

Clinical Study KPI

Legend	IRB - Institutional Review Board
	OCR - Office of Clinical Research
	ORA - Office for Research Administration
	IUSM - Indiana University School of Medicine
	CTA - Clinical Trial Agreement
	CDA - Confidentiality Disclosure Agreement
	CTO - IUSCCC Clinical Trials Office

ENTERPRISE METRICS

AREA OF FOCUS	METRIC/KPI TITLE	DEFINITION
Enterprise Goal	10-year enterprise clinical research goal	6% of IU Health patients that consent to a clinical study
Biobank	Biobank Enrollment Performance	Monthly consented patient and biospecimen sampling data

AGGREGATE CLINICAL STUDY ACTIVATION METRICS

AREA OF FOCUS	METRIC/KPI TITLE	DEFINITION
Study Preparation	IRB Turnaround Time	Time from IRB new study submission to full board approval <i>Report Mean & Median times</i>
Study Preparation	OCR/ORA Contracting (CTA's, Amendments, CDA's) Turnaround Time	<p>Volume, average, and median time for completion. Measure time from the date a complete contract routing* is received to the final negotiation date**.</p> <p>*Complete contract routing - Draft agreement, draft budget, draft ICF, List of study sites, protocols</p> <p>**Final negotiation date is the date the contract is fully executed if there is no budget. If there is a budget, it is the day the account is set up.</p> <p><i>Report both Mean & Median times to account for extreme outliers.</i></p>
Study Preparation	Coverage Analysis Turnaround Time	<p><i>Study Added to Queue date on Additional Protocol Information tab in REDCap project is start date, and OCR Signoff/Account Signoff completed date in OnCore is the end date.</i></p> <p><i>Report Mean & Median times</i></p>

Study Preparation	Time from first Submission to IU Office* to Open to Accrual**	<p>*Submission to IU Office: First received at IRB/OCR/ORA **Open to Accrual: OnCore Open to Accrual</p> <p><i>Report Mean & Median times</i></p>
--------------------------	---	--

CLINICAL STUDY EXECUTION KPIs

AREA OF FOCUS	METRIC/KPI TITLE	DEFINITION
Clinical Study Execution	Study Activation Time Frames	Time from when study team accepts the study and first Submission to IU office* , including first draft documents
		Time from first submission to IU Office to OCR/CTO Sign Off** , following final documents
		Time from OCR/CTO Sign Off to Open to Accrual***
		*Submission to IU Office: First received at IRB/OCR/ORA
		**OCR/CTO Sign Off: Time when all approvals have been received
		***Open to Accrual: OnCore Open to Accrual
	First Patient Enrolled	Time from Open to Accrual to first enrollment
	Investigational Drug Services (IDS)	Time from Submission to IU Office to <i>IDS ready*</i> to Open to Accrual *IDS has completed all training/order sets, DOA documents etc. **TBD - Timepoint for when IDS is notified
Patient Recruitment and Enrollment Plan Accuracy	Number of subjects screened Actual Enrollment Rate – subjects enrolled per month Actual enrollment relative to enrollment targets (ex. 2pts/month)	
Non-Enrolling Studies: Evaluation & Conclusions	The process of assessing studies that fail to enroll patients. (reporting of non-enrolling studies via OnCore reports) Report on non-enrolling studies and development of conclusions for not enrolling within 6 months of initiation. Determine status & why they are not enrolling	
Studies without enrollment	Number of studies open to accrual without enrollment in 6 months	

	Dropout Rates	The percentage of enrolled patients who withdraw or are lost to follow-up before study completion.
	Overall time to complete study enrollment with OnCore Closed to Accrual Endpoint	Time from first submission to IU Office to OnCore Study Closeout
	Overall time to complete study enrollment with OnCore IRB Closure Endpoint	Time from first submission to IU Office to IRB Closeout

CLINICAL STUDY PORTFOLIO KPIs

AREA OF FOCUS	METRIC/KPI TITLE	DEFINITION
Study Accrual	Number of Studies Open to Accrual	Studies entered in OnCore with a status of "open to accrual" (School, IUSM Type, Dept.)
	Total Subjects Accrued	Subjects enrolled in OnCore as participating in studies open to accrual
	Average/Median Percent of Accrual Target	The number of subjects enrolled in a study (in OnCore) as a percentage of the accrual target, averaged across all interventional studies in the organization that are listed as open to accrual.
	Average/Median Accrual Ratio Metric	The average/median Accrual ratio for all interventional studies across the organization that are listed as open to accrual.

Expected Reporting Cadence –

Dashboard Data (Updated Nightly): Dashboard data is refreshed nightly. Study teams are expected to update applicable data in real time, with review by the designated point of contact (POC) at least monthly. This includes study KPIs and operational metrics displayed within the dashboard tables.

Monthly Reporting: Biobank patient data is received and updated monthly.

Annual Reporting: Enterprise research metrics related to the 6% goal are currently provided annually.

Additional Metrics: Metrics such as study preparation activities and other dashboard measures are available for ongoing review through the dashboard and should be monitored regularly by study teams and POCs rather than through a separate formal reporting cadence.