

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 31 March 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member (Observer)
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Service (DARS) (SAT Observer: item 2.1) (Items 5, 7.3)
Duncan Easton	Data Access Request Service (DARS) (SAT Observer: items 3.4)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Items 7.1 - 7.2)
Florence Geut	Data Access Request Service (DARS) (Observer: item 5)
Dan Goodwin	Data Access Request Service (DARS) (Item 3.4)
Karen Myers	IGARD Secretariat
Frances Perry	Digi-Trials (Items 3.1)
Kimberley Watson	Data Access Request Service (DARS) (SAT Observer: items 3.1 - 3.2)
Anna Weaver	Data Access Request Service (DARS) (Observer: item 2.1)
Louise Whitworth	Associate Director of Information Governance (IG) Services, Privacy, Transparency & Ethics (PTE) (Items 2.1, 3.1 – 3.2)

Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Service (DARS) (Item 3.2)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 24th March 2022 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 meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Briefing Notes
2.1	<p><u>University of Glasgow / University of Dundee - Briefing Paper (Presenter: Anna Weaver / Dave Cronin) NIC-72180-R2L5Y-v5</u></p> <p>The briefing paper was to inform IGARD about a potential breach under this data sharing agreement (DSA), in respect of the University of Dundee sharing pseudonymised data, supplied under previous versions of the DSA with Menarini International Operations Luxembourg société anonyme (S.A.). The briefing paper also contained further information on the recommended approach by NHS Digital in respect of this breach.</p> <p>The application is for a study designed to find out whether febuxostat is safer, less safe or just as safe as allopurinol for long term use in practice. The FAST study focuses on the cardiovascular safety profile of allopurinol, when taken for an average of 3 years in patients aged 60 years or older with chronic hyperuricaemia, in conditions where urate deposition has already occurred. The secondary study objectives are to evaluate other cardiovascular adverse events for both products.</p> <p>NHS Digital reported its understanding that the University of Dundee had onwardly shared data supplied by NHS Digital with a third party, Menarini International Operations Luxembourg S.A. following the completion of a clinical trial sponsored by Menarini.</p> <p>NHS Digital noted that, based on the information provided, this was not thought to be a breach of confidentiality or data protection law but the DSA between NHS Digital and the University of Dundee did not authorise the sharing.</p> <p>NHS Digital provided an update on its communications with the University of Dundee, the actions taken to date and the planned next steps.</p> <p>NHS Digital stated that it is keen to support universities doing important work but stressed the importance of maintaining public trust and highlighted the importance of data controllers understanding and executing their contractual responsibilities.</p> <p>NHS Digital confirmed that under its Data Sharing Framework Contract (DSFC) with the University of Dundee, NHS Digital has powers to terminate the Contract and/or any DSA in the</p>

	<p>event that the University of Dundee is in material breach of the Contract and/or any DSA and that breach cannot be remedied or if that breach can be remedied but the University of Dundee fails to do so within 30 days starting on the day after receipt of a written notice from NHS Digital.</p> <p>NHS Digital confirmed its intention to carry out a further audit of the University of Dundee following a previous audit which highlighted several nonconformities including two areas where the DSA did not reflect current practice (see: https://webarchive.nationalarchives.gov.uk/ukgwa/20210201163226mp_/https://digital.nhs.uk/binaries/content/assets/website-assets/services/dars/data-sharing-agreement-audit---uni-of-dundee.pdf).</p> <p>IGARD welcomed the briefing paper and provided high-level comments including, but not limited to:</p> <ol style="list-style-type: none"> 1. IGARD endorsed the contents of the briefing paper and the planned course of action. 2. IGARD suggested that DARS engage with NHS Digital's Legal Team with regards to enforcement of the DSFC. 3. IGARD suggested that any future meetings between NHS Digital and the University of Dundee should include all relevant parties (e.g. other processors). 4. IGARD noted that all audit reports are detailed, published and are easily searchable on NHS Digital's website. 5. Noting that the DSFC makes a provision for charging for audits where there is a breach, NHS Digital may wish to utilise that provision. <p>Subsequent to the meeting: IGARD noted that the briefing paper mentioned two entities: Menarini International Operations Luxembourg S.A. and Menarini Pharma SAS. NHS Digital were unable to confirm if they were two separate entities or the same entity.</p>
3	Data Applications
3.1	<p><u>University of Oxford: ATEMPT: Antihypertensive Treatment in Elderly Multimorbid Patients (Pilot Study) (Presenter: Frances Perry) NIC-414909-M5W6W-v0.6</u></p> <p>Application: This is a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC) and HES:Civil Registration (Deaths) bridge.</p> <p>The purpose of the application is for a study, aiming to improve the understanding of blood pressure (BP) management in older, multimorbid people, by comparing the effectiveness and safety of changing the number of prescribed antihypertensive drugs in two similar groups of such individuals. The study additionally aims to assess the acceptability and tolerability of the intervention and to rule out any major excess harms (risk of serious adverse events).</p> <p>The study aims to test the feasibility and reliability of the remote recruitment, monitoring and follow up procedures without any scheduled clinic visits, and to obtain information about resource requirements for the larger trial. The experience gained from utilising IT-enabled systems to remotely recruit and monitor participants will be evaluated with a view to expanding the use of the software to manage other research trials within the department and wider University.</p> <p>The cohort consists of approximately 221 consented individuals, recruited between December 2020 and July 2021.</p>

The University of Oxford has a separate data sharing agreement (DSA) (NIC-311182-F5W4X) for Demographic data to facilitate the initial recruitment for the ATEMPT Clinical Trial (Pilot).

NHS Digital noted that prior to the meeting, an IGARD specialist member had submitted a query in respect of the consent materials, and how clear it was to participants that historical data would be processed, in light of the references within the consent materials to *“my health status”*, and how this could be perceived by participants. NHS Digital advised that they had reviewed the consent materials, and supported the use of the historic HES data and the participants understanding of this in light of the following statements within the consent materials *“I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Oxford, and from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records” and “I understand that the information held and maintained by NHS Digital / NHS Central Register and Pharmacy 2U may be used to provide information about my health status and medications.”*

Discussion: IGARD welcomed the application and noted the importance of the study.

IGARD noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application; and the glossary within section 5(a) (Objective for Processing), which supported the review of the application by Members.

IGARD also noted and commended the applicant on the patient and public involvement and engagement (PPIE), in particular the inclusion of the two PPIE members that formed part of the trial steering committee.

IGARD noted and thanked NHS Digital for the verbal update, in respect of the query shared prior to the meeting, of how clear it was to participants that historical data was being processed. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application.

Separate to this application, IGARD suggested that a learning and development session for NHS Digital was arranged to discuss consent materials, for example, the language used within consent materials, with IGARD members, and colleagues within the Data Access Request Services (DARS), DigiTrials and Privacy, Transparency and Ethics (PTE).

IGARD had a lengthy discussion with regard to the content of Pharmacy 2U's privacy notice, noting that this was specifically referenced within the patient information sheet provided as a supporting document and in addition, noted that the study privacy notice stated *“Please note that third party websites have their own Privacy Policies and we do not accept any responsibility or liability for these policies. Please check these policies before you submit any personal data to these websites”*. IGARD queried the statement within Pharmacy 2U's privacy notice *“We use the information we hold about our customers for direct marketing purposes including sending direct marketing materials about our products and services that we believe may be of interest to you...”*, and noting that participants had not consented to direct marketing, asked that written confirmation was provided that Pharmacy 2U would **not** include any individuals taking part in this trial on their direct marketing database, unless the participants in this trial had specifically consented to be part of the database; and that the written confirmation was uploaded to NHS Digital's CRM system for future reference.

IGARD also noted the significant reputational risk to NHS Digital of participants receiving marketing communications from the commercial company and / or its affiliates following recruitment to this trial.

	<p>IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that there was “no” commercial purpose to the study, however asked that this was reviewed and updated in line with NHS Digital DARS Standard for Commercial Purpose, and that relevant updates were made to section 5(e); for example, noting the potential financial / reputational commercial benefit to Pharmacy 2U in terms of their involvement in the study. In addition, IGARD asked, for transparency, that following the review / update to section 5(e), a brief summary was also provided in the public facing section 5(a), which forms NHS Digital’s data uses register.</p> <p>IGARD queried the references in the application to the data being “<i>pseudonymised</i>”, and noting that the data would be identifiable once in the hands of the recipient (they would have the means to reidentify via the study ID); and therefore asked that the application was updated where relevant to correctly reflect that the data requested would effectively be “<i>identifiable</i>” and not “<i>pseudonymised</i>”.</p> <p>IGARD noted that section 3(b) (Additional Data Access Requested) incorrectly stated that the Civil Registration (Deaths) - Secondary Care Cut data was being requested for a period of 5 years, from 2017 up to the end of June 2022; however asked that this was amended to correctly reflect that the data collected will be from the date of consent.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the Pharmacy 2U direct marketing database: <ol style="list-style-type: none"> a) To provide written confirmation that Pharmacy 2U will not include any individuals taking part in this trial on their direct marketing database, unless they have consented to be part of the database. b) To upload the written confirmation to NHS Digital’s CRM system for future reference. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of the commercial aspects of Pharmacy 2U’s involvement: <ol style="list-style-type: none"> a) To review and update section 5(e) in line with NHS Digital DARS Standard for Commercial Purpose; and, b) To provide a brief summary in section 5(a) of the commercial aspects of this application, as per the update to section 5(e). 2. To update the application where relevant to reflect that the data requested will effectively be “<i>identifiable</i>” and not “<i>pseudonymised</i>”. 3. To amend section 3(b) to reflect the correct age range for the Civil Registration (Deaths) - Secondary Care Cut data. <p>Significant Risk Area: The reputational risk to NHS Digital of participants receiving marketing communications from a commercial company and/or its affiliates following recruitment to this trial.</p> <p>Separate to this application: A learning and development session to be arranged to discuss consent materials for colleagues within Data Access Request Services (DARS), DigiTrials and Privacy, Transparency and Ethics (PTE).</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.2	<p><u>Harvey Walsh Ltd: Harvey Walsh Ltd - data dissemination (Presenter: Clare Wright) NIC-05934-M7V9K-v13.4</u></p> <p>Application: This is a renewal to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Emergency Care Data Set (ECDS), Hospital</p>

Episode Statistics (HES) Civil Registration (Deaths) bridge, HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Summary Hospital-level Mortality Indicator.

It was also an amendment to add the following datasets to the data sharing agreement: Diagnostic Imaging Dataset - Medicines dispensed in Primary Care (NHSBSA data), Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Second Generation Surveillance System (SGSS) and COVID-19 Vaccination Status.

The purpose of the application, is to permit Harvey Walsh Ltd to provide services to help public healthcare organisations monitor and improve their services. Processing is designed to benefit patients and society through better healthcare.

The data will be used to undertake analysis, research studies, develop services and provide solutions to providers of healthcare and life sciences services such as, including (but not limited to) Clinical Commissioning Groups (CCGs), Integrated Care Services (ICSs), Hospital Trusts and NHS England. The data will also be used to provide services to commercial organisations within the pharmaceutical, medical device industry, patient organisations, healthcare charities and Academic Health Science Networks (AHSNs). These organisations use the outputs and insights provided to work collaboratively with NHS organisations to promote health and improve the well-being of patients.

NHS Digital noted that, prior to the meeting, an IGARD specialist member had submitted a number of queries, the first was in respect of the reference in section 5(e) (Is the Purpose of this Application in Anyway Commercial) to special conditions reflecting the commercial restrictions, that did not appear to have been populated in section 6 (Special Conditions). NHS Digital advised that this was an error and section 6 would be updated to include the special conditions referenced in section 5(e).

NHS Digital advised that the second query was in relation to the outputs register, which contained a list of organisations who have commissioned Harvey Walsh Ltd to carry out work with the NHS Digital data, together with confirmation that a data sharing agreement (DSA) or Contract was in place with each organisation; and why this was not publicly available. NHS Digital confirmed that the applicant had advised that due to commercial sensitivities, the output register was not published online, however, there was a publicly available statement on their website that outlined the types of organisations they work(ed) with and how the data was processed.

NHS Digital reiterated the information within section 1 (Abstract), that in relation to the special condition in section 6 that only 10 years of data were held, and that NHS Digital had requested a data destruction certificate for the years 2010/11, and that this had been provided by the applicant and was currently being reviewed by NHS Digital's Security Team.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 16th August 2016, 20th September 2016, 13th December 2016, 15th June 2017, 22nd June 2017, 29th June 2017 and 8th November 2018.

It was also discussed as part of NIC-274351-Y9N6J at the IGARD BAU meeting on the 5th March 2020.

IGARD noted and supported the addition of special conditions in section 6 reflecting the commercial restrictions set out in section 5(e), as per the verbal update from NHS Digital.

IGARD noted and thanked NHS Digital for the verbal update in relation to the issues addressed in section 1, in respect of the ongoing review by NHS Digital's Security Team in

relation to the data destruction certificate provided for the 2010/11 data, and asked that section 1 was updated with the latest information of the data destruction undertaken.

IGARD also noted NHS Digital's verbal update in relation to the query raised on the outputs register, and the explanation from the applicant as to why this was not in the public domain; however, IGARD reiterated previous comments that the applicant should consider giving greater transparency to the public on their clients and the work undertaken.

Separate to this application, IGARD suggested that NHS Digital may wish to review the [NHS Digital DARS Standard for Transparency](#), and [NHS Digital DARS Standard for Commercial Purpose](#), in respect of the commercial use of NHS Digital data to see whether further transparency could be achieved, particularly regarding a company's clients, and what those clients want the data used for.

IGARD noted the constraints placed in the [Direction](#) for the collection of NHSBSA data, specifically, "*Providing intelligence about the safety and effectiveness of medicines...*"; and asked that in line with [NHS Digital DARS Standard for Objective for Processing](#), when referencing processing of NHSBSA data, including in section 5(a) (Objective for Processing), to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction.

In addition, IGARD asked that a special condition was inserted in section 6, that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection.

Separate to this application, IGARD suggested that the Data Access Request Service (DARS) update their relevant onboarding documentation to ensure DARS staff are aware of the constraints placed in the Direction for the collection of NHSBSA data and the relevant updates required within the DSA.

IGARD noted the National Institute for Health and Care Excellence (NICE) weblink that had been added to section 5(c) (Specific Outputs Expected) when referring to communication of results / outputs, however asked that this was correctly moved to the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits). IGARD also asked that when the NICE weblink had been moved to the yielded benefits section, that further narrative was provided outlining how the data provided to the applicant contributed to the yielded benefit, in line with the [NHS Digital DARS Standard for expected measurable benefits](#).

IGARD queried the content of the yielded benefits in section 5(d) (iii), and noting that some of the information was quite vague, and asked that this was reviewed and the yielded benefits were updated, in line with the [NHS Digital DARS Standard for expected measurable benefits](#), and that there was a clear link to the benefit to the health and care system.

IGARD queried the specific yielded benefit in relation to Irritable Bowel Syndrome (IBS), that stated results of IBS "*...can be acquired within 48 hours...*", and noting that this would be ground-breaking in determining those who suffered from the condition, asked that further narrative was provided, as to how the data provided to the applicant had contributed to this particular yielded benefit. IGARD also advised that there was minimal information within the public domain in respect of this benefit, noting the information on the University of Liverpool [website](#) in relation to an IBS diagnosis method published on the 12th February 2021.

IGARD queried the statement in section 5(a) "*However, individuals are made aware through the privacy policy how they are able to opt out...*", and, noting that this was incorrect and contradicted statements elsewhere in section 5(a), asked that this was removed.

IGARD queried the statement in section 3(b) (Additional Data Access Requested) that “*GDPR does not apply to data solely relating to deceased individuals*”, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate.

IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), such as “*OLAP cube*” and “*SQL Server environment*”, and asked that this public facing section, which forms [NHS Digital's data uses register](#), was amended throughout, to ensure acronyms be defined upon first use and technical terms are explained in a manner suitable for a lay audience.

IGARD advised that they would wish to review this application when it comes up for renewal, due to the large quantum of data flowing, the transparency and public interest in the use of health data by commercial organisations.

Outcome: recommendation to approve

The following amendments were requested:

1. In respect of the NHSBSA Medicines Dispensed in Primary Care dataset:
 - a) To update section 5(a) and in line with [NHS Digital's DARS Standard for Objective for Processing](#), when referencing processing of NHSBSA dataset to ensure a clear narrative is provided linking the purposes to the relevant Direction.
 - b) To insert a special condition in section 6, that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection.
2. To insert special conditions in section 6 reflecting the commercial restrictions set out in section 5(e).
3. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE.
4. To remove the inaccurate sentence from section 5(a) that starts “*However, individuals are made aware through the privacy policy how they are able to opt out...*”.
5. In respect of the yielded benefits in section 5(d) (iii):
 - a) To move the NICE weblink from section 5(c) to section 5(d) (iii); and,
 - b) To provide further narrative alongside the NICE weblink in section 5(d) (iii), outlining how the data provided to the applicant contributed to the yielded benefit.
 - c) To review and update all the yielded benefits in section 5(d) (iii) in line with the [NHS Digital DARS Standard for expected measurable benefits](#) and that there is a clear link to the benefit to the health and care system.
 - d) To provide further narrative on the specific yielded benefit that states results of IBS “*...can be acquired within 48 hours...*” and how the data provided to the applicant has contributed to this.
6. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms [NHS Digital's data uses register](#), was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example, “*OLAP cube*” and “*SQL Server environment*”.
7. To update section 1 with the latest information of the data destruction undertaken (as per the verbal update from NHS Digital).

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant undertake further work in respect of greater transparency to the public on their clients and the work undertaken. 2. IGARD advised that they would wish to review this application when it comes up for renewal, due to the large quantum of data flowing, the transparency and public interest in the use of health data by commercial organisations. <p>Separate to this application: IGARD suggested that NHS Digital review the NHS Digital DARS Standard for Transparency and NHS Digital DARS Standard for Commercial Purpose in respect of the commercial use of NHS Digital data to see whether further transparency could be achieved, particularly around a company's clients, and what those clients use the data for.</p> <p>IGARD suggested that DARS update their relevant onboarding documentation to ensure DARS were aware of the constraints placed in the Direction for the collection of NHSBSA data and the relevant updates required within the DSA.</p>
3.3	<p><u>NHS Derby and Derbyshire CCG: DSfC - NHS Derby and Derbyshire CCG, Comm. IV and RS (Presenter: Dan Goodwin) NIC-281073-Y5G3F-v5.1</u></p> <p>Application: This is an amendment application to the data minimisation applied to the data received by the CCG. The CCG has highlighted several providers that will be working within the ICS when it comes into existence. The CCG is requesting access to data for these providers and their patients to support commissioning and planning activities alongside patients within the current CCG footprint. The data sharing agreement (DSA) data minimisation has been amended to refer to the relevant practices.</p> <p>The overall purpose of this application 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.</p> <p>NHS Digital noted that, prior to the meeting, an IGARD specialist member had submitted a query in respect of the CCG's published privacy information, that stated CAG 2-03(a)/2013 supported "<i>transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH)</i>", and had queried if this was still the case, and if so, if it allowed linkage of all of the datasets. NHS Digital advised that Health Research Authority Confidentiality Advisory Group (HRA CAG) support was not required for commissioning, and that the applicant would need to update their privacy notice to remove any incorrect information.</p> <p>In addition, a further query had been submitted in respect of whether the CCG had provided examples of where re-identification might happen, in addition to the generic examples provided in section 5(b) (Processing Activities). NHS Digital noted that further information had been shared by the applicant in relation to this query, and shared this verbally with IGARD members in- meeting.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 30th May 2019.</p> <p>IGARD noted and thanked NHS Digital for the verbal update on the incorrect information within the CCG's published privacy notice, and supported the updates to correctly reflect the fact that HRA CAG support was not required for this commissioning.</p>

IGARD noted the verbal update from NHS Digital in respect of the queries submitted prior to the meeting, and confirmed that they supported the update to the privacy notice to reflect the fact that HRA CAG support was not required for this commissioning.

IGARD also noted the examples shared by NHS Digital, of where re-identification had happened, and asked that section 5(b) was updated to reflect this new / additional information for transparency, and in line with [NHS Digital DARS Standard for processing activities](#).

IGARD noted and commended the applicant on the bespoke, geographical yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits).

IGARD queried the content of some the yielded benefits outlined relating to the three “*service reviews improvements*”, and asked that further information was provided, including **1)** further quantitative information relating to the Home Oxygen Services benefit; **2)** further specific examples of the pulmonary rehabilitation virtual programmes; and **3)** how the data provided supported the Stroke Pathway Review governance structure and integrated pathway. In addition, IGARD asked that the yielded benefits were reviewed and updated in line with the [NHS Digital DARS Standard for expected measurable benefits](#).

IGARD suggested that NHS Digital satisfied itself that the Data Controller has sufficient grounds and reasonable instruction to collect and process NHS Digital data, on a prospective basis, for individuals not currently in their geographical area. Evidence for such grounds might be, for example, by way of confirmation from an appropriate body that they have instructed the CCG to collect and process that data, in anticipation of the ICB coming into effect on the 1st July 2022.

IGARD noted the incorrect reference in section 1 (Abstract) to the Integrated Care Systems (ICS) coming into existence in “*June 2022*”, and asked that this was correctly updated to “*1st July 2022*”.

IGARD noted the incorrect references to “*Integrated Care Board*” and asked that the application was reviewed throughout, to correctly amend the references from “*Integrated Care Board*” to “*Integrated Care **Bodies***” where applicable.

IGARD queried the references in section 5(b) (Processing Activities) to NHS Derby and Derbyshire CCG “*absorbing*” providers, for example “*NHS Derby and Derbyshire CCG will be absorbing...providers into it's Integrated Care Board (ICB)...*”; and asked that this was amended to reflect the factual scenario.

IGARD noted the references throughout the application to “*merger*”, and asked that the application was reviewed and amended where appropriate, to ensure the reference is used in the correct context and removed where not appropriate.

Outcome: recommendation to approve

The following amendments were requested:

1. To update the privacy notice to reflect the fact that HRA CAG support is not required for this commissioning (as per the verbal update from NHS Digital)
2. To provide further specificity in section 5(b) on the CCG examples (provided in-meeting) of where re-identification might happen.
3. To amend the incorrect reference in section 1 to the ICS coming into existence in “*June 2022*” and replace with “*1st July 2022*”.
4. To amend the reference in section 5(b) to NHS Derby and Derbyshire CCG “*absorbing*” providers, to reflect the factual scenario.

	<ol style="list-style-type: none"> 5. To review the application throughout to amend the references from “<i>Integrated Care Board</i>” to “<i>Integrated Care Bodies</i>” where applicable. 6. To review the application throughout to ensure any reference to “<i>merger</i>” is used in the correct context and remove where not appropriate. 7. In respect of the yielded benefits in section 5(d) (iii): <ol style="list-style-type: none"> a) To update the yielded benefits in line with the NHS Digital DARS Standard for expected measurable benefits. b) To provide further information on the yielded benefits for the three “<i>service reviews improvements</i>” referred to in section 5(d) (iii). <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital satisfied itself that the Data Controller has sufficient grounds and reasonable instruction to collect and process NHS Digital data, on a prospective basis, for individuals not currently in their geographical area. Evidence for such grounds might be, for example, by way of confirmation, from an appropriate body, that they have instructed the CCG to collect and process that data, in anticipation of the ICB coming into effect on the 1st July 2022.
3.5	<p><u>University College London (UCL): Assessing the impact of the COVID-19 pandemic on vulnerable children: the ECHILD-COVID study (No Presenter) NIC-381972-Q5F0V-v1.3</u></p> <p>Application: This was an amendment application to 1) transfer to the Office for National Statistics Secure Research Service (ONS SRS) a pseudonymised ‘mum-baby’ linkage flag, attached to the relevant pseudonymised Hospital Episode Statistic (HES) record; 2) to enable inclusion of maternal characteristics (such as age), and to follow up the health of young people to the age of 34; 3) to extend the age range to all ‘young’ people in England born on or after 1st September 1984, from the current age limit of 1st September 1995; 4) the extension of the data retention period for the identifier file of all individuals linked in NPD-MPS/PDS and MPS/PDS-HES and all the postcodes used in linkage and postcode dates from 12 months to 24 months; 5) clarification of the funding sources; 6) updates related to the use of MPS for new data linkage.</p> <p>This agreement will allow the data to be linked to data held under NIC-393510- D6H1D, which is already held at UCL.</p> <p>The purpose is for a study looking at the impact of COVID-19 and lockdown on Children and young people (CYP) and whether there are any differences in the health and social effects of household confinement on vulnerable children and young people when compared to other CYP. CYP who are vulnerable due to social welfare or chronic health needs are expected to experience more adverse health and social effects of the COVID-19 lockdown than other CYP. Key concerns for services are the effects of household confinement during the COVID-19 lockdown, combined with the limited access to support from health, social care and education services. The researchers need to understand what impacts COVID-19 infection and related public health responses (such as lockdown) have had on CYP aged 25 years and under, to inform strategies for the current wave of infection, and any future waves.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 25th November 2021; where the application had been recommended for approval with conditions, amendments and advice.</p> <p>IGARD noted that as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed</p>

	<p>on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken.</p> <p>The condition from the 25th November 2021 BAU meeting was as follows:</p> <ol style="list-style-type: none"> 1. In respect of the “<i>vulnerable</i>” cohort(s): <ol style="list-style-type: none"> a) To provide confirmation as to what definition of “<i>vulnerable</i>” applies to the 25 - 37-year-old cohort, for whom the Children’s Act definition of ‘vulnerable’ does not cover (it is only relevant up to age 24). b) To provide an explanation as to how the applicant has identified the cohort of vulnerable parents and what is the criteria for inclusion in that cohort. c) To provide an explanation of how “<i>previous birth</i>” contributes to the vulnerable characteristics of the cohort of vulnerable mothers. d) To note if at any point ethnicity data will be used as a determinant of vulnerability. e) To update section 5 with a clear definition of what is meant by children who were “<i>otherwise vulnerable</i>” as part of the cohort, including (but not limited to) what factors would lead a child to be defined as “<i>otherwise vulnerable</i>”. <p>A quorum of IGARD members were content that the multi-limbed condition had been met.</p>
4	<p><u>Applications progressed via NHS Digital’s Precedent route, including the SIRO Precedent</u></p> <p>Applications that have been progressed via NHS Digital’s Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).</p> <p><i>No items discussed.</i></p>
5	<p><u>Oversight & Assurance</u></p> <p>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.</p> <ul style="list-style-type: none"> • NIC-10029-G5R2H-v1.2 Northern Ireland Clinical Trials Unit (CTU) (extension & renewal) <p>NHS Digital noted that the application was to be presented at an imminent IGARD BAU Meeting.</p> <p>IGARD noted that the application had been out of agreement and that a short term one year extension had been put in place to retain the data for a further year.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent due to the fact that it had never had a previous independent review.</p> <ul style="list-style-type: none"> • NIC-147783-6T2MW-v2.2 the University of Nottingham (simple amendment / class action: risk assessed DSA extension) IGARD noted a number of high risks being identified: confidential data was being used and there was concern about the legal

basis for the proposed use and the applicant had not made progress towards completion of their action plan.

IGARD noted a number of medium risks had been identified: the DSA has never been seen by IGARD or its predecessor DAAG, the purpose section did not meet NHS Digital DARS standards, and the previous DSA's special conditions were only partially met.

IGARD noted that the previous DSA had expired on the 18th September 2019.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the fact that the application had not had an independent review in the last three years, a number of NHS Digital DARS Standards had not been met (data minimisation, objective for processing, processing activities, expected outcomes, expected measurable benefits, ethical approval, duty of confidentiality, transparency) and noted that it appeared to have progressed inappropriately down the simple amendment / class action precedent route.

- **NIC-164594-K4C5N-v5.3 University College London (UCL) (Simple Amendment)**

IGARD noted that the governance pathway for APMS data had not been updated to correctly reference when applications for APMS should come via IGARD or via the APMS precedent. IGARD reiterated previous advice and asked that internal processes be updated accordingly.

IGARD noted that the application appeared to have progressed down the wrong precedent pathway and should have considered under the APMS precedent.

IGARD asked that section 1 (Abstract) be corrected since the date listed for a previous BAU review was not an IGARD meeting date. The application was last seen by IGARD as part of oversight and assurance on the 11/02/21.

- **NIC-147776-69CX7-v2 University of Manchester (simple amendment / class action: risk assessed DSA extension)**

IGARD noted that the application had been assessed as medium risk: the DSA had not had an independent review by IGARD or its predecessor DAAG in the last three years, the purpose section did not meet NHS Digital DARS standards, the study did not appear to have a privacy notice and did not align with NHS Digital's DARS Standard for transparency (fair processing), and NHS Digital had reviewed the consent materials and found them incompatible with the processing outlined in the application.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the fact that the application had not had an independent review in the last three years, a number of NHS Digital DARS Standards had not been met (data minimisation, objective for processing, duty of confidentiality, transparency), the purpose section did not align with NHS Digital DARS Standards, and the consent appeared to be incompatible with the processing, and noted that it appeared to have progressed inappropriately down the simple amendment / class action precedent route.

- **NIC-25945-T8Q0Z-v6.7 University of Cambridge (Class action: risk assessed DSA extension)**

	<p>IGARD noted that the application had been assessed as medium risk: the DSA had not had an independent review by IGARD or its predecessor DAAG in the last three years, an action plan had been partially completed and previous special conditions had only been partially met.</p> <p>IGARD noted that when they had reviewed this application under oversight and assurance on the 30th April 2020, they had specifically requested that the application should return to IGARD at its earliest opportunity and this advice had been provided to DARS in-meeting due to the fact that when previously reviewed it had appeared that the applicant had been holding data between 2017 and 2020 without a DSA in place.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the fact that the application had not had an independent in the last three years and a number of NHS Digital DARS Standards had not been met (data minimisation, objective for processing, transparency).</p> <ul style="list-style-type: none"> NIC-70235-T6P9F-v5 The Met Office (class action: risk assessed DSA extension) <p>IGARD noted that the application had been assessed as medium risk: the DSA had not had an independent review by IGARD or its predecessor DAAG in the last three years and the NHS Digital Security Advisor had noted that the applicant's SLSP had some areas to addressed.</p> <p>ACTION: IGARD reiterated their request, which had been supported by the NHS Digital DARS Head of DARS Service, to be provided as a supporting document for all applications submitted to IGARD for a recommendation or under oversight & assurance, a copy of the NHS Digital DARS scoring matrix (high risk, medium risk, low risk) alongside a copy of the analysis undertaken by NHS Digital to ascertain the risk assessment of the application: high risk, medium risk or low risk.</p> <p>IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022.</p> <p>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022.</p> <p>IGARD also noted that the NHS Digital webpage Excel spreadsheet was for the period March 2020 to May 2021 and that they had queried for some considerable time with PTE why the COVID-19 (non-DARS) data release register was not being updated in a timely fashion: NHS Digital Data Uses Register - NHS Digital</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7	<p><u>AOB:</u></p>
7.1	<p><u>Foundry Platform ("Foundry") / Palantir Technologies UK Limited ("Palantir") – Access to GDPPR data (Presenter: Liz Gaffney)</u></p>

	<p>NHS Digital attended IGARD to discuss a briefing paper (please see appendix B), in respect of a request made by GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) for clarification as to whether Foundry / Palantir have access to GDPPR data as part of their Data Sharing Agreement (DSA) with NHS England; and that the response to this query was noted in section 2 of the briefing paper.</p> <p>IGARD noted the contents of the briefing paper and thanked NHS Digital for sharing the information. IGARD noted its support for transparency as to what entities are data processors in all agreements but did not support ‘blanket’ exclusions. It suggested exclusion of any particular processor would need a clear justification.</p> <p>IGARD reiterated their previous comment and noted that PAG had specifically named an organisation within their minutes and cautioned against NHS Digital naming specific companies, and instead ask PAG to provide broad principles which would be incorporated into any assessment of the data processors.</p>
7.2	<p><u>NHS Digital DARS Standard for Ethical Review (Presenter: Liz Gaffney)</u></p> <p>NHS Digital attended the meeting to discuss the comments IGARD had shared with regards to the updated DARS Standard for Ethical Review. NHS Digital agreed to provide the finalised version of the DARS Standard to IGARD and update the NHS Digital DARS webpage accordingly.</p>
7.3	<p><u>NHS Digital DARS Standard for Length of Data Sharing Agreement (DSA) and Draft DARS Annual Confirmation Report (“Report”) (Presenter: Dave Cronin)</u></p> <p>NHS Digital attended the meeting to discuss the comments IGARD had shared with regards to the updated DARS Standard for Length of Data Sharing Agreement (DSA) and Draft DARS Annual Confirmation Report.</p> <p>It was agreed that the DARS Standard for Lengthy of DSA would be decoupled from the DARS Annual Confirmation Report. NHS Digital agreed to provide the finalised version of the DARS Standard to IGARD and update the NHS Digital DARS webpage accordingly.</p> <p>IGARD asked that their comments on the draft DARS Annual Confirmation Report were incorporated, accepted or discussed further and suggested that the draft Report was not piloted any wider than the current recipient Grail.</p> <p>IGARD asked that the NHS Digital Clinical Trials Head of Business Operation attend a future IGARD meeting (28th April or 3rd May 2022) to give an update to IGARD and discuss the inclusion of the IGARD comments on Grail’s version of the Draft Annual Confirmation Report.</p> <p>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.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 25/03/22

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-433176-J8Q2S-v1.2 -	AstraZeneca AB	10/03/2022	1. In respect of the AstraZeneca Executive Committee: <ol style="list-style-type: none"> To provide written clarification of the term “<i>contracted to</i>” and what it meant, for example is it a substantive contract of employment or another form of contractual connection, and In either case and subject to the clarification in point 1(a) to describe how this impacts on the data controllership arrangements, as borne of the facts, and in line with NHS Digital DARS Standard for Data Controllers, and To provide written confirmation that the Executive Committee member based in Texas (USA) will not receive any data under this DSA, noting the permitted territory of use is restricted to UK and EEA, and To upload the written confirmation(s) as appropriate to NHS Digital's CRM system, AND / OR 	IGARD members	Quorum of IGARD members	None

			e. To amend section 5 of application with relevant narrative.			
NIC-629056-F4L4B-v0.3	University of Warwick	10/03/2022	1. In respect of reliance on Regulation 3 of The Health Service (Control of Patient Information) Regulations 2002 (COPI): <ul style="list-style-type: none"> a. NHS Digital PTE to confirm the Reg 3 COPI is an appropriate legal basis for the flow of confidential data under this DSA, noting that Long covid, the subject of this research, is not itself a communicable disease. b. To upload the written PTE confirmation to NHS Digital's CRM system. 	IGARD members	Quorum of IGARD members	IGARD were content that the condition has been met if the following additional wording can be added to the existing special condition in section 6: <i>The data shared under this agreement via COPI regulations will only be provided by NHS Digital, and processing of such data may only continue, up to and including the COPI notice expiry date (currently on 30/06/2022) unless an alternative legal basis has been provided and approved by NHS Digital, or the COPI notice expiry date is extended.</i>

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:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Professional Advisory Group

NHS England Data Sharing Agreement (NIC 402116)

Action

The Professional Advisory Group requested clarification on whether Foundry / Palantir have access to GDPPR data as part of a Data Sharing Agreement with NHS England.

NHS Digital Response Submitted to PAG 16.12.21

NHS England hold a Data Sharing Agreement with NHS Digital (NIC 402116) which supports the NHS England national call/recall flu and COVID vaccination programmes. The dissemination provides Ethnic Category data to link to their existing systems.

Ethnic category is required for:

- Risk stratification of COVID patients to identify those at high risk of complications
- Management reporting for flu/COVID vaccinations to address health inequalities

The management and coordination of the flu and COVID vaccination programmes is vital to ensure the programmes can proceed efficiently. The two are linked by the time required in between an individual taking the flu vaccination and the first COVID vaccination. The two processes are intrinsically linked and the provision of ethnic category data is vital to both.

Certain ethnic groups have been connected with increased morbidity and mortality in cases of CV19 and optimal uptake in these populations would be desirable if and when a CV vaccine is available.

It is essential that the two programmes are coordinated to accommodate the developing characteristics of the pandemic, and any interfaces between the vaccines, and their delivery processes as they are established.

Data disseminated under the agreement will not be used for performance management purposes.

GDPPR data is combined with HES data to create the Ethnic Category Dataset, this use was supported by PAG.

As part of the Data Sharing Agreement the data that flows from the Ethnic Category Dataset (which utilises GDPPR data) is

- NHS Number (primary key)

- Ethnic category
(https://www.datadictionary.nhs.uk/data_dictionary/data_field_notes/e/ep/ethnic_category_de.asp?shownav=1)
- Data source* (GDPPR Journal, GDPPR Patient, HES)
- Date of attribution (Episode end date if HES IP, Appointment Date for HES OP, Attendance date for HES AE, Journal Record Date if GDPPR - Journal, Reporting period end date if GDPPR - Patient)

* Within the GDPPR dataset ethnic category can be recorded in 2 places, the GDPPR Journal Table and the Patient Table, therefore the data is collected from both these fields. For more information on the data model see [General Practice Extraction Service \(GPES\) Data for pandemic planning and research: a guide for analysts and users of the data - NHS Digital](#)

NHS Digital send NHS Number and Ethnic Category data to System C and Graphnet who are NHS England's data processor for direct care purposes. Identifiable data then flows to Arden GEM CSU (as part of NHS England). Arden GEM CSU Deidentify/Pseudonymise the data before sharing with Palantir as a data processor for NHS England. No patient identifiable data flows to Palantir.

Palantir are permitted within the Data Sharing Agreement to be a data processor for vaccination reporting only and would use pseudonymised ethnicity data for that purpose. No other GDPPR data would be used by this processor.

History

NIC 402116 V1 had been reviewed by the Profession Sep 2020 and the Profession confirmed their support of the flow to ethnicity code to support the Flu Vaccine Programme

NIC 402116 version 1.2 January 2021, NHS Digital received an urgent request from NHS England to add Palantir as a Data Processor, to allow for Palantir to receive pseudonymised ethnicity to enhance their vaccination reporting service provided by Palantir to NHS England.

Due to the urgent need for this support the application was progressed through our SIRO Precedent. This route allows approval without prior advice being provided by IGARD but that NHSD will advise IGARD of the decision made. The request was progressed by the Information Asset Owner who sought assurance from appropriate Subject Matter Experts prior to gaining ultimate approval from NHS Digital SIRO on 14th January 2021

The Associate Director for Data Access advised the IAO that IGARD and PAG should be updated in regard to the addition of Palantir being added as processor.

IGARD were appraised of the amendment to the agreement and use of the SIRO precedent by DARS on the 26th January 2021. However there was a failure to appraise PAG of the decision taken.

The outcomes from the 26th IGARD January session are below

1. IGARD members noted that NHS Digital should be assured that NHS England have been fully transparent in public-facing materials about their use of Palantir and their involvement in the processing of the data requested for the purposes outlined in the application.

Response; NHS England made aware and Special Condition added: NHS England as Data controller must ensure that their transparency and privacy notices are clear about the involvement of all data processors in line with their obligations under GDPR.

2. IGARD members also queried if Palantir was a legal entity in its own right (noting the parent company was a United States ("US") based company under US jurisdiction) or if it was a branch office of the larger company where it could be obliged to share data with its parent company due to the operation of foreign law. In addition, NHS Digital should be assured that AWS, who are hosting the data for Palantir in their agreement, have no ability for any resilience services to hold the data outside of the UK.

Response; NHS England confirmed Cloud storage and processing is restricted to UK data centres email from Ming Tang which also confirms the security assessment in place between NHS E and AWS

3. IGARD members noted that NHS Digital should also be assured that NHS England have an appropriate data processing agreement in place for Palantir for the work they are undertaking, and that they explicitly set out how they satisfy Regulation 7 (1) and (2) of COPI.

Response; NHS England made aware and Special Condition added: NHS England must ensure that they have appropriate contractual arrangements in place with all of its data processors and contractors handling data under this agreement which satisfy section 7.1 of the COPI legislation

4. IGARD raised Significant areas of risk: Based on the verbal update at the session, IGARD suggested that there was a potential public perception risk related to the involvement of Palantir that could be mitigated by appropriate General Data Protection Regulation (GDPR)-compliant transparency by NHS England. The home jurisdiction, company structure and any intra-company data sharing issues regarding Palantir should also be explored and addressed, as necessary.

Response; NHS England made aware and Special Condition added: NHS England as Data controller must ensure that their transparency and privacy notices are clear about the involvement of all data processors in line with their obligations under GDPR.

SIRO Authorisation

NHS Digital's data disseminations are ultimately approved by NHS Digital's Senior Information Risk Owner (SIRO), who in turn may delegate authority to DARS and Information Asset Owners. As such, NHS Digital may, via the SIRO, decide to sign a data sharing agreement without an IGARD recommendation for approval.

In reaching such a decision, the SIRO is balancing the risk of dissemination against the benefits of release and the risks of not disseminating the data. To help in that judgement, the SIRO would expect to seek views from appropriate SME's to ensure informed balanced input before making a decision based on an assessment of risk.

The type of SME input would be dependent on the risk for example where the request involved direct care, clinical input may be sought, or for legal matters (e.g. consent) an SME from the Privacy Transparency and Ethics may be engaged.

In all cases the SIRO approval should follow the SIRO approval process, which includes the requirement to notify IGARD and (where applicable) PAG.

Lessons enacted and assurance

DARS checked all the existing flows of GDPR data progressed via DARS and confirm that no other agreements have been progressed via SIRO approval other than the 2 noted agreements below of which both gained PAG support before progressing under SIRO precedent:

- DARS-NIC-396113-N9L4L-v2., Community-based Virtual Electronic Wards for remote monitoring in suspected cases of COVID-19 (coronavirus): C-VIEW Stud, Imperial College London, PAG supported, DARS approved this via SIRO sign off.
- DARS-NIC-420168-K4N1F-v0.11 University of Bristol - Longitudinal Linkage Collaboration, University of Bristol, PAG supported, DARS approved via SIRO sign off.

Having reviewed the original ask we would still expect the same ultimate decision to add the data processor to NHS England's Data Sharing Agreement would be made by NHS Digital. However, improvements have been made to the processes informed to ensure complete transparency.

- The SIRO precedent has been updated to ensure that exceptions raised by IGARD and PAG are flagged appropriately to SIRO to inform the consideration of risk. This will be circulated for review by IGARD and PAG
- A SIRO approval report will be shared as a standard agenda item with both groups to inform of any SIRO approvals.