

## 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: 31<sup>st</sup> March 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):

The amendment explains the growth of the programme and associated scaling up of the processes and aims articulated in the original application and seeks permission to expand the number of invitations issued over the next 6-12 months.

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

Our Future Health originally applied for S251 permission in March 2022, to issue 3 million invitations, with a commitment in that early phase to testing and learning, especially regarding the use of and optimising of letters to maximise understanding and efficacy. At the time, the mechanism to provide a schedule of appointments was also being piloted. A partnership with Boots plc and procurement of a managed service partner were both established in July 2022 in

small pilot forms, to enable set up of the clinics and development of the processes.

The first clinic opened at the start of August 2022 in Boots, Bradford, the week after 6,000 invitation letters were issued. A one month opt out campaign had been conducted prior to this, throughout July, with adverts in 2 newspapers, 1 radio station, and 3 social media channels (Twitter, Instagram and Facebook).

Over the following 2 months, additional Boots stores were opened until 5 were in operation, each in a separate town or city and all preceded by a local opt out campaign involving newspapers, radio stations and social media channels. In October, the first managed service clinics were opened and, over the following 2 months, we increased the clinic capacity leveraging the use of the maximum 100k invitations per day to fill available appointments.

Given the success of these initial pilot activities, an amendment in November 2022 sought to enable extension of the S251 to 12 million invitations, which represented the population of the geographic areas where new clinics were planned to open between November and March.

Since November, we have established a standard operational process encompassing clinical set up, opt out media campaign and invitation issue. Expansion of clinic locations, specifically co-located within particular geographical regions, has enabled the use of regional media advertising in the opt out campaigns, supporting the use of bigger publications and radio stations with greater reach.

Deciding where to place a clinic takes place through considerations as to:

- Local area expansion
- Population composition
- Population density
- Number of residents within a 5-mile and 10-mile radius of potential clinic locations
- Existing or future potential coverage from other planned clinics.

Once a site is chosen, we decide upon an optimal go-live date and the period for which the site will be open. We then ensure that all preparatory actions will have been conducted by the go-live date including:

- Opt out campaigns
- Local awareness raising through advertising and social media
- Stakeholder engagement
- NHS Digitrials invitations planning (numbers, age ranges, sex at birth, postcode areas, which letter template(s))
- Clinic service provider liaison to ensure staff and equipment
- Clinic staff training
- Site contract
- Site material production (branding, fit-up, phlebotomy supplies etc),
- Digital booking system preparation – loading clinic and creating bookable appointments based on number of staff available
- Logistics to courier blood samples from clinic to processing laboratory.

A dedicated team ensure that all of this work is coordinated and remains on schedule, with careful tracking aimed at ensuring all dependencies are completed prior to site opening.

The following worked example shows the dates and activities in 2 areas – 2 sites in Peterborough and Cambridge, and 2 in the Northwest:

clinic_ref	clinic_label	region	mobile	Status	Opt Out Dates	calendar_go/ no-go date	live_date	close_date	address	postcode
Boots/138	Peterborough	East of England	N	Open	Feb-23	08/03/2023	21/03/2023		Queensgate Centre Pet	PE1 1NW
Boots/6492	Cambridge	East of England	N	Open	Feb-23	08/03/2023	02/05/2023		Unit 3, Cambridge Retail	CB5 8WR
Acacium/Ch	Chorley Mo	North West	Y	Planned	Mar-23	20/03/2023	12/04/2023	12/05/2023	Asda (Car Park), Bolton	PR7 3DL
Acacium/LN	Liverpool St	North West	N	Planned	Mar-23	30/03/2023	14/04/2023	24/09/2023	12-14 Roe St, Liverpool	L1 1HL

The corresponding opt out campaigns completed for these areas:

Geographic region	Dates of opt out campaigns	Details of campaign (social media = Meta, LinkedIn and Twitter for four weeks)
Cambridgeshire and Peterborough	February 2023	<p><b>Social media:</b> Adverts on 3 channels for 4 weeks</p> <p><b>Press:</b> 16 half page adverts across 8 titles (Luton News, Peterborough Telegraph, Basildon and Southend Echo, Thurrock Gazette, Cambridge News, Norfolk Eastern Daily Press, Essex County Standard) Bexley News Shopper)</p> <p><b>Radio:</b> regular 40 second adverts across seven stations over 4 weeks (Heart Bedfordshire; Heart Peterborough; Heart Chelmsford; Star Radio, Cambridge, Greatest Hits Norwich, Greatest Hits Essex, DAX Radio)</p>
North-west England	March 2023	<p><b>Social media,</b></p> <p><b>Press:</b> 20 half page adverts in 10 titles (Lancashire Gazette, Blackpool Gazette, Burnley Express, Warrington Guardian, Macclesfield Express, Lancaster Guardian Series, Liverpool Echo, Nelson Leader, Lancashire Post; Stoke Sentinel)</p> <p><b>Radio:</b> regular 40 second adverts on six radio stations (Capital Lancashire, Greatest Hits Blackpool, Greatest Hits Stafford, Greatest Hits Lancashire, Greatest Hits Liverpool)</p>

A centralised mobilisation forward plan is maintained on our Microsoft Sharepoint, enabling access by all to the most up to date data, and providing a basis for forward planning within each team to deliver the component activities that will enable the go-live dates. Any issues which arise are rapidly translated into potential impact on delivery dates.

The forward plan uses check points to confirm key stages such as:

- Confirmation before booking media advertising
- Confirmation media campaign has run for the 4-week period
- Confirmation that all aspects of clinic set up and staff training are in place.

This culminates in a final 'Go/No Go' call 10 days before the clinic is due to go live.

If the team is confident all remaining actions will be completed for the planned opening date, this triggers two specific actions:

- Creation of the invitations request file, describing how many invitees should be in each age/sex category by postcode area. This is created by Epidemiology, drawing on data from:
  - Summary PDS data setting out the number of inhabitants in a post code area by age and gender (subject to small number suppression)
  - ONS deprivation quintiles
  - Information on the cohort composition, specifically age and sex at birth
  - Census 2021 data on ethnicity by geographic area.

The invitation request file is issued to NHS Digitrials 1 week before the clinic is opened. Letters are posted 2 days after we issue the file to NHS Digitrials and take 2-3 days to arrive on doorsteps.

- Creation of the new clinic on the appointment booking system, and release of bookable appointment slots. This ensures letter recipients experience a slick process from registration through consent and can book an appointment in the clinic nearest to them.

This process has enabled the issue of *up to* 100k invitations on almost every weekday since the end of October (Public Holidays excluded).

Having established a robust process and strong partnerships with both Boots and the managed service provider, Our Future Health would like to extend the volume of invitations issued.

Based on the development of this process, Our Future Health is seeking permission to extend the number of invitations issued during the financial year 1<sup>st</sup> April 2023 to 31<sup>st</sup> March 2024 on the following basis:

- Planned activity to improve the conversion rate of invitation recipients means that, for the whole year, Our Future Health anticipates issuing circa 16 million invitations.
- Forward planning of clinic locations, securing short term leases and enabling appropriate staffing requires a 6-month forward commitment.
- CAG is asked to consider approval of one of two options:
  - Option A - Approval of an additional 8 million invitations (50% of the annual volume anticipated) to provide invitation capability to service the 6-month forward plans, with an interim report to CAG in September (after 3 months) identifying:
    - Invitations sent
    - Consents
    - Questionnaires completed
    - Bookings made
    - Booking attended and completed
    - Conversion rate
    - Showing the proportion recruited via NHS Digitrials
    - Complaints and opt outs registered
    - Any other data requested by CAG.

A further amendment for the following 6 months would be submitted 3 months ahead of the likely exhaustion of the 8 million, to enable forward commitment to clinic plans such as leases, staff recruitment and training and opt out planning.

- Option B – Approval of an additional 16m invitations, subject to provision of a quarterly report, as set out above, to provide CAG reassurance regarding the need for, use of and appropriateness of continued use. CAG agreement on the template for the report would be valuable.

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

In September last year, Our Future Health began, in earnest, the process of recruiting 5 million participants. In line with the NHS Long Term Plan which states: “**We will work to increase the number of people registering to participate in health research to one million by 2023/24**”, the aim is to create the largest ever research resource to support development of investigations and treatments for earlier stages of disease.

Our Future Health is a charity funded by the UK Government with support from Industry and affiliate Charities. The pseudonymised research resource we are creating will be made available through a secure data environment to any Registered Researcher who has their application approved by the independent Access Board so we can provide an evidence-base to improve the health of the UK population.

+  
Our  
Future  
Health

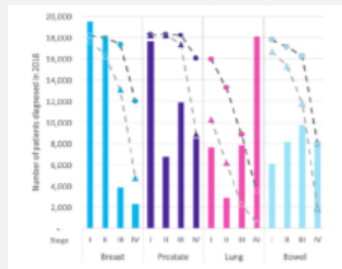
In the UK we face an increasing burden in treating late -stage chronic disease & increases in healthy life expectancy have stalled despite advances in healthcare

There are 2.5 million people living with **cancer** and by 2030 this figure may be as high as 4 million

The number of people with **diabetes** is expected to increase from 3.9 million people in 2017 to 4.9 million in 2035

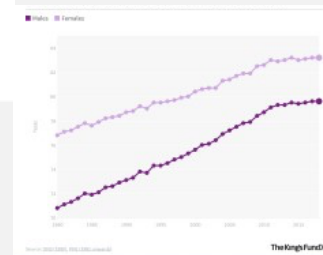
**CVD** is estimated to cost £19bn a year. There are more than 100,000 hospital admissions each year due to heart attacks

The cost of **dementia** is expected to more than double from £26bn in 2015 to £55bn in 2040



Many cancers continue to be diagnosed at a late stage

Life expectancy was increasing by nearly 3 years every decade but between 2011 -18 that dropped to <0.5



Our Future Health has based its overall recruitment strategy on the APEASE criteria which was rigorously developed and is widely used to evaluate potential behavioural interventions in health and healthcare research and policy.<sup>1</sup> These are:

- **Acceptability**; how far an intervention or some part or aspect of it is likely to be liked or engaged with.
- **Practicability**; how far an intervention or part of an intervention can or is likely to be able to be delivered as planned and at the scale intended.
- **Effectiveness**; how far an intervention or part of an intervention achieves or is likely to achieve a desired outcome and provides value for money.
- **Affordability**; how far an intervention or part of an intervention can or is likely to be implemented within an available budget.
- **Spill-over effects**; how far an intervention or part of an intervention has or is likely to have unintended positive or negative effects.
- **Equity**; how far an intervention or part of an intervention affects or is likely to affect inequalities.

Issuing Our Future Health invitations through NHS Digital is a key plank in the recruitment strategy for England in that it enables the programme:

1. to recruit in a geographic and demographically specific manner (Practicability)
2. to collaborate with NHS Digital to test and deploy behaviourally informed messaging improving the service and the response rates (Effectiveness)
3. to quickly recruit participants to Our Future Health which will facilitate a large amount of future research (Effectiveness)

<sup>1</sup> <https://www.futurelearn.com/info/courses/behaviour-change-interventions/0/steps/242207>

4. to build trust with potential participants by respecting the wishes of those who have opted out, by only sending an invitation once to each potential participant, and by demonstrating collaborative links through government supported organisations and the NHS. (Acceptability)

5. to promote equity by ensuring all England resident adults, particularly those of historically under-represented groups in health research, receive a personalised invitation (Equity).

It is particularly in the public interest for Our Future Health to continue to collaborate with NHS Digitrials on invitations to our programme because it is the best mailing platform for equity of opportunity. For far too long, certain population groups have been given inadequate opportunities to be part of health research.

This has resulted in:

- an inability to conduct high quality research in specific subpopulations, such as highly deprived or ethnic minority.
- public health decisions resultantly being based on extrapolating research findings from predominantly white, predominantly non-deprived populations to the whole.

This exacerbates inequalities as there is no evidence base to address the needs and improve the health of under-represented populations. Our Future Health seeks to address this by ensuring we reflect the UK population using NHS Digitrials for England residents and prioritising those traditionally under-represented in health research.

The unique equity of opportunity provided by NHS Digitrials includes the ability to test and deploy tailored message types so that we can speak to all sections of society, as opposed to basing messaging on the common denominator.

It should be noted that part of our consent includes the ability to recontact participants to invite them to additional studies (for which they would undergo a further consent). Unless we provide equity of opportunity in being part of Our Future Health, inequities will also be apparent in precluding representation of these populations in additional studies and trials based within Our Future Health.

Invitations through NHS Digitrials also helps us build trust with all potential participants by enabling us to address this opportunity to them personally while also demonstrating the power of collaborations between our government funded organisations and overlapping missions—improving the health of the UK population.

If the opportunity to expand our collaboration with NHS Digitrials is not approved, we would need to switch to a different, non-NHS mailer likely leading to a lower response rate due to the inability to personalise invitation by geography and demography, as well as named recipient; and the inability to determine who had opted out or who we had already written to. Thus, for all of the reasons stated above, it is strongly in the public interest to provide a continuation of our expansion, ensuring equity of opportunity to be part of this programme.

As shown in the below Table 1, letters through NHS DigiTrials currently account for 88% of all participants registering on the participant portal. We have tested, and continue to test, alternative mechanisms of inviting potential participants to Our Future Health.

However, alternative options do not provide the same, or even similar, equity in opportunity in that the base populations are less representative of the UK population, they cost more leaving less resources available for community-based recruitment of seldom heard populations, are less adaptable and personalized, and do not provide a test and deploy framework—a workflow we have optimised in collaboration with NHS DigiTrials.

**Table 1. Results from the registration question “How did you hear about Our Future Health?”**

Response	Count	Percentage
NHS DigiTrials Letter	304816	88%
Friends and Family	15931	5%
News	7071	2%
Text Message	6337	2%
Email	4499	1%
Other	3590	1%
Social Media	2250	<1%
Leaflet	1376	<1%
Advertising	769	<1%
Search Engine	199	<1%
Not Selected	14526	—

Data are from 23 December 2022, when the question went live, through 31 March 2023

While DigiTrials is a key plank in our recruitment strategy, other channels have been piloted and are in various stages of wider roll out. These include exploration of opportunities to partner with:

- **Other NHS organisations**, where blood collection is already taking place. For example, our collaboration with NHS Blood and Transplant. This channel uses text and email contact from NHSBT to registered donors ahead of planned donations.

A short pilot in 2021 demonstrated the feasibility of this route. A scaled-up approach is due to begin in July 2023, in England only. Between July and November, the number of donation locations involved will gradually increase from 4 to 72.



Modelling suggests up to 24k participants may be recruited in that time. Over a three-year period, we anticipate contacting 1.3 million donors. The modelled annual conversion rate ranges from 80k (as achieved by the Strides study) up to 118k/annum over a 3- year period.

Although this collaboration with another NHS entity will undoubtedly help with the recruitment goals of our programme, the NHSBT blood donor population is predominantly female, white, less deprived, and middle-aged relative to the UK population—this collaboration will not enhance equity in opportunity.

- **Well-known high street names**, with scope to contact volumes of potential participants. For example, in a partnership with Boots, we invited advantage card holders to our programme. Although this provided a geographically specific framework in which to invite potential participants, the Boots advantage card population are known to not be representative of the UK population in any individual parameter. In addition, the response rates were very low (**0.1%** consented) demonstrating the weaker ability to connect with potential participants and offer the opportunity to be part of our programme which provides individual (see below) as well as population benefits.

Separately, in collaboration with Pharmacy2U, we are conducting a series of pilot studies of sending emails to their customer distribution list within Bristol and Liverpool. This will initiate in May and we plan to send approximately 80k emails, with a further 1m-1.5 million in the remainder of the year. The response rate in initial trials is around 0.1%.

- **Collaboration via Primary Care routes** – for example our collaboration with IPLATO enables us to send SMS invitations to patients across 120 GP practices who have consented for data to be used in this way.

Data from Wigan indicate that the response rate to appointment booking is approximately 1.5%. The total possible reach of IPLATO is 1.4 million patients which is obviously only a subset of the UK population.

You have to be registered with a GP and have access to a mobile phone which, again, restricts representativeness of the UK population and reduces equity in opportunity of becoming a participant of Our Future Health.

The challenges of creating a 5m strong cohort include:

- 1) The critical need to ensure the proper balance of traditionally under-represented groups. Achieving this is a major public interest factor, as it will enable research that cannot otherwise take place using other research resources which are not representative, and supports treatments and approaches tailored to specific groups.
- 2) The need to demonstrate capability to funders and meet agreed milestones for volume of participants.

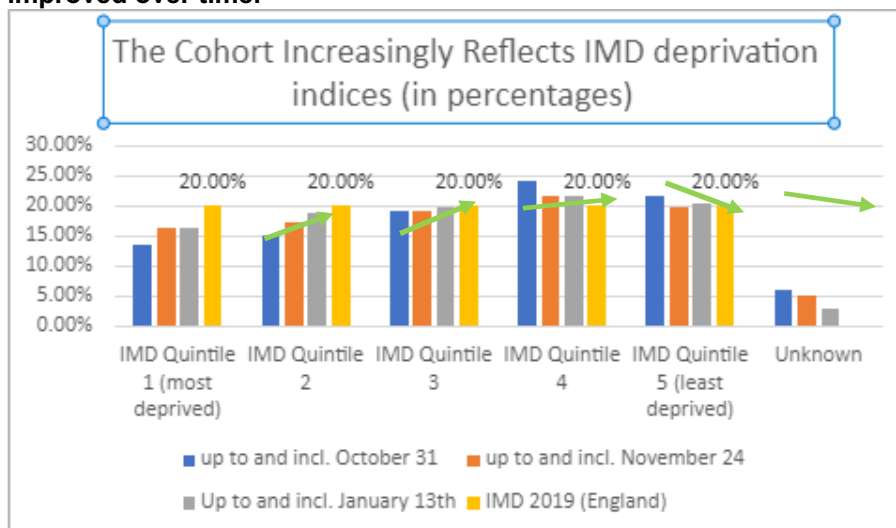
NHS Digitrials process provides a robust method to safely invite the volume of individuals required, and to prioritise and over-select certain categories, e.g. age, sex at birth etc, to deliver cohort balance/significantly increased participation by traditionally under-represented

groups as early as possible. Alternative sources of name and address, such as the Electoral Role, are not suitable because:

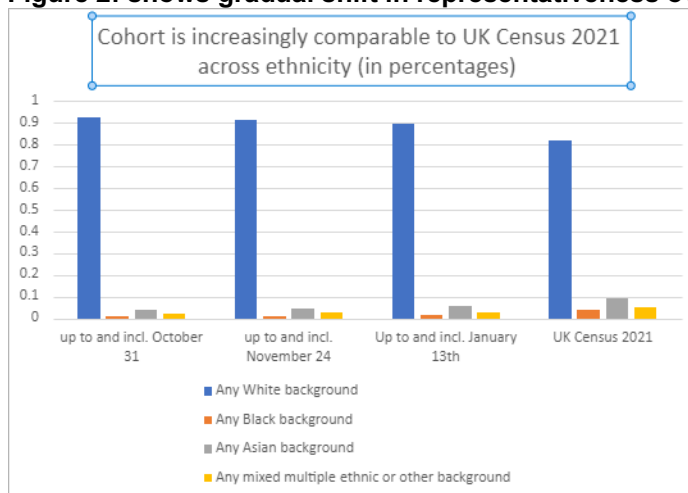
- 1) They do not permit segmenting/prioritisation of the potential recipients and over-selection of certain groups to tackle cohort balance and equity of access to research as early as possible.
- 2) Our Future Health has no mechanism to hold the electoral role as a database that can be queried to create cohorts and generate individually named letters
- 3) Our Future Health does not receive the details of those sent an invitation. With no way of knowing who has already received an invitation, and having issued 10 million invitations, any new process based on the electoral roll will necessitate the significant risk that some people will receive a second letter or receive a letter after opting out via the NHS.

To date, cohort balance has gradually improved as targeting of invites and oversampling of key groups has had a positive effect.

**Figure 1: shows how the representation of each IMD deprivation category has gradually improved over time.**



**Figure 2: shows gradual shift in representativeness over time compared to Census 2021**



## Benefits of the Programme:

**Immediate benefits to Individuals** – the ability to process higher volumes of participants is already delivering a significant benefit as the clinic visit includes:

- Blood pressure check
- Cholesterol check
- Height, weight and waist measurement

These results are provided at the appointment using a REC-approved proforma that aids interpretation of the results and indicates when an individual may wish to attain a follow-up test. High blood pressure and high cholesterol are two of the biggest predictors of an early death. In the UK, it is suspected that millions of people live with undiagnosed high blood pressure and/or cholesterol – leaving them at an increased risk of various serious health conditions, such as heart attack and stroke.

Our Future Health is offering every adult in the country the chance to learn their blood pressure and cholesterol levels for free. If a person is found to have a dangerously high reading, they can then take steps with the help of healthcare professionals to lower their chances of suffering from life-threatening health complications.

Data is now being collated on the specific numbers, but having processed over 100,000 participants through the clinics, it is clear that a significant number are receiving information which enables them to act to improve their health. Anecdotal examples include:

*██████████ is a retired post office manager who joined Our Future Health in Leeds: “When I had my appointment at Our Future Health, my blood pressure reading was sky-high. It was quite a shock. I always thought I was quite fit – I haven’t needed to go to the doctors since 2013 and I’ve never had a health issue. The healthcare assistant advised me to see my GP, and my GP sent me to Bradford Royal Infirmary to have more checks done. I’m now on blood pressure medication, to manage the issue.”*

*██████████, joined Our Future Health in Manchester: “Before my appointment, I’d never had my cholesterol checked. I’m a fit person, I run and go to the gym a lot. But even then, the phlebotomist told me that my healthy cholesterol isn’t as good as it should be. So coming away knowing that was absolutely worth it. It means I can make some changes to my diet.”*

**Medium-term Benefits to Individuals** – Our Future Health has a stated aim to provide Integrated Risk Scores to all participants who wish to receive this information. Combining lifestyle factors—based on analysis of questionnaire responses—with genetic risk analysis, integrated risk scores provide opportunities for individuals to make decisions about lifestyle, potential investigations or interventions or actions that could help them live healthier lives for longer.

**Short- to Medium-term Benefits to Researchers** – the more rapidly a cohort of significant size can be created, the sooner researchers can begin to use the resource to discover, test,

validate and implement new ways of detecting, intervening and treating common chronic diseases.

**Longer-term Benefits to Public/Health and Social Care System** – as the number of episodes of improvement, earlier detection, and earlier treatment of disease begin to accrue, there is an overall benefit to both individuals, society, and the health system from reduced co-morbidity and impact of disease.

### **Public Views of the Extended Use of NHS Digital:**

Having shared the full PPIE programme previously, Our Future Health has completed targeted PPIE to capture views on the extension of the permission to send invitations using NHS-held addresses. A survey sought views from 15 members of the Public Advisory Board, the Ethics Advisory Board and the Equality Diversity and Inclusion Board.

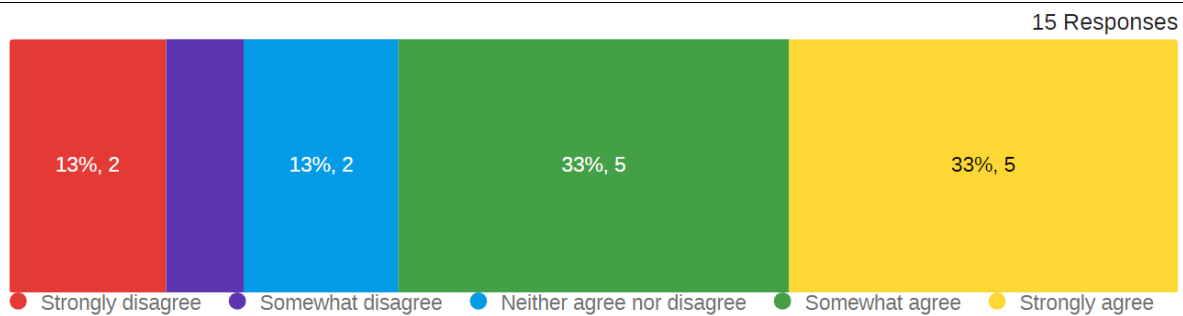
Supporting information provided to the respondents described the legal framework of a Section 251 approval, and the process of issuing invitations via NHS Digital. It set out benefits and risks as follows, and all respondents were offered the opportunity to attend a Q&A session (either in a group session, or in smaller groups/one to one sessions where availability required it) to help them explore their views, ask questions and confirm their understanding prior to completing the survey.

The supporting information highlighted the following key risks and benefits:

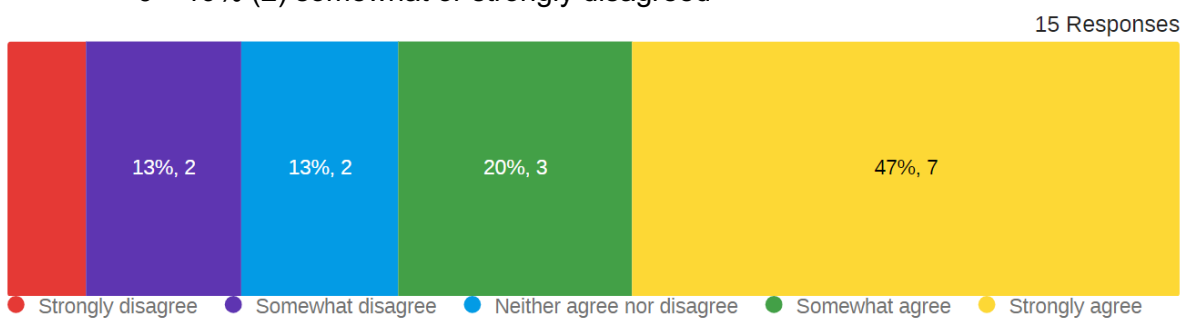
- 1) Key benefits of using this approach include:
  - a) Ability to provide a personal invitation letter reaching every adult, especially those in traditionally under-represented groups. This will maximise our opportunity to create a health research database that includes more people from these groups than has previously been achieved
  - b) Ability to prioritise those who live in areas of high deprivation, and areas with higher levels of ethnic minorities to maximise the opportunity for people in these groups to join.
- 2) Key risks include:
  - a) Individuals might not feel comfortable being personally contacted by Our Future Health via our partnership with the NHS. This might cause some people to experience anxiety or anger.
  - b) The 3<sup>rd</sup> party mailing house responsible for printing and sending the invitations misuses the name and address information of the individuals we are contacting.

Summary results showed:

- in response to the question asking if the *benefits* of increasing the volume of invitations (to 45 million) outweighed the *risks*,
  - 66% (10) of respondents strongly, or somewhat agreed.
  - 19% (3) of respondents strongly or somewhat disagreed.
  - 13% (2) neither agreed nor disagreed.



- In response to the question “Would you be personally comfortable with Our Future Health expanding the current S251 permission to contact an additional 33 million people using the process prescribed” respondents replied:
  - 66% (10) somewhat or strongly agreed
  - 13% (2) neither agreed or disagreed
  - 19% (2) somewhat or strongly disagreed



### Specific concerns included:

- Some people, especially those we particularly want to reach, may not understand or be able to read the letter. Do we need different formats, languages etc to reach the people we particularly want to attract?
- How do we know if the letter is effectively reaching those we particularly want to participate?
- The mitigations for the risks in the process have been clearly set out, so happy to agree with the proposal. It's an effective way of reaching very large numbers of people across the country. There's no obvious reason not to extend the reach in this way.
- Agrees with the proposal to send more letters.
- The facility to opt out of receiving a letter is an important factor.
- Local community groups, councils, surgeries radio stations and the like, which are likely to be trusted, could alert communities that letters are on the way.
- What is the response rate to the letters? How effective are they as a recruitment channel? Is there a drop-off at each stage?
- Representativeness based on census data does not necessarily mean representativeness that will be useful scientifically. There could therefore be more effective ways of achieving better scientific outcomes. Focus on getting participants who will be less likely to join but may provide the most useful genetic data.

Without an approved amendment:

- the planned clinics for the next 8 months cannot proceed, and contract costs will be incurred.
- NHS Digitrials accounts for 75% of full participants (those who have completed the questionnaire and attended a successful clinic appointment) which means progress in assembling the cohort and enabling research will significantly slow down.
- Failure to hit recruitment targets set by funders may result in reduced funding,
- Health checks on consenting participants will be significantly reduced, limiting the benefit of identifying high blood pressure or cholesterol as early signs of cardiovascular disease.
- We would need to transition to a different invitation collaboration, which would lead to us inviting individuals who have opted out via the Digitrials campaigns, or those we have already written to, as Our Future Health do not receive details of those who have opted out or received an invitation already – this data is held by NHS Digitrials team and is not shared as part of the current approvals from CAG and the Advisory Group on Data (previously iGARD).
- NHS Digitrials collaborative learnings from our significant investment in behaviourally informed messaging would be discontinued.
- Further optimization of a geographic- and demographic-specific invitation workflow would discontinue (a work flow we have stood up from scratch in collaboration with NHS Digitrials).

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 source is requested.

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.

6. All applicants processing confidential patient information under the Regulations are required to demonstrate that appropriate technical and organisational measures are taken to prevent unauthorised processing of that information.

This evidence is demonstrated through maintaining a satisfactory Information Governance Toolkit (IGT) submission for the length of time approval is in place. Please complete the following details:

Is a current IGT in place? Yes / No

If 'no', please explain current status, and predicted timescale to reach a satisfactory IG Toolkit score:

If 'Yes':

IGT Organisation code:

Current percentage score: %

IG Toolkit version:

Improvement plan in place?

Has the HSCIC IG Toolkit Team provided confirmation directly to the CAG that a satisfactory IGT submission is in place? (If not known please contact the HSCIC IGT Team

[exeter.helpdesk@hscic.gov.uk](mailto:exeter.helpdesk@hscic.gov.uk)) to ensure they send this information to [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk)

As per original application, Our Future Health does not see, handle or process any confidential data from NHS Digital. NHS Digital acts as Data Processor on our behalf and has all appropriate certifications.

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.

Our Future Health received a favourable opinion by the East of England - Cambridge East Research Ethics Committee (REC reference: 21/EE/0016, <https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/our-future-health/>) on 29<sup>th</sup> March 2021 for a period of 5 years.

REC have confirmed to CAG support that no change is needed to the REC submission to account for this amendment.

## 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]

Full address: Our Future Health, 2 New Bailey, 6 Stanley Street, Manchester M3 5GS

Telephone: [REDACTED]

Email: [REDACTED]

Information Guardian/Chief Investigator Name: [REDACTED]

Signed: [REDACTED]

Date: 6 April 2023

This form should be submitted, in conjunction with any relevant supporting documentation, to [cag@hra.nhs.uk](mailto: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](mailto: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.



