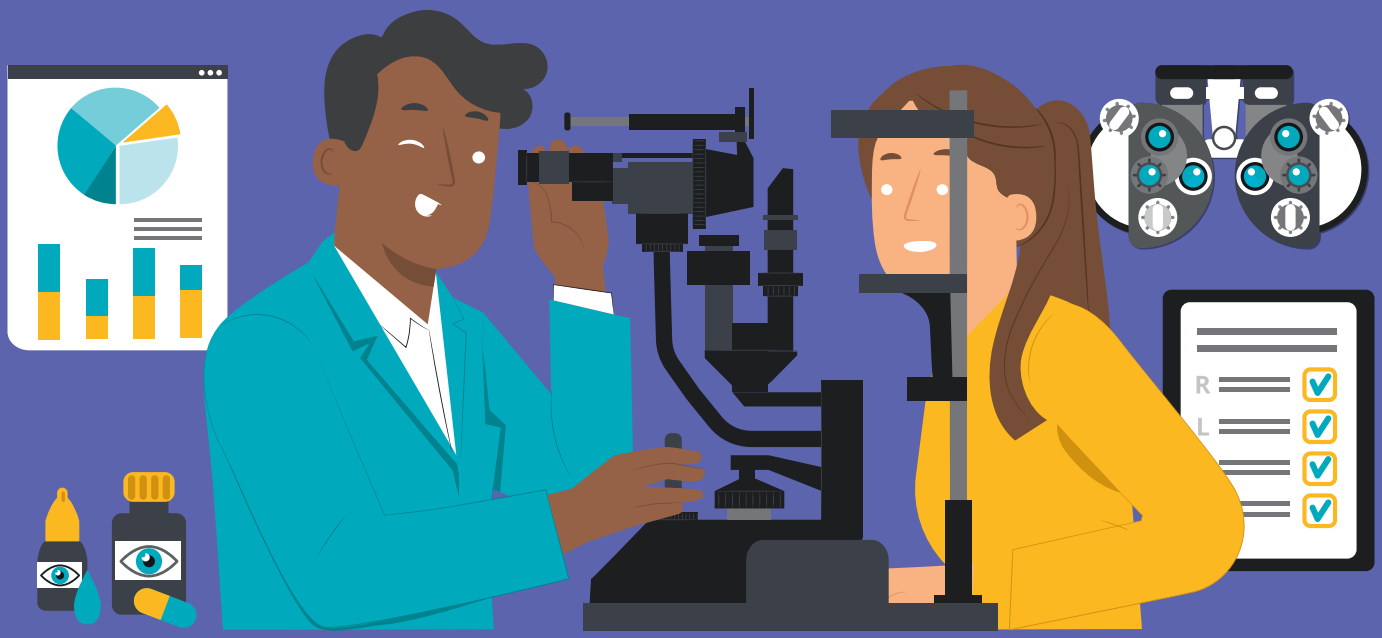
CASE STUDY - OPHTHALMOLOGY

Kayentis offers a wealth of experience in conducting clinical trials for ophthalmic conditions



Kayentis offers tailored decentralized solutions with qualitative ePROs (PRO VFQ 25 / NEI VFQ28R / NAVQ / drop comfort assessment), **and extensive experience in ophthalmology** (eg, Central/branch Retinal Vein Occlusion; Neovascular Age-Related Macular Degeneration; Diabetic Macular Edema; Diabetic Retinopathy; Presbyopia; Chronic Ocular Pain; Dry Eye Disease).

Kayentis

Global eCOA & DCT provider

Ophthalmic conditions and vision impairment currently affect 2.2 billion people globally.[1]

- The leading causes of vision impairment and blindness are diabetic retinopathy, glaucoma, refractive errors, cataracts, and age-related macular degeneration.[1]
- The incidence of autoimmune diseases that affect eye health is increasing.[2]
- Vision impairment is associated with a reduced quality of life.[3]
- The impact is pronounced for children who develop vision impairment at an early age because they may encounter delays in the development of motor skills, language acquisition, social interactions, and cognitive abilities.[1]
- The global ophthalmic clinical trials market size increases every year.[4]

→ **Data collection can be very challenging for patients with visual impairment, but the patient- and site-centric research approach that we've seen growing for several years allows clinical trials to be better adapted to patient needs.**

→ **Measuring patients' perception of their symptoms and their quality of life using efficient ePRO solutions is essential in ophthalmology clinical research.**

[1] Blindness and vision impairment (who.int)

[2] Epidemiology of Ocular Manifestations in Autoimmune Disease - PMC (nih.gov))

[3] The Impact of Vision Loss - Making Eye Health a Population Health Imperative - NCBI Bookshelf (nih.gov)

[4] Ophthalmic Clinical Trials Market Size & Share Report, 2030 (grandviewresearch.com)).

KAYENTIS KEY SUCCESS FACTORS IN OPHTHALMOLOGY STUDIES

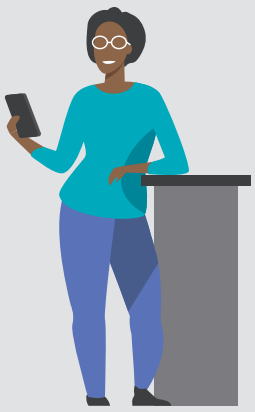
1 Securing ePRO data collection with adapted electronic devices and multiple data collection modes

To cope with patients' visual conditions, we must be able to provision adapted electronic devices and offer visually impaired patients the flexibility of multiple data collection modes.

When patients are on site

- The use of large electronic devices such as 10'' tablets is recommended.
- With the support of site staff and thanks to a user-friendly solution, completing ePROs becomes an easy task.

When patients are at home



- Interview mode can be a good alternative for data collection: with properly trained site staff, this allows patients to complete the required PROs through a simple phone call.
- The option for patients to complete questionnaires using WebCOA on their own computer can be valuable.

- ✓ The use of intuitive solutions reinforces patient engagement and thus patient compliance.
- ✓ Selecting the method of questionnaire administration taking into account what the preferred or most appropriate method would be for the patient will encourage regular and accurate responses.
- ✓ Reflecting on how to reduce potential biasing effects will increase data reliability.
- ✓ Proposing multiple data collection modes is a must, which is why we offer telemedecine, BYOD, and interviews to make life easier for patients and to ensure that the data are properly collected and secured.

2 Understanding and integrating patients' specificities and preferences

Ophthalmology clinical trials require a deep understanding of the patient's day to day life, as everyday actions can be more challenging for a visually impaired population.
Both personal and cultural differences need to be considered, and patients may have preferences for a given data collection method or for the way their eDiary reminder alert will be activated and its timing. As such, listening to patients and developing a deep understanding of their needs is paramount.

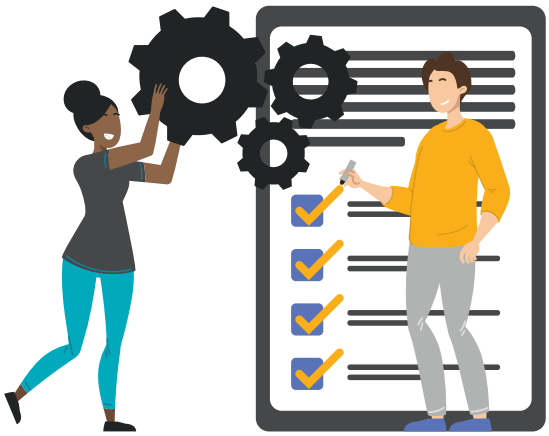
- **At Kayentis, we partner with multiple patients.** We organize collaborations and focus groups to continually deepen our comprehension of patients' challenges.
  → Ongoing improvements to the user-friendliness of our solution and allowing us to develop suitable and relevant tools.

- **We offer an embedded media player** providing access to study or disease information co-created with patients, as well as training material.
  → Patients better informed about their study, the specifics of their disease, and the protocol requirements, which has a positive impact on compliance.

- **Our extensive experience with patients** across age groups, from infants to elderly populations.
  → Study-specific questionnaires or an adapted data collection mode.

- **With a "Participant Feedback Questionnaire"** we give a voice to patients. Providing feedback on their study experience.
  → Enhanced patients' perception of a clinical trial, which can be beneficial in long-lasting trials.

3 Anticipating unscheduled visits with strong product capabilities and processes



Every trial has its own specificities, but in ophthalmology studies patients can be particularly sensitive to adverse effects of the treatment or to disease symptoms, which may directly impact the patients' ocular capacity.

This can lead to a higher frequency of unscheduled visits, which may complicate data collection and data reconciliation.

At Kayentis we manage these situations with:

- **Strong processes,** allowing unscheduled visits to be anticipated, included in the study specifications, and programmed into the Kayentis Clin'form solution from the beginning so that no amendments are necessary when they occur.
- **A robust technological solution,** which allows visits to be added easily even if they were not anticipated, to cover all eventualities.
- **Dedicated and very experienced teams** in both project and data management, with very good relationships with clinical sites, CROs, and sponsor teams, allowing for a deep understanding of trial complexities and a quick response to any study requirements.

Kayentis at a glance

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