Dear CTO/CRSL Colleagues,

We are reaching out to provide another update on the Clinical Trials operational planning initiative. Our aim is to keep you up to date on ongoing and emerging priorities. You can expect to receive similar updates regularly. As always, if you have questions regarding this initiative, please reach out to ctoplanning@yale.edu.

Clinical Trials Operational Planning Update

Some of you may recall from prior presentations that the Huron team* is working through an evaluation of the YCC CTO to assist YCC in developing a more sustainable model that supports the current portfolio as well as positions YCC for growth. The steps in that process are assessment, design, implementation and refine.

The assessment phase of the Clinical Trials operational planning effort is nearing completion. The Huron team has concluded benchmarking, interviews, and solicited feedback from staff through surveys and open discussions. The Huron team is in the process of synthesizing observations and drafting a report. That part of the Huron team is preparing to pivot to the next phase of the Clinical Trials operational planning initiative, shifting from assessment to design.

The draft assessment report will be presented to the Steering Committee in mid-January, which will include supportive benchmarking data and strawman organizational model(s) that address pain points identified during the assessment. The Huron team will solicit the Steering Committee's feedback on these models and establish guardrails for the design phase. The Steering Committee includes:

- Roy Herbst (Chair)
- Nita Ahuja
- Alyssa Gateman
- Margaret Gilshannon
- Tesheia Johnson
- Edward Kaftan
- Lori Pickens
- Brian Rebeschi
- Adam Roshka
- Brian Smith

Following the Steering Committee meeting, we expect to convene design sessions with our Advisory Teams. These groups will help further define and refine the future state using the guidance provided by the Steering Committee. The Advisory Teams may be asked to weigh various options, speak to the impacts of decisions, or otherwise guide the implementation planning for a given model (e.g., design workflows). We look forward to meeting with you and gaining your insight on the best path forward for YCC Clinical Trials operations, and will provide more information on this phase in the New Year.

**The Huron team consists of a consulting team, an interim staffing team, and a project management office. The group working on the assessment are the consulting team.*

Advisory Teams:

Your engagement and input are critical to the above efforts. We would like to thank those of you who volunteered to take part in one or more of our Advisory Teams. The Core Team** will work to finalize rosters for these groups, which will include both volunteers and nominees to ensure cross-functional representation. We anticipate convening these groups in the New Year in line with the kickoff of the design phase of the initiative – please stay tuned for more updates.

***Core Team members are Roy Herbst, Margaret Gilshannon, Alyssa Gateman, Adam Roshka, Leah Guidry, and Erin Pennington.*

Rapid Assessments
In parallel with the broader Clinical Trials operational planning initiative, the team is undertaking smaller rapid assessment projects that seek to address challenges in current state processes to generate some "quick wins." Currently, we are targeting two areas for this work: Study Intake and an enhanced DART Review Process. Both rapid assessments are part of a larger Protocol Review and Monitoring System (PRMS) Process Improvement initiative driven by the need to strengthen YCC's current PRMS process in alignment with National Cancer Institute (NCI) expectations of comprehensive cancer centers.

Training and Education:
All CTO staff are being added to the CTO Training Calendar within Outlook. Once added, you will find all upcoming trainings listed there. If you have questions about whether you should attend any upcoming training, please check with your manager.

- Cancer 101 will be offered December 22nd from 10:00 – 11:00 AM EST and will be recorded for those unable to attend.

Please reach out to Melanie Anderson (melanie.anderson@yale.edu) with questions. Further, thank you to the CTTMs, CRNs, and the CRCs who participated in the staff training survey. This feedback will be used to drive priorities for the training and education program.

eRegulatory (eReg) Optimization
The eReg optimization team finished optimizing protocols for the first two disease teams (Lymphoma and Myeloma), and 32 in-scope protocols have been converted to the new electronic Regulatory Binder.

Please ensure you are signing off on all document signature requests in a timely fashion, as several regulatory staff processes depend on timeliness of signoffs. We have attached a quick tip that describes how to locate and sign documents requiring your signature.

Thank you for your continued engagement in this initiative!

Sincerely,

Core Team:
Alyssa Gatemen (YCC)
Margaret Gilshannon (YCC)
Leah Guidry (Huron)
Dr. Roy Herbst (YCC)
Erin Pennington (Huron)
Adam Roshka (YCC)

Project Management Office:
Shannon Chism (Huron)
Evan Korn (Huron)
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Erin Pennington (Huron)