Best practice
Translations in clinical research

medax
Medical Translations.

Conducting trials

The top ranking countries worldwide regarding the number of clinical trials conducted are the USA and China, followed by Spain, the UK, Canada and Germany.

7.8 billion euros

... and more are spent on research and development every year in Germany alone.

This whitepaper explains:

What SAE J2450 is and how this metric makes quality measurable.

The points in a trial where translation services are relevant.

Linguistic validation – one trial, multiple languages.

Carefully planned clinical trials for results of international relevance.

Medical translations

SAE J2450

Clearly structured, with a systematic approach. Supporting your research with the highest quality standards.

Translation quality

7 checks for international clinical trials

1. Terminology
2. Content
3. Completeness
4. Structure
5. Spelling
6. Punctuation
7. Others

Translations in clinical research

All medical treatments, whether it be a simple painkiller or an advanced life support strategy, have to undergo a long and arduous process before they are made available to patients at an international level. Once researched and developed, every single aspect has to be approved and certified. **Clinical trials** are amongst the most heavily regulated markets. In Germany, the Medicinal Products Act (AMG) sets forth the legal requirements for conducting a clinical trial. The aim of this Act is to assess medicinal products, forms of treatment, medical interventions and medical devices for their quality, efficacy, safety and benefits.

Internationalisation

Many clinical trials are conducted in a number of countries, in order to get innovative therapies to as many people as possible worldwide. An international trial can only be implemented if the corresponding translations are available, because understanding is a basic prerequisite for the safety of the subjects. All relevant documents therefore have to be translated with the highest degree of precision. These documents include:

1

Trial documents

Trial documents such as protocols, informed consent forms, questionnaires, and patient information sheets need to be translated into different languages to enable patient participation in the countries concerned.

2

Regulatory documents

As a rule, regulatory documents such as clinical trial reports and applications for approval have to be submitted in the language of the country in which the medicinal product is to be approved.

3

Communication with patients and investigators

Communication with patients and investigators takes place in the languages of the countries concerned. In the interest of patient safety, it is essential to ensure that all relevant information is understood.

4

Training materials

Training materials for investigators and trial staff are required in multiple languages. This is the only way to ensure that all relevant information is easily understandable for everyone.

Helping to shape innovative therapies

Multinational clinical trials…

A professional language service provider assists with all of these aspects and, through its expertise, helps the clinical trial achieve success. Qualification depends not only on a high level of linguistic proficiency, but also on a deep understanding of clinical research and all regulatory requirements.

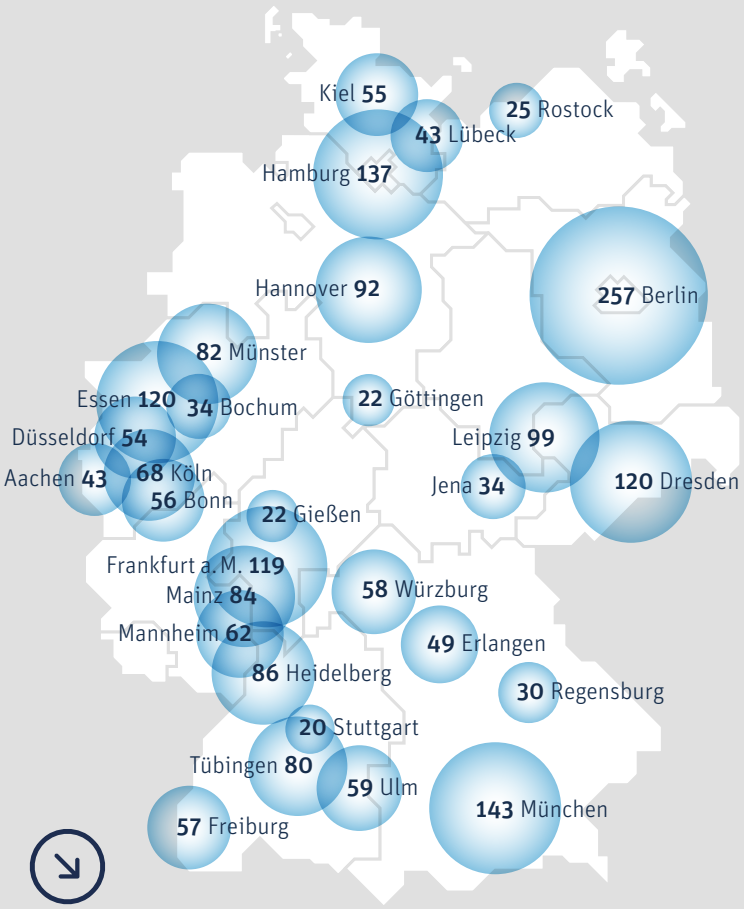
Opportunities for effective treatments

Berlin tops the list of cities with the highest number of trials by far. However, unlike in some neighbouring countries, the commitment to trials in Germany is not concentrated in just a small number of cities.

Transcending borders …

Involvement in clinical studies of pharmaceutical companies, started in 2021

TOP 30 (according to number of studies)



Source: vfa, based on the clinicaltrials.gov database for clinical trials
As of: November 2022

vfa. Die forschenden Pharma-Unternehmen

Quality of translators – put through their paces

Especially in the context of clinical research and the translation of trial documents, translations have a legal and safety relevance.
At medax, we use three different approaches for measuring the quality of our translations.

Translator evaluation

Developed originally for the automotive and aerospace industries, **SAE J2450** is a metric for measuring the quality of translations. We evaluate our translators three times a year using the system for classifying and weighting translation errors. The quality rating is based on the final score. We use only those providers who achieve a score of 98.5 percent or higher for translation of clinical trial documents.

Translation standard ISO 17100

ISO 17100 sets global requirements for high-quality translation services and exacting standards not only for language, style and consistent terminology, but also for information security, standardised processes and professional project management. In the definition of the process, the translation itself is just one of the phases, as quality is only guaranteed through the revision of the translation by a second person. It also requires professional expertise from each and every person involved in the process. Going beyond linguistic accuracy, it also focuses on the consideration of the target group concerned and regional characteristics.

Triple-check principle

medax provides medical translations with a seal of quality guaranteed by our triple check principle. Native speakers qualified for medical texts translate and proofread your text – and, finally, your personal project manager checks everything once again down to the last detail, free of charge. Quality and data protection guaranteed.

How is translation quality measured?

SAE J2450

Metric for measuring translation quality

Taking terminology as an example

A term is defined as a single word or multi-word phrase used as a linguistic unit of meaning, including abbreviations, acronyms, numbers, numerals, and proper names.

"For , just when our ideas fail us, a well-coined word may best avail us."

Quote from Goethe's Faust ///

A term is wrong if it ...

/ Violates a glossary.
/ Violates common language or industry usage.
/ Does not match other translations of the same source term.
/ Describes a concept other than the one indicated by the source term.

Classification of serious or minor errors ...

Serious errors potentially cause:

/ Harm to users, operators, patients or consumers.
/ Damage to the product or to the equipment used in combination with the product.
/ Serious misrepresentation of the originator's intentions or the client's products or services.
/ Damage to the client's reputation.

Primary error categories

- Wrong term (WT)
- Syntactic error (SE)
- Omission (OM)
- Addition (AD)
- Word structure and accordance errors (SA)
- Spelling errors (SP)
- Punctuation errors (PE)
- Miscellaneous errors (ME)

Numerical weighting

WT	**5 / 2.5**
SE	**3 / 1.5**
OM	**3 / 1.5**
AD	**3 / 1.5**
SA	**3 / 1.5**
SP	**1.5 / 0.75**
PE	**1.5 / 0.7**
ME	**1.5 / 0.75**

2 secondary categories

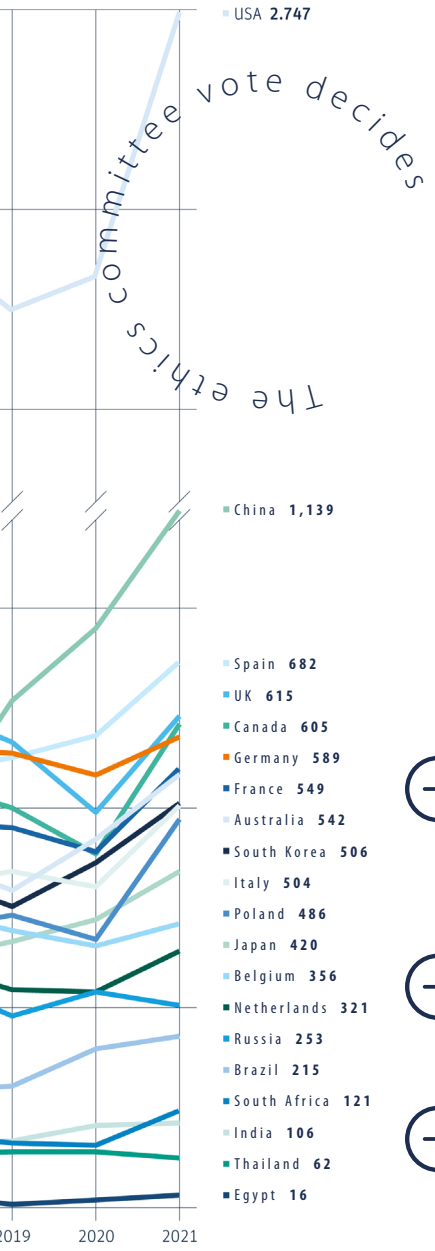
If an error falls into one of the primary categories, it is assigned to a secondary category: **serious or minor.**

The score is the sum of all numerical weightings divided by the number of source words. A score of **98.5% or higher** is considered a pass.

Result

SAE J2450 Metric for measuring **translation quality**

At what points in a trial are language services relevant?



Before the trial begins

Trial protocols, patient informed consent forms and other relevant documents have to be translated even before the trial begins. Professional translators with a medical background ensure highly accurate translations. The **clinical trial protocol**, with master files for the **patient information sheet** and **informed consent form**, is submitted to the competent ethics committee and the competent higher federal authority for review and approval before the trial begins. Patient information sheets and informed consent forms for trial participants in the country concerned must precisely describe the content and procedure of the clinical trial, yet at the same time be easy to understand. To ensure success across all languages, it is important to only use experts who translate exclusively into their native tongue.

Our tip: Involve your language service provider in the editing process as soon as the master file is created. **Optimising the source text for translation** brings you a host of advantages:

If the source language file - which is usually written in English - is easy to understand, the translator will have fewer queries.

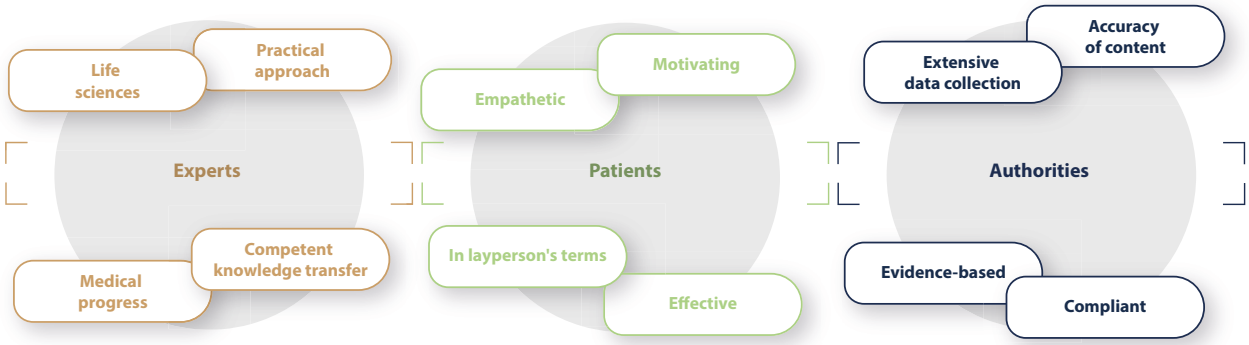
Culture-neutral wording speeds up the translation process and reduces sources of error.

A source text written with translation in mind can be easily understood, even by a layperson. This is especially important if your texts are aimed at patients.

Incidentally:

A **back translation** helps you identify not only ambiguous translations, but also misleading wording in the master file. Here, you can find out all there is to know about **back translation...**

Medical writing for translation – focus on target groups



All of the documentation mentioned contains medical terminology, abbreviations, and complex sentence structures. Only qualified translators, who are closely familiar with the subject matter, have the prior knowledge required to understand it – this is key to an accurate translation.

Qualified translators are are familiar with the medical technical terms and abbreviations used and know how to translate them correctly.
If there are any doubts about the meaning, they consult with medical experts to ensure the accuracy and precision of the translation.

During the course of the trial

During the course of the trial, the translation of **questionnaires** and documentation forms is essential. Experienced technical translators are familiar with the terminology concerned and ensure consistent results. Information on the administration of medicinal products must also be translated in such a way that all subjects worldwide receive the same information.

Case Report Form, **Trial Master File** and **Investigator Site File** are usually to be translated into the languages of those countries in which the trial is conducted. This ensures that all participants properly understand the trial and its requirements. In addition, the translation into the language of the country concerned is usually a basic requirement for the approval of the trial.

In the interest of **pharmacovigilance**, adverse event reports (AEs, SAEs, and SUSARs) on subjects in different countries must be very carefully documented, translated, and submitted to the appropriate authorities at regular intervals. The top priority here is complete accuracy in translation. Participants are only able to respond appropriately, and patient safety can only be ensured if they correctly understand the meaning and context of these events.
The translated reports are often an important basis for adjusting the clinical trial design – and are also required by the authorities.

Linguistic validation

Translation | Comparison | Back translation | Comparison with the original | Testing | Proofreading

A total of **5** professionally qualified linguists ensure absolute precision in the **linguistic validation** process.

Clinical Outcome Assessments (COA) call for a specific approach to the translation. They are extremely important in determining whether the medicinal product has a benefit for the patient, and must therefore undergo the process of linguistic validation. This workflow ensures that the target language content is precise and appropriate. The COA include:

- Patient-Reported Outcomes (PRO)
- Clinician-Reported Outcomes (ClinRO)
- Observer-Reported Outcomes (ObsRO)
- Performance Outcomes (PerfO)

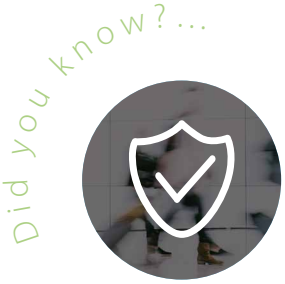
If a document is translated into multiple languages for the same trial, linguistic validation ensures that the exact same meaning and tone is conveyed to all international participants. The ISPOR principles prescribe ten steps for inclusion in the linguistic validation. In simple terms:

1. Working independently, two or more translators **translate** the document into the same target language.
2. The two translations are compared and **merged**.
3. Another translator translates the merged target text **back** into the original language.
4. A reviewer **compares** the back translation with the original to eliminate any discrepancies.
5. The original text and the translation are **tested** on small target groups to check for conceptual equivalence.
6. Lastly, a proofreader **checks** the final translation.

In the final step, medax seamlessly integrates customer contacts at the national companies into the review process. This is how, together, we make sure that you can submit linguistically and culturally equivalent results to the regulatory authorities for all trial centres.

A tip on **compliance**

Structured terminology management improves the quality, precision and consistency of multilingual trial documentation – for more reliable trial results and a higher level of acceptance by regulatory authorities and experts.
Here, you can learn more about **terminology...**



At the end of the trial

At the end of the trial, all documents – including the trial reports – have to be merged and translated. In this process, a language service provider's key task is to ensure consistent translation across all documentation and all languages. The translation of trial reports is particularly critical: these documents are reviewed by regulatory authorities to guarantee the efficacy of the treatment method and patient safety.

At medax, the revision is, in accordance with **ISO 17100**, part of the translation process and therefore included in the price.

Did you know? Wherever possible, a professional translation service uses a **Translation Memory System** (TMS). A TMS is a special tool for storing translation data. It offers the advantage that the stored translation units can be reused across multiple documents. This ensures consistent wording and makes translation faster, more accurate, and more cost-effective. Here, you can find more information on the use of **CAT tools...**

Regulatory affairs

As part of the approval process, the necessary documents are translated for submission to the relevant authorities and ethics committees. In addition to trial documents, this includes product labelling, directions for use, contracts and agreements with contractors or suppliers, and correspondence with regulatory agencies.

Due to the diversity of the documents and target groups, there is almost always an overlap between different areas of expertise. For example, the translation of correspondence with international authorities or the relevant ethics committee requires not only medical expertise, but also knowledge of the legal requirements involved. And when translating a contract, it is not only important to reproduce the content correctly, but also to know the exact wording of contractual clauses in the target language.

A **revision** allows experts from different fields to work together. A proofreader with legal training, for example, can check the work of a medical translator – or vice versa. Here, you can learn more about **proofreading ...**

Incidentally:

medax not only translates your written correspondence into 160 languages, but also offers you the services of a qualified interpreter to ensure effective communication between all parties involved – on-site or remotely via video call.

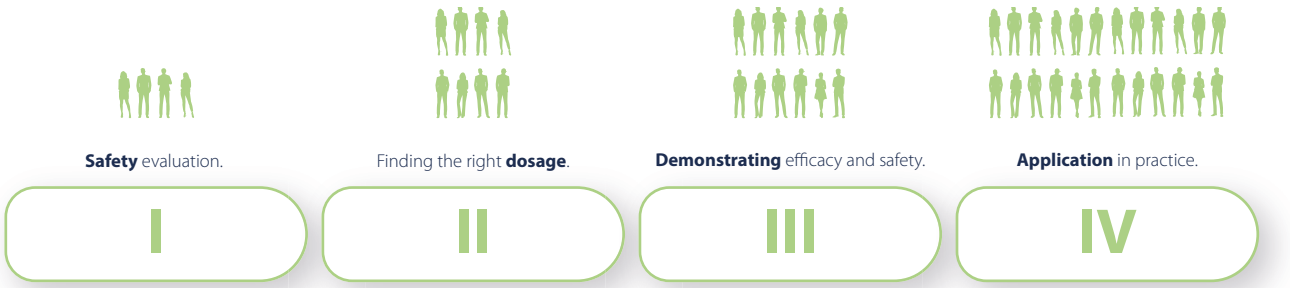
Did you know? Notarisation, apostilles, certification

When submitting registration documents to an authority, a certified translation is usually required. **Certified translations** can only be provided by translators who are authorized to do so by the regional court under whose jurisdiction they fall. They confirm, via a stamp and their signature, that the translation has been prepared correctly and completely to the best of their knowledge and belief.

medax handles all official business on your behalf. The certified documents arrive in your inbox quickly and easily – ready for submission.

An **apostille** may be required for submission to foreign authorities. In this case, medax will additionally submit your certified translation to the relevant office or court on your behalf. This means that it is easily recognized internationally.

If your company is due an audit, or the sponsor of your trial requires a certificate of the quality of your translated texts, a **translation certificate** guarantees that



Peer review ...

For **70%** and more, publishing the trial results before and after market approval presents a major challenge.

the translators and editors used are linguistically and professionally qualified, translate into their native tongue, have worked with the utmost care and have faithfully translated the text into the target language.

Market launch

The primary goal after successful approval is to get the medicinal product on the market. The results of the clinical trial will be translated and published in international journals for this purpose. For a **scientific publication**, translators must have extensive knowledge of statistics and scientific language usage.

Last but not least: Linguistic consistency in your corporate wording must also extend to your marketing materials, online content and training materials. medax selects the right expert for you from our pool of 5,000 specialist translators worldwide. We provide you with multidisciplinary support in our experienced competence teams – from SEO to multimedia to app localization.

Translations are an important component in the complex framework of an international clinical trial.

What needs to be translated?

Trial and test protocols / Synopses / SAE reports / Case Report Forms (CRF, eCRF) / Data collection forms / Questionnaires / Clinical protocols / Insurance for subjects / Informed consent forms (ICF) / Patient charts and journals / Physician and patient guides / Ethics and authority correspondence / Trial and investigator contracts / Inspection, surgery and diagnostic reports / Patient reports (PRO) / Training materials / Approval documents / Publications / Press releases / Summary of the product characteristics (SmPC) / Certificates of analysis (COA) / Patient information leaflets (PIL) / Marketing materials / Websites / Apps / ...

Looking to the future

Some 60 companies from the medical technology and pharma sectors in the European region answered the following questions: **How are clinical trials set to change in the years to come? And what trends will shape the landscape of clinical data collection?**

Minimal on-site monitoring through eCRF integration into the electronic medical record (89%), decentralised or virtual trials (58%) and the widespread use of wearables (47%) are the top trends. In addition, more than two-thirds of participants had planned decentralised trials.

They cited cost savings (75%), faster trial completion (70%) and simplified patient recruitment (50%) as benefits of decentralised studies.

Source: Climedo Health GmbH / https://climedo.de/blog/klinische-studien-was-laeuft-gut-und-was-koennte-verbessert-werden

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Content
Editor
Stefanie Bartos-Scott, Transline

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Markus Selent, María Catalina Caicedo

Concept and design
Birgit Neu, Transline

Graphics co-worker
Daniel Kern, Transline

Internationalisation strategy for CROs

medax
Medical Translations.

Comprehensive language services for demanding multilingual projects

medax – Medizinischer Sprachendienst GmbH
Ilzweg 9 / 82140 Olching
/ T +49 8142 66937-0 / info@medax.de
www.medax.de/en