

FY24 Q1 OCR Scorecard

****Confidential--Internal Emory Use Only****

As of December 1, 2023, there were 2,469 total active clinical research studies conducted by Emory faculty with 71,025 participants on-study. There were 489 studies with no enrollment.

Education & QI Team:

28 educational seminars/courses with 1530 attendees (1366 attendees online & 164 attendees in-person) awarded 1051.5 total CMEs/CEUs

109 clinical research personnel received CPR certification for Emory Healthcare credentialing.

47 clinical research personnel (RNs and Non-RNs) were credentialed for Emory Healthcare hospital facilities at 2 applications pending approval

164 newly trained clinical research personnel received OnCore user access for subject enrollment and visit tracking for study activities

1665 of 1665 active investigators conducting FDA-regulated clinical trials completed the GCP course (100% compliant)

919 of 919 active study coordinators coordinating FDA-regulated clinical trials completed the CRC course, including GCP (100% compliant)

Customer inquiries processed: 2,046; Internal QA/EHC Quality Process Improvement Projects completed: 1

Pre-award Team:

(Turnaround metrics based on completion date)

New studies submitted to OCR for review: 183

Pre-award review completed (budget, PRA, OCR review needed &/or LOI): 162 studies

PRAs completed: 99 Business days from receipt to submission for 93 externally funded studies (all effort): 84 mean; 71 median

Business days from receipt to submission for 162 all studies² (all effort): 71 mean; 52 median

Total \$ and % difference between OCR negotiated sponsor budget & sponsor initial offer for 74 studies: 6,480,248; 57% mean; 27% median

²All studies include externally funded, non-negotiable studies, no OCR review needed, & LOIs (letters of intent for industry studies)

Data Integrity & Integration Team

Clinical Research New Studies: 94 activated in OnCore & EPIC

IRB Initial Approval pushed to EPIC 103 New Process started 1/19/2023 (for Beacon Team)

MRNs Generated through Red Cap: 420

Signed Informed Consent Documents (ICD): 1435 Reviewed/Uploaded from OnCore to EPIC

Clinical Research Key Points: 75 uploaded to Emory SharePoint and linked to EPIC

Investigational Drug Data Sheets: 43 uploaded to Emory SharePoint and linked to EPIC

Calendars released in OnCore New and Amended/Revised and then released in EPIC: 157

Billing Grids release in OnCore new and Amended/Revised and then released to EPIC: 450 (Some studies have more than one billing grid)

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ClinicalTrials.gov Team

Total eIRB Studies Reviewed: 132 ; Total ad Hoc Studies Reviewed: 63 ; Total eIRB studies reviewed: 69
EHC Billables: 7 studies not submitted for CA prior to enrollment/IRB approval: --> **Medicine, Cardiology (1); Medicine, Endocrinology (1), Surgery, General & GI Surgery (1), Rehabilitation Medicine (1); Psychiatry (1); Medicine, Infectious Diseases (1), and Pediatrics, Neurology (1).**
Non-EHC Billables: 13 studies not submitted to OCR for activation in ERMS
As of November 30, 2023, Emory was listed as a sponsor in clinicaltrials.gov for 1,283 studies (315 active studies with 71 problem records)
Clinicaltrials.gov inquiries for problem updates: 293 ; ERMS review for NCT numbers required for billing compliance: 94
OCR-initiated study registration for 9 studies, updated 121 study records, addressed 14 QA Review Comments, updated records for 25 amendments, and entered results for 9 studies
% of Clinical Trials registered prior to 1st subject enrolled: 9/9 100% ; % of Results reported before deadline: 6/9 67% ; # study records suspended due to COVID-19 or other reasons: 15

*(suspended are still considered active)

Invoicing Team (as of November 30, 2023):

Metrics based upon ERMS Study Dashboard and ERMS/OnCore Tracked Items implemented 7/10/2023

Active Studies: 1008 ; Active Research Participants with Invoicing Activity: 1989 ; Research Visits Reviewed: 12,138
Outstanding Invoices This Quarter (excluding withheld): \$10,754,071 ; To Date: \$13,594,648
Outstanding Monies Withheld This Quarter: \$26,461 ; To Date: \$964,696
Payments Received This Quarter: \$9,080,684 ; To Date: \$407,085,971
Overpayments This Quarter: \$5,902 ; To Date: \$998,205
Advance Payments This Quarter: \$0 ; To Date: \$3,490,693
Study Expenses Paid by OCR This Quarter: \$285,273 ; To Date: \$6,320,647