



Develop Child and Orphan  
Device Evaluation support



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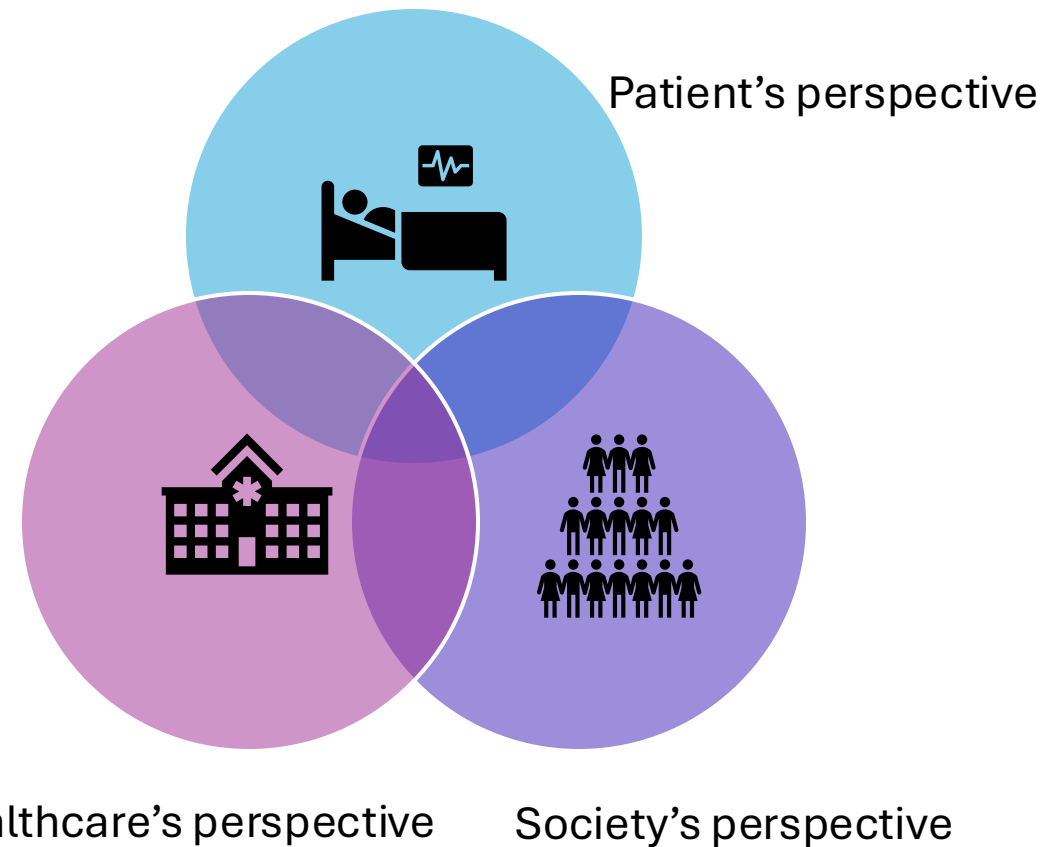
# DeCODE – Background

- RD patients have an unmet need for paediatric and orphan medical devices
- There is a need to foster and guide the development of orphan devices, for paediatric patients, in particular in areas of unmet need.
- The MDCG has developed a guidance for the development of orphan devices
- DeCODE takes inspiration of the Pediatric Devices Research Consortia of the FDA.



# Unmet need for devices

- Previous research
  - Majority of clinicians indicate need for new device
  - Existing devices have limitations
  - Current legislation provides options but also sees challenges
  - Pediatric focus brings unique challenges



# Barriers to orphan device development



Clinical  
hurdles



Technical  
hurdles



Financial  
hurdles



Regulatory  
hurdles

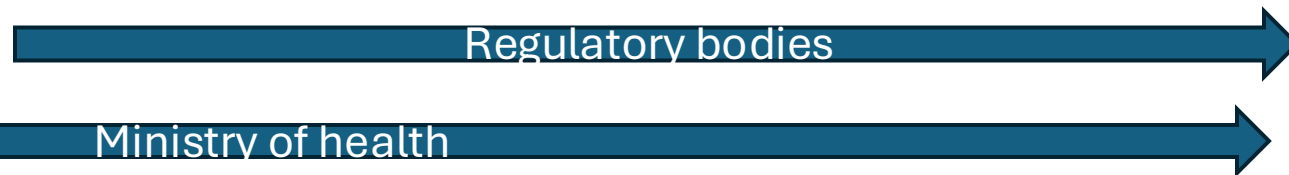


Ethical  
hurdles

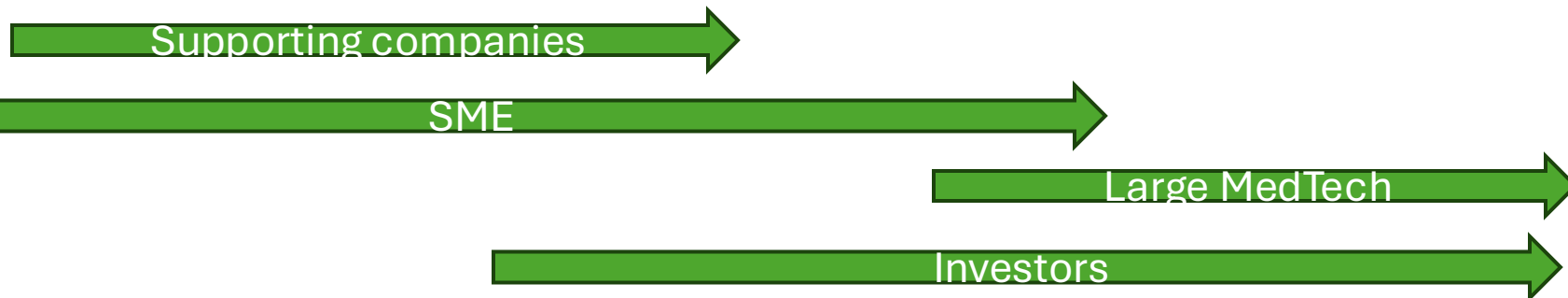


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Regulatory & Funding



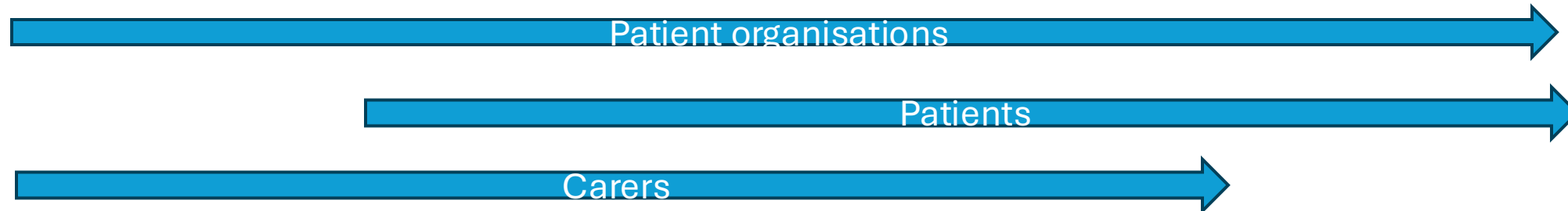
Industry



Research



Society



Technology Readiness Levels



# DeCODE strategic objectives

01

Mapping and analysing the paediatric and orphan medical device ecosystem

02

Set out the critical path for the development of a paediatric and orphan medical device

03

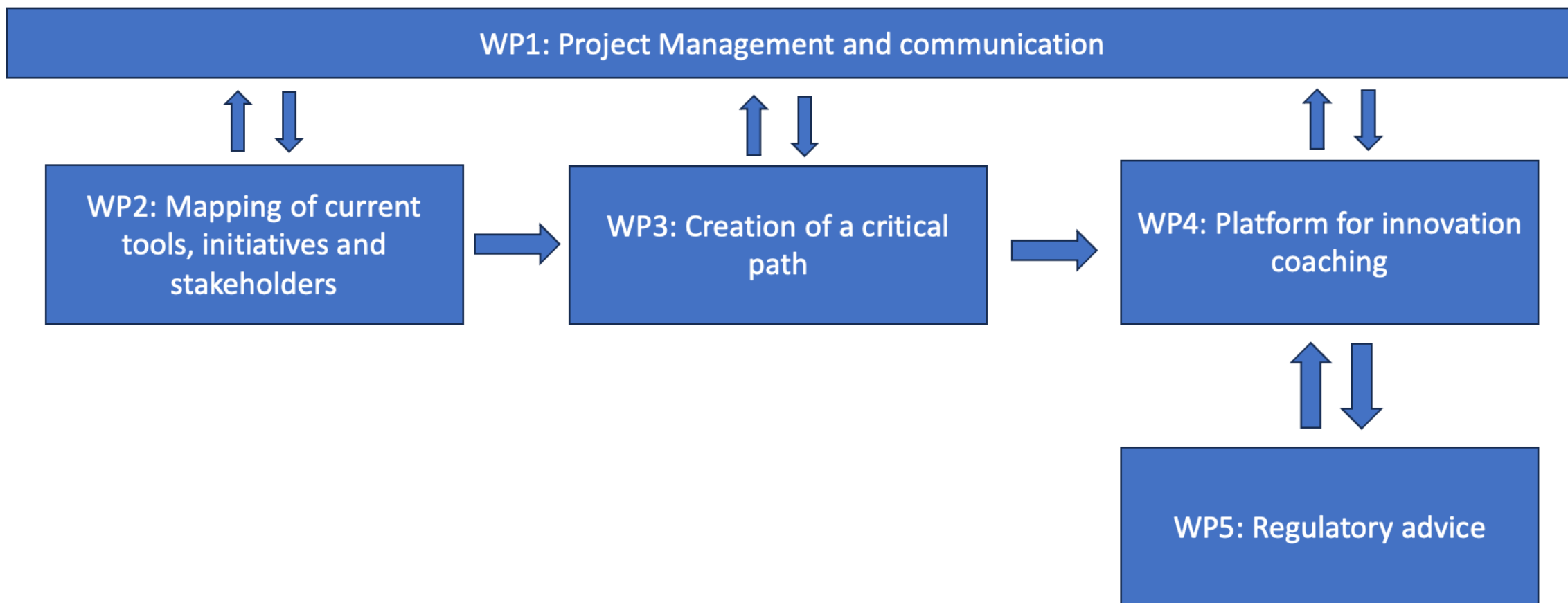
Provide innovation coaching for the development of innovative paediatric and orphan medical devices via the DeCODE platform

04

Form novel partnerships that advance paediatric and orphan medical device development



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DeCODE Pert-Chart



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# Critical path analysis



Collection of experts and tools: Collected by literature and survey



Analysis of hypothetical case studies



Use of tools and initiatives throughout the different phases and milestones of device development



Roadmap Check-lists of “what to do” and “when to do it”



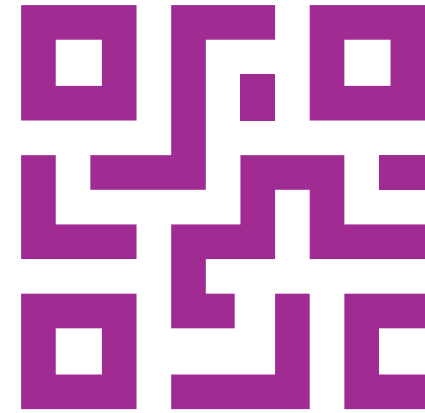
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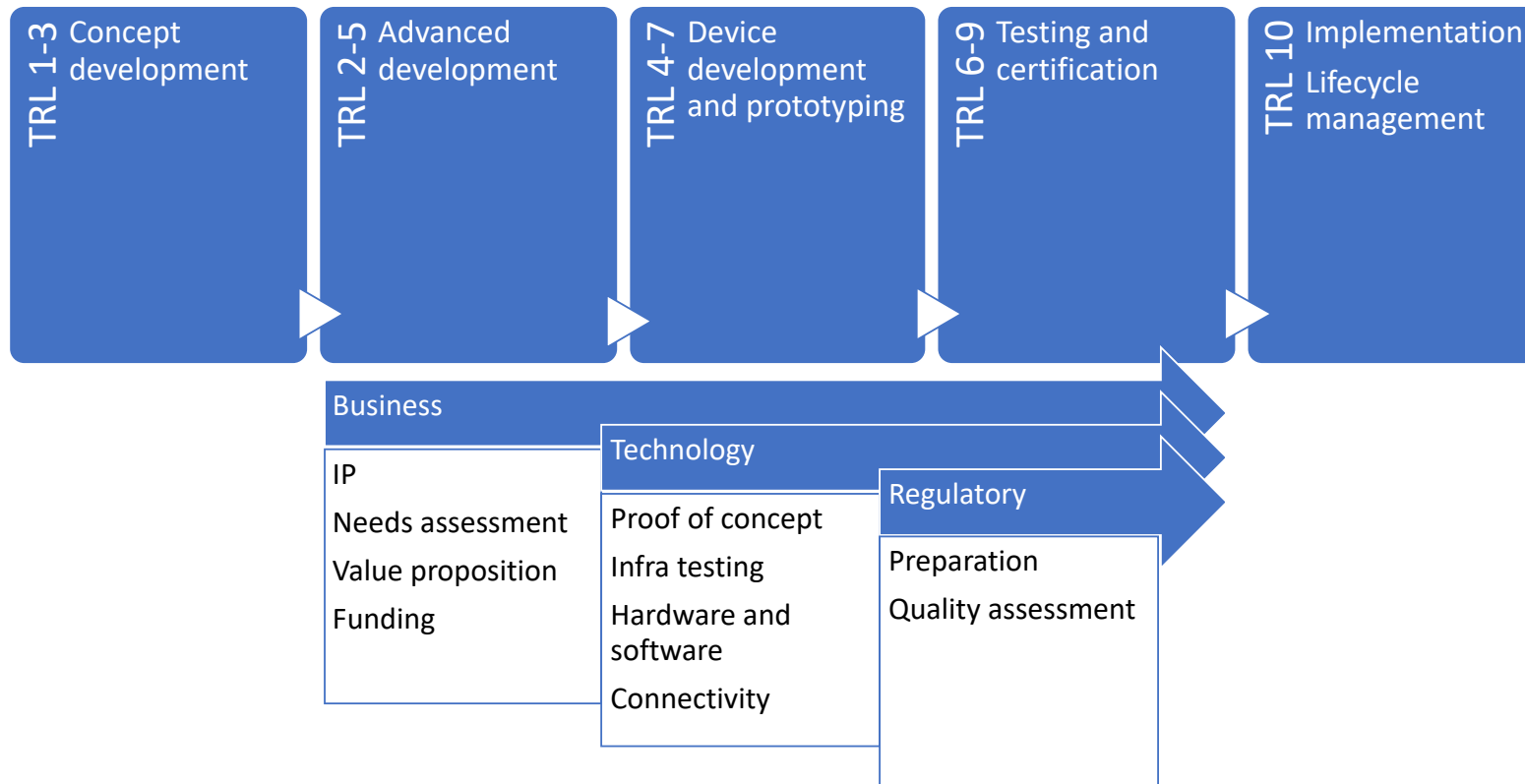
# Pilot cases

- 5 cases
- Rare and paediatric
- Unmet need, potential for significant benefit
- Off label going towards on label use, de novo development
- Device developers get min 6 months of support



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# DeCODE pipeline orphan device development and support



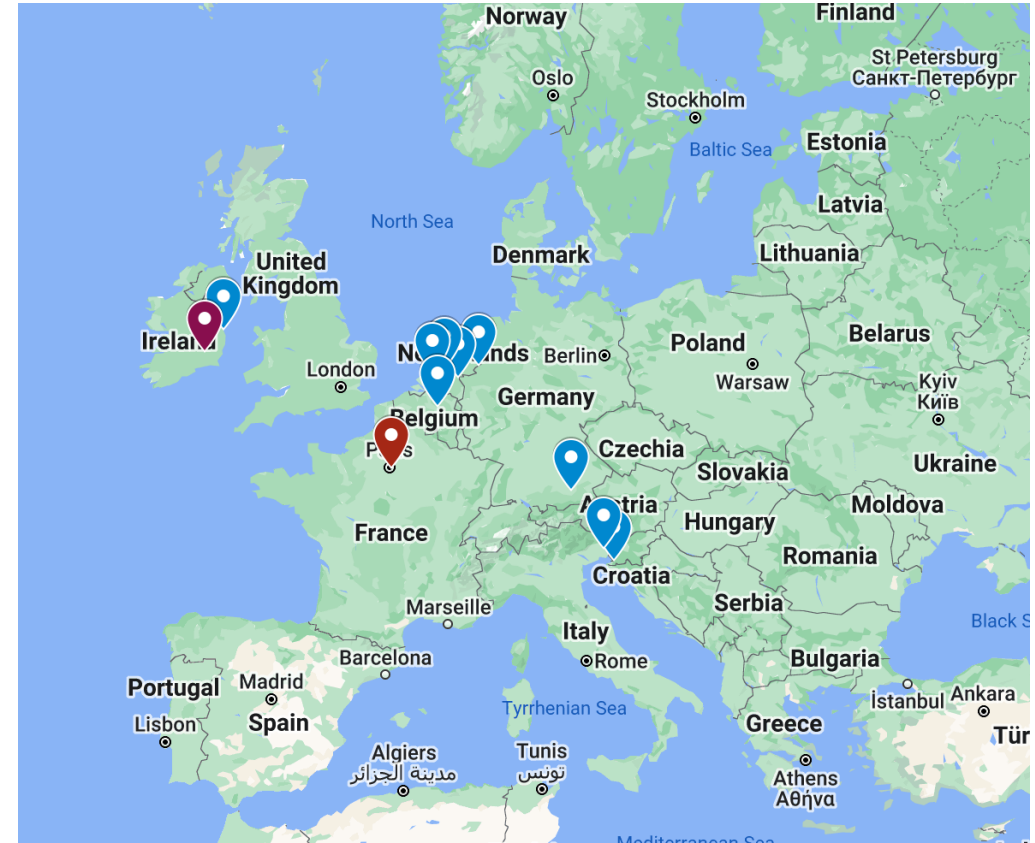
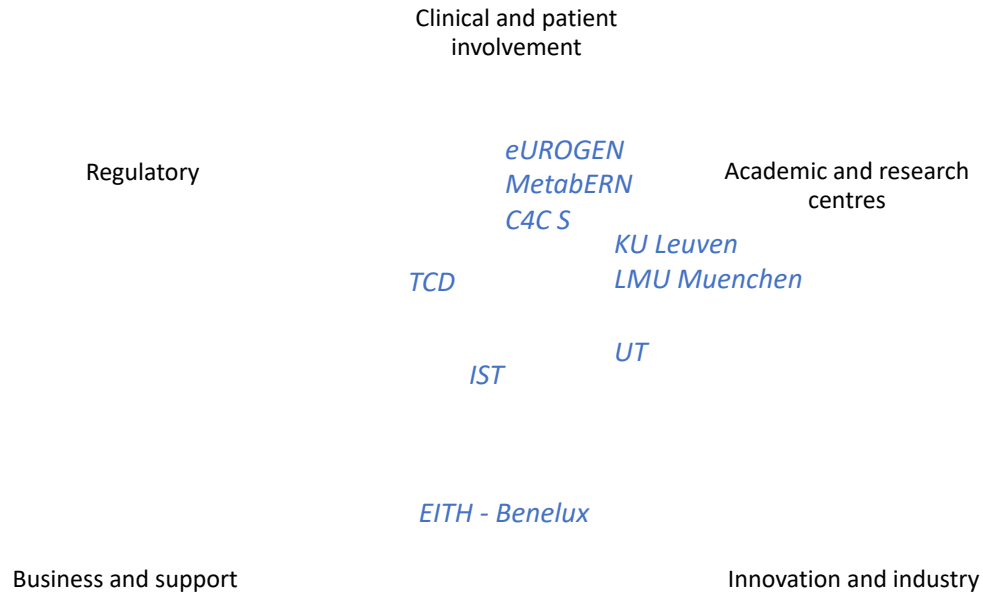
Open call for applications  
Deadline: March 31  
One-page application  
Open for different RD  
Open for different TRL



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# DeCODE consortium



## SAB:

- Kolaleh Eskandanian – PDRC/ Children’s National, Washington DC, USA
- Virginie Hivert – Eurordis-Rare Diseases Europe, France
- Donal O’Connor – HRP, Ireland



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# DeCODE – summary

- Overall Aim: to support the development of paediatric and orphan devices
- Consortium co-funded by the EC, consistent of academics, developers, clinicians, regulatory experts, funding experts, in-silico testing experts
- Goal: develop a critical path for orphan device development, and provide support to 5 orphan device developers





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# Thank you!

[www.decode-rd.com](http://www.decode-rd.com)

## The consortium partners

UNIVERSITY  
OF TWENTE.



MetabERN  
European Reference Network  
for Hereditary Metabolic Disorders

ERN eUROGEN  
Rare Urogenital Diseases  
& Complex Conditions