Gap analysis and regulatory support in view of first in human (FIH) trial planned to be conducted in Europe

A US-based customer contacted BlueReg (BR) for assistance in reviewing the CMC and non-clinical development package in view of a FIH clinical trial that will be conducted in Europe.

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Challenges

The gap analysis should take into account the followings:

- Development strategy for Europe to comply with local regulatory requirements in view of ensuring FIH clinical trial approval by local Regulatory Authorities.
- Evolving regulatory context applicable to the development programme. In particular, at the time of the review, the EMA Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMP) in clinical trials and Guideline on strategies to identify and mitigate risks for FIH and early clinical trials with IMP were under revision and planned to be applicable at time of clinical trial conduct.

BR was contacted a short time ahead of the planned submission date for clinical trial application with a low visibility on the exact project scope available.

BlueReg support

BR constituted a dedicated team of consultants composed of international drug development expert in addition to two experts on CMC and preclinical, respectively.

The following support was provided:

- Gap analysis on the CMC requirements and non-clinical studies to be performed before a FIH trial according to European regulatory requirements
  - Review of CMC and preclinical development package
  - Identification of potential questions raised by authorities
  - Advices provided on future development stages
- Review of documents for clinical trial application:
  - Regulatory and scientific content review of IMP dossier (IMPD) and Investigator brochure (IB)
- Close collaboration with CMC, non-clinical and medical experts missioned by the client to address identified issues

BR project team was extended during the course of the project with additional resources allocated to the project in order to adapt to the client's specific needs (eg. short timelines to review deliverables that could not be released by the client according to predefined schedule).

Achievements

- Phase 1 clinical study approval within the timelines agreed without any validation issues and main questions raised during clinical trial application procedure identified during gap analysis
- Customer's recognition of EU regulatory expertise
- Extension of scope of activities subcontracted to BR:
  - BR acts now as regulatory representative for all EU related activities
  - Scope of support extended to the scientific writing of regulatory documents to be submitted in Europe (orphan drug designation, paediatric investigation plan, briefing package for scientific advice)