Develop Child and Orphan Device Evaluation support

Project Number: 101160939

Deliverable title: Communication and dissemination plan

Version: 2.1

Date: 27 March 2025

Task number: T1.2

Task name: Communication and dissemination management

Co-funded by the European Union

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Document details

Project number	101160939
Project title	DeCODe
Deliverable number	D1.3
Title deliverable	Communication and dissemination plan
Due date deliverable	28 February 2025
Work Package number and name	WP1 – Project management and communication
Lead beneficiary	University of Twente
Author(s)	Jen Tidman (eUROGEN)
Reviewers	Michelle Battye (eUROGEN), Anneliene Jonker (UT), Marco Raaben (UT), Tom Melvin (TCD)
Dissemination level	Public — fully open
Date of submission	14 January 2025 – V1.0 21 March 2025 – V2.0 27 March 2025 – V2.1
Number of pages (incl. cover)	14

Co-funded by the European Union

TABLE OF CONTENTS

Co-funded by the European Union

List of figures

Symbols, abbreviations and acronyms

D	Deliverable
HaDEA	European Health and Digital Executive Agency
M	Month
MS	Milestone
TCD	Trinity College Dublin
UT	University of Twente
WP	Work Package

Abstract

The DeCODe project is a two-year European initiative, co-funded by the European Health and Digital Executive Agency (HADEA) under the EU4Health programme, to overcome clinical, technical, financial, regulatory, and ethical challenges in developing orphan medical devices for paediatric care. Nine European partners are involved, each bringing expertise in medical technology, regulatory science, clinical trials, innovation support, and the scientific advisory board partners.

The project's core mission is to support three to five different orphan device developers focused on developing an orphan device for an unmet need in the paediatric population. This device can be an off-label product brought on-label or a de novo development. Overall, DeCODe aims to accelerate the development of innovative medical devices for paediatric and rare diseases across Europe.

Co-funded by the European Union

Introduction

According to the grant agreement, the DeCODe beneficiaries must promote the action and its results by strategically, coherently, and effectively providing targeted information to multiple audiences (including the media and the public).

Therefore, this Communication and Dissemination Plan provides a structured approach to communicating, disseminating, and exploiting DeCODe's activities and results, ensuring maximum impact and sustainability. The plan defines how project results and deliverables will be made accessible to stakeholders and the broader public. Its significance cannot be overstated; it is pivotal for fostering uptake, vital for the project's success, and indispensable for sustaining long-term outputs and catalysing impactful outcomes.

Overall, this plan aims to raise awareness of DeCODe's role in advancing paediatric and orphan medical device development, overcoming clinical and regulatory challenges, and promoting innovation in this specialised field.

This plan can be further adjusted with specific goals and targets aligned with DeCODe's grant agreement requirements and progress in each work package.

Communication and dissemination plan

Objectives

DeCODe focuses on overcoming five types of hurdles in orphan device development: clinical, technical, financial, regulatory, and ethical hurdles. Its Strategic Objectives (SO) are:

- SO1: Map and analyse the paediatric and orphan medical device ecosystem
- SO2: Set out the critical path for the development of a paediatric and orphan medical device
- SO3: Provide innovation coaching for the development of innovative paediatric and orphan medical devices via the DeCODe platform
- SO4: Form novel partnerships that advance paediatric and orphan medical device development

It will deliver on its objectives through five WPs, being:

- WP1: Project management and communication
- WP2: Mapping of current tools, initiatives, and stakeholders
- WP3: Creation of a critical path for orphan device development
- WP4: Platform for innovation coaching
- WP5: Regulatory advice

WP1: Project management and communication has objectives to:

- Communicate with the European Commission and ensure information flow to/within the consortium
- Ensure the communication and dissemination of the project's results
- Ensure that all generated data is openly accessible and usable for the different purposes of DeCODe

The objectives for communication and dissemination are:

- **Communication**: Spread information about DeCODe's mission, goals, and impact on developing orphan and paediatric medical devices to increase visibility and raise awareness and support; communicate with orphan medical device developers that are potentially interested in making use of the DeCODe platform; identify appropriate orphan medical device developers and other target groups to address.
- **Dissemination**: Transfer the knowledge and results from the DeCODe project to a wider variety of target groups/stakeholders (beyond the consortium partners) interested in the uptake of the results.
- **Exploitation**: Coordinate with other initiatives and EC-funded projects and encourage relevant stakeholders to adopt and apply DeCODe's pathways, tools, and innovations to optimise paediatric device development.

Key Messages & Timing

DeCODe's communication and dissemination will highlight several core messages:

- **Innovation in Paediatric and Rare Diseases Care**: DeCODe supports the development of essential medical devices for paediatric and rare diseases, addressing unmet clinical needs through innovation and regulatory guidance.

- **Collaboration & Support**: Through its platform and network of experts, DeCODe fosters partnerships and guides device developers, improving their paths from ideation to market. The DeCODe consortium provide practical support in different domains to five different orphan device developers.
- **Enhanced Pathways**: DeCODe introduces structured pathways and regulatory advice to streamline development processes and ensures high efficacy standards in paediatric devices.
- **EU-wide Impact**: DeCODe's outcomes aim to improve European healthcare quality for children with rare conditions, enhancing cross-border collaboration and support.

The three critical communication moments are the kick-off meeting (September 2024), the launch of the call for proposals for support (15 January 2025), the outcomes of the critical path analysis (October 2025) and the project results/final meeting (September 2026).

Target Audiences

DeCODe's target audiences include both internal and external stakeholders critical to the project's mission:

- **Internal**: Project partners, strategic advisory board members, and work package teams. DeCODe aims to ensure that all parties are well-informed and well-briefed about activities, progress, outcomes, project planning, and all other issues. This provides the maximum efficiency of resources and consistency of results, increases the synergy and integration of the partners, and ensures effective collaboration. All information generated within the project will be communicated to the coordinator, who oversees channelling this information to the other parties, as appropriate.
- **External (Figure 1)**: Paediatric medical device developers, regulatory bodies, such as the EMA expert panels, EU healthcare providers, healthcare policymakers, academic researchers, industry stakeholders, people living with a rare disease, patient advocacy groups, and the general public. The overall aim with all external target audiences is to raise awareness about the existence of DeCODe and its objective to advance paediatric and orphan medical device development, overcome clinical and regulatory challenges, and promote innovation in this specialised field, highlighting the EU-added value in this innovative project and how it's impacting citizens' lives.

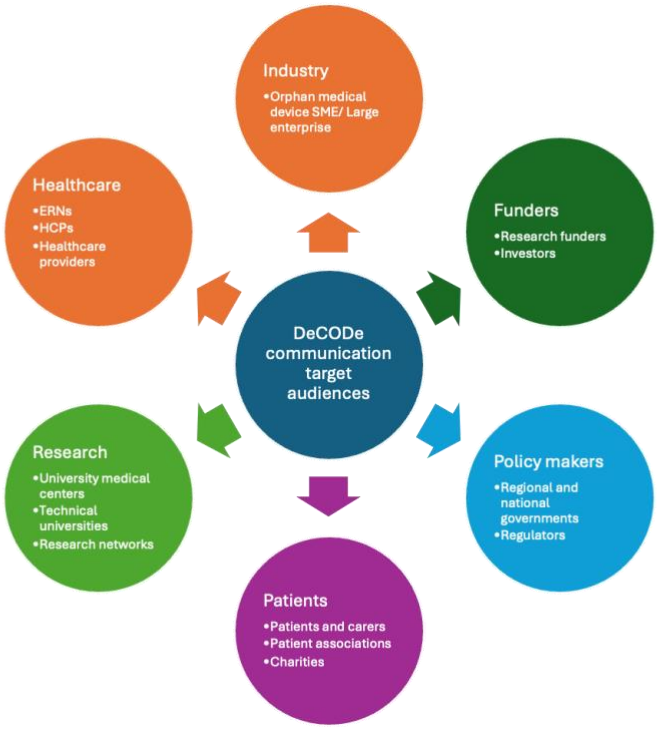

Figure 1. The external DeCODe communication target audiences, and specific subgroups.

Communication & Dissemination Activities

The focus of communication and dissemination activities will be:

- **Internal Communication:** Online project meetings will be held for everyone involved in the project every last Friday of the month at 14:00-15:00 CET, with the Strategic Advisory Board joining every 3 months. Virtual work package/workstream meetings will be organised when necessary or upon request of the involved parties. Microsoft Teams will be used as the channel for internal communication and for sharing documents such as templates, logos, photos, and press releases.
- **Stakeholder Identification**: WP2 (Mapping of tools and stakeholders in paediatric and orphan medical devices) will identify and create a network of key stakeholders to be targeted with communication and dissemination.
- **Project Website**: A dedicated website will be continuously updated to provide information on the project, the available tools, updates, resources, and reports and serve as a repository for project deliverables, with 500 visits expected per year.
- **External Websites**: External websites, such as partners, HaDEA, and national websites, will include news on DeCODe project results.
- **Platform**: WP4 (Set up a platform for innovation coaching for paediatric and orphan medical device development) will create a web-based platform for applications for support, the call for use cases, the selection of the use cases, and innovation coaching.
- **Short Educational Videos:** Three short educational training videos will be made on the material developed (critical path analysis, use cases) and will be made available via the online platform.
- **Critical Path of Orphan Medical Device Development**: WP3 (Creation of a critical path for paediatric and orphan medical device development) will build a critical path analysis of orphan medical device development, test this critical path, and, based on this, develop recommendations for orphan device developers, regulatory bodies, policymakers, and funders. The critical path

analysis will be performed at an in-person two-day workshop in Brussels planned for April 8-9, 2025, with three persons per project partner + 4-5 extra experts (i.e., a 20–25-person meeting). The results of the critical path analysis will be published on the website in an easy-to-use format.

- **White Paper:** Partners will publish a white paper with best practices and strategies reflecting on the paediatric and orphan medical device developers who applied for support and the support provided. Potential alignment for best practice exchanges will be sought with the other EU4H-funded projects.
- **Position Paper**: Partners will publish a position paper on the critical path analysis, including the tools and initiatives available for developing orphan medical devices.
- **News and Press Releases**: Articles in the media will update stakeholders on DeCODe's progress, deliverables, upcoming events, and key findings. They will also provide information on the development of, and challenges encountered with paediatric and orphan medical devices.
- **Social Media**: Different platforms will be used to increase visibility, share achievements, and engage stakeholders, especially around critical milestones (e.g., call launches and major findings). They will be updated regularly, and social media campaigns will be launched when necessary. Partners will reshare prepared social media outlets. So that the European Commission can follow the communication actions, the hashtags #EUfunded #HealthUnion #EU4Health #HealthierTogether and #StrongerTogether will be used, and their social media accounts will be tagged:
    - Bluesky: @ec.europa.eu/
    - Facebook: @EuropeanCommission
    - Instagram: @europeancommission @one_healthenv_eu
    - LinkedIn @EU Health and Food Safety @European Health and Digital Executive Agency (HaDEA) @European Commission
    - X: @EU_Health @EU_HaDEA @EU_Commission
- **External Events**: Partners will participate in events related to rare diseases or medical devices, emphasising project findings and innovations in paediatric and orphan medical device development. Potential opportunities are:
    - EIT Health Summit
    - ERICA ERN Research Conference
    - European Academy of Paediatrics Events
    - European Conference on Rare Diseases & Orphan Products
    - International Medical Device Regulators Forum
    - Medtech Conference
    - RE(ACT) Congress
    - Regulatory Affairs Professionals Society Convergence
    - World Orphan Drug Congress
    - Conferences of national and subspecialty paediatric associations
- **Collaboration with Similar Initiatives**: Actively seek collaboration with other projects and organisations in the paediatric medical device field to promote resource sharing and mutual learning, e.g.:
    - Avicenna Alliance
    - conect4childrenStichting (c4c)
    - CORE-MD
    - EATRIS

- EDITH
- European Academy of Paediatrics (EAP)
- European Institute of Technology (EIT) Health
- European Medicines Agency (EMA)
- European Paediatric Translational Research Infrastructure (EPTRI)
- European Rare Diseases Research Alliance (ERDERA)
- European Rare Disease Research Coordination and Support Action consortium (ERICA)
- European Reference Networks
- EURORDIS
- FDA Pediatric Device Research Consortia
- In Silico World
- IRDiRC WG MedTech for RD
- MedTechEurope
- Orphanet
- Rare Diseases International
- SimCardioTest
- Vanguard Initiative Pilot Smart Health
- Other EU4Health projects funded under the Paediatric and Orphan Devices call

Exploitation Strategies

The focus of exploitation strategies will be:

- **Adoption by Device Developers**: Provide a structured critical path for developers, enabling DeCODe's insights to be applied directly to ongoing and new projects.
- **Policy Influence**: Share results of the critical path, identified gaps, and best practices with EU and national policymakers to influence supportive regulatory environments for orphan devices.
- **Long-term Sustainability**: Ensure that DeCODe's platform and network are sustainable beyond the project lifecycle, aiming for long-term partnerships and continuous support to developers.

Responsibilities

- **University of Twente (Coordinator)**: Oversee communication, manage the platform, and ensure deliverable quality.
- **Radboudumc/ERN eUROGEN**: Lead the development of communication and dissemination materials in collaboration with other partners. Follow-up/coordinate with the Communication Leads from each project partner institution to align on messages and actions.
- **All Partners**: Contribute to dissemination by sharing content, engaging stakeholders, and promoting DeCODe's activities within their networks. Provide the Coordinator with the names and emails of the Communication Leads for their organisations.

Regulations

- **Keeping HaDEA Informed** – The beneficiaries will inform the granting authority when the project has just reached a major milestone (e.g. has published key deliverables and produced communication material), when organising events that are open/of interest to a wider/specialised public, and before engaging in a communication or dissemination activity that is expected to have a major media impact.

- **Keeping the Project Officer at the granting authority informed**: The beneficiaries will inform the Project Officer before engaging in a communication or dissemination activity that is expected to have a major media impact. We will contact the Project officer whenever needed or appropriate.
- **Visibility of EU Funding** – DeCODe will ensure communication and dissemination activities acknowledge EU support by displaying the European flag (emblem) and funding statement:

"DeCODe is co-funded by the European Union."

The emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands or text. Apart from the emblem, no other visual identity or logo may be used to highlight the EU support. When displayed in association with other logos (e.g. of beneficiaries or sponsors), the emblem must be displayed at least as prominently and visibly as the other logos.

- **Disclaimer –** DeCODe will display the following disclaimer for all communication statements (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.): "Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them"
- **Confidentiality** – DeCODe will keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.
- **Personal data** – DeCODe will process any personal data (e.g., name, address, identification number, e-mail, phone number) gathered for communication and dissemination purposes according to the principles and conditions of the General Data Protection Regulation
- **Security** – DeCODe will request written approval from the Granting Authority for security recommendations restricting disclosure or dissemination before disclosure or dissemination to a third party.

Conclusion

The DeCODe project is a two-year European initiative, co-funded by the European Health and Digital Executive Agency (HADEA) under the EU4Health programme. Its goal is to address clinical, technical, financial, regulatory, and ethical challenges in developing orphan medical devices for paediatric care. The project supports the development of 3-5 orphan devices, focusing on innovation and regulatory guidance. The Communication and Dissemination Plan outlines strategies for raising awareness, disseminating project results, and ensuring stakeholder engagement. It emphasizes fostering partnerships, supporting device developers, and promoting the project's impact on paediatric healthcare across Europe.