

1st Step: Industry Survey

- Web-based industry survey as a guide to
 - current working practices
 - potential recommendations for ECG Performance Metrics developed within current initiative (as well as future revisions)
- Sent out June 2006
- Distributed to broad audience (including non-participant companies) to promote interest and conduct a landscape analysis of industry

Survey Questions

1. # of readers used by ECG core labs (and/or required by pharmaceutical sponsors) on a study (stratified by phase)
2. # of core labs utilizing fully manual vs. semiautomated vs. fully automated (and/or number of sponsors requesting either)
3. % of ECGs used for inter- & intra-reader variability; how many sponsors request QA from their own study vs. accepting the core lab routine practice of using weekly/monthly workload?
4. Training practices for qualifying and continuous monitoring/re-certification of readers
5. Area of ECG collection that is in the most need of improvement (multiple choice question)

2nd Step: ECG Metrics Working Groups

- Outsourcing - Solomon Babani
- Operations - Steve Asbury
- Clinical - Nenad Sarapa

Expectations of Working Groups

- Evaluate existing metrics
- Develop new, meaningful metrics
 - Including definitions
 - Means and frequency of measurement
 - Units of measure
 - Benefit statements for metric
- Will occur from 31May through 17Sep (with further meetings until final rollout of the ECG metrics in April 2007)
- Potential Participation in Conferences to Rollout Metrics Initiative

3rd Step: ECG Metrics Survey

- Provide survey to Extended Group on 18Sep
 - Responses required by 13Oct
- Compile all Working Group derived metrics
 - Metrics will be ranked in order of importance by each responder
 - Comments will be added for each metric by responder
- Provide compiled rankings and comments to the ECG Steering Committee by 1Dec

- Steering Committee (with feedback from the ECG Working Groups) will review rankings and comments from the survey to create final draft of 15-20 ECG metrics
- Definitions, formulas/examples, unit of measure, reporting frequency, target, and potential benefit statements for each metric will be reviewed and edited

Development of Baseline ECG Metrics

- Format for draft ECG metrics adopted from existing MCC lab performance metrics and steering committee input on additional metrics
- Serve as the baseline for each working group to consider and amend

Potential ECG Metrics (Outsourcing)

- Plan, forecast and actual financial report
- Length of time between contract award and contract signature
- Average number of days from contract signature to vendor ready to receive ECGs
- Number of change orders for a contract

Potential ECG Metrics (Operations)

- % on-time equipment shipments to site(s)
- % of queries from vendor to site and type of query
- % alerts/panics successfully communicated to sites within defined turnaround time
- Turnaround time on resolution of site queries
- % ECGs reported within turnaround time
- % on time accepted file transfer
- Average months from study closeout to return of all equipment
- Key personnel turnover during study
- % of audit findings closed with agreed timelines

Potential ECG Metrics (Clinical)

- Best practices for
 - certification and continued training of readers
 - generating inter-/intra-reader variability data
- Research to drive best practices for pharma and service providers and future metrics research:
 - Performed by extended group members on fully blinded data from MCC sponsors
 - Use and timing of use of the XML ECG warehouse to assess the quality of ECG core lab performance
 - Use of XML ECG warehouse to assess the quality of sponsor's ECG data to improve likelihood of FDA approval
- Additional proposals to be developed

4th Step: Rollout of ECG Metrics

- January 17-19, 2007 (IIR Partnerships Meeting in Anaheim, CA) – Rollout of the Final Draft ECG Metrics
- April 2007 – Finalization of the ECG Metrics version 1.0
- DIA Annual meeting 2007 – Rollout of ECG Metrics version v1.0

Conclusion

- Involvement of sponsors and service providers early and throughout development
- Improved and potentially new ECG metrics resulting from survey of current practices and collaborative research between sponsors and service providers
- Not limiting number of participants
- Rollout draft metrics in January 2007 and release final version in April 2007
- Need to be visible to gather the best individuals in the industry to assist in making metrics meaningful