



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

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

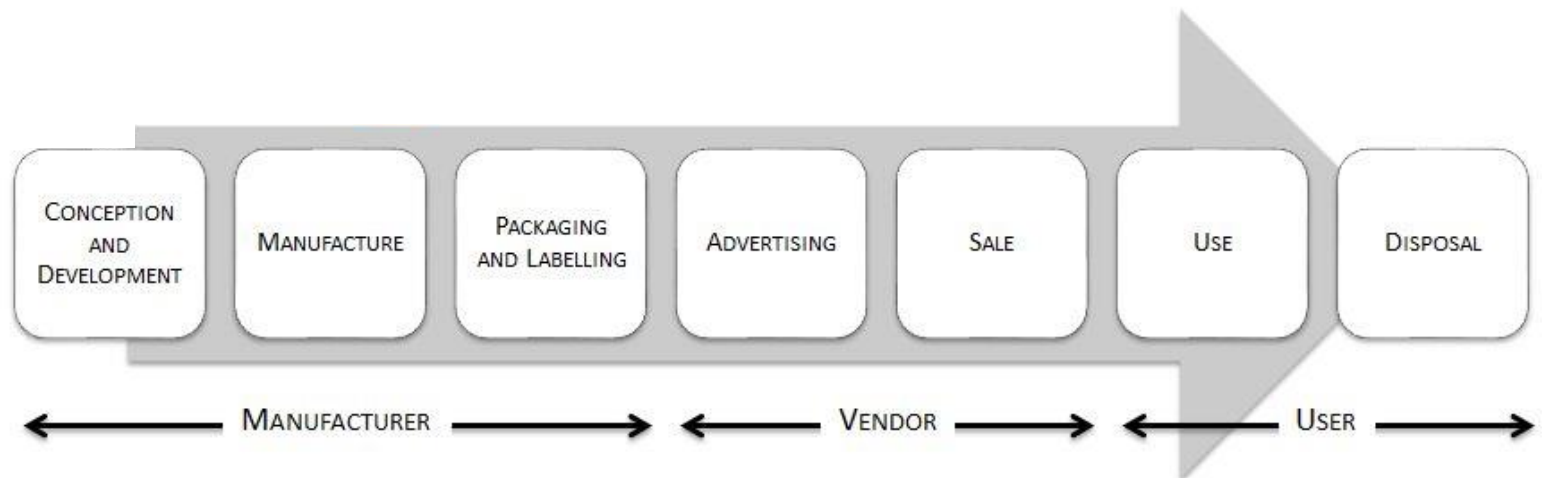


Background



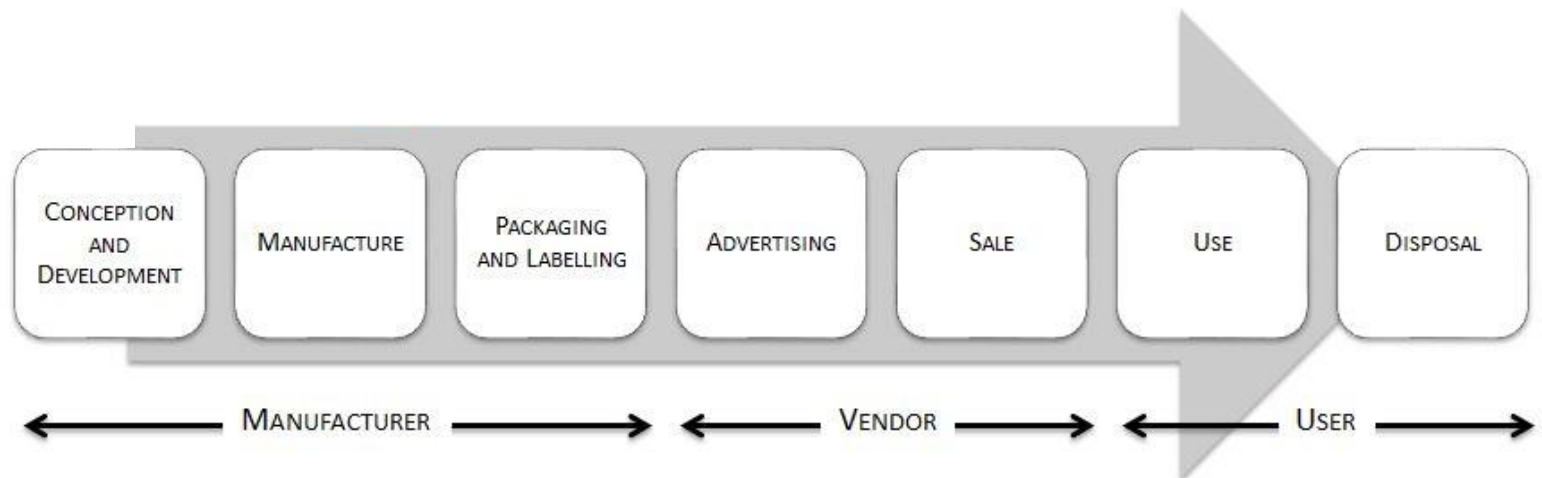
	1 st ISS	2 nd ISS	3 rd ISS	4 th ISS	5 th ISS
Period	2012	2013	2014	2016	2017
Place	Kampala (Uganda)	Nairobi (Kenya)	Dar Es Salam (Tanzania)	Addis Ababa (Ethiopia)	Cairo (Egypt)
Hosting Institution	Kyambogo University	Kenyatta University	Muhimbili University of health and Allied Science	Addis Ababa Institute of technology	Cairo University
Topic	Universities formed the Africa Biomedical Engineering Consortium (ABEC)	Introduction to Biomedical Device Regulations 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



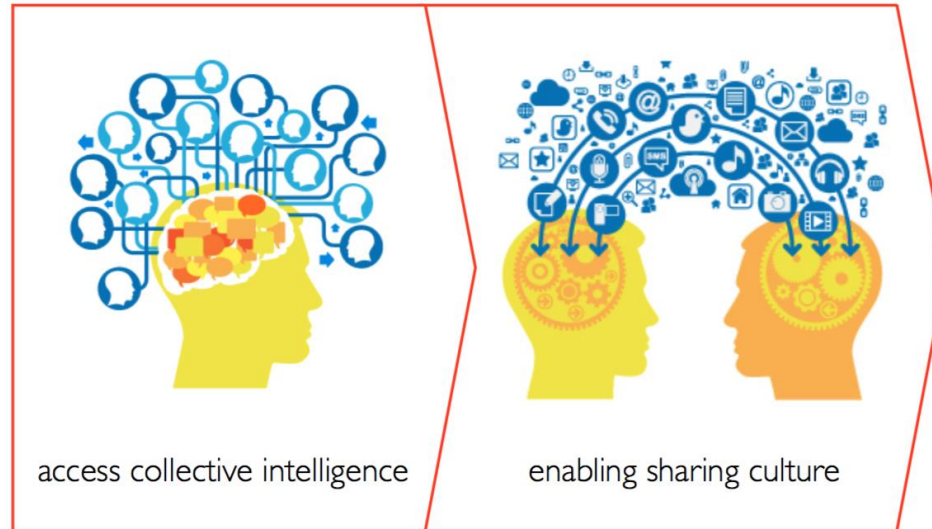
- Defined on the basis of the **intended use**
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High cost!



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



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

BY

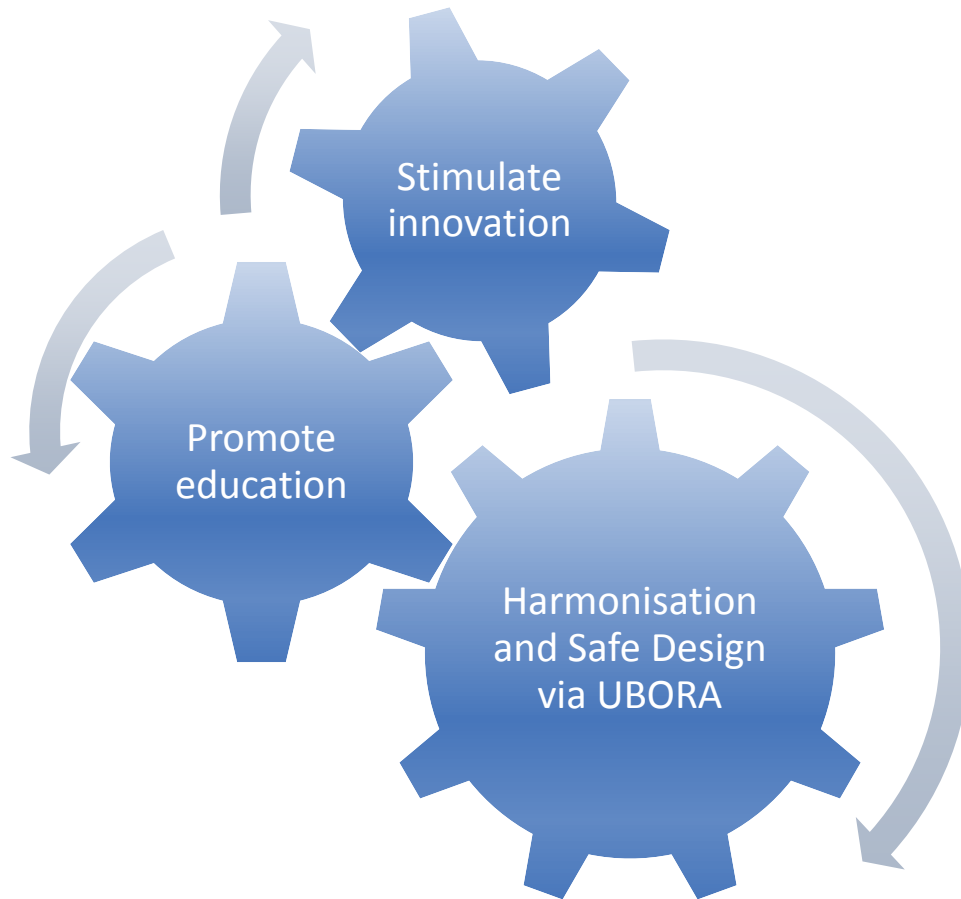
Exploiting networking, **knowledge** on rapid prototyping of new ideas and **sharing** of **safety** criteria and performance data

THROUGH

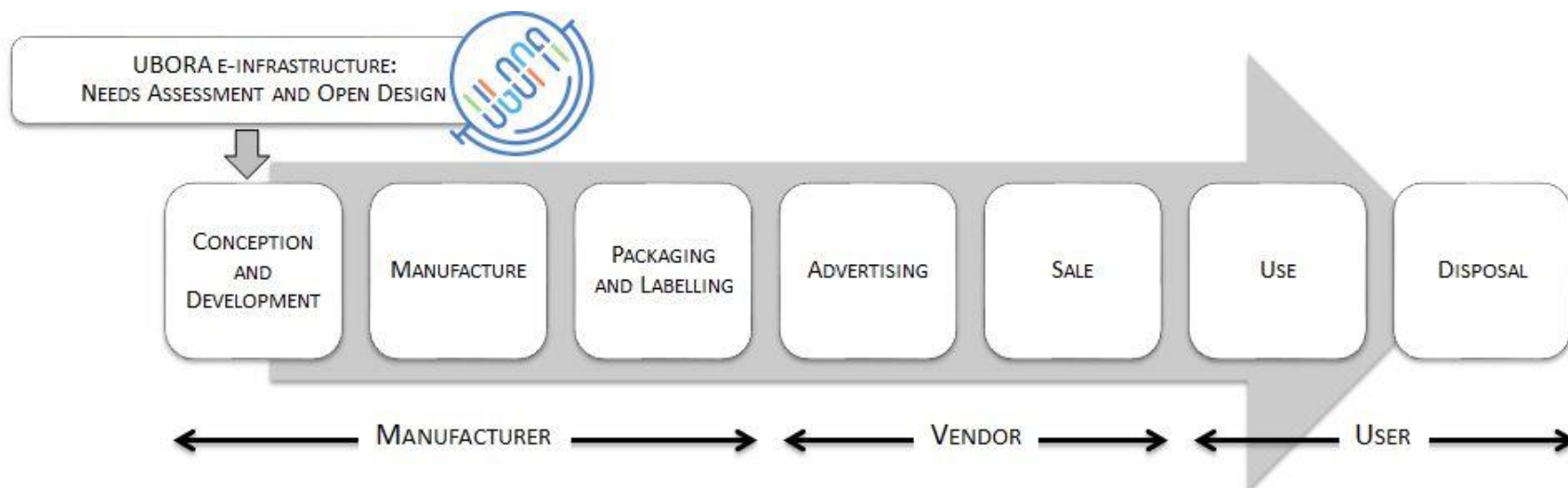
A open e-Infrastructure, **UBORA**



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



[Search](#) [Community](#) [Log in](#)

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

The EU funded project aims at creating an e-platform – 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.

[Read latest news on our blog](#)

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UBORA e-Infrastructure



Sign up to UBORA e-platform

Email address

email@example.com

First name

First name

Last name

Last name

Secret password

Secret password

Secret password again

Secret password again

☐ I agree to [Terms of Service](#)

Sign up

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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

Device classification

Is it intended to administer medicines?

- ☒ Yes
☐ No

[Answer](#) [Go to previous question](#)

Device classification

What is the time length of its use?

- ☐ Transient (less than 60 minutes)
☐ Short term (from 60 minutes to 30 days)
☐ Implantable or long term (more than 30 days)

[Answer](#) [Go to previous question](#)

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

The screenshot displays a web application interface for 'Applicable regulations'. The top navigation bar includes 'Search', 'Community', 'My projects', 'Notifications', 'Admin', 'Profile', and 'Log out'. The main content area is titled 'Questionnaire results:' and contains a table with three columns: 'Question', 'Standard', and 'Description'. The table lists several questions related to medical device standards, such as 'Is your device "implantable" and "not active"?' and 'Is your device "active" and its source of energy is electrical?'. The 'Standard' column lists specific standards like 'IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)' and 'EN 62304:2006+A1:2015'. The 'Description' column provides brief explanations of these standards. A sidebar on the left shows a progress indicator for various stages of the process, including 'Design planning', 'Medical need and product specification', 'Conceptual design', 'Design and prototyping', 'Implementation', 'Operation', and 'Project closure'.

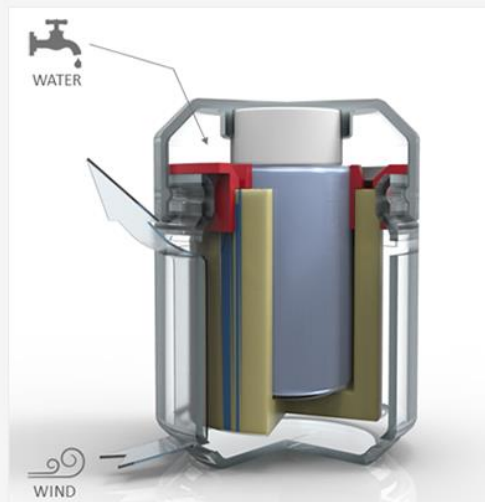
Question	Standard	Description
Is your device "implantable" and "not active"? You answered: No		
Is your device "active" and its source of energy is electrical? You answered: Yes	IEC 60601-1:2005+AMD1:2012 CSV (consolidated version)	This standard specifies requirements for electromedical devices; it has more than 60 related publications, that describe very specific areas of electromedical devices.
Is your device a software or does it contain software (applies also to firmware)? You answered: Yes	EN 62304:2006+A1:2015	This standard specifies how to design and code software for medical devices and sets requirements for SW change control.
Is the device containing software intended to be part of a IT-network? You answered: No		
Is your device "implantable" and "active"? You answered: No		
Is your device intended to be sterilized? You answered: No		





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:	Ila

[View project →](#)



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



UBORA

Search Community Log in

Have a need for a Bioengineering Solution?

Find a suitable Bioengineering solution to healthcare problems through open discussion

Forum

Looking for...

Find materials... Design selected by UBORA mentors.

Medical resources

An alpha version is being used by 17 universities across Europe and Africa. The final release open to any registered user will be in September 2018

Support UBORA

You can support UBORA by spreading the word, by collaborating on open-source projects or by supporting financially.

Donate

Conference: 1-2 September 2018



CALL DEADLINE:
June 30, 2018



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 manufacturers 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!



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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 731053

