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
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
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