THE FIRST "UBORA" DESIGN SCHOOL OF NAIROBI: A ONE-WEEK INTENSIVE AND INTERNATIONAL "CDIO"EXPERIENCE CENTERED ON MEDICAL DEVICES

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ABSTRACT

UBORA is an educational and design online platform or infrastructure aimed at the collaborative development of open-source medical devices (OSMD) to address current and future global healthcare challenges. It pretends to help medical professionals and related industries with new methods for creation of innovative solutions that take into account patients' needs, safety, feasibility, efficacy and performance. In our quest towards universal healthcare, in which we expect UBORA to play an important supporting role, teaching-learning actuations constitute an essential foundation. In consequence, in parallel to the creation of UBORA as co-design resource, international design schools and competitions are being developed. In this study we present the results from the "First UBORA Design School", held in Nairobi in December 2017.

This "First UBORA Design School" has placed students from several European and Africa universities and countries in an international context of collaboration and learning. The school has been implemented with the CDIO methodology in mind and with the challenging objective of making teams of students live through complete "conceive-design-implement-operate" processes, linked to innovative medical devices (focused in this edition on child and maternal health), in just one week. The school has been prepared with a set of morning lessons linked to: patients' needs and global health concerns, engineering design methodologies, standardization and safety issues, prototyping and manufacturing topics, socio-economic aspects of the medical industry; and with the support of more specific afternoon workshops connected with: creativity promotion techniques, high-level programming, medical signals and sensors, mass-production processes, among others. Hands-on activities including: the conceptual design of the biomedical projects, the computer-aided design and modeling of the proposed solutions, materials and manufacturing processes selection tasks, rapid prototyping and testing, among others, have been performed and discussed in the late afternoons and evenings, mainly between the students, but also with the continued support of professors and mentors. Final presentations of results and discussions with the jury have served as key assessment procedure.

Main benefits, lessons learned and future challenges, linked to these international medical device design schools, are analyzed and discussed, taking account of the available results from this first implementation, so as to improve towards the future editions. The next one will be held in Pisa in summer 2018.

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KEYWORDS: CDIO implementation, Case studies & best practices, Integrated learning experiences, Active learning. (Standards: 1, 3, 7, 8).

INTRODUCTION

Biomedical engineering (BME) requires multidisciplinary collaborations to promote holistic approaches, so as to more effectively address patients' needs and to adequately support medical professionals in their daily practice. Scientific-technological excellence of biomedical engineers is a prerequisite for understanding the complex multi-physical/chemical and multi-scale phenomena of the human body and intervening in related pathologies by employing dedicated medical devices. International development teams are also needed for the incorporation of pertinent opinions for obtaining user-oriented devices, involving local populations to accelerate the uptake of innovative medical devices, and for verifying that socially relevant health concerns do not remain unattended. Furthermore, such teams are mandatory to enable BME professionals to follow international standards and regulations that support safe developments, necessary for reaching both market and patients. Gathering global talent for BME projects, combined with recent groundbreaking scientific-technological advances, will allow for the resolution of complex health problems, both local and global, and will enlighten the transformation of the field, towards the democratization of medical technology, as a key for achieving universal equitable health care, which is one of the World Health Organization's 2030 objectives and is directly related to the United Nation's Sustainable Development Goals.

Nevertheless, this renovations can only be accomplished if BME education also transforms continuously, focusing on the internationalization of students, the promotion of collaborative design strategies, the orientation towards relevant medical needs and the relevance of biomedical standards and medical device regulations. While maintaining an in-depth theoretical focus on basic disciplines of science, medicine and technology, other fundamental aspects have to be taken into account for training the biomedical engineers of the future and implementing formative programs. Issues including: the relevance of design, prototyping and manufacturing technical skills, the need for understanding the roles of regulations and standards, the potential of open-source approaches (De Maria, 2014, 2015) and an overall promotion of high ethical standards for professional practice, among other aspects, should be considered and encouraged in years to come.

Towards the aforementioned improvements and pursuing academic excellence together with a more global integration of all the stakeholders, participants, decisions and technologies present in the development of any medical product, we believe that applying the CDIO (Conceive – Design – Implement – Operate) methodology (Crawley, 2007) constitutes a very adequate approach. Previous CDIO experiences in connection with biomedical engineering have succeeded in transforming national panorama (Díaz Lantada, 2016), but here we work with a more global view and within a highly-intense framework, which we refer to as "express-CDIO".

In this study we present the conception and implementation of the "First UBORA Design School", a complete CDIO experience in just one week devoted to open-source medical devices developed in the framework of the "UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education" project, an EU funded research and innovation project pursuing a reinvention of Biomedical Engineering by means of innovative collaborative design strategies and educational activities in a global context. The project is described further on, before entering into details regarding the educational aspects and results of the first UBORA Design School.

THE “UBORA” PROJECT

The EU funded UBORA project (*H2020-INFRASUPP-2016-2017 call: Support to policy and international cooperation*) aims at creating an e-Infrastructure, UBORA, for open source co-design of new solutions to face the current and future healthcare challenges of Europe and Africa, by exploiting networking, knowledge on rapid prototyping of new ideas and sharing of safety criteria and performance data. The e-Infrastructure is being implemented to foster advances in education and the development of innovative solutions in Biomedical Engineering, both of which are flywheels for emerging and developed economies. It is conceived as a virtual platform for generating, exchanging, improving and implementing creative ideas in Biomedical Engineering underpinned by a solid safety assessment framework. Besides the provision of resources with designs, blueprints and support on safety assessment and harmonization, specific sections for needs identification, project management, repositories and fund raising are also foreseen.

UBORA (“excellence” in Swahili) brings together European and African Universities and their associated technological hubs (supporting biomedical prototyping laboratories and incubators), national and international policymakers and committed and credible stakeholders propelled by a series of summer schools and competitions (Ahluwalia, 2017). Through the UBORA e-Infrastructure, the biomedical community can generate and share open data and blueprints of biomedical devices, accompanied by the required procedures for respecting quality assurance, and assessing performance and safety. When properly implemented, as guaranteed by authorized Notified Bodies, these biomedical devices can safely be used in hospitals and on patients. In a nutshell, UBORA couples the open design philosophy with Europe’s leadership in quality control and safety assurance, guaranteeing better health and new opportunities for growth and innovation.

The teaching-learning experiences within the UBORA project, mainly summer schools and competitions, are being implemented on the basis of the CDIO (conceive-design-implement-operate) principles linking European and African students sharing the complete development process of innovative medical devices for global health concerns. Such collaborative open design teaching-learning experiences are expected to promote and rethink Biomedical Engineering Education across Europe, Africa and throughout the globe, while also serving as main initial input for making the UBORA e-Infrastructure become a key resource for the future of personalized and universal healthcare.

We believe that the approach is quite innovative, especially regarding the open-access strategy and the collaborative design approach, all of which, when connected with the CDIO methodology, may prove a relevant breakthrough in the Biomedical Engineering and Biomedical Education fields.

In this work, we present the results from the first UBORA Design School, performed at Kenyatta University in Nairobi in December 2017, which is also the first in a series of international biomedical device design schools focusing on open innovation and collaborative design approaches and devoted to making students live through the complete CDIO cycle, applied to the development of biomedical devices, in just one week. The teaching-learning objectives of the design school, its planning and implementation, the main results achieved in the first edition and the more relevant future challenges are presented in the following pages.

COMPLETE BIOMEDICAL ENGINEERING “CDIO” EXPERIENCE IN ONE WEEK: THE FIRST “UBORA” DESIGN SCHOOL (NAIROBI 2017)

Teaching-learning objectives and planning

The main objective of the UBORA Design School was to let students live through the complete CDIO cycle, linked to the development of innovative medical devices, in an international context and in just one week, which can be referred to as “express-CDIO” experience. Accordingly, the planned timetable (see Figure 1) was especially intense, with some lessons focused on engineering-design methodologies adapted to medical devices (including introductions to safety and standardization issues, to taking account of patient needs and to design and manufacturing technologies) and with several workshops and keynote presentations focused on more specific biomedical engineering topics (see Table 1). This overview of both general and specific issues connected to medical practice and to successful biomedical device development projects helped us to complement and leverage the different backgrounds from students and gave them a quite complete approach to biomedical engineering projects and related professional practice. Besides, a very relevant part of the week was devoted to hands-on activities, which were performed by the different teams and supervised by mentors; each team counted, at least, with a couple of mentors along the week. Participants of this first UBORA Design School were selected on the basis of merit, among the finalists of the first UBORA Design Competition, also presented in this 14th CDIO International Conference. To this end, the competition itself was arranged as a complete CDIO experience on its own, in which teams of students presented preliminary concepts and designs of innovative medical devices, which were evaluated according to their descriptions of medical needs, their proposals for solving such needs in creative ways and the actual technical & economical feasibility of the designs.

<table>
<tr><th>Time</th><th>Day 1</th><th>Day 2</th><th>Day 3</th><th>Day 4</th><th>Day 5</th></tr>
<tr><td>8:30 – 9:30</td><td>Registration
Opening ceremony</td><td>Class on project development</td><td rowspan="2">Class on project development</td><td>Class on project development</td><td rowspan="2">Hands-on</td></tr>
<tr><td>9:30 – 10:30</td><td>Presentation of the School</td><td>Hands-on</td><td>Keynote presentations</td></tr>
<tr><td>10:30 – 11:00</td><td colspan="5">Health Break</td></tr>
<tr><td>11:00 – 11:30</td><td rowspan="2">Keynote presentations</td><td rowspan="2">Workshops</td><td rowspan="2">Hands-on</td><td rowspan="2">Hands-on</td><td rowspan="3">Hands-on</td></tr>
<tr><td>11:30 – 12:30</td></tr>
<tr><td>12:30 – 13:30</td><td>Student’s pitch
Students assignment</td><td>Keynote presentations</td><td>Keynote presentations</td><td>Keynote presentations</td></tr>
<tr><td>13:30 – 14:30</td><td colspan="5">Lunch</td></tr>
<tr><td>14:30 – 15:30</td><td>Class on project development</td><td rowspan="3">Hands-on</td><td rowspan="3">Hands-on</td><td rowspan="6">Tour in Nairobi</td><td rowspan="6">Closing Ceremony</td></tr>
<tr><td>15:30 – 16:30</td><td rowspan="2">Hands-on</td></tr>
<tr><td>16:30 – 17:00</td></tr>
<tr><td>17:00 – 17:30</td><td colspan="3">Health Break</td></tr>
<tr><td>17:30 – 18:30</td><td rowspan="2">Workshops</td><td rowspan="2">Workshops</td><td rowspan="2">Workshops</td></tr>
<tr><td>18:30 – 19:30</td></tr>
<tr><td>19:30 – 21:00</td><td colspan="4">Dinner</td><td rowspan="2">Gala Dinner</td></tr>
<tr><td>21:00 – 23:00</td><td>Hands-on</td><td>Hands-on</td><td>Hands-on</td><td>Hands-on</td></tr>
</table>

Figure 1. Proposed timetable for the “First International UBORA Design School”. Additional details: http://ubora-biomedical.org.

Actual implementation and main results

The UBORA Design School was implemented according to the initial planning, with a total of 40 students working together in 8 teams of 5 persons and devoted to the complete development of 8 innovative biomedical devices including: a continuous positive airway pressure system for neonate, an instrumented pacifier, a thermal blanket for babies, a face protecting splint for recovery after broken nose, a universal articular splint, a system for UV-based treating of infant jaundice, a portable cooler for vaccines and a resuscitation device. The devices were selected by the organizers and focused on the proposed topic for the design school, which was “child and maternal health”. All students, mentors and professors were hosted at Kenyatta University (Nairobi) and the UBORA Design School was performed from the 11^{th} to the 15^{th} of December 2017, with most participants arriving on Saturday 9^{th} / Sunday 10^{th} and returning home on Saturday 16^{th} / Sunday 17^{th}. Logistically it was challenging, but the support of the organizers from the University of Pisa and of the resident colleagues at Kenyatta University proved fundamental for letting students and professors concentrate on a successful teaching-learning experience.

Globally speaking the teaching-learning experience was successful, with an overall attendance to programmed lessons above 90% and with all teams living through the complete CDIO cycle and reaching satisfactory concepts and designs, backed up by basic conceptual rapid prototypes. We counted with supporting resources including common CAD programmes, simulation software, low-cost prototyping systems (3D printers, one Arduino kit per team, a Kynect scanner), among others. Figure 2 includes some examples of the implemented designs and prototypes and additional information can be found in the UBORA project’s website (http://ubora-biomedical.org). There was even some time for leisure activities, including an afternoon devoted to visiting the National Park of Nairobi and a final Gala Dinner at Safari Park Hotel Nairobi, which let students, mentors and professors relax after days of very intense work starting at 8:30 and finishing well beyond 23:30. To our knowledge, this constitutes one of the very first examples of “express CDIO” experiences devoted to medical devices. According to students’ opinions, being placed in an international context and having to communicate effectively in multidisciplinary teams were among the most positive aspects in terms of promotion of professional skills. Besides, for many of them, it was one of their first approaches to the development of medical technology and to the use of engineering design professional practice tools (CAD programs, rapid prototyping…).

Table 1. Summary of contents: Lessons on biomedical project development, workshops or seminars and keynote presentations of the “First International UBORA Design School”.

Event	Topic	Date
Lessons	CDIO Methodology for Medical Devices	Day 1
	Standards and Regulations on Medical Devices	Day 2
	Technologies for Prototyping and Manufacturing Biodevices	Day 3
	Usability of Medical Devices	Day 4
Workshops	Creativity Promotion in Biomedical Projects	Day 1
	Programming in Matlab®	Day 1
	Tracking Movements	Day 2 (M)
	Electronic Rapid Prototyping	Day 2 (M)
	Electronic Measurements	Day 2 (A)
	Mass Production by Injection Molding	Day 2 (A)
	Medical Imaging Processing and Matlab®	Day 3
	Arduino and Matlab® for Prototyping Medical Devices	Day 3
Keynote talks on:	Economic Development and Healthcare Technology, Clinical Needs, In Vitro Models, Textile Technology in BME, Soft Robotics, Affordable Healthcare, From Mind to Market.	Days 1-4

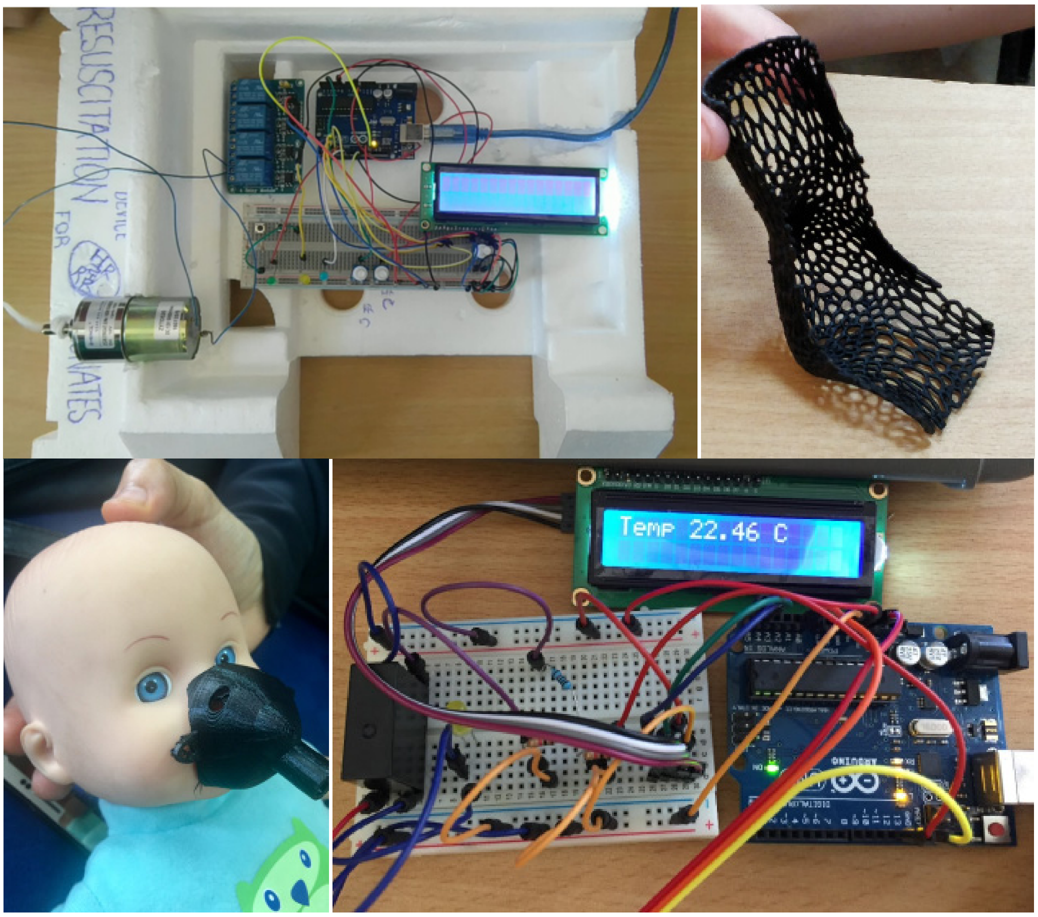

Figure 2. Some examples of the implemented and tested prototypes:
a) Conceptual prototype of the electronic board for a baby resuscitation device.
b) 3D printed ankle splint for baby. c) CPAP device for neonate.
d) Prototype of the electronic board for monitoring baby temperature.

It is necessary to highlight that the results of the developed projects are shared through the UBORA e-infrastructure, in the form of open-source projects, with all the relevant information of the specification and planning, conceptual design, implementation and operation phases, including datasheets, documents, CAD files and lists of components, for the promotion of collaborative design approaches. Besides, the e-infrastructure is created with the CDIO process in mind and supports biomedical designers (and in this case students) in their engineering design process. Figure 3 shows schematically part of the information shared through the e-infrastructure, as results from one of the projects developed in the “UBORA Design School”. The different work packages and tasks proposed within the e-infrastructure to guide designers / students (including motivating questions) can be appreciated on the left part of Figure 3 and constitute a balanced combination between the CDIO methodology and the systematic engineering design process proposed in ISO on “*Medical devices - Quality management systems - Requirements for regulatory purposes*”. The guided and collaborative process is from its conception arranged in order to promote straightforward, safe and standard-oriented developments. Our view is that open-source medical devices may turn out to be safer than those obtained through traditional processes, thanks to shared information and involvement of a larger number of experts in the development. To this end, teaching-learning activities as these UBORA Design Schools may prove fundamental, as they will help to achieve a new generation of biomedical engineers focused on open-source and collaborative developments.

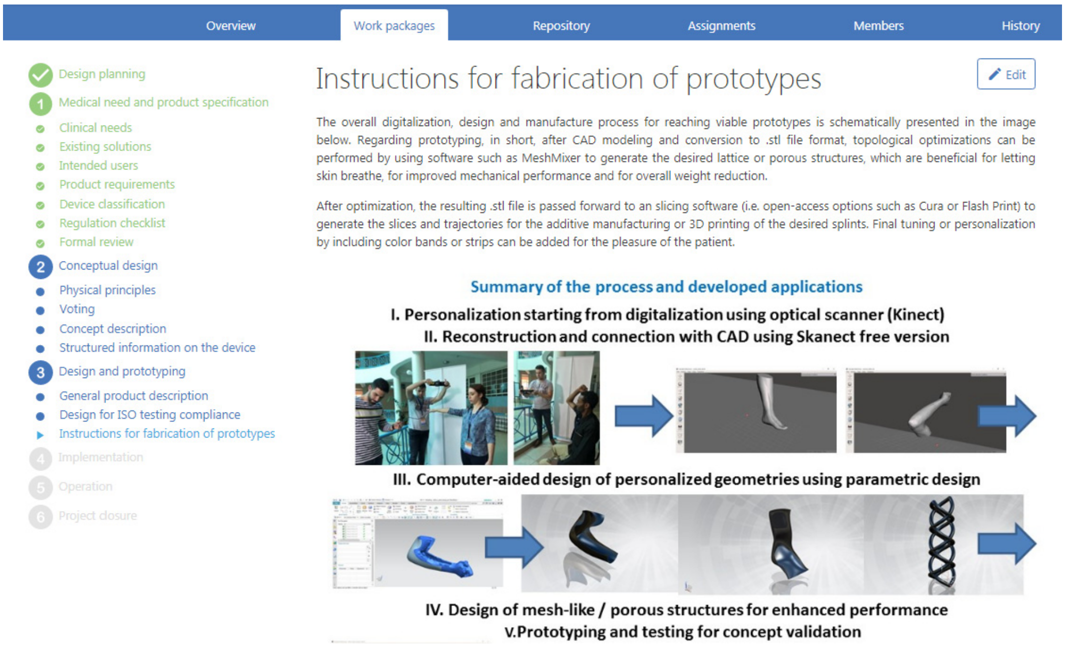

Figure 3. Example of a project developed within the UBORA e-infrastructure: Universal splint with list of work packages, tasks and design & prototyping description.

Some important lessons learned and remarkable good practices applied, thanks to taking into account the CDIO syllabus and standards during the implementation of the experience, are described in the following subsection, together with a description of current challenges and future proposals.

Connection to CDIO syllabus and standards, current challenges and future

One of our main concerns during the school was to let students live through a complete CDIO experience in just one week. To this end, teams were formed in advance by the coordinators. As there would be 40 participants and we wanted them to develop 8 medical devices, we formed teams of 5 students making sure that no team counted with more than one student from the same country and that an adequate gender balance was achieved. All teams counted with at least two European and two African students to promote the multiculturalism of the experience.

Regarding the tight schedule, the first day was devoted to working on the conceptual stage, the second was devoted to working on the conceptual design, the third was dedicated to designing the geometries and to starting with their manufacture, which was finalized along the fourth day, so as to reach the fifth day with devices ready to be tested, which corresponded to the operation stage of this "express CDIO" week. In accordance with this schedule, the lessons went from the more general aspects to the more specific ones and the workshops we varied to let us balance the different backgrounds.

The teaching materials developed, both from the lessons and workshops, will be made available through the online infrastructure, so as to support future express CDIO experiences in biomedical engineering. These teaching-learning resources, will serve us to implement massive open online courses and to balance the level of participants in of the design schools before their being developed, so as to better concentrate in the medical device developments. Besides training of mentors will be paid extra attention, according with CDIO standards 9 and 10.

As for the future, the second UBORA Design School will take place at the University of Pisa in September 2018, again counting with an international team of professors and mentors and with students selected worldwide after the results of the second UBORA Design Competition (http://ubora-biomedical.org/design-competition-2018). The topic for such second UBORA Design School is “promotion of healthy ageing” and will deal with solutions aimed at letting individuals live longer and healthier lives covering also devices used in treatments of age-related diseases, syndromes and disabilities.

The more relevant challenge we now face is the long-term sustainability of the “UBORA Design Schools”, as these international educational experiences, requiring mobility of students and professors from across the World need some sort of funding or sponsorship for performing in adequate conditions. After the two first ones (Nairobi 2017 and Pisa 2018), funded by the UBORA EU project, we expect to have generated enough international impact, so as to make these experiences clearly sustainable.

We will search for sufficient sponsorship from universities, consortia, organizations and engineering companies for being able to implement the following ones. To this end, the role of already created consortia (i.e. UBORA and ABEC), the continued support of UNECA and of the EU Commission and the impact of original mobility schemes and projects (i.e. ABEM: https://www.africanbmemobility.org) will prove essential for transforming BME and its education towards open-source approaches linked to equitable access to healthcare technology (De Maria, 2014, 2015), also in connection with “engineering education for all” concepts (Díaz Lantada, 2016).

CONCLUSIONS

We have presented the conception, implementation and main results of the first “UBORA Design School”, an intensive complete CDIO experience in just one week devoted to the development of biomedical devices. This experience is the first of a series of international CDIO-related schools aimed at establishing new methods for teaching-learning in the biomedical engineering field and connected with open-source medical devices and with the democratization of medical technology towards equitable healthcare. This first “UBORA Design School” took place in December 2017 at Kenyatta University, where 40 students and a team of 15 professors-mentors joined for living a passionate week of collaboration. The CDIO approach has proven effective for truly achieving the desired holistic teaching-learning experience. All teams were able to complete their designs and reach, at least, conceptual prototypes for validating the designs. In some cases the solutions are almost ready for mass-production or mass-personalization, which may be achieved in the future, as these devices will be completely shared following open-source strategies and using the UBORA e-infrastructure**.

These UBORA Design Schools try to achieve an equilibrium between theory (experts’ lessons) and practice (case studies and CDIO projects), so as to introduce students to the complex issues that arise in the development of medical devices. In forthcoming editions we will promote and support these biomedical “express-CDIO” schools with additional educational activities, including MOOCs, additional competitions or derived final degree theses and we hope that these actuations may help us to achieve improved student mobility and joint degrees in Biomedical Engineering.

We expect that the International CDIO Initiative may hence be additionally promoted across EU and African countries and that it may provide a framework for the future of Biomedical Engineering Education.

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BIOGRAPHICAL INFORMATION

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