

## Our advanced therapy clinical trial experience

### Why choose Ergomed for your next Advanced Therapy trial?

- Advanced therapies experience in oncology (including chimeric antigen receptor CAR-T cell therapy) and rare diseases
- Experienced regulatory team to support your regulatory strategy with innovative global approaches
- Broad experience with adaptive trial and dose escalation designs
- Global reach and access to patients with rare and ultra-rare diseases
- Patient Concierge and Site Support services to optimize recruitment, retention and data quality
- Genuine patient and family centricity.

**10+**  
years' experience  
with advanced  
therapy studies  
(including CAR-T)

**50%**  
of our regulatory affairs  
managers have experience  
with advanced  
therapy projects

## We like a challenge!

Ergomed thrives on complex and challenging studies.

### Watch our recent Webinar



"Involving the Patient Community in Rare Disease trials".

**Ergomed first became involved in cell-therapy studies in 2010 and has since delivered on numerous advanced therapy studies.**

We are specialists in designing and executing complex clinical development programs requiring innovative regulatory and clinical approaches in Europe and the US.

We also understand how important the patient and their families' experiences are in order to keep them engaged in potentially life changing trials with a long follow-up period. Our wide range of

patient-concierge services decrease the study-burden and increase patient-retention.

Ergomed's unique Study Physician Support and Site Support Service provide crucial assistance in running cell and gene therapy trials successfully:

- Specialized support for pharmacy management
- Coordination of investigational medicinal product (IMP) and biological sample (cells/tissue) shipment
- Coordination with apheresis units.



# Case Study:

## Rare Tissue Transplant Study

Recruitment closed 6 months early

### Setting

An early phase multi-center study into the treatment of an experimental tissue infusion for treatment of low grade degenerative lumbar spondylolisthesis (DS).

### Result

Recruitment was closed 6 months ahead of schedule. Ergomed delivered trial success by ensuring the patient, investigator and drug were in the right place, at the right time.

Challenges	Ergomed's Solution
<b>Prolonged study set-up period in Poland due to local regulations for tissue sample collection, requiring a lot of additional site support.</b>	Ergomed's Site Management Team: <ul style="list-style-type: none"> <li>● Oversaw the large amount of extra documentation required by local regulations insisting that tissue samples be handled in the same manner as genetically modified products</li> <li>● Coordinated the regulatory inspections so that each site could be licensed for tissue sample collection.</li> </ul>
<b>Transport time of tissue to the tissue bank in Belgium: 24-hour requirement from collection, including all administrative work at local tissue bank.</b>	As timing was crucial, the Ergomed team was able to plan effective strategies and adapt to different forms of transport and timetables as required.
<b>Limited number of slots for producing tissue at the tissue banks, requiring careful planning.</b>	The Ergomed Project Team's careful coordination ensured all stakeholders were in the right place when required, in addition to considering the availability of investigators and subjects for surgery in due time.

## Some of our cell/gene therapy experience

### Oncology

- A first-in-human study with a dendritic cell vaccine to prevent relapses in patients with acute myeloid leukemia.
- A first-in-human study with engineered autologous T-cells (CAR-T) in patients with various hematological malignancies - acute myeloid leukemia (AML), myelodysplastic syndromes (MDS) and multiple myeloma (MM).

### Other indications

- A first-in-human study using adeno-associated virus (AAV)-vector gene therapy to treat Duchenne muscular dystrophy.
- Two phase I/II studies with a tissue-regeneration platform, utilizing autologous adipose-derived stem cells (ASCs) for the treatment of recalcitrant lower limb nonunion and in patients undergoing lumbar spine fusion surgery.

To learn more about Ergomed plc's expertise in cell-therapy studies, contact us at:

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### Ergomed plc

The Ergomed group of companies is dedicated to the provision of specialist services to the global pharmaceutical industry and supports companies with services spanning all phases of clinical trials, post-approval pharmacovigilance and medical information. We offer a full range of high-quality clinical research and clinical trial management services and internationally recognized expertise in orphan drug development together with an industry-leading suite of specialist pharmacovigilance solutions.