

[Launch of the report ‘Challenges and opportunities for effective paediatric innovation in Europe’](#)

i4KIDS-EUROPE sets out strategic actions to strengthen paediatric innovation in Europe

- **Children represent 25% of the world's population, but only 1.6% of venture capital investment in health is allocated to paediatric-related projects.**
- **Nearly half of paediatric medicines are used off-label and most medical devices are not designed and validated for use in children under the age of 18.**
- **The report, published by the i4KIDS-EUROPE consortium and coordinated by Sant Joan de Déu Barcelona Children’s Hospital and EIT Health Spain, analyses the state of paediatric innovation and includes recommendations to boost the paediatric and maternal health innovation sector in Europe.**
- **Increase public and private investment with social impact, make regulation more flexible, develop incentives for companies to invest in paediatric solutions are some of the proposals.**

Barcelona, 15 January 2025 _ The [i4KIDS- EUROPE](#) project, coordinated by the Sant Joan de Déu Barcelona Children's Hospital, has just presented the report [‘Challenges and opportunities for effective paediatric innovation in Europe’](#). The report examines the current state of innovation in paediatrics, highlighting challenges and opportunities, and proposes concrete actions to drive the development of specific solutions for the paediatric and maternal populations.

The White Paper has been led by Fundació EIT Health Spain, a Co-Location Centre (regional hub) of [EIT Health](#), which is part of the [European Institute of Innovation and Technology](#), a body of the European Union, and has been developed in the framework of the i4KIDS-EUROPE project, which aims to establish an efficient and inclusive European paediatric innovation ecosystem and to stimulate Europe's competitiveness and economic growth in the field of paediatric innovation. This consortium brings together eight multidisciplinary European institutions as as Sant Joan de Déu Barcelona Children’s Hospital, Fundació de Recerca Sant Joan de Déu, HUS Helsinki University Hospital, Fundacja K.I.D.S. Children’s Hospitals Innovators’ Club, Fundació EIT Health Spain, Inveniam Group, Children’s University Hospital Latvia, and RegionH Mary Elizabeths Hospital – Rigshospitalet.

The report is based on the results of extensive research, including questionnaires, interviews and working sessions with leading paediatric, foetal and maternal healthcare professionals,

research institutions, the business sector (SMEs, start-ups and corporates), patient associations and institutional representatives from 16 European countries. The analysis reveals the barriers to the development and adoption of paediatric-specific innovations, such as financial, policy and regulatory, commercial, human resources, cultural and infrastructural issues, and addresses how these barriers differ between countries.

"The i4KIDS-EUROPE project represents a unique opportunity to transform the paediatric innovation landscape in Europe by addressing one of the most neglected areas in healthcare. There is an urgent need for specific solutions for children's health and this project offers visibility of the most disruptive innovation in this area", says **Izabel Alfany, Managing Director of Fundación EIT Health Spain.**

Main barriers to innovation in paediatrics

50% of medicines in paediatrics are used outside their approved indication, age, dose or route

The absence of formulations, dosages and studies specifically designed for children means that almost half of the medicines used in paediatrics are not specifically approved for this population group. In neonatal intensive care units, this figure rises to 90%, reflecting the almost total reliance on adjustments to treatments formulated for adults.

This situation makes correct dosing difficult, increasing the risk of adverse effects or lack of efficacy of the drugs. In addition, the risk of toxicity and adverse reactions is increased, as the absorption of medicines in children differs significantly from that of adults, especially in neonatal patients, who are particularly vulnerable due to their physiological immaturity.

Devices designed for adult bodies

Medical professionals often have to adapt pacemakers, cannulae, and surgical equipment intended for adults for use in paediatric patients. This practice increases the risk of complications, as the proportions, materials, and functionalities are not optimised for a child's body. In addition, these modifications may compromise clinical outcomes by not providing the same level of accuracy, efficacy and safety as if the device were specifically designed for children. For example, an adult device may not correctly adjust to the patient's growth rate.

Investment opportunity in a market calling for more paediatric solutions

Only 1.6% of venture capital investment in healthcare is allocated to paediatric-related projects, a surprisingly low percentage considering that children represent 25% of the world's population today and are the backbone of a healthy future society. Comparatively, projects for adults receive most of the funds due to their larger potential market and lower perceived risks, which is not in line with real market needs. Moreover, in Europe, most public funding calls are still targeted at conditions prevalent in adults, such as cardiovascular or metabolic diseases, leaving out important paediatric needs. As a result, the development of paediatric

start-ups is not encouraged, limiting their ability to develop and commercialise new paediatric solutions.

Regional disparities

Countries with advanced innovation ecosystems, such as Germany, France or the Netherlands, concentrate most of the financial, human and technological resources. In contrast, moderate and emerging regions, especially in southern and eastern Europe, face a lack of infrastructure, funding and collaborative networks, which limits the advancement of innovation in paediatrics. These disparities perpetuate a fragmented system where advances are not shared equitably. This reduces the overall efficiency of the European paediatric innovation ecosystem and means that children in less advanced regions have less access to innovative treatments and personalised technologies, potentially impacting their health.

Priority actions to boost paediatric innovation

The i4KIDS-EUROPE white paper aims to give visibility to the gaps identified in driving innovation in paediatric and maternal health and to promote their inclusion in the European agenda. The proposals aim to generate a cohesive ecosystem to drive the development of effective solutions for child and maternal health at European level, using success stories from different countries as inspiration to adapt or generate new solutions in Europe.

In the area of **funding**, it emphasises the need to increase both public and private investment, earmarking specific resources for paediatric projects in European programmes and introducing tax incentives to encourage business participation. In addition, it proposes the creation of interim funding mechanisms to allow promising projects to continue once the initial funds have been exhausted, as well as a change in the mentality of investors towards a focus more oriented towards social impact than immediate economic return.

Regarding the **regulatory** environment, it recommends making legal frameworks more flexible through tools that facilitate supervised research in paediatric developments, while reviewing and updating existing regulations to prioritise treatments targeted at children's diseases. It also suggests the use of real-world evidence as a basis for accelerating the approval and monitoring of new paediatric products and the development of harmonised guidelines for medical devices and digital therapies that address the specific needs of children.

To improve the **commercialisation and adoption of innovation**, measures are proposed to reduce barriers to market entry, especially for start-ups and small companies, by facilitating their access to hospitals and health systems and by creating reimbursement schemes adapted to paediatric technologies. It underlines the importance of strengthening collaboration between public and private sectors, promoting open innovation initiatives focused on the needs of end-users. It is also recommended to involve patients and their environment in the design of new solutions, attracting talent and facilitating their implementation in hospital settings.

In terms of **human resources and infrastructure**, the report emphasises the need for an internal innovation team in hospitals dedicated to paediatric innovation to address unmet patient needs. It also proposes to implement European programmes based on multidisciplinary co-creation methodologies, with the involvement of clinicians (such as the Biodesign methodology), as well as to foster specific training that equips researchers, healthcare professionals and entrepreneurs with the necessary skills to address the challenges of paediatric innovation (i.e. i4KIDS Training Capsules, EIT Health Academy).

The document also highlights the importance of raising the **visibility** of paediatric and maternal innovation by creating digital platforms that centralise information on funding opportunities for projects and success stories. In addition, it recommends organising events of pan-European relevance to foster collaboration between countries and sectors, as well as highlighting successful innovation projects to inspire and attract new investment in the paediatric field.

Arnau Valls, Director of i4KIDS and Coordinator of i4KIDS-EUROPE, affirms that *‘investing in children’s health is not only an ethical necessity, but also a key strategy to guarantee the future of our society. This report represents a crucial step towards making the existing gaps visible and ensuring that all children in Europe have access to the healthcare they deserve’*.

About EIT Health

[EIT Health](#) is a network of best-in-class health innovators with approximately 120 partners and is supported by the [European Institute of Innovation and Technology \(EIT\)](#), a body of the European Union. We collaborate across borders to deliver new solutions that can enable European citizens to live longer, healthier lives.

As Europeans tackle the challenge of increasing chronic diseases and multi-morbidity and seek to realise the opportunities that technology offers to move beyond conventional approaches to treatment, prevention and healthy lifestyles, we need thought leaders, innovators and efficient ways to bring innovative healthcare solutions to market.

Our commitment to driving healthcare advancement is evident in our proactive role in mentorship, funding, and research facilitation. Recognised as a pivotal player in healthcare innovation, EIT Health’s record of accomplishment includes: catalysing over 2,500 start-ups and scale-ups, helping EIT Health-supported startups attract €1.9 billion in investment, propelling 113 healthcare solutions to the market, and training 49,000 students and professionals.

EIT Health addresses these needs. We connect all relevant healthcare players across European borders – making sure to include all sides of the “knowledge triangle”, so that innovation can happen at the intersection of research, education and business for the benefit of citizens.

EIT Health: Together for healthy lives in Europe. For more information visit <https://eithealth.eu/>.

THE I4KIDS-EUROPE INITIATIVE

i4KIDS-EUROPE, a Coordination and Support Action (CSA) funded by Horizon Europe, operates across five European countries (Spain, Finland, Denmark, Poland, and Latvia), from January 2023 to January 2025. Uniting a diverse array of expertise and resources, the consortium comprises the following leading European institutions: Sant Joan de Déu Barcelona Children's Hospital, Fundació de Recerca Sant Joan de Déu, HUS Helsinki University Hospital, Fundacja K.I.D.S. Children's Hospitals Innovators' Club, EIT Health Spain, Inveniam Group, Children's University Hospital Latvia, and RegionH Mary Elizabeths Hospital – Rigshospitalet. Its mission is to strengthen sector competitiveness and unlock the innovation potential within the European paediatric sector. The initiative seeks to integrate and support underrepresented actors, particularly in moderate and emerging innovator countries, into the paediatric innovation ecosystem, ensuring a more interconnected and cohesive environment to drive significant advancement in the sector.

This European project expands the current i4KIDS, Pediatric Innovation Hub created in Barcelona at the end of 2020, led by Sant Joan de Déu Barcelona Children's Hospital (HSJD). It has more than 60 member and associated entities as well as 93 research groups to promote the development of innovation and research projects in foetal, paediatrics and maternity health to improve diagnosis and treatment.

For further details on the i4KIDS-EUROPE initiative, please visit this website: <https://www.innovation4kids.org/en/i4kids-europe/>

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