

DERMATOLOGY

CASE STUDY

Global Phase III Studies in Psoriasis

- 5 years of successful collaboration with a Top 3 Pharma, 10+ studies, 6,000 patients, 1,000 sites, 60 countries and languages, adult, elderly, and pediatric populations

Objective

- Solutions for ePROs, ClinROs



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 eClinRO & ePRO data collection. ePen technology was an alternative solution used for studies with older populations
- Our solutions were judged simple to use, very intuitive, and totally seamless for all users. The tablet's dual connectivity (3G/WiFi), which allowed immediate transmission and synchronization at any time and 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 for adult, elderly, and pediatric populations
- Inclusion of countries worldwide
- Technology/device adapted for ePRO and ClinRO requirements
- Need to obtain PASI Score immediately
- Short data management timelines

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, 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

REAL-TIME REPORTING - INSTANT SCORE AVAILABLE

- The use of the tablet was key to increasing data quantity and improving data quality; the configuration that allowed the clinician to review patients' data was particularly useful in minimizing missing data and errors
- The tablet's dual connectivity (3G/WIFI) enabled the clinical staff and study team to have immediate access to the data. Once entered in the tablet, the PASI score was calculated instantly, transmitted, and available immediately on the Kayentis web portal
- The use of the tablet combined with the integrated web portal access allowed clinical staff and the study team to monitor eCOA compliance and the eCOA study results easily and in detail

PROACTIVE STUDY MANAGEMENT - EFFECTIVE DATA MANAGEMENT - CLOSE RELATIONSHIPS TO ENSURE LONG-TERM COLLABORATION

- Implementation of study indicators to allow follow-up of study conduct:
 - Follow-up of signals including weak signals of sites' behaviour/understanding
 - The KPIs were followed; pre-analysis was done by the Kayentis team and shared with the sponsor
- Benefits of the Clin'Form platform were huge for the clinical staff and sponsor monitors:
 - Real-time data access and instant scores/alerts
- Query management and online queries for the investigator site
- 100% on-time for set-up & database lock timelines
- Establishing working process and implementing improvement for the set-up of new studies resulted in time efficiencies and cost savings. Overall these benefits ensured a continuous and successful collaboration between Kayentis, the sponsor, and linguistic translation/validation vendors

SPONSOR - SITE SURVEY

- A survey showed excellent feedback from the sites and customers regarding our products and services, with a Net Promoter Score of >90%
- 90% of end users judged our tablet solution equal (40%) or superior (50%) to other tablet solutions they had used before
- Operational flexibility and a spirit of innovation
- Expert team and senior management easily accessible
- Competitive pricing

Kayentis offers strong eCOA expertise in dermatology

eCOA INSTRUMENTS

- **eClinROs instantly available:**
 - PASI, IGA, BSA, PGA
- **ePROs/eDiary instantly available:**
 - DLQI (Dermatology Quality of Life Index)
 - DPS (Dynamic Pruritus Scale)
 - EQ-5D (EuroQoL Quality of life questionnaire consisting of five dimensions - mobility, self-care, usual activities, pain/discomfort, anxiety/depression)
 - FACIT-Fatigue
 - HADS (Hospital Anxiety and Depression Scale)
 - NAPPA (Nail Assessment in Psoriasis and Psoriatic Arthritis), with different components: NAPPA-QoL (questionnaire assessing quality of life), NAPPA-PBI (questionnaire assessing patient-relevant treatment benefits - the Patient Benefit Index)
 - Pruritus NRS, Pruritus CRS (Pruritus Category Scale), Pruritus VRS
 - SF36 (The Short Form (36) Health Survey)
 - Sleep Disturbance NRS
 - Symptom-specific (visual analogue scale [VAS])
 - WPAI, WPAI-GH (Work Productivity and Activity Impairment Questionnaire-General Health)

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, development, implementation, and validation through collaboration with experts, authors, and translation companies
- 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

EXPERIENCE

- 10+ years of eCOA experience, innovation, and operational expertise in clinical trials
- Device and instrument expertise to match the specificities of dermatology and its populations
- 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 challenges of specific countries (e.g. Russia, China, Japan)
- Knowledge of local management practices and practical eCOA expertise in dermatology

Worldwide clinical trials

35+ Global Phase II/III Studies

75+ countries

90+ languages (including Chinese, Japan, Thai)

13,000+ patients

1,000 active sites using the eCOA device

eCOA/ePRO solutions

used for eDiaries, ePROs, eObsRO, eClinRO & disease assessments in skin disease including Psoriasis, Eczema, Atopic Dermatitis