



BIOTECH CASE STUDY

First-in-man, Class III Device, UK and pan-European clinical trial for treatment of acute-on-chronic liver failure



FS 767169

As an experienced CRO in liver disease, PHARMExcel was approached to lead this multi-centre, randomised controlled clinical trial to evaluate the safety and performance of the DIALIVE liver dialysis device verses standard of care in patients with acute-on-chronic liver failure.

Bespoke solutions for client

- Protocol Development
- Project Management
- Regulatory Approvals
- Monitoring and Site Management
- Safety Reporting
- Data Management Oversight
- Quality Assurance

Challenges we overcame

PHARMExcel was instrumental in designing a well-thought out protocol to overcome the risks and challenges with the patient population, the clinical delivery and safety reporting. We worked closely with the central Biobank to ensure sample management and accountability were adhered to. This high scientific value trial, funded by Horizon 2020 and published in the Journal of Hepatology, was only possible through effective collaboration and existing experience with this patient population.



Milestones hit



Primary
endpoint of
safety met



Proof of
concept
**successfully
delivered**



**32 patients
recruited** in
8 EU hospitals
in 6 countries

Expertise

- PHARMEExcel, member of the UK Foundation for Chronic Liver Failure (UK CLIF) and experts in medical device management.
- Prof Rajiv Jalan, Professor of Hepatology at UCL, Founding Member of EASL CLIF Consortium.
- Daniel Green, CEO and Entrepreneur, Yaqrit.
- Dr Banwari Agarwal, Chief Investigator, Royal Free Hospital.
- ALIVER consortium partners, including EF CLIF, UCL, Royal Free Hospital London and Yaqrit.



Why did the client choose PHARMEExcel?

With in-depth knowledge of liver disease and direct experience of delivering logistically challenging trials, PHARMEExcel has the ability to contribute quickly to study requirements, providing invaluable expertise, ISO accredited operational infrastructure and the relevant scalable services where needed. Our clinical and scientific collaboration with UK-CLIF enables us to provide value add for all our clients' hepatology studies.

"PHARMEExcel's passion for their projects, the flexibility shown by the team, combined with direct access to the CEO, sets PHARMEExcel apart from other CROs."

Daniel Green
CEO and Sponsor, Yaqrit



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