SCRS Global Oncology

Oncology Education Workstream Meeting Summary
January 2022

The group was able to split after much discussion on appropriate paths forward into two smaller teams this month. One team focused on personnel, logistics, and infrastructure (Group 1) while the other team focused on regulations, feasibility, and start-up (Group 2) as both pertain to Phase 1 clinical trials in Oncology.

Below is a summary outline of the notes from both teams.

1 Group 1:

- Try not to recreate information that might exist
- Focus on treatment trials and sites already doing research
- Assumptions: they have certain personnel in place. PI, Data, Pharmacy, Managers
- Personnel
  - Checklist for finding staff
  - Outside/beyond baseline trials
- Physician who has experience in this area.
  - Roles we know in research and note what it means for that role to be in Phase 1
- How can I gain the experience I need as a PI, for example
- Mentorship
- Does NCI offer training program for investigators (for early phase?)
  - Access to skills and external relationships - what are those staff
- Overnights? Ophthalmologists? Cardiologists
  - Expectations for execution
- Important to understand how this is different - i.e. increased communications, expected participation
- Protected Time demonstration to the Sponsors
  - PI, Coordinators, Research Nurse (RN), Data, Pharmacy, Lab Personnel
  - Experience level, Training Level, Time commitments, expectations, licensure
  - Nice to have vs Need to have
- Dedicated staff for the extra requirements and resource requirements from Phase 1
- Logistics and Infrastructure
  - Leverage ASCO information
- From Phase 3 and 2 to Phase 1
- Physician engagement differences as examples
  - Decommissioning hospital beds from clinical care to dedicate to research.
- You have to have the hospital beds - how you do that is up to you
  - Capital Expenses - What do they need to “buy” and what can that look like
- Charging the right rates for the equipment
  - Having the equipment nearby for careful monitoring
- Assure they start at the right place for best success

2 Group 2:

- Phase I investigators choose drugs/targets, not protocols. The protocol design is far less important because dose-finding has many standards. The science of the compound and how it might play out in dose-finding in the clinic is an essential component of feasibility.
- Access to patients is NOT the same thing as patient density. Especially in phase I, solid referral networks/channels and curated, pre-screened waiting lists of patients is more important than patient density.
- Industry spends a lot of time on SiteID and Feasibility for phase I oncology based on prior performance and "speed to startup" but not much in a different way than any other study. Understanding the dynamics of phase I and having conversations with key productivity leaders in the field is FAR more valuable than data-driven site/PI identification.
- Most phase I trials expand into phase Ib/II. Feasibility cannot be a one-and-done exercise.
- Industry recommendations:
- Stop/slow the guessing before reaching out to KPLs. Use data to find experts to talk to, not to find experts and tell them what they should be doing based on the data you happen to have access to
- Have operations built specifically for phI. Don't try to setup and run the study like a phase II or III trial. Fir-for-purpose SOPs and procedures based on how sites work in this space.
- Site recommendations:
- Know your referral channels and be able to articulate that proactively to Sponsors/CROs
- Feasibility on the site logistics and capabilities are equally as important to feasibility of the IP's science and patient pathways. Sites should have study development managers employed to look at the whole picture because PIs, RPhs, RNs, Admins etc., will all have different levels of varying feasibility.
- Have a transition plan(s) for phase Ib/II expansions. Can you hand the study off to a DFG in expansion? Will you have the referral channels in place for the intended/known expansions? Does the sponsor even know what the expansions will look like yet? If not, have a discussion about what they might be relative to your referral network(s).

The next meeting will be spend reviewing these summaries, as well as continuing to set the stage for each of the domains for the individual groups. Subsequent meetings will be spend diving a bit more into specifics after the high level work has been resolved.