Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 23rd February 2023

09:30 – 17:00

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Ball (MB)	Data Access Request Service (DARS) (**Presenter**: item 4.3)
Lorna Branton (LB)	Assistant Director of Communications (**Presenter**: item 6)
Vicky Byrne-Watts (VBW)	Data Access Request Service Senior Approval Team (DARS SAT) (**Presenter**: item 4.5)
Michael Chapman (MCh)	Data and Analytics representative
Garry Coleman (GC)	Senior Information Risk Owner (SIRO) representative (not in attendance for part of item 4.4)
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.1 & 4.2)
Duncan Easton (DE)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.3, 4.4 & 4.5)
Suzanne Hartley (SH)	Data Access Request Service (DARS) (**Presenter**: AOB item 9)
Dickie Langley (DL)	Data Protection Officer (DPO) representative (Delegate for Jon Moore) (**Presenter**: item 6)
Jon Moore (JM)	Data Protection Officer (interim) (in attendance for item 6)

Karen Myers (KM)	Secretariat Team
Dr. Jonathan Osborn (JO)	Caldicott Guardian Team representative
France Perry (FP)	Digi-Trials Team (**Presenter**: item 4.1)
Aisha Powell (AP)	Data Access Request Service (DARS) (**Presenter**: item 4.2)
Eva Simmonds (ES)	Programme Director (**Presenter**: Item 6)
Anna Weaver (AW)	Data Access Request Service (DARS) (**Presenter**: item 4.4) (**Observer:** item 5.2)
Vicki Williams (VW)	Secretariat Team
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Maria Clark (MC)	Lay Member Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Dr. Arjun Dhillon (AD)	Caldicott Guardian Team Representative (Delegate for Dr. Jonathan Osborn)

1	**Welcome and Introductions** The NHS England Senior Information Risk Owner (SIRO) Representative advised attendees that, noting the statutory guidance and the AGD Terms of Reference (ToR) had not yet been agreed, the meeting could not be held under the draft ToR, until they have been approved, and recognised that the draft ToR may change as the statutory guidance evolves. As NHS England would like to seek advice on a number of areas, the NHS England SIRO Representative therefore 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); Privacy, Transparency, Ethics and Legal (PTEL); the Caldicott Guardian; 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 9th February 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.	
3	**Declaration of interests:** Dr Maurice Smith noted a professional link as a practising GP in the Cheshire & Merseyside geographical area and also knowing two of the Clinical Core Collaborators relevant to item 4.2, NIC-147982-J7KGV-v6.13 University of Liverpool. Dr Maurice Smith noted a professional link as a GP Partner in a Cheshire & Merseyside GP Practice and as the Chief Clinical Informatics Officer (CCIO) at Cheshire & Merseyside Integrated Care Board (ICB) relevant to item 4.3, NIC-308166-T2Z1J-v0.7 Warrington Borough Council.	
4. EXTERNAL DATA DISSEMINATION REQUESTS:		
4.1	**Reference Number:** NIC-604851-W0M3S-v5.2 **Applicant:** Grail Bio Ltd / University of Oxford (Data Controllers) **Application Title:** SYMPLIFY Study Clinical Trial Outcomes Data Request **Presenters:** Frances Perry **SAT Observer**: Louise Dunn **Linked applications:** This application is linked to NIC-604851-W0M3S, NIC-456778-J0G3H and NIC-651660-J5T6C. **Previous Reviews:** The application and relevant supporting documents were previously presented at the IGARD meetings on the 13th January 2022 and 3rd February 2022. It was also discussed as part of "*applications progressed via NHS Digital's SIRO precedent*" on the 5th May 2022, 15th December 2022 and 12th January 2023. **Application:** This was an amendment application. The purpose of the application is for a multi-centre, observational study with prospective collection and retrospective analysis of blood samples to evaluate the performance of a multi-cancer early detection test within the NHS in England and Wales. 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: **4.1.1** Noting that the legal advice provided by NHS England's Privacy, Transparent, Ethics & Legal (PTEL) team was subject to legal privilege in relation to the transfer of data to the United States of America (USA), the independent advisers had not been sighted on the documentation, unlike the NHS England representatives who were able to view the PTEL legally privileged documentation. The independent advisers noted that PTEL supported the	

	legal basis put forward and any advice given today was based on that (unseen) legal gateway. **4.1.2** The independent advisers reiterated previous comments made by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) in respect of NHS Digital's (as it then was) United Kingdom General Data Protection Regulation (GDPR) transparency pages about the datasets held and disseminated by NHS Digital (as it then was). The independent advisers suggested that NHS England ensure that all of NHS England's UK GDPR transparency materials were updated to reflect which datasets may be used worldwide, since UK GDPR information for a number of datasets still stated they could **only** be used within the UK and / or England & Wales, and in fact those datasets were disseminated to other jurisdictions. **Significant Risk Area:** NHS England's UK GDPR transparency information on its website is inaccurate as to the possible territory of use for a number of datasets. **4.1.3** Noting that NHS England do not have the resources in place to audit uses of data in the USA and the practical challenges of the NHS England audit team auditing in the USA, the independent advisers suggested that NHS England may wish to consider this aspect when sharing data outside of the UK. **4.1.4** In addition, the independent advisers noted that IGARD had raised in 2021 the question as to whether NHS Digital, and now NHS England, had a policy position with regard to the handling of data, vis-à-vis the USA Patriot Act 2001, and noted that the Head of Data Access had raised this with NHS Digital's SIRO to seek a view from NHS Digital's Board. The Group asked for the NHS England policy position on this legislation, including any other relevant US state or federal law or regulation, pertinent to the sharing of data with a US-based controller or processor. **ACTION:** NHS England representatives to provide an update to AGD at a future meeting (provisional date: 9th March 2023) **4.1.5** The independent advisers noted PTEL were advising that when an applicant listed "*EEA*" in the Territory of Use section of the data sharing agreement (DSA), that the specific countries be named in section 6 (Special Conditions) and suggested that this should also apply when an applicant lists "*worldwide*". In addition to listing "*USA*" in the special condition wording, the independent advisers suggested that the state or territory where the data was held was also listed (as the relevant law would be different, dependent on geographical location within the USA). **4.1.6** IGARD had not supported the "*annual confirmation report*" template that had been provided to Grail prior to IGARD submitting their own comments in early 2022, and the Group looked forward to receiving the Grail annual confirmation report at a future meeting. In addition, the Group made the following observations on the application and / or supporting documentation provided as part of the review: **4.1.7** The independent advisers suggested all references to "***lead***" from "***lead*** *controller*" from section 5(a) of the application be removed or updated to "*the party leading this activity*", or similar, as advised by IGARD on the 27th October 2022. **4.1.8** The independent advisers suggested that a brief summary be provided in section 5(a) of the commercial aspect, as outlined in section 5(e) (Is the purpose of this application in anyway commercial?).	SIRO MC

	4.1.9 The independent advisers suggested that the sentence "…*including intangible and indirect commercial benefits*…" in section 5(a) (Objective for Processing) and 5(e) be updated to include "*tangible*".	
4.2	**Reference Number:** NIC-147982-J7KGV-v6.13 **Applicant:** University of Liverpool (Data Controller) **Application Title:** The Roy Castle Lung Cancer Research Programme, Liverpool Lung Project - University of Liverpool **Presenter:** Aisha Powell **SAT Observer**: Louise Dunn **Previous Reviews:** The application and relevant supporting documents were previously presented at the IGARD meetings on the 20th July 2017, 12th April 2018, 21st July 2018 and the 23rd July 2020. **Application:** This was a renewal application. The purpose of the application is for an observational study, investigating the differences between those diagnosed with lung cancer and control subjects without lung cancer, or between different lung cancers, to identify opportunities for improving diagnosis or treatment. 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 broadly supportive of the application if the following significant comments were addressed, and wished to draw to the attention of the SIRO the following significant comments: **4.2.1** The Group noted that the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had previously recommended the application for approval for 1 year on the 23rd July 2020 and highlighted the commercial involvement and meeting relevant transparency requirements. **4.2.2** The Group noted that this application had been assessed using the DARS application assessment form pilot. Although helpful narrative was included in the application assessment form, it could be further improved by: **4.2.2.1** explaining any lapses in the data sharing agreement (DSA), **4.2.2.2** identifying the process issues encountered and how they had been addressed, **4.2.2.3** clearly articulating how all the previous comments by the IGARD had been addressed, not addressed or were not applicable – since the current assessment form was silent on how IGARD's previous comments from 2020 had been addressed. **ACTION:** The independent advisors suggested that all previous AGD, IGARD and DAAG minutes should be included, in full, and that it be clearly articulated how each point had been addressed on the DARS application assessment form. **4.2.3** The independent advisers asked that the special condition requested by IGARD on 23rd July 2020 that the applicant will: (a) publish a list of what data has been shared, and (b) provide NHS England with a list of the organisations who the derived data has been shared with, and ensure that this is publicly available, be reinstated in section 6 (Special Conditions).	DARS

	4.2.4 The independent advisers noted the application of the National Data Opt-out (NDO) when there were members of the cohort who had consented to be part of the study, which raised a significant policy issue and an ethical concern (overriding a person's consent). **4.2.5** Noting the onward recipients of data, the independent advisers asked for a written justification in section 5 (Purpose / Methods / Outputs) with regard to the non-disclosure of companies receiving or handling the data/results, since it raised concerns in the round with NHS England developing their derived data policy. **4.2.6** The independent advisers noted that the contention that Health Research Authority Confidentiality Advisory Group (HRA CAG) support would not be required in the future for the retention of data, but suggested that the applicant seek HRA CAG's view, since it was not for AGD to make that assessment. **4.2.7** The independent advisers supported NHS England in bringing this application under a short term 3 month DSA and noted that this application did not need to return to AGD during that time, but brought to the attention of NHS England that the HRA CAG support ran out before the end of the 3 month extension. In addition, the Group made the following observations on the application and / or supporting documentation provided as part of the review: **4.2.8**The independent advisers suggested that a brief summary be provided in section 5(a) (Objective for Processing) of the commercial aspect, as outlined in section 5(e) (Is the purpose of this application in anyway commercial?), plus additional narrative around the funding source.	
4.3	**Reference Number:** NIC-308166-T2Z1J-v0.7 **Applicant:** Warrington Borough Council (Data Controller) **Application Title:** Warrington Borough Council Health and Wellbeing Survey Sample **Presenter:** Michael Ball **SAT Observer**: Duncan Easton **Application:** This was a new application. The purpose of the application is to enable Warrington Borough Council to invite patients to be part of a Health Wellbeing Survey which will inform local commissioning and planning. 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 broadly supportive of the application if the following significant comments were addressed, and wished to draw to the attention of the SIRO the following points: **4.3.1** It was unclear to the Group whether the data would exclude patients with a sensitive flag (s-flag), and suggested that written assurance be provided within section 5 (Purpose / Methods / Outputs) that the s-flag will be upheld, and data will **not** flow for those where an s-flag had been applied to a patient record. **4.3.2** The applicant had provided a copy of the 'Warrington Health & Wellbeing Survey 2022 letter' and 'Warrington Health & Wellbeing Survey 2022 Poster', however the independent	

	advisers suggested that the letter and / or poster could be improved by making the following amendments: **4.3.2.1** helpful narrative from the Poster which explained how the recipients of the letter had been selected and what was happening could be included on the reverse of the letter in a 'for information' section, **4.3.2.2** both the letter and the poster should remove reference to "*random*" because it was not a random sample, but a stratified sample of the population. **4.3.2.3** a brief explanation of the Health Research Authority Confidential Advisory Group (HRA CAG) and s251 could be included on the reverse of the letter in a 'for information' section and on the poster**.** **4.3.2.4** to remove from the letter the paragraph "*Please note that the mailing list for this survey was taken in October 2022, if the person named on this letter is no longer a resident at this address please accept our apologies and ignore this correspondence and any subsequent reminders*" since it can be a criminal offence to open someone else's mail without their consent as outlined in part 5 of the Postal Service Act 2000. **4.3.3** The independent advisers assumed that anyone in the personal demographics service (PDS) data and **not** registered with a General Practitioner (GP) would **not** be in the stratified pool. If, however, those **not** registered with a GP were in the pool, then the letter would need to be revised in addition to the points raised in 4.3.2 above. In addition, the Group made the following observations on the application and / or supporting documentation provided as part of the review: **4.3.4** The Group were supportive of the useful piece of proactive research and potential yielded benefit results. **4.3.5** The independent advisers noted reference to "*gender*" in section 5 and asked that it was clarified if it was actually "*sex*", since they were not interchangeable fields and the Group noted that only a very small proportion of NHS England datasets collected "*gender*". **4.3.6** The independent advisers noted that section 5 should be amended to ensure that statistical terms of art or technical terms were used only where necessary, and explained in a manner suitable for a lay audience. **4.3.7** Reference to "*Warrington Borough Council are permitted to process the data*" should be removed from section 1(c) (Data Processors). **4.3.8** The independent statistical adviser noted that if this became a stratification model, more thought should be given to oversampling in certain geographical areas or further ethnicity data to help the stratification of the local population.	
4.4	**Reference Number:** NIC-609893-N5P5L-v0.17 **Applicant:** Imperial College London (Data Controller) **Application Title:** neoWONDER: Neonatal Whole Population Data linkage approach to improving long-term health and wellbeing of preterm and sick babies **Presenter:** Anna Weaver **SAT Observer**: Duncan Easton	

	Previous Reviews: The application and relevant supporting documents were previously presented at the IGARD meeting on the 18th August 2022. **Application:** This was a new application. The purpose of the application is for a study hoping to provide population level data on the long-term outcomes of the cohort and looks to examine how interventions and exposures in the neonatal period affect these outcomes. 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 comments: **4.4.1** Assuming that the PhD student was not an employee of the University of Oxford, the independent advisers suggested that NHS England simply seek written confirmation from the University of Oxford that they will enforce their own academic standards and sanctions should the student **not** follow Imperial College London's policies and procedures. **4.4.2** The independent advisers noted the transparency materials provided including an engaging video on the study website. However, it was noted this was technically incorrect as the health data is **not** going to the Department for Education (DfE). The Group did not think this was materially misleading in a way detrimental to the target audience. **4.4.3** It was not clear within the application and supporting documentation how many neonatal units had opted out and since the application was silent on the rate of opt out for these neonatal units, the independent advisers suggested that a justification for opting out be included in section 5 (Purpose / Methods / Outputs), alongside any implications to the validity of the study, should significant numbers of neonatal units have opted out. In addition, the Group made the following observations on the application and / or supporting documentation provided as part of the review: **4.4.4** The independent advisors noted references in section 5(a) (Objective for Processing) to specific software and suggested that these restrictive references be removed. **4.4.5** The independent advisers noted reference to "*Spring 2023*" in section 5(c) (Specific Outputs Expected) and suggested that the applicant may wish to review this reference. **4.4.6** The independent advisers noted to the applicant that they may wish to consider how they will respond to the opt out results and process which followed, since it may not be possible to remove cohort members after the data has flowed, and although the independent advisers were not suggesting the applicant should, the applicant should have in mind a future review point at which time cohort members could be removed, if they had opted out of the study.	
4.5	**Reference Number:** NIC-658395-F0F9N-v0.4 **Applicant:** University of Essex (Data Controller) **Application Title:** National Child Measurement Programme (NCMP) School Level Results - unsuppressed data request **Presenter:** Vicky Byrne-Watts **SAT Observer**: Duncan Easton	

	Previous Reviews: NCMP had been previously discussed at the Data Access & Advisory Group (DAAG) on the 13th December 2016, and the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 11th May 2017 (letter for advice), 31st August 2017 (letter for advice) and 15th December 2022 (briefing paper). **Application:** This was a new application. The purpose of the application is for a study is to investigate the impact of Universal Free School Meal (UFSM) programmes run in several local authorities in England since 2004 on children's bodyweight outcomes. 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. The Group made the following observation on the application and / or supporting documentation provided as part of the review: **4.5.1** To update the citation wording in section 6 since the data subjects are not patients and remove reference to "*NHS Digital*" (Special Conditions). **ACTION**: The independent advisers asked DARS that the citation special condition be harmonised to reflect the merger and to ensure that the most recent version was being used in section 6 of the data sharing agreements (DSA).	
5. EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
5.1	**Reference Number:** NIC-15814-C6W9R **Applicant:** NHS England (Data Controller) **Application Title:** Internal data flow covering Patient Level Costing (PLICS) data **Previous Reviews:** The application and relevant supporting documents were **last** presented at the IGARD meeting on the 26th May 2022. **Application:** The purpose of the application is to support the delivery of NHS England's statutory function and support direct improvement and / or oversight of Trusts. **Outcome of discussion**: The Group appreciated that the NHSE SIRO representative was seeking advice on interpretation of a precedent, and seeking to ensure that NHS England acted transparently and in accordance with agreed process. The Group were supportive of the application proceeding via precedent. The Group also noted that any discussion on an application "seeking SIRO approval" did not represent full consideration by AGD of an item, or formally providing full advice on an application and thus is not a way to circumvent the current agreed processes. The NHS England SIRO representative thanked the Group for their time.	
5.2	**Reference Number:** NIC-194340-D6F3B-v3.2 **Applicant:** Office for National Statistics (ONS) (Data Controller) **Application Title:** ONS Longitudinal Study	

	Previous Reviews: The application and relevant supporting documents were **last** presented at the IGARD meeting on the 11th February 2021. **Application:** The purpose of the application is for the ONS Longitudinal Study, which is the largest longitudinal data resource in England and Wales. It contains linked census and life events data for an approximate 1% sample of the population of England and Wales. **Outcome of discussion**: The Group appreciated that the NHSE SIRO representative was seeking advice on interpretation of a precedent, and seeking to ensure that NHS England acted transparently and in accordance with agreed process. The Group were supportive of the application proceeding via precedent. The Group also noted that any discussion on an application "seeking SIRO approval" did not represent full consideration by AGD of an item, or formally providing full advice on an application and thus is not a way to circumvent the current agreed processes. The Group were supportive of the application proceeding via the SIRO approval precedent route. However, the Group wished to draw to the attention of the SIRO the following significant comments: **5.2.1** The Group agreed that the applicant should ensure that all points previously raised by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had been addressed before the application was presented to a future AGD meeting. **5.2.2** The independent advisers were particularly concerned with the applicant's responses to IGARD's previous points including, but not limited to, **5.2.2.1** the provision of the longitudinal study to NSDEC where it was noted in NSDEC minutes that IGARD did not raise any concerns, when in fact the IGARD minutes noted a number of significant concerns and repeated IGARD's previous advice that "…*as a minimum, NSDEC should review the Longitudinal Study*", and be provided with copies of all previous IGARD minutes. **5.2.2.2** The Group reiterated IGARD's previous advice from the 24th March 2022: "*Given that the role of the Health Research Authority (HRA) is to protect and promote the interests of patients and the public in health research, the applicant should consult the HRA to see if the Longitudinal Study requires a review by a HRA Research Ethics Committee*" **5.2.3** The Group noted that the applicant had consulted the Information Commissioner's Office (ICO) about what information should be provided to the public to enable data subjects included in the study to exercise their UK General Data Protection Regulation (GDPR) rights, however given how the IGARD information was (not) presented to NSDEC, were similarly concerned as to what information was presented to the ICO. The NHS England SIRO representative thanked the Group for providing advice and was content to give a 2 month extension, under the SIRO precedent, with the understanding that the application and full suite of supporting documents were presented at a future AGD meeting, and the advice provided was without prejudice to the future consideration by AGD.	
5.3	**Reference Number:** NIC-656847-K4L8H-v1.3 **Applicant:** Newcastle University (Data Controller)	

	Application Title: Investigating inequalities in utilisation of targeted therapies (ODR1819_325) **Application:** The purpose of the application is for analysis on patients, their cancer tumour and the treatment that they have received. **Outcome of discussion**: The Group noted that the NHS England SIRO had already provided SIRO approval. The Group thank NHS England for the written update and made the following observations on the documentation provided: **5.3.1** The Group noted the NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review. **5.3.2** An NHS England representative noted that individual researchers were named in section 5 (Purpose / Methods / Outputs) of the application, and advised NHS England that these should be removed. The NHS England SIRO representative thanked the Group for their time.	
5.4	**Reference Number:** NIC-656862-L4M7T-v1.2 **Applicant:** University of Sheffield (Data Controller) **Application Title:** A comparison of the effectiveness of different treatment regimens for pancreatic cancer using English cancer registry data **Application:** The purpose of the application is for a project, which aims to investigate whether or not English cancer registry data is sufficient for reliably comparing the effectiveness of different cancer treatments given in the NHS. **Outcome of discussion**: The Group noted that the NHS England SIRO had already provided SIRO approval. The Group thank NHS England for the written update and made the following observations on the documentation provided: **5.4.1** The Group noted the NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review. **5.4.2** An NHS England representative noted that individual researchers were named in section 5 (Purpose / Methods / Outputs) of the application, and advised NHS England that these should be removed. The NHS England SIRO representative thanked the Group for their time.	
5.5	**Reference Number:** NIC-656876-L4B0V-v1.2 **Applicant:** University College London (UCL) (Data Controller) **Application Title:** Modelling impact of interruptions to cancer screening with COVID (ODR2021_016) **Application:** The purpose of the application is for a project which aims to estimate what impact delayed cancer diagnosis and delayed treatment; model the impact of disruptions to breast cancer screening and identify strategies that could be used when re-starting screening that minimise any harms resulting from such disruption; and predict the demand for diagnostic, treatment, and screening services.	

	Outcome of discussion: The Group noted that the NHS England SIRO had already provided SIRO approval. The Group thank NHS England for the written update and made the following observations on the documentation provided: **5.5.1** The independent advisers suggested that the NDRS citation special condition be included in section 6 (Special Conditions) of the application. **5.5.2** The independent advisers noted that section 7 (Approval Considerations) of the data sharing agreement (DSA) stated that "*ethics approval is not required because extension not new data*", however the SIRO approval form, provided as part of the supporting documents, stated "*HRA ethics – favourable ethical opinion*" and suggested that this mismatch be corrected in order to provide assurance to the NHS England SIRO representative The NHS England SIRO representative thanked the Group for their time.	
6	Proposal to transition OpenSAFELY from the Health Service (Control of Patient Information) Regulations 2002 (COPI) to NHS England COVID-19 Direction **Presenters:** Dickie Langley, Eva Simmonds, Lorna Branton OpenSAFELY was set up during the COVID-19 pandemic to help with the response. There is a specific COPI Notice in place obliging GP Practices to share data with OpenSAFELY, and this is the only remaining COPI Notice in place, expiring at the end of April 2023. NHS England were seeking early advice from the independent advisers on a proposed approach, any perceived risks, any additional engagement and any other high level observations. **Outcome of discussion:** The independent advisers were broadly supportive of the approach and wished to draw to the attention of NHS England the following high level comments: **6.1** The independent advisers saw a rationale for the proposed legal basis moving from the COPI Notice to the COVID-19 Direction. However, whether a direction is needed to pseudonymise this data within the GP IT supplier systems to enable it to be used for research is unclear. **6.2** The independent advisers noted that communications with the GP Practices was a key consideration, since it was interwoven with both the controllership of the data and public trust. **6.3** The independent advisors noted the proposal to move away from Practices opting in, and noted that this model, alongside an opt out model or no opt out at all, all had advantages and disadvantages. **6.4** The independent advisers specifically noted that a Citizen Jury dialogue had considered how any decision to continue OpenSAFELY should be taken. Jury participants wanted transparency ,with many suggesting review from independent experts and lay people. . **6.5** The independent advisers noted a potential risk that general research could be "covidised" in order to gain access to GP data – and noted that the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had also expressed similar concerns that applicants may add a COVID-19 limb to a long running research study, which was unrelated to COVID-19, and that there was a real risk of scope creep. **6.6** The independent advisers noted that the Data Protection Impact Assessment (DPIA) provided as a supporting document was an old version and would need to be revised accordingly.	

	6.7 The independent advisers noted the proposal that type 1 objections are now applied but took varying views. Such an approach may or may not be in line with the wording of type one objections or what citizens understood when making such objections. A further concern was whether it would hamper the research and compatibility with previous research conducted on the platform. It was suggested that NHSE consult relevant bodies and test the views of citizens before decided on its approach to type one objections here. **6.8** The independent advisers noted that NHS England would be the data controller for this resource, relying on the data powers transferred from NHS Digital. They suggested that access to and oversight of this resource was held to appropriate governance standards, comparable to those in place in respect of data held as a result of the other transferred data functions. The Group welcomed further discussions on the programme at a future AGD meeting.	
AGD Operations		
7	**Standard operating procedures** The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
8	**New Operational Actions & those carried forward from previous meetings of AGD:**	
	Inside Scope of IR35	
8.1	The NHS England representatives noted that NHS England was still considering the issue of IR35 and the impact on independent advisers who were previously on IGARD. **ACTION:** NHS England to provide an update at the 2nd March 2023 meeting.	DL
8.2	**Outstanding IGARD actions** AGD discussed the outstanding actions from the Independent Group Advising on the Release of Data (IGARD), as outlined in the final IGARD minutes from the 26th January 2023. It was agreed that this would be discussed at today's AGD meeting to determine an agreed process for reviewing outstanding actions, and how this could be made transparent to the public, however due to time constraints, the item was not discussed. **ACTION:** the NHS England representatives agreed to discuss the outstanding IGARD actions outside of the meeting, and bring the proposed way forward at the AGD meeting on the 2nd March 2023.	MC
8.3	**Privacy Notice** Michael Chapman had discussed with NHS England colleagues the suggestion that applicants provide a link to their privacy notice in section 4 (Privacy Notice) of data sharing agreements (DSA). **ACTION:** NHS England to have a wider transparency discussion with AGD to discuss applicant privacy notices, the data uses register, internal data use register, process etc (provisional date: 9th March 2023).	AGD VW/KM
8.4	**Annual confirmation report**	

	Michael Chapman asked that this item be scheduled for the 16th March 2023 meeting of AGD in order to allow time to prepare the materials and circulate to AGD in advance (provisional date: 16th March 2023).	VW/KM
8.5	**AGD Terms of Reference (ToR) and statutory guidance** Michael Chapman noted that the Department for Health & Social Care was still receiving comments from various organisations and so the AGD ToR and statutory guidance were still in draft. Michael Chapman also noted that once the finalised version was received by NHS England it would need to go through relevant internal approvals, including the NHS England Board.	To note
8.6	**AGD Webpage** The AGD Secretariat Manager noted that the interim AGD webpages were now live and that minutes of AGD would be published on the webpage, following ratification.	To note
Any Other Business		
9	**Derived Data update in advance of a future application** Suzanne Hartley gave a brief verbal update on a future application and the NHS England work starting on derived data. The independent advisers noted that derived data had been the subject of two discussions at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 4th August 2022 and 22nd September 2022, and were keen that such previous work was considered in the new approach. The Group thanked NHS England for the verbal update.	
10	**NDRS Congenital Anomalies finalised Briefing Paper** The Group noted that the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had requested that the finalised briefing paper be provided to AGD and that it be appended to their minutes. The Group noted that a finalised briefing had been received and was attached at Appendix A, however wished to draw to the attention of NHS England the following observations: **11.1** The Group noted that the briefing paper did not easily distinguish which individuals, adults or children, were covered in the data collection and suggested that NHS England transparency pages clearly articulate whose data was being collected and for what purpose. **11.2** The Group noted that the author had not taken the opportunity to update relevant parties, for example NHS Digital to NHS England. **11.3** The independent advisors noted that section 10, National Data Opt Outs (NDO), was not easy to follow and could be simplified.	
11	**Meeting Closure** As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.	

Appendix A

IGARD BRIEFING PAPER – National Disease Registration Service (NDRS) Congenital Anomalies Data Sets

Information Asset Owner: Sarah Stevens

Briefing prepared by: Fran Hancox

Date: 17/01/2023

Executive Summary

This briefing paper is to inform IGARD of the onboarding of the National Disease Registration Service (NDRS) Congenital Anomaly data products.

The NDRS is split into two disease registers:

- National Cancer Registration and Analysis Service (NCRAS)
- National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

NDRS were formerly managed by Public Health England (PHE) prior to its closure and have now been brought into NHS Digital.

The NDRS data sets within scope of this briefing paper are the two NCARDRS Congenital Anomalies data sets:

- Congenital Anomalies Data Set (national data from 2018 onward)
- Regional Congenital Anomalies Data Set (2015-2017, with data collection led by NCARDRS but only some regions reporting data)

The following NCARDRS Congenital Anomalies data is not yet available to request through DARS:

- Legacy Regional Congenital Anomalies Data Set (pre-2015), which has varying levels of completeness and data quality. The legacy data only exists for some regions across a range of years prior to 2015; it has not yet been onboarded into DARS so it will not be possible for DARS applicants to request this data until further onboarding work has been completed.

1. Data controllers and processors

Following the transfer of functions from Public Health England (PHE) to NHS Digital on 1st October 2021, external providers of the data continue to submit data in the same way as previously. The NDRS systems are currently hosted by the UK Health Security Agency (UKHSA), who act as a Processor on behalf of NHS Digital. A Memorandum of Understanding and a Data Processing Agreement are in place between NHS Digital and UKHSA to set out these arrangements.

Under the Directions, NHS Digital is a joint data controller with the Secretary of State in relation to determining the purposes for which personal data is collected and analysed pursuant to the Directions.

NHS Digital is the sole data controller in relation to determining who data may be shared with and for what purposes and disseminating personal data when exercising its discretionary powers under section 261(5) of the Health and Social Care Act 2012.

Customers will request data via successful application to the Data Access Request Service (DARS) supported by appropriate data sharing agreements and with oversight from the Independent Group Advising on Release of Data (IGARD) where appropriate.

2. Purpose of processing

The National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) collects data on individuals with confirmed, suspected or at high genetic or other risk of congenital anomalies or rare diseases; and relevant family members in England. This includes data pertaining to affected foetuses. Congenital anomalies are structural or functional anomalies present at delivery, originating before birth, and include structural, biochemical, chromosomal and genetic anomalies. In cases of congenital anomalies, details of the mother are also registered.

Data about congenital anomalies is collected in order to help the NHS in England, researchers, charities, people with congenital anomalies and the public understand what is happening with congenital anomaly in this country and to support the wider understanding of these conditions. The data collected will be used to:

- Count the number of people with congenital anomalies in England;
- Conduct surveillance on the type, trends and distribution of congenital anomalies and important risk factors for developing them;
- Describe the outcomes of people with congenital anomalies;
- Describe and evaluate the quality and outcomes and impact of treatment and services for people with congenital anomalies across England and how they can be improved;
- Understand the end-to-end pathway of people with congenital anomalies;
- Work with NHS and other government partners to support and monitor screening programmes for congenital anomalies;
- Carry out research where appropriate ethical approval is in place, and support external research where appropriate legal and ethical approvals are in place, into congenital anomalies and precision medicine including basic science, cause, prevention, diagnostics, treatment, and management;
- Understand the links between risk factors and causes for congenital anomalies;
- Support direct care through evaluation and monitoring of screening programmes and data sharing with clinical networks;
- Improve understanding of genotype-phenotype correlations in congenital anomalies, and personalisation of treatment (precision medicine) in these disorders;
- Understand the impact of COVID-19 on the treatment and outcomes of congenital anomalies;
- Understand the impact of relevant policy interventions such as folate supplementation.

The collection aims to provide the following benefits for patients and the public:

- Provide a resource for clinicians to support high quality clinical practice;
- Support and empower patients, their carers and other family members by providing information relevant to their disease or disorder;
- Provide epidemiology and monitoring of the frequency, nature, causes, and outcomes of these disorders;

- Support ethics approved research into congenital anomalies and precision medicine including basic science, cause, prevention, diagnostics, treatment, and management;
- Inform the planning and commissioning of public health and health and social care provision; and
- Provide a resource to monitor, evaluate and audit health and social care services, including the efficacy and outcomes of screening programmes.

Once a person is registered, the service will continue to receive information about their condition through both notification by data providers and linkage to data sets where available.

Data collection continues up to and includes details of the individual's death. People from other countries receiving a diagnosis, screening and/or treatment for congenital anomaly in England are also registered, though record completeness will vary.

3. Types of processing activities

The data collection covers individuals in England diagnosed, treated, or tested for suspected or confirmed or at high risk of congenital anomaly.

A Congenital Anomalies record is made up of multiple tables of data describing information about the:

- Mother
- Pregnancy
- Anomaly
- Baby
- Clinical tests including diagnostic and screening genetic test information

These tables are created with one-to-many relationships, meaning that for example a baby can have multiple anomalies and test events while a mother can have multiple pregnancies and babies within the data set.

Data is submitted from provider organisations (see Section 6) to the NDRS system hosted by UKHSA, with UKHSA acting as a data processor under the instruction of NHS Digital. The NDRS staff managing the data are employed by NHS Digital.

Releases of data that occurred prior to the closure of PHE on 1 October 2021 can be found on the PHE data release register, including details of the applicants' intended purpose for processing the data: https://www.gov.uk/government/publications/phe-data-release-register

As an interim step, data will continue to be processed by the UKHSA system and NDRS staff following DARS onboarding but applications for the data will be managed by DARS rather than the previous Office for Data Release (ODR) arrangement. As data will not be processed by the typical DARS data production route, it will not yet be possible to link to other DARS data sets until further onboarding work is completed.

The data sets in scope of this briefing paper can be minimised at a field level, with applicants expected to justify their data requirements to ensure that only the minimum data necessary for their purpose is disseminated. This is in addition to the standard row level data minimisation process undertaken during the review of DARS applications.

4. Background and context

The National Disease Registration Service (NDRS) manage the National Cancer Registration and Analysis Service (NCRAS) and the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS).

For these population-based registration services NDRS collect, curate and quality-assure data from every patient in England diagnosed and/or treated with these registerable conditions. NDRS provide expert analysis and interpretation of the data collected, to understand the frequency, nature, cause and outcome often working in partnership with academic and third-sector colleagues. This data is used by NHS clinical teams to help plan and improve treatments and healthcare in England, to assess the quality of care, and to guide local performance management and quality improvement. The data has supported academics with their research and NHS bodies with informing policy decisions.

IGARD have previously been briefed on the NCRAS data sets, and should expect a future briefing on the Rare Diseases aspect of NCARDRS as that does not fall within the scope of this briefing paper.

Following the closure of PHE on 1 October 2021, NDRS transitioned into NHS Digital. Applications for NCARDRS data were previously managed separately by staff in the Office for Data Release (ODR), which is now within the UKHSA. Similarly to the approach taken with NCRAS data sets, requests for data will now begin to instead be handled by the standard DARS application process.

5. The nature and type of data

a) Congenital Anomalies Data Set (national data)

National data for the whole of England is available for babies born from 1st January 2018 onwards. The data set contains details of the mother, baby, pregnancy, congenital anomaly, and genetic tests; it contains identifiable fields such as names, NHS numbers and dates of birth but the data set can alternatively be provided in pseudonymised form without these identifiers.

The data collection covers individuals in England diagnosed, treated, or tested for suspected or confirmed or at high risk of congenital anomaly. For babies with a congenital anomaly, some details of the mother are also collected. As of January 2023, this means that the cohort size is approximately 160,000 infants and 240,000 adult records, with approximately 25,000 to 30,000 new records added each year. Individuals' data will continue to be held within the register indefinitely unless an individual (or their parent / representative) makes a request via the NCARDRS Opt-Out to be removed, in which case data is deleted from the register.

b) Regional Congenital Anomalies Data Set (2015-2017)

Prior to 1st January 2018, some data is available depending on the region of the country and whether data collection was ongoing before the formation of NCARDRS on 1st April 2015. Requests for historic regional data are expected to require additional discussion with NDRS to agree requirements, as there are data quality limitations with the available data.

Region:	**Babies with a date of delivery between:**

Thames Valley	1st Jan 2015- 31st Dec 2020
Wessex	
South West	
North East	
East Midlands & South Yorkshire	1st Jan 2016- 31st Dec 2020
Yorkshire & Humber	
West Midlands	
London and SE	1st Jan 2018 - 31st Dec 2020
East of England	
North West	

In some regions, legacy data was collected by historic registers prior to 2015. This legacy data is not yet available to request through DARS.

6. Data flows

Most of the data collected comes from NHS healthcare settings but may also include data from private healthcare providers (for NHS commissioned services alongside that of private patients.)

Congenital anomaly data is collected by NCARDRS from a range of sources including maternity units, multidisciplinary team meetings, post-mortem reports, molecular testing results, treatment records, national data sets describing hospital activity, hospital trusts' patient administration systems, clinical data systems and biochemistry and genetic laboratories. Hospital trusts submit data which are processed and combined by trained registration officers into a comprehensive clinical record of each baby and anomaly. Detailed clinical and demographic information describing the mother, baby, anomaly and pregnancy are recorded.

The submitted data is reviewed by skilled registration officers with the assistance of some automated tools for data linkage and de-duplication of identical data sources. Processing of the data may include manual extraction of clinical information from scan reports, post-mortem reports, clinical letters or free text comments in clinical software systems. Registration officers require detailed knowledge of congenital anomalies, clinical coding and clinical pathways for the range of different conditions collected. The data are clinically coded using the International Classification of Diseases version 10 (ICD-10), adding the British Paediatric Association (BPA) 5th digit extension. As data can be received from different sources, inconsistencies can be identified, and these are resolved during the registration process. Registration officers will examine all data sources, review missing data and incomplete records and can seek additional information either by requesting this from the relevant clinician or, where agreed with the relevant provider of the data, by direct interrogation of patient records via secure

remote access to clinical software systems or clinical documents in accordance with a data processing agreement with the relevant data controller.

Currently, congenital anomaly registration is complete within approximately 2 years of a baby's expected date of delivery; this allows further information to flow in from multiple sources of antenatal and postnatal notification. For example, registration of data for babies with an expected due date between January and December 2020 was completed in August 2022.

7. All actors involved

NHS Digital are the sole data controller for these data sets in relation to determining who data may be shared with and for what purposes.

Data is processed by the UKHSA following the closure of PHE, as the UKHSA hosts the NDRS technical system; this is intended to change at some point in the future with data processing instead being taken on by NHS Digital, but details of this are not yet confirmed. A data processing agreement is in place between NHS Digital and UKHSA. There are no other funding bodies or other key actors involved in the data flow.

8. The legal bases for the requirement

Prior to 1st October 2021, the disease registries maintained by NDRS were collected and processed by PHE under section 2B of the National Health Service Act 2006 and Regulations 2 and 5 of the Health Services (Control of Patient Information) Regulations 2002 (COPI).

The Health and Social Care Act 2012 (HSCA 2012) makes two specific provisions the flow of data through NHS Digital:

1. Section 254 – In order to establish and operate a system for the collection or analysis of information the Secretary of State, or devolved authority, must provide to NHS Digital a description of the requirement in the form of a Direction.
2. Section 259 – In order to require and request the provision of information from any health or social care body; or any person (other than a public body) who provides health services, or adult social care in England, NHS Digital must publish a procedure for notifying persons of requirements imposed, and requests made.

With respect to section 254, NHS Digital has been Directed by the Secretary of State to establish and operate a system for the collection and analysis of congenital anomaly registration data. A link to the published Direction is here: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/national-disease-register-service-directions The technical requirements specification, which includes more details of the included data sets, can also be found on the same webpage.

9. The legal bases for the processing

The UK GDPR Article 6 lawful basis for the processing (collecting, analysing or disseminating) of the personal data within this collection falls under:

- Article 6(1)(c) the processing is necessary for compliance with a legal obligation to which the controller is subject (in this case, the Direction).

The conditions which apply to NHS Digital's processing (collecting, analysing or disseminating) of special categories of personal data are:

- UK GDPR Article 9(2)(g) - processing is necessary for reasons of substantial public interest, on the basis of domestic law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject, supplemented by:
    - Data Protection Act 2018 Schedule 1, Part 2, paragraph 6: Statutory etc and government purposes.
- UK GDPR Article 9(2)(h) - processing is necessary for the… management of health or social care systems and services, supplemented by:
    - Data Protection Act 2018 Schedule 1, Part 1, paragraph 2: Health or social care purposes.
- UK GDPR Article 9(2)(i) - processing is necessary for reasons of public interest in the area of public health, supplemented by:
    - Data Protection Act 2018 Schedule 1, Part 1, paragraph 3: Public interest purposes.
- UK GDPR Article 9(2)(j) - processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1), supplemented by:
    - Data Protection Act 2018 Schedule 1, Part 1, paragraph 4: Research etc purposes.

Which Article 9 subsection applies will depend on the organisation with whom data is being shared and how they plan to use it. Examples include that data processed to share with an academic organisation carrying out health research would be expected to fall within Article 9(2)(j), while data processed to share with a national health body for planning and commissioning purposes would be expected to fall within Article 9(2)(h) or Article 9(2)(i) depending on the details of the specific request and intended purpose.

The common law duty of confidentiality is met when NHS Digital collects and analyses confidential patient information for NCARDRS because compliance with a legal obligation (the Directions) provides a defence to a breach of confidence claim. Where NHS Digital proposes to disseminate confidential patient data, the recipient must have a lawful basis under the common law to receive such information, such as:

- explicit informed patient consent; or
- specific section 251 approval from the Confidentiality Advisory Group to access confidential patient information without consent; or
- a legal obligation that requires confidential patient information to be shared without consent, e.g. a Court Order or regulation 3 of the Health Service (Control of Patient Information) Regulations 2002.

The recipient's lawful basis to receive confidential data will be established as part of the standard Data Access Request Service (DARS) application process.

10. Transparency requirements

A transparency notice has been published on the NHS Digital website: https://digital.nhs.uk/services/national-disease-registration-service/transparency-notice

A Data Provision Notice has also been published: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/data-provision-notices-dpns/national-disease-registration-service

NDRS has taken steps to try and ensure that all individuals within scope of NCARDRS are made aware of their right to object to their personal information being processed for registration purposes, and all opt-out requests received (via the NDRS opt out described at the end of this section) are honoured.

NDRS has a range of patient privacy information resources about NCARDRS and is transparent about why it needs to process personal data. NDRS raises awareness of its aims and activities among patients and the public, in various ways including:

- The NCARDRS leaflet and poster is provided to all NHS settings from which NCARDRS directly receives notifications. The materials were developed in conjunction with patient groups at the outset of the service. NCARDRS ensures the materials are used when communicating with NHS colleagues in these settings.
- The leaflet Screening Tests for You and Your Baby, contains information about NCARDRS and the right to opt out and is given to every expectant mother at their booking appointment. Just under 1 million copies of this leaflet are sent out each year.
- Multiple NHS.UK webpages relating to congenital anomalies contain information about NCARDRS and the right to opt out. For example: https://www.nhs.uk/conditions/phenylketonuria/
- Information on the NDRS website: https://www.ndrs.nhs.uk/
- Patient and public awareness events.

Patient and public information resources have been updated to communicate that congenital anomalies data is still collected by NCARDRS but is now within NHS Digital rather than PHE.

Any dissemination of the data will be published in the NHS Digital Data Uses Register at: https://digital.nhs.uk/services/data-access-request-service-dars/register-of-approved-data-releases#view-the-most-recent-publications

National Data Opt-Outs do not apply to the flow of NDRS data (including NCARDRS) into NHS Digital, as this data is collected under Direction, but the National Data Opt-Outs can be applied at the point where data is disseminated from NHS Digital to a DARS data recipient. If an individual opts out under the National Data Opt-Out then their data is not destroyed, but in line with established DARS policy the records of individuals who opted out will be removed prior to data dissemination in some circumstance. National Data Opt-Outs will apply to this data set in line with standard DARS practice. Further information on the National Data Opt-out can be found here: https://digital.nhs.uk/services/national-data-opt-out/operational-policy-guidance-documentIn addition to the National Data Opt-out, there is the option for individuals to opt out of NDRS specifically. If individuals do not want their data to be used by the NDRS, they can opt out and their data will be deleted from the relevant register

(cancer, congenital anomalies, or rare diseases). This means that data for individuals who have opted out directly through NDRS will not be included in the data from the relevant register made available through DARS, as data about them will have been deleted.

11. Other requirements

There are no further requirements.

12. Data Retention

The Collected Data shall be subject to the NHS Digital Records Management Policy which requires retention periods to be set and reviewed by Asset Owners to prevent personal data being retained for longer than considered necessary. DARS applicants will be expected to follow requirements for data retention as set out within the terms of their data sharing agreements.

If an individual's data has been collected in the registry and they subsequently opt-out of their personal data being included, information about them is deleted from the registry. An encoded version of the individual's NHS number is added to an exclusion list to stop any new data about them from being registered again. This is a policy decision in relation to NCARDRS rather than a right under UK GDPR.

13. Permitted dissemination of the data

All requests for data will be managed through the DARS Applications and Approvals route. Data dissemination will be managed by NDRS staff within NHS Digital, in collaboration with DARS, once a Data Sharing Agreement has been approved.

Further work is planned to enable data production and dissemination using established DARS processes, which is intended to enable linkage to other NHS Digital data sets.

14. Restrictions on processing

There are no specific restrictions on the processing of this data beyond the requirements of the standard DARS applications process.