

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 21 October 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark (Chair)	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Service (DARS) (Observer: items 3.2 – 3.7, 7.1)
Dan Goodwin	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1 – 3.2)
Denise Pine	Data Access Request Service (DARS)
Charlotte Skinner	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	Declaration of interests: Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.
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	<p>Nicola Fear noted a personal and professional link to the Lead Investigator and application at the University of Oxford [NIC-148322-TMFVQ-v7.6], however confirmed that no discussions had taken place with the staff involved about the application, and it was agreed this was not a conflict of interest. Nicola noted an error in the 13th May 2021 minutes whereby the wrong University of Oxford application / NIC number had been cited as a declaration of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 14th October 2021 IGARD meeting were reviewed, and subject to a number of minor amendments 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
	<i>There were no briefing papers submitted for review.</i>
3	Data Applications
3.1	<p><u>Hertfordshire County Council: LA access to Specified datasets Gemima (Presenter: Dan Goodwin) NIC-391553-J4Z1L-v0.4</u></p> <p>Application: This was a new 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), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births) - Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), NHSBSA Medicines Dispensed in Primary Care dataset and Adult Social Care Data.</p> <p>The purpose of the data request is to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised IGARD that as part of the Integrated Care Systems (ICS), the Local Authority (LA) would like to contribute further to commissioning decisions with the CCG; however becoming joint Data Controller with the CCG is currently not an option, due to the CCG seeking approval to onward share data with the ICS, which the LA will not be a Data Controller for.</p> <p>Discussion: IGARD noted the verbal update from NHS Digital, in respect of the CCG and the LA having separate Data Sharing Agreements (DSAs) and discussed whether the LA should be part of the CCG application or whether the CCG should be part of the LA application. In summary, IGARD felt separate DSAs were a valid approach, but this application would have to be restricted to the LA's commissioning activities.</p> <p>IGARD noted that over 20 datasets would flow under this Data Sharing Agreement (DSA), and queried if the large volume of data was required. IGARD noted that there was no information within section 3 (Datasets Held / Requested) in respect of the data minimisation efforts undertaken and in line with NHS Digital's DARS Standard for Data</p>

[Minimisation](#). IGARD asked that section 3 was updated with a rationale of the large volume of data requested, and in line with the [NHS Digital's DARS Standard for Data Minimisation](#). In addition, IGARD asked that the public facing section 5 (Purpose / Methods / Outputs) was updated with details of any efforts taken to minimise the data required, which supported the volume of data requested for the LA's commissioning purpose and in line with [NHS Digital's DARS Standard Objective for Processing](#).

IGARD noted that the LA would commission different services to the CCG, and queried why some of the datasets had been requested, for example, but not limited to, the NHS Business Services Authority (NHSBSA) Medicines Dispensed in Primary Care dataset and that if this data was required that section 5 was updated with as to why, noting the constraints placed in the Direction for the collection of this data.

In addition, IGARD asked that if the NHSBSA dataset **was** required, noting the constraints placed in the Direction for the collection of NHSBSA dataset, by NHS Digital, specifically *"Providing intelligence about the safety and effectiveness of medicines..."*; that the application was updated throughout, to align with the scope of the Direction to ensure that the objectives, processing and outputs are permitted uses of the data.

IGARD also asked, that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection.

IGARD also asked that NHS Digital provided written confirmation from the NHS Digital Information Asset Owner for the NHSBSA dataset as to how the full extent of the processing of the data outlined in the application is within the scope of the Direction, namely *"to deliver comprehensive data about the medicines dispensed, and drive the linkage of data to provide intelligence about the safety and effectiveness of medicines"*; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

If the NHSBSA dataset was **not** required, IGARD asked that the application was updated throughout, to remove all references to the NHSBSA dataset.

IGARD noted the references within the application to patients being reidentified by the LA for direct care; and queried if this was correct since the examples related to the CCG and GPs. IGARD asked that the application was updated throughout, to remove any references to the data being *"reidentified"* by the LA.

IGARD queried the references in the application to Optum Health Solutions UK Ltd (known as "Optum" in these minutes) and what their role was in this application, noting that they were a Data Processor for the local CCG. NHS Digital advised IGARD that Optum were conducting a piece of work on population health management for the CCG, and that the LA also wanted to see the results of this, to help inform future commissioning decisions. IGARD noted the verbal update from NHS Digital but noted that just because both the CCG and LA were receiving the same data and had the same Data Processor, that did not entitle the LA to receiving the results and asked that section 5 was updated with further details of what data was being shared by Optum on behalf of the CCG, for example, aggregated data with small numbers suppressed.

IGARD also asked that, for transparency, further clarification was provided of the processing being undertaken by Optum on behalf of the LA, as this was not clear within the application. If Optum were not considered a joint Data Processor, then IGARD asked that all references to Optum were removed from the application.

<p>IGARD noted the references within the application to the “CCG”, and noting that the application was for the LA and not the CCG, asked that the application was updated throughout to correctly reflect that this was a LA application.</p> <p>IGARD queried the statement in section 3(b) (Additional Data Access Requested) that “<i>GDPR does not apply to data solely relating to deceased individuals</i>”, 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. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course.</p> <p>IGARD noted the inclusion of statistical terms of art and technical terms within section 5(c) (Specific Outputs Expected) such as “<i>key vectors</i>” and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use.</p> <p>IGARD noted points 7 and 8 in section 5(c) under “<i>Commissioning Insights</i>”, specifically “<i>Budget reporting down to individual GP Practice level</i>” and “<i>GP Practice level dashboard reports</i>”; and asked that these were removed as they were not relevant to the application.</p> <p>IGARD noted the Data Processors outlined in section 5(b) (Processing Activities), and noting that some of them are in relation to the CCG application and not the LA, asked that these were reviewed and amended / removed as appropriate.</p> <p>IGARD also noted that some of the benefits outlined in section 5(d) (Benefits) were also specific to the CCG application and asked that this was reviewed and updated as appropriate to reflect the benefits of the LA work.</p> <p>NHS Digital queried if this application could be considered as a class action, however IGARD were clear that any request for a class action should follow due process and be included as a separate discussion item and not as part of an application discussion.</p> <p>Outcome: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. In respect of the large volume of data requested: <ol style="list-style-type: none"> a) To provide a rationale in section 3 of the large volume of data requested. b) To provide a justification in section 5, which supports the Local Authority’s commissioning. 2. In respect of the NHSBSA Medicines Dispensed in Primary Care dataset: <ol style="list-style-type: none"> a) To clarify in section 5, if the NHSBSA dataset is required, noting the constraints in the Direction for the collection of this data. If the data is required: b) To update the application throughout to align with the scope of the Direction to ensure that the objectives, processing and outputs are permitted use of the data, and in line with the NHS Digital DARS Standard for Objective for Processing. c) 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. d) NHS Digital to provide written confirmation from the NHS Digital Information Asset Owner for the NHSBSA dataset as to how the full extent of the processing of the data outlined in the application is within the scope of the Direction, namely “<i>to deliver comprehensive data about the medicines</i>”

	<p><i>dispensed, and drive the linkage of data to provide intelligence about the safety and effectiveness of medicines”.</i></p> <ul style="list-style-type: none"> e) To upload the written confirmation from the IAO to NHS Digital’s CRM system for future reference. <p>If the data is <u>not</u> required:</p> <ul style="list-style-type: none"> f) To update the application to remove all references to the NHSBSA dataset. <ol style="list-style-type: none"> 3. To update the application throughout, to reflect this is an application from a Local Authority, for example, removing reference to the CCG. 4. To update the application throughout to remove any references to the data being “re-identified” by the Local Authority. 5. 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 approach is supported by advice on this point from PTE. 6. In respect of Optum Health Solutions UK Ltd: <ul style="list-style-type: none"> a) To clarify in section 5 what data is being shared by Optum, for example, aggregated data with small numbers suppressed. b) To clarify the processing being undertaken on behalf of the Local Authority. c) To remove all references to Optum from the application, if they are not considered a Data Processor. 7. In respect of section 5(c): <ul style="list-style-type: none"> a) To amend section 5(c) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, “key vectors”. b) To amend section 5(c) to remove points 7 and 8 under “Commissioning Insights” as they are not relevant to this application. 8. To amend section 5(b) with regards to the Data Processors outlined, and remove any reference to “CCG”. 9. To update section 5(d) to reflect the benefits of the Local Authority work.
3.2	<p><u>University of Manchester: Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (Diabetes Prevention – Long term Multimethod Assessment) (Presenter: Dan Goodwin) NIC-196221-K4K3Y</u></p> <p>Application: This was a renewal and extension application for pseudonymised National Diabetes Audit (NDA); and an amendment to 1) add the dissemination of historic NDA data for the fields T2D diagnosis date, CCG code and Year of Birth, 2) the dissemination of historic Non-Diabetes Hyperglycaemic (NDH) data for the field Audit Year.</p> <p>The purpose is for a research programme, with the aim of providing a comprehensive assessment of the implementation, delivery and outcomes of the NHS Diabetes Prevention Programme (NHS DPP) to inform commissioning.</p> <p>The data will be used in three of eight work packages in the overall DIPLOMA research project. These are: Work package 1: Access and Equity – the aim is to assess the accessibility of the NHS DPP and identify inequalities in access; Work package 5: Comparative Effectiveness – the aim is to examine whether the NHS DPP leads to a reduction in the prevalence of Type 2 Diabetes and other outcomes related to Type 2 Diabetes compared to those without access to the NHS DPP; and Work package 7: Economic Evaluation – the aim is to explore the cost-effectiveness of the NHS DPP, from the perspective of the NHS and Personal Social Services.</p>

<p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 27th June 2019 and the 21st May 2020.</p> <p>IGARD noted and commended both the applicant and NHS Digital, on the quality of the information provided within the application, which supported the review of the application by Members.</p> <p>IGARD noted the statement in section 5(a) (Objective for Processing) <i>“Type 2 diabetes is a common health condition that can cause serious health problems and reduce people’s quality of life...”</i>, however asked that this was updated further, to include a reference outlining that diabetes can also reduce life expectancy.</p> <p>IGARD queried the statement in section 5(a) <i>“The unit of analyses will be individual”</i>, and noting that it was unclear what this was referring to, asked that it was either removed or that a further supportive explanation was provided.</p> <p>IGARD noted a minor typo in section 5(a) when referring to Clinical Practice Research Datalink (CPRD) data; and asked that, to avoid any confusion, the incorrect reference to <i>“CPDR”</i> data was amended to correctly state <i>“CPRD”</i>.</p> <p>IGARD queried the paragraph in section 5(b) (Processing Activities) that started <i>“The principle of least privilege is applied to all projects hosted within the DSH environment”</i>, and noting that the meaning was unclear, asked that this was reviewed, and either amended with a clearer description of the meaning, or removed if not relevant.</p> <p>IGARD noted that the applicant had referred to internal documents within the public facing section 5(b), for example, Standard Operating Procedures; and asked that the references were reviewed, and either updated to include an external reference or removed if not relevant.</p> <p>IGARD queried the reference in section 5(b) to a <i>“walled garden security model”</i>, and since this terminology was not familiar to Members asked that this was updated with a further supportive explanation or removed if not relevant.</p> <p>IGARD noted the reference in section 5(b) to <i>“painted screen approach”</i> and asked that a further supportive explanation was added for clarity or removed if not relevant.</p> <p>IGARD noted that as section 5 (Purpose / Methods / Outputs) formed NHS Digital’s data uses register, the above points had been raised in line with NHS Digital’s DARS Standard for Objective for Processing and NHS Digital DARS Standard for processing activities to ensure that the narrative was easily understood for a lay audience.</p> <p>IGARD noted in section 5(d) (Benefits) (iii) (Yielded Benefits), that there were no yielded benefits to record at the present time, however asked that in addition to the statement <i>“...the University still expects to meet the expected benefits described in this agreement”</i>; reference was also made to NHS Digital’s DARS Standard for Expected Measurable Benefits, in preparation for the future yielded benefits.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of section 5(a): <ol style="list-style-type: none"> a) To update section 5(a) to include a reference outlining that diabetes can reduce life expectancy.

	<ul style="list-style-type: none"> b) To either remove the reference in section 5(a) <i>“The unit of analyses will be individual”</i>, or provide a further supportive explanation. c) To amend the incorrect acronym in section 5(a) from <i>“CPDR”</i> to <i>“CPRD”</i>. <p>2. In respect of section 5(b):</p> <ul style="list-style-type: none"> a) To review the paragraph in section 5(b) that starts <i>“The principle of least privilege...”</i>, and either amend with a clearer description of the meaning, or remove if not relevant. b) To review the references in section 5(b) to any internal documents, and either update to include an external reference, or remove if not relevant. c) To provide a further explanation in section 5(b) in respect of the reference to <i>“walled garden security model”</i>, or remove if not relevant. d) To provide a further explanation in section 5(b) in respect of the reference to <i>“painted screen’ approach”</i>, or remove if not relevant. <p>3. To update section 5(d) to make reference to NHS Digital’s DARS Standard for Expected Measurable Benefits, in preparation for the future yielded benefits.</p>
<p>3.3</p>	<p><u>University of York: ‘Your Tube’: the role of different diets in children who are gastrostomy fed (Presenter: Charlotte Skinner) NIC-334459-R9H4C</u></p> <p>Application: This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients.</p> <p>There are increasing numbers of children with complex health care needs that require having all, or part, of their nutritional intake via gastrostomy feeds. The recommended feed for children via gastrostomy is commercially produced formula, however, there is a growing body of parents who are interested in feeding their children home-blended meals. These parents often report benefits such as improved gastro-oesophageal reflux symptoms, less constipation and less distress in their child.</p> <p>The ‘Your Tube’ study is a consented cohort study, aiming to recruit 300 children aged between 6 months - 18 years, who are fed via a gastrostomy tube and follow them up for an 18-month period. The main research question for the study is: What are the risks, benefits and resource implications for using home-blended food for children with gastrostomy tubes compared to currently recommended formula feeds.</p> <p>NHS Digital advised IGARD that as part of patient and public involvement and engagement (PPIE), the applicant had a Parental Advisory Board that included parents / guardians of those children who were fed via a gastrostomy tube and met three times per year. In addition, there was a Steering Committee that involved charity representatives, for example, ‘Together for Short Lives’.</p> <p>Discussion: IGARD noted and thanked NHS Digital for the verbal update in respect of the PPIE.</p> <p>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 for those participants not recruited via the applicant’s “consultee form”.</p> <p>IGARD noted information in section 5(a) (Objective for Processing) that stated clinicians had consented to the participation of some of the children recruited and queried if this was correct. IGARD noting that although this was a complex aspect of the law, it was IGARD’s understanding that the involvement of children in health research required the consent of</p>

	<p>a parent / guardian, unless the research had the potential to benefit the child and an urgent decision was required, which did not appear to be the case with this study. NHS Digital advised IGARD that clinicians did not provide consent for children recruited into the study, however the applicant had confirmed that 15 children were recruited via the consultee form, and that there was an outstanding query with NHS Digital's Privacy, Transparency and Ethics (PTE), in respect of the appropriate legal basis for the 15 participants. IGARD noted the verbal update from NHS Digital, and asked that written confirmation was provided, on the appropriate legal basis for the 15 participants who were part of the cohort, where the consultee form had been used; and that this was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p>Noting the verbal update from NHS Digital, IGARD asked that section 5(a) was updated to remove the incorrect references to the clinician providing consent.</p> <p>IGARD noted that some of the information in section 5(b) (Processing Activities) 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, the reference to "<i>Poisson or negative binomial models</i>", and in line with NHS Digital DARS Standard for processing activities.</p> <p>IGARD queried the content of the paragraph in section 5(b) that started "<i>Estimates and 95% confidence intervals...</i>", and asked that this was reviewed and replaced with simplified language, for example, "<i>statistical analysis</i>", and in line with NHS Digital DARS Standard for processing activities.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the consultee form: <ol style="list-style-type: none"> a) To provide written confirmation from NHS Digital's PTE, on the appropriate legal basis for the 15 participants, who are part of the cohort, where the consultee form was used instead of consent / assent. b) To upload the written confirmation from PTE to NHS Digital's CRM system for future reference. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) to remove references to the clinician providing consent. 2. To update section 5(b) to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to "<i>Poisson</i>" or "<i>binomial models</i>" 3. To review the paragraph in section 5(b) that starts "<i>Estimates and 95% confidence intervals...</i>", and replace with simplified language for example, "<i>statistical analysis</i>". <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.4	<p><u>The Brain Tumour Charity (TBTC): BRIAN (Brain tumouR Information and Analysis Network) is an online information system that will enable patients to make better-informed decisions about their treatment and accelerate research to find a cure. (Presenter: Denise Pine) NIC-158754-R5T3V</u></p> <p>Application: This was an extension application, to permit the holding and processing of pseudonymised Civil Registration (Deaths) Secondary Care Cut, Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients.</p>

It was also an amendment to **1)** add Costello Medical Consulting as a Data Processor; **2)** update the application to reflect the commercial element from adding Costello Medical Consulting as a Data Processor; and **3)** update section 3 to reflect the addition of variables that are classed as 'sensitive' or 'identifiable' that were not previously authorised.

TBTC has a strategy to double survival and halve the harm that brain tumours have on quality of life, one of the ways TBTC strives to achieve this is by funding research and the aim is to establish a research database (BRIAN) which can be used to facilitate research projects from third parties with suitable permissions and to enable cohort data to be included and selected from a data dictionary. BRIAN will also allow those patients who have consented to access their own identifiable medical records and read them in plain text.

TBTC has supplied NHS Digital with a consented cohort of approximately 640 participants who have agreed to share their NHS Data with BRIAN, which will allow TBTC to identify the consented individuals and link their data to quality-of-life data already entered into BRIAN.

NHS Digital advised IGARD that as outlined in section 1 (Abstract) of the application, there had been a breach in relation to this Data Sharing Agreement (DSA), which occurred when TBTC provided access to the data to BrightSparks Innovations Limited, who were providing support to TBTC with the construction of the BRAIN database. NHS Digital noted that as the DSA had already expired, senior colleagues within the Data Access Request Service (DARS), had implemented a one-year extension to the DSA to ensure TBTC were not out of agreement; and the relevant updates had been made to the DSA to ensure the correct organisations were added to the DSA, hence the submission of this application for IGARD to review.

In addition, NHS Digital confirmed that TBTC were no longer working with BrightSparks Innovations Limited, and they had therefore not been included in the DSA and advised that the company had "*disbanded*".

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 28th June 2018 and the 14th March 2019.

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.

IGARD noted the verbal update from NHS Digital, in respect of TBTC permitting access to the data under this DSA to BrightSparks Innovations Limited; and the subsequent updates to the application to ensure the correct organisations were contained within the DSA going forward. IGARD did however query the verbal update in respect of BrightSparks Innovations Limited being disbanded, noting that the company's website was still active and had been updated recently, plus the information on the website that referred to the work they were doing with TBTC on the BRAIN database. IGARD therefore asked that written confirmation was provided, of the enduring relationship between TBTC and BrightSparks Innovations Limited.

IGARD queried information on the TBTC BRIAN website that referred to a number of Data Partners, Research Partners and Technology Partners that TBTC were working with but that were not outlined in the application. In addition, IGARD noted the statement on the

website “*BRIAN links up with a whole spectrum of different registries and databases...it brings all that data together*”. IGARD therefore queried what the relationship was with the Partners outlined, for example, would the NHS Digital data be linked to other data; and noting the application was silent on this, asked that written confirmation was provided, confirming TBTC’s relationship with the Data Partners, Research Partners and Technology Partners as outlined on the TBTC website and section 5 (Purpose / Methods / Outputs) of the application was updated accordingly.

IGARD noted the amendment to the application to add Costello Medical Consulting as a Data Processor; and noting that they were a commercial company, suggested that the TBTC gave consideration as to how this would be made transparent to the public, for example, in order to retain trust and confidence in the charitable organisation, and in line with [NHS Digital’s DARS Standard for Commercial Purpose](#).

IGARD noted the reference in section 5(e) (Is the Purpose of this Application in Anyway Commercial) to “*pro bono*” and asked that this Latin wording was replaced with “*no charge*” or “*no fee*”.

IGARD queried the information in section 5(e) that stated “*...but the overall benefit to the provision of health and social care in England is far greater than any potential benefit to Costello Medical.*”; and asked that this was removed as it cannot be known in advance.

IGARD noted that the consultant code had been requested for the HES Outpatients and HES APC dissemination of data, however queried why this data had been requested, noting that no supportive explanation had been added to the application as per usual process and in line with [NHS Digital’s DARS Standard for Objective for Processing](#).

IGARD asked that reference to the specific Legitimate Interests Assessment (LIA) was made at the beginning of section 5(a) (Objective for Processing), as per usual process and in line with [NHS Digital’s DARS Standard for Objective for Processing](#).

IGARD noted a number of abbreviations in section 5(a) and section 5(d) (Benefits), and asked that this public facing section be updated to ensure that all abbreviations upon first use were clearly defined with a supportive explanation if the meaning was not self-evident, for example, “*the pink drink*”; and in line with [NHS Digital’s DARS Standard for Objective for Processing](#) and [NHS Digital’s DARS Standard for Expected Measurable Benefits](#).

IGARD noted the inclusion of a number of technical phrases and words within section 5(b) (Processing Activities), for example, “*SNOMED and NICIP Codes*”, and suggested that these were replaced with a term, such as “*diagnostic and imaging codes*”; and that this section was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use; and in line with [NHS Digital DARS Standard for processing activities](#).

IGARD suggested that section 5(a) and section 5(d) be updated to remove reference to “*it will...*” or “*it can...*”, and instead use a form of words such as “*it is hoped...*”.

IGARD also noted in section 5(d) a number of potentially hyperbolic statements made in terms of immediately delivering marginal improvements in the lives of brain tumour patients, and asked this was reviewed and amended as appropriate; and in line with [NHS Digital’s DARS Standard for Expected Measurable Benefits](#).

IGARD queried the benefit in section 5(d) that stated, “*The Charity has a campaign that has reduced diagnosis time for children from nine weeks to six and half weeks and this will*

be reduced to four weeks by 2020”; and noting that there were no follow-up details on this, asked that this was updated.

IGARD noted the reference in section 5(b) to the “*Data Access Board*”, and asked that this was updated to provide confirmation of the patient and public involvement and engagement (PPIE), noting that this aspect was not clear. IGARD suggested that if there was no PPIE on the Data Access Board, then consideration to this should be given.

Outcome: recommendation to approve subject to the following conditions:

1. To provide written confirmation, confirming TBTC’s relationship with the Data Partners, Research Partners and Technology Partners; as outlined on the TBTC website.
2. To provide written confirmation of the enduring relationship between TBTC and BrightSparks Innovations Limited.
3. To provide a clear justification in section 5(a) as to why the consultant code has been requested.

The following amendments were requested:

1. To amend section 5(a) and section 5(d) to ensure that all abbreviations upon first use be defined and further explained if the meaning is not self-evident, for example, “*the pink drink*”.
2. IGARD noted the inclusion of a number of technical phrases and words within section 5(b) such “*SNOMED and NICIP Codes*” and suggested replacing with “*diagnostic and imaging codes*”.
3. To update section 5(a) and section 5(d) to use a form of wording such as “*it is hoped ...*”, rather than “*it will...*” or “*it can*”.
4. To update section 5(b) to provide confirmation of the patient and public involvement on the Data Access Board.
5. To ensure the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a).
6. In respect of section 5(d):
 - a) To review any hyperbolic statements made in section 5(d), and amendment as appropriate.
 - b) To update the specific benefit in relation to reducing “*...diagnosis time for children from nine weeks to six and half weeks and this will be reduced to four weeks in 2020...*”.
7. In respect of the commercial element in section 5(e):
 - a) To amend the reference in section 5(e) to “*pro bono*” and replace with “*no charge*” or “*no fee*”.
 - b) To remove the sentence in section 5(e) “*...but the overall benefit...*”.

The following advice was given:

1. IGARD noted the involvement of the commercial company involved with the database, and suggested that the TBTC gave consideration as to how this would be made transparent to the public.
2. IGARD suggested that the Data Access Board have PPIE membership (if not already in place).

It was agreed the conditions would be approved out of committee (OOC) by IGARD members.

3.5

Department for Health and Social Care (DHSC): Access to pseudonymised SUS PbR and MHSDS datasets (Presenter: Frances Hancox) NIC-365145-G2P9F

Application: This was a renewal and extension application for pseudonymised Mental Health Services Data Set (MHSDS), Secondary Uses Service (SUS) Payment by Results (PbR) Accident & Emergency (A&E), SUS PbR Episodes, SUS PbR Outpatients and SUS PbR Spells.

The SUS PbR datasets and MHDS will enable the applicant to access the data for a wide range of data analytical purposes in support of the Secretary of State for Health in delivery of their duties set out within the National Health Service Act 2006 (and as subsequently amended) and inform policy decisions. The data will also be used to respond rapidly to emergent challenges and issues; and provide briefings to decision makers.

NHS Digital noted in section 1(b) (Data Controller(s)) that the applicant's Data Protection Act (DPA) Registration had expired, and advised that this would be updated to reflect the correct expiry date.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 19th March 2020.

IGARD noted the update from NHS Digital that that the DPA Registration date had been updated on the Data Sharing Agreement (DSA).

IGARD noted that when the application was last reviewed, IGARD noted and endorsed NHS Digital's review that the applicant did not meet [NHS Digital's Standard for Transparency \(fair processing\)](#) and asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that upon renewal / amendment of this application, the applicant should have published a Privacy Notice that was compliant with the transparency requirements under the UK General Data Protection Regulation (UK GDPR). NHS Digital advised IGARD that DHSC had provided NHS Digital with a draft copy of the privacy notice, however confirmed that this had not yet been published. IGARD noted the verbal update, however, noting the importance of transparency, reiterated previous comments that upon renewal IGARD would expect to see an updated UK GDPR compliant Privacy Notice.

IGARD noted a reputational risk to NHS Digital where the applicant had not fulfilled its obligation to publish an accessible and UK GDPR compliant privacy notice.

In addition, IGARD suggested that DHSC may wish to engage with members of the public, to review the draft privacy notice prior to publication, as per the verbal update to IGARD by NHS Digital, in respect of plain language and comprehension; and amend as appropriate.

IGARD noted the large volume of datasets flowing under this Data Sharing Agreement (DSA), and queried if the volume of data was required. In addition, IGARD noted that there was no information within section 3 (Datasets Held / Requested) in respect of the data minimisation efforts undertaken by the application. IGARD asked that section 3 was updated with a rationale of the large volume of data requested, in line with [NHS Digital's DARS standard for data minimisation](#). In addition, IGARD asked that the public facing section 5 (Purpose / Methods / Outputs) was updated with details of any efforts taken to minimise the data requested which supported the volume of data requested or why no

data minimisation is possible, and in line with [NHS Digital's DARS Standard Objective for Processing](#).

IGARD queried if, in light of the large volume of data requested, DHSC had produced a Data Protection Impact Assessment (DPIA), in line with Article 35 of the UK General Data Protection Regulation (UK GDPR), which stated that you must do a DPIA where a type of processing is likely to result in a high risk to the rights and freedoms of individuals. IGARD asked that written confirmation was provided that a DPIA existed. If a DPIA had not been undertaken IGARD suggested that the applicant should consider completing one. IGARD asked that if a DPIA was already in place that DHSC ensure that it is refreshed, in line with the processing being undertaken in this application and a copy provided to NHS Digital for future reference.

IGARD strongly suggested that the applicant expressly address the proposed processing within its DPIA, which is designed to assess the risk to the rights and freedoms of natural persons, with particular reference to the rights of individuals including, but not limited to, the right to erasure, the right to restricted processing and the right to object.

IGARD noted the statement in section 5(a) (Objective for Processing) "*They will also use the data and evidence to respond rapidly...*", and asked that the reference to "*rapidly*" was amended to say, "*respond appropriately*".

IGARD noted that some of the information in section 5(a) 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 removing out of date text and reducing references to statutory legislation; and in line with [NHS Digital's DARS Standard for Objective for Processing](#)

IGARD queried the statement in section 5(a) "*Waiting times for common procedures such as hips, knees...*", and asked that this was updated to make it clear that it was referring to hip and knee "*replacements*", rather than, as written, a new type of surgery.

IGARD queried the first line of the benefits in section 5(d) (Benefits) that stated "*The use of the SUS PbR datasets and MHSDS gives DHSC users secure access for the analysis of the data*", and asked that further clarity was provided what this meant or what the benefit was, and in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

IGARD queried the reference in section 5(d) to "*GP One Stop*", and noting that it was unclear what this was, asked that a further explanation was provided.

IGARD noted the benefits outlined in section 5(d) in respect of the individual patient pathways, however asked that further information was provided on what these were and what benefits had flowed; and in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will...*" or "*it can...*", and instead use a form of words such as "*it is hoped...*".

IGARD noted that section 5 made several references to the Data Access Environment (DAE), however, noting that the applicant was currently not accessing these datasets via the DAE and that extracts of data were being provided, asked that these references were removed, and additional examples were provided.

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 volume of data flowing and the outstanding transparency points.

Outcome: recommendation to approve subject to the following conditions:

1. In respect of the large volume of data requested:
 - a) To provide a rationale in section 3 of the large volume of data requested.
 - b) To provide a justification in section 5, as to why no data minimisation has been undertaken.
2. In respect of the DPIA:
 - a) To provide written confirmation as to whether a DPIA already exists.
 - b) The applicant to consider if they should complete a DPIA; or,
 - c) If a DPIA is already in place, to ensure it is refreshed, in line with the processing being undertaken in this application.

The following amendments were requested:

1. To update section 5(a) and section 5(d) to use a form of wording such as "*it is hoped ...*", rather than "*it will...*" or "*it can*".
2. In respect of section 5(a):
 - a) To amend the reference to "*rapidly*" in section 5(a) to "*respond appropriately*".
 - b) To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example removing out of date text and reducing references to statutory legislation.
 - c) To update section 5(a) to add "*replacement*" after the references to "*hip*" and "*knee*".
3. In respect of section 5(d):
 - a) To provide a further explanation as to what is meant by "*GP One Stop*".
 - b) To provide further information in section 5(d) with regard to the individual patient pathways.
 - c) To provide further clarity on the first sentence in section 5(d).
4. To remove the reference to "*DAE*" from section 5, and provide other examples, in due course.
5. To remove the special condition in section 6, in respect of the DSPT.

The following advice was given:

1. IGARD strongly suggest that the applicant considers expressly addressing the proposed processing within its DPIA, which is designed to assess the risk to the rights and freedoms of natural persons, with particular reference to the rights of individuals including, but not limited to, the right to erasure, the right to restricted processing and the right to object.
2. In respect of the privacy notice:
 - a) IGARD advised the upon renewal IGARD would expect to see an updated GDPR compliant Privacy Notice.
 - b) IGARD suggested that DHSC may wish to engage with members of the public, to review the draft privacy notice, as per the verbal update to IGARD by NHS Digital, in respect of the plain language and comprehension; and amend as appropriate.
3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the volume of data flowing and the outstanding transparency points.

	<p>4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the volume of data flowing and the outstanding transparency points.</p> <p>Significant risk area: IGARD noted a reputational risk to NHS Digital where the applicant had not fulfilled its obligation to publish an accessible and UK GDPR compliant privacy notice.</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.6	<p><u>University College London (UCL): Assessing the impact of the COVID-19 pandemic on vulnerable children: the DHSC-ECHILD-COVID study NIC-381972-Q5F0V</u></p> <p>The application was withdrawn by the presenter.</p>
3.7	<p><u>University of Oxford: MR576 - EPIC-Oxford. A prospective cohort study of 65,000 mainly vegetarian men and women, to examine how diet influences the risk of cancer, particularly for the most common types of cancer in Britain, as well as other chronic diseases. (No Presenter) NIC-148322-TMFVQ-v7.6</u></p> <p>Application: This was an amendment application to 1) change from section 251 approval to Consent (Reasonable Expectation) for the Hospital Episode Statistics (HES) data; 2) to request HES Admitted Patient Care (APC) from 1997/98 to 2015/16 data to be linked again; 3) a renewal of HES APC data from 2016/17 to the latest available year with annual releases going forward; 4) the addition of NHS number to the demographics product; 5) to add 24 additional fields in Civil Registration (Deaths) data request; 6) a 3 year Agreement as part of this amendment which will include a renewal of Demographics, mortality and cancer data.</p> <p>The purpose is for a study, to examine the effects of diet on long-term health, with a specific focus on vegetarians.</p> <p>The study's overall aim is to provide reliable evidence on choices people can make in adult life to help increase their chances of staying healthy into old age. The aim of the scientific research is to reliably inform the public and health providers and regulators about the statistical findings on risk factors including diet and lifestyle and environmental factors and risk of cancer and other medical conditions.</p> <p>The cohort consist of 60,642 men and women aged 20 and above who were recruited between 1993 and 1999 from throughout the UK.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 13th May 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 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</p>

	<p>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 13th May 2021 BAU meeting was as follows:</p> <ol style="list-style-type: none"> 1. To provide an action plan as to how the current consent materials will be augmented by way of communication and transparency measures to bring them in line with the NHS Digital DARS Confidentiality Standard. <p>A quorum of IGARD members were content that the 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. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.</p> <p>IGARD noted that they had requested an IG COVID-19 release register suite of documents on a particular data release for review as part of their oversight and assurance. This follows an agreement with the Executive Director Privacy, Transparency and Ethics (PTE) in June 2020 that IGARD review such documentation as part of continuous improvement and quality. Documentation has been received but has not yet been circulated to IGARD Members due to other conflicting priorities.</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.</p> <p>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.</p>
6	<p><u>COVID-19 update</u></p> <p>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.</p> <p>IGARD noted that due to member availability, and as notified to NHS Digital on the 27th September (by the IGARD Secretariat), the COVID-19 response meeting on Tuesday 19th October 2021 was cancelled.</p>

<p>7</p> <p>7.1</p>	<p><u>AOB:</u></p> <p><u>Northeast Staffordshire CCG: DSfC - STP - NHS Staffordshire and Stoke on Trent CCGs - Comm (Presenter: Dan Goodwin) NIC-234915-J3K4V-v2.2</u></p> <p>Application: This is a renewal and amendment for NHS North Staffordshire CCG, NHS East Staffordshire CCG, NHS South East Staffordshire and Seisdon Peninsula CCG, NHS Stoke on Trent CCG, NHS Stafford and Surrounds CCG and NHS Cannock Chase CCG to receive data for the purpose of commissioning.</p> <p>The application follows the agreed NHS Digital DARS precedents and IGARD agreed class actions apart from one element, which was the linkage of commissioning data to GP data; and so the application has been submitted to the IGARD business as usual (BAU) meeting at the request of the NHS Digital SIRO to seek advice on this point.</p> <p>IGARD did not review the application or any supporting documentation due to the fact that the documentation had not been provided timely, but made a positive statement of support with regard to the linkage to GP data for the purpose of commissioning only.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD reiterated their previous advice that the reidentification of patients for direct care should only be done in exceptional circumstances, and not as a routine function of “<i>commissioning</i>” applications. <p>Significant risk area: using data for direct care where that may not be envisaged as part of the scope for the collection of the data, for example, SUS for commissioning.</p> <p>There was no further business raised, the Chair of the IGARD meeting thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 15/10/21

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-253220-Q1X8H	University of Manchester	11/03/21	1. To update section 1 and throughout section 5 to clarify that this study relates to the economic evaluation of point of prescription decision support and not just one commercial product.	IGARD Members	Quorum of IGARD Members	<p>IGARD Member comment:</p> <ul style="list-style-type: none"> Amendment 1 “<i>To update section 5(e) to reflect any commercial aspects, for example, the IP rights</i>” <p>The example cited in the outcome by IGARD was an example. IGARD suggest that the NHS Digital DARS Standard for Commercial Purpose is re-visited since for example OptimiseRX software may gain a commercial advantage and this is drawn out in point 2 of the published DARS Standard “<i>any party involved in the application receives any form of commercial benefit¹ (including intangible or indirect commercial benefits</i></p>

						<i>such as positive publicity for a commercial venture)</i> <i>from the use of data, for example commercial funders or sponsors."</i>
NIC-484452-H8S1L-v0.3	Department of Health & Social Security	16/09/21	<ol style="list-style-type: none"> 1. To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. 2. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they are clear as to the benefits to both the patients and the health and social care system more generally and comply with NHS Digital's DARS Standard for Expected Measurable Benefits. 	IGARD Members	Quorum of IGARD Members	N/A
NIC 362237-Y5K7L-v3.2	NHS Bath & North East Somerset, Swindon & Wiltshire CCG	12/08/21	<ol style="list-style-type: none"> 1. In respect of the yielded benefits: <ol style="list-style-type: none"> a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits, and are clear as to the benefits to the local population and the health care system. b) To update the yielded benefits in section 5(d) (iii), to reflect the purpose(s) for processing. c) To update the yielded benefits in section 5(d) (iii) to clearly distinguish between 'initiatives' and 'strategic objectives'. 	IGARD Members	Quorum of IGARD Members	N/A

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-527503-Z3W0N-v0.3 NHS Wakefield CCG - Comm, IV, RS

Optum Health Solutions UK Limited Class Actions:

- NIC-281073-Y5G3F-v4.4 NHS Derby and Derbyshire CCG, Comm. IV and RS
- NIC-95040-Y0P3W-v4 NHS Cambridgeshire & Peterborough CCG

Graphnet Class Actions:

- None