Kayentis offers 17 years of global experience in **Immuno-Inflammation** clinical trials

EXPERIENCE

- 20% of our experience in Immunology/inflammation
- 13,000+ patients, 3,500+ sites
- 90% phase II, III and IV
- Up to 40 countries per study - Truly global delivery: North America, South America, Europe, Middle East, Asia-PAC and Australia, including Japan & China

INDICATIONS

- Ankylosing spondylitis, Psoriatic arthritis, Osteoarthritis, Rheumatoid arthritis, Tendinopathy
- Psoriasis, Palmoplantar pustulosis, Active lupus nephritis, Multiple Sclerosis
- Crohn's disease, Ulcerative colitis
- Sjögren's syndrome

eCOA assessment:

Site-based PROs/ ClinROs are typically combined with score calculation, and immuno-inflammation studies often encompass disease specific instruments and numerous patient diaries:

- **ClinRO build & score calculation:** PhGA, ESSDAI, CDAI /MAYO Score, PASI
- **Typical PROs :** EQ-5D, SF36-V2, WPAI, FACIT- Fatigue, PGA , DLQI, HADS...
- **Disease specific instruments:**
  - WOMAC Index/ ASQoL / ASAS HI/ BASFI / BASDAI/ HAQ-DI / Swollen joint count / Tender joint count /ESSPRI /IDEEL/ PaGa/ Pain intensity NRS, VAS on active movement, PsA Pain, Spinal Pain
  - IBDQ
- **Patient Diaries:**
  - VRS, NRS Pain, Patient's Lesion Count, Worst Pain, Sleep Disturbance NRS, Sjögren's disease diary
  - NSAID /Medication Log, Rescue Medication, study drug intake
  - UC-PRO/MCS/pMCS/ stool frequency/ rectal bleedings

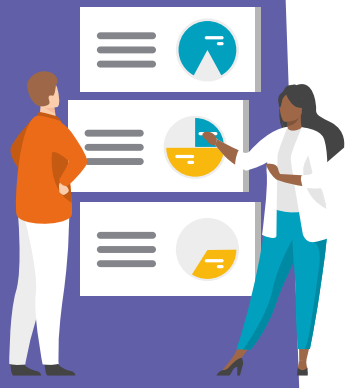
CHALLENGES of immunology/ inflammation studies

COMPLEX ECOA BUILD

- Questionnaires are often long and contain **numerous questions and domains**
- **Body maps are frequent**, which generate design complexities
- Questionnaires are very often associated with **score calculations**, which adds programming challenges
- **eDiaries** are collected daily over a long period (up to 60 weeks), robust eDiary design and strict compliance are critical to success

KEY SITE STAFF ROLE DURING THE STUDY PROGRESS

- Immuno- inflammation trials frequently require measures of **biological parameters** or **results of exams** reported by the study site
- **Scores** based on both the patient's diary and site visit data require input from the study site staff, strong support, and reliable programming from the eCOA vendor
- Sites need to fill in the patient information data and results in a **timely manner**, as this can trigger follow-up actions and scheduling of the next study visits



LONG STUDY DURATION AND PATIENTS IN PAIN

- Immuno-inflammation studies can last several years, and with long-lasting studies comes the risk of **losing compliance and patient engagement**. The engagement of sites can also become at risk
- Patients are exposed to **acute inflammation and pain crises** which can have an impact on patients' day-to-day lives and make the completion of questionnaires very difficult

KEY SUCCESS FACTORS

The endpoints of Immuno-Inflammation clinical trials are mostly based on eCOA values: having a strong and robust eCOA solution, along with an understanding of the specific challenges of this therapeutic area, is therefore critical to the success of clinical trials.

1- EXPERIENCED TEAMS AND A POWERFUL SOLUTION TO FACE eCOA COMPLEXITIES

All of our operational project managers have a scientific background, they understand the complexity of your protocol and adapt the eCOA strategy based on the specifics of the study

- **Experienced data managers and programmers are** involved from the beginning of the study and will manage the specifics of the questionnaires, such as the design of eDiaries, body maps, the generation of adapted screens for long questionnaires, and the implementation of all the relevant edit checks, triggers or alerts to facilitate use and compliance.
- Our **Clin'form solution** offers user-friendly navigation, a device-agnostic display, and allows instant score calculation and transfer

2- ADAPTED OPTIONS TO SUPPORT SITE STAFF

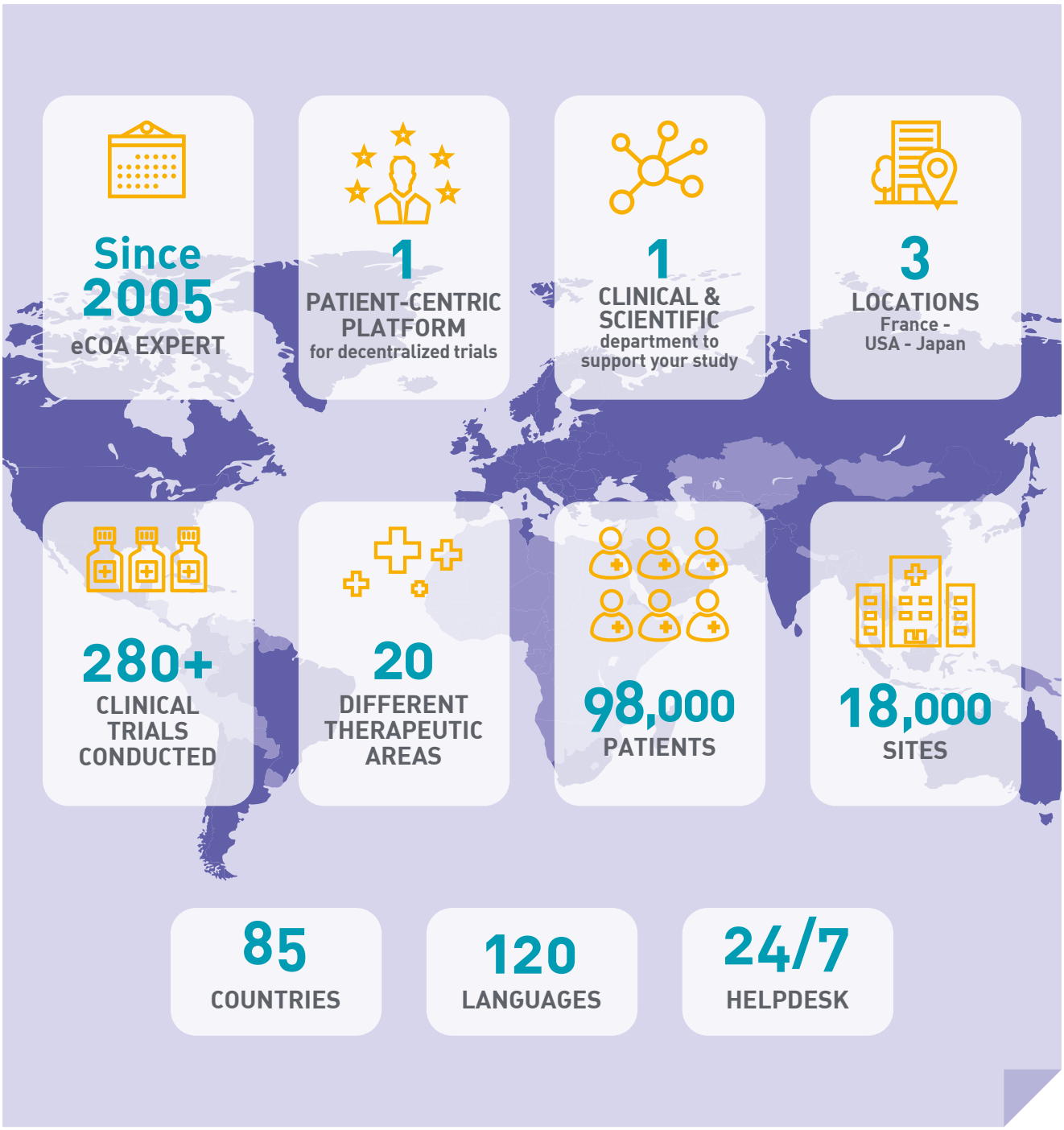
- **The Clin'form WebPortal** enables site staff to perform **timely monitoring** of patient data and allows a large scope for the calculation of scores. Site staff can also generate appropriate data clarifications and review compliance reports in a timely manner
- **Data managers** handle query management through close communication with the sites and use a streamlined process, ensuring timely data cleaning
- **Integration with *QualityMetric*** allows for SF-36 score calculation and integration into the study database in a manner that is completely transparent for the study team.
- **Chat feature** allows site staff to easily communicate with the helpdesk via instant messaging, on top of e-mailing and phone contact options
- **Adapted training material** is made available to site staff at the time of the investigators meeting, and via Clin'form for quick access and future reference as needed

3- ADDITIONAL FEATURES TO IMPROVE PATIENT COMFORT AND COMPLIANCE

- An **embedded media player** allows patients to access study or disease information, as well as training material. This key feature contributes to informing patients about their study, the specifics of their disease, and the protocol requirements, which has a positive impact on compliance
- With our "**Participant Feedback Questionnaire**" we give a voice to patients; providing feedback on their study experience helps to enhance patients' perception of the clinical trial, which can be beneficial in long-lasting trials
- **Televisit** allows visits to happen remotely between the patient and the site, which can be particularly useful in immuno-inflammation trials when pain can make traveling and moving difficult
- Our **BYOD solution helps to improve compliance**: this easy-to-use solution has a surprisingly simple set-up via QR code that is convenient for eDiary completion in long-term studies
- **Interview mode** is also an option for completing questionnaires with the help of the site; answering a PRO via a phone interview can bring relief to a patient with joint pain

KAYENTIS at a glance

A KEY PLAYER IN eCOA & DECENTRALIZED CLINICAL TRIALS



85 COUNTRIES

120 LANGUAGES

24/7 HELPDESK

Kayentis

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