

ENGINEERING in
MEDICINE and BIOLOGY

BIOMEDICAL ENGINEERING RANGING
FROM WELLNESS TO INTENSIVE CARE MEDICINE

July 23-27
41st **EMB** CONFERENCE 2019
BERLIN



CO-DESIGN OPEN-SOURCE MEDICAL DEVICES: HOW TO MINIMIZE THE HUMAN ERROR USING UBORA E-INFRASTRUCTURE

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



Centro E. Piaggio
bioengineering and robotics research center



DIPARTIMENTO DI
INGEGNERIA
DELL'INFORMAZIONE



UNIVERSITÀ DI PISA

Access to health products is in SDG3



SUSTAINABLE DEVELOPMENT GOALS

Medical devices are required to achieve SDG3:

- universal health coverage,
- Including financial risk protection,
- access to quality essential healthcare services.



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What is a medical device?



MDR 2017/745 Article 2 (1)

“Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes...”[7]

Diagnosis of disease



<http://www.mobisante.com>

Replacement of the anatomy



<https://www.ottobock.co.uk/>

Treatment of disease



<https://www.designthatmatters.org/firefly>

Compensation for disability



<https://corsuhospital.org/>





Challenges of medical devices in developing countries

The WHO estimates that 70% of medical equipment coming from the most developed nations not work in developing world hospitals [1].

Over 95% of medical equipment in public hospitals is imported. There is no local production of medical equipment [2].

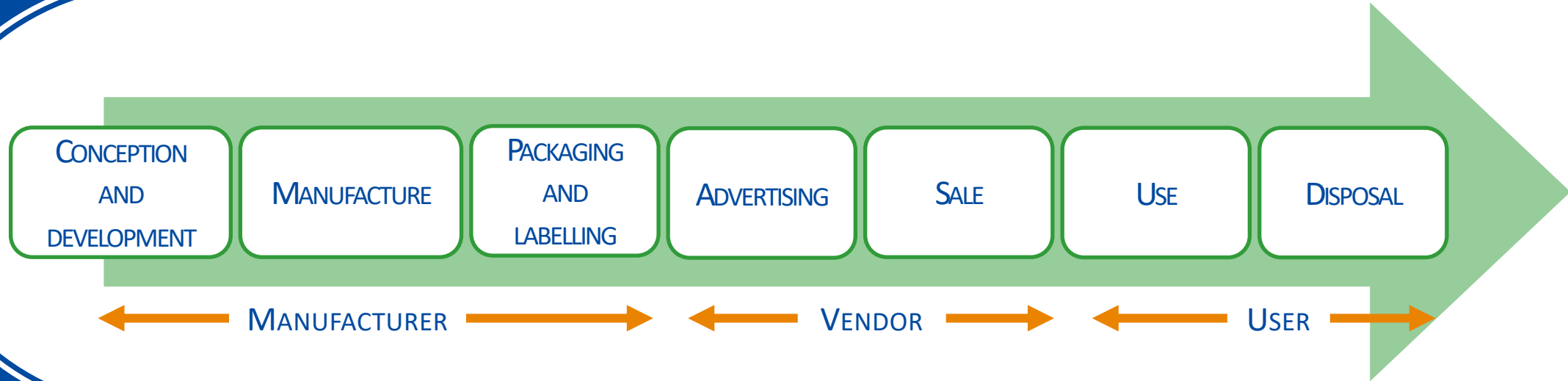
Imported equipment of poor quality, 96% is not working just 5 years after donation and 39% never worked due to lack of training, manuals or accessories [3].

Lack of spare parts, consumables and trained technical staff [4].

Lack of reliable power supply and water [5].

Doctors have adapted their practice to developing world conditions engineers **have not** developed medical equipment design practices for developing world conditions [6].

Life cycle of medical device

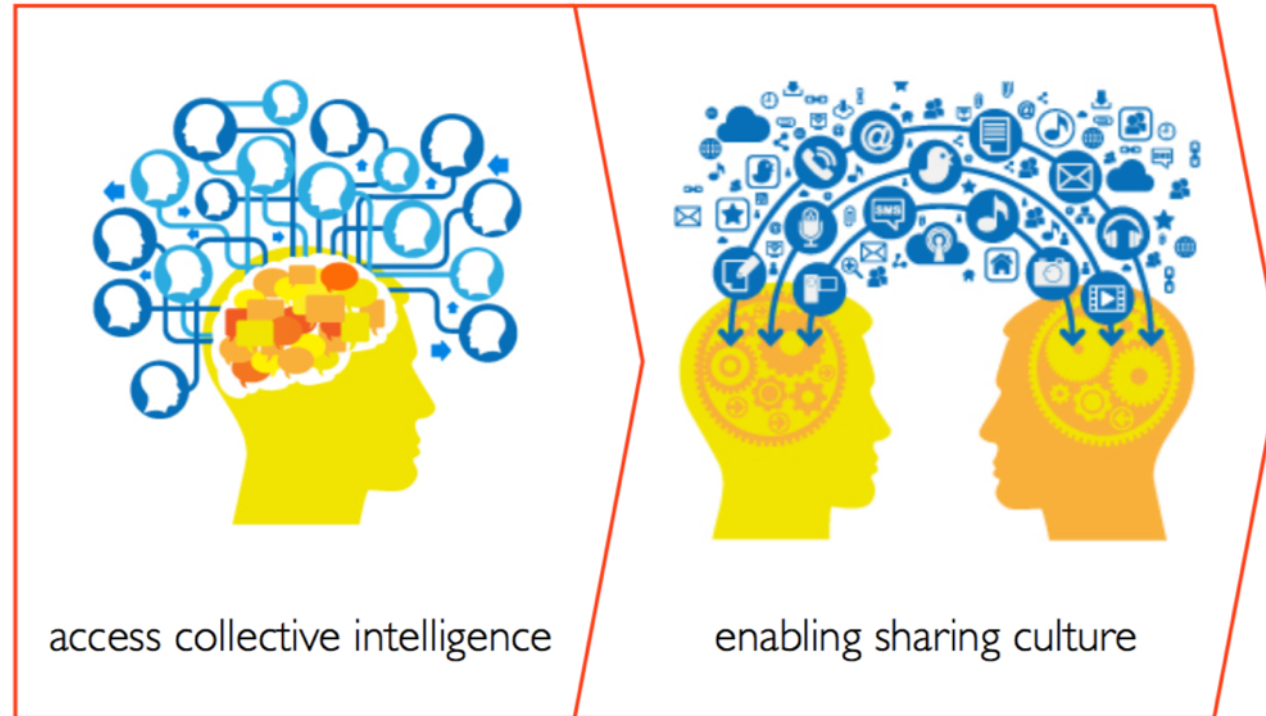


- Defined on the basis of the **intended use**
- Safety and efficacy
- Classification and Certification (I, IIa, IIb, III)
- Risk management: ensuring safety of patients, users, bystanders, healthcare providers, environment





Open and collaborative design



The open source approach results into:

- accessibility, sustainability, improved performance, reliability and safety.

Everyone can review the design dossier.



Open source 3D printing



<http://enablingthefuture.org/>

What is Open source?

<https://github.com/GliaX/Stethoscope>



Gallup, et al (2018).. *Geriatrics*, 3(4), 89.

- Sharing of “blueprints”
- Sharing of open data on device statistics
- Sharing of [design errors or dead ends](#)
- Needs based design

Gallup, et al (2018).. *Geriatrics*, 3(4), 89.





UBORA: 'Excellence' in Swahili

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

THROUGH

An EU-Africa e-Infrastructure, **UBORA**



The UBORA approach

Empowering open source approach

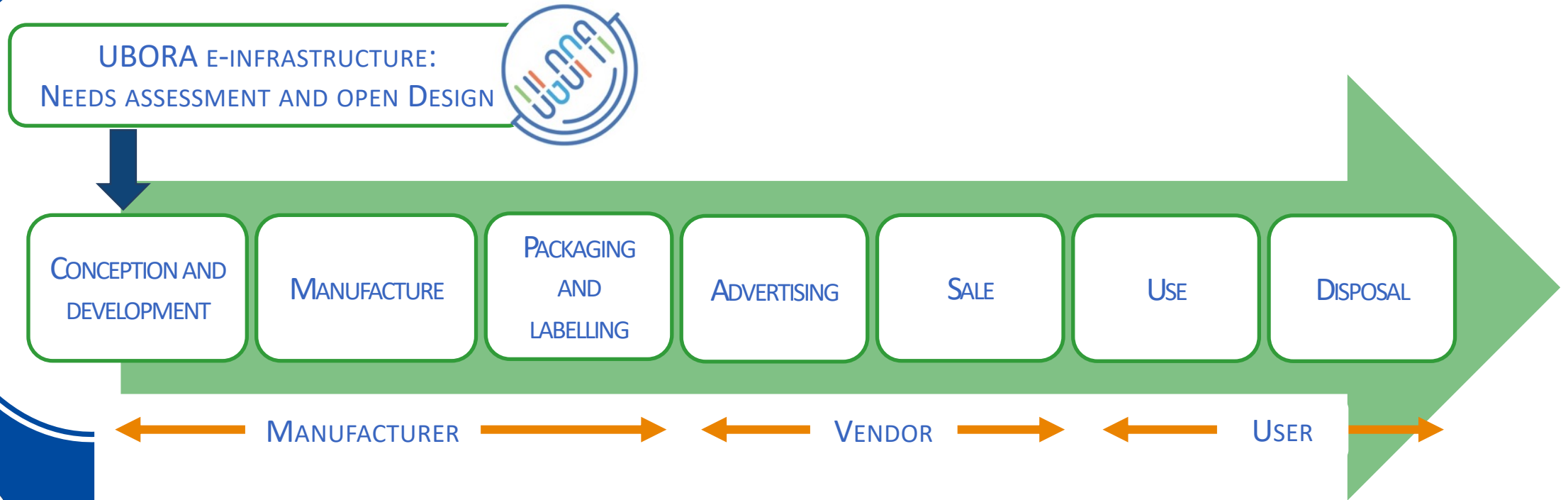
- Quality and safety guidelines for biomedical devices, under the guidance of international standards and European MDR are the foundations.
- Expert mentoring will ensure that the designs comply to highest technical standards at all steps.
- Mentors from Academia and Industry.



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



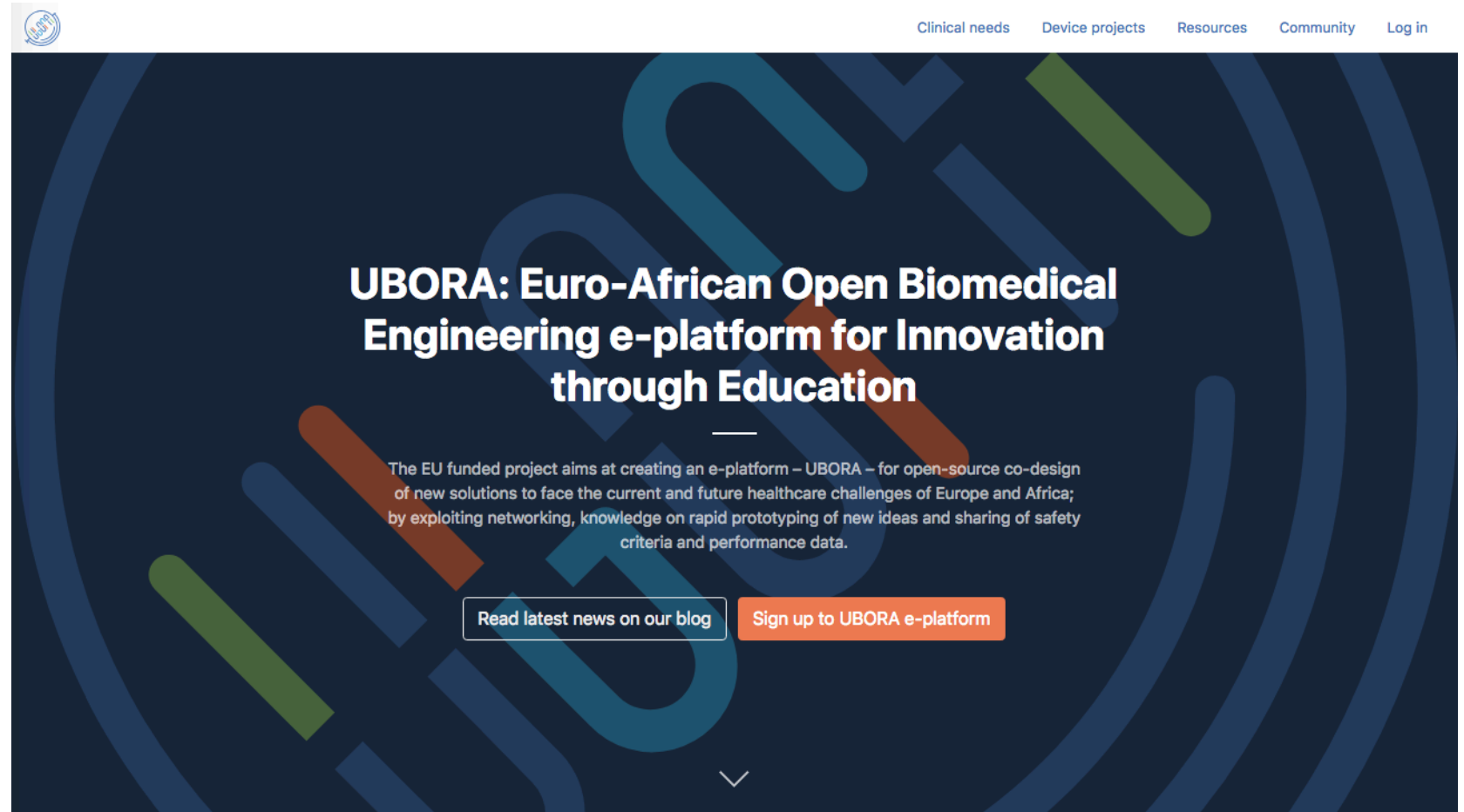
UBORA in the life cycle of medical device



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

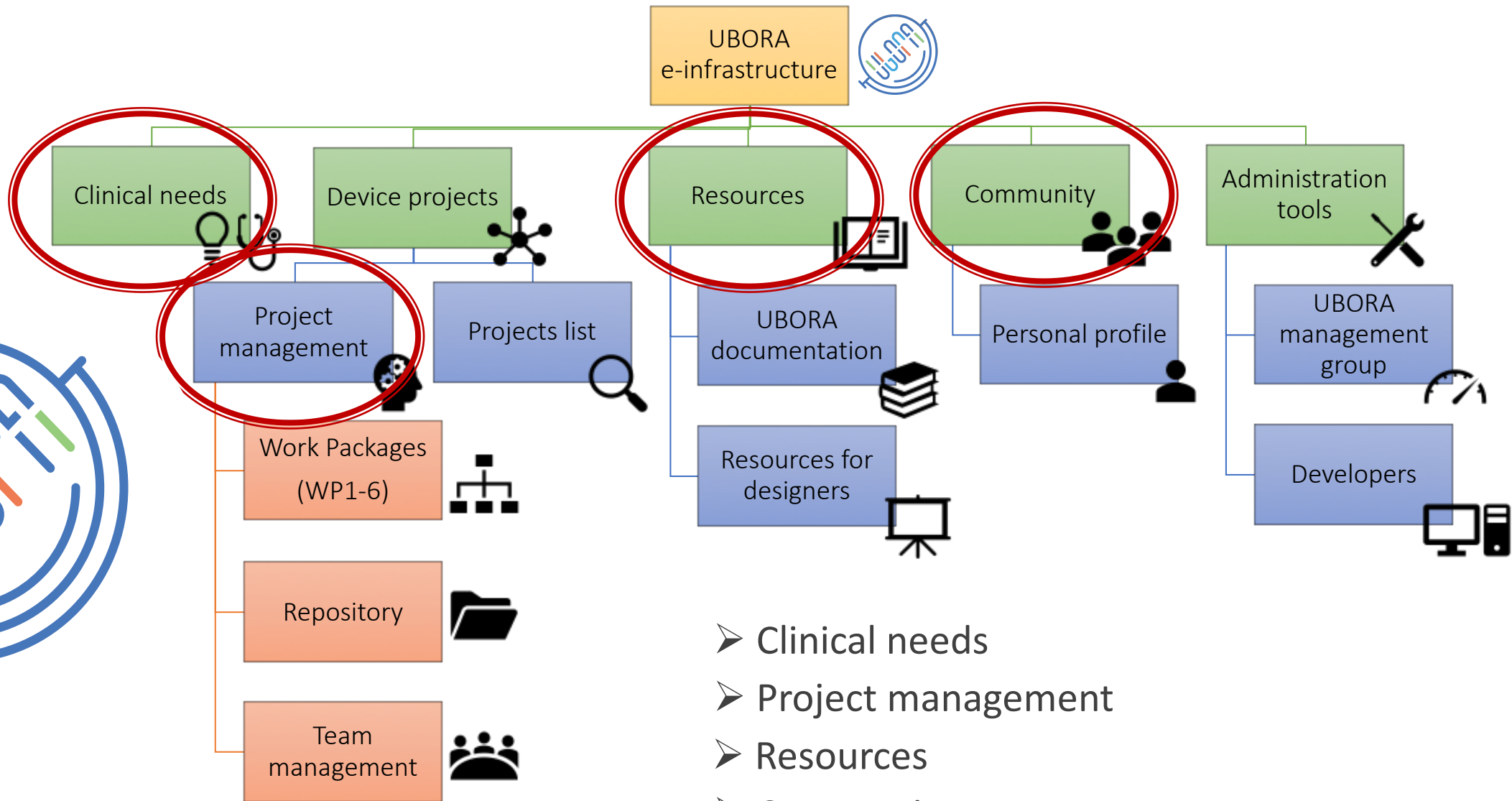


UBORA e-Platform



<https://platform.ubora-biomedical.org>

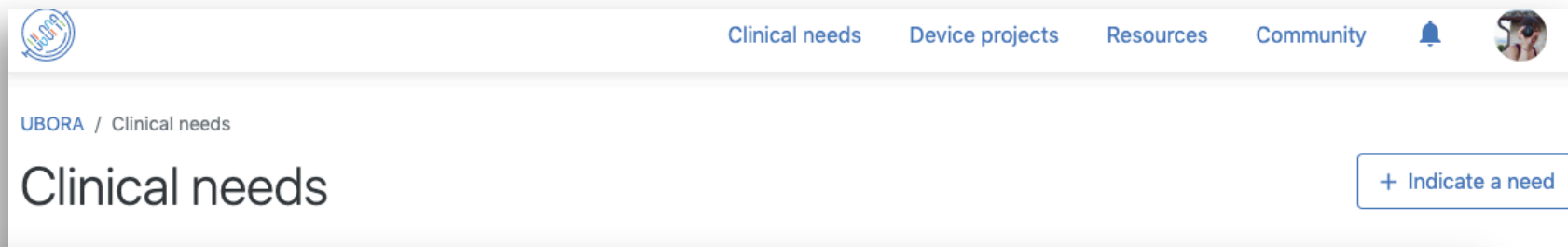
UBORA e-Platform



- Clinical needs
- Project management
- Resources
- Community

Clinical needs

Aimed at identifying bioengineering solution linked to specific **clinical needs**. To create safety and impactful **medical solutions**, this section provides an environment for **healthy discussion** between patients, healthcare providers and engineers to ensure that are turned into projects.



Development of a Low Cost Automatic Dialyzer Reprocessing Machine.

by Jawwad Hossain

Clinical need
Support to medical practice

Area
Nephrology

Technology
Other supporting equipment

Keywords
Automatic cleaning, Reuse extension,
, Better
is etc.

Medical Simulator: The inception of uprooting the curse of medical error

by Shurav Kumar Das

Clinical need
Support to medical practice

Area
Public health

Technology
Ergonomic support

Keywords
Medical Simulator, medical error, lung
and heart sound simulator, endoscopy,
catheter simulator, haptic simulator

0 comments • 0 related projects • Last activity 29.06.2019



Project management

A **guided design process** for supporting researchers in the **standard-oriented design** of medical devices with specific features for identifying **risk class** and relevant **applicable standards**; it includes a repository for **file sharing**, and a section that prepares the project for **fund raising**.

WP1

Medical need and product specification

WP2

Conceptual design

WP3

Design and prototyping

WP4

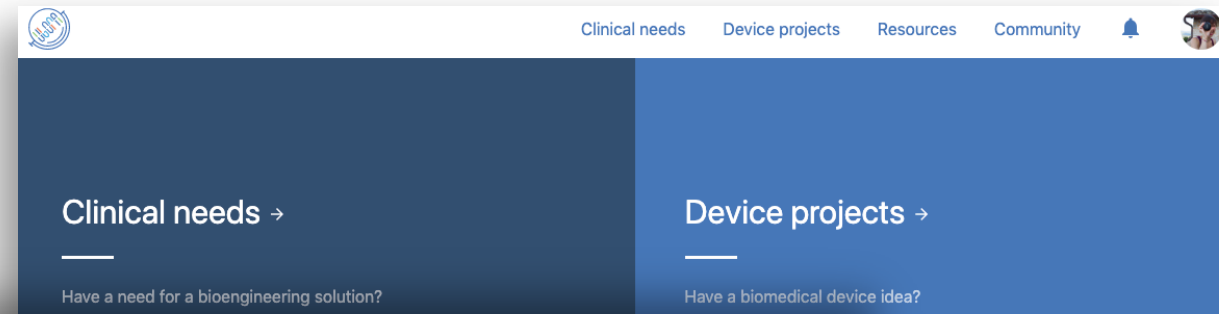
Implementation

WP5

Operation

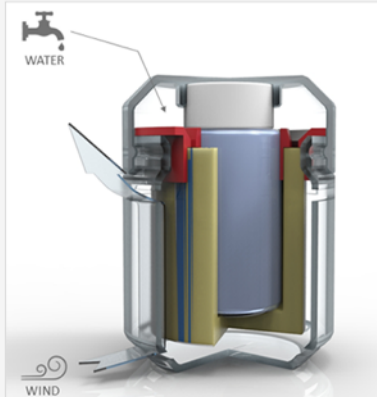
WP6

Project closure



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 →](#)

WP1

Clinical needs

Existing solutions

Intended users

Product requirements

Device classification

Regulation checklist

Formal review

- Risk classification according to the MDR 2017/745
 - From I (Low Risk) to III (High Risk)
 - Decision tree with 30 questions
 - Validated with the help of expert consultant
- Promoting harmonization of medical device regulation

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



WP1

Clinical needs

Existing solutions

Intended users

Product requirements

Device classification

Regulation checklist

Formal review

Applicable regulations

ubora-kahawa.azurewebsites.net/Projects/753b19aa-266f-4e63-bc8b-9488d220a36f/ApplicableRegulations/Review?questionnaireId=c0...

In-development preview

Search Community My projects Notifications Admin Profile Log out

Overview Work packages Repository Assignments Members History

Design planning

1 Medical need and product specification

- Clinical needs
- Existing solutions
- Intended users
- Product requirements
- Device classification
- Regulation checklist
- Formal review

2 Conceptual design

3 Design and prototyping

4 Implementation

5 Operation

6 Project closure

Questionnaire results:

Most of the cited standards are issued by ISO; some of them are also harmonized (=approved) by the European Commission and in this case they are identified by the DzENDz code. Since the EN version contains more information than the general version, links are provided to the EN version in English language if appropriate.

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 sterile? You answered: No		



International
Organization for
Standardization



INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

- Identification of Horizontal standards (ISO and IEC)
 - Focused on the "ontology of the device"
 - Hard to identify using keywords
 - Decision tree with 30 questions
 - Validated with the help of expert consultants

Resources

with selected **teaching/learning** materials on Biomedical Engineering.

UBORA teaching material

Tutorials

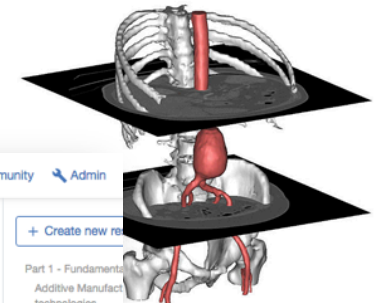
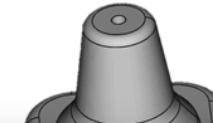
UBORA developer's manual

UBORA user's manual

Additive manufacturing process workflow

The general workflow consists of 7 steps:

1. **Solid 3D Modelling.** The starting point of all AM processes is a digital model representing the object to be fabricated. It can be designed from scratch, using a Computer Aided Design (CAD) software, or obtained by the elaboration of data from specific instrumentation (e.g. segmentation of tomographic



UBORA (in-development preview)

Projects Resources Community Admin

Introduction

- UBORA teaching materials
- Mass personalization of medical devices
- Standards and regulations in Europe
- Usability for medical devices: an introduction
- Tutorials
- Resource categories

Resources / Mass personalization of medical devices

Read Files Edit History

Mass personalization of medical devices

Part 1 - Fundamentals

Additive Manufacturing technologies

Additive manufacturing (AM) is a process of making a 3D solid object of virtually any shape from a digital model. It is achieved using an additive process, where successive layers of material are laid down in different shapes.

Part 1 - Fundamentals

Additive Manufacturing technologies

Additive manufacturing workflow

Part 2 - European regulations

Additive Manufacturing in healthcare

Part 3 - Example of Personalization of Medical Devices

into a fileformat which can be
The file can describe just the
(on) or its the voxels, the "bricks"
ce and inner parts).



Community

Joining UBORA means being part a **community** of developers, including **professional engineers** and **healthcare providers**, aimed at designing new **open source solutions** for current and future **healthcare challenges**, for a larger access to medical devices.

Developers

Mentors

Managing group

> 500 verified users



Arti Ahluwalia

Mentor verified UBORA mentor

[About](#) [Projects 1](#)

Personal

Country: Italy

Academia

University: University of Pisa

Degree: PhD

Field: Biomedical Engineering

Working experience

Institution: Research Center E.Plaggio



Isabel Alvarez



Ishmael Ofori
Aboagye

Developer



Janno Torop

Mentor



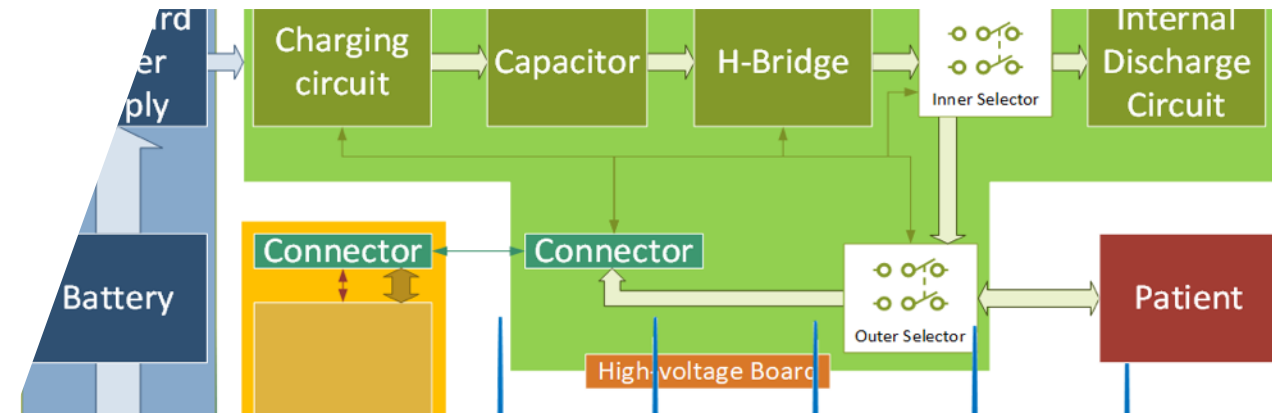
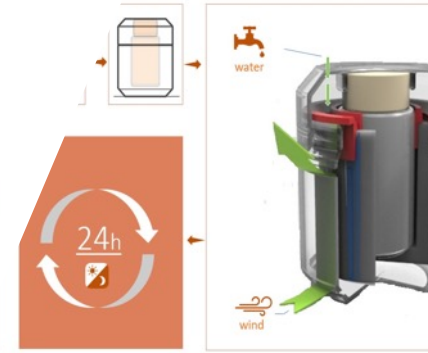
jim Gitonga

Developer

UBORA e-Platform



- Open source automatic defibrillator
- Solar powered autoclave
- 4D printed articular splint
- 3D printed cat for Ponseti method
- Preservations system of the breastmilk
 - Infant warmer
 - A life box for burned child patient
 - Walking frame in carbon fiber
 - Modular multi-finger splint
 -



UBORA e-Platform Testing



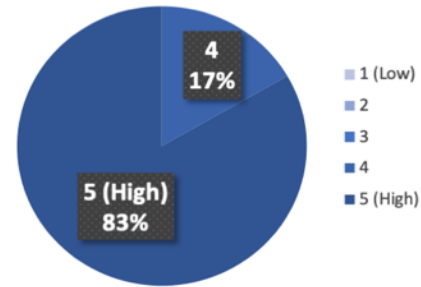
WHO Global Forum on Medical Devices

13 - 15 December 2018 Visakhapatnam | India

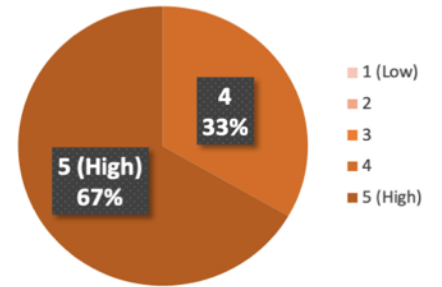
The aim of the workshop:

- demonstrating the UBORA's ease of use,
- promoting and pushing harmonization on medical device legislation.

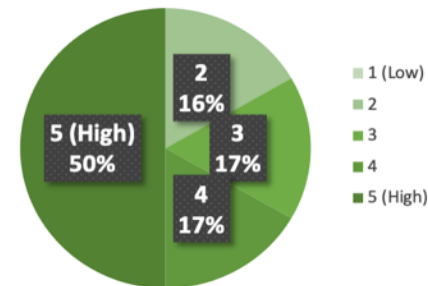
HOW EASY WAS CREATING A PERSONAL PROFILE?



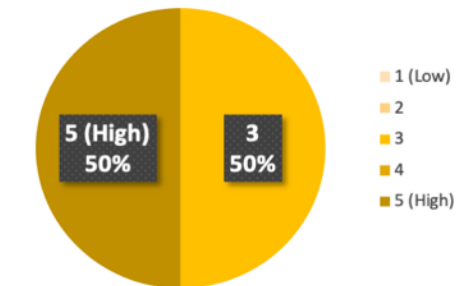
HOW EASY WAS CREATING A NEW DEVICE PROJECT?



HOW EASY WAS IDENTIFYING THE MEDICAL DEVICE CLASS?



HOW EASY WAS IDENTIFYING THE REFERENCE STANDARDS?





**GLOBAL
HEALTH
INNOVATION**



The Kahawa Declaration: a manifesto for the de

Arti Ahluwalia^a, Carmelo De Maria^a, Andrés Díaz Lantada^{b*}

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^bMechanical Engineering Department, Universidad Politécnica de Madrid, Mad

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Abstract

Most medical technology is employed and accepted passively by patier
Patients are not involved in the development of medical technology, whic
by proprietary know-how and by costs. This has so far impeded equitabl
or healthcare coverage. Understanding the relevance of international p
specially committed to the promotion of the Goal on "Good Health and
engineering approaches may play in the future of medical technology, v
transformation of the biomedical engineering field, towards the democra
health care. This paper presents the content of the Kahawa Declaration.



**African Biomedical
Engineering Consortium**
Innovation through Education



UBORA: Euro-African Open
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THE KAHAWA DECLARATION: A MANIFESTO FOR THE DEMOCRATIZATION OF MEDICAL TECHNOLOGY

Joint Declaration of the UBORA and ABEC partners
Presented and signed at Kenyatta University, December 2017

EXECUTIVE SUMMARY

Most medical technology is passively employed and accepted by patients, doctors and engineers who have little or no say in its design or usability. In addition, patients are not involved in the development of medical technology, which is undertaken behind closed doors and whose global impact is hindered by proprietary know-how and by costs. This has so far impeded equitable healthcare as most of the world does not have access to the technology or healthcare coverage. Indeed, the benefits of quality medical

Ahluwalia, Arti and Maria, Carmelo de and Díaz Lantada, Andrés (2018).

The Kahawa Declaration: a manifesto for the democratization of medical technology. "Global Health Innovation",
v. 1 (n. 1); pp. 1-4. ISSN 2617-1155.

<https://doi.org/10.15641/ghi.v1i1.507>.

<http://ubora-biomedical.org/kahawa-declaration/>



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<https://platform.ubora-biomedical.org/>

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7. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN>

