The USTEKID Study
DRU Cymru work package leads, Professor Colin Dayan and Professor John Gregory, were successful in securing a five-year grant from the National Institute of Health Research Efficacy and Mechanism Evaluation programme (NIHR EME). This is the first successful bid from Wales and will be used to evaluate the effectiveness of a monoclonal antibody (ustekinumab), already licensed for use in the treatment of psoriasis and Crohn’s disease, as a means of preserving insulin producing cells in young people with recent onset Type 1 diabetes.

Members of the DRU Cymru core team have been involved in the resulting study, USTEKID, since its inception in a number of ways.

Public and Patient Involvement
Ensuring that research benefits the people it is meant to be helping is extremely important in research. The DRU Cymru public engagement team, Sharon Parsons and Moira Morgan, have been instrumental in making sure that people living with diabetes views were taken into account for the USTEKID study. This involved arranging a focus group for young people living with diabetes and their parents, to find out more about the research and help with the study design. Those taking part in the group had the opportunity to discuss the proposed procedures with the study Chief Investigator and how acceptable and practical these would be to potential participants. The points raised by the young people and their parents were taken into account in the final study design and the study specific information film that has been developed.

The engagement team also arranged for participant information sheets to be reviewed by young people of a similar age to those who the study is aimed at, prior to review by the ethics committee. A parent contributor from the DRU Cymru Public Reference Panel then attended the Ethics Committee meeting with the study team to provide a public perspective on the study. That member of the Reference Panel now sits on the Trial Steering Committee along with another member of the panel.

"For this trial, we need 12-18 year olds. The PPI team advised us that a 3-4 minute "clickable" online film would help teenagers and their families see and understand what the study involves better than a traditional written information sheet - so we made the first "video patient information sheet". DRU Cymru advised us on a Swansea based film-maker (ehealthdigital) they had used before and the PPI team and families with type 1 diabetes guided us on style and content with a great result.....even the ethics committee thought it was fantastic!"

- Colin Dayan
Professor of Clinical Diabetes and Metabolism
**Study Design and Documentation**

DRU Cymru core members Ivy Cheung and Sarah Dowrick worked with the USTEKID study team to provide support on the study design and documentation. Ivy is the designated statistician for the study and as part of this has worked out the statistical tests needed for the study to show the safety and effectiveness of the study drug. Sarah has been involved in writing the Patient Information Leaflets for the study. To make sure that they convey the study information to the potential participants and their parents in an accurate and understandable way, the leaflets were reviewed by children and young people before being finalised.

**Laboratory**

Input from the DRU Cymru lab team has been integral to the design of the study protocol and site sampling manual. The lab team have been able to advise on the 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 and the lab. Going forward, the DRU Cymru lab will carry out laboratory analysis of study samples; this will include both rapid testing and reporting to determine a participant’s eligibility for the trial and longer-term ‘batched’ analysis of samples from enrolled participants over the planned four and a half year duration of the study.

**Potential Impact:** This study could show that interrupting the destruction of the insulin producing cells at the time of diagnosis may be able to preserve and maintain some insulin secreting capacity.

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**Type 1 Diabetes UK Immunotherapy Consortium (T1D UK)**

The USTEKID Study will be delivered through the Type 1 Diabetes UK Immunotherapy Consortium (T1D UK) with support from the Swansea Trials Unit. The T1D UK consortium has been funded by Diabetes UK and the Juvenile Diabetes Research Foundation (JDRF) since 2015 to promote, develop and support immunotherapy research in type 1 diabetes. The consortium has established a network of 15 research sites strategically distributed across the UK.

The consortium is led by Professor Colin Dayan from Cardiff University.

To find out more visit their website [https://www.type1diabetesresearch.org.uk/about-us/](https://www.type1diabetesresearch.org.uk/about-us/)