



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



Carmelo De Maria – University of Pisa



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



<https://www.notimpossible.com/>



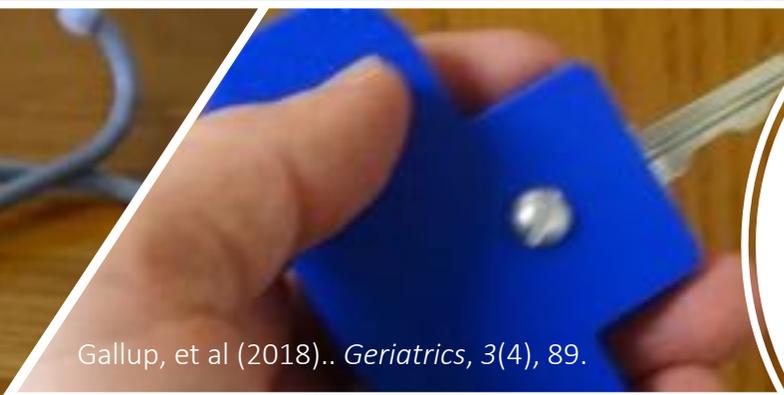
<http://enablingthefuture.org/>



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



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



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



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

UBORA E-INFRASTRUCTURE:
NEEDS ASSESSMENT AND OPEN DESIGN



CONCEPTION AND
DEVELOPMENT

MANUFACTURE

PACKAGING
AND
LABELLING

ADVERTISING

SALE

USE

DISPOSAL

MANUFACTURER

VENDOR

USER

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.

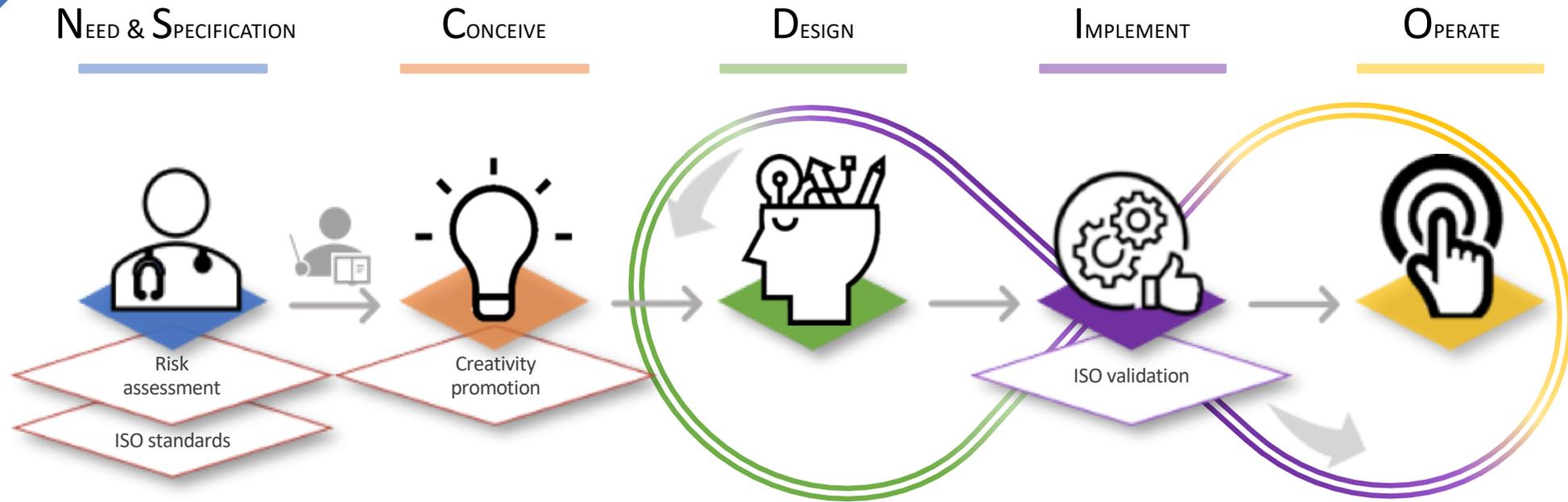


UBORA: Euro-African Open
Biomedical Engineering
e-Platform for Innovation
through Education

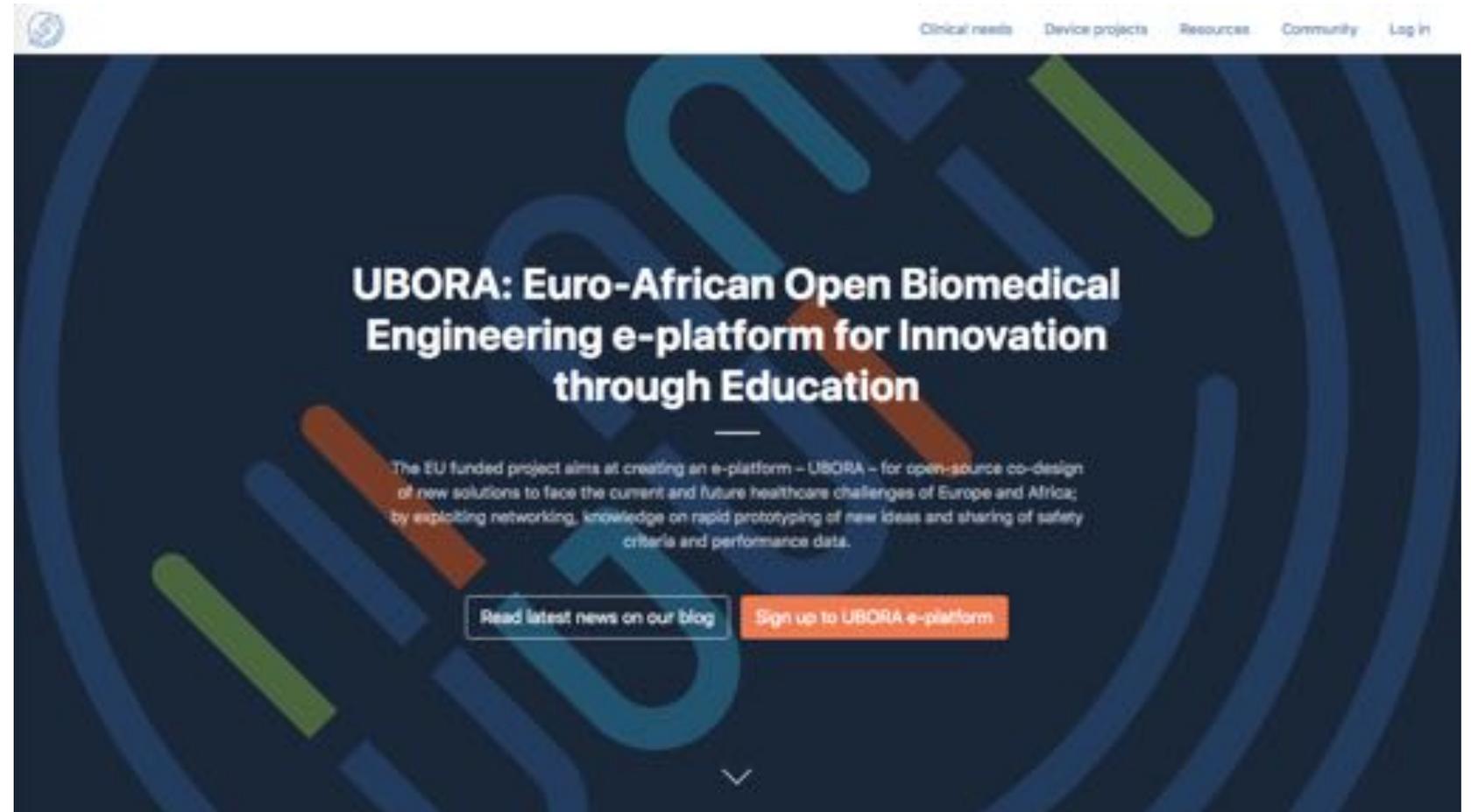




UBORA methodology: safety by design

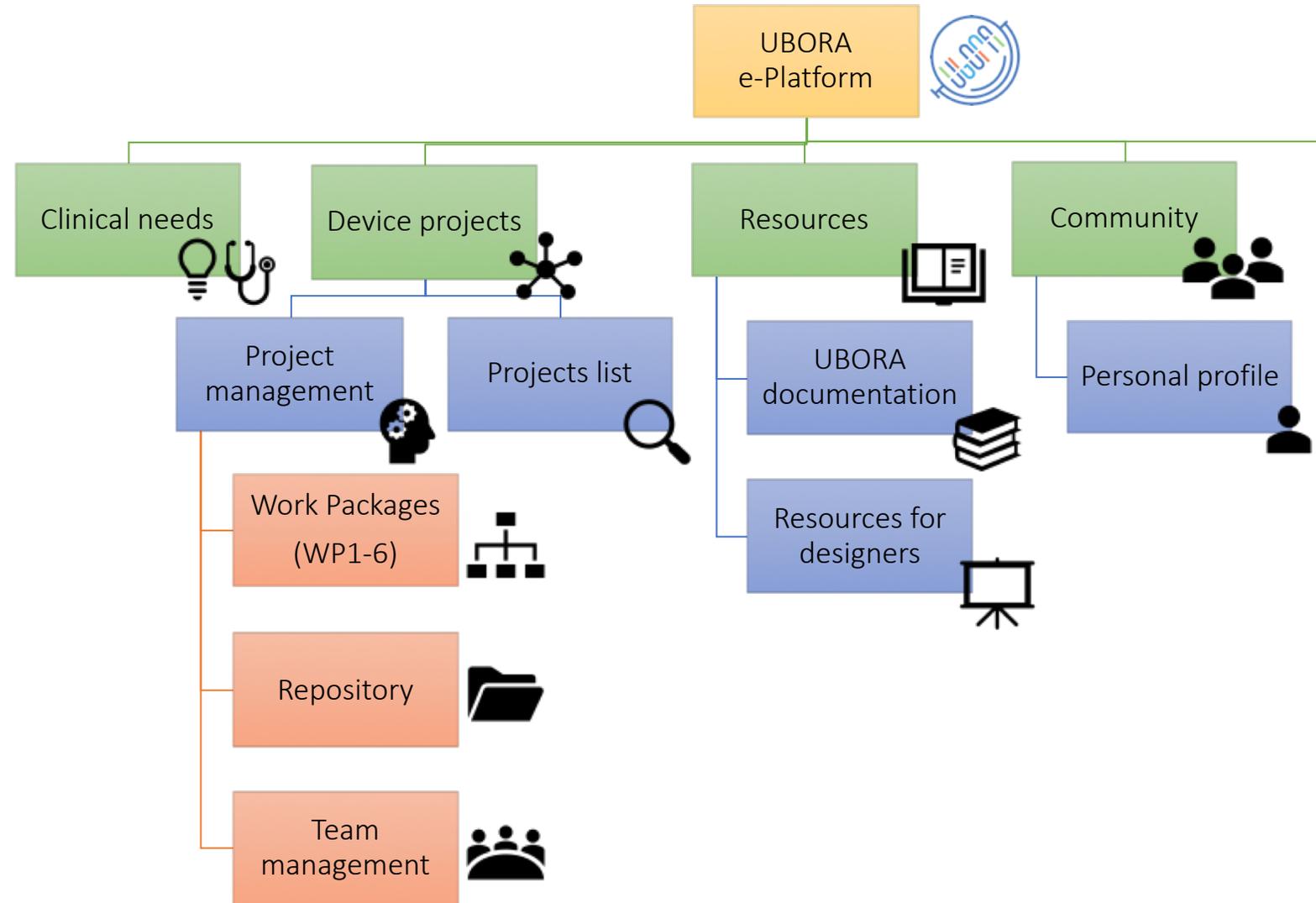


UBORA e-Platform



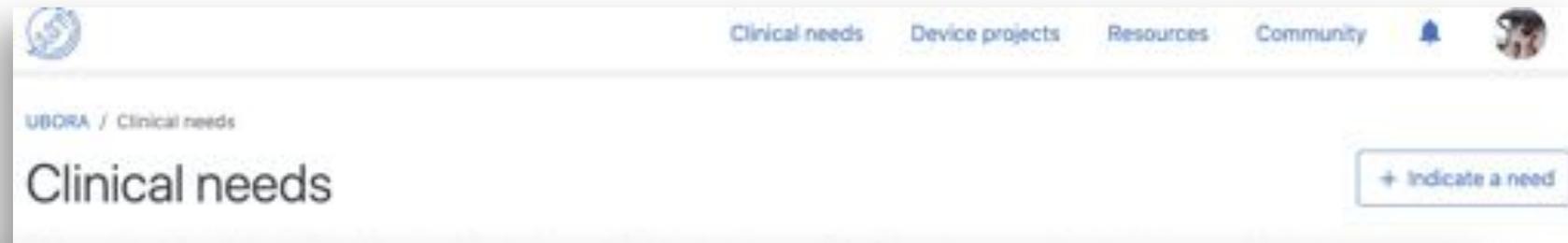
<https://platform.ubora-biomedical.org>

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.



Development of a Low Cost Automatic Dialyzer Reprocessing Machine.
by Jawwad Hossain

Clinical need	Area	Technology	Keywords
Support to medical practice	Nephrology	Other supporting equipment	Automatic cleaning, Reuse extension, Better is etc.

Medical Simulator: The inception of uprooting the curse of medical error
by Shurav Kumar Das

Clinical need	Area	Technology	Keywords
Support to medical practice	Public health	Ergonomic support	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

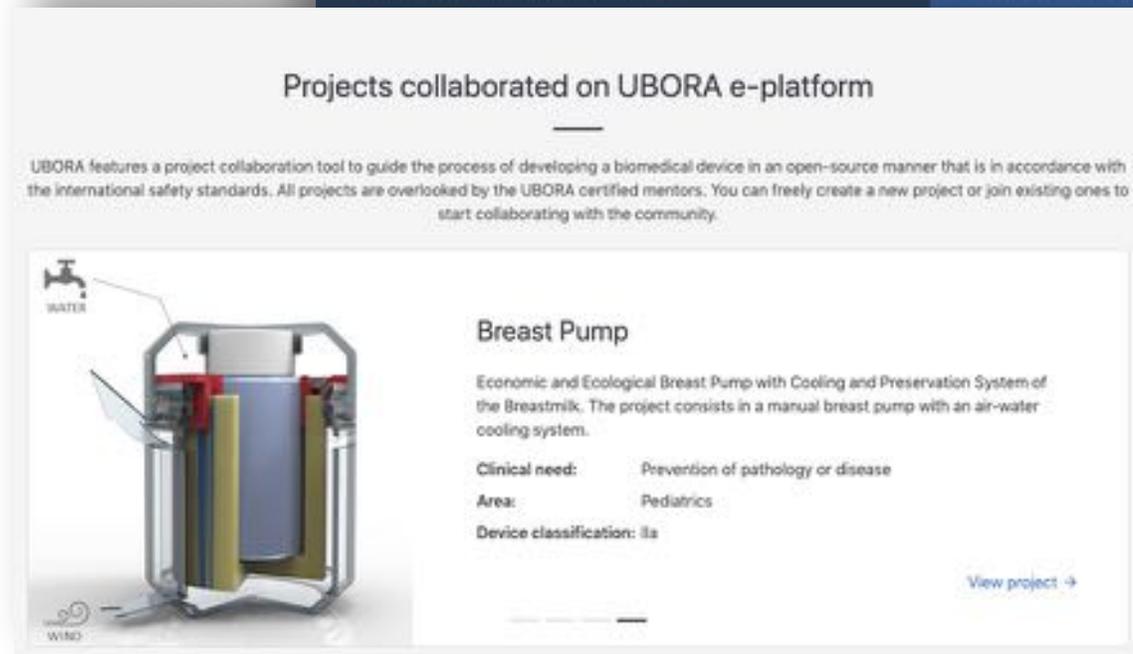
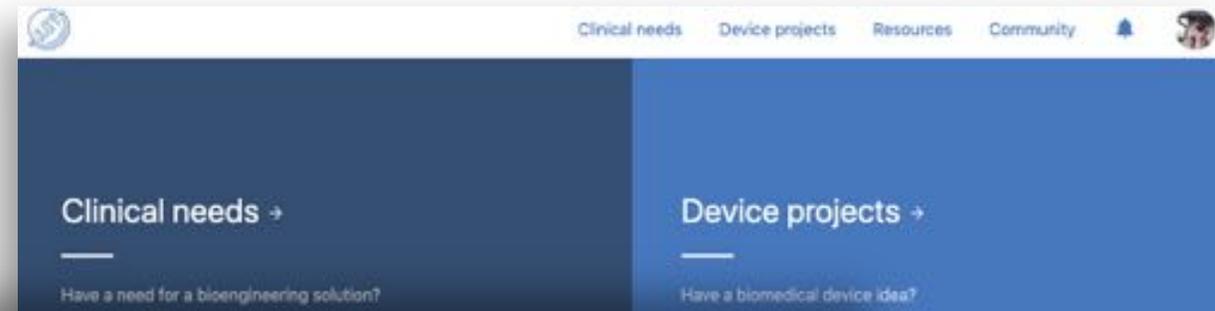
Implementation

WP5

Operation

WP6

Project closure



WP1

Clinical needs

Existing solutions

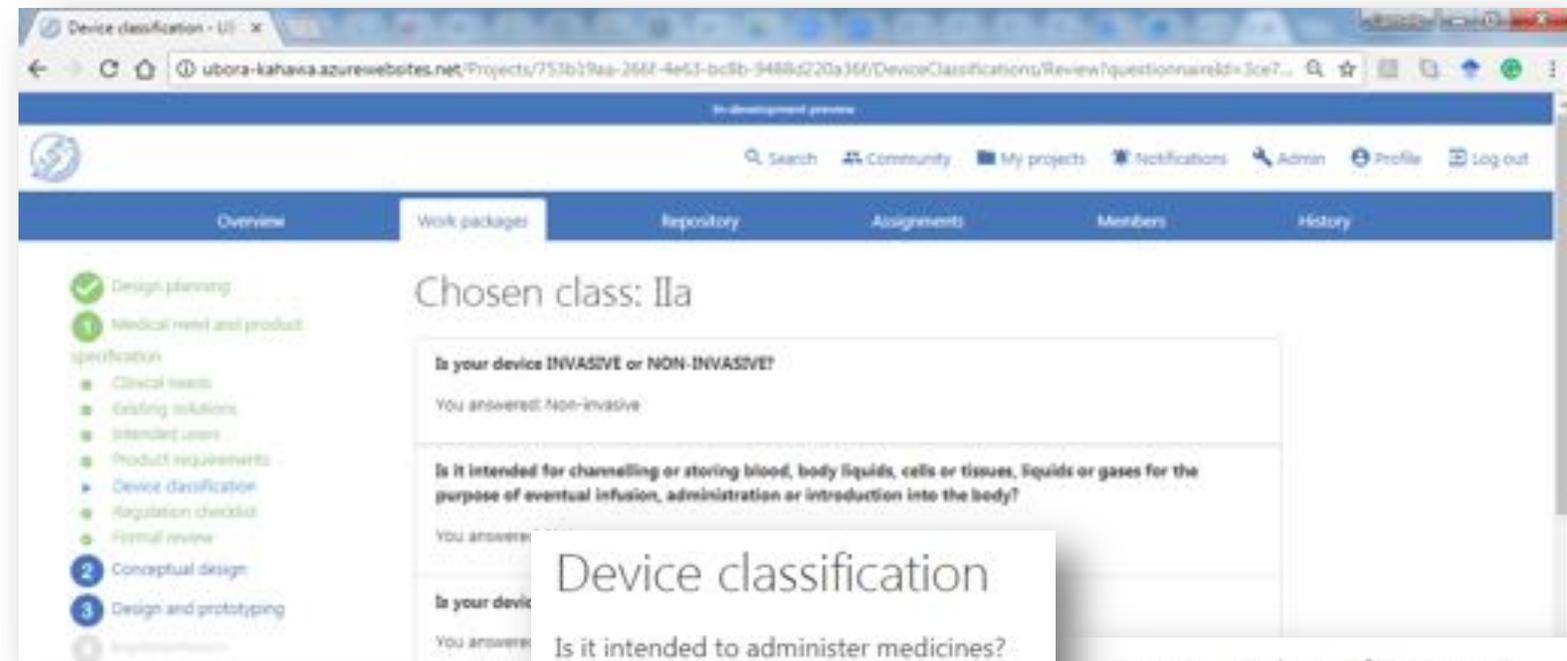
Intended users

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

Clinical needs

Existing solutions

Intended users

Product requirements

Device classification

Regulation checklist

Formal review

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 DoNdr 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		



- 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

Physical principles

Voting

Concept description

Structured information
on the device



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

WP4

IMPLEMENTATION

Prototypes and considerations for safety assessment

Quality criteria

ISO compliance

Results form vitro/vivo

Structured information on the device

Preproduction document



Production documentation

Commercial documentation

Business model canvas

Agree on terms of UBORA



Info graphic public

Real life use or simulation

Presentation for press



Resources

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

UBORA teaching material

Tutorials

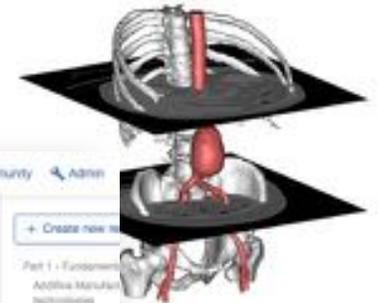
UBORA developer's manual

UBORA user's manual

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



The screenshot shows the UBORA web application interface. The main content area displays a document titled "Mass personalization of medical devices" with the following structure:

- Introduction
- UBORA teaching materials
 - Mass personalization of medical devices
 - Standards and regulations in Europe
 - Usability for medical devices in production
 - Tutorials
- Resource categories

The document content includes:

- Resource 1: 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.

At the bottom, there is a diagram illustrating the additive manufacturing process: a computer monitor showing a 3D model, an arrow pointing to a 3D printer, and another arrow pointing to a hand holding a small blue printed part.



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

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



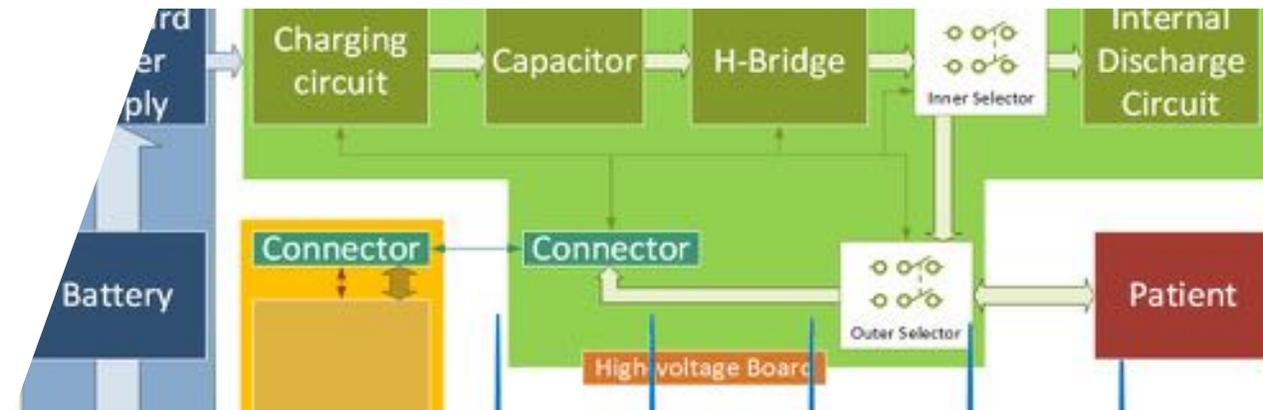
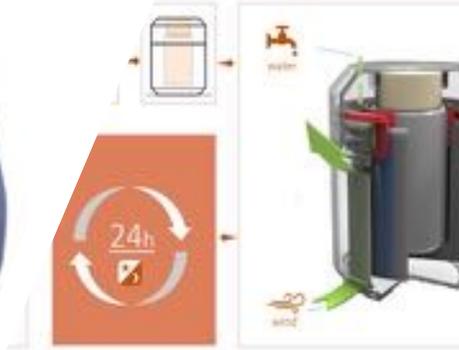
jim Gitonga

Developer

UBORA e-Platform



- Open source automatic defibrillator
- Solar powered autoclave
- 4D printed articular splint
- 3D printed cat for Ponseti method
- 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



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

info@ubora-biomedical.org



Project

One week contest



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



Evaluation criteria

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



Teamwork

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

Create to promote diversity:

- Competences
- Gender
- Background





Teams

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
Loisce	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

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