Navigating the complex landscape of clinical trial transparency: What medical writers need to know

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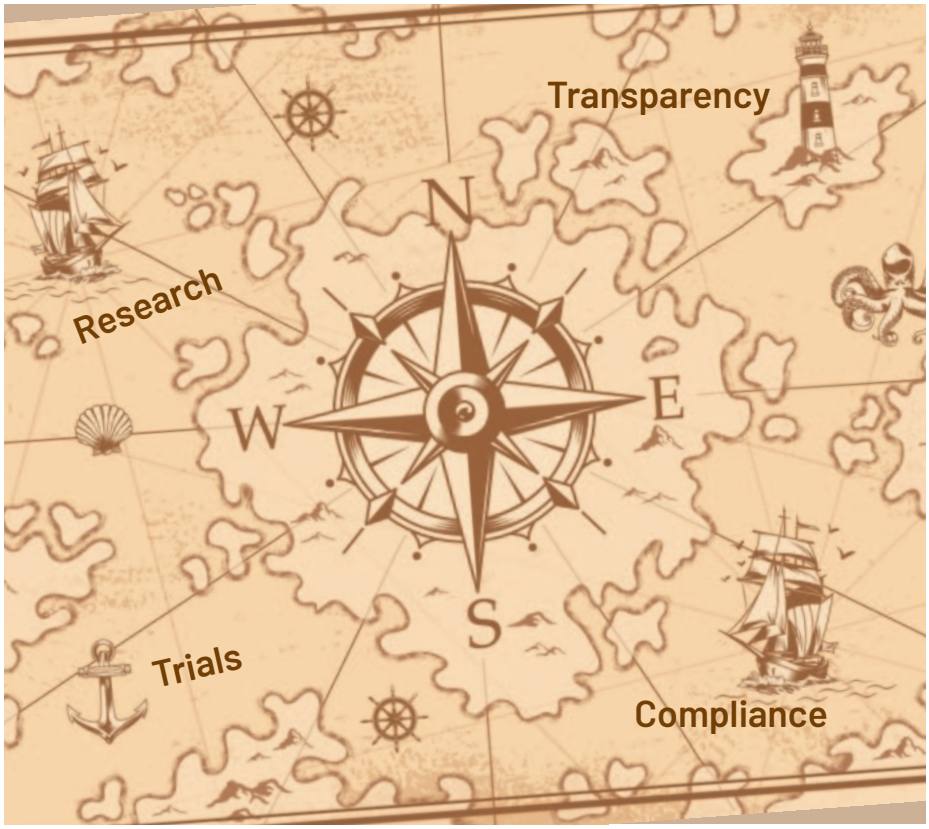
Abstract

Clinical trial transparency is beneficial for patients, researchers, and the general public. However, rapidly evolving regulatory requirements for transparency have increased the information that will be published. Medical writers can play a key role in driving compliance with applicable regulations. This paper provides an overview of transparency regulations and provides some points for medical writers to consider in this rapidly evolving area.



Introduction

The transparency of clinical research has been increased through voluntary initiatives and regulations. This has helped inform patients about clinical trials, reduced reporting bias and selective publication of data, provided information for secondary research, and fostered greater public trust in clinical research (Figure 1).[1]

A multitude of transparency-related regulations now applies from the start of clinical trials through to marketing authorisation applications.[2] Consequently, the regulatory framework governing transparency is ever more challenging to navigate. The scope of transparency is increasing and there is little harmonisation across regional regulations or transparency platforms.

Medical writers play an important role in the generation of information required for transparency and therefore need to be familiar with

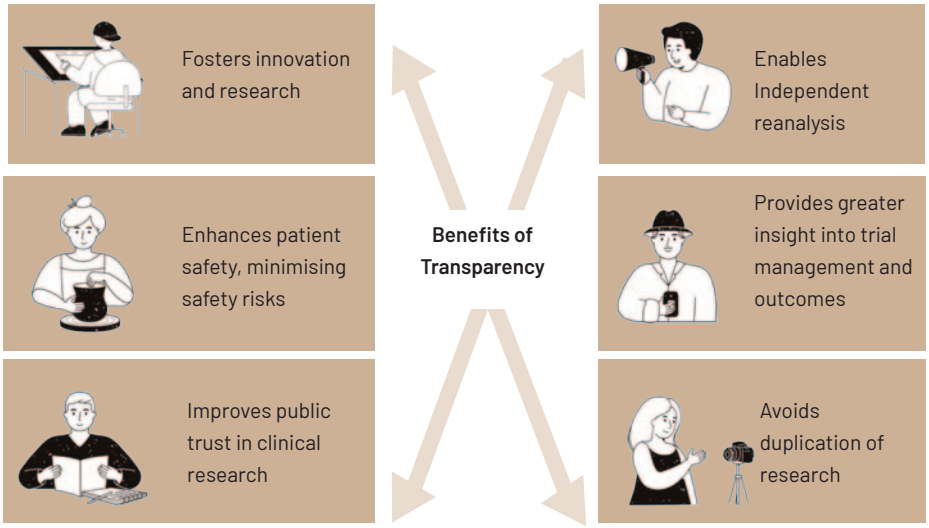


Figure 1. Benefits of transparency

relevant requirements. This article provides an overview of the main transparency regulations and offers some key points to consider for medical writers involved in transparency activities.

Types of transparency requirements

Transparency requirements can be broadly considered in 3 categories (Figure 2):

1. **Clinical trial registries:** Providing information on planned, on-going, and completed clinical trials, usually through a searchable interface
2. **Data and document sharing:** Publishing of clinical trial documents and data that have been suitably anonymised to protect personally protected and company confidential information
3. **Plain language writing:** Presenting clinical research information in language that is accessible to those without a scientific or medical background.

Clinical trial registries

Prospective trial registration on a public registry has been an obligation for medical researchers since the FDA Amendments Act of 2007 (known as FDAAA)[3] and the World Medical Association's 2008 revision of the Declaration of Helsinki (WMA, 2013).[4] Various clinical trial registries have been established across the globe and compliance with these is often mandatory. Trial sponsors must upload protocol information to registries prior to recruiting trial participants, maintain this information during the trial, and post summaries of trial results after trial completion.[5,6] There are similarities between registries, but differences include the studies in scope, the information required, and timelines. The section below highlights some of the main differences between the largest registries.

In addition to regulations, a significant incentive for researchers is that since 2004, the International Committee of Medical Journal Editors (ICMJE) has stipulated that registration of trials in a public database is a precondition for publication of trial results.[7]

Penalties for not adhering to registry requirements include monetary fines, but perhaps the greatest incentive is the risk to reputation as lists of organisations that are not compliant are frequently published.[8]

US

The ClinicalTrials.gov registry provided by the US National Library of Medicine (NLM) was launched in February 2000. It is the largest global registry with approximately 500,000 studies from over 200 countries.[9] This website provides patients and their advocates, health care practitioners, researchers, and the general public access to information on publicly and privately funded clinical research trials for a wide range of diseases and medical conditions. In June 2024, the NLM launched a modernised ClinicalTrials.gov website which enhances the user experience and provides greater functionality for searching, viewing, and downloading clinical trial information.[10] ClinicalTrials.gov registry requirements are presented in Table 1.

European Union/European Economic Area

The European Union (EU) clinical trials registry, the EU Drug Regulating Authorities Clinical Trials database (EudraCT), was launched in 2004. This currently contains almost 44,000 clinical trials with a EudraCT protocol.[11] The EMA has, over the last 2 years, introduced EU Clinical Trials Regulation 536/2014 (EU-CTR) that has increased the amount of clinical trial related information required for publication.[12] This information is submitted during the clinical trial application (CTA) process through a portal called the EU Clinical Trial Information System (CTIS). CTIS will replace EudraCT as the EMA's clinical trial registry from January 2025.

The EMA implemented in June 2024 a new version of the CTIS portal and revised the transparency rules.[13] The revised rules reduced the scope of publication to key documents of interest. The deferral mechanism was also revoked, meaning that sponsors must rely on redaction as the method to protect personally protected data (PPD) and company confidential information (CCI) within published documents.[14]

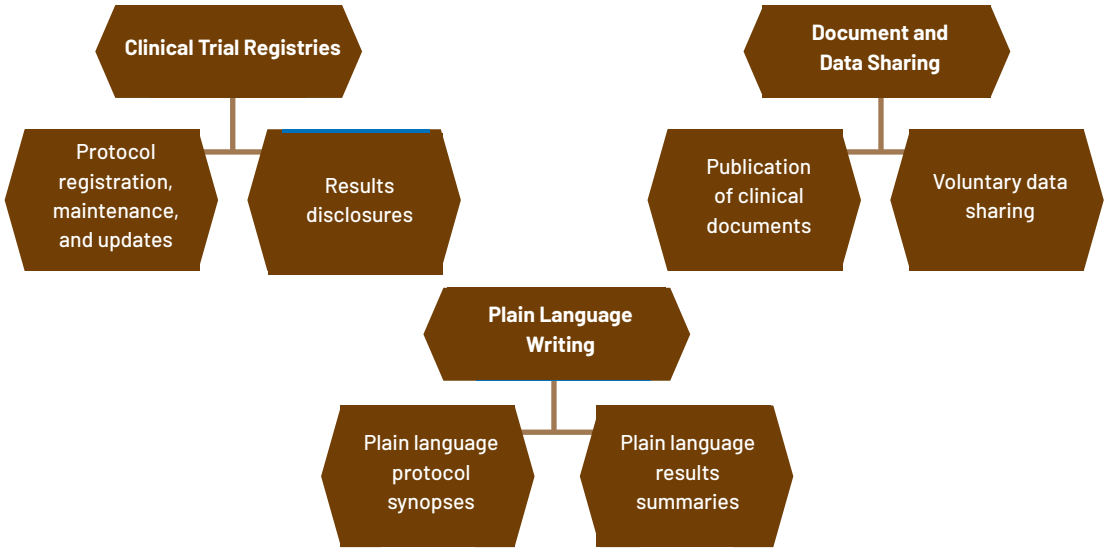


Figure 2. Categories of transparency

Table 1. Clinical trial registry requirements in the US and EU/EEA

Requirements	USA	EU/EEA
Applicable regulation	Created under the FDAMA of 1997 and expanded in the FDAAA of 2007	Initially governed by EU Clinical Trial Directive 2001/20/EC (EU-CTD); from January 31,2022, EU Clinical Trial Regulation No. 536/2014 (EU-CTR) applied
Scope	Controlled clinical investigations of drugs, biologics or medical devices (excluding Phase I studies) with at least 1 of the following: ● At least one US site ● Conducted under an FDA IND or IDE ● Involves a drug, biologic, or device manufactured in the US and exported for research	● All interventional trials on medicinal products submitted to National Competent Authorities of the EU/EEA ● All trials conducted outside of the EEA that are part of a PIP or are conducted under Article 45 or 46 of Regulation (EC) No 1901/2006
Information included	● Trial information ● Summary results (with some adverse event information) ● Redacted protocol and statistical analysis plan ● Indication of plans to make IPD and data dictionaries available	● Structured data fields containing trial information ● Documents including but not limited to protocol, protocol synopsis, plain language protocol synopsis (optional), patient facing documents, subject information sheets, informed consent forms ● Scientific summary of results, plain language summary of results, CSRs
Timelines	● Trials should be registered within 21 days of the first participant enrolled ● Summary results should be provided within 12 months of the trial's primary completion date	● Timelines for documents publication is based on the trial category*, defined in the revised transparency rules

Abbreviations: CSR, Clinical Study Report; EEA, European Economic Area; EU, European Union; FDA, Food and Drug Administration; FDAAA, FDA Amendments Act; FDAMA, FDA Modernisation Act; IDE, Investigational Device Exemption; IND, investigational new drug; IPD, individual participant data; PIP, paediatric investigation plan.

*Category 1 Trials: Phase 0 and Phase I clinical trials in healthy volunteers or patients, bioequivalence and bioavailability trials, biosimilarity trials

Category 2: Phase I and Phase II integrated clinical trials, Phase II and III clinical trials

Category 3: Phase III and Phase IV integrated clinical trials, Phase IV clinical trials and low interventional clinical trials

A comparison of the clinical trial registry requirements in the US and European Union/European Economic Area (EU/EEA) are presented in Table 1.

Other countries and regions

By creating their own clinical trial registries, countries can gather data to support local policy-making and healthcare decisions. Consequently, dozens of national clinical trial registries now exist.

The WHO operates the International Clinical Trials Registry Platform (ICTRP). This is not a clinical trials registry, but it facilitates access to trial information from various primary registries within its network, including ClinicalTrials.gov.[15]

In the UK, the Health Research Authority requires sponsors to register clinical trials in a publicly accessible database before they begin, report results within 12 months of trial completion, and make lay summaries of trial results available to the public.[16]

Other countries also mandate registration of trials either in a national registry or on a globally recognised registry or platform such as WHO ICTRP. Currently, this also applies, but is not limited to, Australia, Brazil, China, India, Iran, Israel, Japan, South Africa, South Korea, Sri Lanka, Taiwan, and Thailand.

Data and document sharing

Clinical trial registries initially provided limited information. The transparency domain has now evolved to provide direct access to certain clinical study documents and datasets. This adds complexity as these documents and datasets may contain PPD and/or CCI that must be appropriately redacted before documents are published. This section describes current key data and document sharing initiatives.

US

- **Freedom of Information Act (FOIA):** Allows any individual or organisation to request access to US federal agency documents. The FDA shares these documents unless they fall within one of nine exemptions or the information has been lawfully disclosed to the public.[2] The FDA received over 11,000 FOIA requests in 2022.[17] These requests cover a variety of topics including 510(k) submissions for medical devices, inspection reports, and compliance documentation such as Form 483 observations. The processing time for these requests varies based on their complexity and sensitivity.
- **NIH Final Rule:** The NIH mandates the publication of redacted versions of protocols and SAPs on ClinicalTrials.gov.[18]
- **FDA's Pilot Programme for Redacted Clinical Study Reports (CSRs):** In 2018, FDA initiated a pilot programme to make

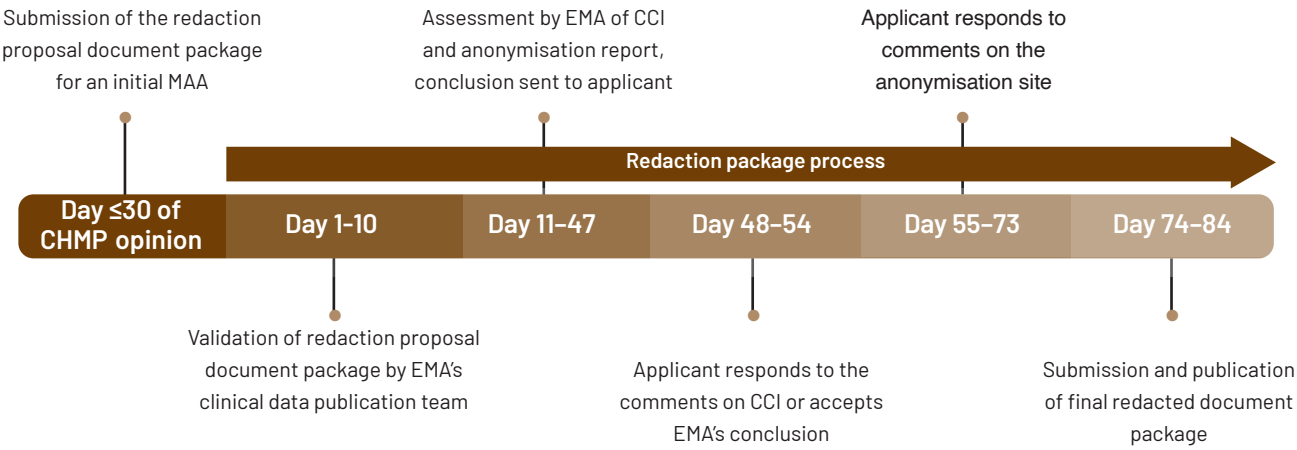


Figure 3. EMA Policy 0070 timeframe

Abbreviations: MAA, marketing authorisation application; CCI, company confidential information

CSRs more accessible to the public. However, on its conclusion in 2020, no additional steps were taken, with the FDA citing concerns about "inefficiencies in having multiregional disclosure requirements relating to often identical clinical data summaries".[19]

European Union/European Economic Area

EMA Policy 0043

EMA Policy 0043, developed in accordance with EU Regulation 049/2001/EC and effective since 2010, outlines the rules for requesting access to documents held by the EMA.[20] Requests can be made for clinical and certain non-clinical documents subject to certain conditions. The EMA can refuse access to a document if disclosure would undermine public interest, an individual's privacy, commercial interest, or court proceedings unless there is an overriding public interest in disclosure. The EMA redacts PPD and CCI from these documents and sponsors can request additional redactions.

EMA Policy 0070

EMA Policy 0070 mandates the publication of clinical trial data within 30 days of a CHMP opinion (Figure 3).[21] The scope of the policy currently includes disclosure of clinical documents only; Phase 2, to be introduced at a date yet to be specified, will require the publishing of individual participant data. Applicants must demonstrate that they have suitably anonymised PPD in documents and can also redact certain CCI if a robust justification is provided. Failure to comply with the policy results in the issuance of a non-compliance notice; financial penalties are not currently imposed. The details of the scope of EMA Policy 0070 are presented in Table 2.

EU-CTR: Requires sponsors to publicly share, through CTIS, redacted versions of Part I documents (scientific and medicinal product related) and Part II documents (national and patient-level) as part of the CTA process.[12] Further details on EU-CTR have been discussed in the previous section.

Canada

Health Canada's Public Release of Clinical Information (PRCI) policy, effective since 2019, makes anonymised clinical data from drug submissions and medical device applications available to the public.[22] It includes mandatory disclosure of new marketing approval submissions with final regulatory decisions made after March 2019, and, on request, prior to this date. (See Figure 4 for a timeline of Canada's PRCI timeline.) The documents in scope and the need to redact personal and confidential business

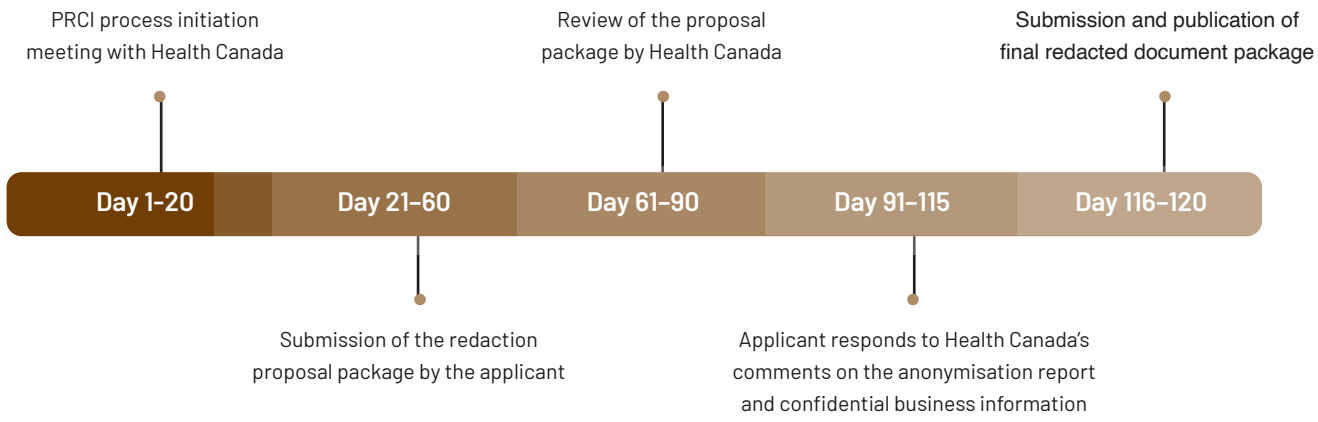


Figure 4. Health Canada PRCI timeframe

Abbreviations: PRCI, Public Release of Clinical Information

Table 2. Clinical trial documents and data sharing requirements in the EU/EEA, Canada, and Japan

Requirements	EU/EEA	Canada	Japan
Applicable regulation/ policy	EMA Policy 0070	Health Canada PRCI	Act for Access to Information Held by Administrative Organs (Act No. 42 of 1999)
Scope	• New marketing authorisation applications (MAAs) • Third-party submissions related to MAAs, procedures under Article 58 of Regulation (EC) No 726/2004 • Line extension applications • Extensions of indications for centrally authorised products	• New drug submissions (NDS) • Supplemental NDS (SNDS) • Abbreviated NDS (ANDS) • Supplemental abbreviated (SANDS) • Extraordinary use NDS (EUNDS) • Supplemental extraordinary use NDS (SEUNDS) • Medical device applications (Class III and IV)	• Japanese new drug applications (JNDAs) • Supplemental new drug applications (SNDAs)
Information included	A redaction proposal document package includes: • A cover letter • Documents marked for redaction (clinical overview [Module 2.5], clinical summaries [Module 2.7], CSRs [Module 5] with appendices [protocol and amendments, sample CRF, SAP]) • A justification table for CCI redactions • An anonymisation report detailing the methodology for re-identification risk management	For drug submissions, Health Canada requires the same documents as EMA Policy 0070. The justification table in Health Canada is known as the "Proposed Redaction Control Sheet" For device applications, documents include: • Device description • Performance study reports (CSR, trial plan, protocol, analytical evaluation), clinical trial summary • Operational information • Applicants must also submit a redaction control sheet • An anonymisation report • A certification letter	The package contains: • CTD Module 1 (review report, Module 1.15-1.10, and 1.12) a • CTD Module 2 (all documents, plus Module 2.7.6 synopses of individual studies) • Justifications for redactions • PMDA's review reports
Timelines	EMA validates the redaction package within 10 calendar days of submission and reviews this within a further 60 calendar days, after this, applicants have 30 calendar days to submit final redacted documents. Documents are published on approval (see Figure 3)	Time from process initiation to publication of redacted submission is 120 days. In addition, Health Canada gives an additional 30 days in case of notice of deficiency-withdrawal (NOD) or notice of non-compliance (NON), to allow for a reconsideration appeal (See Figure 4)	Final redaction document package submitted within 3 months of receiving marketing approval

Abbreviations: CCI, commercially confidential information; CRF, case report form; CSR, clinical study report; CTD, Common Technical Document; EEA, European Economic Area; EMA, European Medicines Agency; EU, European Union; PMDA, Pharmaceuticals and Medical Devices Agency; PRCI, public release of clinical information; SAP, statistical analysis plan.

information are the same as EMA Policy 0070. It is beneficial that packages approved by the EMA under Policy 0070 can subsequently be used for Health Canada submissions. Currently, there are no financial penalties for non-compliance with timelines.

Japan

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) mandates public disclosure on its website of new drug development information. This requires the publication (primarily in Japanese) of appropriately redacted new drug approval information packages.[23] Non-compliance with timelines and other requirements is subject to penalties.

A comparison of clinical trial document and data sharing requirements in different regions is presented in Table 2.

Other data and document sharing initiatives

Other data sharing initiatives have been led by trade associations and other organisations. These

Table 3. Other data sharing initiatives

Organisation	Initiatives
• The European Federation of Pharmaceutical Industries and Associations (EFPIA) • International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) • Pharmaceutical Research and Manufacturers of America (PhRMA)	These organisations encourage members to share clinical data through disclosure of study results, provide access to IPD, and make CSRs available for secondary analyses, in a way that protects patient privacy and respects commercial confidentiality
• Vivli • clinicalstudydatarequest.com • Yale Open Data Access (YODA) Project	Independent platforms that provide access to clinical trial data from multiple sponsors, and make clinical trial data available to external investigators
• ICMJE	Requires authors to share de-identified IPD underlying research articles
• WHO	Endorses the timely release of clinical trial results and supports platforms that facilitate data sharing

Abbreviations: CSR, clinical study report; ICMJE, International Committee of Medical Journal Editors; IPD, individual participant data; WHO, World Health Organisation.

initiatives collectively aim to maximise the utility of clinical data, foster innovation, and improve health outcomes globally (Table 3).[24-27]

Plain language writing

Much of the published clinical research information can only be understood by those with scientific or medical training. In recognition of this, there is a groundswell of support for presenting clinical trial information in plain (or laypersons') language. This field is rapidly evolving and regulations are being introduced to encourage it.

European Union/European Economic Area

The EMA is taking the lead in requiring plain language summaries. Article 37 of EU-CTR requires sponsors to publish a plain language summary of clinical trial results (PLS).[28] The PLS is generally written to the literacy level of a 12-year-old. PLSs must be completed within 12 months of the end of the trial (6 months for paediatric trials or trials listed in a Paediatric Investigation Plan [PIP]). EU-CTR also includes a recommendation to include a plain language protocol synopsis in CTA submissions.

US and other countries

The FDA does not require PLSs, however in 2022, NIH produced a "Plain Language Checklist for Lay Brief Summaries". This guidance can be used to create content for two fields required in the ClinicalTrials.gov registry: the "Brief Title", a short title describing the trial, and the "Brief Summary", a short summary that provides a high-level overview of the study.[29]

In the UK, The Medicines and Healthcare Products Regulatory Agency, as part of their "Make it Public" strategy, requires research sponsors to publish a plain language summary of their findings no later than 12 months from the end of the study.[16]

The Netherlands' Medical Research Involving Human Subjects Act requires trials conducted in The Netherlands to disclose study results either as a scientific summary or PLS within 12 months of study completion on their Central Committee on Research Involving Human Subjects (CCMO) registry.[30]

Other countries, such as Ukraine and Türkiye, may be introducing requirements for plain language summaries of results.

Considerations for medical writers

Medical writers play a key role in preparing documents and information required to promote clinical data transparency (Figure 5). The considerations outlined below can help medical writers effectively prepare disclosure-ready clinical documents, meet regulatory requirements, and ensure transparency while maintaining data privacy, confidentiality and the integrity of data. Some of the key considerations are listed in Table 4.

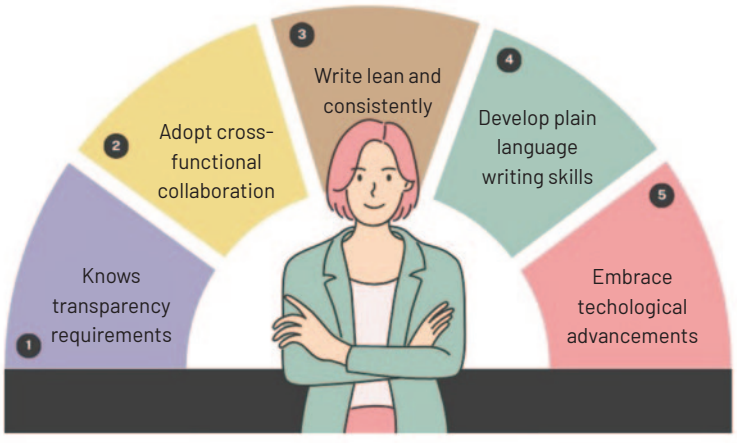


Figure 5. Considerations for medical writers

Table 4. Considerations for medical writers

Category	Practical application	Impact
Transparency requirements	• Understand what must and what must not be disclosed • Prepare documents with disclosure timelines in mind	Achieves compliance with regulations
Collaboration	Facilitate agreement between and train diverse stakeholders in transparency processes (e.g., legal, regulatory, and medical teams)	Greater consistency and reduced timelines
Lean writing and consistency	• Include CCI and PPD only when necessary • Create lean document templates • Maintain CCI glossaries for each product	Reduces the amount of redaction required and avoids cross-document variation
Plain language skills	Learn how to write in plain language, use infographics and engage patients directly in creating documents	More efficient and engaging plain language summaries
Technological advances	Be aware of how new tools (e.g., CORE reference secondary-use CSR, TransCelerate templates, generative AI) can support clinical trial transparency	More efficient writing processes

Abbreviations: AI, artificial intelligence; CCI, commercially confidential information; CORE, Clarity and Openness in Reporting; PPD, CSR, Clinical study report protection of personal data.

Conclusion

There are significant benefits of increasing transparency of clinical research, however the regulatory requirements in this area are becoming more widespread and more complex. Medical writers can be proud that they are often at the vanguard of making clinical information more widely available. Effective and compliant disclosure requires medical writers to stay informed about relevant regulations and to seek opportunities to improve the efficiency and consistency of transparency processes.

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Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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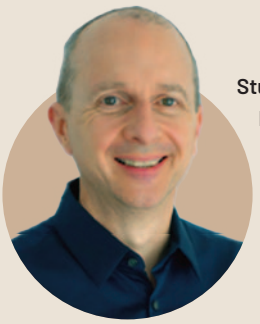

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