CASE STUDY

Kayentis & RWS

(global provider of eCOA and DCT solutions)

(language service provider (LSP) and linguistic validation experts)

Partnering for success

Study Overview

A Global Small Cell Lung Cancer Phase II Study, spanning 26 languages and 7 instruments, with 100 participating sites.

COAs in scope:

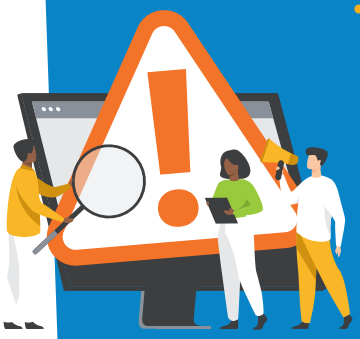
- EORTC Quality of Life Questionnaire - Core 30 (QLQ-C-30)
- EORTC Quality of Life Questionnaire - Lung Cancer (QLQ-LC)
- EuroQol Quality of Life - 5 Dimensions - 5 Levels (EQ-5D-5L)
- Functional Assessment of Cancer Therapy - Item GP5 (FACT GP5)
- Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
- Patient Global Impression of Change (PGIC)
- Patient Global Impression of Severity (PGIS)

Kayentis and RWS were selected to create and implement the electronic versions of the COAs (eCOAs) on a high priority study with a new client, pioneer in biotechnology.

- The collaborative work on the study involved licensing the COAs and obtaining existing translations, eCOA migration and implementation. In addition, there was paper development required for the PGIC and PGIS for all languages.
- RWS and Kayentis deployed a collaborative process, working simultaneously to ensure a seamless delivery in adherence with the sponsor's timelines.

Challenges

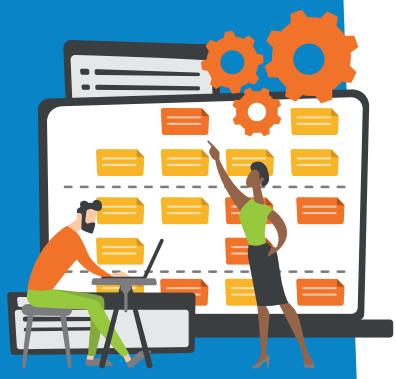
A STUDY MARKED AS HIGH PRIORITY



- The study team had tight timelines to meet both regulatory/IRB submissions and 'first patient in' dates, in which all activities required for eCOA implementation had to be completed. This was a study marked as high priority by the sponsor, proceeding at risk as submission dates were on the critical path.
  - Indeed, initial translation timelines did not align with planned submission dates, therefore strong communication between all parties, proactivity and flexibility were required.

As this was a new client that Kayentis and RWS had not supported together previously, time and engagement were committed, in order to deliver a successful study.

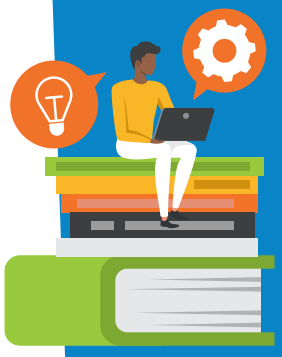
INSTRUMENT DEVELOPERS' REQUIREMENTS



- Instrument developers' requirements needed to be considered, including their reviews of translation reports, and the source English and subsequent translated screenshots (pertaining to the EQ-5D-5L).
- These requirements can cause timeline challenges as any required external review adds additional time for receiving developer feedback and implementing requested changes.

In these situations, a good collaboration between the LSP and the eCOA provider is more important, especially when facing a tight timeline to meet submission requirements.

FACT GP5 COPYRIGHT HOLDER PROCESS CHANGE



Additional challenge relating to the FACT GP5 questionnaire implementation:

- Previously the copyright holder would provide existing translations containing the Kayentis-specific instructional text, however the process changed at this time and the versions provided were no longer Kayentis-specific but rather generic.
- Therefore, there was an element of rework needed for this specific instrument while eCOA edits were already underway.
- Different options for this rework were quickly provided to the sponsor, some impacting timelines negatively and some not. Recommendations were made and risks flagged.

The sponsor could make an informed decision and chose the option with zero impact to overall timelines because of the urgency of the study.

Efficiencies of Kayentis-RWS collaboration

RWS and Kayentis employed a range of different approaches during the collaboration on this study to ensure a smooth project. Clear communication between the teams was key to a successful partnership, and the project management teams for both groups worked closely together throughout the duration of the study, hence aligning expectations and option proposals.

✓ EXAMPLES OF THE SUCCESSFUL COLLABORATION INCLUDE:

- **Integrated translation start-up:** a timelines tracker was created by the RWS project manager at the study kick-off including timelines for Kayentis' steps in the localization process. This allowed the outlining of required processes to the new client and accurate planning to streamline the delivery and ensure that the expectations of all parties were met.

> *"We thought that the translations would be the rate limiting factor for on-time delivery (they are a current pain point with other vendors), but the early engagement by the eCOA vendor (Kayentis) with the translation vendor (RWS) was greatly appreciated and helped set up the understanding of priorities very quickly"*
>
> Sponsor study team

- **Quick questionnaire design:** Kayentis designed electronic versions of the questionnaires within two business days after kick-off; after only two weeks the reference language was approved by the sponsor and available for screen review by RWS.
- **Smooth coordination:** the client's study team as well as both Kayentis and RWS key stakeholders were included in weekly meetings, to ensure a smooth and regular communication through the project. It allowed everyone to discuss overall project progress and put the focus on advancement of the key work. Regular calls also occurred between RWS and Kayentis prior to meetings with the sponsor, to ensure alignment and solid preparation to guarantee efficient meetings with the client.
- **Synchronisation of development:** the paper development of the PGIC and PGIS, and waiting for EuroQol to provide the existing EQ-5Ds, could have led to delays but RWS proceeded with the translation of the metatext and eCOA edits for the remaining instruments (EORTC-QLQ-C-30, EORTC-QLQ-LC and FACT GP5) while waiting for those to be completed/provided.

> *"The system and tablet is very user friendly, esp. compared to others used"*
>
> Sponsor UAT tester

- **Short eCOA build turnaround time:** in parallel to the paper development work Kayentis team pursued the specification process and the eCOA build to meet the clients' tight timelines. As such, the platform could go live for first patients' inclusion on the expected date.
- **Fast developer reviews:** working collaboratively to plan required deliveries enabled the external reviewers to be made aware of when they could expect to receive files for review, helping achieve forward planning and mitigating delays. RWS was able to secure first-time approvals for most languages. This was critical as developer reviews can be time-consuming.
- **Priority management:** closely working together, Kayentis and RWS adjusted timelines for process steps and milestones as the project progressed, taking into consideration the external review requirements. Deliveries were prioritised based on client requirements and made available between 8 to 28 business days ahead of quoted timelines.

> *"We were impressed by the communication and proactive nature in alerting of potential delays. You did work hard in getting screenshots as soon as possible: they came in earlier than forecasted"*
>
> Sponsor study team

Outcomes

The continuous communication between both teams and a long-standing partnership between Kayentis and RWS enabled a successful study start-up so that the final study materials were completed and delivered earlier than quoted timelines. The collaborative efforts established between both partners helped mitigate any potential delays arising from external review requirements and changing priorities to ensure a successful study.

KAYENTIS at a glance

A KEY PLAYER IN eCOA & DECENTRALIZED CLINICAL TRIALS

Broad experience...

Since **2005**
eCOA expert

300+
clinical trials
phase I-IV

20
different
therapeutic
areas

...in a wide range of study types

From **15** patients
in an early phase trial to
+10,000
in a late-phase study

From local to
global studies
100%
of countries covered

Studies lasting
up to 10
years

...with strong scientific and operational support

Clinical & Scientific
dedicated team to
support your study

Operational capabilities
USA - Europe - Asia

24/7
HELPDESK

kayentis

To learn more, please contact us at sales@kayentis.com