Safety by open design

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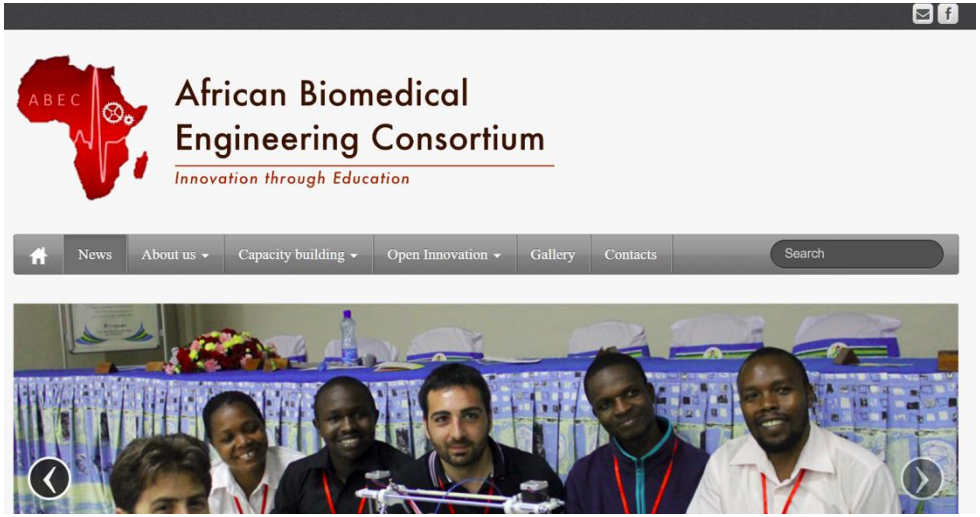
Background

- UNECA recognises the **importance of Biomedical Engineering** for improving healthcare in Africa (2011)
- University of Pisa invited to attend the first summer school at Kyambogo University (2012)
- **Creation of ABEC** (2012) and focus on Africa-relevant BME



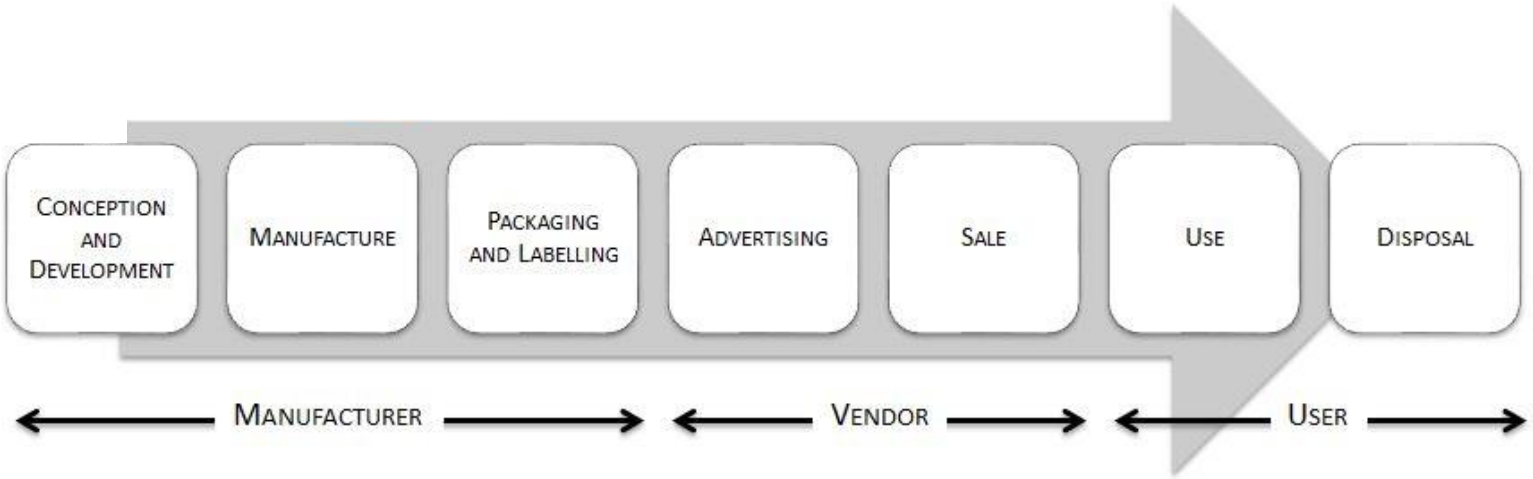
ABEC
African Biomedical
Engineering Consortium
Innovation through Education

United Nations
Economic Commission
for Africa

Background

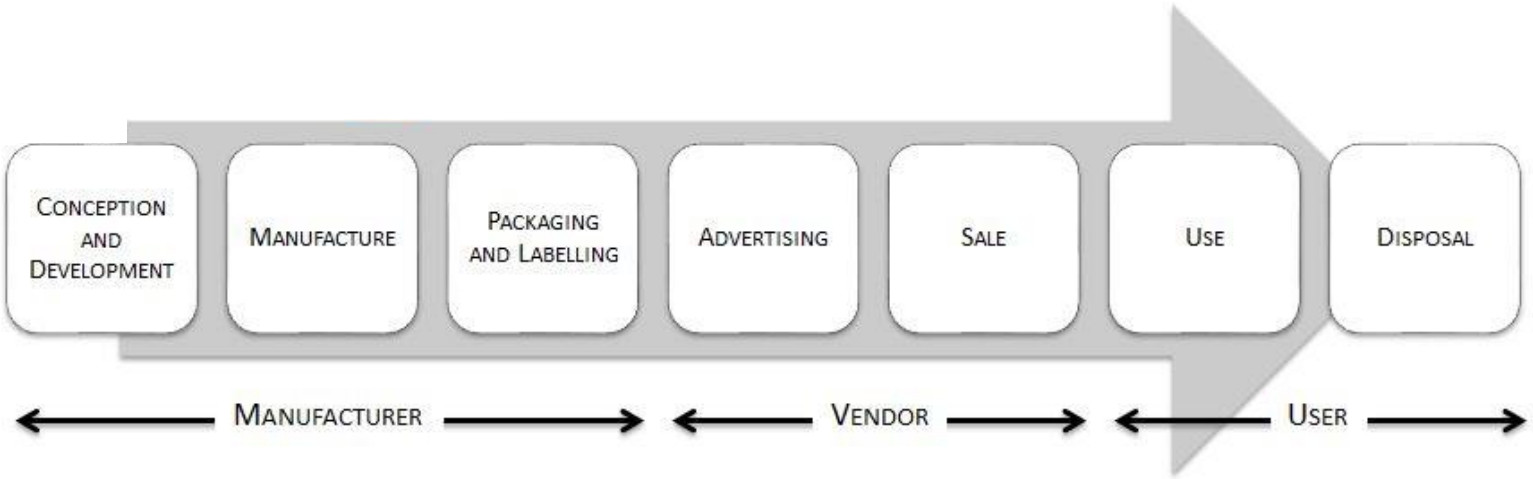
	1st ISS	2nd ISS	3rd ISS	4th ISS	5th ISS
Period	2012	2013	2014	2016	2017
Place	Kampala (Uganda)	Nairobi (Kenya)	Dar Es Salam (Tanzania)	Addis Ababa (Ethiopia)	Cairo (Egypt)
Hosting Institution	Kyambogo University	Kenyatta University	Muhimbili University of health and Allied Science	Addis Ababa Institute of technology	Cairo University
Topic	Universities formed the Africa Biomedical Engineering Cons ortium (ABEC)	Introduction to Biomedical Device Regulation s and Rapid Prototyping	From Making to Marketing	Application of mobile phones in healthcare product design and development	Biomedical and Clinical Data and Informatics for Development in Africa

Life cycle of a medical device



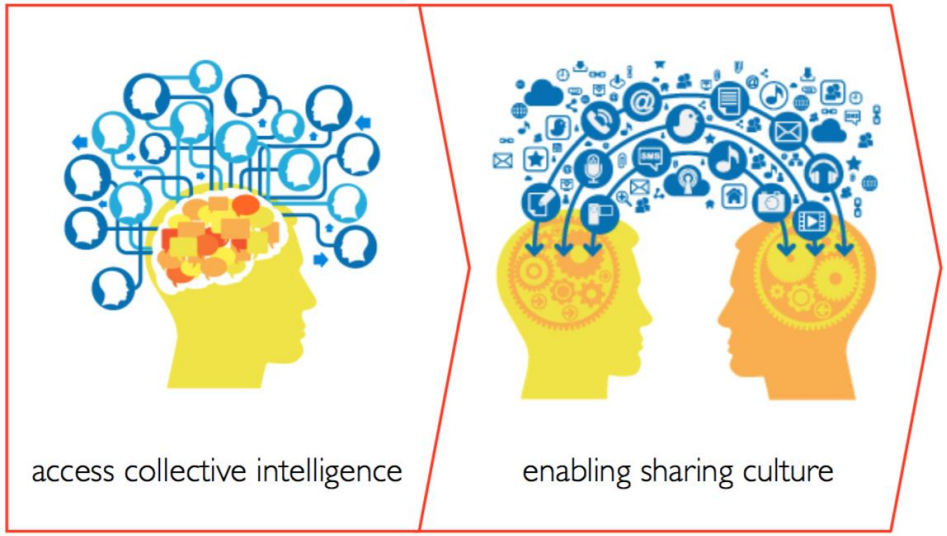
- Defined on the basis of the **intended use**
- Classification and Certification (I, IIa, IIb, III)
- Risk management: ensuring safety of patients, users, bystanders, healthcare providers, environment
- High cost!

Life cycle of a medical device



- Defined on the basis of the **intended use**
- Classification and Certification (I, IIa, IIb, III)
- Risk management: ensuring safety of patients, users, bystanders, healthcare providers, environment
- High cost! → Use open source approach and appropriate technologies for reducing development cost!

Safety and innovation by open and collaborative design



What: Developing a medical device by sharing ideas and concepts, design files, documentation, source-codes, blueprints and prototypes, testing results and all collected data

Why: accessibility, sustainability, lower costs, improved performance and safety because everyone can review the design dossier

HOW

- Open access **e-infrastructure**
  - Innovators and designers create a profile
- **Open source design**
  - No IP protection, Open Data on device performance, blueprints
- **Compliant** with EC Medical Device Regulation
- **Peer-to-peer** review
  - e-infrastructure allows open access to all designs under development
- Expert, open **mentoring** from Academia and Industry
- **Needs based Design**

Quality means safety

- Quality and safety guidelines for biomedical devices, under the guidance of **international standards and European MDD (soon MDR)**, are the foundations
  - Technical state-of-the-art in safety
- Expert mentoring will ensure that the designs comply to highest technical standards at all steps
  - Mentors from **Academia and Industry**

Open means:

- Sharing of **open data** on device statistics (performance, field tests, quality control)
- Sharing of mentor comments **and design errors or dead ends**
- **Needs based design** on the highest priority medical devices backed with research on current disease burdens

UBORA

Open source co-design of new solutions to face the current and future global healthcare challenges

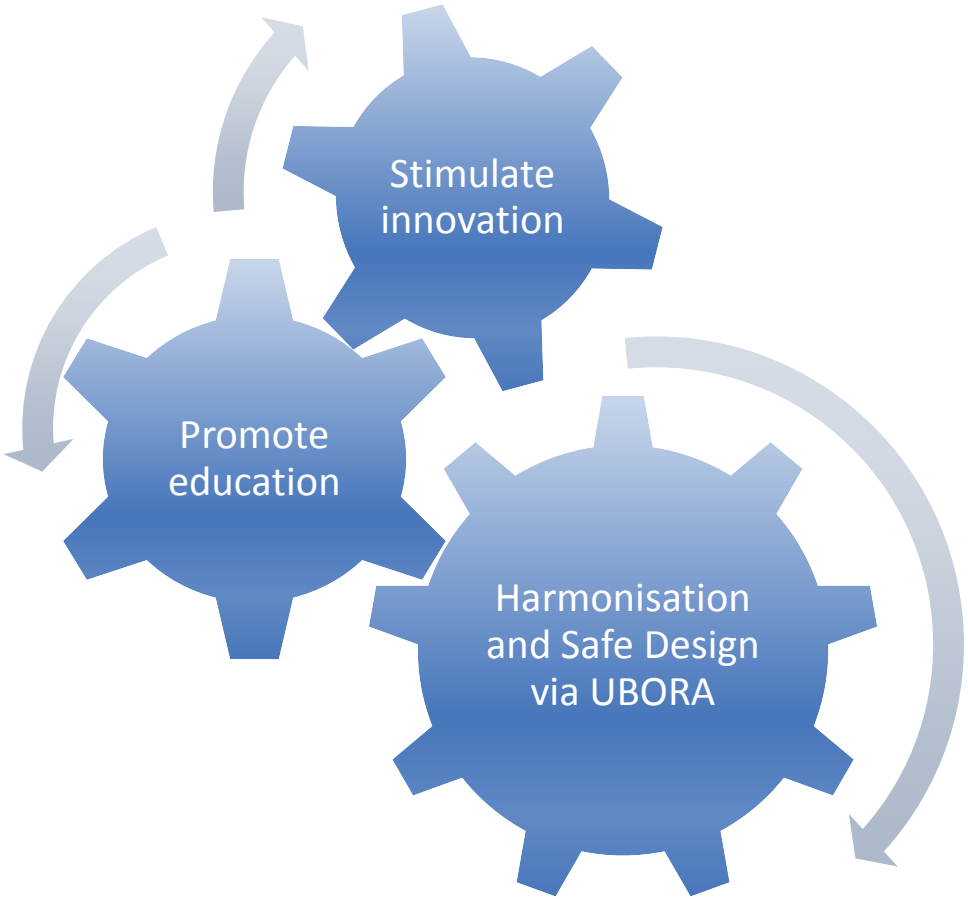
BY

Exploiting networking, **knowledge** on rapid prototyping of new ideas and **sharing** of **safety** criteria and performance data

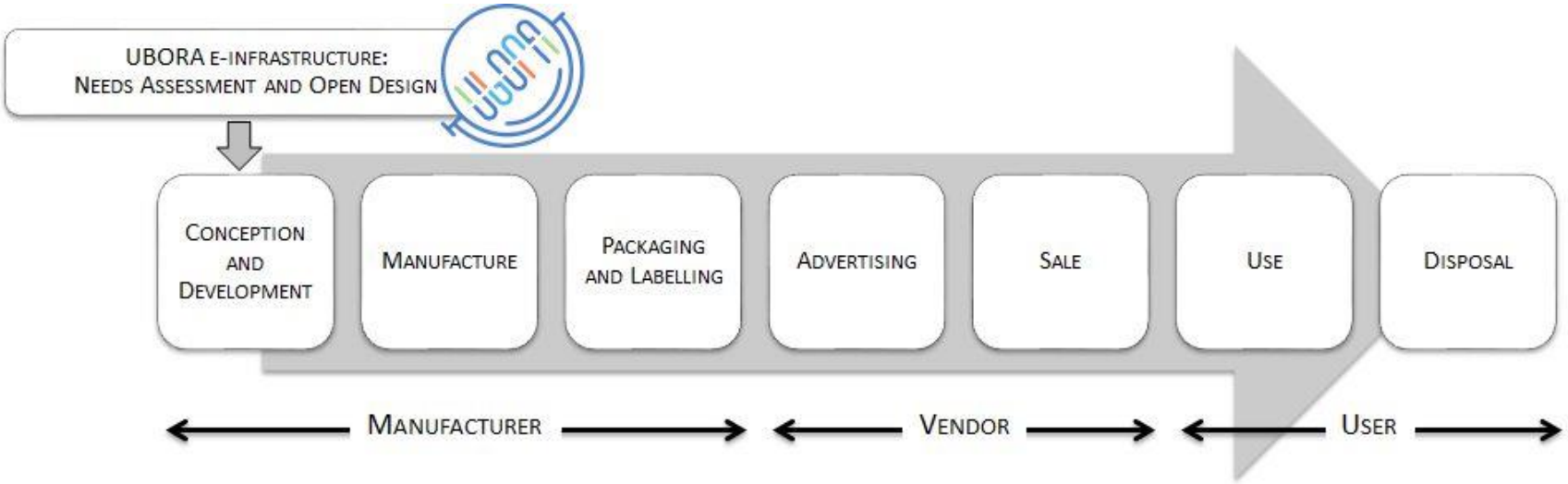
THROUGH

A open e-Infrastructure, **UBORA**

UBORA: Our objectives

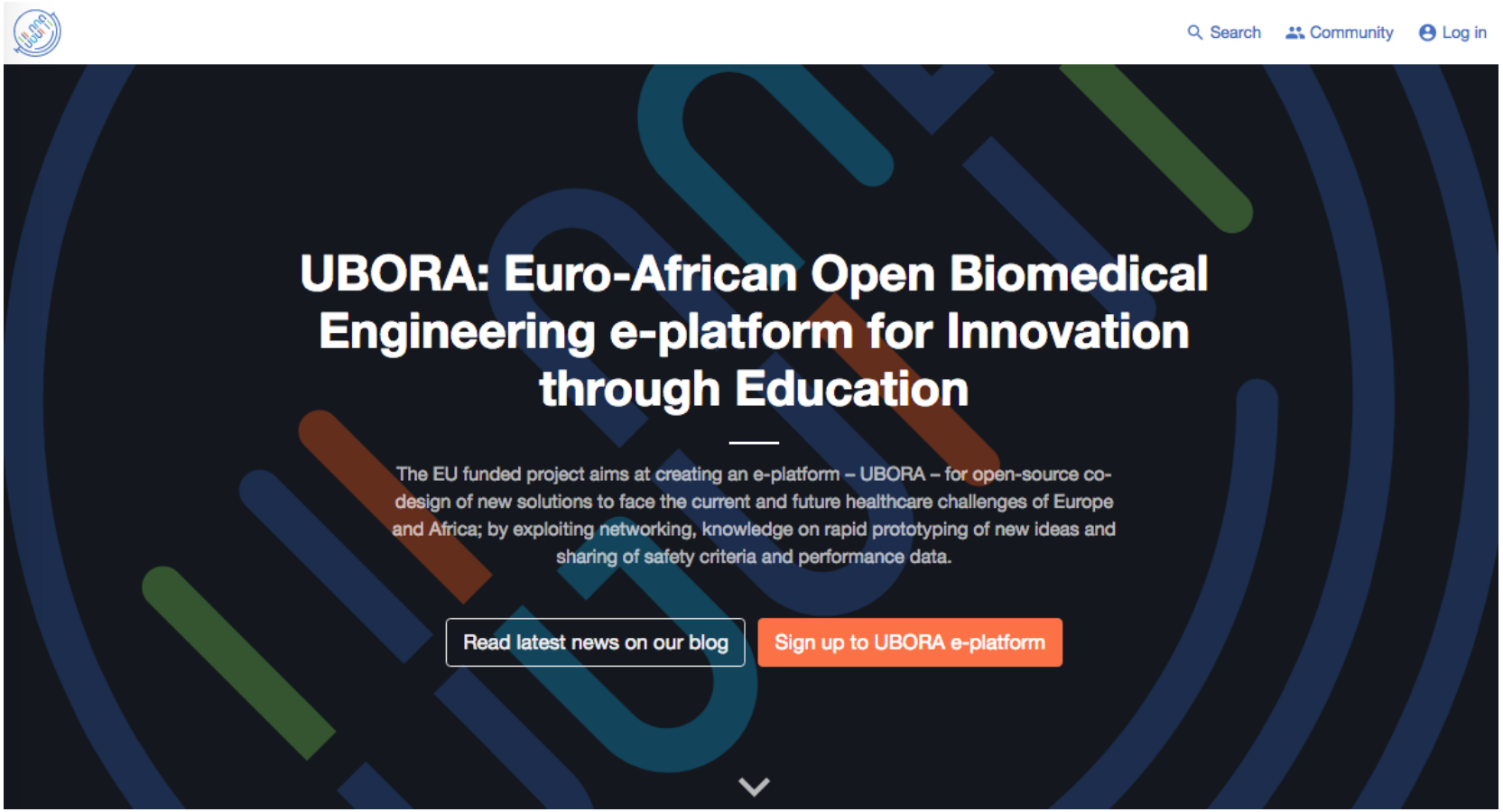


UBORA in the life cycle of a medical device



Use open source approach and appropriate technologies for reducing development costs and increasing safety!

UBORA e-Infrastructure



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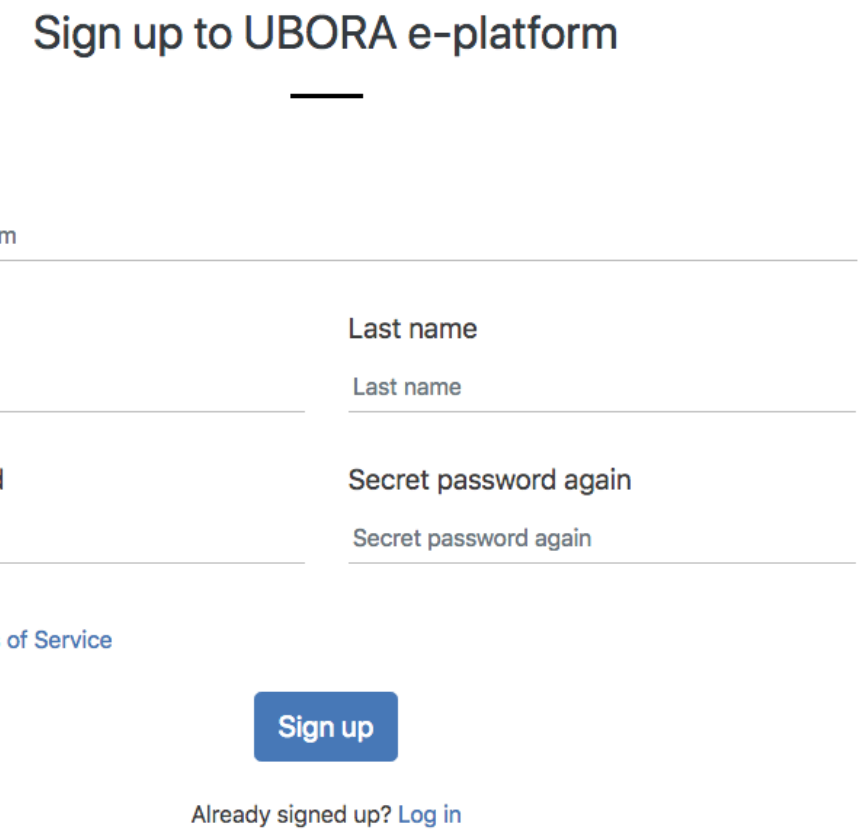
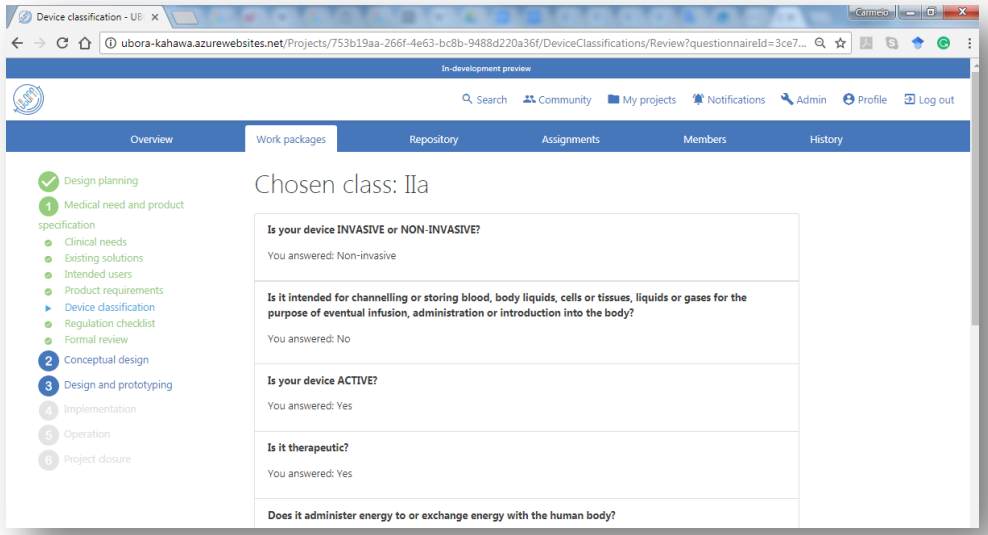
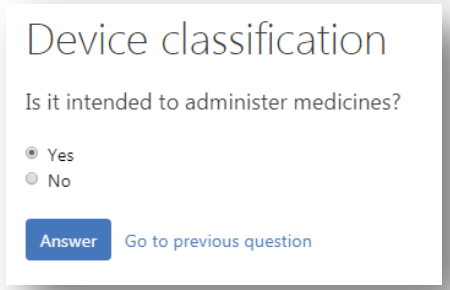
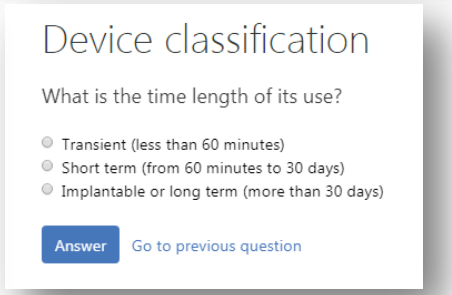


UBORA e-infrastructure: Risk Classification

- Classification according to the Medical Device Regulation MDR 2017/745
  - From I (Low Risk) to III (High Risk)
  - Decision tree with 30 questions (mainly binary, e.g. Yes/No)
  - Validated with the help of expert consultant

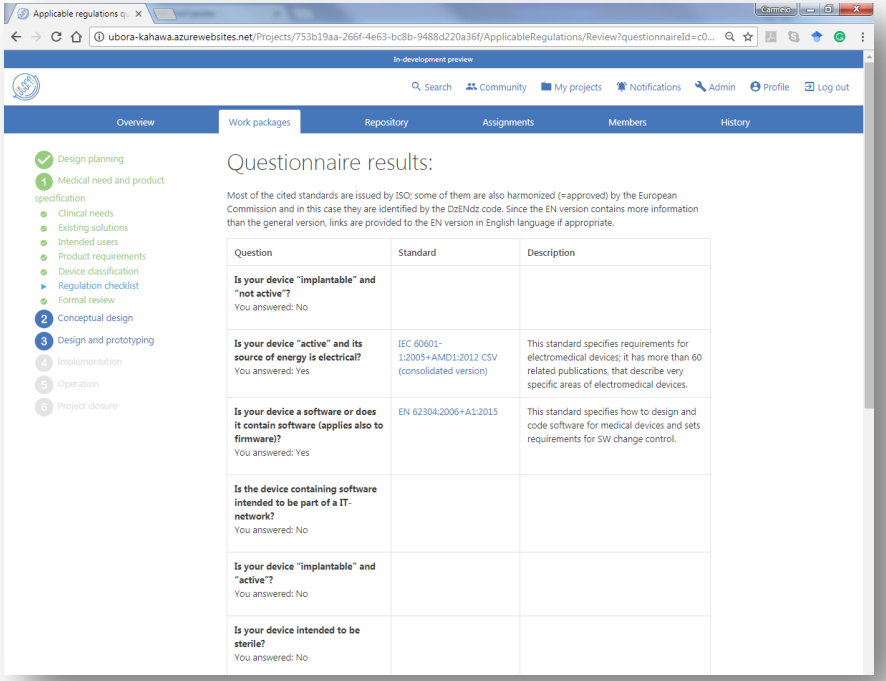






UBORA e-infrastructure: Standard identification

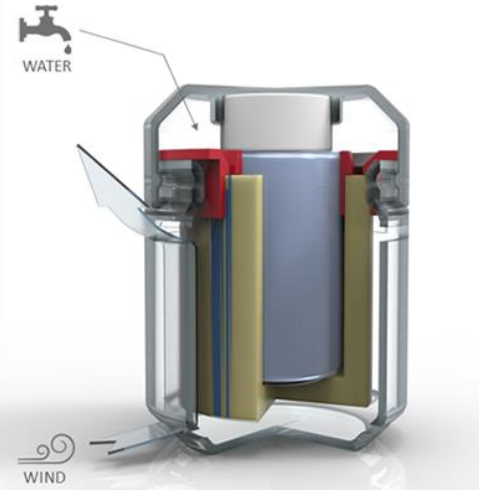
- Identification of **Horizontal Standards** applicable to a Medical Device
  - Focused on the «ontology» of the device
  - Hard to identify using keywords in a search engine
  - Decision tree with 30 questions (mainly binary, e.g. Yes/No)
  - ISO and IEC standards
  - Validated with the help of expert consultants



UBORA e-Infrastructure: examples

Projects collaborated on UBORA e-platform

UBORA features a project collaboration tool to guide the process of developing a biomedical device in an open-source manner that is in accordance with the international safety standards. All projects are overlooked by the UBORA certified mentors. You can freely create a new project or join existing ones to start collaborating with the community.



Breast Pump

Economic and Ecological Breast Pump with Cooling and Preservation System of the Breastmilk. The project consists in a manual breast pump with an air-water cooling system.

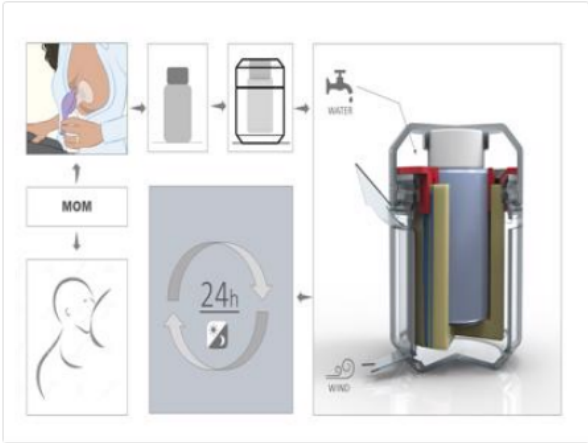
Clinical need:	Prevention of pathology or disease
Area:	Pediatrics
Device classification:	IIa

View project →

UBORA e-Infrastructure: examples

Economic and Ecological Breast Pump with Cooling and Preservation System of the Breastmilk

Draft



Medical tags

Clinical need:	Prevention of pathology or disease
Clinical area:	Pediatrics

Project description

The leading causes of deaths in children under 5 are: pneumonia, diarrhoea, sepsis e severe malnutrition. Breastmilk is more than just food for babies – it is also a potent medicine for diseases prevention that is tailored to the needs of each child. Breastfed babies are less susceptible to ear infections, diarrhoea, pneumonia and other childhood illnesses.

Our project fights not necessary and wrong use of artificial milk, caused by mother's illiteracy or poverty and use of unsafe water. It supports women who choose to breastfeed assisting breastmilk production and preservation without electric energy.

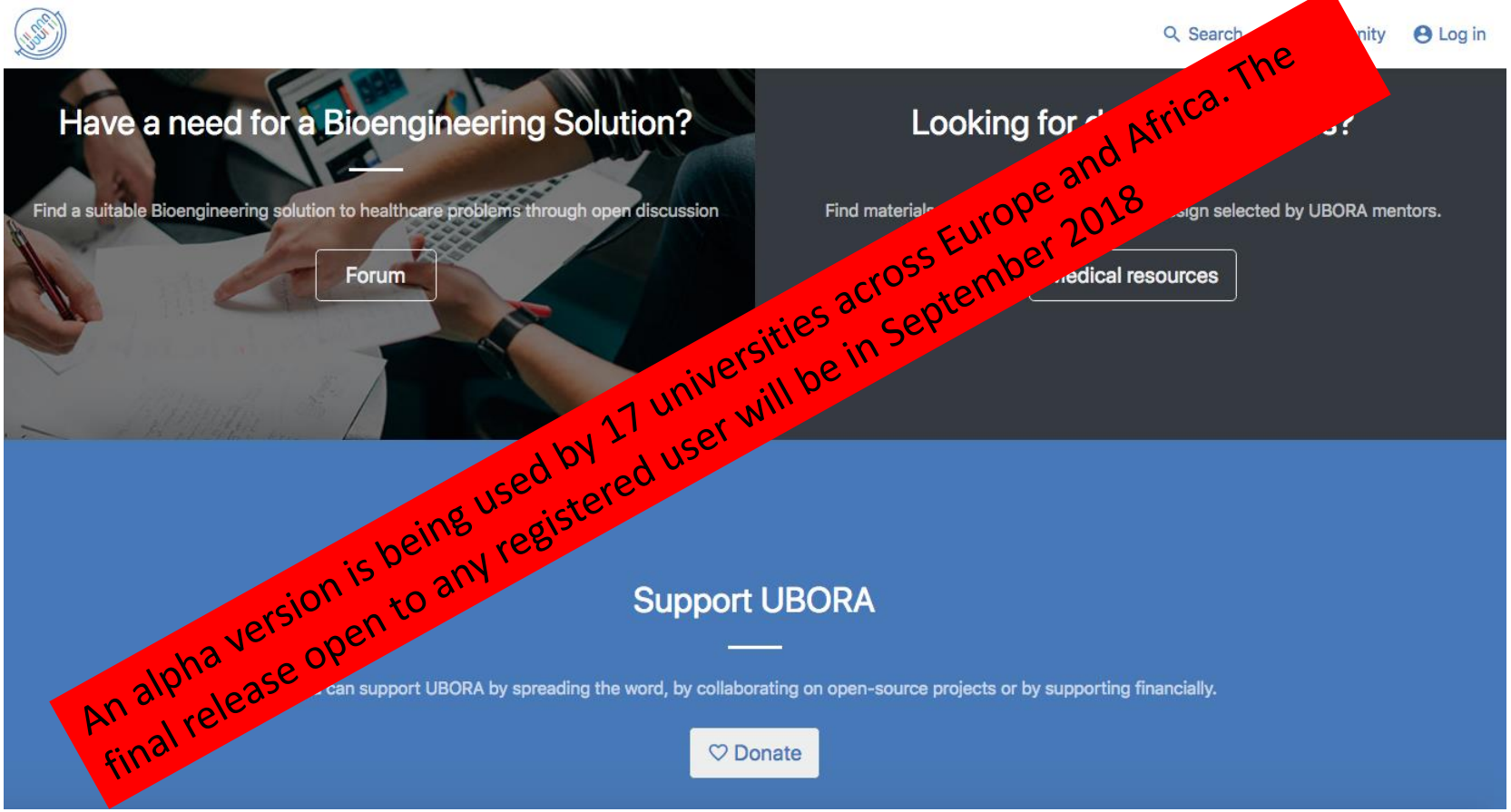
Addressed target population is developing country population.

The project consists in a manual breast pump with an air-water cooling system. Through the water evaporation the collected breastmilk is cooled and preserved at 15°C for 24 h, 5 times more than the storage time at room temperature.

Our technology is very easy and cheap to be accessible to illiterate and poor people as well. The cooling system is made with the smallest possible number of pieces and it is very easy to assemble and clean. The instruction book will present only images, without words.

The system works and is made only with available, economic and recyclable materials to be completely sustainable.

UBORA e-Infrastructure



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Safe innovation: On medical device legislation in Europe and Africa

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KEYWORDS
Medical devices regulation;
Standards;
Africa;
Europe;
Open Source Medical Devices

Abstract
Objectives: The principal motivation for regulating medical devices is to protect patients and users. Complying with regulations may result in an increase in development, manufacturing and service costs for medical companies and ultimately for healthcare providers and patients, limiting the access to adequate medical equipment. On the other hand, poor regulatory control has resulted in the use of substandard devices. This study aims at comparing the certification route that manufactures have to respect for marketing a medical device in some African Countries and in European Union.
Methods: We examined and compared the current and future regulations on medical devices in the European Union and in some countries in Africa. Contextually we proposed future approaches to open design strategies supported by emerging technologies as a means to enhance economically sustainable healthcare system driven by innovation.
Results: African medical device regulations have an affinity to European directives, despite the fact that the latter are particularly strict. Several states have also implemented or harmonized directives to medical device regulation, or have expressed interest in establishing them in their legislation. Open Source Medical Devices hold a great promise to reduce costs but do need a high level of supervision, to control their quality and to guarantee their respect for safety standards.
Conclusion: Harmonization across the two continents could be leveraged to optimize the costs

Thank You!

UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education

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