Shaping User-Centered Health Innovation Through Assessment

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Abstract: Historically, evaluation methods for innovative projects have focused mainly on technological development aspects. However, recent research suggests that, in the context of consumption by the general public, the decision parameters for acceptance seem to be based more on characteristics extrinsic to technological maturity. In the present work, we present a model for the evaluation of innovative projects, the Concept Maturity Level Santé France model, inspired by the CML model developed by the National Aeronautics and Space Administration and specified in the context of MedTech project development, and placing co-design with the end-user and its ecosystem on the same level of importance as the regulatory and technological development aspects, and giving it a theoretical and fundamental basis.

1 INTRODUCTION

Traditionally, the evaluation of innovative systems has focused on risk prevention in three challenging areas: performance, schedule, and budget (Mankins, 2009). Such evaluation should be incorporated in each step of the life cycle of new systems in order to avoid products failure and anticipate technical risks and needs.

In order to standardize the evaluation of these aspects of research and development, and project programming, a number of tools have been developed, such as the Technology Readiness Levels (TRLs) grid, which was developed by the National Aeronautics and Space Administration (NASA) in the early 1970s and completed in 1995 (Mankins, 1995). It was initially developed to standardize the assessment of the maturity of spaceflight projects through a technology readiness assessment (TRA) examining key concepts, technological needs, and demonstrability, while taking into account economic aspects, making it possible to establish an inventory of risks as well as to produce a standard understanding of technological status (Dawson, 2013). However, while this model and its direct descendants such as the Concepts Maturity Levels model (Wessen et al., 2013) seem relevant in the evaluation of institutional projects, it appeared limited in the evaluation of subsequent acceptability if the device were placed in the hands of a wider population (Salazar &Russi-Vigoya, 2021). These authors have highlighted that the TRL scale does not allow the reading of the ease of use, the satisfaction of the final user, the human performance in the use of the device, as it does not allow the reading of the comprehensiveness of the program or the device as well (See et al., 2019). Thus, the grid does not seem exhaustive in an innovation approach centered on the user and not the technology *per se*. It is also of interest to mention that TRL scale is used largely in different

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fields, for instance by funders for tender of calls in health research, asking candidates to estimate their pre and post project TRL level, and justifying consequently the improvement of maturity thanks to the activities they wish to develop thanks to the grants.

Indeed, it would seem that the technology development factor represents only one aspect of the decision-making process for the acceptability of a device by a user (Claudy et al., 2015). Consumer Behavioral Reasoning Theory predicts that the main barriers to acceptability of innovative devices lie in a trade-off between the use value and the functional barriers perceived by the user (ibid.).

However, and as highlighted by (Claudy et al., 2015), while the number of works investigating resistance to innovation has increased significantly in recent years, the majority of works are conceptual and no operating system has yet been proposed, particularly for the French and European MedTech ecosystem.

In response to these challenges, several key players in the French Medtech ecosystem have undertaken an initiative codenamed "CML Santé France", for Concept Maturity Levels, aiming to establish a more inclusive, legible and structured process for collaborative innovation processes in the French Medtech ecosystem (Béjean et al., 2021, ANR Dynsanté). This approach differs from other existing more 'top-down' approaches (e.g. CIMIT) in that it is highly participatory and community-based. Mobilizing a national network, this endeavor brings together, since 2017, partners covering the entire Medtech value chain, from research labs to start-ups and SMEs, including the Clinical Investigation Centers in Technological Innovation (Inserm CIC-IT) of the National Institute of Health and Medical Research (INSERM) as well as new types of actors called "Living Labs", the initiative having been driven by the Forum of Living Labs in Health and Autonomy (LLSA Forum).

So far the "CML Santé France" initiative has resulted in the formalization of a vocabulary associated with the design process of an innovative dispositive, from the formulation of the initial idea (CML1) to the post-industrialization follow-up of the solution (CML9), passing through various intermediate evaluation stages. This process provides a methodological framework that integrates (i) the definition of 9 levels of maturity, (ii) concrete actions to structure the maturation activities for each level; (iii) a mapping of the tools and skills needed to carry them out. All of this was integrated into a collaborative platform developed by the start-up Agile Solutions. Consortium DynSanté, an ANR program, was further constituted to further develop and test the use of CML Santé France. Dynamically integrating the CMLs Santé, the "CML Santé Forum" platform has been used on concrete projects since 2019.

In the present work, we will present the "CML Santé France" model, and the extent to which it addresses the contemporary challenges of innovation design in a user-centered approach in the context of Health. Through the use of CMLs, we suggest a tool aiming to participate in facing the very actual demanding context around particularly medical devices, that must anticipate the complex and multidimensional regulatory, industrial, and clinical evidence aspects as well.

2 THE IMPORTANCE OF NEEDS AND USAGE VALUE

Innovations in technology are accelerating at a rapid pace, in a way that the user can barely get used to a technology, the following one that has just come out. Innovation levels of the newly developed and highly sophisticated systems do not reflect its degree of acceptance by consumers admitting that innovative products mean change for consumers, and resistance to change is a common consumer response that must be overcome before adoption can begin and that consumers would instead prefer efficient and easy-to-use systems that meet their needs (Laukkanen et al., 2007). The application of self-concept to customer behavior suggests that customers purchase products and/or brands that are similar to their own self-concept (Sirgy, 1982).

Hence the importance of integrating the concept of user acceptance and satisfaction of needs in the marketing approach of the product (Dunphy &Herbig, 1995). In this direction, some manufacturers rely on Kano model (KANO et al., 1984) which has been widely adopted by industries and consists of classifying and prioritizing customer needs based on how they affect customer satisfaction. (KANO et al., 1984). This customer survey-based model (table 1) is able to illustrate the relationship between product performance and customer satisfaction in four types of product attributes: (1) must-be attributes are expected by the customers and they lead to extreme customer dissatisfaction if they are absent or poorly satisfied, (2) one-dimensional attributes are those for which better fulfillment leads to linear increment of customer satisfaction, (3)

attractive attributes are usually unexpected by the customers and can result in greater satisfaction if they are available, and (4) indifferent attributes are those that the customer is not interested in the level of their performance (KANO et al., 1984; Xu et al., 2009). Statistics showed that kano model-based marketing strategies were positively influenced by the model (Asian et al., 2019; Huang, 2017; Rotar&Kozar, 2017). On the other hand, the theory of reasoned action suggests that consumers evaluate innovations in regard to product attributes like relative advantage, compatibility, and complexity, which have a strong influence on their adoption decision (Claudy et al., 2015b; Fishbein & Ajzen, 1977).

Before buying a product, customers have the intention to consult different information sources helping to decide which product to choose (Broilo et al., 2016; Nici&Creutlein, 2017). To deal with the increasing volume of information that may be false and/or negatively influence customers, it may be essential to include a usability evaluation in a simulated environment. Such an approach reminds the third attribute in Kano model product attributes highlighting the importance of a pre-purchase study englobing the product usage in a realistic environment not only to stand out from competitors (Joachim et al., 2018) but also to aid the consumer decision-making (Broilo et al., 2016).

(Claudy et al., 2015b) analyzed the behavior of users toward innovation and showed that there are 5 factors that manufacturers have not paid attention to and which lead to user resistance to innovation. These factors are subdivided into two categories: functional and psychological barriers. Functional barriers include usage, value and risk barriers that consumers may associate with a new product or service whereas psychological barriers are issues that consumers may experience when innovations force them to change existing beliefs or break with traditions and norms (Antioco&Kleijnen, 2010; Claudy et al., 2015b). Customers do evaluate both the reasons for and against adoption, which can have a greater influence on consumers' adoption decisions. This result reflects the behavior of consumers in the market in a positive or negative way. For example, in the first study conducted by Claudy et al. (Claudy et al., 2015b) reasons against adoption: high upfront costs, perceived incompatibility with existing infrastructure, and uncertainty regarding overall performance; have a stronger influence on the consumer adoption decision than reasons for adoption: energy cost savings, environmental benefits, and being independent from conventional sources of energy like oil or gas; which influence intentions only indirectly via attitudes (i.e. the psychological tendencies that are expressed by evaluating a particular entity with some degree of favor or disfavor (Eagly and Chaiken, 1998)). These results have helped managers to focus on overcoming barriers to adoption, instead of over-emphasizing reasons for adoption in order to improve the diffusion of their product in the market. Unlike study 1, study 2 showed that reasons for adoption: saving money, convenience and flexibility; have a stronger influence on customer adoption decisions than reasons against

Table 1: Example of Kano items. (Xu et al., 2009).

Kano question	Answer
Functional form of the question (e.g., if the car has airbags, how do you feel?)	● I like it that way ● It must be that way ● I am neutral ● I can live with it that way ● I dislike it that way
Dysfunctional form of the question (e.g., if the car does not have airbags, how do you feel?)	● I like it that way ● It must be that way ● I am neutral ● I can live with it that way ● I dislike it that way

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adoption: availability and security; and that reasons against adoption influence customer decisions only indirectly via attitudes. Reasons for and against adoption were elicited by a group of nearly equal numbers of males and females, and it included different age groups and educational levels (Claudy et al., 2015b). These findings insist on integrating the customer self-concept in the marketing strategies at the pre-purchase phase to help businesses in identifying the required needs they must fulfill (basic), characteristics they should be competitive with (i.e. performance) and the advantages making a differential in the eyes of the customer (i.e. excitement) (Tontini, 2007).

Specifically for medical devices we can also cites the "IEC 62366 standard for usability engineering to medical devices", as well as the medical device regulation (MDR) (EU) 2017/745 that cites explicitly the importance of usability and users, to take into account also for pre clinical and clinical evaluation.

3 THE FRENCH CML HEALTH MODEL

The French CML Health (CMLH) model is an iterative reading grid that decomposes the innovation process into three interdependent axes: needs, technology, and programmatic. It is therefore a direct descendant of the original CML model, which integrates these last two domains, by completing it with an equivalent user-centered axis. It also specifies the two original domains of technology and programmatic in order to adapt them to the French and European regulatory specificities in terms of research methodology and data management (Table 1).

3.1 Technological Maturity

An example of the milestones used to assign maturity levels on the technology axis is shown in Table 2.
The first axis of the CML Santé France model comes from the direct heritage of the TRL model mentioned above. It assesses the development of technological concepts, the management of the products that it allows to obtain, as well as their ownership, by being formalized on three axes: technological development, data management, and intellectual property. The first axis of technological development allows us to gradually assess, on a scale of 1 to 9, the development processes from the evaluation of the bibliographic state of the art, through its critical functionality simulations, to the management of the product life cycle. The second axis permits us to appreciate the way in which the project leaders will manage the data resulting from their own devices, from the R&D data (including bibliographic) to the protocols allowing their protection as well as the automation of the product life cycle data. Finally, its last axis of intellectual property gives an insight about the competitive study, from the monitoring of existing patents to the management of infringements that could emerge.

Table 2: Factorial structure of the French CMLH model

Domain	Sub-domain
Needs	Usage
	Market
	Clinicalproofs
Technology	Technicaldevelopment
	Data management
	Intellectualproperty
Schedule	Project management
	Regulation
	Funding

Table 3: Example of the different maturity levels for each sub-area of the "Technological Maturity" domain.

	CML1	CML2	CML3	CML4	CML5	CML6	CML7	CML8	CML9
Technological development	State of the art	Theorizing	Functional simulation	Software demonstrator	Prototype alpha	Technological analysis for improvement	Automation of function testing	Software bug reports and corrections	Product lifecycle management
Data management	/	R&D data collection	Software data structure	Cybersecurity	Data availability	Exploitation of clinical data	Data server access	Implementation of data collection devices	Production of material-epidemiology data
Intellectual property	Patent monitoring	Patent-in-principle	Specific patents	Freedom of operation	Process patents	Intellectual property of clinical data	/	/	Competitive intelligence

3.2 Programmatic Maturity

An example of the milestones used to assign maturity levels to the Programmatic axis is presented in Table 3.

The second axis of the CML Santé France model is the first real adaptation of the CML model as developed by NASA. It conceptually takes up the project management axis as well as part of its regulatory axis, specifying it for the European and French particularities which are organized for the devices themselves (everything for access to market, under the CE mark certification), but also for the researches that focus on. The idea is also to follow the "Good Clinical Practices" (GCP) and all ethical principles protecting the individual that participates in a research, from all kinds of risks when he or she is involved in research aimed at acquiring new biological or medical knowledge. It should be remembered that researches are organized and carried out on healthy or sick volunteers with a view to developing new knowledge in the biological or medical fields, and that the regulatory framework in France is based on the european regulations, and with recent updates for innovation that claims a medical devices status ("clinical investigations" categories proposed by ANSM french authority). It is also a matter of ensuring that the methods for collecting and processing health data comply with the General Data Protection Regulation (GDPR) as well as the French reference research methodologies (MR-00X), which range from level 1 to 3.

Thus, the Programmatic axis of the CML Santé France model enables the programmatic maturity of the project to be assessed in three areas: project management, regulatory aspects, and financial aspects. The first axis, project management, is used to assess the consortium formed for the project, from the identification of the pilot to the renewal of the development partnership, including the creation of Test Beds, by assessing the nature of the partnerships created. The second axis, called regulation, evaluates the programmatic maturity from the first legal investigation surrounding the project to the renewal of the CE mark, including product risk analysis and compliance with European (e.g. MDR, RGPD…) and French (i.e. ethics; clinical investigations for medical devices…) regulatory constraints. Finally, the last axis, called financing, allows for a gradual evaluation of the financial aspects, ranging from the identification of potential sources of financing to the updating of business economic assumptions in line with the real-life use data of the device.

3.3 Needs Maturity

An example of the milestones selected for the assignment of maturity levels on the Need axis are presented in Table 4.

Finally, the last axis of the CML Santé France model is the real innovation of the consortium in the specification of the CML model as described by NASA. It integrates the elements of the theory of consumer behavior and in particular the jargon of its barriers within the CML grid and thus makes it possible to evaluate maturity in terms of needs on three axes: uses, market, and clinical evidence. Therefore, the first axis, Uses, provides an insight into the value of use of the device as well as a metric of the development process to ensure that the user has been put at the center of the product development in terms of uses. This axis allows us to gradually assess its development from the identification of the social context and in terms of public health, to the methods of evaluation of the quality of care perceived by the patient (PREM), through the performance of

acceptability studies. This axis thus makes it possible to verify the removal of certain functional barriers, in particular the conflict with usage patterns as described by (Ram &Sheth, 1989). The second axis, called the market axis, allows us to obtain information on the competitive study that was carried out in terms of uses, in particular from the establishment of a review of the market literature to the evaluation of the multicentricity of the market segments, including the respective market access strategies. This axis thus allows us to verify the removal of functional value barriers as described by (Molesworth &Suortti, 2002), in particular by verifying the uniqueness of the value proposition conveyed by the device. Finally, the last axis, called Clinical Proof, makes it possible to assess the quality of the clinical investigation that the device has undergone, up to the establishment of fundamental proofs through an exhaustive analysis of the literature, up to the formalization of the processes for evaluating the quality of the results of the device as perceived by the patient (PROM). It is this last axis that will manage the functional barrier of uncertainty as described by (Stone &Grønhaug, 1993) and which occurs when end-users have only limited access to devices under development.

Table 4 : Example of the different maturity levels for each sub-area of the "Technological Maturity" domain.

	CML1	CML2	CML3	CML4	CML5	CML6	CML7	CML8	CML9
Project mangement	Driver identification	Initial analysis of the project risk	Tests beds	Identification of complementary skills required	Detailed development plan of the solution	Update of project elements and risks	Identification of marketing and sales skills	Closing of the project	Review of industrial development partnerships
Regulation	Regulatory framework	RGPD Compliance	/	Ethical analysis of the product	Collection of regulatory data for clinical investigation	Consolidation of the technical file for deposit	CE mark file	Regulatory framework for data use	Renewal of the CE marking
Funding	Identification of funding sources	Preparation of the business plan	Demonstrator financing plan	Formalization of the business plan	Financial modeling	Minimum Viable Business Model	Series A Capital Raising	Updating economic assumptions with real-life data	

Table 5: Example of the different maturity levels for each sub-area of the "Need Maturity" domain (PREM : Patient Reported Experience Measure ; PROM : Patient Reported Outcomes Measure).

	CML1	CML2	CML3	CML4	CML5	CML6	CML7	CML8	CML9
Usage	Social and public health context	Qualification of a practice situation justifying the need	Co-construction of adapted usage scenario	UX/UI lab evaluations	Definition of the usage industrialization scheme	Usability and acceptability assessment	Ecological evaluation of a pre-series	Real-life organizational impact study	Quality control PREM
Market	Review of the market literature	Identification of the value proposition	Product positioning and expected impact	Quantification of the expected impact	Market access strategy	Characterization of the device on the basis of usage surveys	Marketing elements (deployment, export)	Refinement of go-to-market strategies by customer type	Marketing on different markets
Clinical proofs	Review of the clinical literature	Identification of the medical need	Clinical strategy	Preliminary clinical trials	Analysis of clinical trials	Drafting of the study report (publication)	Multi-center clinical trials	Medico-economic studies	Quality control PROM

3.4 An Example of the Implementation of the Grid in a Health Project

In order to illustrate the use of the grid, we will now present, as an example, some of the results obtained during a project appraisal that was recently conducted during the validation studies of the CML Health questionnaire. They concern a particularly mature project, but with some rooms for improvement localized majoritarily at median and very advanced CML levels.

3.4.1 General Maturity

Results for the self-reported General Maturity measures for the sample project (anonymized) are available in Figure 1. Data suggest that the project is at the CML9 level, with an important homogeneity on the needs and programmatic domains.

Regarding the general maturity and taking into account all the sub-domains (Figure 1; Top-Left), the self-reported data from the project leader suggest that the entire sample project is at CML9 (M_G=9), as the project has exceeded the critical milestones on all the maturity domains and sub-factors.

Furthermore, regarding maturity by CML domain and considering the nine CML levels (Figure 1, Top-Right), the self-reported data show that the most mature and homogeneous domain is the Needs domain [μ=5.67±.63], followed by the Programmatic domain which seems slightly less mature and homogeneous in its overall development [μ=5.49±.81]. Finally, the data suggest that the most heterogeneous domain in its development is the one covering Technology, despite a higher average maturity [μ=5.57±.89].

3.4.2 Focus on the Heterogeneity: Looking at the Technological Domain

The results for the self-reported maturity measures of the Technology domain are available in Figure 2. The data suggest that the project is at the CML8 level in the technology domain, with notable heterogeneity in its constituent factors.

Regarding the maturity of the Technology domain and considering all the factors that constitute it (Figure 2; Top-Left), the self-reported data by the project owner suggest that the sample project is at CML8 level (M_T=8), given that the project could not exceed the critical milestones of CML9 at the level of data management and intellectual property.

Regarding the maturity of the Technology domain by CML factor and considering the nine CML levels (Figure 2; Top-Right), the self-reported data show that the most mature and homogeneous factor is Technology Development [μ=5.81±.39], and whose factorial CML level is 9. This factor thus contrasts with the factors measuring data management [μ=5.2±1.39] and intellectual property [μ=5.25±1.16] whose data suggest a slightly lower level of maturity (factorial CMLs at 8) with a more heterogeneous development.

Regarding the maturity of the Technology domain, for each CML level and each constituent factor (Figure 2; Bottom), the self-reported data suggest several possible areas of improvement. Regarding intellectual property, these are mainly at the CML1 level [μ_{pi}=4.5±.5]. This contrasts with the data management factor, where the areas of improvement are more likely to be found in CML5 [μ_{gd}=4±0] and CML6 [μ_{gd}=4±0] as well as in CML9 [μ=5.09±1.04] regarding data management [μ_{gd}=3.75±2] and intellectual property specifically [μ_{IP}=3±0].

Once the data was reported on the grid, recommendations could be made to the project leader. It was suggested for this specific domain to focus on the production of solution exploitation data and to update its competitive intelligence on services and patents.

4 SHAPING USER-CENTERED INNOVATION THROUGH ASSESSMENT: THE LIVING LAB MODEL

Now that we have described a model capable of a priori catching the different parameters for estimating the maturity of a health project, the framework in which it can be used will be detailed and to formalize the approach for its effective implementation.

In the current paper, we propose that the Living Lab model, which emphasizes the collaboration between the user and the designer throughout the design process, is an effective method for developing new devices. This model is based on iterative evaluations, which are repeated over time, and incorporates methodological techniques from both the exact and social sciences. This approach allows us to identify and understand the facilitators and constraints associated with the use of the device, as well as to ensure that these factors are taken into account in future versions of the device under examination. Additionally, this model allows for a

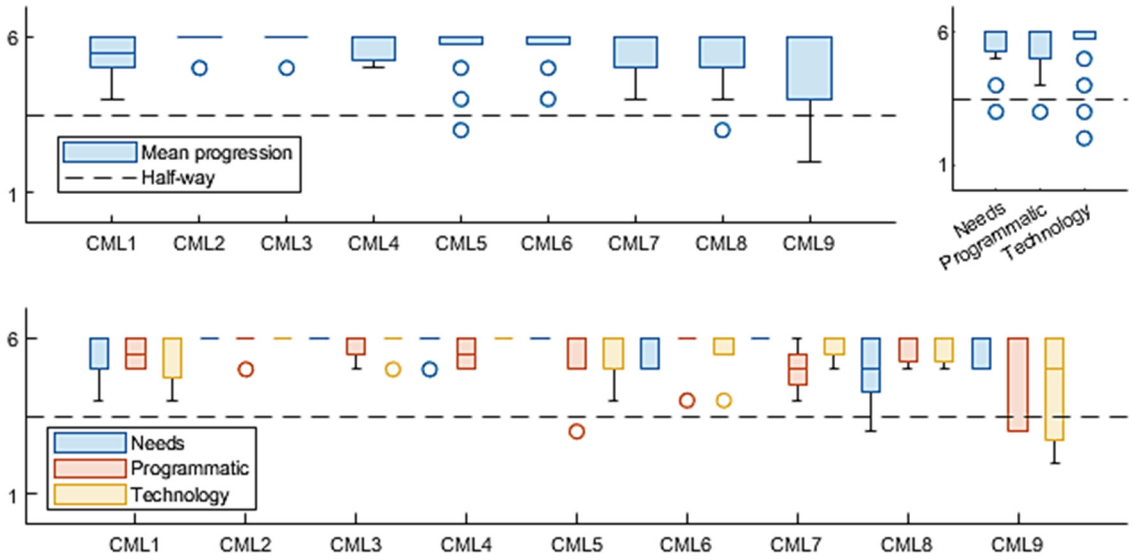

Figure 1: Dashboard of global maturity by level in self-assessment by the project leader (Association Innov'Autonomie - DynSanté Concept Maturity Levels Questionnaire 180-items ; data taken from psychometric validation project runned by Association Innov'Autonomie for illustration purpose). [Circle : outliers data].

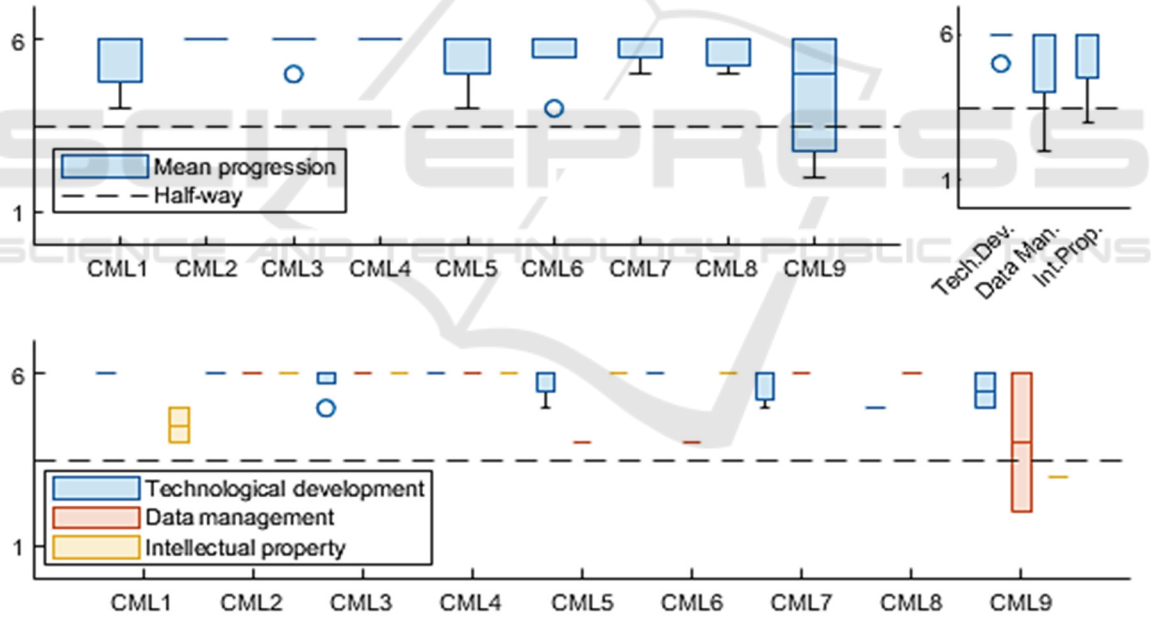

Figure 2: Dashboard of Technological maturity by level in self-assessment by the project leader (Association Innov'Autonomie - DynSanté Concept Maturity Levels Questionnaire 180-items ; data taken from psychometric validation project runned by Association Innov'Autonomie for illustration purpose). [Circle : outliers data].

more efficient and effective development process, as it allows for constant feedback and improvements based on user needs and preferences (Zipfel et al., 2022).

Generally speaking, a Living Lab is defined as a place that practices user-centered research methodologies to develop by co-design, use test, and implement MedTech innovations in real-life contexts;

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with a focus on placing the user[1] at the center of the creation process and all of its stakeholders, such as caregivers, academics, and entrepreneurs (Ballon et al., 2005; Leminen et al., 2012; Pallot et al., 2010; Veeckman et al., 2013).

A recent meta-analysis (Zipfel et al., 2022) concluded that Living Labs methodologies had a positive impact on the acceptability of the system and the subsequent feasibility of the procedure and made it possible to predict the perenniality of the implementation which will be carried out later, as observed previously by (Mulder et al., 2008). In general, this work and its precursors have shown that the implementation of a Living Lab evaluation methodology allows us to hope for a better subsequent adoption of the device (Kim & Chung, 2017).

Figure 3 describes the process of developing an innovative solution in the Living Lab approach. The first preparatory condition is to bring together all the actors of the project ecosystem, from the end-users with their caregivers, the academics, and the main actors of the sector (e.g. industrials, funders...) directly in the end-user's living place. The co-creation process (1) then begins. It can take the form of interviews or focus groups to highlight the needs of the population in all their ecosystemic complexity as well as their constraints of use, the main grievances as well as to have a first estimation of the resultant benefit/risk balance.

Once the device and its usage network have been modeled for the first time, a validation phase (2) takes place. It can take the form of technical tests (i.e. tests on the basis of procedures to be followed) ensuring the usability of the essential functions and especially of use tests. A major importance must be given to the evaluation methods in technical tests and usability tests in order to ensure their interpretability and their reproducibility on several subjects or several samples and any hypothesis must be tested on a statistical level.

Once the validation phase is completed, the adaptation phase (3) begins. Its objective is to modify the device in order to adapt its use to the constraints of use that were identified in (2). Indeed, the first circle of co-design, which was reduced, probably contains biases that constrained the generalisability of the device to a larger population (i.e. such as a population of a market segment). These biases must be corrected by the parameters measured during the tests.

Thus, we understand that phases (2) and (3) are cyclic, and that they allow to correct the device iteratively until arriving at a satisfactory version on the technical level (i.e. as evidenced by the technical test) and on the usage level (i.e. as evidenced by the usage test).

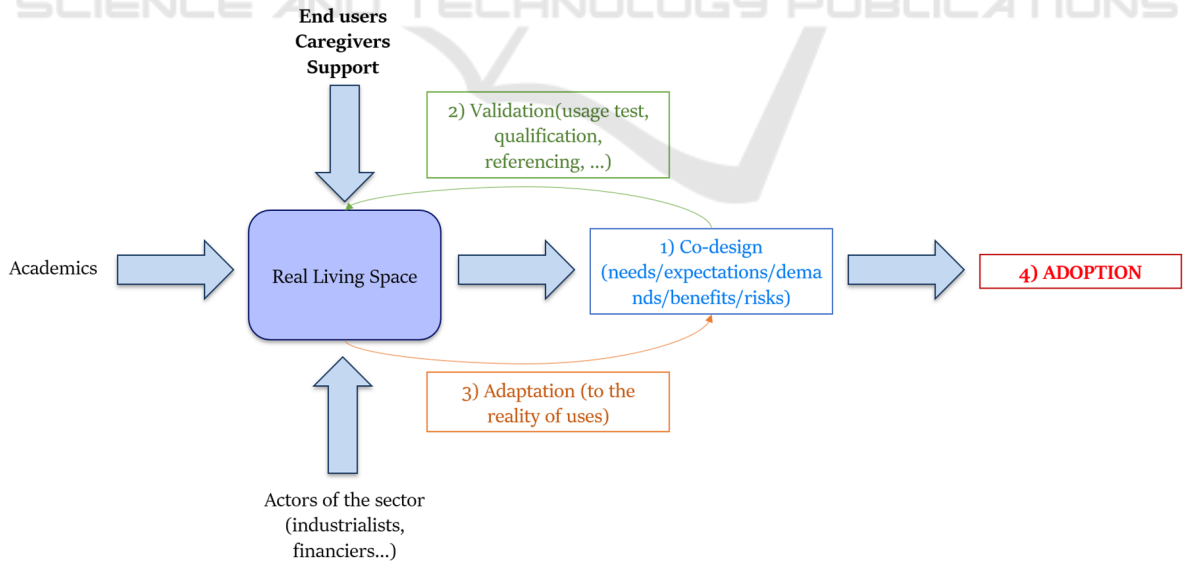

Figure 3: Co-creation process implemented in the Living Lab approach.

[1] As a subject of experimentation rather than as a rights holder in terms of intellectual property.

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5 DISCUSSION AND PERSPECTIVES

The objective of this work was to establish a fundamental bibliographic link between successful implementation and acceptability of a MedTech innovation, as well as to provide a methodological framework for applying this fundamental knowledge in practice.

We first described the canonical models used by our contemporaries, and in particular the TRL and CML models developed by NASA (Mankins, 1995; Wessen et al., 2013), which assess the maturity of a project on technology development and proof-of-concept metrics in the aerospace field. However,, we have also highlighted through elements of the literature that the acceptability and use of an innovative MedTech device was not primarily based on its intrinsic characteristics (Claudy et al., 2015), contrary to spatial projects, but is indeed based on criteria related to the consumer himself as well as his usage traditions (Antioco&Kleijnen, 2010), where the innovative parameter may even become a strong barrier to the use of the device due to its perceived uncertainty of use (Agarwal & Teas, 2001; Stone &Grønhaug, 1993).

Thus, the TRL and CML models as canonically described do not seem relevant for the evaluation of consumer-related parameters rather than intrinsic device parameters. The TRL and CML models are particularly interesting for institutional evaluation and the development of solutions for industries. The TRL and CML models are particularly interesting for institutional evaluation and lead to the development of solutions for industries. These grids allow us to arrive at solutions but they do not take enough into account the acceptability and the use of these solutions once developed..

We have therefore proposed a variant of the CML model, the CML Santé France model, which specializes the classical CML scales centered on Technology by also opening its reading grid to the elements of French and European regulations (standards for scientific research methodology, ethics, RGPD), and above all by granting a capital place to the evaluation of the place of the end-user and his ecosystem. Indeed, the CML Santé France levels constitute a reference framework that does not replace the interaction between the coach and the entrepreneur, but provides to the coach a way to save time, a knowledge base, a shared language, and to the entrepreneur a rich, structured result that can be shared and understood by other coaches or experts who have adopted the method. The French field of study is particularly interesting because regulation in terms of health innovation is particularly heavy and complex. This legislation is constantly evolving and this is why there is a significant need for support in this field. Even if there is a European will to define common schemes for all countries, the regulation is different from one country to another and must therefore be adapted by country.

The use of this approach allows us to measure maturity, to help companies optimize their evolution. The goal is to carry out this type of assessment within a controlled time frame, and to renew it at regular intervals (for example, every year) to continue to support the choices and decisions of start-ups.

In this sense, the CML Santé France evaluation methodology seems particularly adapted to the co-design methodological approach resulting from Living Labs, where the user is placed at the center of a creation process in partnership with all his potential ecosystem (caregivers, funders...) and making it possible to adapt the device to the reality of the uses in an iterative fashion. Now that the framework for the development of the system and a relevant evaluation model have been described in the literature, further research will focus on the construction of CML Santé France tools for project leaders and the experts who evaluate them. For the time being, two standardized repeatable evaluation questionnaires are being constructed, one for project leaders, allowing them to quickly assess their level of CML Santé France on all dimensions; the other for expert evaluators of projects, enabling them to assess the level of CML Santé France maturity on the basis of a short oral presentation (i.e. pitch) by a project actor. The data from these events are now being analyzed as part of the psychometric validation of the scale, in order to ensure the content and divergent validity of the CML Santé France model as evaluated in the construction of psychometric questionnaires for clinical purposes (Gonzalez et al., 2021; Messick, 1989; Schmeiser et al., 2006). Moreover, its ease of use and its effectiveness in comparison to existing models is yet to be demonstrated in a large sample of non-expert end-users.

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