ONCOLOGY CASE STUDY

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 (eg, 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 (eg, silent mode)

✓ A kit of back-up solutions to maximize data entry

- **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

Broad experience...

Since 2005
eCOA expert

300+
clinical trials phase I-IV

100,000+
patients

20
different therapeutic areas

...in a wide range of study types

Up to 8,000
patients per study

Up to 1,000
sites per study

Up to 50
countries per study

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

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