Axcelead Consultation

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- Recommend the nonclinical development strategy base on the 100+ IND and 20+ NDA experiences.
- Select and design nonclinical safety and DMPK studies according to the indication, pharmacological target, and physicochemical and biological properties of the candidate.
- Analyze obtained toxicology data to determine whether they are adverse and clinically relevant or not.
- Propose the selection of target metabolites and the handling strategies for reactive metabolites in consideration of NDA.
- Support interactions with regulatory authorities to file IND and to succeed in further clinical development.
- Propose the mechanistic studies to clarify the MOA and to find biomarkers of the dose-limiting toxicity.

Recent achievements:

✓ Filed IND of an oncology program originated from a start-up venture company.
✓ Lifted clinical hold and resume clinical development of a NCE originated from a pharmaceutical company.
✓ Supported DD to license out/in candidate molecules from ventures to pharmaceutical companies.

AXCELEAD Drug Discovery Partners