ONCOLOGY

CASE STUDY

Global Phase III Oncology Study - Melanoma

- 500 patients, 200 sites, 45 countries and languages, 36 months study duration

Objective

- Solutions for on-site ePRO assessments (EORTC QLQ-C30 / EQ-5D / FACT-M)

Kayentis
Dedicated to eCOA & Patient Engagement

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 (3G/ WIFI) that allowed immediate transmission and synchronisation 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

CHALLENGES

- At the beginning of the program, the Sponsor switched from paper COA to electronic COA
- Solution required ePRO on-site requirements
- 45+ countries/languages worldwide (including Japan, Thai, Greek)
- Short study set-up timelines for the Full Package Protocol (FPP) submission -screenshots to be provided in all languages for faster IRB / Ethics Committee (EC) submissions-

EXPEDITE MANAGEMENT OF STUDY SET-UP FOR PREPARATION OF THE FPP

- Proactive study management and effective collaboration with authors and translators for the generation of screenshots and training material in all languages for IRB/EC submission
- Established working processes and implementation of improvements for the set-up of new studies; availability of assessment scales, previous experience, and knowledge of country specificities have in time efficiencies. Overall these benefits ensured a successful collaboration between Kayentis, the Sponsor, and translators/validation vendors and resulted in faster submission of eCOA documentation to IRBs/ECs

WORLDWIDE LOGISTICS SUPPORT & TRAINING

- Dedicated 24/7 multilingual Help Desk with 3 levels of escalation (English, German, Spanish, French, Italian provided as standard languages; over 150 additional languages on demand)
- Investigator & CRA meeting training - local site initiation 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

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, smartphone devices, ePEN, web solutions, APPS
- ePRO instrument design & validation through collaboration with experts, authors, translation companies for the implementation, development, and validation of ePRO instruments
- Project management & training
- Technology, equipment supply, logistics & technical support
- 24/7 multilingual Help Desk
- Data management, alerts process and web portal for online reporting
- 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 IN-PATSAT32 - Satisfaction with care measures
- EORTC QLQ-C15-PAL - Palliative care questionnaire

Quality of Life Questionnaires FACIT

- FACIT Measurement System
- FACT-G - Functional Assessment of Cancer Therapy - General
- Scales - For symptoms of specific cancers such as FACT M (Functional Assessment of Cancer Therapy –Melanoma)
- Scales - For specific symptoms – e.g.anemia, fatigue such as FACIT – fatigue

Other scales

- EuroQoL (EQ-5D): Quality of life questionnaire consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) offered by EuroQoL group
- Symptom-specific (e.g. pain visual analoge scale [VAS])

EXPERIENCE

State of the art technology and connectivity options adapted to global and local requirements; high interoperability and data integration capability.

- 12+ years of eCOA experience, innovation, and operational expertise in clinical trials.
- Device and instrument expertise to match the specificities of cardiology and its patient populations.
- Strong partnerships and established processes with translation companies as well as automated tools to manage languages in an efficient and timely manner.
- Familiarity with complex logistic support and challenges of specific countries (e.g. Russia, China, Japan).
- Knowledge of local management practices and practical eCOA expertise in oncology

Worldwide clinical trials

150+ clinical trials

80% phase II/III

75+ countries

90+ languages
(including Chinese, Japanese, Thai)

50,000+ patients

6,500+ sites

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

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