

100%  
dedicated  
to eCOA



**Kayentis**  
Dedicated to eCOA & Patient Engagement

# From setup to completion



## SETUP

- Scientific expertise on choice of instruments/endpoints
- Dedicated PM to assist you from trial setup to completion
- Kick-off meeting and definition of communication and escalation processes
- Client specifications & trial documentation
- Translation/validation steps for Final Protocol Package with selected partners
- Platform setup (hardware & software, programming, UAT, validation)
- Data Management setup
- Site supplies, device preparation and logistics
  - Customs clearance expertise
  - Worldwide experience
  - Partnership with courier companies
  - Dedicated logistics for China



## SITE INITIATION

- Proactive personalized site calls for setup
- Ensure site and users can access Clin'Form and initiate their accounts
- Full training process
  - Investigator meeting and training (face to face or webex)
  - Online training on devices for users
  - Ad hoc training on request



## TRIAL MANAGEMENT

- PM coordinates internal/external resources for trial deliverables and manages scope, budget, and timelines
- Real time web access to eCOA and alerts for sponsor and sites, alarms and reminders for patients and sites, and instant score calculations
- Full data management (checks, cleaning, reconciliation with CRF/IVRS) - data transfers and integration
- 24/7 multilingual Helpdesk for sites and patients, remote technical site support and troubleshooting



## CLOSE OUT

- Recall and return management of devices
- Final data reconciliation and lock
- Final data transfer
- Administrative closeout
- Archiving
- Lessons learned

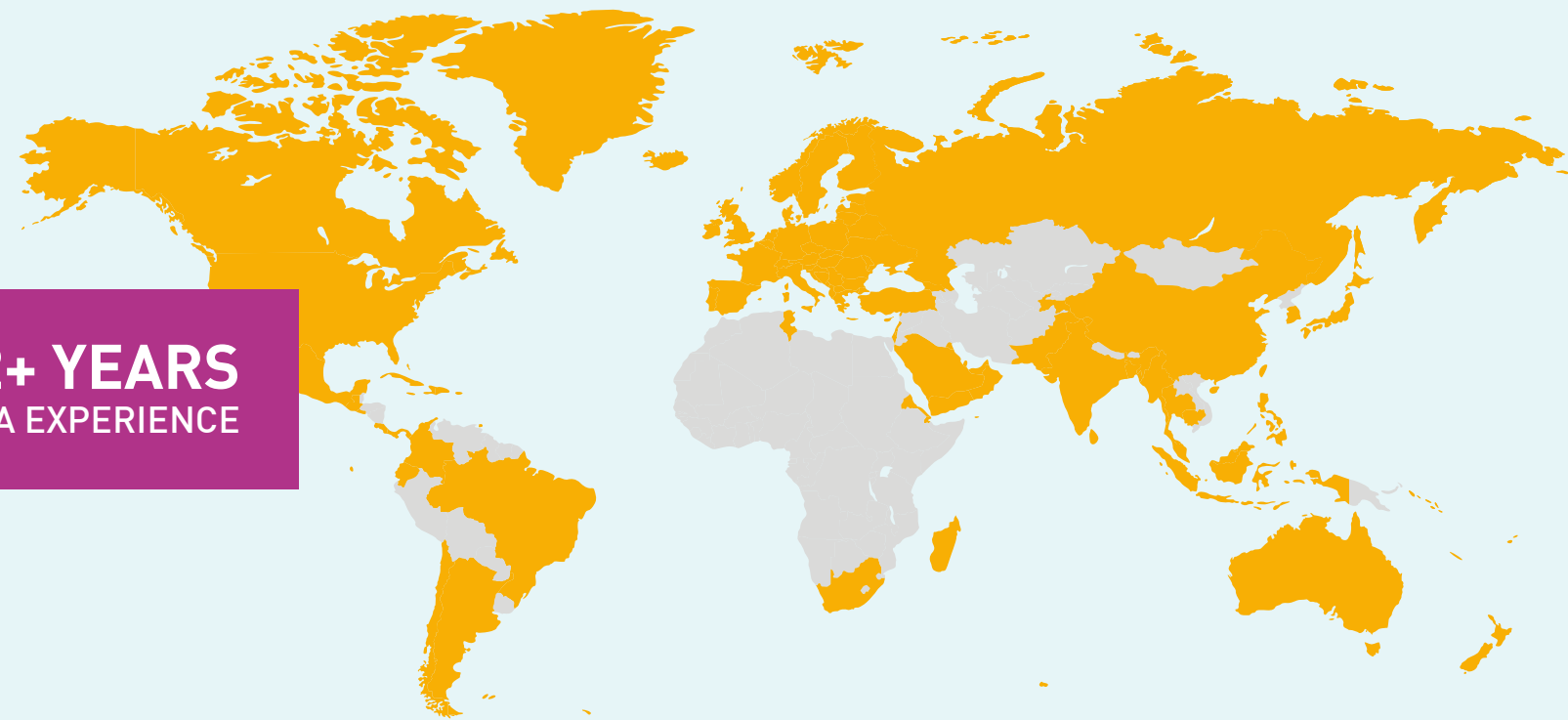


## PROGRAM MANAGEMENT GOVERNANCE

- Program director
- Quarterly operations meeting
- Governance committee
- Program synergies and working process efficiencies

# Global eCOA experience in a broad range of therapeutic areas

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



**12+ YEARS**  
OF GLOBAL eCOA EXPERIENCE

**50,000+** users / patients  
**5,000+** sites  
Expert network & specialized teams  
**150+** clinical trials  
**75** countries  
**90** languages

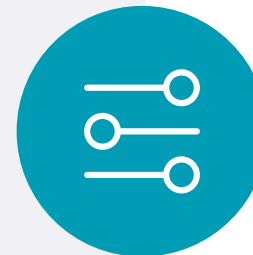
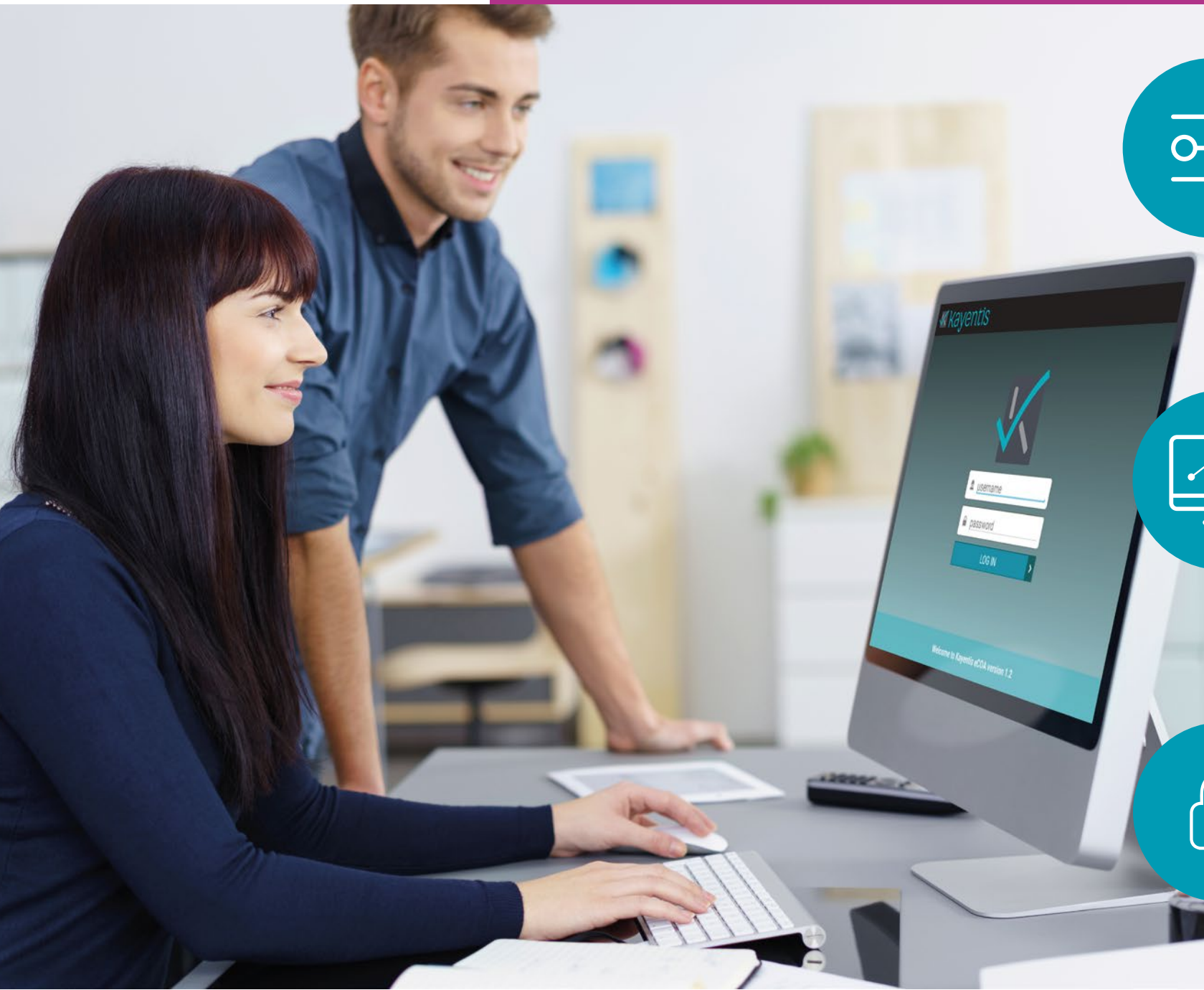
# Powerful and flexible portal to monitor your project

**CLIN'FORM**

**COLLECTING DATA FOR 12+ YEARS**



Modalities change and evolve,  
the portal manages them all



## SETUP YOUR STUDY

- Dynamic library of instruments
- Automated accounts management with standardized site lists, profile-driven web portal
- Alerts/scores/actionable items
- Highly customizable dashboards
- Connectors allowing for high interoperability (e.g. IVRS, EDC)
- DB in a CDISC ODM format providing easy integration



## MONITOR YOUR STUDY, AND CLEAN YOUR DATA

- Web portal
- Instant scores/alerts (visible in the portal/sent via email)
- Full audit trail
- Query management
- Interoperable system, easily connects to any EDC/CDMS
- 21 CFR part 11 compliant



## BASED ON A ROBUST & DEDICATED INFRASTRUCTURE

- Backup servers ensure total security and availability of our applications
- Hourly data backups ensure full protection of your data
- Disaster recovery plan in place

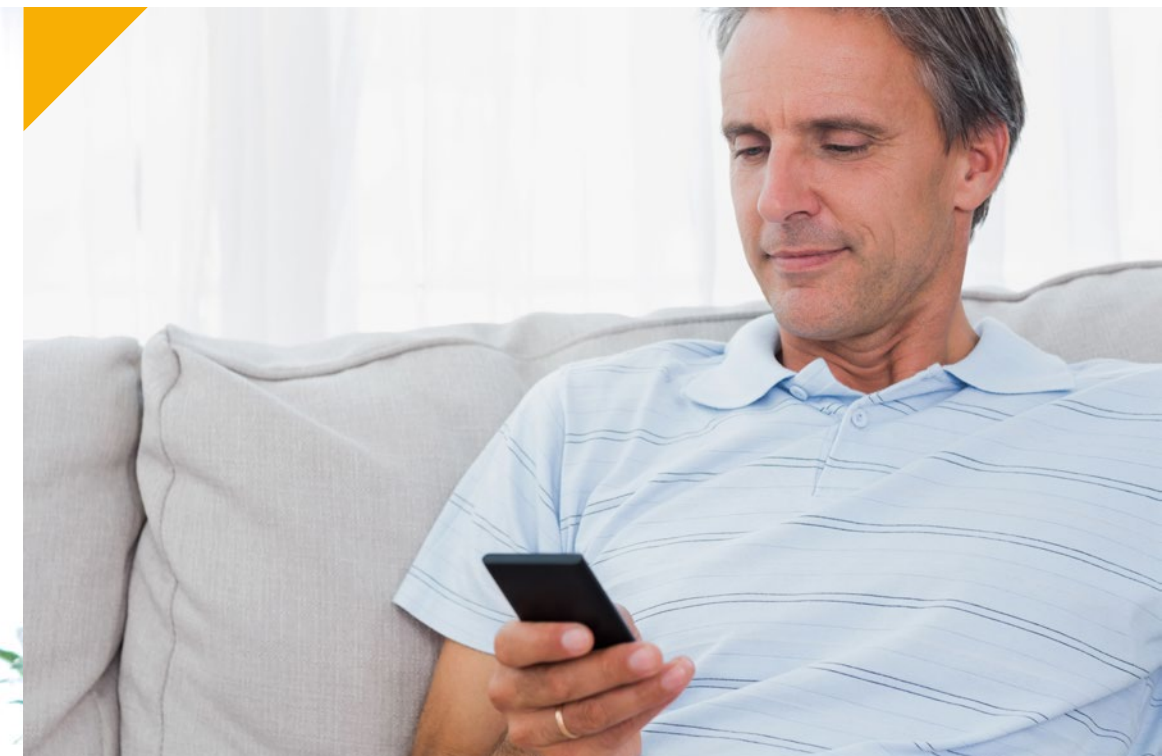
# 4

## Data captured anywhere



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

- One single App for all needs (ClinROs, PROs, Diaries)
- Integrated with SecureConsent (one single device/helpdesk)
- Robust protection
- Embedded alerts and instant edit checks
- Devices connect via Wifi/4G and work offline
- Investigator review within the devices (with status management)
- Remote control of devices with AirWatch and Kayentis Controller, including timestamp consistency





# Kayentis added values for sponsors



- Our level of service and flexibility is acknowledged by all our customers
- All our PMs are highly experienced
- Strong Data Management practices are part of our DNA; our value proposition is to deliver you a fully cleaned DataBase
- Our DataBase is built in CDISC ODM offering high interoperability
- Competitive and transparent pricing philosophy
- Our solution offers a combination of ClinRo/PRO/Diary on the same device & user interface improving simplicity for the patients and sites.
- Our services can be used with other CROs to ensure seamless collaboration

Partner program for CROs,  
built on business needs,  
synergy development & governance

- ✓ Synergy development
- ✓ Commitment to provide a full proposal in less than 3 days
- ✓ Governance (objectives, lessons learned)

## INNOVATION CLINICAL TRIALS OF THE FUTURE

Our energy and roadmap are solely focused on eCOA solutions. Our R&D program using Pepper Robot\* is dedicated to evaluate the potential use of robots in clinical trials (both at home and on-site).

### The role of robots in clinical trials:

- improved patient compliance
- patient encouragement
- gateway for medical devices
- emergency assistance
- telemedicine support
- ...and much more to define together!



\* Pepper,  
made by SoftBank Robotics

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



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