An Example of Personalized Pathway in Medical Device Evaluation for a Master Student in Clinical Research

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Abstract: The aim of this paper is to explore the possibility of combining several training lessons to offer students a personalized pathway in the field of medical device regulation. Feasibility is demonstrated through an experiment currently being conducted between the universities of France-Comte, Lille, Montpellier and Rennes.

1 INTRODUCTION

For several years now, with the advent and democratization of the use of communications and distance training tools, the idea has been to design personalized lessons for students. With the help of a tutor, students can build their own pathways and specialize in the area of their choice, while maintaining the coherence of their training. This article summarizes the experiment currently being conducted by the universities of France-Comte, Lille, Montpellier and Rennes. This experiment is intended to serve as an anchor for the AMI-CMA project named ARCliMeD which proposed the structuration of a Training Pathway for Regulatory and Clinical Affairs in the Medical Device Industry. After an initial description of the general framework and objectives of the ARCliMeD project, the two training diploma are briefly introduced. The difficulties encountered during the experimentation are then presented and some conclusions are drawn.

2 GENERAL CONTEXT

Recent European regulations on medical devices require the identification of people responsible for ensuring compliance with regulations within companies and notified institutions (which issue CE markings for medical devices). A recent survey by France's leading medical device trade union, SNITEM (Snitem, 2020), showed that ¾ of companies find difficulties to recruit such regulatory executives. This sector, constituted of 93% of start-ups and small and medium companies, urgently needs support to meet the regulatory requirements. The need for training was defined in 2020 by a national working group (Medical Devices Coordination

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Group, 2020), led by the national research and teaching ministry, with numerous stakeholders (SNITEM, biomedical engineering school, EUROPHARMAT, Tech4Health network, …). The aim is to train 1,000 regulatory affairs executives for the medical device industry over 5 years. This objective meets companies' needs in terms of training and new skills for the professions of the future. It is fully in line with the France 2030 re-industrialization plan (France 2030, 2022), to create the tomorrow medical devices in France and to support companies in their market access initiatives.

With the rapid evolution of digital health, every medical device company already has, or will soon have, digital products in its medical device portfolio. The qualification criteria for regulatory affairs are generic. It is then important to train staff able to manage digital products and on all the aspects of the company's products such as risk, quality managements and clinical evaluation.

2.1 The ARCliMeD Project

The ARCliMeD project purpose, funded by ANR, is to elaborate individual pathways for students and professionals in activity, who want to specialize in the 3 domains of Quality, Regulatory Affairs, clinical evaluations for the Medical Device industry. The project targets professionals already working in the health products industry, and to students who have completed a Master 1 degree. The diploma will enable them to meet regulatory requirements and to apply for positions as regulatory affairs managers, particularly in digital health, but also in notified institutions or health authorities (ANSM, HAS, …).

The proposal is based on existing, complementary training lessons at national level, which already have close links with manufacturers and their representatives. A computerized coordination platform will serve as a shared resource for defining, with applicants the personalized training path. These actions will be offered both in initial training and in continuing education as part of a professionalization or apprenticeship contract. The teaching methods used (e-learning, streaming, visio, webinars, reverse training, Masterclasses, in-company and hospital internships, ...) will determine the optimum path for the learner, with the necessary modules.

2.2 Objectives and Target Groups

The need expressed by medical device companies is to train qualified staff in regulatory affairs. To reach this main objective, the ARCliMeD project will deploy the following actions:

i) Draw up a detailed map (content, hourly volume) of the offerings proposed by the project partners, and recompose the training offering based on feedback from previous learners, updating the existing offering in line with changing skills requirements,
ii) Create a 3D skills matrix, based on job profiles and proposed training units,
iii) Submit these proposals: for consultation (healthcare competitiveness cluster, student networks, and so on),
iv) Adapt lessons/skills/trades to the needs and constraints (size, structure, organization) of companies or organizations.
v) Accelerate the training process by combining several master's degrees
vi) Increase the number of student trained, by raising awareness among students in initial training.

Three target groups are involved:

i) staff performing this function within companies (around 1,440 companies),
ii) staff of competent authorities (ANSM, HAS) (30 students are expected before 2024),
iii) students in initial training.

3 THE EXPERIMENTATION

To demonstrate the feasibility of the ARCliMeD project an experimentation was conducted. The experimentation is based on the DIU (Inter-University Diploma) EvalDM: *Evaluation des dispositifs Médicaux dans le contexte du Règlement Européen* (Montpellier, Franche Comté and Lille Universities) and the Master II Biology and Health from Rennes University, Pathway clinical research (Master BS ReClin, 2023).

The aim of the DIU EvalDM is to describe the regulatory context and provide the basis for understanding and designing clinical evaluation methods for medical devices throughout their development and life cycle (from proof of concept to post-market clinical follow-up including CE marking and reimbursement applications in the context of European regulation 2017/745-2017/746). The skills acquired are multiple and concern knowledge of i) the general basics of the life cycle of a Medical Device (MD), ii) methodologies specific to the clinical evaluation of MD in pre-CE marking or CE marking, iii) the basics of usage studies, iv) the principles of post-marketing studies (Moreau, 2019). It also covers

the importance of Economics and Epidemiology training. Indeed, the notion of materioepidemiology is an integral part of Post Market Clinical Follow-up. Materioeconomics (or medical device economics) and materioecology are new disciplines in which expertise is important. Both should be developed and taught in future years. Finally, it provides the tools needed to fulfill a clinical evaluation document in line with European regulations, to critically analyze the scientific literature on the MD clinical evaluation and to propose appropriate investigation schemes.

It is open to students in initial training (residents in medicine studies, students in biomedical engineering or Masters) and continuing education (engineers, doctors, pharmacists, odontologists), as well as industrial project managers who manufacture medical devices (regulatory affairs managers, R&D teams) and assessors from notified authorities. The course has been running since 2018, with one session per year, and has continued to evolve in terms of content and format. Twelve students follow in average the DIU every year representing a total 60 students already trained.

Today, it is organized in 2 main blocks: general methodology from September to November and specific methodology from December to March. Each block is organized in 3 stages: i) knowledge acquisition via asynchronous videoconferencing; ii) 3-day face-to-face seminar with practical courses illustration previously seen; iii) summative assessment. A dissertation on a topic of interest, with oral defense, closes the course.

The Master's degree in Biology and Health at Rennes University provides training in research: in Cancerology, in Pharmacology, in Health Nutrition, in Clinical research. This is this last pathway that has been selected for experimentation and denoted ReClin Master in the following. The courses alternate theoretical sessions and personal homework projects. The various training units are briefly presented in Figure 1 below. Two options Units (10 ECTS) are proposed for *traditional students* (Students who do not participate to the experimentation). The year ends with a research internship. Evaluation is based on a continuous assessment and a dissertation.

The aim of the Master's program is to train high-level clinical research professionals capable of supervising the practical implementation of a trial. The courses cover clinical research methodology, the organization and regulatory aspects of academic and private clinical research, pharmacology and preclinical studies. The ReClin Master's degree prepares students more specifically for careers in clinical research, professions at the interface between research and health, and the pharmaceutical industry.

The ReClin Master has been running since 2017. Fifteen students follow in average the ReClin Master every year representing a total 108 students already trained.

The idea of a personalized pathway between the 2 trainings diploma is to provide students in the Master's degree in Biology and Health in Rennes a specialization in MDs. In the context of the experiment, it was decided then that students in the Biology-Health Master's program in clinical research could follow the DIU instead of the two optional UEs (since these skills are already part of the DIU but MDs-oriented).

UE	TRAINING LESSONS IN THE MASTER RECLIN	ECTS
DBT	Biotechnology in Therapeutic and Diagnostic Research	20
EN	English	
RISP or TAC	Professional Insertion or Advanced Technics in life sciences	
COM	Communication, Management	
MPP	Management and Planification	
MR1	Methodology for Clinical Research 1	
MR2	Methodology for Clinical Research 2	
RPT	Precinical and Translational Research	5
SPT	Monitoring and Treatment individualization	5
Intership	InternShip	30
	MANDATORY	
	OPTIONAL	

Figure 1: The different UE of the Biology and Health Master. ECTS stands for European Credit for Transfert System and UE for Training Unit. The two optional UE are replaced by the DIU training Courses.

4 EXPERIMENTATION RESULT

Thirteen students were enrolled for the DIU EvalDM, and 4 students over 20 students from the Master 2 Biology-Health chose to follow the DIU. It should be emphasized that, like the other candidates, the Master's students were selected on the basis of an interview and a motivation letter.

The 4 students selected came from a variety of backgrounds: Master 1 Biology and Health, Master 1 Integrative Biology and Physiology, Master 2 Biotechnology. The choice expressed by the students, through a quiz, to follow the DIU EvalDM was motivated by the fact that they would benefit from comprehensive training in clinical research and thus meet the requirements of the new European directive. They also want to participate in the development of new knowledge on innovative technologies. They would like to take advantage of the career opportunities offered by this field and the possibility of contributing to the development of innovative treatments or medical devices.

As described previously, the reverse training proposed by the DIU EvalDM, with the acquisition of prior knowledge based on documents and video clips, represents real pedagogical potential and fits in perfectly with the logic of a Master degree with differentiated courses. In addition, the face-to-face sessions enable students to reinforce and consolidate their skills.The DIU EvalDM teaching volume is 60 hours, fully compatible with the two clinical research master's lessons that students will not follow. It is important to mention -and this is a crucial point of the experimentation- that the two face to face session do not alter the students' Master's training insofar as the chosen date for the first face to face session coincides with a dedicated week focused on orientation, insertion and entrepreneurship and the second date is proposed during the students' long study internship.

The experiment also highlighted several critical points. Solutions were proposed to solve them and are summarized in Table 1.

Table 1: Synthetic presentation of all critical points and solutions provided.

Critical points	Proposed solutions
Distinct back-to-university dates between the two diplomas	The two back-to-university dates were synchronized at the beginning of September
Access to courses in different geographical sites and temporal constraints	Asynchronous video courses were proposed
Registration at University level.	Registrations were proposed in both university
Managing official student e-mail addresses	A generic official student e-mail address was used
Registration fees at the university in charge of the DIU	The ARCliMeD Project covered the additional costs
Extra costs introduced by the two 3 days face to face seminars (travel, hotel, ...)	Additional costs were covered by the Montpellier University and Lille University through the ARCliMeD project, depending on the seminar location.
Internship sites	The 4 students took an active part in finding internships. This is a critical point to look forward to in the next years.
Dissertation defense date	Examination dates were differentiated to take account of the longer internship in the clinical research master's degree

In summary, the analysis of the above table illustrates the points to keep in mind and to take care when building courses across several universities. A deeper analysis is reported in the discussion section. From the students' point of view after a quiz, they felt that the implementation was effective, that the video capsules were clear and that the face to face seminar was very well organized. Only small difficulties were encountered concerning the reimbursement of travel expenses.

5 DISCUSSION

The first critical point was to know what selection process would be used for students volunteering to follow a combined course of this kind between the ReClin Master degree and the DIU EvalDM. Would they have to go through both selection processes, as each diploma has its own recruitment criteria? The two teaching teams agreed that the Master's selection process alone was sufficient for admission. But students who were interested and volunteered for this combined pathway would benefit from a specific question and answer information session followed by written confirmation from the students. These confirmation letter should have expressed their motivation to follow this combined pathway. Five students had initially expressed an interest in this blended pathway and four of them confirmed and justified their choice to pursue this pathway.

A second critical point in the experiment was also not to overload the students with a simple accumulation of the expectations of two existing training programs. The training teams try to optimize and to adapt a training transformation of the existing lessons. This critical point can be illustrated in particular with the dissertations that students were required to produce during their year. For ReClin Master, the expected dissertation was a placement covering clinical research activities around 6 month in a professional environment. The dissertation required to validate the DIU EvalDM is of a different nature. It has to attest a reflective skill in applying specific regulatory and methodological knowledge focused on medical devices and/or in vitro diagnostic medical devices. The ReClin Master and DIU EvalDM teaching teams were agreed that students should not have to complete two dissertations (a work placement dissertation and a cognitive dissertation), which would overload the students. A solution has been found so that students have to write one dissertation that meets the criteria expected by both courses. As a result, the orientation of the internship

(only offered in the ReClin Master program) has been adapted to also meet the criteria of a cognitive dissertation as expected for the DIU EvalDM. Thus, the ReClin master dissertation would propose a section on the design of a clinical investigation study within the meaning of the European Regulation on Medical Devices. The work placement itself had to include, at least in part, activities geared towards such a design. This training transformation was approved for ReClin Master students wishing to complete and validate the course with the DIU EvalDM. Other logistical issues then arose, which were also resolved by the two teaching teams, in particular concerning the procedures and dates for dissertations defense.

6 CONCLUSIONS

This initial experiment showed that, for a small number of students, a personalized training program offering a double diploma could be offered, with a few adaptations. The experiment clearly demonstrated the difficulties to be overcome, such as registration, but also the advantages of offering a training program based on existing, complementary training courses at a national level. The DIU EvalDM and ReClin Master's degrees were used as an experimental resource to define, with students, a personalized training pathway for the acquisition of identified skills. The sharing of content, via *Moodle* for example, can be considered as a success and a guarantee of completion for the future. The next step will be to fuse several degrees from several universities and to offer a truly personalized course pathway.

Even if it is, at this stage of the experimentation, too early to draw more specific clues to this particular double training approach dedicated to the MD industry, it could be interesting to mention that the students participating in both programs develop new skills and competencies compared to *traditional students.* As examples among others, we can cited: Knowledge of the life cycle of a Medical device, Knowledge of specific methodologies to the Medical device clinical evaluation before CE marking, Basis for usage studies, Know how to establish evaluation document, Propositions of investigation plans adapted to Medical device.

In terms of training, and from the industrial point of view, the two degrees combined here enable the students to meet regulatory requirements and apply for regulatory affairs managers or regulatory focus position within digital health companies but also in notified health authorities (ANSM, HAS, ...).

Next steps will be to enlarge to any European equivalent initiatives and establish any bridge possible between different training from different countries and identify abilities of the students that will be trained to match expectations not only in France but also in Europe.

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