CASE STUDY

Support for a Paediatric Investigation Plan in the European Union for a US-based client

BlueReg supported a US-based client with a European Paediatric Investigation Plan (PIP) for their product. BlueReg initially provided guidance with the paediatric regulatory strategy and its potential impact on the PIP Application positioning. Subsequently, BlueReg wrote the PIP Scientific Document and prepared the ready-for-submission PIP Application

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Challenges

BlueReg was asked to provide, first, regulatory guidance in terms of paediatric strategy for a monoclonal antibody, currently being developed in adults. In a second step, BlueReg assisted the client with the scientific writing of the PIP Scientific Document and the regulatory preparation of the ready-for-submission PIP Application.

The challenges associated with this project were the followings:

- Identification of the paediatric condition/indication, since the development in adults was complex and the adult indication covered multiple therapeutic areas.
- Difficulty in finding recent, paediatric- and EU-specific treatment guidelines and prevalence/ incidence data to support the PIP Application.

BlueReg support

BlueReg put in place a team of highly experienced consultants with solid expertise in paediatric development/strategy and scientific writing to meet the client's and project's needs.

A project manager:

- Acted as the main contact person for an optimal coordination of all activities (e.g. mutual agreement on timelines, regular meetings).

- Provided regular up-dates on the project's progress to the client.

A Regulatory Affairs Expert:

- Guided the client to clearly define the paediatric condition/indication and its impact on the PIP content positioning (i.e. waivers, deferrals, paediatric development).

- Provided detailed project planning from strategy to PIP approval, including the option of a paediatric Scientific Advice.

- Led the preparation of a ready-for-submission PIP Application.

A Scientific Writing Expert:

- Guided the client with the identification of relevant source documentation to write the Scientific Document (e.g. selection of keywords for literature search and extraction of European and paediatric specific published data).

- Authored the PIP Scientific Document covering all paediatric subsets in line with the agreed paediatric strategy.

Achievements

- BlueReg made key recommendations on the paediatric strategy and facilitated consensual agreement between client's internal stakeholders.
- BlueReg produced a high-quality and convincing ready-for-submission PIP Application to support the client's paediatric strategy.
- The client greatly appreciated BlueReg's contribution to their PIP Application and recognised the valuable regulatory and scientific expertise provided by each BlueReg team member.

How BlueReg can support you ?

Paediatric Investigations Plans and Peadiatric Study Plans

A Paediatric Investigation Plan (PIP) or Pediatric Study Plan (PSP) is a development plan intended to support the authorisation of a medicine for children by ensuring data are obtained through studies in the paediatric population.

Our consultants can advise as to whether a deferral or waiver may be appropriate and can provide a complete PIP writing service as well as any PIP modifications through the lifecycle of the product within the EU or US.

In Europe, PIPs are described in Regulation (EC) No 1902/2006 which came into force in the EU on 26 January 2007. This paediatric regulation put in place the PIP to be agreed upon by a new expert committee (the Paediatric Committee [PDCO]); it also regulates a system of obligations and rewards and different transparency/information measures. The objectives are to improve and better protect the health of children with high quality & ethical research, increasing availability of appropriately authorised medicines for children specific information on the use of medicines in the paediatric population.

In the US the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) are the basis of the paediatric US legal framework. The Pediatric review Committee (PeRC) was established by legislation to carry out the activities described under PREA and BPCA. The ultimate goal of PREA and BPCA is to develop new pediatric labelling to encourage the appropriate use of medications to treat pediatric patients. The outline of the pediatric studies the applicant plans to conduct will be compiled in the Pediatric Study Plan (PSP)

Our consultants can advise you in all steps of the preparation and design of your initial PIP/PSP:

- Assess the right strategy concerning the PIP/PSP scope and timelines to meet your objectives

- Agree on the right condition and indications to be studied through a systemic approach and rigorous methodology

- For all age subsets, assess whether a waiver and/or deferral options can be considered based on available data and propose a risk mitigation

- Interact with agencies in case of Paediatric Scientific Advice, presubmission meeting and all along the PIP procedure.

- Write the corresponding documents: briefing packages, slide decks, paediatric plans and corresponding synopses or justifications for waivers/deferrals

- Coordinate on your behalf the full procedures (scientific advice/agency meeting, presubmission meeting, PIP/PSP) and can represent you at agency level in case of face-to-face meeting

Our consultants will also assist you with any PIP amendments in your paediatric developments through the lifecycle of the product within the EU or US, the compliance check procedure or annual deferral report preparation and submission. BlueReg consultants have built a long experience these past years by supporting our clients in all key steps of the paediatric development.

For more information please contact us

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