Beyond the Prototype: Exploitation Strategies for Proof of Concept Biomedical Devices

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Abstract

Advances in technology have been allowing the automation and optimization of development activities, helping innovators to reach the deployment phase of their solutions faster than ever before. A remarkable example is rapid prototyping, which pertains the use of easily available fabrication technologies to accelerate the creation and validation of proof-of-concept solutions. In the field of biomedical engineering, particularly, rapid prototyping has seen an ever-growing interest over the past years, with applications ranging from medical device ideation, to organ production by means of 3D bioprinting [3]. Nevertheless, when attempting to transfer such results to the real world, biomedical innovators are often hindered by strategic and regulatory aspects that prove to be difficult to overcome. This struggle mainly results from the lack of a clear path to deployment, as well as from the latter's demanding character as it requires a great amount of resources from the very beginning.

Therefore, this work aims to develop and characterize exploitation strategies that can potentially facilitate the path-to-market of biomedical solutions created by means of rapid prototyping, particularly of medical devices, using the e-CoVig project as case study. A conceptual framework focused on user engagement, regulation and data protection, and the employment of facilitating methodologies and technologies, is described and successfully delivered in this work. Its validation and application are sought after by performing two different studies. The first consisted of conducting 16 open-ended semi-structured interviews with key players of the medical device industry. The results obtained were consistent with the content described in the proposed conceptual framework, thereby validating it with significant confidence. The second study aimed to assess the e-CoVig monitoring system's usability and added value to the user. For it, an usability test was conducted in a non-clinical setting, namely, an elderly home. The feedback obtained from the technicians that used the system (subjects A and B) supported the system's utility and efficiency, however, the quantitative results of the evaluations performed show the system as having a high workload associated to its use, as demonstrated by NASA TLX's scores of 55.00 (subject A) and 66.33 (subject B). Moreover, the results evidenced that, depending of the subject's technology literacy, there could be resistance and/or difficulty on employing the system, as revealed by the divergent SUS's scores of 77.5 (subject A) and 57.5 (subject B). Thus, improvements have to be made for the system to be applicable in this type of setting.

Keywords: medical devices, regulation, path to deployment, e-CoVig, case study, usability.

1. Introduction

We are now experiencing Health 4.0, a more technological, patient-centred, and reachable era of health and its related industries [23]. Innovations with the power to face healthcare's challenges of today and tomorrow have been settling in its industries, allowing for a higher quality and precision to be delivered to patients [13]. Examples include: i) the digitization of health records, which, by increasing the volume of data collected per person, promotes the provision of a more tailored care; yet, it simultaneously exposes each person's information to a possibly compromising level [24]; ii) the rapid prototyping technologies, allowing to create different types of medical solutions in an affordable manner [3]; iii) and the Internet of Medical Things (IoMT), that enables the consistent communication between a network of medical devices, such as monitoring wearable devices (mHealth), which collect and expose a great amount of their users' health data, allowing health professionals to easily access and act upon such information from a distance (telemedicine) [20].

The development of the aforementioned innovations was only possible due to the collaboration of multidisciplinary fields such as that of biomed-

ical engineering. This field works to surpass society's numerous challenges, namely those regarding its health, reason why is it essential that both the development and deployment of biomedical solutions are performed successfully. For it, innovators can employ optimizing technologies such as those of rapid prototyping, developing frameworks that quickly deliver safe and effective solutions, among others. Nevertheless, these solutions' path-to-market is not yet clear for most biomedical innovators, hindering their chances of getting their innovations out to the market. Furthermore, given biomedical developments' diversity and sensitive nature - as they deal with human health - the outline of a single path-to-market, suitable for all their intricate requirements and characteristics, is very hard to achieve.

Thereby, this work focuses on outlining a clear path, from concept to market, for, particularly, medical devices, providing innovators a valid framework for them to lean on throughout the journey to enter this intricate, but thriving, industry [2][1]. Focus will be given to medical device new entrants, such of academic backgrounds, who may lack experience and know-how to successfully deploy their innovations, as well as to the Medical Device Regulation (MDR) [10] - which greatly impacts the medical device path-to-market - and the General Data Protection Regulation (GDPR) [9] - evermore important in today's technological paradigm, where users' data are collected and processed by most of this market's products, processes, and services. The proposed conceptual framework suggests to complement an effective and compliant development cycle with an user engagement roadmap focused on the devices' usability and, thereby, safety [12].

2. Background

Innovation is key for society's development and well-being. Whether it consists of incremental improvements to previous solutions, or of disruptive concepts able to change the industry's and society's ways, all innovations mean progress, contributing for both local and global growth [7]. Today's technological landscape has been allowing for innovation to emerge everywhere, at anytime. With the world being more connected as ever before, knowledge and resources are more easily reached and shared, encouraging all types of profiles to innovate, from researchers and students, to hobbyists and simple users. Open source communities encouraging collaboration between innovative minds, toolkits providing the necessary materials and equipment for one to experiment and create, and rapid prototyping technologies empowering people to materialize their ideas in a quick and affordable manner, are just a few examples of the outstanding concepts emerging in all industries, including that of medical devices [18][3]. Companies are no longer the only providers of innovation. Users and their insight on the market's needs have been showing, for the last decades, their power to shape industries and economies, so much so that their input is sought after by companies when developing their products, processes, and services [15]. Furthermore, industry, for long focused on revenue and bulk metrics, has been increasingly invested on responding to the users' wishes and expectations through their developments. For example, we are now experiencing Health 4.0, a more technological, patient-centred, and reachable era of health and its related industries, such as that of medical devices [23]. The focus is now on delivering, not only effective and reliable devices, but solutions that the user values and which development emphasizes usability. Moreover, with the increase of society's longevity and its health-driven mindset, healthcare-related industries have been growing and thriving, aiming to provide a better and personalized care, empowered by today's digital revolution [17].

Nonetheless, even with all the advances made, technologically and ideologically, the deployment of innovative products, processes, and services, in the market, is still challenging. Especially in the medical device industry, the intricacy of its path-to-market's (whether related to regulation, clinical validity, among others), along with its high-resource demands, have been dooming many innovations to failure [17]. New entrants, particularly, struggle to get the necessary resources to complete the research and development activities and to mature their devices, ending up in the "Valley of Death", the infamous home of many failed Small and Medium Enterprises (SMEs) for which the path-to-market's costs were unbearable and failed to be covered by other sources [14]. Nevertheless, this faith is not set in stone, being possible to surpass such challenge if the right measures are taken. For example, the alignment of the innovator's motivation with the force driving the development is essential to get both funding and creating a sound business. Especially academics, which are inserted in an environment nurtured by knowledge and driven by scientific merit, must allow themselves to be entrepreneurs, to focus on business value as much as on merit. This complementarity between academia's principles and those of industry is exactly what is needed to allow the important technology transfer from the advanced knowledge centers to the key markets. Collaborative programs (such as internships, webinars and innovation challenges) and business deals (such as licensing, and spin-off and start-up creation), are just a few exam-

ples of how can the academia-industry relationship be nurtured to permit the deployment and commercial exploitation of academia's important developments [7]. However, the challenges of the medical device path-to-market do not disappear by only partnering and networking with the industry's key players. Regulators and governments must proportionate an encouraging environment for innovation, and all the industry's intricate dimensions must be well understood by the innovator before this allocates any resources to the solution's development. Its regulatory framework is particularly hindering of an innovators' path. The MDR's dense set of requirements and obligations demand a great investment of resources from the medical device manufacturer who, most times, can not bare. Similarly to MDR, the GDPR's principles and requirements can many times be viewed as an innovation's bottleneck. To surpass this big cornerstone of the medical device industry that is regulation, the innovators must fully understand its scope and demands and search for guidelines, tools and expert advise that could facilitate their compliance.

Furthermore, timely planning, multidisciplinary teams, employment of facilitating frameworks such as those promoting user engagement and ergonomics principles (like Design Thinking and User-Centred Design, [16][19]) and efficient development philosophies such as those of Lean and Agile [8][**?**], are all measures that can simplify the development and deployment process of a medical device. These same facilitating tools are gonna be used as based to the proposed conceptual framework of this work.

3. Conceptual Framework Overview

The proposed conceptual framework (Figure 3) comprises a medical device's whole journey from concept to deployment, dividing it in intuitive blocks to streamline its approach.

The first block of "Conceptualization & Design" comprises the research and ideation efforts needed to turn an idea into a strong concept sustained by reliable data and realistic goals. Includes both scientific research on the solution's functional and technical dimensions, and market research, where both the device's user and industry are identified, characterized, and prioritized based on their adequacy to the project and/or business value. Market research, particularly, is suggested to be conducted in close proximity with the user and other key stakeholders of the medical device market to ensure their needs and expectations are understood and applied in the solution's development. Alike the solution's targets, also its technology must be defined. A de-risking exercise is proposed, on which each technology set, selected based their potential and adequacy to the project, is assessed, firstly, on its individual performance and, secondly, on its maturity and readiness to be employed. Once identified the most suitable technologies, each set is put to test through a "optimizing loop" (see Figure 2). This was developed based on the "learning loop" advocated by Lean Development [8], however, is adjusted to serve medical devices, focusing not on speed (as it is not bearable for most devices' prototyping) but on compliance. Furthermore, the optimizing loop is to be used as a tool to efficiently climb the medical device's maturity ladder that is the Technology Readiness Level proposed in Figure 1.

The proposed loop will thereby be employ in the medical device's development stage (Figure 3's middle block). In the loop's first phase, "Build", a prototype of the technology is built by means of rapid prototyping technologies, yet, stripped of any detail, including only the core characteristics that allows its functioning evaluation. In the second phase, "Test", the prototype is evaluated under increasingly rigorous settings (such as simulated environments and laboratory), which parameters and constraints rise to those of the device's real-world application. Furthermore, the participation of the user is encouraged throughout the technical and quality testing of the prototypes, helping not only to assess the intuitiveness of the device's structure, but to refute assumptions and discard options. In the third, and last, phase of the loop, "Improve", both quantitative and qualitative data previously attained is used as input to improve the tested prototype. Ideally, after each loop, a better prototype is built, evermore proximate to the envisioned technical performance, and sustained by reliable data.

Simultaneously to this prototyping loop, a design is being built based on the requirements and information collected through market research (completing this way Figure 3's first block's activities). Alike the loop previously described, design can also be approached as so. Its testing activities benefit from the users' participation to identify preferable features and/or configurations, and those not valued. Furthermore, the design stage here proposed integrates the principles of human-centred frameworks, such as Design Thinking [19], User-Centred Design, and Human Factors (or Ergonomics) [16]. These encourage the innovator to design with, and for, the user, and to focus as much on the device's effectiveness as on its usability, creating a solution which use is intuitive, eliminating any usage errors that could endanger the user's safety [12]. The commercial design developed, and the technically functional low-fidelity prototype previously obtained are then put together and matured (the scale-up stage) through yet another optimizing loop. At this point, the new comprehensive

TRL	Description
TRL 9	Actual system proven in operational environment (competitive manufacturing the case of key enabling technologies; or in space). **Medical device in its final form and in full commercial deployment. Post-market studies and surveillance.**
TRL8	System complete and qualified. **Medical device is in its final form. CE marking apposition.**
TRL 7	System prototype demonstration in operational environment. **Final product design is validated, and final prototypes are produced and tested in an operational environment.**
TRL 6	Technology demonstrated in relevant environment (industrially relevant environment in case of key enabling technologies). **Demonstration of the prototype in a relevant environment, such as high-fidelity laboratory and simulated operational environments. Safety of medical devices of higher risk classes is demonstrated. Technical Documentation and QMS are finalized.**
TRL 5	Technology validated in relevant environment (industrially relevant environment in case of key enabling technologies). **Validation of a higher fidelity model by testing it in a relevant environment. Beginning of clinical investigation processes, if needed.**
TRL4	Technology validated in lab. **Test of low-fidelity models in lab environment to prove that the different elements will work together.**
TRL 3	Experimental proof of concept. **Test of assumptions through analytical and laboratory-based studies. Demonstration of Proof-of-Concept. Beginning of Technical Documentation and QMS processes.**
TRL 2	Technology concept and/or application formulated.
TRL 1	Basic principles observed. **Conduction of scientific research to be translated.**

Figure 1: The Technology Readiness Level (TRL) scale comprising the nine stages of a technology's development process, being particularized, in bold, for medical device development. Source: US Army Medical Department

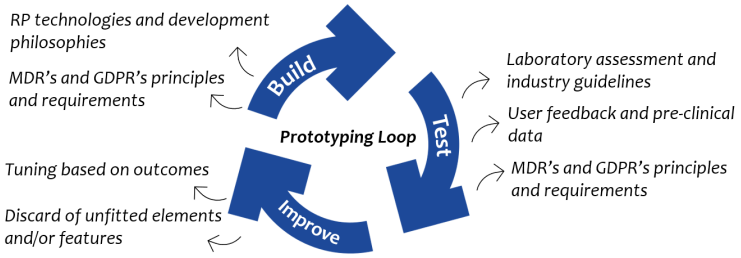

Figure 2: Proposed loop for medical device prototyping activities, based on lean development's framework [8].

models are tested under relevant and operational environments, collecting enough evidence on their safety, effectiveness and usability, thus conquering the solution's clinical value (Figure's 3 final phase). Testing activities include, at this point, pilot testing and clinical trials (when needed). In the end of this final loop, the solution's final form is achieved and its commercial design closed, ready to be mass produced and deployed.

Parallel to this development journey, a regulatory path is being walked on. The medical device manufacturers have to comply to many requirements and guidelines in order to be able to commercialize their devices. In Europe is the Medical Device Regulation (MDR) who regulates the trade of medical devices, demanding, among others, for them to have acquired the CE marking to be commercialized. The latter is the European seal of conformity which apposition is only possible once both the manufacturer and the device are validated. Respectively, this validation regards the Quality Management System and the Technical Documentation, two pillars that have to be built and maintained throughout the device's whole life cycle. Moreover, the MDR classifies medical devices based on the risk they pose to users' health if faulty. Four classes exists - Class I (the lowest risk class), Class IIa, Class IIb, and Class III (the highest risk class) - each with their own pre- and post-market requirements driving their development. In fact, the MDR emphasizes the need of assessing the device's performance after deployment. In the post-market period, clinical data must be continuously collected and made available to official entities, such as it is needed before deployment. This can be either acquired by claiming similarity with other existing solutions, by conducting clinical evaluations, or by conducting clinical trials (an resource-intensive modality that, furthermore, is only mandatory to be performed for higher risk devices). Regarding the GDPR, this regulatory framework that targets all organizations that process personal data, aims to give users more control over their own information, promoting transparency, lawfulness, privacy, accountability, and other principles, through its requirements. The GDPR's compliance is demon-

strated by implementing a group of organizational and technical measures, such as encryption and limiting the collection of data to what is strictly necessary, being erased once the purpose if fulfilled. Both the MDR and the GDPR have guidelines and official bodies for one to count on to achieve compliance [6][22], nevertheless, conformity is not a one-time job, and must be nurtured throughout the device's and the organization's life-cycle.

The proposed conceptual framework (Figure 3) comprehends all the suggested actions and measures to implement in order to deploy a medical device to the market. In order to validate the latter, an interview study was conducted to assess the opinion of medical device market's key players. Once validated, the framework was applied in this works's case study, the e-CoVig project. An experimental study was conducted to advance the e-CoVig's path-to-market.

4. Methodology

For this work, two studies were conducted.

4.1. Interview Study

The first consisted of performing 16 open-ended semi-structured interviews with key players of the medical device industry (the experts) and the e-CoVig team (the new entrant). The research objectives were to:

- Identify any barriers to safe and effective adoption throughout the path-to-market.
- Identify the key actions that must be performed to ensure a successful development, and deployment, of a medical device.
- Evaluate the contributions described throughout the present thesis.
- Characterize the e-CoVig's path so far, identifying potential improvement points and, with the teachings attained throughout this work, outline a plan for the e-CoVig project's future.

Composing the group of interviewees were individuals of both academic and non-academic profiles, with knowledge in areas such as regulation, intellectual property and technology transfer, medicine, engineering, and management. Due to such diversity of profiles, different interview guides were elaborated in order to question each interviewee about the path-to-market's stages more suitable to her/his knowledge. For instance, MDR's experts discussed matters of clinical evaluation and CE marking apposition, while the physicians addressed the growing interest of the industry on mHealth solutions and their future applicability. Once performed, and recorded with the participant's consent, the interviews were transcribed and analysed thematically according to four concept umbrellas: "Ideation & Innovation", "Design & Development", "Pre-Clinical & Clinical Validation", and "Commercial Adoption". The categories were created based on the proposed conceptual framework in order to later facilitate its evaluation. Furthermore, the results obtained, translating the matters perceived as relevant by the participants to successfully develop and deploy a medical device, were also analysed in a way that evidence the consensual and, most importantly, non consensual opinions between the e-CoVig team and the experts. This segmentation facilitated the detection of possible improvement points of the e-CoVig's path, and evidenced the project's next steps, two objectives of this study.

4.2. Usability Testing

This work's second experimental study aimed to assess the e-CoVig's system usability. To do so, this monitoring device was implemented in a elderly home (with 19 residents) as its registry modality, for a three-week period. Once designed the experiment according to the elderly home's resources and needs, and selected the institution's two technicians to conduct the experiment - "Subject A", 28 years old; "Subject B", 50 years old - the e-CoVig system was implemented (the mobile application was supported by a tablet and a computer supported the web-based platform). The technicians were then asked perform, each one, a monitoring activity per week (making a total of six activities in the duration of the study). These monitoring activities aimed to assess, and register, the elder's clinical status with just the e-CoVig system (replacing the paper-based method previously used). Each activity was timed and consisted of: 1) accessing the elder's profile on the platform (on the computer), 2) scanning with the table's camera the associated QR code to enter her/his profile on the mobile application, 3) selecting and responding to an appropriate protocol (contained requests and questions to be answered to regarding both the elder's physiological data and mental health). This process was repeated for each of elder.

Since the experiment implied a technological shift on the elderly home's practices the latter's technology literacy was assessed before the study's beginning. Three questionnaires - the eHealth Literacy Scale (eHEALS) [5], the Mobile Device Proficiency Questionnaire- 16 (MQDP-16), and the Functional Assessment of Currently Employed Technology Scale (FACETS) [4] - were performed to evaluate how comfortable and prepared were the technicians to handle the e-CoVig system. In the end of the study, the technician's feedback was collected through an informal interview.

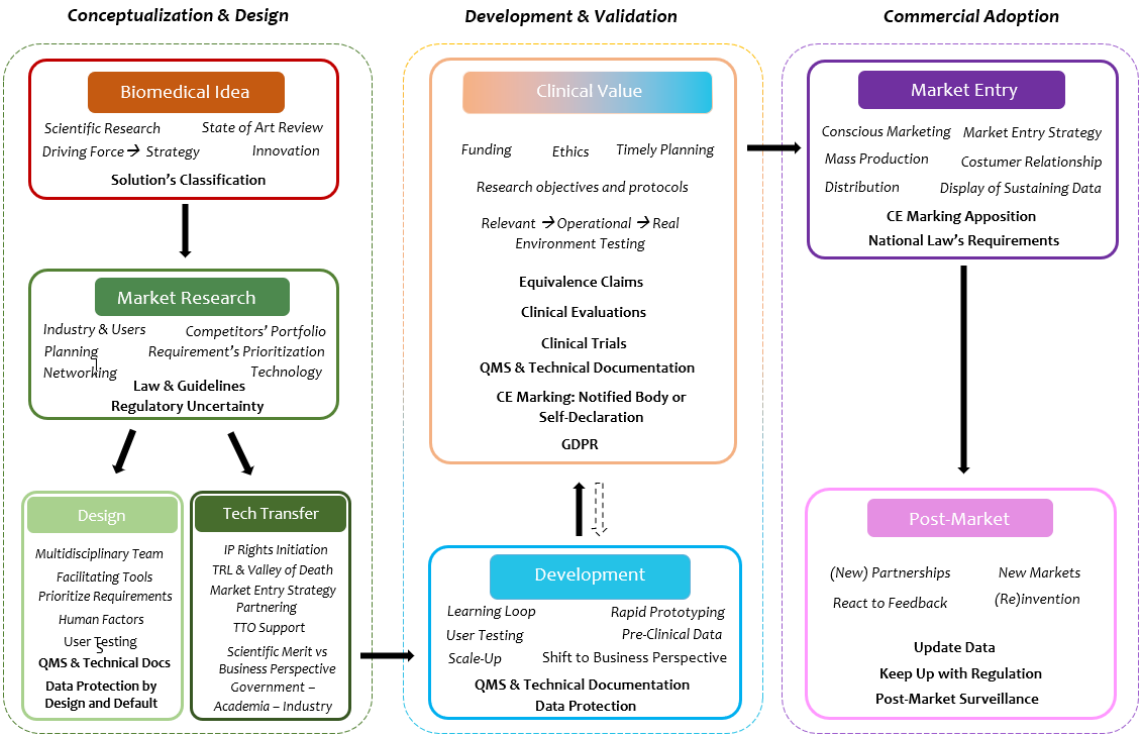

Figure 3: Final suggested workflow of the medical device path-to-market. Matters regarding regulation are highlighted in bold.

The qualitative data was complemented with that provided by two other sources: the System Usability Scale (SUS) [11] and the NASA Task [21] Load Index (TLX) questionnaires. The latter aimed to assess the system's usability and value from the point of view of the user (the technicians) as well as the effort required to handle the system, respectively. Furthermore, the times of each monitoring activity were analysed and compared with the paper-based registry modality in order to understand the actual efficiency on delivering information of the digital modality. Additionally, by comparing the times of Subject A with those of Subject B, and relating them to the technological literacy's results, one could identify the impact that experience and knowledge on technology has on the system's learning curve.

5. Results & Discussion

The results of this paper regard the two studies conducted in the scope of validity and application of the proposed conceptual framework, the interview study and the usability testing, respectively.

5.1. Interview Study

The results of the interviews study (displayed in Figure 4) show that, in its grand majority, the matters perceived as relevant by the e-CoVig team matched those highlighted as key by the medical device industry experts, a positive indicator of the work done so far by the new entrants. Particularly, methodology-related matters, such the employment of rapid prototyping technologies and work frameworks that streamline and accelerate the solutions' development cycles, as well as the construction of a multidisciplinary team which core knowledge should include the clinical field, were consensual among the two big groups of interviewees. Furthermore, both experts and the e-CoVig team recognize the value of developing for, and with, the user, particularly on today's technological landscape in which such contact is eased, and on seeking opportunities to network and/or partner with the experts of the medical device industry since their know-how and resources can be essential to enter such a competitive and intricate market such as this one.

Nevertheless, the experts group's highlights were not always mentioned by the e-CoVig team. Matters relating to regulation (namely, the MDR and the GDPR) and other legal frameworks (such as that of intellectual property), as well as to conceptualization (such as market research) were often left out by the new entrants during the interview process. Generally speaking, many of these differences can be partially justified by the context from which the e-CoVig project emerged. The funding call to which the e-CoVig team responded, and which was seeking solutions for the challenges posed by COVID-19 pandemic to Portugal's health system, firstly, demanded a short delivery timeline and, secondly, had already pre-defined the intend and user of the solution. Because of the

scarce time the team had to develop the solution, its focus was directed to practical activities (such as prototyping), from which tangible results could be obtained, postponing more lengthy and bureaucratic matters such as regulation and property protection. The second imposition, facilitated the project's planning, however, a proper research on the solution's user and purpose was neglected which proved to hinder the project later on, when the system's adoption at national scale gradually lost strength and support by national bodies. Given the remarkable professionals composing the team, it was possible to surpass this new challenge, and identify new purposes for the e-CoVig system. Finally, comparing the teachings provided by the interviews (Figure 4) and the conceptual framework proposed in this paper (Figure 3), it can be verified the consistency between both results as the all matters mentioned by the interviewees were described in the suggested model, a strong indicator of the latter's validity.

5.2. Usability Testing

From the experimental study assessing the e-CoVig system's usability, both quantitative and qualitative results were obtained. The first regarded all the formal evaluations performed during the three-week period, and are displayed in Figure 5, while the second regarded the feedback collected from the technicians in the end of the study.

Technology Literacy

The scores obtained for all three questionnaires assessing the technicians experience and ease with technology, showed that Subject A (the younger technician) was more comfortable and aware of today's technological applications and capabilities than Subject B, scoring higher in two out of three evaluations (MDPQ-16 and FACETS) and having about the same score as the other technician in the third assessment. Nevertheless, the results, for both technicians, were significantly high for both MDPQ-16 and FACETS, indicating that also Subject B was familiar with technology and mobile devices' functionalities, a good indicator to the appropriateness of the technicians to carry on the task designated to them in the scope of the e-CoVig project. Note, however, that the results for eHEALS, which evaluates the confidence and knowledge that the users' have on health technology, was relatively low for both subjects, which can predict some resistance on adopting these tools.

Learning Curve

By analysing the times of the six monitoring activities conducted, it can be stated that, when the technicians follow the stipulated protocol and performed the task individually, Subject A always performed the activity quicker than Subject B, indicating that the first better adapted to the e-CoVig system as forecasted by the technological literacy assessments. Nonetheless, the difference between their times never exceed 12 minutes which, given the environment the experiment is being conducted, could be due to more factors than the technician's technological literacy (such as the motivation of the elders' to participate in the task that day; how pressured were the technicians by that day's schedule; among many others). Nevertheless, both technicians' decreased their times from one week to another, a positive indicator of the effort needed to learn and adapt to the system, later confirmed by the NASA TLX's scores.

Note that, in the first two activity days, the technicians teamed up to perform the task (a choice solely made by the technicians). If analysis such results, it shows that teaming up made the task more efficient since, other than the last acquisition of Subject A, no other time was smaller than those of the first two days. This indicates that, most probably, the employment of the system benefits from teaming-up. In fact, when talking with the technicians in the end of the experiment, it was said that, not only they felt more confident when accompanied, but it was much easier to complete the task if one technicians performs the measurements and/or asks the questions, and other is just inputting the results and/or feedback, and doing each resident's log in. Furthermore, it was suggested the merging of the platform and the mobile application, if possible, to diminish the number of devices being handled and to, perhaps, make the an individually performed task as efficient as when collaborating. These and other suggestions of the technicians were communicated to the e-CoVig team to be analysed and, if appropriate, implemented.

Performance Time

The performance times obtained, for both the e-CoVig system and the paper-based method previously used by the institution, were longer for the e-CoVig system, with, about, a six minute different. However, they were actually favorable to the latter if one considers that the e-CoVig system assesses an extra important dimension of the human health in those extra 6 minutes: the mental health. Thereby, although not directly comparable, results show that, by spending less than an extra minute per elder, one can collected the same information as the paper-based method and also data on the resident's mental status, an evermore important dimension to be aware of in today's world.

Usability Assessment & User Feedback

Regarding the assessment of the overall experiment, in the end of the three weeks, with the tech-

Category	Mentioned matters	Perceived as relevant by the interviewees: Experts	Perceived as relevant by the interviewees: e-CoVig
Conceptualization ***13 interviewees:*** *Ideation &Innovation (6)* *Tech Transfer (2)* *Regulation (2)* *Entrepreneurship (3)*	Level of innovation	✓	✗
	Market research	✓	✗
	Regulatory awareness	✓	✗
	Clinical expertise	✓	✓
	Intellectual Property	✓	✓
	Technology and its maturity	✓	✓
	Organize and plan	✓	✓
	Networking and partnering	✓	✓
Design & Development ***All 16 interviewees***	Work philosophies	✓	✓
	Usability	✓	✓
	Team heterogeneity	✓	✓
	User-centred approach	✓	✓
	Facilitating tools	✓	✓
	MDR	✓	✗
	GDPR	✓	✗
Pre-Clinical & Clinical Validation ***11 interviewees:*** *e-CoVig founders (5)* *Regulation (2)* *Entrepreneurship (4)*	Ethics	✓	✓
	Clinical trials	✓	✓
	CE marking	✓	✗
	Financing	✓	✗
Commercial Adoption ***7 interviewees:*** *Regulation (2)* *Entrepreneurship (5)*	Regulatory surveillance	✓	-
	Business plan	✓	-
	Industry-University	✓	-
	Market entry strategies	✓	-
	Evolution	✓	-

Figure 4: Interviewees' most mentioned matters of each category approached. Particularly, each group's ("e-CoVig" and "Experts") mention to the latter is indicated with intuitive symbology.

Evaluation	Description	Results
Technology Literacy	To respond to three questionnaires that assess the user's technology literacy: ✓ eHEALS ✓ MDPQ-16 ✓ FACETS	**Test** / **Subject A's Score** / **Subject B's Score** **eHEALS**: 25/40 / 26/40 **MDPQ-16**: 40/40 / 34/40 **FACETS**: 49/60 / 34/60
Learning Curve	To time the performance of the monitoring activity (when employing the e-CoVig system), of all residents, every time it is done.	**# Week** / **Time (≈ minutes)** / **# Residents** / **Date** / **Subject** 1st: 36 / 10 / 10/08/2021 / A & B 1st: 32 / 9 / 12/08/2021 / A & B 2nd: 45 / 9 / 17/08/2021 / B 2nd: 35 / 10 / 19/08/2021 / A 3rd: 40 / 10 / 24/08/2021 / B 3rd: 28 / 9 / 26/08/2021 / A
Performance Time	To time the acquisition-registry activity's duration in two moments: one when using the paper-based method and other when resorting to the e-CoVig system.	**Paper- Based Time:** ≈ 30 minutes * *Excluding mental health assessment **e-CoVig Time:** ≈ 36 (± 5.9) minutes
Usability Assessment	To respond to two questionnaires: SUS and NASA TLX. Further feedback was collected by posing open-ended questions	**Test** / **Subject A's Score** (out of 100) / **Subject B's Score** (out of 100) **SUS**: 77.5 / 57.5 **NASA TLX**: Raw: 40.83, Weighted: 55.00 / Raw: 65.83, Weighted: 66.33

Figure 5: Quantitative results of the evaluations performed during the elderly house's usability study.

nicians, this provided both quantitative and qualitative data, both supporting the system's usability.

When analysing the scores obtained by both technicians in the two questionnaires performed, it can be verified that the Subject A perceived usability of the system is significantly high (77.5), mak-

ing it likely to recommend the system to pears, according to literature. On the contrary, Subject B (the older technician), obtained a 57.5, significantly lower than Subject A and representative of her resistance to use the system. Regarding NASA TLX scores, these were significantly high for both Subjects A and B, meaning that the system's functioning is associated to a high workload. Although the reasoning behind both scores was different - with Subject A identifying the task's physical and temporal dimensions as the sources of such workload, and Subject B selecting mental and temporal efforts as the hindering of the experience - the results show that the system and its functioning have room for improvement.

From the informal interviews conducted in the end of the experiment with the technicians, many strengths were identified on the e-CoVig system. Its aesthetics and architecture were said to be appealing although simple, and intuitive and practical, respectively. The technicians very much appreciated being able to have access to an overview of each elder's health status, over time, said to facilitate the communication with nurses and doctors, when necessary, and to help keep track of all their needs. Furthermore, system (mobile application and platform) was said to encourage the performance of more health assessments because of their technological character, a great result to have since it is very important to monitor any person's health, but specially, the elder's. The improvement points identified are mostly related to the technological character of system as elderly homes often lack of equipment that can support such solutions, as well as of professionals capable of using them.

6. Conclusions

The objective of this work was to provide a conceptual framework for medical device development and deployment that could be employed, with confidence, by all innovators, especially by the industry's new entrants. Throughout this work, the main cornerstones of the medical device industry were addressed in detail, namely, the regulation under which is it ruled (the Medical Device Regulation) and that of data protection (the General Data Protection Regulation) for its increasing importance in today's technological landscape. Furthermore, facilitating strategies and tools were proposed to facilitate the device's development and deployment in the market.

Comparing the interview study's results, displayed in Figure 5, with the content of Figure 3 that translates the main matters described throughout this thesis's proposed conceptual framework, one views that most of the matters highlighted by the key players of the industry and professionals of the e-CoVig project were approached in this work's framework. Furthermore, although the interview study's sample was relatively small (16 participants) and, thereby, not representative of all the medical device industry's opinion, the participant's fields of expertise matched, in their grand majority, with those encompassed in the medical device path-to-market (such as biomedics, medicine, design, regulation, computing, management, intellectual property, among others), thus representing a significantly big scope of knowledge that, being in concordance with the proposed approached, gives the author confidence to on the work developed and on its validity, fulfilling this thesis' ultimate goal. Some of this framework's main teachings were that:

- Anyone can be an innovator in today's world. The fourth industrial revolution is, among other things, allowing to accelerate the developing cycles of most solutions and highlighting the need of collaborating with one another while innovating. User engagement has been particularly advocated in the healthcare sector's own revolution Health 4.0 [23].
- Compliance with both the MDR and the GDPR can be less of a burden if: 1) regulation is interpreted as an ethical work methodology on which integrity and quality reign; 2) it is timely prepared for; 3) governments and official entities provide facilitating tools and know-how to innovators. Regulatory knowledge should, perhaps, be taught in innovative centers such as universities, as part as their curriculum.
- The collaboration between academia and industry must be nurtured for the technology transfer processes to succeed. Entrepreneurship must be promoted in academia, focus on revenue must be balanced by focus on the society's well being.
- Matters such as those of IP rights, technology transfer, MDR, and GDPR, would greatly benefit if more trained and competent individuals would be available to integrate their human resources. Furthermore, regulators should push to provide streamlined information regarding such intricate matters.
- The innovator who will succeed on achieving and thriving in the medical device market will not be necessarily the most experienced, intelligent, nor resourceful, but that who better adapts to the industry.

Regarding the experimental research conducted on the e-CoVig system's usability, this was performed based on the proposed framework. The

research was successful in the sense that all the research objectives were achieved. The feedback obtained from the technicians was satisfactory, as they recognized the system's value and utility. However, the quantitative results, from the formal evaluations, proved that the system needs to be improved for it to be employed in this type of setting with success. The technicians suggestions for improvement should, thereby, be considered. Furthermore, since the evaluation of usability only regarded the system's registry modality (the mobile application and platform), the author purposes the conduction of the same study with all three elements (thus, including the acquisition device). Additionally, because the institution's paper-based registry activity did not assess the resident's mental health as the e-CoVig system did, the reliability of results of their direct comparison are limited. Thereby, the author also suggests to perform an usability test in which the paper-based method addresses exactly the same dimensions as the digital modality.

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