

MCC ECG Performance Metrics v 1.0

Metric	Category	Metric Title
1	Contract Signature	Average number of days from ECG study award to contract signature Note: For stand-alone ECG projects
2	Protocol Initiation	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs
3	Site Initiation	% of on-time ECG equipment shipments to sites
4	Site Initiation	% of sites who conduct a successful test ECG transmission prior to 1st subject visit
5	General Operations	% of ECGs reported to Investigator Sites within agreed turnaround time
6	Data Cleaning	% of ECG data queries from vendor to site
7	Data Cleaning	Turnaround time on resolution of ECG site queries from central vendor
8	Safety	% of ECG alerts successfully communicated to sites within defined turnaround time

Metric	Category	Metric Title
9	Quality Control of ECG processing and interval duration measurement (IDM) by the core lab	% of ECGs received from one study that were interpretable by the core lab
10	Quality Control of ECG processing and interval duration measurement (IDM) by the core lab	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)
11	General Operations	% of ECG equipment failure
12	General Operations	Average turnaround time on replacing faulty ECG equipment
13	Data Management	% of on-time, accepted ECG file transfers
14	General Operations	Key ECG core lab personnel turnover during protocol
15	Quality Assurance	% of ECG core lab audit/assessment findings closed within agreed timelines
16	Financial Management	Average % of variance maintained in the ECG budget

SPECIAL NOTE

Inter-/Intra-reader Variability Metrics: Due to the various ECG over read methodologies as well as the variety or manners of assessing inter-/intra-reader variability amongst the core labs, a defined and standardized set of variability metrics is not available at this time. However, since the ICH E14 (“The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs”) calls for these metrics (by stating “The degree of inter- and intra-reader variability should be established by having the assessors reread a subset of the data (both normal and abnormal) under blinded conditions”), it is very important that the core labs create these variability data and the sponsors should both review the data as well as understand how it was created. The data generated by each core lab should be a standard adhered to by that lab for all work performed as this can have an impact on the quality of data generated during the study.