

Transparency and Disclosure Services

Publication-ready clinical documents

Preparing a document for public disclosure comes down to making judgment calls: which indirect identifiers still pose a re-identification risk once direct identifiers have been addressed, and what justification for a commercially confidential redaction will withstand regulatory scrutiny.

Worldwide Flex transparency and disclosure services make those calls with your team and carry them through to a publication-ready package. Because Flex draws on teams from across Worldwide, the medical writing organization that authors your regulatory and safety documents also prepares them for disclosure, across your global programs and under one scope of work.

What we do



CTIS disclosure support

- Disclosure readiness assessment
- Identification of publication-ready documents
- Disclosure strategy planning and execution
- CTIS submission support and modifications
- Regulatory transparency consulting



Anonymization and redaction

- Protected personal data assessment and redaction
- Commercially confidential information review
- Marked for Redaction document preparation
- Metadata and hidden-information sanitization
- Quality control and consistency review



Disclosure program management

- Dedicated Transparency and Disclosure Lead
- Coordination across sponsor and regulatory teams
- Disclosure timelines and milestone management
- Centralized document tracking through a validated, access-controlled repository



Compliance support

- GDPR-aligned privacy protection
- EMA transparency requirements and redaction labeling
- Unified anonymization strategy applied across all study documents that are subject to publication
- Inspection-ready documentation and audit trail

How the work runs



Onboarding. In-scope documents are identified with the Worldwide Regulatory Affairs team. Requests come through a dedicated Transparency Mailbox, and documents are exchanged through a validated study repository with access control.



Protected personal data. Standard redaction rules for personal data are agreed with the sponsor and applied per GDPR and EMA guidance.



Commercially confidential information. CCI is identified and assessed with the sponsor, supported by a literature search for information already in the public domain, and captured in a project-specific CCI Redaction Control Sheet.



Redaction proposal. A Marked for Redaction version is provided for sponsor review, then quality checked for compliance and consistency.



Final redacted document. Redactions are applied with irremovable labels, the document is sanitized of metadata and hidden information. Sponsor approval of the anonymization strategy is required for every protocol amendment. That approved strategy is then applied consistently across the remaining documents in the publication package, including informed consent forms and patient-facing documents.

What gets protected



Protected personal data (PPD)

- Direct identifiers such as name, signature, personal ID, phone number, and email address
- Indirect identifiers such as age, gender, race, ethnic origin, title, IP address, insurance policy numbers, and specific financial arrangements
- Redacted per GDPR and EMA CTR personal information protection guidance, labeled per EMA redaction recommendations



Commercially confidential information (CCI)

- Information that, if disclosed, could undermine the legitimate economic interest of the company
- Information known to the research organization but not to the public
- Redacted per sponsor instruction and labeled per EMA redaction recommendations

Why sponsors work with us



One team from authoring through disclosure.

Transparency and disclosure is delivered by the same medical writing organization that supports your regulatory and safety documents, so redaction decisions stay aligned with document content and fewer handoffs are needed.



Support across global programs.

Worldwide Flex draws on teams across North America, the UK, Europe, and India, so disclosure work scales with the geographic reach of your development program.



Specialists, not generalists.

The team brings CRO and anonymization services experience across quality assurance, data protection, medical writing, and regulatory compliance, with training in clinical transparency delivered by industry specialists.



A named lead on your study.

A Transparency and Disclosure Medical Writer Lead manages the redaction campaign under a defined SOP, with a QC reviewer appointed for every package.



Delivery that fits your timeline.

Expedited handling is available for urgent requests, and support extends to non-English documents and multinational programs.



Worldwide
Clinical Trials

Start a conversation.

Our experienced team of medical and scientific writers provides high-quality and accurate content for your needs. [Contact us](#) today to learn more.