TFS HealthScience
Clinical Research Excellence

Adoptive Cell Therapy in Oncology

Successful Study Start Up During COVID-19 Pandemic

Case Study

TFS was selected by a biotech company in late 2019 to provide clinical services in the Netherlands for an Adoptive Cell Therapy (ACT) / Advenced Therapy Medicinal Product (ATMP) study investigating autologous gene-modified TCR T cells in patients with advanced hematologic malignancies.

Study specifics

IMP
Autologous gene modified TCR T cells for adoptive cell theraphy

Indication
Advanced hematologic malignancies

Study Phase
Phase I

Country
Netherlands

Study Design
Open label dose escalation

Challenges

- Complicated regulatory pathways involving multiple national and local agencies or governing bodies for ATMP studies
- Large volumes of technical documents needed for regulatory submissions
- The start of COVID-19 pandemic and ensuing shutdowns, travel restrictions and regulatory uncertainties demanded rapid responses to the ever-changing situation and drastic changes in ways of working by the sponsor, TFS team as well as the site

TFS Advantages

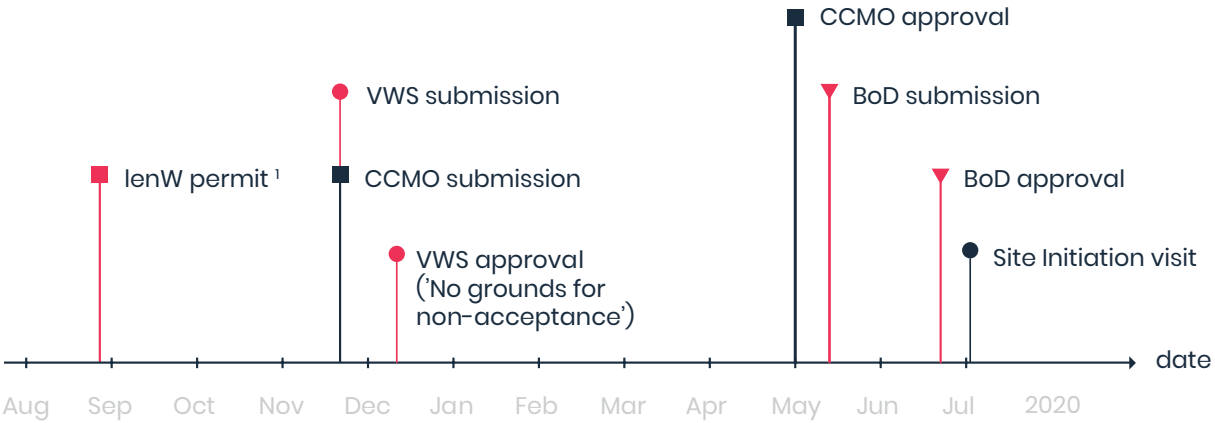
- TFS ' regulatory team was not only well-versed in ATMP submission requirements, but also skilled at maintaining good communication with regulatory bodies and rapidly adapting to new situation and processes
- TFS' local project manager owned weekly calls with the sponsor and site to quickly exchange information and collect proper submission documents, tracking aganist timelines and deploying risk mitigation plans
- TFS' medical expert and the hematology-oncology business unit executives were closely involved in the submission process providing direct oversight and advices

Results

TFS completed the initial regulatory submissions **6 weeks** ahead of schedule

Regulatory approvals were obtained within the original timelines set by the sponsor despite of the COVID -19 pandemic

Remote site initiation visit was successfully completed and the site was activated within **1 week** of the final regulatory approval being granted



[1] Site already had a valid permit for a similar type of study. Therefore, the site only submitted and Amendment for IenW approval.

Ministry of Infrastructure and Water Management (IenW)

The applicant/permit holder for IenW approval is usually the BoD of the hospital/institution where the treatment is provided, (the legal entity that bears final responsibility). Submission is then executed by the study site.

Central Committee on Research Involving Human Subjects (CCMO)

Act as Ethics Committee for review of studies involving Gene Therapy/medicinal products with Genetically Modified Organisms (GMO). Submission executed by TFS.

Local Board of Directors (BoD) of participating study site

BoD approval can be requested locally after all other approvals are obtained. Executed by the study site.

Ministry of Health, Welfare and Sport (VWS)

Act as Competent Authority for studies involving Gene Therapy/medicinal products with Genetically Modified Organisms (GMO). Submission executed by TFS.