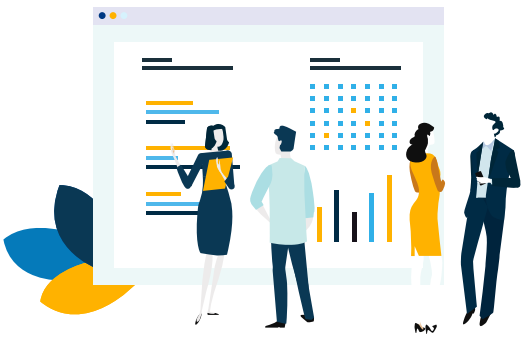
Case Study

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.

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:

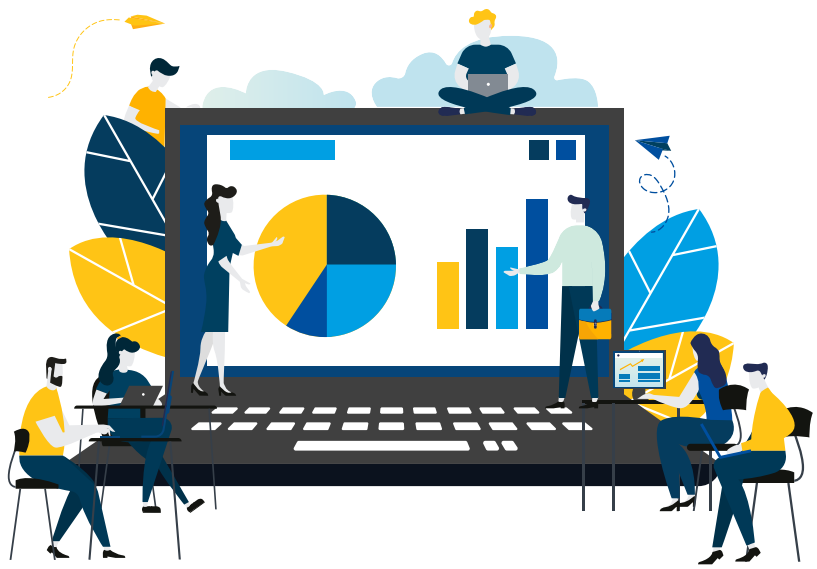
- Acted as the main contact person for an optimal coordination of all activities (e.g. mutual agreement on timelines, regular meetings).
- Provided regular up-dates on the project's progress to the client.

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.