Academia & Industry in Partnership

UNIVERSITY OF OXFORD

The Diabetes Trials Unit Translational Research Group

"Driving innovation in the prevention, diagnosis and treatment of diabetes"

The Diabetes Trials Unit

The Diabetes Trials Unit (DTU), founded in 1985 by Professor Rury Holman, specialises in conducting diabetes-related national and multinational mega trials, and has a long track record of working in partnership with industry.

DTU trials are all conducted to International Conference of Harmonisation (ICH) standards, and range from proof of concept and efficacy studies (Phase IIA/B) to Phase III and Phase IV randomised multi-centre, international controlled trials. The DTU is a fully registered UKCRC Clinical Trials Unit, a founder member of the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM), a part of the RAE2008 4* rated University of Oxford Nuffield Department of Medicine, and a founder member of the Oxford Comprehensive Biomedical Research Centre, funded by the UK National Institute for Health Research (NIHR).

The Translational Research Group

The Translational Research Group (TRG), part of the Diabetes Trials Unit, undertakes early phase research on potential future therapies and new medical devices. The TRG specialises in academic-led Phase I and II trials of novel therapeutic agents and devices, the clinical aspects of which are conducted in a purpose-designed, ICH compliant Clinical Research Facility.

Interventions and devices chosen for evaluation by the TRG are carefully selected by an experienced strategy board according to their relevance to the group's main areas of clinical and academic interest - beta-cell function, cardiodiabetes and metabolism - as well as their feasibility and potential to improve patient care or disease prevention.

Contracting made easy

The DTU values the synergistic relationship between academia and industry and has a history of successful collaborations. Utilising a UK-wide, commercially endorsed, standard trial agreement and a transparent costing approach, we can provide a smooth and rapid contract negotiation process with efficient study initiation timelines.

An agreed 'division of responsibilities' is negotiated from the outset, drawing on the respective strengths and interests of both partners - forming a vital component of the final trial agreement.

What we deliver

We have a proven track record with industry, having demonstrated our ability to conduct trials to exacting standards and meet firm deadlines. Our key strengths include:

- **Trial design & protocol development**
- **Rapid and reliable patient recruitment**
- **Sample size calculations**
- **Data management**
- **Trial co-ordination**
- **Statistical analysis & modelling**
- **UKPDS Risk Engine, HOMA Calculator and Outcomes Model**
- **In-house site monitoring**
- **Access to Clinical Biomanufacturing Facility (Qualified Person)**
- **Integrated, ICH GCP compliant Electronic Data Collection technologies**
- **Solid relationships with key opinion leaders/academic investigators**
- **Dedicated senior project managers and study managers**
- **Automated global electronic SOP management system**

Rapid participant recruitment & retention

The DTU has an in-house, DPA compliant, electronic recruitment register that holds an increasing number of records from volunteers who have consented to be contacted about all future TRG research. Automated, targeted mail shot facilities allows us to streamline contact with potential trial participants and greatly reduces recruitment lead times. Our experienced research staff and purpose built facilities also mean that we are well placed to not only recruit participants but crucially to also retain them to the end of the study.

Regulatory Approvals

A major reason for delays in reaching FPFV is securing the necessary regulatory approvals. The DTRG has a dedicated Project Manager, with experience in both IMP and device submissions, who oversees all such submissions. Our unit has an excellent track record in obtaining approvals and has developed sound relations with local R&D offices, ensuring that local approvals are also effectively managed.

Patient materials are thoroughly reviewed by our Communications Manager and the Thames Valley Diabetes Research Network Patient Panel, that helps ensure we present studies in a readily comprehensible form. Engaging with patients at the study design stage not only provides constructive feedback, but also strengthens our applications for ethical approval.

Project Management

All TRG trials are allocated a Project Manager who ensures that realistic timelines for key deliverables are agreed and communicated with all stakeholders and that the project is managed professionally and effectively throughout.

All projects are assigned a dedicated project team who communicate frequently with the study sponsor via documented meetings or teleconferences.

Electronic Data Capture

An in-house, GCP compliant EDC Trial Management System is used to manage data collected on all DTRG studies. This bespoke electronic data collection system is developed to run Internet-based clinical trials, and has been tailored by the DTU Bio-Informatics group to deliver the facilities and performance characteristics required by the DTU.

Find out more

For further information, please email trg@dtu.ox.ac.uk

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