

# Research OF PAEDIATRIC MEDICINES



## Recommendations for Promoting Patient Participation

### What is it?

This document is a guide for researchers, healthcare authorities, pharmaceutical companies, and patients and their relatives, which aims to help ensure that the research process of new paediatric medicines is focused on this patient profile and underpinned by the close collaboration of these patients.

### Why?

It is necessary to involve patients who will participate in clinical trials - as well as their caregivers - throughout the entire research process, as this will ensure a better experience and contribute to gearing research toward patient needs, which will have an impact on the quality of the research. Children are not small adults; their metabolism, which is constantly developing, requires research into medicines specifically intended for them.

### Who developed it?

This guide is the result of efforts made by a working group organised by Farmaindustria in which representatives from the Sant Joan de Déu Hospital of Barcelona (Grupo KIDS Barcelona and a parents' group), the Spanish Paediatric Clinical Trials Network (RECLIP), and the Spanish Paediatrics Association (AEP). The final version has been revised by patient organisations, pharmaceutical companies, paediatric research professionals, and the Spanish Medicines Regulatory Agency (AEMPS).



### Are there any similar initiatives in Europe?

This guide is the only one existing within the European context. It is a further step in reinforcing Spain's leading role in the field of clinical research within the international context.

### Are there specific diseases affecting paediatric patients?

Children and youth suffer from some diseases that are not present in the adult population, and therefore require R&D efforts adapted to these particularities and which can lead to finding the best possible treatments.

### To date, what is the Spain's position in paediatric clinical trials?

In Spain the commitment to paediatric research over the last 5 years (2016-2020) has increased, with over 500 clinical trials (15% of the total) aimed at the paediatric population – 87% of which being sponsored by the pharmaceutical industry. The therapeutic areas on which these studies have focused are oncology, vaccines, infectious diseases, haematology, dermatology, and respiratory conditions.

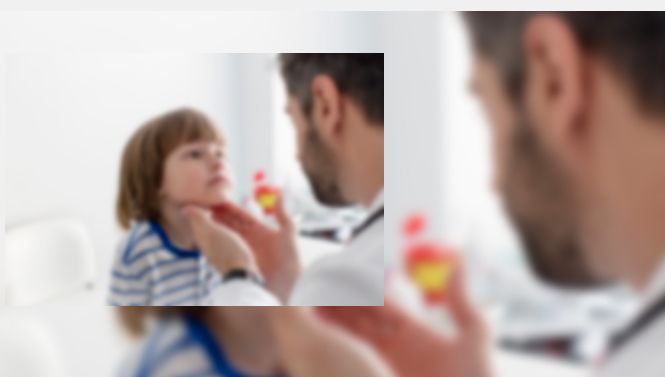
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### What challenges lie ahead?

The outlook is hopeful in respect to the number of potential innovative treatments already being trialed in humans. Nevertheless, there is still a long way to go, and it is crucial to continue fostering the collaboration among all stakeholders involved in the research in order to best respond to many diseases that exclusively affect the paediatric population.