc.) and outside hospital (design and fabricate prosthesis) will be connected through a PLM hub as shown in Figure 3.1. In addition, it is necessary to provide the stakeholders with a common knowledge repository and a set of knowledge-based assistance facilities that are able to support the medical and engineering activities with the KM-PLM approach. Also, due to the high sensitivity of disease data, access management should be considered in the proposed approach to guarantee that each actor will get access only to the appropriate data according to his role in the whole treatment process. With this proposition, actors can share data, knowledge to each other. They can view, modify data or only give comments depending on their roles in the process and the objectives of their related activities.



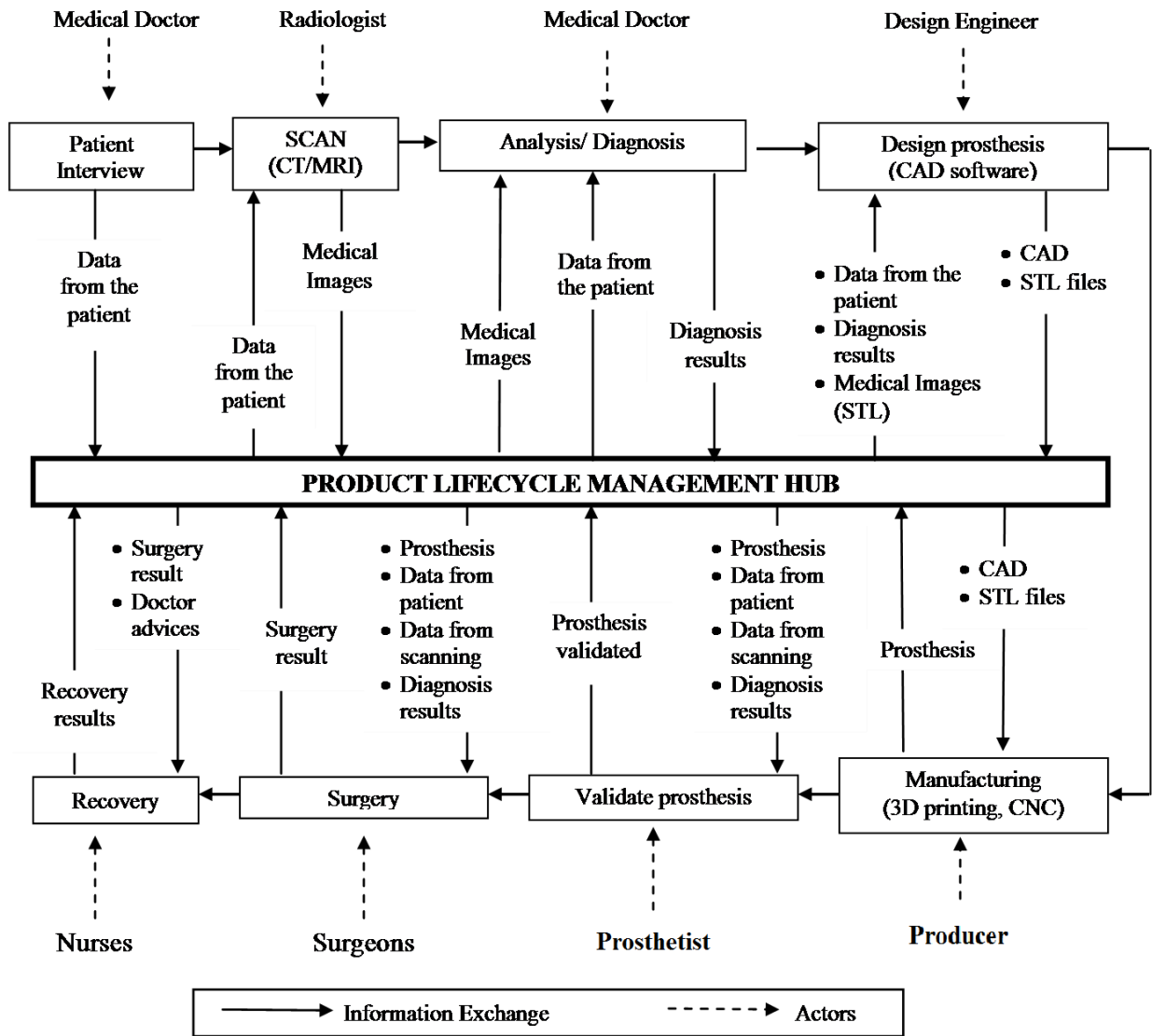


Figure 3.1 – The PLM as a hub connecting disease and prosthesis data

The aim of this research work is to study the potential of current PLM approaches to manage the complexity of medical treatment requiring prosthesis in terms of processes, data, collaborations and knowledge. This chapter gives the key issues for the conceptual specification of PLM approach dedicated to medical domain. This conceptual approach is built as an implementation of PPRO (Product-Process-Resources-Organization) model to cover the different business facets resulting from the linkage of disease and prosthesis lifecycles. Concretely, a business scenario-based strategy is followed to analyze the complexity of the medical treatment process subject of this study.

Based on the research questions identified in section 2.7, the design of the conceptual framework is built and validated progressively based on analysis of state of the art and interviews with expert. To do so, the following steps are conducted. Firstly, the treatment process is described in details using IDEF0 diagram. The IDEF0 diagram

is a function-based process modeling language that helps the identification of activities but also: all flows transformed by these activities, resources involved and control signals that managing the realization of each activity.

Secondly, the mapping of the identified activities to different steps of the medical treatment process is used to identify the various stages of both disease and prosthesis lifecycles as well as the connection between these stages. Thirdly, the deep analysis of the identified linkages helps the identification of key concepts and the construction of a semantic model covering the entire treatment process. In order to know the nature of these links, five main dimensions are considered in the analysis of the linkages: flow, tool, process, stakeholder and requirement. This helps to identify the key data to share between stakeholders within a PLM approach. Finally, as a prerequisite for the construction of a common knowledge repository, the semantic model is extended in form of ontology for the medical domain.

### **3.2 Process modeling framework for medical sector**

Based on analyses of literature and interviews with experts in medical sector, a process model is built and formalized using IDEF0 diagrams. IDEF (for Icam DEFinition for Function Modeling, where 'ICAM' is an acronym for Integrated Computer Aided Manufacturing) is a functional modeling method designed to model the decisions, actions, and activities of an organization or system. It was derived from the established graphic modeling language Structured Analysis and Design Technique (SADT) IDEF0 modeling language (Marca and McGowan, 1987) shows the order of sub-processes/activities and represents each one in terms of input/output flows, control signals and mechanisms. The key property of this formalism is the hierarchy of processes that allows the decomposition of complex process into small sub-processes. Because of the simplified graphical notation proposed by this language (in difference with other tools like BPMN), IDEF models are easier to read and understand by experts that are not familiarized with business modeling tools. So IDEF0 is chosen to support the communication with medical actors and engineers during the analysis step because of its high capacities to represent in a simplified and common way several aspects of the business processes.

This section gives an overview of the main processes. For instance, Figure 3.2 presents a global view of the patient treatment process, which is divided into 4 main activities: (A1) Analyze patient data to extract both medical and administrative information. It is the first step to identify the disease and take a decision about the

prosthesis implantation; (A2) realize the prosthesis according to a set of requirements; (A3) prepare the surgery and (A4) achieve the treatment surgery.

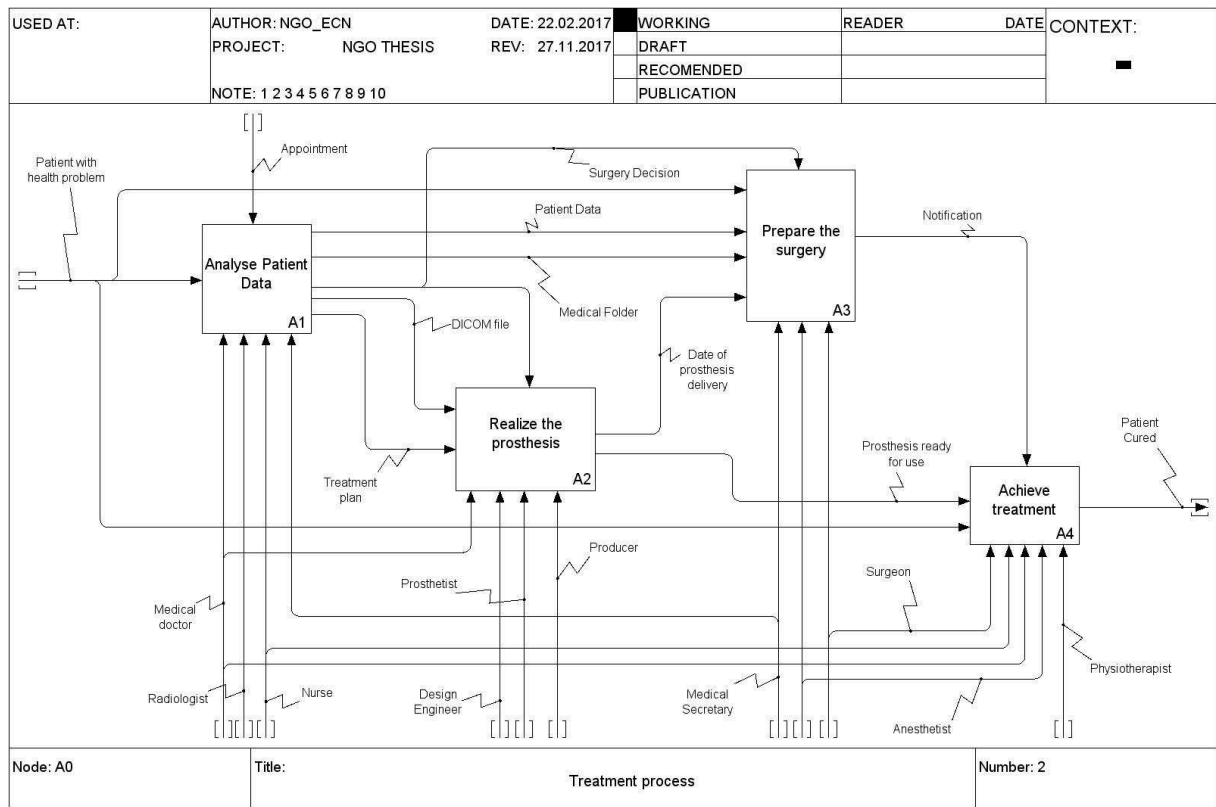


Figure 3.2 - General diagram of the treatment process

For deeper analysis, every main activity is decomposed into sub-processes respecting to the IDEF0 Hierarchic organization principle. For instance, Figure 3.3 shows the sub-process of the analysis of patient data. It is composed to 4 macro activities (from A11 to A14): firstly, the patient is interviewed by medical doctor to extract information about the current disease as well as previous health problems. In order to know exactly the health problem of the patient, radiologist will scan patient to obtain medical images and nurse will take set of medical exams based on the interview result. After having results from interview, scan and exam process, the medical doctor synthesizes them to make a medical record that will be compared with disease symptoms repository to make next decisions. At this stage, diagnosis is then fulfilled based on all this gathered data to identify the suitable treatment plan and to decide if this treatment requires a prosthesis.

Four categories of stakeholders are involved in this process: medical doctor, radiologist, nurse to realize medical exams and medical secretary is in charge of collection of other patient data.

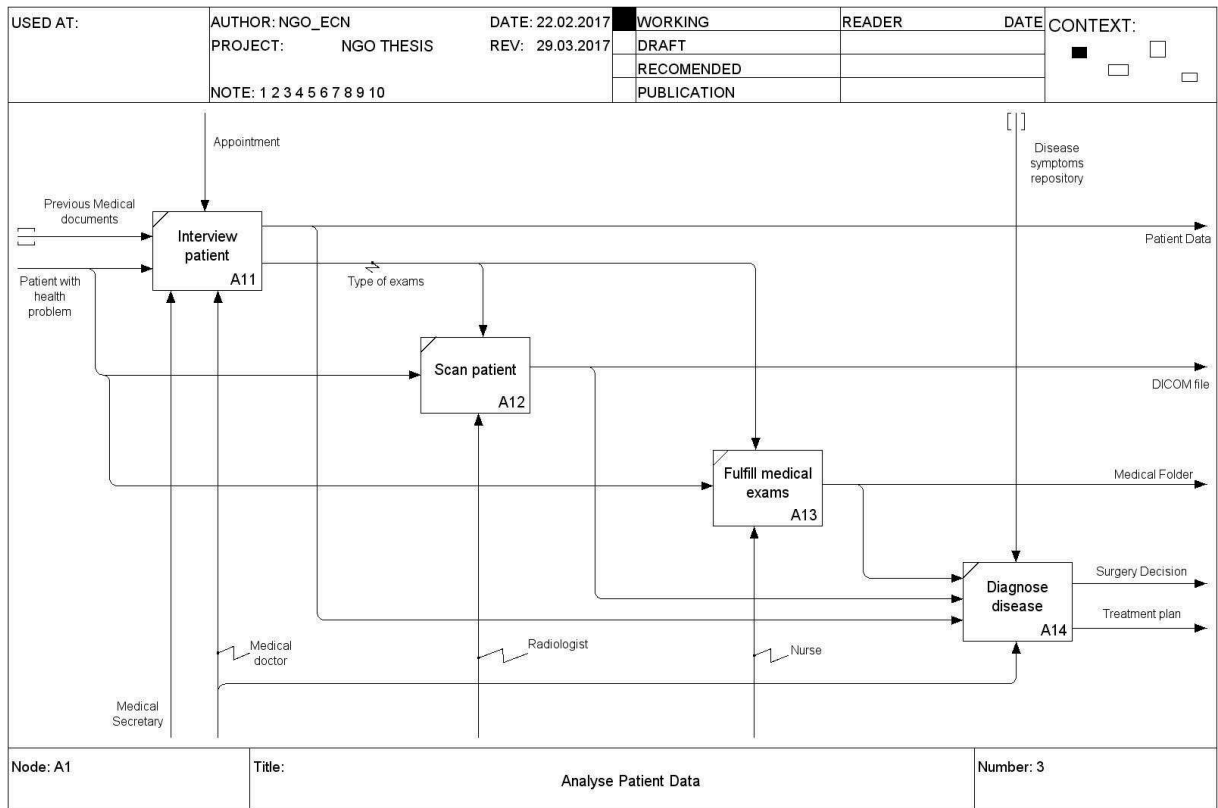


Figure 3.3 - Patient data analysis process

This research focuses on the case of medical treatment requiring customized prosthesis. So, Figure 3.4 details the design and manufacturing process of the requested prosthesis. Before going to design prosthesis, the medical images (DICOM format) are converted into STL file by a medical image converter software (For example: Mimics, Amira, SliceOmatic, PyFormex, Simpleware, etc. Among them, the most popular software is Mimics). Then, design engineer refers prosthesis specifications and uses CAD software to design prosthesis CAD model. This model is validated by the prosthetist before transferring to manufacturing process. Depend on the kind of prosthesis, the producer fabricates it with suitable methods. The prosthetist validates the prosthesis before delivering it to the hospital.

Four actors involved in this process are design engineer, medical doctor, producer and prosthetist. Surgery preparation process is very necessary before doing surgery. Anesthetist reads patient data and performs additional interviews. Then he will decide dosage and the appropriate drug for the patient. The medical secretary will investigate the time of the actors and facilities to select the surgery date that will notify to all concerned actors. This last process is shown in Figure 3.5.

## Chapter 3: A conceptual approach for connecting medical and engineering processes

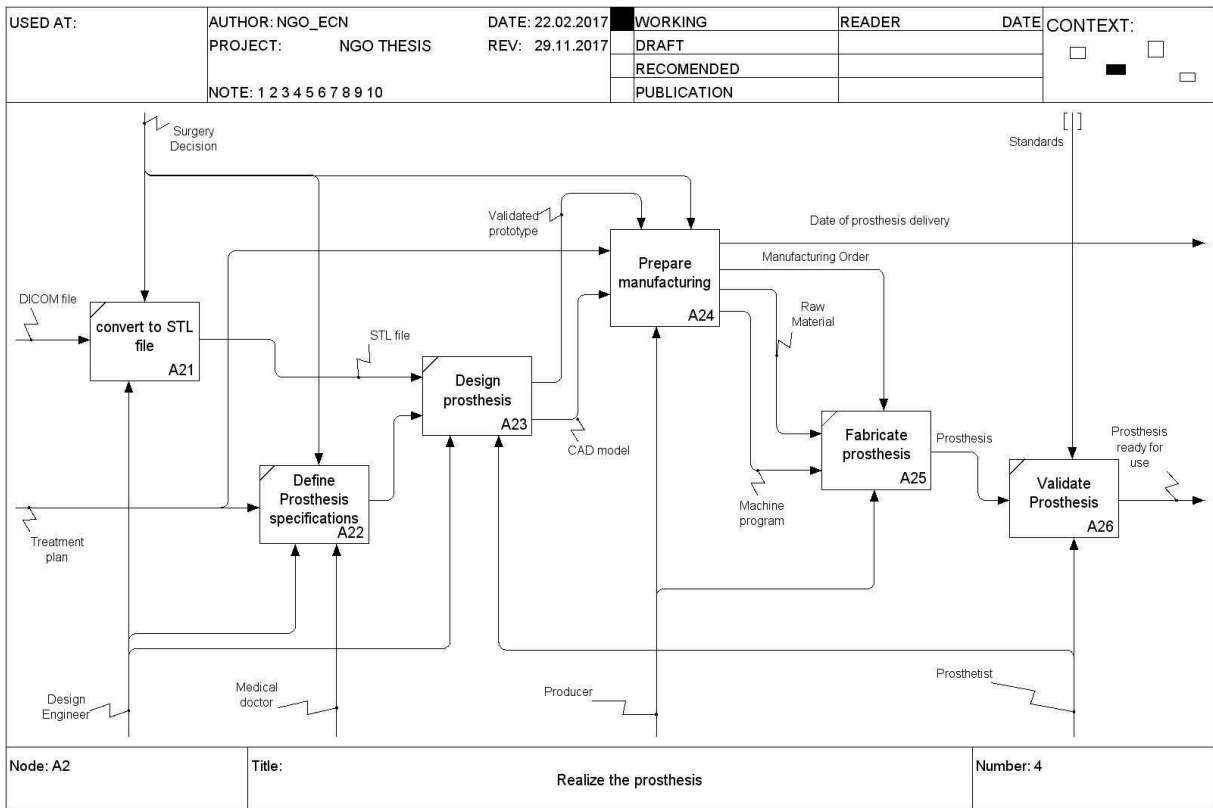


Figure 3.4 - Prosthesis realization process

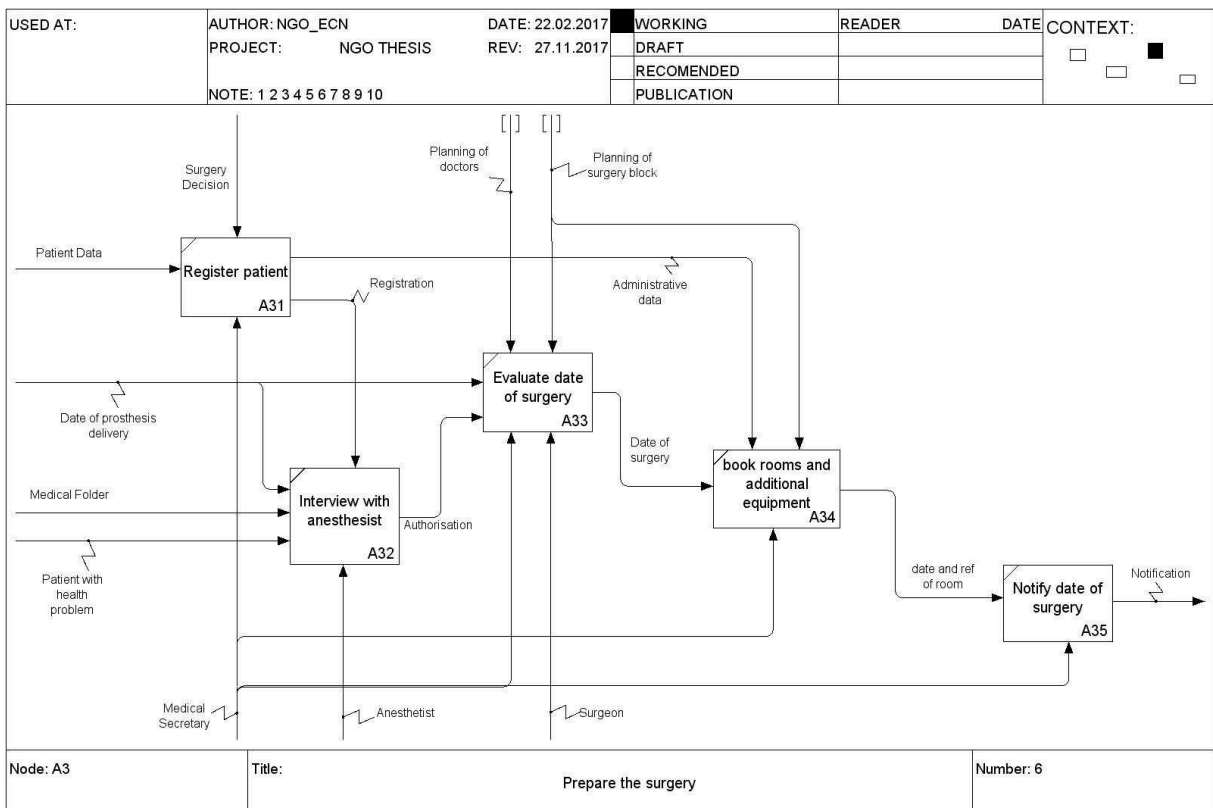


Figure 3.5 - Surgery preparation process

Figure 3.6 describes surgery and recovery process. When everything is ready (prosthesis, patient, as well as surgery tools), based on the treatment plan, surgeon implants prosthesis on the patient’s body. Then the nurse will care and provide medicines for patient after completing surgery process. Besides, the patient will do physiotherapy in order to accelerate the recovery process. Finally, the medical doctor will check patient’s health again to assess and follow the patient’s rehabilitation.

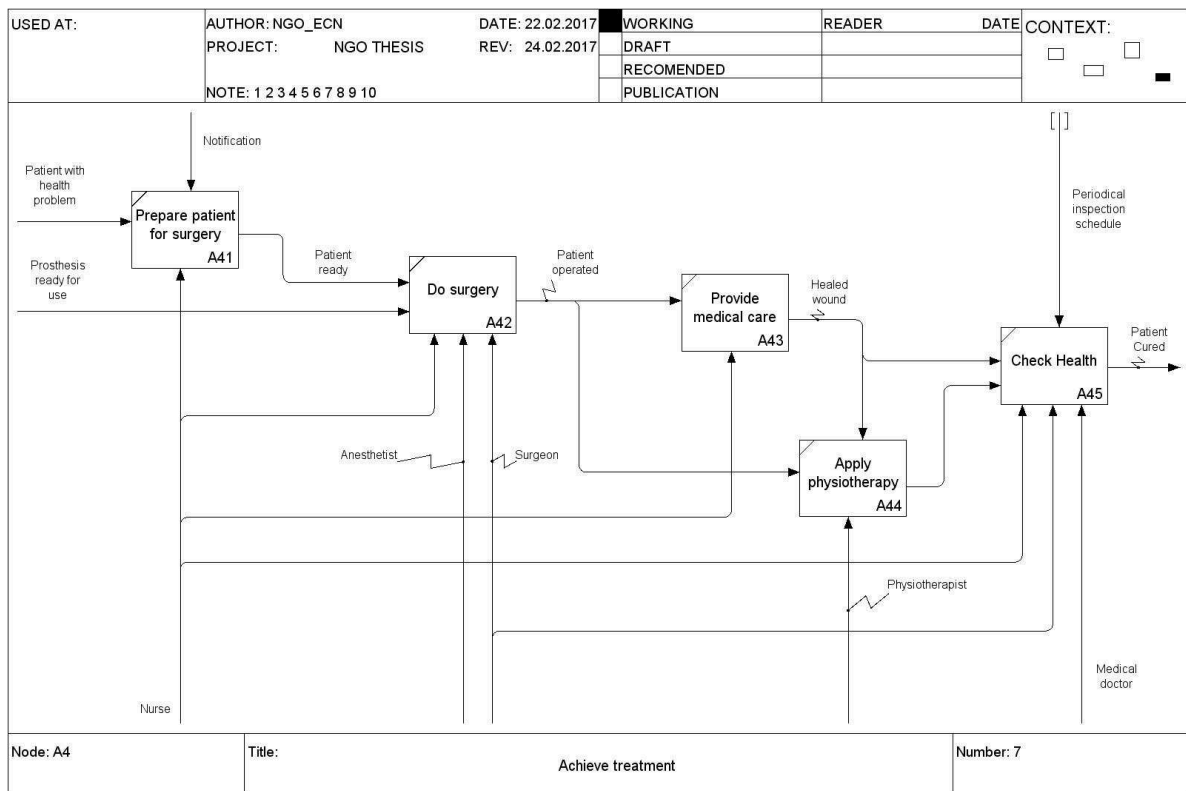


Figure 3.6 - Treatment achievement process

The analysis of the medical treatment process highlights the distinction of many actors involved in separate business fields: medical, engineering and manufacturing. Each actor has different tasks but they support each other to achieve the fastest and most effective results. These actors are: Personal doctor, Radiologist, Design engineer, Producer, Anesthetist, Nurse, Surgeon, Physiotherapist and Medical secretary. Their roles are summarized and explained in detail as follows:

- **Medical doctor** is the first person who interviews and collects patient’s health data when he has abnormal health symptom. It can be the personal doctor who regularly follows patient’s health or the doctors of the hospital emergency service.
- **Radiologist** is the medical actor who specializes in realizing and reading medical images obtained from scan devices such as x-rays, computed tomography (CT), magnetic resonance imaging (MRI), etc.

- **Design engineer** collects the requirements from medical actors and design the suitable prosthesis by using computer-aided software. He/she modifies and reconstructs the 3D CAD model before transferring it to the manufacturing stage.
- **Producer** is in charge of the realization of the prosthesis. He receives 3D CAD files (for example STL file) from design engineer and additional delivery requirements to make real prosthesis ready for surgical operation.
- **Anesthetist** is responsible for keeping patient safe and comfortable during and after the surgery. Anesthetist chooses the appropriate anesthesia depending on the specific patient. He also helps the patient to prevent the pain caused by surgery.
- **Nurse** assists physicians and surgeons to complete the patient treatment plan. She is an indispensable actor in the surgery process; she also provides pre-admission and post-admission planning.
- **Surgeons** are the medical actors who perform surgical operations to remove diseased tissue, organs, repair body systems, repair/replace diseased organs or implement prosthesis.
- **Physiotherapist** helps patients recover quickly after the surgery by using mechanical force and movements.
- **Medical secretary** is a member of staff in health care facilities; she performs administrative and supportive functions for the management of the treatment process, the relation with patient and other stakeholders as well as the planning of the surgeon activities.

As mentioned in chapter 1 and confirmed by the functional analysis described above, these various actors can be involved at a macro level in the same activity and iterate to on their own tasks progressively to obtain the final result. The result of each activity could be used by another actor as input for his own activity or as an event to trigger or to stop one action. Therefore, the activities of the medical sector can be classified according to the treatment process phase or the object of interest of these activities. Looking to this classification, the different stages of the both lifecycles are identified and analyzed as described in section 3.3.

### **3.3 Lifecycles Analysis Framework**

Some particularities should be pointed in the context of medical treatment requiring a prosthesis. First, the product (prosthesis) is completely linked to its final user (patient). Generally, the geometry of the prosthesis depends on the morphology of the patient. Second, all decisions taken about the prosthesis lifecycle depend on the concerned patient disease data. Base on this analysis, two independent but concurrent lifecycles

could be identified: “disease lifecycle” for the medical point of view and “prosthesis lifecycle” for engineering point of view as it is described in the next section.

### 3.3.1 Prosthesis and disease Lifecycle

At a macro analysis level, there are some semantic similarities between two lifecycles shown in Figure 3.7. For instance, the stage of requirement analysis (prosthesis lifecycle) refers data, information, and requirement from the stage of treatment definition (disease lifecycle). Prosthesis manufacturing is based on requirements from the stage of treatment realization. The processes behind the both lifecycles imply a lot of linkages between the tools and stakeholders involved in the related life stages. These linkages justify the need to manage collaborative actions and the creation of a common repository making the collaborative work efficient.

The life cycle of disease is a closed loop including stages: Health problem, disease checking, treatment definition, treatment realization, recovery and end of treatment. The life cycle of a prosthesis includes stages: prosthesis request, requirement analysis, prosthesis design, prosthesis manufacturing, using and end of life.

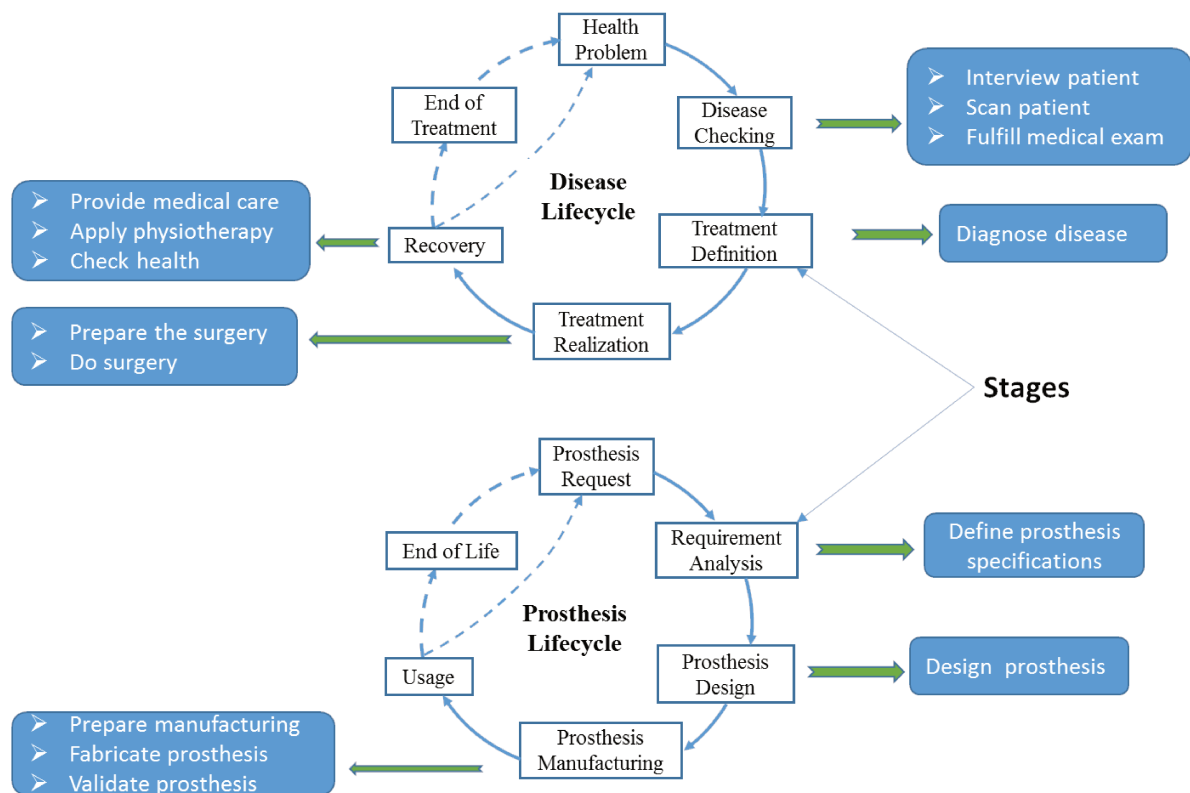


Figure 3.7 - Two lifecycles in the treatment process requiring prosthesis

As described in Figure 3.7, after recovery stage, there are 3 possible cases that may occur as part of the end of treatment as shown in Figure 3.8.



- Case 1: The patient adapts well to the new prosthesis. Prosthesis will exist forever along with the rest of the patient's lifetime. In this case, the prosthesis lifecycle stop on the usage stage.
- Case 2: The prosthesis is used temporary to fix some health problems. Another surgery is needed to remove the prosthesis.
- Case 3: During the recovery process, some problems may occur such as: A patient has an accident in daily life; a prosthesis became unsuitable with the patient's physical morphology, deflection or need of replacing according to the predefined calendar. In this case, the patient will be cured again with a new prosthesis that follows the whole lifecycle. The previous one is recycled.

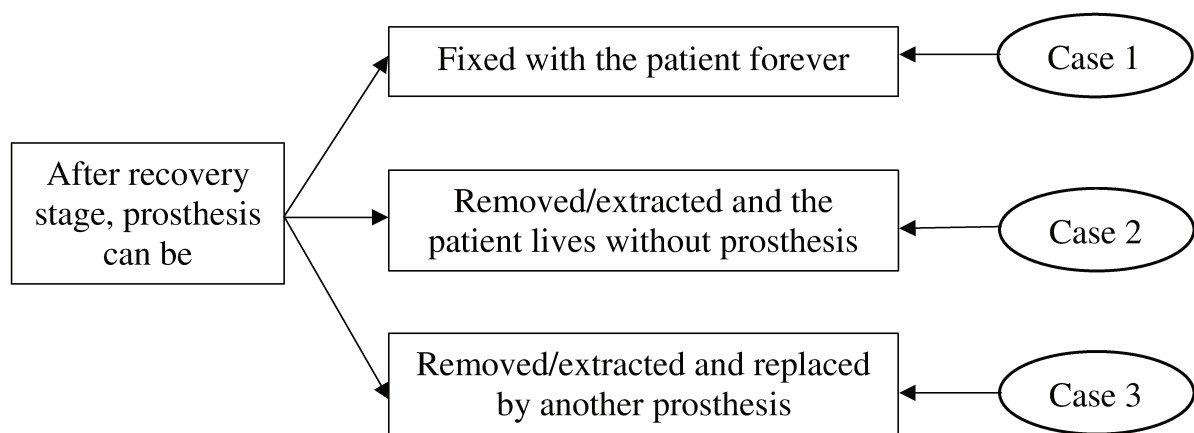


Figure 3.8 - Three possible cases of prosthesis after recovery process

In parallel, the disease lifecycle is engaged in a new iteration starting by the identification of new problems on the actual prosthesis implying less adaptation of the patient. The treatment stage is achieved when the patient is completely recovered. However, the removal of the prosthesis could be needed if there is new health problem or the validity time of this prosthesis is achieved.

Following the case 3, the treatment process could be repeated until the final curacy of the patient. This is the example of a prosthesis implanted in a child body and should be replaced continuously to follow the evolution of the patient morphology. At this case, the patient will be cured in the same order as the previous loop. However, in the case 1 also and in particular context of unexpected emergency (i.e. accident), the patient status could be moved from case 1 to case 3. In all these situations, the doctors and the engineers can gain time and money when starting the diagnosis of disease and the design of the prosthesis from existing data. Especially, in emergency situation for example, the doctors have to know rapidly, why the actual prosthesis is implanted and what are the precautions to respect if this prosthesis has to be manipulated? It is the same need when the engineer wants to realize a new prosthesis to replace an existing

one or to create a new prosthesis similar to some patient pathology. Knowing the types and characteristics of the prosthesis, the doctor can better select the most suitable prosthesis for his patient.

Knowing that the aim of this research work is to propose a PLM approach for the consistent management of both prosthesis and disease lifecycles, one of the main challenges is the identification and the analysis of all links between life stages in terms of data, tools, processes and actors. The next section focuses on the analysis of the main links as part of the conceptual approach.

From the treatment process described in detail using process modeling in section 3.2 and analyses in section 3.3, we can identify the relation between stages of two lifecycles. This relation is described by links that connect the stage of one lifecycle to the stage of another one. This double lifecycles connection is the kernel element of the proposed conceptual framework. An important step for the definition and the implementation of the proposed PLM approach consists of the understanding and the modeling of each life stage as well as the main linkages between these life stages, following a coherent modeling framework.

Figure 3.9 shows six links numbered from L1 to L6. The arrows indicate that the stage is receiving or providing data. For instance, link L1 implies that after analyzing medical data at stage “treatment definition”, medical doctor will decide patient needs prosthesis or not. The decision will send to stage “prosthesis request”. This link demonstrates the connection and data exchange between medical doctors belong to “disease lifecycle” and design engineer from “prosthesis lifecycle”.

Before starting the design process, the collection of data (patient data, medical image) as well as the requirements of the doctors is necessary. Then engineers will design a prosthesis based on this collection process that is described through links L2 and L3.

In order to finish the design process, after completing the virtual prosthesis prototyping, the surgeon and prosthetist will validate the virtual prosthesis prototyping to ensure that it meets all the requirements before going to manufacturing process. This collaboration is described by link L4 that connects between two stages: treatment realization and prosthesis design.

Two arrows in link L5 that describes the collaboration and data sharing of stakeholders in 2 stages: prosthesis manufacturing and treatment realization, the first arrow implies surgeon and prosthetist validate the real prosthesis after fabricating. The second arrow means that producer notifies the delivery date of a prosthesis for

surgeons to prepare the surgery process. Finally, after surgery process, prosthesis exists on the patient body. Link L6 displays the feedback of the patient (customer) during the using process. Based on this feedback, doctors will follow up and propose next treatment direction.

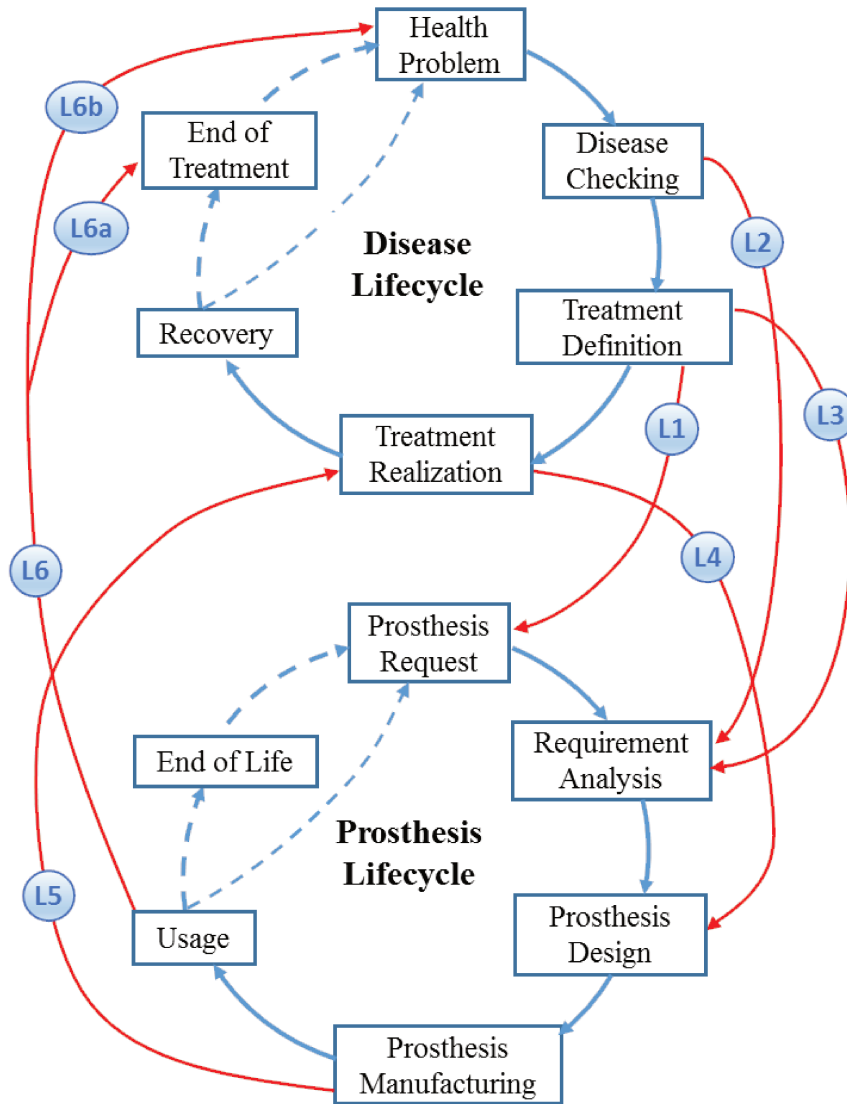


Figure 3.9 - Linking between disease lifecycle and prosthesis lifecycle

The above figure focuses on the main interactions as an example of the analysis strategy within the construction of the PLM approach. Further links can be identified at low detail level when connecting sub stages or elementary processes. However the key issue to exploit the identified links is to conduct a systematic analysis that shown the implication of these links in terms of requirements for the integrated KM-PLM approach. The next section provides the so called five pillars analysis model.

### **3.3.2 The five pillar analysis model of lifecycle stages connections analysis**

Inspired from the existing modeling frameworks such as the PPRO (Product-Process-Resource-Organization), the proposed modeling framework suggests analyzing every life stage and every potential links between life stages according to five complementary dimensions: Flows, processes, stakeholders, tools and requirements (Figure 3.10). The concept of the requirement is not covered by the PPRO approach but it is an important concept that is currently studied by several researchers. Generally, the requirement management process aims to set-up an agreement between the concerned stakeholders on the content and the goals of the project as well as the priorities and the satisfaction rules of the requirements (Pohl, 2010). In the proposed framework, the requirement dimension aims to summarize the different objectives of the life stage and the links between lifecycles. This covers also the needs expressed by stakeholders and any additional integration constraints to be considered in the collaborative activities. The classical resource dimension is divided into material resources (tools in our model) and human/organizational resources (stakeholders). Stakeholder is more generic concept that include the patient as well (object of some activities). Process dimension describes the different activities while the Flow dimension is compared to the classical product dimension. However, the flow concept helps better representation of both physical and information entities concerned by the medical processes.

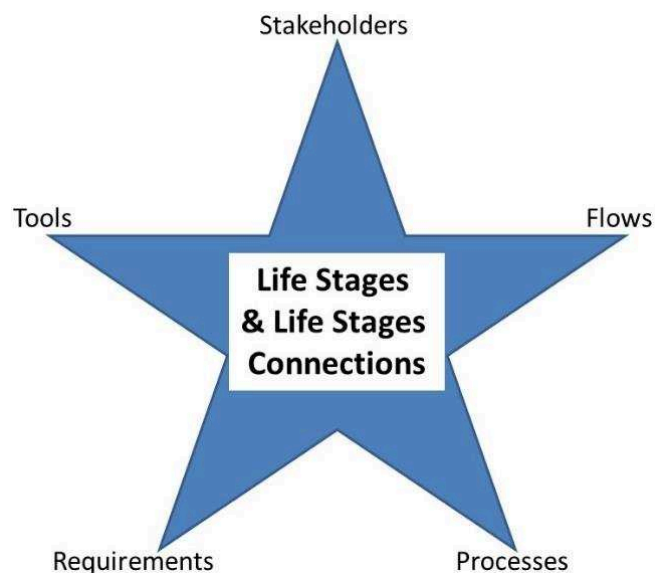


Figure 3.10 - Main concepts in the treatment process

The analysis of the links between the disease lifecycle and prosthesis lifecycle is important to understand the nature of collaborations and data exchanges between stakeholders and tools involved in the medical treatment process. In addition,

requirements in terms of PLM assistance functionalities and collaborative workflows could be identified. In summary, this section will analyze in details the most important links (numbered from L1 to L6 in Figure 3.9) according to the five knowledge dimensions established in the previous section.

The first link L1 is shown in Figure 3.11. Medical doctors analyze and diagnose the patient disease based on medical data. They decide if the patient needs prosthesis for the treatment process or not. This decision is sent to design engineer who analyzes medical image and then designs prosthesis. This link demonstrates the collaboration between medical doctor and design engineer. Link L1 is categorized based on 5 main concepts as follows:

- Requirements: define the characteristics of the requested prosthesis from the identification of the disease pathology and the suitable treatment.
- Exchanged Flows: Prosthesis decision including prosthesis functional specifications.
- Used Tools: Mail, doc manager, analysis software for medical imaging
- Concerned Processes: Diagnosis process, design process.
- Involved Stakeholders: Medical doctor, design engineer, prosthetist.

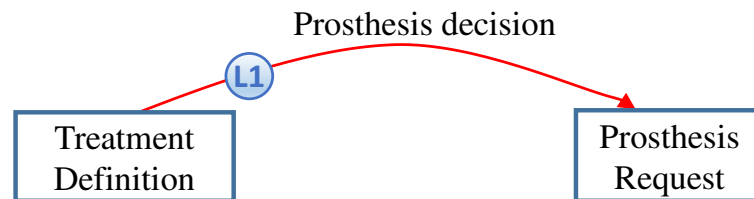


Figure 3.11 – Description of Link 1

Figure 3.12 shows the link between “Disease checking” and “requirement analysis” life stage. Before designing prosthesis, the design engineer will receive medical images of patient (DICOM file) from radiologist. Then the medical images are converted to STL format that is suitable with the input of CAD software. This link shows the collaboration and data exchange between two actors: radiologist and design engineer. Link L2 is categorized based on 5 main concepts as follows:

- Requirements: describe the constraints to be respected according to the bone morphology and motion difficulties. It includes additional considerations related to the presence of specific allergy by the patient to some materials, etc.
- Exchanged Flows: Patient medical image (DICOM file), patient medical history
- Used Tools: CT/MRI machine, 3DMIP tool.
- Concerned Processes: Scan process, design process.
- Involved Stakeholders: Radiologist, medical doctor, design engineer.



Figure 3.12 - Linking between disease checking and requirement analysis stage

Figure 3.13 shows the link between “Treatment definition” and “requirement analysis” stage. The design engineer receives additional necessary information, requirements and treatment plan from the surgeon. The integration of these requirements in the design is very important to facilitate the surgery and the implantation of the prosthesis. Link L3 is categorized based on 5 main concepts:

- Requirements: the objective of this relation is to make explicit the type of prosthesis, its dimensions, material and fixture system. These requirements also include the handling constraints to be respected during the surgery and the possible limitations due to the presence of other devices in the patient body.
- Exchanged Flow: Treatment plan including surgery operations, prosthesis specifications
- Used Tools: Mail, doc manager
- Concerned Processes: Diagnosis process, design process.
- Involved Stakeholders: Medical doctor, Surgeon, design engineer.

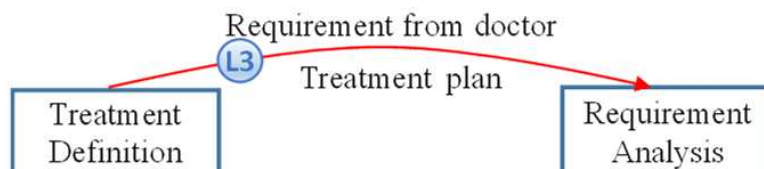


Figure 3.13 - Linking between treatment definition and requirement analysis stage

Figure 3.14 describes the link between two stages: treatment realization and prosthesis design. In order to meet all requirements for the final prosthesis product, surgeon validates the virtual prosthesis prototyping before sending the designed model to manufacturing process. This link illustrates the cooperation between a surgeon and a design engineer. Based on 5 main concepts, link L4 is categorized as follows:

- Requirements: send by the designer to the surgeon to validate the designed 3d model in conformity with the set of requirements and surgery constraints.
- Exchanged Flows: Virtual prosthesis prototype file.
- Used Tools: CAD software
- Concerned Processes: Design process
- Involved Stakeholders: Surgeon, design engineer, prosthetist.

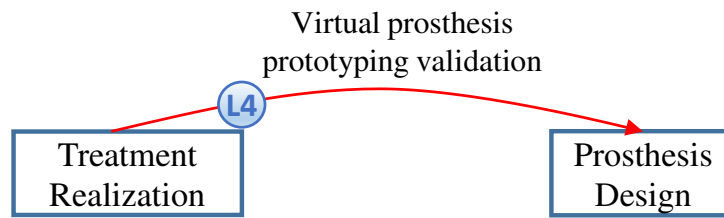


Figure 3.14 - Linking between treatment realization and prosthesis design stage

Before going to surgery process, the manufactured prosthesis is again validated by the prosthetist and surgeon. It make sure that the prosthesis is manufactured precisely and meets the initial requirements. This collaboration is described by link L5(1) as shown in Figure 3.15. Another link L5(2) illustrates the connection between the producer and relevant stakeholders (medical secretary, surgeon, and anesthetist). Once producer estimates the delivery time, they immediately notify all relevant stakeholders to update the surgery planning. The surgery planning is created through a collaborative process that aims to create a consensus between the delivery date of the prosthesis, the availability of the surgeon and the planning of the surgery room. In emergency situation, the delivery time could be considered as a constraint from the medical domain to the manufacturing domain. Concretely, Link L5 is categorized by the following items according to the five pillars of the analysis model:

- Requirements: Obtain a consensus on the surgery date based on the delivery date and other constraints.
- Exchanged Flows: Date of delivery, date of surgery, prosthesis.
- Used Tools: Planning manager, 3D printing machine, CNC machine
- Concerned Processes: Surgery, planning, manufacturing process.
- Involved Stakeholders: Surgeon, manufacturer, medical secretary, and prosthetist.

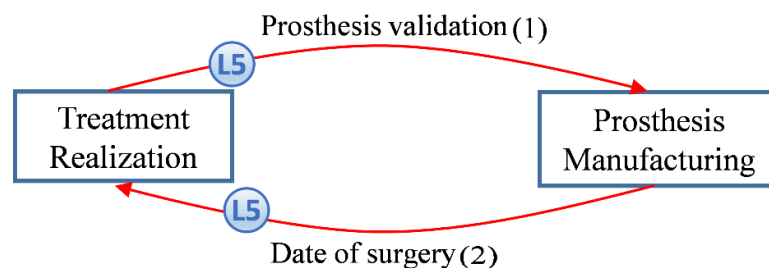


Figure 3.15 - Linking between treatment realization and prosthesis design stage

After surgery, the prosthesis was implemented on the patient. The collection of information from the user is very necessary. It helps doctors to evaluate the success of treatment, to follow the states of the prosthesis and to monitor the acceptance of the prosthesis by the patient along his life. From this collection, doctors can recommend new curative or preventive actions.

As shown in Figure 3.16, link L6 is used to describe the connection between the prosthesis usage on one side and end of treatment and health problem identification stages on the other side. Based on the five pillars analysis model, link L6 is described as follows:

- Requirements: Monitor the status of the prosthesis based on patient's health data.
- Exchanged Flows: medical images and reports; health problems, prosthesis data
- Used Tool: Scan; Mail, doc manager
- Concerned Processes: recovery, rehabilitation
- Involved Stakeholders: Surgeon, medical doctor, patient

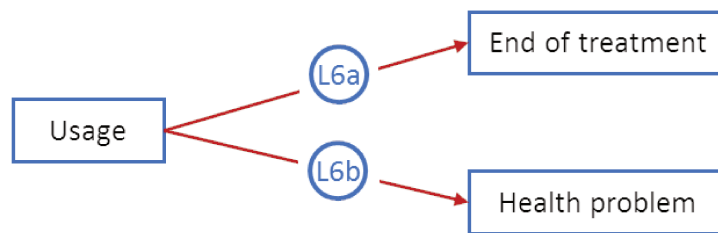


Figure 3.16 - Linking between Usage and Health problem stages

For further analysis the treatment process and understand how the connections between life stages could be managed, it is necessary to identify and represent all concepts used in the different activities and the relations between these activities. In the next section, a semantic model for the medical sector requiring prosthesis is explored and extended as ontology. This model is constructed based on the five analysis dimensions framework and propose a classification of key knowledge objects to be shared by the stakeholders.

### **3.4 Ontology-based modeling of the target medical domain**

As discussed in the previous chapters, there is always the exchange and re-use of knowledge among stakeholders during the treatment process. The final result of the proposed framework is the building of the whole semantic model for medical sector structuring the common knowledge repository. As shown in the following Figure 3.17, the role of the knowledge repository is to help actors to share the knowledge between medical and engineering experts. The knowledge repository results from the collection of meta-data of business files and the capitalization of expert rules provided by the stakeholders. The business files are created by CAx (Computer Aided X business activity) tools and are stored in a file base through a dedicated connector.

Ontology based modeling approach is necessary to facilitate the classification, the reuse as well as the update of shared knowledge. In general, semantic model is used to



organize the different concepts in the common repository. The files are connected to business activities and related knowledge domain to make it easier to find and reuse in the correct process. This section illustrates the main elements of the proposed modeling framework.

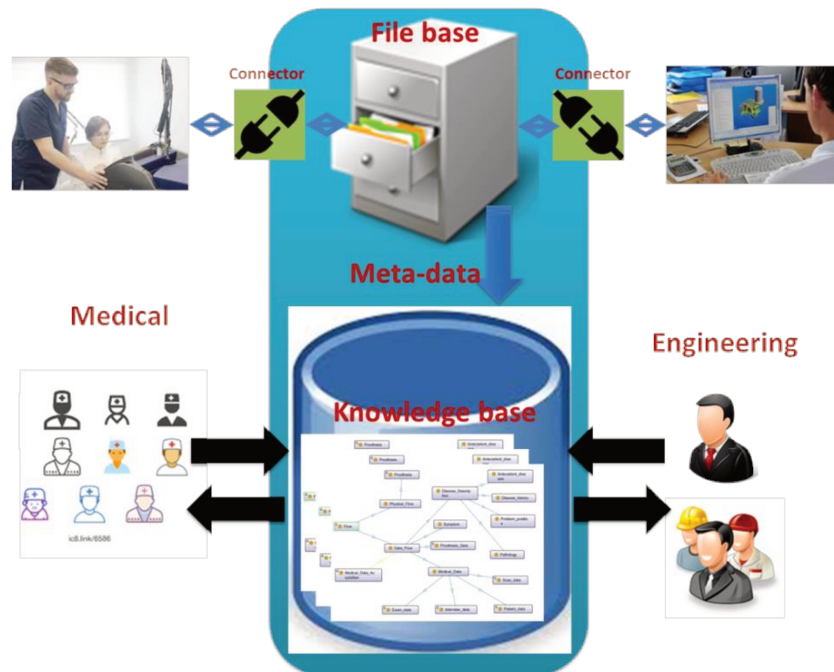


Figure 3.17 - Knowledge repository concept

For the definition of the global knowledge model behind the repository, the first step is to construct the meta-model as a kernel of the modeling framework as shown in Figure 3.18. The meta-model implements the main foundation of the analysis framework through the concept of an entity as a container of all medical and engineering business objects. Every life stage (of disease and prosthesis lifecycles) is composed by a set of entities that can be classified by the UML inheritance relation according to the above five analysis pillars (i.e. Flow, Tool, Process, Stakeholder and Requirement).

According to this model, Prosthesis lifecycle and Disease lifecycle are composed by many different life stages implemented by various managerial and operational processes (patient interview, scan, prosthesis design, patient registration, etc.). Any process is composed by a set of activities that can be technical that modify an object of the situation, collaborative to share knowledge between stakeholders, or decisional for the selection of the suitable treatment and prosthesis. Each activity transforms an input flow to an output. It can be physical flow (like the prosthesis) or data flow (like the medical data, disease description, symptom, and prosthesis data). The data flows are stored in variety of business files to be stored separately in a data repository.

The last dimension covered by the meta-model concerns the organization view to distinguish the belonging of the variety of stakeholders. The organizations involved in the medical treatment process requiring prosthesis are various such as the hospital, the post-treatment clinic, the manufacturing shop as well as the whole supply chain. Every organization has its own rules and every stakeholder has a function in the organization and contributes with specific role to the concerned activities. This double information is useful for the configuration of user management module in the PLM.

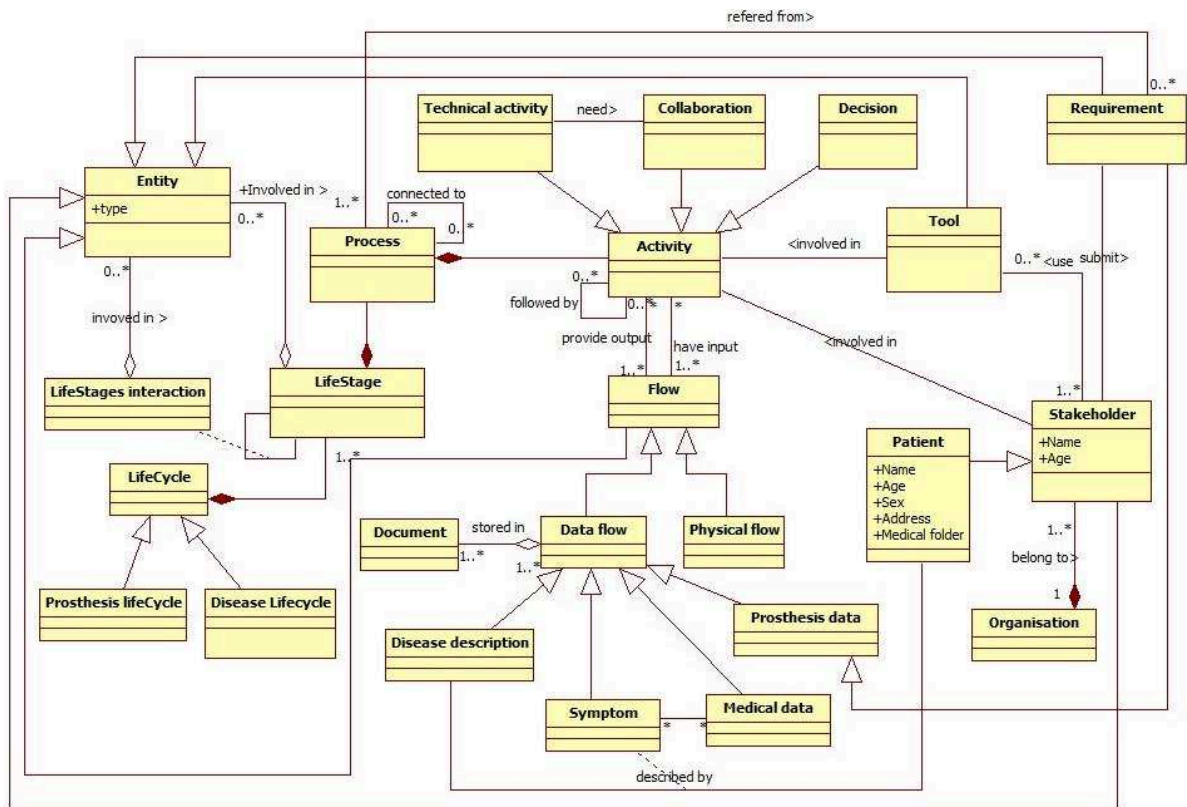


Figure 3.18 - Global semantic model for the treatment process

Based on the core semantic meta-model, the ontology is built following the process shown in Figure 3.19. This process begins by identifying the main concepts from the treatment process, then indicating the properties and relationships of all concepts in the conceptual model. Finally, taxonomy is constructed by extending these concepts in detail. With each main concept, we build a corresponding taxonomy. The whole ontology is developed using the Protégé tool. For instance, the following taxonomies are developed as part of the semantic model: Flow taxonomy; Prosthesis taxonomy, requirement taxonomy, prosthesis taxonomy, stakeholders and tools taxonomy.

### Chapter 3: A conceptual approach for connecting medical and engineering processes

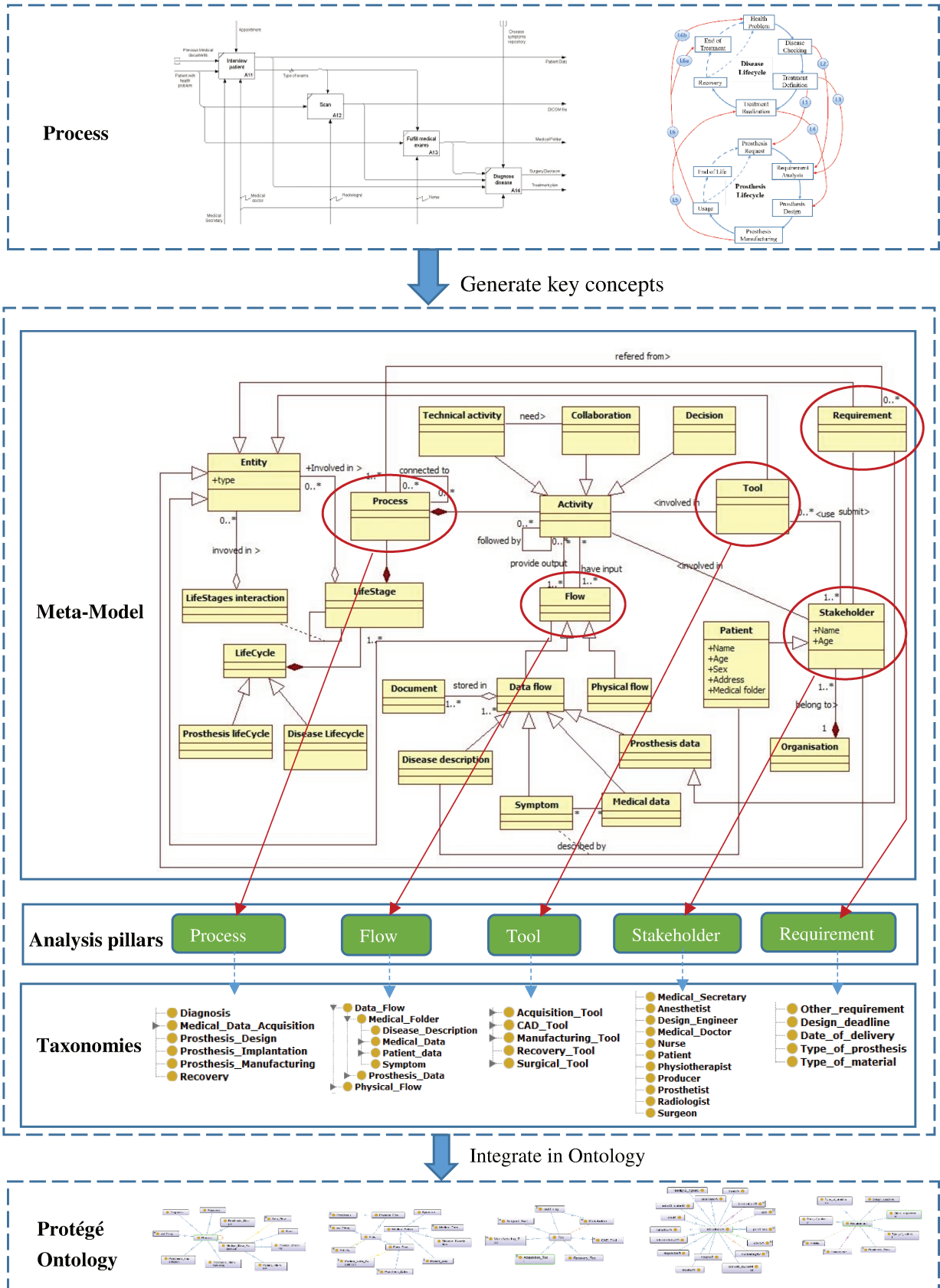


Figure 3.19 – Ontology construction process

- **Flow taxonomy**

The concept of flow is used to express different types of exchanged objects between activities and life stages. This concept supports the representation of two categories of knowledge: data and physical. The first category includes mainly medical knowledge while physical flow focuses principally on prosthesis data among others. Prosthesis as a physical flow includes the different types and components of the prosthesis. Data flow is composed by four data groups: disease description, symptom, prosthesis data and medical data. At a more detailed level, each data group is composed by many different sub-data as shown in Figure 3.20. The disease description concept for instance is composed by antecedent, history and pathology description.

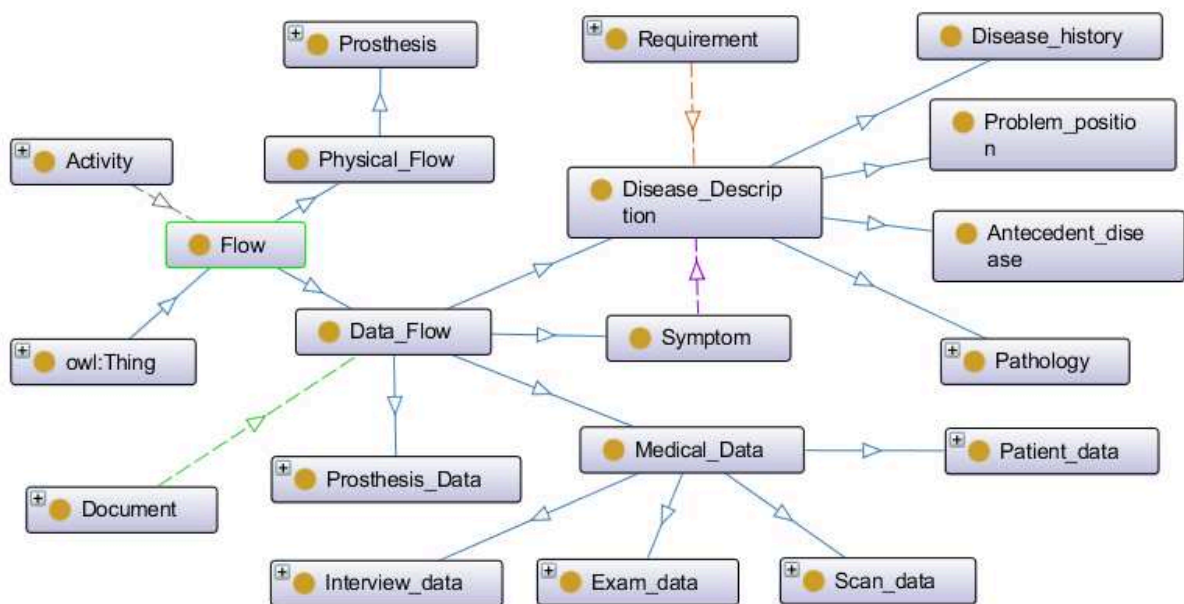


Figure 3.20 - Flow taxonomy

- **Pathology classification for disease description**

To make the description of disease efficient, a classification of main pathologies is given in Figure 3.21. Each pathology is described with corresponding symptoms as useful knowledge that help the medical doctor to easily identify the patient disease through a comparison between the diagnosed symptoms and the symptoms describing the standard pathologies. This taxonomy is also needed to describe the linkage of every prosthesis type to their concerned usage context representing the disease type. The actual taxonomy is described partially for demonstration perspectives and requires deeper analysis with practitioners to cover all knowledge in this field.

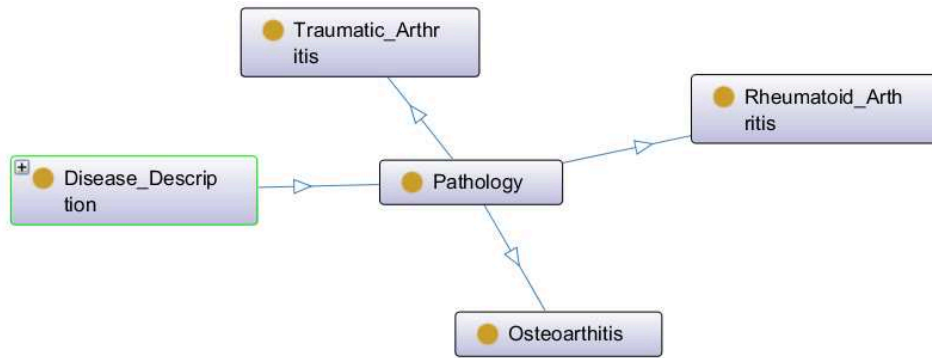


Figure 3.21 - Patient pathology classification

• **Prosthesis taxonomy**

At the detail level of the physical flow, the taxonomy of a prosthesis is defined to classify the different types of prosthesis according to their domain of application (Figure 3.22). Each prosthesis type is described by its main characteristics in terms of material, fixture mode and components among others. The concept of the prosthesis is connected to the corresponding disease descriptions to support the decision making tool identify the suitable usage context. This category of knowledge is created by the engineers and should be accessible by the doctors through the PLM approach as a decision support to identify suitable treatment for every disease. With the traceability of prosthesis types and disease pathologies obtained from the patient, the surgeon can compare the possible solutions based on similar case studies before selecting the appropriate prosthesis.

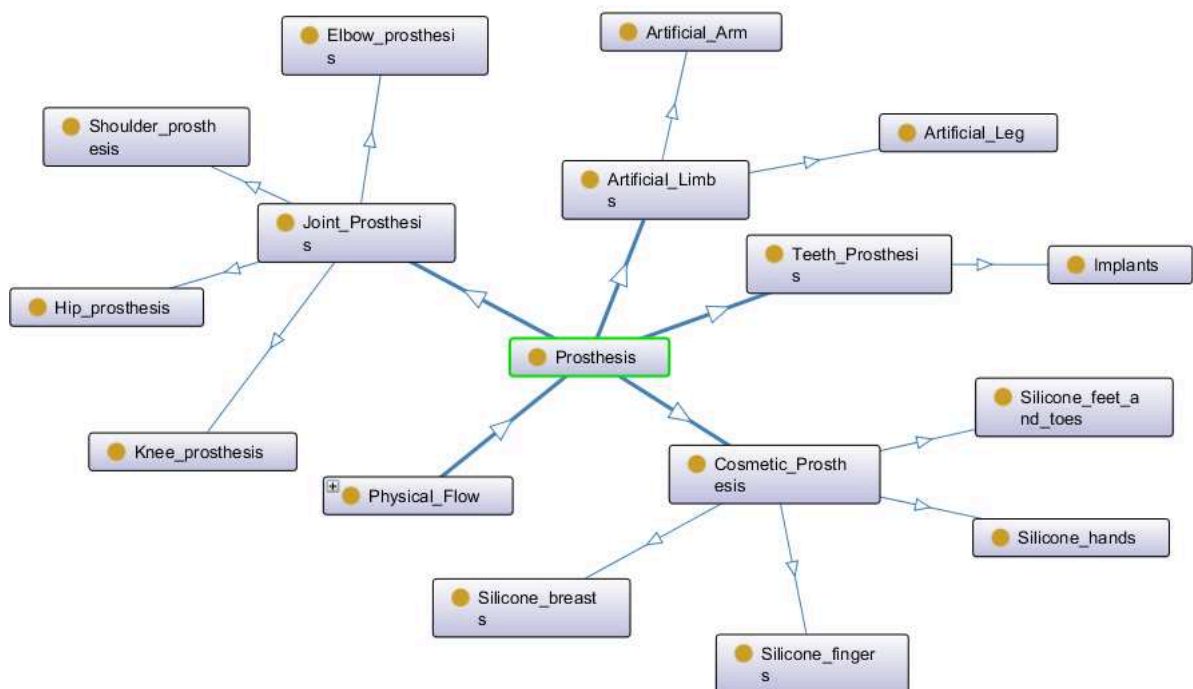


Figure 3.22 – Prosthesis taxonomy

- **Requirement taxonomy**

Requirement taxonomy consists on the key concepts representing the necessary information to obtain a consensus between stakeholders on the characteristics of the desired prosthesis. The idea is that by creating sub-categories of requirements, the stakeholders will be provided by a tool to define their needs within a standard syntax. For instance, the proposed taxonomy of requirements includes the following items: prosthesis type, disease type, packages of constraint, prosthesis dimension, prosthesis type, implantation constraint, type of material and other delivery deadlines (Figure 3.23). The requirement taxonomy is connected to the stakeholder taxonomy in order to identify the source of each requirement and check if there is redundancy between requirements.

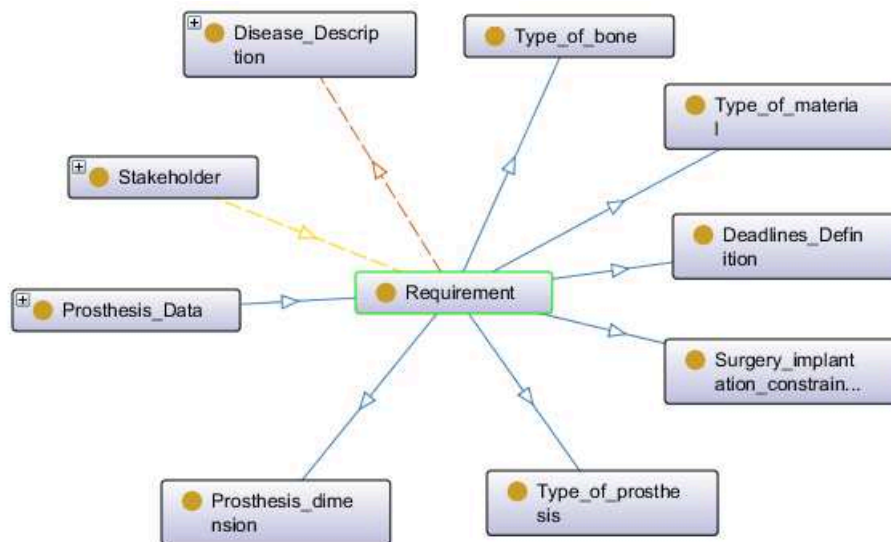


Figure 3.23 - Requirement taxonomy

- **Process taxonomy**

The process taxonomy includes all necessary processes from medical and engineering domains as well as the key collaborative activities connecting these processes. The idea is to identify all types of activities and their characteristics, especially the skills required to realize the activity. The process in the semantic model consists of medial data acquisition, diagnosis, prosthesis design, prosthesis manufacturing, prosthesis implantation and recovery (Figure 3.24). The classification of process helps to manage all of the activities involved in the entire treatment process and to verify if any activity is missed. This helps stakeholders to visualize the order and content of this process.

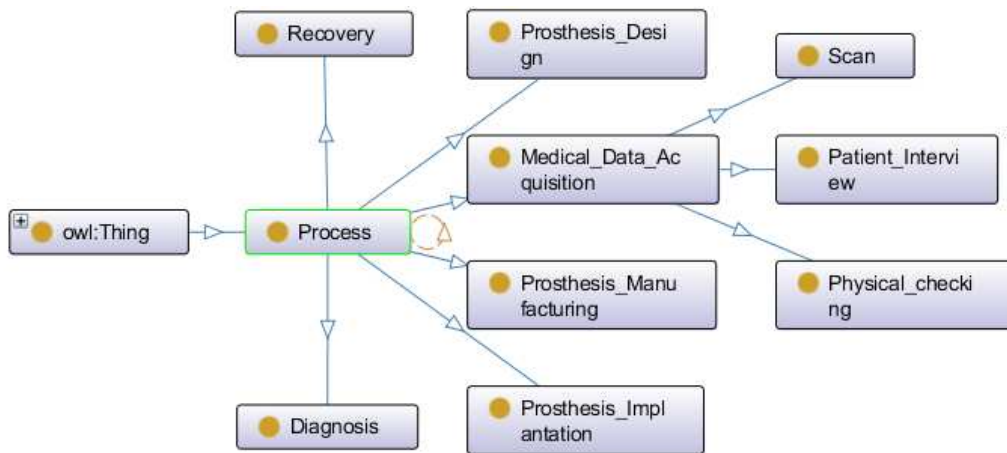


Figure 3.24 - Process taxonomy

- **Tool taxonomy**

The tool taxonomy synthesizes the main categories of used software during the treatment process. The tool section of the proposed ontology gives additional information about their characteristics and the type of files managed by such tools. Figure 3.25 shows a tool taxonomy that describes all possible tools that can be classified in 4 different groups: Acquisition tool to collect and capture data from a patient and requirement on prosthesis, CAD tool used to design the prosthesis, manufacturing tool used to transform the files and connect with the machineries for the realization of different components of the prosthesis and surgery tool. This taxonomy helps stakeholder choose quickly the suitable tools in the knowledge repository.

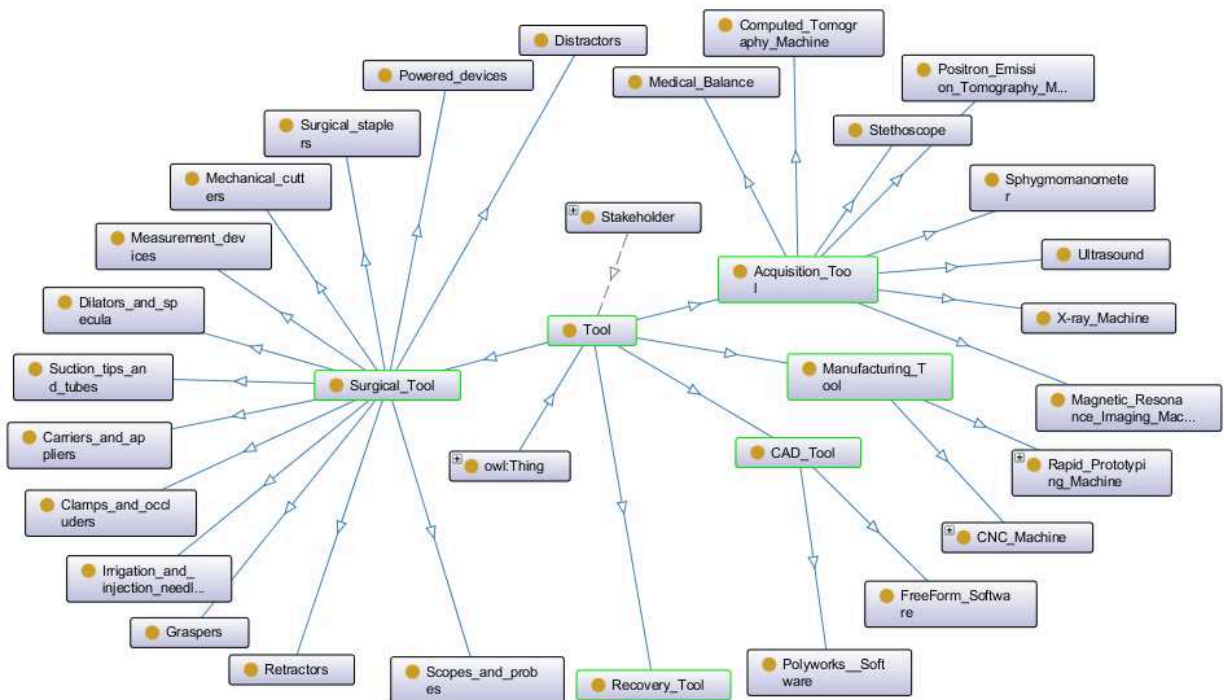


Figure 3.25 - Tool taxonomy

• Stakeholder taxonomy

The stakeholder taxonomy is complementary to the process taxonomy and aims to identify different types of actors involved in the processes as well as their roles and authorities in the treatment process. According to the semantic model, stakeholder belongs to an organization; it uses tools to fulfil activities. Stakeholder in the semantic model consists of surgeon, medical secretary, anesthetist, radiologist, producer, requirement, nurse, medical doctor, patient, physiotherapist, design engineer and prosthetist. This helps the system to visualize and manage all of the actors involved (Figure 3.26).

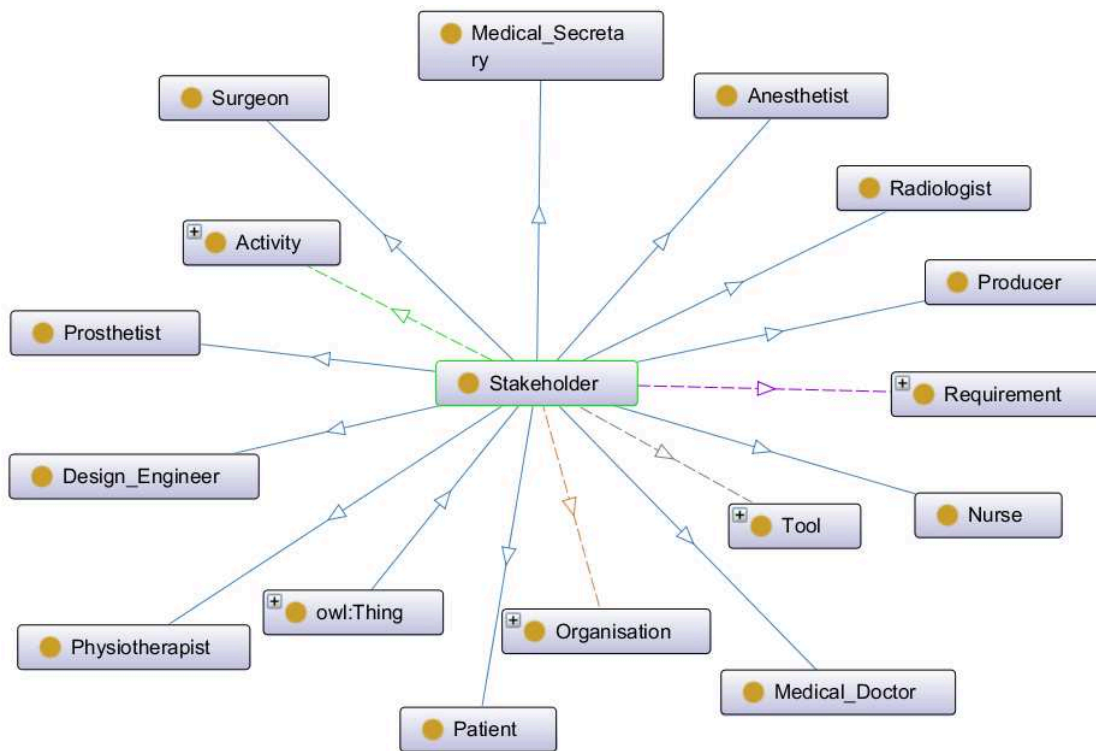


Figure 3.26 - Stakeholder taxonomy

3.5 Conclusion

The objective of lifecycles analysis framework presented in this chapter is to identify the main requirements for the PLM approach able to manage the whole medical treatment process requiring prosthesis. For instance, formal process models are realized to clarify the list of stakeholders to be connected within such approach and what activities require more attention in terms of computer-aid functionalities. The five dimensions used for the analysis of life stages linkages allow answering to several questions such as: what kind of data is needed to share? What kind of files is needed to save and transfer? What kind of tools to connect? Etc.



Looking to these questions, the PLM approach should work as a common repository on which heterogeneous files, related meta-data and expert knowledge will be managed. For instance the classification of business files used in medical and engineering domains connected to the files to be exchanged give information about the connectors to be developed. Within an automatic processing, the PLM connectors can be used to extract data from the files and upload them in the repository. The evolution of these business files throughout the different life stages implies the need to develop version management mechanism so that the users will work on the current version. This functionality requires the development of collaborative workflows that ensure the revision and validation processes before updating the version of the paper. Finally, the exploitation of stored data and knowledge in the repository requires from one side the structuration of all concepts representing this knowledge and the proposition of query requests associated with intuitive displaying.

Based on this analysis, a semantic model is constructed and extended as domain ontology for the medical domain covering all stages of the entire treatment process requiring prosthesis. The resulted modeling framework includes both taxonomies of concepts necessary to classify knowledge for easier finding and reuse and relationships between the concepts shared between medical and engineering actors.

The following research focuses on the implementation of the proposed models in PLM tool for data sharing and knowledge reuse perspective. Collaborative workflows and document management are also considered. However, less attention is given to the problematic of interoperability because that the current tools provide interesting facilities for the transformation of DICOM files to STL. The next chapter gives an overview of the experimentation results that aim to validate the proposed principle of solution and related models.

# Chapter 4

## Implementation of the proposed framework in AUDROS PLM tool

### Contents

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4.1 Introduction .....	94
4.2 Implementation strategy .....	95
4.2.1 Global architecture within AUDROS tool .....	95
4.2.2 Implementation scenario and related PLM functionalities .....	96
4.3 Implementation of main use cases in AUDROS .....	100
4.3.1 Prosthesis project management with the Flowboard module .....	101
4.3.2 Scenario of disease knowledge update.....	102
4.3.3 Scenario of functional requirement creation and update .....	105
4.3.4 Scenario of prosthesis design .....	108
4.4 Administration issues: Construct the workflows.....	111
4.4.1 Medical data workflow .....	112
4.4.2 Disease workflow.....	113
4.4.3 Requirement workflow .....	113
4.4.4 Prosthesis workflow .....	114
4.5 Conclusion .....	114

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## **4.1 Introduction**

This chapter is dedicated to the experimentation of the proposed framework for demonstration of principle of solution perspectives. The list of PLM functionalities is obtained from the analysis of current initiatives presented at the end of chapter 2. Particularly, the QSIT based PLM framework shown in Figure 2.21 gives interesting directions to identify the key PLM functionalities with respect to the medical domain specificities. Looking to the fact that the PLM has to manage also the prosthesis data as a product, The PLM functionalities for medical domain have to be coupled with PLM functionalities as applied in engineering and manufacturing domain. This double integration of heterogeneous information systems is a key contribution of this PhD.

To do so, the chosen solution is a French PLM solution named AUDROS<sup>5</sup> because it proposes a set of flexible and robust tools able to be adapted to any functional domain through an intelligent merge of the business process model, the data model generator and the user interface design (Zancul et al., 2013). Indeed, the AUDROS PLM solution has always relied on the interoperability, scalability and customization of its own PLM engine and their core business. Due to its flexibility and its capability to be adapted to any functional demand through the merge of its business process model, its data model generator and as well its user interface design, the AUDROS system provide a very powerful and flexible tool to handle any need. AUDROS solution is actually used by several companies in several domains, with very little customization effort: machinery and equipment, aeronautics and defense, watch makers and precision engineering and processes, electronic, consumer goods. As a centralized technical documentation repository, AUDROS not only collects documents but also all data related to products (specifications, drawings, BOMs, images, weight properties, materials etc...). By recognizing the files most used in industry, AUDROS can automatically create professional documents such as catalogs and configurators (AUDROS website).

The flexibility of the modeling engine offered by AUDROS to customize the business data models is of great interest to our work and encourages us to use this tool for the implementation of hybrid models combining medical and engineering related concepts. Moreover, Audros has some useful modules, they make it easy to create workflows and user interfaces. Also, because of the high adaptability of the AUDROS PLM tool to SME contexts of work and its capacity to manage both product and service centered businesses; it is assumed that the AUDROS PLM tool could be a

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<sup>5</sup> <https://www.AUDROS.fr/>

suitable solution to try answering to the research questions identified in the problem statement section of chapter 2.

In order to conduct the implementation process in a simplified and easy to understand way, a global scenario of treatment process is defined. Then, UML use-case diagram is used to specify the key functionalities expected by the PLM approach. The realization of these functionalities is obtained by the combination of various AUDROS software modules according to a pre-defined operational scenarios specified by UML sequence diagrams. Administration issues in terms of user rights definition and workflows management are also explained at the end of the chapter.

## **4.2 Implementation strategy**

### **4.2.1 Global architecture within AUDROS tool**

Based on the conceptual framework proposed above for the analysis of linkage between prosthesis and disease lifecycles, a set of PLM functionalities have been identified and part of them tested in the AUDROS solution. Figure 4.1 shows the global implementation framework within AUDROS tool. Thanks to its capacity to centralize the management of documents and data, this software is used as a common repository on which prosthesis and patient disease data are stored and managed with the same modules. The types of medical data and prosthesis data stored in the AUDROS data base are those identified in the knowledge model. Medical and prosthesis files are managed in terms of versions and iteration. Medical Files are images and other reports (interview, image analysis and post-treatment). Prosthesis related files are mainly CAD files and standards. Query and workflow mechanisms are used to support decision making process. Examples of decision making for medical staff are the identification of pathology based on comparison with standard symptoms, the selection of good type of prosthesis and the identification of necessary equipment for the chosen prosthesis. The design support is limited to the research and visualization of CAD files of similar prosthesis. Files about standards and design rules could also be stored in the repository so that to make the quality of the prosthesis. For a complex prosthesis, the product management module is used to manage the bill of material (BOM). The BOM is shared between design actors and manufacturer to describe the detailed characteristics of the prosthesis components.

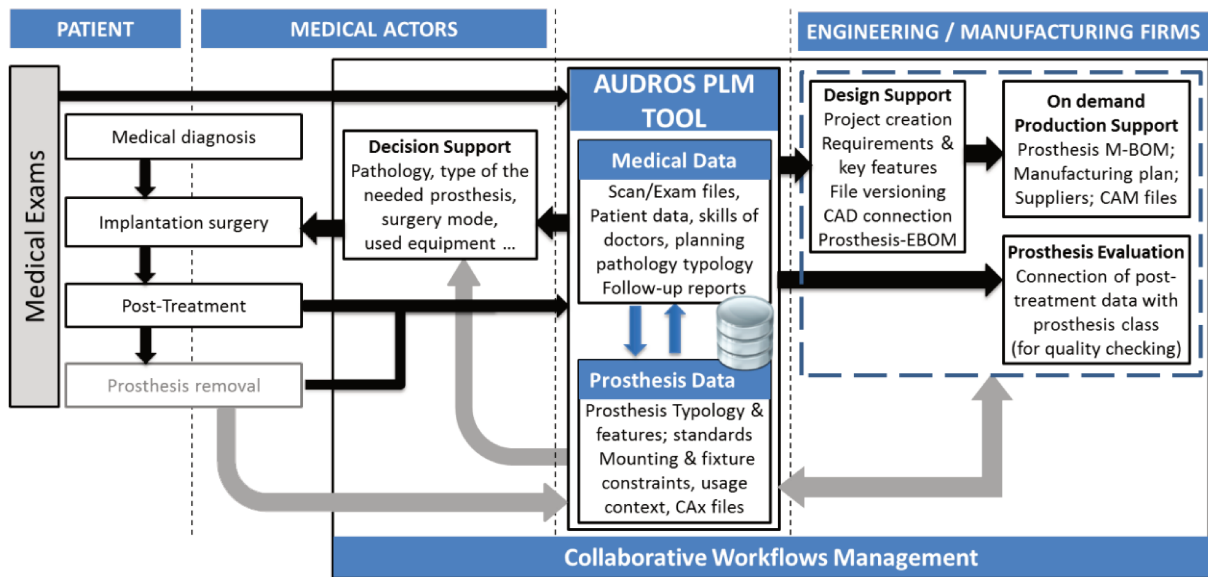


Figure 4.1 – Implementation strategy within the AUDROS PLM tool

In addition to the BOM management facility, the AUDROS PLM could be used to manage the list of suppliers for the outsourcing of the prosthesis components. The Flowboard module of AUDROS software proposes interesting functionality to manage design and manufacturing activities within a unique project. The medical files are connected as inputs to the engineering activities and CAD files are connected as deliverables to the same activities. Finally, the storage of post treatment files for long period makes possible to follow-up the status of the prosthesis based on the patient health data.

#### 4.2.2 Implementation scenario and related PLM functionalities

For demonstration issues, a nominal scenario is conducted to show how the key functions of AUDROS PLM can be used to enhance the main steps of the treatment process requiring prosthesis. The nominal scenario is divided into several steps as shown in Table 4.1. Each step is described in terms of objectives, actors involved, manipulated PLM objects, managed business files, knowledge based assistance functionalities and the collaborative workflows.

For instance, in the first step, the actors collect medical data from the patient and update it into PLM system. It is done by 4 actors: medical secretary, medical doctor, radiologist and nurse. All medical files (interview report, medical image, exam results) are also attached in the system. At the end of this step, medical secretary sends the notification for medical doctor to do the next step. After receiving the notification, the medical doctor identifies the patient pathology based on medical data and knowledge

repository. Then the medical doctor also fills in other disease information of the patient. Finally, the notification will be sent to the surgeon at the end of step 2.

From the patient medical data at step 1 and disease information at step 2, the surgeon will synthesize and propose the functional requirement of a prosthesis in step 3. At this stage, it is proposed that the surgeon creates a new project for the prosthesis as a container of all engineering documents. The medical data are connected to the prosthesis and the related project. Then, the system sends a notification to prosthetist to update the technical requirement at step 4. At the end of this step, the system sends notifications to the designer to begin the design process and to the producer to prepare the prosthesis fabrication.

Based on the functional requirement, technical requirements and patient medical data, the design engineer begins to design the prosthesis model. The designer is in charge of the updating of the project plan and the connection of all necessary files as inputs or deliverables. The designed prosthesis will be validated by the prosthetist to get the final model for manufacturing process (step 6). The producer will prepare the manufacturing process. At this time, the system sends the progress of fabrication to the medical secretary, surgeon and anesthetist to prepare the surgery. After completing the manufacturing process, the produced prosthesis will be validated by the prosthetist and surgeon before going to implant it on the patient. The last step is post-surgery process; nurses will follow the rehabilitation process and notify the medical doctor and surgeon about the current patient situation. This is achieved as a set of meta-data uploaded in the patient medical folder and connected with the reference of a prosthesis in order to follow-up the status of prosthesis from the traceability of the health status of the patient.

Table 4.1 - Scenario of the implementation process in AUDROS

STEP	Objective	Actors	PLM object	Attachment	Lifecycle/Workflow	PLM/KM functions
1	Medical data collection	Medical secretary Medical doctor Radiologist Nurse	<b>Medical data:</b> <b>Patient:</b> + Name of patient + Disease + Comment <b>Interview</b> + Date of interview + Initial identified problem + Medical doctor <b>Scan</b> + Type of scan + Scan position + Date of scan + Radiologist <b>Exam</b> + Type of exam + Date of exam + Nurse	Interview report Medical image Exam results	Medical folder workflow	<ul style="list-style-type: none"> <li>• Create knowledge about the disease of patient</li> <li>• Medical secretary send notification for medical doctor, radiologist and nurse to enter the patient data depending on their roles.</li> <li>• Send notification to medical doctor to describe the patient disease in the next step</li> </ul>
2	Disease identification	Medical doctor	<b>Disease:</b> +Pathology (it is an object from catalog) +Problem position +Antecedent disease +Disease history +Date of identification	Medical report	Disease workflow	<ul style="list-style-type: none"> <li>• KM function: help the doctor identifying the disease based on the catalog of pathology</li> <li>• Send notification to surgeon (to do the next step)</li> </ul>

## Chapter 4: Implementation of the proposed framework in AUDROS PLM tool

3	Functional specification	Surgeon	<b>Requirement</b> + Type of prosthesis (it is an object from catalog) + Material + Requested date of delivery + Other requirements	Prosthesis specs V1 Functional specification (Generated from doc star)	Requirement workflow	<ul style="list-style-type: none"> <li>Project Management: Create a prosthesis project and define the related plan.</li> <li>KM function : help the surgeon identifying the prosthesis type based on the catalog of prosthesis</li> <li>Create functional specifications of prosthesis based on identified disease.</li> <li>Send notification to prosthetist (To update the requirement)</li> </ul>
4	Technical specification	Prosthetist	<b>Requirement</b>	Prosthesis specs V2 Technical specification STL file	Requirement workflow	<ul style="list-style-type: none"> <li>Create technical specifications</li> <li>Send notification to designer to begin the design process</li> <li>Send notification to producer to prepare the prosthesis fabrication.</li> </ul>
5	Design prosthesis	Design engineer	<b>Prosthesis</b> + Order date + Design engineer	CAD file V1	Prosthesis workflow	<ul style="list-style-type: none"> <li>Update project plan with deliverable</li> <li>Send notification to prosthetist</li> </ul>
6	Prototype validation	Prosthetist	<b>Prosthesis</b>	CAD file V2	Prosthesis workflow	<ul style="list-style-type: none"> <li>Validate prosthesis model</li> <li>Send notification to producer</li> </ul>
7	Prosthesis fabrication	Producer	<b>Prosthesis</b> + Estimate date of delivery + Producer	Notes for using	Prosthesis workflow	<ul style="list-style-type: none"> <li>Send the delivery date of prosthesis to the medical secretary, surgeon and anesthetist.</li> <li>Send notification to surgeon, medical secretary and anesthetist when the real prosthesis is validated.</li> </ul>
8	Prosthesis implantation	Surgeon	<b>Surgery</b> + Date of surgery + Surgery duration	Surgery result	Surgery workflow	<ul style="list-style-type: none"> <li>Send notification to nurse when finishing the surgery process.</li> </ul>
9	Post-surgery	Nurse	<b>Post-surgery</b> + Disease description + Recovery folder	Feedback report	Post-surgery workflow	<ul style="list-style-type: none"> <li>Send notification to medical doctor and surgeon to report about recovery process of patient.</li> </ul>



Based on the nominal scenario presented above, the PLM main categories of PLM functionalities are specified using the UML use case diagram. In UML, a use case is attached to one user of the system and represents at a macro level the interaction of the user with the system of interest. The realization of this macro-interaction is described operationally using sequence or activity diagram. The list of stakeholders extracted from the business processes (c.f. section 3.2) is extended as users in the use case diagram presented in Figure 4.2. Around 15 use cases are identified and tested in the AUDROS software. Globally, these use cases concerns the creation, update and management of data and files, the classification and reuse of knowledge, and the management of the project plan. Versioning and notification functions are automatically managed by the tool according to the pre-defined workflows and do not appear in this model.

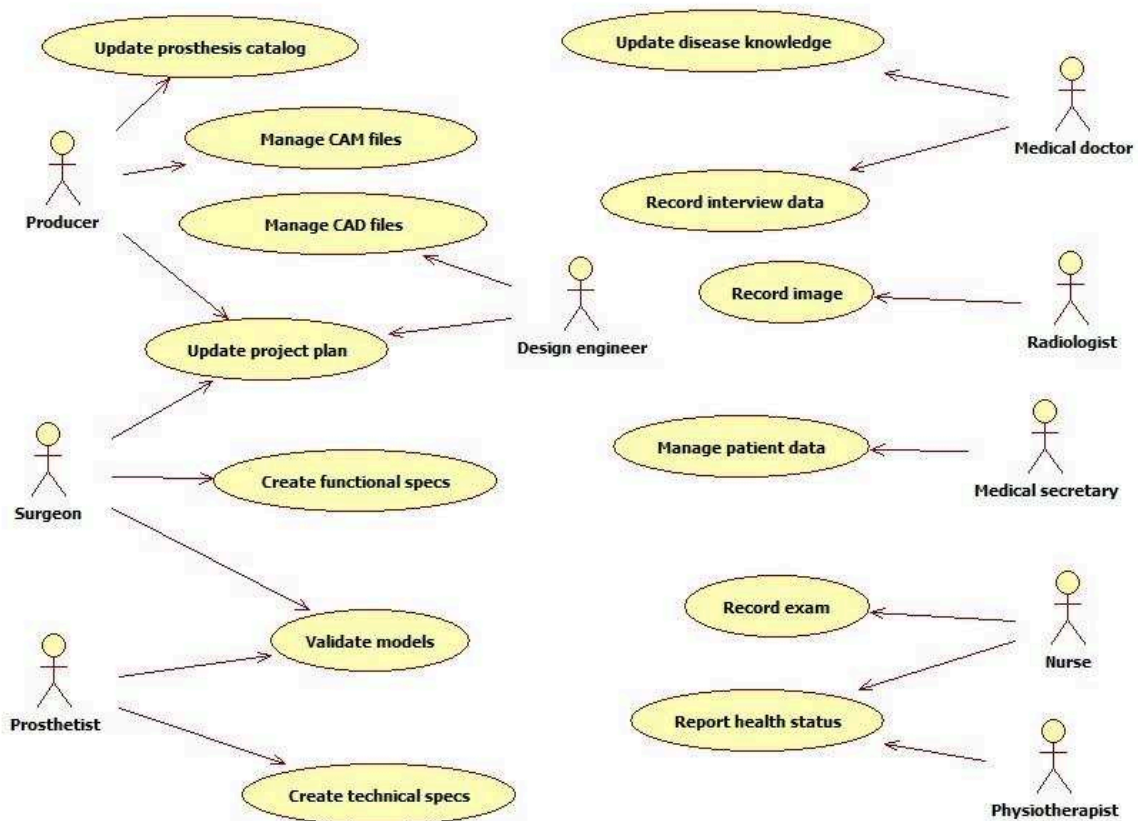


Figure 4.2 - Use case diagram

### 4.3 Implementation of main use cases in AUDROS

The PLM functionalities are implemented throughout various software modules for a database and workflow administration and connectors to manage the interoperability

with legacy Computer Aided Applications. For instance, the main AUDROS modules are used as follows. More details about these modules are given in the appendix.

- **ModelShape:** to create all classes, attributes, and the relationship between them. This module also definition of actors and grants access right for them depending on their role.
- **View designer:** to design customized graphical interfaces to be used by various users to create and manage medical and prosthesis data.
- **SE manager** to create medical and engineering objects' lifecycle and to structure all shared data in folders and files. This module is also used to refine necessary queries parameters for knowledge based decision making support.
- **AUDROS Applet:** is the module to implement the variety of medical sub-processes in terms of PLM workflows.
- **Flowboard** is the module offered by AUDROS solution to create project planning in terms of activities and resources. It also allows the attachment of parts and documents to allow deliverable based management of the project.
- **Docstar** is another interesting module for the generation of office documents (such as forms) and fulfil some fields from met-data stored in the repository. The last module is particularly interesting when creating/updating the prosthesis requirements and exchanging the specification document between medical and engineering stakeholders.

In the following, three PLM based scenarios are explored to show examples of KM-PLM functionalities within the AUDROS solution. These scenarios concerns disease knowledge update, functional requirement creation and sharing, prosthesis design. Each key function is clarified with a sequence diagram scenario and illustrated with customized AUDROS user interfaces. Before these scenarios, the function of project management with Flowboard module is illustrated in the next sub-section.

### **4.3.1 Prosthesis project management with the Flowboard module**

The nominal scenario illustrated in section 4.2 is implemented as a project plan within the Gantt editor of AUDROS. The idea is to describe all medical and engineering activities in the same process in order to link the related actors and resources as well as the deliverables. By the way all the documents stored in the PLM are shared with the right actors independently from his domain of expertise (medical or engineering).

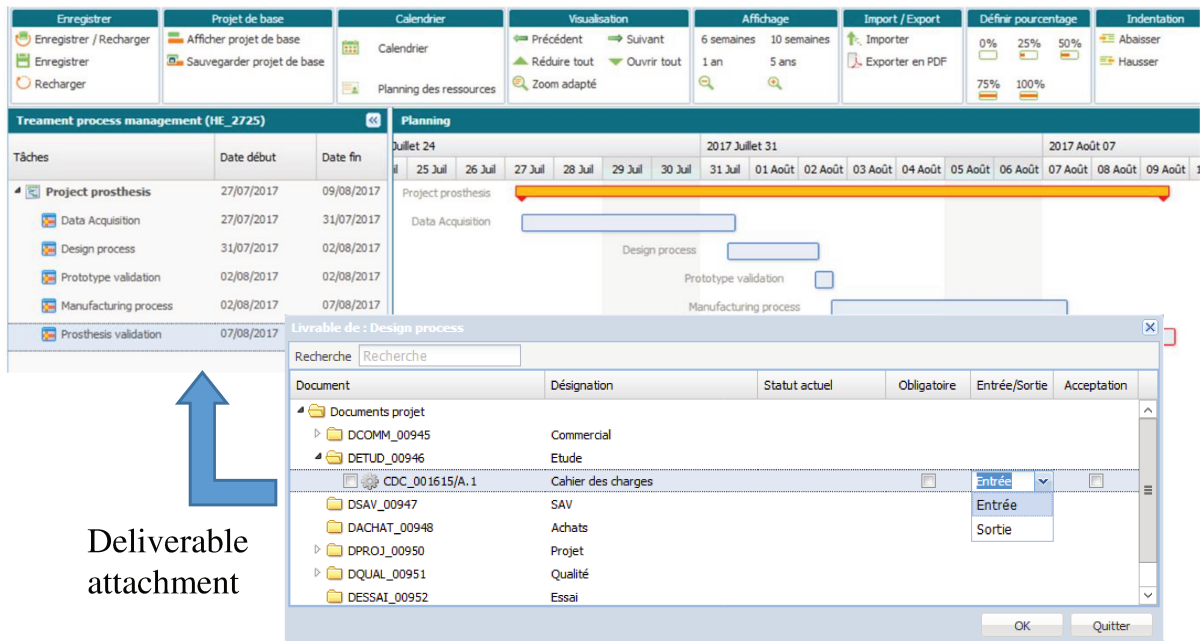


Figure 4.3 – Creation of the project prosthesis

### 4.3.2 Scenario of disease knowledge update

Figure 4.4 shows the scenario of medical knowledge update as a list of pathologies in Audros PLM based on the ontology in section 3.4. Following this scenario, Firstly, the medical doctor collects the medical data of a patient and store it in the medical data section of the patient data sheet (Figure 4.5). Then, the patient symptoms are described by the doctor. These symptoms are compared with the list of symptoms (Figure 4.6) to identify the suitable pathology (Figure 4.7). The pathology will appear in the main interface of PLM object “DISEASE” (Figure 4.8). After selecting the suitable pathology, the medical doctor completes the disease description process, the disease diagnosis lifecycle is updated and the system automatically notifies the new problem to the surgeon (Figure 4.9). The surgeon will receive the notification by email using the standard AUDROS mailing facilities (Figure 4.10).

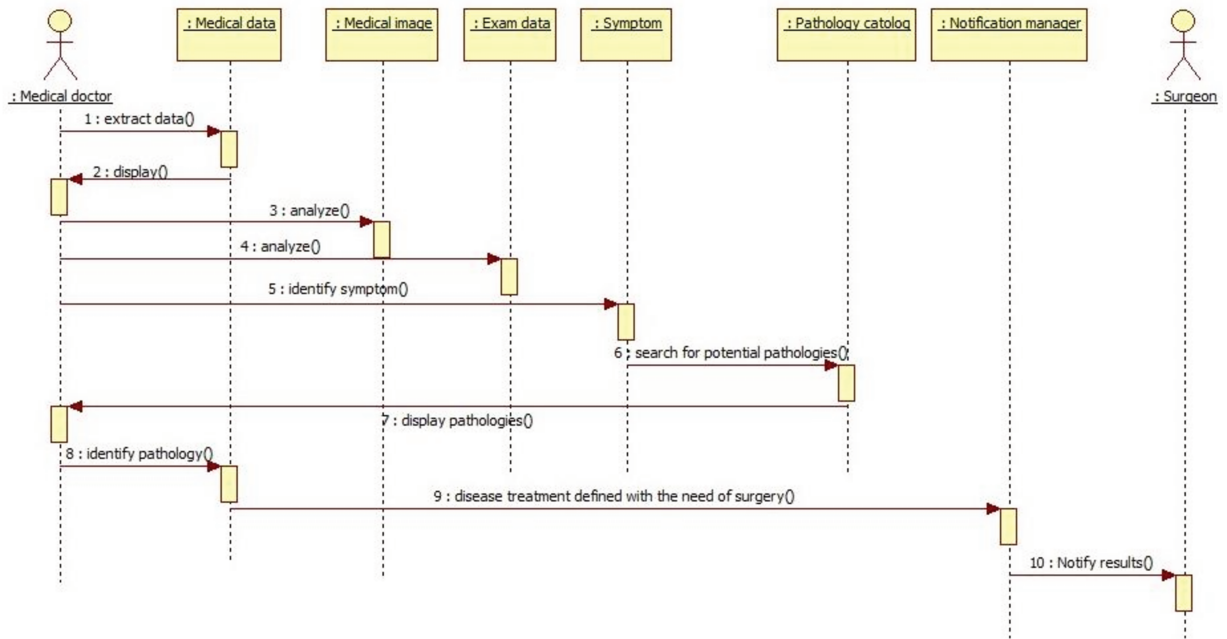


Figure 4.4 - Scenario of disease knowledge update

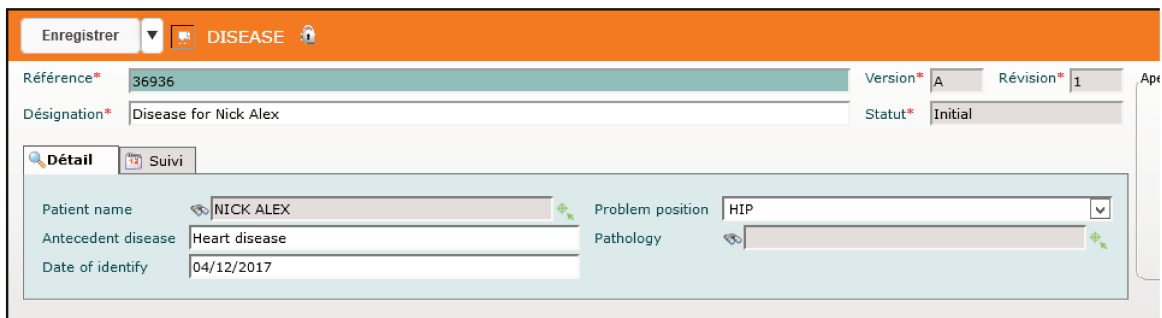
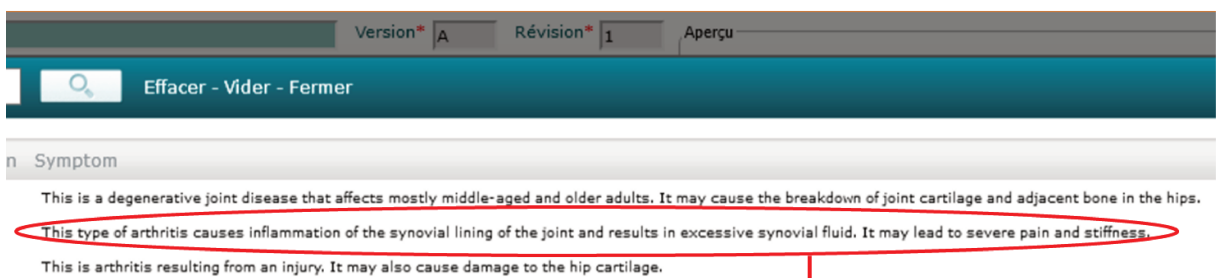


Figure 4.5 - Main interface of PLM object "DISEASE"



The type of arthritis causes inflammation of the synovial lining of the joint and results in excessive synovial fluid. It may lead to severe pain and stiffness

Figure 4.6 - List of symptoms



Figure 4.7 - Identify pathology of patient from symptoms.

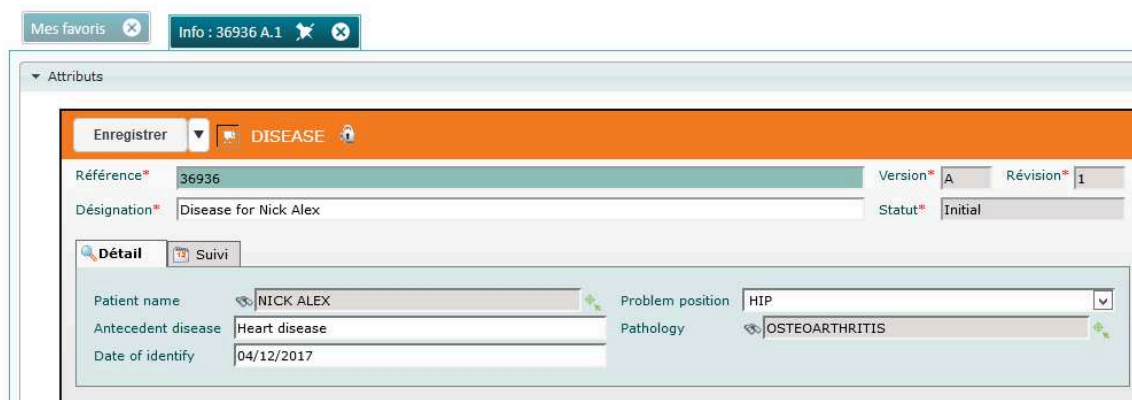


Figure 4.8 - Patient disease defined with pathology

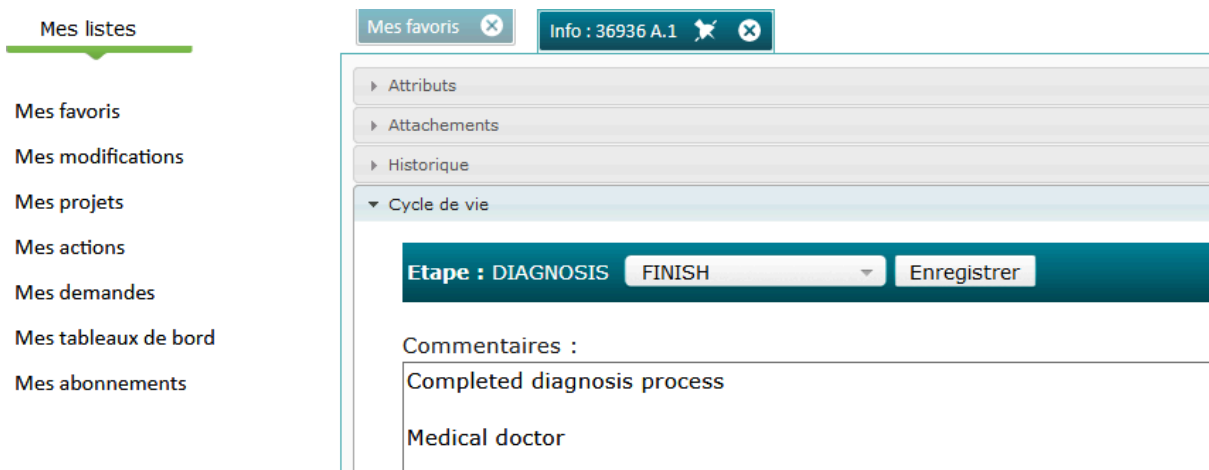


Figure 4.9 - Notify results to surgeon

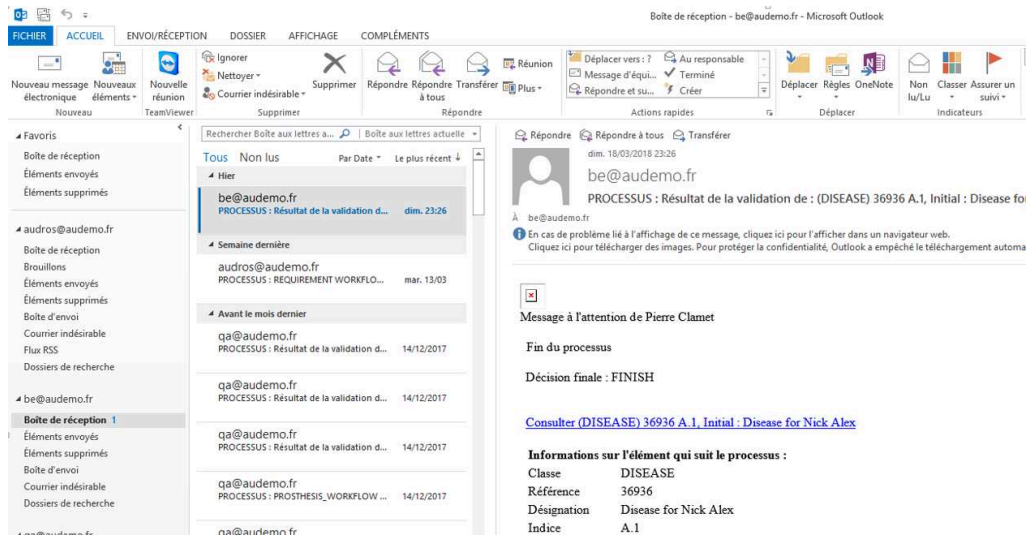


Figure 4.10 - Surgeon receives the notification from medical doctor

In this scenario, the data is mainly shared between medical doctor and surgeon. Besides, the medical doctor can choose a suitable pathology of a patient corresponding to the symptom descriptions. This shows a simplified but efficient example of knowledge reuse aspect that the research wants to improve. Indeed, in a lot of cases, the doctor who realizes the first checking is not specialist, and his decision on the type of pathology has a direct incidence on the rest of the process. By classifying the pathologies according to a list of standard symptoms, the medical doctor can be assisted by useful knowledge to reduce risk of errors.

### 4.3.3 Scenario of functional requirement creation and update

If the decision at the diagnosis stage is to implement prosthesis, the direct consequence is to define the characteristics of the requested prosthesis as a formal requirement. Figure 4.11 shows the roles of surgeon in creating and updating the functional requirement. After receiving the notification from medical doctor, the surgeon will log in with his account and create PLM object "REQUIREMENT" (Figure 4.12). Based on the medical data, the surgeon chooses type of prosthesis. In Audros PLM, the description of prosthesis types and characteristics are based on the ontology in section 3.4. Then a table appears with all information: prosthesis types (Figure 4.14) and their descriptions (Figure 4.13). From this table, the surgeon compares and chooses a suitable type of prosthesis with the patient medical data. Next, he completes the PLM object "REQUIREMENT" (Figure 4.15). After that, the surgeon creates a functional requirement and the related specification document is generated in version 1 and

attaches to the same PLM object (Figure 4.16). Finally, the system notifies prosthetist to update the technical requirement (Figure 4.17).

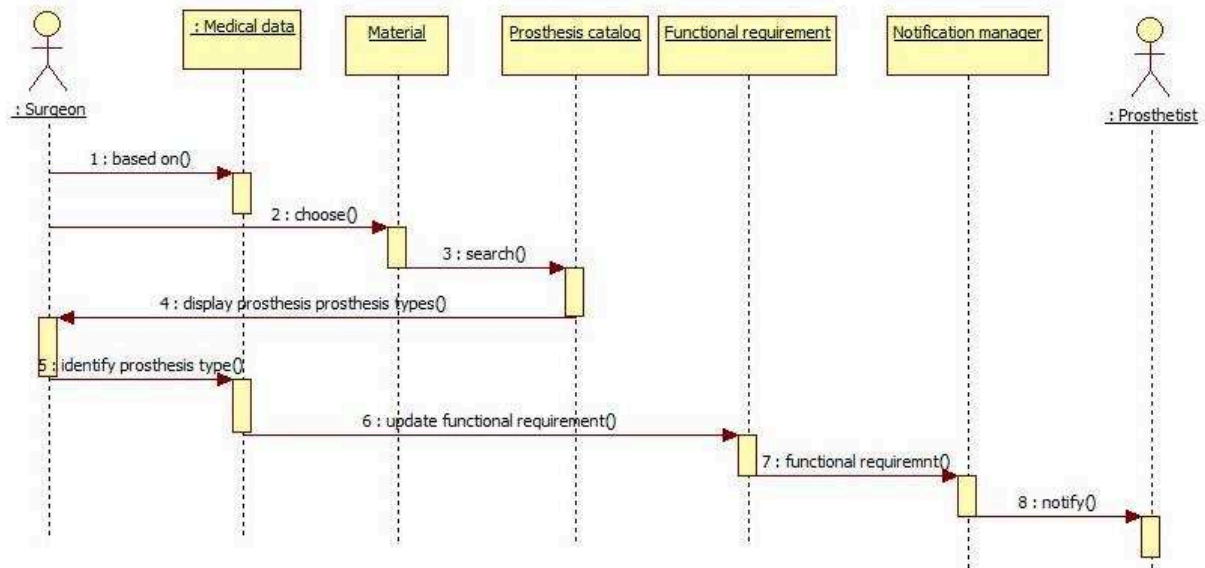


Figure 4.11 - Scenario of functional requirement creation

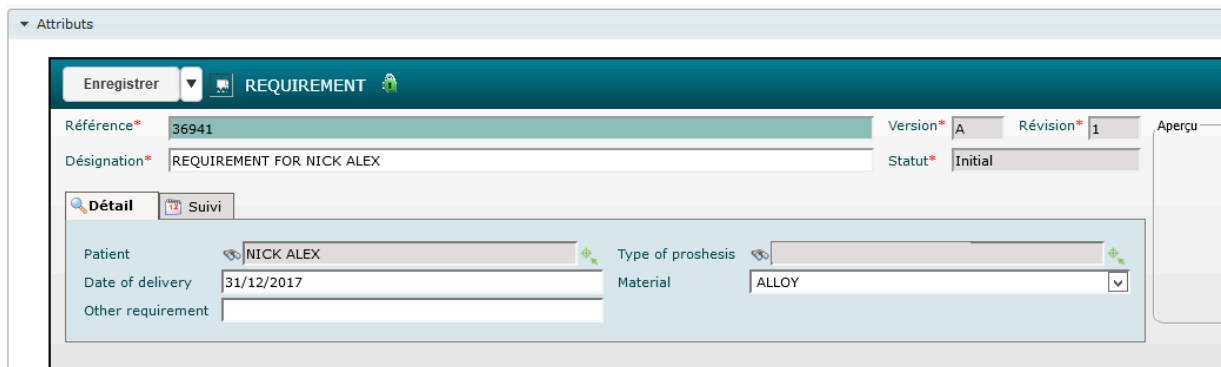


Figure 4.12 - Main interface of PLM object "REQUIREMENT"

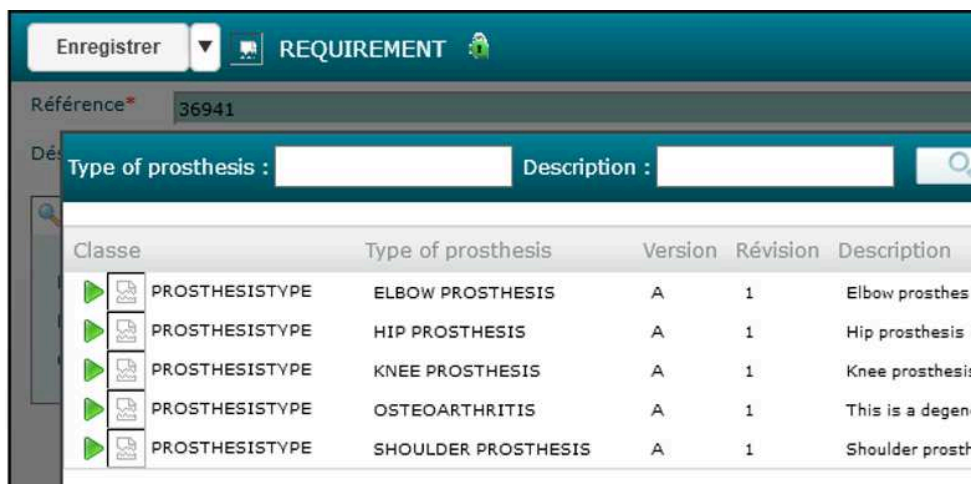


Figure 4.13 - Identify prosthesis type from descriptions.

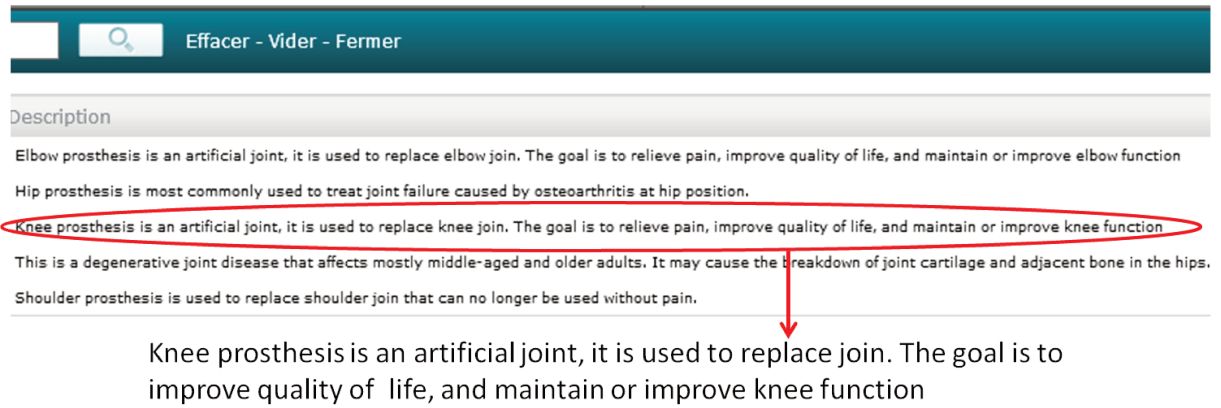


Figure 4.14 - Descriptions of prosthesis types

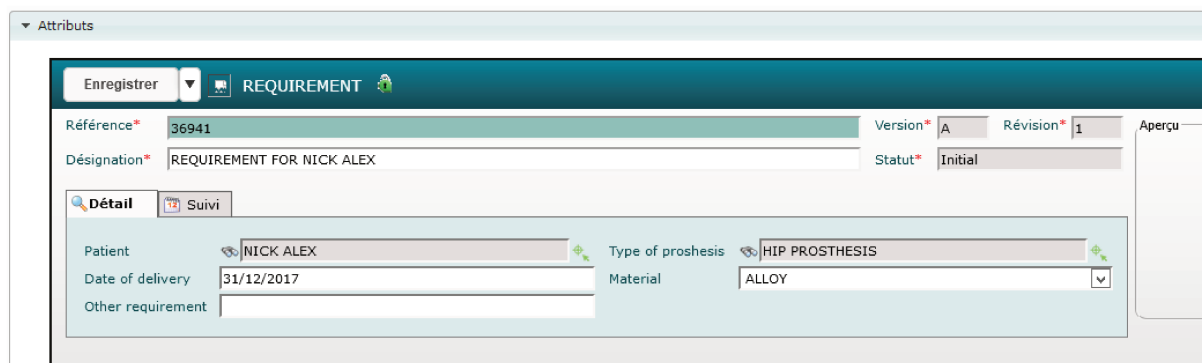


Figure 4.15 - Requirement defined with type of prosthesis

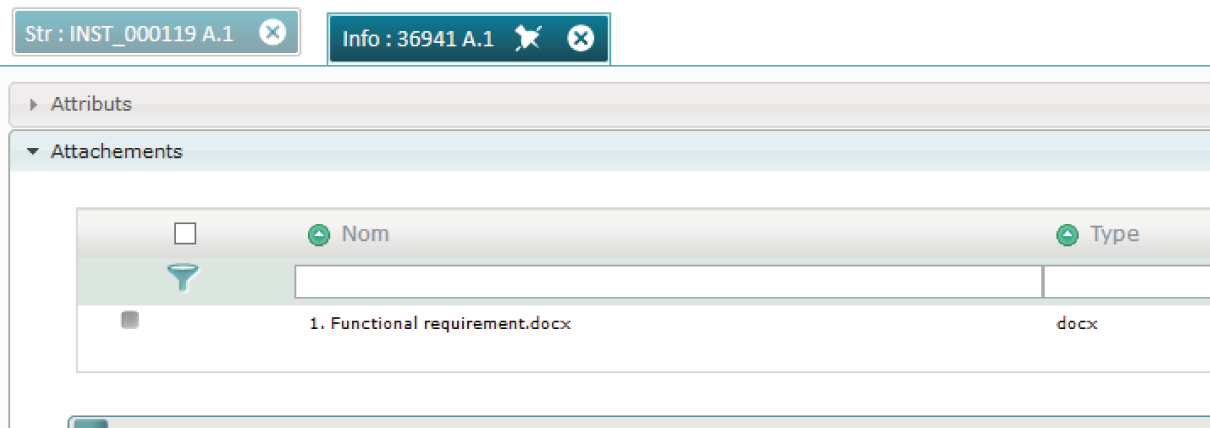


Figure 4.16 - Functional requirement attachment.



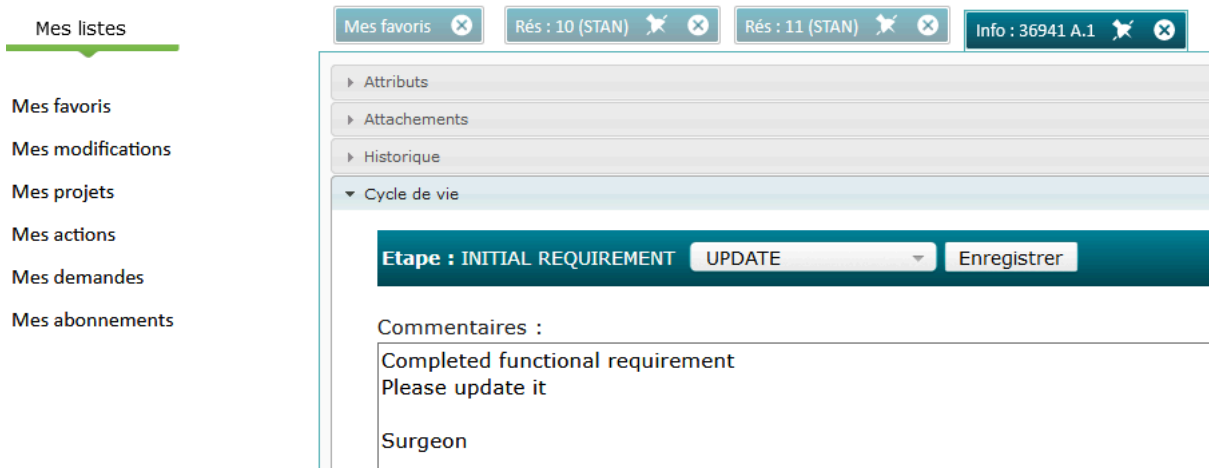


Figure 4.17 - Verify and send notification to prosthetist

The requirement management functionality of showed in this scenario highlights the importance of the tool to help the medical doctor appropriating engineering knowledge to define the functional specifications of the desired prosthesis. Based on these functional requirements the next step is to build the technical specifications with exact values of the prosthesis dimensions and other features. In the PLM, the evolution from the functional to technical specification is managed as a version update of the same object requirement (with the associated file). A collaborative workflow is used to validate the different versions of the document by the appropriate actors. Thus, in addition to the consideration of the key concept of the requirements, this functional scenario can be considered as a contribution to the following main aspects:

- Knowledge reuse: the surgeon can easily select a suitable prosthesis type corresponding to medical data description and define the functional specifications.
- Data sharing: the prosthetist can receive and update all data from the surgeon through this system to write the technical requirements.
- Collaborative functions to support the validation of the specifications

#### 4.3.4 Scenario of prosthesis design

While the technical specifications are defined and validated, the design process is started. Figure 4.18 illustrates the role of design engineer from the beginning to end of design process and how he collaborates via the PLM with the prosthetist and the producer as well as the surgeon in charge of the validation of the prototype.

Concretely, after receiving email, the design engineer will log in with his account and create PLM object “PROSTHESIS” (Figure 4.19). He converts medical image to

STL file. Based on the requirements (functional and technical requirement), he begins to design prosthesis. After completing the design process, the design drawing model will be attached in this PLM object (Figure 4.20). Finally, the system notifies prosthetist to validate the virtual model (Figure 4.21) and notifies the producer to prepare the manufacturing process (Figure 4.22).

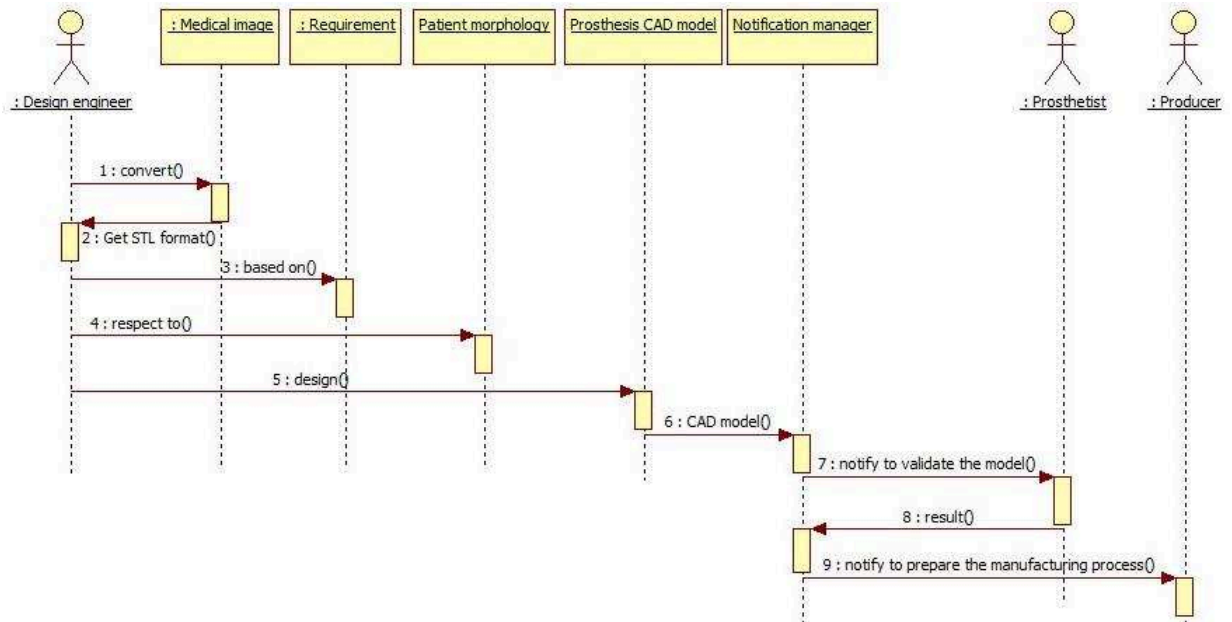


Figure 4.18 - Scenario of prosthesis design



Figure 4.19 - Main interface of PLM object "PROSTHESIS"

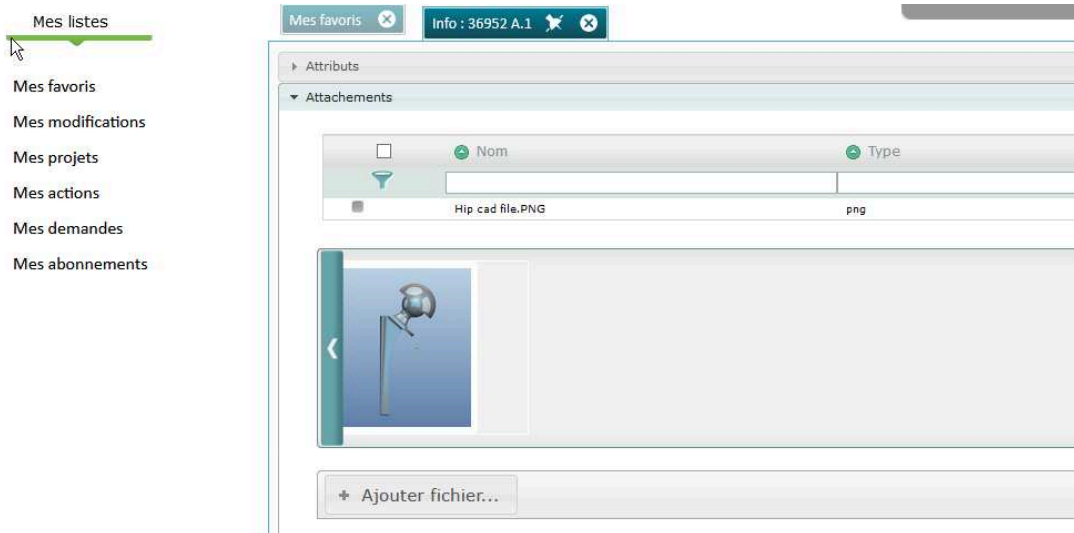


Figure 4.20 - 3D design drawing attachment



Figure 4.21 - Prosthesis CAD model validation

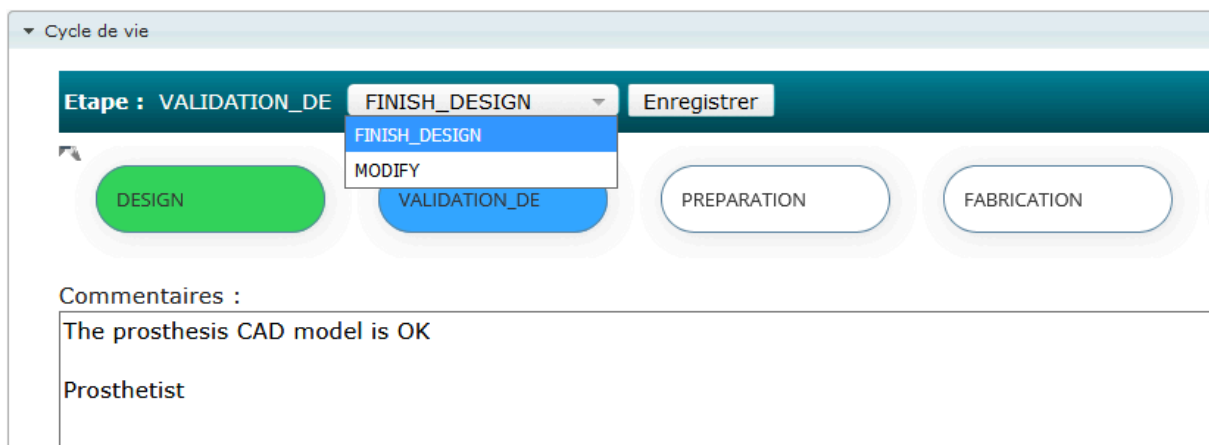


Figure 4.22 - Notify the completion to producer

Thus, the functionality of the system with this scenario is demonstrated by collaboration and data sharing aspects similarly as for the previous scenario. However, the designer can also do a research on the AUDROS repository the models of the

previous prosthesis developed to similar pathologies and bone morphologies. This functionality is very interesting when the designer has to realize new device in an emergency situation. However, to realize the validation processes, it is necessary to define the collaborative workflows in the PLM and associate the documents and actors affected by the modifications. The next section gives indications on how this workflows are constructed based on the conceptual process models and the PLM assistance functionalities presented in chapter 3.

Because the patient data is very sensitive, it needs to be secured and managed in a consistent way to share such information only with the authorized persons. To do this when implementing the proposed framework in Audros, one of the most important issue to consider is the access management. Audros system will provide each actor a corresponding account with specific authorithis on the shared data and files depending on its role. Figure 4.23 describes the roles of a medical doctor in the management of medical data.

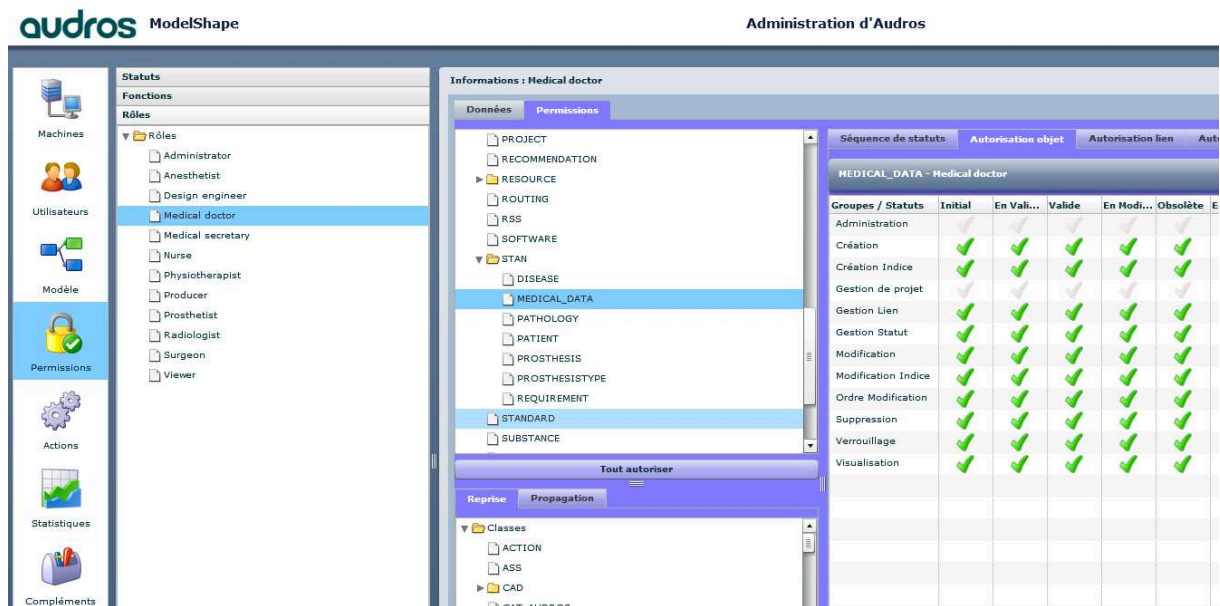


Figure 4.23 - Roles of the medical doctor in the system.

#### 4.4 Administration issues: Construct the workflows

The ultimate goal is to build an optimal treatment system. This system consists of a variety of processes that operate according to workflows. In each workflow, it shows series of activities as well as the actors involved. In this research, the system operates base on 6 workflows: Medical folder workflow (for objective: Medical data collection), Disease workflow (for objective: Disease identification), Requirement

workflow (for objective: Functional specification and Technical specification), Prosthesis workflow (for objective: Design prosthesis, Prototype validation and Prosthesis fabrication), Surgery workflow (for objective: Prosthesis implantation), Post-surgery workflow (for objective: Post-surgery).

In order to create and manage these workflows, the research uses the function of AUDROS Applet. Each workflow is defined by a series of activities to be fulfilled by the actors (like validation) and/or by the tool (like notification). In this research, the system operates base on six workflows: Medical folder workflow (for the management of data collection), Disease workflow (for the identification and the treatment of disease), Requirement workflow (for the management of functional and technical specifications), Prosthesis workflow (for the management of prosthesis design data, Prototype validation and Prosthesis fabrication), Surgery workflow (for the management of prosthesis implantation procedures), and post-surgery workflow (for the continuous traceability of aftercare patient data).

#### 4.4.1 Medical data workflow

Medical secretary creates PLM object “Medical Data” and sends the notification to nurse, radiologist and medical doctor. When receiving the notification by email, nurse fills in the exam results, radiologist fills in the scan results, and medical doctor fills in the interview results in the PLM form. If the form is filled by 3 actors, medical secretary will validate it and the system will send a notification to medical doctor to begin the next step (Figure 4.24).

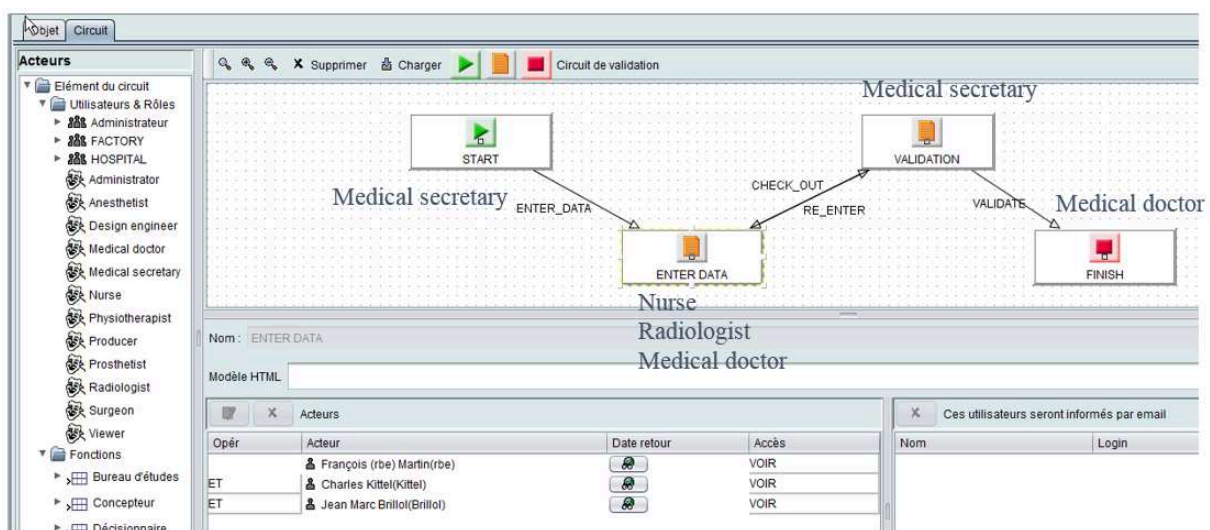


Figure 4.24 - Workflow of medical data

#### 4.4.2 Disease workflow

Medical doctor creates PLM object “Disease”. He fills in all information and then notifies the surgeon to begin the next step (Figure 4.25).

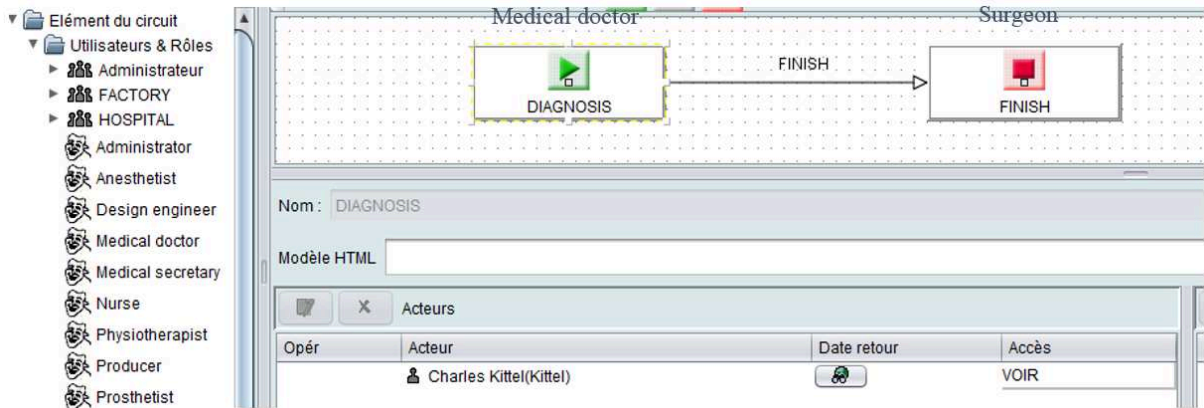


Figure 4.25 - Workflow of disease

#### 4.4.3 Requirement workflow

The surgeon creates PLM object “Requirement”, then fills in initial requirements. Based on these requirements, prosthetist will update it with technical requirements. Then, the system will notify the design engineer to begin the design process and notify the producer to prepare the manufacturing process (Figure 4.26).

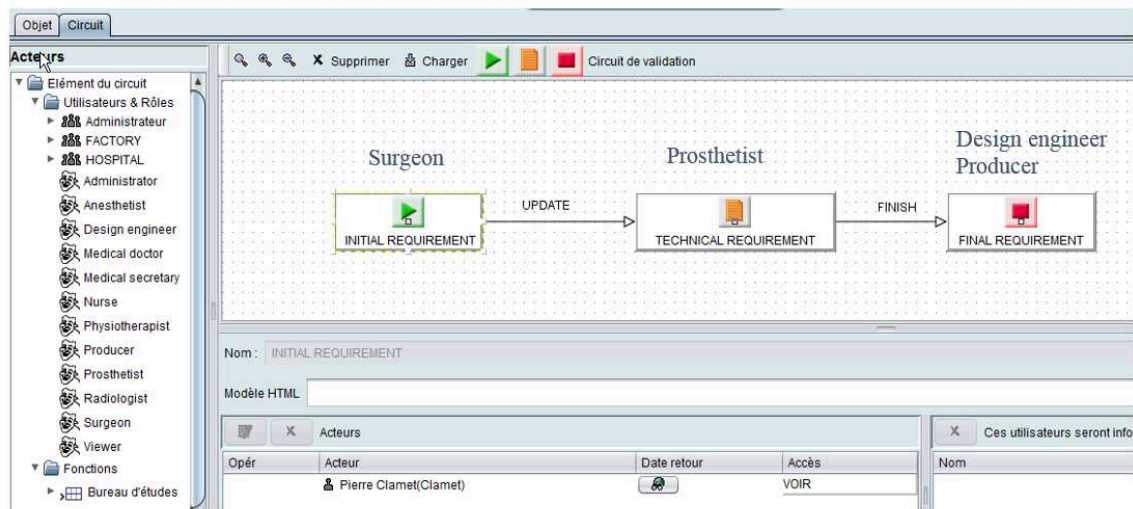


Figure 4.26 - Workflow of requirement

#### 4.4.4 Prosthesis workflow

The design engineer begins to design prosthesis that will be validated by prosthetist. If it is not satisfactory, prosthetist requests redesign it. If the prosthesis 3D model is validated, the producer will receive a notification and begin to prepare the manufacturing process. After finishing the preparation for manufacturing process, the system sends a notification to anesthetist, medical secretary, and surgeon to prepare the surgery process. At the same time, producer begins to fabricate prosthesis. It will be validated by prosthetist before sending to hospital. Finally, the system will notify the result to anesthetist, medical secretary and surgeon to begin the surgery process (Figure 4.27).

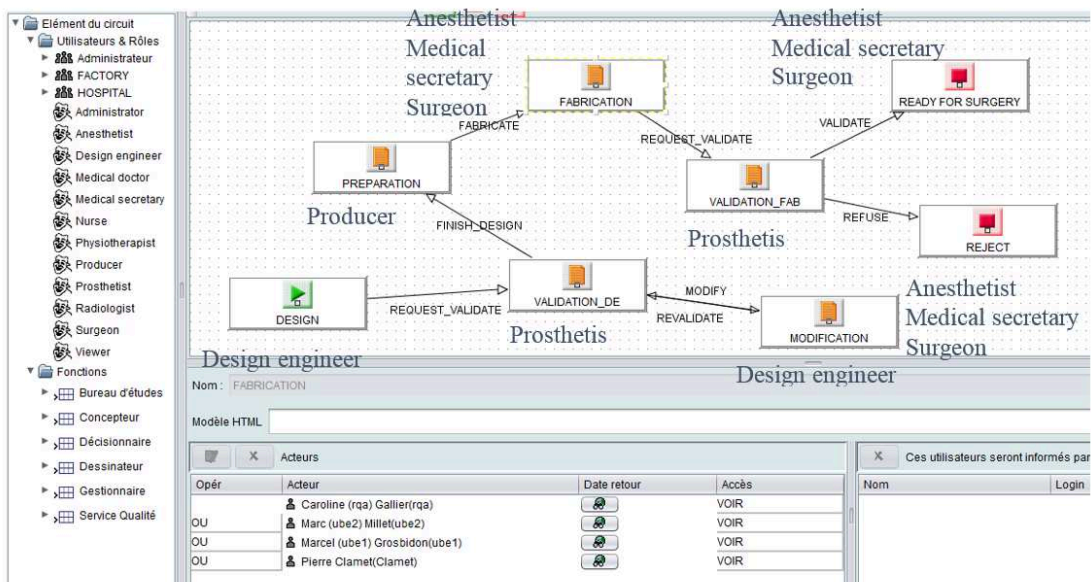


Figure 4.27 - Workflow of prosthesis creation and validation

The list of workflows described above demonstrates the main logic behind the configuration of a PLM tool for the implementation of the proposed conceptual framework. Other workflows could be considered to cover unexpected process alternatives and additional configurations with complementary PLM modules are achieved to correctly activate the automatic actions of the PLM.

#### 4.5 Conclusion

This chapter used AUDROS to implement the propositions in chapter 3. To do that, the role of stakeholders in the system is shown by the use-case diagram. Then sequence diagrams are used to describe the operation of each action. Finally, they are

implemented in AUDROS and operate under workflows. The operations of system in AUDROS are illustrated by snapshots corresponding to each action.

As a result, the system makes the data sharing between stakeholders in the system more easily (notifications and data sharing between stakeholders in AUDROS) and improves knowledge reuse in the treatment process (illustrated by the selection of suitable type of prosthesis from disease description and the identification of the pathology of patient from symptoms).

This means, the demonstrative scenario give affirmative answers to the research questions described in section 2.7. For instance, the potential to use PLM applications to connect medical and engineering processes is important. As stated by the literature, by removing the re-entry and by thinning the exchange of data between applications, AUDROS allowed us to reduce working errors due to redundancy of the stored data and the inconsistency of multiple versions created by the different actors.

However, the test and experimentation by medical actors is still limited because of the lack of interoperability with their daily tools and the difference of interface ergonomic between medical and engineering tools. Indeed, since the objective of this work is mainly to validate the principle of solution, the focus is principally made on the configuration issues for the implementation of conceptual models rather than on the customization of the interfaces.



# Final Conclusion and Future Perspectives

In this PhD, the basic objects, actors and tools involved in the treatment process requiring prosthesis are described as part of the analysis framework with the aim to highlight main limitations in such a process. Based on these limitations, critical problems that can strongly affect the processes' performances in the medical sector are pointed out at the end of chapter 1. These problems concern the issues of information exchange and collaboration between actors. It shows also that because of the cultural barriers between actors of medical domain and engineering domain, the current practices suffer a lack to exploit knowledge generated by other actors.

As an answer, this research validates the hypothesis about the potential to use the PLM approach as a mediator to solve the identified problems. The characteristics of such approach are identified and the foundations of a robust conceptual model are described. To do so, chapter 2 investigated the literature on knowledge management, ontology and PLM issues. An overview of some interesting applications on both industrial and medical domains is presented. From this survey, the useful functions of PLM are indicated in order to analyze what can be extended to medical domain and what are the requested adaptations. This conducts to the problem statement of this PhD as a combination of three research questions at the end of the chapter 2.

Since the objective is to validate the hypothesis that the PLM approach is a great interest to support the medical treatment process requiring prosthesis, chapter 3 proposes a theoretical framework that aim to clarify the key characteristics of a PLM approach dedicated to medical domain. A collaborative model is presented as part of the conceptual framework supporting the PLM approach. The key idea is to connect the disease and prosthesis life stages. The relations between these two lifecycles were analyzed in detail based on 5 main dimensions: requirements, involved stakeholders, used tools, shared flows and collaborative processes. From this, a semantic model was built and extended as ontology for knowledge classification and sharing.

The implication of the conceptual framework is that all actors and processes could be connected through a PLM hub as a common knowledge repository equipped with

queries and workflow mechanisms to make the collaboration and knowledge reuse efficient. Besides that, Actors can monitor the progress of other processes, so they can make their own plan actively.

By defining the characteristics of the PLM approach, the conceptual framework proposed in chapter 3 gives an evidence that it is possible to extend such kind of solutions from industrial domain to medical domain and other service centered business areas. It also gives a great proof to validate the hypothesis that it is possible to connect heterogeneous objects coming from various domains within a same solution. The data and processes of engineering and medical domains are managed by dedicated and applications, different in their architectures and ergonomic.

To confirm this potential, chapter 4 implemented the proposed principle of solution in a commercial PLM tool (AUDROS software in this research) to illustrated how this solution can operate in the reality. A set of KM-PLM functions are defined and tested with the objective to illustrate how the research questions can be implemented in real software: how actors can get access and reuse heterogeneous knowledge? How the data and files produced by separate departments and companies are structured and shared? And how the collaboration between all stakeholders is enhanced to validate the decision at both medical and engineering domains? Inversely, the implemented solution shows the utility of the medical-oriented ontology as a core semantic model developed in chapter 3 to classify all elements involved in the medical treatment requiring prosthesis and their characteristics.

For the engineering and medical actors, the assumption is that the PLM solution as a common repository managing both technical and medical data in the same manner could minimize errors during the treatment process and improves the quality of prosthesis as well as shortens completion time of the whole process. Reusing past experience to maximize the chance to obtain a prosthesis fully adapted to the patient within a short development time is obviously very interesting in emergency situations.

For the PLM software editor, there is already the need to enlarge the scope of users they can target and to enhance and speed up the innovation process. This could be possible by extending the applications domains of their solutions without changing the core logic at the back office of the tool. By enlarging the capability to the people from separate business domains to work together on a very huge blackboard, will be in one step consider all current constraints, and will have as a consequence to shorten the development cycle, and first-time right manufacturing solutions. AUDROS wants to

set a new benchmark by exploiting the proposed framework to build new version of its solutions within dedicated functionalities to medical domain.

### **Perspectives**

This the proposed prototype aims at the validation of the principle of solution and the conceptual framework behind it. To make this prototype exploitable in real context within commercial software solutions like AUDROS, further work is required. The development works concerns principally the extension of the knowledge model by including among others the existing standards, other categories of prosthesis rather orthopedic ones, list of symptoms, etc. The interoperability with legacy CAX tools is also an important issue for direct extraction of useful data into the knowledge repository. Another development pillar is the creation of intelligent engines for intuitive research and finding of knowledge at every step of the process. By the way, it could be more efficient to help the stakeholders with operational guidelines to follow progressively along the development process. In this case, an intelligent system can automatically provide the requested data to the right step. In addition, societal and ergonomic aspects should be also considered to analyze how this kind of tools could be well adopted by the users. This aspect concerns for example what kind of patient data can be stored and how this storage will be managed looking to the current policies, what is the right form to present knowledge for each category of actors (medical, engineers, producers, etc.). Finally, the proposed framework in this research is very focused on the treatment process requiring prosthesis with two identified lifecycles. In the future, the proposed framework will be adapted in other applications of medical domain requiring different types of medical devices.

# Scientific Valorization

## **International journal**

- Ngo, T. N.; Belkadi, F.; Bernard, A.: Managing Collaborations between Medical and Engineering Actors in Case of Prosthesis Implantation: A Plm-Based Approach Computer-Aided Design and Applications, 2018.

## **International conferences**

- Ngo, T. N.; Belkadi, F.; Bernard, A.: The Use of Plm to Improve Collaboration and Data Sharing in the Treatment Process, International CAD Conference, Paris, France, 2018.
- Ngo, T. N.; Dang, P. V.; Belkadi, F.; Bernard, A.: Supporting Data and Knowledge Sharing in the Medical Treatment Process: A Plm Perspective, International Conference on Material, Machines and Methods for Sustainable Development, Da Nang, Viet Nam, 2018.
- Ngo, T. N.; Belkadi, F.; Bernard, A.: Semantic Modeling of Collaborative Processes in Medical Sector for Plm Approach Perspective, 12th International Conference on Industrial Engineering, Compiègne, France, 2017.
- Ngo, T. N.; Belkadi, F.; Bernard, A.: Applying Plm Approach for Supporting Collaborations in Medical Sector: Case of Prosthesis Implantation, International Joint Conference on Mechanics, Design Engineering & Advanced Manufacturing, Catania, Italy, 2016.
- Ngo, T. N.; Belkadi, F.; Bernard, A.: Towards a Plm Approach Supporting Collaborations in Medical Sector, IFAC Conference on Manufacturing Modelling, Management and Control, Troyes, France, 2016.

## **National conferences**

- Ngo, T. N.; Belkadi, F.; Bernard, A.: Interest of Plm for Data Sharing in the Patient Treatment Process Requiring Prosthesis Implantation 15ème Colloque National AIP PRIMECA, La Plagne, France, 2017.

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# Appendix A

## AUDROS PLM TOOL

### A.1 Main commercial PLM tools

There are many PLM software that are built by different companies in the world. Zancul et al. (2013) synthesized the list of 10 PLM software suppliers available in the market as shown in Table A.1. Each software has its different advantages and disadvantages. Depending on the needs and size of the system, we choose the suitable software.

Table A.1 - List of PLM software

PLM tool	Company	Website
Windchill	PTC	<a href="https://www.ptc.com">https://www.ptc.com</a>
Teamcenter	Siemens	<a href="https://www.plm.automation.siemens.com">https://www.plm.automation.siemens.com</a>
Enovia	Dassault systems	<a href="https://www.3ds.com">https://www.3ds.com</a>
Agile	Oracle	<a href="https://www.oracle.com">https://www.oracle.com</a>
SAP PLM	SAP	<a href="https://www.sap.com">https://www.sap.com</a>
IBM PLM	IBM	<a href="http://www.ibm.com">www.ibm.com</a>
AUDROS	AUDROS	<a href="https://www.AUDROS.fr">https://www.AUDROS.fr</a>
SofTech	SofTech	<a href="http://www.softtechgroupinc.com">http://www.softtechgroupinc.com</a>
ProFile Procad	Procad	<a href="https://www.procad.de">https://www.procad.de</a>
Autodesk PLM 300	Autodesk	<a href="http://www.autodeskfusionlifecycle.com">http://www.autodeskfusionlifecycle.com</a>

## A.2 AUDROS PLM tool

AUDROS is one of popular PLM software available in the market (Zancul et al., 2013). It has functions that can meet the requirements of the system. For instance, it can establish collaboration between actors, reuse knowledge, make traceability, etc. Especially, it can integrate with other software such as MS office, CAD software. With these useful functions, AUDROS tool is used to illustrate the operation of system in this research.

The AUDROS PLM suite is the solution created by AUDROS Technology. AUDROS solution is French PLM systems which provide a set of flexible tools able to be adapted to any functional domain. It is now deployed in more than 150 French and international companies and has more than 10,000 users worldwide. For more than twenty years, the AUDROS PLM is intended for industrial companies, mainly SMEs (Small and medium enterprises). These SMEs come from a few major industrial sectors, including energy and electronics, automotive and transport, aerospace and defense, luxury, etc. Like other PLM systems, AUDROS is a tool for centralizing information and technical data of industrial products. It allows all users to have information products at various stages of their life cycles.

There are many useful modules in AUDROS. In general, it is characterized into the main modules such as: ModelShape, SE Manager, View Designer, AWS, AUDROS Addons, AWS creation and AUDROS Applet. In the next section, we will introduce and analyze the function of each module in more details.

### A.2.1 ModelShape

ModelShape is the administration and supervision tool. It allows managing the rights of the users, the classification of the data as well as the authorized structures. Figure A.1 shows its user interface. The main functions of ModelShape are the following:

- Machine management: sites, machines, storage cabinets, etc.
- User Management: defining users and user groups
- Definition of the data model: classes, relationships, attributes, life cycles, etc.
- User interface management.
- User rights management
- Trigger management: definition of AUPL scripts to associate with AUDROS events
- Statistics on the information contained in AUDROS

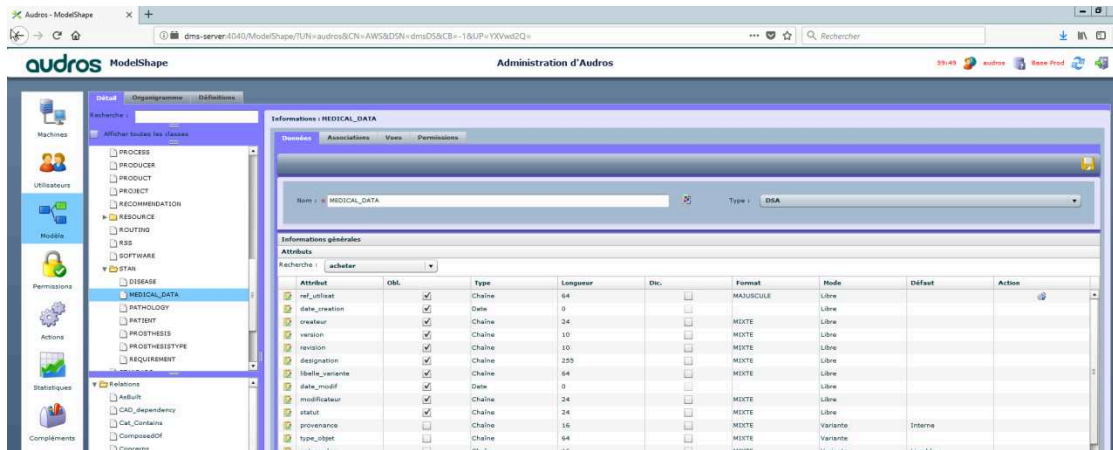


Figure A.1- User interface of AUDROS Model Shape

## A.2.2 View Designer

View designer is a tool for designing user interfaces of classes created in Model Shape (Figure A.2). All attributes of class will be shown in a graphic user interface. It helps users manage and access data more easily.

They mainly include:

- Textual areas (text, labels, and attribute values)
- Graphic elements (images, visualization of a sticker of the attachments)
- Components to visualize and/or manipulate data structures

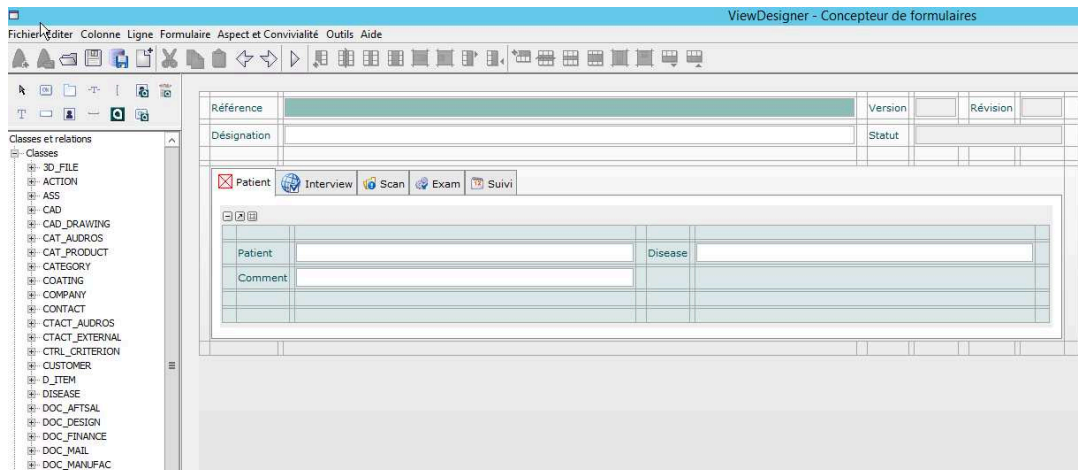


Figure A.2 - User interface of View Designer module

## A.2.3 SE Manager

SE Manager is a configuration tool complementary to Modelshape. The user interface is shown in Figure A.3. SE Manager allows users to:

- Define the list of classes to display/hide by package (Project management, range management, document management, etc.)
- Configure system behavior according to customer needs
- Manage settings (formerly "properties" files)
- Create simple attributes on object classes
- Define the coding rules on AUDROS object classes
- Define business rules associated with object lifecycles

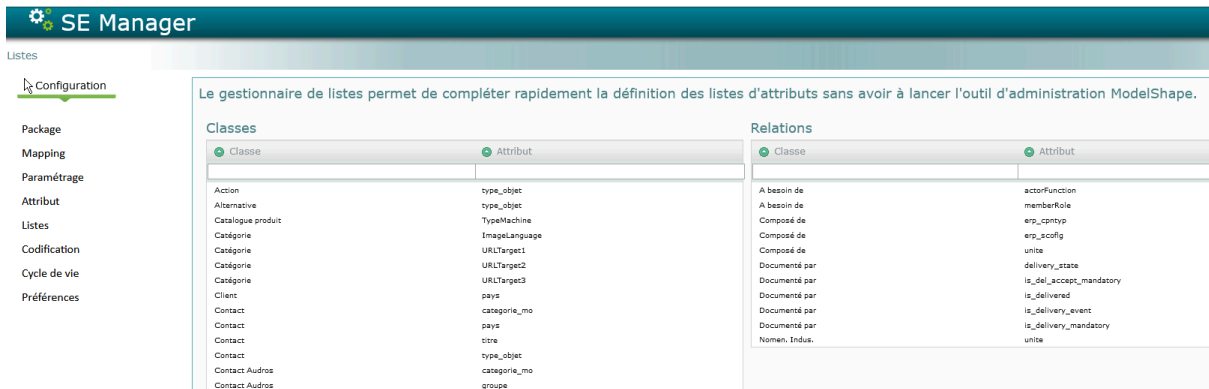


Figure A.3 - User interface of AUDROS SE Manager

## A.2.4 AWS

AWS (AUDROS Web Service) is the HTML interface of the AUDROS PLM solution. It allows users to view data, multilevel bills of material and documents from an internet browser, respecting the access rights defined in the ModelShape module.

With AWS, users can perform any type of search by class and document attributes or directly in the content of attached documents. AWS is fully customizable by the company. The system can be easily integrated into an existing intranet or corporate portal. Finally AWS has the particularity to export the data from research in PDF or EXCEL format.

## A.2.5 AUDROS Addons

AUDROS Addons is an administration tool that allows to:

- Manage contextual menus of AUDROS modules.
- Manage a dictionary for automatic translation of terms in AUDROS.
- Manage acronyms.
- Manage internationalization: translation of class names.
- Set up and customize the style of the AWS module.

- Manage data source.

## A.2.6 AWS creation

AWS creation (Figure A.4) allows users to:

- Create and manage objects.
- Manage project progress.
- Deploy the system following workflows
- Manage change and traceability

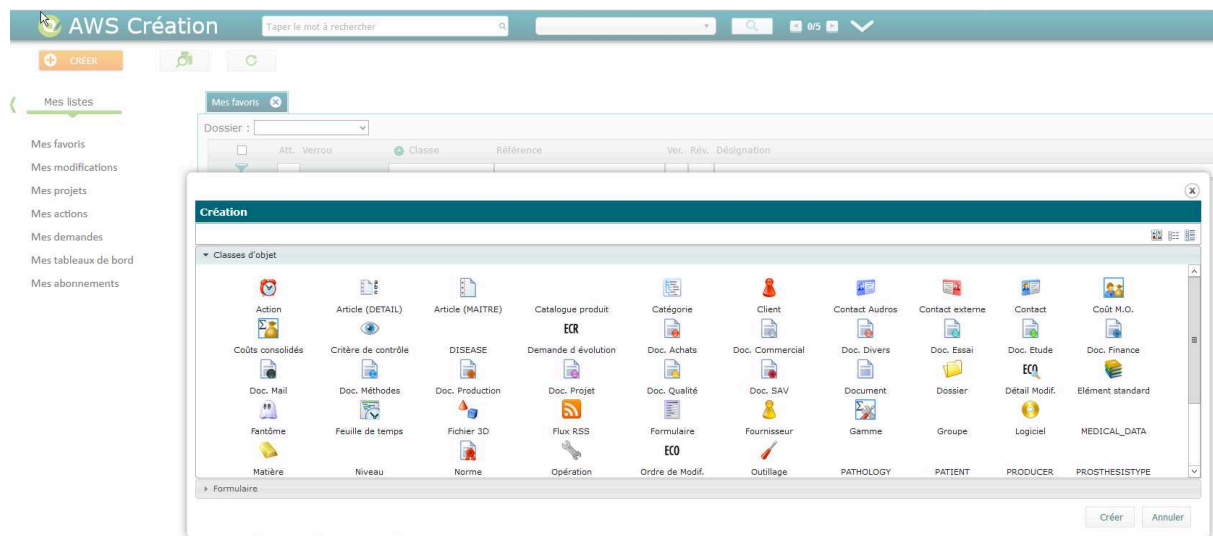


Figure A.4 - User interface of AUDROS AWS Creation

## A.2.7 AUDROS Applet

AUDROS Applet is the AUDROS interface for "frequent" users who regularly access the database to search, create, or modify data. Accessible from a standard web browser (Figure A.5). Thanks to this interface, users can easily find information and share it securely. The management rules are defined in the system and are binding on everyone according to their rights to ensure the coherence of the information system.

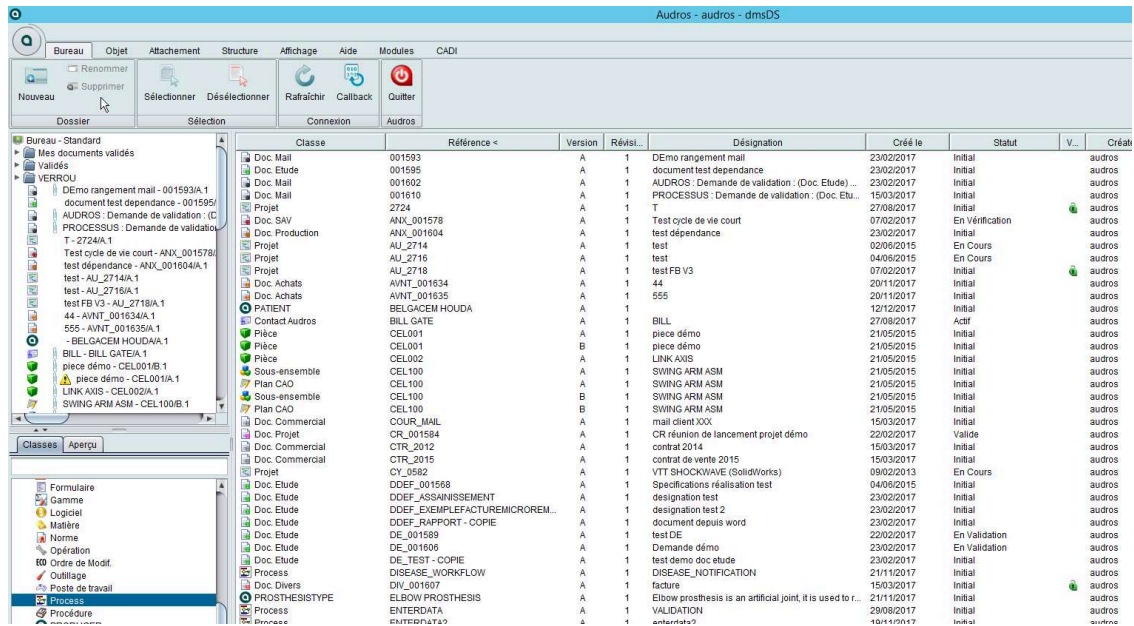


Figure A.5 - User interface of AUDROS Apple



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**Titre :** Une approche PLM pour supporter les collaborations et le partage des connaissances dans le secteur médical: Application aux processus de soins par implantation de prothèses.

**Mots clés :** PLM, Processus de soins, Prothèse, Partage des données, réutilisation des connaissances, Audros.

**Résumé :** Le secteur médical est un domaine dynamique en constante évolution, nécessitant des améliorations continues de ses processus métier et une assistance intelligente aux acteurs impliqués. Ce travail de thèse se focalise sur le processus de soins nécessitant l'implantation d'une prothèse. La particularité de ce processus est qu'il met en interaction deux cycles de vie appartenant respectivement au domaine médical et celui de l'ingénierie. Ceci implique plusieurs actions de collaboration entre des acteurs métier très variés. Cependant, des problèmes de communication et de partage de connaissances peuvent exister en raison de l'hétérogénéité de la sémantique utilisée et des pratiques métiers propres à chaque domaine.

Dans ce contexte, ce travail de thèse s'intéresse aux apports des approches d'ingénierie des connaissances et de gestion du cycle de vie du produit pour répondre aux problématiques sous-jacentes au processus de soins médicaux nécessitant l'implantation d'une prothèse. Pour se faire, un cadre conceptuel est proposé pour analyser les connexions entre les cycles de vie de maladie (domaine Médical) et de la prothèse (domaine d'ingénierie). Sur la base de cette analyse, un modèle sémantique sous forme d'une ontologie pour le domaine médical est défini dans le cadre de la construction d'une approche PLM à base de connaissances. L'application de cette proposition est démontrée à travers l'implémentation de quelques fonctions utiles dans un outil PLM du marché nommé AUDROS.

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**Title :** A PLM based approach for supporting collaboration and knowledge management in the medical domain: Application to the treatment process requiring prosthesis implantation

**Keywords :** PLM, Treatment process, Prosthesis, Data sharing, Knowledge reuse, Audros.

**Abstract :** Medical sector is a dynamic domain that requires continuous improvement of its business processes and assistance to the actors involved. This research focuses on the medical treatment process requiring prosthesis implantation. The specificity of such a process is that it makes in connection two lifecycles belonging to medical and engineering domains respectively. This implies several collaborative actions between stakeholders from heterogeneous disciplines. However, several problems of communication and knowledge sharing may occur because of the variety of semantic used and the specific business practices in each domain.

In this context, this PhD work is interested in the potential of knowledge engineering and product lifecycle management approaches to cope with the above problems. To do so, a conceptual framework is proposed for the analysis of links between the disease (medical domain) and the prosthesis (engineering domain) lifecycles. Based on this analysis, a semantic ontology model for medical domain is defined as part of a global knowledge-based PLM approach proposition. The application of the proposition is demonstrated through an implementation of useful function in the AUDROS PLM software.