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THE UBORA E-PLATFORM FOR OPEN SOURCE INNOVATION IN MEDICAL TECHNOLOGY

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What is UBORA

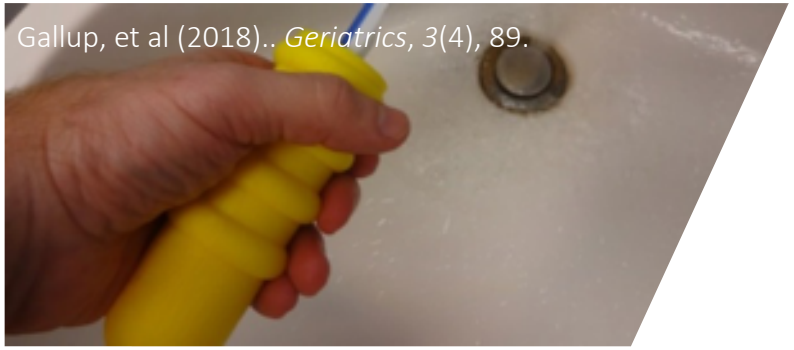
An e-Platform and its community

FOR

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

BY

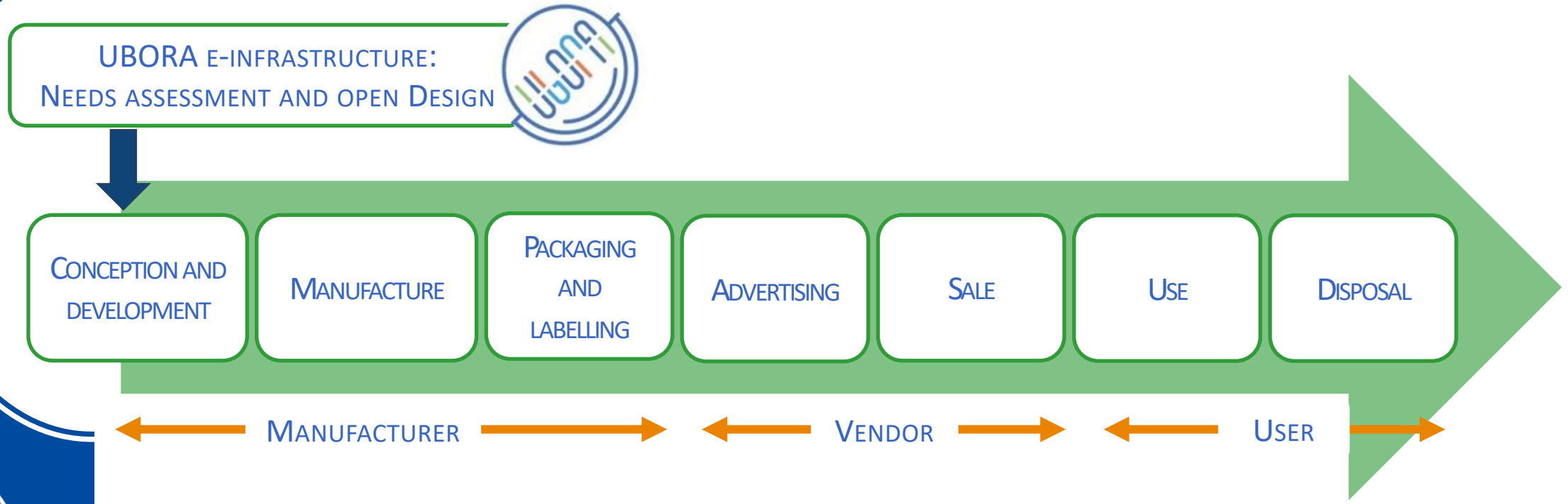
Exploiting networking, **knowledge** on rapid prototyping of new ideas and **sharing** of **safety** criteria and performance data



What is an Open source Medical Device?

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

UBORA in the life cycle of medical device



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

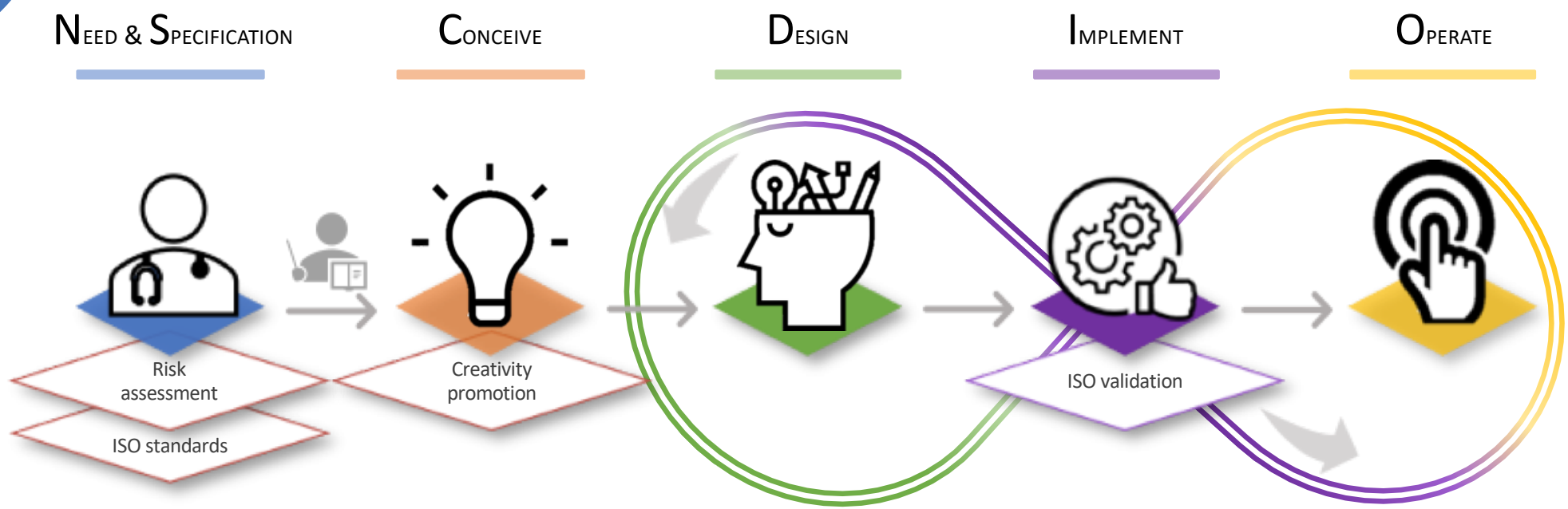
The UBORA approach

Empowering the open source approach

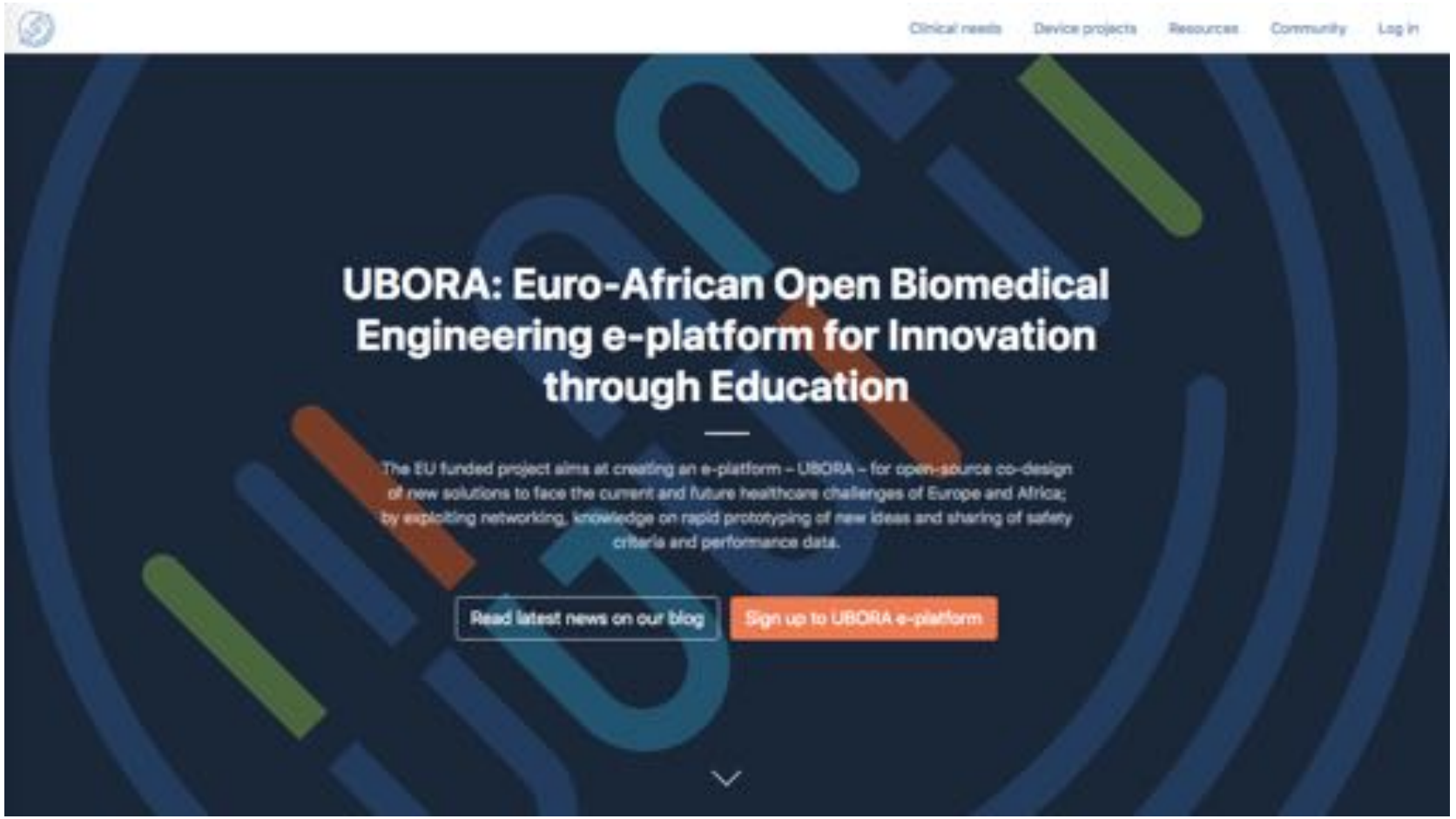
- Quality and safety guidelines for biomedical devices, under the guidance of international standards and European MDR are the foundations.
- Expert mentoring will ensure that the designs comply to highest technical standards at all steps.
- Mentors from Academia and Industry.

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

UBORA methodology: safety by design

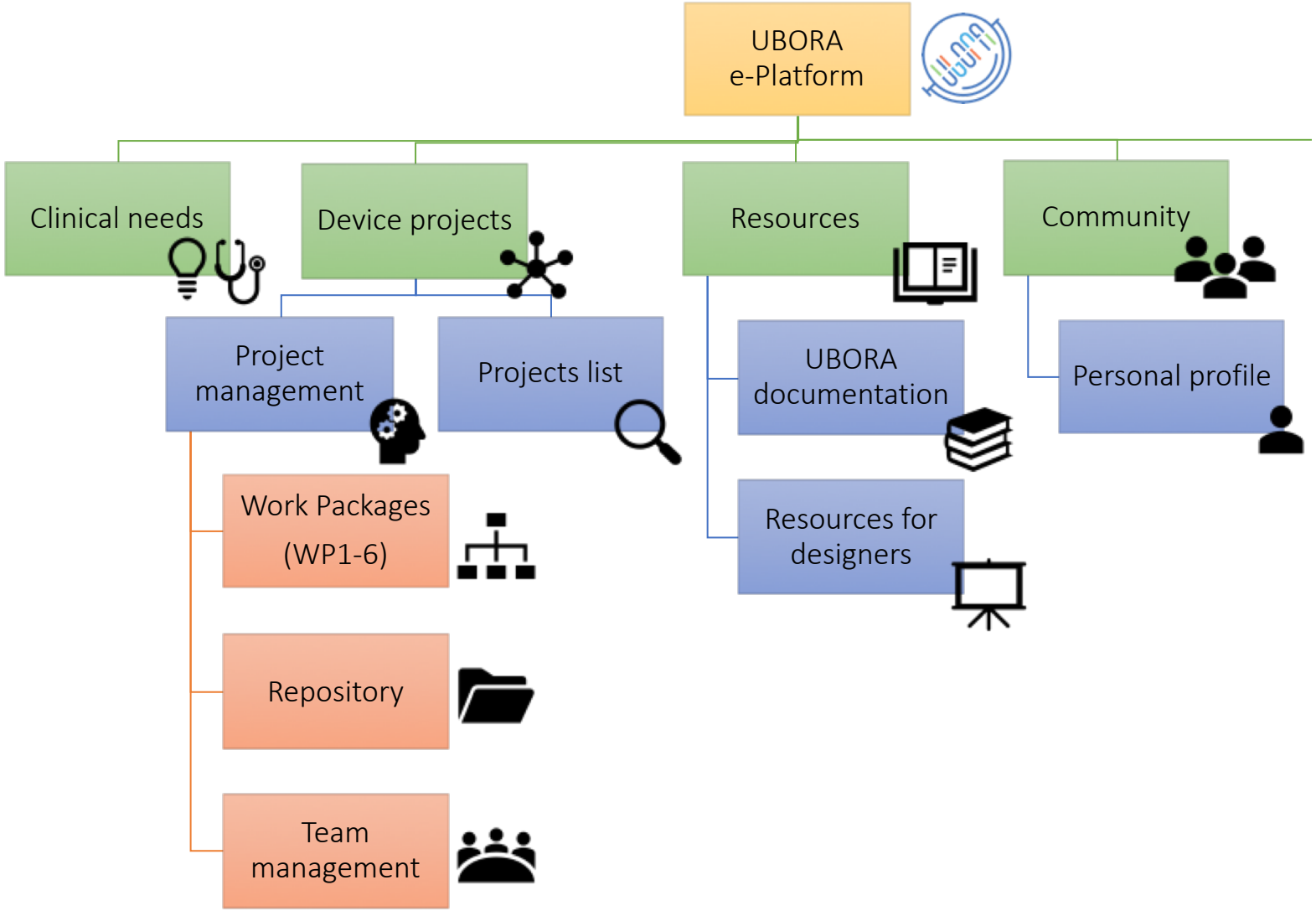


UBORA e-Platform



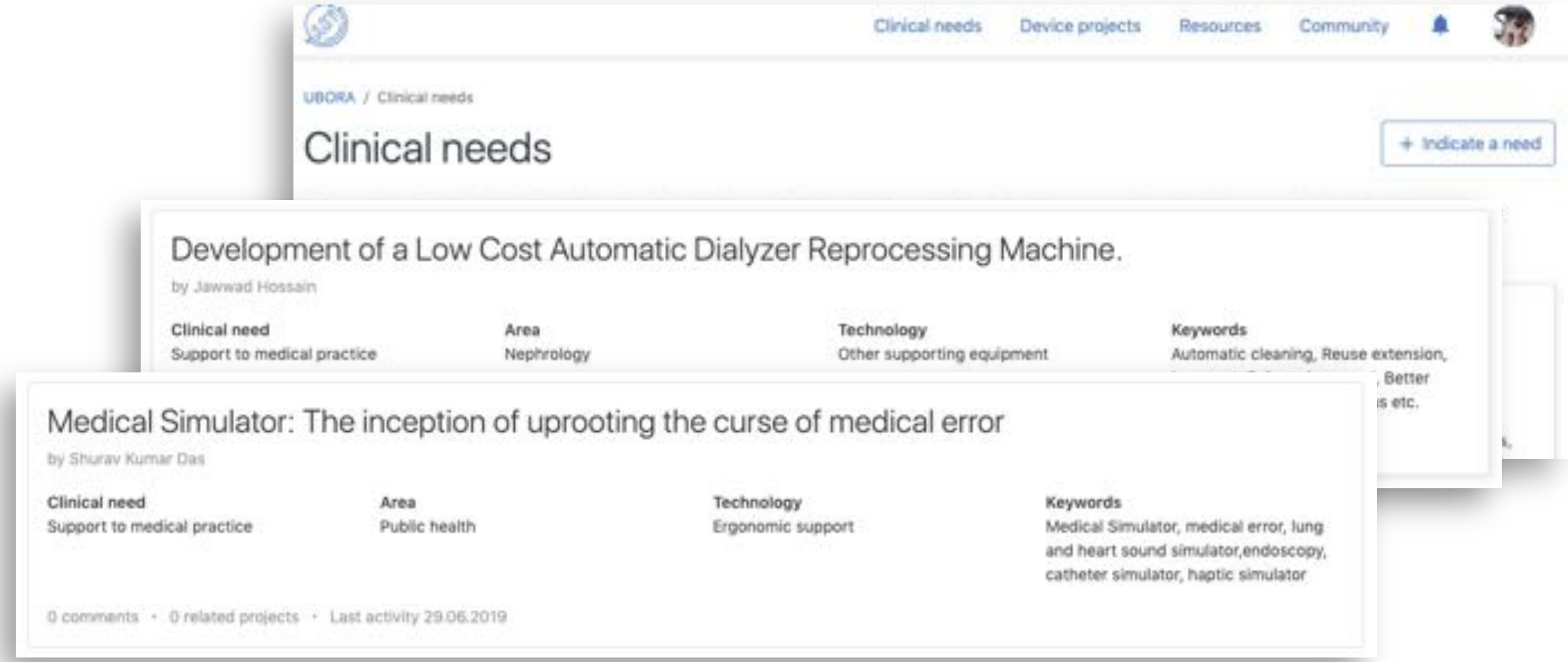
https://platform.ubora-biomedical.org

UBORA e-Platform



Clinical needs

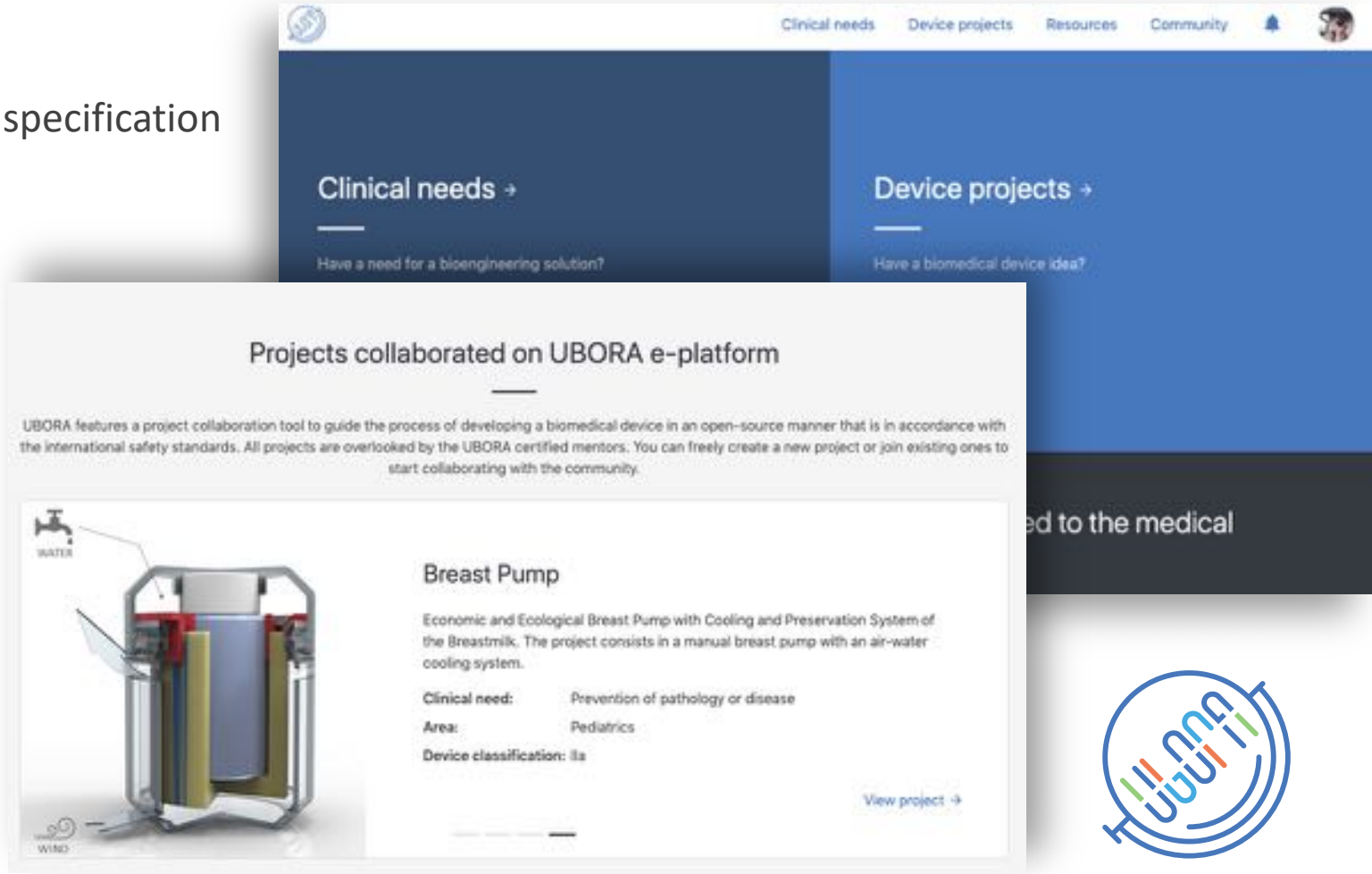
Aimed at identifying bioengineering solution linked to specific **clinical needs**. To create safety and impactful **medical solutions**, this section provides an environment for **healthy discussion** between patients, healthcare providers and engineers to ensure that are turned into projects.



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

MEDICAL NEED AND PRODUCT SPECIFICATION

Clinical needs

Existing solutions

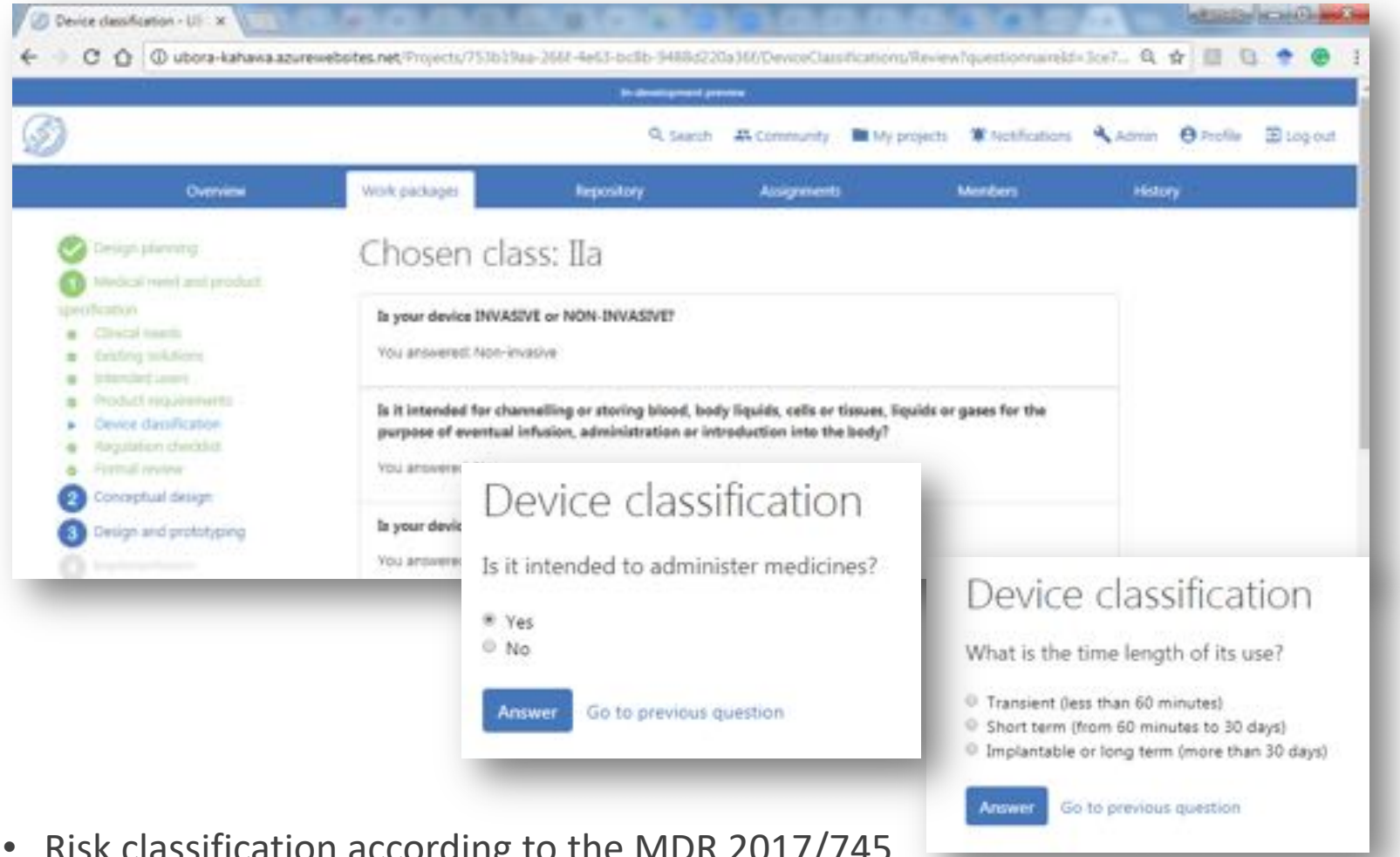
Intended users

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

MEDICAL NEED AND PRODUCT SPECIFICATION

- Clinical needs
- Existing solutions
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- **Regulation checklist**
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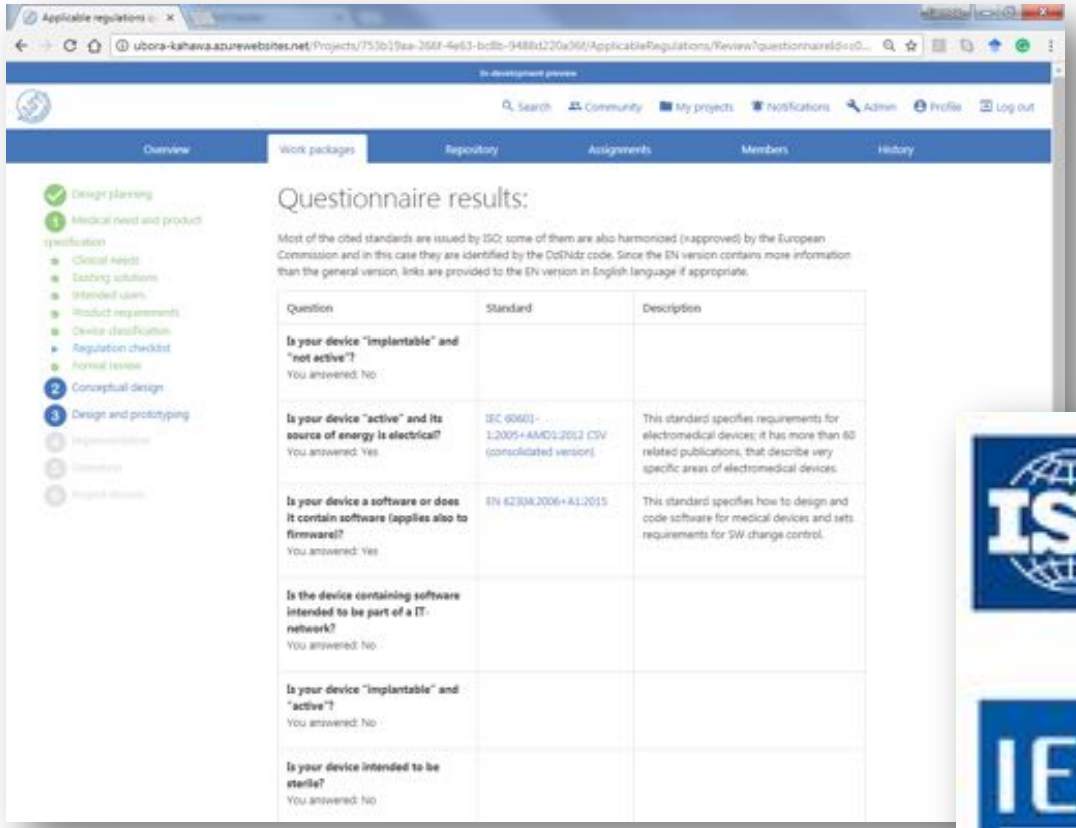


ISO International Organization for Standardization

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

CONCEPTUAL DESIGN

WP2

- Physical principles
- Voting
- Concept description
- Structured information on the device

DESIGN AND PROTOTYPING

WP3

General product description

- Hardware
  - Commercial parts - Purposely designed parts - Prototypes and functional trials
- Electronic & Firmware
  - Commercial parts - Purposely designed parts - Prototypes and functional trials
- Software
  - Commercial parts - Purposely designed parts - Prototypes and functional trials
- System integration
  - Prototypes and functional trials

Design for ISO testing compliance

Instruction for fabrication of prototypes

IMPLEMENTATION

WP4

- Prototypes and considerations for safety assessment
- Quality criteria
- ISO compliance
- Results form vitro/vivo
- Structured information on the device
- Preproduction document

WP5

OPERATION

- Production documentation
- Commercial documentation
- Business model canvas
- Agree on terms of UBORA

PROJECT CLOSURE

WP6

- Info graphic public
- Real life use or simulation
- Presentation for press

Resources

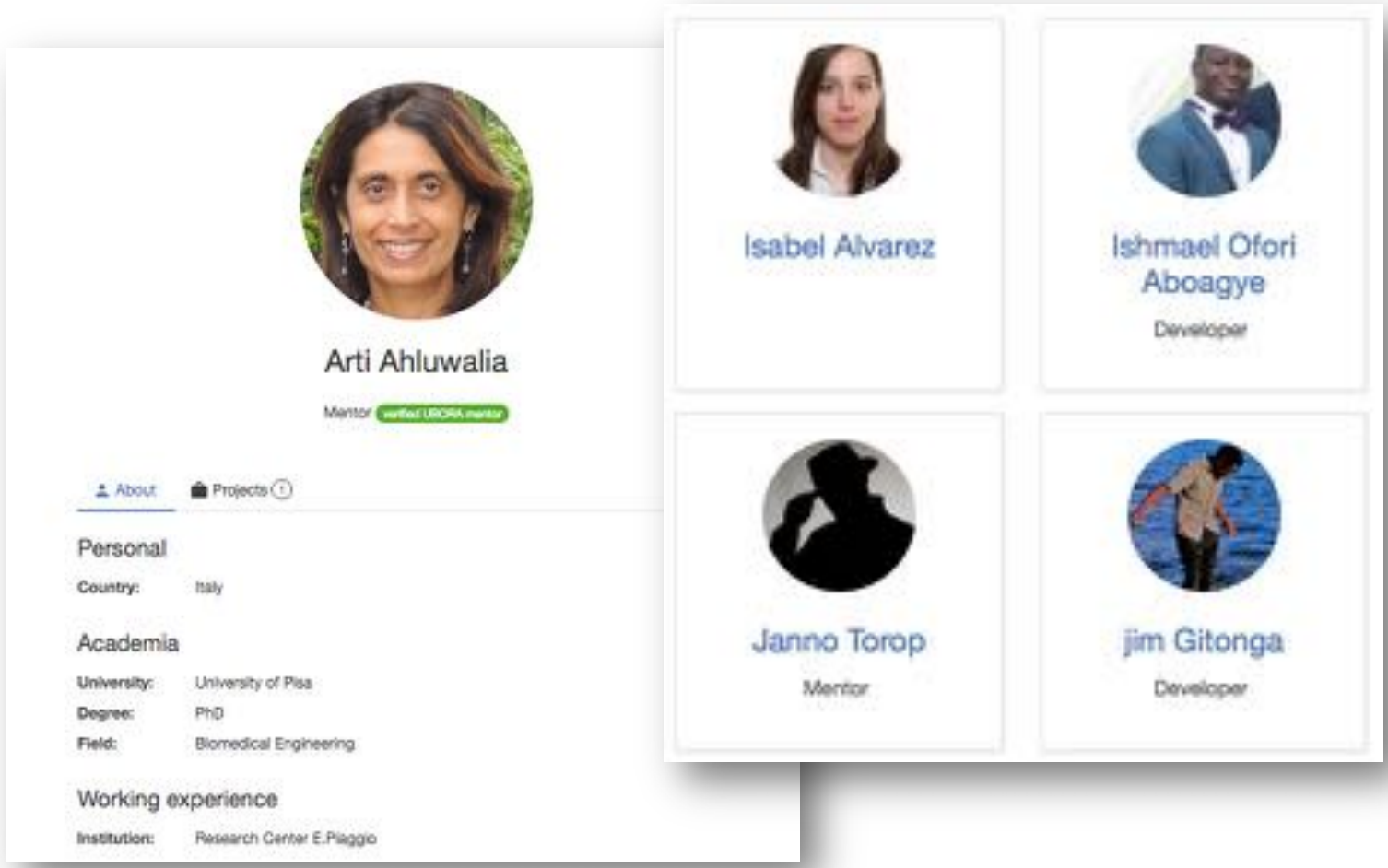
with selected **teaching/learning** materials on Biomedical Engineering.

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

Community

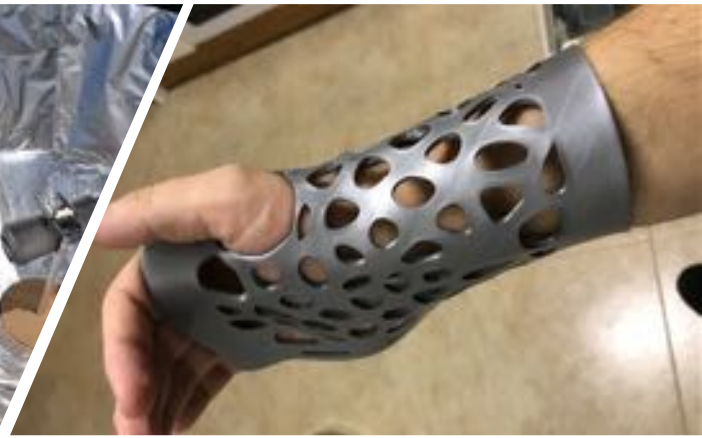
Joining UBORA means being part a **community** of developers, including **professional engineers** and **healthcare providers**, aimed at designing new **open source solutions** for current and future **healthcare challenges**, for a larger access to medical devices.

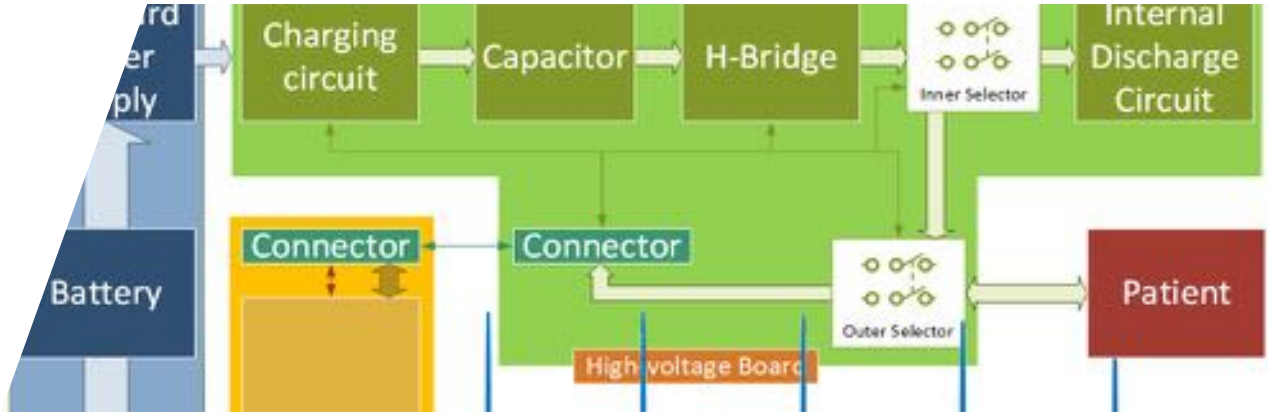
- Developers
- Mentors
- Managing group
- > 500 verified users



UBORA e-Platform

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





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

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

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Project

One week contest

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Instruction for the contest

- Identify an unmet clinical need
- Develop a technological solution
- Present it on Thursday afternoon (5 minutes)!

- It is a teamwork
- You can ask help to mentors
- Use the UBORA platform as guideline

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Evaluation criteria

- Identification of the clinical need
- Technical implementation
- Presentation and documentation

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Teamwork

Teams composition will be published on the teaching/learning platform.

Create to promote diversity:

- Compentences
- Gender
- Background


Teams

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On site teams

Team1	
Cappon	Giacomo
Ronca	Alessandra
Barzaghini	Bianca
Dallera	Debora
Idi	Elena
Pederzani	Elia
Romagnoli	Sofia
Toffoli	Simone
Guazzo	Alessandro
Cossu	Christian

Team2	
De Gaetano	Francesco
Soldo	Brigida
Batoni	Elisa
De Lazzari	Beatrice
Iscra	Katerina
Perico	Francesca
Ronchi	Davide
Usai	Francesca
Manzoni	Eleonora
Corrias	Francesca

Team3	
Marcantoni	Ilaria
Casini	Gaia
Usai	Chiara
Benini	Martina
Dell'Eva	Francesca
Lai	Chun-Feng
Piazzalunga	Chiara
Rota	Ilaria
Verga	Matteo
Marrone	Flavia

Team4	
Bassi	Federica
Venieri	Federica
Bernasconi	Sara
Fan	Ke
Lo Iacono	Francesca
Salurso	Eleonora
Zhao	Jianzhuang
Messa	Letizia
Esposito	Alessio
Torelli	Francesco

Team5	
Quaglini	Silvana
Bocconi	Alberto
fanizza	francesca
Loi	Giada
Poletti	Gianluca
Serrani	Alessio
AL-HADDAD	HIND
Molinaro	Nunzia
Mengarelli	Alessandro
Piersanti	Agnese

Team6	
Tigrini	Andrea
Fontana	Flavio
Tanskanen	Jarno
Bondi	Elena
Farabbi	Andrea
Mancini	Piera
Quaranta	Stefano
SHAPOSHNIKOV	ROMAN
Belay	Birhanu
Monoli	Cecilia

Team7	
Brunetti	Antonio
Lonoce	Giuseppa
Berloco	Francesco
Botte	Ermes
Ferrari	Federica
Marsilio	Luca
Ramella	Anna
She	Ziyu
Luschi	Alessio
Noaro	Giulia

Team8	
Buongiorno	Domenico
Molisani	Michele
Catalano	Chiara
Candidori	Sara
Fu	Junling
Molani	Alessandro
Rando	Alessandra A.
Starita	Serena
Almuhini	Abdulaziz
Pavan	Jacopo

Team9	
Noli	Valentina
Cordiale	Alessandro
Chen	Ziyang
Furco	Marco
Morabito	Aurelia
Rescalli	Andrea
Stratakos	Efstathios
Cannatà	Alessia
Schiavoni	Raissa
Ventresca	Alessandra

Team10	
Pau	Chiara
Rubicondo	Marialucia
Ciriello	Luca
Gambosi	Benedetta
NAKAS	ANESTIS
Ricci	Andrea
Tassi	Emma
Casu	Giulia
Spairani	Edoardo
Cisuelo	Owain

Team11	
Pellizzari	Elisa
Sibilano	Elena
Coro	Florinda
Goretti	Francesco
Nannini	Guido
Ritter	Paolo
Tauro	Emanuele
Vivarelli	Cecilia
Stokes	Katherine
Busola	Oronti

Team 12	
Riccomini	Simone
Atzeni	Michele
Cossu	Luca
Guidetti	Ilaria
Nardini	Alessandra
Rizzi	Stefano
Testa	Carolina
Donno	Lucia
Su	Wanzi

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Online teams

Team1	
Accardo	Agostino
Cafiso	Marco
Crestani	Gloria
corvini	giovanni
Fiorotto	Riccardo
Giannattasio	Raffaele
Marin	Benedetta
Pace	Anna
Perot	Laura
Rossetto	Gianluca

Team2	
Sansò	Alessio
Ajcevic	Milos
Barosso	Elena
Callegaro	Alessia
de Barros Fernandes	Hélia Cristina
Nifosí	Matteo
Goldoni	Riccardo
Marzolla	Elena
Ganassin	Sara
Altini	Nicola

Team3	
Pace	Teresa
Perrella	Antonio
Schastlivaia	Valentina
Alessandrelli	Giulia
Bertola	Andrea
Casagrande	Giustina
Bulfoni	alice
Di Stefano	Marina
Di Sopra	Ermanno

Team4	
Guerra	Chiara
Masetto	Laura
Pagnin	Giulia
Pili	Giulia
Severino	Mario
Dumitrescu	Mihai
Caselli	Alessandro
Husen	Nahimiya
Bonomi	Beatrice
Cece	Enza

Team5	
De Marchi	Beatrice
Garbugio	Francesca
Mengoni	Giada
De Toma	Simona
Ranaldi	Simone
Traldi	Cecilia
Ambrosio	Simone
Borsetti	Ginevra
Ballarini	Federico
Zuanon	Alberto

Team6	
De Piccoli	Isacco
Feidaki	Kyriaki
Gastaldello	Alberto
Iammarino	Erica
Mingoni	Stefano
Pampanin	Luigi
Rigo	Mario
Ugliono	Elettra
Baldan	Matteo
Brunasso	Alessandro

Team7	
De Clemente	Claudia
Fiorentin	Anna
Ferrante	Lorenzo
Gastaldi	Vanessa
K-Papai	Levente
Pandolfo	Nicolò
Vardabasso	Irene
Baliviera	Filippo
Gallucci	Silvia

Team8	
Del Giudice	Libera Lucia
Del Borrello	Giulia
GAZZOLA	SELLY
Marchiori	Hadija
Pavlovic	Lara
Salvato	Alberto
ZHOU	YI
Palasciano	Michele
Chino	Filippo