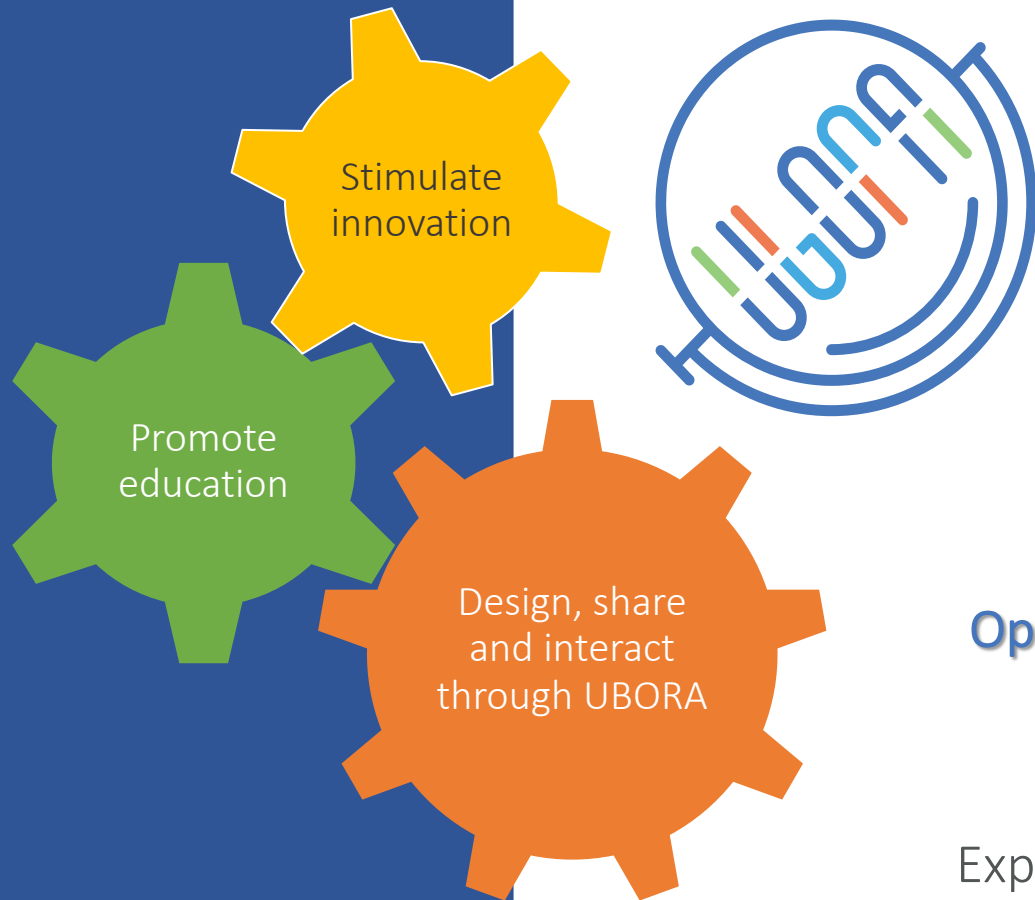


# THE UBORA E-PLATFORM FOR OPEN SOURCE INNOVATION IN MEDICAL TECHNOLOGY



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Carmelo De Maria – University of Pisa



# What is UBORA

An e-Platform and its community

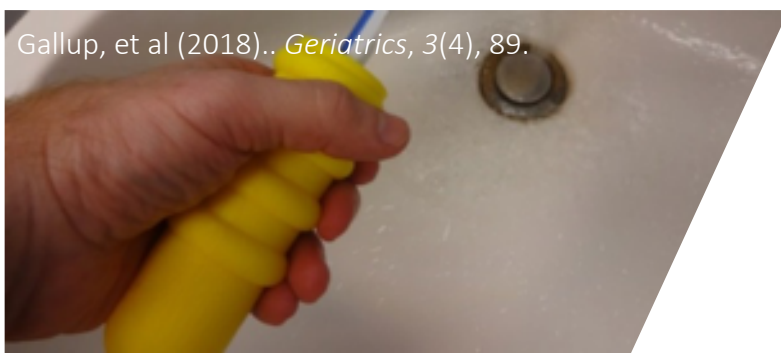
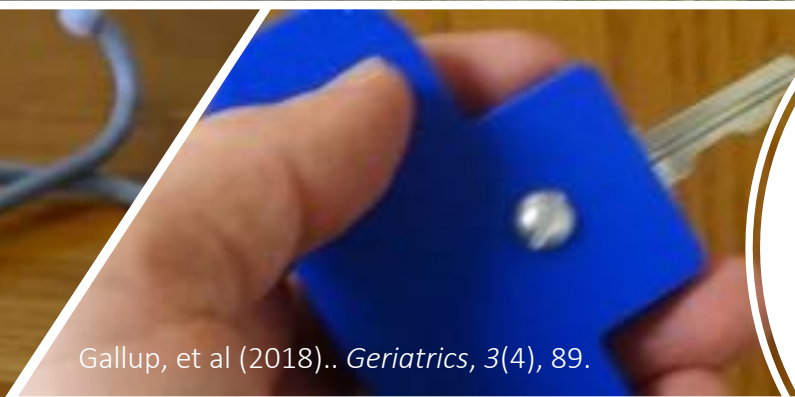
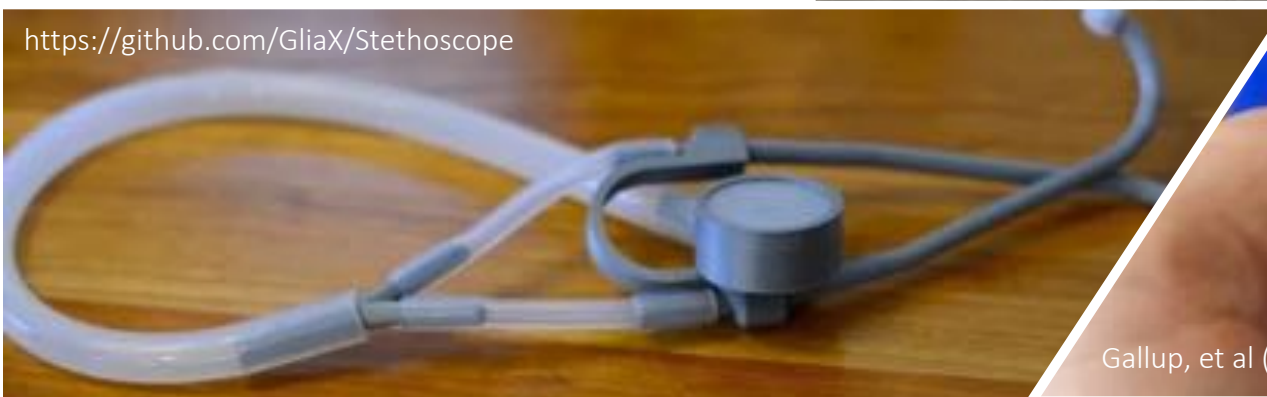
FOR

**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





## 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.

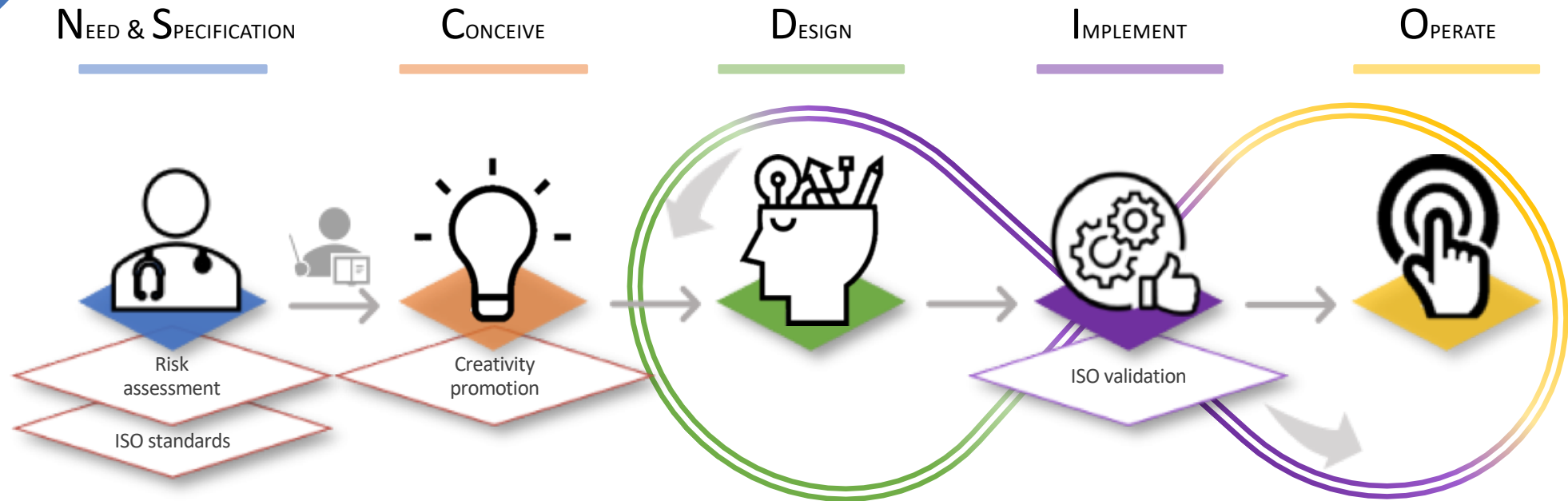


UBORA: Euro-African Open  
Biomedical Engineering  
e-Platform for Innovation  
through Education





# UBORA methodology: safety by design

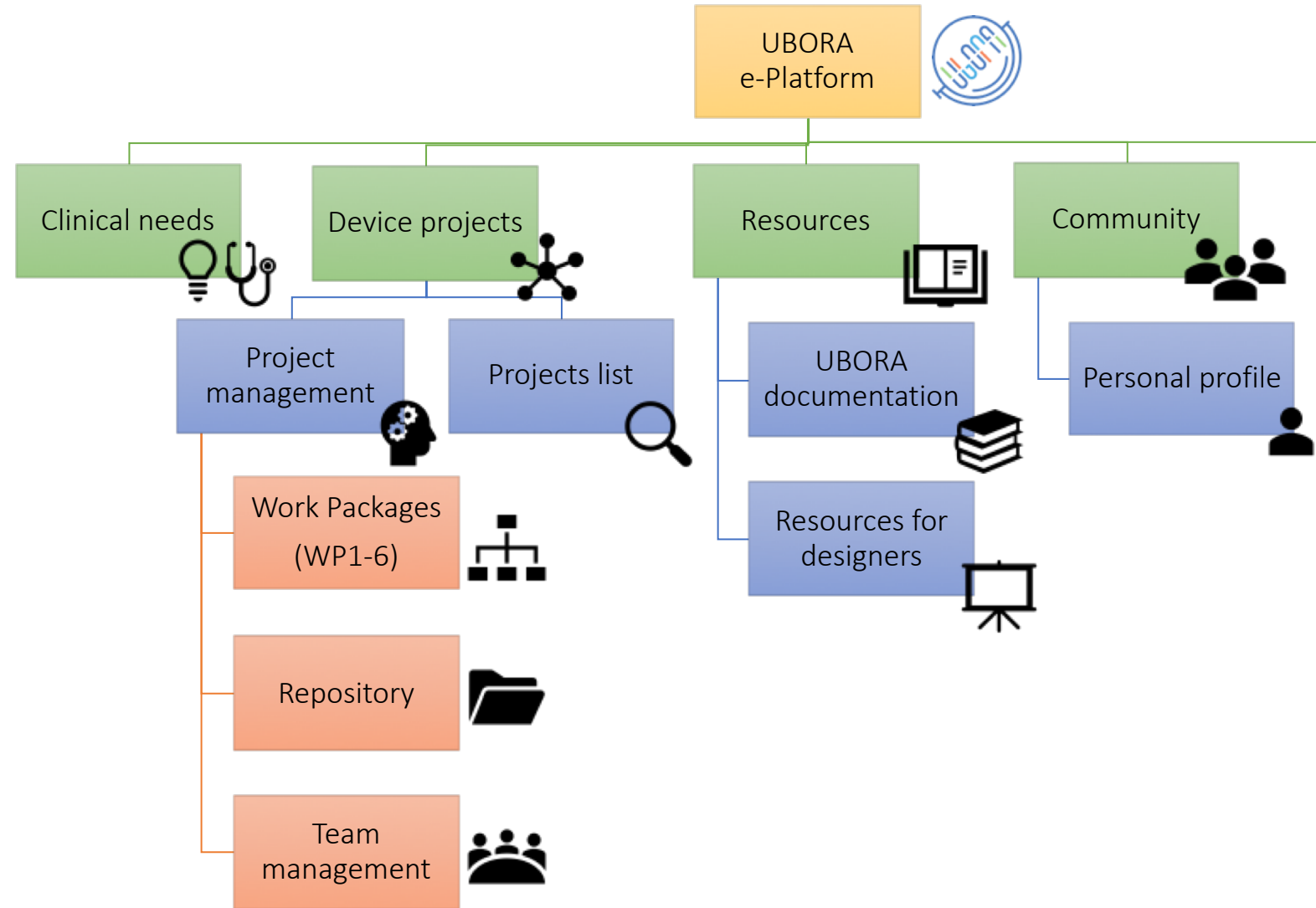


# UBORA e-Platform



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

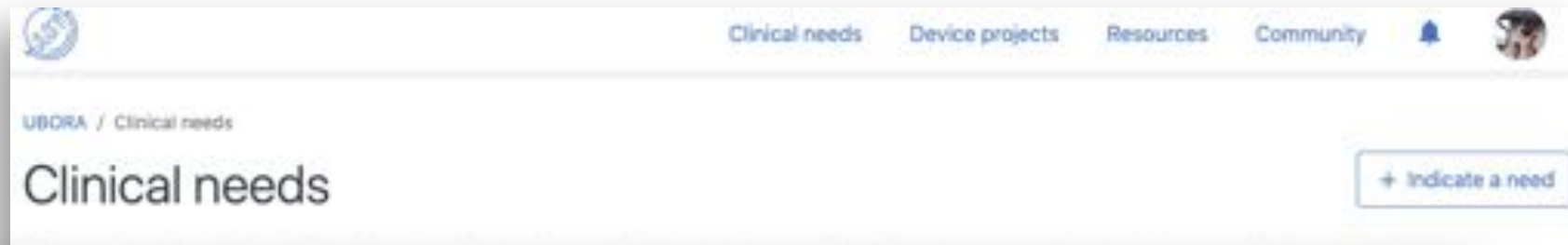
# UBORA e-Platform





## 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

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

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# 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

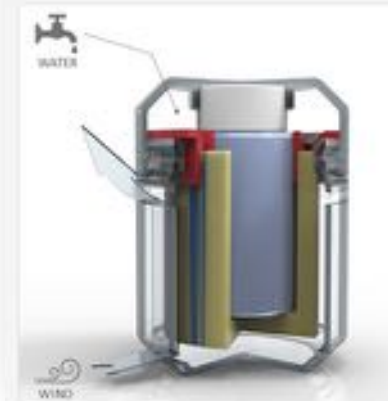
WP6

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: Ila

[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



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

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

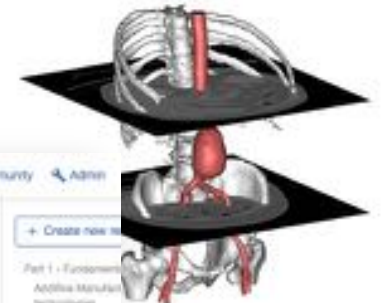
UBORA developer's manual

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



UBORA (in development preview)

Introduction

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

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.

Part 1 - Fundamentals  
Additive Manufacturing technologies  
Additive manufacturing workflow  
Part 2 - European Additive Manufacturing roadmap  
Part 3 - Example of Personalization of

into a fileformat which can be  
The file can describe just the  
an) 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](#)

## 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



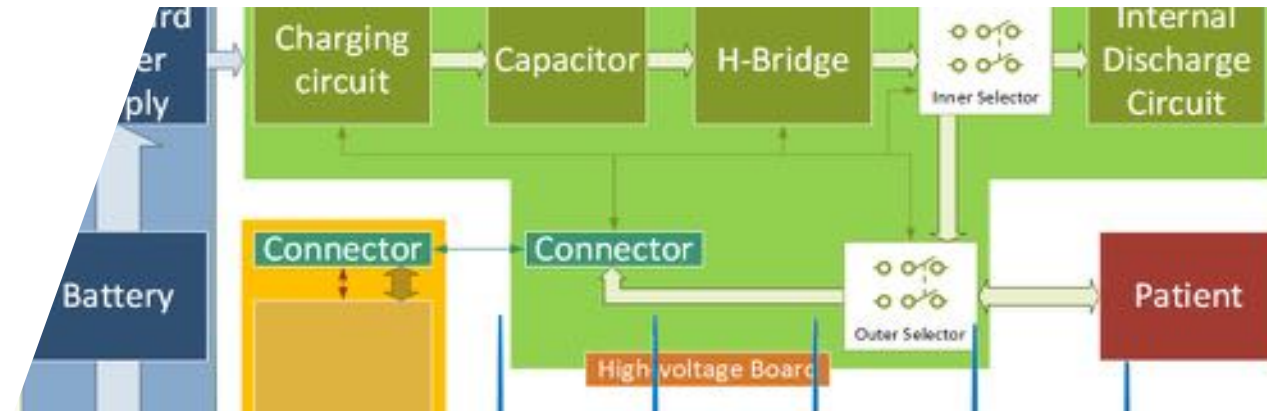
jim Gitonga

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](mailto:info@ubora-biomedical.org)



# Project

One week contest



# Instruction for the contest

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- 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

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



## Teamwork

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

Create to promote diversity:

- Competences
- Gender
- Background





# Teams

# On site teams

<b>Team1</b>		<b>Team2</b>		<b>Team3</b>		<b>Team4</b>		<b>Team5</b>		<b>Team6</b>	
Cappon	Giacomo	De Gaetano	Francesco	Marcantoni	Ilaria	Bassi	Federica	Quaglini	Silvana	Tigrini	Andrea
Ronca	Alessandra	Soldo	Brigida	Casini	Gaia	Venieri	Federica	Bocconi	Alberto	Fontana	Flavio
Barzaghini	Bianca	Batoni	Elisa	Usai	Chiara	Bernasconi	Sara	fanizza	francesca	Tanskanen	Jarno
Dallera	Debora	De Lazzari	Beatrice	Benini	Martina	Fan	Ke	Loi	Giada	Bondi	Elena
Idi	Elena	Iscra	Katerina	Dell'Eva	Francesca	Lo Iacono	Francesca	Poletti	Gianluca	Farabbi	Andrea
Pederzani	Elia	Perico	Francesca	Lai	Chun-Feng	Salurso	Eleonora	Serrani	Alessio	Mancini	Piera
Romagnoli	Sofia	Ronchi	Davide	Piazzalunga	Chiara	Zhao	Jianzhuang	AL-HADDAD	HIND	Quaranta	Stefano
Toffoli	Simone	Usai	Francesca	Rota	Ilaria	Messa	Letizia	Molinaro	Nunzia	SHAPOSHNIKOV	ROMAN
Guazzo	Alessandro	Manzoni	Eleonora	Verga	Matteo	Esposito	Alessio	Mengarelli	Alessandro	Belay	Birhanu
Cossu	Christian	Corrias	Francesca	Marrone	Flavia	Torelli	Francesco	Piersanti	Agnese	Monoli	Cecilia

<b>Team7</b>		<b>Team8</b>		<b>Team9</b>		<b>Team10</b>		<b>Team11</b>		<b>Team 12</b>	
Brunetti	Antonio	Buongiorno	Domenico	Noli	Valentina	Pau	Chiara	Pellizzari	Elisa	Riccomini	Simone
Lonoce	Giuseppa	Molisani	Michele	Cordiale	Alessandro	Rubicondo	Marialucia	Sibilano	Elena	Atzeni	Michele
Berloco	Francesco	Catalano	Chiara	Chen	Ziyang	Ciriello	Luca	Coro	Florinda	Cossu	Luca
Botte	Ermes	Candidori	Sara	Furco	Marco	Gambosi	Benedetta	Goretti	Francesco	Guidetti	Ilaria
Ferrari	Federica	Fu	Junling	Morabito	Aurelia	NAKAS	ANESTIS	Nannini	Guido	Nardini	Alessandra
Marsilio	Luca	Molani	Alessandro	Rescalli	Andrea	Ricci	Andrea	Ritter	Paolo	Rizzi	Stefano
Ramella	Anna	Rando	Alessandra A.	Stratakos	Efstathios	Tassi	Emma	Tauro	Emanuele	Testa	Carolina
She	Ziyu	Starita	Serena	Cannatà	Alessia	Casu	Giulia	Vivarelli	Cecilia	Donno	Lucia
Luschi	Alessio	Almuhini	Abdulaziz	Schiavoni	Raissa	Spairani	Edoardo	Stokes	Katherine	Su	Wanzi
Noaro	Giulia	Pavan	Jacopo	Ventresca	Alessandra	Cisuelo	Owain	Busola	Oronti		

# Online teams

Team1		Team2		Team3		Team4	
Accardo	Agostino	Sansò	Alessio	Pace	Teresa	Guerra	Chiara
Cafiso	Marco	Ajcevic	Milos	Perrella	Antonio	Masetto	Laura
Crestani	Gloria	Barosso	Elena	Schastlivaia	Valentina	Pagnin	Giulia
corvini	giovanni	Callegaro	Alessia	Alessandrelli	Giulia	Pili	Giulia
Fiorotto	Riccardo	de Barros Fernandes	Hélia Cristina	Bertola	Andrea	Severino	Mario
Giannattasio	Raffaele	Nifosí	Matteo	Casagrande	Giustina	Dumitrescu	Mihai
Marin	Benedetta	Goldoni	Riccardo	Bulfoni	alice	Caselli	Alessandro
Pace	Anna	Marzolla	Elena	Di Stefano	Marina	Husen	Nahimiya
Perot	Laura	Ganassin	Sara	Di Sopra	Ermanno	Bonomi	Beatrice
Rossetto	Gianluca	Altini	Nicola			Cece	Enza

Team5		Team6		Team7		Team8	
De Marchi	Beatrice	De Piccoli	Isacco	De Clemente	Claudia	Del Giudice	Libera Lucia
Garbugio	Francesca	Feidaki	Kyriaki	Fiorentin	Anna	Del Borrello	Giulia
Mengoni	Giada	Gastaldello	Alberto	Ferrante	Lorenzo	GAZZOLA	SELLY
De Toma	Simona	Iammarino	Erica	Gastaldi	Vanessa	Marchiori	Hadija
Ranaldi	Simone	Mingoni	Stefano	K-Papai	Levente	Pavlovic	Lara
Traldi	Cecilia	Pampanin	Luigi	Pandolfo	Nicolò	Salvato	Alberto
Ambrosio	Simone	Rigo	Mario	Vardabasso	Irene	ZHOU	YI
Borsetti	Ginevra	Uglio	Elettra	Baliviera	Filippo	Palasciano	Michele
Ballarini	Federico	Baldan	Matteo	Gallucci	Silvia	Chino	Filippo
Zuanon	Alberto	Brunasso	Alessandro				