CASE STUDY – TOP 5 PHARMA

18+ years of Success Stories with Big Pharma

"Kayentis is the best vendor we have worked with. The team is interested in the success of the study, and every team member at Kayentis is experienced in their job and able to execute their work."

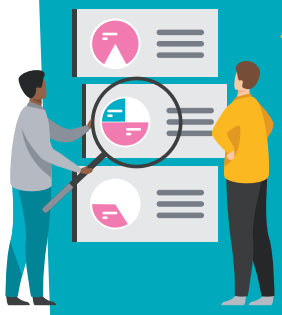
A Top 5 pharma clinical team member

eCOA ASSESSMENT & DECENTRALIZED CLINICAL TRIALS

- Site-based and/or at-home completed ePRO
- Implementation of patient eDiaries, design of protocol-specific eDiaries
- Combination of ePRO/eDiaries/eClinROs/eObsROs
- Management of complex studies, e.g., pediatric studies with multiple age ranges and combination of ePRO/eObsRO
- Provisioned Devices & BYOD strategies
- Televisits

Successful Collaboration to help Big Pharma Mitigate Clinical Trial Challenges

Large programs, multiple studies, time constraints and quality requirements for all projects



LARGE PROGRAMS ENCOMPASSING MULTIPLE STUDIES

Despite the size of the projects and their multiple constraints, the need to save time and maintain efficiency for study set-up and initiation remain key factors. Timelines cannot be continually extended, despite the necessity to amend protocols, and the large number of countries and sites that are often involved.

> Kayentis guarantees very strong eCOA project coordination to facilitate this aspect within the clinical trial

STUDIES ARE MORE AND MORE COMPLEX

As study complexity increases, difficulties can occur within the protocol or within the eCOA build itself.

- Protocols may require multiple visits, or the visit scheduling may change over time, or visits can be completed in a hybrid mode (i.e., on site or at home).
- Studies may include very sick patient populations or pediatric populations with multiple age ranges. Such studies may also include complex designs that require well-articulated branching logic or complex score calculations.

> Kayentis has focused on eCOA excellence and has built a team of experienced eCOA specialists who know how to handle these complexities

TIMELINES WILL ALWAYS BE TIGHT

Meeting the expected timelines remains one of the main challenges during study implementation.

There are always unplanned hurdles that have an impact on the flow of study start-up activities, and as such, efficiencies here and there are always welcome.

> At Kayentis, we go the extra mile to guarantee we get to GoLive on time

HIGH QUALITY AND REGULATORY REQUIREMENTS

Clinical research has always been extremely regulated, and the evolution towards more decentralized operating processes will not reverse the trend.

> Kayentis' rigorous quality processes ensure we answer to regulatory requirements, as the FDA and other regulators will be reviewing eCOA data with a magnifying glass

KAYENTIS KEY SUCCESS FACTORS

Our governance structure is made to manage Big Pharma needs and builds long-term relationships

✓ AN EXPERIENCED TEAM DEDICATED TO ACCOUNT MANAGEMENT

- **The Kayentis Governance team** includes dedicated Portfolio Managers and Executive team members
  - Run regular project portfolio overviews
  - Consolidate and share regular key performance indicators and identify areas for improvement
  - Ensure client specifications and expectations are well understood by all stakeholders
  - Adapt the format and frequency of meetings to pharma governance structure

✓ A CLOSE COLLABORATION WITH CLIENTS FOR CONTINUOUS IMPROVEMENT

- **Regular measures of client satisfaction:**
  - Surveys used to monitor client satisfaction and recommendation rate with an annual questionnaire
  - Systematic lessons learned exercise performed after key study milestones and shared with our sponsors to improve our collaboration
- **Transparent sharing of Kayentis roadmap:** regular review of roadmap and evolution plans

Operational excellence

✓ EXPERIENCED AND EAGER CLINICAL TEAMS

- **Operational team members have scientific backgrounds** and work very closely with sponsor teams

"Very communicative team: provides regular updates, emails are answered quickly, and meeting minutes are sent on time"

A Top 5 pharma clinical team member

- **Strong engagement from the medical and scientific department:**
  - Systematic protocol review at RFP to flag any area that might require caution prior to project start-up
  - Dedicated analyses of complex studies to propose the best implementation from clinical, scientific and product considerations
  - Established partnerships with patient associations and sites: to develop solutions that better fit patient's journey
- **Low attrition rate, minimizing staff turnover during studies**

CLIENT-CENTERED OPERATIONAL PROCESSES

- **Consistent, reproducible, and risk-based processes across studies** through upfront establishment of clear requirements, timelines, and responsibilities
- **Data management throughout the study**
  - With data managers involved from the very start
  - Maintains clean database in an ongoing and continual exercise
  - Aligned with GCP and regulatory expectations

"Over the last 18 months, we have delivered 100% GoLive and database locks on time!"

Guillaume Juge, CEO Kayentis

STREAMLINED COMMUNICATION TO ENSURE PERFECT ALIGNMENT AND RESPONSIVENESS

- **Established key contacts with all sponsor's stakeholders** to align on a common vision and requirements
- **Proximity** of pharma and Kayentis operational teams through offices in Europe, North America, and Asia
- **Short escalation path** to the executive team is ensured for prompt resolution

STRONG RELATIONSHIPS WITH LINGUISTIC VALIDATION AGENCIES

to ensure efficient and short timelines during the set-up phase

"The good collaboration between Kayentis and the Linguistic Validation Agency made things much easier to handle"

A Top 5 pharma clinical team member

Our Quality Commitment: one quality management system to support Big Pharma quality requirements

COMPLIANCE WITH WORLDWIDE REGULATIONS/ STANDARDS

on IT security, data security, data privacy, and confidentiality

ROBUST PRODUCT DEVELOPMENT AND CONFIGURATION PROCESSES:

- State-of-the-art software development life cycle processes, including validation
- Robust, repeatable, and agile processes to configure solutions to the needs of the study

CONTINUOUS PROCESS IMPROVEMENT

based on users' feedback and internal audits

ROBUST INVESTIGATION AND CAPA MANAGEMENT

ESTABLISHED SUPPORTING PROCESSES:

staff training, external provider monitoring, documentation management

AUDIT-READY SYSTEM

Powerful & flexible technology to support sponsor and study needs

- **MULTIPLE DATA COLLECTION MODES** to adapt to every type of protocol or patient population (provisioned devices, BYOD, webCOA, interview mode), all in a single platform

- **POSSIBILITY TO CREATE ANY TYPE OF ACCOUNT:** Patient, observer, clinician

- **USER-FRIENDLY AND FLEXIBLE TECHNOLOGY** for every type of patient population, including very sick patients, pediatric populations with multiple age ranges, elderly populations.

- **ABILITY TO BUILD PROJECTS WITH COMPLEX DESIGN:**
  - Multiple triggers, complex branching logic
  - ePRO/eClinRO/eObsRO/eDiary within the same protocol
  - Complex score calculation
  - Specific eDiary design. e.g., video, illustrations for pediatric populations, country-adapted medication log

- **ABILITY TO INTERCONNECT WITH OTHER SYSTEMS,** e.g., IRT systems, Quality Metric for SF-36 and SF-12 score calculation, wearables

Strong CSR approach

- **TO ALIGN WITH CSR ENGAGEMENTS OF PHARMA COMPANIES,** Kayentis implemented a Carbon-Neutral Program in 2020, which aims to reduce CO_2 emissions in clinical trials without having an impact on their cost, quality, or timelines.

"With a 95.6% recommendation rate in 2022, we are proud of the trust-based relationships we have established with several large pharma companies for many years."

Guillaume Juge, CEO Kayentis

*2022 recommendation rate

KAYENTIS at a glance

A KEY PLAYER IN eCOA & DECENTRALIZED CLINICAL TRIALS

Broad experience...

Since 2005
eCOA expert

300+
clinical trials phase I-IV

100,000+
patients

20
different therapeutic areas

...in a wide range of study types

Up to 8,000
patients per study

Up to 1,000
sites per study

Up to 50
countries per study

Studies lasting **up to 10** years

...with strong scientific and operational support

Clinical & Scientific
dedicated team to support your study

3
LOCATIONS
USA - France - Japan

24/7
HELPDESK

kayentis

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