Breakout Session Overview – Combinatorial NAMs

Unmet Regulatory Needs and/or Question of Interest Statements:

- What is a NAM?
  - **Could be anything, but needs to be defined for the intended use**
- What is a combinatorial NAM?
  - **Combo of different modalities (ex: in vitro + in silico)**
- Do individual NAMs need to be qualified prior to combinatorial?
  - **Establish technical aspects of each first, each method must perform as intended**
  - **No – combined approach**
- Use of combinatorial NAMs to reduce animal testing
  - **Reduce need for long-term animal studies**
- Best way to share data

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Opportunities:

- Use specific examples to create general guidelines
  - **Document lessons learned**
- Training program for reviewers – make process publicly available
- Provide resource for how to reduce animal testing (by species instead of endpoint)
- Meet with FDA to get advice
- FDA guidance/checklist (in process) – validation considerations for CIVM
- NAMs registry – increase awareness/access to information
  - **Database for methods that have been accepted – in process, live by SOT (end March)**
  - **FDA can only provide general guidance from what they have**
  - **Companies to provide their data**
  - **EU has database**
  - **3RsC + IQ**

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Gaps and Challenges:

- Validating AI/ML work
- FDA has limited information to provide thorough guidance
- Sharing proprietary data
- Data entry into shared databases