



HPTN

HIV Prevention
Trials Network

CRS Performance

HPTN Performance Evaluation Committee

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Introduction

- 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

CRS Performance Standards

Quality of Data

- <10 queries/100 pages submitted

QC Responsiveness

- 80% resolved \leq 7 days

Protocol Deviations

- None

Timely submission of AEs

- 90% of AEs submitted \leq 3 days

CRS Performance Standards

Quality of Specimen
Handling/Shipment

- 90% received within protocol specific timeframe

Specimen Storage
Completeness

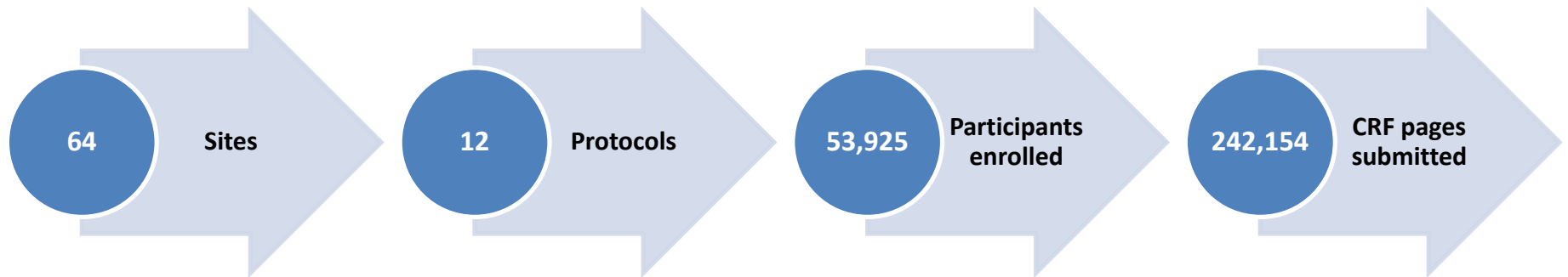
- 95% complete

CRS Performance Reports

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



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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