openinnovation

AstraZeneca

How to submit a clinical or translational research proposal

Application

- Select a compound
- Read the 'Instructions for authors'
- Generate a brief, non-confidential Concept Proposal
- Submit your proposal

Review

- Decisions (accept, additional information requested, or declined) will be communicated with reviewer feedback, typically within 8 weeks
- Proposals will be judged based on:
    - scientific merit, strength and uniqueness of the hypothesis (the suggested patient population must be distinct from those previously studied by AstraZeneca or others for the mechanism)
    - compelling nature of the medical need
    - technical feasibility
    - probability of a successful patient outcome, including a clear advantage over current standard of care

Full project proposal generation

- The Investigator's Brochure and important additional proposal specific information are shared, typically under a bidirectional Confidential Disclosure Agreement
- Collaborative discussions to compile details for the 'full' project proposal and clinical protocol
- Milestones, key decision points and criteria, timelines and party responsibilities are constructed
- Collaborative discussions identify funding, typically public/private grants, for the project

Final approval and set-up

- A Collaborative Research or Clinical Trial Agreement (CRA or CTA) is executed
- Typically, AstraZeneca supplies formulated compound and matching placebo as well as cross-referencing permission and bridging CMC regulatory documentation for IND filing
- The Principal Investigator files an investigator-sponsored IND to execute the studies

Project execution and reporting

- Principal Investigator executes the study
- Regular meetings and reports to discuss and track progress and enable course revision(s) as needed
- Final report and manuscript submission within 6 months of study completion

Potential rewards

- Publications
- Access to follow-on studies and grant applications
- Royalties if project IP is licensed and commercially successful