Daiichi-Sankyo

IIS Submission Guidance

Daiichi Sankyo accepts unsolicited IIS proposals for clinical or non-clinical studies. At minimum, the following information must be submitted to Daiichi Sankyo at IIS@dsi.com for us to conduct a review:

- Principal Investigator
- Institution Name
- Curriculum Vitae (CV) for Principal and any Sub-Investigators (if named on the concept)
- Type of Study (clinical, non-clinical)
- Type of Request (Drug Product, Financial, or both)
- Budget and Drug Product Request details
- Study Rationale
- Study Design (e.g. control, number of treatment arms, product doses, treatment duration, numbers of animals)
- Primary Objective(s)
- Planned timelines

The following are additional information requirements for clinical IIS proposals:

- Inclusion/Exclusion Criteria
- Study Population/Indication
- Study Endpoints
- Planned Sample Size and Statistical Powering Justification
- Planned number of subjects and sites/site locations (country only)
- Study Visit Schedule of Events
- If enrolling patients, the following are required:
  - Planned number enrolled
  - Planned FPFV date
  - Planned LPFV date
  - Planned LPLV date
  - Planned FSR date

If you have questions about the submission process, please contact us at IIS@dsi.com.