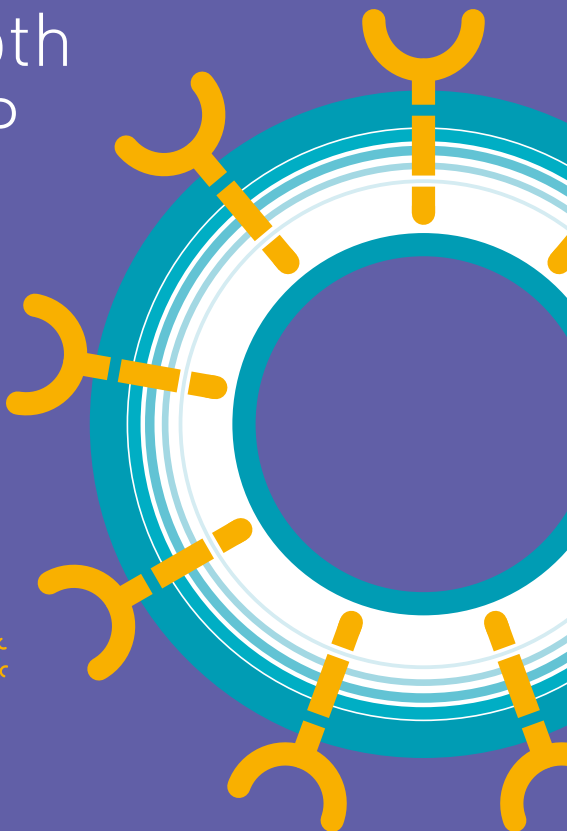
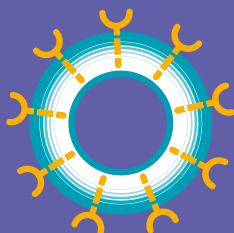
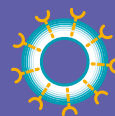


Kayentis

supports the **first**
personalized
immunotherapy
treatment

approved by both
FDA and CHMP



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.



✓ **5 000** cases of ALL are diagnosed annually in the US¹.

✓ Children are particularly affected:

- **60%** of cases occur in patients **<20 years** of age¹
- Accounts for approximately **25%** of cancer diagnoses in children **<15 years** of age
- Is the most common childhood cancer in the US:
80-90% of adults with ALL will have complete remission **BUT ROUGHLY HALF OF THEM RELAPSE** - and the chance of survival in patients who relapse or fail to attain remission is **5-8%** in adults & **16-30%** in children.

Hence, there is a desperate need of treatment options for refractory and relapse ALL patients for whom the prognosis is poor.

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

¹National Cancer Institute. SEER Cancer Stat Facts: Acute Lymphoc. Bethesda, MD, <http://seer.cancer.gov/statfacts/html/alyL.html>. Accessed May 2017.



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 & 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.

Kayentis offers key eCOA expertise in oncology overall



✓ **14+** 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.



www.kayentis.com

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