

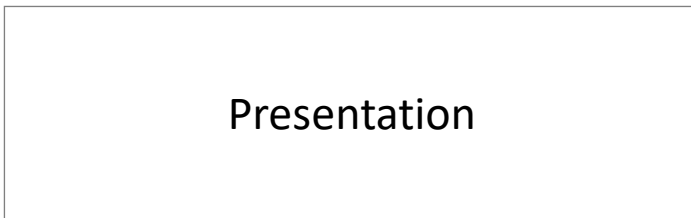
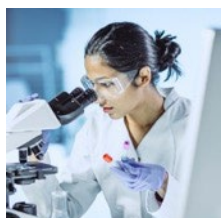
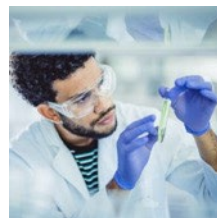
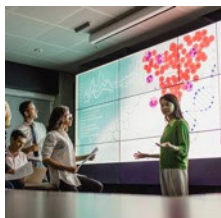


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# Evidence generation to advance regulatory excellence, preparing for tomorrow

Author: Lianna Ishihara Date: 18/11/2024



# EFPIA Statements

## Genetics/Genomics

- Opportunities for precision medicine and RWE to complement data in CTs with the increased availability of genetics/genomics data and advanced analytics methods
- Data sources with linkage of deep genetic, genomic and other biomarker data to detailed clinical data are extremely valuable to support drug discovery and development
- Need for fair and simple terms of access by industry researchers, as well as agreement on how to allow for linkage while maintaining data privacy (e.g. GDPR)

## Digital tools and mHealth

- Data standards to be developed and published
- Clarity on evidence generation requirements for regulatory submissions
- Clarity on regulatory submission expectations when used in clinical trials
- Maximise value for research
  - E.g. collect/analyse data on patient reported outcomes

# EFPIA Statements



## Social Media

- Balance the potential value of the data with consideration of noise and biases
- Clarify the acceptability and relative value of this type of supporting evidence in different scenarios
  - E.g. value for RCT recruitment while also ensuring diversity

**Concluding statement:** Overall interest in more timely and effective data access for industry researchers for drug discovery and development



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# Thank you

