i4KIDS-4RARE NEUROEPILEPSY INNOVATION PROGRAMME

PARTICIPATION RULES

1. INTRODUCTION

Children's rights are set out in the United Nations Convention on the Rights of the Child, one of the most widely ratified treaties in history. The treaty calls on states to guarantee children's access to the highest standards of health and healthcare services.

Despite this, children, who represent 21% of the population, receive far fewer health innovations than adults do. The reasons include risk perception, ethical and regulatory barriers, limited awareness of paediatric needs, and fragmented investment. As a result, many opportunities with potential impact remain unexplored.

This gap is especially evident in rare diseases. Paediatric patients are underserved due to small market size, complex regulations, and limited knowledge sharing, which slow down the arrival of new solutions to families.

To address these challenges, **i4KIDS-4RARE** has been launched as a European initiative to accelerate paediatric innovation, with a focus on rare diseases and orphan medical devices. The programme supports projects, connects clinical, industrial and patient stakeholders, and promotes new opportunities for child health.

In collaboration with **EpiCARE**, the European Reference Network for rare and complex epilepsies, the **i4KIDS-4RARE Neuropilepsy Innovation Programme** has been created. Its aim is to identify and support solutions for unmet needs in paediatric epilepsy and related rare conditions.

Epilepsy affects 1% of children, and one in three of these patients has drug-resistant epilepsy (DRE). They face persistent seizures, delayed diagnoses, cognitive decline, and significant social and economic challenges. Current advances in neuroimaging, genetics and therapies are important, but gaps remain:

- Early, accurate detection of epileptogenic foci
- Systematic monitoring of cognitive impact
- Personalized adjustment of treatments to improve safety and efficacy

New tools and strategies are needed that can be integrated into clinical practice, scaled across Europe, and keep patients and families at the centre. The **i4KIDS-4RARE Neuropilepsy Innovation Programme** is a step towards a stronger, more inclusive and patient-driven paediatric innovation ecosystem.

2. CHALLENGE DEFINITION

The **i4KIDS-4RARE Neuroepilepsy Innovation Programme** seeks to identify innovative solutions that enhance early and accurate diagnosis, enable systematic monitoring of cognitive development, and support personalized therapeutic strategies for children with rare epileptic conditions.

Proposals are welcome from different fields (technological, clinical, educational, or social) and can be at an advanced stage of development (TRL 7–8), ready for implementation

The three priority challenges identified are:

A. CHALLENGE 1: AI-DRIVEN NEUROIMAGING FOR SURGICAL PLANNING

Paediatric epilepsy affects approximately 1% of the paediatric population, and about 30% of these patients develop drug-resistant epilepsy (DRE), defined as the persistence of seizures despite adequate use of at least two well-tolerated and appropriately selected antiepileptic drugs.

High-resolution magnetic resonance imaging (MRI) is the gold standard method for localization of the epileptogenic focus. However, structural abnormalities are detected in only 70-80% of cases. In patients with DRE, 20-30% have an MRI considered normal, which delays diagnosis and limits early access to surgical therapies. Treatment is pharmacologic and surgical, and to perform surgery it is necessary to know where it is [1].

Delay in treatment is associated with an increase in seizure frequency and severity, which can lead to progressive cognitive impairment. Evidence suggests that uncontrolled seizures early in life negatively affect intellectual and social development. In addition, late identification and treatment significantly reduces the surgical success rate.

The impact of DRE is not restricted to the patient alone. Families also suffer substantial emotional and economic consequences, characterized by high levels of stress, caregiving overload and deterioration of family quality of life.

We are looking for solutions that:

- Improve the detection and localization of epileptogenic foci using neuroimaging and advanced analysis.
- Facilitate earlier surgical planning and better prediction of surgical outcomes.
- Can be integrated into existing hospital workflows and made accessible across different healthcare systems.

B. CHALLENGE 2: EARLY DETECTION AND MANAGEMENT OF COGNITIVE IMPAIRMENTS

Cognitive impairment in children with epilepsy is a frequent and often underestimated complication. Although clinical control of seizures may be considered successful, between 20 and up to 60% of paediatric patients develop persistent cognitive impairment [2]. These alterations impact on attention, memory, language and other executive functions, severely affecting the child's academic performance and socioemotional development.

The origin of these difficulties is multifactorial. On the one hand, epileptogenesis interferes with brain maturation from early stages, especially in areas such as the frontal and temporal lobe. On the other hand, interictal discharges (epileptic activity not associated with clinical seizures) can produce subtle but cumulative neurological dysfunction. Added to this are the side effects of certain antiepileptic drugs (AEDs), such

as topiramate, phenobarbital or valproate, which can adversely affect language, processing speed and attention span, even without obvious symptoms.

Currently, the assessment of cognitive impact is irregular and not very standardized among centres. Neuropsychological tests such as NEPSY-II, WISC-V or Bayley-III are not systematically applied, and the detection of impairment usually occurs late, when children already present school or behavioural difficulties. This lack of early follow-up prevents the implementation of interventions that could mitigate cumulative cognitive impairment.

We are looking for solutions that:

- Provide sensitive and standardized approaches to monitor cognitive impact from the earliest stages.
- Facilitate timely interventions and follow-up strategies adapted to each child's needs.
- Can be used across different healthcare and educational settings.

C. CHALLENGE 3: PERSONALIZED DOSAGE ADJUSTMENT FOR ANTI-SEIZURE MEDICATIONS

Rare genetic epilepsies represent between 5% and 10% of cases of childhood epilepsy, and constitute a highly heterogeneous group within paediatric neurology [3,4]. These diseases are associated with mutations in genes such as SCN1A, CDKL5, STXBP1 or PCDH19, which alter key processes such as ion channel activity, synapse or neuronal signalling. These alterations cause seizures that are difficult to control, and are often accompanied by cognitive, motor and developmental disorders.

The diagnosis is supported by advanced genetic tools, such as the complete exome or specific gene panels, which make it possible to identify the molecular origin even in patients with normal MRI scans. Prolonged EEG and metabolic studies are also part of the diagnostic process.

Treatment ranges from traditional antiepileptic drugs to targeted therapies such as cannabidiol (CBD), ketogenic diet or neurostimulation (VNS). However, optimal dosing remains a major challenge, as response varies widely between patients and there are no standardized protocols. Genetic, metabolic and tolerance differences make adjustment difficult, which may compromise efficacy or generate adverse effects.

In addition, clinical and cognitive monitoring is often discontinuous, which prevents a sensitive assessment of the response to treatment. Follow-up requires multidisciplinary and continuous care, which is often not guaranteed. This complexity results in a significant emotional, social and economic burden for families

We are looking for solutions that:

- Enable personalized and safe adjustment of treatments based on clinical, pharmacological and genetic information.
- Support monitoring of treatment response at home and in the clinic.
- Reduce side effects and improve children's daily quality of life.

3. EXPECTED RESULTS:

i4KIDS-4RARE is looking for technology-driven proposals at an advanced stage of development (TRL 7–8), ready for implementation. Proposals should include a clear and feasible implementation plan and be designed with a user-centric approach, addressing the needs of paediatric patients and their families. Solutions must be scalable and easily integrated across diverse European healthcare systems, promoting accessibility and equity across regions.

4. ELEGIBILITY CRITERIA

Candidates must meet the following General Criteria:

- Only established companies or products ready for implementation can apply for this call.
- The proposed solution must comply with current regulations in order to be marketed in Europe (MDR, GDPR, etc.) if applicable.
- Solutions must be at a TRL 7 or higher.
- Candidates can apply for more than one challenge, but must fill in one form for each challenge.

5. PARTICIPATION IN THE PROGRAMME

5.1. Application process

Participants must complete this Application Form:

https://forms.gle/uq389nYEPYZuCceo9

Applications must be submitted in English using the aforementioned form.

All project submissions must be completed before the specified deadline of **November, 30th at 23:59 CEST.**

5.2. Candidate selection process

An initial evaluation will be carried out to identify the projects that meet the eligibility criteria. Selected projects will be assigned to evaluators for review according to the evaluation criteria described below. The evaluators will be experts in the field of healthcare.

A maximum of one project will be selected to participate in the i4KIDS-4RARE Neuroepilepsy Innovation Programme.

In the event that no participant is selected, the organizer reserves the right to declare the relevant challenge(s) null and void.

5.3. Evaluation criteria

Proposals participating in the **i4KIDS-4RARE Neuroepilepsy Innovation Programme** will be evaluated according to the following criteria:

Idea (35%)

- Soundness and innovativeness level of the proposal.
- Capacity to respond to the proposed challenge.

Feasibility, implementation capacity and Budget (35%)

- Current state of development and technological readiness.
- Quality and realism of the development and implementation plan.
- Adequacy and justification of the proposed budget and use of resources.
- Involvement of patients and users in the development phase.
- Capability to be implemented in EU hospitals.
- Previous experience of implementation in other centres.

Impact (20%)

- User-centric innovation.
- Engagement strategy.
- Scope of the impact.
- Paediatric focus.

Team (10%)

- Previous experience in the field.
- Candidate's capacity to implement the proposed solution.

If deemed necessary, the evaluation committee may ask applicants to verify the information provided in the proposals, either in person or online. In case of untruthful information, the application will be rejected

5.4. Grant

The i4KIDS-4RARE Neuropilepsy Innovation Programme offers a maximum total budget of €10,000 to support the implementation of Proof of Concept (PoC) pilot studies in collaboration with hospitals from the EpiCARE network.

The allocated funds must be used exclusively for the execution of the pilot study and the generation of data to validate the proposed innovation. Funding cannot be used for any activities outside the defined scope of the PoC.

Applicants are required to submit a detailed preliminary budget and a concise economic justification, clearly describing the budget categories and resources needed to conduct the pilot study at the selected hospital.

The Evaluation Committee will assess all applications and determine whether to award the grant. The final grant amount (up to €10,000) will depend on the project's identified needs, scientific and technical merit, and overall evaluation outcome.

The selected project will be entitled to issue an invoice covering the approved expenses associated with the execution of the pilot study, following the financial and administrative procedures established by the organizers.

In addition to financial support, selected projects will receive mentorship and strategic guidance from the Innovation Department of Hospital Sant Joan de Déu (HSJD) and will be invited to join the i4KIDS Network, fostering collaboration, visibility, and impact.

5.5. Timeline

The Neuroepilepsy Innovation Programme 2025 will follow a structured timeline to ensure a fair and transparent evaluation process:

- Call 4 Solutions (28rd October – 30th November 2025)
  During this period, the programme will be open for the submission of proposals. Researchers, innovators, and multidisciplinary teams will be invited to present their solutions addressing the identified challenges.

- Project Selection (15st December 2025)

6. ACCEPTANCE OF THE RULES

Participation in the Programme entails full and unconditional acceptance of these Rules. Recognition as a valid participant is subject to compliance with the requirements set forth in these Rules.

7. ASSIGNMENT OF THE RIGHT TO USE THE IMAGE

Applicants irrevocably and free of charge authorise i4KIDS-4RARE consortia to make use, reproduce, edit, in whole or in part, or broadcast their full or partial name as well as their image, in any publicity or advertisement made through any media or format, whether written, audiovisual or internet, for the maximum period permitted by law, worldwide, in relation to the participation in the programme for the purpose of promotion, information and advertising of the programme and the i4KIDS Network.

8. ETHICS

All activities carried out as part of i4KIDS-4RARE Neuropilepsy Innovation Programme must be conducted in compliance with:

- Ethical principles (including the highest standards of research integrity) and
- Applicable international, EU and national law.

The participants must ensure that the activities have an exclusive focus on civil applications.

9. PROCESSING OF PERSONAL DATA

Under the provisions of the regulations on protection of personal data, it is reported that the data provided by participants under the Programme will be incorporated into a file or files, owned by the Sant Joan de Déu Barcelona's Children Hospital (HSJD) and Fundació per a la Recerca i la Docència Sant Joan de Déu (FSJD), coordinators of the i4KIDS-4RARE project.

They will be processed for the purposes of: (i) maintenance, compliance, development, control and proper management of their participation in the Programme and subsequent related activity (including any communication that is necessary to notify or publicise their status as a finalist, winner or alternate); (ii) as well as for any other purpose provided for in these Rules of Participation.

In the event of providing data of third parties, now or in the future, the participant guarantees that each third party will have been previously informed and their consent obtained on all those aspects foreseen in the present clause, as well as in the Rules.

Likewise, the participant guarantees that the data provided are accurate and truthful. Any false communication of personal data will entitle to disqualify the participant and his/her team.

Participants may exercise their rights of access, rectification, cancellation and opposition, under the terms provided in the data protection regulations.

HSJD and FSJD undertakes to treat personal data confidentially at all times and in accordance with the purposes set out in this clause and Rules of Participation; to adopt the necessary technical and organisational measures to ensure the security of your data and avoid its alteration, loss, unauthorised access or processing, given the state of technology, the nature of the data stored and the risks to which they are exposed, all in compliance with the provisions of the data protection regulations in force at all times.

In case of providing personal data, participants authorise HSJD and FSJD to process them according to the above.

10. MODIFICATION OF THE RULES

i4KIDS-4RARE reserves the right to modify at any time the Rules of Participation, without assuming any responsibility for these modifications, provided that there is a justified cause, due to force majeure or circumstances beyond the control in a way that does not prejudice the rights acquired by the participants, committing to communicate with sufficient notice the new conditions of participation.

11. EXTENSION OR SUSPENSION OF THE CONTEST

i4KIDS-4RARE reserves the right to be able to extend the deadline for completion of the Programme or suspend the Programme, for good cause or force majeure and in the event that it could not be developed by fraud detected, technical errors or any other nature that are not under the control of i4KIDS-4RARE and may affect its normal development. Should any of these situations arise, all participants will be duly notified.

12. DISCLAIMER OF LIABILITY

i4KIDS-4RARE are not responsible for any possible losses, deterioration, data theft, delays or any other circumstances attributable to third parties that may arise from your participation in the present Programme.

Furthermore, i4KIDS-RARE does not guarantee the availability, continuity or infallibility of the operation of the Website, and consequently excludes, to the maximum extent permitted by current legislation, any liability for damages of any kind that may be due to the lack of availability or continuity of the operation of the web pages used in the Programme. i4KIDS-4RARE shall not be liable for any damages of any nature whatsoever that may be suffered by the winner and/or third parties arising out of or in connection with the use of the prize.

13. INDUSTRIAL AND INTELLECTUAL PROPERTY

The names, logos, icons and any element that identifies with the Programme are property and trademarks of HSJD and FSJD being reserved all their exploitation rights.

Selected programme participants are allowed to use the brand and names of the Programme and i4KIDS-4RARE for current and future communication and marketing activities related to the team's and project's participation in the Programme.

Any intellectual or industrial property rights, know-how, trade secrets or trade secrets belonging to the programme participant which are incorporated or used in connection with the provision of the Programme shall remain the property of the programme participant, and nothing contained in this Agreement shall be construed as an assignment or licence thereof.

All information provided and presented into the Programme by programme participants will be treated confidential with the exception declared in provision 6.

14. CONTACT

Should you have any questions about the call, please contact us at:
contact@innovation4kids.org

15. REFERENCES

[1] Gogi Kumar, Evaluation and management of drug resistant epilepsy in children, Current Problems in Pediatric and Adolescent Health Care, Volume 51, Issue 7, 2021, 101035, ISSN 1538-5442, https://doi.org/10.1016/j.cppeds.2021.101035.

[2] Paramonova A.I., Lysova K.D., Timechko E.E., Senchenko G.V., Sapronova M.R., Dmitrenko D.V. Cognitive impairment in childhood-onset epilepsy. Epilepsy and paroxysmal conditions. 2024;16(1):54-68. https://doi.org/10.17749/2077-8333/epi.par.con.2024.176

[3] Barbour K, Tian N, Yozawitz EG, Wolf S, McGoldrick PE, Sands TT, Nelson A, Basma N, Grinspan ZM. Population-based study of rare epilepsy incidence in a US urban population. Epilepsia. 2024 Aug;65(8):2341-2353. doi: 10.1111/epi.18029. Epub 2024 May 25. PMID: 38795333; PMCID: PMC11315636.

[4] Gogi Kumar, Evaluation and management of drug resistant epilepsy in children, Current Problems in Pediatric and Adolescent Health Care, Volume 51, Issue 7, 2021, 101035, ISSN 1538-5442, https://doi.org/10.1016/j.cppeds.2021.101035.