

Development of Paediatric Medicines

Fulcrum Pharma is a professional service company providing clients with expert solutions for the development of therapeutic products.

Since the new EU Paediatric Regulation came into force on 26 January 2007 we have worked with clients to define solutions to ensure that they meet the requirements of this legislation.

The Paediatric Investigation Plan (PIP) is a key aspect of this EU Regulation and represents an opportunity in terms of additional market exclusivity but it also poses a challenge for many Pharmaceutical companies.

Submission of a PIP and/or a waiver request is obligatory for new medicinal products and also for development of new indications, routes of administration or new pharmaceutical forms for marketed products. Fulcrum is uniquely placed to advise on regulatory, clinical and commercial aspects of how and when the PIP should be produced:

- We generate the regulatory documentation necessary to satisfy the requirements
- We facilitate the commercial assessment and analysis of return on investment for paediatric development
- We design and implement non-clinical and clinical studies to provide meaningful paediatric data

Inspired Solutions in a Regulated World

We will work with you to define solutions to ensure you meet the requirements of the new EU Paediatric Regulation through:

- Strategic advice on the best approach to this new legislation including commercial evaluation of paediatric development programmes
- Expertise in the legal and regulatory framework with a particular emphasis on the cost/benefit analysis for your company
- The review of any studies already concluded/underway and advice on their adequacy to satisfy the regulations
- Risk assessment for product development plans
- Regulatory and technical advice on the development of suitable formulations for the paediatric population
- Review of current non-clinical data to support use in children
- Design and implementation of juvenile toxicology studies, if required
- The design & implementation of appropriate clinical studies including safety and efficacy studies in children
- The writing and review of clinical trial protocols
- Paediatric development advisory boards
- Preparation of PIP, PUMA, waiver or deferral applications, including the submission of e-PIPs and e-PUMAs
- Access to key skills in paediatric pharmacovigilance and risk management

For more information please contact us at:
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Consulting

Development

Regulatory

Safety