Overview of Protocol Deviations: Summary and Trends to Date

MTN Annual Meeting
ASPIRE Protocol Team Meeting
February 10, 2013
Introduction

- Review of PD reporting process
- Summary of ASPIRE PDs to date
- Trends
- Questions
PD Reporting Process

- **Identify the PD**
  - Prospectively
  - Retrospectively
  - Prior to occurrence

- **Document the PD**
  - Site staff
    - No stipulation on who must document it, as long as it is recorded in the participant’s study record
    - What works best at the site

- **Report the PD**
  - Complete PD CRF Log
# ASPIRE PD Summary and Trends

## Total ASPIRE PDs by Category

n=377

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study product management deviation</td>
<td>1</td>
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<tr>
<td>Study product use/non use deviation</td>
<td>79</td>
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<tr>
<td>Study product not returned</td>
<td>34</td>
</tr>
<tr>
<td>Conduct of non-protocol procedure</td>
<td>4</td>
</tr>
<tr>
<td>Improper AE/EAE follow-up</td>
<td>3</td>
</tr>
<tr>
<td>Unreported AE</td>
<td>4</td>
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<tr>
<td>Physical assessment deviation</td>
<td>44</td>
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<tr>
<td>Lab assessment deviation</td>
<td>11</td>
</tr>
<tr>
<td>Mishandled laboratory sample(s)</td>
<td>157</td>
</tr>
<tr>
<td>Questionnaire administration deviation</td>
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<tr>
<td>Use of non-IRB/EC-approved materials</td>
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<tr>
<td>Use of excluded con. meds, devices or non-study products</td>
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<tr>
<td>Informed consent process deviations</td>
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<tr>
<td>Visit completed outside of window</td>
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</tr>
<tr>
<td>Other</td>
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</tbody>
</table>
Summary and Trends

- 377 PDs reported thus far

- Three most commonly reported PDs
  1. Mishandled Laboratory Sample Deviation 42%
  2. Study Product Use/Non Use Deviation 21%
  3. Physical Assessment Deviation 11%

- Constitute 75% of all reported PDs in ASPIRE

- 2 PDs (~ .5%) have been reported to DAIDS as potential Critical Events thus far
Summary and Trends

- Mishandled laboratory sample(s), 42%
- All other reported PDs, 25%
- Physical assessment deviation, 11%
- Study product use/non use deviation, 21%
Summary and Trends

- FDA’s “Most Commonly Cited PD’s*” are:
  - Inappropriate enrollment (participant failed to meet eligibility criteria)
  - Physical assessment deviation (incomplete, incorrect, and/or missed assessment)
  - Laboratory evaluation deviation (incomplete, incorrect, missed evaluation and/or review of laboratory results/reports)
  - Study product non-adherence

* FDA site inspections occurring during 2008 and early 2009
Summary and Trends

- **Laboratory evaluation deviation**
  - Mishandled Laboratory Sample Deviation (42%)

- **Study product non-adherence**
  - Study Product Use/Non Use Deviation (21%)

- **Physical assessment deviation**
  - Physical Assessment Deviation (11%)
Breakdown of “Other” PDs
n=32

- Enrolled on menses: 10%
- Missed visit: 28%
- Product retrieval issue: 6%
- Wrong ring dispensed and inserted: 3%
- No pelvic when indicated/refusal (bleeding): 6%
- Participant scheduling obstacle (traveling, etc): 3%
- Visit scheduling error in clinic: 6%
- Temperature excursion (product): 38%
Questions & Discussion
Thank you!