# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative Metrics Context/Overview</td>
<td>01</td>
</tr>
<tr>
<td>Quantitative Metrics Q2/Q3 2016</td>
<td>02</td>
</tr>
</tbody>
</table>
Quantitative Metrics
Context/Overview

Provides an overview of how quantitative metrics are calculated
Study Progression and RBM Adoption

Note: Reporting of trial inventory is voluntary
Note: Implementation of RBM has been voluntary and companies that have implemented may be in various stages (all 18 member companies are either implementing or plan to implement RBM)
Note*: Does not reflect 4Q16 data
RBM Metrics Context for Collection and Analysis

• Collection process and limitations across 140 unique trials eligible to report data across 7 Companies for periods ending in Q2 & Q3 2016
• Analysis
  – Trial data with similar level of maturity (“RBM + x months”) is aggregated into stacked charts. In example below, the first quarter of metric data was grouped together into stacked charts (red circles), the second quarter of metric data was grouped together for analysis (green circles) and so on, regardless of actual calendar quarter.

Metric #1 Example

Trial 1
- RBM + 3 Months
- RBM + 6 Months
- RBM + 9 Months
- RBM + 12 Months
- RBM + 15 Months

Trial 2
- RBM + 3 Months
- RBM + 6 Months
- RBM + 9 Months
- RBM + 12 Months

Trial 3
- RBM + 3 Months
- RBM + 6 Months

Trial 4
- RBM + 3 Months
These Metric Narratives illustrate the expectations of RBM’s impact as well as alternative observations

<table>
<thead>
<tr>
<th>Metric</th>
<th>Expected Observations</th>
<th>Potential Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of major/critical audit findings per audited site</td>
<td>• Average number of major/critical findings per audited site will decrease</td>
<td>• Audit findings may initially rise due to focus on critical data and processes</td>
</tr>
<tr>
<td>Percentage of unreported, confirmed SAEs as compared to total SAEs as</td>
<td>• Unreported, confirmed SAEs will decrease</td>
<td>• Percentage of unreported, confirmed SAE findings may rise initially due to shift in</td>
</tr>
<tr>
<td>compared to total SAEs as discovered through any method</td>
<td></td>
<td>focus from SDV to SDR</td>
</tr>
<tr>
<td>Significant Protocol Deviation rate per treated subject (total # of</td>
<td>• Significant Protocol Deviations will decrease</td>
<td>• Significant protocol deviation findings may rise initially due to shift in focus from</td>
</tr>
<tr>
<td>deviations/ total # of subjects for the protocol)</td>
<td></td>
<td>SDV to SDR</td>
</tr>
<tr>
<td>Average Monitoring (all types) cost per site</td>
<td>• Average monitoring costs will decrease</td>
<td>• Costs may remain flat until second quarter of analysis or later</td>
</tr>
</tbody>
</table>
## Metrics Narratives (cont’d)

<table>
<thead>
<tr>
<th>Metric</th>
<th>Expected Observations</th>
<th>Potential Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average interval between on-site monitoring visits per site</td>
<td>• Interval between on-site monitoring visits will increase</td>
<td>• Average interval between on-site monitoring visits may remain flat until second quarter of analysis or later</td>
</tr>
<tr>
<td>Median number of days from patient visit to eCRF data entry</td>
<td>• There are no expectations to improve the median number of days from patient visit to eCRF data entry</td>
<td>• The site may delay performing a crucial function that empowers central monitoring due to the potential decrease in on-site visits</td>
</tr>
<tr>
<td>Median number of days from query open to close</td>
<td>• There are no expectations to improve for the median number of days from query open to close</td>
<td>• The site may delay performing a crucial function due to the potential decrease in on-site visits</td>
</tr>
<tr>
<td>Median number of days from significant/major issue open to close</td>
<td>• Median number of days from issue open to close will decrease</td>
<td>• Findings initially may rise if issues management process is new to the organization</td>
</tr>
</tbody>
</table>
Quantitative Metrics Q2/Q3 2016

Actual Metrics
140 studies
from 7 member companies
Quality: Audit findings per audited site

Average number of major/critical audit findings per audited site

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.
Quality: SAE reporting

Percentage unreported, confirmed SAEs as compared to total SAEs

Responses compiled, blinded and aggregated by third party before dissemination to member companies.
Not all metrics are reported for all trials across all time periods.
Quality: Significant Protocol Deviations

Significant Protocol Deviation rate per treated subject

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.
Efficiency: Overall Monitoring Cost

Average Monitoring (all types) cost per site

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.
Efficiency: On-site visit interval

Average interval between on-site monitoring visits per site

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.
Cycle Time: eCRF Entry

Median number of days from patient visit to eCRF data entry

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.
Cycle Time: Query Open to Close

Median number of days from query open to close

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.
Cycle Time: Issue Open to Close

Median number of days from issue open to close

Responses compiled, blinded and aggregated by third party before dissemination to member companies. Not all metrics are reported for all trials across all time periods.