

What you need to run your **pediatric asthma** clinical trials successfully



Global eCOA & DCT provider

Asthma clinical trials specificities

Use of disease-specific health-related quality of life instruments (developed by Professor Juniper and colleagues):

- ✓ To evaluate both the physical and emotional impact of the disease: the Asthma Quality of Life Questionnaire (AQLQ)
 - ✓ To measure the control of the disease: the Asthma Control Questionnaire (ACQ)
- > Need to choose an eCOA solution validated for the AQLQ and ACQ questionnaires



Asthma clinical research often involves pediatric population

According to www.ct.gov, more than 40% of interventional asthma clinical trials (both currently recruiting and not recruiting) involve children. This adds to the challenges of already complex pediatric clinical research.

- > Need to partner with an eCOA vendor experienced in pediatric clinical trials



Running asthma clinical trials can require caregiver involvement

Asthma trials may need caregivers with a variable role, from emotional support to regular questionnaire completion.

As caregivers have a unique role, it's important to decrease their burden too.

- > Need to work with system providers who are able to propose user-friendly solutions with flexible options for caregivers while ensuring high data quality



The choice of relevant and meaningful endpoints is complex

Developing new endpoints, specifically adapted to pediatric research, is a current clinical research focus.

- > Need to be supported by an eCOA provider able to design and support validation of new questionnaires



KAYENTIS KEY SUCCESS FACTORS

At Kayentis, we have the full capability to run your asthma studies successfully

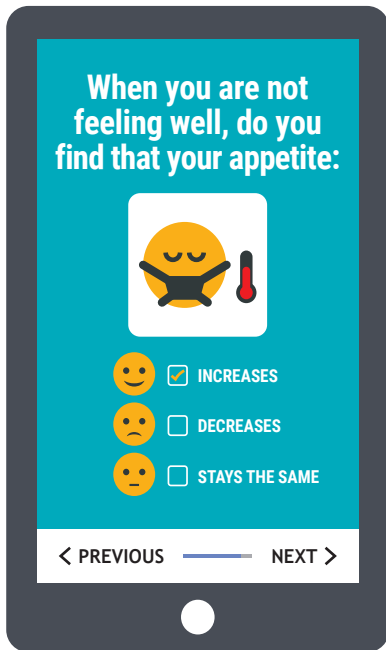
✓ VALIDATED TO USE PROFESSOR JUNIPER SCALES IN ASTHMA STUDIES

- We are a qualified vendor for Professor Juniper's quality of life instruments for asthma trials, which allows us to implement measures in every asthma clinical trial, including ACQ and AQLQ quality of life instruments.



✓ ABLE TO IMPLEMENT ASTHMA-SPECIFIC QUESTIONNAIRES ON ANY TYPE OF DEVICE

- We can use any type of device: **tablet, smartphone, or computer (using WebCOA).**
- These questionnaires can also be implemented on the patient's own device in a **BYOD mode!**
- Knowing that asthma studies can involve young children, we also offer an **interview mode option** that can be useful when very young children are enrolled: the questionnaires authors recommend the administration of ACQ by a trained interviewer for children aged 6-10 years.



✓ **STRONG CAPABILITY TO DESIGN WELL-SUITED AND CUSTOMIZED QUESTIONNAIRES FOR CHILDREN**

- **Strong experience in pediatric clinical research:**

- Multiple therapeutic areas including Respiratory, Oncology, Hematology, Metabolism, Dermatology and Rare Diseases.
- Multiple patient age groups within the same study.
- Numerous specific children ePROs, eObsROs and eDiary questionnaires: EQ5D-3L, EQ-5D-5L Self, EQ-5D-5L PROXY version - PedsQL Child (young adult, adolescent and pediatric versions) - CGI-I, CGI-S, CGIS-H, CGIC-H, CgGIS-H, CgGIC-H - PROMIS, BPI-SF, HQ-CT, cDLQI, UPDD/UAS, C-ACT.

- **Experience with the development of innovative animated questionnaires and the use of emoji characters perfectly adapted to pediatric populations:**

- We supported a collaborative project that aimed at using an animated character to help children self-assess their symptoms. It was shown that the character, that contributed significantly to the novelty of the tool, helped facilitate the child's independent completion of the diary items, regardless of reading ability.
- The use of an interactive character with synchronized audio, allows the questionnaire to be understood by children with a range of reading and cognitive capabilities.

✓ **FLEXIBLE SOLUTION TO FIT CAREGIVER NEEDS**

- We bring the same functionality and flexibility to caregivers as for study patients, enabling ObsRO completion on any type of device, even one that is different to patient's device
- Kayentis Clin'form solution goes further by offering multiple synergies in the data collection mode, e.g., single device for all stakeholders, even with multiple caregivers having their own credentials

Kayentis, global eCOA & DCT provider

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



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