Universal OnCore Use at URMC

September 2024 Update

University of Rochester Medical Center | CTSI Clinical & Translational Science Institute

Universal OnCore Use Policy

May 2024

- Policy drafted and circulated to OCR and CTSI for review and comments

June 2024

- Policy shared with CRRPIT for review and comment

July 2024

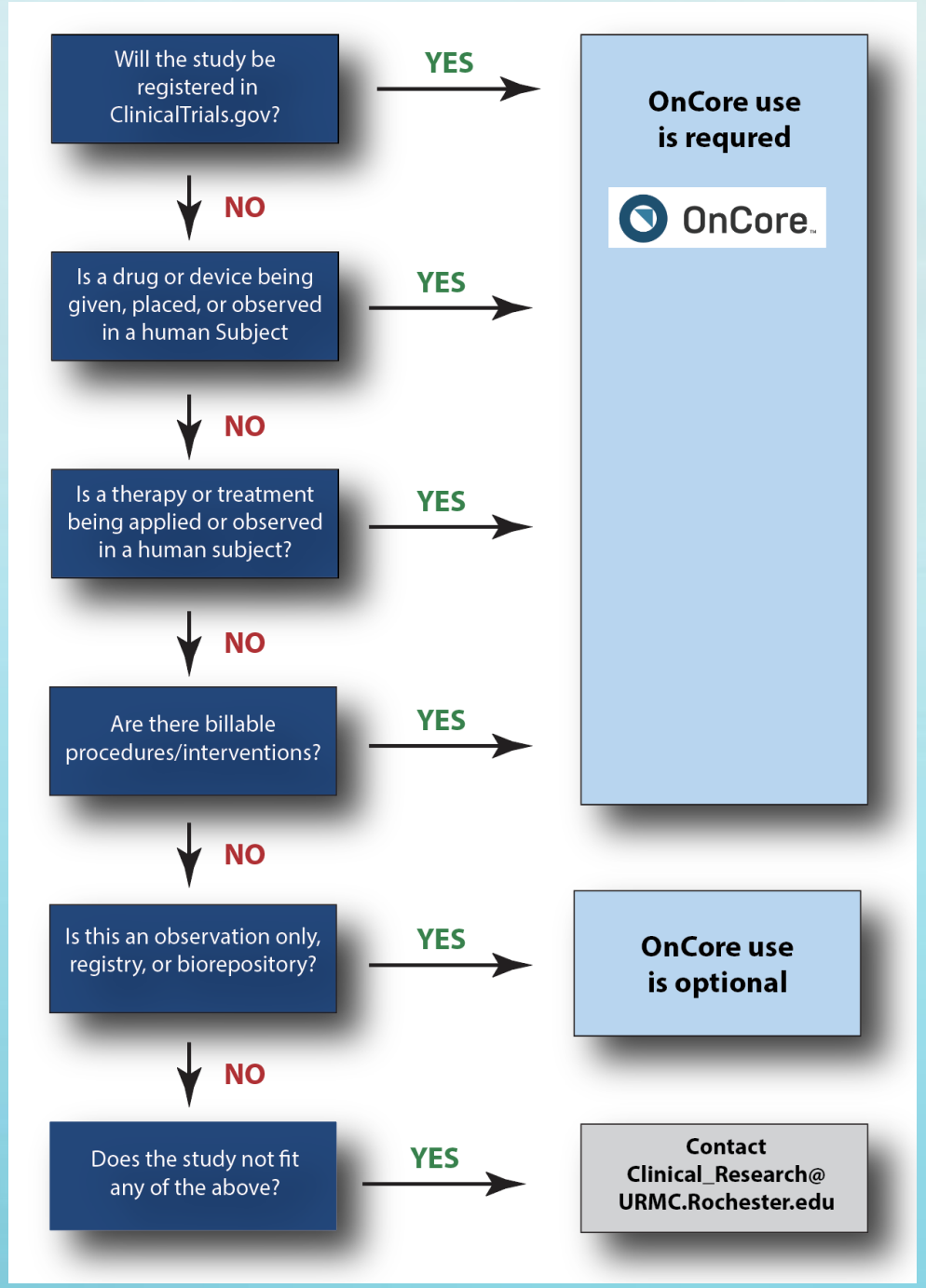
- “Optimizing Clinical Trials Management @UR” Universal OnCore use justification presented at MedSAC

August 2024

- Policy finalized and published online: Universal OnCore Use Policy

September 2024

- Working with CTSI Communications team to spread the word.

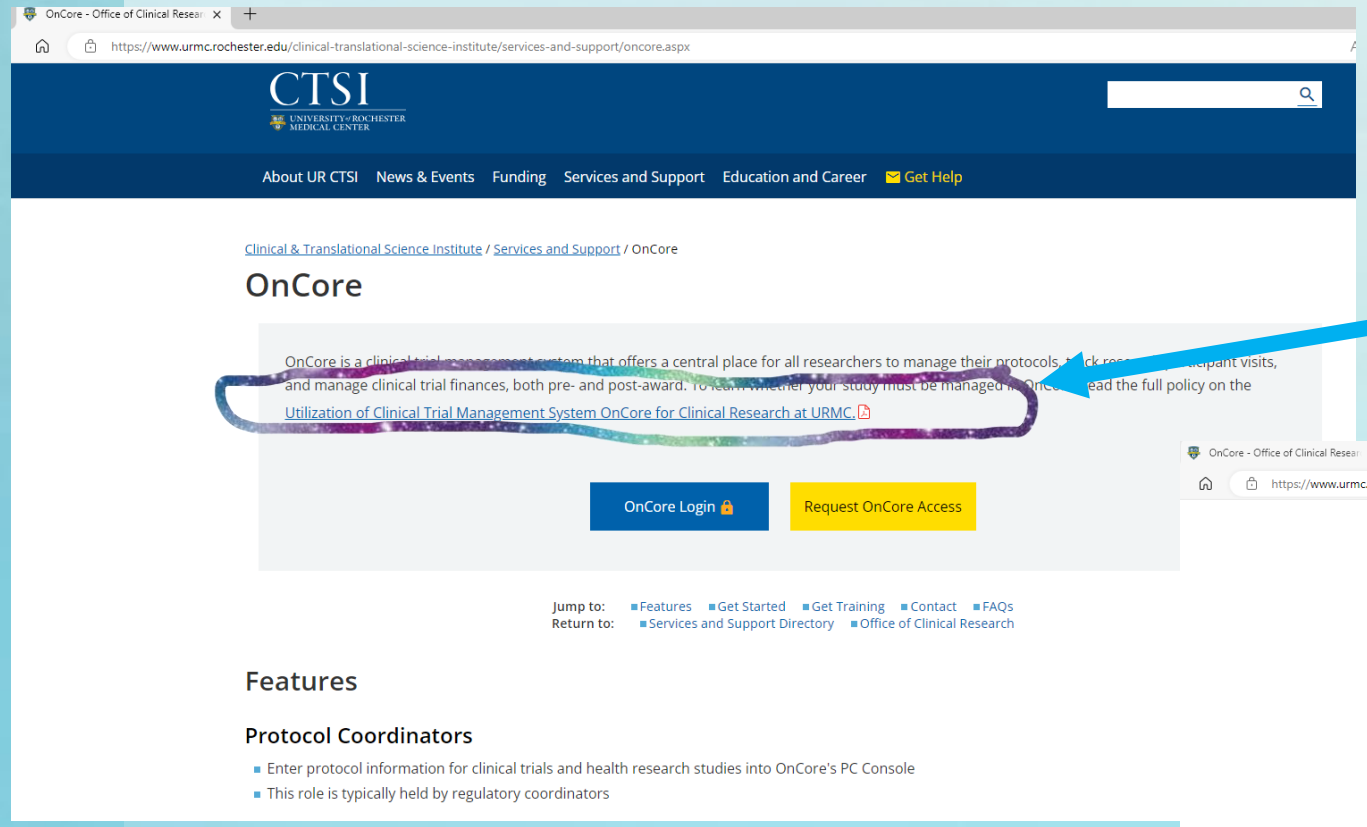


Goal:

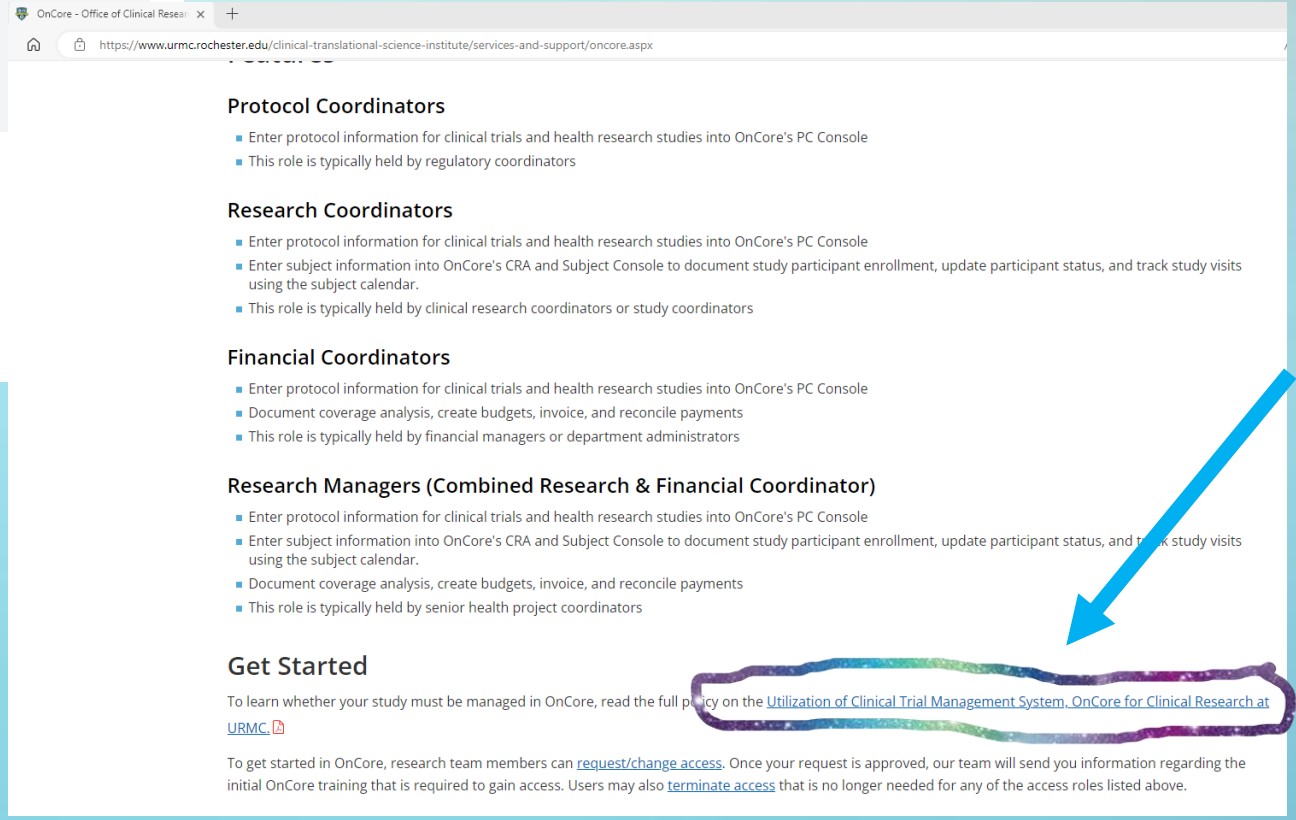
All Qualifying Studies in OnCore by July 2025

University of Rochester Medical Center | CTSI Clinical & Translational Science Institute

Where to find more information?

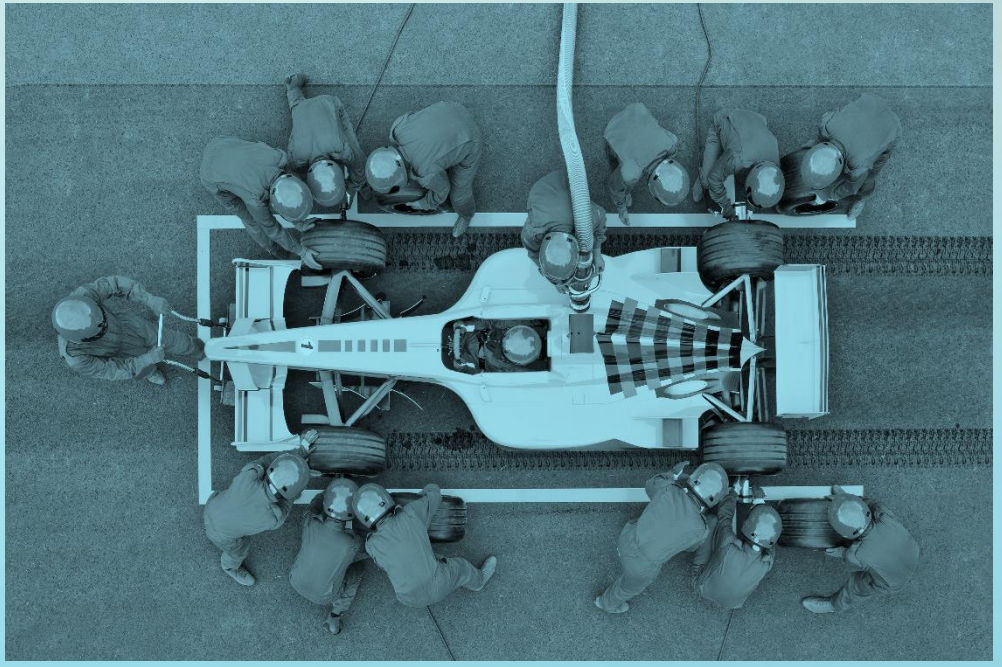


Look for communication:
Faculty@
URMC This Week
Levy Letter
WCI Update
UR CTSI Weekly Update
Research Liaison Email
OCR Exchange



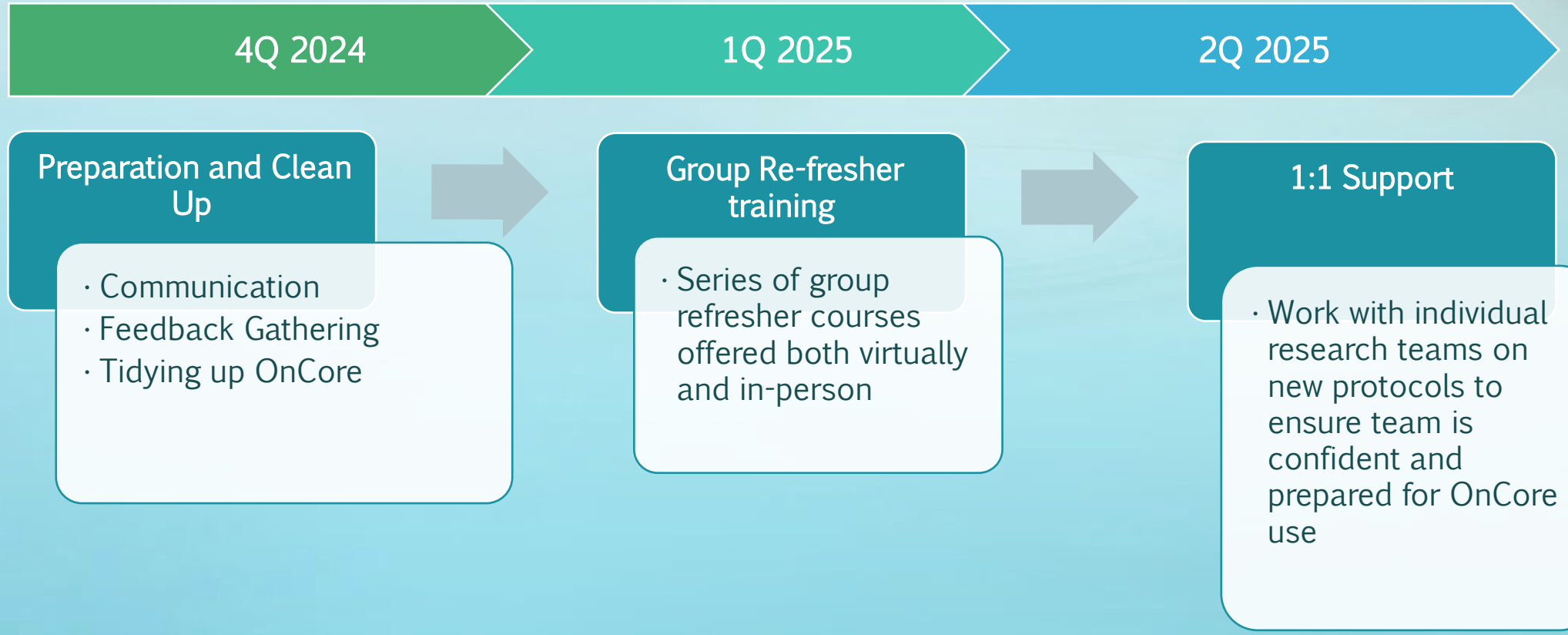
Preparation for Implementation

- OnCore Use Survey – March 2024
- Departmental/Divisional meetings to gather input and improve communication
  - "We Can't Fix It If We Don't Know It's Broken"
- OCR Staff additions
- Develop New Training Opportunities
- Health Check (review) of current OnCore practices and integrations



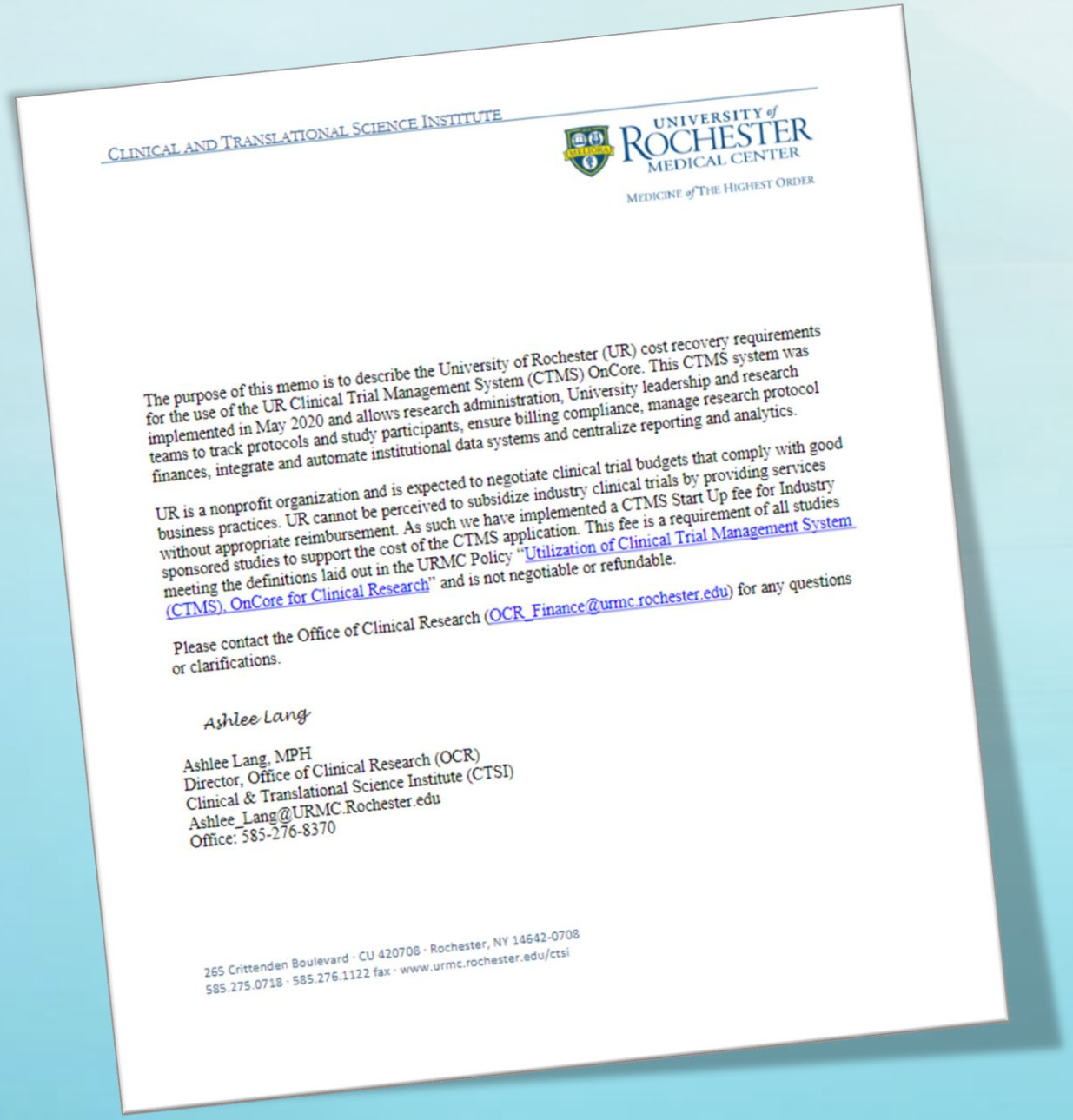
Implementation Plan

OnCore Re-RollOut will be split into 3 phases:



Desired Outcomes

- **Dashboards and Reporting**: Develop reports and dashboards to provide clear and comprehensive information to research team leadership and university leadership.
- Provide **metrics** to allow research teams to make data-driven decisions regarding their portfolio and the best use of their resources
- **Target and track enrollment** for all trials
- **Increase** clinical trial **cost recovery**
- Begin cost recovery for Advarra applications through $2500 **CTMS start up fee** for industry-only studies



CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

UNIVERSITY of ROCHESTER MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

The purpose of this memo is to describe the University of Rochester (UR) cost recovery requirements for the use of the UR Clinical Trial Management System (CTMS) OnCore. This CTMS system was implemented in May 2020 and allows research administration, University leadership and research teams to track protocols and study participants, ensure billing compliance, manage research protocol finances, integrate and automate institutional data systems and centralize reporting and analytics.

UR is a nonprofit organization and is expected to negotiate clinical trial budgets that comply with good business practices. UR cannot be perceived to subsidize industry clinical trials by providing services without appropriate reimbursement. As such we have implemented a CTMS Start Up fee for Industry sponsored studies to support the cost of the CTMS application. This fee is a requirement of all studies meeting the definitions laid out in the URMC Policy "Utilization of Clinical Trial Management System (CTMS), OnCore for Clinical Research" and is not negotiable or refundable.

Please contact the Office of Clinical Research (OCR_Finance@urmc.rochester.edu) for any questions or clarifications.

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[(6) OCR Shared Information for Departments | Powered by Box]

NEW CTMS Start up Fee

1. 1) For departments using OCR for budgeting: OCR has began charging all new industry-sponsored trials a one-time $2500 CTMS Start Up Fee (including indirects/OH)
2. For departments handling their own budgeting: the CTMS fee plus indirects should be negotiated in your budget as a pass-through to the sponsor. OCR has provided a memo for use when communicating with the sponsor.

The CTMS Start Up Fee will be billed upon calendar completion through CTSI in the same manner as the other OCR Finance services.