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:
  o 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)
  o compelling nature of the medical need
  o technical feasibility
  o 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