

Kayentis (global provider of eCOA and DCT solutions) and RWS (language service provider (LSP) and linguistic validation experts) 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 study is a Global Small Cell Lung Cancer Phase II Study, spanning 26 languages and 7 instruments, with 100 participating sites.

The 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.

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.

[Download the case study](#)

Key Words:

- eCOA
- RWS
- ePRO
- eDiary
- data collection
- clinical trial

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