**Detailed description of activities:**

* Gap fill analysis IMPD/IB
* IMPD parts:
  + - Nonclinical Pharmacology Integrated Analysis – review and supplement,
    - Pharmacokinetics Integrated Analysis- review
* Toxicology and Safety Pharmacology Integrated Analysis – write, translation of preclinical results into the clinic and risk assessment for patients
  + - * + Summary of Data and Guidance for the Investigator – write
        + Predicted effects in humans – review and write
* Consultation of preclinical data/reports, especially in the field of toxicology, hepatotoxicity and immunotoxicology
* Preparing answers to the Agency's questions during the clinic application regarding preclinical data.

**Deliverables:**

* Prepared documentation for preclinical part of IMPD/IB and Appendices parts
* Report (analysis of preclinical results, Q&A sessions)
* Replies to Agency