

# Case Study

**Type:**  
Oncology

**Geography:**  
Europe

**Study Type:**  
Phase I/II

**Client:**  
Biotechnology  
Company

## PROJECT TITLE:

“A phase I/II, multicentre study evaluating the feasibility, safety, and efficacy of XXXX in subjects with relapsed/refractory B-cell non-Hodgkin lymphoma”

### Objective 1

To evaluate the safety of XXXX of first in human CAR-T treatment in non-Hodgkin's Lymphoma and Leukaemia patients

### Objective 2

To determine the recommended Phase 2 dose

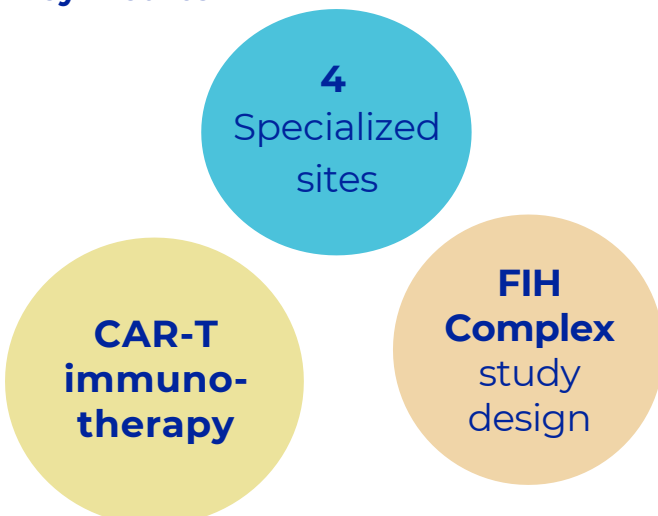
### Study Challenges:

- 1) Complex first in human design - logistics and safety concerns led to strict data collection requirements, putting pressure on the sites
- 2) Ongoing evolution and adaptation of study design/sponsor requirements throughout the study

### Excelya Solutions:

- 1) The Excelya team maintained daily contact with sites, while also respecting the balance required by sites to put patient care first. Our close relationships and hand-on, personal approach with sites and site personnel ensured compliance with critical events and data. Excelya recommended streamlined processes to reduce friction during data collection
- 2) Excelya remained flexible regarding client needs and changing study design. We were able to adapt and make recommendations based on previous experience in similar trial structures

### Key metrics



### Impact:

Close cooperation between the sponsor, sites and Excelya enabled study milestones to be met, and effective close of the study, on time and on budget