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Streamlining Academic Research Through Meta-Analysis Enhanced by CDISC Standards Integration
Presented by Yen Phan, Founder and Sr. Clinical Data Scientist,

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Meet the Speaker

Yen Phan

Title: Founder and Sr Clinical Data Scientist

Organization: CodLad/University of Oxford

Yen Phan is a founder of CodLad and a Senior Data Scientist with over 10 years of experience in the industry. She has also been lecturing at Technological University Dublin, Ireland for 8 years on Pharma Science and Evidence based healthcare. At the same time, she is finalizing her dissertation at University of Oxford with a focus of a meta-analysis. She has been actively involved in CDISC standard implementation, she has given a speak at CDISC TMF Interchange in USA and she is on the Conference Co-ordinating Committee in the upcoming CDISC Interchange in Berlin 2024.

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Agenda

- 1. The importance of CDISC standards in academic research
- 2. Meta-Analysis in Academic Research and its challenges
- 3. Enhancing Meta-Analysis with CDISC Standards
- 4. Future of Research with CDISC

The importance of CDISC standards in academic research

Data harmonization and interoperability

 Provide a common framework for collecting, organizing, and sharing clinical research data

Improved data quality and consistency

 Define clear and consistent definitions for data elements, reducing the risk of errors and misinterpretations

Enhanced data sharing and collaboration

Facilitate data sharing and collaboration among researchers

Streamlined data analysis and visualization

 Enable researchers to more easily analyze and visualize their data using a variety of software tools

Increased data reusability and repurposing

Make data more reusable and repurposable for future research

Promotes regulatory compliance

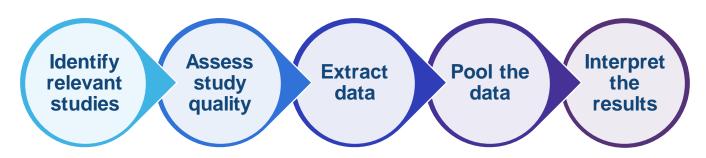
 Can help researchers expedite regulatory approvals and bring their findings to patients more quickly



Meta-Analysis in Academic Research

- Meta-analysis is a statistical technique that combines the results of multiple studies to come up with a more comprehensive and reliable understanding of a research topic.
- It is a powerful tool for synthesizing research findings and drawing stronger conclusions than would be possible from any single study.

Steps in a Meta-analysis





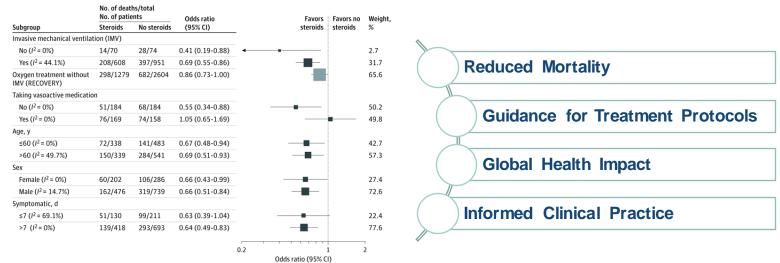
Role of Meta-analysis in Synthesizing Research Findings

Provides a more precise estimate of the effect of an intervention or treatment Helps to identify and explain heterogeneity Can be used to identify subgroup effects Can be used to inform clinical practice and policy decisions



Example: Association Between Administration of Systemic Corticosteroids and Mortality Among Critically III Patients With COVID-19A Meta-analysis

- Conducted by WHO; it was published in JAMA in 2021.
- Prospective meta-analysis that pooled data from 7 RCTs that evaluated the efficacy of corticosteroids in 1703 critically ill patients with COVID-19





Challenges in Meta-Analysis

- Scenario: Loop Diuretics and Weight Change in Heart Failure: A Meta-Analysis
- Being conducted at University of Oxford, pooling multiple IPD RCTs trial data from pharmaceutical companies



Challenges in Meta-Analysis



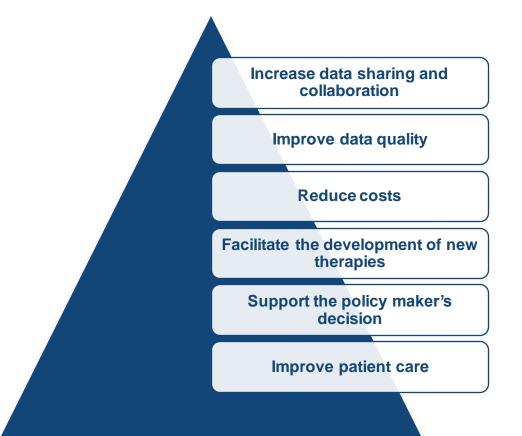


Enhancing Meta-Analysis with CDISC Standards

Provide standardized definitions for variables Heterogeneity Difficulties in and data elements across of Data Provide a standardized framework **Assessing** Formats and different studies **Study Quality** for documenting study design, **Definitions**/ procedures, and data collection methods Facilitate the sharing and exchange of IPD by providing a standardized format for storing and transferring IPD Inconsistent Limited Reporting of Access to IPD Covariates Include standardized definitions and collection guidelines for covariates Lack of MedDRA **Standardized Coding for AEs**



Future of Research with CDISC





CDISC is being used in academic research

- The Alzheimer's Association is using CDISC standards to collect and share data from its Alzheimer's Disease Neuroimaging Initiative (ADNI).
- The National Institutes of Health (NIH) is using CDISC standards to collect and share data from its many clinical trials.
- The Cancer Research Institute (CRI) is using CDISC standards to develop a database of cancer clinical trials.



Alzheimer's Disease Neuroimaging Initiative (ADNI)

- ADNI, launched in 2004, aims to develop and validate biomarkers for Alzheimer's disease through neuroimaging and biofluid analysis. It has undergone several phases, including ADNI1, ADNI-GO, ADNI2, and ADNI3.
- The Private Partners Scientific Board (PPSB), composed of industry, biotechnology, diagnostic, and non-profit organizations, has been instrumental in financing and providing scientific support to ADNI.
- The PPSB has established working groups that assess new technologies, platforms, and methods for potential adoption by ADNI.
- During ADNI2, a Database WG was formed, dedicated to common interests and issues for sponsors such as reconciliation of the clinical database. CDISC standards is used for the creation of a common relational database, and annotation of endpoints in the database.



Thank You!

