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
**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

### Network
- Cardiff CRF
- BCUHB North Wales Clinical Research Centre
- CTMUHB Clinical Research Centre
- SBUHB JCRF

### Leadership
- 2 Wales Lead Principal Investigators
- Local PIs and Sub Investigators

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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

**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

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**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
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
Any questions please?