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Tailored Solutions.
Proven Results.

CASE STUDY

Non-Small Cell Lung Cancer (NSCLC) Case Study:

Working in close partnership on the CTIS submission to accelerate start up timelines

In the EU, the Clinical Trials Regulation #536/2014 came into force for all initial study applications made from 31-Jan-2023, thus replacing the Clinical Trials Directive # 2001/20/EC. The EU Regulation now enables Sponsors to submit a single Regulatory application (known as Part 1), rather than individual applications, for approval to run a clinical trial in multiple European countries, making it more efficient to carry out such multinational trials. This is done via an online platform known as the Clinical Trials Information System (CTIS). The national Ethics submissions also use the same platform too, these are known as Part 2.

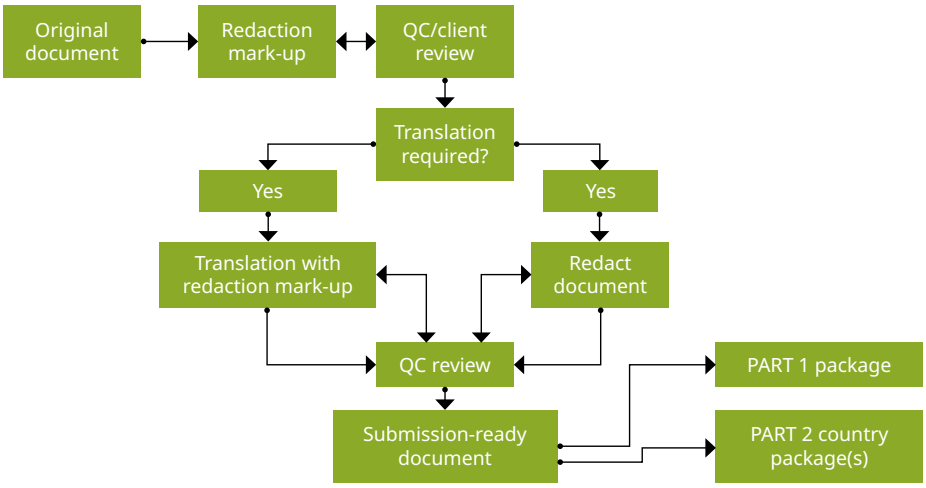
TMC Pharma Services has been working with this system since its inception and has successfully made a number of submissions in CTIS. Below provides a case study & some of our lessons learnt that we applied to our recent NSCLC project.

Study design	A phase 1/2 study of client IMP in combination with approved product in patients with KRAS G12C mutant Non-Small Cell Lung Cancer (NSCLC
Purpose of study	Dose evaluation & expansion cohorts to determine efficacy/safety of novel formulation with approved product
Number of patients	121
Number of sites	26 (US, UK, ES, NLD, BEL, FR)
Study start	April 2023
Final sites selected	June 2023
EU Submission via CTIS performed	July 2023 (ahead of schedule)

Highlights

- Submission completed within 8 weeks of receiving final client documents
- >250 documents uploaded for entire CTIS submission (Part 1 & Part 2)
- Strong collaboration within team ensured quality deliverable

Considerations		
Client	• FINAL core documents provided asap • Defined timelines for client review, translation and redaction to all documents within the packages	• Enabled teams to translate and redact documents in parallel to collecting site documentation • Ongoing QC of documents to allow uploads to take place in real-time
Site	• Feasibility questionnaire included EU CTIS specific items (such as collection of site Organisation ID and site processes for document completion) • Site selected on rolling basis to initiate collection of submission documents	• Enabled early system set-up including site details • Generated timelines on when sites would be able to provide documentation • QC and completeness checks done on rolling basis • Creation of 'master' templates of local documents where possible to transfer knowledge to all countries participating – faster completion



Items for consideration

- Predefine terms for redaction
- All documents require redaction – for CCI, PPI or metadata
- Documents may go through multiple reviews – timeline allowance required
- To reduce cycle time for the review process, final documents to be provided by the client,any edits to documents kick start the process again

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