Kayentis offers global experience in complex

oncology trials

• 65+ studies, 14,000+ patients, 5,000+ sites

Large programs

- 90% Global Phase II/III trials across patient populations
- √ 10 to 45 countries per study, worldwide
- Long term studies: up to 8 years

• Extensive experience, including:

- CAR-T cell treatment developments
- Many indications:
 - ALL, AML, CML, Large B-cell lymphocytic leukemia
 - Follicular lymphoma, myelodysplastic syndrome, multiple myeloma
 - Renal carcinoma, lung, breast, prostate, pancreas, thyroid cancer
 - MTC, Melanoma

ePRO, eClinRO, eObsRO and eDiary assessment:

Many ePROs used to assess disease-related symptoms (eq. pain, fatigue) as well as physical, social & emotional aspects, satisfaction survey:

- EORTC: QLQ-C30, QLQ-C31, QLQ-LC13, QLQ-MY20, QLQ-BR23, IL-134, IL-46
- FACT Fatigue: FACT-M, FACT-BR, Fact-P, FACT-G, FACT-BMT, FACT-GP5
- EuroQoL: EQ-5D 3L/EQ-5D Youth, EQ-5D 5L, PedsQL, young adult & adolescent
- PROMIS-29, PROMIS PSF, PROMIS Parnt Proxy 7
- PRO-CTCAE, MDASI, NSCLC SAQ, PGI-C, PGI-I, PGI-S, NCCN NFBrSI-24



eCOA CHALLENGES of oncology studies

- ✓ Complex study design generates complex eCOA builds:
- Numerous ePROs, eClinROs and eDiaries
- Multi-modality therapy, multiple arms, multiple triggers
- Numerous edit checks, large volume of data management activities

Frequent amendments

- Additional visits, inclusion/exclusion criteria modification, additional safety procedures
- Implementation of amendments:
 - Must happen remotely
 - Can vary significantly from one country to another (approval timelines)
- Long study duration can affect patient engagement and site organization
- Patient compliance can be affected by adverse events & perception of study burden over time
- Sites progress in the study at a different pace, and site closures must happen in a staggered way

KEY SUCCESS Factors

EXPERIENCED TEAMS AND STRONG PROCESSES TO FACE TRIAL COMPLEXITIES AND AMENDMENTS

 Our scientific & clinical department performs thorough protocol review & highlights key points of attention

 All our operational project managers have a scientific background: they understand the complexity of your protocol

- Our experienced data managers
 - Are part of the team from study start: they run data cleaning and data export in a very timely manner, even when study implementation is staggered
 - Actively carry out impact assessments and implementations in response to protocol changes
 - Provide clean data files regularly and a fully cleaned database at the study end
- We develop strong processes to support impact analysis & change management
- We are used to planning extra visits from the beginning to anticipate protocol amendments/study extension



LARGE SET OF DATA COLLECTION MODES FOR AN OPTIMAL DATA ENTRY

- ✓ A single provisioned device to combine ePRO & eDiary collection
- A user-friendly device adapted to both on-site and home use
- A mid-size, handheld and comfortable device with ergonomic advantages, clear display of assessment scales & possibility of data entry in landscape or portrait mode; light and portable
- ✓ A BYOD mode for eDiaries
- An easy-to-use solution for the patient: very simple set up (QR code flash), provided in the patient's language
- A solution optimized for compliance: notifications for questionnaire completion, alerts if the device settings are not favorable to data entry (eq. silent mode)



 WebCOA, interview mode or spare provisioned device option can be selected to guarantee a reliable back-up plan. Possibility to switch easily to alternative data entry when needed

ADDITIONAL FEATURES FOR THE COMFORT OF THE PATIENT

- **Telemedicine** allows virtual visits between the patient and the site: very helpful when the patient cannot go to the site (eg, fatigue, weakness, conflicting schedule)
- An embedded media player pushes information or training material to patients: patient has direct access to clear and simple information
- eDiaries customizable alerts: increased flexibility according to patient's own schedule
- "Participant Feedback Questionnaire": gives a voice to the patient regarding their study experience

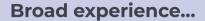
FUNCTIONALITIES ADAPTED TO SUPPORT SITE STAFF

- Televisit embedded in the Clin'form App: allows the study visit to take place regardless of the situation
- Training material (slide decks, videos, recordings) always available: quick and easy access
- **Chat feature**: site staff can easily communicate with the helpdesk via instant messaging
- Kayentis Clin'form Web Portal: site staff can perform timely monitoring of patient data, generate appropriate data clarifications and review compliance reports
- Back-up collection modes can be activated when necessary: site staff control their utilization



KAYENTIS at a glance

A KEY PLAYER IN eCOA & DECENTRALIZED CLINICAL TRIALS











...in a wide range of study types









...with strong scientific and operational support







