SUCCESS FACTORS & KAYENTIS’ SOLUTION

CHOOSE THE MOST SUITABLE DEVICE TO MATCH INSTRUMENT SPECIFICITIES AND THE PATIENT POPULATION
- The Kayentis tablet was used for site-based ePRO data collection. Our solutions were judged as being simple to use, very intuitive, and seamless for all users.
- The tablet dual connectivity (2G/3G) that allowed immediate transmission and synchronization at any time and place at the local cost was considered a key advantage.
- Moreover, our powerful tools that allow monitoring of connectivity status for each tablet in real time were beneficial for the detailed monitoring of study sites. Immediate actions were taken remotely to resolve potential issues in a timely manner.

EXPEDITED MANAGEMENT OF STUDY SET-UP FOR IMPLEMENTATION OF THE FPP
- Proactive study management and effective collaboration with experts and investigators for the generation of screenshots and training material in all languages for IRB/EC submission.

WORLDWIDE LOGISTICS SUPPORT & TRAINING
- Dedicated 24/7 multilingual Help Desk with 3 levels of escalation (English, German, Spanish, French, Italian) in addition to standard languages; over 150 additional languages on demand.
- Device and instrument expertise to match the specificities of oncology and its populations. 10+ years of eCOA experience, innovation, and knowledge of country specificities have in time efficiencies. Overall these benefits ensured a successful collaboration between Kayentis, the Sponsor, and multiple local sites: immediate actions were taken remotely to resolve potential issues in a timely manner.

Kayentis offers key eCOA expertise in oncology

ADVANTAGES OF KAYENTIS’ eCOA/ePRO services & capabilities to Sponsors/CROs

- Manage the entire process of eCOA implementation.
- Determine the best mode of electronic data capture.
- Tablets, smartphones devices, ePEN, web solutions, APSS.
- ePRO: instrument design & validation through collaboration with experts, systems, vendors, companies, the implementation, development, and validation of the instrument.
- Project management & training.
- Technology, equipment supply, logistics & technical support.
- 24/7 multilingual Help Desk.
- Data management, alerts process and web portal for online monitoring.
- Metrics & risk-based monitoring.

eCOA INSTRUMENTS used for PROs & disease assessments

Quality of Life Questionnaires (European Organization for Research and Treatment of Cancer [EORTC])
- EORTC QLQ-C30 - Patient reported outcomes assessment.
- EORTC QLQ-C15-PAL - Palliative care questionnaire.
- EORTC QLQ-C30 - Patient reported outcomes assessment.
- EORTC IN-PATSAT32 - Satisfaction with care measures.
- EORTC QLQ-C15-PAL - Palliative care questionnaire.
- EORTC QLQ-C15-PAL - Palliative care questionnaire.

Other scales
- ECOSS, NCI-CTCAE Quality of life questionnaire consisting of the dimensions: disability, self-care, usual activities, pain/discomfort, anxiety/depression offered by EuroQol group.
- Symptom-specific (e.g. pain visual analog scale [VAS]).

Worldwide clinical trials
- 80% Phase III/III
- 50+ countries
- 70+ languages (including Japan)

EXPERIENCE
- 15+ years of eCOA experience, innovation, and operational expertise in clinical trials.
- Device and instrument expertise to match the specificities of the instruments and their applications.
- Established working partnerships with linguistic and validation companies.
- State of the art technology and connectivity options adapted to global and local requirements.
- Familiarity with complex logistic support and challenging specific countries (e.g. Russia, China, Japan).
- Knowledge of local management practices and practical eCOA expertise in oncology.

1,500+ patients

500+ sites

eCOA/ePRO solutions used for PRO & disease assessments including multiple myeloma, renal carcinoma, LAL, breast cancer, melanoma.

Challenges
- At the beginning of the program, the Sponsor switched from paper COA to electronic COA.
- Solution required ePRO on-site requirements.
- 45+ countries/lanuages worldwide (including Japan, Thai, Greek).
- Study set-up timelines for the Full Package Protocol (FPP) submission - screenshots to be provided in all languages for IRB/EC.
- Instructor & CRA meeting training – regular training and implementation of Key Performance Indicators (KPIs) with the Help Desk Level 1 partner to ensure a high level of site and patient satisfaction.