

YCC CTO/CRSL Feedback Survey Results

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. The Core Team* and Huron team** will use your feedback to inform the ways in which we communicate and engage with you and focus our design work.

In addition, you submitted questions covering a variety of themes, including:

- Ways in which you can get involved in the Clinical Trials operational planning initiative
- The scope and purpose of Huron's interim support
- Plans for onboarding, training, and education
- The status of recruitment efforts
- Means to retain and recognize CTO and CRSL staff

In line with our commitment to transparency, you will find answers to these questions below grouped by theme. In some cases, the Core Team consolidated similar questions in the spirit of brevity. If you have additional questions or concerns, please email ctoplanning@yale.edu. Thank you again for your engagement in this effort!

General Questions

Engagement and Transparency:

Q: How will we be kept informed of ongoing initiatives as they become more concrete?

A: The Core Team is committed to keeping you informed on the progress and outcomes of the Clinical Trials operational planning initiative. You can expect to receive updates via email, on our website, and in dedicated initiative-specific meetings. In addition, there are opportunities for you to participate in planning activities, including by providing your feedback and by participating in the design phase. Please note that there may be some repetition of information across communications to ensure the information reaches everyone.

Q: Will we have input on proposed changes before they are finalized?

A: Yes, you will continue to have the opportunity for input on the future design of YCC clinical trials infrastructure. At this time, the primary way in which you can get involved is on an Advisory Team, which will help to inform decisions and operationalize our new model. To volunteer, please reach out to ctoplanning@yale.edu.

Q: How will CTO staffs' perspective be incorporated into the assessment?

A: CTO staffs' perspective has and will be incorporated into the assessment and our design work. While the assessment work is nearly complete, the Huron Assessment team received your feedback through a combination of interviews, town hall follow-up sessions and surveys, and office hours. Thank you again for providing your feedback! Additionally, there

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***The Huron team consists of a consulting team, an interim staffing team, and a project management office. The group working on the assessment are the consulting team.*

will be more opportunities to be heard, including through Advisory Teams and via additional forums (e.g., listening sessions).

Q: Can you expand on the logistics and composition of the Advisory Teams and how we can get involved?

A: Advisory Teams are one of the primary ways in which you can get directly involved in our Clinical Trials operational planning work. These groups will be responsible for shaping communications and change management, and informing the future state of our processes, operating model, SOPs, and technology. Largely, these groups will be volunteer based, and the Huron Project Management Office will work with the Core Team to ensure appropriate cross-functional representation. The size of these groups may vary depending on the subject matter. Advisory Teams' work will begin in the New Year and these groups will meet regularly to discuss the future state of the CTO, including how best to operationalize the new model.

Q: How will the assessment account for inefficiencies that occur outside the CTO's control?

A: The Huron Assessment team met with a variety of stakeholders within and outside the CTO including leadership and faculty to understand both pain points experienced by CTO staff and due to broader clinical trial structures, practices, and organizational culture.

Q: How do we remain transparent with YNHH partners?

A: The Clinical Trials operational planning initiative's Steering Committee includes representation from YNHH leadership, which ensures leadership-level awareness of our work. Additionally, a broader YNHH audience is included on the general updates on our project sent via Yale newsletters (e.g., Smilow Updates).

Organizational Structure Questions:

Career Ladders

Q: When will career ladders begin?

A: As each role's career ladder is finalized, it will be reviewed in conjunction with any structure change conversations that are already taking place.

Q: Will the career ladders include different salary ranges?

A: The goal for the career ladders is to provide a clear trajectory for professional job growth within the clinical research arena. Each role will correspond with a defined set of competencies, establishing clear expectations for the skills and abilities required to progress to the next level. Until these are defined, we will not have confirmation of salary ranges.

Q: Will there be a re-evaluation of financial compensation of paygrades?

A: The CTO, like all units of the Medical School and the University follows the University structure of position classification and pay grades. If a new role or a modification to existing roles is recommended and accepted as part of the new design, a compensation analysis would be performed and standard University HR practices to maintain equity within a unit and across the campus would be followed. Please note that C&T compensation and raises must be consistent with the Local 34 labor contract.

People Questions:

Interim Support

Q: What roles are being filled with Interim employees? What tasks will be their focus in the year ahead?

A: Interim staff currently fill 30 roles within the CTO. These include

- 1 Interim CTO Administrative Director
- 1 Interim Sr Associate Director, Clinical Operations
- 1 Interim Associate Director, Training and Education
- 4 Interim Project Managers assisting with activation and closure tasks
- 2 Interim Clinical Research Nurses assisting on Epic Beacon builds
- 2 Interim Regulatory Managers
- 18 Interim Regulatory coordinators and assistants, 3 of which are dedicated to eRegulatory project
- 2 Interim Training and Education Project Managers focused on standardizing and structuring the training program, starting with clinical operations

CTO leadership anticipates adding 6-9 more interim positions over the next month including additional Interim Associate Directors, an Interim Sr. Regulatory Project Manager to help with QA of the eRegulatory optimization work, and an Interim CRSL Project Manager. Our intention remains to provide CTTM support in the form of five clinical research coordinators (in addition to existing training and education resources and project managers) to alleviate some of the strain on this team. However, these efforts have been slowed due to recruiting challenges. We continue to pursue all CRC staffing options while also discussing alternative ways to support CTTMs.

Q: How will Huron be able to help with on-campus required positions?

A: Included in the 6-9 positions identified above, five are intended to be on site CRC positions. CTO leadership is specifically looking for experienced coordinators within a reasonable commute distance and intend these to be temp-to-perm. There are multiple vendors looking to fill these needs, they have proven quite difficult to recruit.

Q: Since most of the CRSL employees are on campus, will Huron help with staffing needs for on-campus roles?

A: There are no plans for interim staffing support for on campus CRSL positions at this time. There are plans for two remote CRSL project manager positions.

Q: Can we more formally introduce interim staff and clearly explain their roles and responsibilities?

A: Yes, look for a communication to come from your AD.

Q: Will Huron Consulting Group's contract terminate once the CTO is fully staffed and trained?

A: The contract with Huron is currently through the end of 2022. The intention is for Huron to provide support in the design and implementation of the new operating model.

Leadership

Q: What processes are in place to review management's performance?

A: The past year has been exceptionally challenging for all CTO members, including our management team, and they have risen to the occasion time and time again. CTO leadership intends to develop competency models for all positions, including managerial positions, so that all staff have a better understanding of expectations and can then begin to leverage these competencies with employees.

Onboarding, Training and Education

Q: What is the plan for training and retaining staff?

A: The Training and Education team is currently focusing on high-priority training based on recommendations from ADs, CTTMs, and the upcoming results of the needs assessment that will be disseminated to the CTTMs, CRCs and CRNs. The long-term vision is to create a robust and comprehensive CTO onboarding and training program to be standardized across the CTO.

Q: Who is training the new CRAs?

A: Currently, CRAs are trained at the team level, typically involving the CTTM and other experienced members of the DART. The Training and Education team's goal is to develop a comprehensive onboarding and training program that will be standardized across the CTO. There will always be a need for some training and/or shadowing at the disease team level, but our commitment is to provide many additional tools and "train the trainer" training, so that staff have what they need to be a part of onboarding.

Q: How will time be protected for educational and growth opportunities?

A: As part of the broader Assessment, YCC is looking at both a more robust training program, better standardized workload acuity assessments, roles and responsibilities, and appropriate staffing levels. Together, the Training and Education team believes this will provide a workload that is balanced and reasonable. Our goal is to allow individuals to take advantage of all the training and other opportunities that are available at Yale.

Q: Can we develop a better “directory” of resources available for continuing education?

A: Absolutely. This will be part of the training program in the future.

Q: Can we develop a better onboarding program, including an employee handbook with basic contacts for questions?

A: Absolutely. A more comprehensive onboarding program is part of the long-term vision for education and training within the CTO.

Q: Are we able to establish a training program like the YNHH nurses have for career development for CRCs and CRNs depending on what you are?

A: The Training and Education team is looking at a variety of ways we can foster career development/growth both within a role or by moving into a new role. The Training and Education team will benchmark within Yale/YNHH and with other academic institutions as we develop our program.

Q: Are there more trainings being developed for the DARTS across the board?

A: As the Training and Education team works to develop this training program, we are focused on a three-pronged approach – general CTO, role-specific, DART-specific. The goal is to standardize trainings across the CTO, while still allowing some flexibility for minor nuances within DARTs.

Q: Will there be specific training requirements new hires will need to complete before being fully independent in their new role?

A: The new training program will include specific requirements including training and shadowing before new hires are expected to operate independently within their role.

Recruitment

Q: How is recruitment going (e.g., applicants applied/interviewed, open positions)?

A: CTO management is working closely with HR and Staffing to aggressively recruit for all open positions within the CTO. This includes using several external nationally recognized recruitment firms. Currently the CTO has approximately 30 open positions approved or posted.

Remote/On-Site Work and Work-Life Balance

Q: What is the future of remote work for YCC?

A: As was announced in the 12/2 email from Jack Callahan, staff with hybrid or remote work arrangements can continue those arrangements at least through June 2022. Some M&P positions have been approved for long term remote work and, as you know, there are other positions within the CTO that have been approved for full remote work through calendar year 2022. CTO leadership is working with HR to determine which positions can remain

eligible for full remote and hybrid remote work long term and will keep you posted as University policy evolves in the new year.

Q: Can we explore work-life balance?

A: The challenges of the past 2 years with the pandemic, coupled with our University and health system staffing shortages have made work-life balance an even more important issue. The Cancer Center and the CTO are committed to helping all staff achieve an appropriate work-life balance. CTO leadership will work collaboratively with staff in 2022 to explore ways to support work-life balance for all our faculty and staff.

Resource Allocation

Q: Will current employees get reallocated within the department or CTO?

A: Presently, there are no defined plans to reallocate current employees. However, as the future state operating model solidifies, CTO leadership will evaluate the most sustainable model for the support of clinical trials at YCC. As reallocating staff would be a significant change, the Core Team would communicate transparently and provide appropriate notice.

Retention and Recognition

Q: How are we recognizing and rewarding M&P staff?

A: CTO leadership recognizes that many M&P staff members are going above and beyond and are pleased that the University recently announced that all eligible M&P staff will receive a 2% salary increase, effective Jan 1, 2022. This is exclusive of any annual merit increase that an M&P staff member may receive in July.

Q: How do rewards and recognition differ for C&T staff?

A: CTO leadership greatly values the contributions of our C&T staff and recognizes that many C&T staff are going above and beyond. One aim of our interim staffing support has been to alleviate workload pressure on C&T staff. However, C&T compensation and raises must be consistent with the Local 34 labor contract.

Q: How will we retain long-term employees in the CTO? What is the CTO doing to remain competitive? Why should we “weather the storm”?

A: Employee retention is a paramount concern throughout the University, the medical school, and the CTO. Our staff are our most valuable resource and CTO leadership is working actively with HR to ensure that we are offering competitive salaries and work arrangements for all positions. CTO and YCC leadership recognize that many people are going above and beyond to ensure that we can provide care to our patients. Where possible, staff members who are covering long term vacancies or peers or subordinates have been approved for extra compensation to recognize the additional work they are taking on. Further, managers are working with staff to ensure that they are recognized for their extraordinary contributions during this challenging time and leadership is committed to supporting those members of the CTO who have shown a commitment to staying with the organization.



Finally, staff and faculty burnout has been a significant concern since the beginning of the pandemic and high turnover has exacerbated this. YCC leadership is working with HR and University leadership to find ways to support our team members. Our aggressive recruitment efforts to help ease the burden on existing staff is one way we are working to address issues related to burnout.