

Kayentis

Dedicated to eCOA and patient engagement

Kayentis supports the 1st personalized immunotherapy treatment approved by both FDA & EMA

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Acute Lymphoblastic or Lymphoid Leukemia (ALL) is a cancer of the lymphocytes that can result in serious complications such as anemia, bleeding and severe infection. Some tumor cells may accumulate in the lymphatic system and can also invade other organs.

CAR-T cell treatment is the first personalized immunotherapy treatment for refractory and relapse ALL patients approved by both FDA and EMA!

KAYENTIS PARTNERSHIP IN CAR-T DEVELOPMENT PROGRAM

Kayentis is supporting a key research program aimed at developing new generation immunotherapies to treat both children and adults.

This program involves global, multi-center, randomized clinical trials

- Global phase II/III studies - 120 to 220 patients per study - in adult, pediatric, and adolescent populations
- 10 to 20 countries in Europe, Middle East & North America, Asia Pacific including Japan.

Quality of life questionnaires used for Patient Reported Outcomes (PRO) & disease assessments

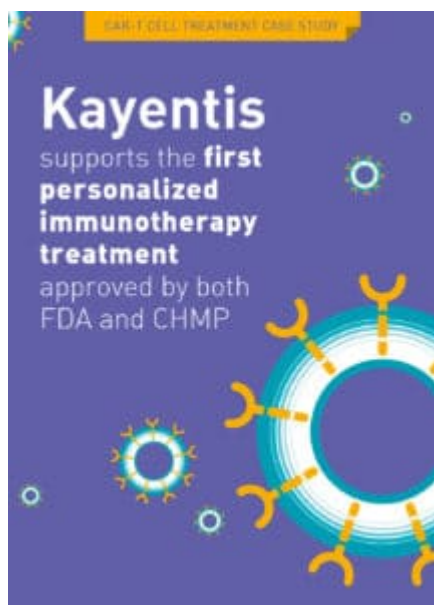
- [EORTC]) especially (EORTC QLQ-C30) & FACIT Fatigue questionnaires
- EuroQoL (EQ-5D 3L / EQ5d Youth) & PedsQL Child questionnaires, young adult and adolescent version.

Key challenges and success

- **Successful set-up** thanks to Kayentis' expertise with oncology and pediatric questionnaires.
- **Efficient multi-branching logic** according to patient ages and questionnaire types.

- **Anticipated device obsolescence management plan** for long term studies, securing permanent availability of the full solution until project completion.

Download our Car-T case study



KAYENTIS OFFERS KEY eCOA EXPERTISE IN ONCOLOGY OVERALL

- 15+ years of eCOA experience, innovation, and operational expertise in clinical trials. 25% of our experience is in Oncology - Hematology.
- Device and instrument expertise to match the specificities of oncology and its patient populations. State-of-the-art technology and connectivity options adapted to global and local requirements; high interoperability and data integration capability.
- Strong partnerships and established processes with translation companies as well as automated tools to manage translations in an efficient and timely manner.
- Familiarity with complex logistic support and challenges of specific countries (e.g. Russia, China, Japan). Knowledge of local management practices and practical eCOA expertise in oncology.
- Experience of eCOA/ePRO solutions used for PROs & disease assessments including multiple myeloma, lymphoma, renal carcinoma, lung cancer, ALL, CML, and breast cancer.

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