

UC Denver TIN Protocol Synopsis form

Title of Study:
Investigators: Name of the UCD investigator(s) who will be responsible for conducting the trial.
Study Center(s): Any information about planned sites that have already been discussed.
Concept and Rationale: Brief justification of concept and rationale, including name and description of the investigational product(s); abbreviated summary of background findings that are relevant to the trial; brief justification for the route of administration, dosage regimen, and treatment period(s); brief rationale for biomarker, imaging, or other correlative studies. [This section is limited to one page in length.]
Is this proposal based on data you and/or our collaborators developed? If so please briefly describe and identify publication status of the pre-clinical work
Primary Objective(s): The primary objective(s) of the trial.
Secondary Objective(s): A list of the secondary objectives of the trial. These can include objectives concerning additional clinical outcomes (e.g., overall survival), correlative outcomes (e.g., biomarkers and PK), and imaging outcomes (e.g., PET-CT).
Primary Endpoint(s): A list of the primary endpoints to be measured and how they will be measured during the trial. Examples include response based on RECIST criteria, time to progression, change in quality of life, dose-limiting toxicities, etc. For example, for a standard phase IA trial of a new targeted therapy agent, the primary endpoint might be: maximum tolerated dose – the dose level below the one at which 1/3 or 2/6 patients experience dose limiting toxicities. For a phase IB trial, studies examining dose response relationship and measurable surrogates of drug action or toxicity in peripheral blood or biopsies might be suitable and important at this stage of design and represent primary endpoints. (MTL)

<p>Study Design: A description of the type/design of trial to be conducted (e.g., double-blind, placebo-controlled, parallel design) and a simple schematic diagram of trial design, procedures and stages; measures taken to minimize/avoid bias, such as randomization or blinding.</p>
<p>Schema: Please include a schematic flow diagram of your study, so the TIN team can get a clear picture of how the study is designed.</p>
<p>Number of Patients: Number of subjects to be enrolled. A brief statement about how many patients are expected to be eligible, how many you expect to accrue of those eligible, and how long it will take to complete the study. This should be based on data obtained on the patient population where you plan to conduct the study.</p>
<p>Briefly describe the key eligibility criteria.</p>
<p>Intervention and Mode of Delivery: Any available information about the treatment(s) to be administered</p>
<p>Duration of Intervention and Evaluation: Any available information about the planned treatment period(s), including the follow-up period(s), for subjects for each investigational product treatment/trial treatment group/arm of the trial.</p>
<p>Funding, Regulatory, and Feasibility Issues: A brief description of how the study is planned to be funded; how the study drug(s) or other intervention(s) will be obtained; and (if applicable) whether the study sponsor or pharmaceutical/biotechnology company has committed to providing the study drug.</p>
<p>Services being requested from the TIN:</p>
<p>Additional Comments for UC Denver TIN Hub Liaison team:</p>