Validation of Early Prognostic Data for Recovery Outcomes after Stroke for Future, Higher Yield Trials:
A Biomarker Validation Study

CRC Webinar Agenda
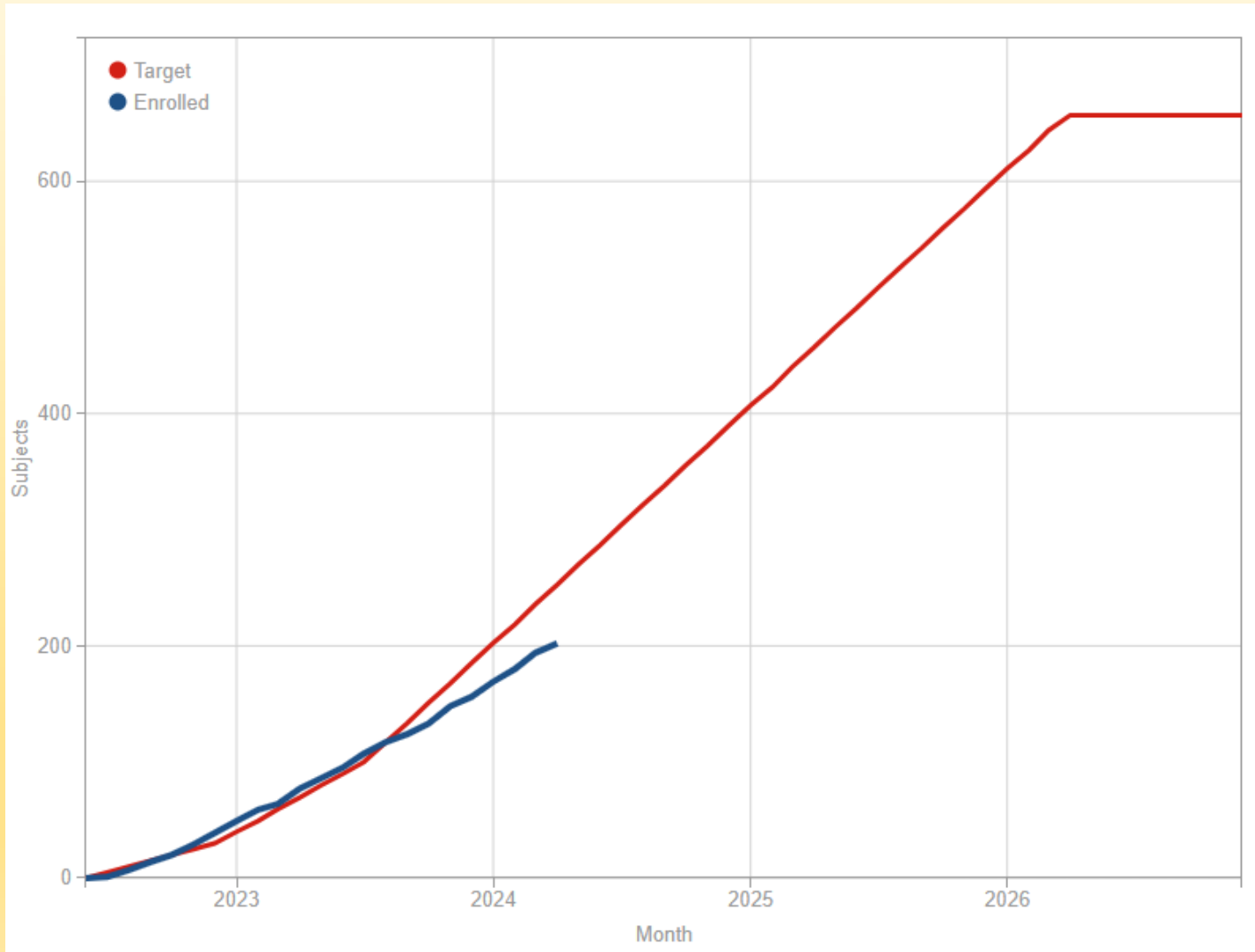# Tuesday, April 23, 2024
12:00pm- 1:00pm ET

1. Welcome, Study Updates/Reminders

2. Protocol v2.0 training reminder

3. ICF updates – Max/Kalli

4. WebDCU updates – Natalia/Abagail

5. Remaining Q&A and Closing Remarks (All)

Projection Curve: Target vs Actual Enrollment

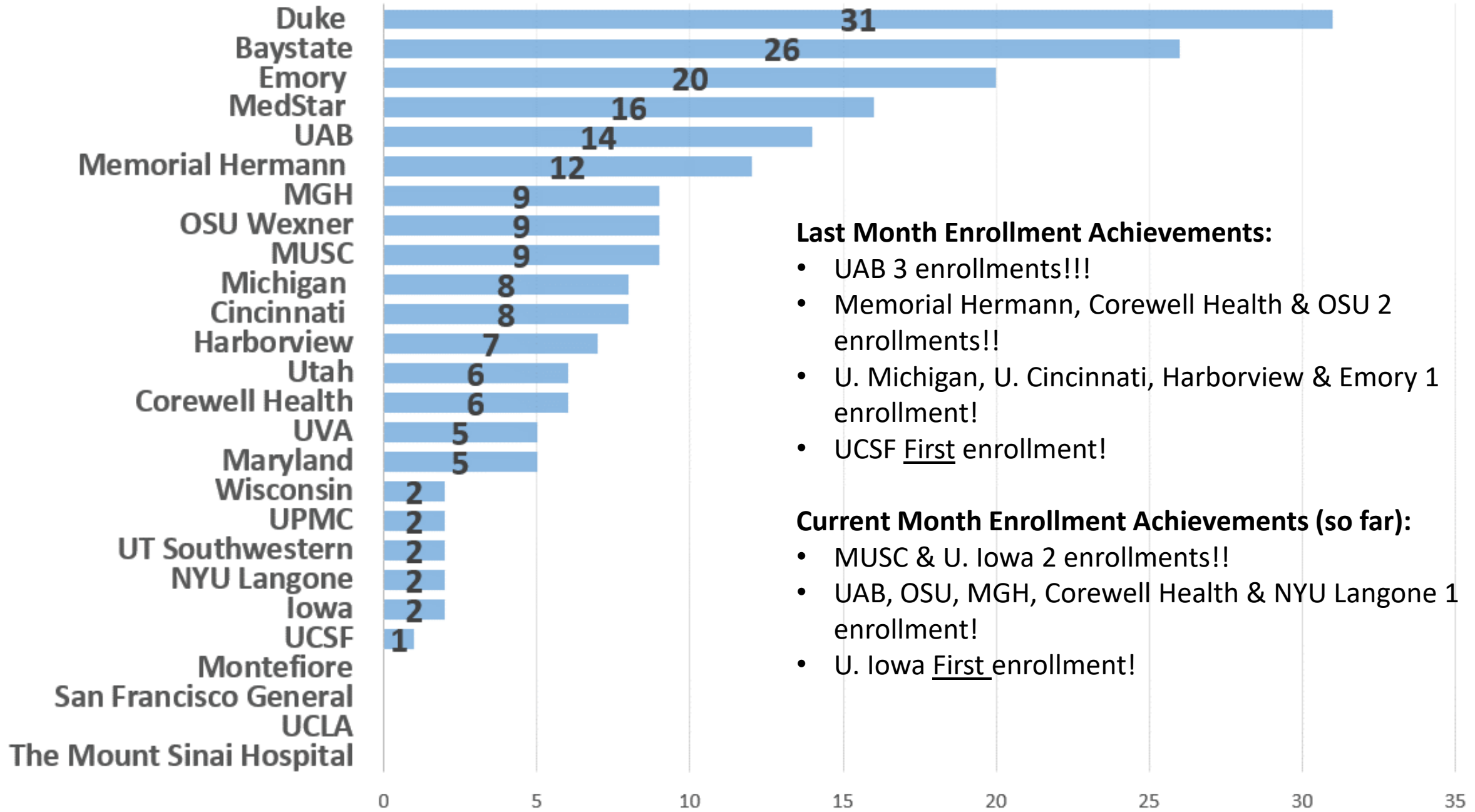**Monthly Goal:**

17

- Last patient to be enrolled by 10/31/2025
  - ➤ March 2024 Enrollment: 14
  - ➤ April 2024 Enrollments (so far): 9

VERIFY TOTAL ENROLLMENTS: 202/657

Site	Enrollments
Duke	31
Baystate	26
Emory	20
MedStar	16
UAB	14
Memorial Hermann	12
MGH	9
OSU Wexner	9
MUSC	9
Michigan	8
Cincinnati	8
Harborview	7
Utah	6
Corewell Health	6
UVA	5
Maryland	5
Wisconsin	2
UPMC	2
UT Southwestern	2
NYU Langone	2
Iowa	2
UCSF	1
Montefiore	
San Francisco General	
UCLA	
The Mount Sinai Hospital	

Last Month Enrollment Achievements:
- UAB 3 enrollments!!!
- Memorial Hermann, Corewell Health & OSU 2 enrollments!!
- U. Michigan, U. Cincinnati, Harborview & Emory 1 enrollment!
- UCSF First enrollment!

Current Month Enrollment Achievements (so far):
- MUSC & U. Iowa 2 enrollments!!
- UAB, OSU, MGH, Corewell Health & NYU Langone 1 enrollment!
- U. Iowa First enrollment!

Site Activation Status

Race to Activation Tracker

Site Name	CTA Executed	CIRB Approved	DOA Approved	Investigator agreement form's uploaded	TMS Shipping Address entered	TMS Machine obtained	At least 1 TMSO online training Completed	Greenlighted to start TMS HV Training	Uploaded TMS HV data to RedCAP	TMS HV Training Completed for at least 1 TMSO	TMS Technique Check	MRI Phantom Approved	All WebDCU Documents uploaded	Site Activation Meeting Completed	Site Activated 🏁
Lahey Hospital & Medical Center	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗		
Penn State Hershey Medical Center	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗			
Prisma Health Richland Hospital	🟩	🟩	🟩	🟩	⬛	🟩	🟩	🟩	🟩	🚗					
Strong Memorial Hospital	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗					
Pennsylvania Hospital	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗					
Froedtert & Medical College of Wisconsin	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗		🟩			
Birmingham VA Medical Center	🟩	🚗					🟩	🟩	🟩	🟩					
Keck Hospital of USC	🚗		🟩		⬛	🟩									
Wake Forest Baptist Health	🚗														

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Protocol 2.0

Protocol 2.0 Study Wide Training

- Date: April 29th 4-5pm EST
  https://ucincinnati.zoom.us/j/93495066428?pwd=RUY4WGxLVVZaYUlOekhkTCt2cmFEZz09
  Meeting ID: 934 9506 6428   Passcode: 895674

- Protocol V2.0 has been CIRB approved!

What the next steps for sites?

ICF Update Process

CIRB- ICF Updates

- Login to ADVARRA-CIRBI
  - Select your sites VERIFY profile
    - Click Modifications

CIRB- ICF Updates

- Scroll down to Sponsor/CRO Submitted Modifications
  - Select the modification listed as Protocol Document

CIRB- ICF Updates

- Review ICF edits
  - Sign off or provide edits/corrections
    - This will send the ICF to StrokeNet for review

    please note that we may make corrections or changes and that will prompt the ICF to be sent back to the site for sign off

- Once all parties approve of the ICF updates, they will go for CIRB sign off
  - They will generate an approval letter
  - Look for an email from StrokeNet regulatory team regarding next steps

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WebDCU Updates

VERIFY Source Documentation

- **VERIFY Studybook** has been provided to all sites in the WebDCU ToolBox.
    - This is to be used as **source documentation** for this study.
    - The study book includes **Instructions and data entry templates** for each study visit.
        - This book is being updated currently and the new version will be provided once approved.
    - Sites can download the study book from WebDCU, save it, and print the sections they need as required. The data on the completed study book should be entered into the CRFs in WebDCU. The completed study book should be retained on site in the appropriate participant binder.
    - Source documentation should always include a **signature of who and date when completed**.
    - Label each page with the subject ID.
    - Currently using v 1.7
        - **Will be changing to V2.0 once WebDCU CRFs have been updated!!**

Do not use WebDCU CRF's for source documentation

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In-person Investigator Meeting - CANCELED
Replaced with:
Virtual- Investigator Meeting 2024

- **Dates: June 4th 2PM EST to 5 PM EST**
- Who should attend? Site PI, PSC, TMS operators, ARAT/FM assessors, and any other team members who wish to attend.
- A placeholder calendar invite has been sent out and the webinar calendar invite will be coming soon
- Stay tuned for more details to come

Also plans for individual sites visits at selected sites

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Questions During Consent/Enrollment

- TMS questions
  - Urgent (during procedure)
    - Call or text hotline at : (833)337-2227
      - Monday – Friday 0800 – 2100h ET

  - Non-urgent questions
    - Email us at verify.study.tms@gmail.com

- Other consent/enrollment questions?
  - Email PMs (Max & Kalli) and VERIFY PIs (Pooja, Steve, Cathy, & Achala)
  - verifystudy@ucmail.uc.edu
    Please include "VERIFY Enrollment Question" in the subject line!!!

Q & As