

CLINICAL TRIALS INVOLVING CARE HOME RESIDENTS

Prof. S.S. Vasan, DPhil(Oxf) EuSpLM FASM FFTM RCPS(Glasg)

Honorary Professor, University of York

Prof.Vasan@York.ac.uk

Director of R&D and Deputy Caldicott Guardian, NHS Grampian

Seshadri.Vasan@NHS.Scot

Declaration: I am Moderna respiratory portfolio advisory board member

Independent report

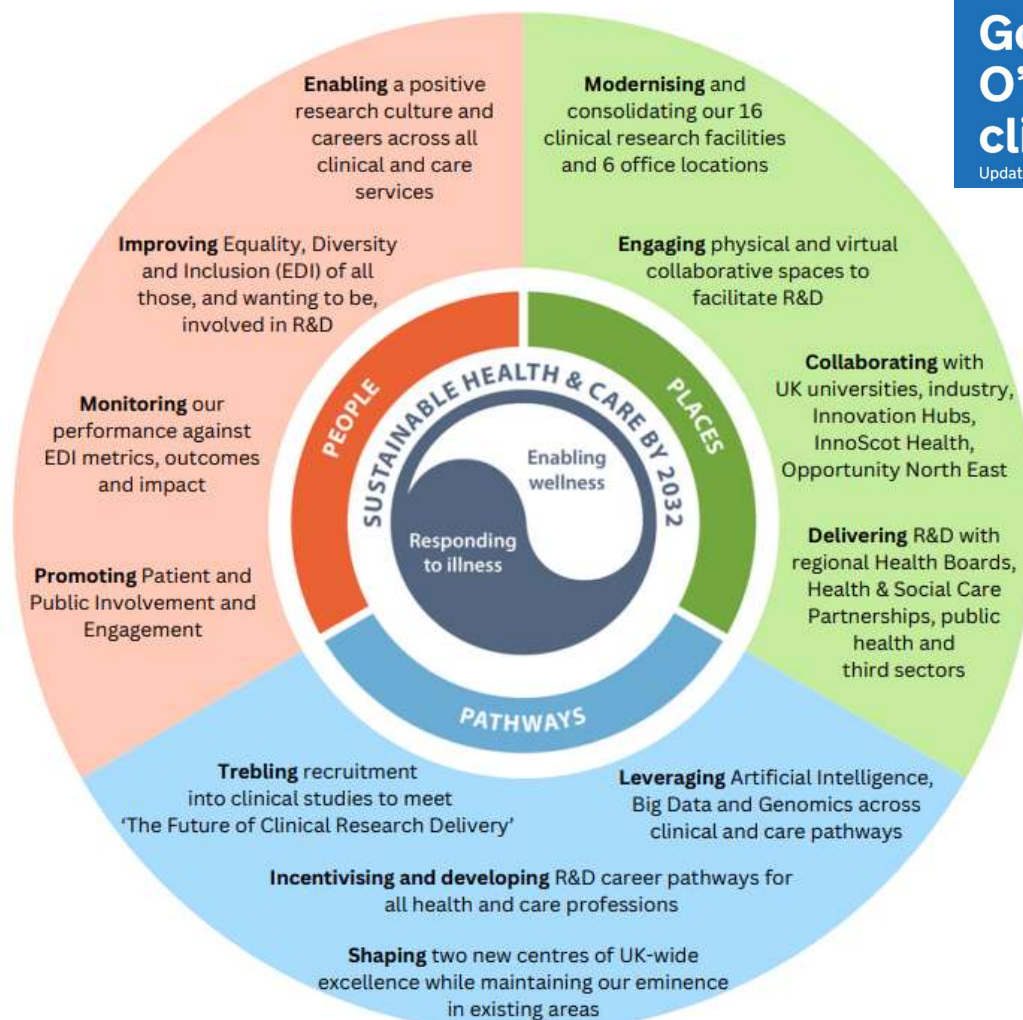
Government response to the Lord O'Shaughnessy review into commercial clinical trials in the UK

Updated 26 May 2023

Press release Published 28 August 2024

UK secures £400 million investment to boost clinical trials

World-first public-private collaboration launched to kickstart economic growth and build an NHS fit for the future.





Independent report

Government response to the Lord O'Shaughnessy review into commercial clinical trials in the UK

Updated 26 May 2023

Press release Published 28 August 2024

UK secures £400 million investment to boost clinical trials

World-first public-private collaboration launched to kickstart economic growth and build an NHS fit for the future.



The Future of UK Clinical Research
Delivery: **Saving and improving lives**

Vaccine Innovation Fund Call 2024

**Widening
Access to
Trials in
Care
Homes**



Work Package Leads

Identify



Solve



Test



Share



People living in care homes are especially prone to infections and may consequently become more seriously ill. Many of these infections can be prevented by safe and effective vaccines.

However, vaccines are usually only tested in younger and healthier people, and we can't be sure that they are just as safe, or work just as well, for people in care homes.

There are many reasons why vaccines are harder to test in care home residents.

For example, some people might have conditions, like dementia, which may make it difficult for them to give permission for research studies, and it might take longer for frail, older people to provide answers to questions.

Another example is that pharmaceutical companies may be reluctant to test their vaccine in people with multiple medical conditions, as any flare-ups of the condition could be confused with side effects.

However, with the right guidance, all these challenges could be overcome.

This grant will pay for a team of expert researchers in the care home setting and for researchers with experience of running vaccine trials in hospitals, to come together with people who work in care homes, to discuss what all the barriers are, and how to overcome them.

We will produce an expert guidance document that can be used by researchers to conduct these trials.

The team will also volunteer to undertake vaccine trials during the project and endeavour to recruit people from care homes in order to test out and refine the guidance further.

If you wish to collaborate please get in touch!

WP1 'Identify' – Scoping reviews to map the state of the art, specifically a) barriers and facilitators of interventional trials in CH settings and b) identifying all vaccine trials that have recruited CH residents (includes searches of clinical trial databases and grey literature to identify trials in set-up).

WP2 'Solve' – Focus groups with key stakeholders, plugging evidence gaps with lived experience and developing innovative solutions to the identified barriers, underpinned by robust Patient and Public Involvement and Engagement (PPIE). This includes learning from investigators and sponsors of interventional trials of medicinal products set in CHs in the UK (identified in WP1) to identify good practice and ongoing challenges.

WP3 'Test' – Active learning from running commercial vaccine trials that could recruit CH residents. The Group will work with NHS Research Scotland (NRS) to reply positively to all requests for expressions of interest from commercial sponsors to run such trials and work with Health Boards, sponsors and CROs to set these up, with the intention to include recruitment from CH. What does and does not work well will be carefully documented, including reason/s for success or failure of site selection, recruitment, data collection, pharmacy, laboratory issues, etc.

WP4 'Share' – Communications and Scalability – Cross-cutting WP to ensure internal and external communication. Responsible for Group meetings, links with topic leaders in other home nations, patient and public engagement, social media and publications.

Time scale – September 2024 to August 2026

NRS Infectious Diseases Research Day 18 September 2024

Co-Leads: Shenkin, Scott, PPIE Group

WP1 IDENTIFY

Literature searches, process mapping, identify past and present IMP trials in care homes

Co-Leads: Vasan, Stewart, Burton, PPIE Group

WP2 SOLVE

Focus groups, interviews, engagement with key stakeholders inc care homes, sponsors, regulators, pharmacy, primary care

Co-Leads: Scott, Vasan, PPIE Group

WP3 TEST

With NRS Vaccine Trials Taskforce, run vaccine trials that recruit from care homes

Co-Leads: Burton, Shenkin, PPIE Group

WP4 SHARE

Write guidance, plan scalability, disseminate learning, plan PPIE event/s

9th Grampian Research Conference + Reproductive Health & Childbirth Speciality

ONE BioHub Aberdeen

4-5 October 2024

Webinar link possible!

Contact Gram.Conf24@NHS.Scot

My contact details

Prof.Vasan@York.ac.uk

Seshadri.Vasan@NHS.Scot

NHS Grampian
caring • listening • improving