

Introduction and Background

The SKCCC Clinical Trials Office (CTO) originally utilized a **localized, disease-group-led** model to prioritize therapeutic expertise. To drive institutional efficiency, the CTO transitioned to a **centralized Study Start-Up (SSU) team** focused on high-accountability, parallel workflows.

This shift revealed a **Centralization Paradox**: while centralized frameworks improve structural metrics, success is ultimately dictated by the **"human variable"**. Operational gains are only realized by navigating the legacy workflows and institutional resistance inherent in moving away from a localized culture.

By managing these diverse personalities and standardizing disparate work styles across MDGs, the centralized model seeks to optimize the trial activation lifecycle while reducing administrative fatigue.

Goals

To optimize the trial activation lifecycle, SKCCC CTO aimed to move away from a linear, siloed workflow to a centralized, high-accountability SSU model.

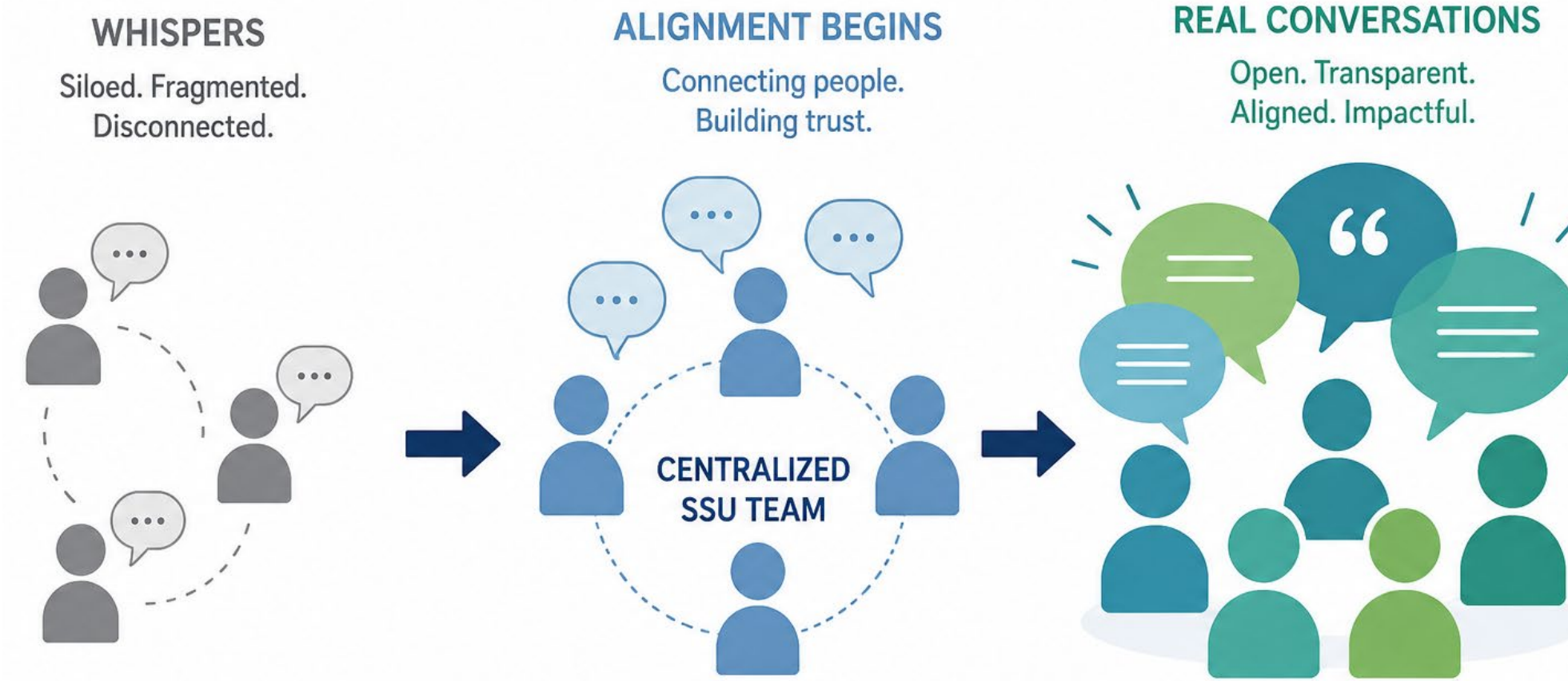
Primary operational objectives included:

Coordinate Project Timelines
Accelerate workflows by transitioning from sequential to concurrent (parallel) workstreams

Standardize SSU Process
Harmonize and document unified, best practice workflows across all distinct Multidisciplinary Disease Groups (MDGs)

Reduce Administrative Burden
Streamline tasks and centralize accountability to mitigate clinical staff administrative fatigue

From Whispers to Real Conversations



Solution and Methods

STEP 1	CENTRALIZED SSU TEAM ESTABLISHED Replaced traditional linear workflows with a centralized SSU team to enable parallel progression across all activation workstreams
STEP 2	PIVOT TO STAKEHOLDER ALIGNMENT Recognized the complexity of the "human variable," shifting towards a transparent strategy that humanizes the transition through intensive stakeholder engagement and feedback loops
CURRENT	OPERATIONAL STANDARDIZATION Actively standardizing operational frameworks to harmonize disparate work styles and communication preferences across MDGs
GOAL	BALANCED, PERFORMANCE-FOCUSED ENVIRONMENT Achieving a balance between centralized efficiency and clinical nuance by prioritizing relationship-building alongside data-driven process design

Outcomes

- Accelerated Problem Resolution**
Early implementation reduced bottleneck timelines from weeks/months to just days through parallel workstreams
- Increased Operational Momentum**
Centralized oversight shifted trial activation from stagnation to active progression across multidisciplinary disease groups
- Enhanced Stakeholder Alignment**
Improved accountability bridged the gap between administrative requirements and clinical team needs

Lessons Learned

Lead with Transparency Prioritize a solutions-driven, open approach over informal communication to stabilize structural changes	Manage the "Human Variable" Address personnel needs with the same rigor as technical processes to build sustainable trust	Reduce Communication Fatigue Streamline interactions to prevent burnout while maintaining high stakeholder engagement
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Future Goals

- REAL-TIME TRACKING**
Utilizing a dashboard for all internal and external partners to know trial status updates
- STANDARDIZATION**
Continuing to standardize the SSU process across the CTO and setting site specific expectations for Sponsors
- DATA DRIVEN CHANGE**
Using data to change budgets, staffing, effort, and continually improve based on historical information
- POINT OF CONTACT**
Continuing to be the point of contact for all things SSU for external and internal partners

Contact Information

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