

## HPTN 106 Protocol Deviations Summary by Group

### Report generated June 17, 2025

|   | HPTN 106 | HPTN 106 only | Day 1 substudy | Day 2 substudy | Day 4 substudy | Day 8 substudy |
|---|----------|---------------|----------------|----------------|----------------|----------------|
| <b>Participants Enrolled</b>  | 83       | 62            | 7              | 7              | 2              | 5              |
| <b>Number of Protocol Deviations</b>  | 11       | 7             | 0              | 2              | 1              | 1              |
| <b>Type of Protocol Deviations</b>  |          |               |                |                |                |                |
| Informed assent/consent process deviation                                   | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Did not meet eligibility criteria   | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Failure to follow trial randomization or blinding procedures                | 5 (45%)  | 4 (57%)       | 0 (-%)         | 0 (0%)         | 0 (0%)         | 1 (100%)       |
| Conduct of non  | 1 (9%)   | 1 (14%)       | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Visit completed outside of window   | 1 (9%)   | 0 (0%)        | 0 (-%)         | 1 (50%)        | 0 (0%)         | 0 (0%)         |
| Blood volume maximum exceeded   | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Study product management deviation  | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Study product dispensing error  | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Study product administration error  | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| AE/SAE/EAE reporting deviation  | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Physical assessment deviation   | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Lab assessment deviation  | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Specimen handling deviation   | 1 (9%)   | 1 (14%)       | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Behavioral intervention deviation   | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Breach of confidentiality   | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Staff performing duties that they are not qualified or delegated to perform | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Use of non  | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| IRB, ethics, or regulatory review deviation                                 | 0 (0%)   | 0 (0%)        | 0 (-%)         | 0 (0%)         | 0 (0%)         | 0 (0%)         |
| Other   | 3 (27%)  | 1 (14%)       | 0 (-%)         | 1 (50%)        | 1 (100%)       | 0 (0%)         |

## HPTN 106 Protocol Deviations Summary by Site

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|   | All Sites | Baltimore | Los Angeles - Care Center | Pittsburgh - U of Pitt | Chapel Hill |
|---|-----------|-----------|---------------------------|------------------------|-------------|
| <b>Participants Enrolled</b>  | 83        | 8         | 5                         | 10                     | 14          |
| <b>Number of Protocol Deviations</b>  | 12        | 1         | 0                         | 2                      | 1           |
| <b>Type of Protocol Deviations</b>  |           |           |                           |                        |             |
| Informed assent/consent process deviation                                   | 1 (8%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Did not meet eligibility criteria   | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Failure to follow trial randomization or blinding procedures                | 5 (42%)   | 1 (100%)  | 0 (-%)                    | 1 (50%)                | 0 (0%)      |
| Conduct of non  | 1 (8%)    | 0 (0%)    | 0 (-%)                    | 1 (50%)                | 0 (0%)      |
| Visit completed outside of window   | 1 (8%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Blood volume maximum exceeded   | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Study product management deviation  | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Study product dispensing error  | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Study product administration error  | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| AE/SAE/EAE reporting deviation  | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Physical assessment deviation   | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Lab assessment deviation  | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Specimen handling deviation   | 1 (8%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Behavioral intervention deviation   | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Breach of confidentiality   | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Staff performing duties that they are not qualified or delegated to perform | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Use of non  | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| IRB, ethics, or regulatory review deviation                                 | 0 (0%)    | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 0 (0%)      |
| Other   | 3 (25%)   | 0 (0%)    | 0 (-%)                    | 0 (0%)                 | 1 (100%)    |

## HPTN 106 Protocol Deviations Summary by Site

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|   | All Sites | Cornell Clinical Research | Atlanta - Hope Clinic | Boston - Fenway | Birmingham |
|---|-----------|---------------------------|-----------------------|-----------------|------------|
| <b>Participants Enrolled</b>  | 83        | 1                         | 18                    | 18              | 9          |
| <b>Number of Protocol Deviations</b>  | 12        | 0                         | 4                     | 3               | 1          |
| <b>Type of Protocol Deviations</b>  |           |                           |                       |                 |            |
| Informed assent/consent process deviation                                   | 1 (8%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 1 (100%)   |
| Did not meet eligibility criteria   | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Failure to follow trial randomization or blinding procedures                | 5 (42%)   | 0 (-%)                    | 0 (0%)                | 3 (100%)        | 0 (0%)     |
| Conduct of non  | 1 (8%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Visit completed outside of window   | 1 (8%)    | 0 (-%)                    | 1 (25%)               | 0 (0%)          | 0 (0%)     |
| Blood volume maximum exceeded   | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Study product management deviation  | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Study product dispensing error  | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Study product administration error  | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| AE/SAE/EAE reporting deviation  | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Physical assessment deviation   | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Lab assessment deviation  | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Specimen handling deviation   | 1 (8%)    | 0 (-%)                    | 1 (25%)               | 0 (0%)          | 0 (0%)     |
| Behavioral intervention deviation   | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Breach of confidentiality   | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Staff performing duties that they are not qualified or delegated to perform | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Use of non  | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| IRB, ethics, or regulatory review deviation                                 | 0 (0%)    | 0 (-%)                    | 0 (0%)                | 0 (0%)          | 0 (0%)     |
| Other   | 3 (25%)   | 0 (-%)                    | 2 (50%)               | 0 (0%)          | 0 (0%)     |