



MDDevNet

TRANSFERÊNCIA DO CONHECIMENTO
CIENTÍFICO E TECNOLÓGICO

REPORT

“First Work Meeting of the Action Groups”

13th April 2018

Cofinanciado por:



UNIÃO EUROPEIA
Fundo Europeu
de Desenvolvimento Regional



Fraunhofer
PORTUGAL

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1. Event Data

Local: Porto Design Factory, Rua Dr. António Bernardino de Almeida 537, 4200-072 Porto, Portugal

Date: 13th April 2018

Schedule: From 10.00am to 12.30am

2. Framework

In Europe, companies have already seen significant regulatory changes in 2016 with the European Union's approval of Medical Device Regulation (MDR), which requires a higher level of compliance and requires a higher level of safety for the user. European companies are currently in the process of reviewing the portfolio of their technologies against this new regulatory framework which will lead to greater transparency on clinical development needs and processes, for example. There are also restrictions on the use of data that are obtained by medical devices and can be characterized as clinical data, which threaten to reduce European innovation in this industry.

This scenario has a major impact on knowledge transfer and innovation as European companies need to invest more effort in obtaining more clinical evidence for both new and existing products in light of new regulatory requirements. They will also have to prepare better and more accessible regulatory dossiers for regulators, who will be more competent and more pressing. As a consequence, users will inevitably have to wait longer to gain access to new products. Companies will have to rethink the approaches to the business as a whole, and the development of new products will be more based on a risk analysis against the precepts and regulatory requirements, posing new challenges in the processes of knowledge transfer that originates the innovation in the products.

Therefore, more efficient and agile forms with more downstream collaborative work should be found in order to make the R&D results in medical devices closer to their end use and with a pre-analysis of risk, with regard to Medical Device Regulation (MDR) compliance.

In this context, Portuguese companies have to deal, additionally, with obstacles in the own national system of innovation, namely: gaps in qualified human resources in the processes of knowledge transfer; lack of definition of the processes of economic evaluation of research results; reduced

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experience in organizing collaborative development among various research institutions; misalignment between research results and the needs of society and the market and few agents involved in the certification processes making them unknown and inaccessible to most of the actors involved in its creation and development.



Figure 1 - MDevNet Network Workshop.

Also in this context, and within the scope of the activities of the MDevNet Network, a first workshop was held on March 9 that brought together various stakeholders involved in the technology transfer process of technology-based medical devices, including development, marketing, regulation and certification. This event led to the identification of several obstacles to the transfer of technology to the market in the development and commercialization of medical devices, and identified three convergent themes:

- **Clarification of regulatory issues associated with medical devices and their impact on national entities involved in the process of transferring and exploiting medical devices (Action Group 1);**
- **Identification of obstacles and promotion of mechanisms of interaction between the national entities involved in the process of co-development and co-validation of medical devices (Action Group 2);**
- **Promotion of effectiveness in the technology transfer processes in the MDevNet network partners for the adequate increase of value and exploitation of technology-based medical devices, based on their specific skills and competences (e.g. technical, scientific or legal) (Action Group 3).**

Up to the date of the first working meetings, 3 Action Groups were created, each focusing on each of the convergent themes identified above.

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3. Goals

Each Action Group will have three working meetings to identify and deepen the main issues of each convergent theme so that relevant information and concrete conclusions can be drawn at the end for sharing with the other members of the MDevNet Network. These meetings will follow this scheme:

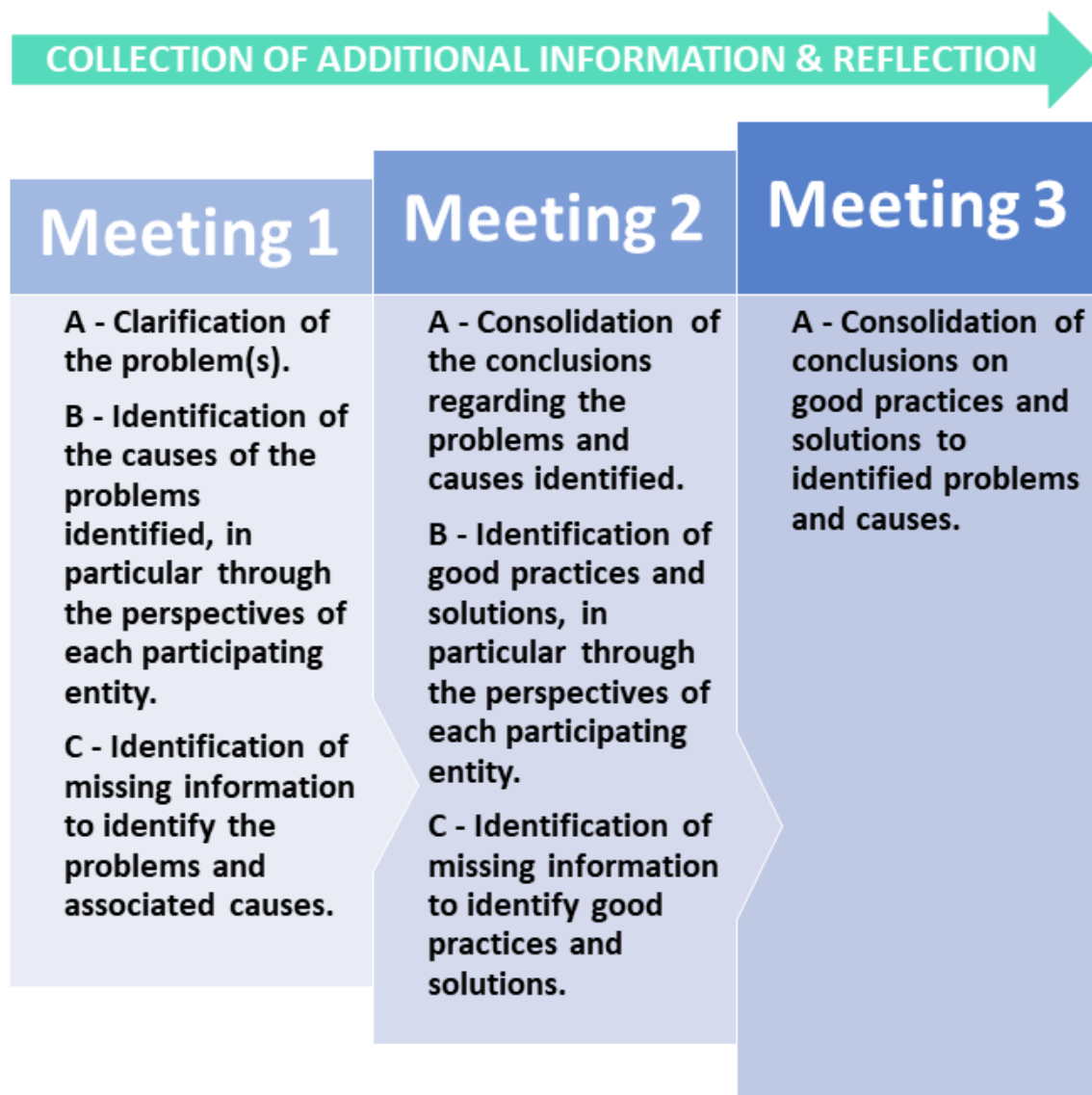


Figure 2 - Structure of the Working Meetings of the Action Groups.

The meeting described in this report corresponds to the "Meeting 1" of this process.

4. Program

Part I - Participants' Reception & Beginning of Meetings

- 10:00: Registration and forwarding of the participants to their Action Groups
- 10:15: Introduction on the structure of the Working Meetings of the Action Groups - Nuno Felício
- 10:25: Start of the 3 Working Meetings of the Action Groups
- 11:15: Coffee-Break & Networking

Part II - Continuation and Conclusion of Meetings

- 11:30: Resumption of Working Meetings of the Action Groups
- 12:20: Conclusion of the Working Meetings of the Action Groups

Part III - Sharing of the Main Points of each Action Group

- 12:25: Dissemination of main problems identified – Meetings' Moderators
- 12:40: Closing

5. Summary and Conclusions

5.1 Summary of the Event

Part I began with the reception of the participants (Porto Design Factory), with a brief networking moment before everyone headed to the meeting rooms of the Action Groups on which they had signed up, where they were introduced to the moderators of their meetings. Subsequently, all groups received an initial introduction by Nuno Felício to highlight the objectives of the session and to ensure alignment on the working method across the 3 Action Groups.

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Figure 3 - Reception of the Action Groups' Participants.

Part II began with a short coffee-break, where participants had the opportunity to network and exchange ideas on the topics. On this occasion, interesting discussions have also been developed which have fed new perspectives for the second part of the meetings.

Part III consisted of the final session where the moderator of each Action Group had the opportunity to share with all participants the main points discussed and problems identified in each group.

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5.2 Conclusions

5.2.1 Main Points

The following points are identified in each Action Group, which illustrate the entities' perspectives on the market for medical devices.

From Action Group 1, the following main discussion points were extracted:

- There is a general awareness that the new Medical Device Regulation has already entered into force and that it is mandatory to comply with the rules. For some entities, the Nando database, which allows finding Notified Bodies, is already known. Even so, the responsibility attributed to these entities, as well as the services they provide, are still unknown by the generality of entities still potential manufacturers;
- ISO standards are not formally mandatory, but they confer credibility to companies and are apparently used as a reference in the certification process. There is a realization that there are companies that do certification (support) in this area, but are relatively unknown to the universe of potential clients, as well as their particular relevance in the process. In cases in which the medical device is a strategic bet, the suggestion was also made that, as an alternative, the company may opt to train a collaborator or hire a new one with the knowledge to implement these norms;
- It was also noted the difficulty in understanding the costs and risks inherent in the certification of a certain technology, for example: what is the level of risk to bear the costs of the process and not achieving certification? What are the main cost elements, and in what stages do they arise? Which are only recommended or merely optional?
- There is also relatively low familiarity with the nomenclature in this area, in particular associated with the rules, processes and entities involved in certification. The most frequent example is the interpretation of the meaning and scope of the classification "Medical Device" (the starting assumption was that it depends on the purpose of use of the medical device and that as such a device will be considered a medical device if it influences the diagnosis or the nutritional habits (so a scale or a skin-fold meter for a nutritionist would actually be medical devices). Other examples are "Clinical Trials," "Clinical Evaluation," "Notified Body," "Competent Authority," or "Class I / IIa / IIb / III", "Invasive / Non-Invasive / Active / Inactive Device";

- Numerous questions arise as to the potential impact of the MDR rules on ongoing research as well as on its potential for technology transfer, such as :
 - Is a device intended for use in medical research and development also to be considered a medical device, and as such, subject to the associated rules?
 - Should a device used in clinical trials be certified (CE or FDA)? What about the lab? What kind of certifications can be expected in this context?
 - If a particular device such as a tablet or computer just allows viewing information (for example, TAC), is it considered a medical device? What design considerations of this interface (for example, what to show and when) can influence this classification? Can Electronic Health Record (EHR) software be considered a medical device?
 - Do the components of a medical device also have to undergo individual certification?
 - Should Class I medical devices be certified?
 - “If computers and smartphones have software installed, can they also be considered medical devices, in the future”?
 - At least one entity has indicated that it has developed a Class I medical device and has learned that in order to perform a clinical trial, the same medical device should be certified (CE or FDA) and also that, in order to obtain certification, the physical production space would itself require industrial licensing.
 - In order to certify a medical device, is it beneficial for an external centre to conduct a validation study (CES or CEIC)?
- The new General Regulation on Data Protection (GRDP) has also been identified as an added difficulty to the development and enhancement of software-based medical devices, since it further underlines the need to raise awareness among professionals in this area (health professionals, researchers, project managers, etc.) to ensure compliance with these rules. This aspect has implication in situations, such as obtaining informed consent, in the form of storage of this information and in the register of access to it;
- There is a sense that the FDA certification process is more demanding, more expensive and more detailed in terms of guidelines for anyone who wants to see their certified device, a topic that affects companies whose target market is global and not just American and / or European. In general, the main differences between these two regulations are not known, and specific approaches to each market;

- There was also a question about the significant differences between the respective submission of a clinical study to the Ethics Committee of a private entity or a public entity.



Figure 4 - Working Meeting of an Action Group.

From Action Group 2, the following main discussion points were extracted:

- Some comments were made regarding the Ethics Commissions, namely :
 - It has been observed that the consultation process with the Ethics Committees is a necessity that, in some cases, can take a lot of time, and whose results can vary significantly between Commissions. As an example, a situation was identified in which the same study had to be re-examined, regardless of whether it had already been approved in another Commission, as an aspect of improvement;
 - It was shared the experience of a researcher whose publication in a journal included as authors the names of 5 clinicians. She also warned against the fact that it would be difficult to apply the same study to several hospitals since in Portugal it would be

necessary to submit the study to different Ethics Commissions, something that in other countries "does not happen";

- The incentives for participation of clinicians in projects were referred to as an aspect of improvement:
 - It has been suggested that although healthcare institutions and practitioners focus primarily on their patients, it may be important to involve clinicians in clinical research processes and the development of medical devices. In this context, it was suggested that management policies could be reassessed in order to give professionals more time to devote to research, which could be a way for institutions not only to devote time to curing diseases but also to preventing them;
 - Another observation was that, in general, the main objective of the clinical decision maker is not necessarily aligned with the strategic vision of the research and development of medical devices with which it is invited to collaborate. The involvement of these clinicians in the development process (from day 1) could be an interesting idea to increase their involvement in the project;
 - It was also suggested the existence of "barriers that hamper the development of these devices" and emphasized the need to create conditions not only for the participation of clinical professionals in this process, but also for the inclusion of companies in an anticipated phase of the same. In the latter case, the difficulty may be compounded by the fact that companies may find it more difficult to determine the return on investment;
- With respect to the usability of medical devices, it was referred:
 - Lack of regulation in Europe, unlike the USA, in the area of human factors and usability, as a non-issue for entities with a particular focus on interaction with medical devices. The existence of a database of medical incidents in the FDA that are categorized by type has been mentioned, with "about half" being software errors that include usability errors (for example, insertion of information). What does the MDR contemplate in this area?
 - That the MDevNet Network could be used as a platform to make available the existing taxonomy in this area (adverse events); sharing of ongoing studies and an indication of the type of research that each institution (companies, universities, research institutes, health institutions) is interested in participating in;
- The existence of a Hospital Innovation Office has been suggested as a potential success factor for the selection of R&D partners. Doubts remained as to whether there would be any

evidence to that effect. In particular, the example of a paediatric hospital in the UK, Alder Hey Children Hospital, has an incubator where there are start-ups, health professionals, funders and research and development;

- The new Data Protection Regulation imposes stricter rules of sharing information and enforcing of privacy. There was doubt about the extent to which such changes could influence collaborations between entities involved in the co-development and validation of medical devices, namely in the sharing of clinical data;
- ISO, NP or IEC standards for the development of technology-based medical devices are generally unknown to the participants.



Figure 5 - Sharing of the Main Points of the Working Meetings.

From Action Group 3, the following main discussion points were extracted:

- A consensus was expressed that it was becoming increasingly important for universities to prepare their students and future researchers to meet the demands of the reality of practical application of research, which is seen as an obstacle to the success of technology transfer of medical devices. Here there is training at the level of:
 - Regulatory framework for medical devices ;
 - Processes associated with certification, the partners involved in the process and the resources available for this purpose ;
 - Intellectual property ;
- A common obstacle in language between firms and researchers has been identified as this misalignment introduces inefficiencies. The researcher tends to be accurate and prudent in his technical assertions, but disconnected as to market potential, while firms tend to communicate in terms of value propositions, impact and cost / benefit ratio, and also less conservative in extrapolating possible applications. Still in the training phase, the need to equip students and researchers with practical skills to interact with industry, such as companies, R&D partners, public entities, end users, etc., was identified;
- Spin-offs were identified as the preferred vehicle for transferring technology from medical devices, while licensing was viewed with mixed opinions as to its relevance in this area. There was a lack of evidence of licensing cases to conclude on the issue. Nevertheless, it was recognized in this model the added difficulty for an R&D entity to find the companies with most interest and potential in incorporating or using the technology, and for the companies to identify R&D results with enough maturity and potential for licensing in R&D organizations;
- The obstacle in the previous section on licensing can be mitigated by a greater commitment of the technology owner to compile a set of documentation that not only clarifies the risk to be taken by the company in the process of bringing the technology to the market but also of the market potential. This exercise, however, is not only demanding in terms of effort but also, by not involving the company, runs the risk of not addressing the real needs of the company such as alignment with its strategy. Just as importantly, it also risks that the value of such effort may simply not be recognized by the company due to underestimation of the knowledge and specific skills required to produce such a value proposition;
- A difficulty was identified in the creation of new partnerships and the search for business partners, where one of the difficulties was to find an interlocutor who can recognize the

merit of technology and who has the authority to decide on the investment (time, resources, attention) in that partnership. In this context, events such as B2B meetings and others in the health area were identified as facilitators of this process;

- Open innovation platforms have been identified as having limited potential for finding potential licensors of R&D results, but as a good platform for meeting R&D partners;
- In order to facilitate contact between companies and researchers, some companies already organize incentive prizes and contests for smaller companies as a means of evaluating the market and supporting co-development;
- A lack of incentive for researchers to participate in marketing activities was recognized (including the preparation of aligned studies to collect useful data for a subsequent certification process), since the incentive remains focused on the publications and not on the commercial success of its research results;
- It has been suggested that the TTOs of the universities that have lines of research in this area should assume a person with the skills to advise the researchers in their marketing roadmaps that provide for the certification process; Along the same lines, incubators can benefit from support professionals with skills in this area;
- There is a widespread lack of knowledge on how clinical trials are carried out, how to prepare the necessary documentation and associated formalities;
- It is increasingly necessary that research, innovation and / or entrepreneurship teams be multidisciplinary so that legal, management and scientific issues are always ensured by people who understand the vocabulary of these particular subjects;



Figure 6 - Sharing of the Main Points of the Working Meetings.

5.2.2 Summary

Each Action Group has identified a number of particular aspects that correspond to obstacles or difficulties to the success of technology transfer and medical device enhancement processes. These aspects are presented in section 5.2.1 and can be summarized as follows: Action Group 1 identified specific cases in which poor knowledge of the nomenclature related to the entities associated with the certification process is a limiting factor for the entities. There was also some lack of awareness of the impact MDR rules might have on some specific R&D or marketing scenarios, including differences between FDA and MDR, among other examples.

Action Group 2 has identified aspects of improvement in the interaction with the Ethics Commissions, as well as incentives for the participation of clinicians in R&D projects or validation of medical devices. Also mentioned was the apparent omission of specific regulations regarding the usability of medical devices and weighted characteristics to consider when selecting partners for research in this area.

Action Group 3 addressed the challenge of training new researchers and practitioners in regulatory, procedural or IP knowledge, as well as the gap identified in the training of researchers in communication with business and interaction with industry. Some obstacles to the licensing of medical device technology were considered, as well as the viability of some platforms for interaction between entities involved in the transfer of medical device technology. Some limitations were also discussed in the current incentives for researchers to participate in marketing activities.

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6. Next Steps

1. Publication of the Report of the First Working Meetings of the Action Groups on the MDevNet Network page;
2. Period up to May 11 to receive complementary suggestions for integration in the Report, by members of the MDevNet Network :
 - a. The Report will remain available on the MDevNet Network website;
3. Date of the next working meeting of the Action Groups: **4th June**.
 - a. The MDevNet Network will remain open to expressions of interest for the integration of Action Groups;
 - b. Before the next set of Work Meetings, a set of information will be collected to answer the questions raised, or at least contribute to clarify the problem;
 - c. These Meetings will focus on consolidating the conclusions of the first set of Meetings as well as on identifying best practices to address these obstacles.

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