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

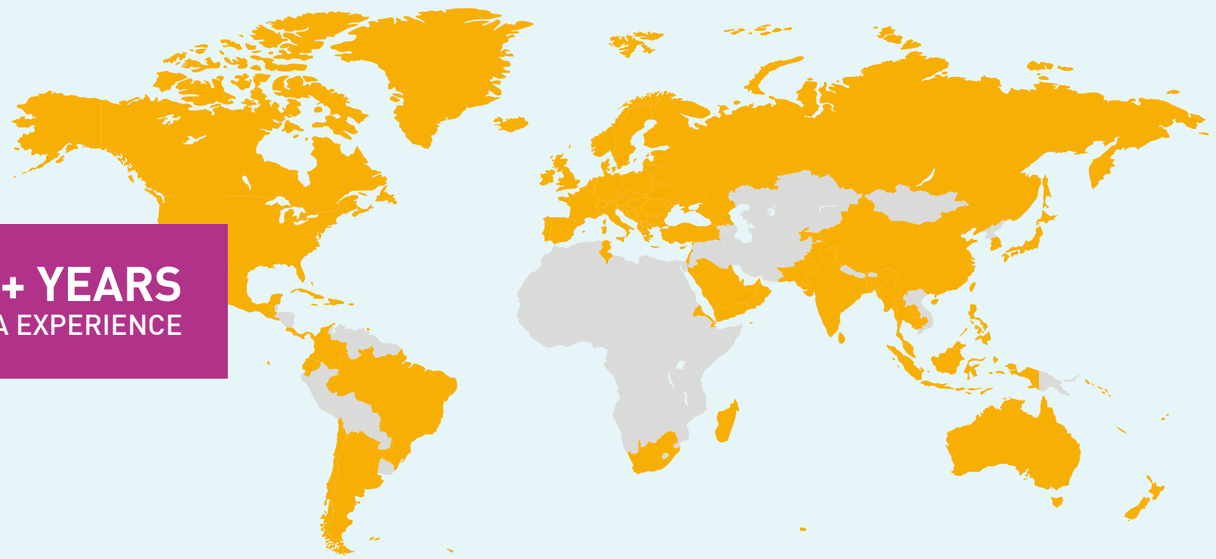
- Recall and return management of devices
- Final data reconciliation and lock
- Final data transfer
- Administrative closeout
- Archiving
- Lessons learned

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



12+ YEARS
OF GLOBAL eCOA EXPERIENCE

50,000+ users / patients

5,000+ sites

Expert network & specialized teams

150+ clinical trials

75 countries

90 languages

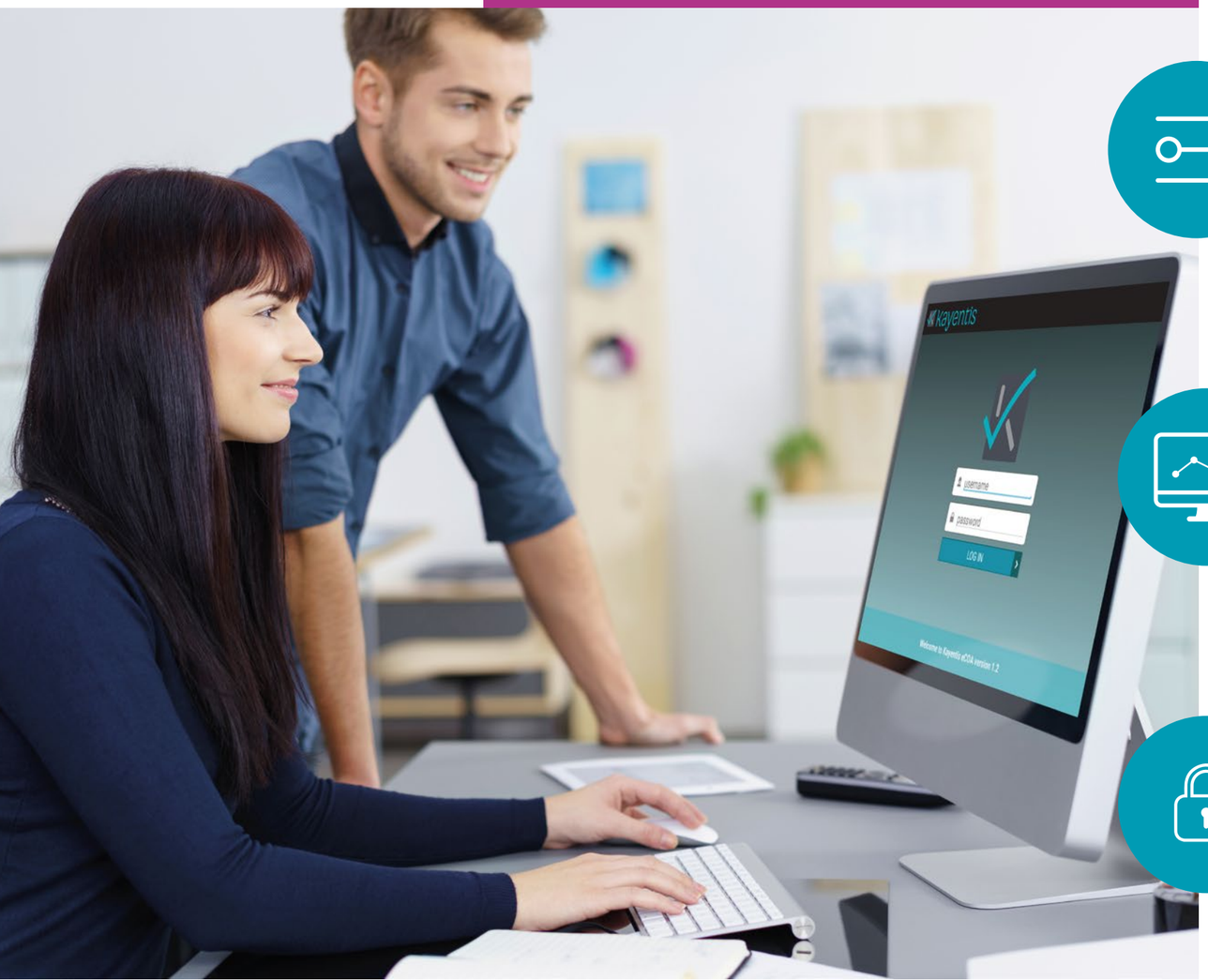
3

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

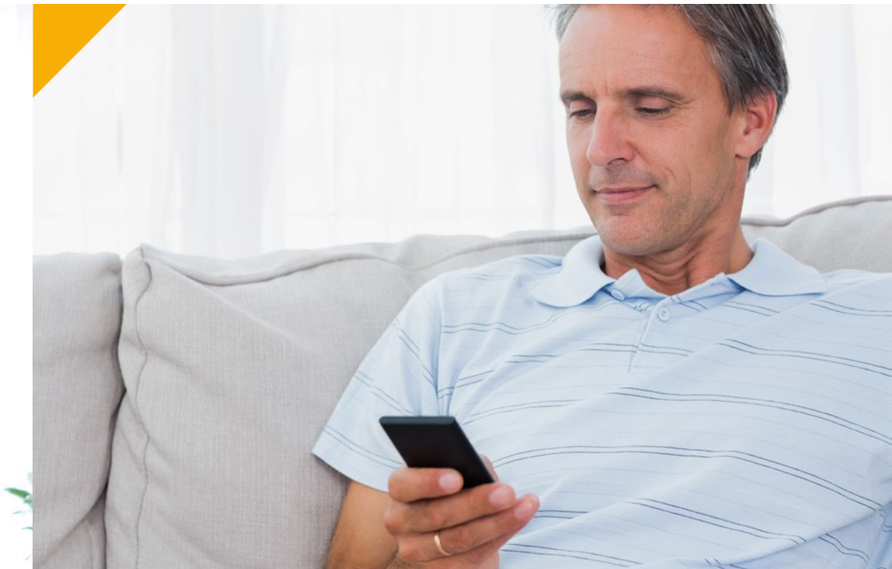
BASED ON A ROBUST & DEDICATED INFRASTRUCTURE

- 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
- telemedecine 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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