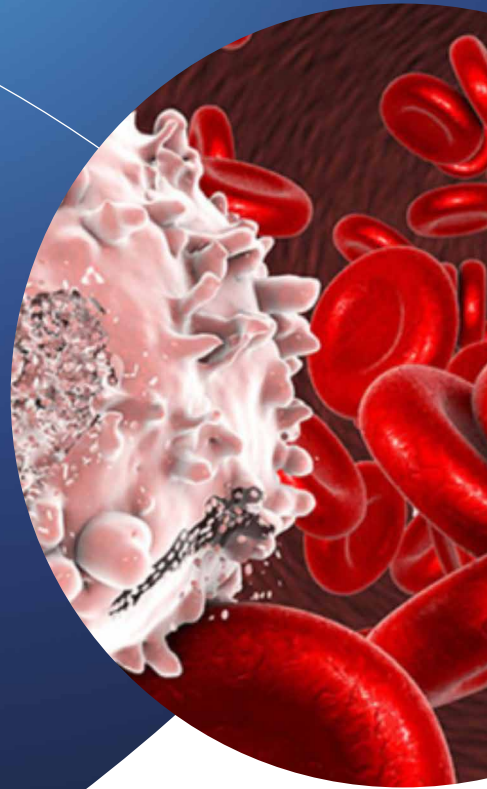




BIOTECH CASE STUDY

The first-in man trial
for a Biotech's novel
therapy to prime
the patient's natural
killer cells to attack
their cancer



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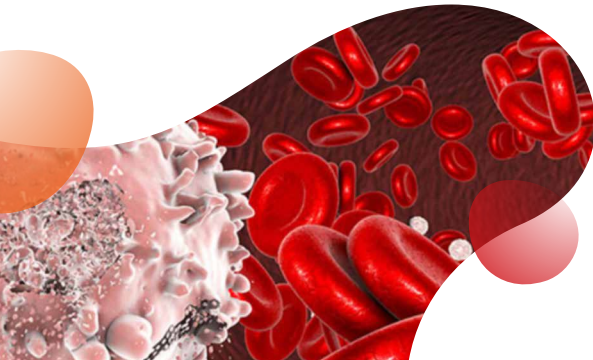
PHARMExcel was approached by a global clinical-stage biotech company to manage its UK/EU Phase I open label dose, escalation study of intravenous NK cell targeted therapy in patients with high-risk Myelodysplastic Syndrome (MDS) and Acute Myelocytic Leukemia (AML) | 2 UK sites, 1 EU site.

Bespoke solutions for client

- Protocol Development
- Clinical Monitoring & Site Management
- Project Management
- Regulatory Submissions
- Quality Assurance
- Safety Management
- Data Management

Challenges we overcame

Despite the hurdles COVID-19 pandemic created, PHARMExcel worked closely with the regulators to obtain site approval quickly. The trial eligibility criteria also posed several challenges, but working closely with the sites we minimized any risk to delaying the opening of the sites. Our expertise in complex ATMP regulatory processes ensured successful IP delivery to sites and full regulatory compliance.



Milestones hit



UK & EU sites
**successfully
activated**



INKmune™
programme
**extended
to US**



70% PTSR
indication
benchmark for
progressing
into Phase II

Expertise

- PHARMEExcel, specialists in delivering ATMP trials.
- Prof Mark Lowdell, CSO at INmune Bio Inc and Professor of Cell & Tissue Therapy, UCL, UK.
- Clinical team at Southampton University, UK, led by Dr Kim Orchard, past president of the British Society of Blood and Marrow Transplantation and Cellular Therapy.
- Dr Chris Dalley, Consultant Haematologist and Bone Marrow Transplant Physician, Southampton Hospital.



Why did the client choose PHARMExcel?

As a trial development partner PHARMExcel has the ability to adapt to biotech needs, providing expertise, ISO accredited operational infrastructure and the relevant scalable services where needed.

"The most collaborative CRO I've worked with. PHARMExcel bothered to know us as a client and understands our studies inside out, making it an efficient and friendly partnership."

Prof Mark Lowdell
CSO INmune Bio Inc



**LET US HELP YOUR
STUDY SUCCEED
REQUEST A PROPOSAL**



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