CRS Performance

HPTN Performance Evaluation Committee

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March 2017, HPTN Performance Evaluation Committee (PEC) finalized 9 new CRS performance metrics

The performance areas include:

- Accrual and Retention (2)
- Data Management (5)
- Laboratory Data Management (2)
Accrual and Retention Indicators

• Enrollment
  – Number enrolled during the evaluation period compared to expected enrollment

• Estimated Retention
  – Cumulative visit completion rate compared to the protocol-specified expectation
Data Management Indicators

• Timeliness of data submission
  – Mean number of days to submit Case Report Forms (CRFs)
  – Percentage of CRFs submitted within standard expectation

• Quality of Data
  – Number of queries per 100 pages of CRFs submitted
Data Management Indicators

- Responses to data queries
  - Percentage of queries resolved within standard timeframe

- Protocol Deviations
  - Number of protocol deviations

- Timely submission of AEs
  - Percentage of adverse events submitted within 3 days of site awareness
Laboratory Data Management Indicators

• Quality of specimen handling/shipment
  – Number of shipments received within protocol specified timeframe

• Specimen storage completeness
  – Number of aliquots stored compared to number anticipated per specimen type per visit per protocol
## CRS Performance Standards

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enrollment</strong></td>
<td>• Meet protocol specified goal</td>
</tr>
<tr>
<td><strong>Retention</strong></td>
<td>• Meet protocol specified goal</td>
</tr>
<tr>
<td><strong>Data Timeliness</strong></td>
<td>• DataFax CRFs submitted $\leq 5$ days</td>
</tr>
<tr>
<td></td>
<td>• 90% submitted $\leq 7$ days for Rave EDC studies</td>
</tr>
</tbody>
</table>
## CRS Performance Standards

<table>
<thead>
<tr>
<th>Category</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Data</td>
<td>• &lt;10 queries/100 pages</td>
</tr>
<tr>
<td>QC Responsiveness</td>
<td>• 80% answered ≤ 7 days</td>
</tr>
<tr>
<td>Protocol Deviations</td>
<td>• None</td>
</tr>
<tr>
<td>Timely submission of AEs</td>
<td>• 90% of AEs submitted ≤ 3 days</td>
</tr>
</tbody>
</table>
CRS Performance Standards

- **Quality of Specimen Handling/Shipment**
  - 90% received within protocol specific timeframe

- **Specimen Storage Completeness**
  - 95% complete
CRS Performance Reports

- Annual HPTN CRS Performance Evaluation completed for the period of 1 June 2016 – 31 May 2017

- All CRS participating in HPTN protocols active during the evaluation period received their data
## Accrual and Retention

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Status</th>
<th>Date First Enrollment</th>
<th>Target Enrollment</th>
<th>Total Enrollment</th>
<th>Evaluation Period Enrollment</th>
<th>Estimated Evaluation Period Target</th>
<th>Evaluation Period % of Target</th>
<th>Expected Visits</th>
<th>Completed Visits</th>
<th>Estimated Retention</th>
<th>Protocol Specified Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPTN076</td>
<td>Closed to Follow-up</td>
<td>13-May-15</td>
<td>48</td>
<td>48</td>
<td>Enrollment completed before evaluation</td>
<td>672</td>
<td>542</td>
<td>81.0%</td>
<td>94.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPTN082</td>
<td>Enrolling</td>
<td>7-Nov-16</td>
<td>200</td>
<td>130</td>
<td>125</td>
<td>59</td>
<td>214</td>
<td>93.0%</td>
<td>98.0%</td>
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</tr>
<tr>
<td>HPTN084</td>
<td>Pending</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

## Clinical and Laboratory Data Management

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Status</th>
<th>Total Pages Submitted</th>
<th>Mean Days to Submit</th>
<th>Percentage submitted within 5 days</th>
<th>QC rate per 100 pages</th>
<th>Percentage QCs Resolved &lt;= 28 Days</th>
<th>Protocol Deviations</th>
<th>Shipments Received within Specified Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPTN076</td>
<td>Closed to Follow-up</td>
<td>1412</td>
<td>5.7</td>
<td>77.0%</td>
<td>14.1</td>
<td>88.0%</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>HPTN082</td>
<td>Enrolling</td>
<td>3919</td>
<td>3.1</td>
<td>82.4%</td>
<td>8.5</td>
<td>92.5%</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>HPTN084</td>
<td>Pending</td>
<td></td>
<td></td>
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Overall, sites met the performance standards during the evaluation period.

- 64 Sites
- 12 Protocols
- 53,925 Participants enrolled
- 242,154 CRF pages submitted
Going forward

• CRS reports will be generated quarterly
• Indicators may be expanded beyond these core indicators
• Protocol-specific sites will need to complete participation in at least two protocols before they will be considered for change to HPTN status
ACKNOWLEDGEMENTS

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