

DeCODE: Develop Child and Orphan Device Support



Anneliene H. Jonker¹ and Michelle Battye²

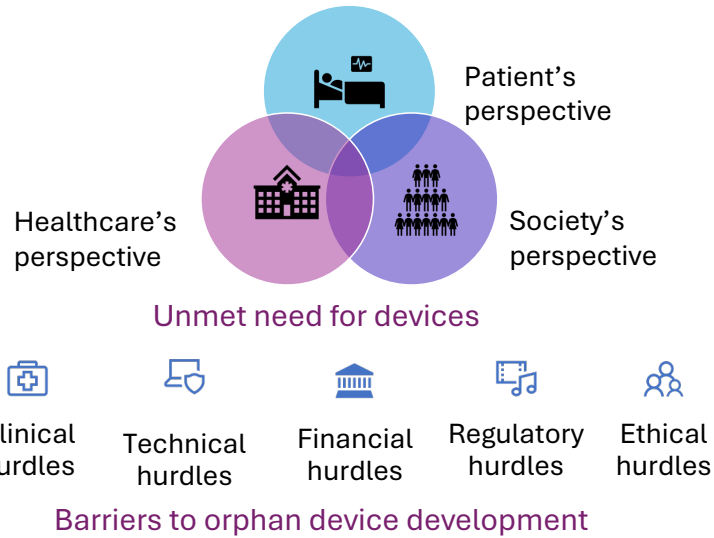
1. Department HTSR, TechMed Centre, University of Twente, Enschede, The Netherlands
2. eUROGEN, RadboudUMC, Nijmegen, The Netherlands



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Introduction

- RD patients have an unmet need for paediatric and orphan medical devices
- Majority of clinicians indicate need for new device, and existing devices have limitations
- Paediatric focus brings unique challenges
- The MDCG has developed a guidance for the development of orphan devices
- DeCODE takes inspiration from and connects to the Paediatric Devices Research Consortia of the FDA.



Objectives

Mapping and analysing the paediatric and orphan medical device ecosystem

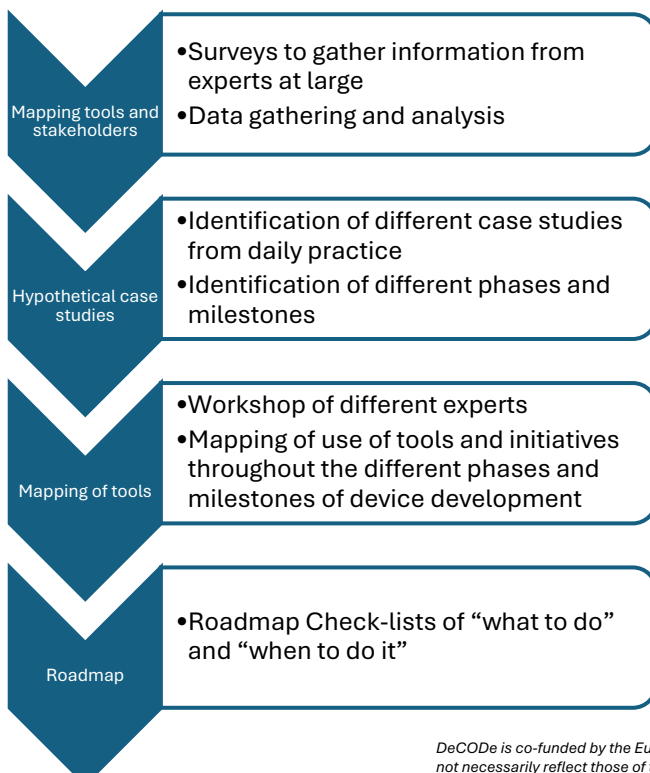
Set out the critical path for the development of a paediatric and orphan medical device

Provide innovation coaching to develop innovative paediatric and orphan medical devices

Form novel partnerships that advance paediatric and orphan medical device development

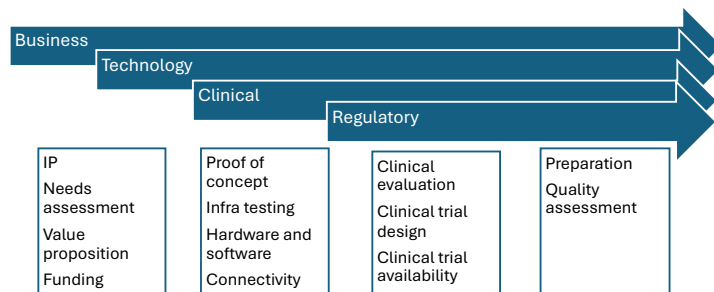
Methodology

Development of device roadmap



Pilot cases

- 5 cases for rare and paediatric
- Unmet need, potential for significant benefit
- Off label to on label use, de novo development, legacy
- Device developers get 6 months support
- Public summaries from each case
- Overall best practices
- **Call open on Jan 15, 2025**



Types of support