Beyond DFdiscover: Visualizing Your Data with iDashboards
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DFdiscover Today

• Rapid data collection for EDC and paper studies
• Easy data management, verification and cleaning
• Standard reports for enrollment, queries, study visits and more
Desires Beyond DFdiscover

• Customizable reports for study specific data
• Compare data across multiple studies
• Not all data has the same value; how can we treat it so?
iDashboards as a Solution

• Create **study-specific** charts into a dashboard
• Connect to subjects through **interactive** charts
• Manage studies using **Risk-based** monitoring approach
• Export data to a SQL server **automatically**
What is Risk-Based Monitoring?

“Monitoring activities should focus on preventing or mitigating important and likely sources of error in the conduct, collection, and reporting of critical data and processes necessary for human subject protection and trial integrity.”

–FDA Guidelines in August 2013
A risk assessment of **critical data** and processes

- Likelihood of error occurring
- Impact of these errors on subject protection and trial integrity
- Extent such errors would be detectable

Interactive visualization tools aid in:
- Identifying data trends and inconsistencies
- Sharing progress with study teams and authorities
- Decision-making
Study-Specific: Safety

Safety Dashboard

- Subjects: 34
- Subjects with serious adverse events: 12
- Subjects screened: 63
- Subjects enrolled: 53
- Subjects active in study: 11

Adverse Events by Preferred Term in the Last 365 days:
- Headache: 7
- Fatigue: 4
- Arthralgia: 3
- Nausea: 3
- Pruritus: 3
- Ligament sprain: 2
- Pyrexia: 2
- Erythema: 1
- Hypertension: 1
- Induration: 1
- Influenza: 1
- Iodine uptake decreased: 1
- Migraine: 1
- Myalgia: 1
- Urticaria: 1

Abnormal Lab Results by Clinical Significance in the Last 365 days:
- Hemoglobin: 1
- Hematocrit: 3
- WBC: 2
- Total Neutrophil Count: 1
- Monocytes: 1
- Eosinophils: 1
- Basophils: 1
- BUN: 1
- Creatinine: 3
- Sodium: 2
- Chloride: 1

Adverse Events Meeting Pause Rule Definition

Data updated on 20SEP2019 at 01:00:11 AM
Study-Specific: Monitoring

Monitoring Dashboard

Screened and Enrolled Subjects by Site

Risk Based Monitoring Summary by Site

<table>
<thead>
<tr>
<th>Site</th>
<th>Overall Risk Score</th>
<th>Protocol Deviations</th>
<th>SAE</th>
<th>Queries</th>
<th>Visit Window</th>
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<tbody>
<tr>
<td>Kisumu</td>
<td>2.46</td>
<td>40.00 %</td>
<td>60.00 %</td>
<td>40.00 %</td>
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<tr>
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<td>0.00 %</td>
<td>20.00 %</td>
<td>20.00 %</td>
</tr>
</tbody>
</table>

Query and Data Entry Metrics for LB-HEM-225
Study-Specific: Endpoint (Expanded)
Study-Specific: Combo demo

Protocol Deviations by Type

Adverse Events by Preferred Term in the Last 365 days

Abnormal Lab Results by Clinical Significance in the Last 365 days

Potential DLTs

Data Entry and Outstanding Query Duration by Plate

Visits Completed by Site

Subjects Enrolled

Subjects Completed Study

Subject Early Withdrawals

Total AEs

Subjects with AEs

Total SAEs
Questions?
Have you utilized DFdiscover reports to visualize your data? Which standard reports are most valuable to you?
Have you used an external visualization platform? What features are you looking for?
In what circumstances would you find iDashboards most useful?
How has technology aided in managing your studies?

DISCUSSION
Thank You

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