Case Study

Type:	**Geography:**	**Study Type:**	**Client:**
Oncology	Europe	Phase I/II	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

4 Specialized sites

CAR-T immuno-therapy

FIH Complex study design

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