

Towards the Development of Paediatric Medical Devices: Identifying and Gathering User Needs

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LA NOSTRA
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MEDICAL DEVICE

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:

- ✓ diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- ✓ providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

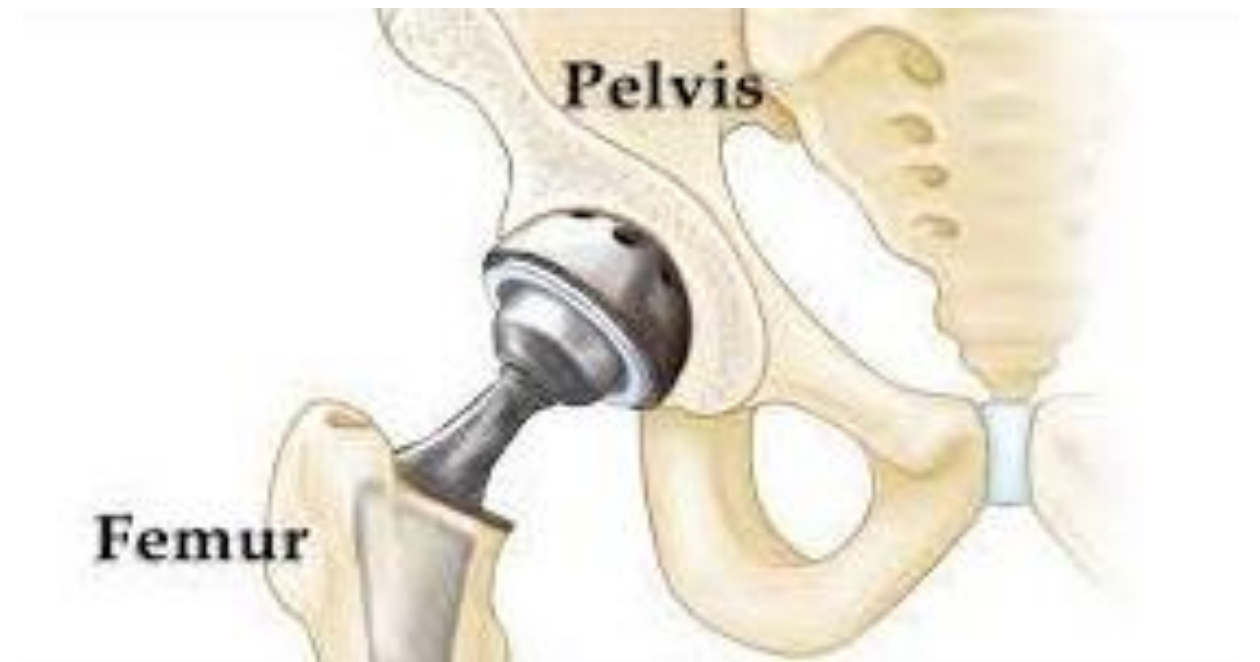
DIFFERENT MEDICAL DEVICES



DIFFERENT MEDICAL DEVICES



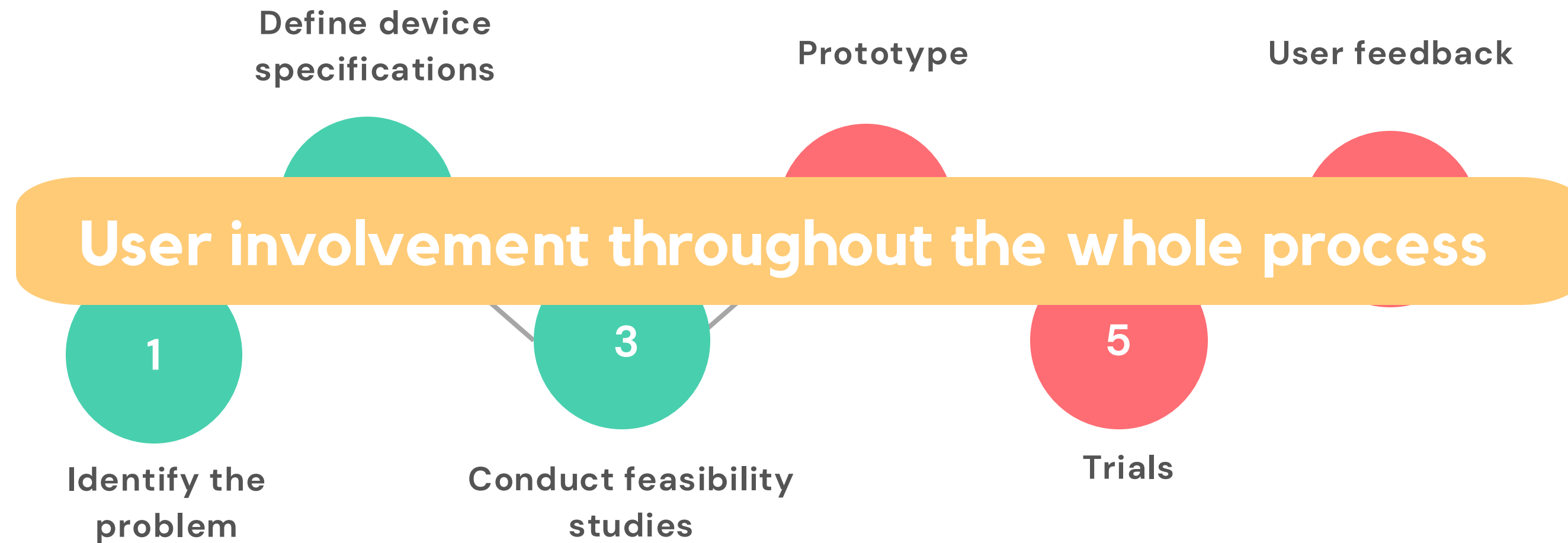
DIFFERENT MEDICAL DEVICES



DIFFERENT MEDICAL DEVICES



STEPS TOWARDS THE DEVELOPMENT OF PEDIATRIC MD



CASE STUDY OF DEVELOPMENT OF MD FOR A RARE DISEASE

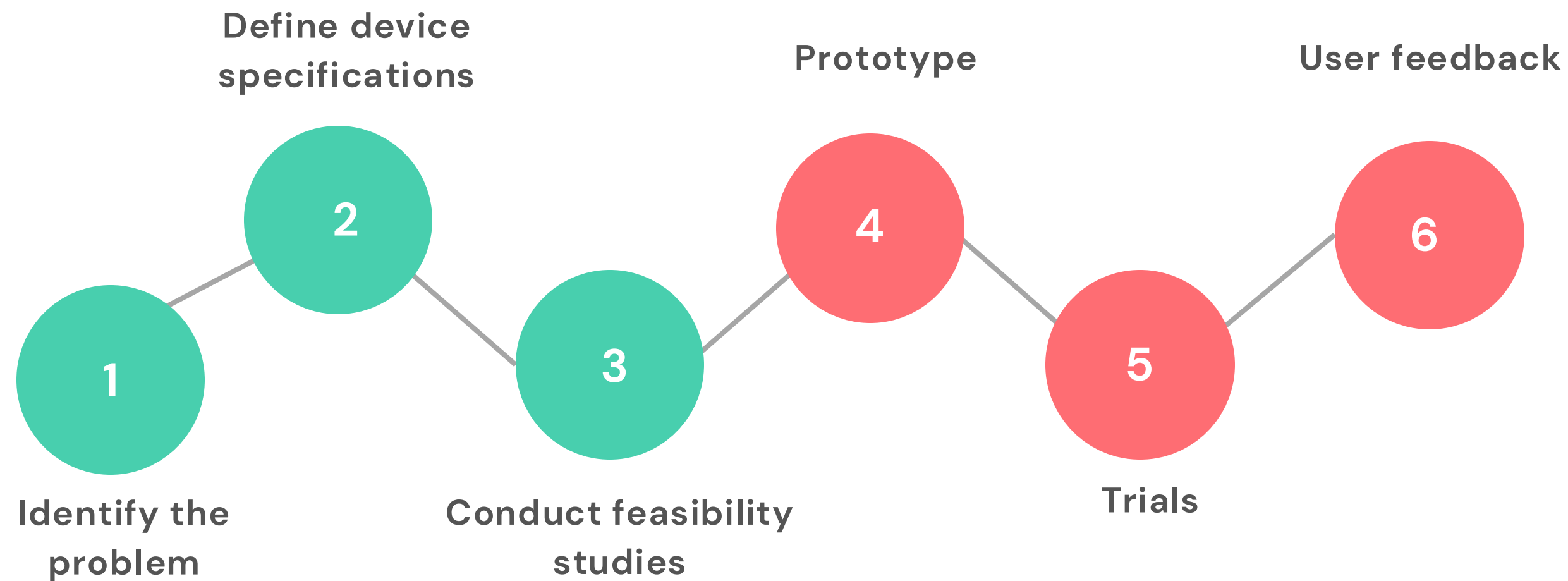
- Congenital Central Hypoventilation Syndrome (CCHS), or Ondine's curse, is a **rare genetic disease** (estimated prevalence 1/200000) , caused by a mutation in the PHOX2B gene.
- It **affects the autonomic nervous** system and it is mainly characterized by **hypoventilation episodes** occurring especially during sleep.
- All patients with CCHS require **lifelong ventilatory support during sleep** and, in some cases, 24 hours per day
- It is suggested to **monitor oxy-hemoglobin blood concentration (SpO2)**, especially during sleep.

MAIN ISSUES IN CCHS MANAGEMENT

- Patients, especially in the case of young children, have to be supervised by a **caregiver**.
- The only **alarm systems** available for patients with CCHS are the ones integrated in the ventilators and monitor devices (e.g. pulse-oximeter).

An adequate domiciliary assistance is still not present!

STEPS TOWARDS THE DEVELOPMENT OF A MD TO SUPPORT AWACKENING



**AISICC
SINDROME
DI ONDINE**

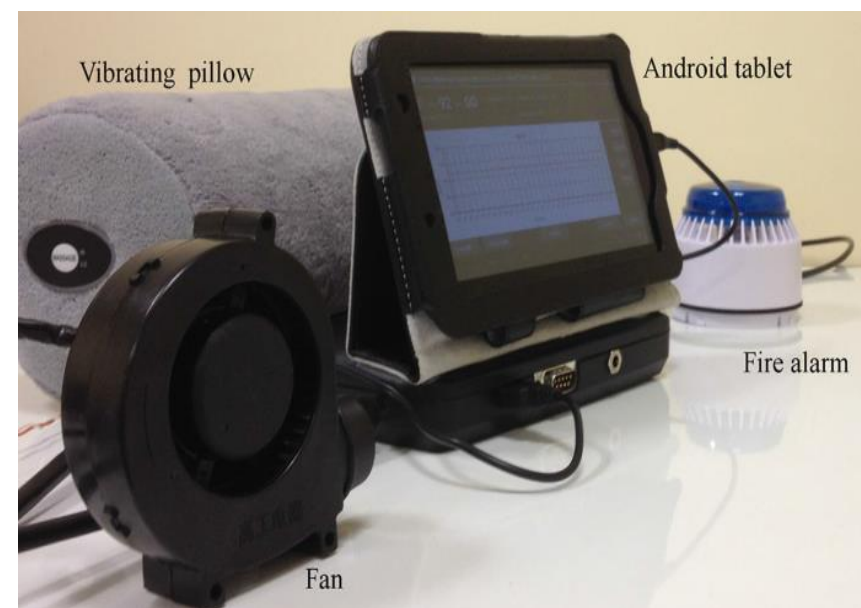


AWACKENING DEVICE



Assistive device, coupled with a pulse-oxymeter, which provides multisensory stimulations based on the patient condition and his oxy-hemoglobin (SpO₂) blood concentration level

Design, prototype and lab tests



Italian Patent (Application n° MI2011A002324)



AWACKENING DEVICE



Clinical trials to collect effectiveness data and feedback from users

Next steps are

- ✓ Re-design to increase acceptability and usability
- ✓ Go to the market

MEDICAL DEVICES FOR PEDIATRIC RARE DISEASES



The OrphaDev4Kids proposal aims to address the challenge of orphan medical devices (MDs) for paediatric use.

WP3 GOALS



To enable the development of an orphan paediatric MD to improve management of Cyanotic Congenital Cardiac Diseases



To connect the experts and stakeholders involved in the development process

FIRST ACTIVITIES

Advice by clinical experts

Advice by researchers

Advice by caregivers

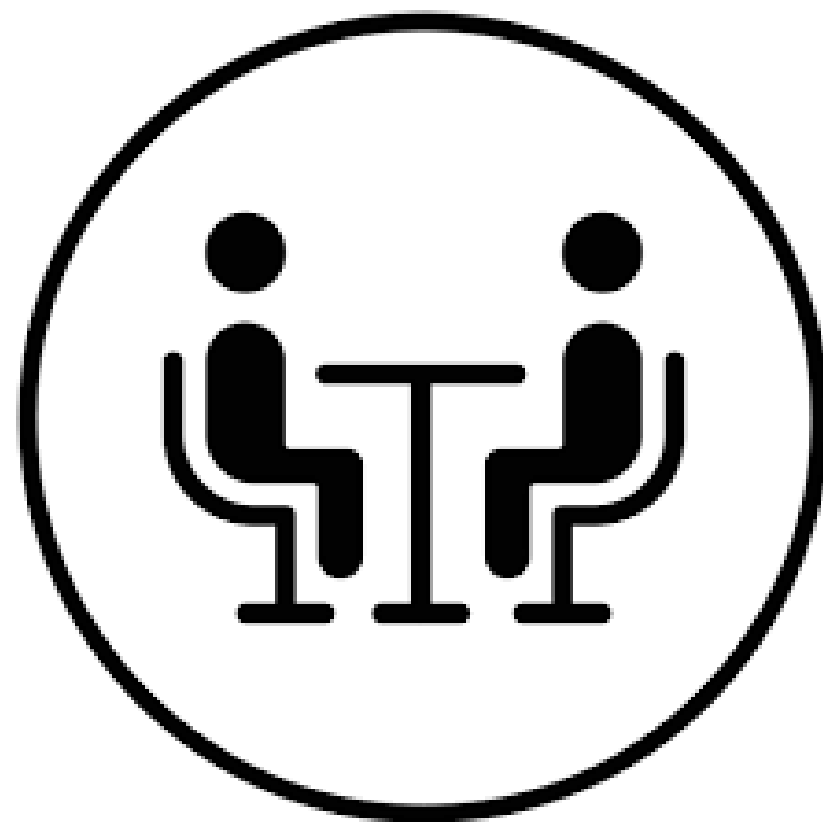
Advice by Patient Expert Committee



HOW TO GET USER FEEDBACK?



Focus groups



Interviews



Online surveys



THANK YOU

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