

Amendment request form

Use this template to submit an amendment to an approved application. The completed template will be reviewed by the Confidentiality Advice Team who will then confirm the appropriate action. The Confidentiality Advice Team can be contacted prior to completion to advise on whether the nature of the change requires a formal amendment. Supporting documentation can be used in conjunction with this form.

Please note that support for amendments will not come into effect until a final approval letter is provided.

PIAG/ECC/CAG reference number: 22AG0051

Application title: Our Future Health

Amendment date: 1st February 2023

Research/Non-Research

1. Please indicate the nature of the change below.

- Data flows
- Data items
- Data sources (see question 4)
- Purposes of application
- Data controller (please note that an amended application form and supporting documents setting out the new data controller arrangements will be required, you are advised to contact the Confidentiality Advice Team prior to submission)
- Data processor (required to have a satisfactory Information Governance Toolkit submission in place - see question 6)

- Duration amendment

- Other (please specify): Current approval covers up to 12 million invitation letters being issued. Our Future Health would like to amend this to 45 million over the coming 3 years. This reflects the adult population of England based on Census 2021 figures.

2. Please summarise the change to the application, specifying how the amendment differs from the detail of the original application:

Our Future Health seeks to recruit 5 million participants over the next 3 years.

A recruited participant is defined as one that has consented, completed the questionnaire and attended a clinic appointment for measurements and biological sample. To manage this, Our Future Health has piloted several methods of providing clinic appointment through fixed dedicated locations, mobile locations (collectively the “managed service”) and a community pharmacy partner (Boots).

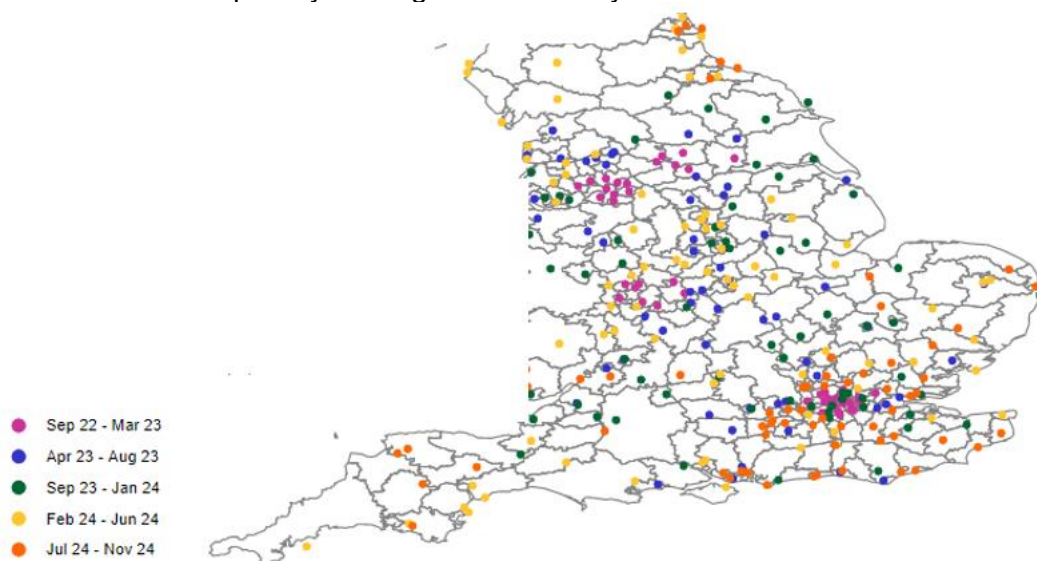
In order to fill appointments we are issuing invitations via Digitrials. Therefore management of future appointment capacity is closely linked to the ability to send invitations.

The current approval supported our activity covering the delivery of invitations across 4 specific regions of England – North West, West Yorkshire, West Midlands and parts of London. Thirty pop up clinics and 5 mobile hubs have provided bookable clinic appointments for the population of these areas (circa 12 million adults).

To date, Our Future Health has issued 7 million invites in these 4 geographic regions. Working in partnership with NHSD, the Digitrials pipeline has been refined and is capable of rapid processing to send ~100k invites per day.

Now that the capability of our in-person appointment contractors are able to match the scale of uptake from the invites, Our Future Health is in a position, sooner than thought, to scale up to invite the rest of the country over the next 3 years. We plan to roll out clinics in Boots stores (circa 200 (not all open concurrently)) and increase our geographic coverage of fixed and mobile locations.

Planned clinic/hub capability for England in next 2 years:



With that in mind, Our Future Health seeks permission to extend the number of invites

covered by the S251, from 12 million to 45 million. No other aspect of the process is changing

3. Please confirm the justification for the amendment. This should explicitly include the following:

- the reason why it is in the public interest for the amendment to proceed
- the benefits that the amendment will, or is expected to, provide
- The time period for which the amendment is expected to be required
- The consequences if the amendment did not go ahead

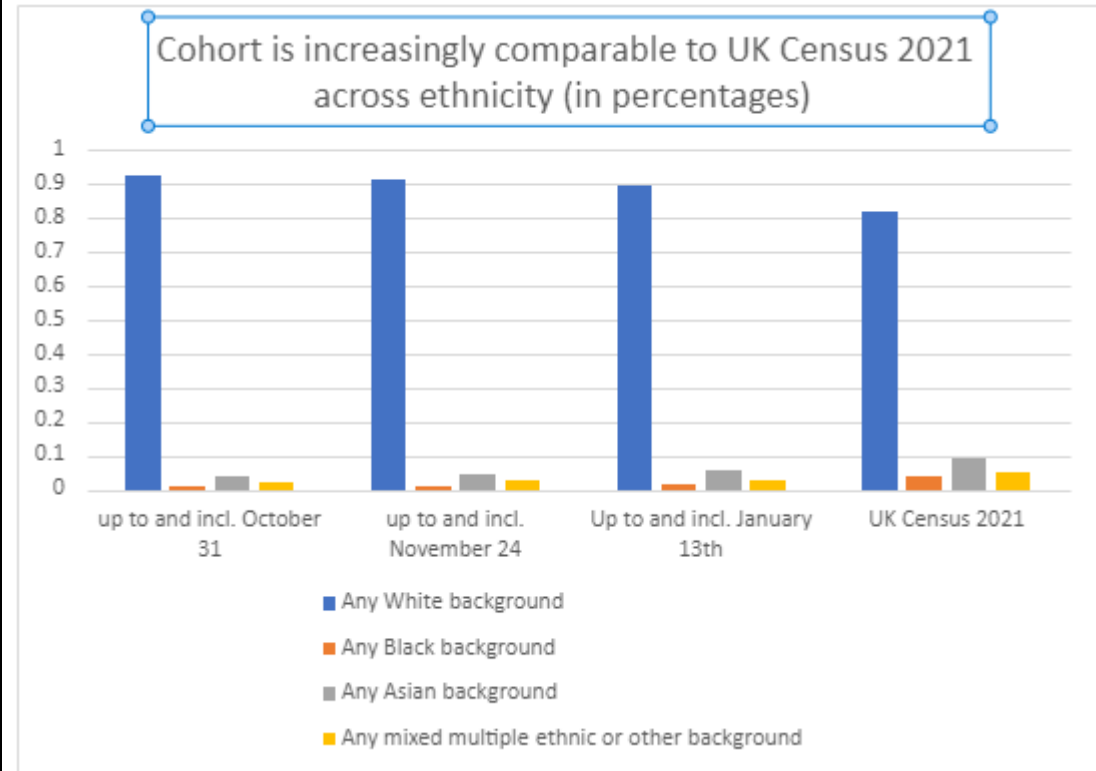
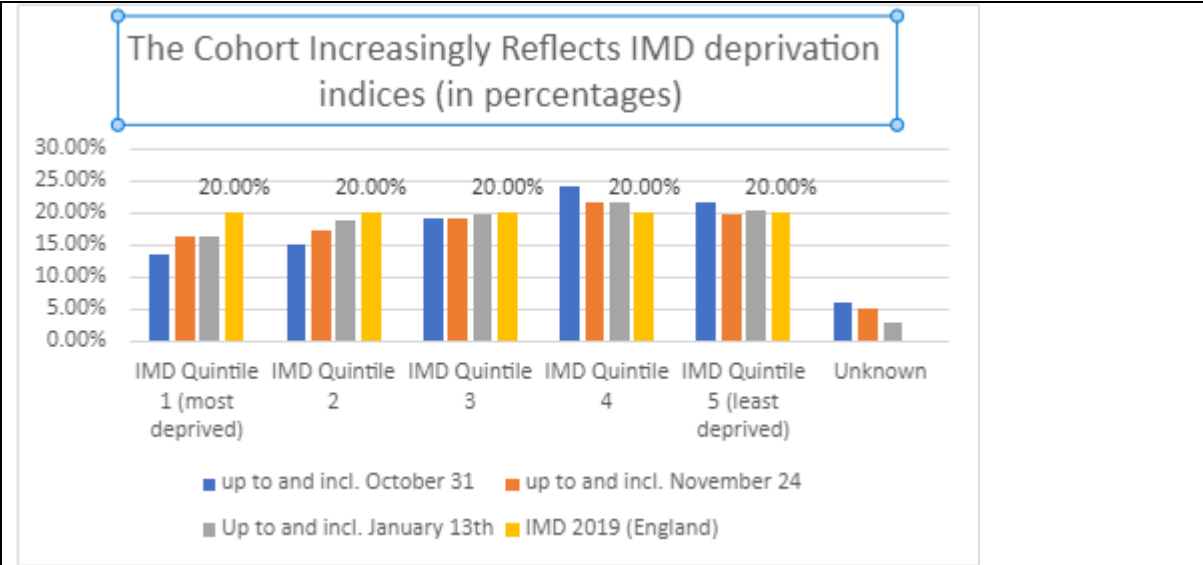
As set out in the approved application, Our Future Health seeks to recruit a total of 5 million volunteers over the next 3 years, creating the largest ever research resource to support development of investigations and treatments for earlier stage disease. The focus is on improving quality of life and reducing the burden of late-stage disease on individuals, families, social care and the NHS.

Success in recruiting to the programme is a key deliverable in meeting this aim. The recruitment process includes consent, provision of personal details, completion of a questionnaire and provision of body measurements and blood sample.

To enable this, Our Future Health has invested in a number of pop-up and mobile clinics, offering appointment slots to enable sign up, measurements and blood samples to take place.

The NHS Digitrials invitation route has proved to be successful in driving recruitment and has enabled over 200,000 volunteers to be consented to date, and currently running at around 3,000 consented volunteers joining per day.

Using NHS Digitrials is enabling the cohort composition to be adjusted by targeting traditionally under-represented groups, by age, gender and ethnicity. The following charts show how current make up is increasingly reflective of wider society and in particular how it has improved over the months since NHS Digitrials began to be used in earnest in October 2022.



Black ethnicity has increased from 1.1% to 1.8% since October, against a census of 4%. Asian ethnicity has increased from 3.8% to 5.8% since October against a census of 9%.

As a result, we anticipate continue targeted use will facilitate greater levelling of the cohort against census 2021.

The current approval covers the issue of invitations to 12 million individuals over a one-year period from July 2022.

This amendment seeks approval to cover invitation to 45 million individuals in the next 3

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years (to December 2025), enabling Our Future Health to extend the geographic coverage and fill clinics/use available appointment capacity.

Without this amendment, Our Future Health will need to reduce the clinic appointments available, will recruit at a slower rate than anticipated, and will struggle to reach the balanced targeted cohort aim of 5m.

4. If amending the data sources, has the data controller for this agreed in principle for this access to be provided? Please provide evidence of any authorization.

Not Applicable - no change to data sources

5. It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. The nature of the change may mean that there is a need to update the current information provided to patients. Please confirm whether patient information materials (websites, leaflets, posters etc.) have been updated to reflect the change and detail the changes below.

If no change is intended to be made, please specify the reasons for this decision.

Not Applicable – the nature of the change does not generate any need to update the information provided to patients. As per the original approved application, a full opt out campaign is run in all areas for 1 month prior to the issue of invitation letters in that area. Patient information materials are as per those approved by REC.

The amendment simply requests approval to use this entire approach to issue 45 million (one to every adult in England, excepting opt out, and deaths) invitations instead of 12 million.

6. All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS Digital at each annual review.

Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

Processing takes place in:	England	Wales	Scotland
Security assurance provided by:	Data Security and Protection Toolkit (DSPT) – by organisation or specific function	Caldicott Principles into Practice (CPIP) report – by organisation	Review by the Public Benefit and Privacy Panel for Health & Social Care
Applicant should contact:	Exeter.Helpdesk@nhs.uk	Darren.Lloyd@wales.nhs.uk	Public Benefit and Privacy Panel (PBPP) for Health & Social Care

How assurance is provided to CAG	<ol style="list-style-type: none"> 1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS Digital to review the relevant DSPT self-assessed submissions 3. NHS Digital review the DSPT submission and confirm to CAG when 'Standards Met' 	Relevant CIPI out-turn report provided directly by NWIS to CAG	An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance
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For applicant completion:

Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHS Digital reviewing the self-assessed submission. Please ensure you have contacted NHS Digital and asked them to review your submission. The annual review will not be valid until NHS Digital has reviewed the submission and confirmed its status as 'standards met'.

If confidential patient information is being processed by NHS Digital, please select this box:

Security assurance has already been provided for NHS Digital so please do not complete any details below for NHS Digital.

Organisation (Full name)	ODS Code	Date self-assessment submitted to NHS Digital	Date NHS Digital confirmed assessment reached 'Standards Met'

Is any processing of identifiable information taking place in Wales? No

Is there any processing of identifiable information taking place in Scotland? No

If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps.

7. If a research application, has an amendment to a Research Ethics Committee been submitted? Please provide supporting documentation/date to be reviewed/favourable ethical opinion.

REC approval was provided on 29th March 2021

In the submission approved by REC the following description of the intent to use NHS DigiTrials

3.3.1. Invitation methods

We will use NHS DigiTrials as the primary route for postal invitation. NHS DigiTrials provides unparalleled scale, the ability to target invitations based on demographic information, and will help us build trust with potential participants. The NHS DigiTrials application process includes Section 251 support which will enable NHS DigiTrials – on our behalf – to select eligible individuals and send named invitations for participation in Our Future Health. We will dynamically adjust the number of invites sent to specific population groups based on conversion rates and our ambition to recruit a diverse cohort that is reflective of the UK population.

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This request falls within that approval.

8. Confirmation of contact details

Please confirm contact details for the purpose of our publicly available register of approved applications.

Applying organisation: Our Future Health

Contact Name and role: [REDACTED] Lead for Data Linkage

Full address: New Bailey, 4 Stanley Street, Manchester M3 5JL

Telephone: [REDACTED]

Email: [REDACTED]



Health Research Authority

Information Guardian/Chief Investigator Name:

Signed:



Date: 1st Feb 2023

This form should be submitted, in conjunction with any relevant supporting documentation, to cag@hra.nhs.uk. If you require any assistance in completing this form you are advised to contact the Confidentiality Advice Team on cag@hra.nhs.uk or on 0207 104 8100.

Once submitted the form will be reviewed by the Confidentiality Advice Team in the first instance who will confirm whether the amendment is valid or if further information is required.

