

Kayentis & RWS Life Sciences Partnering for Success

- Global Immunology and Dermatology Phase II Study
- 9 countries and 13 languages
- A review of the Clinical Outcome Assessment (COA) Licensing, Translation and Linguistic Validation, and electronic COA (eCOA) Migration study between Kayentis and RWS Life Sciences



STUDY OVERVIEW

■ THREE PATIENT-FACING COAs REQUIRED IMPLEMENTATION ONTO KAYENTIS' DEVICE FOR USE IN A GLOBAL STUDY:

The Children's Dermatology Life Quality Index (CDLQI), Urticaria Patient Daily Diary (UPDD) and the Angioedema Activity Score (AAS).

> *RWS Life Sciences (Language Service Provider and Linguistic Validation experts) and Kayentis (eCOA specialists) worked together to create the electronic versions of the COAs (eCOAs).*

■ THE COLLABORATIVE WORK ON THE STUDY INVOLVED LICENSING THE COAs AND OBTAINING EXISTING TRANSLATIONS TO BE MIGRATED ONTO THE ELECTRONIC PLATFORM

The UPDD and AAS were unavailable in some of the required languages, so full linguistic validation, including cognitive debriefing interviews with an adolescent population, was conducted.

> *RWS Life Sciences and Kayentis deployed a collaborative process, working simultaneously to ensure a seamless delivery.*

EFFICIENCIES OF COLLABORATION

RWS Life Sciences and Kayentis employed a range of different approaches during the collaboration on this study to ensure the smooth conduct of the project. Clear communication between the teams is key to a successful partnership, and the Project Management teams for both groups worked closely together throughout the duration of the study to align expectations.

Examples of the successful methods of collaboration include:

- **Production of a Timeline tracker:** this document was created by the RWS Project Manager at the study kick-off and was shared and discussed with Kayentis to include their timelines. This allowed initial structuring of required processes and accurate planning in order to streamline the delivery and ensure that the expectations of all parties were met.
- **Regular meetings:** weekly meetings were held between the RWS Life Sciences, Kayentis and Client's study team to discuss progress and focus on advancement of the work and required prioritization.
- **Synchronization of the Patient-Facing Metatext and Patient Guide:** Kayentis brought RWS Life Sciences into the development process of the Patient Guide, ensuring consistency between the various documents, allowing for a smoother translation process. This also helped to mitigate potential translation issues later on that could potentially have caused timeline delays.
- **Reuse of previously translated questionnaire wording from existing studies:** RWS and Kayentis identified existing text from previous collaborative studies, which reduced the timelines and decreased the number of reviews.
- **Developer Reviews:** Given the number of external reviews required for this study (3 per language), both teams worked together to manage the requirements of the instrument developers. This involved frequent and accurate updates on the progress of the work and the upcoming milestones to allow the correct information to be passed on to the instrument developers. 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.
- **Priority Management:** RWS and Kayentis worked together to adjust timelines for process steps and milestones as the project progressed, taking into consideration the external review requirements, in order to prioritize deliveries based on client requirements.

CHALLENGES

- **Tight timelines**
The submission timelines were tight, during which all of the activities required for eCOA implementation had to be completed.
- The complexity of the project was increased by the requirement of **cognitive debriefing interviews with a pediatric population.**
- **Instrument developers' requirements** also needed to be considered, including their reviews of translation reports, Data Collection Forms from the cognitive debriefing interviews, and the source English and subsequent translated screenshots.

These requirements can cause timeline issues on a linguistic validation project as the recruitment of an adolescent population can be more challenging than an adult population, and any required external reviews can cause delays in production due to the time taken both for the review itself and the implementation of the requested changes.

In these situations the collaboration between the Language Service Provider (LSP) and eCOA Provider can be more challenging, especially when facing a tight timeline to meet submission requirements.

OUTCOMES

The continuous communication between both teams enabled a successful partnership and the final study materials were completed and delivered on time. The collaborative efforts established between RWS Life Sciences and Kayentis helped mitigate any potential delays arising from a potentially difficult patient population, external review requirements, and changing priorities to ensure a successful study.

CLIENT APPRAISAL

You have done an excellent job in guiding us through all the steps from the very beginning. From the start we had very tight timelines but you really made it happen, perfectly on time, no delay! You have been a key player in helping us to adhere to our commitment to the PDCO (EMA). I have rarely seen such flexibility and commitment from a 3rd party vendor. Communication between RWS and Kayentis could not have been smoother. It helped us significantly in the clinical team so that we could concentrate on other tasks. You have really gone beyond expectations with regards to responsiveness, document turn-around time, quality, resolving any issues and fulfilling the clinical team requirements. Excellent job!