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

The Huron team has completed the assessment and is in the process of reviewing observations and recommendations through the established project governance structures.

The project Core Team continues to meet regularly and is increasingly engaging with Dr. Winer and Dr. Krop to establish priorities and shape the next phase of the project. The design phase is anticipated to take approximately three months.

Some goals for the design phase include:

- Determine a future state operating model for the CTO
- Determine decisions that impact CTO roles, workflows, and policies
- Create an implementation plan and timeline

A design phase kickoff meeting is planned for CTO managers, faculty, and staff. We will share more details as they become available. Namely, the methodology for this phase of the project and the function of the Advisory Groups in that process.

eRegulatory (eReg) Optimization

The eReg optimization team began optimization on Phase I protocols January 24th. Phase I represents 30% of the optimization scope and we expect to be working through these protocols throughout the month of February.

New Feature Alert: You now have the ability to choose the columns that appear in the protocol staff table. Advarra has added the Choose Columns button as well as the Export button. As part of this change you can choose to include:

- Active User Account
- Delegation of Authority Start Date
- Delegation of Authority Stop Date
- Delegated Tasks Status
- PIN Status

Review the attached eReg Quick Tip - Customizing and Exporting the Staff List for more detail.

Other CTO Updates

The following upcoming training modules are scheduled on the CTO Training Calendar within Outlook.

- Regulatory 101: Wednesday, February 9th 1:00-1:30 PM
- Tumor Type Series Myeloma: Wednesday, February 9th 3:00-4:00 PM
- Tumor Type Series Lymphoma: Thursday, February 10th 2:00-3:00 PM
- Basics of Pathology: Monday, February 14th 1:00 2:00 PM

The Subject Eligibility Training from last week has been uploaded to <u>Training and Education Resources</u>, in addition to all previously delivered training modules that have been recorded.

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

Thank you for your continued engagement in this initiative!

Sincerely,

Core Team:

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