ENGAGING WITH ISMPP TO PROMOTE GOOD PUBLICATION PRACTICES

LEARNING OBJECTIVES

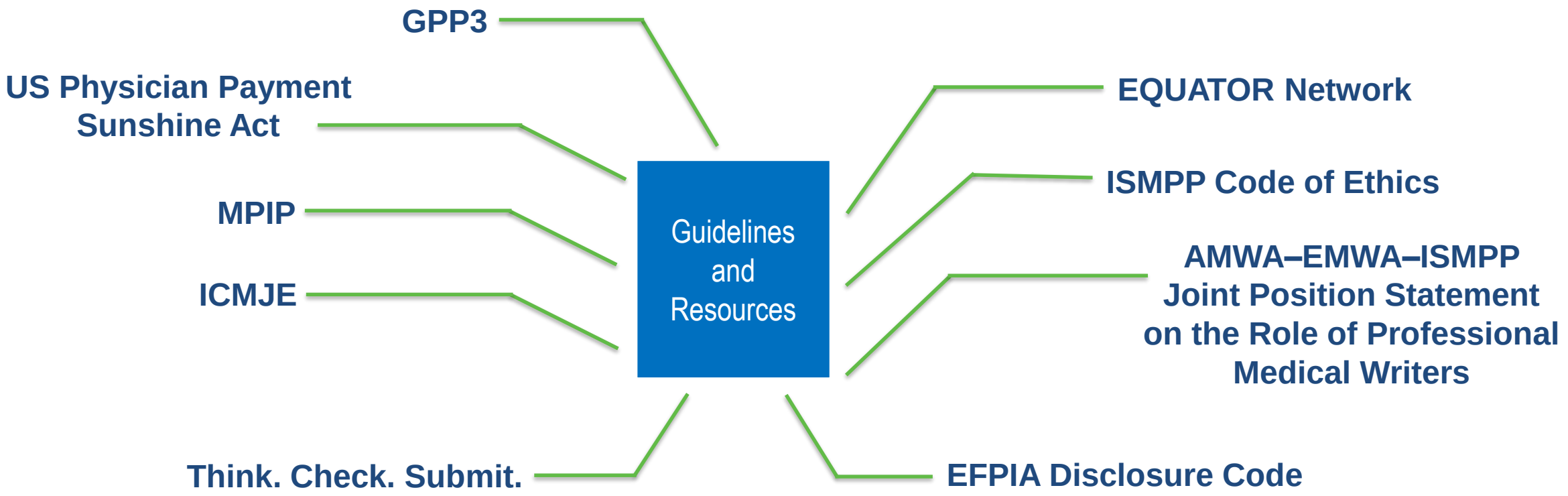
By the end of this session, you should:

- Be familiar with good publication guidelines and resources
- Know how to access key guidelines and resources
- Understand how ISMPP can help your organization adhere to good publication practices

MEDICAL PUBLICATIONS IMPACT RESEARCH, HEALTHCARE, PRACTICE STANDARDS, AND PATIENT CARE

Guidelines establish/reinforce best industry practices to advance scientific and medical research		
Unbiased, data-driven publications	Transparency (data, authorship, contributors)	High documentation standards

CURRENT TRANSPARENCY LANDSCAPE: AVAILABLE GUIDELINES AND RESOURCES



Medical writer Joint position by ISMPP, AMWA, EMWA http://www.ismpp.org/advocacy; ICMJE, International Committee of Medical Journal Editors; MPIP, Medical Publishing Insights & Practices; Sunshine Act, Physician Financial Transparency Reports; EQUATOR, Enhancing the QUAlity and Transparency Of health Research; ISMPP, International Society for Medical Publication Professionals; AMWA, American Medical Writers Association; EMWA, European Medical Writers Association; EFPIA, European Federation of Pharmaceutical Industries and Association.

GOOD PUBLICATION PRACTICE GUIDELINES ARE CONSTANTLY EVOLVING

Good Publication Practice (GPP) guidelines were developed with the aim of ensuring that "clinical trials sponsored by pharmaceutical companies are published in a responsible and ethical manner"

GPP guidelines were first published in 2003 and have been updated twice: in 2009 (GPP2) and in 2015 (GPP3)

New topics addressed in GPP3[1] include:

Direction on the most recent ICMJE authorship criteria	Frequent issues regarding authorship	Better clarity on author payment and reimbursement	Explanation as to what constitutes ghost writing or guest authorship	Role and advantages of professional medical writers	Guidance for appropriate data sharing

[1] GPP3 Guidelines, 2015. The International Society for Medical Publication Professionals. http://www.ismpp.org/gpp3. Accessed March 13, 2018.

ISMPP CULTIVATES EXCELLENCY IN PROFESSIONAL ETHICS AND ENCOURAGES MEMBERS TO MEET SUCH STANDARDS

ISMPP supports medical publication professionals and fosters the highest medical publication planning and development practices worldwide

ISMPP has established standards to serve members with ethical principles as a resource for professionals

- ❑ Members should act in a manner that promotes integrity and reflects positivity on the individual, profession, ISMPP, and the medical publication profession, consistent with accepted ethical and legal principles
- ❑ Released in 2011 and revised in 2016

[1]CODE of ETHICS for MEDICAL RESEARCH PUBLICATION. The International Society for Medical Publication Professionals. http://www.ismpp.org/code-of-ethics-a. Published November 1, 2016. Accessed March 13, 2018.

ICMJE STRIVES TO IMPROVE THE QUALITY OF MEDICAL SCIENCE AND ITS REPORTING

- Medical journal editors meet yearly to work on the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals[1]

ICMJE will require the following as conditions of consideration for publication of a clinical trial report in member journals[2]:

- 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*

ICMJE recommends that data sharing statements will need to indicate[2]:

- ❑ If individual de-identified participant data and data dictionaries will be shared
- ❑ Specific data that will be shared
- ❑ If related documents will be available, such as study protocols and/or statistical analysis plans
- ❑ The availability of data and how long it will be available
- ❑ Which access criteria data will be shared (including with whom, for which analysis types, and by what mechanism)

*The ICMJE's policy regarding trial registration is explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. Accessed March 12, 2018. [1]About ICMJE. ICMJE | About ICMJE. http://www.icmje.org/about-icmje. Accessed March 12, 2018.
[2]http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html#two. Accessed March 12, 2018.

MPIP ENCOURAGES AN EFFECTIVE AND TRANSPARENT PARTNERSHIP BETWEEN JOURNALS AND SPONSORS

MPIP Initiatives and Resources

Authors' Submission Toolkit: A Practical Guide to Getting Your Research Published
http://www.mpip-initiative.org/toolkit.html

Enhancing Transparency and Efficiency in Reporting Industry-Sponsored Clinical Research: Report From the Medical Publishing Insights and Practices Initiative
http://onlinelibrary.wiley.com/doi/10.1111/j.1742-1241.2010.02416.x/full

Recommendations to Improve Adverse Event Reporting in Clinical Trial Publications: A Joint Pharmaceutical Industry/Journal Editor Perspective
http://www.mpip-initiative.org/adverse_events.html

Five-Step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-Sponsored Clinical Trial Publications
http://www.mpip-initiative.org/5-step-framework.html

Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research: A Joint Journal and Pharmaceutical Industry Perspective
http://www.mpip-initiative.org/recommendations.html

MPIP-IDENTIFIED APPROACHES THAT NEED TO TAKE PLACE TO ADDRESS THE CREDIBILITY GAP

Results of industry-sponsored research should be reported with[1]:

- Trust
- Transparency
- Integrity

10 Recommendations to close the credibility gap[2]

Answer clinically important questions	Report all results	Improve COI disclosure	Educate authors on manuscript development	End ghost writing and guest authorship
Improve adverse event reporting	Provide access to protocols	Report statistical methods transparently	Ensure authors can access study data	Support sharing of prior reviews

[1]Medical Publishing Insights and Practices Initiative (MPIP). The International Society for Medical Publication Professionals. http://www.ismpp.org/mpip. Accessed March 13, 2018.
[2]Mansi BA, Clark J, David FS, et al. Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective. *Mayo Clin Proc*. 2012;87(5):424-9. doi:10.1016/j.mayocp.2012.02.009.

FIVE-STEP AUTHORSHIP FRAMEWORK ENCOURAGES BETTER DECISION-MAKING BY AUTHORS[1]

Authorship Framework Overview

- Create an authorship working group of core trial contributors before accepting patients for trial
- Based on the ICMJE authorship criteria and the specific trial, clearly communicate which authorship contributions will qualify as significant and substantial
- Create a transparent process to track and document individual progress toward substantial contributions based on set qualifications
- Evaluate the trial contributions process for a specific study and invite those making a significant contribution to join as author(s)
- ICMJE authorship criteria should be met by all authors from start to finish of the publication

[1]MPIP. Five-step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-Sponsored Clinical Trial Publications. https://www.mpip-initiative.org/5-step-framework.html. Accessed March 13, 2018.

THE SUNSHINE ACT INCREASES FINANCIAL TRANSPARENCY WORLDWIDE

The Sunshine Act Task Force and Global Transparency Committee were established by ISMPP to meet several objectives

- Follow the financial and transparency issues in both the US and globally
- Understand the details and requirements of the US National Physician Payment Transparency Program: Open Payments
- Provide information and tools for membership with respect to the implications of the Sunshine Act and other financial/ transparency regulations affecting medical publications

THE EQUATOR NETWORK IS A RESOURCE FOR REPORTING GUIDELINES

EQUATOR Reporting Guideline Decision Tree
Which guidelines are relevant to my work?

Goal: Strengthen the quality and transparency of medical research

Flow chart helps authors, editors, and peer reviewers identify the appropriate checklist and reporting guideline

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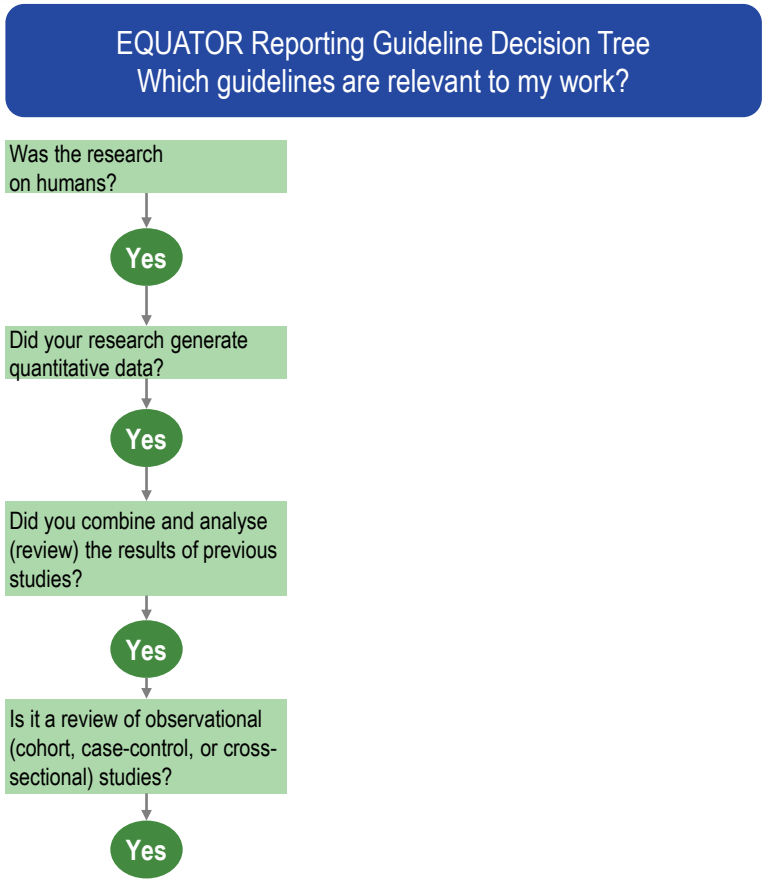

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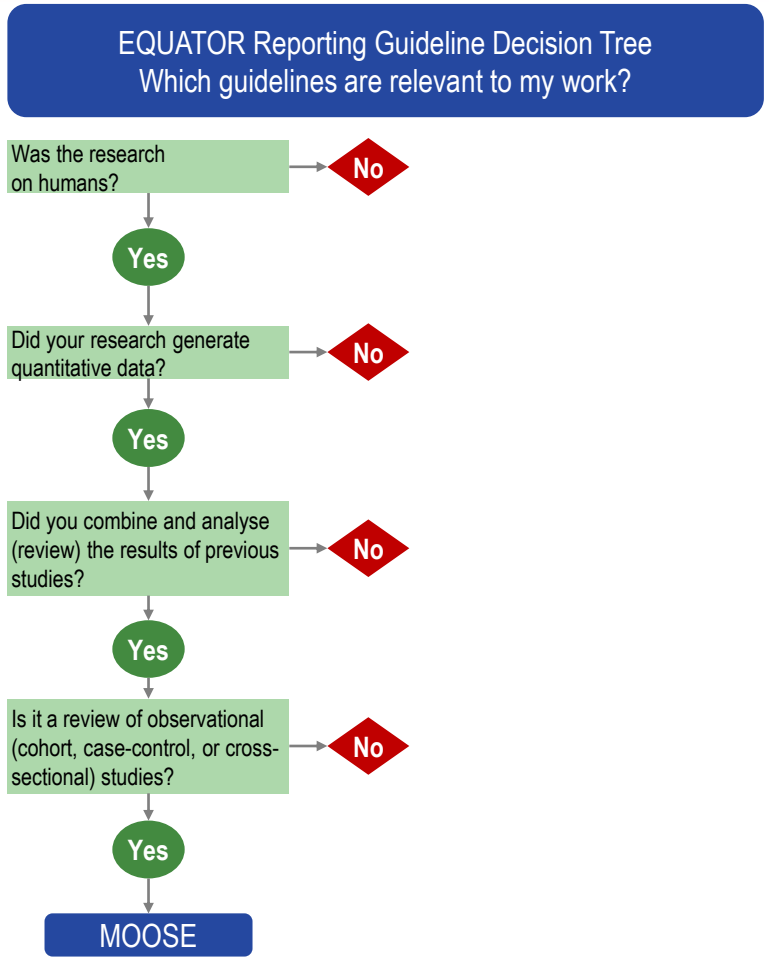

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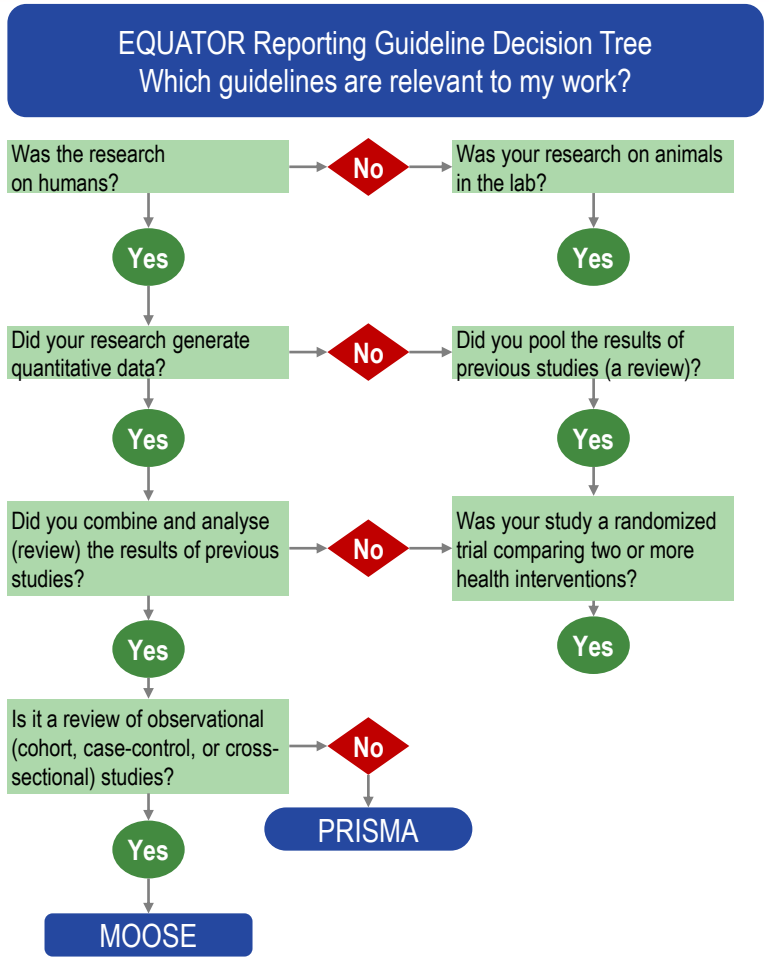

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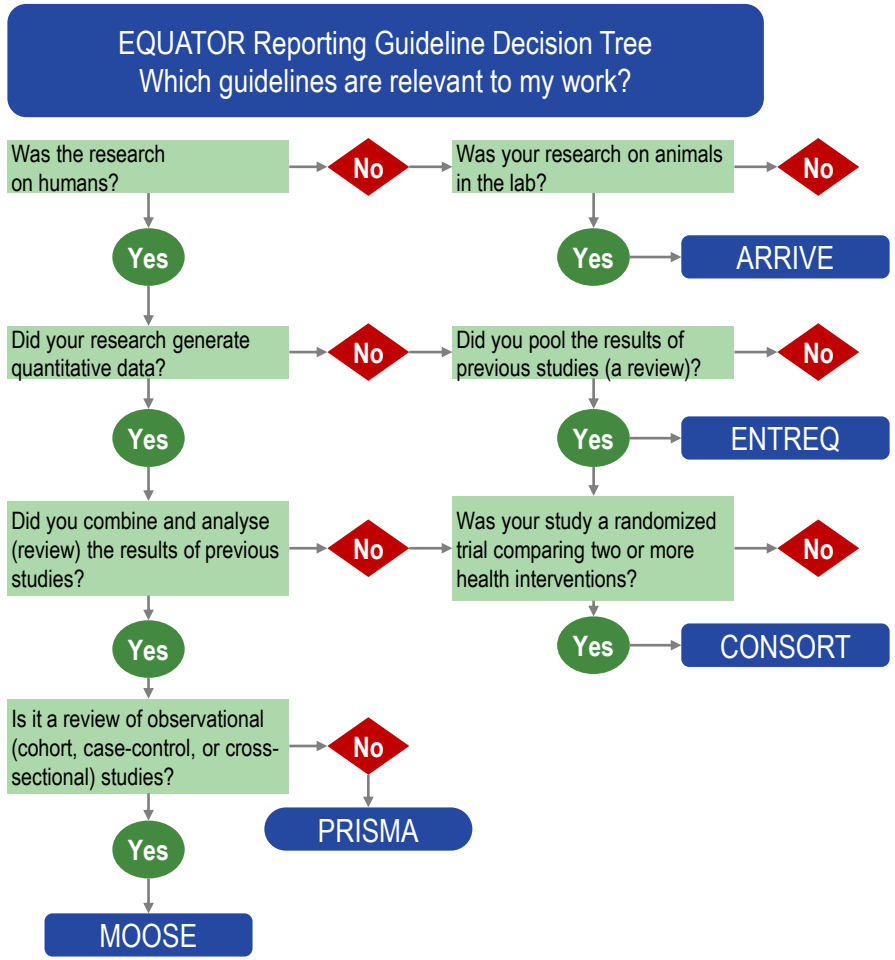

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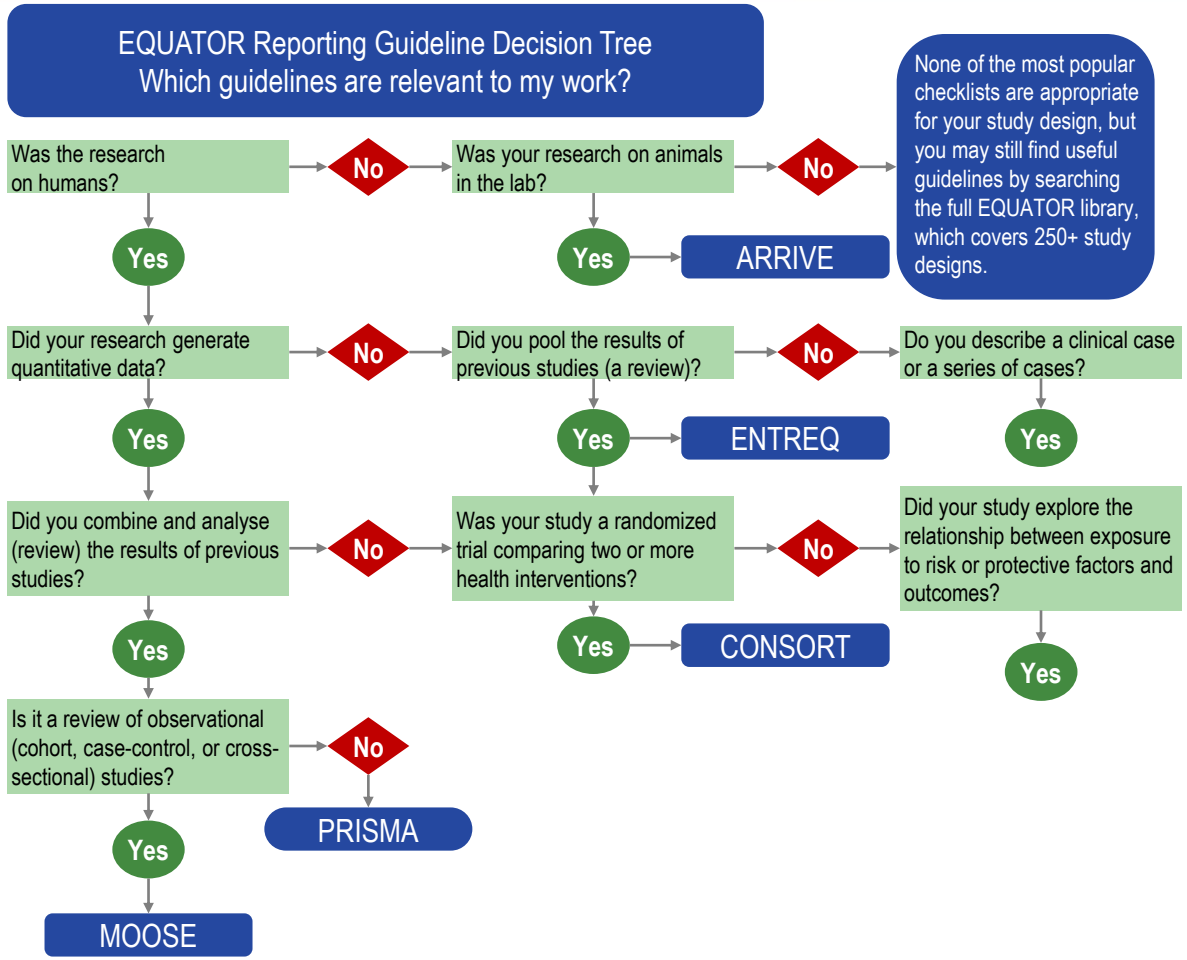

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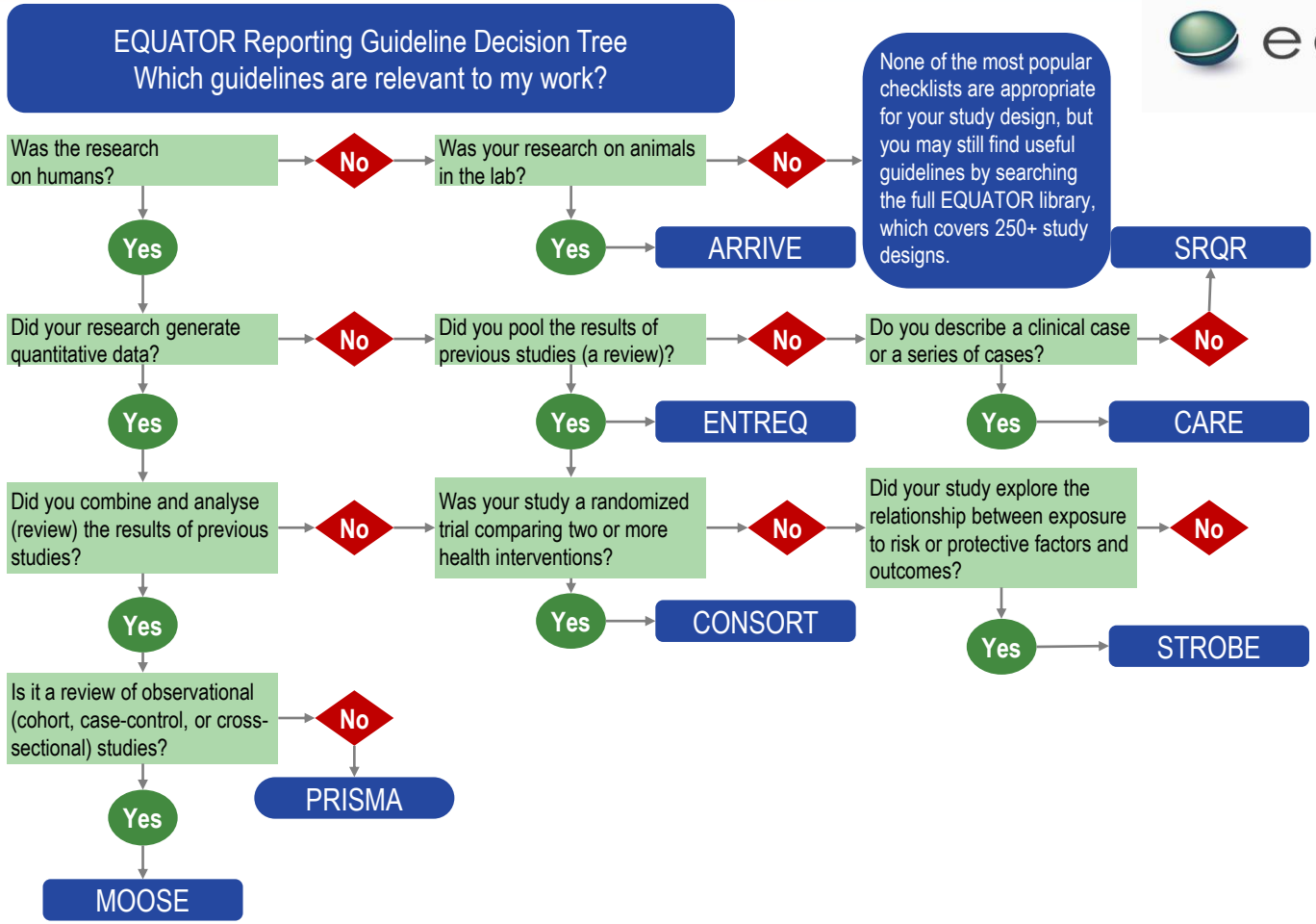

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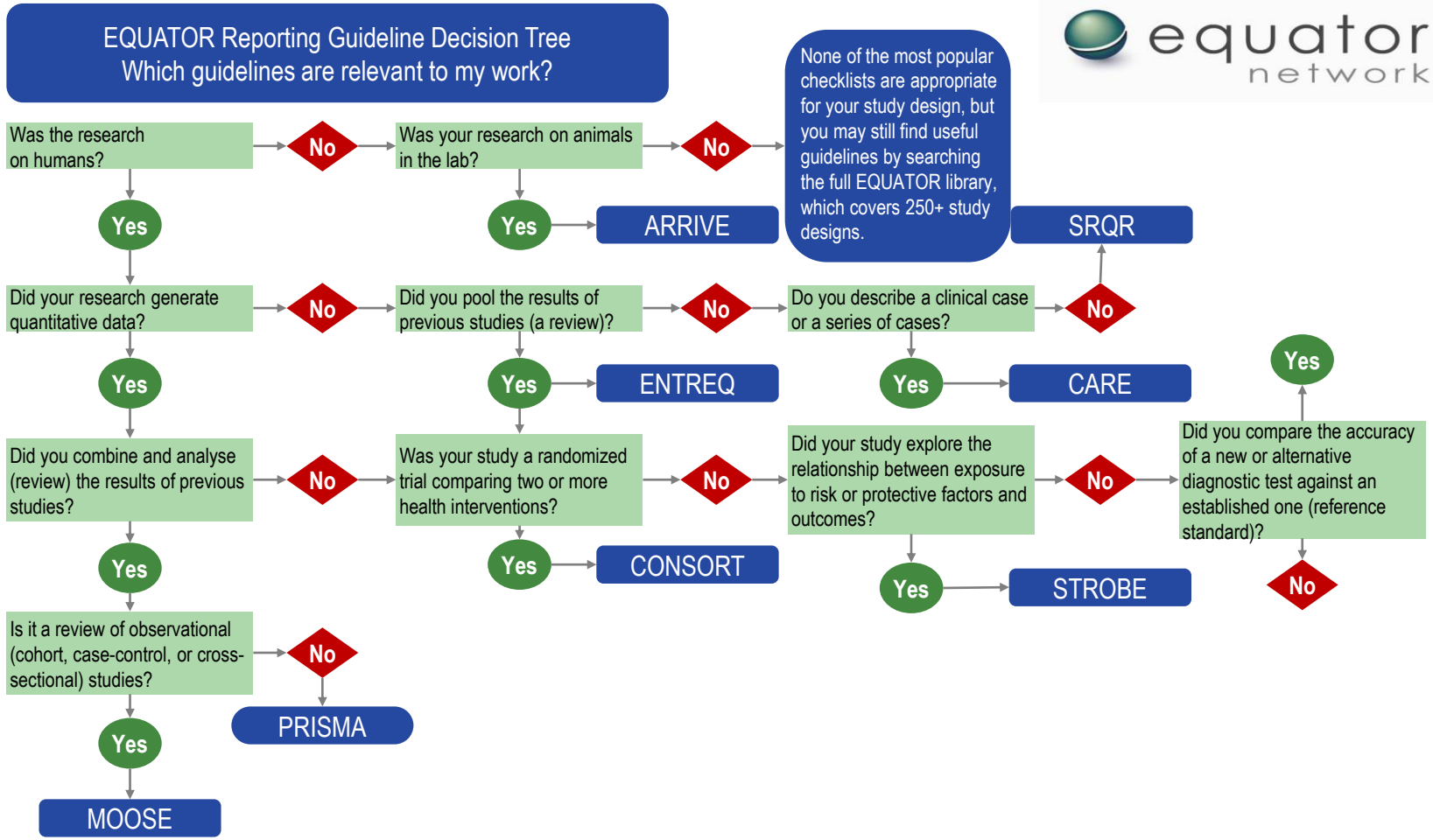

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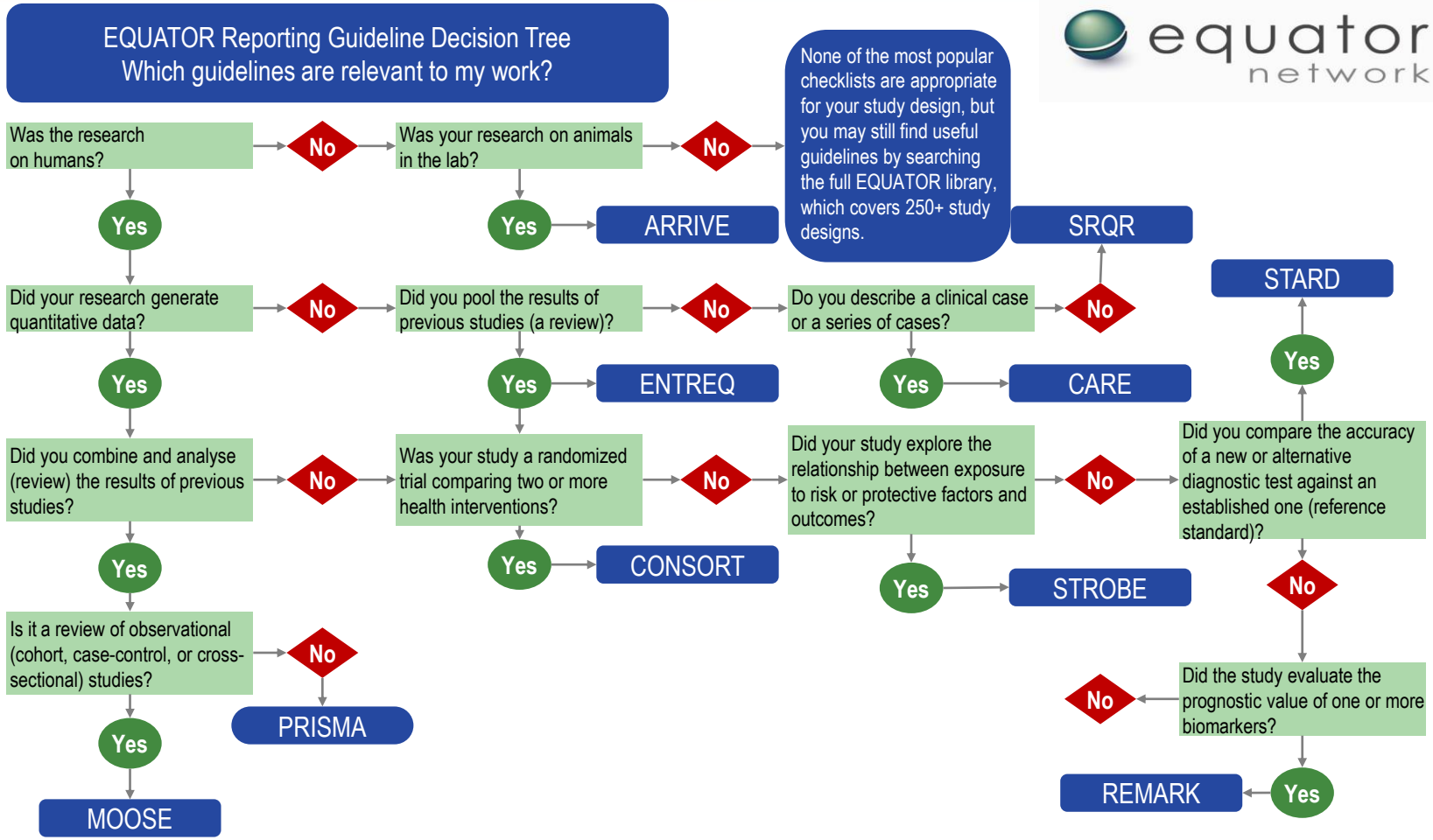

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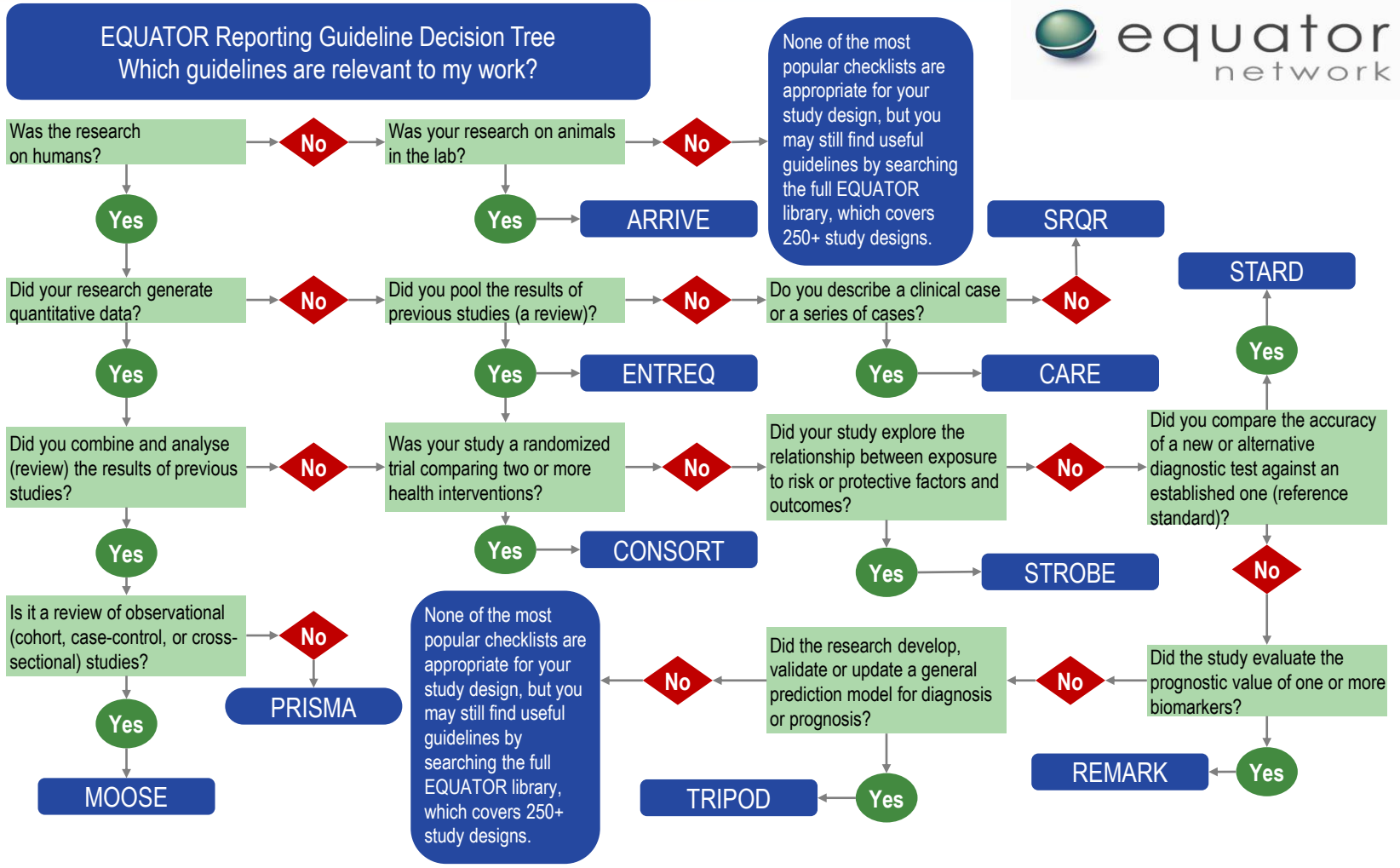

AMWA-EMWA-ISMPP ISSUED A JOINT POSITION STATEMENT ON PROFESSIONAL MEDICAL WRITING SUPPORT

"Professional medical writing support helps authors and sponsors to disclose their research in peer-reviewed journals and at scientific congresses in an ethical, accurate, and timely manner, with the ultimate aim of advancing patient care."

Overview of position statement:

- ❑ Describes best practices for professional medical writers globally
- ❑ Provides a template for disclosing medical writing support appropriately
- ❑ Explains the value of professional medical writing to evidence-based medicine by summarizing current evidence on the professional medical writer's role in the ethical, accurate, and timely disclosure of research results

AMERICAN MEDICAL WRITERS ASSOCIATION
The Resource for Medical Communicators

EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

ISMPP International Society for Medical Publication Professionals

EFPIA DISCLOSURE CODE REQUIRES MEMBERS TO RELEASE PAYMENTS TO HCPS & HCOs

- EFPIA is the blanket pharmaceutical trade organization of the EU
  - Requires its members to "publicly track and disclose payments and other transfers of value" to HCPs and HCOs[1]
- The first disclosure was made at the end of June 2016
- Disclosures will be made annually and the information will be available for 3 years depending on the country[1]

Types of disclosure[2]:

- Individual disclosure of transfers of value to HCOs
- Individual disclosure of transfers to HCPs
- Aggregate disclosure
- Non-duplication

[1]European Society for Medical Oncology. EFPIA Disclosure Code: What you need to know. ESMO. http://www.esmo.org/Policy/EFPIA-Disclosure-Code. Accessed March 13, 2018.
[2]European Society for Medical Oncology. EFPIA Disclosure Code: Frequently Asked Questions. ESMO. http://www.esmo.org/Policy/EFPIA-Disclosure-Code/Frequently-Asked-Questions. Accessed March 13, 2018.

THINK. CHECK. SUBMIT. INITIATIVE HELPS RESEARCHERS TO SUBMIT ARTICLES TO REPUTABLE JOURNALS INSTEAD OF PREDATORY JOURNALS

Researchers use a checklist to check the qualifications of a journal or publisher[1]

Think → Is your research going to a trusted journal? Is it the correct journal for your work?

Check → Offers several questions to assess and help decide if you should trust your selected journal

Submit → 5 yes/no questions help determine if your article should be submitted

[1]Founding Organizations: thinkchecksubmit. http://thinkchecksubmit.org/about/. Accessed March 13, 2018.

HOW CAN ISMPP HELP YOUR ORGANIZATION ADHERE TO GOOD PUBLICATION PRACTICES?

- Connect with journal publishers/editors, industry professionals, professional medical writers, academic researchers, and legal/regulatory consultants
- Provide resources/guidelines on good publication practices
- Understand and apply good publication practices
- Gain in-depth understanding of legislative issues related to publications
- Reduce your organization's compliance risks
- Become a leader in good publication practices and standards