Novel CTMS task list implementation to expedite startup, streamline communication, and facilitate process and TTA optimization

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Background

Time to Activation (TTA), the duration from Scientific Review Committee submission to open to accrual status, is a defining metric for cancer centers: minimizing it, without compromising compliance or the bottom line, is paramount to maximize the efficiency of the study startup process. The Lombardi Clinical Trials Office (CTO) and the centralized Clinical Research Operations Office (CROO) at Georgetown University partner to continuously explore new ways to improve TTA.

Previous analysis into the largest components of Lombardi Comprehensive Cancer Center's (LCCC) TTA revealed that between 5 and 15% is attributable to communication issues and extraneous lag time during task handoffs. A time-burden analysis revealed regulatory startup staff spent 12 to 30% of each day sorting and addressing emails, leaving less time for startup tasks.

Sample Individual Time-Burden Analysis

Job-Specific... 23.4%
Meetings 45.6%
General/Admin 13.3%
Emails 17.7%
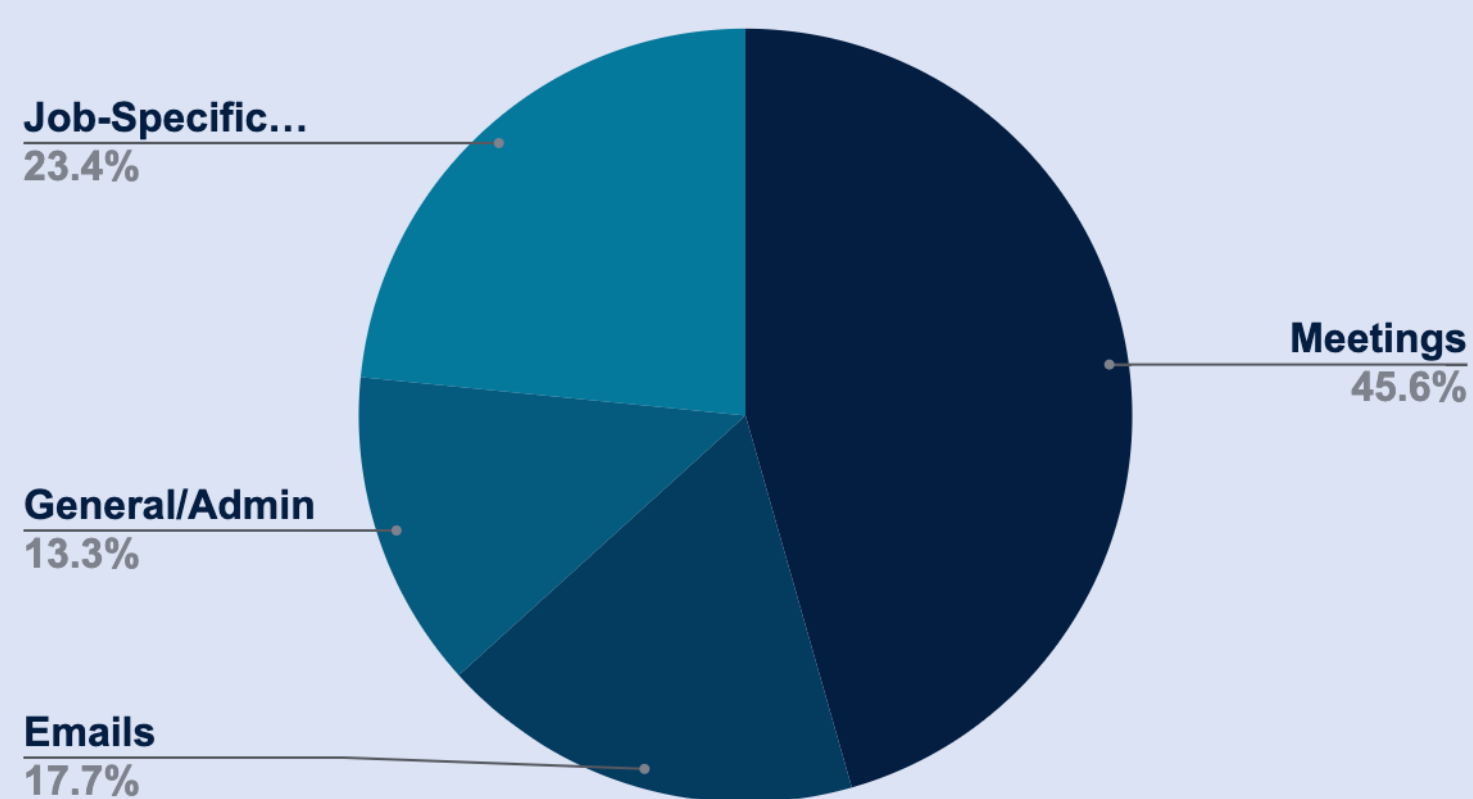
Goals

- Reduce internal startup-related emailing
- Reduce communication inconsistencies
- Minimize task hand-off periods
- Reduce TTA by >15%

Solutions and Methods

1. Design a series of customized task lists to comprehensively capture the entirety of the study activation process, focusing primarily on key milestones not organically tracked elsewhere
2. Use LCCC's clinical trial management system (CTMS), OnCore, to display these task lists and:

Pulling from a study-specific task list, auto-assign individual items
Generate relative task due dates based on milestone dates entered
Facilitate the simultaneous storage and sharing of primary study documents that are not already a part of the ISF maintained by the startup regulatory team (*e.g.,* initial budget and contract drafts and calendar schema)
House important communications and status updates

3. Implemented these OnCore-housed task lists under the oversight of the Study Activation Coordinator, cross-departmentally, beginning in April 2023

Task List Interface

Internal emails per study

Quarter	Emails/Study
Q1 CY 2023	18.6
Q2 CY 2023	15.4
Q3 CY 2023	7.1
Q4 CY 2023	4.1
Q1 CY 2024	3.9

Emails/Study vs. Quarter

Δ %-79
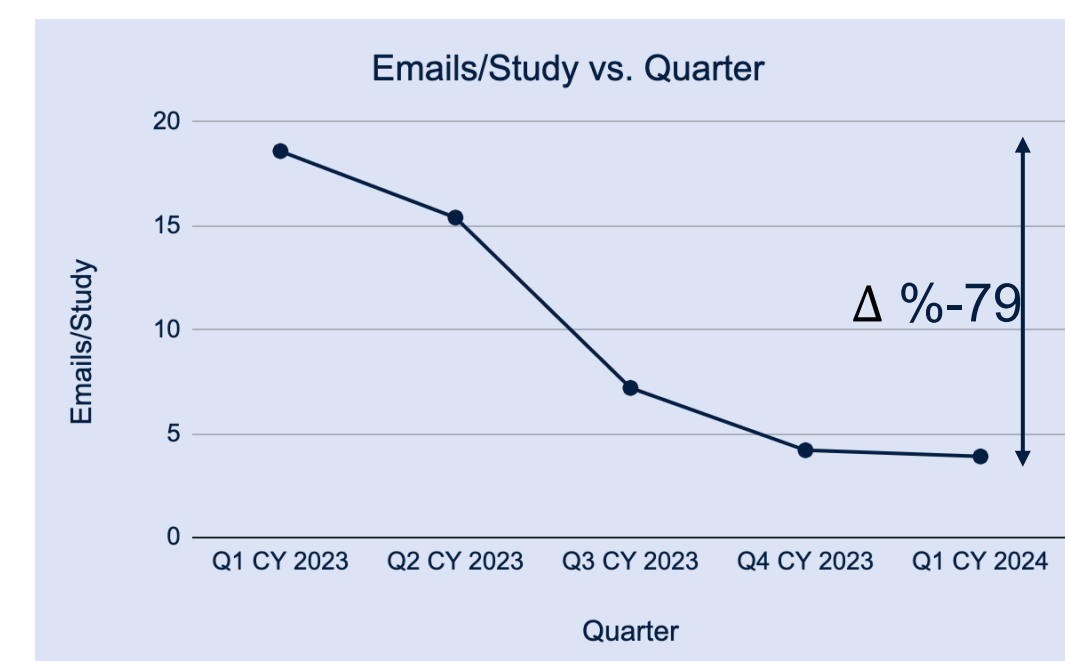
Task Handoff (HO) Time (hours) by Activity and Quarter

Quarter	HO 1	HO 2	HO 3	Total
Q1 2023	56	65	35	156
Q2 2023	25	54	36	115
Q3 2023	17	44	33	94
Q4 2023	13	41	36	90
Q1 2024	14	34	30	78

Monthly Study TTAs, by Year

	2022	2023
Jan	168	218
Feb	173	255
Mar	184	213
Apr	229	-
May	234	-
Jun	271	176
Jul	161	174
Aug	126	157
Sep	264	101
Oct	-	29
Nov	199	96
Dec	168	75
Avg.	198	149

Monthly Study TTAs, by Year
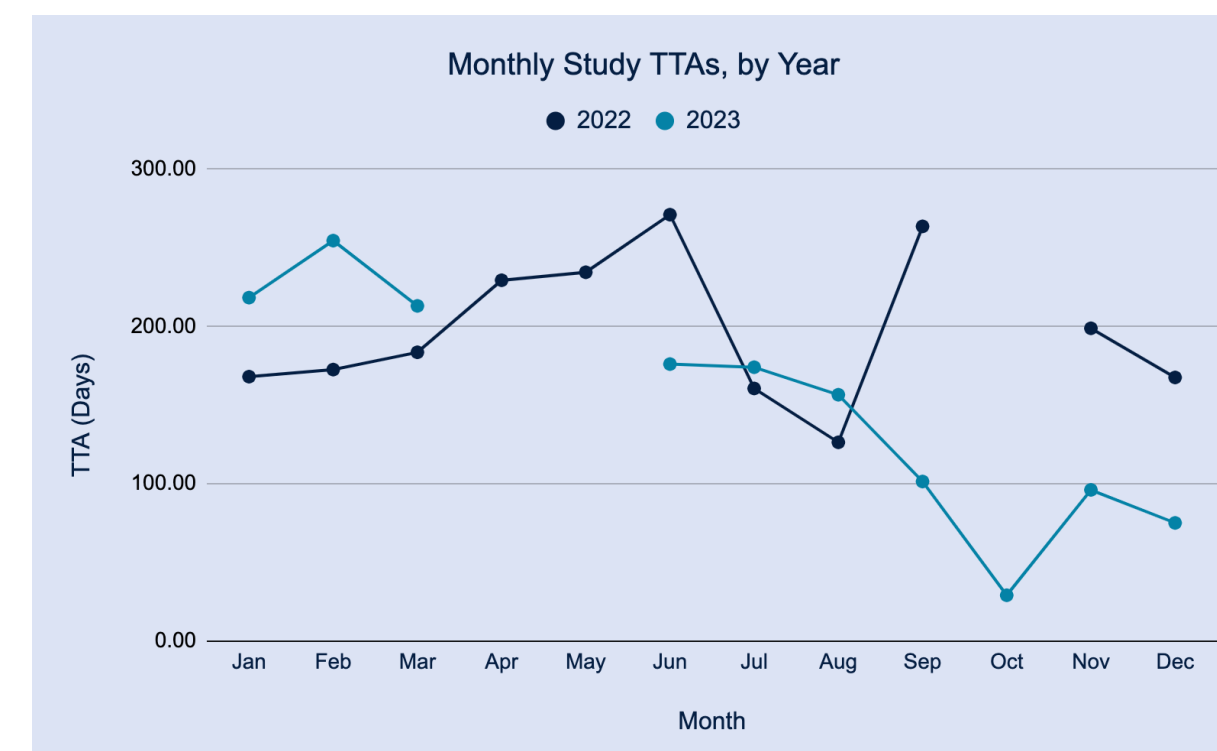
● 2022 ● 2023

TTA Summary	2022	2023
Annual Average	198	149
Apr-Dec Average	206	115
Annual Reduction %	24%	
Reduction % Apr-Dec	42%	

Outcomes

- Reduced roughly 80% of internal email traffic pertaining to study startup
- Decreased average task handoff time by 50%
- Studies submitted to the SRC in 2023 activated, on average, 25% quicker than those submitted in 2022
  - On average 42% quicker if examining studies after April 2023
- Reduced task handoff from an average of 12% to 4% of TTA
- We continued to maintain the above outcomes without a substantial reduction in studies submitted to the SRC per month (1 less per month, on average)

Lessons Learned

Task lists alleviated startup pain points and allowed dedicated study start-up staff to focus on tracking and improving negotiations, expanding study offerings, and other future growth initiatives including an expedited startup program. Though not originally posited as a benefit, the transition to task lists from email-centralized tasks facilitated better consistency during staff turnover or extended out of office periods and allowed others to easily view statuses, access materials, and request assistance between departments. Centralization of work tracking has facilitated the generation of reports and made the process of identifying areas for improvement far simpler.

Future Directions

- Expand task lists further to incorporate tasks belonging to the clinical operations team
- Increase the percentage of contracting and regulatory staff using task lists for work and project management purposes
- Incorporate new tasks to standardize the process of assigning staff to new studies
- Introduce third party vendors, as needed, into task lists of their own for centralized reporting and accountability purposes

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