DERMATOLOGY CASE STUDY

Kayentis

offers extensive experience in dermatology

- **50+** studies, 12,000+ patients, 2,500 sites
- **60+** countries/languages per study
- **Adult, elderly, teenage, and pediatric** populations
- **85%** Phase II/III

Indications:

- ✓ *Atopic Dermatitis, Prurigo Nodularis*
- ✓ *Chronic Urticaria, Chronic Spontaneous Urticaria, Eczema*
- ✓ *Psoriasis, Nail Psoriasis, Palmoplantar Psoriasis*
- ✓ *Hidradenitis suppurativa and hyperhidrosis*

ePRO, eClinRO, eObsRO, and eDiary assessments:

- Typically, site-based PROs and ClinROs combined with home eDiary
- **Complete ClinRO** build with fast data entry and efficient score calculation: PASI, EASI, IGA, BSA, SCORAD
- **Solid experience with several typical PROs:** DLQI, WPAI, and NAPPA with different components (NAPPA-QoL, NAPPA-PBI, UCT & AECT, PFQ)
- **Extensive experience with Patient Diaries:** VRS, NRS Skin Pain-Itch Scale, Patient's Lesion Count, Worst Pain – NRS, such as Pruritus NRS, Pruritus PCS, Sleep Disturbance NRS, DPS, UPDD, Medication Log, Rescue Medication, CholUAS7, UPSS with UAS and AAS

CHALLENGES of Dermatology studies

- Often combine ePRO and eDiary questionnaires
- Often include diverse patient populations: adult, elderly, and pediatric
- Studies run in several countries worldwide
- Need very high compliance rate to ensure the success
- Need easy & fast score calculation (eg, PASI, EASI, SCORAD)
- Often need body maps for data entry
- Short data management turnaround time

KEY SUCCESS Factors

A LARGE SET OF DATA COLLECTION MODES TO FIT DERMATOLOGY STUDY NEEDS

A single device to combine ePRO/eDiary collection

Kayentis small tablet can be used as single device for both patient & site:

- **A user-friendly device adapted to both on-site and home use:**
  - Both supervised and unsupervised modes are available
  - Consistent training of clinical site staff and patients
  - Facilitated patient tasks, leading to better compliance
- **A mid-size, handheld and comfortable device with ergonomic advantages:**
  - Larger interface than smartphones
  - Better display of assessment scales & possibility of data entry in landscape or portrait mode
  - Light and portable

A BYOD mode for eDiaries

Kayentis offers a BYOD solution for patients & caregivers to support decentralized clinical trials:

- Very easy set up via QR code
- Optimized solution for data entry compliance: notifications for questionnaire completion, alerts if the device settings are not favorable to data entry (eg, silent mode)
- Full audit trail

A kit of back-up solutions to maximize data entry

Kayentis offers the most flexible set of data entry possibilities, enabling switching to alternative data entry easily when needed: WebCOA, interview mode or spare provisioned device option

EFFICIENT INSTANT SCORE CALCULATION & REAL-TIME REPORTING

- Clinical staff and the study team both have immediate access to data on the Clin'form webportal thanks to direct transmission and dual connectivity of the device (4G/WIFI):
  - Instant score calculation & transmission
  - Easy & timely monitoring of data and patient compliance
- Clin'form Web Portal allows clinical staff and the study team to monitor eCOA study data and compliance easily and thoroughly

KEY PATIENT ENGAGEMENT FEATURES

To improve patient experience and compliance, we offer a large set of patient-centric functionalities:

- Flexible options for data entry (large or small tablet, smartphone, BYOD)
- Virtual visit via telemedecine app
- Embedded media player for information push to patients
- eDiary reminders

HIGH QUALITY DATA MANAGEMENT PERFORMED THROUGHOUT THE PROCESS

At kayentis, we combine both strong data management teams & robust functionalities to support your study from specifications to close-out

Data management from study start

- Active contribution to solution build and deployment
- Data reconciliation with external databases
- Provision of a fully cleaned database at study end

Open philosophy

- Minimum data loss: we maximize data entry whilst controlling data consistency
- Maximal flexibility: open data entry for sites and patients

KAYENTIS at a glance

A KEY PLAYER IN eCOA & DECENTRALIZED CLINICAL TRIALS

Broad experience...

Since **2005**
eCOA expert

300+
clinical trials
phase I-IV

20
different
therapeutic
areas

...in a wide range of study types

From **15** patients
in an early phase trial to
+10,000
in a late-phase study

From local to
global studies
100%
of countries covered

Studies lasting
up to 10
years

...with strong scientific and operational support

Clinical & Scientific
dedicated team to
support your study

Operational capabilities
USA - Europe - Asia

24/7
HELPDESK

Kayentis

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