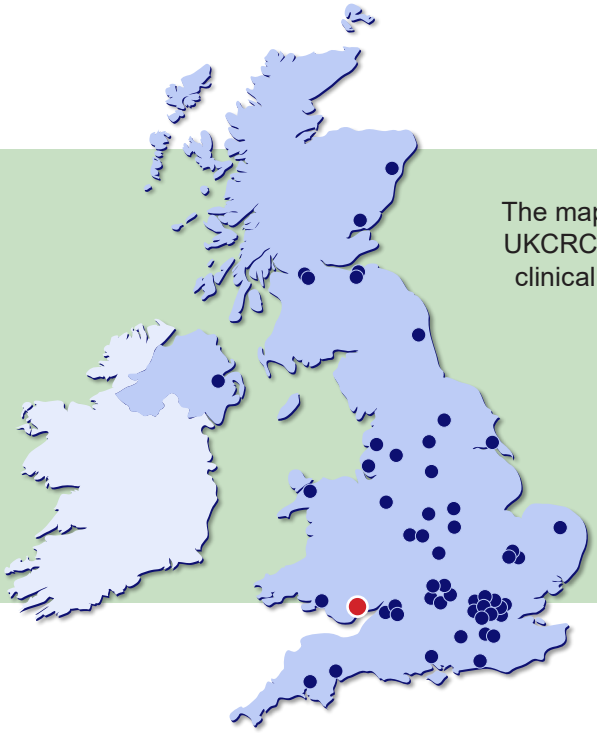
UKCRC Registered Clinical Trials Units

Cardiff University
Prifysgol Caerdydd
Centre for Trials Research
Canolfan Ymchwil Treialon

Cardiff Centre for Trials Research Unit supports the Oxford Vaccine Group in opening Vaccine study in Wales in just three weeks



The map shows all UKCRC registered clinical trials units

The Centre for Trials Research Unit helped research into a highly anticipated vaccine for COVID-19 progress from a phase I study (COV001) to a phase II/III study (COV002) that is hoping to recruit over 10,000 volunteers across 20 UK sites.

The vaccine was made from a replication-deficient version of the common cold adenovirus that infects chimpanzees (ChAdOx1), which had been engineered (genetically modified) to contain the Spike protein antigen found on the surface of SARS CoV-2 (nCoV-19). Participants were randomised to receive either ChAdOx1 nCoV-19 or an active control licenced meningitis vaccine (MenACWY) as part of the double blinded trial. The effectiveness of the vaccine was assessed by looking at COVID-19 infection rates between the two groups.

This trial was designed and run by our sister UKCRC Registered CTU the Oxford Vaccine Group at the University of Oxford.

To facilitate the study set-up in Wales, Public Health Wales (PHW), Aneurin Bevan University Health Board (ABUHB) and Health and Care Research Wales (HCRW) collaborated with Centre for Trials Research (CTR). Daily update meetings created the platform for communication

between the groups to discuss prioritisation and preparation for regulatory green-light study approvals. With the ongoing support of Oxford Vaccine Group and ABUHB, the CTU were able to facilitate the preparation and review of the GMO (Genetically Modified Organisms) risk assessment and put study specific SOPs in place in order to be compliant with Genetically Modified Organisms (contained use) regulations 2014 (version Dec2018), the first GMO application in ABUHB.

UKCRC Registered Clinical Trials Units

Centre for Trials Research
Canolfan Ymchwil Treialon

The CTU supported operational and practical strategies for the study. The teams worked cross-divisionally to locate and prepare an appropriate location for screening and vaccinating large numbers of participants whilst socially distancing. The team also identified staff members, provided study training, established a sample flow for blood and saliva swab sampling and ensured contractual arrangements have been put in place. The CTR worked cross-divisionally with ABUHB, PWH and HCRW to supplement the Oxford training material with site-specific training and to support the development of the communication plan for participants and staff. This work was led from the Centre by Dr Ruby Ray (Senior Trial Manager) and Dr Emma Thomas-Jones (Senior Research Fellow), with guidance from the Director Prof Kerry Hood.

Numerous challenges were overcome by the team's enthusiasm and ability to rapidly adapt to changes both at the trial level and on-site. Communication between the two CTUs allowed the team to highlight and overcome local challenges in trial delivery by problem solving.

By working together, Wales was able to open to the study at ABUHB within 3 weeks a total of 435 participants were recruited to the Aneurin Bevan site and over 10,000 participants were recruited nationally (across 21 sites).

The CTR will continue supporting the follow-up aspects of the study and have used CTR links with influential clinicians to help establish important parts of the study pathway.

Cardiff University website:

https://www.cardiff.ac.uk/news/view/2397496-wales-to-play-major-role-in-national-trial-for-covid-19-vaccine

BBC Wales online:

https://www.bbc.co.uk/news/uk-wales-52773777

ITV Wales online:

https://www.itv.com/news/wales/2020-05-22/welsh-healthcare-staff-to-take-part-in-coronavirus-vaccine-trial/

Wales online:

https://www.walesonline.co.uk/news/health/coronavirus-vaccine-trial-wales-oxford-18293480