

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.

YCC CTO/CRSL Survey Q & A

Thank you for your participation in the YCC CTO/CRSL Feedback Survey. You provided invaluable insight into the issues that are most important to the CTO and CRSL. In line with our commitment to transparency, we have compiled the attached Q&A document, providing answers to the questions you submitted concerning the Clinical Trials Operational Planning initiative.

If you have additional questions or concerns, please e-mail 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 and positions YCC for growth. The steps in that process are assessment, design, implementation and refine.

The assessment portion of that effort is nearing completion. The Huron assessment team has concluded benchmarking, interviews, and solicited feedback from staff through surveys and open discussions. The project management office and Core team** are working through the findings and recommendations from that assessment.

Key observations from the draft assessment report were presented to the Steering Committee in mid-January. The next step is to continue conversations on Huron recommendations, share benchmarking data and a strawman organizational model(s) that address opportunities and pain points identified during the assessment. The Core 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 (transitioning with Dr. Winer's onboarding)
- Eric Winer, effective 2/1
- Alyssa Gateman
- Margaret Gilshannon
- Tesheia Johnson
- Edward Kaftan
- Lori Pickens
- Brian Rebesch
- Adam Roshka
- Brian Smith
- Ian Krop, effective 3/1

As discussed during the Townhall, we expected to begin socializing the assessment with a broader YCC audience around this time. There will be a delay from that planned schedule to allow the new YCC leaders, Dr. Eric Winer and Dr. Ian Krop, to be fully onboard in order to provide their guidance and leadership for the future vision of the YCC CTO. We will continue to keep you informed via these regular updates.

Once the assessment phase of our work is completed, we will share findings and recommendations more broadly that support the future vision for the YCC CTO. At that time, we anticipate convening 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 CTO.

**The Huron team consists of an assessment team, an interim staffing team, and a project management office.*

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

Advisory Teams:

As we initiate the Design phase of this initiative, we will convene several Advisory Teams to help shape the future of YCC clinical trial operations using the guidance provided by the Steering Committee. We will structure an Advisory Team around each of the following areas:

1. Workflow and Process Design
2. Operating Model Design
3. Standard Operating Procedure and Policy and Procedure Documentation Development
4. Technology Optimization

In addition, on January 21st, we kicked off our Change Management and Communications Advisory Team to: advise on the content, audience, mechanism, and frequency of communications; incorporate employee feedback into the communication plan; and attend regular meetings to discuss communications. This group is co-led by Dr. Stacey Stein and Huron's Project Management Office. Change Management and Communication Advisory Team Members include:

- Dr. Stacey Stein
- Dr. Kira Pavlik
- Dr. Michael Cecchini
- Alison Kannon
- Carol Deminie
- Sarah Andrychowski
- Rachel Hurtado
- Lauren Slater
- Rosy Cruz
- Lindsey Waggoner
- Gabby Douglas

Your engagement and input are critical to the success of the Clinical Trials Operational Planning initiative. We would like to thank those of you who have already volunteered to take part in one or more of our Advisory Teams. If you are interested in participating as a member of one of the Advisory Teams listed above, please feel free to reach out to: ctoplanning@yale.edu. The Core Team will review a list of volunteers and compose Advisory Team rosters with a mix of volunteers and nominees to ensure cross-functional representation. Thank you in advance for your engagement and participation in these teams.

Rapid Assessments

In parallel with the broader Clinical Trials Operational Planning initiative, the team is undertaking smaller rapid assessment projects 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.

As we’ve previously reported, two smaller rapid assessment projects have been identified to address current state process improvements:

1. The enhanced DART Review Process was initiated last week with a revised DART Protocol Review and Scoring Form that has been drafted to help ensure that DARTs are fulfilling the expectations set out by the National Cancer Institute (NCI). The revised form is currently under review and will be piloted across all DARTs in the coming weeks.
2. The Study Intake Process is currently being scoped out and more information will follow soon.

eRegulatory (eReg) Optimization

The eReg optimization team finished optimizing protocols for GU/Endo (23 protocols), Pediatrics (26 protocols), and Cellular Therapy (9). The team will begin optimization on 64 Phase I protocols beginning January 24th.

Did you know: Everyone who has access to eRegulatory can run reports? If you need to quickly confirm if a team member is approved to participate in research activities, (completed training and/or delegated tasks are signed off by the investigator) there are four key reports

1. Delegation of Authority Log
2. Electronic Signature Status for Protocol Documents
3. Staff Training Tracker by Protocol
4. Staff Training Tracker by Staff Member

Review the attached eReg Quick Tip – eRegulatory Reports for more detail.

Other CTO Updates

Training and Education:

The following trainings are scheduled on the CTO Training Calendar within Outlook.

- CRA Meeting: Tuesday, January 25th 10-11 AM
- CRC/CRN Meeting: Friday, January 28th 9-10 AM

The Subject Eligibility Training and Regulatory 101 Training will be finalized and scheduled this week. We are also collaborating on a tumor type series. Please keep an eye on the CTO Training calendar as these are added.

As a reminder, the CTO now has a dedicated space on the intranet for [Training and Education Resources](#). The How to Read a Protocol Training from last week has been uploaded, in addition to all previously delivered trainings that have been recorded.

If you have any questions or concerns, please let reach out to Melanie Anderson (melanie.anderson@yale.edu).

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)
Cheryl Majeske (Huron)
Erin Pennington (Huron)