

# CTMS Optimization: A Tale of One Platform, Three Clinical Sites, and One Combined Dataset to Improve Trial Activation, Portfolio Management, and Clinical Trials Reporting

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## Background

The Lombardi Comprehensive Cancer Center (LCCC) consists of three clinical sites. Managing harmonized consortium-wide metrics, to measure progress and guide operational decision making for LCCC, requires entering and accessing clinical trials data in two separate accounts from a single CTMS vendor, OnCore. Previously, each site manually generated single-site reports, which were collated, in order to present consortium-wide metrics. To standardize consortium operations, LCCC set consortium-wide data entry and quality assurance practices and data locks to ease the issuance of metrics.

## Goals

The CTMS Optimization Project goals included:

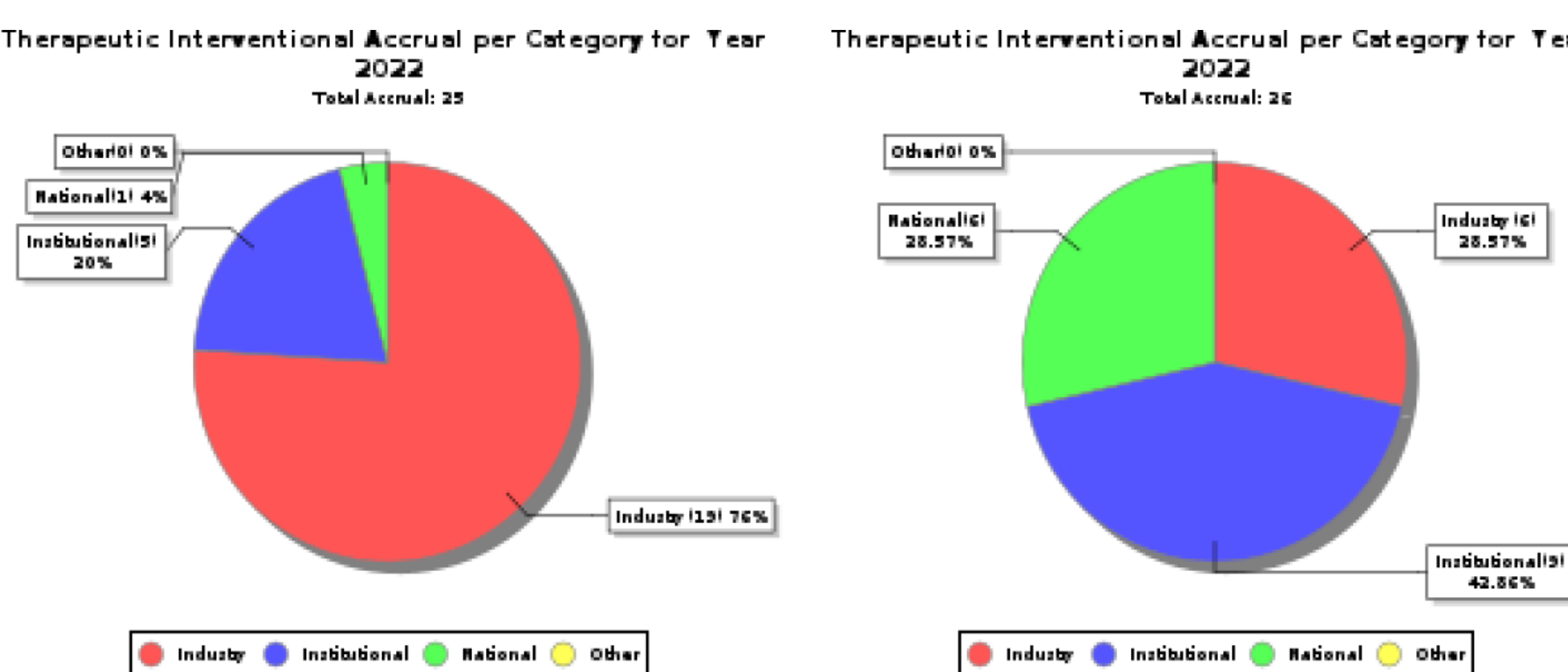
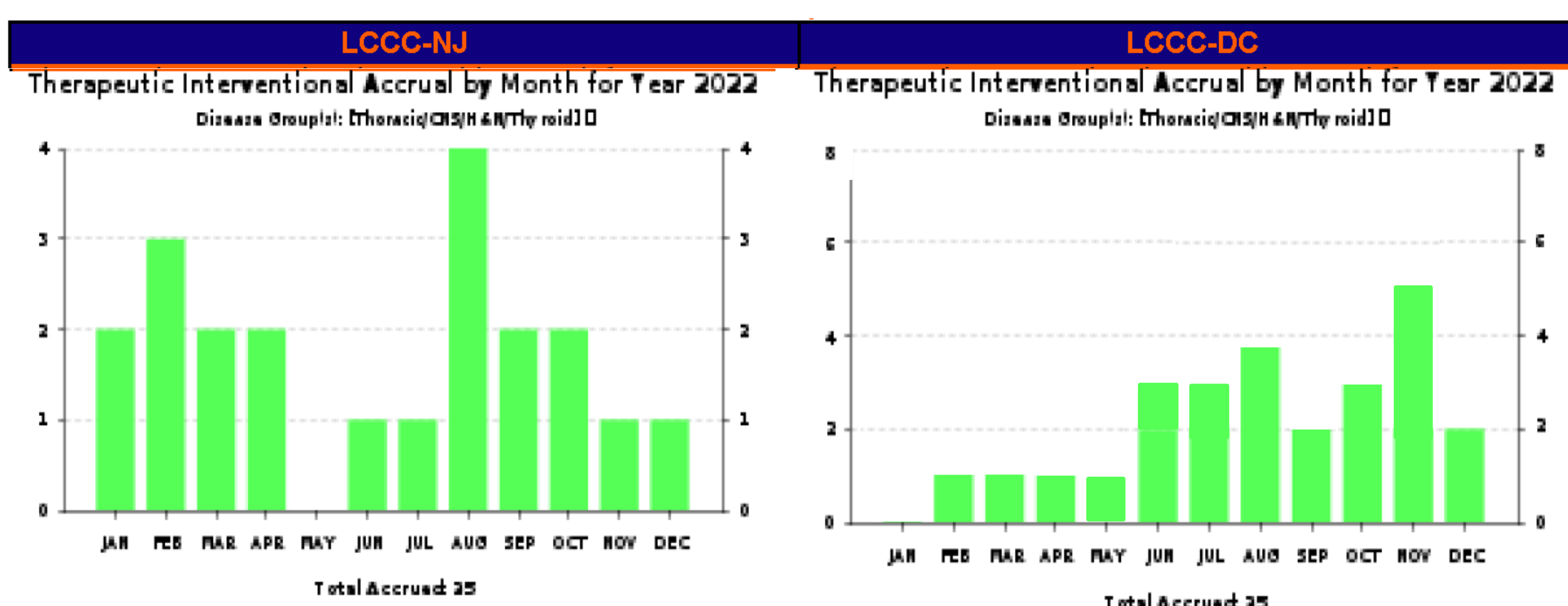
- Provide at-a-glance metrics via dashboards to LCCC Leadership, Clinical Research (CR) Leadership, and Disease Group (DG) Leaders
- Increase efficiency and accuracy of LCCC consortium reporting, measured by a decrease in the person-hours required to provide reports and reproducibility of clinical trials metrics across the consortium
- Harmonize operations across the institutions (e.g., eCRF validation, standardized reporting intervals, monitoring plan)
- Ensure portfolio management via disease group and PRMC activities (e.g., dashboards, reports) and prioritization of Institutional, multi-Institutional, and National protocols to shift protocol portfolio in alignment with NCI expectations

## Solutions & Methods

1. Determine and implement predictable reporting cadence with standardized dashboards and reports
2. Deploy TIBCO JasperSoft Studio to create custom coded reports in Java/XML/SQL with dynamic visualizations benchmarked against NCI standards
3. Distribute pilot reports displaying pipeline activity, time to activation, accruals trends, and portfolio composition to LCCC stakeholders
4. Establish continuous process improvement to ensure relevance
5. Solicit stakeholder feedback for additional improvements.

### Dashboard Components

Disease Group Dashboard							Reporting Prepared: 01/10/2023						
Trials by Current Status							Current Pre-Submission & Start-Up						
Protocol Status	THERAPEUTIC			NON-THERAPEUTIC			TOTAL	Current Status	Awaiting PRMS Submission	<=30	31-90D	>90	TOTAL
	LCCC DC	LCCC NJ	LCCC DC	LCCC NJ	LCCC DC	LCCC NJ							
OPEN TO ACCRUAL	9	11	1	0	0	21							
CLOSED TO ACCRUAL	21	11	0	1	0	33	Therapeutic	0	0	0	2	2	
IRB STUDY CLOSURE	29	13	0	0	0	42	START-UP	1	0	0	1	2	
SUSPENDED	1	0	0	0	0	1	Non-Therapeutic	0	0	0	0	0	
TERMINATED	2	0	0	0	0	2	PRE-SUBMISSION	0	0	0	0	0	
PRE-SUBMISSION	2	0	0	0	0	2	START-UP	0	0	0	0	0	
START-UP	1	1	0	0	0	2	Other	0	0	0	0	0	
ABANDONED	13	10	0	0	0	23	PRE-SUBMISSION	0	0	0	0	0	
							START-UP	0	0	0	0	0	



### Report Keys

#### Current Pipeline Overview Key

- ✓ Completed within intended completion window.
- ✓ Completed not within the intended completion window.
- Started and still within the completion window.
- Started and exceeds the intended completion window.
- Not Started. Protocol has not been submitted to PRMS.
- n/a Not Applicable: One task or multiple tasks have been marked as NA in the task list.

#### Milestone Completion Windows

- 60 PRMS (Days)
- 60 Budget (Days)
- 90 Contract (Days)
- 90 IRB (Days)
- 120 Overall (Days)

#### Accrual Progress Key

- OPEN TO ACCRUAL AND no enrollment in the last 6 months and < 40% target accrual reached, no enrollment in the last 12 months OR no enrollment life to date
- OPEN TO ACCRUAL AND < 40% target accrual reached and enrollment in the last 6 months OR >=40% target accrual reached with 0 enrollment in the trailing 6 months
- OPEN TO ACCRUAL AND >=40% target accrual reached and active enrollment within the last 6 months

#### Date Parameters:

MTD = From 12/01/2022 to 12/31/2022  
YTD = From 01/01/2023 to 12/31/2022

## Outcomes

- LCCC/CR Leadership & each DG received at-a-glance quick reference dashboards & reports
- Saved > 200 person-hrs via coding/ automation
- Condensed monthly report of >80 files
- Provided customized reports to accurately & efficiently capture data across OnCore
- Benchmarked data visualization against NCI expectations for trial activation & accruals
- Increased efficiency & decreased error for PRMC Scientific Progress Review Committee via auto-populated agenda from custom report

## Lessons Learned

Gap in services provided by Advarra for managing clinical trials data for NCI-designated Comprehensive Cancer Centers. Bridging the gap with internal solutions allowed LCCC to provide consolidated consortium reports and dashboards to LCCC and CR Leadership, along with DG Leaders – an essential component to assessing progress and tracking activity.

## Future Directions

1. Deploy consortium-wide task lists to capture additional data points,
2. Code customized monthly reports & upload to cloud environment to feed interactive dashboard run via automated coding,
3. Conducting feasibility review to determine automated data transfer to fully automate real-time dashboards for consortium-wide access.

## Contact

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