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Lambotika: A Post–Surgical Remote Monitoring System by the Biotika® Biomedical Company

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Abstract

Biotika® is simultaneously a double teaching module of the ISIFC engineering school and a non-profit company performing social–solidarity actions within the University. Via this innovative teaching module, which was founded in 2006, the students work in a biomedical company in quasi-real conditions and therefore with highly restrictive quality and regulatory demands. This article will focus on the quality management system in order to show how the ISIFC students develop their know-how and thus increase their skills just before they leave for internships at the end of their studies. Lambotika is one of the many projects developed at Biotika®. It consists of the design and creation of a system enabling the collection of signals from an apparatus monitoring the oxygen pressure of flaps of skin after reconstructive surgery, in order to make them accessible to the surgeon via smartphone and to generate alerts in the event of problems.

Keywords: Remote monitoring, tissue oxygenation levels, transplant, medical devices, entrepreneurship, innovation, pedagogy, eHealth.

1. Introduction

The Institut Supérieur d'Ingénieurs de Franche-Comté (ISIFC), is a university school of engineers which, in three years, trains engineers specialising in medical devices (MD) through a triple culture approach: technical, medical and regulatory. Since 2006, the ISIFC has been convinced of the pedagogic worth of Learning Through Projects and created Biotika® [1]. Biotika® is simultaneously an innovative optional teaching module over two semesters at the Masters degree level and a non-profit company undertaking social-solidarity actions. The students can propose their own projects through an annual brainstorming session which unites the entire year's ISIFC students and a wide panel of experts. The objective is to encourage innovation and entrepreneurship via intrapreneurship. Each year, between 30% and 60% of the year's students worked at Biotika®. Recruitment through CD and interviews (project leaders, R&D engineers, communication, quality…), Working on real innovative biomedical projects with the quality management system (QMS) of the company which meets the ISO 13 485 standard [2],

mission description sheets and objectives, resource and project management, regular audits… place the students in a truly professional situation and allow them to develop their skills just before they leave for internships at the end of their studies. After the "brainstorming" process, described hereafter, three teams from Biotika® and one team from the Besançon Hacking Health challenge worked on the Lambotika project from 2017 to 2019. Lambotika is an eHealth system to more rapidly alert a surgeon, via their smartphone, about an oxygen deficit in a flap of skin of the patient in reconstructive surgery. This project is highly interesting from a pedagogic point of view because as well as the transversal stakes (such as quality, regulatory affairs, and client relations) it deals with IT problems, digital electronics and to a smaller degree mechanics and analogue electronics.

2. Biotika®

2.1 Academic Organisation & Motivation

Currently, for semesters 4 and 5 (S4 and S5) of the ISIFC, which is to say the second semester of the second year of a Master's degree (Baccalaureate + 4 years of study) and the first semester of the final year (Baccalaureate + 5 years of study), the students must choose one of the three optional modules: Biotika®; R&D cell; or Industrial Strategy. The R&D cell is an individual research project teamed with a researcher. The Industrial Strategy module (for the moment only during S4) is in partnership with the micro-technical competitivity group. The students, in teams of two, are given the mission to provide companies with information on medical devices (product market studies or geographical zone studies, cost analyses of process internalisation, supplier mapping…) to help them in their decision-making. These modules include 80 hours of training in S4 (between mid-March and the end of June) and 120 hours in S5 (between the beginning of September and the end of November). They are therefore based on the civil year calendar, interrupted by the July–August summer break.

On the pedagogic front, the objectives of Biotika® are: better understanding of industrial logic processes by the engineering students, immersion in professional situations with real examples, the real-world development of MD and the practical implementation of many modules taught at the ISIFC (mechanics, electronics, IT, leading projects, quality, regulatory affairs, clinical investigations…).

The core values of Biotika® are to encourage entrepreneurship and innovation. The aim of Biotika® is to detect the needs and new practices in health through the feedback of the experiences of ISIFC students but also through its professional clinical and industrial networks. Since 2017, Biotika® has been a central player in the annual Besançon *Hacking Health* challenge (steering committee, prospection, showroom and volunteers). In mid-October, this innovation marathon unites over 230 participants who work intensely throughout 48 hours on approximately 20 medical/technological challenges.

2.2 Recruitment

Each year, the company must renew the totality of its student workforce (only the teaching staff remain). For practical reasons, above all that of time/resource management, the recruiting procedure begins before the choice of new projects. An "Open Doors" day for the three options (Biotika®, R&D cell, industrial strategy) takes place mid-October when third year students present their projects with second-year students. In particular this enables them to show the workings of the company and the many posts available. The executive posts such as President, Human Resources Director, Quality Director, Regulatory Affairs director, Project Director are filled by members of the teaching staff. The others such as R&D engineers (RDE), Project Leaders (PL), Quality Engineers, etc… are always student posts and therefore need to be filled. Note also the existence of posts of responsibility for design (in electronics, mechanics, prototyping, clinical investigation…), and experts that the students can consult as needed. The major portion of the work is the responsibility of the students.

The students applying to be candidates send in their CV and letter of motivation for one or more positions, before a specific date. Based on the quality of their application they can be invited to one or more interviews. Rarely some students, with insufficient motivation levels, may not be selected and must choose another module. The interviews are scheduled for November in order to select the new Project Leaders before the third year students leave for their internships, which helps preserve continuity of the project leadership. Provisional attribution of positions is decided by the HR Director, who is helped by the rest of the teaching staff. On average each year four different versions of the flowchart are drawn up. This is due to the students who leave to work in foreign countries and/or the arrival of new students, and internal reassignments of HR resources. This is also the reason for the opening / suspension / closing of projects, and of the results of the brainstorming described hereafter and requests from external clients.

2.3 Choice of projects: The innovation process, its brainstorming and preparation.

Given the workforce of around 20 students, Biotika® generally incubates four or five R&D projects. Some projects are the continuity of projects from previous years: this is the case of Lambotika which was developed over three consecutive years. A system of electronic documentation is shared on the AGORA collaborative workspace [3] where all the previous work is conserved as well as a handover procedure which facilitates the continuity of all the projects.

For more than 12 years, Biotika® policy has been to include at least one new R&D project originating from the students. Firstly, this helps improve the students' motivation levels. Secondly, it encourages technological innovation and this despite the fact that projects from previous years may not yet be finished. The other projects are chosen by the directors, based on discussions with academic partners (hospital–universities or researchers) or economic structures or patient representatives. There are also orders from external clients (private, partners or otherwise) or new clients prospected in tradeshows or business conventions (small enterprises, French or foreign start-ups, business incubators…). The starts-up especially help students to connect with real life prospects and to

help them understand entrepreneurship strategies and the development of new activities. The revenues generated help finance part of Biotika®'s expenses (equipment, mission expenses, quality program costs, manufacture of demonstration models, purchase of standards…).

During the brainstorming session, the ideas for new projects are generated by the entire second year ISIFC student body, including those who are not part of Biotika®. Shortly before their mandatory six weeks internship in a hospital environment, the student engineers receive a two-hour training course on the methodology of detecting needs. The goal is to prepare them to be attentive during their internship in order to detect the innovation needs in medical technology, care organisation or personnel training. These ideas can also be useful for the Hacking Health challenge and the R&D cell module. In this way, even if the projects are principally based on medical devices, they can also be based upon any health-related innovation [4-5]. During this course they are introduced to the basics of TRL (Technology Readiness Level) with examples. Biotika®'s projects involve TRL levels 3 to 6. Because the ideas can come from patients, doctors or nurses, they are reminded of the concepts of confidentiality and intellectual property (these problems have already been introduced in the first year of their studies). To conclude the training session they are shown – through an example drawn from previous years – how to fill out an ENR (recording) form for project proposals. For each idea, they are required to very rapidly explain its context, goal and socio-economic impact. Also, a succinct market competition analysis (documentary research for patents and competitors' solutions) and to fill out the TRL. They can also provide leads to begin the investigation of the project's technical solutions and potential restrictions.

Students must send their forms in by email one week after the post-course oral defence, i.e. more than 2½ months after the methodology training. Even though the majority of ideas originate in the experience gained during their hospital internship, some may come from their personal experience or be linked to a project concept they have been thinking over for a long time. The various ideas are then debated during a three-hour long "ISIFC brainstorming" session where all of the year's students are present and where members of the Biotika® management team and academic and industrial partners are invited. All the people present sign a confidentiality agreement. The ideas selected are presented in just a few minutes with a slide deck of no more than two or three slides. This is followed by a good-natured Question and Answer session. The management team and the guests are particularly interested in the innovative character and social impact as well as the reliability (financial, technical, temporal), which will lead to an initial score. At the end of the presentations, all the students will vote (by raising their hands) which will give a second score. The final score will be the average of both scores. Without exception the winning projects will be preincubated at Biotika® immediately or during the next semester. Based on the effort invested in preparing the form and the presentation, 0.5 to 3 bonus points will be awarded to the students who proposed the subjects (this bonus will be added to the grades obtained for the relevant Biotika, R&D cell or Industrial Strategy module). This bonus will be based on the quality and the work on the form and is independent of a project winning or not. For 12 years this very specific procedure has enabled the selection of 34 projects out of the 54 new projects developed at Biotika® , it has enabled the creation of four start-ups and the launch of seven clinical trials with the INSERM clinical investigation service of the Besançon Hospital-University (two of them are still active: ScarWars and PISTACHE).

1.1 The Quality Management System (QMS)

One of the goals of Biotika® is to put into practice what the students learn during their various lessons especially those relating to quality. Since 2006 a quality management system (QMS) has been developed with a company orientation and not as a teaching module, which truly immerses students in real-world conditions. Thus a policy (of orientations), objectives, clear flowchart, stages of development (processes), procedures (procedures, instructions…) and associated tools (support documents to record and track all activities completed) have been deployed with recordings and indicators in order to quantify the results.
The QMS objectives of Biotika® are listed below:

- Increase client satisfaction,
- Ensure coherence throughout the company via common orientations,
- Master functions with the improvement of work practices (efficacy and efficiency).
- Enable the transmission of best practices to future teams without requiring them to redo what has already been done (this is vital given that the entirety of the student personnel is renewed every year).

Biotika®'s QMS is deployed according to the demands of the ISO 13485 : 2016 standard for its activities involving «Project development including quality, regulatory and clinical technical assistance, relating to devices for health based on physics and electromechanics ».

The QMS documentation has been codified in the form of a pyramidal documentary structure (see Fig. 1: QMS documentation)

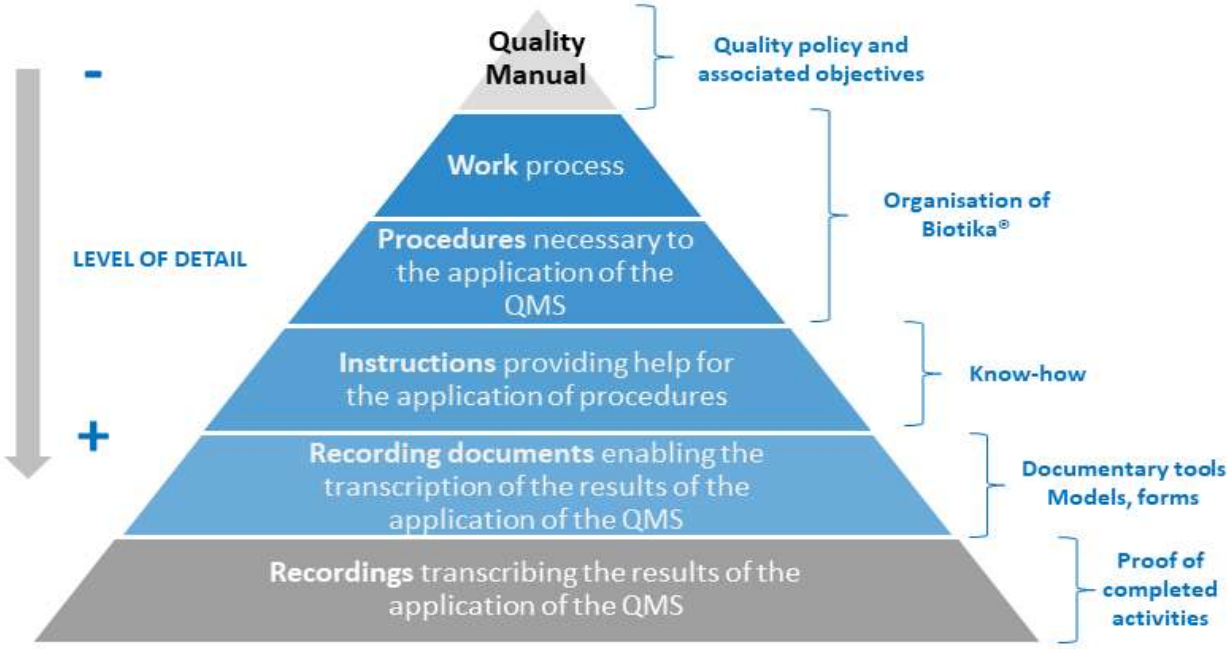

Fig. 1: QMS documentation

The working procedures (quality manual, processes, procedures, instructions and recording forms) are made available to the entirety of the personnel via Agora [3]. The student personnel also upload the results of their activities (minutes of meetings, project specifications, schedules…).

At this time, the 20th edition of the quality manual is being prepared. Biotika® distinguishes between several varieties of process (see Fig. 2):

- A « Project » process: the group of activities which - starting from a client request - permits the completion of a project which then supplies the deliverables expected by this client.
- A « Supports » process: the group of activities which record the material (or information management) resources
- A « Steering » process: the group of activities which, depending on the data from the clients or other interested parties, enables the definition of Biotika® orientations and organisation rules

• An «Improvement» process: the group of activities which, starting with the identification of a dysfunction and/or lead towards potential progress enables the definition then the evaluation of improvement actions. See Fig. 2: The QMS Process flowchart

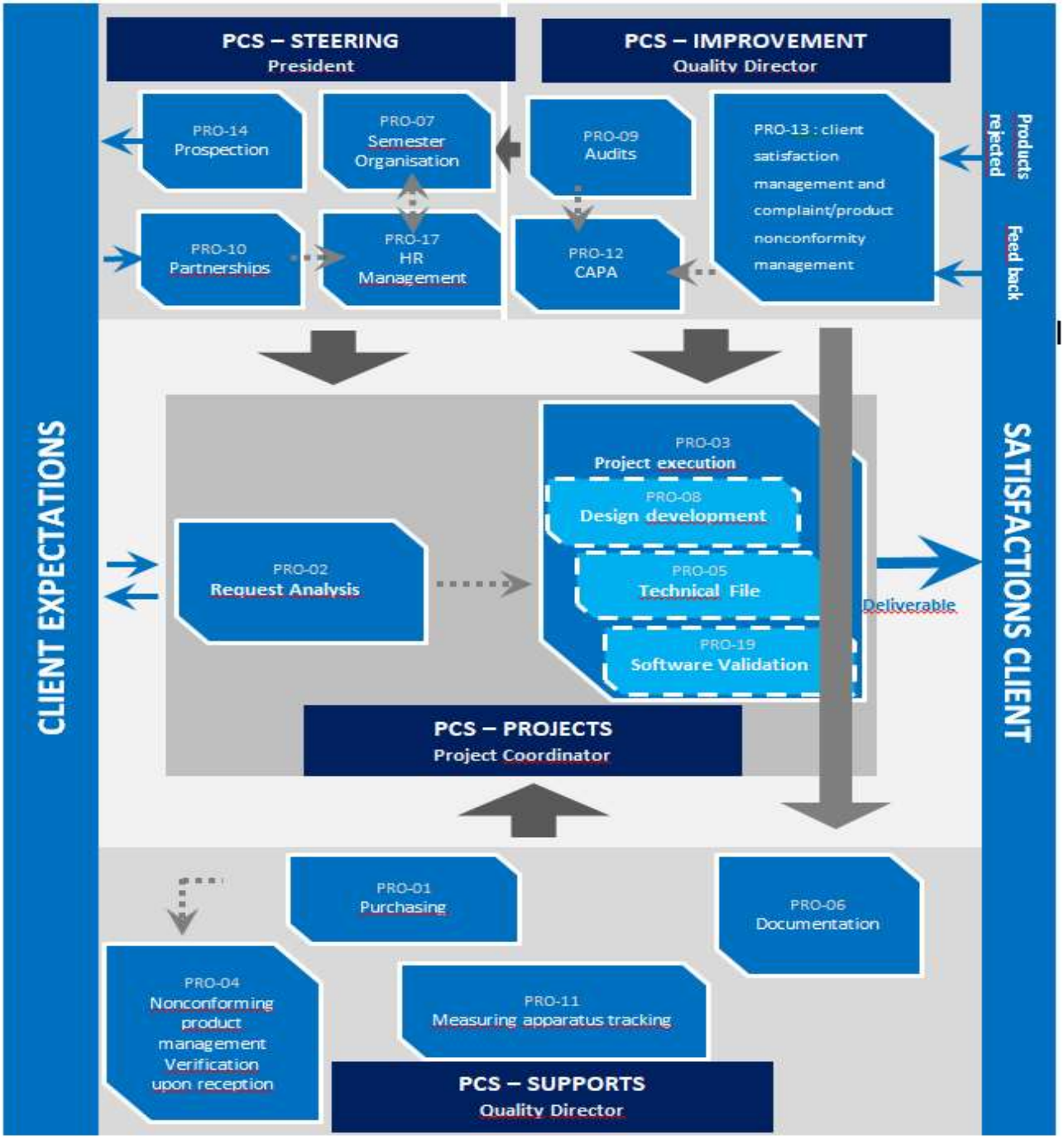

Fig. 2: The QMS Process flowchart

The principle interactions between processes are described in the process sheets and their performances are measured and tracked thanks to the indicators. For each process, each of the activities to be mastered is described in a documented procedure. There are around 15 different procedures and 86 documents used to record activities (project logbook, training presents sheets, forms for the improvement actions, client satisfaction evaluation sheet…).

The quality orientations of Biotika® are defined in a policy presented each semester when the students return to the University and include objectives which are defined as:

- At least one new project per year in preincubation detected by ISIFC students (internal client)
- At least three new projects per year as service providers for R&D services, Regulatory, Clinics, Marketing or Quality (external client)
- Adhering to deliverables' due dates
- At least eight communications or publications actions (professional trade shows, congresses, seminars…) per year to promote Biotika®.

Since 2006, Biotika® has benefited from 26 audits and 28 management review committees as specified by the ISO 13 485 standard with 14 consecutive teams and 100% turnover in the student personnel every year in December. The demands of the European regulations and standards are continually being reinforced and shaking up the medical device industry. The contents of the teaching programmes must be rapidly and reactively adapted. This gives rise to a great many CAPA (corrective actions/preventive actions) and the development of an exemplary quality management system. This has allowed Biotika® to continuously improve its documentary system and to be the example to follow for the 50 ISIFC engineering students trained each year and for the clients that it accompanies and advises regularly. The proof of the quality of Biotika®'s work is that the LNE/G-MED certifying body awarded Biotika® ISO 13485 certification from 2012 to 2015.

1.2. Evaluation

As with all pedagogic modules, grades must be awarded. These include a HR evaluation by their peers and self-evaluation. For R&D projects, the RDE's superior is the Project Leader (PL) who is also a student. The Project Director (PD) is the superior of the Project Leader and always a teacher or expert bought in for the purpose. At the beginning of the semester (launch review), the Project Leader fills out the mission description sheets in consensus with the PD and RDE. These sheets list the primary and secondary missions (including the order of priority) and the objectives and deliverables with provisional dates. At the halfway stage, the mission description sheets can be modified or adjusted. This allows complementary internal training sessions to be scheduled. At the end of the semester, the PL fills out the evaluation sheets for the various RDEs, which enables the noting of strong points and weak points and laying out radar graphs for skills and attitudes (depending on the positions, different characteristics may be more or less important). The RDE also performs a self-evaluation which is overlaid on these graphs. In the same way the RDE evaluates his PL. The Project Director will then individually interview them and discuss the achievement or otherwise of the objectives. The second half of the interview, more informal, focuses on how to improve Biotika® in the coming years. Using the interview evaluation sheets, and the observations of the teaching team during the semester, the Project Director decides on the grades of the PL and their RDEs.

2. Lambotika

2.1 Background and evolution of the stakeholders

See Fig 3 (Lambiotika schematic). This project was proposed by a student (Anthony Pérignon (AP) during the brainstorming session of March 2017 following his internship in the Besançon CHU Hospital-University. At first the client was composed of two people: the student and Julien Pauchot (a surgeon and supervisor of the internship of the student, who was later obliged to leave Besançon for professional reasons). AP, who had chosen the « Industrial Strategy » module was therefore not part of the first team which was made up of a PL and two RDEs. The following semester, the PL left the team for the ERASMUS programme and AP became the new PL. He presented the project at the Hacking Health (HH) challenge of October 2017 and his team won the Numerica prize and an award of €2500. This allowed him to work with web developers and IT specialists and energised the project even further. The surgeon then handed over complete responsibility for the project to the student who became an external client of Biotika®, in partnership with the cosmetic and reconstructive plastic surgery units of the Besançon CHU and Isabelle Pluvy, a surgeon. The student (at that point undertaking an internship at the end of his studies, in a start-up) took the decision to pass on all the work done to Biotika® with the support of the CHU's IT systems manager, Jean Baptiste Aupet – who was recruited by Biotika® as Project Director. Thus, the project was incubated at Biotika® during three years. The names of the students who successively took on these responsibilities are cited in the Thanks section at the end of this article.

2.2 Context

In reconstructive surgery, flaps of skin can be used. Unlike transplants skin flaps are vascularised. When they are « free » they are transported with their pedicle – their associated grouping of arteries, veins and possibly nerves – to the receiving site. The vascular network is then anastomatised (connected) in order to re-establish arterial and venous circulation. It is therefore important to monitor the oxygen pressure in the tissues in order to prevent potential complications. In the Besançon Regional Hospital University Centre this is performed with a commercial apparatus: the LICOX® monitor (from Integra Life Sciences). However, the caregiving personnel cannot be permanently present to verify the absence of problems. There is therefore a certain interval between a problem arising and the moment where it is detected, to which we must add the time needed to contact the surgeon. Therefore, a more effective management of emergency cases would consist of directly informing the surgeon via an application on his smartphone. Furthermore, this would also reduce the demands on the time of the caregiving personnel, who would need to visit the patient's room less frequently to check the monitor.

The LAMBOTIKA® project therefore consisted of an interface which would collect the data from the LICOX® monitor and transmit it to a health data server where it would be stored in order to be consulted at will by the surgeon from an application installed on his smartphone. The development of the application generate alerts, was also part of the project specifications.

3.3 Technical aspects

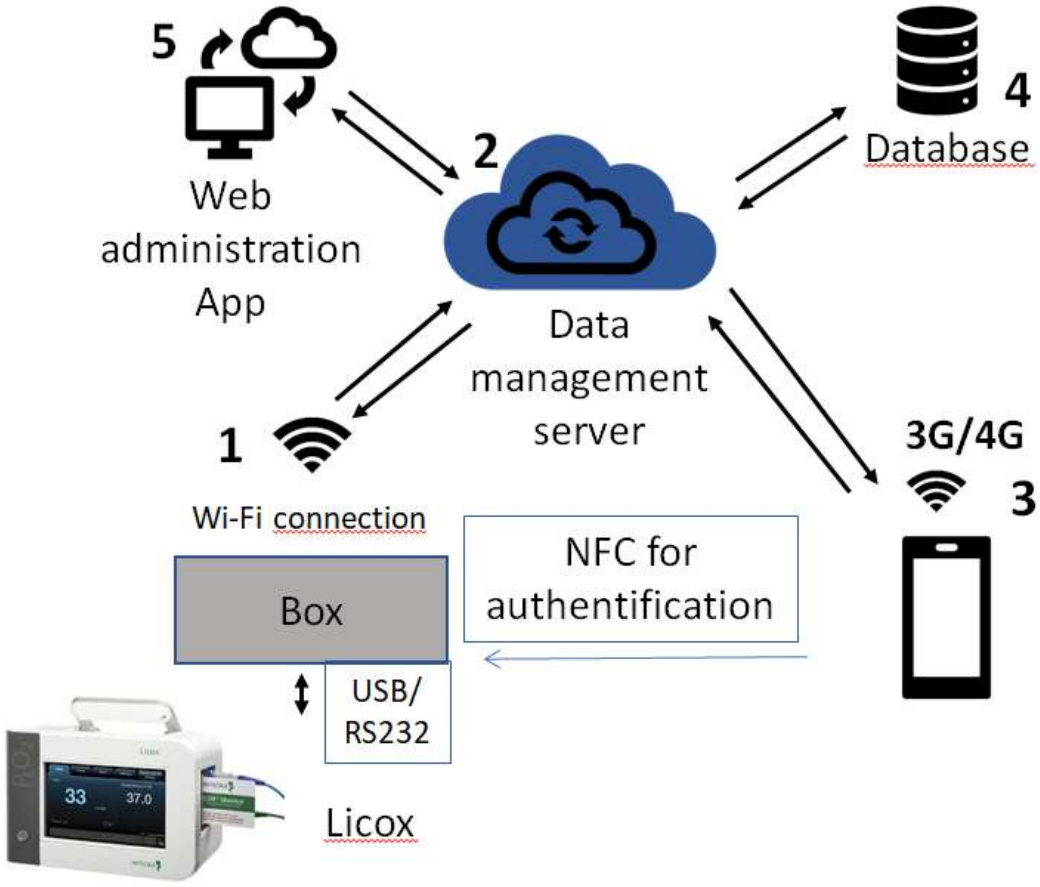

Fig. 3: Lambotika schematic

Figure 3 provides the basic schematic of the project. At first, with no LICOX® monitor available, tests were performed with signals generated with the help of a Labview® program.

The programme consisted of the creation of a prototype box, the Flap Phonitor plugged into the LICOX® monitor, the Fl'app smartphone application, and database management system.

1 – the core of the Flap Phonitor is a Raspberry board enabling WiFi communication with the server (2). It recovers the LICOX® data via its USB port. A USB hub installed on the board enables the connection of a keyboard and mouse if console mode access is required. Furthermore, the HDMI output port permits the connection of a monitor screen. A PN532 Adafruit card is used to enable synchronisation with the smartphone of the surgeon or nurse, via a NFC (Near Field Communication) chip (3). This synchronisation allows the rapid pairing of the smartphone with a monitor and the recovery of the monitor's data history from the database. The smartphone must be previously logged and authorised by the platform's administration program.

2- The server recovers the data recorded by the LICOX®, processes it and stores it in the database (4).

3- The Fl'app smartphone application permits real-time monitoring of the changes in data values sent by the LICOX® thanks to the archiving of the data. The platform also enables push alerts to be sent directly to the smartphone of the connected caregivers (doctors, nurses) in the event of detection of "abnormal" values by the monitor. The alert thresholds are set by default by the administrating program and can be modified on a case-by-case basis as needed.

4- The database enables the storage of data and the creation of graphs of monitoring data through its data archival system.

5- The management interface enables the configuration of the system to link the monitors in the rooms, and users with the right to administer/use the system and their telephones. Initially the names of patients are not stored in the application: the monitors are assigned to rooms in the management interface. Computer Assisted Design (CAD) was also used for the mechanical part of the box

3.4. Pedagogic aspect and conclusion

The majority of the knowledge and skills that the students were had to put to use were related to computing. The Labview® programs (simulation of LICOX® data) and Python (recovery of the data by the box), Bash commands, PHP server management, and SQL database management were all involved. Use-Case techniques and the Merise method with data logic modules (DLM) and data concept modules (DCM) were employed. Concepts from digital electronics were also useful. The design and creation of the mechanical parts of the box (its casing) called upon their knowledge of CAD. Finally, the fact that they were working in Biotika® permitted them to put to good use the Quality courses and the Regulatory Affair courses for their risk management. They also learnt how to deal with the availabilities of their client and their various interlocutors.

Finally, a functional prototype, a proof of concept, the technical dossier for the CE mark and the validation of the programme according to the CEI 62304 standard were completed. The idea was also to later use these results as illustrations and examples of the practical work done during ISIFC teaching in telemedicine, IT security and programme validation.

4. Conclusion

Since the founding of Biotika® in 2006, the students have been delighted by their experiences. Over the years, this module has evolved both in its training framework (originally it was only one of the three options in their final year of study and is now open to all) and in its organisation and its QMS. This model enables the experience of multidisciplinary collaborative work, it encourages creativity and it helps reinforce student–teacher bonds. Biotika® experience truly enhances the CVs of the students and helps them to obtain internships and even employment, facilitating their insertion into the working world. Frequently feedback from alumni highlights how Biotika® helped them in their professional lives. Furthermore, as the concrete application of what they learn in their courses, Biotika® permits them confirm their professional objective and gives them experience very close to what they will find in companies. This encourages their entrepreneurship and develops the leadership. Many of them do not hesitate to call on Biotika®'s services.

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