ISMPP University

The program will begin promptly at 11am EST

September 20, 2017

ISMPP International Society for Medical Publication Professionals™

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ISMPP Announcements

- **REGISTRATION NOW OPEN!** 2018 European Meeting of ISMPP, *Advancing Medical Publications in a Complex Evidence Ecosystem* January 23-24 in London
- **ONLY TWO WEEKS LEFT** to submit your abstract before the submission deadline for the European Meeting of ISMPP. Deadline is MONDAY, 2 OCTOBER 2017 at 5:00 PM EDT/10:00 PM GMT
- The ISMPP U Committee wants to hear from you! Groups or individual members can submit topic ideas via the ISMPP U proposal form located on the ISMPP U Committee page: http://www.ismpp.org/ismppu
- This ISMPP U has been approved for 1 ISMPP CMPP™ CE Credit

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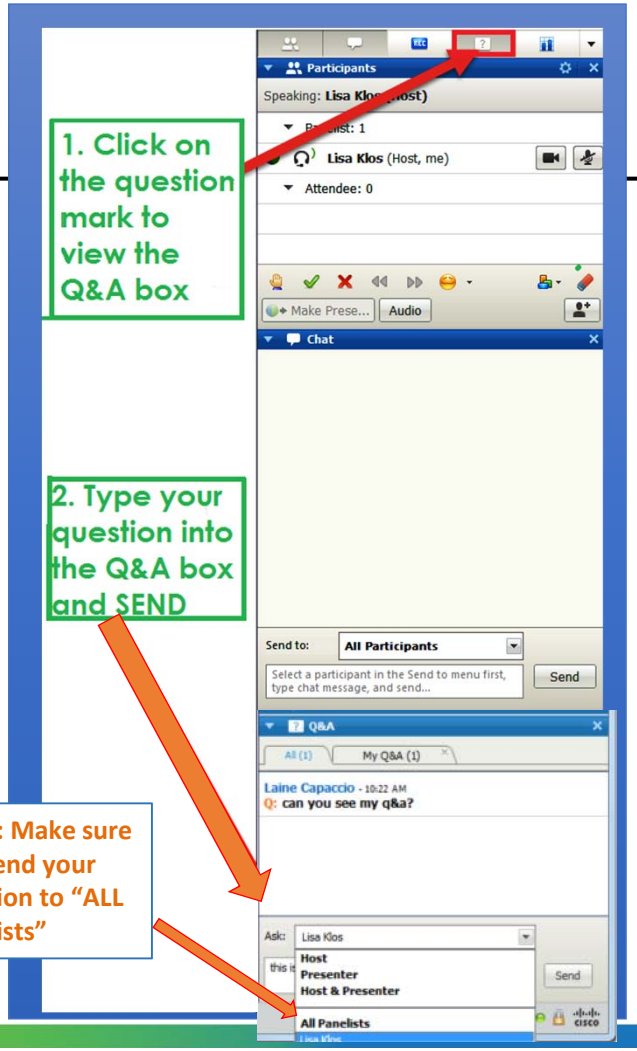
Questions

- To ask a question, please type your query into the Q&A box
  - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "ALL Panelists" Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions



NOTE: Make sure you send your question to "ALL Panelists"

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Introductions

- FACULTY: Bhakti Kshatriya is an author, speaker, and scientific communications expert with over 20 years' experience in scientific communications planning & implementation, spanning from pre-launch preclinical stage to launch and through end of product lifecycle, including Rx-to-OTC switch. Her recently published book, *Recoding Scientific Publishing: Raising the Bar in an Era of Transformation*, provides key insights into scientific publication planning, development and publishing process with a vision for further positive transformation. She is founder of Publication Practice Counsel™, Truposha LLC, an agency that provides scientific communication services to pharmaceutical, biotech and medical device companies, and academic institutions. Bhakti holds Doctor of Pharmacy degree from Rutgers University College of Pharmacy and BS in Pharmacy from Philadelphia College of Pharmacy & Science (now University of Sciences in Philadelphia).

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Introductions

- FACULTY: Karen Mittleman has been with the Sanofi Group since 2003 and was previously Senior Director/Publications Compliance Officer in the Medical Expertise and Innovation Department of Global Medical Affairs. Since 2016, her role as the Head of Publications within Data Dissemination in the Chief Medical Office is to oversee development and review of scientific and medical publications across the Global Business Units and R&D. She also works closely with Data Sharing and Trial Transparency groups within Sanofi for clinical trial data dissemination. Karen has nearly 20 years of experience in medical publication planning and development. She currently serves on the newly formed Transparency Committee of the International Society of Medical Publication Professionals (ISMPP).

  Karen received a BSc from Penn State University, a Masters degree in Exercise Physiology from San Diego State University, and a PhD in Environmental Physiology from Simon Fraser University, British Columbia, Canada. She was a National Research Council Resident Research Associate with the Diving Medicine Department, Naval Medical Research Institute in Bethesda, Maryland, and was a postdoctoral fellow in renal physiology at Rutgers University. She was an assistant professor in Exercise Science at Rutgers before moving to medical communications.

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Introductions

- MODERATOR: Robert J. Matheis is Executive Director and Head of Global Scientific Communications with Celgene located in Summit, NJ. He is Past President of ISMPP. Prior to joining Celgene, Dr. Matheis was Head of Evidence Based Medical Communications for Sanofi. He was trained as a clinical psychologist and obtained a masters degree in behavioral statistics. Dr. Matheis has over 14 years of medical research and communications experience in both government and industry. Dr. Matheis advocates for the evolution of medical communication tools to translate medical evidence for use by health care decision makers, providers, and patients. He champions innovation and novel technology in medical communications. Most recently, Dr. Matheis has been involved in conceptualizing and synthesizing performance indicators to support a strong value proposition for medical affairs organizations. Dr. Matheis has an extensive bibliography of scientific congress presentations and peer-reviewed publications across various disease states, in addition to research and publication accomplishments in alternative medicine and psychosocial factors impacting healthcare.

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EDUCATIONAL SERIES ON DATA & FINANCIAL TRANSPARENCY:

A Project of the ISMPP Global Transparency Committee

ISMPP International Society for Medical Publication Professionals™

Ask us about. . .

Our Initiatives

Financial Reporting Survey

How are companies currently managing **Sunshine Act** and **EFPIA**? WE asked.

Educational Series

Everything you ever wanted to know about publication financial and data transparency. All in one **modular slide deck**.

Publication Process Transparency

Communicating **standard processes** that companies now employ to ensure sound professional ethics in medical publishing.

who WE are

Robert J. Matheis, Chair

Bhakti Kshatriya
Karen Mittleman
Teresa Pena
Kalyan Pulipaka
Sonia Schweers
Brian Sharkey
Kevin Sharkey
Kanaka Sridharan
Julie Vandekerckhove
Christine Vanderlinden
Susan Wieting
Eric Yu

The ISMPP Global Transparency Committee

*Dedicated to **driving** member initiatives related to publication **data** and **financial** transparency*

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Agenda

- Overview of ISMPP Global Transparency Committee and initiatives
- Highlights of the educational series on data & financial transparency
- Q&A

Introduction

Bhakti Kshatriya, PharmD

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Current Transparency Landscape: Impact on Publication Professionals

- Many statements and guidance documents on data and financial transparency from different sectors, including government regulatory agencies and professional associations of biopharmaceutical industry and editors
- Each company's compliance and legal teams interpret differently the laws and devise recommendations to be followed by employees including publication professionals
- Different practice in different countries – not all countries in the emerging markets have laws for data and financial transparency
- Global guidance may not necessarily be aligned with local guidelines
- Need to ensure authors and sponsors are aware of their obligations, including disclosure and potential conflict of interest under these guidelines and keep up to date with advances in medical communications ethics and best practices.[1]

1. Medical writer Joint position by ISMPP, AMWA, EMWA http://www.ismpp.org/advocacy

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Educational Series Objectives

- This module serves as an educational reference primer for data and financial transparency. The objectives are to:
  1. Increase awareness among publication professionals on the various guidances/policies/standard processes that exist surrounding this topic
  2. Provide an overview of the different regulations in place in various countries
  3. Provide insight into ethical and compliant way of conducting and reporting clinical trial and other publications

Disclaimers

- This module is built as a reference guide to increase awareness among medical publication professionals on the various guidance/policies/standard process that exist.
- Providing details of every guideline/policy/standard process that is published is beyond the scope of this module, but a link is provided for additional reading
- Please refer to company policies on data and financial transparency. Any information provided in this module SHOULD NOT BE CONSIDERED AS A SUBSTITUTE FOR COMPANY POLICIES

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Educational Series on Data & Financial Transparency: Table Of Contents

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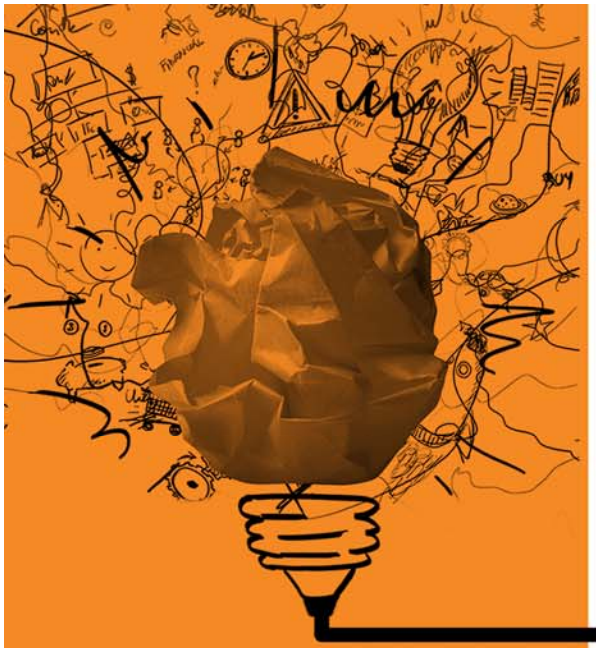
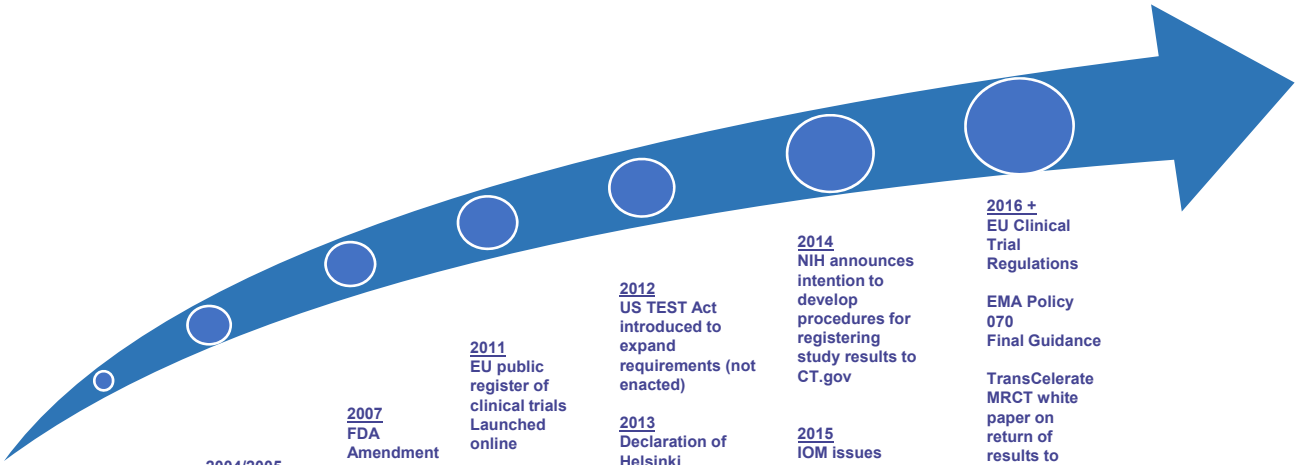


Data Transparency

Karen Mittleman, PhD

ISMPP International Society for Medical Publication Professionals

Escalating Demands for Clinical Trial Transparency, Data & Information Sharing



2000
Clinical Trials.gov Launched in US

2004/2005
ICMJE requirement registration of trials for consideration to publish

Pharmaceutical Joint Position on Public Disclosure (EFPIA/IFPMA/JPMA/PhRMA)

2007
FDA Amendments Act

2009 / 2010
Joint Position revised

Joint Position of Clinical Trial Results in Scientific Literature

2011
EU public register of clinical trials Launched online

US requires disclosure of results notification process during informed consent (in effect 2012)

2012
US TEST Act introduced to expand requirements (not enacted)

2013
Declaration of Helsinki Revised article 26

AllTrials Campaign Launched

PhRMA / EFPIA issued principles for responsible data sharing

2014
NIH announces intention to develop procedures for registering study results to CT.gov

2015
IOM issues report on sharing clinical trial data

EMA Policy 070 in effect

WHO endorses all results public

Bioethics Int'l – "Good Pharma Scorecard" published in *BMJ Open*

2016 +
EU Clinical Trial Regulations

EMA Policy 070 Final Guidance

TransCelerate MRCT white paper on return of results to clinical trial participants (input from EMA / FDA)

ICMJE data sharing statement for publication

NIH Final Rule Released

TrialsTracker and OpenTrials.net Launched

Modified from TransCelerate BIOPHARMA INC

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US Legal Requirements

- US Regulations
  - Food and Drug Administration Modernization Act of 1997 (FDAMA) – first U.S. Federal law to require trial registration
  - Food and Drug Administration Amendments Act of 2007 (FDAAA) - Section 801 (TITLE VIII—CLINICAL TRIAL DATABASES) – expanded the requirements for submission to ClinicalTrials.gov
    - Required registration of more types of trials; additional trial registration information; and submission of summary results, including adverse events, for certain trials
    - Included penalties for noncompliance

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

History, Policies, and Laws

Sources:
https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/fdama/default.htm;
https://www.clinicaltrials.gov/ct2/about-site/history

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EU Legal Requirements

- EU Regulations (European Medicines Agency)
  - EudraCT database was established in Article 11 of the Clinical Trial Directive 2001/20/EC
    - Contains information on interventional clinical trials on medicines conducted in the European Union (EU), or the European Economic Area (EEA) which started after 1 May 2004
    - EU Clinical Trials Register (EU CTR) launched to provide the public with information held in the EudraCT database
    - Since 2011, EU CTR is primary registry in the World Health Organization (WHO's) Registry Network
  - Updated regulation CTR EU No 536/2014 (effective June 16, 2014)
    - Requires sponsors to submit summary of results and lay person summary 1 year after the end of the trial in the EU
  - EU pharmaceutical legislation (Article 57 of Regulation (EC) No 726/2004 and Article 41 of the Paediatric Regulation (EC) No 1901/2006)
    - Allowed some of the information held in the EudraCT database is to be made public

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraCT

EU Clinical Trials Register

Sources:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=;
https://ec.europa.eu/health/human-use/clinical-trials/regulation_en
https://eudract.ema.europa.eu/
https://www.clinicaltrialsregister.eu/about.html

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Rest-of-world Legal Requirements

- Global Regulations
  - Many countries have their own legal requirements related to transparency commitments for marketed products that may supercede the FDA and EMA requirements
  - Understanding the local requirements and regulations is important

Medicines & Healthcare products Regulatory Agency

Портал о вашем здоровье МЕДИЦИНА meditsina.com

REPUBLIC OF SLOVENIA MINISTRY OF HEALTH

pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

国家食品药品监督管理总局 CFDA China Food and Drug Administration

mcc MEDICINES CONTROL COUNCIL

ansm The French National Agency for Medicines and Health Products Safety

Ministerio de Salud Gobierno de Chile

fimea

UNITED ARAB EMIRATES MINISTRY OF HEALTH & PREVENTION

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Data Transparency Global Standpoint

- Regulatory Action U.S. Department of Health and Human Services – “Final Rule”
- A complementary policy was also issued by NIH for registering and submitting summary results information to ClinicalTrials.gov for all NIH-funded trials, including those not subject to the final rule
- EMA guidance for industry

Friday, September 16, 2016

HHS takes steps to provide more information about clinical trials to the public

EUROPEAN MEDICINES AGENCY
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Overview
Research and development
Marketing authorisation
Advanced therapies
Accelerated assessment
Biosimilars

Home ▸ Human regulatory ▸ Marketing authorisation ▸ Clinical data publication

Clinical data publication

As of October 2016, the European Medicines Agency (EMA) publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. This is based on EMA's flagship policy on the publication of clinical data.

By proactively publishing clinical data, EMA intends to help:

- avoid duplication of clinical trials, foster innovation and encourage development of new medicines;
- build public trust and confidence in EMA's scientific and decision-making processes;

Source: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22129.pdf https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22379.pdf http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac05809f363e. Accessed on 14-Mar-2017

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Legal requirements: What Do These Mean for Publication Professionals?

- Be knowledgeable about what information is publicly available on registries to ensure consistency of data and methodology
- Understand when results will be posted to ensure optimal planning of primary publications of clinical trials
  - Putting results in clinical context rather than simply posting summary results
  - Explicitly describe *post-hoc* nature of analyses in publication
- Ensure cross-functional communication on publication plans (e.g., inform clinical trial transparency teams)
- Be familiar with legal requirements in regions in which you are supporting publication activities

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Voluntary Commitments on Data Transparency

- Joint Industry Position on the Publication of Clinical Trial Results in the Scientific Literature
  - Commitment of publication of clinical trial results
  - Timely publication as manuscript in scientific journals
  - Authorship, acknowledgement and disclosures

Source: http://www.ifpma.org/resource-centre/new-industry-position-requires-submission-for-journal-publication-of-all-phase-iii-clinical-trials/

Voluntary Commitments on Data Transparency

- Principles for Responsible Clinical Trial Data Sharing
  - Guidance to biopharmaceutical companies on sharing clinical trial information to researchers, patients, and members of the public
  - Q&A

PhRMA RESEARCH • PROGRESS • HOPE

efpia European Federation of Pharmaceutical Industries and Associations

Source: http://transparency.efpia.eu/responsible-data-sharing

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External Influences
ICMJE

Annals of Internal Medicine

EDITORIAL

Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

- Authors required to provide data sharing statements as condition of consideration for publication of clinical trial results
- More details provided in the 'Patient-level Data Sharing' section

http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf

External Influences
Declaration Of Helsinki

Clinical Review & Education

Special Communication

World Medical Association Declaration of Helsinki
Ethical Principles for Medical Research
Involving Human Subjects

World Medical Association

- The World Medical Association developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data

World Medical Association, World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013 Nov 27;310(20):2191-4

External Influences WHO

- WHO calls for increased transparency in medical research
  - Decisions related to safety and efficacy of vaccines, drugs and medical devices for use by populations should be supported by best available evidence[1]
- International Clinical Trials Registry Platform (ICTRP)
  - In 2017, ICTRP released the Joint Statement on Public Disclosure of Results from Clinical Trials proposing common elements of funding agencies' policies on results reporting which include registration, timely reporting of results, data sharing, etc. They also identified need for establishing monitoring[2]

World Health Organization

[1]http://www.who.int/mediacentre/news/notes/2015/medical-research-transparency/en/
[2]http://www.who.int/ictrp/results/jointstatement/en/

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External Influences AllTrials

- AllTrials campaign was launched in January 2013 and calls for all past and present clinical trials to be registered and their results reported.
  - Developed TrialsTracker tool to assess trials on ClinicalTrials.gov that haven't published results two years after the end of the trial[1]
  - Examined and compared published company policies on trial transparency[2]

+AllTrials

http://www.alltrials.net/

[1] https://f1000research.com/articles/5-2629/v1
[2] http://www.bmj.com/content/358/bmj.j3334

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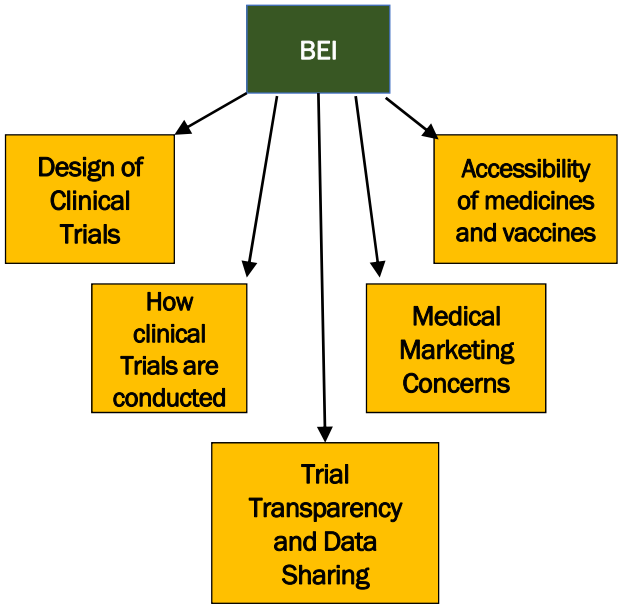
External Influences OpenTrials.net

- An open, online database of information about the clinical research trials worldwide, designed to increase transparency and improve access to research
  - To increase discoverability, facilitate research, identify inconsistent data
  - Enable audits on the availability and completeness of the information
  - Support advocacy for better data, and drive standards around open data in evidence-based medicine

https://okfn.org/press/releases/open-trials-open-knowledge-announces-plans-open-online-database-clinical-trials/

External Influences
Bioethics International (BEI)

- **Mission:** To advance patient and global public health by improving the ethics, transparency, patient-centricity, and governance of healthcare innovation and delivery
- Developed Good Pharma Scorecard that ranks large pharma companies and every new FDA approved drug on key ethics, human rights, and public health criteria



http://bioethicsinternational.org/good-pharma-scorecard-overview/ethics-transparency/

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External Influences
MPIP

MPIP | MEDICAL PUBLISHING INSIGHTS & PRACTICES

https://www.mpip-initiative.org/

- MPIP is a collaboration among members of the pharmaceutical industry and the International Society for Medical Publication Professionals (ISMPP)
- MPIP recently launched *MPIP* *Transparency Matters* and a companion site "What Transparency Means to Me" which are designed to broaden the conversation around transparency in medical publications, promote best practices, and engage interested parties in this important mission

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Types of Disclosures

Bhakti Kshatriya, PharmD

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Clinical Trial Registration & Results Posting

Registration in publicly accessible database

- WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/network/primary/en/)
  - Includes registries from different countries that meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration.
  - Primary Registries meet the requirements of the ICMJE.
- Other major registries:
  - US NIH ClinicalTrials.gov (https://clinicaltrials.gov/)
  - EudraCT (European Union Drug Regulating Authorities Clinical Trials) (www.clinicaltrialsregister.eu/)
  - ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) (www.encepp.eu/)

Zarin D, et al. *N Engl J Med* 376;4 nejm.org January 26, 2017. Accessed: http://www.nejm.org/doi/full/10.1056/NEJMsr1601330

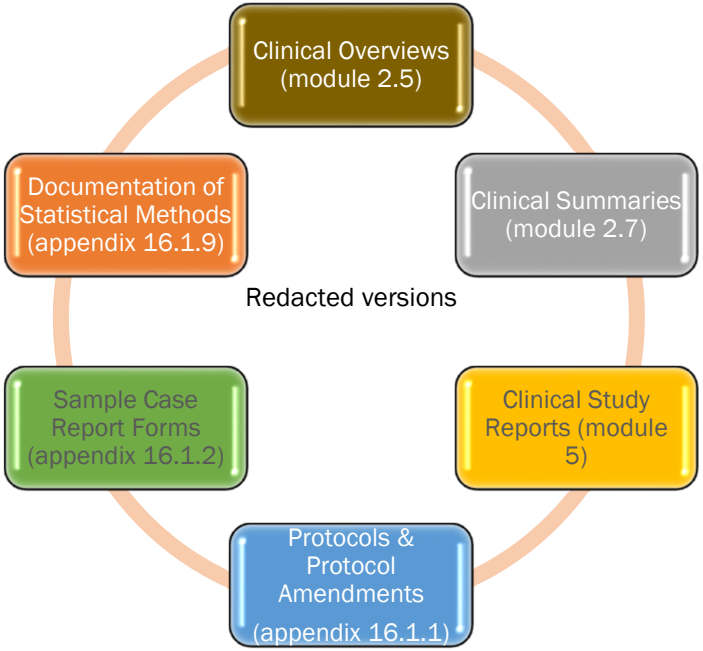
EU Policy 70 Background

- In 2014, the European Medicines Agency (EMA) released its policy (often referred to as EU Policy 70) on:
  - Publication of clinical trial data for human medicines "once the decision-making process on an application for a European Union (EU)-wide marketing authorization is complete"
  - Regardless of whether the drug receives EU regulatory approval
- Goals:
  - Increased transparency to improve public trust & confidence in EMA's decision-making process
  - Avoid duplication of clinical trials
  - Help researchers to re-assess clinical data
- Clinical data defined as:
  - Clinical reports
  - Individual patient data (IPD)

1. EMA Clinical Data Publication. Accessed: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac05809f363e
2. EU Policy 70. Accessed: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

EU Policy 70
Clinical Reports – Types Of Documents

Companies are expected to provide EMA with redacted versions (i.e., removal of personal data/information and commercially confidential information) of the documents for public posting.



EU Policy 70. Accessed: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

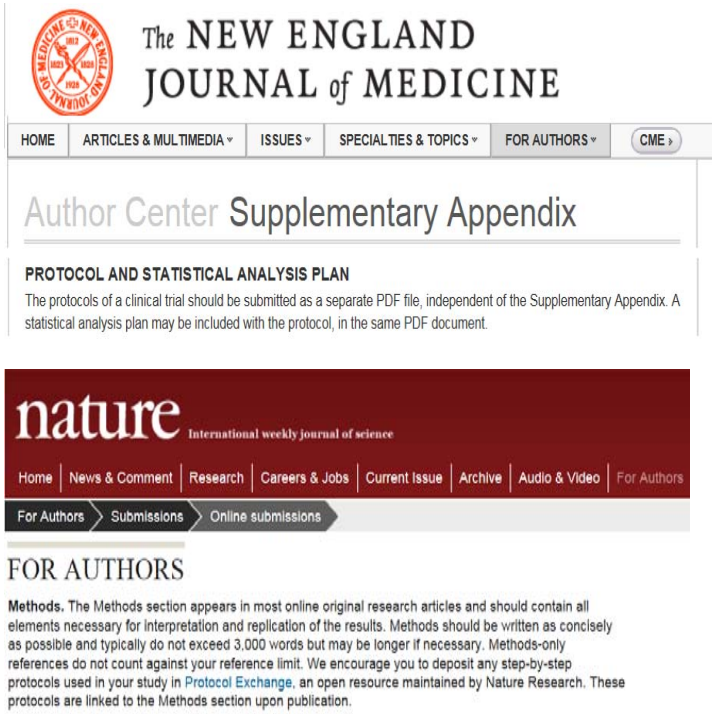
Journal Requirements
Registration of Trials on Public Registry

- Registration of clinical trials on public registry improves full transparency on performance and reporting of clinical trials,[1] including completeness, reliability, and quality of the interpretation of clinical research[2]
- ICMJE does not advocate one particular registry, however the member journals require authors to register their trial in a registry that meets several criteria[1]
- Several public registries are available such as clinicaltrial.gov[3], ISRCTN Registry[4], EU Clinical Trials Register[5]

1. Catherine De Angelis et al. **Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors.** N Engl J Med 2004; 351:1250-1251.
2. Charlotte Haug et al. **Registries and Registration of Clinical Trials.** N Engl J Med 2005; 353:2811-2812
3. *https://clinicaltrials.gov/*
4. https://www.isrctn.com/
5. https://www.clinicaltrialsregister.eu

Journal Requirements on Supplementing Study Protocols

- Several journals ask for study protocols while submitting the manuscript, which may or may not be published
- Requirements for protocol submission and policy for publishing the protocols may varies between the journals (for example)
  - NEJM: The protocols of a clinical trial should be submitted as a separate PDF file, independent of the Supplementary Appendix
  - Nature encourage to deposit any step-by-step protocols used in the study



- http://www.nature.com/nature/authors/submissions/subs/. Accessed on 1-Apr-2017
- http://www.nejm.org/page/author-center/supplementary-appendix. Accessed on 1-Apr-2017

Patient-level Data Sharing

Karen Mittleman, PhD

ISMPP International Society for Medical Publication Professionals

Patient-level Data Sharing NIH

- All data should be considered for data sharing.
- Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data
- Investigators submitting a research application requesting $500,000 or more of direct costs in any single year to NIH are expected to include a plan for sharing final research data for research purposes, or state why data sharing is not possible

Source: https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

Patient-level Data Sharing Voluntary Commitments

PhRMA
RESEARCH • PROGRESS • HOPE

efpia
European Federation of Pharmaceutical Industries and Associations

- Biopharmaceutical companies commit to sharing upon request from qualified scientific and medical researchers patient-level clinical trial data while protecting patient privacy
- Resulted in development of mechanisms for sharing patient level data through www.clinicalstudydatarequest.com, YODA, SOAR [see details in later section]

Source: http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf

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Patient-level Data Sharing IOM Report

The National Academies of SCIENCES ENGINEERING MEDICINE — HEALTH AND MEDICINE DIVISION

- In 2015, IOM released their report on guiding principles and a framework for responsible sharing of clinical trial data
- Guiding Principles
  - Maximize benefits while minimizing the risks of sharing clinical trial data
  - Respect individual participants whose data are shared
  - Increase public trust in clinical trials and the sharing of trial data
  - Conduct the sharing of clinical trial data in a fair manner
- Proposed timelines for sharing data

Source: https://www.nap.edu/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk

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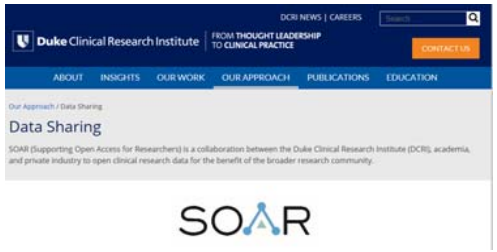
Patient-level data sharing WHO Joint Statement

- We will continue to engage with partners in support of an enabling environment to allow data sharing to maximize the value of health research data. We will support activities that enable the development of explicit ethical and legal frameworks that govern data collection and use and enable development of international norms and standards for sharing of IPD from clinical trials.

Available at:
http://www.who.int/ictrp/results/jointstatement/en/

Data sharing for INDUSTRY-sponsored Trials

- Multi-company sponsored platform – www.clinicalstudydatarequest.com
  - 13 participating companies (Astellas, Bayer, Boehringer Ingelheim, Daiichi Sankyo, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB, ViiV)
  - Each company retains its own study listing criteria and requirements for data sharing
  - Review & approval of data requests by independent review panel
  - Completion of data sharing agreement prior to access to data
  - Access to data on secure web portal
- Industry partnerships with academia
  - Yale University Open Data Access (YODA) - http://yoda.yale.edu
    - 3 participating companies (Johnson & Johnson, Medtronic, SI-BONE)
    - Review & approval of data requests by independent review panel
  - Duke Clinical Research Institute (DCRI)'s Supporting Open Access for Researchers (SOAR) - https://www.dcri.org/our-approach/data-sharing/
    - Participating company – BMS
    - Review & approval of data requests by independent review panel
- Individual company websites



Vivli Project: Centralized Platform for Data Sharing In Development

- Sponsored by Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University (MRCT Center)
- Key elements
  - Centralized platform that pulls information from existing data sharing platforms and communities
  - Serve as hosting platform for researchers who wish to share data but lack resources to do so
- Proposed requirements for data sharing
  - Completion of data use agreement
  - Hosted data must be anonymized according to risk based international anonymization standards for deidentification
  - Data access upon request – to be reviewed & approved by independent review panel
  - All data sets will have digital object identifiers (DOI) and linked to original data generators via ORCID
  - Access to data in secure environment
- For more details, visit www.vivli.org

Bierer BE et al. A global, neutral platform for sharing trial data. *NEJM* 2016;374(25):2411-2413.

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Patient-level Data Sharing ICMJE

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

- As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement
- Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration
  - If data sharing plan changes after registration, this should be updated in the registry record accordingly, and reflected in the statement submitted and published with the manuscript
- Data sharing statements must indicate the following:
  - Whether individual deidentified participant data (including data dictionaries) will be shared
  - What data in particular will be shared
  - Whether additional, related documents will be available (study protocol, statistical analysis plan, etc)
  - When the data will become available and for how long
  - By what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism)

Source: Taichman DB, et al. *Ann Intern Med.* 2017;167(1):63-65. doi: 10.7326/M17-1028 (Published 6 June 2017). Accessed: http://annals.org/aim/article/2630766/data-sharing-statements-clinical-trials-requirement-international-committee-medical-journal

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Proposal for Authorship Credit on Publications from Data Sharing Analyses: MRCT/AAMC

- With increasing call for data sharing, there needs to be appropriate and standardized approach for providing credit to data generators
  - Ensure fairness and provide incentive for data sharing
- Propose a system of recognition for data generators that is standardized and distinct from designation of authors of peer-reviewed journal articles
- Propose using the term 'data author' as credit for data generators
  - "substantial contributions to the original acquisition, quality control, and curation of the data, be accountable for all aspects of the accuracy and integrity of the data provided, and ensure that the available data set follows FAIR Guiding Principles"
- A number of possible scenarios on how to provide credit to data generators, who may or may not have served as collaborators on data sharing analyses, have been outlined in the editorial

MRCT: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard University; AAMC: Association of American Medical Colleges
Source: Bierer BE, Crosas M, Pierce H.H. *N Engl J Med* 2017; 376:1684-1687. DOI: 10.1056/NEJMsb1616595. Accessed: http://www.nejm.org/doi/pdf/10.1056/NEJMsb1616595.

Publications from Data Sharing Studies

- Proposed Additions to Journal Instructions for Manuscripts Derived from Shared Datasets

1. The cover letter for submissions of manuscripts based on shared data must disclose:

- The manuscript is based on shared data.
- Whether the research plan is publicly available.
- Whether the research plan was peer reviewed for scientific validity.
- Whether the statistical analysis code is publicly available to allow replication of findings.
- Whether the submitted manuscript was reviewed or approved by the investigators of the original study.
- Any relationships with industry relevant to the manuscript.

2. The abstract should:

- State that the data were derived from a shared dataset.

3. The Methods section should:

- Indicate that the analyses were based on shared data.
- Concisely describe how the data were obtained.
- Specify the version of the study dataset that was used.
- Disclose the relationship, if any, between the authors of the manuscript and the investigators of the original study.
- Describe the human subjects and ethics approvals for the analyses performed.

4. The Discussion section should:

- Address any differences in results or conclusions from those previously published by the original study.
- Include a disclaimer that the analyses and conclusions are those of the authors, and do not necessarily represent the opinions of either the original study investigators or the study sponsor

Hlatky MA, Januzzi JM. Manuscripts Based on Datasets Shared by Clinical Research Studies. *J Am Coll Cardiol*. 2017;69(15):1983-1985.

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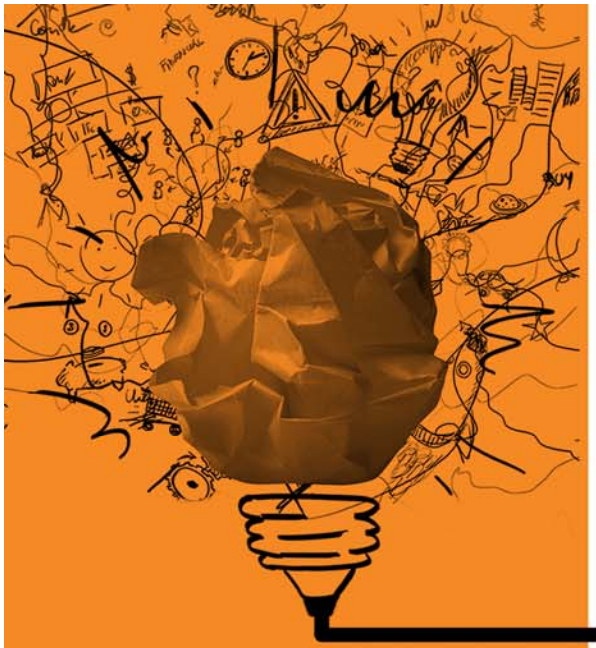

Financial Transparency

Bhakti Kshatriya, PharmD

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What is Financial Transparency?

- Financial transparency means disclosure of any financial relationship and business transactions that exists between physicians and healthcare industry
- Variety of forms of relationship including
  - Payments for consultancy services
  - Compensation received as an investigator for a trial by the sponsoring company
  - Travel reimbursement to present at a medical congress (or attend a congress- applies to ex-US physicians)
  - Physicians investment in a life science company including stocks

Perry JE et al. Trust and transparency: patient perceptions of physicians' financial relationships with pharmaceutical companies. J Law Med Ethics. 2014;42:475-91
FDA guidance on financial disclosure. Feb 2013 report https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

Why the Need to Disclose?

- Physician payment can adversely affect patient trust
  - *"wide-ranging financial ties to industry may unduly influence professional judgments involving the primary interests and goals of medicine. Such conflicts of interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public's trust in medicine".*
    - Institute of Medicine, COI committee

■■■■■ *In response*

Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Washington (DC): National Academies Press (US); 2009. Summary. Available from: https://www.ncbi.nlm.nih.gov/books/NBK22926/

Klein E, et al. Physician compensation for industry-sponsored clinical trials in multiple sclerosis influences patient trust. *Mult Scler Relat Disord*. 2016;8:4-8.

US Sunshine Act

- Congress passed the Patient Protection and Affordable Care Act (ACA) in March 2010
- Opportunity to mandate greater transparency regarding these financial relationships
  - by including a provision known as the Physician Payment Sunshine Act (Sunshine Act)
- Final rule published in 2013

Affordable Care Act. Section 6002. Final Rule 2013
https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf

US Sunshine Act – Requirement

- Requires pharma companies and medical devices manufacturers that participate in government-funded healthcare programs to **record and report payments** and **transfers of value** to healthcare professionals and teaching hospitals
- A central reporting system set up by the Centers for Medicine and Medicaid (CMS), and the information available on a public website. https://www.cms.gov/openpayments/

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Financial Transparency – Voluntary Efforts

- The European Federation of Pharmaceutical Industries and Associations (EFPIA) established a common transparency framework by adopting a voluntary code for companies to report transfers of value to health care professionals (HCPs)- http://transparency.efpia.eu/the-efpia-code-2
- EFPIA represents the interests of around 1,900 pharmaceutical companies operating in Europe.
  - National pharmaceutical industry associations in the following 33 European countries are members of EFPIA: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, the Russian Federation, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom. http://transparency.efpia.eu/codes-of-conduct/countries

Summary

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Summary

- This module serves as a reference guide to increase awareness among medical publication professionals on the various guidances/policies related to:
  - Clinical Trial Disclosure
  - Data Sharing
  - Financial Transparency
- Please refer to company policies on data and financial transparency. Any information provided in this module SHOULD NOT BE CONSIDERED AS A SUBSTITUTE FOR COMPANY POLICIES

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Thank You

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Questions

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, **ALL** audience members will be able to see your submitted question

Thank You for Attending!

- We hope you enjoyed today's presentation. Please check your email for a link to a survey that should take only a few minutes to complete. We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!

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