CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Breakout Sessions Guidelines and Topics for Discussion

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

Breakout Groups

Three breakout groups

	Group 1	Group 2	Group 3
Discussion co-leads	Sabrina Comic-Savic Charles Knirsch	Kirsty Reith Vance Fowler	Mark Behm Gary Noel
Writers	Pamela Tenaerts	Cheri Janning	Peter Hoffman

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

Report out: Breakout Group Recommendations

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.)**

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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.