



**PHARME**Excel

**BIOTECH CASE STUDY**

**A safety and feasibility study of a novel hydrogel pill for weight loss in adults**



FS 767169

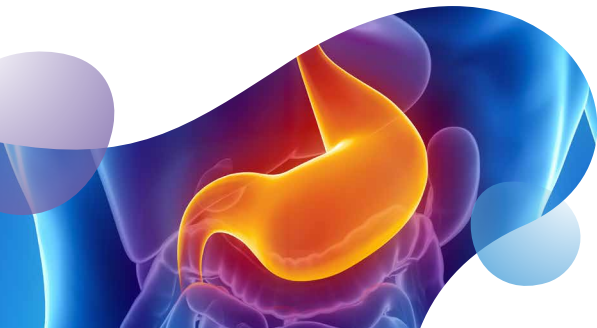
**PHARME** Excel was approached by an Oxford-based biotech on a first-into-man interventional study of a novel self-expanding hydrogel; to investigate feasibility, safety and tolerability as the primary outcomes, and also collect secondary outcome measures to inform estimated numbers for a fully powered randomised trial.

## Bespoke solutions for client

- Protocol Development
- Regulatory Approvals
- Monitoring & Site Management
- Project Management
- Safety Management & Reporting
- Statistics & Data Management
- Quality Assurance

## Our impact

Open communication and collaboration are the driving force behind our partnerships. We engaged quickly with the project team to customise our services to meet the client/clinical sites specific needs. Our experienced team provided guidance in the study design and regulatory pathway for this novel weight-loss product. With our flexible business model, we were able to adapt quickly to study design changes required by the Ethics Committee and obtain the necessary approvals to commence this pivotal study.



## Milestones hit



Initial **safety phases** complete



**2 sites activated**  
3rd in set up



Main trial **now actively recruiting**

## Expertise

- PHARMEExcel, experts in delivering complex, first in human trials.
- Chief Investigator Prof James Byrne, University Southampton NHS Trust.
- Co-Investigator Prof Julian Hamilton Shield, NIHR Bristol Biomedical Research Centre.
- NIHR Southampton and Bristol Biomedical Research Centre.



# Why do Sponsors select us?

Through long-standing relationships and experience working across the UK NHS research network, we are able to bring unique knowledge to complex early phase trials. We are recognised for our flexibility and genuine purpose driven approach, providing commercially competitive pricing, invaluable expertise and ISO accredited operational infrastructure to ensure regulatory compliance.

*“PHARMExcel has been a pleasure to work with, responsive and flexible.”*

**Prof Saul Faust (OBE)**  
Director NIHR Southampton  
Clinical Research Facility



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