

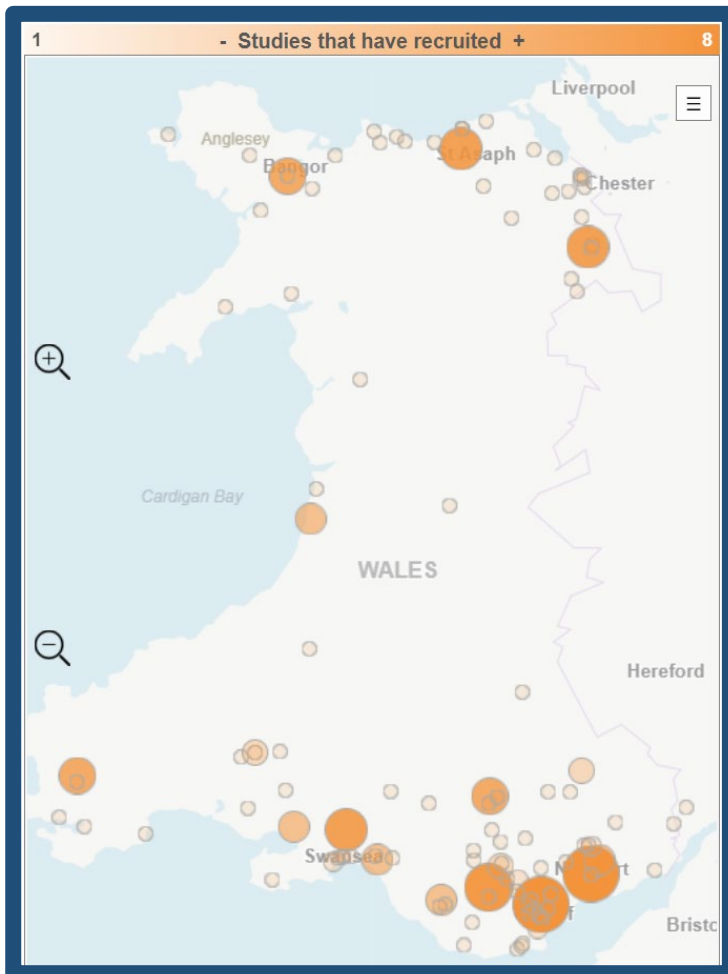
The One Wales approach to COVID-19 vaccine research

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The context of COVID-19 vaccine research delivery in Wales

UPH research portfolio in Wales



- Rapid COVID-19 vaccine development globally
- UK VTF remit to secure vaccine supply
- Lessons learned from Oxford/AZ COV002 study
- National Vaccine Registry launched



The Wales COVID-19 vaccine research delivery model-key milestones

- VTF call and funding to strengthen and expand vaccine research delivery capacity and capability
- Proposal for Health and Care Research Wales/Public Health Wales partnership
- Appointment of Lead PIs for Wales
- Rapid assessment of Wales's facilities and capability



Llywodraeth Cymru
Welsh Government



Department
of Health &
Social Care



GIG
CYMRU
NHS
WALES | Iechyd Cyhoeddus
Cymru
Public Health
Wales

NIHR | National Institute
for Health Research



GIG
CYMRU
NHS
WALES



Centre for
Trials Research
Canolfan
Ymchwil Treialon



GIG
CYMRU
NHS
WALES | Bwrdd Iechyd
Addysgu Powys
Powys Teaching
Health Board



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

Wales 'regional' vaccine research delivery model

Wales Vaccine Research Delivery Hub roles

- Programme Board – leads for clinical, delivery, laboratory, pharmacy, logistics, facilities, workforce, communications, finance & funding, contracts

Wales Vaccine Research Delivery Hub remit

- UK engagement
- Programme management
- EOI management
- Trial oversight and planning (programme level)
- Administration
- Wales Vaccine & Preventable Diseases Programme links (Public Health Wales)

All-Wales delivery Support

- Central booking and appointment team
- Remote screening capability
- Reserve delivery workforce
- All-Wales Out of Hours team development
- Individual trial oversight
- Costings and contracting
- Training

Cardiff CRF

BCUHB
North Wales
Clinical
research
Centre

CTMUHB
Clinical
Research
Centre

SBUHB
JCRF

2 Wales Lead Principal Investigators

Local PIs and Sub Investigators 3



Working across the UK



- UPH panel
- NIHR vaccine research delivery operational group
- NIHR study placement and response team
- Weekly CI/PI calls



The NOVAVAX experience

Novavax in numbers

10 days to set up
120 staff on delegation log
28 doctors
40 nurses
140 miles longest commute
202 miles furthest recruit
800 participants screened
400 target recruitment
490 actual recruitment
2,250 study attendances
1,700 blood samples
1,500 future attendances
1,200 swabs
10,000 data queries
25,000 eCRF pages QCd
50% unblinded

Structure

Double blind, placebo control
15,000 UK recruitment
2 doses, 3 weeks apart
Day 35, 3 & 6 month follow-up
Cross over

Timelines and milestones

First participant: 02/11/2020
Interim results: 29/01/2021
NHRA approval: Pending
NEJM publication: May 2021
CRF development: ongoing



The JANSSEN ENSEMBLE 2 experience

- Human adenoviral vector vaccine – 2 doses (8 weeks apart) vs placebo
- Opened late Nov 2020
- Global study – 6,000 UK participants
- 224 recruited in Cardiff over 3 week period
- Significant number of HCWs
- 4 confirmed COVID diagnoses – all between 1st & 2nd dose
- Majority of participants have had to be unblinded due to offer of NHS vaccine
- Now in crossover phase – placebo arm offered single dose of Janssen
- Over-complex IT systems



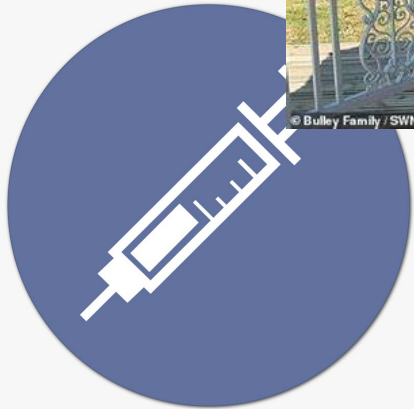
Achievements and benefits

- >1100 Wales participants and counting
- Rapid set up
- Data quality
- Exceeded target recruitment
- GMO capability
- Developed teams and training
- Dedicated facilities offering high capacity for delivery
- Access to target populations
- Wide geographical coverage
- Public engagement
- Increased UK profile for Wales research
- Sponsor engagement
- Collaborative working and shared learning
- Standard operational processes and documents
- Opportunities to provide research infrastructure legacy for long term

Approved vaccines



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Any questions please?