

Dear Colleagues,

We hope this e-mail finds you well and you are enjoying the summer. Please find updates on the Clinical Trials Operational Planning Initiative below. We will continue to send out email updates as new information becomes available and encourage you to visit the [YCC Clinical Trials Operational Planning < Yale Cancer Center](#) website for the most updated information regarding the project.

### **Leadership Updates:**

- Congratulations to Alyssa Gateman, MPH CCRP, who has accepted the position of Executive Director for the Yale Cancer Center Clinical Trials Office. Nirmala Thevathasan will continue to serve as Interim Director for the CTO and assist in the transformation effort as Alyssa transitions from her current YCCI role. It is anticipated that Nirmala will continue in her current role through the Fall.

### **What Has Been Completed?**

- The design phase of Step 1 is complete and will move to the Step 1 Advisory Team\* before implementation. Step 1 focused on the organizational structure, staffing, and workflows of the clinical operations side of the Yale Cancer Center Clinical Trials Office. Key decisions included:
  - The proposal of designated YCC CTO Career Ladders for Clinical Research Staff.
  - Training programs to help support YCC investigators with the development of Investigator Initiated Trials (IIT).
- In June, The Transformation Team met with Drs. Chiang and Kortmansky to review the data needs and processes for opening trials at the Care Centers.
  - Goals to come from this group:
    - To optimize the trial site selection process in order to improve clinical trial accrual and better manage the workload placed on staff members.
- Step 2 discussions started last month. Step 2 will focus on Care Centers, Study Activation, Investigator-Initiated Support Roles, and the Regulatory Team.

*\*To see the members of the Advisory Teams, please visit: [YCC Clinical Trials Operational Planning < Yale Cancer Center](#)*

### **What's Next?**

- The Step 1 Advisory Team meetings are anticipated to be held in **mid-August**.
- The Step 2 design phase is anticipated to conclude in **September**. At that time, the Step 2 Advisory Team will meet.
- Additional on-site meetings are scheduled in **August**, focused on Regulatory and Activation which will include workflows, roles and responsibilities, and career ladders.
- The Transformation Team is in the process of identifying the Step 2 Advisory Team members, and if you are selected, you will be reached out to individually to confirm your participation.

### **Technology Updates:**

Several tools have been identified to help improve efficiencies and support our teams, including the following:

- Implementation of OPAL to help ensure appropriate resourcing, work volume, and the evaluation of staffing levels;
- Integration of IRES IRB and OnCore eRegulatory programs.

As always, if you have any questions regarding the Clinical Trials Operational Planning Initiative, please reach out to [CTOPanning@yale.edu](mailto:CTOPanning@yale.edu)

Thank you for your continued dedication and support!

The Change Management and Communications Advisory Team