Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 15 April 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS)
Belinda Garrow	Data Access Request Service (DARS)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 1, 3.1 - 3.4)
Karen Myers	IGARD Secretariat
Dr. Peter Short	Clinical Informatics
Charlotte Skinner	Data Access Request Service (DARS)
Jas Uppal	Data Access Request Service (DARS) (Observer: item 1, 3.1 - 3.2)
Gemma Walker	Data Access Request Service (DARS) (Observer: item 1, 3.1 - 3.2)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Paul Affleck noted professional links to the University of Leeds [NIC-109867-M8S6B] but no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. Dr. Maurice Smith noted that in his role as a GP partner at Mather Avenue Surgery, Liverpool he had a conflict of interest with the GP Data for Planning & Research (beta) Briefing Paper (item 2.1), however it was agreed this did not preclude Dr. Smith from taking part in the discussions about this briefing paper. **Review of previous minutes and actions:** The minutes of the 25th March 2021 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Papers**

2.1	<u>GP Data for Planning & Research (beta) Briefing Paper v0.4 (Presenter: Dr. Peter Short)</u>
	
	The briefing paper was to inform IGARD about GP Data for Planning & Research (also referred to as GP Data), the pilot version of this data set is due to be released shortly. GP Data will initially run in parallel, but eventually it will replace the GPES Data for Pandemic Planning and Research (GDPPR) data set.
	
	The processing of standard GP data is required to meet the aims of the GP Data for Planning & Research service, which are:
	
	• strategic replacement of the GP Extraction Service (GPES);
	• supporting the strategic priorities of NHS Digital in respect of data, including:
	  ○ modernising the information analytics approach to harness benefits of greater automation and ensure improved data quality;
	  ○ work to support effective use of data in the health and care system;
	• reducing the burden of data management for GPs;
	• incurring potential cost savings in data access for commissioners and researchers.
	
	IGARD was advised it is planned that NHS Digital will be directed by the Secretary of State under section 254 of the Health and Social Care Act 2012 under the General Practice Data for Planning and Research Directions to establish and operate a system for the collection and analysis of the information specified within the Directions.
	
	IGARD queried the statement within section 1 of the briefing paper, that NHS Digital would be the *"sole"* Data Controller, noting that elsewhere in the paper it stated that NHS Digital would be joint Data Controllers with the Secretary of State; and asked that the paper was reviewed and updated with further clarification of who the joint Data Controller was, for example, the Department for Health and Social Care.
	
	In addition, IGARD noted that processing of the GP data would be done in accordance with the Direction, which was due to be published the week commencing the 19th April 2021, and that in order to comply with the Direction, the relevant Data Controller(s) would be responsible for the collection and processing of the data.

	IGARD queried the purpose of the processing, and advised that the paper was not clear on this point, and asked that the paper was amended to include further details including specific examples of the benefits to both GPs and patients, for example, how this would improve the quality of care for patients. IGARD noted the statement within the paper that *"Data will only be re-identified for approved specific uses…"* , and asked that for transparency further information was provided of examples of where re-identification might occur. IGARD queried the statement that only structured and clinically coded data would be collected, for example *"free text"*, and asked that further clarification was provided as to whether this free text would contain any personal data. IGARD noted that the National Data Opt-out would not be applied due to the data being processed under a legal obligation, and queried if this was correct, given other similar flows of data where legal gateway was used for the processing; and asked that further clarification was sought from NHS Digital's Privacy, Transparency and Ethics (PTE) (formerly Information Governance). IGARD welcomed the draft and looked forward to receiving the updated briefing paper along with the full suite of documentation, either out of committee or at a future meeting. IGARD made the following high level suggestions: 1. To clarify who the joint Data Controller is, for example, the Department of Health and Social Care. 2. To note that the joint Data Controllers are responsible throughout the collection and processing of the data. 3. To update the briefing note throughout in line with the minor clarificatory points raised in verbal discussion, for example; detailing the purpose for processing, noting that data will only be reidentified for specific uses, clarification with regard to free text fields, operation of National Data Opt-outs.
2.2	<u>Patient-level medicines data from Electronic Prescribing and Medicines Administration (EPMA) systems in Secondary Care (England) for COVID-19</u> The briefing paper was to inform IGARD about the latest product onboarded to the Data Access Request Service (DARS) to support the response to the COVID-19 pandemic, the EPMA. This is a part of the wider programme of work which will see a roll out of the medicine data collection and dissemination across both primary and secondary care. This data set is required to support the response to COVID-19. Data from EPMA systems pertaining to medicines prescribed and administered can: • support identification of patients who might be at higher risk of morbidity or mortality if they contract COVID-19 • understand any patterns of prescribing as a result of COVID-19 compared with patterns pre-COVID-19 NHS Digital has been directed by the Secretary of State for Health and Social Care under s254 of the Health and Social Care Act 2012 by virtue of the COVID-19 Public Health Directions 2020 to establish and operate information systems to collect and analyse data in connection with COVID-19.

	IGARD noted that this briefing paper had been reviewed by members out of committee, and comments had been shared (via the IGARD Secretariat) with the presenters on the 5th March 2021. IGARD welcomed the briefing paper and made no further comments. IGARD looked forward to receiving the finalised briefing paper as a supporting document, alongside a first of type application.
3	**Data Applications**
3.1	University of Leeds: UK Women's Cohort Study (UKWCS)-HES new database (Presenter: Dave Cronin) NIC-109867-M8S6B-v1.4 **Application:** This was an amendment application to the existing Data Sharing Agreement (DSA), to 1) permit the University of Leeds to deposit a subset of their UKWCS dataset including variables derived from NHS Digital data in the Consumer Data Research Centre (CDRC) so that external researchers can, subject to an independent approval process, access and use the data within the CDRC for the purposes of their own research projects; 2) to permit the University of Leeds to share a defined subset of their UKWCS dataset including variables derived from NHS Digital data with a researcher at the University of Oxford for the purpose of a specific project; 3) to permit the University of Leeds to retain the full UKWCS data, including the linked NHS Digital data at the University of Leeds for use, when required, in research projects/analyses undertaken by members of the University of Leeds under the control, and subject to the approval of, the UKCWS Principal Investigator. The purpose is for a study of women, to explore links between diet, lifestyle and chronic disease, in particular cancer. The objective is to create a new database to support analysis of a number of key research questions so that links can be explored between diet, lifestyle and health outcomes and to create a unique research data set for the UK. The cohort of patients for the study is limited to 34,312 within the UKWCS database; and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD welcomed the application and noted the interesting and valuable research, and commended the applicant for the transparency of the research within the public domain. IGARD noted that supporting document 3.2, the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 letter of support, dated the 2nd February 2018, referred to a condition (3a), in respect of the Patient and Public Involvement (PPI), that stated the applicant must *"Provide a detailed plan for public and patient involvement and engagement activity which will be undertaken as the project progresses."*, by the time of the first annual review. Noting that the initial HRA CAG was provided on the 23rd June 2017, in light of the time-bound condition set by HRA CAG, and that there was no evidence of the report having been produced, IGARD asked that written confirmation was provided, that s251 HRA CAG support was continuing; and that this written confirmation was also uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted one of the amendments to the application, specifically that the University of Leeds would provide a derived subset of UKWCS data to a researcher at the University of Oxford, and queried how the applicant would ensure that the flow of data would be reviewed in order to satisfy condition 3a of the HRA CAG condition of support, in terms of public and patient involvement and engagement as the projected progressed; and asked that written confirmation of this was provided.

	IGARD queried the references within the application to the Principal Investigator and Senior Management Team (SMT) approval with regard to the Consumer Data Research Centre (CDRC) applications, and asked that the application was updated throughout, to ensure that the references were amended to reflect condition 3a of the s251 HRA CAG conditions of support, namely, how the independent review aspect of the HRA CAG condition would be satisfied, for example, through a formal committee review or other process with lay involvement. IGARD queried the references within the application to the proposed variables being *"sufficiently derived"*, and noting that the meaning of this was not clear, asked that the application was updated throughout to further define the references and to be clear that the data would no longer be identifiable as the data that has been supplied by NHS Digital. IGARD noted a reference in section 5 (Purpose / Methods / Outputs) to a supporting document, and asked that this public facing section be updated to provide a web link, further details or to remove the reference. IGARD queried the statement in section 5 that *"Middle-class people generally have healthier diets than lower-class people"*, and asked that this was amended to more appropriately refer to *"socioeconomic groups"*. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the HRA CAG support: a) To provide written confirmation that s251 HRA CAG support is continuing, in light of the time-bound condition 3(a) noted in the HRA CAG letter of support. b) To upload the written confirmation to NHS Digital's CRM system. 2. In respect of the sharing of the subset of the UKWSC dataset with the University of Oxford, to provide written confirmation of how the applicant will ensure that the flow of data will be reviewed so as to satisfy condition 3(a) set by HRA CAG. The following amendments were requested: 1. To update the application throughout to further define the references to *"sufficiently derived"* to be clear that the data would no longer be identifiable as the data that has been supplied by NHS Digital. . 2. To update the application throughout, to ensure that where there is reference to the Principal Investigator and SMT approval with regard to the CDRC applications, those references are amended to reflect para 3a of the HRA CAG conditions of support. Namely, how the independent review aspect of the HRA CAG condition will be satisfied, for example, through a formal committee review or other process which involves lay involvement. 3. To update the references to supporting documents in section 5, to either remove or add a relevant web link. 4. To amend the reference to *"lower"* and *"middle"* class people in section 5 to socioeconomic groups. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	North West EHealth Limited: Retrospective data analysis of HES and DID data from patients with Refractory Chronic Cough (RCC) who have given consent for their electronic healthcare records to be used in the analysis of healthcare resource utilisation. (Presenter: Dave Cronin) NIC-290527-P5C0Y-v1.3

	Application: This was an extension and renewal application for identifiable Diagnostic Imaging Dataset (DIDs), Hospital Episodes Statistics (HES) Admitted Patient Care (APC) and HES Outpatients data. The purpose is for a feasibility study aiming to increase the understanding of the profile and characteristics of patients with unexplained Refractory Chronic Cough (RCC) by understanding the healthcare resource utilisation (HRU) and treatment patterns of these patients. The primary objective of the initial work is: To determine the outpatient and primary care healthcare costs in the 5-years prior to a diagnosis of RCC, compared to a control cohort, matched by demographics and smoking status. This application is limited to patients who have consented, and the estimated size of the cohort is approximately 200 patients. **Discussion:** IGARD noted that the joint Data Controller Merck Sharp & Dohme Limited, had published a statement on their website on the 1st March 2021, confirming that the U.S. Food and Drug Administration (FDA) has accepted for review, the company's New Drug Application (NDA) for Gefapixant, an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough (RCC) or unexplained chronic cough (UCC) in adults. Noting that there was no reference to this within the application, IGARD asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated to clearly outline Merck Sharp & Dohme Limited and the applicant's involvement in the development of the drug, and any potential benefits of that drug for patients with RCC. In addition, IGARD asked that in light of the advanced stage of Merck Sharp & Dohme Limited's development of the RCC drug, that the application was reviewed throughout, to ensure it was not solely for a commercial purpose and to establish clear benefits to patients and / or the NHS generally. IGARD queried the statement in section 5(e) (Is the Purpose of this Application in Anyway Commercial) *"This study is an initial analysis to see if it is even worth MSD focusing their research on RCC."*, and asked that this was removed, since there was also a subsequent commercial benefit to reach that conclusion and avoid investing future money. IGARD noted the benefits that were outlined in section 5(d) (Benefits), however asked that this was updated further, to clearly highlight, that **not** proceeding with further research, may be a disbenefit to individual patients, but may benefit the wider health community, due to funds being deployed to other areas. IGARD drew to the attention of NHS Digital, the specific requirement in the consent materials, that the data would only flow from 5 years before and 2 years after the date of diagnosis, and to ensure that the NHS Digital data flow was in accordance with the express consent given by participants. In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions), that the applicant must **only** hold data in accordance with the specific consent provided, namely, 5 years before and 2 years after the date of diagnosis. IGARD noted a number of references in section 5(a) (Objective for Processing) and section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care Including Target Date) to patients *"languishing"* in the health system, and suggested an alternative, less emotive term be used such as "remain".

	IGARD queried the information in section 5(a) and section 5(d) that compared RRC to Chronic Obstructive Pulmonary Disease (COPD); and asked that these were removed as it was not an appropriate direct comparator. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the speculative and commercial nature of the application; and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve the flow of data, in accordance with the timeframes set out within the patient consent materials. The following amendments were requested: 1. To update section 5 to clearly outline Merck Sharp & Dohme Limited and the applicant's involvement in the development of the P2X3 receptor antagonist drug Gefapixant, and the potential benefits of that drug for patients with RCC. 2. To remove the reference in section 5(e) to *"…initial analysis to even see if its worth MSD focusing their research on RCC…."*, since there is also a subsequent commercial benefit to reach that conclusion and avoid investing future money. 3. In light of the advanced stage of Merck Sharp & Dohme Limited development of the RCC drug, to review the application to ensure it is not solely for a commercial purpose and to establish clear benefits to patients and/or the NHS generally. 4. To update section 5(d) that not proceeding may be a disbenefit to individual patients, but may benefit the wider health community, because funds can be deployed to other areas. 5. To insert a special condition in section 6, that the applicant must only hold data in accordance with the specific consent provided, namely, 5 years before and 2 years after diagnosis. 6. To update section 5(a) and section 5(d) (ii) to remove reference to patients *"languishing"* in the health system. 7. To update section 5(a) and section 5(d) to remove reference the direct comparison with COPD as its not an appropriate direct comparator. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the speculative and commercial nature of the application. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. 3. IGARD drew to the attention of NHS Digital, the specific requirement in the consent materials, that the data would only flow from 5 years before and 2 years after the date of diagnosis, and to ensure that the data flow is in accordance with the express consent given by participants.
3.3	<u>UK Haemophilia Centre Doctors' Organisation (UKHCDO): National Haemophilia Database (NHD) (Presenter: Dave Cronin) NIC-148030-Q5N4D-v3.6</u> **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS Cohort Event Notification Report, MRIS Flagging Current Status Report, MRIS Members and Postings Report, and Civil Registration (Deaths) data.

	The National Haemophilia Database (NHD) is a registry of more than 30,000 patients with bleeding disorders registered since 1968, and has monitored treatment trends and morbidity and mortality associated with bleeding disorders and changes in life expectancy. The UKHCDO requires data for the purposes of maintaining the NHD and using that database for both research and non-research purposes. The cohort of patients for the study is limited to 31,387 within the UKWCS database; and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital data for this database was previously issued under various iterations of another Data Sharing Agreement (DSA), which expired in November 2020, however due to the expiry of the DSA, and significant changes that needed making to the application, this has been submitted as a *"new"* application. NHS Digital advised IGARD that discussions had taken place with the applicant's Data Protection Officer (DPO), where it had been agreed that the consent materials needed to be revised; and confirmed that s251 support had been received from the Health Research Authority Confidentiality Advisory Group (HRA CAG) for the majority of the cohort, with the exception of approximately 2,000 cohort members. NHS Digital also advised IGARD that following submission of the application and supporting documents for review, they had received additional information from the applicant, in respect of the commercial element, and advised that section 5(e) (Is the Purpose of this Application in Anyway Commercial) would need updating further to reflect the latest information and to ensure that it complied with NHS Digital's DARS Commercial Purpose Standard. **Discussion:** IGARD noted the verbal update from NHS Digital in respect of the incompatibility of the historical consent materials, and the confirmation that s251 support that had been sought from HRA CAG for the majority of the cohort members. IGARD also noted the verbal update from NHS Digital in respect of additional information that had been provided by the applicant in respect of the commercial element, and supported the update to section 5(e) to reflect the latest information. IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that if s251 was **not** relied on as a legal basis, that section 1 (Abstract) was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD noted the involvement of NHS England and Manchester University NHS Foundation Trust within the application, and queried if consideration had been given to both of those organisations being considered as joint Data Controllers; and were advised by NHS Digital that discussions had taken place with the applicant, who had confirmed that it was their view, that UKHCDO were the sole Data Controllers. IGARD noted the confirmation from NHS Digital, however, in light of public interest and scrutiny on this issue, asked that confirmation was provided, in terms of the UK General Data Protection Regulation (UK GDPR) and NHS Digital's DARS Standard on Data Controllers, as to why NHS England were **not** considered a joint Data Controller, particularly in light of its commissioning role.

	In addition, IGARD also asked that confirmation was provided in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers, as to why UKHCDO ***Ltd*** were **not** considered a Data Controller. IGARD also asked that depending on the outcome of the ongoing data controllership discussions, that the application was updated throughout, as may be required, to reflect the factual scenario. IGARD noted the involvement of Greater Manchester Shared Services (Hosted by NHS Oldham CCG) and Medical Data Solutions and Services Ltd, and queried if either or both of those organisations should be considered joint Data Processors; and asked that written confirmation was provided, noting NHS Digital's DARS Standard on Data Processors. IGARD also asked that depending on the outcome of the Data Processor discussions, that the application was updated throughout, as may be required, to reflect the factual scenario. IGARD noted the reference in section 5 (Purpose / Methods / Outputs) to *"direct patient care"* and asked that this was removed and replaced with a more accurate term, for example, *"management of patient care"* or similar. IGARD queried the references in section 1, section 5(a) (Objective for Processing) and section 5(b) (Processing Activities), to the Central Manchester Healthcare Foundation Trust (CMFT) Caldicott Guardian inspecting the registry / database, and asked that the references were removed otherwise it may suggest that an external party was inspecting the data, which was not what was happening in this case. In addition, IGARD also noted the references in in section 1 and section 5(a) to adherence with the Caldicott Guardian principles, and asked that they were removed since their inclusion was incorrect, and to instead, correctly refer to the Hospital Episodes Statistics (HES) analysis guidelines. IGARD noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, for example, *"Poisson regression",* and that consideration was given to the public audience of NHS Digital's data release register. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the public scrutiny that has been given to the controllership and operation of this dataset; and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve for 1 year subject to the following condition: 1. In respect of the data controllership: a) To provide satisfactory confirmation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why NHS England are **not** considered joint Data Controllers, particularly in light of materials in the public domain which indicate that NHS England may be considered a Data Controller for this dataset. b) To provide confirmation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why UKHCDO Ltd are **not** considered joint Data Controllers. c) To update the application throughout, as may be required, to reflect the factual scenario. The following amendments were requested: 1. In respect of the Data Processor:

	a) To provide confirmation if NHS Greater Manchester Shared Services should be considered a joint Data Processor (in terms of NHS Digital's DARS Standard on Data Processors). b) To update the application throughout, as may be required, to reflect the factual scenario. 2. To update section 5 to remove reference to *"direct patient care"*, and replace with *"management of patient care"* or similar. 3. To update section 1, section 5(a) and section 5(b) to remove reference to CMFT Caldicott Guardian inspecting the registry / database. 4. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the public audience of NHS Digital's data release register (for example when referring to *"Poisson regression"*). 5. To remove reference in section 1 and section 5(a) to adherence with the Caldicott Guardian principles and instead refer to the HES analysis guidelines. 6. To amend section 5(e) as per the verbal update from NHS Digital, and in line with the NHS Digital DARS Standard for Commercial Purpose. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the public scrutiny that has been given to the controllership and operation of this dataset. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.4	University of Manchester: MR559 - The Norfolk Arthritis Register (NOAR) (Presenter: Dave Cronin) NIC-147811-YTH88-v3.6 **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS Cohort Event Notification Report, MRIS Flagging Current Status Report and MRIS Members and Postings Report. The Norfolk Arthritis Register (NOAR) is a large community-based study investigating the cause and outcome of inflammatory polyarthritis, with the purpose of studying the natural history of arthritis and to identify genetic and non-genetic factors which may be related to the onset of arthritis, response to treatment, and to long-term outcome. In addition, the study is also interested in learning more about the effects which arthritis may have on other medical conditions. The cohort of patients for the study is currently limited to 4,481. NHS Digital data for this database was previously issued under various iterations of this Data Sharing Agreement (DSA) and another DSA (NIC-333021-B6W2C), which both expired in February 2021. Both applications were given interim extensions, permitting retention but no other reuse of the data, and to support the progression of this application, this had been submitted to IGARD for advice on a number of ongoing issues, including (but not limited to) the consent materials, the proposed legal basis, and the proposed processing. **Discussion:** IGARD welcomed the application which came for advice on the consent materials, the proposed legal basis, and the proposed processing, and without prejudice to any additional issues that may arise when the application is fully reviewed.

	In respect of the consent materials, IGARD noted the references within the materials to *"completing a study"*, and queried what this was referring to, in light of the fact that the data requested was for a database and suggested the wording was updated appropriately. In respect of the objective for processing, IGARD noted that section 5(a) (Objective for Processing) contained a good introduction to the registry, however suggested that this was updated further to include additional detail outlining why the registry was required, and to make it clear that it was a research register and **not** a project or a programme. IGARD noted the 5-year cohort and queried if this was the applicant's methodology going forward, and were advised by NHS Digital that this model had been agreed with the Research Ethics Committee (REC), and would engage with cohort members on anniversaries etc, and would see more regularly when attending clinics. IGARD noted the verbal update from NHS Digital in respect of the 5-year cohort, and suggested that the consent materials were uplifted to reflect this information. In respect of the s251 support, IGARD noted Health Research Authority Confidentiality Advisory Group (HRA CAG) had provided s251 support for the HES data only, however, a query had been raised as to whether this should also be sought for the death data, and for those who had not re-consented; NHS Digital advised that there was ongoing communication with HRA CAG on this issue. IGARD noted the verbal update from NHS Digital in respect of the ongoing dialogue with HRA CAG, however agreed with NHS Digital's assessment that s251 should be sought. IGARD advised that they had no comments to make on the purpose for processing, data minimisation and the proposals for onward sharing of data. **Outcome:** IGARD welcomed the application which came for advice on the consent materials, the proposed legal basis, and the proposed processing, and without prejudice to any additional issues that may arise when the application is fully reviewed.
3.5	<u>University of Exeter: Tracking the impact of Covid-19 on the mental health of children, young people and families; follow up of a national longitudinal probability sample: follow-on interviews (Presenter: Charlotte Skinner) NIC-402080-N3V5Z-v0.5</u> **Application:** This was a new application for an identifiable subset of Mental Health of Children and Young People (MHCYP) 2020 survey participants; for the purpose of inviting participants to take part in a follow-up research interview study. The follow-up study forms part of a wider project called *"Tracking the impact of Covid-19 on the mental health of children, young people and families; follow up of a national longitudinal probability sample"*; and the follow-up interviews are referred to as the RESHAPE study (**RE**flecting on the impact**S** of covid-19 on c**H**ildren **A**nd young **P**eople in **E**ngland: exploring experiences of lockdown, service access and education) as this is more accessible for participants. The main aims of RESHAPE are 1) to explore the experiences of children, young people and parents of lockdown during the pandemic and the impact of school closures on children, young people and their families; and 2) to examine mental health related service contacts in children and young people, both pre-pandemic and during the pandemic, and to explore the barriers and facilitators to seeking and receiving help. This application is limited to the parents of children / young people themselves, aged 5-22 who have previously consented to be contacted for further research in the survey and the estimated size of the cohort is approximately 600 – 1,000 patients.

	Discussion: IGARD noted that following receipt of the application and supporting documents for review, additional information had been sent through from the applicant in respect of how individuals would be contacted for follow-up review. IGARD thanked the applicant for their careful consideration of this issue, and for taking the time to clearly outline the proposed process. IGARD suggested that future iterations of the transparency materials could be updated to be clearer that the invitation to take part in the research may come **direct** from the researcher and not from a named party. IGARD noted that the information in section 5 (Purpose / Methods / Outputs), appeared to suggest that the NHS Digital data would flow prior to any review to see who was eligible to participate in the follow-up study; and were advised by NHS Digital, that this was not correct, and the current wording could be open to misinterpretation. IGARD noted the verbal update from NHS Digital, and asked that section 5 was updated, to ensure that only the minimum amount of data was flowing between the parties in order to generate the contact list, and in line with NHS Digital's DARS Standard for Data Minimisation. IGARD suggested that section 5(d) (Benefits) be updated to remove references to "*it will*…" and instead use a form of words such as "*it is hoped*…" **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to ensure that the minimum amount of data is flowing between the parties in order to generate the contact list, and in line with NHS Digital's DARS Standard for Data Minimisation. 2. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…". The following advice was given: 1. IGARD suggested that future iterations of the transparency materials could be clearer that the invitation to take part in the research may come direct from the researcher and not from a named party.
3.6	NHS Birmingham & Solihull CCG: DSfC - NHS Birmingham and Solihull CCG - IV, RS, Comm (GP Beta) (Presenter: Dan Goodwin / Michael Ball) NIC-186883-L6C8Y-v8.2 **Application:** This was an amendment application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Diagnostic Imaging Data Set (DIDS), Community Services Dataset (CSDS), National Cancer Waiting Times Dataset (NCWT), Civil Registries Data (CRD) (Births and Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and GP Data (Beta). This application was previously presented as part of a Class Action (NIC-281239-V4X7H) for NHS Midlands and Lancashire CSU and recommended for approval on the 28th March 2019. The overall purpose is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for

	identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care, and to provide intelligence to support the commissioning of health services. **Discussion:** IGARD welcomed the first of type application which came for advice, and without prejudice to any additional issues that may arise when the transparency materials and Direction are finalised, and the application can be fully reviewed. IGARD noted the processing taking place for the NHSBSA data, and reiterated advice given on other applications requesting this data, that the processing must be strictly within the scope of use set out in the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019, relating to this data collection and dissemination. IGARD noted the statements within the application that, in respect of the flows of GP data, that this would be flowing directly from GP Practices, and asked that these references were clearly highlighted and distinguished from the GP beta data flows. In addition, IGARD also asked that it was made clear within the application that there would be a period of overlap between the GP beta data as well as existing GP data flows. IGARD noted that Section 5(a) (Objective for Processing) did not reference the GP beta data set until mid-way through the section, and suggested that the beginning of section 5(a) was updated with a specific reference to the GP beta data, and to highlight where it overlapped with existing data flows, what was new or additional from the addition of the GP beta data, and the objective for processing in respect of the GP beta plan. IGARD also suggested that section 5 (Purpose / Methods / Outputs) was updated throughout, to ensure that where the GP beta flow of data was referred to, that it was explicitly clear as to what the aims and objectives were. In addition, that the criteria was outlined for understanding whether or not the GP beta programme was a success, for example, outlining specific outputs and benefits. IGARD noted that the privacy notices for the GP data had **not** been published, and advised that it was essential that there was transparency, and noted that the NHS Digital and GP Practice privacy notices would need to be live, and before any data flowed, this was also confirmed as a requirement by NHS Digital. IGARD queried the references to *"individual patients"* when referring to Risk Stratification, and asked that these were removed as they were not relevant. IGARD noted the reference in section 5(c) (Specific Outputs Expected) to *"Using value as the redesign principle"* when referring to the purpose of the data, and asked that this was removed as it was not relevant. IGARD queried information in section 5(b) (Processing Activities) in respect of data minimisation, in particular which aspects of the GP data would be used, how the data would be minimised, noting that the GP beta programme would have a broader range of data fields than the end product, and asked that section 5(b) was updated to reflect these points and in line with NHS Digital's DARS Standard for Data Minimisation. IGARD noted that section 3(c) (Patient Objections) did not currently reflect that the GP beta data would have Type 1 objections applied before it flowed the data to NHS Digital, and that the data would be pseudonymised at source, and asked that this was updated accordingly to reflect this information. IGARD noted the special condition in section 6 (Special Conditions) that stated *"Processing of the Medicines Dispensed in Primary Care (NHSBSA Data) dataset is only permitted to provide*

	intelligence about the safety and effectiveness of medicines, as specified by the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019.", and asked that the benefits outlined in section 5(d) (Benefits) were updated to ensure there was a specific link to patient safety. IGARD noted the large volume of data that had previously flowed, and queried if there were any additional yielded benefits that could be reflected in section 5(d) (iii) (Yielded Benefits);and if so, asked that this was updated as appropriate. IGARD advised that when this application returned to the IGARD BAU meeting for a full review, IGARD would expect to receive a full suite of supporting documentation, including (but not limited to) the final published Direction and the NHS Executive Board minutes formally adopting the Direction. In addition, IGARD also noted that this first of type application would require an extended slot on the agenda. **Outcome:** IGARD welcomed the application which came for advice, and without prejudice to any additional issues that may arise when the transparency materials and Direction are finalised, and the application can be fully reviewed.
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday 30th March 2021** can be found attached to these minutes as Appendix B. IGARD noted that due to the Easter break, and as agreed between IGARD and NHS Digital, the COVID-19 response meetings on Tuesday 6th April and Tuesday 13th April 2021 were cancelled.
6	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 09/04/21

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-07289-G8J6C	Northgate Public Services (UK) Limited	11/03/21	1. In respect of the cohort members consented on the older versions of consent materials (expressly referencing an ethical review before any onward sharing), the applicant to establish or evidence a procedure that would meet the requirement of providing an ethical review.	IGARD members	Quorum of IGARD members	IGARD made the following comment which the applicant may find helpful with regard to condition 1: *the Committee may find it helpful to review the expanded ToR in six month's time in light of its experience*
NIC-400304-S1P1B	Office for National Statistics (ONS)	18/02/21	1. In respect of the requisite PAG support: a. To provide written confirmation, by way of a copy of their minutes, that PAG have given their full support for this application; OR b. Should PAG request further information or assurances, that confirmation be provided that PAG have been satisfied; and c. To upload the written evidence to NHS Digital's CRM system. 2. In respect of the change to the applicant's legal basis:	IGARD Members	Quorum of IGARD members	**Condition 3** - Set aside *"It is unclear whether NSDEC saw the application on the 17th February 2021 and it is not stated that it is on the agenda for the next meeting. However, since NSDEC are considering the application via correspondence this condition can be set aside."*

			a. To confirm in writing that NHS Digital's PTE Directorate are content with the change of legal basis and that all the proposed processing aligns with the production of official statistics; and b. To update section 5 to expressly state that all the data requested is necessary for the production of official statistics; and c. To upload the written evidence to NHS Digital's CRM system. 3. In respect of the ethical approval to either: a. Confirm that the NSDEC considered the application at their quarterly meeting on the 17th February 2021; OR b. To confirm that NSDEC received a briefing on the application at their quarterly meeting on the 17th February 2021 and did not raise any substantial points; OR c. To confirm that the application has been scheduled on the next NSDEC agenda for consideration.			

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- NIC-422218-V6L8T-v0 DSfC NHS Coventry and Warwickshire CCG - IV, RS & Comm
- NIC-422183-C3K9L-v0.2 DSfC NHS Bedfordshire, Luton and Milton Keynes CCG
- NIC-445826-K3H7D-v0.2 DSfC - NHS Oxfordshire CCG - RS & IV

- NIC-422189-G8H5X-v0.4 - DSfC - NHS Hampshire, Southampton and Isle of Wight CCG - Comm, RS & IV

Optum Health Solutions UK Limited Class Actions:

- NIC-422183-C3K9L-v0.2 DSfC NHS Bedfordshire, Luton and Milton Keynes CCG
- NIC-197669-K8J6D-v3.2 DSfC - NHS Basildon and Brentwood CCG - Comm - Mid & South Essex STP
- NIC-422189-G8H5X-v0.4 - DSfC - NHS Hampshire, Southampton and Isle of Wight CCG - Comm, RS & IV

Graphnet Class Actions:

- None

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 30th March 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Prof. Nicola Fear (IGARD Specialist Academic Member)
	Dr. Geoff Schrecker (IGARD Deputy Specialist Chair / IGARD Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (DARS)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Deputy Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	NIC-420168-K4N1F University of Bristol **Background:** this was an application that would usually be presented to an IGARD business as usual (BAU) meeting for a recommendation, however due to the Easter holiday period, the application had not been prioritised as an application to review at the meeting on Thursday, 25th March and would therefore be progressed via NHS Digital's SIRO precedent. Previous versions of the application for the consented cohort and relevant supporting documents had previously been discussed at the COVID-19 response meetings on the 16th March, 2nd February, 26th January, 12th January 2021, 15th December and 8th December 2020, and at the IGARD business as usual (BAU) meeting on the 4th March and 4th February 2021. This was a verbal update by NHS Digital with regard to the consented cohort and Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 cohort applications progressing under the National Health Service (Control of Patient Information Regulations) 2002 (COPI), rather than consent and HRA CAG s251 support respectively. NHS Digital noted

	that the applicant had spoken with HRA CAG and CAG had suggested NHS Digital look to support the use of COPI in the short term with a view to a subsequent s251 application in respect of the cohort dependent on s251 and the applicant sought advice from DARS regarding progressing both cohorts under this gateway. The following observations were made on the basis of the verbal update and letter of support from Sir Patrick Vallance (UK Government Chief Scientific Adviser) with regard to the commencement of the National Core Studies. **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted this was potentially valuable and useful work. IGARD members noted that they were supportive of the National Core Studies and thanked NHS Digital for the overview, however, they were not clear how this study related to the longitudinal health study led by Nish Chaturvedi at University College London "*understanding the impact of COVID-19 on long term health to inform the design of mitigating policy (this is about bringing together information from existing studies and cohorts)*" and asked that, should the application proceed using COPI as the legal basis, it was clearly articulated in the application how the longitudinal study related to the longitudinal study cited in Sir Patrick's letter of support. IGARD members welcomed the verbal update from NHS Digital with regard to the discussions held with HRA CAG, who had advised them to pursue COPI in the short term. However, given that the consented cohort application is awaiting the applicant returning their response to the condition set by IGARD at its BAU meeting on the 4th March 2021, it may be quicker and more appropriate to address the condition and move this consented cohort application forward with consent as the legal basis. In parallel, for the other cohort, HRA CAG be asked if they anticipate setting aside national data opt-outs in a future application to move to s251, since if opt-outs are not applied under COPI it will create challenges for the applicant (they may have to delete the data and receive a fresh flow with opt-outs applied). NHS Digital noted that the Privacy, Transparency and Ethics Directorate (PTE) had not yet reviewed the processing within the consent and s251 applications against COPI, and IGARD members were of the view that PTE support will need to be in place before the application(s) proceeded under COPI. Nevertheless, the applicant is reminded that no matter the legal basis cited, this does not reduce the requirement for transparency, as per NHS Digital's DARS Standard for Transparency (fair processing) and that if the application(s) proceed under COPI that the applicant ensure that members of both cohorts have access to appropriate transparency materials. IGARD members noted that this application had been presented to the Profession Advisory Group (PAG) on the 10th March (after its presentation at the IGARD BAU meeting on the 4th March 2021), and therefore the PAG minutes had not been through a formal review (see

	appendix A) and suggested that the SIRO, or their delegate, review the comments made by PAG. IGARD members welcomed the verbal update and noted that due to the urgency of the application, that the application(s) may progress under NHS Digital's SIRO Precedent. **Significant risk areas:** if the study is not part of the longitudinal health NCS then COPI may not apply; the use of and transition from COPI to consent and s251 may lead to a situation which could negatively impact on public trust; IGARD members noted that all previously raised significant areas of risks and points were still live.
2.2	<u>NIC-374190-D0N1M-v2.2 Genomics England</u> **Background:** this was an amendment and renewal application that would usually be presented to an IGARD business as usual (BAU) meeting for a recommendation. However due to the Easter holiday period, and given the application had not been prioritised as an application to review at the meeting on Thursday 25th March, it would be progressed via NHS Digital's SIRO precedent. Previous versions of the application, and relevant supporting documents, have been discussed at the COVID-19 response meetings on the 6th October, 21st July, 14th July, 23rd June, 16th June, 12th May, 5th May and 28th April 2020, and at the IGARD business as usual (BAU) meetings on the 6th August and 25th June 2020. The renewal aspect is to continue to disseminate the same data as requested under v1 of the application on a monthly basis for the GENOMICC cohort. The amendment aspect is to change the legal basis for dissemination. Genomics England are currently reliant on the National Health Service (Control of Patient Information Regulations) 2002 (COPI) Notice Reg 3(4) to provide the legal gateway for transfer and dissemination of identifiable information. Genomics England have been working with NHS Digital and IGARD to bring the Consent and Patient Information Sheets (PIS) for this study in line with NHS Digital's DARS Standards. The following observations were made on the basis of v2.2 of the application and relevant supporting documentation only (specifically the Patient Information and Transcript documents (SD22.1 and SD22.2) and new Patient Information Sheet (PIS) (SD12.4). **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD Members, noting that COPI remains in place until the 30th September 2021, suggested NHS Digital and the applicant may wish to renew the application using the current COPI legal basis, pending consideration of points previously raised. IGARD members suggested that a change in the legal basis should be formally reviewed at an IGARD BAU meeting. NHS Digital noted that the applicant was seeking Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support for those patients who had been part of the study via consultation with a consultee, but not regained capacity and had subsequently died, in

	order to retain their data in the study. In addition, IGARD members suggested that for those that had not regained capacity but were still alive that the applicant consider also including them in the s251 support. IGARD members felt the latest consent materials being used with the severely ill cohort were compatible with the processing outlined in the application. However, IGARD members noted they had not seen the new consent form for healthy members of the cohort, so were unable to comment further. IGARD members noted that the Patient Information Sheet (PIS) for healthy members of the cohort was clearly focused on COVID-19 research and only briefly mentioned wider "*healthcare research*". However, the accompanying record of consent may be more explicit with regard to wider research (without seeing that record IGARD members were unable to comment further). In addition, IGARD suggested there is an ethical 'check' for any future research built into the internal data access process not least because ethical approval is a requirement for the use of the DNA sample and that use might well include healthcare data. IGARD members noted that the weblink provided in documentation for participants to withdraw from the study took participants to a 100,000 Genomes Project withdrawal form dated 2017 and suggested that the applicant update the webpage. For those participants consented on the original documents (for example SD2.4 PIS version 2.1 dated 24th April 2020) there is a concern that participants were not informed that identifiable information would flow to NHS Digital. Noting the applicant's commitment to communication with participants, IGARD members suggested that the applicant consult with a small number of participants (more than 1 but not necessarily more than 7) that received the early materials to check their understanding of the processing being undertaken within this application. In particular whether they feel the processing aligns with the information they received and whether they are concerned or surprised (and therefore whether DARS' Duty of Confidentiality Standard is met). IGARD members supported NHS Digital's assessment that the renewal of application would be approved under the NHS Digital SIRO Precedent in respect on the renewal element if the legal basis remained the same. **Significant risk areas:** not having the appropriate legal basis in place to flow data for those participants whose involvement was via a consultee.
3	<u>AOB</u> There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Record of feedback: Wednesday, 10th March 2021

Application & application version number: **DARS-NIC-420168-K4N1F-v0.9** **Organisation name: University of Bristol** **Profession Advisory Group Agenda item: 2**
PAG support the work the applicant is undertaking relating to Covid-19. PAG request NHS Digital to confirm if this application could be supported within the NHS Digital TRE. If confirmed PAG support this application to proceed within the TRE. If NHS Digital cannot service this application within the TRE (unable to load bespoke cohorts), PAG support the application on a time-limited basis until that capability is developed.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Louise Dunn	Data Approvals Officer	NHS Digital