

IQVIA Language Solutions: Ensuring Timely and Accurate EU-CTR Submissions

Delivering translated 30+ informed patient consent forms (ICFs) for 13 countries, ahead of timelines

As part of the EU Clinical Trials Regulation (EU CTR), a leading pharmaceutical company needed timely submission of Informed Consent Forms (ICFs) to ensure regulatory approval. IQVIA managed the translation of **30+ ICFs into 13 languages within 8 days**, delivering ahead of the deadline.



The challenges

The EU Clinical Trials Regulation (EU CTR) brought stringent requirements for translations of clinical trial documents. It set out guidelines and requirements for informed consent in clinical trials, including the use of ICFs, to ensure that participants are adequately informed and protected throughout the trial process. The need for patient-centricity, transparency, and access to information required accurate translations across various local authorities, each with their own nuanced requirements. Delays or inaccuracies can lead to regulatory approval setbacks. Failure to comply with these translation requirements can result in delays in obtaining regulatory approval or even rejection of the trial application.



The solution

Constant and clear communication between the client and the IQVIA team was key to the project's success. IQVIA faced these challenges head-on with a comprehensive language solutions framework designed to meet the stringent requirements of the EU CTR:



Regulatory compliance

Accurate translation for key documents into multiple languages as required by different 13 member States.



Patient safety

Layperson translation to ensure consent forms were precise, allowing participants to fully understand the risks and benefits involved.



Quality framework

Rigorous quality framework that enabled the delivery of translations within tight deadlines while maintaining high standards of accuracy and reliability.



The outcomes

IQVIA tackled EU CTR compliance with a robust language solutions framework, prioritizing regulatory compliance, patient safety, and quality. They translated **30+ informed consent forms into 13 languages in less than 8 days**, achieving timely approvals, enhancing patient understanding and safety, and improving operational efficiency.

The trial's patients received the necessary information to make informed decisions about their participation in a CNS clinical trial.