Key Questions for MDG Committee Members

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| Pending Trials |
| **Scientific merit of the protocol** |
| Is it “good” science?  |
| Can TJU publish? |
| What type of trial is it (industry, institutional, national)? |
| What is the primary objective? |
| Does it align with SKCC’s mission? |
| Are there any known upcoming publications/abstracts/FDA approvals that may change the merit/necessity of this trial? |
| **Fit into the committees disease map** |
| Where does this fit in the disease map?  |
| Are there too many trials open for the same line of therapy or indication?  |
| How does this one differentiate itself from the others? |
| If the trial has multiple arms, and, say, only one does not overlap with other trials: Can you open just one arm of the trial? Is it worth it to open the whole trial for one arm? |
| **Staffing** |
| Discussion of PI selection |
| How many trials are currently open? What is the current workload of each coordinator? |
| Is the team understaffed?  |
| What is the complexity of the trial from a data and coordination standpoint—how much time per week would a trial like this take for the CRCs? |
| Do we have an existing backlog of data that prevents us from meeting sponsor expectations of enrollment and data entry? |
| **Availability of subjects?** |
| How many patients can we enroll per year?  |
| How many typically patients do we see at Jefferson per year? |
| Any study requirements that would make subject recruitment challenging? |
| Would this be a rare tumor status trial? |
| What is the global accrual of the study? Has it reached 50%? |
| **Competitive trials** |
| (see disease map section)  |
| What else is opening that may hinder success to this trial?  |
| What is closing that will open the slot? |
| **Inclusion of Women and Minorities** |
| Does this trial help with accrual to women and minorities? If so, how? |
| **Recruitment plans** |
| What is the anticipated TJU open to accrual date?  |
| What are the sponsor timelines? (First to Enroll date, Last to Enroll date, etc) |
| What is the total enrollment needed and how many enrollments does the sponsor have already?  |
| How will patients be identified?  |
| Will this be a multi-institutional trial?  |
| Do we want to involve the network (RLO)? |
| **Feasibility to conduct the trial** |
| Have the inclusion/exclusion criteria been reviewed and is there anything in particular that may prevent our enrollment goal?  |
| Is there particular procedures/tasks that will hinder success?  |
| Any barriers to patients completing the trial such as the patient schedule/timeline? |
| Is there enough interest that physicians will accrue? |
| **Preliminary budget considerations** |
| Is the trial funded? |
| Have we seen a budget?  |
| Keep in mind for an IIT, is it funded (grant supported)? |
| Do you know any information that this study can help support the overall MDG account?  |
| Does JCRI need to draft a formal budget (for a protocol concept/IIT)? |
| **Other** |
| When do they want us to open? Can we accomplish this timeline goal? |
| What is the plan for site selection (this gets in the way of the 3 months from MDG to PRC deadline)? |
| Has a CDA been executed (another obstacle for MDG-PRC timeframe)? |
| Would scientific merit/interest be likely to change in the time it takes to open this trial? |
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| Concepts  |
| Are there any investigators that are currently drafting a protocol concept or have been in communication with JCRI about a potential negotiation for an IIT? Would the interest include a multisite or RLO component? |
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| Active Trials |
| Are any trials that will be on the PRC’s Activation Monitoring Notification list? |
| (When reviewing each trial, see below) |
| What are barriers to enrollment?  |
| What are the successes of the trial? |
| Are there any workflow/communication issues that need reworking? |
| Will this trial be meeting accrual goal soon? |
| Will this trial be closing soon? If so, for what reason? |
| Does this trial have a current amendment in process or a potential one? |
| Data management or monitoring challenges to be highlighted? |

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