CRS Performance

HPTN Performance Evaluation Committee

Quarraisha Abdool Karim, PhD
Scientific Director: CAPRISA
Professor in Clinical Epidemiology, Columbia University
Adjunct Professor in Public Health, University of KwaZulu-Natal

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In March of 2017, the HPTN Performance Evaluation Committee (PEC) finalized 9 new indicators to measure CRS performance.

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**
  - Visit completion rate compared to the protocol-specified expectation
Data Management Indicators

• Data timeliness
  – 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

• QC Responsiveness
  – 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

Enrollment
- Meet protocol specified goal

Retention
- Meet protocol specified goal

Data Timeliness
- CRFs submitted within 5 days
- 90% submitted within 7 days for EDC studies
<table>
<thead>
<tr>
<th>CRS Performance Standards</th>
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<tbody>
<tr>
<td>Quality of Data</td>
<td>• &lt;10 queries/100 pages submitted</td>
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<tr>
<td>QC Responsiveness</td>
<td>• 80% resolved ≤ 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>
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</table>
CRS Performance Standards

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

Specimen Storage Completeness
• 95% complete
Annual HPTN CRS Performance Evaluation completed for the period of 1 June 2016 – 31 May 2017

All CRSs participating in HPTN protocols active during the evaluation period have received their site data

Of note, the indicators of specimen storage completeness and timely submission of AEs were not included in this year’s report
CRS Performance

• 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 CRS status change
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