What Did We Hear?

Session 1 Partnerships

- Many different models for collaboration
- Many different ways to collaborate
- Need for “evaluative science” involving broad research community
- Need for training in regulatory science
- Need to change the rewards to incentivize “team science”
- Consider “simplification” when possible
- Continue opportunities to share lessons

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What Did We Hear?

Session 2 Safety Biomarkers

- There has been much progress with biomarkers and with collaboration across multiple groups
- Many challenges – legal, logistical, cultural, regulatory, resources, achieving impact
- Need metrics, sustainability plans
- Positive attitude for future with recommendations made based on experience and data
- FDA's OTS has made huge progress: Letter of Support; enhancing the process (guidances, MaPPs, CPIM, etc.); several qualification decisions

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What Did We Hear?

Session 3 Data Sharing

- **Range of objectives for data sharing drives differences in implementation**
- **Competing requirements need to be addressed**
  - Need to comply with all applicable regulations
  - Need to protect patient privacy
  - Need to respect sponsor confidential information and intellectual property
  - Need to optimize utility of shared data
- **Complicated by access and use of data from multiple sources**
- **A wide range of data types need to be handled**
  - Clinical trial data, observational study data, registry data
  - Comprising genotypic, phenotypic, treatment, outcome data
- **Ability to share the organized and curated data with a wide range of researchers.**

Thank you for participating!

Good-bye

Au Revoir

Auf Wiedersehen

Adios

Ciao