LANGUAGE SCIENTIFIC

CASE STUDY
Accurate and timely ICFs for CRO

NOVOTECH
The Asia Pacific CRO

WHY LANGUAGE SCIENTIFIC?

Novotech is a global Contract Research Organization (CRO) headquartered in Australia, supporting clinical trials across multiple regions and therapeutic areas. As Novotech expanded its clinical research activities, particularly within the U.S., the organization needed to translate Informed Consent Forms (ICFs) into multiple languages to support enrollment of non-English-speaking participants.

Given the strict regulatory and approval requirements associated with informed consent documentation, Novotech required a partner with deep therapeutic and regulatory expertise, the ability to work efficiently across multiple study sites, and a proven track record of delivering accurate, timely, and compliant translations.

The Problem

Novotech needed to translate ICFs into multiple languages to ensure eligible patients could be enrolled without delays. These translations were critical to meeting regulatory requirements and maintaining study timelines across geographically distributed sites. The challenges included:

- Translating highly regulated Informed Consent Forms into multiple languages
- Executed updates around quickly, minimizing delays across study sites
- Ensuring translations were approved quickly within a strict regulatory review process

Any delays in translation or approval could directly impact patient enrollment which is a critical success factor for clinical trials.

RESULTS

Efficient Multilingual Translation, Faster Enrollment, and Regulatory Confidence

Achieved accurate, regulator-ready translations of Informed Consent Forms

Improved operational efficiency through reuse of translation memory

Delivered a cost-effective, scalable solution for ongoing and future studies

ACTIONS TAKEN

- Delivered accurate, certified translations of ICFs.
- Applied scientific and clinical Subject Matter Experts to ensure regulatory and medical accuracy
- Leveraged translation memory to efficiently manage template-based content and amendments
- Turned updates around quickly, minimizing delays across study sites
- Supported a smooth, cost-effective workflow aligned with Novotech's regulatory processes

"We were able to provide participants with a translated informed consent so they could participate in the applicable study."

— Tracie Thaxton, Senior Regulatory Associate, Novotech