

WHY LANGUAGE SCIENTIFIC?

MCRA is a market-leader medical device, diagnostics, and biologics CRO and consulting advisory firm. Their translations are subject to high-stakes regulatory scrutiny, and often involve multiple versions from global clinical trial sites.

When MCRA needed highly accurate translations of patient-reported outcome documents and patient-facing instructions for a knee evaluation form and pain scale, they turned to Language Scientific's deep medical expertise and technical proficiency.

As one of MCRA's approved translation providers with a track record of success in medical translation and FDA/EMA-regulated processes, Language Scientific was already aligned with the project's quality and compliance requirements.

The Problem

MCRA needed highly accurate translations of patient-reported outcomes and patient-facing instructions for a subjective knee evaluation form and an associated pain scale.

- There was no margin for error; translation accuracy was directly tied to regulatory compliance
- Clinical meaning had to remain intact. The evaluation form and pain scale required precise terminology to preserve the initial intention of the questions and instructions.
- Patient-reported outcomes raised the stakes. Inaccurate or vague wording could change a patient's interpretation of the information, thus affecting data quality.
- Multiple versions made the project more complex. Back-and-forth e-mails during the scoping phase led to a version of the survey being dropped.
- The deadline was the deadline. Any corrections or clarifications had to be handled immediately, to avoid downstream delays.

RESULTS

Regulatory-ready translations, aligned with the project timeline



Translations preserved clinical intent and patient clarity



FDA and EMA requirements were met



Scope and version issues were resolved without missing deadlines

ACTIONS TAKEN

- Translated the IKDC Subjective Knee Evaluation Form and the VAS Pain Scale with close attention to clinical intent
- Aligned deliverables with FDA and EMA translation requirements
- Identified and corrected a scoping issue involving a missing version of the survey instructions
- Applied specialized medical and regulatory expertise throughout the process