Apply New Technology to Improve Data Quality

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Meta Clinical Technology®
May 2017
Agenda

• Data Review – Traditional Perspective
• Benefit of New Technology
• Data Visualization and Analysis
Data Quality Elements - ALCOA+

- Attributable
- Legible
- Accurate
- Original
- Contemporaneous
- Available/Accessible
- Complete
- Enduring

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Data Review – Traditional Perspective

- CRAs perform SDV
- Data Cleaning and validation
  - System Checks
  - Automated Checks
  - Manual Checks
- Data Review – focus on individual data point
- Treats ‘all data as equal importance’
Data Validation ensures that the data is sensible before it is processed.

- The data meets a defined set of rules – As per protocol standards.
  - Complete
  - Correct
  - Consistent
Manual Checks

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- Review 100% Offline listing and CRF
  - SAS Programming for Offline listing
  - Too much data or working too longer
  - Exhausting, error prone
Data Review – Traditional Perspective
Challenges in Clinical Trials

- Decrease costs
- Speed up the research and development process.
- Improve the data quality
Benefit of New Technology

- Not only focus on individual data points, but also observe the data trend
- Easy to find outlier or non-compliance data
- Find inconsistent data between different countries or sites
- Productively
- Decrease human error
Current trend in many areas – Risk Based
Risk based approach to Systems … Risk Analysis …
Risk based monitoring
Risk based site selection for audits (FDA)
Risk Based ...

- Current trend in many areas – Risk Based

- Risk Based = Focus on highest risk issues

- Don’t get ‘bogged down in the weeds’
Clinical Data Review

Review clinical data – from an aggregate view – to the details.

Review summarized views of the data - for an overview of the data in your trial – lets you look into the items of interest based on the aggregate view of the data, rather than doing a patient by patient review of a detail line listing directly.
Data Visualization Tools

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▲ JReview
▲ JMP
▲ Tableau
▲ Others
Patient Profiles

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- Time-oriented (days on drug) graph display of user selected parameters
- Dynamically choose categories and items to include
- Drilldown to selected data of interest
- Graphical or tabular (formatted) output
- Export to Excel, HTML, PDF
- Optional batch report option
Patient Review Tracking

- System keeps track of patients reviewed
- Patients with new data are highlighted
- Review state for all patients can be displayed, as well as highlighted rows in patient profile – with new data since last review
- DataType review tracking – to track data review by domain, i.e., AE, CM, LB, etc.
- Data listings optionally display ‘New Data’ highlighting – associated with Patient Review Tracking feature
Patient Visit Data Report

- Special multi-pass – date merge report – developed with the NCI
- Very useful for AE-ConMed display, or any other data which is aligned more naturally by observed date (start date, onset date, etc) rather than typical visit joins
Patient Profile Viewer

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### Aggregate Table

**Aggregate Table**

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#### (Req'd PSC) Abnormal Labs per Arm - Subset of patients

<table>
<thead>
<tr>
<th>LBTEST</th>
<th>ACTIVE</th>
<th>PLACEBO</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALANINE AMINOTRANSFERASE</td>
<td>3 (0.54%)</td>
<td>10 (2.14%)</td>
<td>13 (2.76%)</td>
</tr>
<tr>
<td>ALBUMIN</td>
<td>2 (0.43%)</td>
<td>10 (2.14%)</td>
<td>12 (2.57%)</td>
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<tr>
<td>ALKALINE PHOSPHATASE</td>
<td>1 (0.21%)</td>
<td>4 (0.86%)</td>
<td>5 (1.07%)</td>
</tr>
<tr>
<td>ASPARTATE AMINOTRANSFERASE</td>
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<td>3 (0.64%)</td>
<td>5 (1.07%)</td>
</tr>
<tr>
<td>BILIRUBIN</td>
<td>4 (0.86%)</td>
<td>3 (0.64%)</td>
<td>7 (1.50%)</td>
</tr>
<tr>
<td>CHLORIDE</td>
<td>28 (6.00%)</td>
<td>15 (3.21%)</td>
<td>43 (9.21%)</td>
</tr>
<tr>
<td>CREATININE</td>
<td>6 (1.28%)</td>
<td>5 (1.07%)</td>
<td>11 (2.36%)</td>
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<tr>
<td>GLUCOSE</td>
<td>15 (3.21%)</td>
<td>15 (3.21%)</td>
<td>30 (6.42%)</td>
</tr>
<tr>
<td>HEMATOCRIT</td>
<td>1 (0.21%)</td>
<td>0 (0.00%)</td>
<td>1 (0.21%)</td>
</tr>
<tr>
<td>HEMOGLOBIN</td>
<td>17 (3.64%)</td>
<td>13 (2.78%)</td>
<td>30 (6.42%)</td>
</tr>
<tr>
<td>LEUKOCYTES</td>
<td>9 (1.93%)</td>
<td>5 (1.07%)</td>
<td>14 (2.85%)</td>
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<tr>
<td>LYMPHOCYTES</td>
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<td>2 (0.43%)</td>
<td>3 (0.64%)</td>
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<tr>
<td>NEUTROPHILS</td>
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<td>4 (0.86%)</td>
<td>13 (2.63%)</td>
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<tr>
<td>PLATELET</td>
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<td>1 (0.21%)</td>
<td>6 (1.23%)</td>
</tr>
<tr>
<td>POTASSIUM</td>
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<td>4 (0.86%)</td>
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<td>1 (0.21%)</td>
<td>4 (0.81%)</td>
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<tr>
<td>UREA NITROGEN</td>
<td>6 (1.28%)</td>
<td>2 (0.43%)</td>
<td>8 (1.62%)</td>
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</table>

#### AE Intensity by Treatment - All Patients

<table>
<thead>
<tr>
<th>Intensity</th>
<th>Active</th>
<th>Placebo</th>
<th>Subjects</th>
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<tr>
<td>(missing)</td>
<td>3 (1.53%)</td>
<td>5 (2.55%)</td>
<td>8 (4.08%)</td>
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<tr>
<td>Mild</td>
<td>20 (10.20%)</td>
<td>18 (9.18%)</td>
<td>38 (19.39%)</td>
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<tr>
<td>Moderate</td>
<td>10 (5.10%)</td>
<td>7 (3.57%)</td>
<td>17 (8.67%)</td>
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<tr>
<td>Severe</td>
<td>1 (0.51%)</td>
<td>0 (0.00%)</td>
<td>1 (0.51%)</td>
</tr>
<tr>
<td>Subjects</td>
<td>97 (49.49%)</td>
<td>99 (50.51%)</td>
<td>196 (100.00%)</td>
</tr>
</tbody>
</table>

(All patients)
Data Visualization and Analysis

- dynamically linked - allowing users to interactively track patients across multiple graphical and tabular outputs
Data Visualization and Analysis

http://www.meta-clinical.com
Data Visualization and Analysis
- Change from Baseline Box Whiskers

Lab Test or Examination Name: Alanine Aminotransferase

<table>
<thead>
<tr>
<th>Visit Number</th>
<th>Reference</th>
<th>Test Therapy</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>0.940</td>
<td>3.466</td>
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<tr>
<td>8</td>
<td>0.518</td>
<td>1.344</td>
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<tr>
<td>12</td>
<td>2.802</td>
<td>0.658</td>
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<tr>
<td>16</td>
<td>3.803</td>
<td>1.997</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Reference</th>
<th>Test Therapy</th>
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<tbody>
<tr>
<td>Mean</td>
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<tr>
<td>Median</td>
<td></td>
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<tr>
<td>Q1</td>
<td></td>
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</tr>
<tr>
<td>Q3</td>
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<td></td>
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<tr>
<td>N</td>
<td>350</td>
<td>380</td>
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</tbody>
</table>

Visit Number
Series
- Reference
- Test Therapy
Data Visualization and Analysis
- Change from Baseline Box Whiskers

- Identifying the outliers and reviewing their data
Data Visualization and Analysis
- Change from Baseline Bar Charts

• Hematology: Platelets lab test % Change from Baseline
Data Visualization and Analysis
- Efficacy - Overall Survival

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THANK YOU!

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