

The role of Translations in the Medical and Pharmaceutical Industry

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- **Where does translation fit into my Clinical Study?**
- **Translation and Linguistic Validation process**
- **Importance of accurate medical translations**

Where does translation fit into my Clinical Study?

Drug development

Early Phase Services

- Clinical Research Unit
- Early Patient Studies
- Pharmacodynamic Models
- Data Visualisation & Analysis
- Protocol Development

Commercialisation & Outcomes

- Real World Strategy & Analytics
- Real World & Late Phase Research
- RWE Research Services & Clinical Operations
- Access, Commercialisation & Communications
- **Patient Centered Sciences**
- Strategic Regulatory Services
- Medical Device & Diagnostics Research

Laboratory Services

- Central Laboratories
- Bioanalytical Laboratories

Drug Development Services

- Non-clinical
- Chemistry, Manufacturing & Controls
- Clinical Development

Clinical Research Services

- Project Management
- Clinical Operations/Monitoring
- Patient Centric Monitoring
- Data Management
- Site & Patient Solutions
 - Site Feasibility – EMR & Data Analytics
 - ICON owned Site Networks
 - Patient Recruitment & Retention
 - Digital Solutions
- Medical Imaging
 - Biostatistics
 - Medical Affairs
 - Pharmacovigilance
 - Regulatory Affairs
 - Endpoint Adjudication
 - Medical Writing & Publishing
 - Interactive Response Technology

Functional Services

- Functional Solutions
- Government Solutions



Language Services required in a Clinical Studies

Translation of Documents

- Regulatory Documents
- Contracts and Correspondence
- Recruitment Materials
- Patient and Site Materials
- Pharmacovigilance/Safety documents
- Patents

Transcription

- Cognitive debriefing
- Focus group sessions
- Hearings and meetings
- Patient visits/interviews
- Closed-captioning

Voice-overs

- IVRS
- Training videos/recordings
- Hearings and meetings
- Multi-media systems

Desktop Publishing

- Insert for use (IFU)
- Packaging/Labeling
- Marketing materials
- Hearings and meetings
- Communications & PR
- Presentations
- MSL support materials

Linguistic Validation


- Patient Reported Outcomes
- Observer Reported Outcomes
- Quality of life measures

Language Services Materials

**Regulatory
Letters &
Applications**



**Clinical Outcome
Assessments
(COAs)**



**Patient Materials
(e.g. ICFs)**



**Budget & Fee
Documentation**



**Site/Investigator
Materials
(e.g. protocols)**



IVR Systems




**Patient
Recruitment
Materials**



**Adjudication
Materials**



**Pharmacovigilance
Materials
(e.g. SAE)**



Translation and Linguistic Validation

What is translation?

- Translation is the process of translating words or text from one language into another.
- Verbatim translations can be dangerous, particularly in COAs. It's about striking the balance and finding an accurate but culturally relevant translation.
- *Translation means “saying almost the same thing”, being faithful to a source document is performing a world for world translation not a word for word translation” Umberto Eco*

What is Linguistic Validation?

- **What?**

- Translation process to ensure that a COA is linguistically and culturally valid for use in another language and/or country and that translations are *conceptually and culturally equivalent* with the source version and with each other.

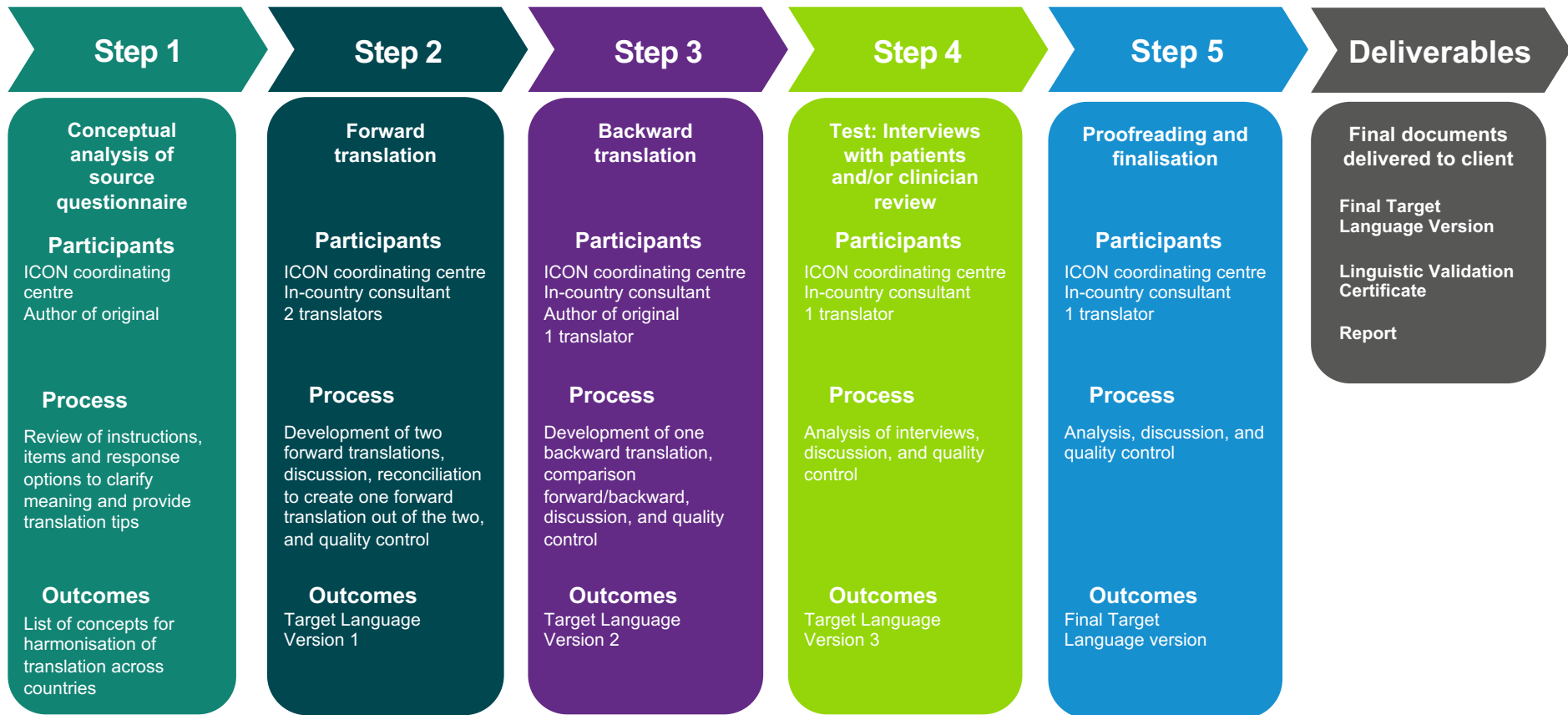
- **Why?**

- To ensure that data obtained using COAs can be compared across languages and cultures.

- **COAs?**

- PROs, ClinROs, ObsROs, PerfOs

Linguistic Validation methodology



Importance of accurate medical translations

Accurate translations

- Translations are collecting data for use in clinical studies
- Human process vs AI?
 - Biased systems?
- Verbatim translations can be dangerous
- Ensure accuracy in meaning
 - Loss of culture – idioms and cultural relevance
 - Concept & Cultural equivalence

Thank you!

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