Masonic Cancer Center Clinical Trial Prioritization

As with other Masonic Cancer Center resources, the Clinical Trials Office was created to advance our faculty’s clinical research careers and to provide best practices for all patients seen in the clinic by offering participation in a clinical trial. In a resource unlimited environment, a broad spectrum of trials would be open regardless of accrual statistics. Currently this is not feasible given the nature of the funding environment, the costs associated with non-accruing trials, increased regulatory demands of complex clinical trials using experimental agents, and the fact that reimbursements are primarily based on accrual.

Because of these constraints, we need to prioritize CTO resourced trials based on mutually agreed upon criteria. The following guidelines should be considered when reviewing and approving trials that will be opened and resourced by the CTO. CTO support will be used to support trials in the following priority order.

Type of Trial

- Peer-review funded trials
- MCC Investigator-initiated
- Cooperative group with leadership and/or major contribution of MCC member
- Trials supported (funded) by MCC member’s academic department and approved by the MCC CPRC
- Business and Industry (B&I) funded trials with MCC member as key investigator (would appear on a manuscript reporting the trial)
- Expectation that at least 5 subjects will be enrolled per year

Phase of Trial regardless of origin

- Phase I and/or pilot trial
- Phase II trial
- Phase III trials as part of a member’s externally supported research
- Biospecimen or biomarker studies requiring MCC expertise (imaging, specimen procurement, pharmacokinetic/dynamic sampling, intensive monitoring, etc.)

PIs portfolio of active studies and historical success in completing trials

- Current number of active open trials meeting accrual goals
- Past success in enrolling subjects to clinical trials
- History of publication of clinical trials

Absent from this list are many phase III B&I trials. MCC recognizes that these trials frequently accrue well, particularly in community settings, and also contribute to the number of patients accrued to studies at our center. However, many of these trials do not require the expertise of MCC faculty (can be opened at community centers) and do not contribute to the academic career of the MCC member (do not result in a publication or peer-reviewed research funding).

For these types of trials, we anticipate that the ongoing single clinical enterprise structure proposed between MCC and the CTSI will serve as an administrative home. Full cost of supporting these trials are expected (including infrastructure costs) if the trials meet accrual goals. Neither the CTSI nor MCC should participate in industry trials that are budgeted to incur a deficit even if accrual goals are met. A
methodology will be developed to monitor ongoing accrual and validity of budget assumptions (screen failures, staff time, etc) to avoid deficits for all studies.

While CTO domain expertise and the skill-based workforce will likely be required for the conduct of these studies (direct patient contact), the fiscal management (budget preparation, sponsor negotiation, invoicing deficit and surplus management) of these studies will ultimately be the responsibility of the MCC member’s academic department (assuming the academic department holds the contract) and the CTSI through support of the financial hub based on their mutual agreement.

CTO and MCC member collaboration to ensure accrual

In order to maximize the value of CTO resources, low accruing trials and trials where the budget assumptions need revision must be identified early in the conduct of the trial with appropriate corrective actions. This process will be overseen by CTO project managers and/or study coordinators assigned to each trial. Once a trial is open to accrual, CTO will assist in the ongoing monitoring and management of subject accrual and validating the budget assumptions. CTO staff will assist MCC members through the following steps.

- If budget assumptions are not correct (for example, more staff time is required than budgeted), the principal investigator will be notified, trial accrual will be suspended, and the financial hub (or the contract holder) will re-negotiate with the sponsor to address a projected deficit.
- If a trial falls below 50% of targeted accrual after the first six months of opening, CTO project managers or study coordinators will meet with the PI to discuss barriers of accrual and to plan a strategy for improved accrual. This is to help prevent the trial from falling below the 30% of targeted accrual that would be used by the CPRC to recommend closure of the trial at annual review.
- For the next six months, the low accrual trial will undergo active management by CTO staff to assist in meeting of accrual goals
- After 12 months, if accrual remains below 50% of targeted accrual the study will undergo review to address:
  - Fiscal implications of keeping the study open
  - Assignment of responsibility of fiscal responsibility (MCC and member’s academic home)
  - Scientific review by MCC CPRC that uses 30% of targeted accrual to recommend closure of trials
- If accrual does not improve after initial 12 months, then the study will be subject to closure by the CPRC.