Support for ODD* in Europe

BlueReg (BR) was engaged to assist a start-up company with the preparation of their orphan drug designation application dossier in europe and to provide regulatory support during the procedure.

* Orphan Drug Designation

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Challenges

Timelines:
The client contacted BR a short time ahead of the planned submission date requesting a review and update of their draft ODD dossier. At this time, the client had been in contact with the EMA but had not followed up them for some time.

Regulatory context:
at the time the project started, a new EU guideline laying down new requirements for ODD, in particular to justify significant benefit over existing therapies that would directly impact this application, was issued.

BlueReg support

BlueReg created a dedicated team of consultants for this project, including a consultant specialised in international drug development to lead the scientific discussions and a second consultant specialised in Orphan Drug development to provide regulatory support.

The following support was provided:

Regulatory support:

- BR advised the client on the evolving regulatory background and how this would impact their submission
- BR provided regulatory assistance before submission and throughout the full ODD procedure

Scientific writing support:

- BR defined and validated with the client the strategy for writing the ODD, taking into account both the evolving regulatory background and the scientific considerations pertaining to the specific product under development
- BR prepared the initial ODD dossier and responses to questions raised by the Committee on Orphan Medicinal Products (COMP) during the course of the procedure

Achievements

- Dossier submitted in accordance with agreed timelines with the client and the EMA
- Orphan Drug Designation granted by the European Commission
- Client acknowledged benefits of the support provided by BR from the regulatory advices and from the scientific support
- BR further assisted the client for ODD in USA