



Yale CANCER CENTER

A Comprehensive Cancer Center Designated
by the National Cancer Institute

Clinical Trials Operational Planning Initiative

Progress Update and Design Phase Kick Off

March 21, 2022

YaleNewHaven**Health**
Smilow Cancer Hospital

Yale CANCER
CENTER
A Comprehensive Cancer Center Designated
by the National Cancer Institute

- **Provide information on how we will approach the next phase of the project**
- **Explain what you can expect in terms of participation and communication**
- **Answer your questions**

- **CTO Vision**
- **How we will get there**
- **What you can expect**

The future clinical trials office will be...



EFFECTIVE

- Facilitate the very best clinical/translational research



SUSTAINABLE

- Account for predictable and unpredictable turnover
- Adjust for trial complexity
- Establish standards across all DARTs



A PLACE TO GROW YOUR CAREER

- Career ladders
- Commitment to growth including leadership opportunity
- Support and train new investigators



SAFE AND COMPLIANT

- Establish the safest research practices
- Develop approaches to maximize quality control
- Rationalize information across systems

Strategy,
Governance,
and Leadership

Organizational
Structure

Tools and
Technology

Personnel

Process or
Procedural

Communication

- The Steering Committee is developing and prioritizing recommendations and strategic decisions that need to be made and will be addressing these over an eight-week timeline that began on March 16th

Week #	Discussion Topics & Decisions
1	Leadership Decisions & Care Centers
2 & 3	Organizational Staffing and DART Support Model
4	Regulatory & IIT Support
5 & 6	CRSL Strategy and Roles
7	Technology Support
8	Pre and Post-Award Administrative Support

CTO Transformation Steps

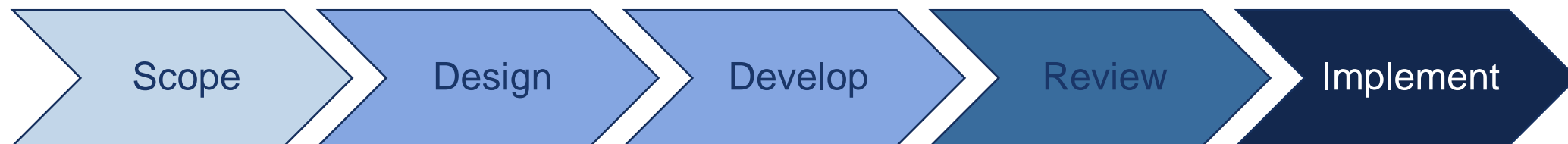
- To manage the work and reach key milestones prior to CCSG renewal timelines, accepted recommendations will be implemented in four steps
- The goal is to have substantial improvements in place before August 2022

Steps #	Focus of Steps
1	Organizational Staffing and DART model
2	Care Centers Regulatory IIT Support Study Activation
3	CRSL Epic Beacon Build Technology Support
4	Pre- and Post-Award Administrative Support Study Closure

What changes are in scope for Step 1?

- Clarification and changes to YCC CTO Leadership roles and responsibilities
- Clarification and changes to YCC Clinical Operations roles and responsibilities
- Clarifications and changes to the project management structure
- Quality and Education roles
- Introduction of a staffing acuity tool and rollout of career ladders for clinical operations
- Modifications to Study Conduct and Maintenance workflows

Each step will follow this process



Scope

The **Steering Committee** will identify the scope of the work to be completed and a project plan will be created.

The **Communication Team** will begin messaging the upcoming changes.

Design and Develop

The **Transformation Team** will work through the details and impacts of the change and plan for Implementation.

The **Workflow Team** will prepare materials to support the change. For example, SOPs, job aids, etc.

Review

The **Advisory Team** will review materials and provide feedback on design and implementation plans, final plans will be approved by the **Steering Committee**.

Implement

The **Communication Team** will inform stakeholders of changes and implementation will begin (jobs posted, new policies and tools rolled out etc.)

Design Phase Team Membership

Steering Committee Member

Dr. Barbara Burtness	Arnim Dontes	Alyssa Gateman	Margaret Gilshannon
Leah Guidry	Dr. Roy Herbst	Dr. Ian Krop	Erin Pennington
Lori Pickens	Rick Rohrbach	Adam Roshka	Nirmala Thevathasan
Dr. Eric Winer			

Communication Team

Sarah Andrychowski	Patti Brand	Dr. Michael Cecchini
Rosy Cruz	Carol Deminie	Gabbi Douglas
Rachel Hurtado	Alison Kannon	Kira Pavlik
Lauren Slater	Dr. Stacey Stein	Katie Wildman

Design Phase Team Membership

Transformation Team			
Dr. Neal Fischbach	Alyssa Gateman	Margaret Gilshannon	Leah Guidry
Dr. Ian Krop	Erin Pennington	Sara Raboin	Adam Roshka
Amber Selvidge	Dr. Stacy Stein	Nirmala Thevathasan	Dr. Amer Zeidan

Workflow Team		
Shannon Chism	Kristi Godbolt	Ryan Maxwell
Catrina VanAllen	Erin Van Hoy	

Advisory Teams will have flexible membership based on the topics being reviewed at each Step. Membership of Advisory Teams will be determined by Transformation Team and will consider personnel bandwidth, subject matter expertise, and expressed interest. We will leverage volunteers solicited at the start of the project and also identify additional key stakeholders.

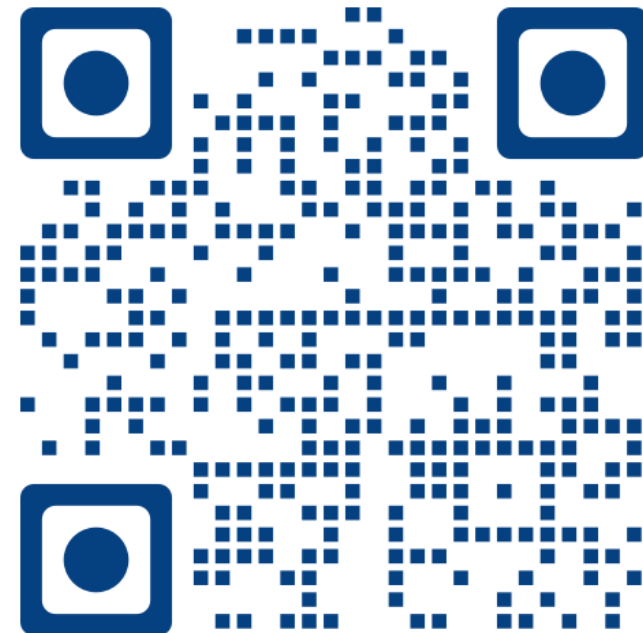


- **Kickoff Meeting** with Transformation Team members and CTO/Leadership Team members and other stakeholders
- **Kickoff communication** information shared regarding Step goals and approach sent to impacted stakeholder
- **Biweekly Updates** (Transformation, Workflow, advisory, & Communication Teams) as teams begin working
- **Supporting materials for all changes including** SOPs, workflows, job aids
- **Advisory Team** given a chance to review changes before implementation
- **Implementation Communication** to faculty and CTO will summarize any changes, approaches to manage changes, and implementation guidance
- **Project Website** updates every other week

Your engagement is critical to our success!

- Visit the Clinical Trials Operational Planning website which will serve as a one-stop shop for updates on our progress, upcoming events, and other resources.
- Please visit www.yalecancercenter.org/intranet/cto/ctoplanning for additional information and send any questions to CTOplanning@yale.edu.

The screenshot displays the Yale Cancer Center website. At the top, there is a blue navigation bar with the text "Yale Cancer Center" and a search icon. Below this, a secondary navigation bar contains links for "Patient Information", "Research & Education", "About Us", "Make a Gift", "News", and "Contact Us". The main content area features a sidebar on the left with a menu under "Intranet" including "Clinical Trials Office", "YCC Clinical Trials", and "Operational Planning Project". The main content area is titled "YCC Clinical Trials Operational Planning Project" and includes social media icons for Twitter, Facebook, LinkedIn, Email, and Print. The text on the page states: "Yale Cancer Center and Smilow Cancer Hospital are committed to: Providing the highest quality therapeutics and innovative treatments focused on curing disease and caring for our patients, and Building and supporting a rewarding environment with career development and growth opportunities for faculty and staff." It further explains that the project is a partnership with Huron Consulting Group to design a contemporary, nimble operating model. The page also mentions that the site contains background information, upcoming opportunities for feedback, and contact information for project team members.



Design Phase Teams

- **Transformation Team** – Responsible for crafting the new model, including job descriptions, competency models and implementation plan management. This process works in parallel with the Workflow Team.
- **Workflow Team** – Responsible for creating and updating materials to align to the change (e.g. SOPs, roles and responsibilities, technology impact analysis, and training plan. Will review and update associated workflows to reflect recommendation changes.
- **Advisory Team** - a select group of faculty and staff members identified by Transformation Team will review and provide feedback on the completed materials and workflows. This team will be asked to react to and identify issues prior to rollout.
- **Communications Team** – Responsible for overseeing the communications plan, developing and reviewing targeted communications, escalating risks to the planning team, and acting as an intermediary between the YCC Staff and the Transformation Team.