mt-g | Streamlining medical translations

Navigating complex workflows for accuracy and compliance Yana Safina (mt-g medical translation)





Outline

- 01 ISO Standards and typical workflows
- 02 Specifics of the clinical studies field
- 03 Software: CAT and MT
- 04 Quality Assurance
- 05 Additional services

00. CLINICAL STUDIES

Typical texts and documents

- Lay summary in accordance with Article 39 EU Regulation 536/2014
- Patient information material and documents, informed consent forms
- Audit reports
- Study-specific specialist documentation: Study protocols, study protocol synopses, SAE reports, case report forms (CRFs, eCRFs)
- Correspondence with ethics committees
- Legal documents: Study contracts, investigator contracts
- Other study-relevant documents: Training materials, "Quality of Life" questionnaires, and press releases



01. ISO STANDARDS AND TYPICAL WORKFLOWS

ISO 9001 (translations, proofreading, back translation, master review)

ISO 18587 Machine translation + Post-Editing

ISO 17100 (text analysis, translation and revision)



WA EUROPEAN MEDICAL WRITERS ASSOCIATION

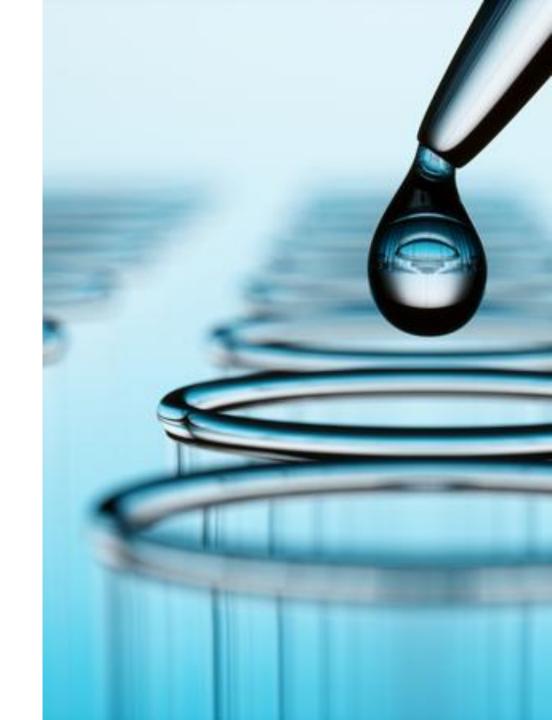
02. SPECIFICS OF THE FIELD (1/2)

Lay Summaries and Lay Synopses

- TM and terminology
- Lay language
- Gendering
- Back translations + Master review
- Country reviews
- DTP and layout check

Correspondence with ethics committees

- CTIS
- Templates
- Terminology (study titles, names of authorities etc.)



02. SPECIFICS OF THE FIELD (2/2)

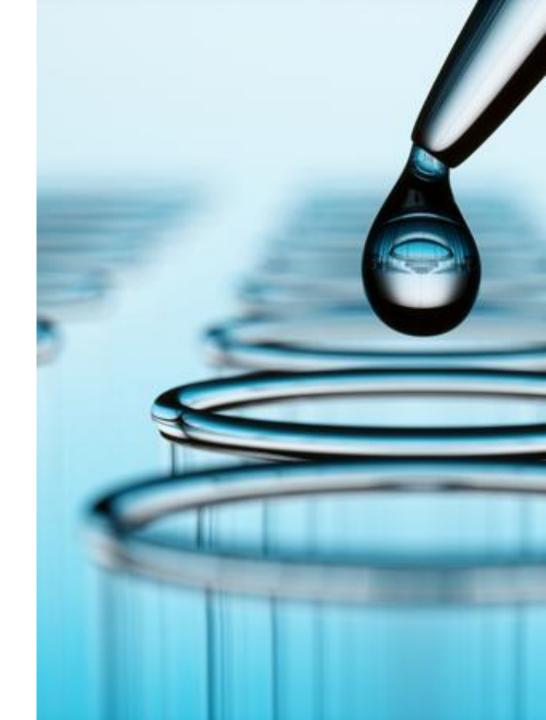
Patient-facing documents

- Target group terminology check and readability check
- Compliance check
- Often a 2-batch workflow
- Medical writing gaining interest

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eCRF (The Electronic Code of Federal Regulations)

• XTM-, Excel-based



03. SOFTWARE: CAT-TOOLS

Advantages for translators

- Spares time (different setting and workflows)
- Enables consistency in terminology and phrasing
- Reduced formatting/layout issues
- Quality Assurance Tools
- Integrated AI Translation
- Translation Management
- Referencing
- Automatic back up etc.

Disadvantages

- Many options to choose from
- Costly
- Learning time





03. SOFTWARE: CAT-TOOLS

Advantages for clients

- Spares time
- Enables consistency in terminology and phrasing
- Reduced formatting/layout issues
- Quality Assurance Tools
- Different formats and add-ons ٠
- Reduced costs due to matches and repetitions

Disadvantages

- Several projects are needed to build up a beneficial TM
- May be more costly for smaller projects (due to file ٠ preparation)
- Different translators, different tools ٠





03. MT & POST-EDITING

- Automation: Machine translations of different document types.
- **Varied**: A dedicated machine can be set up and trained for each required language.
- **Speed**: Even large amounts of text can be translated in the shortest time (10k words in 1-2 days)
- **Cost saving**: With a clever setup and a high-quality machine, translations can be produced faster and more cheaply as a result.
- <u>MTPE</u> demonstrates the translation **quality equal to a human** translation (not MT alone)





03. MT & POST-EDITING

HOWEVER:

- Not every text is suitable for MT (sphere, style, language pair, text structure, abbreviations, context) → Post-editing can be not worth it
- Not so cost-effective when TM is full (many 100% matches)
- Permission to use a cloud-based engine
- Additional proofreading is still a thing
- Not many translators are trained for PE yet

MT DOES NOT REPLACE TRANSLATORS! but supports them in their daily business





04. QUALITY ASSURANCE

begins with

- Tested translators
- Client's requirements
- Feasibility check
- Desired ISO Standard

continues with

- Established workflows
- Preparation of the source texts
- Choice of CAT-Tool

ends with

- TM and terminology check
- Internal QA in CAT Tool (soon AI?)
- DTP and layout check



05. ADDITIONAL SERVICES



