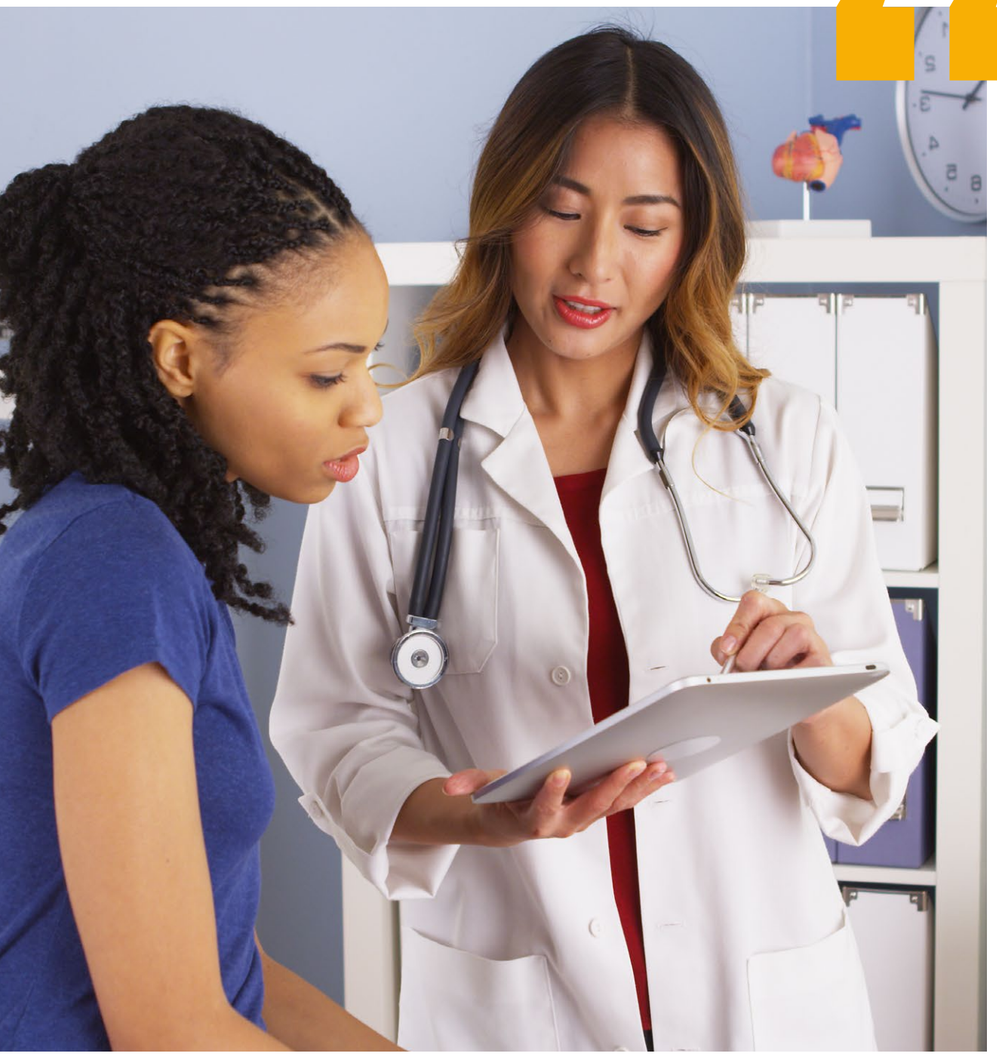
Flexible. Robust. User-friendly.

The eCOA solution to simplify your clinical trial experience

Kayentis

Kayentis, developing innovative eCOA solutions for capturing the patient's voice in clinical trials



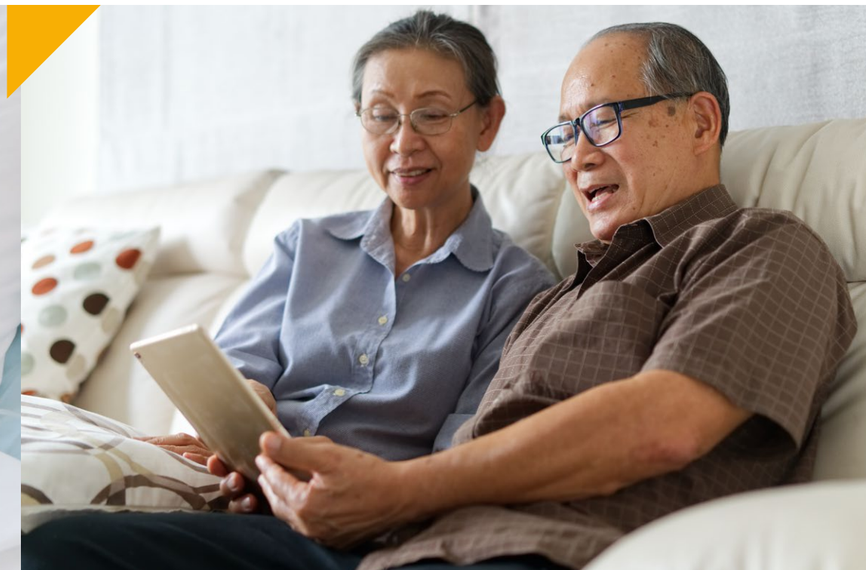
Patients and sites are at the heart of our considerations in the design of our solutions

- **User-friendly and intuitive solutions** for patients data collection at home (eDiary) or on-site (ePRO), and for caregivers (ObsRO)
- **Cutting-edge technology** to facilitate the investigator site journey throughout the study: real-time data access & patient monitoring through our powerful Clin'form Web Portal
- **Flexible WebCOA solutions** to support various protocol designs
- **An expanding portfolio of solutions to support the post-COVID new normal and Decentralized Clinical Trials** (enabling telehealth visits, and integration with other apps or external devices)

Capturing patients' data anywhere

We implement solutions that are intuitive and easy-to-use for patients and sites

- One single App for all needs (ClinROs, PROs, Diaries)
- Large range of provisioned devices or BYOD option
- Devices connect via Wifi/4G and work offline
- Embedded alerts and instant edit checks
- Investigator review within the devices (with status management)
- Remote control of devices, including timestamp consistency
- WebCOA back-up solution with web-based data entry for any user



2 Monitoring your project with a powerful and flexible portal

ONE SINGLE PLATFORM

CLIN'FORM WEBPORTAL ALLOWS YOU TO MONITOR YOUR STUDY AND CLEAN YOUR DATA

- Web portal with the same role-based user login as the Clin'form App
- Real-time data access
- Instant scores/alerts (visible in the portal)
- Patient compliance management & tracking
- Intuitive dashboards
- Full audit trail
- Data management – integrated DCF process
- Interoperable system, easily connects to any EDC/CDMS

BASED ON A ROBUST & SECURE INFRASTRUCTURE

- Back-up servers ensure total security and availability of our applications
- Hourly data back-ups ensure full protection of your data
- Disaster recovery plan in place
- AZURE Cloud Hosting

21 CFR part 11 compliant
GDPR compliant
Validated according to GAMP5 guidance

Supporting your project team from set up to completion

STUDY SET-UP

- Dedicated PM to assist you thoughout the study, including: definition of client specifications & trial documentation, translation/validation management, data management set-up
- Platform set-up: hardware & software, programming, UAT, validation, webCOA back-up...
- Site supplies, device preparation, and logistics: Customs clearance expertise, worldwide experience, partnership with courier companies, dedicated logistics for China

STUDY CONDUCT

- Site initiation including site and user access initiation, and full training proccess
- Trial management:
  - Project coordination
  - Full data management
  - 24/7 multilingual Helpdesk for sites and patients
- Close out:
  - Logistics of devices
  - Data reconciliation, data fransfer, and archiving
  - Lessons learned

MEDICAL SUPPORT

- Review of each protocol, helping to build a proposal that is fully adapted to the specificities or design complexities of your project
- Insights from the perspective of both the patient and the site
- Collaboration with key institutions: ePRO consortium, DIA, patient advocates, patients

PROGRAM MANAGEMENT GOVERNANCE

- Portfolio director & Governance committee
- Quaterly operations meeting
- Development of synergies and process efficiencies

Kayentis, a global eCOA experience in a broad range of therapeutic areas

IMMUNOLOGY INFLAMMATION
ONCOLOGY
GASTROENTEROLOGY
NEUROLOGY PAIN PSYCHIATRY
DERMATOLOGY
HEMATOLOGY
ALLERGY
OPHTHALMOLOGY
RESPIRATORY
WOMEN'S HEALTH
VACCINES
RARE DISEASES
ENDOCRINOLOGY METABOLISM CARDIOVASCULAR
INFECTIOUS DISEASES
PEDIATRICS

16+ years of global eCOA experience

3 offices Europe-USA-Japan
and logistics partner in China

90,000+ patients

16,000+ sites

260+ clinical trials

79 countries

120+ languages

Kayentis added values for sponsors

- **Our solutions are comprehensive, simple and reliable** being designed specifically for the differing needs of patients, sites and study teams
- **We design our solutions in close collaboration with patients:** collaboration with patient associations, collection of patient feedback
- **We address the complexity of each clinical protocol** with an approach combining technical and medical expertise. We show agility to navigate through the complexity of clinical trials
- **We have a strong delivery record** including integrated processes with language service companies
- **We provide a flexible solution that is open to integration** with other services, and can potentially incorporate external solutions in our devices, App and Platform
- **We are part of the clinical trial eco-system:** member of ePRO Consortium

Kayentis Program for carbon-neutral clinical trials

WE ARE COMMITTED TO CONDUCT CARBON-NEUTRAL CLINICAL TRIALS

- We evaluate the carbon impact of all our projects and propose solutions to our clients to limit carbon emissions - number of devices, WebCOA back up, virtual meetings...
- We also offset the amount of residual carbon emissions of our eCOA projects by making a donation to the Carbon Solidarity Action Program from the GoodPlanet Foundation.

Learn the best modality for your study, schedule an eCOA demo

sales@kayentis.com

+33 (0)4 76 00 54 20

www.kayentis.com

KAYENTIS EUROPE
19 bis, chemin du vieux Chêne
38240 Meylan
France

KAYENTIS US
186 South Street - Suite 600
Boston, Massachusetts 02111
USA

KAYENTIS JAPAN
Kayabacho South Building 4F
2-8-7 Nihonbashi Kayabacho
Tokyo 103-0025
Japan

Kayentis