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DRU Cymru: How a Multidisciplinary Team Supports a Clinical Trial

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Introduction:

The Diabetes Research Unit Cymru (DRU Cymru) facilitates and supports research into diabetes across Wales. The multidisciplinary team provides expertise in areas including study design and set-up, statistical support, public and patient involvement (PPI) and laboratory support. Colleagues in Cardiff University secured a grant for Wales' first NIHR EME funded study (NIHR EME 16/36/01), evaluating the effectiveness of a monoclonal antibody as a means of preserving insulin producing cells in young people with recent onset Type 1 diabetes (T1D).

Challenge Faced:

Funding for the project could not be released until the study design and protocol were finalised.

DRU Cymru were contacted for guidance and support, and to provide protocol development in the following ways to allow the project to proceed:

Our Approach:

Study Design and Support:

A member of the DRU Cymru team is the designated statistician for the trial, providing full statistical support alongside the statistical analysis plan.

The DRU Cymru Clinical Trials Officer was involved in producing the participant information sheets for the study, ensuring that they were age appropriate before being reviewed by young people with T1D. DRU Cymru also part funded the participant information video for the study, which can be viewed via the following link: https://www.type1diabetesresearch.org.uk/current-trials/

DRU Cymru Engagement Team:

Members of the engagement team were instrumental in ensuring that the views of people living with diabetes were taken into account.

This involved arranging a focus group for young people living with T1D and their parents to gather their views on the proposed research and study design. The engagement team also disseminated participant information sheets for review by individuals living with T1D prior to ethical review.

The team supported a member of the DRU Cymru Public Reference Panel in attending the Ethics Committee meeting, and provide continued support for the members who sit on the Trial Steering Committee.

Laboratory Support:

Input from the DRU Cymru laboratory team has been integral to the design of the study protocol and site sampling manual. The lab team have advised on sample collection, storage and analysis processes as well as the logistics of transport of 'sample collection kits' and subsequent temperature controlled transport of study samples between the multiple study sites across the UK. The team are also providing ongoing support in carrying out laboratory analysis on samples.

Conclusion:

The collaborative work of the DRU Cymru team allowed for protocol development to commence prior to the designated clinical trials unit engaging with the study. This allowed for the release of project funding and full trial development and set-up to begin.

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