



Yale Center for  
Clinical Investigation

# Protocol Activation and Lifecycle Management (PALM) Operational Overview

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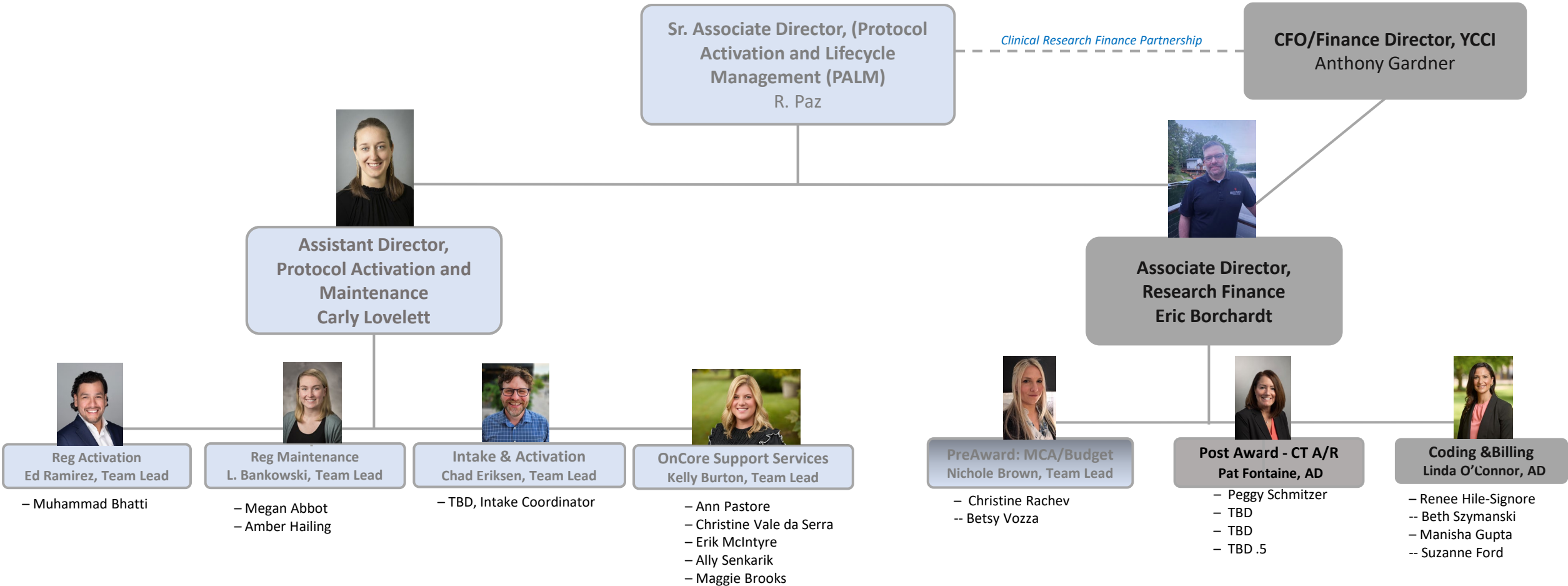
June 26, 2024

# Protocol Activation and Lifecycle Management (PALM): Purpose

1. Form a cohesive study activation & maintenance team under one accountable leader
  - 4 units – 4 separate leaderships (Reg; OnCore Support; MCA; Pre-Award)
2. Financial viability and long-term operational sustainability
  - Implement chargeback/cost recovery mechanism
  - Minimize YSM research infrastructure subsidy
3. Accelerate/Improve study activation timelines
  - Optimize performance of Investigator Services
  - Gain efficiencies through optimized workflows

# Protocol Activation & Lifecycle Management (PALM)

Organizational Diagram, 2024



- Outsource Vendors:
- Huron – MCA; Budget; Calendar (primary)
  - Advarra – Calendar and financial build (primary)
  - TBD – Regulatory (overflow)

# PALM Services



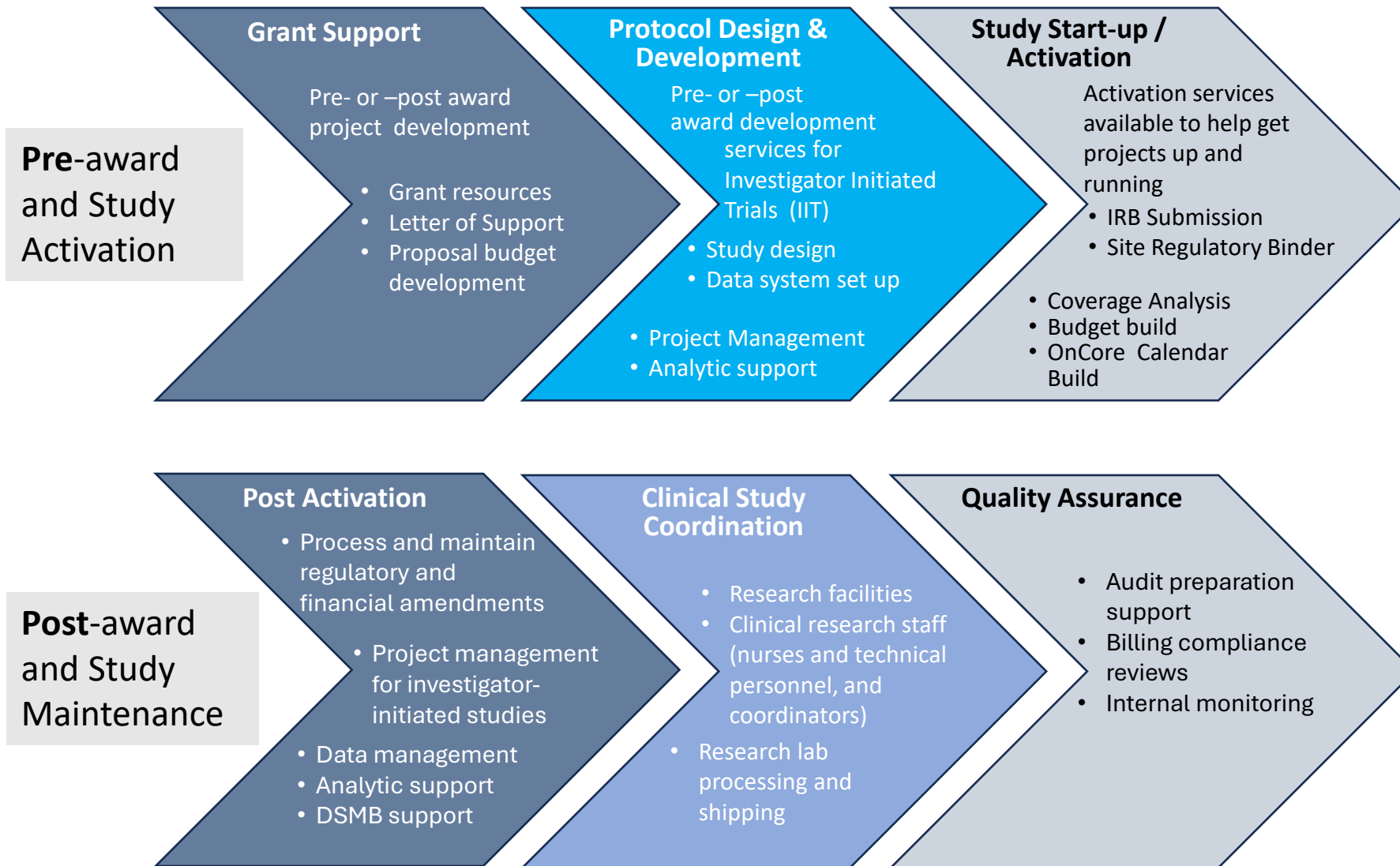
## Available Activation Services:

- Medicare Coverage Analysis (MCA)
- Budget development/negotiation
- Regulatory start-up:
  - IRB submission & ancillary committee submission (e.g., IBC)
  - Regulatory document collection
  - eReg binder set-up
  - OnCore calendar and financial builds (including ePayments)

## Available Maintenance/Modification Services:

- Protocol/Budget/ICF amendment processing
  - Calendar/Financial build modifications
- Annual IRB renewals
- Reportable New Information (RNI):
  - Serious Adverse Events
  - IRB-reportable deviation
- eRegulatory binder maintenance (including IND report management, communication filing, etc.)
- Monitoring visit/closeout visit prep

# YCCI Services



# Process: Activation

## 1. Study Team Preparation & Submission:

- Register your study in the [IRES IRB system](#) (before completing the intake form)
- Submit [YCCI intake form](#) including the following:
  - Final protocol
  - Informed consent template
  - Draft budget
  - Lab, Pharmacy, and Investigator Brochure manuals

## 2. PALM Initial Processing:

- MCA
- Initial submissions: IRB, any ancillary committees & regulatory packet submission,
- Budget development/review
  - Department Business Offices and OSP will be included in an initial budget review

# Process Cont. & Tips

## 3. PALM Study Activation:

- Communication with study team, sponsor, and IRB as needed until approval
- eRegulatory binder setup
- Budget negotiation and finalization
- OnCore calendar and financial builds and release (contingent on fully executed CTA)

### Tips:

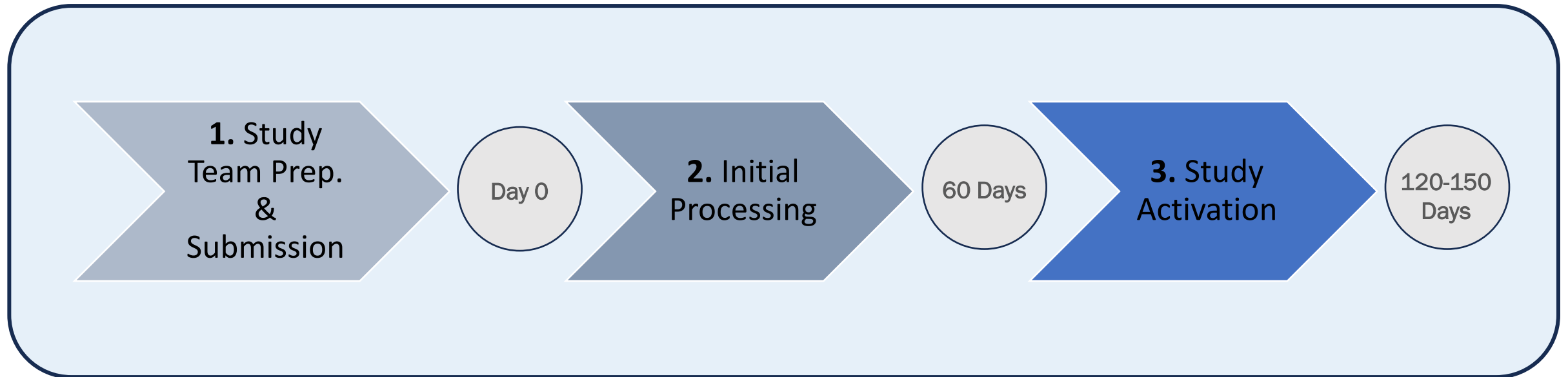
- ✓ Ensure you submit to Office of Sponsored Products (OSP) for contract negotiation separately
- ✓ Submit an intake form only when you are **approved** as a site and **have all of the necessary documents**: Final protocol, draft budget & ICF, IB, any manuals (e.g., lab, pharmacy)
- ✓ If you're not sure – ask!

# Strategies to Accelerate Timeline

YCCI	Study Teams	Sponsors
<ul style="list-style-type: none"><li>• Have an efficient intake process.</li><li>• Bring the appropriate parties into the process at the right times.</li><li>• Provide guidance when needed.</li><li>• Collaborate and communicate across departments.</li><li>• <b>Be responsive throughout the process.</b></li></ul>	<ul style="list-style-type: none"><li>• Submit intake only after study award &amp; receipt of required documents.</li><li>• Be timely in answering questions/ requests after submitting an intake form.</li><li>• Inform YCCI of any relevant updates (e.g., upcoming protocol amendment).</li><li>• <b>Be responsive throughout the process.</b></li></ul>	<ul style="list-style-type: none"><li>• Provide all final docs to set start date (including unlocked contract and budget templates).</li><li>• Accept the Yale rate sheet and incorporate it into the draft Sponsor budget.</li><li>• Have an MSA/MCTA with Yale and agree to use Yale standardized payment terms.</li><li>• Be fully Sponsor paid.</li><li>• <b>Be responsive throughout the process.</b></li></ul>
All Parties: be responsive throughout the process		



# Timeline

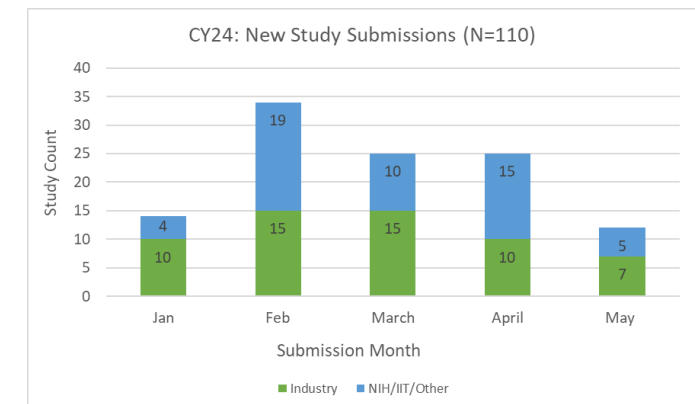
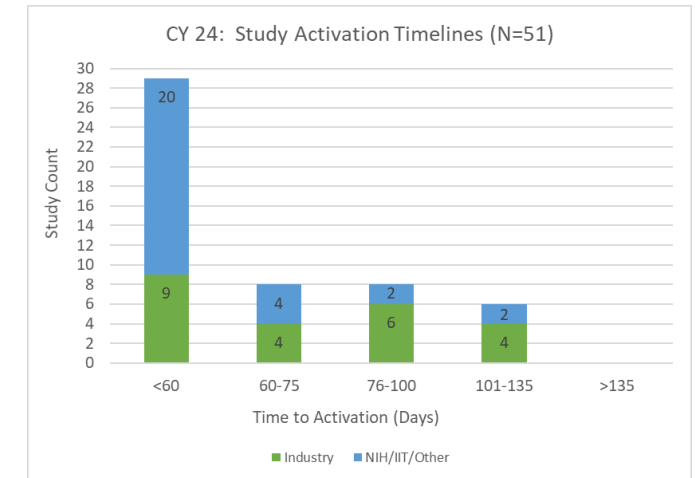


*Goal: 120 days or less*

*Stretch Goal: 90 days or less*

# New Process Outcomes:

- **CY 24 - Activation timeline for new trials**
  - Goal: 120 days or less compared to historically: ~300 days
  - new PALM workflow proving consistent
    - 88% of trials coming in under 100 days or less
- **CY 24 - New trial submissions**
  - CY24 monthly average: 22 new trials submitted
  - Portfolio = 52% Industry; 48% = NIH/IIT/Other



# Service Rates

- Rates: <https://medicine.yale.edu/myysm/research/clinical-research/ycci-rates/>
- There are four mandatory fees for any study that will enroll participants and has any billable events\*
- Ensure to include the following if negotiating your own budget:
  - Medicare Coverage Analysis fee (where applicable)
    - Qualifying Clinical Trial (QCT) Standalone fee
  - CTMS Annual Licensing fee
  - CTMS Calendar Build
  - CTMS Financial Build

\* per YSM policy mandating use of OnCore

# Service Rate Setting

- USP annual rate setting
- Goal: to find the most economical way to deliver the services
- Outcomes:
  - Gained efficiencies through process reengineering
  - Cost savings per study for calendar and financial build
    - ✓ Approximately \$3700 per study savings – NIH/IIT
    - ✓ Approximately \$3900 per study savings – Industry
  - Tiered pricing levels based on trial intensity: MCA, Calendar builds
    - ✓ ePayments only fee
    - ✓ QCT only fee

# Resources and Tools

- New YCCI website launch – mid to late July
- Budgeting tools and templates to be uploaded and announced as determined and available
- Rate justification tool for Industry Sponsors – available to DBOs now

# Contact Information

Streamlined, focused communications based on topic/needs:

- Assistant Director PALM: Carly Lovelett, [carly.lovelett@yale.edu](mailto:carly.lovelett@yale.edu)
- Associate Director Research Finance, Eric Borchardt, [eric.Borchardt@yale.edu](mailto:eric.Borchardt@yale.edu)
- **PALM Activation Inbox:** [yccipalmactivation@yale.edu](mailto:yccipalmactivation@yale.edu)
  - Communication on study activation and maintenance *after* submission of intake form
- **Coverage Analysis Inbox:** [coverageanalysis@yale.edu](mailto:coverageanalysis@yale.edu)
  - Discussion of QCT/MCA needs and updates
  - Team Lead: Yvonne “Nichole” Brown, Brown, [yvonne.brown@yale.edu](mailto:yvonne.brown@yale.edu)
- **OnCore Support Inbox:** [oncore.support@yale.edu](mailto:oncore.support@yale.edu)
  - General OnCore support needs, access requests, etc.
  - Team Lead: Kelly Burton, [kelly.burton@yale.edu](mailto:kelly.burton@yale.edu)

# Q & A

