Kayentis

Global provider of eCOA and patient-centric solutions

Cardiovascular case study: Global Phase III Study – Heart Failure & Actigraphy

kayentis · Thursday, May 18th, 2017

After case studies about autoimmune & skin diseases, psoriasis and oncology, Kayentis releases its cardiovascular case study regarding heart failure and actigraphy. Kayentis offers combined eCOA / ePRO expertise in cardiovascular and medical device.

Global Phase III study – Cardiovascular & heart failure

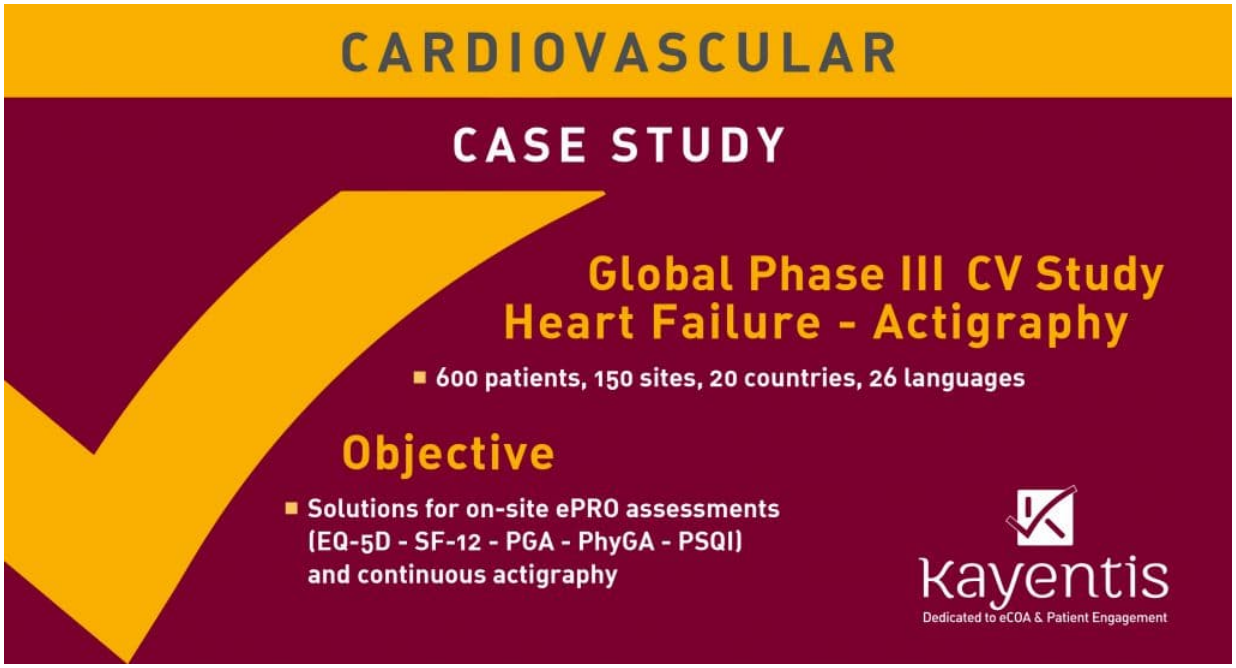
- 600 patients
- 150 sites
- 20 countries
- 26 languages

Challenges of the cardiovascular case study

- An eCOA partner that could deliver an ePRO solution combined with proven data management and actigraphy expertise.
- On-site ePRO solution and data management of actigraphy data.
- Short study set-up timelines and interaction with the sponsor and different CROs for study implementation.

Frédérique MARION, Kayentis Business Development Director – May, 18, 2017

To download this case study, please click here:



Success Factors & Kayentis' Solution

State of the art technology and web platform interoperability

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. The solution was judged as simple to use, very intuitive, and seamless for all users.
- The tablet's dual connectivity (3G/WIFI), which allowed immediate transmission and synchronisation at any time and place, was considered a key advantage.
- Moreover, powerful tools that allow monitoring of the 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.
- Data review tools on the tablet were indispensable at each visit for study site staff and the investigator to confirm that patient answers for potential adverse events had been reviewed.

Clinform – Strong data management, alerts process, and web portal for online reporting and data integration

- The use of our devices combined with the integrated web portal access allowed clinical staff and the study team to have immediate access to the study data and scores, and to monitor the study easily and in detail.
- Moreover, Clinform can provide alerts to the site for specific ePRO data for each patient as well as for external activity data that are transmitted.
- Our powerful data management tools allowed full data management of eCOA data as well as a high standard quality check and database reconciliation to ensure the high quality of a continuous, large volume of actigraphy data collected and transmitted.

Efficiences for expedited management of study set-up: global logistics

and helpdesk support & training

- Proactive study management and effective collaboration with an actigraphy device company for study implementation, the generation of training material, and the development of the data management specifications played a key role in the success of the setup of the study on time.
- Our logistics experience, knowledge of country specificities, and global capacity for multi device shipments within short timelines were essential.
- With the implementation of new technologies a dedicated 24/7 multilingual Help Desk was provided to sites and patients to ensure appropriate support for device use and questionnaire completion. The implementation of Key Performance Indicators (KPIs) with our Help Desk level 1 partner ensured a high level of site – and patient – satisfaction.
- In addition, Kayentis provided training at the investigator meeting and at regional site initiation meetings – initiation training calls were provided by the Help Desk support for dummy patient training on device and tablets, and a tutorial video was implemented to ensure appropriate online training of all stakeholders.
- Overall, these aspects ensured a successful collaboration between Kayentis, the Sponsor, and the CRO/actigraphy vendors, and resulted in faster study implementation and effective study management.

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