

MCC ECG Performance Metrics v 1.1

Metric	Metric Title	Who's Being Measured?
1	Average number of days from ECG study award to contract signature Note: For stand-alone ECG projects	SPONSOR and CORE LAB
2	Average number of days from signed ECG technical specifications document (TSD) signature to vendor ready to receive ECGs	CORE LAB and SPONSOR
3	% of on-time ECG equipment shipments to sites	CORE LAB and SPONSOR
4	% of sites who conduct a successful test ECG transmission prior to 1st subject visit	SITE
5	% of ECGs reported to Investigator Sites within agreed turnaround time	CORE LAB and SPONSOR
6	% of ECG data queries from vendor to site	SITE
7	Turnaround time on resolution of ECG site queries from central vendor	SITE
8	% of ECG alerts successfully communicated to sites within defined turnaround time	CORE LAB

Metric	Metric Title	Who's Being Measured?
9	% of ECGs received from one study that were interpretable by the core lab	SITE
10	% of manual adjustments of automated QT annotations from one study (semi-automatic "computer assisted" method with visual inspection and manual adjustment whenever necessary)	UNKNOWN – PROBABLY ECG EQUIPMENT AND CORE LAB
11	% of ECG equipment failure	ECG EQUIPMENT, CORE LAB AND SITE
12	Average turnaround time on replacing faulty ECG equipment	CORE LAB
13	% of on-time, accepted ECG file transfers	CORE LAB
14	Key ECG core lab personnel turnover during protocol	CORE LAB
15	% of ECG core lab audit/assessment findings closed within agreed timelines	CORE LAB
16	Average % of variance maintained in the ECG budget	SPONSOR

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.