Dear CTO/CRSL Colleagues,

Thank you for your responses to the YCC CTO/CRSL Feedback Survey. In response to your feedback, we are providing an email update on our progress in the Clinical Trials operational planning effort. Below, you will find a brief report on a few ongoing and emerging priorities. As always, if you have any questions or concerns regarding this initiative, please reach out to ctoplanning@yale.edu.

In addition, we would like to thank those of you who participated in the CTO Planning Initiative Office Hours. We are in the process of scheduling one additional open session – please keep an eye out for more information via email.

Advisory Teams:

As you know, your engagement and input are critical to our planning efforts. Thank you to all of those who have volunteered to-date to participate in one of our Advisory Teams, groups responsible for helping to shape communications and change management, and the future state of our processes, operating model, SOPs, and technology. Your responses have been recorded and, as we finalize the rosters for each group, we will reach out to confirm your participation.

We anticipate the bulk of Advisory Teams' work will occur in the New Year except for the Change Management and Communications Advisory Team, which may convene sooner. If you have not yet volunteered but would like to, please complete the survey

here: https://surveys.huronconsultinggroup.com/Survey.aspx?s=908bd9b4ecf74eca9ca278779fb5633a.

Training and Education:

In addition, we are aiming to standardize and organize onboarding and training within the CTO. We are currently focusing on our short-term goals of identifying immediate training needs. A needs assessment will be disseminated in the next week to the CTTMs, CRCs and CRNs to help our team prioritize the trainings that need to be facilitated as soon as possible. The trainings that are currently scheduled are listed below:

- Oral Drug Compliance: December 6th 3:00 4:00 PM EDT
- Informed Consent: December 7th 3:00 4:00 PM EDT
- Intro to Clinical Trials: December 14th 12:30 1:30 PM EDT

All trainings are posted on the CTO Training Calendar within Outlook. If you have problems accessing or have any additional questions, please reach out to Melanie Anderson (melanie.anderson@yale.edu).

eRegulatory (eReg) Optimization

As you know, YCCI revamped the eReg platform and, in line, we have implemented key changes to processes, In addition, we have kicked off our eReg Optimization project for protocols that are being managed in the system. We want to thank the over 300+ CTO individuals who signed-off on their master delegation of authority tasks.

As part of the eReg Optimization project the YCCI eReg website and a new eReg Access Request Form for internal users and external monitors are now live. The eReg Support team will no longer be accepting the old paper forms for access and those requesting a regulatory role will require the additional YCCI content-specific training moving forward.

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)
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