

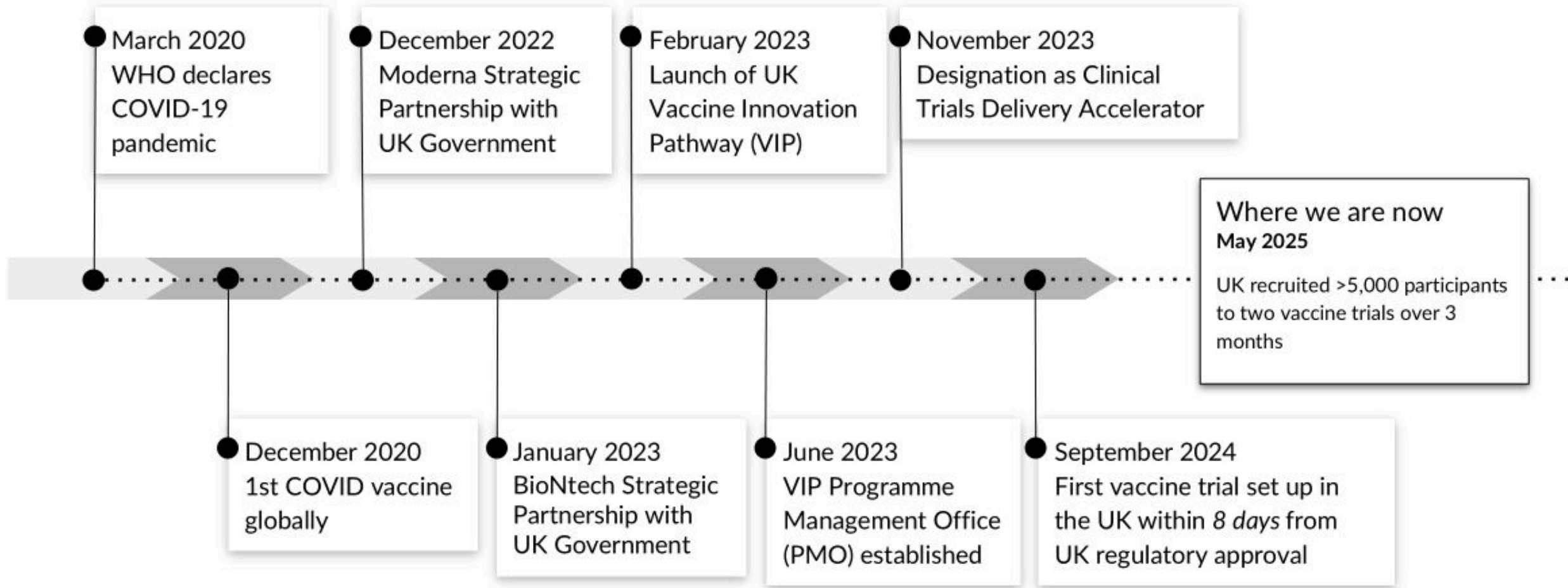
Innovative Models for Accelerated
Clinical Trial Delivery:
Insights from the UK Vaccine Innovation
Pathway and Greater Manchester's
Research Ecosystem

UK Vaccine Innovation Pathway

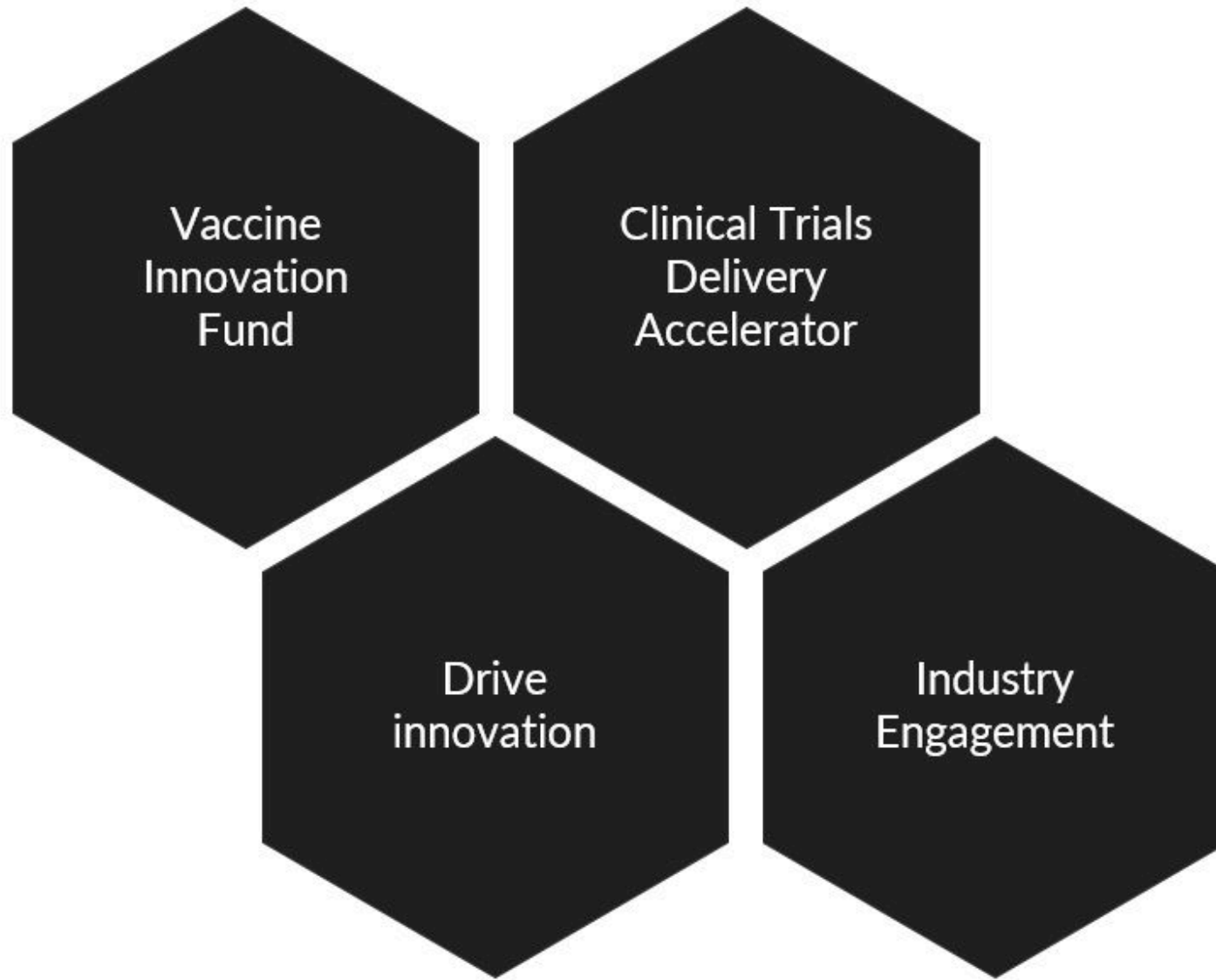
The first UK Clinical Trials Delivery Accelerator

Dr Angela Parker

Introduction to the Vaccine Innovation Pathway (VIP)



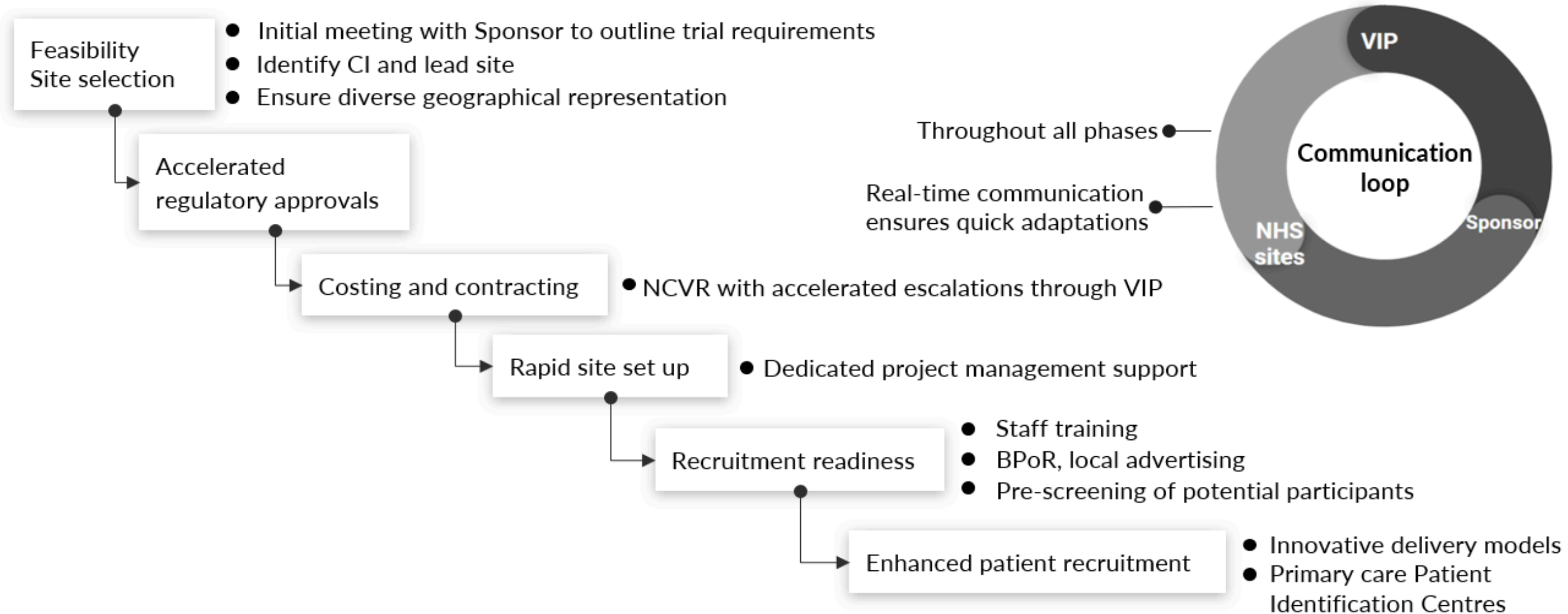
VIP Role



VIP structure and framework

1. Access to Clinical Leadership	2. Optimised Research Infrastructure	3. Accelerated Trial set up and optimised site management	4. Innovative Models of Trial Delivery	5. Build Patient Centric and Inclusive Systems	Aims
<ul style="list-style-type: none"> • Access to 300+ clinical experts registered in the VIP forums. • Provision of online training resources customised to protocol families. • Vaccines apprenticeship scheme for naïve sites- mainly aimed at research nurses and support staff. • Mentorship scheme for new investigators. 	<ul style="list-style-type: none"> • Data for site capacity and capability for infectious diseases and cancer therapeutic trials • Data-driven optimisation of site selection • Develop research capacity and capability in GP practices, and residential care homes. 	<ul style="list-style-type: none"> • Single Point of Entry and bespoke support to navigate the UK research ecosystem • Streamlined site set up processes including confirmation of capacity and capability, R&D project management, contracting and invoicing • Target for infectious disease trial set up is 42 days • Performance oversight: the VIP facilitates monthly meetings bringing together all research delivery agencies across the UK to identify and resolve delays in study set up and accelerate delivery in recruitment. 	<ul style="list-style-type: none"> • Support with identifying and contacting with the appropriate digital systems to identify, recruit, and follow up of patients • Support with the introduction of decentralised and hybrid models for delivery/follow up • Support patient identification and recruitment in non- hospital settings 	<ul style="list-style-type: none"> • Support with developing bespoke patient and public involvement and recruitment incentivisation schemes. • Support with developing bespoke public awareness campaigns to support with recruitment. • Support with meeting diversity and equity of access targets in recruitment. 	Goals
A. Partnerships		B. Data	C. Continuous Process Improvement		Enablers

Accelerated Setup and Enhanced Delivery Model



Track Record of Delivery

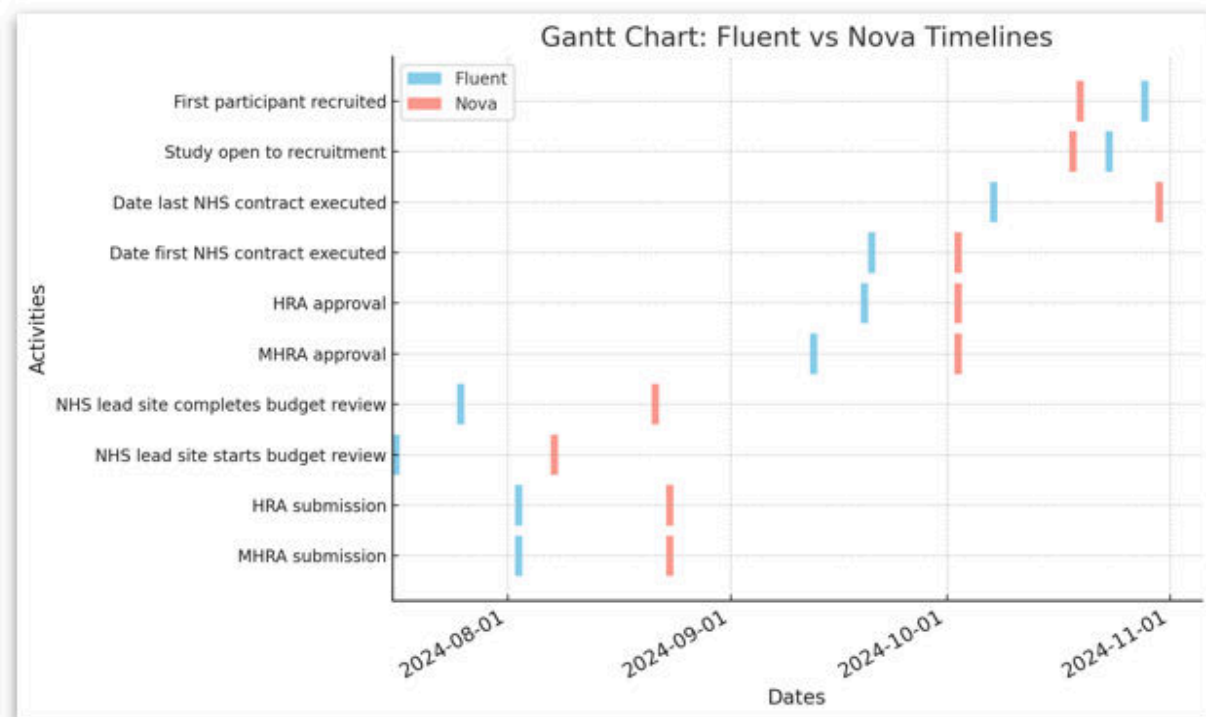
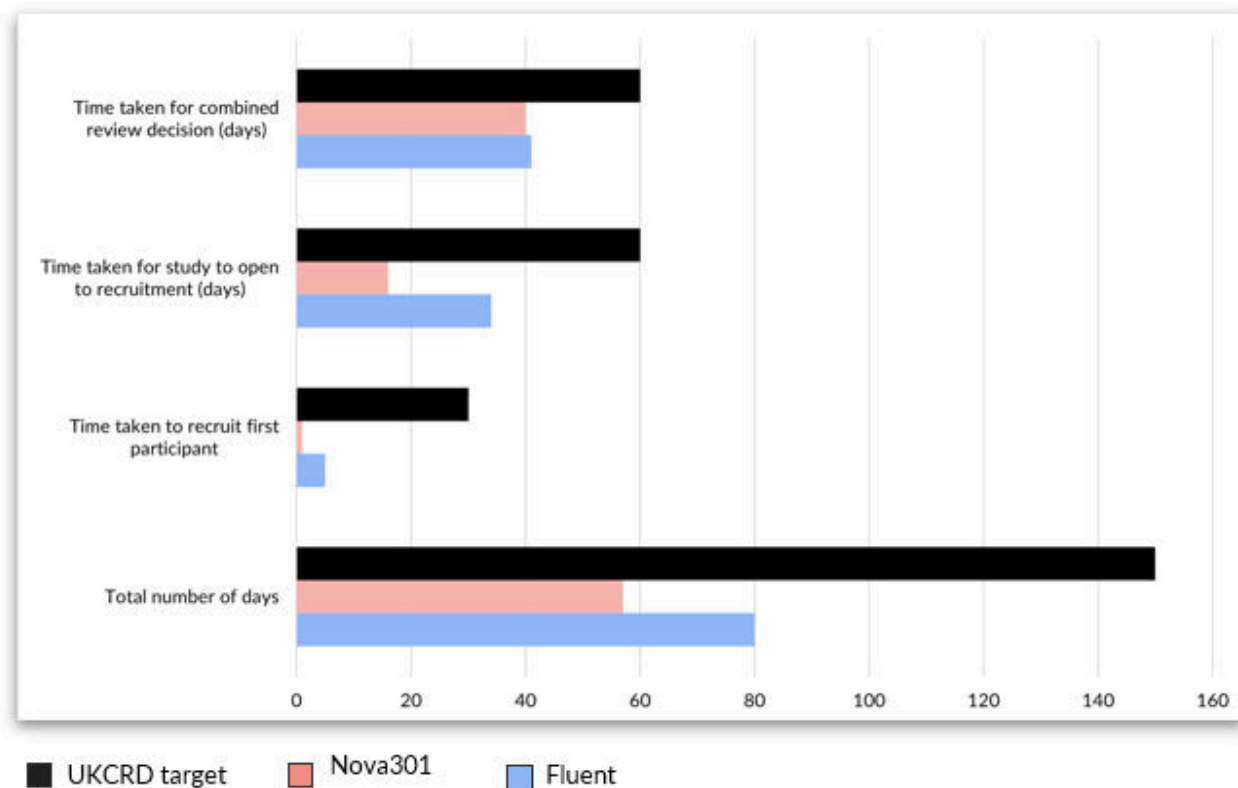
1. Moderna Seasonal flu vaccine study for adults over the age of 50 (Fluent)

- To run alongside the NHS Flu Vaccination Programme in Oct/Nov
- 19 NHS sites
 - Combination of primary and secondary care sites
- 10 private sites
- 38-day recruitment window

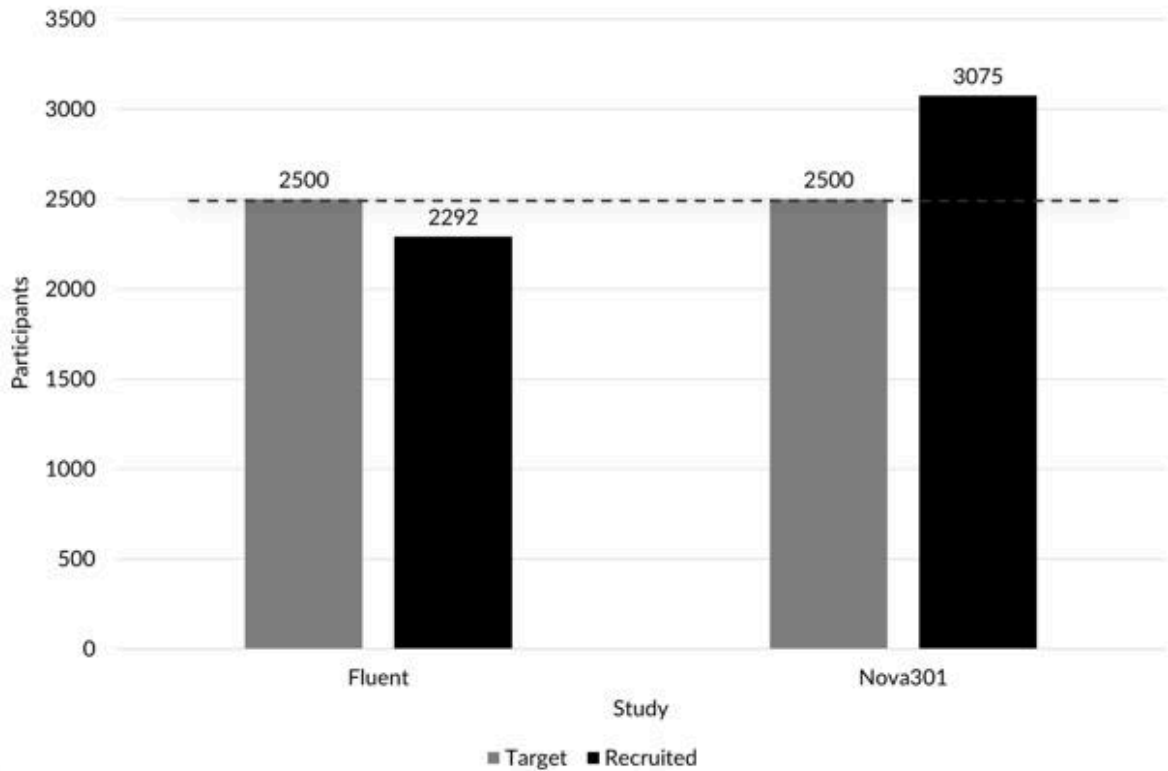
2. Moderna norovirus vaccine study for adults over the age of 18 (Nova301)

- To run concurrently with Fluent
- 27 NHS sites
 - Combination of primary and secondary care sites
- 12 private sites
- 2.5-month recruitment window (to date)

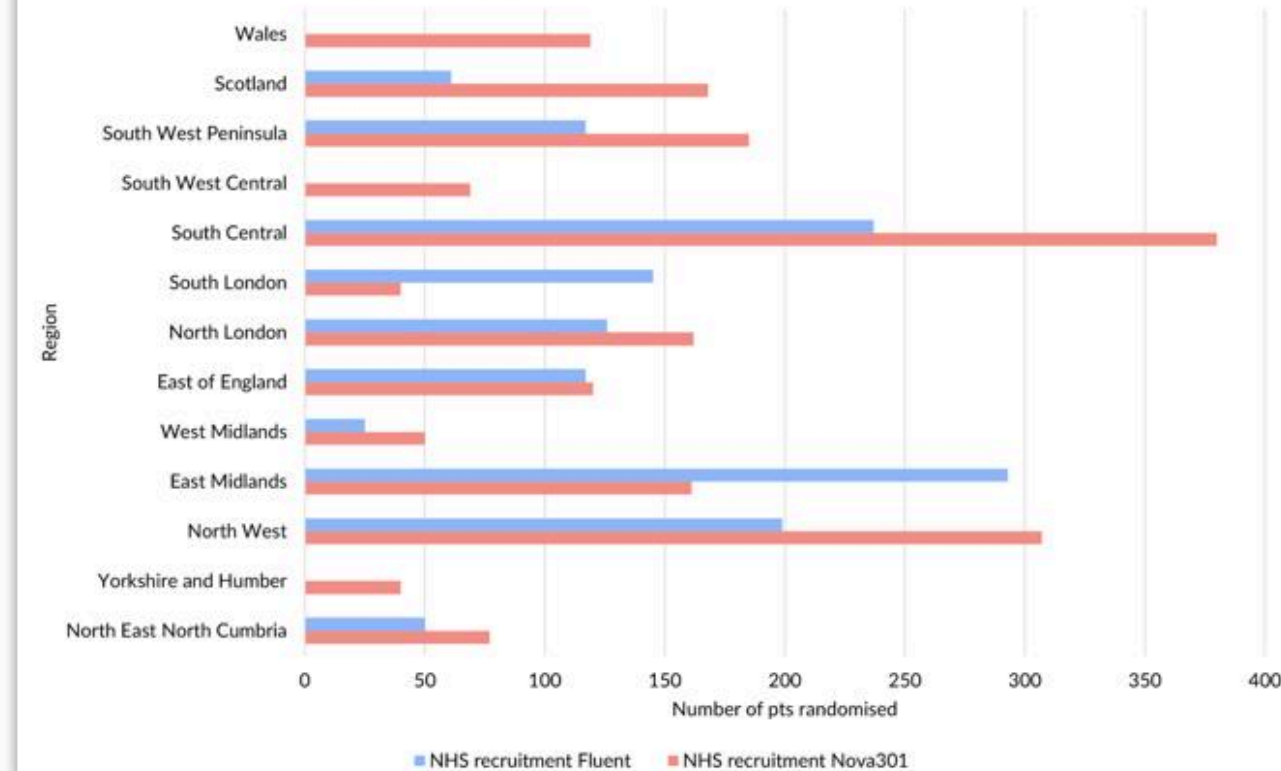
Accelerated Setup Pilot Summary



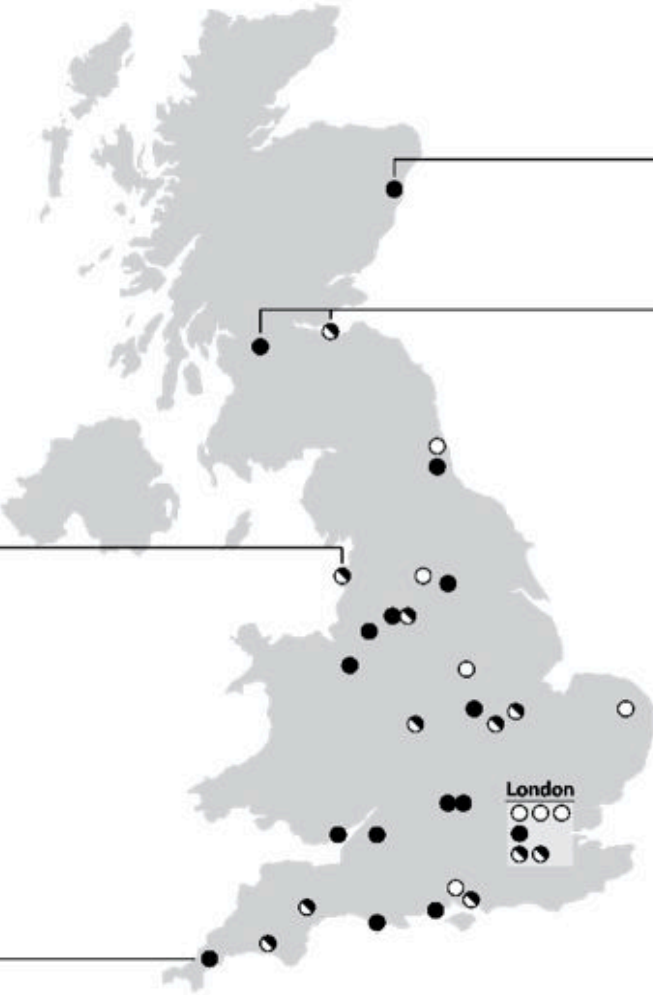
UK Recruitment Performance for Fluent and Nova301



Fluent and Nova301 - NHS recruitment by region



Pioneering Mobile Research Units, Residential-Based Recruitment, and Regional Hubs



Impact to Date



1. Accelerated Clinical Trial Setup

- Record timelines for trial setup
- Contracts finalized and sites ready for recruitment within 1 week



2. Innovative Recruitment Models

- Expansion beyond hospital clinics to diverse, community-based settings
- Inclusive recruitment improving diversity and geographic reach



3. Enhanced Partnerships and Coordination

- Collaboration with DHSC, NIHR, NHSE, UKHSA, and Devolved Administrations
- Facilitating faster decision-making and national trial delivery strategies



4. Out-of-Hospital Research Capabilities

- Enabling patient-centered research in non-traditional settings (e.g., Eynsham, Cornwall)
- Reducing strain on hospital infrastructure



Greater Manchester Strategic Collaborative Regional Working Group for Vaccine Readiness and Delivery

Monika Cien, Janette Dunkerley, Beatriz Duran

Structure and workstreams

Programme Lead
Monika Cien

Study setup
Monika Cien

- Explore how we can work together in a non-competitive way
- Create joint feasibility process
- Create One GM vaccine study delivery model

Flexible Workforce
Janette Dunkerley

- Create a flexible clinical workforce model
- Agree training, competencies, pre-placement checks and induction
- Create process for sharing of equipment

Pharmacy
Beatriz Duran

- Finalise and implement the pharmacy Risk Assessment
- Create training to develop pharmacy workforce
- Create GM pharmacy booklet

High throughput models
Jo Henry/Ash Minchin

- Promote high throughput models
- Create high throughput model resource pack
- Provide support to sites

Collaborating Organisations



NHS
Pennine Care
NHS Foundation Trust

NHS
Northern Care Alliance
NHS Foundation Trust

NHS
Stockport
NHS Foundation Trust

NHS
Manchester University
NHS Foundation Trust

NHS
Bolton
NHS Foundation Trust

NHS
East Lancashire Hospitals
NHS Trust
A University Teaching Trust

NHS
The Christie
NHS Foundation Trust

NHS
East Cheshire
NHS Trust

NHS
Wrightington, Wigan and
Leigh Teaching Hospitals
NHS Foundation Trust

NHS
Tameside and Glossop
Integrated Care
NHS Foundation Trust

NHS
Greater Manchester
Mental Health
NHS Foundation Trust

NHS
North West
Ambulance Service
NHS Trust

NHS
Bridgewater
Community Healthcare
NHS Foundation Trust

Study setup

- FutureNHS sharing platform has been designed and launched to support the collaboration.
- GM facilities and resources document has been created to share the awareness of overall capability and resources within the region.
- GM Vaccine Gantt chart has been developed to enhance shared understanding of vaccine studies being delivered within the region. This document will also inform the Flexible Workforce Group and help manage the staff resources.
- Study setup checklists have been shared between partnering organisations with the aim of improving internal processes at individual trusts.

GM Strategic Collaborative Regional Working Group

Create a new item

Welcome to your new FutureNHS workspace

This space is to support strategic collaborative regional working with aim to increase system efficiencies and joint working between trusts in GM region and and position the region competitively for vaccine studies.



Content

Minutes

Oversight of GM facilities and resources

Rapid decision making flowchart

Share files

Meeting minutes

Oversight of GM facilities and resources

Study setup checklists

GM Flexible Workforce Documents

High Throughput Models

Study Setup

- The One GM brochure highlighting benefits of joint working has been developed.
- Coordinated joint feasibility process developed, and first regional EOI completed. Once confirmed we were planning to work on the following in parallel to study setup:
 - Process for delegation of responsibilities and oversight of spoke sites
 - Create a sharing screening process to enable participants to attend for study visit at preferred location
 - Test Flexible workforce model
- The H&S model agreement will be utilised to contract between partnering organisations.

NIHR National Institute for Health and Care Research
GREATER MANCHESTER
Vaccine research trials

In Greater Manchester, we have a regional vaccine group which oversees a joint strategy for the delivery of trials across our geographical footprint. This approach allows us to increase overall capacity in our region, by combining our resources for the benefit of our patients.

This model encourages innovative ways of working together and streamlines processes. Benefits of our 'One Greater Manchester' approach include:

ONE GREATER MANCHESTER CONTRACT
Deal with a single point of contact to finalise a Greater Manchester-wide contract.

ONE PHARMACY RISK ASSESSMENT
Sign a single risk assessment for pharmacy which applies to all active sites across the region.

FASTER STUDY SET-UP AND DELIVERY
Study is ready to go live quicker with a recruitment target shared across all participating sites.

ACCESS TO MOBILE WORKFORCE
Agile delivery staff available to support research delivery across individual locations in the region and can share equipment.

COMBINED SCREENING PROCESS
Participants offered appointments close to where they live.

DIVERSE POPULATION
Our model offers equity of access across Greater Manchester, helping to ensure trial participants are representative of our region's ethnically diverse population.

NIHR For all queries, contact: researchsupportcmgm@nhr.ac.uk

Study Setup

Delivery models

- Screening at all sites/dosing at hub/follow up at spoke
- Screening and dosing activities at hub site (using shared resources to deliver) and follow up at spoke
- All activities at one location
- One study setup process but each partner delivers their own part of the study

Joint feasibility statement

- Agreed paragraph to be added to all Expressions of Interest regarding the GM flexible workforce model

High throughput models

- Meetings with research staff across Greater Manchester experienced in delivering studies via high throughput delivery model were held across GM. These meetings provided an **insight** to what the **benefits and challenges** are and what needs to be considered when using these models.
- An interactive tool was designed to inform on various high throughput delivery models.

NIHR National Institute for Health and Care Research

High Throughput Delivery Models



Contents Page

- [Locations](#)
- [Research Van](#)
- [Participant flow](#)
- [Appointment booking](#)
- [Consenting](#)
- [Sample collection](#)
- [Sample transport](#)
- [Participant questionnaires](#)
- [Pharmacy](#)
- [Miscellaneous](#)
- [Further information](#)

Stations model

'Conveyor belt' model - participant moves logically around the area from station to station following the trial visit journey, seeing a different staff member at each station, e.g. consent → medic review → pregnancy test → observations → samples → vaccine administration → data collection/questionnaires

Benefits: equipment required at each station can remain in situ (particularly helpful when BP/ECG machines, computers, etc are required); anticipated bottlenecks can potentially be minimised e.g. more staff in data collection area, more medics made available for examinations (all capacity allowing)

Challenges: bottlenecks can occur at stations for various reasons meaning participants have to sit and wait until the previous participant has moved on; more disruptive for participant having to move around; someone needs to be available to guide participants round and 'crowd control'; participant meets many different staff so less chance of building rapport.

Example study: Ensemble at Nowgen (MFT), Novavax (NCA & Stockport)

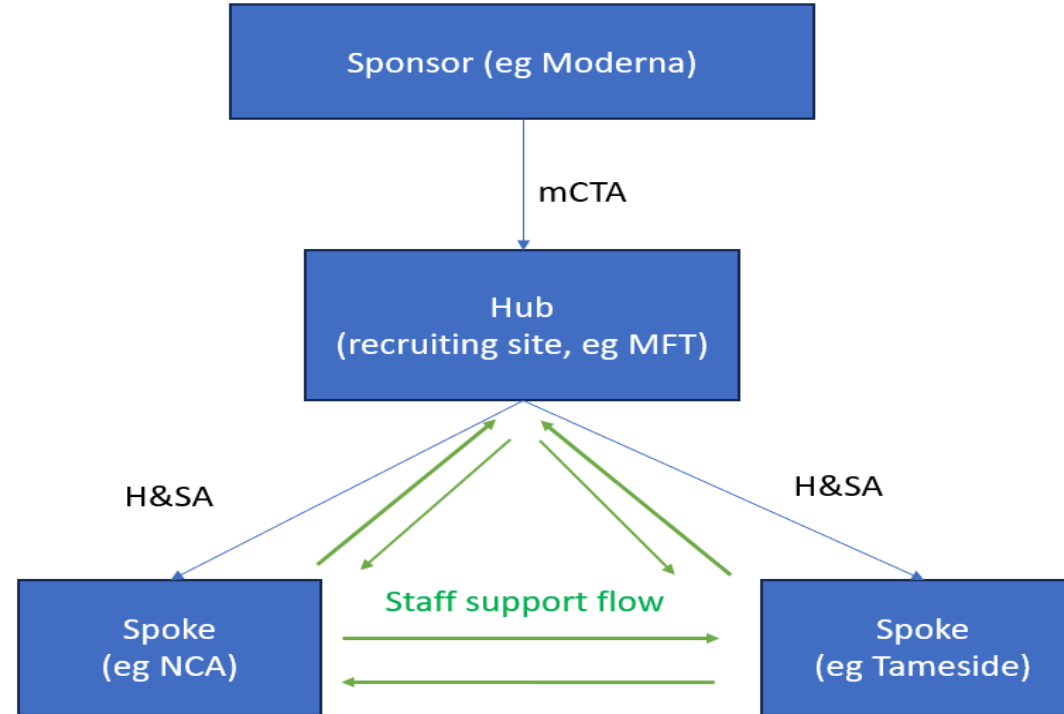
Flexible Workforce

➤ Partnering **NHS** organisations:

- Manchester University NHS Foundation Trust
- Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust
- Northern Care Alliance NHS Group
- East Lancashire Hospitals NHS Trust
- East Cheshire NHS Trust
- Stockport NHS Foundation Trust
- Tameside and Glossop Integrated Care NHS Foundation Trust

Out of core hours	Within core hours
Scoping exercise, staff signed up to NHS Professionals to support out of hours work.	ToR document setting out the principles of cross-working developed, agreed and gained approval. Includes agreement on finance reimbursement.
NHS Professionals research workforce codes standardised across all partner organisations. Bank share agreement established.	The H&S model created to allow flow of staff between organisations within working hours.

Flexible Workforce



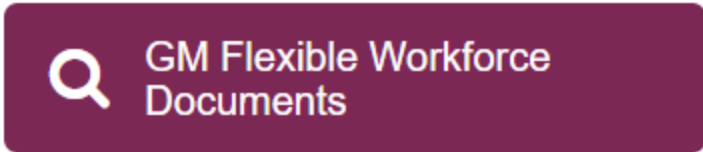
Vaccine workforce can flexibly be at spoke sites and/or at Hub site.

Needs to be written into the H&S agreements' work description, as per GM vaccine workforce [ToR](#). There can be as many spokes as needed, each with their own H&SA with the Hub.



Flexible Workforce

- CRN GM Vaccine-Specific Clinical Competence document developed; agreed vaccine-specific training profile
- Agreed minimum mandatory training requirements
- Equipment inventory and an equipment loan agreement
- All GM flexible workforce documents are stored on the FutureNHS GM Strategic Collaborative Regional Working Group platform



CRN GM Vaccine-Specific Clinical Competence Summary

Scope this document acts as a summary of vaccine-specific training profile to enable workforce flexibility across participating GM NHS organisations. It is drawn down from the NIHR CRN vaccine skills matrix (V2, Jan 23), held within the NIHR Learn Vaccine Training course, and includes additional, agreed GM preferences. It does not include research-specific training.

Staff Member Information	
Name	
Topic	Last Training Date
Basic Life Support - Level 2	
Anaphylaxis Training inc algorithm	
ANTT practical & theory	
Infection Prevention & Control for clinical staff	
Venepuncture	
Medicines Management for Registered Staff - NMC/HCPC/GMC	
Injectable Medicines - NMC/HCPC/GMC	
Immunisation	
Immunology	
Immunology for Immunisers	
Contraception for Vaccine Trials	
GCP - GMO regulations	
Human Tissue Act	
Lab skills for delivery staff	
Dry Ice	
<p>Confirming statement - I confirm that I have completed the training above on the dates stated and can provide evidence for study Sponsors, should this be required.</p> <p>Signed _____ Dated _____</p>	

Employing Trust Confirmation	
Name	
<p>Confirming statement - I confirm that the person named above fulfils vaccine training requirements as agreed by the GM Flexible Research Workforce Group.</p> <p>Signed _____ Dated _____</p>	

Receiving Trust Confirmation	
Name	
<p>Confirming statement - I confirm that the information about the person named above has been reviewed.</p> <p>Signed _____ Dated _____</p>	

Flexible Workforce

- Process for requesting support
- Induction/ pre-placement checklist
 - **Car parking**
 - **ID badges**
 - **Access to buildings**
 - **Access to EPR systems**



Pharmacy



44% Patient enrolment post-pandemic (NIHR supported studies- 2021-2022)



UK fall from 4th place to 10th place globally

GM was highlighted as a region which maintained and expanded number of participants in a trial; but in general pharmacy was identified as one of the constrains

Problem statement 4: Research is not systematically prioritised by or within the NHS

- Shortfall of research nurses, pharmacy and imaging resources, and aseptic teams as constrains to deliver clinical trials
- Infrastructure

Recommendation 12: income generated by commercial sponsors should be explicitly directed to units and departments leading trials in NHS sites to provide direct financial incentives to take part in commercial trials

Pharmacy

Community of Practice Oct 2023. FutureNHS workspace launched in Jan2024 (11 NHS Trust in GM)

GM-Risk Assessment available for use from Jan2024. The GM-RA covers all IMP management activities, including injectables, ATIMPs, GMO, HOMECARE...

GM-CRN providing a monthly report showing multi-centre trials taking place across GM

28 multi-centre GM trials identified since Jan 2024 (Apr 25)

Greater Manchester Clinical Trial Pharmacy Network

Create a new item

Welcome to the Greater Manchester Clinical Trial Pharmacy Network

The aim of this network is to facilitate collaborative working and the sharing of best practice in Pharmacy units across NHS Trusts in Greater Manchester, building a support network and working towards a faster, streamlined process for Clinical Trial set-up and delivery.



[Read more](#)



Risk Assessment

Pharmacy Risk Assessment template and additional supporting documentation



Sponsor Site Selection Information

GM Pharmacy Information for Clinical Trial Sponsors



Discussion forum

Questions, discussion and support for Clinical Trials in Pharmacy

The following initiatives are designed to support Clinical Trial set-up and delivery in Pharmacy:

- [GM-wide Risk Assessment for Clinical Trials](#)
- [Sponsor information booklet for pharmacy clinical trials, covering all NHS Trusts in GM](#)
- [Mentoring/buddy scheme](#)
- [Clinical Trials Pharmacy training programme](#)



GM Pharmacy Group - meeting minutes/actions

GM CRN training events

NIHR National Institute for Health Research



Resources and guidance

Pharmacy

EUROPEAN JOURNAL OF
HOSPITAL PHARMACY

Short report

A single harmonised pharmacy process to improve clinical trial set-up times



 Miriam Lettieri¹, Sophia Boydell², Andreea Chivu³, Sarah Fallon⁴, Andrew Ustianowski⁴, Monika Cien², Claire Cole², Sophia Burgess¹, Carolyn Davies¹, Claire Keatley⁵, Anne-Marie Peers⁵, Maxine Syme⁶, Deborah Sutton⁷, Nicola Hermitage⁸, Lydia Sutherland³, Michelle Beecroft⁹, Ali Aghabeigi¹⁰, Beatriz Duran Jimenez¹

Correspondence to Dr Miriam Lettieri, Pharmacy, Manchester University NHS Foundation Trust, Manchester, UK; miriam.lettieri@mft.nhs.uk

Abstract

The UK has fallen from fourth to 10th place in the global ranking for clinical trial activities in the past 6 years. Due to the limited capacity of the clinical trial pharmacy workforce and delays in providing pharmacy approvals, pharmacy has been identified as one of the constraining services that delays the set-up and delivery of clinical trials. To tackle this problem, we developed a single pharmacy review process for multicentre trials across Greater Manchester (GM) and tested its feasibility and implementation in our region. A survey completed by each GM Trust suggests that this harmonised pharmacy review process for multicentre studies would expedite trial set-up time at each pharmacy site and standardise the pharmacy review process in GM. We therefore believe that this harmonised review process could potentially reduce pharmacy set-up time and reposition the UK in the global market for clinical trials.

Overall Challenges

➤ Set up

- Industry readiness to adapt to new models of working

➤ Flexible Workforce

- Inclusivity of NHS Professional organisations
- Balance of organisational research delivery portfolio
- Workforce resistance

➤ Pharmacy

- Difficulty obtaining data of trials in feasibility at the right time
- Workforce in pharmacy CT services is minimal- difficulty attending meetings (small teams)
- Finding an IT platform
- Change resistance in sites with well established RA SOPs



Overall opportunities

➤ Study Set up

- Transferable model to other disease/ specialty groups
- Continuity of work through GM CRDC delivery and future collaboration with PC CRDC
- Innovative models of delivery

➤ Flexible Workforce

- Widen the model to research operational colleagues
- Community of Practice 'GM lead research nurse forum'

➤ Pharmacy

- Community of Practice- mentoring forum
- GM Feasibility Booklet
- Education and training standardisation - competency framework
- Fastest, standardised and higher quality of review

EFFICIENT AND CONSISTENT



Quality and Safety



IMP Management



Regulatory and GCP Compliance

INCREASE QUALITY
STREAMLINE AND
CONSISTENCY
FASTER SET UP
FLEXIBLE WORKFORCE
COST EFFECTIVE
FOSTER INNOVATION....

Future Plans

Where we are now

May 2025

VIP working in partnership with GM to cascade good practice across the UK

1. VIP's work is not limited to vaccines: The **next frontier** includes expanding to immune therapies.

2. Scale up GM pharmacy model across UK in partnership with BioNTech

3. Plans to **scale recruitment strategies** for broader clinical trials across the UK, ensuring rapid, inclusive recruitment.

4. Build on GM success in residential home recruitment for Nova-301 to develop national pathway-VIF project in partnership with NHS Grampian

5. VIP as a **blueprint** for Commercial Research Delivery Research Centres (CRDCs) across UK

Thank you

For further details:

- Dr. Angela Parker: Vaccine Innovation Pathway Project Manager (ID) angela.parker19@nhs.net
- Monika Cien: Senior Research and Innovation Manager monika.cien@mft.nhs.uk
- Janette Dunkerley: Assistant Chief Nurse Research and Innovation janette.dunkerley@mft.nhs.uk
NIHR Regional Research Delivery Network North West Health & Care Director (NMAHP) janette.dunkerley@nihr.ac.uk
- Dr. Beatriz Duran: Consultant Pharmacist – Clinical Trials and ATIMPs: Beatriz.duran@mft.nhs.uk