

Clinical or Translational Research Concept Proposal Instructions for authors

Concept Proposals should be brief (2-3 pages; maximum 5 pages) and include:

- A descriptive Title
- A statement of the Hypothesis for the compound/mechanism and indication/patient population
- Background – especially human evidence – that support or refute the hypothesis. This could include preclinical *in vitro* and *in vivo* data and human data such as genetic, expression profiling, pathway biomarker, pharmacology, etc.
- Medical Need – briefly describe the specific patients that will benefit, the current standard of care and distinct advantage(s) of this new therapy over standard of care. Include prevalence and incidence for the specific patient population and other information that articulates the medical need and transformational benefit.
- A Research Plan for validating the indication/compound hypothesis leading to:
 - Specific Aims – including rationale and positive:negative decision (endpoint) criteria for:
 - Preclinical studies, if needed; include evidence for translational link of these to the human disease
 - Clinical study or studies; consider including interim analysis possibility and/or adaptive extension as appropriate, as well as the link of this initial clinical ‘validation’ study to what might follow
 - Explanation of the Research Plan Decision Tree and associated criteria
 - Assessment of operational feasibility – what has/has not been done before by you or members of your team? Note: Innovative, novel, approaches are welcome.
 - Capabilities of the investigator(s), their labs, institutions, collaborators
- Overall Project Success Criteria

Note:

Only **non-confidential** information should be included in a *Concept Proposal*. If confidential data exists that would strengthen the proposal, the author may indicate that confidential information is available to share under a Confidential Disclosure Agreement (CDA). If AstraZeneca finds the non-confidential Concept Proposal sufficiently interesting, execution of a CDA will be discussed.