Organizing Medtech Innovation with Concept Maturity Levels

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Abstract: This paper presents an integrative approach to the maturation of concepts in the field of Medtech Innovation by using Concept Maturity Levels (CMLs). CMLs have been introduced by JPL (NASA-Caltech) during the last decade to cope with the early phases of space mission concept development. Extending well-known TRLs, their strength is to evolve an innovative concept guided by an incremental set of assessment needs. The article draws on an on-going research led in France where CMLs are being tested as a methodology for structuring Medtech Innovation complexity. Exploratory results provide an emerging framework showing what could be CMLs for Medtech Innovation. They also provide insights of why and how they could be implemented as a solid basis to stimulate more formative and adaptive design and evaluation methods.

1 INTRODUCTION

The Medtech sector is a highly diversified and complex one. According to MedTech Europe (2016), it includes more than 500,000 medical technologies ranging from familiar, everyday products such as blood glucose meters, sticking plasters, syringes or latex gloves, to high-tech medical technologies including molecular diagnostics, total body scanners, ultrasounds, life-supporting machines, implantable devices (i.e. heart valves pacemakers), neurostimulators and replacement joints for knees and hips. Likewise, the industry structure brings into play various economic actors ranging from small and medium-sized companies to big technological firms and high ranking research laboratories.

Another important characteristic of the medical devices market is its dynamic nature. In average, a medical device product has a life cycle ranging from 18 to 24 months, which forces companies to invest constantly in research and development. This leads to an increase in the relevance of development upstream phases, where many Medtech experts try to anticipate the different risks emerging from the complexity they face. However, medical devices projects often fail or result in products with no market-fit, for not having sufficiently integrated the perceptions and insights of end-users early enough (Habib et al., 2017).

Despite their strategic importance, the upstream phases of medical devices development are still insufficiently understood and documented. Available approaches for exploration and evaluation often tend to offer a sole snapshot of the product at the end of its development cycle, neglecting the activities required to incorporate the habits and needs of end users, especially the patients. These facts and the complex context mentioned above call for new approaches which do not only evaluate the quality of a new medical device and its market fit, but also clarify the path to transform a promising idea into a solution that is financially viable and easily adopted by patients and their healthcare ecosystem.

This paper aims to fill this gap by studying an integrative approach using "Concept Maturity Levels" (CMLs) (Ziemer et al., 2013). CMLs are a new metric inspired by Technology Readiness Levels (TRLs) developed by NASA in the 80s. Allowing the evaluation of knowledge robustness for a given technology at a given moment, TRLs have become a world-wide tool for project organization and communication. CMLs extend TRLs by both adding divergent phases to TRLs convergent orientation and integrating needs (value proposition, end-users…) as well as organizational aspects (costs, organization…) to the technological ones.

To do so, the paper draws on an on-going research led in the French context, where CMLs are being

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introduced to cope with Medtech innovation complexity. After having provided the theoretical background of the research, the article presents the research context and methods used. Exploratory results are then presented, leading to discuss the opportunities and potential risks of implementing CMLs for Medtech Innovation.

2 THEORETICAL BACKGROUND

This section provides basic elements on the literature on concept maturation activities in both management and engineering sciences.

2.1 Innovation and concept maturation

In the field of innovation management, the streams of "radical innovation" (O'Connor, 2008), "open innovation" and "collaborative innovation" (Chesbrough, 2003) have paid attention to the new organizational forms of innovation, their strategies, their processes, their business models. An important aspect of recent literature concerns the more "upstream" phases of exploration, including the maturation and formulation of innovative concepts (Markovitch et al., 2017).

During these maturation activities, it no longer consists of evaluating and selecting ideas, as advocated by "new product development" inspired by project management (Cooper, 1994), but also of structuring complete management systems intended to "mature" concepts and the organizations which sustain them to transform the starting intention into a value proposition implemented into a new ecosystem of uses (Hooge et al., 2016).

In this context, the strategic challenges are that of formalization and instrumentation of new "upstream" processes which are more agile and participative, integrating a wide range of stakeholders, both internal and external, including the end-users. Contemporary approaches therefore call for novel approaches to evolve and enrich innovative concepts throughout their design process; CMLs are one of these.

2.2 Concept Maturity Levels (CMLs)

CMLs are a special metric developed by the JPL Innovation Foundry (Caltech/NASA) for dealing with the most early formulation phases of space mission concept development. They are inspired by Technology Readiness Levels (TRLs) already developed by NASA in the 80's. Allowing the evaluation of knowledge robustness for a given technology at a given moment, TRLs have become a world-wide tool for project organization and communication. CMLs aim at extending TRLs by adding a divergent phase to their convergent orientation and adding two more "drivers" to technological maturity: the maturity of needs understanding (value proposition, end-users…) and the organizational maturity (costs, organization…).

Conceived as a generic language, CMLs aim to assess a concept's maturity making it possible to select and prioritize the ones to support. JPL has defined 8 different CMLs:

- CML 1: Cocktail Napkin
- CML2: Initial feasibility
- CML3: Area of application (Trade space)
- CML4: Design components (Point Design)
- CML5: Reference concept
- CML6: Integrated concept
- CML7:Preliminary referential implementation
- CML8: Integrated referential

3 RESEARCH CONTEXT AND METHODS

3.1 Research Context

3.1.1 Context

This study emerged in the context of a partnership between the French Forum of Living Labs in Health & Autonomy (LLSA) and the INSERM CIC-IT Network. Forum LLSA is a non-profit organization which federates a community of over 30 Living Labs and about 20 other members interested – and generally involved – in codesign and living lab approaches. CIC-IT Network brings together Research Centers specialized in clinical research for MedTech projects, providing support in clinical protocols design, regulatory constraints and solution assessment to project manager and enterprises.

The diversity of LLSA and CIC-IT members reflects the one of the health ecosystem: professionals, researchers, patients, manufacturers. Recently, they formed a working group, named "EVAL". These members were both practitioners and academics involved in use and/or clinical evaluation before, during and after the design process of a medical device. In February 2018, the group EVAL decided to launch an intervention research based on

the idea of implementing CMLs in the Medtech sector. A research project team was set.

3.1.2 Case Selection

Regarding the case selection, the research goals were to deepen the understanding of co-creation, evaluation and project management best practices applied in the lifespan of a concept maturation process. Three criteria were established: organization maturity, case maturity and trust relationships with potential interviewees:

- **Organizational Maturity:** it was decided to investigate cases managed by Living Labs and CIC-IT with a well-established practice in the co-creation and evaluation of medical devices. This choice was based upon two rationales: the need to clarify current design and management practices and, as previously mentioned, to serve as a stepping stone for the construction of a methodology of evaluation.
- **Project Maturity:** it was agreed to study projects that were further advanced in the development cycle, i.e. that had already passed or were near to pass regulatory certification (CE marking in these cases). This characteristic would allow the study to be based upon longitudinal cases, with rich steps of development cycle and potentially a wide range of relevant tools and best practices.
- **Trust Relationships:** more active members regularly take part in the working group sessions. As a consequence the suggested case studies were those under direct or indirect responsibility of those members. A potentially positive consequence of this fact is that the trust relationship between the Forum and the chosen structures could allow the informants to feel more at ease during interviews, possibly sharing project pain points that would not otherwise been communicated.

Considering these three criteria, five projects were selected: Hemogyn 2 (CIC-IT, Grenoble), Motio (Kyomed, Montpelier), Careware (Infoautonomie, Nancy), Connected Glass (Evalab, Lille) and Modu-Lab (CHL, Castres).

3.2 Data Collection

3.2.1 Selecting Informant's Profile

Following guidelines suggested by Eisenhardt (2007), the research team opted for interviewing multiple informants for each case, preferably from different organizations and having different roles in the case. This approach limits biases, since the same situation is described from different perspectives. According to each project ecosystem, a list of interviews was set to include the project manager, the organization responsible, the operational team and partners of development.

For each project, the responsible organization had to contact participants of the project and arranged an interview. Strategy during the interview was to assign all investigators with slightly different roles. According to Eisenhardt (1989), this allows the case to be interpreted from different, sometimes divergent perspectives, which has the potential to enhance richness of the study. The lack of representation of the voice of patients could consist in a source of weakness of this research, and should be accounted for in similar future studies.

3.2.2 Exploratory Phase

This paper presents an on-going research. At this stage, it only concerns the exploratory phase of the research, consisting of 17 interviews carried out between June and July 2018, lasting from 30 min to more than 2hours.

All interviews, except for two, followed a semi-directive protocol. During the interview, a member of the research team would introduce the purpose and the process of the study, as well as the general goal of the interview. During the interview, all of the investigators would ask questions; however, the lead of the interview was taken by the scientific responsible of the study. The two other investigators would take notes according to their own perspectives of the case.

After obtaining consent, all the interviews were registered by using a voice recorder.

3.3 Data Analysis

The first round of data analysis consisted of the following steps: Interviews summary, Interviews transcriptions, Defining CML criteria, Coding interviews according to criteria:

- **Interviews Summary:** we consolidated our impressions and notes in form of an interview summary, produced shortly after the field study. The aim was to serve as a quick reference to the team, offering a way of recovering essential information quickly, which proves to be useful in studies composed of large amounts of interviews.
- **Interviews Transcriptions:** all interviews were entirely transcribed, following sound recordings by using the software o-transcribe.

- **Confronting Field Data to CMLs:** three representative interviews were confronted, in extenso, to the CML framework.

During data analysis, the main findings were organized to elaborate a generic model that defines the maturity of an innovative concept in the sector of medical devices, as well as a generic process to transform an initial concept idea into a functional proven concept. In the following we refer to this emerging framework as the "CML-FS framework" (FS for "Forum Santé"). As already mentioned, this is an on-going research and further research is needed to strengthen and enrich this model. The next section presents the CML-FS framework.

4 RESULTS

4.1 The CML-FS Framework

At this stage, the CML-FS framework defines 6 progressive levels, which describe the increasing maturity of a healthcare concept:

- **CML1-Framing the Idea:** this includes the understanding of social and health care background to contextualize and prove solution's relevance. Building project team is another key step in CML 1.
- **CML2-Understanding Usage Requirements:** this includes that rapid prototyping and financing plan have been identified as the main validation steps in CML 2.
- **CML3-Shaping the Design:** this maturity level requires listing the platform concept, regulatory affairs and definition of usage scenarios as essential milestones to give shape to the chosen concept design.
- **CML4-Fine-tuning the Design:** this maturity level must achieve pre-clinical trials and help building clinical trials as well as use test protocols.
- **CML5-Clinical Trials, use Tests and Certification:** this maturity level consists of preparing and executing clinical trials, if applicable, as well as leading user tests. Certification is the last critical step to this level.
- **CML6-Planning Implementation:** this maturity level is achieved after completing activities needed to consolidate product and commercial specification to the industrial development of the solution.

The division into six maturity levels is not arbitrary. The findings allowed for grouping activities according to chronologic order of main milestones revealed during the interviews. We found six to be the minimal number of activities chunks to be represented in order to mature a concept. Every CML phase could be further divided, resulting in more levels. Further research will serve to validate the model and its levels or to modify it if needed.

4.2 Towards a New Design Process

Figure 1 depicts the design process model corresponding to the progressive nature of CML-FS framework. It provides structure in the form of a "diamond" including milestones and corresponding activities per level, enabling the definition of a concept development roadmap.

The diamond background (fading grey shape) illustrates the diverging and converging moments in the framework: levels 1 to 3 consists in the divergent phase aiming at exploring the field, opening up the perceptions about the chosen healthcare problem, and allowing for problem reframing, if necessary.

At the end of CML 3, however, design iterations end once few preferred design solutions are chosen. Starting a convergent phase, the preferred solutions are further matured and tested with users in CML 4.

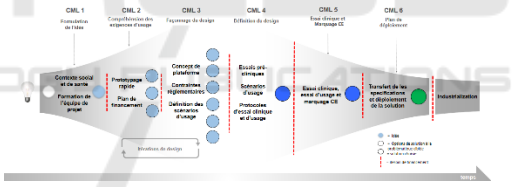

Figure 1: The evolution of an innovative healthcare concept over time.

It is relevant to notice the role of design iterations between CML 2 and 3. This iterative process is inherent to the divergent phase of design. According to our interviewees, it is an essential step to identify the problem at stake and discover which ideas are the most relevant to figure it out. In practical terms, it allows ideas to be developed and tested a number of times, with weak ideas dropped along the way. The result, at last, is one concept that has been evaluated and refined several times before its launch, by a wide range of stakeholders.

4.3 Opportunities and Potential Risks

Interesting information shown by the CML-FS framework is the level of financing requested before entering each CML phase. As per the studied projects,

the largest amounts of financing are needed in the transition between CMLs 4 and 5 in order to execute clinical trials, use tests and apply for product certification. Likewise, our research suggests that research work needed to go from CML1 to 3 is still lacking, at least in the French context. Using CMLs might be a way to better analyze and structure these early financing phases.

However, the CML-FS design model is merely illustrative, aiming at warning project owners to account for such expenses beforehand. A quantitative estimation of financial needs is not in the scope of the current exploratory research, given the broad spectrum of products that could make use of this framework. Each one of these products, according to certification classification, would present considerable variations in development budget and financing needs, one of the current perceived risks being to overlook this diversity of products and situations.

5 CONCLUSIONS

Our exploratory research thus suggests that CMLs could provide an integrative approach to the upstream co-design difficulties, by opening new ways of combining real-life data with results of clinical investigations, or even exploring complex polymorphic therapeutic solutions at different levels of maturity. One of the main interest could for instance be avoiding the so-called "techno push" phenomenon, as applicable to the spatial domain and the Medtech sector.

Furthermore, health projects are highly supported by public funds. At the end, they deliver products and services which are subsidized to a large extent. Therefore, evaluation of these projects concerns not only project manager, stakeholders involved but also public authorities and policy makers.

The interest of using the CML approach will be enforced by adding to the process description some indicators that are likely to be available at an early stage rather than requiring evidence of final impact. This could enable the "clock speed" of the evaluation cycle to increase, bringing it more in line with the policy cycle.

As quoted in (Warwick and Nolan, 2014): "The developmental evaluation approach [...] is particularly well matched to the modern conception of industrial policy where policy makers engage in an iterative process of dialogue with business and others, and there is a combination of top-down and bottom-up approaches. Experimental methods are increasingly being used in the evaluation of some facets of industry and innovation policies, but there is potential to do more."

The use of experimentation and the iterative approaches of developmental evaluation fit well not only with the CML approach, but also with the notion of a "smarter state", which seeks to learn from the market and the discovery process of entrepreneurs in selecting appropriate targets for public policy.

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