

TRP MEDICAL DEVICES

Emilia Biffi
IRCCS Eugenio Medea

EPTRI General Assembly– Bari – 18-19/07/2024

Mission of the TRP Medical Device



Paediatric Medical
Devices

The Paediatric Medical Devices TRP is aimed to

- ✓ improve the diffusion of knowledge on paediatric medical devices,
- ✓ foster the research in this field
- ✓ increase the number of new medical devices tailored for children based on their needs



Coordinator
Paul Dimitri
Sheffield Children's NHS
Foundation Trust

MD TRP CORE GROUP	
Name	Institution
Emilia Biffi	IRCCS Eugenio Medea
Roberta Nossa	IRCCS Eugenio Medea
Paul Dimitri	SHEFFIELD CHILDREN'S NHS FOUNDATION TRUST
Annelie-Martina Weinberg	University of Medicine of Graz
Tamar Weiss	ALYN Hospital
Arie Melamed-Yekel	ALYN Hospital
Ahmi Ben-Yehudah	ALYN Hospital
Natalia Szyperk	Warsaw Children's Memorial Health Institute
Magdalena Pawlowska	Warsaw Children's Memorial Health Institute

Why Medical Devices?



Paediatric Medical Devices (MDs) development faces **unique challenges**.

Size, growth,
development



Psychosocial
maturation



Physiology and
pathophysiology



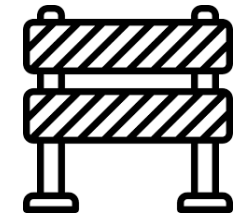
New EU MDR
requirements and
deadlines



Adapt MD for adults to children

Orphan medical devices for children may become unavailable

Barriers for development of paediatric MD



Ethical barriers

- children are vulnerable and investigations are considered to be more risky than with adults
- children cannot fully understand risks and thus give an informed consent to participate in research

Clinical barriers

- children's physiology and anatomy drastically changes over time: technological solutions to accommodate (miniaturisation or adaptability)
- children may not have the cognitive capacity to interact with or operate medical technology
- around 60-75% of devices are used for off-label indications for pediatric patients

Regulatory barriers

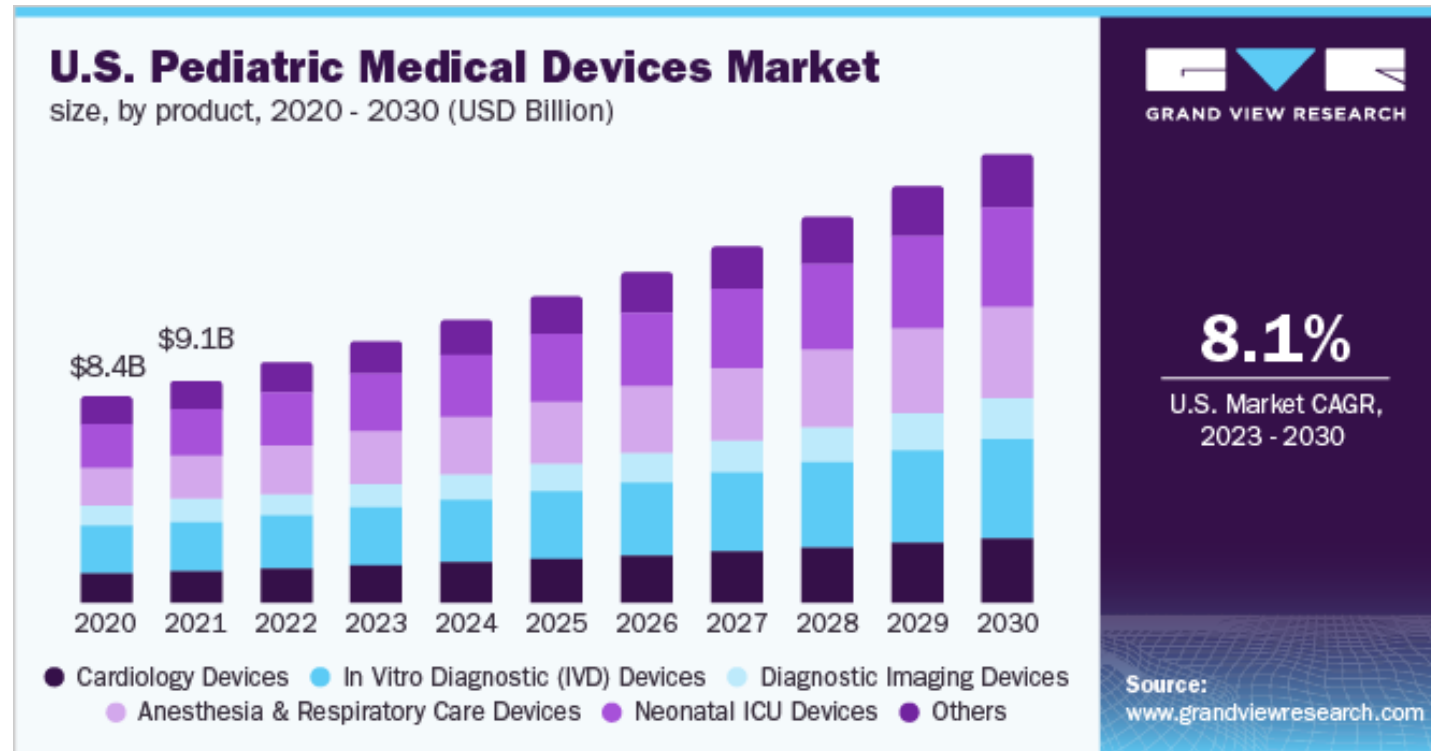
- smaller sample size and age heterogeneity within the paediatric population renders reliable safety data difficult to obtain
- the regulatory agencies have a higher standard for paediatric device approvals

Financial barriers

- due to a small market size, paediatric medical device innovators struggle to procure venture capital funding necessary to support device development
- the device reimbursement rates are lower in paediatrics and no standardised national coverage exists

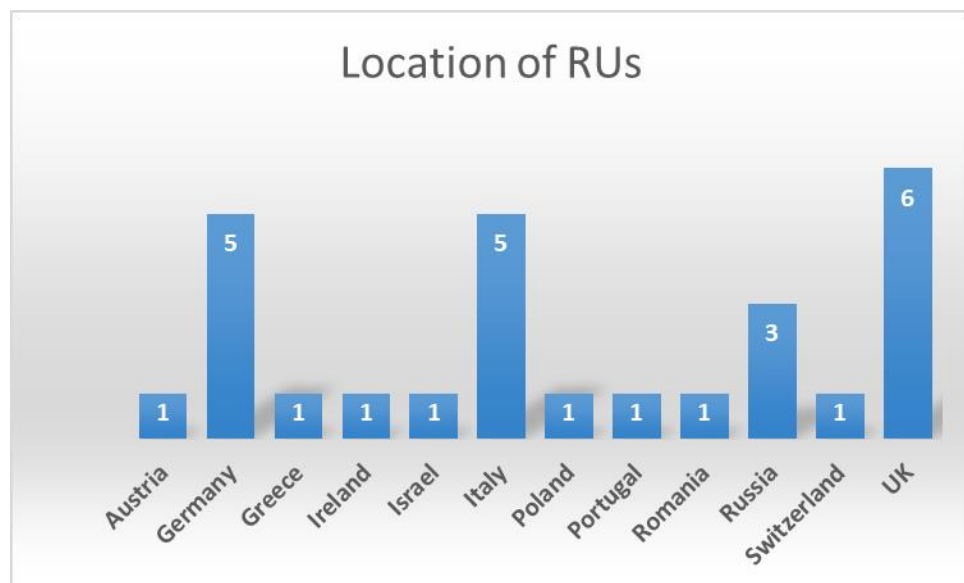
Opportunities for paediatric MD

- 40% of the global population is under 24, creating significant future healthcare market opportunities
- Rising chronic diseases among the children such as respiratory disorders and asthma
- Global pediatric healthcare market is expected to generate around USD 15,984 million by 2025

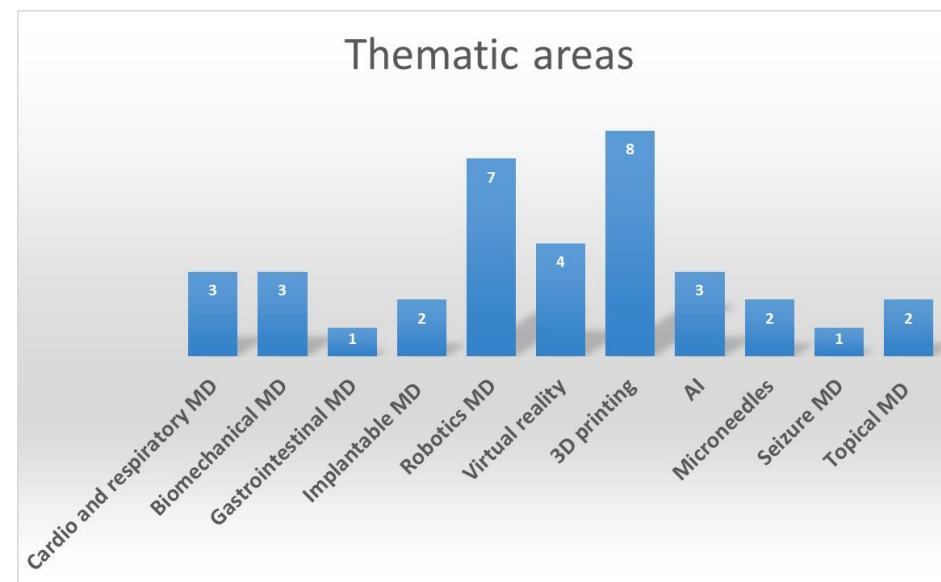


Participants to MD TRP

27 research units involved in the TRP



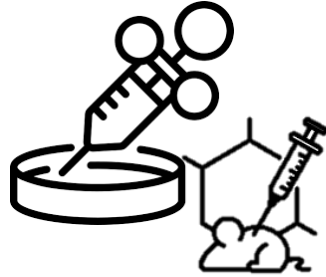
Several services provided



Services offered by MD TRP



Design of the medical device



In vitro e in vivo pre-clinical test of medical devices



Medical devices' prototype and safety analysis

- Microbiological testing of medical devices
- Physico-chemical characterisation of medical devices
- Mechanical, electrical, electronic or non-clinical toxicological testing of medical devices
- Biocompatibility testing of medical devices



Clinical validation of medical devices
End user/usability assessment

Actions performed by MD TRP

Educational activities: webinars

Planned webinars (every two months) to **rise awareness and share knowledge** about MD

Delphi survey

To **detect unmet needs** on MD

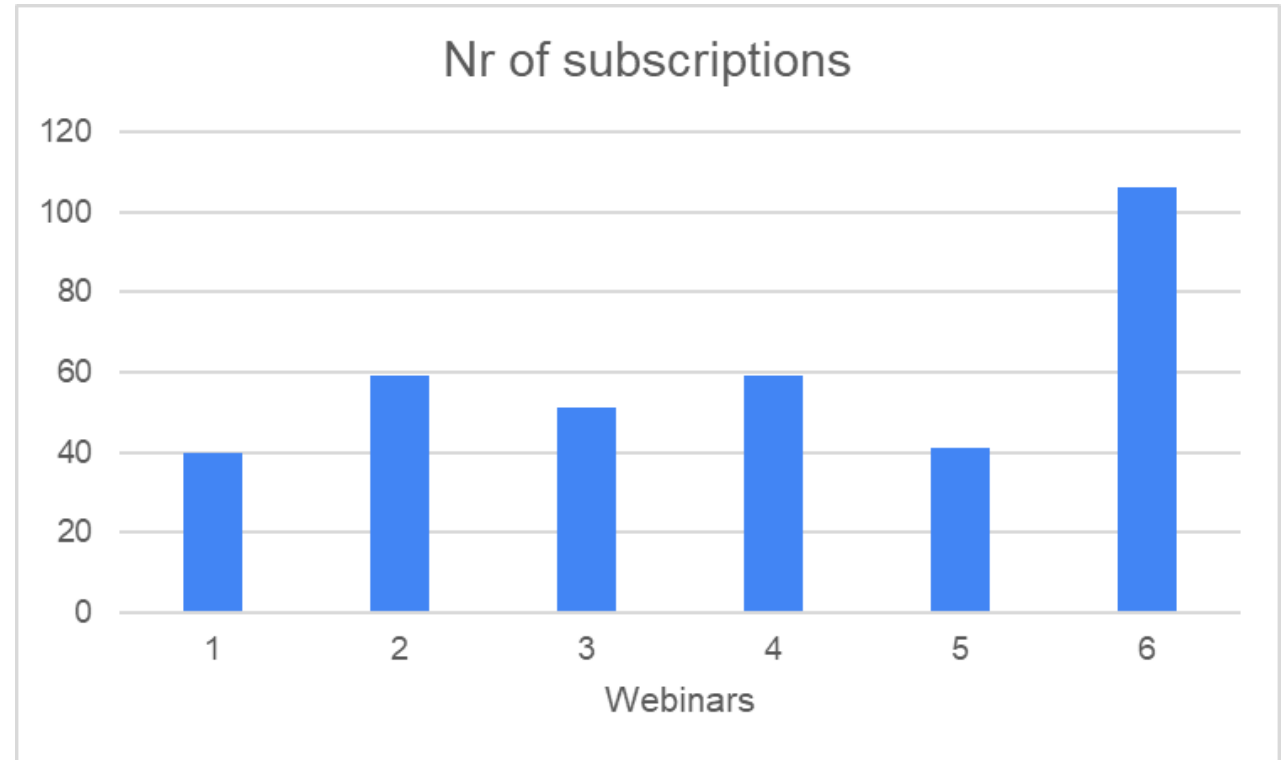
EPTRI webinars: participants and statistics

Educational activities: webinars

Planned webinars (every two months) to **rise awareness and share knowledge** about MD



<https://www.youtube.com/@eptri2547>



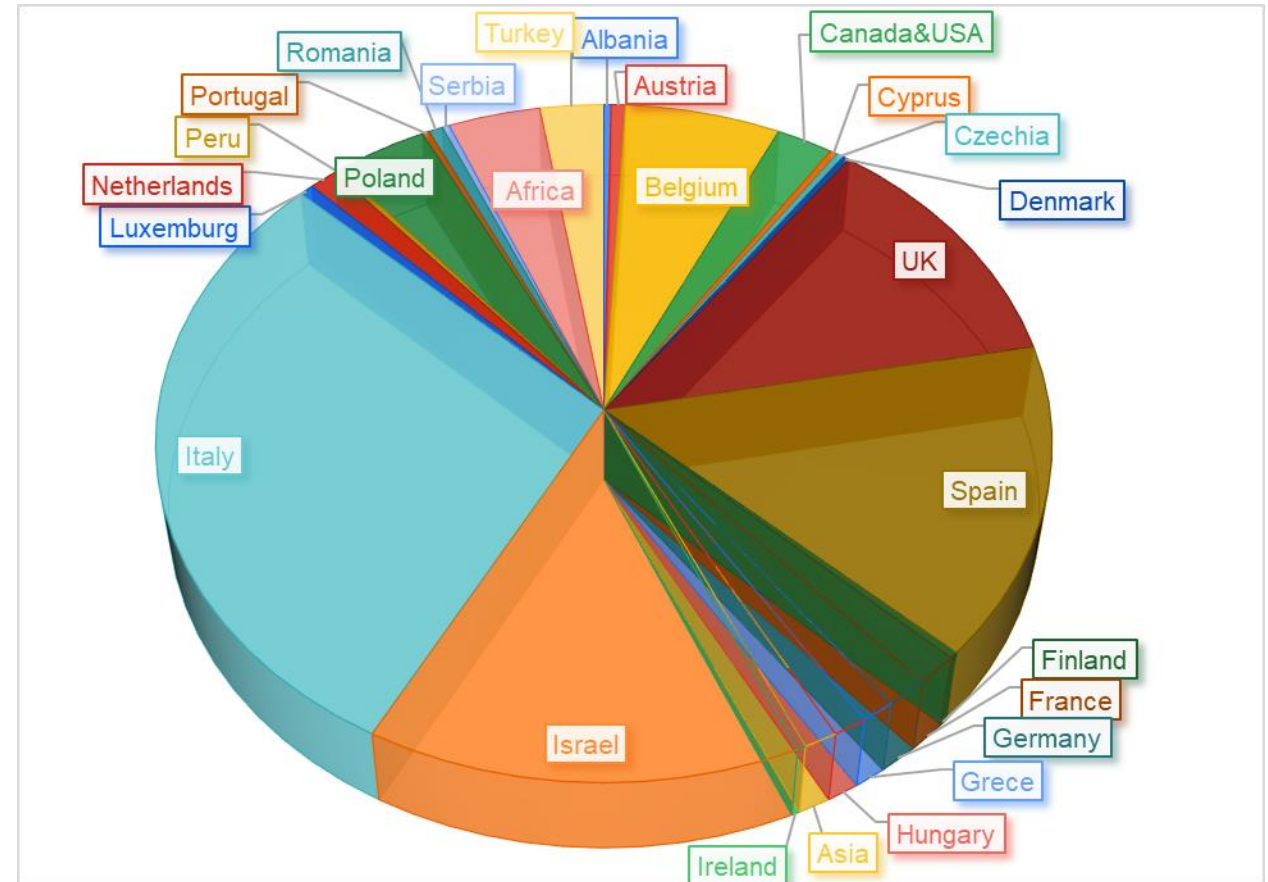
EPTRI webinars: participants and statistics

Educational activities: webinars

Planned webinars (every two months) to rise awareness and share knowledge about MD



<https://www.youtube.com/@eptri2547>



Delphi survey

Educational activities: webinars

Planned webinars (every two months) to **rise awareness and share knowledge** about MD

Delphi survey

To **detect unmet needs** on MD

Next steps:

- circulate the survey among EPTRI members (1 st phase) to assess their opinion
- refinement
- circulate it among other stakeholders (2 nd phase)
- prepare publication of the top 10 unmet needs in this field.

Thank you



Paediatric Medical
Devices