

Operations Work Group on Metrics Characterizing the Execution of Clinical Trials

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- 15 unique metrics identified
- 7 unique metric categories
 - Site start-up
 - Image acquisition
 - Image processing
 - Image quality
 - Missing imaging
 - Image queries
 - Export submission
- Focus:
 - Training
 - Operational delivery
 - Quality
 - Timeliness

Operations Imaging Metrics

“Site Start-Up” Category

Metric Title	Definition	Formula	Business Driver(s) / Benefit Statement
% of sites qualified vs. actual	<p>Average number of days from the original timeline for all sites ready vs. actual</p> <p>Additional analysis on a "for cause" basis: Include analysis for site delays and will be measured in days</p>	Number of sites up within timeframe divided by total number of sites (sponsor / core lab specific)	Early escalation of site delays / Address issues proactively for immediate remediation
Average number of days from site designated ready to first date of image receipt	<p>Average number of days between site ready (training, start up kit, etc...) and actual image receipt at the ICRO. One-time metric per site, split into 3 components:</p> <ol style="list-style-type: none"> 1) Days Site ID to Site training 2) Day from site training to site qualification 3) Days from site qual to first image received <p>Additional analysis on a "for cause" basis: Include analysis for site delays and will be measured in days</p>	Number of days from defined site ready to first image received	Early escalation of site delays and start up activities / Address issues proactively for immediate remediation

Operations Imaging Metrics

“Image Acquisition” Category

Metric Title	Definition	Formula	Business Driver(s) / Benefit Statement
Average number of days from image acquisition to image receipt	Average number of days from when a scan was acquired at site vs. image receipt at the ICRO	Difference in days from image acquisition at site to image receipt at core lab	Early escalation of site compliance and image shipment issues
Average number of days from image receipt to initial feedback to site	Average number of days from when a scan was received at the ICRO vs. the initial feedback to the site (Initial feedback is defined as initial QC check or query and not just image receipt)	Difference in days from image receipt at core lab to date of initial feedback to site	Early escalation of potential core lab issues that require immediate remediation and site related issues are being communicated to the sites in a timely manner

Operations Imaging Metrics

“Image Processing” Category

Metric Title	Definition	Formula	Business Driver(s) / Benefit Statement
Average number of days from image QC complete to reporting of eligibility results	Average number of days from image QC completion to when the ICRO delivers the results of an eligibility review to the site	Difference of date of QC complete from date eligibility results sent	Early escalation of potential protocol, image acquisition and / or core lab issues that require immediate remediation
Average number of days from image receipt to ready for independent review	Average number of days from when the image was received at the ICRO vs. when the image is ready for independent review	Difference of date image receipt to ready for review	Early escalation of potential core lab issues that require immediate remediation
Average number of days from image designated for review to completion of the review	Average number of days from when the image is designated for review vs. completion of initial read (after first review, after adjudication, after oncology, etc...?)	Difference of ready for review from date of final review	Early escalation of potential independent reviewer delays that require immediate remediation

Operations Imaging Metrics

“Image Quality” Category

Metric Title	Definition	Formula	Business Driver(s) / Benefit Statement
Suboptimal but evaluable images	Percentage of images that have an acquisition parameter deviation but can be evaluated during independent review	Number of images with an acquisition parameter deviation and reviewed divided by number of images reviewed	Identification of a need to retrain sites or redesign image acquisition guidelines
Non-evaluable images versus total received	Percentage of images received vs. the amount not interpretable	Number of images not interpretable divided by number of images received	Early escalation of potential core lab or site performance issues that require immediate remediation
Non-evaluable baseline images	Percentage of baseline images received that were not interpretable	Number of baseline images not interpretable divided by number of baselines images received	Early escalation of potential core lab or site performance issues that require immediate remediation

Operations Imaging Metrics

“Missing Imaging” Category

Metric Title	Definition	Formula / Example	Business Driver(s) / Benefit Statement
Percentages of missing imaging visits	Percentage of "lost" imaging visits. Type of loss can be classified as follows: <ul style="list-style-type: none"> - lack of site response (unresolved query) - non-acquisition (as confirmed by site) - study protocol deviation 	Number of "lost" imaging visits divided by number of imaging visits expected	Early escalation of potential site performance or study protocol design issues

Operations Imaging Metrics

“Image Queries” Category

Metric Title	Definition	Formula	Business Driver(s) / Benefit Statement
Percentage of queries by site	Percent number of queries by site Additional analysis on a "for cause" basis: If query percentage threshold is exceeded, query types should be evaluated for trending	Number of queries divided by number of timepoints received	Early escalation of site image acquisition or performance issues / Address issues proactively for immediate remediation
Average number of days an imaging query is outstanding	Days query outstanding from query sent date to query resolution	Difference of query sent date from date resolved	Early escalation of site image acquisition or performance issues / Address issues proactively for immediate remediation

Operations Imaging Metrics

“Export Submission” Category

Metric Title	Definition	Formula	Business Driver(s) / Benefit Statement
Average number of days from last patient reviewed to delivery of dataset	Average number of days from when the last patient was independently read vs. the submission of the imaging export to the sponsor or third party CRO	Difference of date last patient reviewed from date of final transfer	Trending for export programming and QC methods
Average number days from original estimate to actual for export submission	Average number of days from the original agreed timeline for data export vs. the actual submission of the final data export	Difference of export date as per contract from actual final export submitted date	Trending for original project assumptions and expectations

Operations Imaging Metrics Group Discussion Prep

- Evaluate scope and feasibility of metrics
- Identify business gaps
- Suggest definition and formula refinements