ENGINEERING in MEDICINE and BIOLOGY
BIOMEDICAL ENGINEERING RANGING FROM WELLNESS TO INTENSIVE CARE MEDICINE
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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

Medical devices are required to achieve SDG3:

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

What is a medical device?

MDR 2017/745 Article 2 (1)

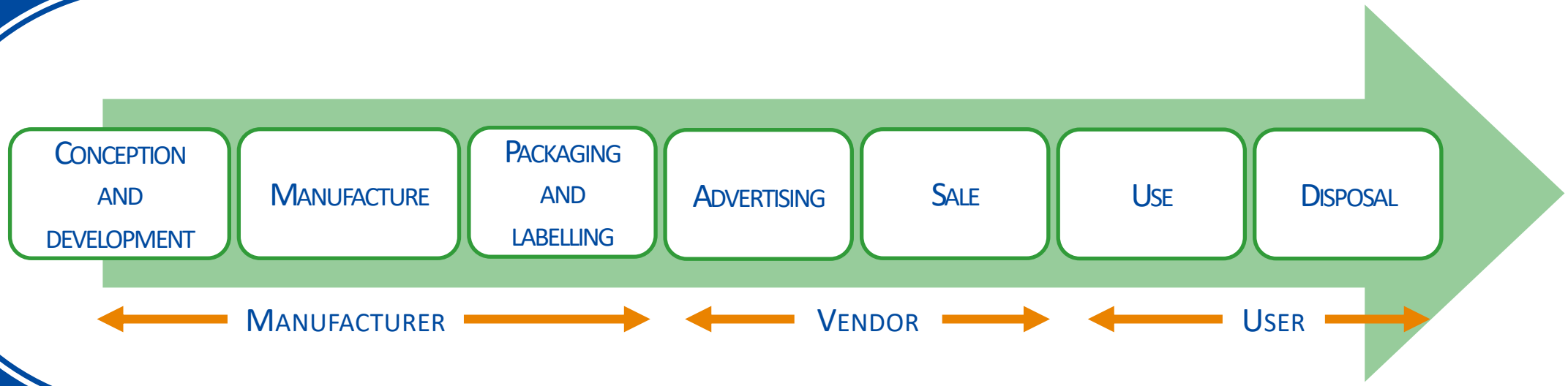
"Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes…"[7]

Diagnosis of disease	Replacement of the anatomy	Treatment of disease	Compensation for disability
			
http://www.mobisante.com	https://www.ottobock.co.uk/	https://www.designthatmatters.org/firefly	https://corsuhospital.org/

Challenges of medical devices in developing countries

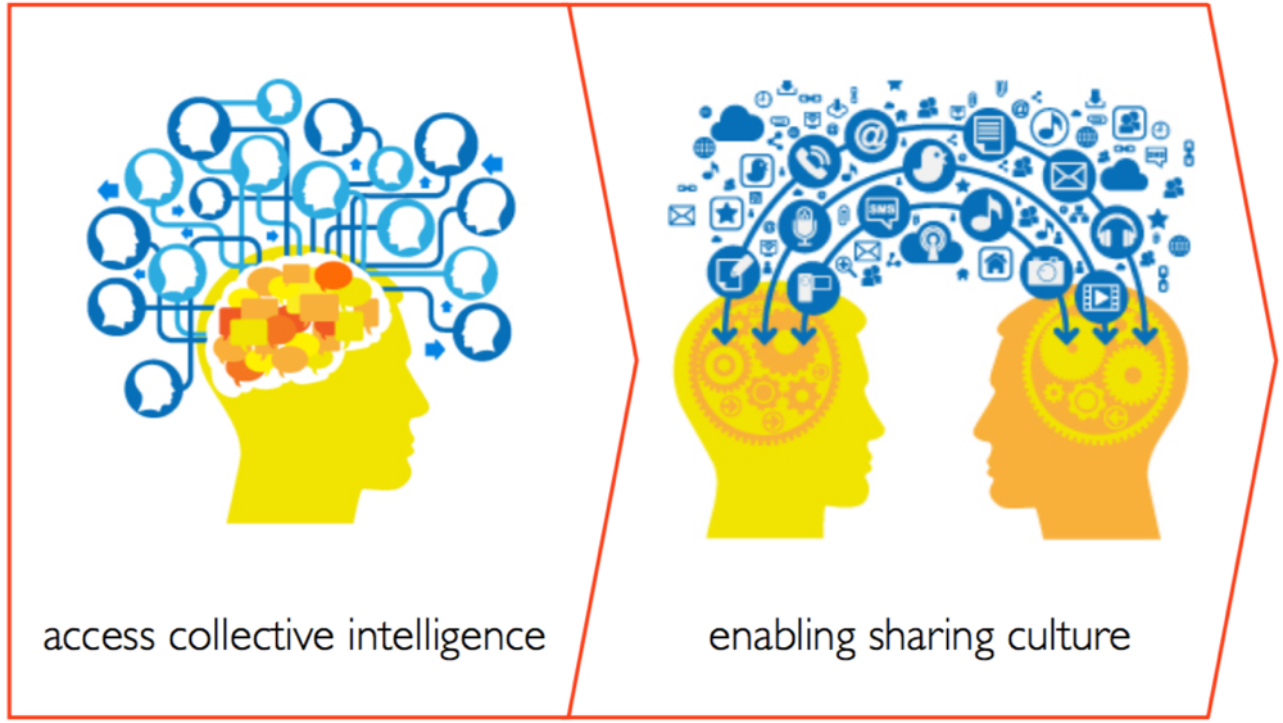
- The WHO estimates that 70% of medical equipment coming form the most developed nations not work in developing world hospitals [1].
- Over 95% of medical equipment in public hospitals is imported. There is no local production of medical equipment [2].
- Imported equipment of poor quality, 96% is not 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.

What is Open source?

Open source 3D printing

- Sharing of “blueprints”
- Sharing of open data on device statistics
- Sharing of design errors or dead ends
- Needs based design

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.

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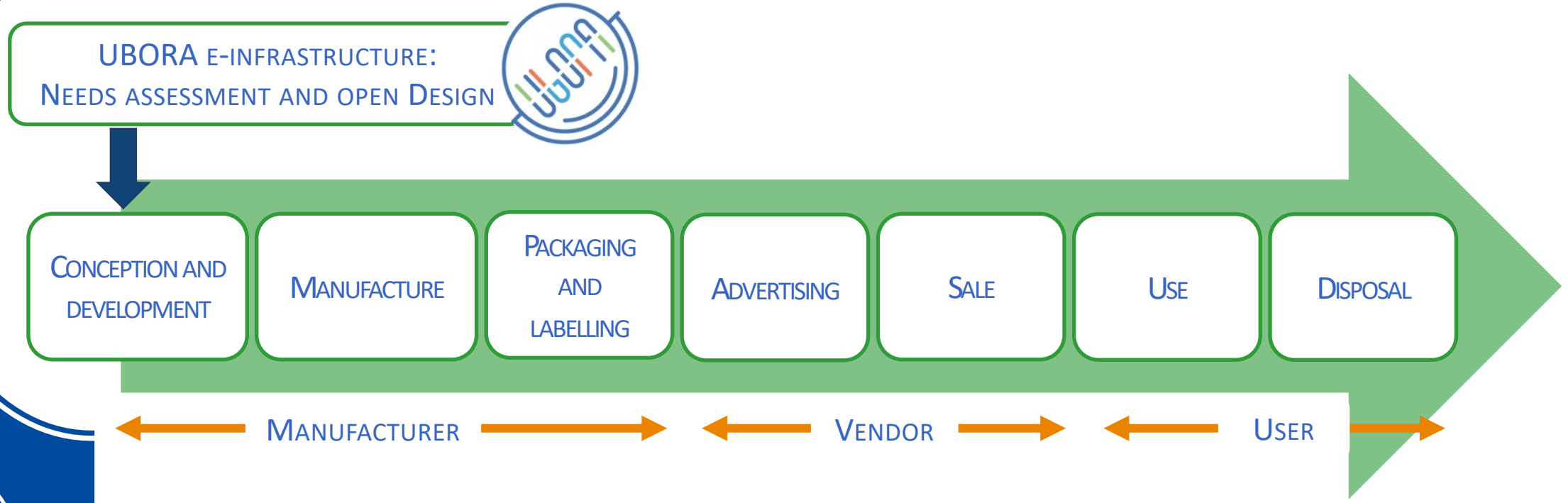
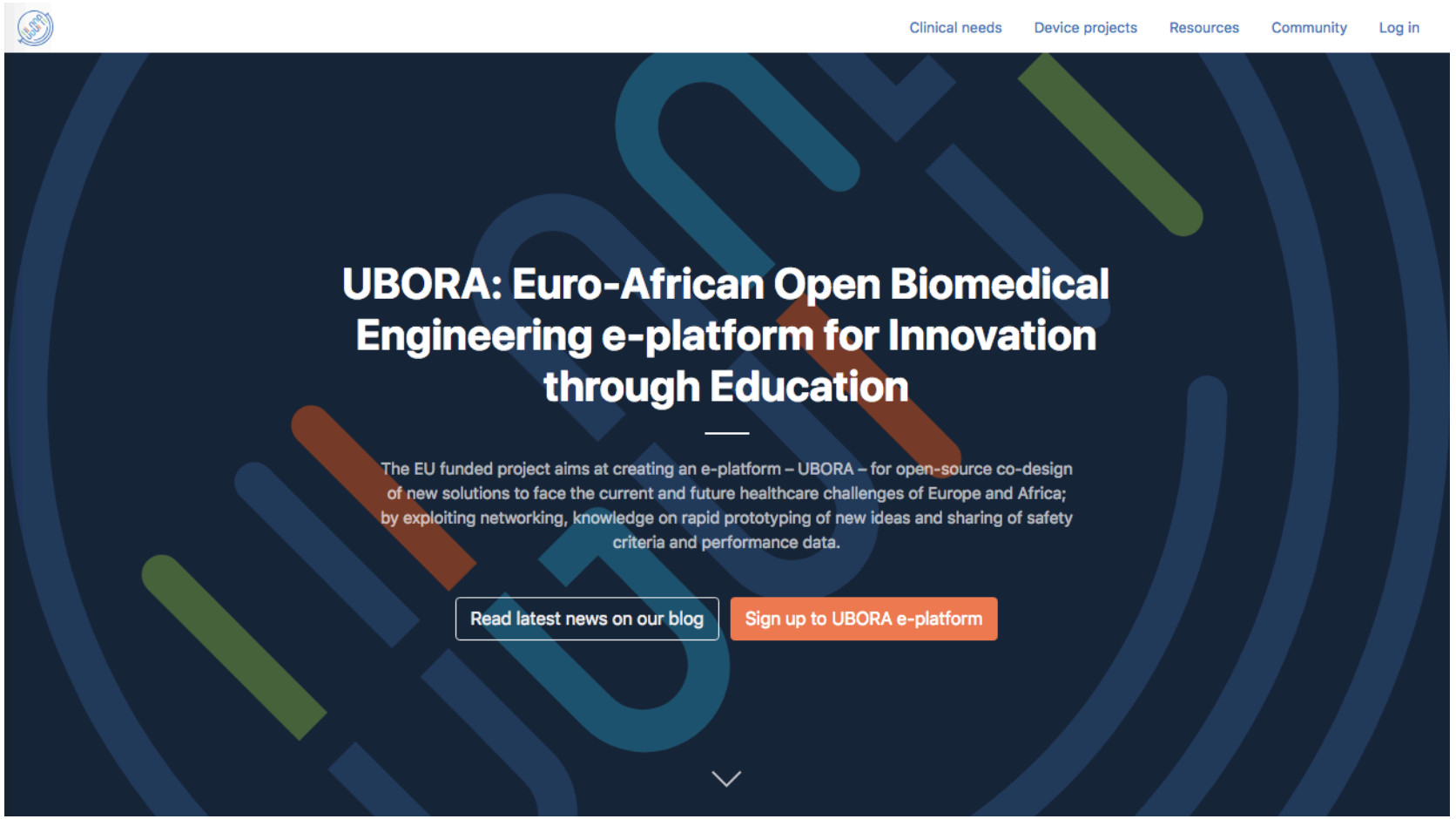
UBORA in the life cycle of medical device



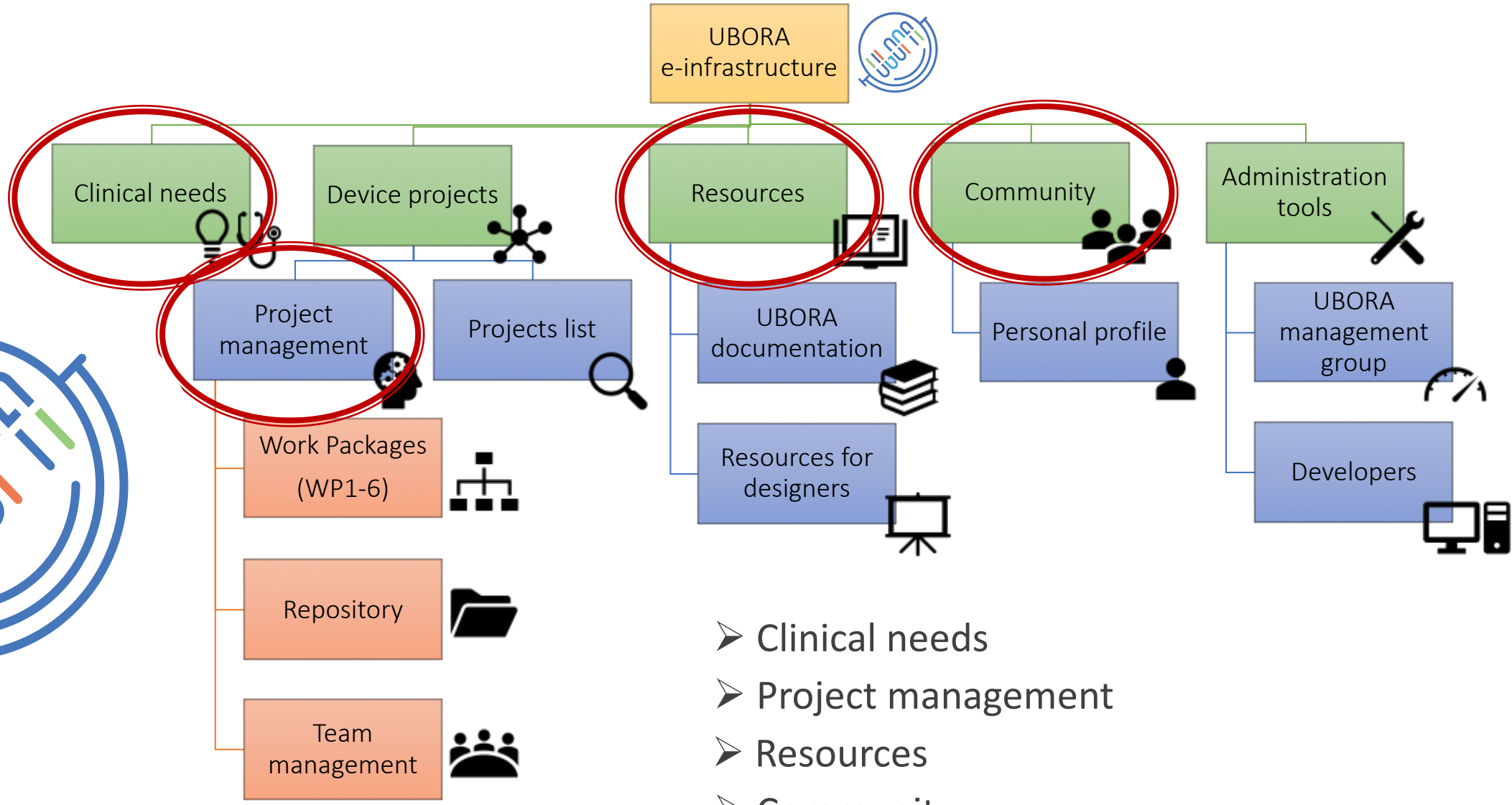
Use open source approach and appropriate technologies for reducing development costs and increasing **safety**

UBORA e-Platform



https://platform.ubora-biomedical.org

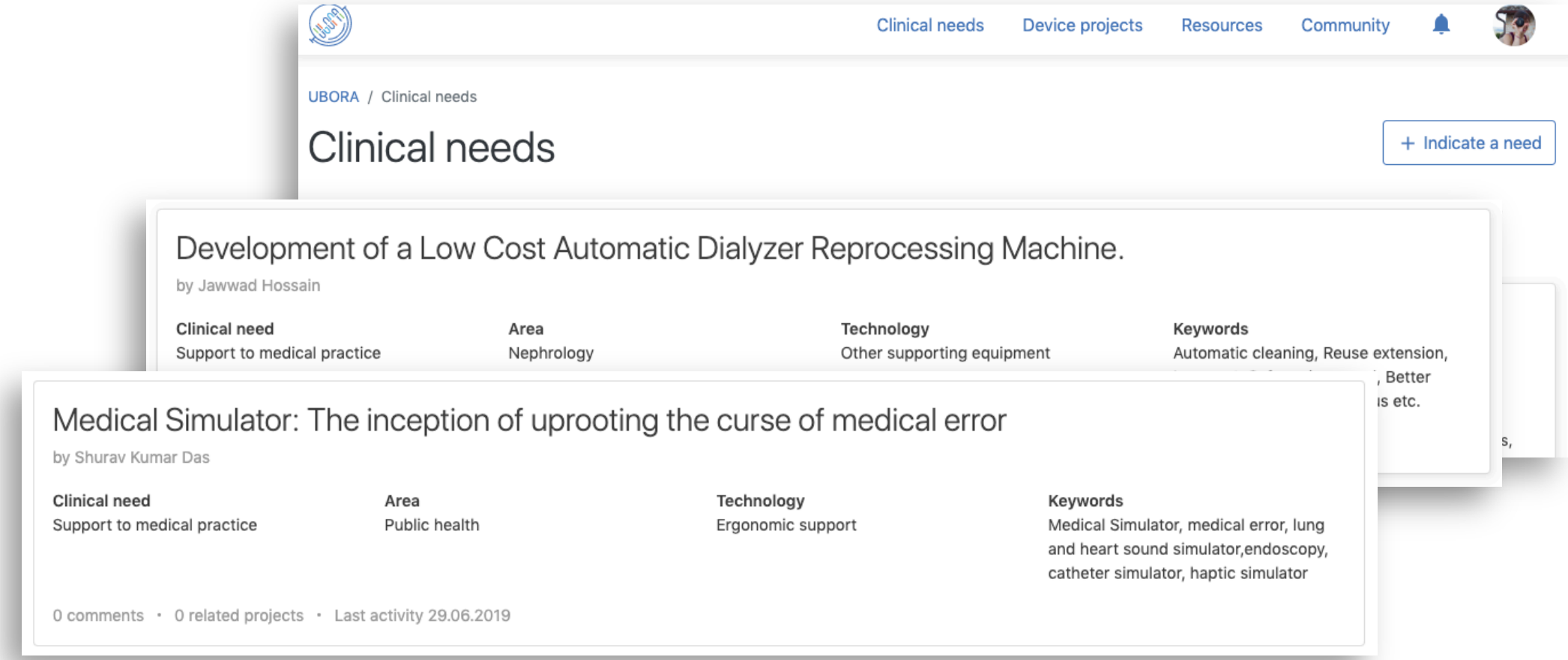
UBORA e-Platform



- Clinical needs
- Project management
- Resources
- Community

Clinical needs

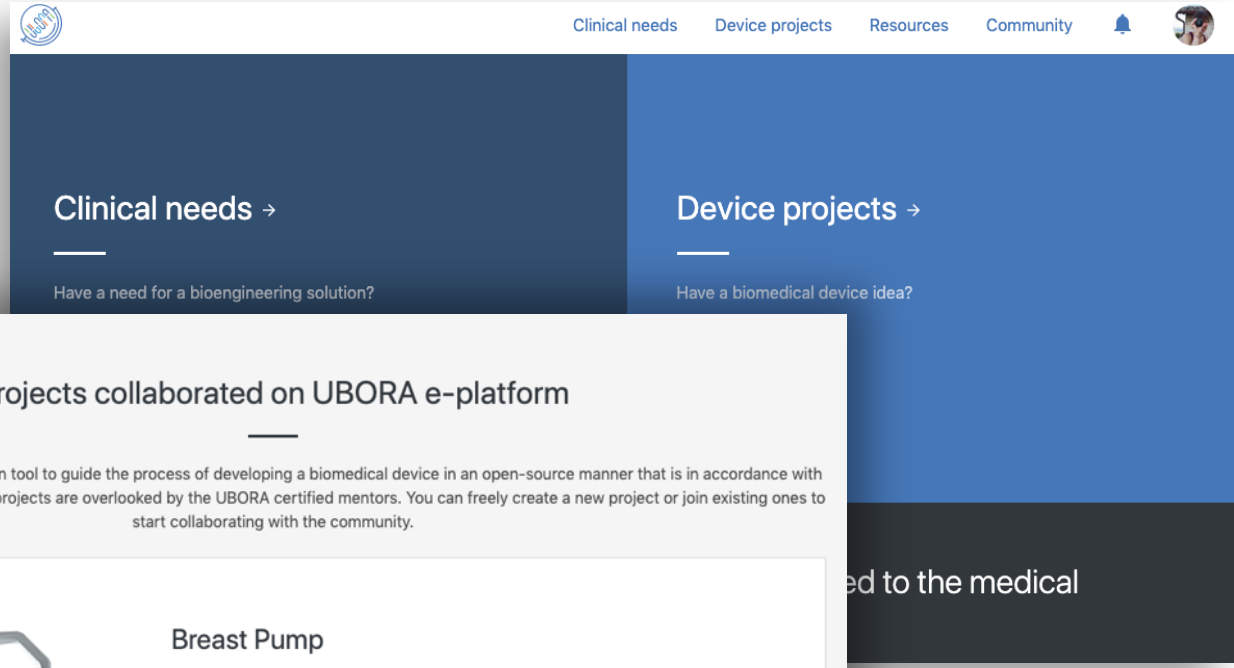
Aimed at identifying bioengineering solution linked to specific **clinical needs**. To create safety and impactful **medical solutions**, this section provides an environment for **healthy discussion** between patients, healthcare providers and engineers to ensure that are turned into projects.



Project management

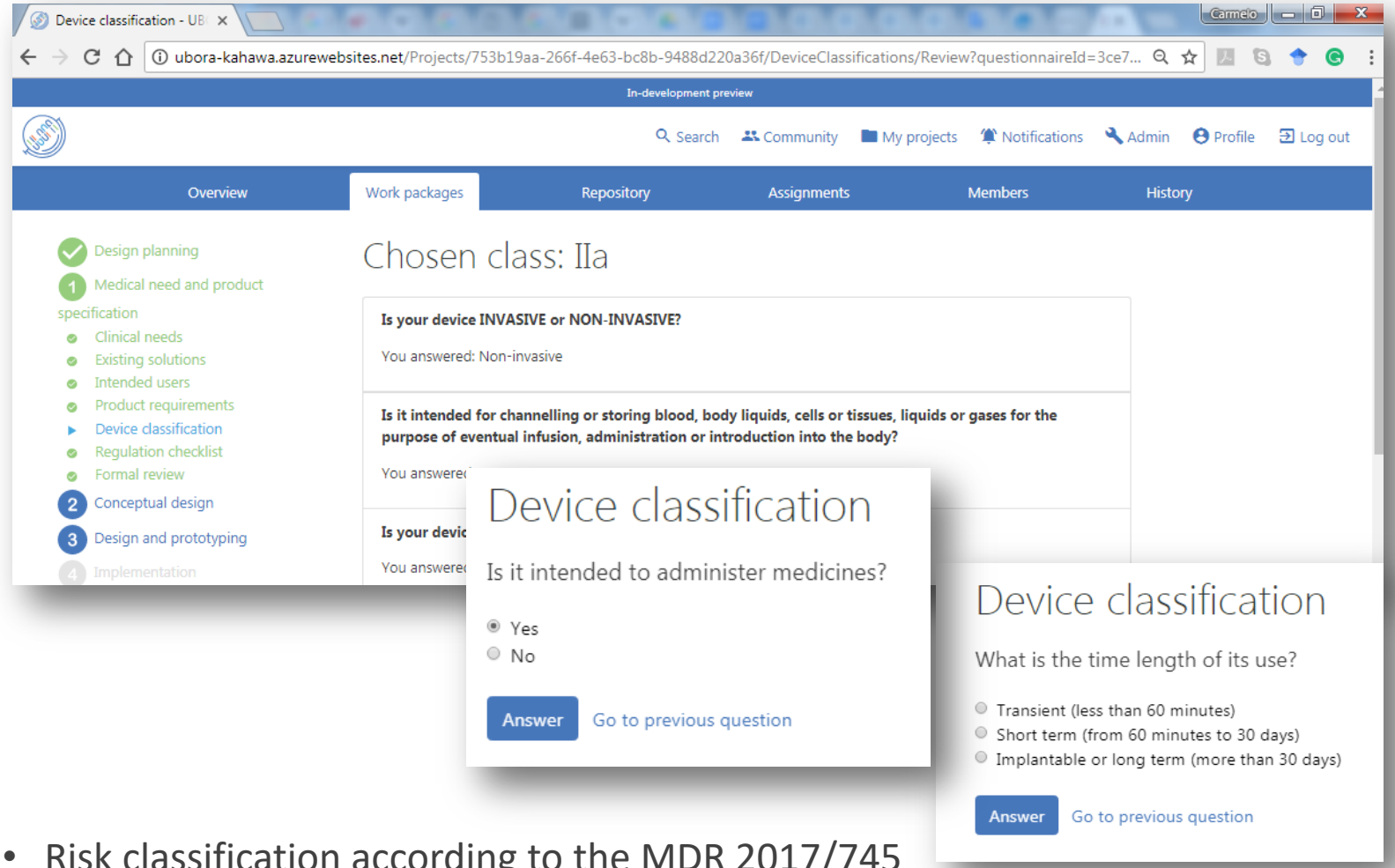
A **guided design process** for supporting researchers in the **standard-oriented design** of medical devices with specific features for identifying **risk class** and relevant **applicable standards**; it includes a repository for **file sharing**, and a section that prepares the project for **fund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

- WP1 Medical need and product specification
- WP2 Conceptual design
- WP3 Design and prototyping
- WP4 Implementation
- WP5 Operation
- WP6 Project closure



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

WP1

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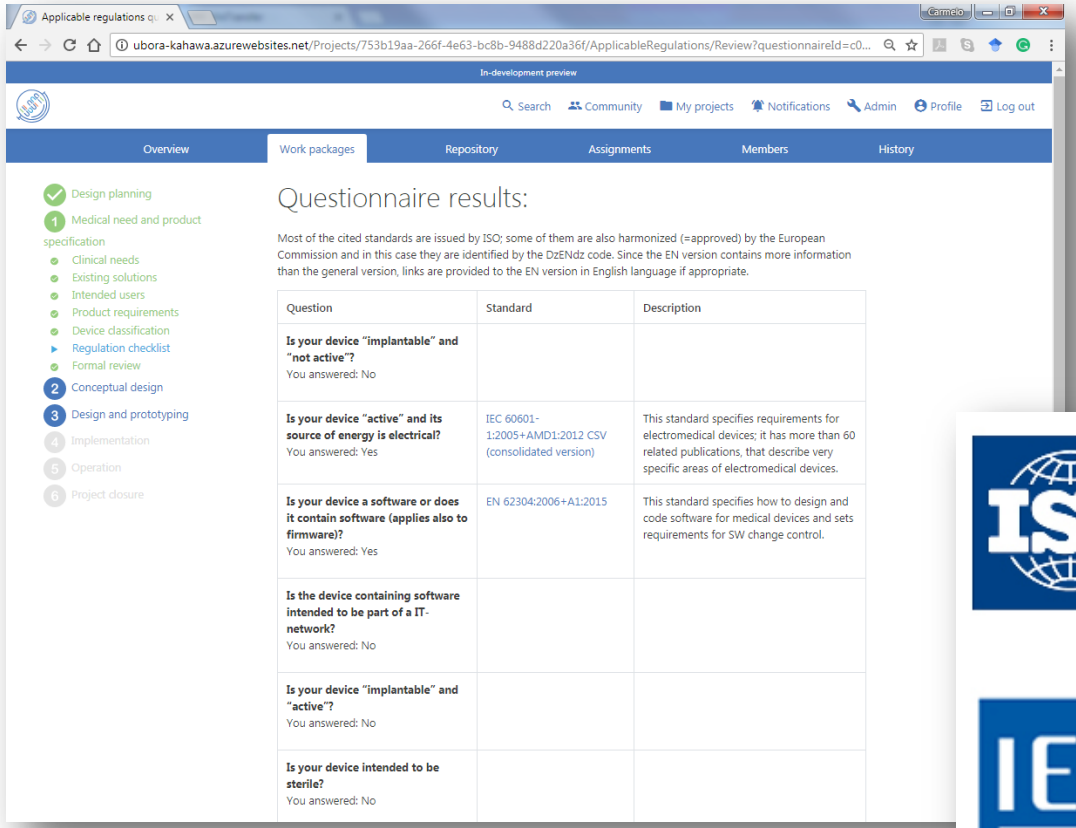


ISO International Organization for Standardization

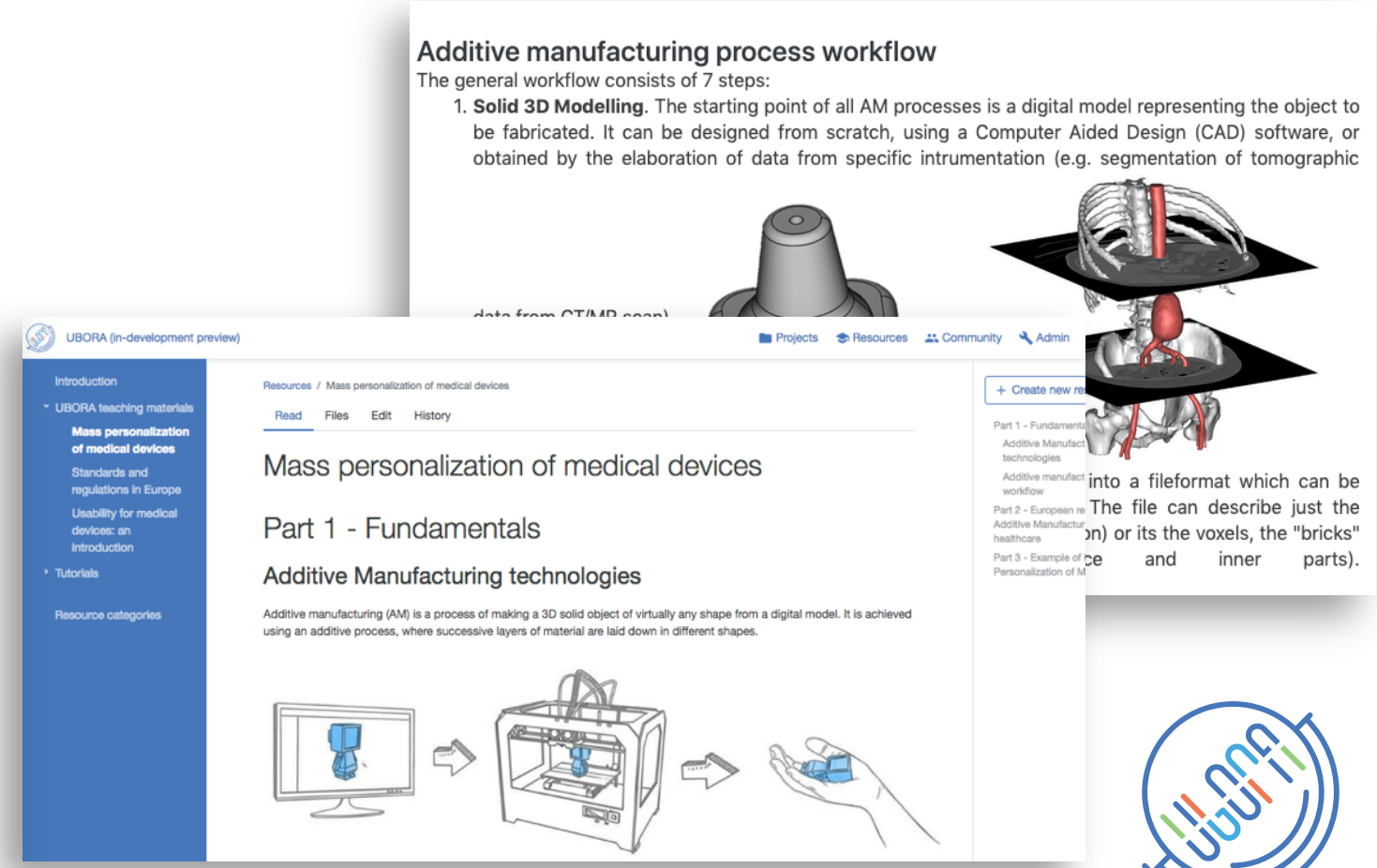
IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

- 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.

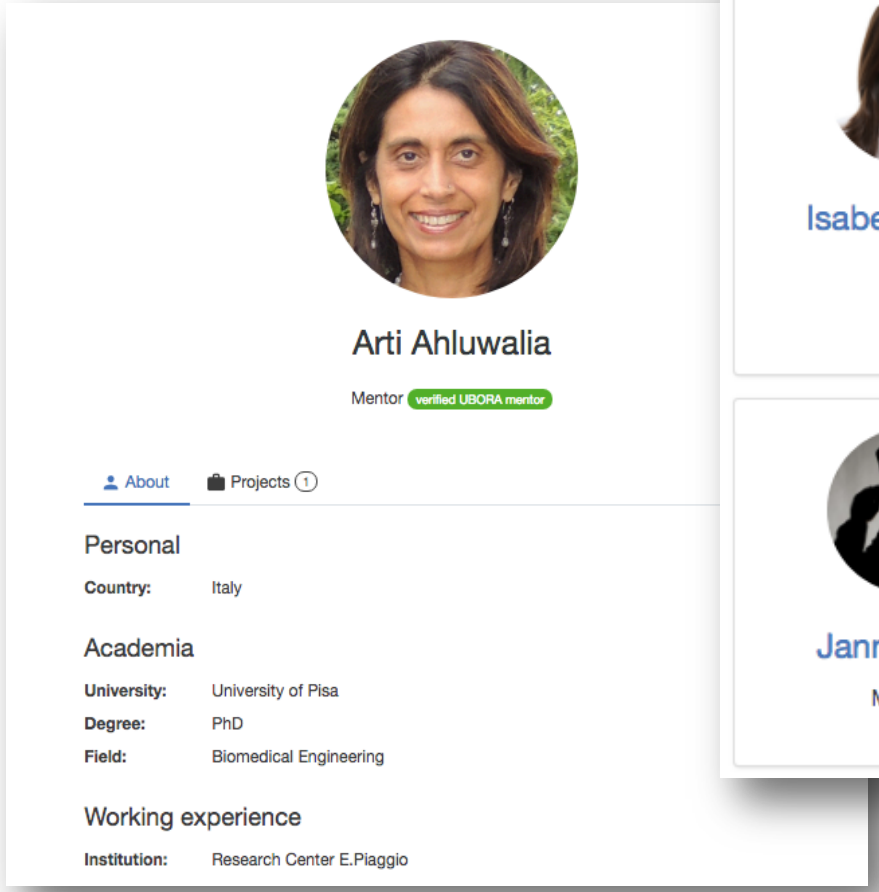
- UBORA teaching material
- Tutorials
- UBORA developer's manual
- UBORA user's manual

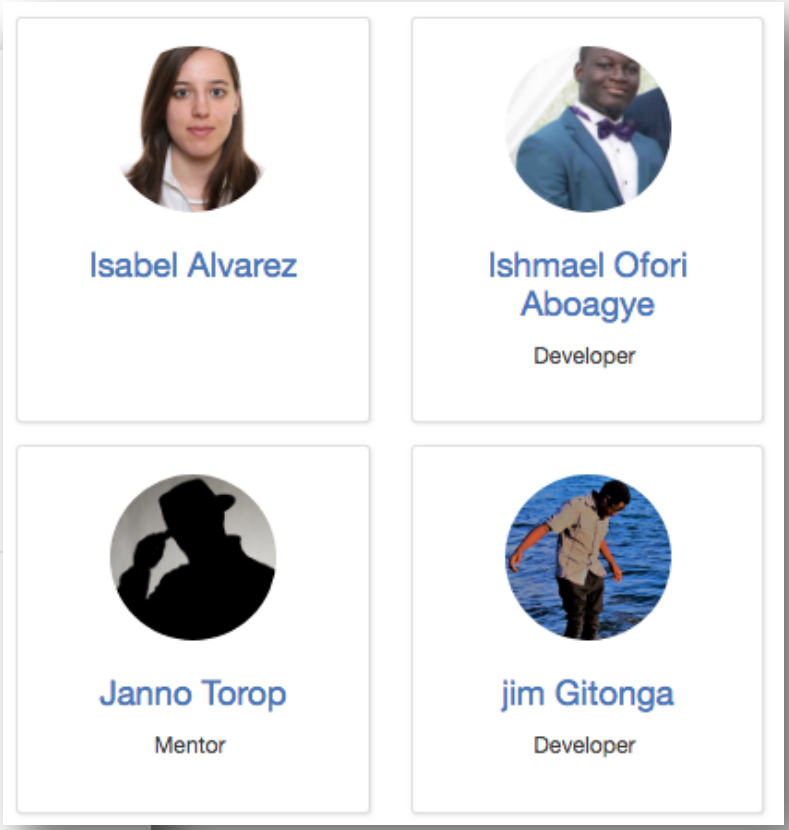


Community

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.

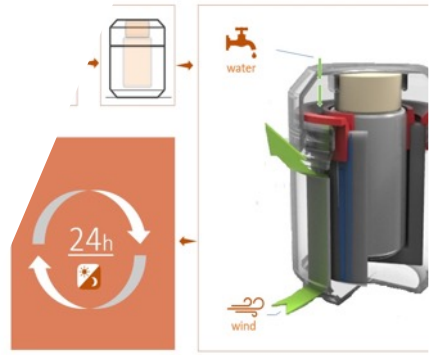
- Developers
- Mentors
- Managing group
- > 500 verified users

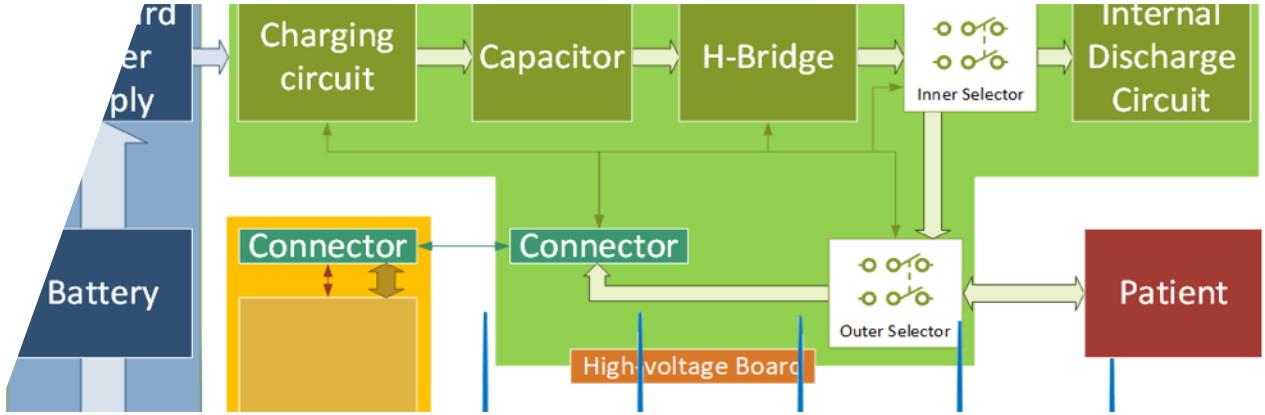




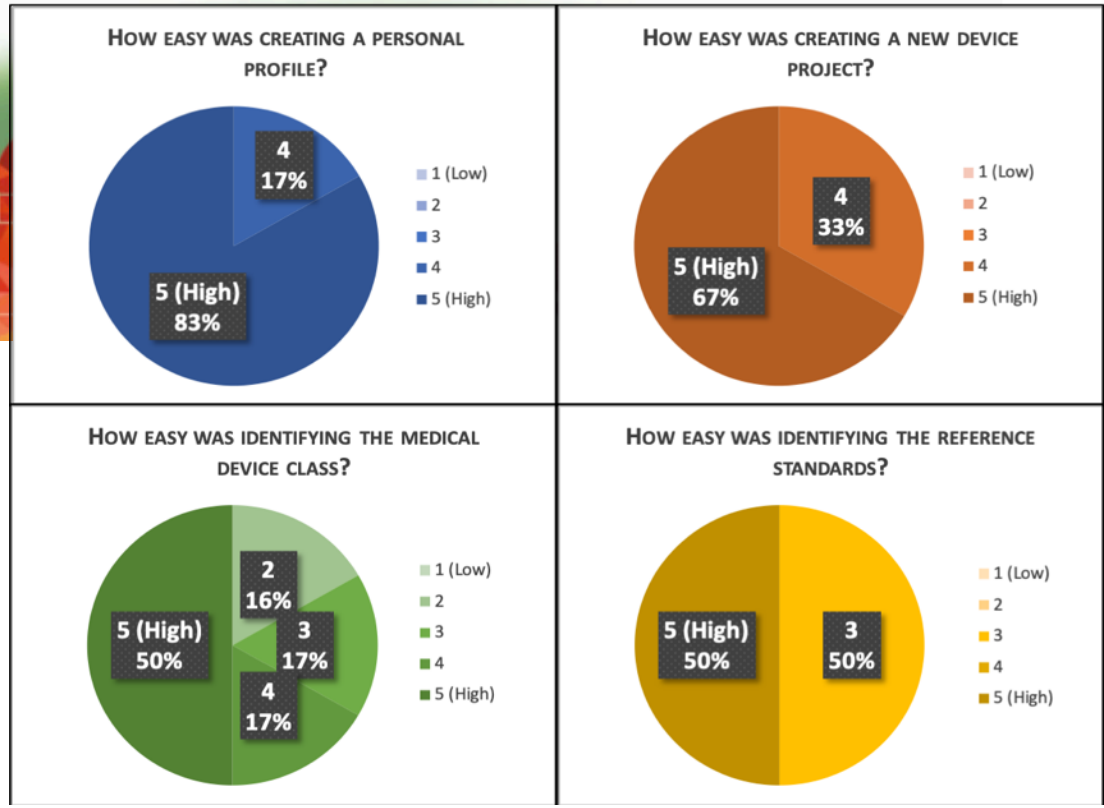
UBORA e-Platform

- 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
    - ….



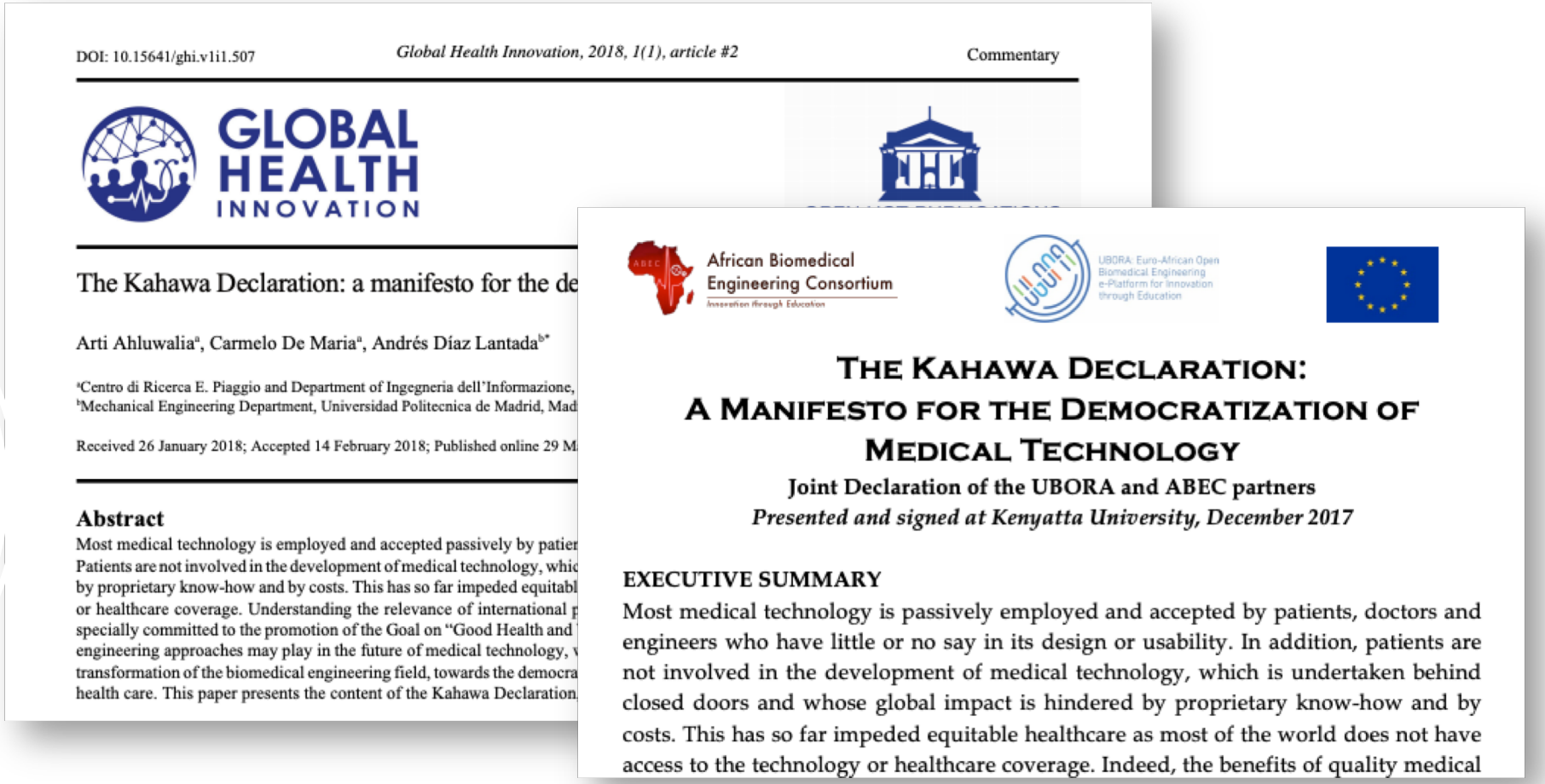


UBORA e-Platform Testing



The aim of the workshop:

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



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GLOBAL HEALTH INNOVATION

The Kahawa Declaration: a manifesto for the de

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Abstract

Most medical technology is employed and accepted passively by patien
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 Biomedical Engineering e-Platform for Innovation through Education

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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