Medical Writing and Publication in the Age of Transparency: Trends, Challenges, and Good Practices

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The Evolving Landscape of Clinical Research and Health Care

- Enhanced transparency
- Patient-centered health care
- Real-world evidence
- Open science

Enhanced Regulations and Policies

United States

- 1997: The Food and Drug Administration (FDA) Modernization Act began requiring registration of clinical trials of *drugs for serious or life-threatening conditions.*
- 2007: The FDA Amendments Act expanded the requirements to include disclosure of *trials for all health conditions* and reporting of summary results from certain trials *for FDA-regulated products.*
- 2014: The National Institutes of Health (NIH) published its Draft Policy on the Dissemination of NIH-Funded Clinical Trial Information requiring registration and summary results reporting for *all interventional clinical trials* funded by NIH.
- 2016: The NIH Policy on the Dissemination of NIH-funded Clinical Trial Information expanded the requirements to *all* NIH-sponsored trials.
- January 2018: FDA announced its new clinical trial transparency pilot program.
- September 2018: FDA published draft guidelines on *Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank*[1].

Europe

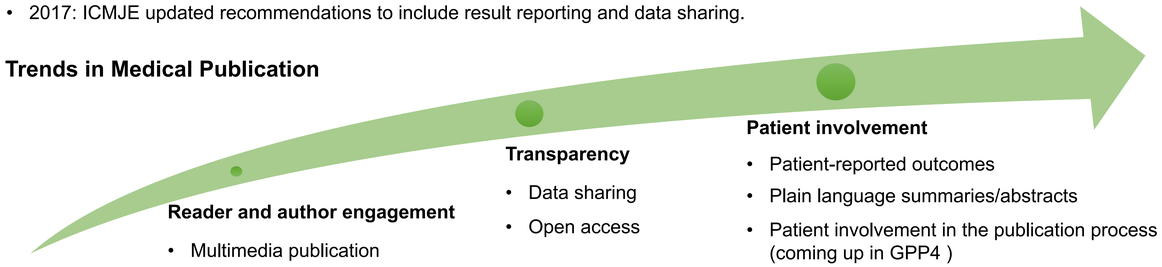
- 2014: The European Medicines Agency published Policy 0070 on publication of clinical data, including clinical reports and individual patient data.
- May 2018 :The General Data Protection Regulation came into force.

Impact on Medical Communication and Publication

Journal Requirements

- 2004: The International Committee of Medical Journal Editors (ICMJE) began requiring clinical trials registration as a condition of consideration for publication.
- 2017: ICMJE updated recommendations to include result reporting and data sharing.

Trends in Medical Publication



Challenges and Opportunities

Challenges for Sponsors and Investigators → Low Compliance Rates → Opportunities for Medical Communicators

Challenges

- Policy interpretation
- Operation challenges
- Balance between privacy and data sharing

Compliance Rates

- The European Commission's requirement on summary result reporting: 49.5%[1]
- US clinicaltrials.gov: 58.5%[1]

Opportunities

- Expanded roles

Penalties

FDA: "…, if a violation is not corrected within 30 days following notification of a violation, not more than *$10,000 for each day* that the violation continues after such period until the violation is corrected."

NIH: Failure to comply may lead to fund termination and may affect future grant applications.

Good Practices

- Understand the trends
- Stay updated with policy and guideline changes
- Follow the guidelines, including:
  - Good publication practice (GPP3)
  - ICMJE recommendations
  - The EQUATOR Network reporting guidelines

References

1. FDA. Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA. 2018. https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM607698.pdf.

2. Goldacre B, DeVito NJ, Heneghan C, et al. Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource. *BMJ* 2018;362:k3218. doi: 10.1136/bmj.k3218 [published Online First: 2018/09/14]

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