Efficiencies for Data Collection in HABP/VABP Trials

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# Breakout Group Topics and Instructions

Three breakout groups – Three discussion topics:

1. **AE, SAE, and Concomitant medications**
2. **Inclusion and exclusion criteria, Med history, baseline characteristics**
3. **Visits and assessments: Vital signs/PE, Clinical labs, Exploratory data**

- Group 1 starts with Topic 1
- Group 2 starts with Topic 2
- Group 3 starts with Topic 3

Groups will rotate to the next topic in line as time permits, and try to discuss all 3 topics during the breakout period. Some topic discussions may take longer to complete.

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www.ctti-clinicaltrials.org
### Breakout Groups

Three breakout groups

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
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</thead>
<tbody>
<tr>
<td><strong>Discussion</strong></td>
<td>Sabrina Comic-Savic</td>
<td>Kirsty Reith</td>
<td>Mark Behm</td>
</tr>
<tr>
<td><strong>co-leads</strong></td>
<td>Charles Knirsch</td>
<td>Vance Fowler</td>
<td>Gary Noel</td>
</tr>
<tr>
<td><strong>Writers</strong></td>
<td>Pamela Tenaerts</td>
<td>Cheri Janning</td>
<td>Peter Hoffman</td>
</tr>
</tbody>
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Discussion Guide

- List data that are typically collected during HABP/VABP trials for each topic
  The HABP/VABP protocol summary, and FDA guidances may be used as an aid

- How can we limit the data collected without compromising quality?

- Consider:
  - What data/procedures don’t significantly impact data analysis or subject safety?
  - What data are critical to determining efficacy and safety of the drug?
  - What data are not critical? Are there redundancies that could be eliminated?
  - What data are dependent on the class of drug (e.g., specific risk for hepatotoxicity)
Classifying Data into Groups:

Critical  Not Critical  Class or Drug Dependent
The breakout groups will answer the following for each topic discussed:

1. What recommendations would you make to limit/streamline data collection based on your discussion today?

2. To whom within the clinical research enterprise would each recommendations apply? (e.g. investigator, regulator, sponsor, IRB, etc.)
Report Out Slides

Indicate Group (1, 2 or 3)

Presenter as determined by group
Recommendations: Topic 1

1.
   A.
   B.

2.
   A.
   B.
Recommendations: Topic 2

1.

A.

B.

2.

A.

B.
Recommendations: Topic 3

1.
   A.
   B.

2.
   A.
   B.