TFS HealthScience
Clinical Research Excellence

Diabetic Foot Ulcer

Case study

General information

TFS was selected by this small European biotech company to provide full service support during the development of their genetically modified bacteria producing human proteins for improving wound healing. This ongoing study is a phase 1/2a study investigating the topical efficacy of an investigational medicinal product (IMP).

The phase 1 was a multi-centre, open-label, non-randomized, uncontrolled dose-finding study. Each cycle of treatment lasted 2 weeks with 3 administrations of the IMP per week on alternate days. Treatment cycles were sequentially administered, without treatment breaks. The actual treatment duration with the IMP depended on the level of healing during treatment and was to be discontinued once the target ulcer was completely closed or when 3 cycles of treatment were completed (6 weeks of treatment). Extension of the treatment beyond 3 cycles (6 weeks) was allowed on a case-by-case basis for maximum of additional 2 cycles (4 weeks).

Result

Patient population

30 randomised patients

Study specific

Countries

4 sites across
Germany and Poland

Challenges

Germany

- **Very high** Investigator Fees
- **Sites' interest low** due to study complexity– specific sites searched (having phase 1 unit & capacity/experience to deal with IMP)
- **Regulatory challenges**–close contact with competent authority (CA) necessary

Poland

- Complex and long **registration process** for Genetic Engineering Unit (GEU)–close contact with authorities (Ministry of Environment) and sites
- **Site identification** was difficult due to study complexity–specific sites searched (having phase 1 unit & capacity/ experience to deal with IMP)

Solutions

- **Open communication** with the client was key to starting this study on time. Issues were discussed on an ongoing basis, and solutions were found quickly
- **TFS regulatory team** maintained awareness of regulatory processes and improvements and turned around questions from the CA rapidly to ensure submissions were on time
- **Central labs' contacted** earlier than usual to have processes well described and in place in advance
- TFS took over investigator fee **negotiations**

Lessons learned

- Responsibilities and accountabilities were **divided** and future studies will be agreed at the beginning of the study
- **Feasibility** was vital to the process to have appropriate sites identified
- **Grants amounts** need to be identified and determined at early stage of the study
- Processes and study procedures need to be well identified

Client advantages

TFS demonstrated our ability to deliver the protocol and submissions on time and to adapt to the changing regulatory environment, achieving approval within the estimated timelines.

There is a mutual trust between TFS and the client, which made the whole process, through contracting, and start-up very straightforward.

About TFS

TFS HealthScience is a global Contract Research Organization (CRO) that supports biotechnology and pharmaceutical companies throughout their entire clinical development journey. In **partnership** with customers, we build **solution-driven teams** working for a healthier future. Bringing together nearly 700 professionals, TFS delivers **tailored clinical research services** in more than 40 countries and supports customers with **comprehensive solutions** through three strong business models: Clinical Development Services (CDS), which provides full-service support at all stages of the clinical development process, Strategic Resourcing Solutions (SRS), which offers expert insourcing and targeted recruitment services, and Functional Services (FSP), to provide customers with strategic workforce management solutions.

700

Nearly 700
Worldwide
professionals

40

Conducting trials
in more than
40 countries

17

Offices and legal
entities in
17 countries

40

Industry leading
expertise in
4 major areas

Detailed information about TFS, and its business offerings can be obtained through **www.tfscro.com.**