Kayentis

Dedicated to eCOA and patient engagement

Oncology Case Study: Global Phase III Oncology Study – Melanoma

kayentis · Sunday, July 5th, 2020

With its strong experience in eCOA market, Kayentis introduces its new case study about oncology and melanoma in global phase III.

Global Phase III Oncology Study – Melanoma

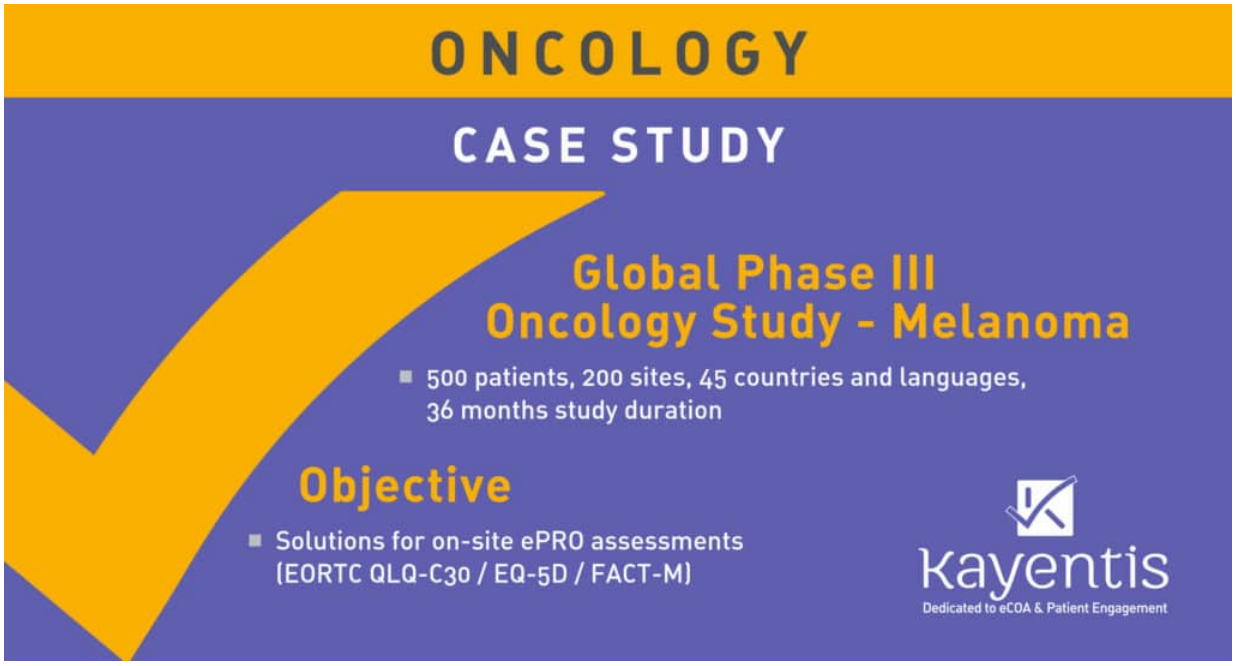
- 500 patients
- 200 sites
- 45 countries and languages
- 36 months study duration

Challenges of this oncology case study

- At the begining 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.

Frédérique MARION, Kayentis Business Development Director

To download this case study, please click here:



Success Factors & Kayentis' Solution

Choose the most suitable device to match instrument specificities, investigator needs, 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

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

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