Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 10th August 2023

09:30 – 15:30

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser
Claire Delaney-Pope (CDP)	Independent Specialist Adviser **(Observer – new AGD member)**
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Miranda Winram (MW)	Independent Lay Adviser **(Observer – new AGD member)**
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Chapman (MC)	Data and Analytics representative
Julie Clarke (JC)	Information Asset Owner (IAO) (**Observer:** 4.1)
Garry Coleman (GC)	NHS England SIRO Representative (**Presenter**: item 7)
Dave Cronin (DC)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.1. 5.1 to 5.5)
Gavin Harrison (GH)	Data Access Request Service (DARS) Onboarding Team (**Presenter:** 4.1)
Andrew Martin (AM)	NHS England Data Protection Office Representative (Delegate for Jon Moore)
Karen Myers (KM)	AGD Secretariat Team
Jonathan Osborn (JO)	Caldicott Guardian Team Representative
Vicki Williams (VW)	AGD Secretariat Team
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	

Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Jon Moore (JM)	NHS England Data Protection Office Representative

1	**Welcome and Introductions** The NHS England Senior Information Risk Owner (SIRO) Representative, noting the Advisory Group for Data (AGD) Terms of Reference (ToR) had not yet been agreed, proposed that: • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); the Caldicott Guardian; Data and Analytics; and the SIRO. • Attendees would not be listed as "members" in minutes during the transitional period; • NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting; • It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing. The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis. Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.
2	**Review of previous AGD minutes:** The minutes of the 3rd August 2023 meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.
3	**Declaration of interests:** Prof. Nicola Fear noted a professional link to the applicant of NIC-659581-D4B1S University of Cambridge, but noted no specific connection with the application or other staff involved, and it was agreed that this was not a conflict of interest. Prof. Nicola Fear noted a professional link to the applicant of NIC-147910-HHGGZ University of Oxford, but noted no specific connection with the application or other staff involved, and it was agreed that this was not a conflict of interest.

BRIEFING PAPER(S):	
4.1	**Title:** COVID Therapeutics Blueteq Briefing Paper **Presenter:** Gavin Harrison **SAT Observer:** Dave Cronin **Observer:** Julie Clarke The Blueteq high-cost drug management system, is used by over 130 NHS Trusts in England to manage High Cost Drug (HCD) pre-approvals. During the rapid roll out of COVID-19 therapeutics, Blueteq was identified as an existing commissioning support tool which could facilitate the necessary data collection to support the monitoring and reporting requirements of the COVID-19 Antivirals programme. Blueteq forms for COVID-19 therapeutics are submitted for both hospital and non-hospital delivered (community based) treatments. The purpose of this briefing paper was to inform the group about this shell onboarded product to support an urgent application by Imperial College London and NHS Blood and Transplant requesting COVID-19 Therapeutics data, for the 'Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people' (MELODY Study). This request has support from the Secretary of State for Health and Social Care. NHS England were seeking advice on the following points: 1. To note the dataset being onboarded, and provide any comments/concerns relating to this. **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: **4.1.1** The group noted the request from NHS England for advice on the dataset being onboarded, and advised that they were **not** providing feedback on any specific use of the dataset, and that this would be subject to a separate review should NHS England require this. **4.1.2** The independent advisers noted that the Data Protection Impact Assessment (DPIA) for the COVID-19 Targeted Therapeutics closure provided with the briefing paper covered several processing purposes and datasets and that type 1 opt outs would not be applied to the flow of data. However published information relating to type 1 opt out states that it *"prevents information being shared outside a GP practice for purposes **other than direct care**"*. The group suggested that NHS England confirm whether type one opt outs should apply to the Bluteq data. **4.1.3** The independent advisers noted the purpose for processing the data outlined in the briefing paper, however, suggested that this was updated further to be clear as to what the COVID Therapeutics Blueteq dataset provides that other onboarded datasets do not provide, noting that this was currently unclear. **4.1.4** The independent advisers noted the web links within the briefing paper were for the purpose of informing clinicians, and suggested that both the briefing paper and the public facing transparency materials were updated with web links for information that was for patients and the public.

	4.1.5 The independent advisers noted in the briefing paper, that a full onboarding of the COVID Therapeutics Blueteq dataset would eventually allow other applicants for NHS England data the opportunity to request access to this data; and advised that they were supportive of this, and that wider access would be in accordance with public policy. **4.1.6** The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting alongside first of type application.	
4.2	**Title:** National Disease Registration Service (NDRS) Agreement Management **Previous Reviews:** The NDRS applications have been discussed a number of times by IGARD and AGD throughout 2022 / 23. The purpose of the briefing paper originally submitted to AGD on the 22nd June 2023, was to update AGD on a proposal to create a new NDRS Precedent which permits: **1) Extensions** – for all Public Health England (PHE) novated agreements which do not meet the NHS England DARS Standards, but wish to further extend beyond the initial 12-months granted until the end of the period for which data is required, without the requirement for them to meet the NHS England DARS Standards. The appropriate legal basis / security checks will be carried out; and **2) Renewals** – if the purpose is not changed and they simply require more of the same data, these being renewable without having to meet NHS England DARS Standards or requiring an AGD review until the end of the period for which data is required. **Outcome of discussion:** The group welcomed the updated briefing paper. **4.2.1** Concern was expressed that "*until the end of the period for which data is required*" was open ended and could, theoretically, be for a decade or more. It was suggested a time limit was included, perhaps of five years. This amendment was accepted by NHS England SIRO representative in the meeting. **4.2.2** The group noted and thanked NHS England for providing a copy of the NDRS Precedent for information and suggested that it be updated to include reference to the DARS annual confirmation report and a time limit.	
EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-667040-B5T1X-v0.12 **Applicant:** University of York **Application Title:** Centre for Health Economics, University of York, Programme Level Agreement **SAT Observer:** Dave Cronin **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 8th June 2023. **Linked applications:** This application is linked to NIC-84254-J2G1Q. **Application:** This was a new application. The purpose of the application is for research to help inform health and social care policy and practice by identifying the effectiveness, efficiency, distribution, and quality of a wide range of services provided to the population. It produces insights that allows the maximisation of health gain and other measures of benefit from	

limited healthcare budgets, along with information on how health and health care is/can be distributed equally to meet the health needs of varying demographics. It may potentially provide a view of health care utilisation to understand how effective delivery of care is distributed both nationally and locally, contributing to the delivery of new healthcare policy aimed at improving the quality of care.

Should the application be approved by NHS England, further details would be made available within the Data Uses Register.

Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:

5.1.1 The group suggested that NHS England ensure that there are tight contractual controls within the data sharing agreement (DSA), including, but not limited to specific milestones and requirements, for example, the publishing of the Centre for Health Economics (CHE) Data Access Request Group (DARG) minutes, clauses around the reporting / transparency of the research undertaken in line with the UK General Data Protection Regulation (UK GDPR), and that this was done in line with NHS England's DARS Standards.

5.1.2 It was also suggested that there should be no updates to the DARG Terms of Reference (ToR) without the prior approval of NHS England.

5.1.3 In addition, it was suggested that the special conditions in section 6 (Special Conditions) were refined to ensure they are aligned with the tighter contractual controls as outlined in point 5.1.1, and in line with NHS Digital DARS Standard for Special Conditions.

5.1.4 It was suggested by the independent advisers that in line with advice provided on other programme level access DSAs, there should be some independent / lay representation on DARG, and that this would also help DARG with implementing the National Data Guardian (NDG) guidance on benefits.

5.1.5 In addition, in respect of the NDG guidance on benefits, it was suggested by the independent advisers that this was specifically referred to within the DARG ToR (citing paragraph 3.9).

In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:

5.1.6 Noting that this was a 'programme level agreement', the independent advisers advised that they were broadly supportive of this approach for this application, noting the governance structures in place; and that it was comparable with other programme level agreements.

5.1.7 Separate to this application, the independent advisers suggested that NHS England considered having an NHS England DARS Standard for programmatic access, that addressed what, if any, difference in approach would be taken for commercial programmatic access; and how any programmatic access is aligned with the Department of Health and Social Care draft data access policy update that states *"Secure data environments (SDEs) will become the default route for accessing NHS data for research and external uses. Instances of disseminating*

	NHS data outside of an SDE for research and external uses will be extremely limited". **ACTION:** NHS England to consider having an NHS England DARS Standard for programmatic access. **5.1.8** Noting that the 'consultant code' field had been requested for the Hospital Episode Statistics Admitted Patient Care (HES APC) dataset, it was suggested by the independent advisers that the applicant notify the British Medical Association (BMA) of the proposed usage of the consultant code and how this will be handled; and that the applicant invite the BMA to respond. **5.1.9** The independent advisers suggested that section 5(a) (Objective for Processing) of the application was updated to include details of any potential future commercial aspects through the research, and how this will be addressed, for example, in line with the DARG ToR, the NHS England DARS Standard for Commercial Purpose and the NDG guidance on benefits. **5.1.10** The independent advisers noted the statement in section 5(a) *"CHE uses PPIE panels at all stages of research projects using NHS England, **where appropriate**"*; and suggested that this was updated to remove the reference to *"where appropriate"*. **5.1.11** Noting the statement in section 5(d) (Benefits) iii (Yielded Benefits) *"CHE developed the online tool, aftermysurgery.org.uk to inform patients about their likely outcome of hip and knee surgery and groin hernia repair"*; it was suggested by the independent advisers that this was updated with further information on the specific yielded benefits of the online tool, in line with NHS England's DARS Standard for Expected Measurable Benefits. **5.1.12** Noting the remote access clauses within this application, and separate to this application, the Data and Analytics representative advised the group that the policy on remote access was in process and would be presented to the group at a future AGD meeting. The group noted the verbal update. **5.1.13** The SIRO representative noted the advice provided, and asked that they had sight of and approved any resulting agreement prior to NHS England signature.	DARS
5.2	**Reference Number:** NIC-659581-D4B1S-v0.9 **Applicant:** University of Cambridge **Application Title:** Long term effectiveness and cost-effectiveness of early behavioural interventions **SAT Observer:** Dave Cronin **Application:** This was a new application The original 'Healthy Start, Happy Start study' was carried out to test the clinical and cost effectiveness of a **V**ideo-feedback **I**ntervention to promote **P**ositive **P**arenting and **S**ensitive **D**iscipline (VIPP-SD) for parents of young children (aged 12-36 months) at risk of developing challenging behaviour.	

	The purpose of this application is for a research project which is a follow up to the 'Healthy Start, Happy Start study'; and will assess the long-term clinical and cost-effectiveness of the intervention. The study is interested in finding out about how children's behaviour changes as they get older; and is particularly interested in how parents and children interact during everyday activities together and whether a programme, delivered to some families earlier in the study, is helpful in thinking about both the positive and challenging moments. The data will be used to support the cost-effectiveness evaluation only. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments: **5.2.1** The independent advisers commended NHS England on the work undertaken on the application. **5.2.2** The Caldicott Guardian Team Representative commended the applicant on the design of the child assent form provided as a supporting document. **5.2.3** The independent advisers noted the breadth and date range of the data requested, and suggested that whilst this was compatible with consent, if there was scope, and it was practicable, the applicant should communicate with the cohort, for example, via an update to the website, to ensure there was sufficient information provided to them, in respect of the potential date range, which may be from July 2015 to July 2022, noting this may be slightly longer than the cohort originally anticipated. **5.2.4** The independent advisers noted that the purpose of the data request was to support the cost-effectiveness evaluation only; and advised that whilst this was compatible with the consent, that in line with Caldicott Principle 8, *"…A range of steps should be taken to ensure no surprises for patients and service users…"*, the applicant should communicate with the cohort in respect of this, noting that this may not be clear in the current consent materials.	
5.3	**Reference Number:** NIC-147910-HHGGZ-v2.2 **Applicant:** University of Oxford **Application Title:** MR415 Cohort Study of cancer incidence and mortality amongst women treated for subfertility. **SAT Observer:** Dave Cronin **Application:** This was an extension and amendment application The purpose of the application is for a study, which will use historical NHS hospital medical record data, already extracted for about 7000 subfertile women and linked to their vital event records at the National Health Service Central Registers (NHSCR). The study's main purpose is to assess whether the particular reproductive history and/or treatments experienced by this Oxford-based cohort affected some of their cancer and mortality risks. This agreement is to allow the processing and retention of the data previously flowed.	

	The amendments are to **1)** update the current Purpose Q&A, which includes the required s251 support to continue the processing of the data; **2)** to add a special condition in section 6 (Special Conditions) to supply a data destruction notice of all computerised and paper documents provided by NHS England up to 2013 once all steps have been completed as described in the purpose. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following high level comments: **5.3.1** The independent advisers expressed concern that the cohort were not originally approached for consent but noted that the applicant had obtained s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG) and updated ethical support. They also queried if it would be appropriate to consult the Human Fertilisation and Embryology Authority (HFEA) who may be interested in the outputs of the research, and a focussed charitable organisation, for example, the Fertility Network UK, who may be able to offer input into or support on the dissemination of the outputs. **5.3.2** Noting the potentially valuable outcomes from this research, it was noted by the independent advisers that there may be a missed opportunity by the applicant, in not requesting follow-up data to 2023; and advised that they would be supportive of the additional data flowing to support the follow-up if required. **5.3.3** If the applicant should require additional data to support the follow-up, the independent advisers suggested that, in line with Caldicott Principle 8, *"…A range of steps should be taken to ensure no surprises for patients and service users…"*, the applicant should communicate with the cohort in respect of this. **5.3.4** Noting that for this iteration of the application, there was no new data flowing, therefore the National Data Opt-out (NDO) would **not** be applied, the independent advisers suggested that the applicant consult HRA CAG and potentially HFEA to determine whether NDOs should be applied, noting the sensitive nature of the study and the historic data being processed. **5.3.5** It was agreed by the group that although there was not a *"new"* purpose in this application, which would require the NDO to be applied, if a new data flow was requested (of the same data), they would be supportive of this with the NDO applied. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.3.6** The DARS SAT observer advised the group that the incorrect dataset had been referenced in the internal application assessment form, and that this would need updating to correctly refer to the right dataset and fields, to align with the application. The group noted the verbal update. **5.3.7** The independent advisers suggested that the internal application assessment form and section 5 (Purpose / Methods / Outputs) of the application were updated to clarify when the women were recruited to the cohort, and what age the women would be now, noting that this was currently unclear.	

	5.3.8 The independent advisers noted that there were two Honorary Researchers at the University of Oxford working with the data held under this data sharing agreement (DSA) who were previously employed by the University of Oxford, but have now retired, who both worked on this study previously. It was discussed where the data would be located, and was noted by the SIRO representative that in line with NHS England's DARS Standard for Special Conditions, a special condition would be added to section 6, stating that the data can only be stored on University of Oxford equipment, noting they were the sole Data Controller and Data Processor. **5.3.9** It was also suggested that there were **clear** contractual provisions in the special conditions in section 6, including, but not limited to, when the identifiers will be deleted in line with NHS England's DARS Standard for Special Conditions. **5.3.10** In addition, it was suggested that the application was updated / aligned throughout to ensure that information relating to the deletion of the identifiers was correct. **5.3.11** The DARS SAT observer noted the historical information in respect of the data in section 5(a) (Objective for Processing), and advised that this would need updating to correctly refer to the data being supplied by NHS Digital or its predecessor organisations. **5.3.12** The SIRO representative noted the references in section 5(b) (Processing Activities) to *"*NHSCR"* and *"**ONS NHSCR"*; and advised that these references would need updating. * National Health Service Central Registers ** Office for National Statistics **5.3.13** The SIRO representative noted the statement in section 5(b) *"The University of Oxford will securely upload the computerised cohort data…"*; and advised that this would need updating with further information to clarify when the data would be securely uploaded. **5.3.14** The SIRO representative noted the statement in section 5(b) *"The data will remain on the servers at the University of Oxford at all times"*; and noting that this did not align with information elsewhere in the application, advised that the application would need reviewing and aligning throughout.	
5.4	**Reference Number:** NIC-59873-D8C6G-v1.5 University College London (UCL) **Applicant:** NIC-59873-D8C6G-v1.5 University College London (UCL) **Application Title:** Using routine data to identify and assess clinical outcomes for the STAMPEDE trial: Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy **SAT Observer:** Dave Cronin **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 9th August 2018, 18th June 2020 and the 16th July 2020. **Application:** This was an amendment application.	

	The purpose of the application is for a research project, with the aim of assessing novel approaches for the treatment of men with prostate cancer who are starting long-term Androgen Deprivation Therapy (ADT). The amendments are to **1)** split the cohort to 9,037 consented participants and 1,554 under s251; and **2)** update the application to reflect the following new objectives: **a)** longer-term follow up of participants (10+ years); **b)** active follow-up of participants in arms K and L and their controls in arm A until 2025 following completion of recruitment in March 2023; and **c)** a methodological assessment of whether death registration data can be used in place of trial-specific collection of death information for future trials involving survival analysis. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application with a caveat regarding those cohort members falling under s251 support and wished to draw to the attention of the SIRO the following substantive comments: **5.4.1** The group discussed those cohort members who were recruited before 2013, where it was 'unknown' if they had also consented to the data linkage, noting that s251 support had been obtained for these individuals. The independent advisers advised NHS England that they should **only** flow data for those individuals where it was genuinely unknown if they had consented and data should not flow for those who had been given the opportunity to *"opt in"* to the linkage of data and declined. **5.4.2** The independent advisers noted that some of the text in the honorary contract provided as a supporting document had been heavily redacted and it was therefore impossible to determine what the contractual arrangements were for the Chief Investigator. It was noted that the honorary contract appeared to use inconsistent party descriptions, for example *"employer"* appeared in the body of the contract but was not a signatory on the contract and was not a defined party. It was suggested that NHS England clarify with the applicant that the correct contractual arrangements are in place and outlined in the honorary contract for the Chief Investigator. **5.4.3** In respect of transparency, the independent advisers suggested that the relevant communication materials were updated to clearly explain the study specific opt out **and** the National Data Opt-out (NDO). In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.4.4** The independent advisers noted the role of the Medical Research Council (MRC) as *"sponsor"* of the research project, and suggested that NHS England seek assurance from the applicant that the MRC **do not** have data controllership responsibilities in line with NHS England's DARS Standard for Data Controllers; and that the internal application assessment form and the application were updated as may be necessary with clarification. **5.4.5** In addition, the independent advisers noted the statement in section 5(a) (Objective for Processing) *"MRC has delegated sponsor responsibility to the *MRC CTU at UCL"*; and suggested that NHS England seek assurance from the applicant	

	that the MRC CTU **do not** have data controllership responsibilities in line with NHS England's DARS Standard for Data Controllers; and that the internal application assessment form and the application were updated as may be necessary with clarification. * MRC CTU at UCL = The Medical Research Council Clinical Trials Unit at University College London **5.4.6** Noting the commercial purpose outlined in section 5(e) (Is the Purpose of this Application in Anyway Commercial), the independent advisers suggested that this was also replicated for transparency in section 5(a), in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.4.7** In addition, the independent advisers suggested that the commercial purpose in section 5(a) and section 5(e) were updated to provide further information on the commercial involvement, including, but not limited to, all benefits in kind, for example, discounted medicines, provisions of placebos, research nurses etc, in line with NHS England's DARS Standard for Commercial Purpose. **5.4.8** The SIRO representative noted the inconsistent information within the application in respect of the storage of the data; and asked that this was reviewed and updated / aligned as may be necessary to reflect the correct information. **5.4.9** The SIRO representative noted that the processing of data under this data sharing agreement (DSA) could be done remotely; and suggested that further information was added to the application on the remote access arrangements, as per usual process. **5.4.10** The independent advisers queried the statement in section 5(b) (Processing Activities) *"Personnel are not technically capable of downloading or copying data to local devices"*; and suggested that this was updated to be clear that this was due to the technical capability, and not the capability of the personnel. **5.4.11** The independent advisers noted that the internal application assessment form stated that the use of the Secure Data Environment (SDE) was **not** appropriate for the processing under this application due to it not having the *"technical capability"*; and suggested that for transparency, this was made clear within section 5 (Purpose / Methods / Outputs) of the application. **5.4.12** Separate to this application, it was suggested that NHS England formulate wording to include in all applications, where an SDE is **not** being used, to clarify why the processing of data cannot be done within an SDE and why. **ACTION:** NHS England to formulate wording to include in all applications, where an SDE is not being used, to clarify why the processing of data cannot be done within an SDE and why.	NHSE
5.5	**Reference Number:** NIC-615958-F7Q7Z-v2.2 **Applicant:** NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board (ICB)	

Application Title: NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board - Comm, RS and IV

SAT Observer: Dave Cronin

Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 28th July 2022, 25th August 2022 and the 26th January 2023.

Application: This was an amendment application.

The purpose of the application is for commissioning, risk stratification and invoice validation.

The amendment is to permit linkage to Police data for the purpose of comparing High Intensity Users (HIU) from Avon and Somerset Constabulary's (ASC) and Bristol, North Somerset and South Gloucestershire (BNSSG) ICB, to allow BNSSG ICB to conduct an initial comparative analysis. The aim is to take a Population Health Management approach to identify overlap between these cohorts and produce key findings to support work between police and health agencies to understand current and future health and care needs for this complex cohort. This will determine whether the Police HIU cohort are also regular users of health service resources, and if so, where the contact points in the health system are.

Should an application be approved by NHS England, further details would be made available within the Data Uses Register.

Outcome of discussion: At the request of the SIRO representative in-meeting, the group provided preliminary advice only on this application, and suggested that the application be brought back to a future meeting.

5.5.1 The group noted that prior to the meeting, a query had been raised with NHS England by an independent adviser, in respect of the legal basis for the police to send confidential data to the NHS South, Central and West Commissioning Support Unit (CSU) (Data Processor) and what the legal basis was for them to then process that data and handle NHS numbers. It was noted that the application, and the Data Protection Impact Assessment (DPIA) provided as a supporting document, were focussed on the legal basis for processing pseudonymised data however it was not clear what the legal basis was for processing confidential data between the police and the CSU, the processing involved to pseudonymise the data, and the handling of the NHS number by the Data Processor.

5.5.2 The group noted that for both the queries raised in advance of the meeting the applicant had provided a response back to NHS England which was verbally fed back to the group by the DARS SAT observer in-meeting; however, the group confirmed that the response did not adequately address the queries raised and suggested that these key points would need addressing when the application returned for a further review.

5.5.3 The independent advisers noted that direct care had been put forward as a legal basis for part of the processing of the data, however advised that, based on the facts available, this was not justifiable.

	5.5.4 The independent advisers noted, due to the sensitive / confidential nature of the police data being linked, there would be significant safeguarding issues with regard to the police flowing this data to the Data Processor. **5.5.5** Noting the recent media reports that the police would be reducing the number of mental health callouts they respond to, the group queried how the proposed processing aligns with this; and suggested that the application and any patient and public involvement and engagement (PPIE) should address this. **5.5.6** The independent advisers also queried if there was public support, trust and confidence for the linkage of the data, for example, from the ICB geographical area; and suggested that this was addressed in the application. **5.5.7** The Data and Analytics representative noted that the DPIA referred to *"research"* and that the templated application was for the purpose of commissioning, risk stratification and invoice validation; and it was queried by the group if this templated application was the most appropriate format for the proposed processing, since this appeared to be a standalone application for a novel use of data. **5.5.8** The independent advisers noted the reference to the Avon Longitudinal Study of Parents and Children (ALSPAC) within the DPIA, however advised that as ALSPAC was a consented study with an opt out available, it therefore differed significantly from the proposal outlined in this application and was therefore not a relevant comparison study. **5.5.9** The SIRO representative asked if the applicant was complying with all of the sub-licence terms; and that this was clarified within the internal application assessment form and the application. **5.5.10** The independent advisers noted the references to those with dependencies *"suffer"* or *"suffering"*; and suggested that these references were removed and updated with a more sensitive form of language, for example, *"experience"* or *"experiencing"*. **5.5.11** The Data Protection Office Representative noted that the Data Security and Protection Toolkit (DSPT) for NHS Bristol, North Somerset and South Gloucestershire ICB had expired and did not appear to have been submitted for 2022/23. **5.5.12** The independent advisers noted in section 1(c) (Data Processor(s)) that the Data Protection Act (DPA) Registration appeared to have expired for some of the Data Processors; and advised that this information would need updating with the updated dates.	
AGD Operations		
6	**Statutory Guidance** The independent advisers again noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were **not** aware of an agreed risk management framework, and requested that NHS England provide further information/ clarity on this, noting this topic had been raised by Lord Hunt in the	

	House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements - UK Parliament. **ACTION:** NHS England SIRO Representative to provide a written response addressed to AGD with further clarity on the risk management framework.	GC
7	**AGD Terms of Reference (ToR)** Garry Coleman noted that NHS England were still considering comments from stakeholders on the AGD ToR. **ACTION:** The NHS England SIRO Representative noted a previous action to clarify when a revised draft of the AGD ToR would be presented to AGD and when the AGD ToR was scheduled to be considered by the NHS England Board / subcommittee of the Board.	GC
8	**Standard operating procedures** The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
Any Other Business		
9.1	**Our Future Health - NIC-414067-K8R6J-v3.2** The group noted that NIC-414067-K8R6J was reviewed at the AGD meeting on the 13th July 2023, for an amendment to increase the total number of invitation mailouts from approximately 16 million to approximately 20 million, to allow recruitment to proceed whilst Our Future Health discuss a further increase to the invitation numbers with the Health Research Authority Confidentiality Advisory Group (HRA CAG). The outcome of the discussion was that the **minority** of the group supported the amendment, and felt that the additional data could flow now, and all the additional work could be completed as part of continuous improvement after the flow; and the **majority** of the group felt that additional work to test the public understanding of the commercial work needs to be completed before additional data could flow and they could be supportive of the amendment. As part of the review, it was advised by the group, that if NHS England supported the additional data being supplied to increase the total number of invitation mailouts, they would be supportive of a robust letter from NHS England in addition to the amended data sharing agreement (DSA), outlining **all** of the previous points / concerns previously made by the group, and with the advice, that all of these points would need to be satisfactorily addressed for any future data flows. Prior to the meeting, a copy of the letter sent to Our Future Health from Jackie Gray, Director of Privacy, Transparency and Ethics was shared with the group (please see appendix A). The SIRO representative advised the group that NHS England believes that it is appropriate to release the details on the additional 4 million patients; however, recognised the concerns raised by the group, that a number of points of advice had not been sufficiently addressed by Our Future Health, and that these were therefore repeated as the application has returned for further advice. NHS England was pleased to note that Our Future Health were actively addressing these points, however, wished to ensure that the current momentum was	

	maintained and felt that a checkpoint as outlined in the letter was a suitable way of ensuring that this was the case. This approach was also intended to take on board the position of the majority of members at AGD in the advice that they provided. The group noted and thanked the SIRO representative for providing a copy of the letter which would be appended to these minutes, and for the verbal update.
9.2	**NHS England Data Access Request Service (DARS) – Work Update** Michael Chapman provided a verbal update of the current applications in progress within DARS and at what stage the applications were at within NHS England's customer relationship management (CRM) system. The group noted the verbal update and advised that they would welcome a regular update on this, including the definition of low, medium and high complexity applications. **ACTION:** AGD Secretariat and the Data and Analytics representative to ensure the NHS England DARS work update is on the AGD meeting agenda as a monthly standing item.

Meeting Closure

As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.

Appendix A

Classification: Official

NHS England

To: Professor Raghib Ali OBE
Chief Medical Officer
Our Future Health
2 New Bailey
6 Stanley Street
Manchester
M3 5GS

NHS England
7 – 8 Wellington Place
Leeds
West Yorkshire
LS1 4AP

8 August 2023

cc. Garry Coleman, Associate Director
(Audit Services & Data Sharing)

Dear Professor Ali,

Our Future Health – Data Sharing Agreement Application – NIC 414067

I am writing regarding your recent application to vary the above Data Sharing Agreement following the advice which was received by NHS England from the interim Advisory Group for Data (AGD) on 13th July. As Deputy Senior Information Risk Owner (SIRO), I have been asked to make a decision on whether NHS England will approve your most recent application, in light of the advice provided by the AGD.

Background

Your application was to increase access to patient contact details by an additional 4 million records, a total increase from 16 million to 20 million records, in order for Our Future Health (OFH) to continue to contact individuals to recruit them into your research programme (Programme). I know that the AGD very carefully considered your application and there was significant discussion. Although some of the members of the AGD supported the increase, the majority of the members advised NHS England against agreeing to the increase, until previous recommendations made by the AGD regarding testing the public's understanding of the commercial work associated with the Programme, had been addressed.

I have reviewed the most recent application and the previous advice that the AGD has provided to OFH in its published minutes. I have also reviewed the most recent decision from the Confidentiality Advisory Group (CAG) on your application to them to amend the Regulation 5 approval to provide a legal basis for the increase to 20 million records, which they supported. I have also discussed the application with Garry Coleman, who is the SIRO representative who works day to day with the Data Access Request Service (DARS) and the AGD and who is familiar with your Programme and the application.

AGD Advice

I note the significant importance of the Programme, which potentially may bring substantial benefits to patients. I am also acutely aware that we are being asked to provide the Programme with access to the confidential contact details of a further 4

million patients, and that we have a responsibility to those patients to consider such requests for access to their confidential data with appropriate care and consideration and to be assured that we are meeting our legal responsibilities, including under the duty of confidence we owe to them and under UK GDPR when we do so. This is particularly important when there have been different views expressed in relation to your application by the members of our AGD, who provide expert and independent advice to NHS England in line with Secretary of State Statutory Guidance[1], which is guidance to which we must have regard when providing access to this data.

The AGD has considered and provided thoughtful advice on each application OFH has made to increase its access to contact detail records and whilst some of their earlier advice has been acknowledged and addressed, I note that there remain a small number of important recommendations which have not yet been addressed. I have included extracts from the AGD minutes identifying those recommendations in the Annex to this letter. Broadly these recommendations relate to the following issues:

1. **Addressing invitations to the householder or using other mechanisms** – significant confidential patient data is being used for the purpose of issuing invitations. Is this necessary and proportionate given the alternative mechanisms for recruitment of participants to the Programme? For example, would there be a similar take up rate achieved by instead addressing invitations to a householder and communicating directly with every household? I note CAG has also raised this point in relation to the potential use of electoral register data instead of confidential patient data.
2. **Evidence that use of confidential patient data increases the reach into under-represented groups** - linked with the point above, one of the justifications provided for using confidential patient data has been that the model significantly increases the reach into under-represented groups, ensuring that they are better represented in the resulting cohort participating in the Programme. However, we have been provided with insufficient early insights from the take up to date (from 16m invitations to date) to support this.
3. **Commercial involvement** – from the information provided in the invitations issued, does the public understand the level of commercial funding and involvement in OFH and its links to industry – would that come as a surprise to the public and participants?
4. **Worldwide use of data from those who consent** – from the information provided in the invitations, does the public understand that once they participate in the Programme that their data will be used worldwide – or would that come as a surprise?

I am reassured by the meetings that you have held with Garry Coleman, that urgent progress is being made on the above areas, and that you also have a work programme in place to address the conditions of any further approval laid out by CAG.

Decision to increase to 20 million records

In relation to increasing the number of records to 20 million, having reviewed the CAG letter of support and taking account of the information you have shared with us to date on future progress in these areas, I have approved the release of the additional 4 million contact details, up to a total maximum of 20 million records in line with the current CAG support. This approval is however subject to the following conditions being met:

[1] NHS England's protection of patient data, published 23 May 2023 - https://www.gov.uk/government/publications/nhs-englands-protection-of-patient-data

1. A checkpoint is put in place before more than 18 million records in total have been provided, such that I can be assured that substantive progress to address the points raised by AGD as summarised above, continues to be made. Specifically, we will require evidence of progress as set out in the Annex to this letter. I will also share this evidence with AGD for their views on the progress. If the evidence or progress is considered satisfactory, we will release the remaining 2 million records. If it is not, we will not release any further records until acceptable progress is made.
2. Although CAG was comfortable with the current ethics approval in place when they recommended support in May 2023, at or before the checkpoint we will require updated approval from your ethics committee or confirmation from them that the current ethics approval cover the increase to 20 million records. This is additional assurance to address the query raised by the AGD in July.

These requirements will be added as a special condition within the data sharing agreement. Failure to deliver the requirements will not be a breach of the data sharing agreement but will mean that NHS England will not release the final 2 million contact details.

Any further application for access to data beyond 20 million records

I must make clear that all of the conditions set by CAG, and updated CAG support under Regulation 5, together with evidence to demonstrate that all of the recommendations by AGD as set out in the attached Annex have been addressed, will be pre-requisites for us to consider any future increase beyond the 20 million records for which you presently have CAG support.

Publication of this letter

NHS England remains committed to being transparent in its approach to data sharing, and AGD will be updated as to this decision at their next meeting, and this letter shared with them to keep them informed of the steps we have taken in line with their advice set out in paragraph 4.1.5 of their minutes of the 13 July. The letter will therefore be included in and published with the minutes of their next meeting.

If you have any queries about this letter then please do not hesitate to contact me or Garry Coleman.

Yours sincerely,

Jackie Gray
Director of Privacy, Transparency and Ethics
NHS England

Annex

Theme	Recommendation made by AGD (from minutes of meeting)	Detail expected from Our Future Health
1. The need for evidence to justify the continued need to use confidential patient data rather than contacting householders **2. This includes the impact and the success from using confidential patient data to target under-represented groups**	**13th July 2023** 4.1.4 The group advised that satisfaction of the HRA CAG conditions of support in itself would not necessarily satisfy the points previously raised by AGD, including, but not limited to, the necessity of using confidential patient information (CPI) to target of the underrepresented groups more effectively than a "Dear Householder" approach, and that there had been no clear evidence provided to further support this objective / outcome. **29th June 2023** 5.5.3 The group noted and applauded the applicant on now taking forward the pilot of the "Dear Householder" mail out approach as discussed / suggested at previous Independent Group Advising (NHS Digital) on the Release of Data (IGARD) / AGD meetings. However, it was suggested by the group that NHS England may wish to consider stopping the flow of data, until the letter had been piloted and initial findings reported on. 5.5.4 In addition, and noting that recruitment was also taking place through GP practices and hospitals, the independent advisers queried whether there had been a comparison across the three recruitment methods; and suggested that clarification was provided within in the application of any comparison data available, which would go to supporting the case that using confidential data was necessary to achieve the stated aims of increasing participation of "hard to reach" groups. 5.5.5 As discussed at the AGD meeting on the 2nd March 2023, noting the objective of increasing recruitment from underrepresented groups, the independent advisers queried whether this was being achieved and whether this method of recruitment was working. The independent advisers noted that given the numbers signing up, there should be early signs as to whether hard to reach groups were being successfully recruited; and suggested that further information be provided on this point within the application. 5.5.7 An AGD NHS England representative queried whether an assessment had been undertaken of the commercial benefits and whether they were proportionate in terms of balancing with public benefits, particularly in respect of underrepresented groups; and suggested that further clarification was provided. **2nd March 2023**	Significant progress made on providing full evidence, including eg firm plans or providing early evidence based on mailing of 16 million to date: • demonstrating the necessity of using Confidential Patient Information as opposed to Our Future Health contacting "the householder" to recruit to the Programme, or other recruitment methods. • demonstrating that using Confidential Patient Information is a more effective way of recruiting underrepresented groups than other methods, including the householder approach.

	It was also noted that the research programme was initially looking at reaching underrepresented groups, and queried the extent to which this has been achieved in the current sample. The independent advisers also noted that potential issue with transparency, as per the risk factor previously articulated by IGARD in that participants may not be aware of the depth of the significant commercial involvement. It was suggested that more robust PPIE was carried out around the commercial involvement and that this was more transparently disclosed in the mail out (cf online privacy notices). the overall objective for the research programme in that it was initially looking at underrepresented groups, general advertising of the research programme with partners and whether this could be improved. Independent advisers expressed concerns over the potentially excessive processing of personal data to send invitations via Digi-Trials, and how this would affect future researchers. The advisors also queried whether it was justified processing all adults' confidential data rather than a "Dear Householder" mail out approach.	
3 Patient understanding of commercial involvement and **4. Patient understanding of the potential worldwide use of their data** **– addressing the "no surprises" principle**	**13th July 2023** 4.1.2 The group suggested that further testing was carried out by the applicant with the cohort, to clarify the breadth and depth of understanding with participants on 1) the transparency in respect of the commercial involvement, and 2) the potential worldwide use of the data. The group noted that while the consent was valid, they suggested that subsequent updates were made to the consent / transparency materials following this testing, to build in further improvements. 4.1.6 The independent advisers suggested that the Caldicott Guardian Team Representative offered a view to NHS England in respect of the specific cohort letters shared with the group, noting that the content of some of the letters may be perceived as being coercive or misleading, including, but not limited to, the suggested involvement / encouragement from the NHS to potential participants. In addition, it was suggested by the group that the applicant should amend the letters to include all of the partners logos, and not just a select few. **29th June 2023** 5.5.6 The independent advisers reiterated the point previously made at the AGD meeting on the 2nd March 2023, in respect of the potential issue with transparency, as per the risk factor previously articulated by IGARD, in that participants may not be aware of the depth of the commercial involvement, including the potential use of health data by pharmaceutical, diagnostic and health tech companies, ; and suggested that further clarification was provided as to how this point had been considered and addressed.	Significant progress made on providing full evidence including eg firm plans to address the following: • Results from patient and public involvement demonstrating that the public understand the commercial involvement and commercial nature of the work being undertaken by Our Future Health, or the changes required to transparency materials to achieve this. This includes the potential use of health data by pharmaceutical, diagnostic and health tech companies. Also, the potential worldwide use of their data. If results are not available, then evidence there is a firm plan for patient and public involvement and that the work is well underway to support that and any changes to transparency material that may result.

	5.5.7 An AGD NHS England representative queried whether an assessment had been undertaken of the commercial benefits and whether they were proportionate in terms of balancing with public benefits, particularly in respect of underrepresented groups; and suggested that further clarification was provided. **2nd March 2023** The independent advisers also noted that potential issue with transparency, as per the risk factor previously articulated by IGARD in that participants may not be aware of the depth of the significant commercial involvement. It was suggested that more robust PPIE was carried out around the commercial involvement and that this was more transparently disclosed in the mail out (cf online privacy notices). the overall objective for the research programme in that it was initially looking at underrepresented groups, general advertising of the research programme with partners and whether this could be improved. Independent advisers expressed concerns over the potentially excessive processing of personal data to send invitations via Digi-Trials, and how this would affect future researchers. The advisors also queried whether it was justified processing all adults' confidential data rather than a "Dear Householder" mail out approach.	• Evidence to demonstrate that the commercial benefits from the Programme are proportionate to the public benefits, particularly with regard to under-represented groups. You may find the guidance issued by the National Data Guardian[2] helpful in this regard.
5. Ethics support	**13th July 2023** 4.1.7 The independent advisers noted in the internal application assessment form, that further ethics advice / approval was not required for the increase to the number of invitation mailouts; however, a specialist independent adviser suggested that this may not be correct noting, amongst other things, the significant volume of additional data flowing; and suggested that this should be clarified with HRA REC.	Updated ethics approval or confirmation from your ethics committee that ethics approval is already in place for the 20 million records requested.

[2] What do we mean by public benefit? Evaluating public benefit when health and adult social care data is used for purposes beyond individual care, published 14 December 2022 - https://www.gov.uk/government/publications/what-do-we-mean-by-public-benefit-evaluating-public-benefit-when-health-and-adult-social-care-data-is-used-for-purposes-beyond-individual-care