SIO Request for Clinical Trial Proposals

The Society of Interventional Oncology in partnership with Guerbet LLC announces a fund for clinical research.

The SIO is soliciting proposals for clinical trials addressing three areas of investigation, in order of priority:

1. Lipiodol transarterial chemoembolization (TACE) in combination with immune modulation therapy, including lipiodol-directed delivery of immunotherapy agents
2. Comparative Effectiveness and Long-term Safety, Cost Effectiveness and Quality of Life comparisons of lipiodol TACE and transarterial radioembolization for hepatocellular carcinoma and/or neuroendocrine tumors
3. Combination therapy with lipiodol TACE plus thermal ablation for tumors > 3 cm

The initial submission should be a Protocol Synopsis in the following format (adapted from the NIH Clinical Trial Template):

1. Title

   A description of the type/design of trial to be conducted (e.g., randomized, placebo-controlled, double-blinded, parallel design, open-label, dose escalation, dose-ranging, adaptive, cluster randomized, group sequential, multi-regional, superiority or non-inferiority design)

2. Background and Rationale for the proposed study (1/2 page)

   State the problem or question (e.g., describe the population, disease, current standard of care, if one exists, and limitations of knowledge or available therapy) and the reason for conducting the clinical trial

3. Primary objective, primary outcome measure (endpoint) and primary hypothesis. Secondary objectives and outcome measures, with hypotheses if applicable

   An objective is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., efficacy, effectiveness, safety) and/or specific purpose (e.g., dose-response, superiority to placebo, effect of an intervention on disease incidence, disease severity, or health behavior).

   A study outcome measure or endpoint is a specific measurement or observation to assess the effect of the study variable (study intervention). Study endpoints should correspond to the study objectives and hypotheses being tested. Give succinct, but precise definitions of the study endpoints used to address the study's primary objective and secondary objectives (e.g., specific laboratory tests that define safety or efficacy, clinical assessments of disease status, assessments of psychological characteristics, patient reported outcomes, behaviors or health outcomes).

4. Phase of Study. Must be a Phase 2 and/or 3 design. Phase 1 studies of safety and feasibility will not be considered.

5. Inclusion and Exclusion Criteria

Inclusion criteria are characteristics that define the population under study, e.g., those criteria that every potential participant must satisfy, to qualify for study entry. Some criteria to consider for inclusion are: provision of appropriate consent and assent, willingness and ability to participate in study procedures, age range, health status, specific clinical diagnosis or symptoms, background medical treatment, laboratory ranges, and use of appropriate contraception. Additional criteria should be included as appropriate for the study design and risk.

Exclusion criteria are characteristics that make an individual ineligible for study participation. Some criteria to consider for exclusion are: pre-existing conditions or concurrent diagnoses, concomitant use of other medication(s) or devices, known allergies, other factors that would cause harm or increased risk to the participant or close contacts, or preclude the participant's full adherence with or completion of the study. Additional criteria should be included as appropriate for the study design and risk.

6. Study Schema and description

7. Statistical design and sample size estimate.

Include number of participants to recruit, screen, and enroll to have adequate power to test the key hypotheses for the study. Provide all information needed to validate your calculations and judge the feasibility of enrolling and following the necessary number of participants. In particular, specify all of the following:

- *Outcome measure used for calculations (almost always the primary variable)*
- *Test statistic*
- *Null and alternative hypotheses*
- *Type I error rate (alpha)*
- *Power level (e.g., 80% power)*
- *Assumed event rate for dichotomous outcome (or mean and variance of continuous outcome) for each study arm, justified and referenced by historical data as much as possible*
- *Statistical method used to calculate the sample size, with a reference for it and for any software utilized*
  Anticipated impact of dropout rates, withdrawal, cross-over to other study arms, missing data, etc. on study power

8. Proposed study sites

9. Estimated accrual time, study duration, and feasibility assessment. Please provide evidence that the investigator has access to a study population sufficient to do the proposed trial.

10. Availability of resources to carry out the proposed trial

11. CV of the Principal Investigator - email with this completed form to info@sio-central.org

Deadline for submission of trial concepts is February 1st, 2020.

After review, the SIO Clinical Trials Committee will request full protocol submissions and budgets from those deemed competitive for funding. Deadline for full protocol submission is April 1st, 2020. Awards will be made by July 1st, 2020.