Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 17 November 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member (items 1 to 6)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Geoffrey Schrecker	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.4 to 3.5)
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (Items 4.3 to 4.4, 7.1)
Catherine Day	Data Access Request Services (DARS SAT) (**Presenter:** item 3.6)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.7 to 3.8)
Duncan Easton	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.1 to 3.3, 3.8)
Mujiba Ejaz	Data Access Request Services (DARS) (**Presenter**: item 3.4)
Dan Goodwin	Data Access Request Services (DARS) (**Observer:** items 4.3 to 4.4)
Charles John	Data Access Request Services (DARS) (**Observer**: items 3.1 to 3.5)
Abigail Lucas	Data Access Request Services (DARS) (**Observer**: items 3.1 to 3.3)
David Morris	Data Access Request Services (DARS) (**Presenter**: item 3.8)

Karen Myers	IGARD Secretariat Team
Denise Pine	Data Access Request Services (DARS) (**Presenter**: item 3.7)
Andy Rees	Digi-Trials (**Presenter:** Item 7.1)
Charlotte Skinner	Data Access Request Services (DARS) (**Presenter**: item 3.5)
Anna Weaver	Data Access Request Services (DARS) (**Presenter:** items 3.1 to 3.3)
Vicki Williams	IGARD Secretariat Team
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Paul Affleck, Maria Clark, Prof. Nicola Fear, Kirsty Irvine, Dr. Imran Khan and Dr. Maurice Smith, noted a professional link to the applicant at Cardiff University (NIC-669808-V6T0M, NIC-669962-W1F6D and NIC-674735-Z0H6K), but noted no specific connection with the application and it was agreed that this was not a conflict of interest; however confirmed that the applications would be reviewed in line with the IGARD 'Applicant is a Member of IGARD' Standard Operating Procedure. Maria Clark noted professional links to the Royal College of Surgeons (NIC-355855-R4G6G), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Prof Nicola Fear noted that as part of her role at King's College London, she may be a future user of the ECHILD data (NIC-381972-Q5F0V), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Prof Nicola Fear noted previous professional links to the applicant (Institute of Cancer Research NIC-148155-K7P19), but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 10th November 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	Cardiff University: STEADFAST Modelling the associations between wider health and social characteristics and diabetes-related health - Cohort Matching Service for NPDA identifier data flows to DfE for linkage in ONS (Presenter: Anna Weaver) NIC-669808-V6T0M-v0.3

	Application: This was a new application for identifiable Demographics data. The application is to cover the flow of identifiers of people in the National Paediatric Diabetes Audit (NPDA) between 2003/04 - 2017/18 into NHS Digital. NHS Digital will supplement this information with full names and remove the NHS number, sending these identifiers onto the DfE as a one-off drop of data. The purpose of the application is for a research study: "STEADFAST - Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes". The study aims to provide a greater understanding of the interrelationship between diabetes-related health and education. The study is grounded in the evidence that most of the costs arising from Type 1 diabetes come not from the day-to-day care and medications, but the complications arising from elevated blood glucose over the life course. There is currently limited evidence on the causes of less optimal diabetes management and the potential mechanisms for interventions to improve this. Thus, this study hopes to broaden the evidence base beyond the purely clinical factors to investigate the wider health and social determinants of diabetes-related health, using linked administrative data and focussing on education. NIC-158283-T2Q2D covers the flow of National Diabetes Audit (NDA) data into the SAIL Databank based at the University of Swansea, and flow of identifiers to Digital Health and Care Wales (DHCW). NIC-669962-W1F6D (Item 3.2) covers the creation of a cohort of people in the NDA born between the 1st September 1983 – 31st August 2002, whose clinical data for the audit period 2003/04 - 2017/18 will be disseminated directly to the Office for National Statistics (ONS) Secure Research Service (SRS) as a one-off drop of data. NIC-674735-Z0H6K (Item 3.3) will cover the flow of identifiers of people in the NIC-669962-W1F6D cohort to the Department for Education (DfE) as a one-off drop of data. The study is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital. **Discussion:** IGARD noted that a member of the study team was a member of IGARD and that this application would be reviewed in line with the IGARD 'Applicant is a Member of IGARD' Standard Operating Procedure. IGARD noted that the application for NIC-158283-T2Q2D and relevant supporting documents had previously been presented at the IGARD meeting on the 14th February 2019 and the 12th September 2019. IGARD noted and commended NHS Digital, and the applicant, on the quality of the information within the application, which supported the review of the application by members. IGARD advised NHS Digital that they were aware that DfE was subject to an audit by the Information Commissioner's Office (ICO) in 2020, which raised a number of concerning issues regarding data handling, and a reprimand in 2022. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD noted the efforts made by the applicant in respect of communication and transparency with the cohort; and suggested that communication continued, including, but not limited to, transparency in respect of the various opt-out options available.

	IGARD suggested that due to the significant volume of data flowing; the type of data being processed, i.e. children and young people; the sensitive nature of the data being processed; and the parties involved, for example DfE; that the applicant carried out a Data Protection Impact Assessment (DPIA) **before** processing commences in line with Article 35 of UK General Data Protection Regulation (UK GDPR). A copy of the DPIA should also be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the statement in section 1 (Abstract) *"All types of diabetes therefore need to be requested…"*; however, noting that the rest of the application only referred to *"Type 1"* diabetes, asked that the application was updated where necessary, to ensure that it accurately reflected that Type 2 diabetes data would be flowing, in addition to Type 1 diabetes data. IGARD also noted that the public facing transparency materials, for example, the study website, were not clear that Type 2 diabetes data would be flowing; and asked that these were updated as appropriate. IGARD noted that the National Pupil Database (NPD) does not contain the details of all children, which may limit the research being undertaken. IGARD asked that for transparency, section 5(a) (Objective for Processing) was updated if relevant to clarify that not **all** children's data would be held by DfE. IGARD queried what would happen to the unmatched cohort data, for example, those cohort members whose data flows to DfE, but were not on the National Pupil Database (NPD), for example, those children and young people who did not attend state schools. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with a further explanation. IGARD queried the role of Cardiff University, noting that they were not listed as a Data Processor within section 1(c) (Data Processor(s)) of the application; however section 5(a) stated *"Cardiff University are the research Sponsor and sole data controller for this DSA, who **also process the data***". NHS Digital confirmed that Cardiff University was not a Data Processor, and the statement within section 5(a) was an error. IGARD noted the verbal update from NHS Digital, and asked that any reference(s) to Cardiff University being a Data Processor was removed from the application and in line with the NHS Digital DARS Standard for Data Processors. IGARD noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was the *"UK"* and asked that this was amended to correctly reflect that the territory of use was *"England and Wales"*, in line with the published NHS Digital DARS Standard for territory of use. IGARD queried if any patient and public involvement and engagement (PPIE) had been undertaken during the design of the study; and noting that this was currently unclear, asked that the public facing section 5(b) (Processing Activities) that forms part of NHS Digital's data uses register was updated with further clarity. IGARD queried the reference in section 5(b) *"…date of birth to nearest day…"*, and noting that it was unclear what this meant, asked that this was updated to give clarity. IGARD noted the reference to *"gender"* in section 5; and asked that it was clarified if it was actually *"sex"*, since they were not interchangeable data fields. IGARD queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"…clinical teams choose to provide extra support…"*; and asked that this was updated to correctly state *"…clinical teams **may** choose to provide extra support…"*, in line with other similar statements in section 5(d) (ii).

	IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* IGARD suggested that there may be further benefit from the inclusion of COVID-19 data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. IGARD suggested that if the application did add COVID-19 datasets to the data sharing agreement (DSA), that Health Research Authority Confidentiality Advisory Group (HRA CAG) and Research Ethics Committee (REC) should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG and REC documentation to support this be uploaded to NHS Digital's CRM system for future reference. IGARD requested that the outcome is reviewed by the NHS Digital Caldicott Guardian and NHS Digital Director Data Access who may wish to formally endorse or add additional conditions, amendments or advice to the recommendation because the applicant is a member of IGARD. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the Type 2 diabetes data: a) To update the application where necessary to reflect that Type 2 diabetes data will be flowing; and, b) To update the public facing transparency materials to reflect that Type 2 diabetes data will be flowing. 2. In respect of the DfE: a) To update section 5(a) if relevant to clarify that not **all** children's data will be held by DfE. b) To update section 5 with an explanation as to what will happen to the unmatched data, i.e. those cohort members whose data flow to DfE but are not on the NPD. 3. To update section 5(a) to remove any reference(s) to Cardiff University being a Data Processor. 4. To amend section 2(c) to reflect the territory of use is *"England and Wales"*. 5. To update section 5(b) to provide clarity of any PPIE undertaken during the design of the study. 6. To provide further clarity in section 5(b) to the references *"date of birth to nearest day"*. 7. To update section 5 to clarify if *"gender"* or *"sex"* is required, since they are not interchangeable data fields. 8. To amend the statement in section 5(d) (ii) *"clinical teams **may** choose to provide extra support…"*. 9. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* The following advice was given:

	1. IGARD noted the NPD does not contain the details of all children, which may limit the research being undertaken. 2. IGARD noted the efforts made by the applicant in respect of communication / transparency with the cohort; and suggested that this communication continues, including (but not limited to) transparency in respect of the various opt-out options available. 3. In respect of any additional COVID-19 datasets: a) IGARD suggested that there may be further benefit from the inclusion of COVID-19 data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. b) IGARD suggested that if the application did add COVID-19 datasets to the DSA, that HRA CAG and REC should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG and REC documentation to support this were uploaded to NHS Digital's CRM system for future reference. 4. In respect of the DPIA: a) IGARD suggested that due to the significant volume of data flowing, the type of data being processed, i.e. children and young people, the sensitive nature of the data being processed, and the parties involved, for example DfE; that the applicant carries out a DPIA **before** processing commences in line with Article 35 of UK GDPR. b) To upload a copy of the DPIA to NHS Digital's CRM system for future reference. **Risk Factor**: IGARD is aware that DfE was subject to an ICO audit in 2020, which raised a number of concerning issues regarding data handling, and a reprimand in 2022. Accordingly, there may be a risk to public trust and confidence in the safe handling of their health data by NHS Digital disseminating data to a project with DfE involvement. **Subsequent to the meeting**: the Deputy Caldicott Guardian noted that "*Due process has been followed and I am content. IGARD have assessed the applications in a fair, transparent and independent manner*"
3.2	Cardiff University: STEADFAST Modelling the associations between wider health and social characteristics and diabetes-related health – Substantive data flows to ONS (Presenter: Anna Weaver) NIC-669962-W1F6D-v0.6 **Application:** This was a new application for National Diabetes Audit (NDA) data. The application is to cover the creation of a cohort of people in the NDA born between 1st September 1983 – 31st August 2002, whose clinical data for the audit period 2003/04 – 2017/18 will be disseminated directly to the Office for National Statistics' (ONS) Secure Research Service (SRS) as a one-off drop of data. The purpose of the application is for a research study: "STEADFAST – Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes". The study aims to provide a greater understanding of the interrelationship between diabetes-related health and education. The study is grounded in the evidence that most of the costs arising from Type 1 diabetes come not from the day-to-day care and medications, but the complications arising from

	elevated blood glucose over the life course. There is currently limited evidence on the causes of less optimal diabetes management and the potential mechanisms for interventions to improve this. Thus, this study hopes to broaden the evidence base beyond the purely clinical factors to investigate the wider health and social determinants of diabetes-related health, using linked administrative data and focussing on education. NIC-158283-T2Q2D covers the flow of National Diabetes Audit (NDA) data into the SAIL Databank based at the University of Swansea, and flow of identifiers to Digital Health and Care Wales (DHCW). NIC-669808-V6T0M (item 3.1) will cover the flow of identifiers of people in the National Paediatric Diabetes Audit (NPDA) between 2003/04 – 2017/18 into NHS Digital. The NPDA is commissioned by the Healthcare Quality Improvement Partnership (HQIP). NHS Digital will supplement this information with full names and remove the NHS number, sending these identifiers onto the DfE as a one-off drop of data. NIC-674735-Z0H6K (Item 3.3) will cover the flow of identifiers of people in the NIC-669962-W1F6D cohort to the Department for Education (DfE) as a one-off drop of data. **Discussion:** IGARD noted that a member of the study team was a member of IGARD and that this application would be reviewed in line with the IGARD 'Applicant is a Member of IGARD' Standard Operating Procedure. IGARD noted that the application for NIC-158283-T2Q2D and relevant supporting documents had previously been presented at the IGARD meeting on the 14th February 2019 and the 12th September 2019. IGARD noted and commended NHS Digital and the applicant, on the quality of the information within the application, which supported the review of the application by members. IGARD noted that prior to the meeting, a query had been raised by an IGARD member, in relation to the statement in section 3(c) (Patient Objections) that patient objections would **not** be upheld; and queried if the National Data Opt-out (NDO) was applied to the flow of data to the DfE to enable linkage, if it also needed to be applied here. NHS Digital advised that further discussion had taken place within NHS Digital in respect of this query, and it had been agreed that the NDO **would** be upheld. IGARD noted and thanked NHS Digital for the verbal update, and confirmed that they were supportive of the NDO being upheld. IGARD asked that section(c) was amended to confirm that patients objections would be applied. IGARD noted the efforts made by the applicant in respect of communication and transparency with the cohort; and suggested that this ongoing communication continued, including, but not limited to, transparency in respect of the various opt-out options available. IGARD suggested that due to the significant volume of data flowing; the type of data being processed, i.e. children and young people; the sensitive nature of the data being processed; and the parties involved, for example DfE; that the applicant carried out a Data Protection Impact Assessment (DPIA) **before** processing commences in line with Article 35 of UK General Data Protection Regulation (UK GDPR). A copy of the DPIA should also be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the statement in section 1 (Abstract) *"All types of diabetes therefore need to be requested…"*; however, noting that the rest of the application only referred to *"Type 1"* diabetes, asked that the application was updated where necessary, to ensure that it accurately reflected that Type 2 diabetes data would also be flowing, in addition to Type 1 diabetes data.

	IGARD also noted that the public facing transparency materials, for example, the study website, was not clear that Type 2 diabetes data would be flowing; and asked that these were updated as appropriate. IGARD noted the NPD does not contain the details of all children, which may limit the research being undertaken. IGARD noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was the *"UK"* and asked that this was amended to correctly reflect that the territory of use was *"England and Wales"*, in line with the published NHS Digital DARS Standard for territory of use. IGARD queried if any patient and public involvement and engagement (PPIE) had been undertaken during the design of the study; and noting that this was currently unclear, asked that the public facing section 5(b) (Processing Activities) that forms part of NHS Digital's data uses register was updated with further clarity. IGARD queried the reference in section 5(b) *"…date of birth to nearest day…"*, and noting that it was unclear what this meant, asked that this was updated with further clarity. IGARD noted the reference to *"gender"* in section 5 (Purpose / Methods / Outputs); and asked that it was clarified if it was actually *"sex"*, since they were not interchangeable data fields. IGARD queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"…clinical teams choose to provide extra support…"*; and asked that this was updated to correctly state *"…clinical teams **may** choose to provide extra support…"*, in line with other similar statements in section 5(d) (ii). IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* IGARD suggested that there may be further benefit from the inclusion of COVID-19 data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. IGARD also suggested that if the application did add COVID-19 datasets to the data sharing agreement (DSA), that Health Research Authority Confidentiality Advisory Group (HRA CAG) and Research Ethics Committee (REC) should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG and REC documentation to support this were uploaded to NHS Digital's CRM system for future reference. **Separate to the application**: IGARD noted the special condition in section 6 *"Information on GP data from Wales cannot be published on a GP level"*; and queried the rationale and whether the restriction should also apply to GPs in England. IGARD requested that the outcome is reviewed by the NHS Digital Caldicott Guardian and NHS Digital Director Data Access who may wish to formally endorse or add additional conditions, amendments or advice to the recommendation because the applicant is a member of IGARD. **Outcome:** recommendation to approve

	The following amendments were requested: 1. To amend section 3(c) to reflect that patients objections would be applied (as per the verbal update from NHS Digital). 2. In respect of the Type 2 diabetes data: a. To update the application where necessary to reflect that Type 2 data will be flowing; and, b. To update the public facing transparency materials to reflect that Type 2 data will be flowing. 3. To amend section 2(c) to reflect the territory of use is *"England and Wales"*. 4. To update section 5(b) to provide clarity of any PPIE undertaken during the design of the study. 5. To provide further clarity in section 5(b) to the references *"date of birth to nearest day"*. 6. To update section 5 to clarify if *"gender"* or *"sex"* is required, since they are not interchangeable data fields. 7. To amend the statement in section 5(d) (ii) *"clinical teams **may** choose to provide extra support…"*. 8. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* The following advice was given: 1. IGARD noted the NPD does not contain the details of all children, which may limit the research being undertaken. 2. IGARD noted the efforts made by the applicant in respect of communication / transparency with the cohort; and suggested that this communication continues, including (but not limited to) transparency in respect of the various opt-out options available. 3. In respect of any additional COVID-19 datasets: a. IGARD suggested that there may be further benefit from the inclusion of COVID-19 data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. b. IGARD suggested that if the application did add COVID-19 datasets to the DSA, that HRA CAG and REC should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG and REC documentation to support this were uploaded to NHS Digital's CRM system for future reference. 4. In respect of the DPIA: a. IGARD suggested that due to the significant volume of data flowing, the type of data being processed, i.e. children and young people, the sensitive nature of the data being processed, and the parties involved, for example DfE; that the applicant carries out a DPIA **before** processing commences in line with Article 35 of UK GDPR. b. To upload a copy of the DPIA to NHS Digital's CRM system for future reference. **Separate to the application**: IGARD noted the special condition in section 6 *"Information on GP data from Wales cannot be published on a GP level"*; and queried the rationale and

	whether the restriction should also apply to whether GPs in England had been given the same opportunity to consider. **Subsequent to the meeting:** the Deputy Caldicott Guardian noted that "*Due process has been followed and I am content. IGARD have assessed the applications in a fair, transparent and independent manner*"
3.3	Cardiff University: STEADFAST Modelling the associations between wider health and social characteristics and diabetes-related health - Substantive data flows to ONS (Presenter: Anna Weaver) NIC-674735-Z0H6K-v0.2 **Application:** This was a new application for identifiable Demographics data. The application is to cover the flow of identifiers of people in the NIC-669962-W1F6D (item 3.2) cohort to the Department for Education (DfE) as a one-off drop of data. The purpose of the application is for a research study: "STEADFAST - Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes". The study aims to provide a greater understanding of the interrelationship between diabetes-related health and education. The study is grounded in the evidence that most of the costs arising from Type 1 diabetes come not from the day-to-day care and medications, but the complications arising from elevated blood glucose over the life course. There is currently limited evidence on the causes of less optimal diabetes management and the potential mechanisms for interventions to improve this. Thus, this study hopes to broaden the evidence base beyond the purely clinical factors to investigate the wider health and social determinants of diabetes-related health, using linked administrative data and focussing on education. NIC-158283-T2Q2D covers the flow of National Diabetes Audit (NDA) data into the SAIL Databank based at the University of Swansea, and flow of identifiers to Digital Health and Care Wales (DHCW). NIC-669808-V6T0M (item 3.1) will cover the flow of identifiers of people in the National Paediatric Diabetes Audit (NPDA) between 2003/04 - 2017/18 into NHS Digital. The NPDA is commissioned by the Healthcare Quality Improvement Partnership (HQIP). NHS Digital will supplement this information with full names and remove the NHS number, sending these identifiers onto the DfE as a one-off drop of data. NIC-669962-W1F6D (Item 3.2) covers the creation of a cohort of people in the NDA born between the 1st September 1983 – 31st August 2002, whose clinical data for the audit period 2003/04 - 2017/18 will be disseminated directly to the Office for National Statistics (ONS) Secure Research Service (SRS) as a one-off drop of data. **Discussion:** IGARD noted that a member of the study team was a member of IGARD and that this application would be reviewed in line with the IGARD 'Applicant is a Member of IGARD' Standard Operating Procedure. IGARD noted that the application for NIC-158283-T2Q2D and relevant supporting documents had previously been presented at the IGARD meeting on the 14th February 2019 and the 12th September 2019. IGARD noted and commended NHS Digital and the applicant, on the quality of the information within the application, which supported the review of the application by members.

	IGARD advised NHS Digital that they were aware that DfE was subject to an audit by the Information Commissioner's Office (ICO) in 2020, which raised a number of concerning issues regarding data handling, and a reprimand in 2022. IGARD noted the efforts made by the applicant in respect of communication and transparency with the cohort; and suggested that this ongoing communication continued, including, but not limited to, transparency in respect of the various opt-out options available. IGARD suggested that due to the significant volume of data flowing; the type of data being processed, i.e. children and young people; the sensitive nature of the data being processed; and the parties involved, for example DfE; that the applicant carried out a Data Protection Impact Assessment (DPIA) **before** processing commences in line with Article 35 of UK General Data Protection Regulation (UK GDPR). A copy of the DPIA should also be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the statement in section 1 (Abstract) *"All types of diabetes therefore need to be requested…"*; however, noting that the rest of the application only referred to *"Type 1"* diabetes, asked that the application was updated where necessary, to ensure that it accurately reflected that Type 2 diabetes data would also be flowing, in addition to Type 1 diabetes data. IGARD also noted that the public facing transparency materials, for example, the study website, was not clear that Type 2 diabetes data would be flowing; and asked that these were updated as appropriate. IGARD noted that the National Pupil Database (NPD) does not contain the details of all children, which may limit the research being undertaken. IGARD asked that for transparency, section 5(a) (Objective for Processing) was updated if relevant to clarify that not **all** children's data would be held by DfE. IGARD queried what would happen to the unmatched cohort data, for example, those cohort members whose data flows to DfE, but were not on the National Pupil Database (NPD), for example, those children and young people who did not attend state schools. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with a further explanation. IGARD queried the role of Cardiff University, noting that they were not listed as a Data Processor within section 1(c) (Data Processor(s)) of the application; however section 5(a) stated *"Cardiff University are the research Sponsor and sole data controller for this DSA, who **also process the data***". NHS Digital confirmed that Cardiff University was not a Data Processor, and the statement within section 5(a) was an error. IGARD noted the verbal update from NHS Digital, and asked that any reference(s) to Cardiff University being a Data Processor was removed from the application. IGARD noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was the *"UK"* and asked that this was amended to correctly reflect that the territory of use was *"England and Wales"*, in line with the published NHS Digital DARS Standard for territory of use. IGARD queried the reference in section 5(b) (Processing Activities) *"…date of birth to nearest day…"*, and noting that it was unclear what this meant, asked that this was updated with further clarity. IGARD noted the reference to *"gender"* in section 5 (Purpose / Methods / Outputs); and asked that it was clarified if it was actually *"sex"*, since they were not interchangeable data fields. IGARD queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"…clinical teams choose to provide extra support…"*; and asked

	that this was updated to correctly state *"…clinical teams **may** choose to provide extra support…"*, in line with other similar statements in section 5(d) (ii). IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* IGARD suggested that there may be further benefit from the inclusion of COVID-19 data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. IGARD also suggested that if the application did add COVID-19 datasets to the data sharing agreement (DSA), that Health Research Authority Confidentiality Advisory Group (HRA CAG) and Research Ethics Committee (REC) should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG and REC documentation to support this were uploaded to NHS Digital's CRM system for future reference. IGARD requested that the outcome is reviewed by the NHS Digital Caldicott Guardian and NHS Digital Director Data Access who may wish to formally endorse or add additional conditions, amendments or advice to the recommendation because the applicant is a member of IGARD. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the Type 2 diabetes data: a. To update the application where necessary to reflect that Type 2 data will be flowing; and, b. To update the public facing transparency materials to reflect that Type 2 data will be flowing. 2. In respect of the DfE: a. To update section 5(a) if relevant to clarify that not **all** children's data will be held by DfE. b. To update section 5 with an explanation as to what will happen to the unmatched data, i.e. those cohort members whose data flow to DfE but are not on the NPD. 3. To update section 5(a) to remove any reference(s) to Cardiff University being a Data Processor. 4. To amend section 2(c) to reflect the territory of use is *"England and Wales"*. 5. To provide further clarity in section 5(b) to the references *"date of birth to nearest day"*. 6. To update section 5 to clarify if *"gender"* or *"sex"* is required, since they are not interchangeable data fields. 7. To amend the statement in section 5(d) (ii) *"clinical teams **may** choose to provide extra support…"*. 8. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support"*. The following advice was given:

	1. IGARD noted the NPD does not contain the details of all children, which may limit the research being undertaken. 2. IGARD noted the efforts made by the applicant in respect of communication / transparency with the cohort; and suggested that this ongoing communication continues, including (but not limited to) transparency in respect of the various opt-out options available. 3. In respect of any additional COVID-19 datasets: a. IGARD suggested that there may be further benefit from the inclusion of COVID-19 data. IGARD advised that they would be supportive of the applicant receiving additional COVID-19 flows of data if required, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. b. IGARD suggested that if the application did add COVID-19 datasets to the DSA, that HRA CAG and REC should be notified and the relevant s251 approvals put in place for this amendment; and that all HRA CAG and REC documentation to support this were uploaded to NHS Digital's CRM system for future reference. 4. In respect of the DPIA: a. IGARD suggested that due to the significant volume of data flowing, the type of data being processed, i.e. children and young people, the sensitive nature of the data being processed, and the parties involved, for example DfE; that the applicant carries out a DPIA **before** processing commences in line with Article 35 of UK GDPR. b. To upload a copy of the DPIA to NHS Digital's CRM system for future reference. **Risk Factor**: IGARD is aware that DfE was subject to an ICO audit in 2020, which raised a number of concerning issues regarding data handling, and a reprimand in 2022. Accordingly, there may be a risk to public trust and confidence in the safe handling of their health data by NHS Digital disseminating data to a project with DfE involvement. **Subsequent to the meeting:** the Deputy Caldicott Guardian noted that "*Due process has been followed and I am content. IGARD have assessed the applications in a fair, transparent and independent manner*"
3.4	University of Glasgow: Data linkage request for FAMOUS-NSTEMI study (Presenter: Mujiba Ejaz) NIC-170589-L2W0Y-v0.21 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) and Hospital Episode Statistics Admitted Patient Care (HES APC) data. Ischaemic heart disease (IHD) persists as the leading global cause of death and lost life years in adults. In the UK, there are more than 2 million men and women living with angina (form of IHD, a condition marked by severe pain in the chest that often spreads to the shoulders, arms, and neck, leading to an inadequate blood supply to the heart). Overall, IHD due to coronary artery disease (CAD) remains a worldwide public health problem of unmet need. The national audit of myocardial infarction (MINAP) in England and Wales indicates around 80,000 patients experience a non-ST segment elevation myocardial infarction (NSTEMI) each year. NSTEMI is the more common type of myocardial infarction (MI, also known as 'heart attack', comprising approximately 70% of MI events). The standard care for acute MI is 'invasive management' with a view to identifying a culprit blockage, or blockages, that could be treated with a stent or

	bypass surgery. Around 100,000 patients undergo a stent procedure in the NHS each year and approximately 60% have a diagnosis of NSTEMI. For patients with MI and multiple narrowed coronary arteries, clinicians and their patients lack information on whether all narrowings should be treated or just the 'culprit'. The FAMOUS-NSTEMI trial was the first to address this question in a registry-based, randomised, controlled trial; and focused on the diagnostic and clinical value of using Fractional Flow Reserve (FFR) to guide treatment decisions in patients with a recent heart attack. The purpose of the application is for a study to enable an analysis of whether, compared with standard care, FFR-guided management is associated with fewer deaths and hospitalisations for a cardiovascular cause in patients undergoing invasive coronary angiography for a NSTEMI. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. The application was previously considered on the 14th February 2019 where IGARD had been unable to make a recommendation for approval. **Discussion:** IGARD welcomed the application and noted the importance of the study, and the potential immediate impact for patient treatment and care. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 14th February 2019. IGARD noted that the application had been updated to address all the previous points. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application; however noting that the Health Research Authority Confidentiality Advisory Group (HRA CAG) annual review was due April 2022, asked that written confirmation was provided that this had been submitted and accepted by HRA CAG, and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. In addition, IGARD asked that section 1 (Abstract) was updated, to reflect that the HRA CAG annual review had been submitted and accepted. IGARD noted the technical language in the first paragraph in section 5(a) (Objective for Processing); and asked that this public facing section that forms NHS Digital's data uses register was updated in line with NHS Digital DARS Standard for Objective for Processing, to ensure it was written in a manner suitable for a lay reader, including, but not limited to, the information relating to *"NSTEMI"*; and that any relevant weblinks were provided. IGARD queried the statement in section 5(a) *"NSTEMI is a condition associated with considerable diversity– patients may present sub-acutely (delayed presentation)…"*; and asked that further clarity was provided on the reference to *"delayed presentation"*, as this was not clear. IGARD noted the reference in section 5(a) to *"Golden Jubilee National Hospital (NHS **National** Waiting Times Centre)"*; and asked that this was updated to make clear that this was not a UK wide initiative, noting that the use of *"National"* may be misleading. IGARD queried what, if any, future patient and public involvement and engagement (PPIE) was planned, noting that this was not clear within the application; and asked that section 5(a) which forms NHS Digital's data uses register, was updated to provide details of an indicative plan of future PPIE activity.

	IGARD suggested, if there was **no** future PPIE planned, that the applicant consider involving the relevant public and patient groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide. IGARD noted the specific timeframes referenced in section 5(c) (Specific Outputs Expected), for example *"The target date is winter 2022…"*; and asked that these were reviewed and amended as appropriate with the most up to date information. IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the s251 support: a. To provide written confirmation that the HRA CAG annual review, due April 2022, had been submitted and accepted, and b. To upload the written confirmation from HRA CAG to NHS Digital's CRM system for future reference; and, c. To update section 1 to reflect that the HRA CAG annual review has been submitted and accepted. 2. To update the first paragraph of section 5(a) to ensure this is written in a manner suitable for a lay reader, including (but not limited to) the information relating to *"NSTEMI"*; and provide any relevant weblinks. 3. To provide further clarity on the reference in section 5(a) *"delayed presentation"*. 4. To update the reference in section 5(a) to *"Golden Jubilee National Hospital (NHS National Waiting Times Centre)"*, to clarify that this is not a UK wide initiative. 5. To update section 5 to provide details of any future PPIE activity. 6. To review the specific timeframes in section 5(c) and amend as appropriate with the most up to date information. The following advice was given: 1. IGARD suggested that the applicant involve relevant public and patient groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide.
3.5	Royal College of Anaesthetists: National Emergency Laparotomy Audit (NELA) (Presenter: Charlotte Skinner) NIC-355855-R4G6G-v9.18 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) data, Demographics data, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES-ID to MPS-ID HES APC; and identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report and MRIS - Flagging Current Status Report. It was also an amendment application to **1)** update the application to reflect NHS England's role as a Data Controller in line with other audits that fall under the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The Healthcare Quality Improvement Partnership (HQIP) is commissioned by NHS England to commission and manage audits that fall under the NCAPOP. Section 5(b) has been updated to provide clarification on the relationship between NHS England and HQIP as joint data controllers; **2)** to update the application to reflect Harbor

	Solutions Limited's role as a Data Processor; including section 2 which has been updated to add their associated storage and processing locations. The purpose of the application is for the National Emergency Laparotomy Audit (NELA); which was commissioned in 2011 by HQIP and is funded by NHS England and the Welsh Government. NELA first began collecting data in 2013 and has continued to do so on a regular basis ever since. NELA's aims are to collect and publish high-quality comparative information from all hospitals in England and Wales at which emergency laparotomies (a major operation where the surgeon has to cut open the abdomen) are performed; in order to drive quality improvement in the care of these patients. It was established in response to the comparatively high death rate after emergency laparotomy, and the substantial variation in this rate between hospitals. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. The application was previously considered on the 25th April 2019 where IGARD had been unable to make a recommendation. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meeting on the 1st December 2015 and the 15th December 2015; and at the IGARD meetings on the 4th April 2019 and the 25th April 2019. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 9th February 2017. IGARD noted that the application had been updated to address all the previous points. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. NHS Digital advised IGARD, that as outlined in section 1 (Abstract), there was a currently an outstanding query from January 2021, with NHS Digital's Privacy, Transparency, Ethics and Legal Team (PTEL) in respect of the scope for the use of the Memorandum of Understanding (MoU) before access was granted to non-substantive employees; and that until this issue had been resolved, a special condition had been added to section 6 (Special Conditions) stating *"…only substantive employees of Royal College of Anaesthetists and The Royal College of Surgeons of England can access the NHS Digital data until there is a clear legal position on the use of the memorandum of understanding for non-substantive employees"*. IGARD noted and thanked NHS Digital for the verbal update and the information within section 1; and suggested that the outstanding PTEL query relating to the MOU was satisfactorily resolved as soon as possible and that the application was updated to reflect the PTEL outcome. IGARD noted that, once resolved, the special condition in section 6 relating to the outstanding PTEL query should be removed. If however the outstanding PTEL query was not satisfactorily resolved, IGARD suggested that this was escalated to NHS Digital's DARS SAT colleagues. IGARD asked that any correspondence relating to the outstanding PTEL query outcome were uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the efforts made by the applicant in respect of communication and transparency with the cohort; and suggested that this communication continued, including, but not limited to, transparency in respect of the opt-out options available.

	IGARD queried the statement in section 1 *"The MRIS – Cause of Death Report product contains a number of fields have been categorised as identifiable by the IAO…. These fields are listed as identifiable only because they are free text fields which may, although they usually will not, contain identifiable data"*; and asked that NHS Digital clarify with the applicant, that the free text has now been pseudonymised; and that once confirmed, section 1 was updated accordingly for future reference. IGARD noted that prior to the meeting, an IGARD member had queried why the rationale for not applying the National Data Opt-out (NDO) did not also apply to the audit specific opt-out. NHS Digital advised that there was still a local opt-out option from NELA, due to a request from HRA CAG, and that the HRA CAG letter of support outlined that as a condition of support for exemption from the opt-out, '*a local patient objection mechanism must continue to be used in relation to CAG 5-07(d)/2013*'. The letter also highlighted the patient engagement activities the Royal College of Anaesthetists had undertaken regarding the opt-out and the conditions that HRA CAG had imposed to ensure continued patient engagement regarding the opt-out. IGARD noted and thanked NHS Digital and the applicant for providing clarification, and asked that for transparency, the public facing section 5 (Purpose / Methods / Outputs) which forms NHS Digital's data uses register was updated with clarification of what opt-outs were applied. IGARD noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was the *"UK"* and asked that this was amended to correctly reflect that the territory of use was *"England and Wales"*, in line with the published NHS Digital DARS Standard for territory of use. IGARD queried the statement in section 5(a) (Objective for Processing) relating to the consultation with the 'Patient and Families Involvement Group' (PAFIG) *"One of the members noted that it would be likely that people would choose to opt-out without a real understanding of the issues; she noted that there is no real risk to the public in sharing data with NELA as it is anonymous"*; and asked that this was removed, noting that the data was **not** *"anonymous"*, and section 5(a) was public facing and forms NHS Digital's data uses register. In addition, IGARD cautioned against citing a single view and suggested instead that general themes should be relied on from patient and public involvement and engagement (PPIE) consultation. IGARD noted and commended the applicant on the excellent yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits); however queried the yielded benefit that stated *"30-day mortality has fallen from 11.8% to 8.7% in the most recent report"*; and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits this was linked with an expected outcome in section 5(c) (Specific Outputs Expected); or if not a yielded benefit, asked that this was removed. IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to clarify that the free text has been pseudonymised (following clarification from applicant). 2. To provide clarification in section 5 of what opt-outs are appliedTo amend section 2(c) to reflect the territory of use is *"England and Wales"*.

	3. To amend section 5(a) to remove reference to the individual PAFIG member describing the data as *"anonymous"*. 4. To update the yielded benefit in section 5(d) (iii) that states "*30-day mortality has fallen"* with an expected outcome in section 5(c); or remove if not a yielded benefit. 5. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support"*. The following advice was given: 1. In respect of the MOU PTEL query: a) IGARD suggested that the outstanding PTEL query relating to the MOU is satisfactorily resolved as soon as possible and that the application is updated to reflect the PTEL outcome; and, b) To remove the special condition in section 6 relating to the outstanding PTEL query; or, c) If the outstanding PTEL query is not satisfactorily resolved, IGARD suggested that this is escalated to NHS Digital's DARS SAT colleagues. d) To upload any correspondence relating to the outstanding PTEL query outcome to NHS Digital's CRM system for future reference. 2. IGARD noted the efforts made by the applicant in respect of communication / transparency with the cohort; and suggested that this communication continues, including (but not limited to) transparency in respect of the opt-out options available. 3. IGARD suggested general themes should be relied on from group PPIE consultations rather than highlighting individual contributions.
3.6	University College London (UCL): Education and Child Health Insights from Linked Data (The ECHILD Research Database) (Presenter: Catherine Day) NIC-381972-Q5F0V-v2.6 **Application:** This was an amendment application to convert and extend the existing Education and Child Health Insight Linked Data (ECHILD) Database used in the UCL study 'Assessing the impact of the COVID-19 pandemic on vulnerable children' to a Research Database for wider use, through a sub-licencing model. ECHILD includes linked data from health, education and children's social care and this linkage is not currently supplied by NHS Digital directly as it combines data from different sectors. ECHILD aims to improve understanding of the relationship between child health, child development, and contact with social care services. UCL require data over the child and adult life course because they are taking a longitudinal perspective across life. Long-term follow-up is required as it is known that exposures in early life (such as entry into care, or early disability such as extreme prematurity at birth) can have lifelong consequences for health. In addition, parental exposures, related to child maltreatment, poverty, or poor mental or physical health, and school factors such as special needs, influence the outcomes of children into adulthood. This application is linked to NIC-27404-D5Z3F. NHS Digital advised IGARD that the Maternity Services Data Set (MSDS) v2.0 had been omitted from this version of the application; and would be included as part of an amendment application in the future. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 25th June 2020, 21st October 2021 (withdrawn by presenter) and 25th November 2021.

	It was discussed as part of UCL application for 'Education and Child Health Insights from Linked Data' (ECHILD) Dataset Sub-Licencing – Briefing Paper on the 26th May 2022. It was also discussed as part of 'AOB' on the 20th October 2022. IGARD noted that the application for NIC-27404-D5Z3F and relevant supporting documents had previously been presented at the IGARD meetings on the 21st September 2017, 14th December 2017 and 18th January 2018. IGARD noted and thanked NHS Digital for the update in respect of the Maternity Services Data Set (MSDS) v2.0. IGARD noted that when the application was last reviewed on the 25th November 2021, IGARD had a lengthy discussion on the National Data Opt-out (NDO) and whether this applied to the data flowing under this Data Sharing Agreement (DSA); and agreed that, on face value, the NDO would **not** be applied, due to the data flowing being pseudonymised. IGARD therefore queried the information within 3(c) of this application that stated that patient objection would be applied. NHS Digital advised IGARD that there had been ongoing discussions within NHS Digital and the applicant, and it had been agreed that due to the increase in the cohort numbers, patient objections would now be applied. IGARD noted the verbal update from NHS Digital, however expressed concern that the decision as to whether the NDO was applied seemed to be inconsistent across applications; and asked that section 1 (Abstract) was updated with clarification as to why the NDO was now being upheld in respect of pseudonymised data, and in the context of the NDO policy. IGARD noted the responses from the UCL Data Protection Officer in respect of the sub-licensing, and queried whether the sub-licensing activity and associated risk(s) were addressed in the Data Protection Impact Assessment (DPIA), and asked that confirmation was provided in section 1 and section 5 (Purpose / Methods / Outputs) of the application. IGARD queried the legal basis for the Department for Education (DfE) to flow data for linkage, noting that the supporting documents provided stated a different legal basis from the application; and asked that this inconsistency was reviewed, and the application was updated with the correct legal basis. IGARD noted that the cohort of children and young people held by the DfE, were pupils attending state sector schools in England, and advised that this would exclude non-state funded schools and children that are home schooled, which may limit the research being undertaken. IGARD asked, for transparency, that section 5(a) (Objective for Processing) was updated clarify that not **all** children's data would be held by DfE. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that there were **no** commercial aspects to the application, however the Terms of Reference, provided as a supporting document, indicated there may be some commercial use of the data; and asked that in line with NHS Digital DARS Standard for Commercial Purpose, the application was updated to exclude commercial applicants from accessing the ECHILD data; or, that the application is revised to encompass commercial applicants for the ECHILD data. IGARD made a number of comments in respect of the public facing section 5(a) that forms NHS Digital's data uses register and in line with NHS Digital DARS Standard for Objective for Processing, including: IGARD queried the statement in section 5(a) *"…continued fair processing (in relation to ECHILD) in line with* **usual policies and practices***"*; and asked that either examples were

	provided of the "*usual policies and practices"* referred to, or that this statement was removed from the application. IGARD noted the reference in section 5(a) to *"…ECHILD denominator"*; and noting that it was unclear what this was, asked that further clarification was provided in section 5(a). IGARD noted the language in section 5(a), and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, including, but not limited to, amending the reference from *"mental disorder"* to *"mental health condition"*. and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. IGARD suggested that section 5(a) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD queried the internal assessments undertaken for requests for data, noting the references within the supporting documents provided, i.e., the 'ECHILD Data Access Committee Terms of Reference'; and asked that section 5(a) was updated with further clarity of any internal assessment(s), for example, who sits on the Committee. IGARD noted the benefits in section 5(d) (Benefits), however asked that these were updated further to ensure they were clear, as to the benefits to both the patients and the health and social care system; and in line with the NHS Digital DARS Standard for Expected Measurable Benefits; noting the significant research undertaken into the disadvantages created by pre-term births. IGARD queried the yielded benefit in section 5(d) (iii) (Yielded Benefits) point vii, and asked that the first sentence was removed that starts *"Analysis showed that children born with early identified chronic conditions contribute more to the burden of poor school outcomes than preterm birth…"*; noting that unless the underlying / related article was read in conjunction with this statement, it could be misleading. IGARD suggested that section 5(d) be updated, where appropriate, to remove reference to "*will*…", and instead use a form of words such as "*should* …" or *"could…"*. Noting that the territory of use was *"UK"*, IGARD suggested that the applicant may wish to consider applicants from the European Economic Area (EEA); and that if appropriate, the application was amended as appropriate in line with NHS Digital DARS Standard for Territory of Use. IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* 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 sub-licensing arrangements and the volume of data flowing. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 with clarification of why the NDO is now being upheld in respect of pseudonymised data and in the context of the NDO policy.

	2. To clarify in section 1 and section 5 if the sub-licensing activity and associated risk(s) are addressed in the DPIA. 3. In respect of the DfE: a) To review the DfE legal basis for disclosing data throughout the application, and amend as appropriate. b) To update section 5(a) if relevant to clarify that not **all** children's data will be held by DfE. 4. In respect of the commercial purpose and in line with NHS Digital DARS Standard for Commercial Purpose: a) To update the application to exclude commercial applicants from accessing the ECHILD data; or, b) To update the application to encompass commercial applicants for the ECHILD data. 5. In respect of section 5(a) and in line with NHS Digital DARS Standard for Objective for Processing: a) To update section 5(a) to provide some examples of the *"usual policies and practices"* referred to, or remove from the application. b) To provide further clarification in section 5(a) on the reference to *"…ECHILD denominator"*. c) To amend the reference in section 5(a) from *"mental disorder"* to *"mental health condition"*. d) To update section 5(a) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". e) To update section 5(a) with further clarity of the internal assessment of the requests for data (as outlined in supporting documents). 6. In respect of the benefits in section 5(d) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits: a) To update the benefits in section 5(d) to ensure they are clear as to the benefits to both the patients and the health and social care system. b) To remove the first sentence under 'point vii' in section 5(d). c) To update section 5(d) to use a form of wording such as "*it should* …" or *"it could…"*, rather than "*it will…*". 7. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support"*. The following advice was given: 1. Noting that the territory of use was *"UK"*, IGARD suggested that the applicant may wish to consider applicants from the EEA; and that if appropriate, the application is amended as appropriate in line with NHS Digital DARS Standard for Territory of Use. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the sub-licensing arrangements and the volume of data flowing. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the sub-licensing arrangements and the volume of data flowing.
3.7	GlaxoSmithKline Research & Development Limited: The Extended Salford Lung Study Data Access Project (Presenter: Denise Pine) NIC-115298-L5X4V-v2.3

	Application: This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients. It was also an amendment application to **1)** remove Ignite Data Ltd (Ignite) as a Data Processor; **2)** the removal of Microsoft Limited as a Data Processor, who previously provided cloud storage services for Ignite; **3)** the removal of the following processing locations: Microsoft Limited - Azure UK South (Primary Data Centre); Microsoft Limited - Azure UK West (Backup Data Centre); and Ignite Data Limited - 400 Thames Valley Park. The Extended-SLS is a follow-on study to the original Salford Lung Studies, two landmark effectiveness trials of fluticasone furoate / vilanterol (an inhaled corticosteroid combined with a long-acting-b2-agonist [LABA] in a single inhaler device) in patients with Chronic Obstructive Pulmonary Disease (COPD) and asthma which ran from March 2012 to December 2016. The data will be used to form a longitudinal patient record, over the lifetime of the study, and will answer questions in the Extended-SLS relating to, **1)** Healthcare resource utilisation and costs (HRG); **2)** Severe exacerbations of COPD and asthma; **3)** Frailty and disease severity defined based on prior hospitalisations (all-cause) and comorbidities not managed in primary care. **4)** Potential, treatment-related adverse events resulting in hospitalisation; **5)** the impact of treatments and / or disease severity / subtypes on all-cause or COPD- and asthma- related mortality; primary care. NHS Digital advised that prior to the meeting, a discussion had taken place with the application in respect of the proposed length of the data sharing agreement (DSA); which was currently three years. NHS Digital noted that as section 5 (Purpose / Methods / Outputs) did not reference any outcomes beyond 2023, that the DSA should be two years in length. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD meetings on the 14th July 2021 and the 22nd July 2021. IGARD noted the verbal update from NHS Digital and advised that they were supportive of the two year DSA length; as opposed to the three year DSA length originally proposed. IGARD noted the useful information in section 5(e) (Is the Purpose of this Application in Anyway Commercial), in relation to the commercial aspect of the application; and asked that this was replicated in section 5(a) (Objective for Processing) of this application for transparency, in line with the NHS Digital DARS Standard for Commercial Purpose. IGARD noted that the minutes from the 22nd July 2021, that were copied into section 1 (Abstract) appeared to incorrectly refer to a cohort size of 382. IGARD noted that this appeared to be an error in the previous minutes, and that this should be removed from section 1 to avoid any confusion in the future. IGARD also noted that the application was inconsistent when referring to the cohort numbers, for example, 1,183 cohort members was referred to in section 5(a), and 1,121 was referred to elsewhere in the application. IGARD therefore asked that the application was reviewed and updated to ensure the cohort numbers references were aligned and consistent throughout. IGARD noted a number of prospective benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and asked that these were moved to section 5(c) (Specific Outputs Expected) in line with NHS Digital DARS Standard for Expected Outcomes. IGARD suggested that section 5(a) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…".

	IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **Outcome:** recommendation to approve The following amendments were requested: 1. To review and update the application to ensure the cohort numbers references were aligned and consistent. 2. To replicate in section 5(a) the useful narrative in section 5(e) with regards to the commercial aspect of the application, in line with in line with the NHS Digital DARS Standard for Commercial Purpose. 3. To remove any prospective benefits from section 5(d) (iii) and move to section 5(c), in line with NHS Digital DARS Standard for Expected Outcomes. 4. To update section 5(a) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 5. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support"*. The following advice was given: 1. IGARD noted the verbal update from NHS Digital and advised that they were supportive of the two year DSA length; as opposed to the three year DSA length originally proposed.
3.8	Imperial College London: The Wynn Database – Metabolism and Mortality (Presenter: David Morris) NIC-148144-69CQ0-v0.10 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data. The Wynn Database is to provide a resource for analyses of the roles of metabolic risk factors in the pathogenesis of chronic disease including cardiovascular disease, diabetes and cancer. The Wynn Database preserves a unique body of electronic and paper records that was accumulated between the years 1965 and 2000 under the direction of the metabolic medicine research team at St Mary's Hospital Medical School (one of the constituent schools of Imperial College London). This work was then migrated to what became the Wynn Institute of Imperial College London (ICL) in 1998. The Wynn Database continues to be a useful resource in understanding the pathophysiology of diabetes, heart disease and cancer; and comprises 29,244 records of metabolic information for 14,615 individuals. The data derives from studies carried out on ethnically diverse, healthy volunteers, and clinic patients receiving anabolic steroid therapy, anti-androgen therapy, oral contraceptives, postmenopausal hormone replacement therapy. Coronary heart disease patients, heart failure patients, lipid clinic patients, obesity clinic patients, endocrine clinic patients are also represented. The purpose of the application is to enable extensive retrospective and prospective analyses of relationships between metabolic risk factors, survival time and cause of death. Provision of age at death and cause of death information for participants represented in the Wynn Database will add key information to this exceptionally rich data collection. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital.

	Discussion: IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was the *"UK"* and asked that this was amended to correctly reflect that the territory of use was *"England and Wales"*, in line with the published NHS Digital DARS Standard for territory of use. IGARD queried the statement in section 5(a) (Objective for Processing) *"Once the linkage is complete, ICL will delete all identifiable information from the database to implement pseudonymised working"*; and asked that this was updated to align the data destruction with the Health Research Authority Confidentiality Advisory Group (HRA CAG) support, which was currently two years. IGARD noted that section 5(b) (Processing Activities) contained some very detailed information in relation to security measures, for example, in relation to swipe cards and CCTV etc; and asked that this was amended with a very brief description of the security measures. IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"…individuals will have passed 90 years of age, mortality may have occurred"*; and asked that this was amended, for example to simply state that they may have died. IGARD noted that no yielded benefits had been recognised, noting that the data had not yet flowed; however asked that in line with the NHS Digital DARS Standard for Expected Measurable Benefits, section 5(d) (Benefits) (iii) (Yielded Benefits) was updated to add a brief acknowledgement of the Wynn Database, noting the valuable resource this had proven to be. IGARD suggested that section 5(a) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **Outcome:** recommendation to approve The following amendments were requested: 1. To amend section 2(c) to reflect the territory of use is *"England and Wales"*. 2. To update section 5(a) to align the data destruction with HRA CAG support. 3. To amend section 5(b) to reduce the narrative relating to the security measures. 4. To amend the statement in section 5(c) *"mortality may have occurred"*. 5. In respect of the benefits in section 5(d) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits: 6. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…". 7. To update section 5(d) (iii) to add a brief acknowledgement of the Wynn Database. 8. To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support"*.
4	Applications progressed / to be progressed via NHS Digital's SIRO Precedent route

	Applications that have been progressed or will / may be progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	<u>NHS England: DSfC - NHS England Data Platform (No Presenter) NIC-139035-X4B7K-v12.2</u> The purpose of the application is to ensure that NHS England can meet their statutory duties as per the NHS Act 2006 and the Health and Social Care Act 2012, and to meet the requirements of the Five Year Forward View. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 22nd September 2022; where, in line with the new process outlined to NHS Digital via email on the 22nd August 2022, and as discussed at the IGARD meeting on the 8th September 2022, the application was being brought to IGARD for advice only and would then proceed under NHS Digital's SIRO precedent if appropriate. IGARD noted that on the 9th November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA). IGARD noted and thanked NHS Digital for the written update; however advised that it appeared that an older version of the application was presented to the Deputy SIRO for sign-off and IGARD asked that NHS Digital ensured that the correct version of the application had been presented to the Deputy SIRO.
4.2	<u>University of Oxford: QResearch-Oxford Data Linkage Project (No Presenter) NIC-382794-T3L3M-v6.7</u> The purpose of the application is for the QResearch database, which links medical records that has been used, and continues to be used, by a variety of research projects undertaken by UK Universities; and consists of the coded pseudonymised electronic health records from primary care patients registered with approximately 1,500 general practices spread throughout the UK. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 11th August 2022; where IGARD had been unable to recommend for approval any retrospective amendments progressed under the SIRO route and / or data disseminated under the NHS Digital IG Letter of Release; and recommended to approve in respect of the sub-licensing amendment only. IGARD noted that on the 7th November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA). IGARD noted that there appeared to be an internal NHS Digital process failure in that the Deputy SIRO had not been provided the requisite 'SIRO approval form' and suggested that the Deputy SIRO may wish to review the process to ensure they consistently had a clear paper trail for audit and transparency of process IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD meeting.

4.3	University College London (UCL): MR472A - SABRE: Southall and Brent Revisited - S251 participants not cancer notifiable (Garry Coleman) NIC-99077-Q0K6Z-v6.2 The purpose of the application is for an academic research study, focusing on identifying and understanding the underlying reasons for ethnic group and sex differences in cardiometabolic disease and in physical, psychological and cognitive function in older age. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 6th April 2017; where IGARD had recommended for approval. IGARD noted that on the 7th November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a short-term extension to the Data Sharing Agreement (DSA); however wanted to seek the views of IGARD before progressing this application. The Deputy SIRO advised IGARD that a renewal of data was approved (v3.13) on the 19th September 2019, which authorised the dissemination of data for the years 2017/18, 2019/20 and 2020/21 without the s251 support being amended to cover this; and that the data was subsequently disseminated. The applicant is now in the process of submitting an amendment to their s251 support to enable them to retain and request HES data that consist of events on and after 2017/18. This proposed extension to the DSA, is an interim measure that allows them to retain the data while the s251 amendment is ongoing with HRA CAG. IGARD noted and thanked the Deputy SIRO for attending the meeting and providing a verbal update. IGARD asked that further information was provided, outlining how this incident occurred and actions taken to mitigate the risk of this occurring again. IGARD advised that they would welcome a further discussion addressing these queries at a future IGARD meeting.
4.4	Institute of Cancer Research: MR1251 - Safety and appropriateness of growth hormone treatments in Europe (SAGHE) (Garry Coleman) NIC-148155-K7P19-v6.2 The purpose of the application is for a study, to provide a large-scale international collaborative cohort study of r-hGH treated patients with long-term follow-up for cancer incidence and mortality conducted independently of pharmaceutical companies. It is the largest and longest follow-up cohort study of growth hormone-treated patients with follow-up and analysis independent of industry and has formed a major international resource for investigating cancer and mortality risks in r-hGH patients. This application had **not** previously had a DAAG / IGARD review. IGARD noted that on the 7th November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO was proposing to authorise an extension to the Data Sharing Agreement (DSA). The Deputy SIRO advised IGARD that HRA CAG register entry has not been updated since 2014; and there has been no evidence provided from the applicant that the relevant annual review reports have been submitted. IGARD noted the verbal update from the Deputy SIRO and expressed concern that the relevant evidence had not been submitted by the applicant, to support the s251 legal basis used for this study, and as required by HRA CAG. IGARD noted there was a public interest argument for the applicant to retain the data but without CAG confirmation NHS Digital could not be certain the common law duty of confidentiality was still set aside. IGARD suggested that

	the Deputy SIRO may wish to escalate to NHS Digital's Caldicott Guardian to seek a further view on this.
5	Oversight & Assurance 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. The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: Our Future Health: Our Future Health Recruitment Programme (Presenters: Garry Coleman / Andy Rees) NIC 414067-K8R6J-v0.2 The purpose of the application, which was recommended for approval at the IGARD meeting on the 5th May 2022; is for a research programme to support people living healthier lives for longer through better prevention, earlier detection and improved treatment of diseases. The programme will aim to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early when outcomes are usually better. The NHS Digital Deputy SIRO and a member of NHS Digital's Digi-Trials Team attended the meeting to advise IGARD that the applicant had submitted an urgent amendment to their DSA; to request permission to increase the number of potential participants contacted for the study from 3 million to 12 million. NHS Digital advised that the study was relying on s251 of the NHS Act 2006 for the flow of contact details out of NHS Digital; and that HRA CAG had urgently reviewed and approved the request to amend the s251 support to increase the number of participants contacted. NHS Digital advised that the application was currently in the process of being updated to reflect the amendment request and would be submitted as soon as possible for review at a future IGARD meeting. The Deputy SIRO noted that he was **not** minded to approve via the NHS Digital SIRO Precedent the request to increase to 12 million, however had been comfortable to increase the request to 5 million as long as the application returned to IGARD for an independent review before the end of the year.

	IGARD noted the verbal update from NHS Digital, and the urgency and importance of the study and the request. The application would need to return before the 15th December 2022 the last IGARD meeting prior to the Christmas break for IGARD members). IGARD also asked that when the application is submitted for review that NHS Digital ensure that all previous points raised by IGARD have been suitably addressed. IGARD confirmed that they were supportive of a two-week extension via NHS Digital's SIRO Precedent route, to allow NHS Digital time to update the application as appropriate. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/11/22

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)
None						

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