



HPTN

HIV Prevention
Trials Network

CRS Performance

HPTN Performance Evaluation Committee

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Introduction

- 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

Enrollment

- Meet protocol specified goal

Retention

- Meet protocol specified goal

Data Timeliness

- DataFax CRFs submitted ≤ 5 days
- 90% submitted ≤ 7 days for Rave EDC studies

CRS Performance Standards

Quality of Data

- <10 queries/100 pages

QC Responsiveness

- 80% answered ≤ 7 days

Protocol Deviations

- None

Timely submission of AEs

- 90% of AEs submitted ≤ 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 CRS participating in HPTN protocols active during the evaluation period received their data

Accrual and Retention

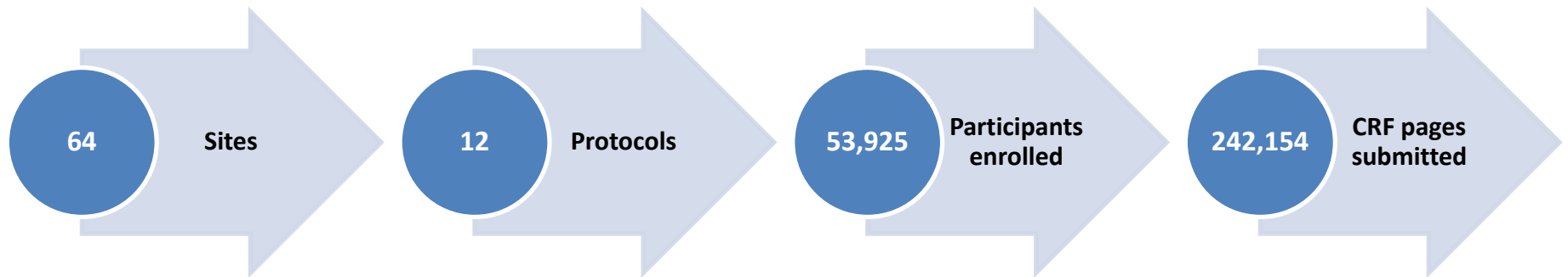
Study	Study Status	Date First Enrollment	Target Enrollment	Total Enrollment	Evaluation Period Enrollment	Estimated Evaluation Period Target	Evaluation Period % of Target	Expected Visits	Completed Visits	Estimated Retention	Protocol Specified Retention
HPTN076	Closed to Follow-up	13-May-15	48	48	Enrollment completed before evaluation			672	542	81.0%	94.0%
HPTN082	Enrolling	7-Nov-16	200	130	125	59	211.3%	214	199	93.0%	98.0%
HPTN084	Pending										

Clinical and Laboratory Data Management

Study	Study Status	Total Pages Submitted	Mean Days to Submit	Percentage submitted within 5 days	QC rate per 100 pages	Percentage QCs Resolved <= 28 Days	Protocol Deviations	Shipments Received within Specified Timeframe
HPTN076	Closed to Follow-up	1412	5.7	77.0%	14.1	88.0%	1	N/A
HPTN082	Enrolling	3919	3.1	82.4%	8.5	92.5%	4	N/A
HPTN084	Pending							

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 change to HPTN status

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