Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 26 January 2023

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member (Item 7)
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member (Item 7)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member (Item 7)
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Services (DARS) (**Presenter**: items 3.1 to 3.4)
Vicky Byrne-Watts	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.8 to 3.9)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 7.4)
Cath Day	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.7)
Dr. Arjun Dillon	Caldicott Guardian (Item 7.4)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.5)
Duncan Easton	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.1 to 3.4)
Lauren Gerraghty	Digi-Trials (**Observer**: item 3.5)
Dan Goodwin	Data Access Request Services (DARS) (**Presenter**: item 3.7)
Dickie Langley	Privacy, Transparency, Ethics and Legal (PTEL) (Item 7.4)
Karen Myers	IGARD Secretariat Team

Frances Perry	Digi-Trials (**Presenter**: item 3.5)
Kimberley Watson	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.6)
Anna Weaver	Data Access Request Services (DARS) (**Presenter**: items 3.8 to 3.9)
Vicki Williams	IGARD Secretariat Team
Clare Wright	Data Access Request Services (DARS) (**Presenter:** item 3.6)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Imran Khan noted a potential conflict due to a contract with a competitor of a commercial organisation involved with NHS Bristol, North Somerset and South Gloucestershire ICB (NIC-615958-F7Q7Z-v1.3); 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 19th January 2023 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	NHS Kent and Medway ICB: DSfC - Kent and Medway ICB - Comm, RS & IV (Presenter: Michael Ball) NIC-615960-G7W1L-v1.2 **Application:** This was an amendment application to update the data sharing agreement (DSA) with the appropriate template wording and special conditions agreed since the DSA's initial approval. The purpose of the application is for **1)** Invoice Validation, which is part of a process by which providers of care or services get paid for the work they do **2)** Risk Stratification, which is a tool for identifying and predicting which patients are at high risk (of health deterioration and using multiple services) or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes; and **3)** Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information)

	is analysed so that health care provision can be planned to support the needs of the population within the ICB area. Sub-licensing to members of the ICB is part of the application. Pseudonymised record-level commissioning data can only be shared by the Data Controller with substantive organisations who are part of the ICB's Integrated Care System (ICS), which includes Trusts, GPs, Local Authorities and other health care providers who will contribute to commissioning decisions. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 30th June 2022. IGARD noted the narrative in section 5 (Purpose / Methods / Outputs) in relation to *"re-identification"* and the specific references to the role of NHS Digital as part of the re-identification process. Noting that NHS Digital merges into NHS England on the 1st February 2023, IGARD asked that the narrative relating to re-identification was reviewed and amended as necessary, to remove the specific references to "NHS Digital", and replace with generic wording that future proofs and addresses re-identification, for example, that this activity will be undertaken by a regional processing centre, or similar. IGARD noted in section 1(c) (Data Processor(s)) that the Data Protection Act (DPA) registration for MedeAnalytics International Limited, had expired on the 21st January 2023; and asked that section 1(c) was updated with the correct / updated DPA expiry date. IGARD noted there were aspect of the applicant's website that needed updating, including, but not limited to, references to *"CCG"* and *"Data Protection Regulations"*; and suggested that the website was reviewed as soon as possible. IGARD also suggested that the applicant updated their website in a timely fashion, to reflect the planned sub-licensing, noting that there was no information currently on the website about this. **Separate to the application**: IGARD noted that at the IGARD meeting on the 21st July 2022, NHS Digital had presented the 'ICB sharing commissioning data with members of their Integrated Care System Briefing Paper', and had advised IGARD that an early audit would be undertaken of an ICB, in respect of sub-licensing and sharing the knowledge with other ICBs. IGARD noted that prior to the meeting they had queried with NHS Digital whether an audit had taken place; and had been advised that NHS Kent and Medway ICB had **not** been audited as the sub-licensing has not started, however NHS Bedfordshire, Luton and Milton Keynes ICB, who had started used sub-licensing has been audited. IGARD noted and thanked NHS Digital for providing the information relating to the audit and suggested that NHS England ensure that the sub-licensing guidance for ICBs was reviewed to check that it was helpful to ICBs in meeting their obligations; and that the findings of the audit were used as part of training, to ensure the ICBs were complying with the guidance and their data sharing agreements (DSA). In addition, IGARD suggested that a review was undertaken to ensure that all the special sub-licensing conditions outlined in ICB DSAs were reflected in the sub licensing guidance. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the narrative on re-identification in section 5, to remove reference to *"NHS Digital"* and replace with generic wording that addresses re-identification. 2. To update section 1(c) to reflect the correct MedeAnalytics International Limited DPA expiry date. The following advice was given:

	1. In respect of the applicant's website: a) IGARD noted there were aspects of the applicant's website that needed updating, including (but not limited to) references to the *"CCG"* and *"Data Protection Regulations"*; and suggested that the website was reviewed and updated as soon as possible. 2. IGARD suggested that the applicant update their website in a timely fashion, to reflect the planned sub-licensing, noting that this information was currently not available. 3. IGARD noted the recent audit of another ICB with sublicensing arrangements, and suggested that NHS England: a) review the guidance to ensure it helps ICBs comply with their obligations; and, b) to use the results of the audit as part of a training exercise to ensure compliance with the guidance and the DSA; and, c) to ensure that the sub-licensing special conditions in ICB DSAs are reflected in the guidance.
3.2	<u>NHS Norfolk and Waveney ICB: NHS Norfolk and Waveney Integrated Care Board - Comm, RS and IV (Presenter: Michael Ball) NIC-616046-J1Q0N-v1.3</u> **Application:** This was an amendment application to **1)** update the data sharing agreement (DSA) with the appropriate template wording and special conditions agreed since the DSA's initial approval; and **2)** to add Newton Europe Limited as a Data Processor for commissioning purposes. The purpose of the application is for **1)** Invoice Validation, which is part of a process by which providers of care or services get paid for the work they do; **2)** Risk Stratification, which is a tool for identifying and predicting which patients are at high risk (of health deterioration and using multiple services) or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes; and **3)** Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the ICB area. Sub-licensing to members of the ICB is part of the application. Pseudonymised record-level commissioning data can only be shared by the Data Controller with substantive organisations who are part of the ICB's Integrated Care System (ICS), which includes Trusts, GPs, Local Authorities and other health care providers who will contribute to commissioning decisions. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 21st July 2022. IGARD noted the narrative in section 5 (Purpose / Methods / Outputs) in relation to *"re-identification"* and the specific references to the role of NHS Digital as part of the re-identification process. Noting that NHS Digital merges into NHS England on the 1st February 2023, IGARD asked that the narrative relating to re-identification was reviewed and amended as necessary, to remove the specific references to "NHS Digital", and replace with generic wording that future proofs and addresses re-identification, for example, that this activity will be undertaken by a regional processing centre, or similar. IGARD noted in section 1(c) (Data Processor(s)) that the security assurance for Amazon Web Services, had expired on the 7th November 2022; and asked that section 1(c) was updated with the correct / updated security assurance expiry date. **Separate to the application**: IGARD noted that at the IGARD meeting on the 21st July 2022, NHS Digital had presented the 'ICB sharing commissioning data with members of their

	Integrated Care System Briefing Paper', and had advised IGARD that an early audit would be undertaken of an ICB, in respect of sub-licensing and sharing the knowledge with other ICBs. IGARD noted that prior to the meeting they had queried with NHS Digital whether an audit had taken place; and had been advised that NHS Kent and Medway ICB had **not** been audited as the sub-licensing has not started, however NHS Bedfordshire, Luton and Milton Keynes ICB, who had started used sub-licensing has been audited. IGARD noted and thanked NHS Digital for providing the information relating to the audit and suggested that NHS England ensure that the sub-licensing guidance for ICBs was reviewed to check that it was helpful to ICBs in meeting their obligations; and that the findings of the audit were used as part of training, to ensure the ICBs were complying with the guidance and their data sharing agreements (DSA). In addition, IGARD suggested that a review was undertaken to ensure that all the special sub-licensing conditions outlined in ICB DSAs were reflected in the sub licensing guidance. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the narrative on re-identification in section 5, to remove reference to *"NHS Digital"* and replace with generic wording that addresses re-identification. 2. To update the Amazon Web Services Security Assurance expiry date in section 1(c). The following advice was given: 1. IGARD noted the recent audit of another ICB with sublicensing arrangements, and suggested that NHS England: a) review the guidance to ensure it helps ICBs comply with their obligations; and, b) to use the results of the audit as part of a training exercise to ensure compliance with the guidance and the DSA; and, c) to ensure that the sub-licensing special conditions in ICB DSAs are reflected in the guidance.
3.3	NHS North East London ICB: DSfC - NHS North East London Integrated Care Board - IV, RS & Comm (Presenter: Michael Ball) NIC-615897-K1Z9C-v0.2 **Application:** This was a new application for pseudonymised Commissioning Datasets; and identifiable Invoice Validation Datasets and Risk Stratification Datasets. The purpose of the application is for **1)** Invoice Validation, which is part of a process by which providers of care or services get paid for the work they do **2)** Risk Stratification, which is a tool for identifying and predicting which patients are at high risk (of health deterioration and using multiple services) or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes; and **3)** Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the ICB area. Sub-licensing to members of the ICB is part of the application. This data sharing agreement (DSA) will supersede several DSAs which previously covered processing conducted by the Clinical Commissioning Groups (CCGs). NHS Digital advised IGARD that as outlined in section 1 (Abstract) of the application, Snowflake Computing UK Ltd (Snowflake) have been included as a Data Processor in this application due to a breach of DSA NIC-422200- Q1K7S, where Snowflake had processed pseudonymised commissioning datasets on servers in the Netherlands, without being named as a Data Processor. NHS Digital noted that the ICB had now migrated all data stored in the

	Netherlands to the UK Microsoft Azure infrastructure. NHS Digital advised that appropriate security checks on Snowflake had been undertaken by NHS Digital's Security Team; and that the breach was reported to the NHS Digital Data Protection Officer (DPO) who had provided advisory recommendations, including informing NHS Digital's Senior Information Risk Owner (SIRO), which had been undertaken. NHS Digital advised that an audit on NHS North East London ICB was expected to commence in early 2023. NHS Digital noted that the NHS North East London ICB DPO had taken a serious view of the breach identified and was doing the necessary checks to ensure that all other aspects of the DSA were being adhered to. **Discussion:** IGARD noted the verbal update from NHS Digital, and supported the proposed audit of NHS North East London ICB due to the breach outlined. IGARD also noted the efforts of the NHS North East London ICB DPO in ensuring that all other aspects of the DSA were being adhered to. IGARD noted that the breach form provided as a supporting document had not been fully completed by NHS Digital's DPO; and that it was unclear if the deletion of the data had been carried out appropriately. Noting that this concerned the data for 2.5 million individuals, IGARD suggested that there should be a re-review of the breach form by NHS Digital's DPO, and that satisfactory confirmation was provided in respect of the deletion of the data. IGARD also asked that written confirmation had been provided by the applicant, that the appropriate actions had been taken by Snowflake Computing UK Ltd's Netherlands office, to confirm data destruction; and, that satisfactory proof had been provided to NHS Digital (or its successor) of the data destruction; and that written confirmation and any supporting evidence of data destruction was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the narrative in section 5 (Purpose / Methods / Outputs) in relation to *"re-identification"* and the specific references to the role of NHS Digital as part of the re-identification process. Noting that NHS Digital merge into NHS England on the 1st February 2023, IGARD asked that the narrative relating to re-identification was reviewed and amended as necessary, to remove the specific references to "NHS Digital", and replace with generic wording that future proofs and addresses re-identification, for example, that this activity will be undertaken by a regional processing centre, or similar. IGARD noted in section 1(c) (Data Processor(s)) that the security assurance for Queen Mary University of London, had expired on the 19th November 2022; and asked that section 1(c) was updated with the correct / updated security assurance expiry date. **Separate to the application**: IGARD noted that at the IGARD meeting on the 21st July 2022, NHS Digital had presented the 'ICB sharing commissioning data with members of their Integrated Care System Briefing Paper', and had advised IGARD that an early audit would be undertaken of an ICB, in respect of sub-licensing and sharing the knowledge with other ICBs. IGARD noted that prior to the meeting they had queried with NHS Digital whether an audit had taken place; and had been advised that NHS Kent and Medway ICB had **not** been audited as the sub-licensing has not started, however NHS Bedfordshire, Luton and Milton Keynes ICB, who had started used sub-licensing has been audited. IGARD noted and thanked NHS Digital for providing the information relating to the audit and suggested that NHS England ensure that the sub-licensing guidance for ICBs was reviewed to check that it was helpful to ICBs in meeting their obligations; and that the findings of the audit were used as part of training, to ensure the ICBs were complying with the guidance and their data sharing agreements (DSA).

	In addition, IGARD suggested that a review was undertaken to ensure that all the special sub-licensing conditions outlined in ICB DSAs were reflected in the sub licensing guidance. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the agreement breach outlined: a) NHS Digital to ensure that written confirmation has been provided, that appropriate actions have been taken by Snowflake Computing UK Ltd's Netherlands office, to confirm data destruction; and, b) To provide written confirmation that satisfactory proof has been provided to NHS Digital (or its successor) of the data destruction; and, c) To upload the written confirmation and any supporting evidence of data destruction to NHS Digital's CRM system for future reference. 2. To amend the narrative on re-identification in section 5, to remove reference to *"NHS Digital"* and replace with generic wording that addresses re-identification. 3. To update the Queen Mary University of London Security Assurance expiry date in section 1(c). The following advice was given: 1. IGARD noted that the breach form provided as a supporting document, had not been fully completed by NHS Digital's DPO; and that this may be impactful as to whether or not the deletion of the data has been carried out appropriately. Noting that this concerned the data for 2.5 million individuals, IGARD suggested that there should be a re-review of the breach form by NHS Digital's DPO, and that satisfactory confirmation was provided in respect of the deletion of the data. 2. IGARD noted the recent audit of another ICB with sublicensing arrangements, and suggested that NHS England: a) review the guidance to ensure it helps ICBs comply with their obligations; and, b) to use the results of the audit as part of a training exercise to ensure compliance with the guidance and the DSA; and, c) to ensure that the sub-licensing special conditions in ICB DSAs are reflected in the guidance.
3.4	<u>NHS Bristol, North Somerset and South Gloucestershire ICB: Comm, RS and IV (Presenter: Michael Ball) NIC-615958-F7Q7Z-v1.3</u> **Application:** This was an amendment application to add Prescribing Services Ltd as a Data Processor for the purpose of Risk Stratification. The purpose of the application is for **1)** Invoice Validation, which is part of a process by which providers of care or services get paid for the work they do **2)** Risk Stratification, which is a tool for identifying and predicting which patients are at high risk (of health deterioration and using multiple services) or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes; and **3)** Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the ICB area. Sub-licensing to members of the ICB is part of the application. Pseudonymised record-level commissioning data can only be shared by the Data Controller with substantive organisations

	who are part of the ICB's Integrated Care System (ICS), which includes Trusts, GPs, Local Authorities and other health care providers who will contribute to commissioning decisions. The processing outlined within the application is relying on s251 of the NHS Act 2006 and s261(7) of the Health and Social Care Act 2012, for the flow of data out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 28th July 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 narrative in section 5 (Purpose / Methods / Outputs) in relation to *"re-identification"* and the specific references to the role of NHS Digital as part of the re-identification process. Noting that NHS Digital merge into NHS England on the 1st February 2023, IGARD asked that the narrative relating to re-identification was reviewed and amended as necessary, to remove the specific references to "NHS Digital", and replace with generic wording that future proofs and addresses re-identification, for example, that this activity will be undertaken by a regional processing centre, or similar. IGARD noted in section 1(c) (Data Processor(s)) that the security assurance for Amazon Web Services, had expired on the 7th November 2022; and asked that section 1(c) was updated with the correct / updated security assurance expiry date. **Separate to the application**: IGARD noted that at the IGARD meeting on the 21st July 2022, NHS Digital had presented the 'ICB sharing commissioning data with members of their Integrated Care System Briefing Paper', and had advised IGARD that an early audit would be undertaken of an ICB, in respect of sub-licensing and sharing the knowledge with other ICBs. IGARD noted that prior to the meeting they had queried with NHS Digital whether an audit had taken place; and had been advised that NHS Kent and Medway ICB had **not** been audited as the sub-licensing has not started, however NHS Bedfordshire, Luton and Milton Keynes ICB, who had started used sub-licensing has been audited. IGARD noted and thanked NHS Digital for providing the information relating to the audit and suggested that NHS England ensure that the sub-licensing guidance for ICBs was reviewed to check that it was helpful to ICBs in meeting their obligations; and that the findings of the audit were used as part of training, to ensure the ICBs were complying with the guidance and their data sharing agreements (DSA). In addition, IGARD suggested that a review was undertaken to ensure that all the special sub-licensing conditions outlined in ICB DSAs were reflected in the sub licensing guidance. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the narrative on re-identification in section 5, to remove reference to *"NHS Digital"* and replace with generic wording that addresses re-identification. 2. To update the Amazon Web Services Security Assurance expiry date in section 1(c). The following advice was given: 1. IGARD noted the recent audit of another ICB with sublicensing arrangements, and suggested that NHS England: a) review the guidance to ensure it helps ICBs comply with their obligations; and, b) to use the results of the audit as part of a training exercise to ensure compliance with the guidance and the DSA; and, c) to ensure that the sub-licensing special conditions in ICB DSAs are reflected in the guidance.

3.5	University of Oxford: ORION-4: Data linkage to support outcome and other clinical data collection for consented participants (Presenter: Frances Perry) NIC-630656-V9W9M-v0.8 **Application:** This was a new application for identifiable Demographics data and Medicines dispensed in Primary Care (NHSBSA data). ORION-4 is an ongoing trial of a new cholesterol lowering drug called inclisiran; and is administered as an injection 2-3 times per year, and reduces low-density lipoprotein (LDL) cholesterol. The trial will determine if this drug is helpful in reducing cardiovascular events such as strokes and heart attacks in people with a previous history of such conditions, and who have high cholesterol levels despite available treatment with established cholesterol-lowering medications. The purpose of the application is for a medicines data research project, to enable the assessment of the efficacy and safety of inclisiran in relation to non-study medications. The trial aims to recruit 12,000 participants in the UK; and, if shown to be effective, this treatment could substantially reduce premature death and disability. A secondary objective of the study is to develop streamlined trial methods that would benefit future research. The study cohort is estimated to eventually include approximately 12,000 consented individuals; recruitment commenced in October 2018 and is ongoing. **Discussion:** IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted within the application that the University of Oxford were the sole Data Controller, however, queried the statement in the protocol, provided as a supporting document *"This study has been **designed jointly** by the Clinical Trial Service Unit (University of Oxford), the TIMI Study Group (Harvard University) and The Medicines Company, which was acquired by Novartis in January 2020"*. In addition, IGARD noted the statement in section 5(a) (Objective for Processing) *"This study… is sponsored by the University of Oxford, and the Medicines Company (MDCO), which was acquired by Novartis - a Swiss-American multinational pharmaceutical corporation - in January 2020, in collaboration with the TIMI Study Group - an academic research organisation - based at Brigham and Women's Hospital, Harvard Medical School, Boston"*. Noting the 'Guidelines 07/2020 on the concepts of controller and processor in the GDPR' which is referred to by the Information Commissioner's Office (ICO), IGARD asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated, to clarify that NHS Digital had satisfied itself that the University of Oxford were the **sole** Data Controller in light of joint sponsorship and linked studies, and as borne out of the facts, in line with NHS Digital's DARS Standard for Data Controllers. IGARD noted the risk to NHS Digital that data controllership listed in the DSA may not reflect an ICO assessment of data controllership. **Separate to this application:** As previously suggested on the 11th August 2022, IGARD recommended that NHS Digital update their internal processes to ensure that applications reflect that where sponsors are not deemed to be carrying out data controllership activities, this analysis and justification is addressed in section 1 and section 5 of the application as a matter of course; as per the NHS Health Research Authority guidance on 'Controllers and personal data in health and care research'. IGARD noted the statement in section 5(c) (Specific Outputs Expected) "*The target data [sic] for all planned outputs will be the end of the year 2023*"; and queried why, if the outputs were

	expected in 2023, the length of the data sharing agreement (DSA) was three years. IGARD asked that a justification for the length of the DSA was provided in section 5(c). IGARD queried the statements in section 5(a) that the commercial element of the application, was not the primary purpose, for example "*If the results show that inclisiran is safe and effective this will could also increase revenue for the manufacturer, funder and cosponsor Novartis, as the manufacturer of the drug. However this is not the primary purpose of ORION-4*"; and asked that these statements regarding the primary purpose were removed as they were incorrect for a commercial company. IGARD noted that section 5(a) (Objective for Processing) provided minimal information on the commercial aspect of the application, and asked that key information in section 5(e) (Is the Purpose of this Application in Anyway Commercial), was replicated in section 5(a), in with NHS Digital DARS Standard for Commercial Purpose and NHS Digital DARS Standard for Objective for Processing. IGARD queried what, if any, patient and public involvement and engagement (PPIE) had been undertaken; and asked that section 5 was updated to provide further details of any PPIE carried out to date; and / or, that an indicative plan of future PPIE activity was provided in section 5(a) for information. IGARD suggested that the applicant may wish to consider involving relevant public and patient groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide. IGARD queried the statement in section 5(b) (Processing Activities) *"The cohort will include all participants randomised in England/Wales* ***regardless of where they were randomised****"*; and asked that further clarity was provided on the end of the statement; or that the statement was amended as appropriate, noting that it was currently unclear what it meant. IGARD noted the incorrect statement in section 5(b) *"Data will be retained for a period of* ***5 years****…"*; and asked that this was amended to correctly state *"25 years"* in line with the applicant's confirmation. IGARD queried the statement in section 5(d) (Benefits) "*The main purpose of the medicines data research project is to enable the assessment of the efficacy and safety of inclisiran in relation to non-study medications*"; and asked that this was updated to remove the reference to *non-study medications"* and replace with *"matching placebo"*, since the statement was currently factually incorrect. IGARD suggested that in respect of transparency, the applicant take the opportunity, for example, in any future newsletters or other communications with participants, to inform them that address and GP details were flowing, maintaining the trust of the cohort and the Caldicott Principle 8 of *"no surprises"*. IGARD also suggested to the applicant, that for future recruitment, the applicant make clear to prospective cohort members that address and GP details would be flowing. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the data controllership and in line with the NHS Digital DARS Standard for Data Controllers: a) To update section 1 that NHS Digital have satisfied itself that the University of Oxford are the **sole** Data Controller in light of joint sponsorship and linked studies; and, b) To update section 5 that NHS Digital have satisfied itself that the University of Oxford are the **sole** Data Controller in light of joint sponsorship and linked studies.

	2. To justify in section 5(c) why a 3-year DSA is required. 3. In respect of the commercial aspect of the application: a) To update section 5 to remove references to the commercial element not being the *"…primary purpose of ORION-4".* b) To replicate in section 5(a) the key information in section 5(e) with regards to the commercial aspect of the application. 4. In respect of PPIE: a) To update section 5 to provide details of any PPIE carried out to date; and / or b) To provide an indicative plan of future PPIE activity in section 5(a). 5. In respect of the language in section 5(b): a) To provide clarity on the statement in section 5(b) *"…regardless of where they were randomised"*; or amend as appropriate. b) To amend the statement in section 5(b) *"…Data will be retained for a period of **5 years**…"* to refer to *"25 years"*. 6. To remove the reference in section 5(d) *"non-study medications"* and replace with *"matching placebo"*. The following advice was given: 1. IGARD suggested that the applicant may wish to consider involving relevant public and patient groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide. 2. In respect of transparency: a) IGARD suggested the applicant take the opportunity in any future newsletters or other communications with participants, to inform them that their address and GP details were flowing; and, b) IGARD suggested that for future recruitment, the applicant make clear to prospective cohort members that their address and GP details would be flowing. **Risk Area:** Data controllership listed in the DSA may not reflect an ICO assessment of data controllership. **Separate to this application:** As previously suggested on the 11th August 2022, IGARD recommended that NHS Digital update their internal processes to ensure that applications reflect that where sponsors are not deemed to be carrying out data controllership activities, this analysis and justification is addressed in section 1 and section 5 of the application as a matter of course; as per the NHS Health Research Authority guidance on 'Controllers and personal data in health and care research'.
3.6	NorthWest EHealth Limited: Retrospective data analysis of HES and DID data from patients with Refractory Chronic Cough (RCC) who have given consent for their electronic healthcare records to be used in the analysis of healthcare resource utilisation (Presenter: Clare Wright) NIC-290527-P5C0Y-v3.4 **Application:** This was an extension application to permit the holding and processing of identifiable Diagnostic Imaging Dataset (DIDs), Hospital Episodes Statistics (HES) Admitted Patient Care (APC), HES Outpatients, Bridge file: HES to DIDs; and pseudonymised HES-ID to MPS-ID HES APC and HES-ID to MPS-ID HES Outpatients data. The purpose is for a feasibility study aiming to increase the understanding of the profile and characteristics of patients with unexplained Refractory Chronic Cough (RCC) by understanding the healthcare resource utilisation (HRU) and treatment patterns of these patients. The primary objective of the initial work was to determine the outpatient and primary

	care healthcare costs in the 5-years prior to a diagnosis of RCC, compared to a control cohort, matched by demographics and smoking status. This application is limited to patients who have consented, and the estimated size of the cohort is approximately 200 patients. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 19th September 2019, 6th February 2020, 11th June 2020 and the 15th April 2021. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 25th August 2022. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted that prior to the meeting, an IGARD member had raised a query in relation to a statement in the patient information sheet (PIS), provided as a supporting document that the study *"…will keep identifiable information about you from this study until 2025"*. NHS Digital confirmed that further clarification had been sought from the applicant, who had advised that, the study could not end until sometime after they received the data to analyse, and they were unable to be precise about the dates. In addition, the applicant had stated that the PIS was part of the documentation pack submitted to Ethics, and was one of the earliest documents to be written; and at the time of writing the PIS it was not known exactly when the study would end, but 2020 was the expectation, therefore, 2025 was the expected retention date for the data. The applicant advised that they did not receive the last of the data from NHS Digital until October 2021 so the data would therefore need to be retained until October 2026. IGARD noted the verbal update from NHS Digital, however advised that the consent materials **did not** permit the holding of the data beyond 2025 and that any data held beyond this date would need to be pseudonymised / anonymised. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that consent provided a gateway to hold identifiable data to the **end of 2025 only**. IGARD noted a number of academic papers cited in section 5(a) (Objective for Processing), for example *"Chung, McGarvey, Mazzone 2013"* and *"Morice, McGarvey, Pavord, 2006"*; and asked that all references to academic papers were updated to provide a full reference and weblink, for ease of reference; and in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted that section 5(a) provided minimal information on the commercial aspect of the application, and asked that key information in section 5(e) (Is the Purpose of this Application in Anyway Commercial), was replicated in section 5(a), in with NHS Digital DARS Standard for Commercial Purpose and NHS Digital DARS Standard for Objective for Processing. IGARD noted the article in The Guardian in October 2022, in respect of the drug being studied; and advised that if this drug proved to be beneficial, it would have significant benefits to patients who suffer from RCC. IGARD therefore asked that the beginning of section 5(a) was updated, to reflect the latest information and apparent potential benefits in respect of the drug. IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove references to "*it will*…", and instead use a form of words such as "*it is hoped*…". **Outcome:** recommendation to approve The following amendments were requested:

	1. To insert a special condition in section 6 that consent provides a gateway to hold identifiable data to the end of 2025 only. 2. To update section 5(a) to add the full reference / weblink to the academic papers referenced. 3. To replicate in section 5(a) the key information in section 5(e) with regards to the commercial aspect of the application. 4. To update the opening paragraph in section 5(a) to reflect the latest information / apparent potential benefits in respect of the drug. 5. To update section 5 to use a form of wording such as "*it is hoped* …", rather than "*it will…*".
3.7	<u>Queen Mary University of London: IBIS-II Prevention & DCIS (Observational) (Presenter: Dan Goodwin) NIC-324220-P6W9Y-v7.5</u> **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (HES APC), Civil Registration (Death), MRIS - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report, MRIS - Members and Postings Report, Cancer Registration Data. It was also an amendment to change the study to a long-term follow-up as an observational study as opposed to a clinical trial of an investigational medicinal product. Established in 2002, the International Breast Cancer Intervention Study (IBIS-II) Prevention and DCIS (Ductal Carcinoma In Situ) studies are designed to continue the work started by the IBIS-I trial in determining whether a chemo preventive strategy towards breast cancer is beneficial. IBIS-II Prevention and DCIS are double-blinded, placebo controlled, randomised trials which recruited post-menopausal women aged 40–70 years. The purpose of the application is for extended follow-up of the study. The study cohort is limited to 2,889 individuals. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) *(IGARD's predecessor)* on the 1st March 2016 and the 24th January 2017. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 20th July 2017. 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 statement in the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support, provided as a supporting document and dated the 25th August 2021 "*The end point for patient follow up for 21/CAG/0137 is June 2026, and the end point for 's251' support will be the time point that any confidential patient information collected without patient consent is deleted*"; and asked that a special condition was inserted in section 6 (Special Conditions), to reflect the specific date of 2026, when the confidential data must be deleted in line with the HRA CAG support. IGARD noted the reference in the HRA CAG letter of support, provided as a supporting document and dated the 25th August 2021, to patient and public involvement and engagement (PPIE) in 2020. Noting that the application was silent on any PPIE, IGARD asked that section

	5(a) (Objective for Processing) was updated with details of any PPIE carried out to date, in line with the HRA CAG support. In addition, IGARD also asked that section 5(a) was updated with an indicative plan of any future PPIE activity. IGARD suggested that the applicant may wish to consider involving relevant public and patient groups for the lifecycle of the study. The HRA guidance on Public Involvement is a useful guide. IGARD noted the volume of information in section 5(a) in respect of the inclusion and exclusion criteria for the study and, noting that recruitment had now concluded, asked that the inclusion and exclusion criteria was reviewed in line with NHS Digital DARS Standard for Objective for Processing, and edited as appropriate, noting that much of this information may no longer be necessary. IGARD noted the references in section 5(b) (Processing Activities) to specific software, for example "*AlienVault Network Vulnerability Scanner*"; and asked that section 5(b) was updated to remove restrictive references to specific software, in line with NHS Digital DARS Standard for processing activities. IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove references to "*it will*…", and instead use a form of words such as "*it is hoped*…", including, but not limited to, the ***statement** "The findings from any future research carried out from being able to collect long term follow up data **will hugely benefit** the medical profession, women at high risk from breast cancer and women who have been newly diagnosed"*. IGARD noted that the adverb 'hugely' might be perceived as hyperbolic. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5(a) was amended throughout, to ensure acronyms be defined upon first use, for example *"SERMS"*. IGARD also asked that section 5(a) was amended to ensure that technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example *"mantle radiotherapy".* IGARD noted that NHS Digital had advised that the applicant did not request remote access under this DSA, so it was prohibited. IGARD suggested that NHS Digital ensure there was a remote access policy to give consistency, and that this was published to inform applicants. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a special condition in section 6, to reflect the specific date of 2026, when the confidential data must be deleted in line with the HRA CAG support. 2. In respect of PPIE: a) To update section 5(a) to provide details of any PPIE carried out to date, in line with the HRA CAG support; and, b) To provide an indicative plan of future PPIE activity in section 5(a). 3. To review the extensive inclusion / exclusion criteria in section 5(a) and edit as appropriate. 4. To amend section 5(b) to remove reference to specific software. 5. To update section 5 to use a form of wording that avoids hyperbole and is conditional about future benefits, using language such as "*it is hoped* …", rather than "*it will*…". 6. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout: a. To ensure acronyms be defined upon first use; and, b. To update section 5(a) to ensure technical terms are used only where necessary and explained in a manner suitable for a lay audience

	The following advice was given: 1. IGARD suggested that the applicant consider involving relevant public and patient groups for the lifecycle of the study. The HRA guidance on Public Involvement is a useful guide. 2. IGARD noted that NHS Digital had advised that the applicant did not request remote access under this DSA, so it was prohibited for this application. IGARD suggested that NHS Digital ensure there was a remote access policy to give consistency, and that this was published to inform applicants.
3.8	University of Cambridge: Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers (Presenter: Anna Weaver) NIC-302473-K6R0Z-v6.13 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Death), MRIS - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report. It was also an amendment to obtain further data for a different cohort of participants using consent to meet the common law duty of confidence, previously data was provided for a cohort where s251 approval had been obtained. The purpose of the application is for a study, established in 1998; and is the largest national prospective study of BRCA1 and BRCA2 carriers and their relatives. The study has recruited more than 10,000 individuals of where approximately 5,000 are known female carriers. The primary aims of this study are to **1)** define a cohort of breast / ovarian cancer gene mutation carriers, and their relatives, identified through clinical genetics centres in the UK, who can be followed prospectively to determine cancer risks and to examine the efficacy of different interventions; **2)** to obtain simple epidemiological information, by questionnaire, on affected and unaffected mutation carriers in order to determine lifestyle factors which may modify risk; **3)** to collect serial blood samples from participants to evaluate: a) genetic variants that may modify the risk of cancer b) blood markers that may be able to detect cancer earlier. A secondary aim of the study is to establish the feasibility of serial cervical sampling to evaluate markers for early detection of ovarian cancer. The study cohort consist of participants who are: **1)** carriers of mutations in the breast and ovarian cancer susceptibility genes identified through clinical genetics centres in the UK; or **2)** family members from families with mutations who themselves do not carry the mutation (treated as “controls” in certain analyses). The legal basis for the processing of data is s251 of the NHS Act 2006 for the retrospective cohort and consent is in place for the prospective cohort. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 27th July 2017 and the 17th January 2019. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application.

	IGARD noted that the cohort size references differed throughout the application, for example, section 1 (Abstract) and section 5(b) (Processing Activities) referred to *"750"* cohort members; and section 3 (Datasets Held / Requested) referred to *"8,780"* cohort members. IGARD asked that the cohort size references were reviewed throughout the application, to ensure they were accurate and consistent; and that any incorrect references were updated as necessary. IGARD queried the statement in section 3 *"…8,780 participants data will be filtered"*; and asked further clarity was provided in section 3, as to what was meant by *"filtered"*, as this was unclear. IGARD noted that at the last review of the application on the 17th January 2019, IGARD had advised that *"the applicant should work with NHS Digital on a fair processing notice that does not contain misleading statements, is GDPR compliant and this should be noted as part of any audit*"; and had also asked that a special condition was inserted in section *6 "to replicate the information provided within section 4 (stating that the applicant will work with NHS Digital to ensure the fair processing notice is GDPR compliant) in section 6 as a special condition"*. IGARD noted that the special condition had been removed from the application, but, noted that the published privacy notice **did not** appear to have been updated since 2017. IGARD asked that the published privacy notice was updated as a matter of urgency and in line with the UK General Data Protection Regulation (UK GDPR); and in harmony with the information that may be published elsewhere on the website. **Outcome:** recommendation to approve The following amendments were requested: 1. To review the cohort size references throughout the application to ensure they are accurate and consistent; and update as necessary. *2.* To provide further clarity in section 3 on the reference to patients *"filtered"*. The following advice was given: 1. IGARD noted the previous concerns raised, in respect of the applicant's privacy notice in 2019; and that the privacy notice available on the applicant's website had **not** been updated since 2017. IGARD asked that this was updated as a matter of urgency, in line with UK GDPR; and in harmony with the information that may be published elsewhere on the website.
3.9	<u>University of York: Evaluating the effect of the Best Practice Tariff for hip fracture on health inequalities (Presenter: Anna Weaver) NIC-50329-G1L1P-v4.18</u> **Application:** This was a new application new application for pseudonymised Bespoke Cohort: MPS_ID Linkage. This is deemed a "new" application, due to the previous data linked under this data sharing agreement (DSA) having been destroyed; and there is a new purpose. The purpose of the application is for a research project into the extent to which the introduction of the Best Practice Tariff (BPT) for fragility hip fracture in English NHS hospitals in April 2010 and subsequent changes to the tariff design, affect health inequalities in this patient population. Identifying data will be supplied to NHS Digital in order to facilitate the linkage of National Hip Fracture Database (NHFD) *(part of the Falls and Fragility Fracture Audit Programme commissioned by the Healthcare Quality Improvement Partnership (HQIP))* data and linked to pseudonymised Hospital Episode Statistics (HES) and Civil Registration (deaths) data, held by

	The Centre for Health Economics (CHE) *(based at the University of York)* which flows under a separate DSA **NIC-84254-J2G1Q** *(to be superseded by NIC-667040-B5T1X within the next 12 months)*. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 13th April 2017 and the 20th April 2017. IGARD noted that the application and relevant supporting documents for **NIC-84254-J2G1Q** had previously been presented at the IGARD meetings on the 14th June 2018, 7th February 2019, 19th November 2020 and the 25th November 2021. 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 in section 3(c) (Patient Objections) that patient objections were applied, however queried at what point(s) the patient objections were applied. NHS Digital advised IGARD that further discussions had taken place prior to the meeting on this point, with NHS Digital's Data Production Team, who had confirmed that patient objections were applied before the data flowed from NHS Digital; and that patient objections would be applied to the linkage file. IGARD noted the verbal update from NHS Digital, and were content that patient objections would be applied to the linkage file, and that this was consistent with the National Data Opt-out policy and asked that the application was updated as necessary, for example a brief explanation in section 1 (Abstract). IGARD noted the new proposed processing under this DSA, and asked that for transparency, the applicant updated the Health Research Authority Confidentiality Advisory Group (HRA CAG) on the new processing taking place; that the use of the Cloud storage provider was consistent with the protocol and to make any necessary updates to the relevant bodies; and confirmation that the HRA CAG annual review paperwork been submitted to HRA CAG, noting that the s251 support expires on the 10th February 2023. IGARD queried the size of the bridging file, noting this was not clear in the application, and asked that section 3 (Datasets Held / Requested) and section 5 (Purpose / Methods / Outputs) were updated with an indicative size of the number of data subjects in the bridging file. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the HRA CAG and REC support: a) The applicant to update HRA CAG on the new processing purpose; and, b) To ensure that the Cloud storage provider is consistent with the protocol and to give any necessary updates to the relevant bodies; and, c) To confirm that the HRA CAG annual review paperwork has been submitted to HRA CAG. 2. In respect of the number of data subjects in the bridging file: a) To update section 3 to provide an indicative size of the number of data subjects in the bridging file.
4	<u>Applications progressed / to be progressed via NHS Digital's SIRO Precedent route</u>

	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	Norfolk and Norwich University Hospitals NHS FT: A national review of Merkel cell carcinoma epidemiology in England 2004-2018 (ODR2021_095) (No Presenter) NIC-656881-X0G0X-v1.2 The purpose of the application is for a project aiming to report national epidemiological data from England on Merkel cell carcinoma (MCC) between 2004 to 2018. Specifically, the total number of people diagnosed with MCC per year and how this varies across age, gender, ethnicity, income, associated cancer, immunosuppression and geographical region. This project will report the body location of MCC and how advanced MCC was at diagnosis. Finally, the project will report the treatment received and survival in MCC. IGARD noted the datasets requested under this DSA, had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous IGARD review. IGARD noted that on the 19th January 2023, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted and thanked NHS Digital for the written update, however, it expressed concern that *"consent"* appeared to have been erroneously selected as the legal basis for the sharing of the data. IGARD also advised that the ODR reference provided on the application, was not bringing any returns on the Public Health England data release register.
4.2	University of Nottingham: Surgical margins in breast conserving surgery for ductal carcinoma in-situ (DCIS) and clinical outcomes (ODR1819_162) (No Presenter) NIC-656832-M8F7G-v1.2 The purpose of the application is to assess the impact of the width of the tissue between the edge of a breast tumour being removed and the edge of the whole surgically excised tissue specimen (known as "margin width"). The aim is to establish the optimum margin width for best clinical outcomes. IGARD noted the NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous IGARD review. IGARD noted that on the 19th January 2023, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted and thanked NHS Digital for the written update and noted that section 5(a) was not written in a lay friendly manner.
4.3	Institute of Cancer Research: MR1251 - Safety and appropriateness of growth hormone treatments in Europe (SAGHE) (No Presenter) 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; however, it was discussed under 'Applications progressed / to be progressed via NHS Digital's SIRO Precedent route' on the 17th November 2022, where IGARD had made a number of points. IGARD noted that on the 25th January 2023, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted and thanked NHS Digital for the written update.
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. **ACTION:** IGARD asked that this outstanding action be captured on the successor group's "action log" or similar and added to future successor group minutes until it had been resolved 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. **ACTION:** IGARD asked that this outstanding action be captured on the successor group's "action log" or similar and added to future successor group minutes until it had been resolved.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: House of Lords Secondary Legislation Scrutiny Committee IGARD noted that a response from the Department of Health and Social Care, published by the House of Lords Secondary Legislation Scrutiny Committee on 19th January 2023, stated that the draft statutory guidance (guidance to NHS England on the measures it should take to protect confidential information when exercising the data functions transferred from NHS Digital) had been shared with IGARD for their views. Members judged that this was not an accurate reflection of IGARD's involvement, since the group had only received a draft of the guidance to review on 18th January 2023 and had been given just two days to respond with comments. IGARD were concerned by the impression that had been given to the House of

	Lords Committee that IGARD had been adequately involved, as members felt they had been given limited opportunity to comment and could have made a more meaningful contribution had they been involved earlier in the drafting process.
7.2	<u>IGARD Closure Report 2017-2023</u> IGARD noted that the '*IGARD Closure Report: a record of activities and impact 2017-2023'* was appended to these minutes at **Appendix B**. The closure report covered a number of topics including the creation of IGARD, IGARD's role, the challenges and opportunities faced by IGARD, how IGARD supported the appropriate use of data, IGARD's governance and accountability, a year-by-year summary of activities and development, and key management information.
7.3	<u>Service Improvement Closure report 2018-2023</u> IGARD noted that the '*IGARD and NHS Digital partnership working and service improvement work programme closure report*' was appended to these minutes at **Appendix C.** The briefing covered the key areas of service improvement which had been undertaken by the IGARD Secretariat Team from 2018 to present to identify and understand where processes were working well, and where additional improvements could be made to ensure a positive and productive experience at IGARD meetings. IGARD supported the Secretariat's recommendation that service improvement forms part of the new successor Group's Secretariat remit following the merger between NHS Digital and NHS England on the 1st February 2023.
7.4	<u>Recording of final thoughts by members and NHS Digital</u> Garry Coleman, Dr Arjun Dhillon and Dickie Langley joined the meeting to thank the IGARD Members (past and present) and the Secretariat Team for their work and service over the previous 6 years. NHS Digital colleagues noted that a lot had happened over the last 6 years but that, throughout that time, IGARD had provided advice, observations and challenge to NHS Digital and wider research community. IGARD members present noted that they had enjoyed being part of the group and that the group was 'more than the sum of the parts' with members supporting and challenging one another. Members emphasised that IGARD had brought together a variety of specialisms and backgrounds, enabling the group to provide more rounded and comprehensive advice than would be possible through individual silo working. In addition, members noted that the work and discussions at IGARD had also informed their other working roles. IGARD members noted that they looked forward to working with NHS England colleagues, but in particular hoped that the current IGARD Secretariat Team of Victoria Williams and Karen Myers would form the new group's secretariat team, due to the excellent support they provided to the meeting and individual members, their skill in managing such a complex workload and meetings, and the invaluable knowledge and experience they brought from their many years of supporting IGARD and its predecessor DAAG. Members expressed the view that this would be vital to successfully establishing a new group.

7.5	IGARD Co-Deputy Chairs The IGARD Chair asked that a discussion item be added to the first meeting of the new group in order to nominate and agree a Deputy Chair, or co-Deputy Chairs, to the new group. **ACTION:** Secretariat to include as an agenda item on the first meeting of the new group.
7.6	National Disease Registration Service (NDRS) Congenital Anomalies Data Sets – Briefing Paper Noting that NHS Digital at the IGARD meeting on the 15th December 2022 had indicated that the updated briefing paper would be tabled at an IGARD meeting in the New Year, IGARD noted that the briefing paper remained outstanding. **ACTION:** IGARD suggested that when the briefing paper was finally updated and a copy provided to the successor Group's Secretariat Team, that the briefing paper be appended to the successor Group's minutes and as agreed by IGARD and NHS Digital.
7.7	GP Data for Planning & Research – invitation to NHS Digital to update IGARD members IGARD noted that they had requested NHS Digital to attend IGARD to update members on the GPDPR programme a number of times, noting that an update was given to the NHS Digital Board back in November 2022 and that the team leading on GPDPR were reaffirming the position with the Ministerial team at the same time. **ACTION:** IGARD suggested that this outstanding action be brought forward to the new group and that an update be provided by NHS England as soon as possible with regard to the current position of GPDPR.
7.8	Policy position: no confidentiality issues for the receipt of pseudo data for those that hold the means to re-identify. IGARD members noted the outstanding action following their meeting on the 15th September 2022, which reiterated an action from the 28th July 2022 that following SAT 'touching base' with HRA CAG to confirm their previous position that there are still no confidentiality issues for the receipt of pseudo data for those that hold the means to re-identify, that a file note be provided of the meeting and be recirculated to HRA CAG, NHS Digital and the IGARD Chair to ensure that everyone had a formal output of the meeting, since it was a key policy change which needed to be kept on file as an "artefact" for future use. **ACTION:** IGARD asked that a copy of the correspondence as noted above be circulated to IGARD's successor group to keep on file.
7.9	Out of Committee (OOC) applications IGARD noted that a number of applications remained outstanding (recommended for approval subject to condition(s)) with NHS Digital and that in line with the published IGARD Standard Operating Procedure (SOP) that the OOCs should be submitted to the successor group's secretariat team for action in line with IGARD's OOC SOP. **ACTION:** IGARD suggested that the Secretariat liaise with NHS Digital / England to ensure that all outstanding OOCs were returned to independent members timely and within 3

	months of the recommendation being made, to ensure that due IGARD process has been followed. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the final meeting of IGARD.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 20/01/23

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

Appendix B

The Independent Group Advising (NHS Digital) on the Release of Data (IGARD) closure report: a record of activities and impact 2017-2023

The Independent Group Advising (NHS Digital) on the Release of Data (IGARD) acts as an advisory body to the NHS Digital Board. The group's independent advice informs NHS Digital stewardship when it shares patient data with other organisations to improve health and care.

NHS Digital is the national digital, data and technology delivery partner for the NHS and social care system. To help create better health and care services, NHS Digital delivers products, platforms, and services, and shares national data and insight. It is an executive, non-departmental public body, sponsored by the Department of Health and Social Care. Its functions are due to merge into NHS England on 1 February 2023.

Published date: 31st January 2023

Contents

Foreword from the IGARD Chair 27
Background and overview 30
The creation of an independent oversight group 30
IGARD's role 30
Challenges and opportunities 31
Supporting appropriate use of data 33
Understanding public views 33
Promoting patient and service user interests 33
Supporting public understanding 34
Changing ways of working 35
The introduction of precedents and standards 36
Collaborative service improvement 38
IGARD member reflections 39
IGARD accountability and governance 40
Accountability 40
Transparency of IGARD work 41
Standard operating procedures 41
Membership and remuneration 41
Members of IGARD 2017-2022 42
Budget 43
IGARD Secretariat 43
Management information 43
IGARD in numbers 43
Year-by-year summary of IGARD activities and development 44
2017 44
2018 44
2019 45
2020 46
2021 47
2022 47
Appendix A – IGARD Management Information – (February 2017 – December 2022) 49
Number of applications / briefing papers presented 49
Type of recommendation made by IGARD 51
Briefing papers to IGARD 51

Number of supporting documents presented to an IGARD business as usual meetings 53
Risk areas / significant risk areas notified to NHS Digital 54
Number of Out of Committee (OOC) approvals 56

Foreword from the IGARD Chair

"Data is precious and should always be treated with respect, ethics, positive outcomes, in the best interest of public benefit. Trust and transparency are essential. Please keep our voices ringing in your ears…"

These words often come to me. They were spoken by a member of the public who took part in a project exploring how to evaluate the public benefits of using health and care data[1]. I was part of the oversight group for the project and had the privilege of taking part in quite a few discussions with public participants. It was heartening to hear the thoughtful contributions from a diverse range of people, enthused by the prospect of information about them being used to improve health and care for themselves, for their family and friends, and for future generations.

It's particularly that plea, that we should keep the public's voices ringing in our ears, that stuck with me. While we have often needed to dive into complex or technical details in our work on IGARD, we always try to keep key public expectations in mind.

As the quote encapsulates, there are two key public expectations that might, at first, seem to pull in opposite directions.

We must make sure that the rich health and care information that NHS Digital collects from hospitals, GPs, mental health care providers and elsewhere is shared so that those positive outcomes for the benefit of the public can be achieved. We know from multiple pieces of research and dialogues with the public that this is what the vast majority of people want and expect[2]. One of the principles in the IGARD terms of reference is that sharing information can be as important as protecting confidentiality and that unnecessary obstacles should not be allowed to prevent information sharing where it is in the interests of patients, service users and the wider public.

We must also treat the privacy of patients and service users with respect. There is also plenty of evidence that people want firm rules around the use of health and care data, particularly when commercial organisations are given access[3]. Part of IGARD's role has been to support NHS Digital to respect and promote the privacy of all those who receive health and adult social care.

By accepting that both these expectations are necessary conditions for people to support the use of health and care data for reasons beyond their own care, we see that they do not, in fact, pull in opposite directions. So it is right that both these expectations have been reflected in IGARD's terms of reference, along with two other important ingredients of trustworthy data stewardship[4] – transparency and independence.

[1] National Data Guardian, 2021. Putting Good into Practice: A public dialogue on making public benefit assessments when using health and care data. Available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/977737/PGiP_Report_FINAL_1304.pdf

[2] See for instance: Stockdale J, Cassell J and Ford E. "Giving something back": A systematic review and ethical enquiry of public opinions on the use of patient data for research in the United Kingdom and the Republic of Ireland: https://wellcomeopenresearch.org/articles/3-6

[3] https://www.ipsos.com/sites/default/files/publication/5200-03/sri-wellcome-trust-commercial-access-to-health-data.pdf

[4] For a discussion of the characteristics of trustworthiness, see here: https://understandingpatientdata.org.uk/what-we-mean-trustworthy-use-patient-data

It has been a consistent finding from research and engagement that transparency is an indispensable condition for people to accept the use of data about them, whether that is information about health or other topics[5]. IGARD has played an important role in supporting NHS Digital's work to explain to patients, service users and the public, how data about them, collected as part of their care, has been used. We have done this in several ways, including publishing detailed information about our recommendations in our minutes[6], suggesting ways to make NHS's register of data use[7] as clear as possible to everyone, lay or otherwise, and advising those who receive NHS data how they can improve their transparency.

Independent oversight, which reflects public views, has often been identified as a hallmark of trustworthy data use in public engagement[8]. Before IGARD, there was not a fully independent group with lay involvement scrutinising releases of data by NHS Digital or its predecessor bodies. The NHS Digital Board decided that such a group was needed following a review[9] which made recommendations aimed at improving controls over data sharing to build greater public trust. The benefits of this independent oversight have been praised by the National Data Guardian for Health and Social Care[10] as an important element of the governance at NHS Digital, alongside the legislative framework and the Data Access Request Service. I was pleased to see this acknowledged in her annual report 2021-22, which said:

"This process and oversight mean that strong safeguards are in place to ensure that the principles of transparency, accountability, quality, and consistency are central to any collection and dissemination of data by NHS Digital."

As we prepare for the changes that will come from NHS Digital's merger into NHS England, I am proud and thankful. I am proud of the way that IGARD has developed and adapted to support NHS Digital's task of sharing data so it can be used for public benefit. I know that data users sometimes find the application process frustrating and lengthy. IGARD has worked positively with NHS Digital to find ways of making the application process quicker and less burdensome while keeping governance controls proportionate to the risk. I'm proud that IGARD recommendations are turned around within a week and that we have always been ready to provide early advice or flex our agenda to discuss emerging issues. We outline some of this in the section: Collaborative service improvement. Some of my fellow IGARD members have kindly provided reflections for this report on their experiences of the group in the section: IGARD member reflections.

I'm also thankful to the many colleagues who have worked so productively to support and enable IGARD to do its work. We are fortunate to have exceptional staff in the secretariat that has served IGARD and kept us on our toes. Among NHS Digital employees, we have benefited from expertise, knowledge, and a determination to make sure data sharing is done in the right way. And, we have been supported by leaders who value independent scrutiny, even though it is not always easy to hear, because they have seen the importance of being challenged to strive for improvements to the way things are done for the benefit of the public.

This report contains a section on Challenges and opportunities as new ways of collecting and using data open up new possibilities for analysis and research. There is much that can be done to evolve the way

[5] https://www.tigtech.org/insights/7-drivers-of-trust
[6] https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data/meetings
[7] https://digital.nhs.uk/services/data-access-request-service-dars/data-uses-register
[8] See for instance: https://www.adalovelaceinstitute.org/wp-content/uploads/2020/03/Foundations-of-Fairness.v.final_.pdf
[9] https://www.gov.uk/government/publications/review-of-data-releases-made-by-the-nhs-information-centre
[10] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1100988/NDG_annual_report_2021-22_v1.0_FINAL_30.08.22.pdf

independent oversight works to meet those challenges: earlier involvement in discussions around what data is needed and how challenges can be addressed; better liaison with data applicants; closer working with data access colleagues and those accountable for dissemination and sharing of data.

We should always be ready to support the appropriate use of data while maintaining the hallmarks of trustworthy data stewardship that the public rightly expects.

Kirsty Irvine
IGARD Chair

Background and overview

The creation of an independent oversight group

The decision that there should be an independent oversight group to advise NHS Digital[11] on data dissemination came as a result of the Partridge Review[12] in 2014. This review, led by NHS Digital board member Sir Nick Partridge, looked at how a predecessor organisation to NHS Digital had shared information from national health datasets with third parties.

It found *"lapses in the strict arrangements that were supposed to be in place to ensure that people's personal data would never be used improperly"* and recommended measures to prevent this from recurring. One of these was that NHS Digital should: "*Ensure there is a clear, transparent and timely decision making process, via the appropriate governance for all data releases, and that all decisions are documented and published on its website"*.

As an interim measure to strengthen oversight, NHS Digital expanded its existing Data Access Advisory Group (DAAG), adding some independent members to the existing staff members. Then, in summer 2015, the NHS Digital Board undertook a public consultation about a proposal to establish a data advisory group with an expanded and more independent remit.

The consultation responses[13] showed strong support for an independent oversight group. Respondents wanted to see an open appointment process for independent members who were not employees of NHS Digital. They wanted the group to have expertise about the needs of data users, and significantly they also wanted lay membership. They called for transparency and a focus on promoting secure access to data. Following the consultation, the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) replaced DAAG[14] on 1 February 2017.

The intention was that with an expanded remit and lay representation, IGARD could increase transparency, accountability, participation, quality, and consistency, thereby strengthening public confidence in NHS Digital's data stewardship. The group was designed[15] to operate as an advisory body to the NHS Digital Board, providing independent oversight of NHS Digital's data dissemination.

IGARD's role

IGARD's published terms of reference (TOR)[16] charge the group with providing clear, independent recommendations or advice to the NHS Digital Board via the NHS Digital Senior Information Risk Owner (SIRO). IGARD has no statutory footing and its role is advisory; decisions about whether or not to make a release of data remain with NHS Digital. IGARD's role is to support NHS Digital to fulfil its duties and responsibilities, ensuring *"… that external organisations can access the information they need to improve outcomes, and the public are confident that their data will be stored safely by NHS Digital. Our goal is to maximise the accessibility, quality and utility of health and care data while respecting privacy, transparency and ethics"*[17].

[11] On its establishment in statute in 2012, NHS Digital was known as the Health and Social Care Information Centre (HSCIC). This was its public name until it was changed, on the recommendation of the then National Data Guardian, Dame Fiona Caldicott, in 2016, to NHS Digital. To avoid confusion, this report uses the name NHS Digital, rather than swapping between both these names.
[12] https://www.gov.uk/government/publications/review-of-data-releases-made-by-the-nhs-information-centre
[13] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/appendix_b_to_daag_closure_report_-_you_said_we_did_%28igard_consultation%29.pdf
[14] https://digital.nhs.uk/binaries/content/assets/legacy/pdf/l/9/daag_closure_report_2017.pdf
[15] https://digital.nhs.uk/binaries/content/assets/website-assets/corporate-information/corporate-statements/igard-history---v0.4---final.pdf
[16] https://digital.nhs.uk/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard_terms_of_reference_v1.7_-_final_for_publication_2.pdf
[17] https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/our-strategy-and-role

IGARD's work falls broadly into two activities. Firstly, to make general recommendations to NHS Digital about data sharing. This has included advice about internal policies and processes and transparency measures, such as the public register[18] that shows who has been given access to data, for what purpose, and what benefits have resulted for health and care. Secondly, IGARD has a role to scrutinise requests for data made by other organisations. Such requests are made by NHS organisations, researchers, academics, commercial bodies, and others via NHS Digital's Data Access Request Service (DARS)[19]. IGARD does not scrutinise every application for data made to DARS. Instead, it focuses on reviewing novel, contentious or repercussive applications[20] to provide independent assurance of NHS Digital's decisions.

IGARD meetings are usually for a full day, once a week, with around 44 meetings per year (additional meetings were held from March 2020 to December 2021 to provide advice on urgent COVID-19 issues). At its regular weekly meeting, IGARD normally reviews around five to six applications and may also give advice on emerging issues, new data collections or other matters. In doing so, IGARD is charged with considering principles such as: the importance of sharing information in the interests of patients, service users and the public; that there must be a secure legal basis for sharing; that the minimum data should be shared for the purpose; the need to protect privacy and to balance potential benefits against risks to privacy; the need to understand and mitigate any risks of data sharing.

Challenges and opportunities

IGARD comes to the end of its work with the merger of NHS Digital into NHS England at the beginning of February 2023. A new group will be established by NHS England to provide advice on the use of data and IGARD members have been invited to join that. As IGARD looks ahead, there are continuing and future challenges.

New and emerging innovations in technology are expanding the possible uses and insights that can be drawn from data. This brings exciting potential benefits but can make the task of transparency more challenging as it may be more difficult to explain to the public how data is being used. In some cases where machine learning is used, it may even be challenging for experts to understand how a finding or conclusion has been drawn from data. The published guidance on evaluating public benefit by the National Data Guardian[21] emphasises the importance of transparently evaluating and communicating the benefits of data use. IGARD has considered how guidance could be implemented to further enhance transparency about data use and its benefits.

There are opportunities presented by the increased use of data environments which provide secure access to health and care data for researchers and analysts, without the need for a copy of the data to be transferred to them. Often called 'Trusted Research Environments' (TREs), their increased use was a key recommendation of the government-commissioned review by Professor Ben Goldacre: *Better, broader, safer: using health data for research and analysis*[22]. These environments provide the mechanisms to mitigate and remove some risks, but they do not address all public concerns. As the Goldacre review acknowledges, transparency, accountability and meaningful patient and public involvement and engagement need to be built in. It may also be the case that for some data uses the need for a copy of data to be shared externally, will remain.

The range and size of the datasets that NHS Digital held and shared continued to grow over the period of IGARD's work. In the last year of NHS Digital's operation, it took on responsibility for important datasets

[18] https://digital.nhs.uk/services/data-access-request-service-dars/data-uses-register
[19] https://digital.nhs.uk/services/data-access-request-service-dars
[20] As defined by IGARD's terms of reference: https://digital.nhs.uk/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard_terms_of_reference_v1.7_-_final_for_publication_2.pdf
21 https://www.gov.uk/government/publications/what-do-we-mean-by-public-benefit-evaluating-public-benefit-when-health-and-adult-social-care-data-is-used-for-purposes-beyond-individual-care
22 https://www.gov.uk/government/publications/better-broader-safer-using-health-data-for-research-and-analysis

that were previously managed by Public Health England (PHE)[23]. They included registers containing information about cancer, congenital abnormalities and rare diseases, which contain rich information for researchers and others to improve health and care. The process of taking on and managing these showed that particular expertise about each dataset – its sources, potential, limitations and restrictions – must be understood when responsibility for an information asset is moved. This learning will be important as NHS Digital and its extensive data assets merge into NHS England.

Preparations for the merger of NHS Digital into NHS England were taking place as this report was being written. The merger means that NHS England will inherit 'data functions' from NHS Digital - the statutory powers and responsibilities that were formerly NHS Digital's due to its position as the safe haven for collecting, using and sharing health and care data[24]. At the time of writing IGARD understood that NHS England intended to establish a new group to provide advice on the way that it would exercise the inherited data functions.

The preparations to establish this group were taking place in the context of statutory regulations[25], setting out that the Secretary of State for Health and Social Care must publish guidance for NHS England about how it uses the data functions. It is expected that the new guidance will cover the use of independent advice and scrutiny and how it should be used by NHS England.

The new regulations were the result of Government commitments made during the Parliamentary passage of the Health and Care Act 2022[26], which laid the foundations for the merger. Responding for the Government in the House of Lords to questions about how protections for patient data would be maintained, Lord Kamall explained that it was the intention to use regulations "*to provide as much statutory protection as possible for the continuation of a data safe haven in NHS England—particularly to retain the confidence of the public in how we make best use of their data, and to improve outcomes*."[27]

IGARD members, secretariat staff and the IGARD Chair have provided advice on the drafting of the terms of reference for the new group, however, whether or not the drafting suggestions are accepted, as well as the group's membership, scope and role will be a matter for NHS England's board to determine. IGARD advice has focused on the benefits of independent advice and oversight in assuring practice and demonstrating trustworthiness, on the importance of incorporating transparency about how the group operates and the advice it gives, and on the need for clarity about the roles that group members will play. IGARD discussions have also covered the proposed aim to increase the use of "Precedent" routes to data access so that more applications could be approved by NHS England staff according to agreed processes without review by the new group. This could allow the group to focus increasingly on assurance and strategic issues. IGARD worked with NHS to introduce Precedents in 2019 and has continued to support work to refine these; reflections and learning from this experience are set out in a section on The introduction of Precedents and Standards later in this report and IGARD encourages NHS England to bear these lessons in mind when looking to increase the use of Precedents.

IGARD anticipates that it will be challenging in the midst of the merger for NHS England to work to reduce the data dissemination timescales while also ensuring appropriate governance is maintained. IGARD members have always been committed to working to streamline processes where possible and have engaged constructively with NHS Digital to do so (see the section below: *Supporting appropriate use of data* for details of previous work). However, it is important to understand that the ethics and governance of gathering, sharing, and using healthcare data are complex. Seeking to simplify institutional, regulatory and

[23] Public Health England was replaced by the UK Health Security Agency and the Office for Health and Improvement and Disparities in 2021 and some of its functions and responsibilities moved to NHS Digital: https://www.gov.uk/government/organisations/public-health-england
24 As set out by the Health and Social Care Act 2012.
[25] The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (legislation.gov.uk)
[26] Health and Care Act 2022 (legislation.gov.uk)
[27] Health and Care Bill - Hansard - UK Parliament

legal frameworks is important, but the complexity needs to be acknowledged with proportionate levels of checks and balances.

Supporting appropriate use of data

Understanding public views

In her third government-commissioned review[28], published in 2016, the late Dame Fiona Caldicott found that "*people hold mixed views about their information being used for purposes beyond direct care. Some are concerned primarily with privacy and are suspicious that information might be used by commercial companies for marketing purposes. Others prioritise the sharing of information to improve health and social care, and for the research of new treatments*".

IGARD's terms of reference require it to consider the privacy of recipients of health service and adult social care in England, meaning that it needs to understand what people would reasonably expect with regard to the use of their information. IGARD has used a variety of methods to do this, bearing in mind the evidence about there being a mix of views. Lay members have been an integral part of IGARD, charged with bringing the perspectives of patients, carers, and service users to discussions, as well as signposting to community groups and relevant third-party organisations. IGARD members have also stayed abreast of public engagement research about the use of data and have been involved in public dialogue projects.

Understanding public views on data sharing has had practical impacts on IGARD's work and recommendations. For instance, IGARD considered an application from a multinational company to use NHS Digital data to validate its software for use in the NHS[29]. IGARD referred to NHS Digital's Benefits Standard[30], evidenced public views on commercial access, and the NDG's guidance on assessing public benefit. All these emphasise the importance of there being a public benefit where commercial organisations are using data. This led IGARD to recommend additional conditions to ensure that the project would actually have a positive impact through working with NHS bodies.

Where there has been uncertainty about whether participants in a research study would expect (and accept) access to (and use of) data, IGARD has advised applicants to consult cohort members. For instance, a COVID-19 study followed IGARD's advice and consulted members of its advisory group as to whether access to health data before study consent was encompassed by "follow your health status" and related statements in the participant information materials. In that case, it was judged compatible but further efforts were made to give transparency to participants[31].

The National Data Guardian's public benefit guidance indicates that independent oversight with lay membership is particularly important where the proportionality of private or commercial benefits needs to be considered. As well as meeting this guidance through its own membership, IGARD has also recommended conditions on some applications to ensure that data recipients add lay members to their data governance bodies[32], thus spreading good practice.

Promoting patient and service user interests

IGARD has actively encouraged data applicants to involve patients and service users at all stages of their projects, so that patients or other people with relevant experience contribute to how a project is designed,

[28] https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs
[29] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---27-october-2022-finalv2.pd f
[30] https://digital.nhs.uk/services/data-access-request-service-dars/dars-guidance/expected-measurable-benefits
31 https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---15-december-2022-final.pdf
[32] See for instance: https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---4-august-2022.pdf

conducted, and disseminated. As the Health Research Authority and National Institute of Health Research[33] emphasise, involving the public and patients at all stages leads to more relevant and impactful studies. Where applicants have done this particularly well, IGARD commends good practice[34].

IGARD has challenged instances where proposed restrictions in data sharing agreements could have had an unintended effect of preventing the quality of care being checked. For instance, some applications have had standard conditions inserted which created a blanket ban on data being used for performance management. Members agreed that data should not be used to draw conclusions about the quality of care and performance where the data user did not have a legitimate role to do this, or the data was inadequate for the purpose. However, there was also concern that such standard conditions could fetter the ability of organisations to carry out analysis about the quality of care in the interests of patients and service users[35].

Where IGARD members believed that additional data access or further datasets would enable applicants to optimise their research, uncovering more useful insights that could improve health and social care, the group has highlighted this and encouraged NHS Digital to consider providing more data to projects. Instances where this has happened include suggesting that additional data that could enhance a study looking at how a mother's health and her baby's health are connected[36] and suggesting that a project to measure the quality of stroke care also receive COVID-19 data for a fuller picture[37].

IGARD has worked to ensure that choices that people have made about data use are respected. For instance, IGARD has made recommendations about the application of national data opt-outs registered by parents on behalf of their children[38].

Supporting public understanding

Dame Fiona Caldicott's 2016 review determined that when the benefits are explained, there is generally broad support for data being used to improve the health and social care system through research and planning. In 2020 an eighth Caldicott Principle[39] was added emphasising the importance of 'no surprises', which said that patients and service users should be informed about how their confidential information is used.

IGARD's terms of reference give it a role in making observations about transparency measures. Members place great importance on supporting public understanding about the use of data, an indispensable element of trustworthy data stewardship.

Information contained in data applications forms the basis of NHS Digital's public-facing data uses register[40]. Applications for NHS Digital data are required to explain exactly what data is needed; what organisations would be involved; the aims of the project; how data would be processed (for instance how it would be stored safely, whether it would be linked to other information); the timescales for the project; the

[33] https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437
[34] See for instance comments on the University of Oxford's WAX study: https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---8-september-2022-final.pdf or the University of Warwick's PROSPER trial: https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---29-september-2022-final.pdf
[35] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---23-june-2022-final.pdf
[36] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---4-august-2022.pdf
[37] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---13-october-2022-final.pdf
[38] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---10-november-2022-finalv1.pdf
[39] The Caldicott Principles - GOV.UK (www.gov.uk)
[40] https://digital.nhs.uk/services/data-access-request-service-dars/data-uses-register

benefits expected for health and care; any commercial aspect to the project. The information needs to be clear and detailed enough for NHS Digital to decide whether data should be shared. But as the wording is also used in NHS Digital's published data uses register, IGARD members pay attention to how intelligible this will be for members of the public and will often advise changes to improve this.

IGARD recommendations have resulted in data recipients improving their transparency. For instance, when working with NHS Digital to develop data sharing agreements with the 42 Integrated Care Boards (ICBs)[41] introduced in England in 2022, IGARD recommended a condition that all the ICBs should maintain and publish a register of how they have shared patient data received from NHS Digital. This was to support public understanding of how these new groupings, with multiple members, would be working together to use data to improve services in their area.

IGARD will also often look at whether applicants have taken steps to inform people about the use of their data. This may mean looking at privacy notices[42] on other organisations' websites. Data recipients retain the legal responsibility for providing concise, transparent, intelligible, and accessible information to data subjects about how they are using personal data. However, where IGARD believes that they need to be made clearer, the group will provide advice[43]. Likewise, IGARD will commend organisations that have demonstrated a commitment to good transparency[44].

IGARD will also review materials, such as patient information sheets and consent forms that are used to gain consent from people invited to join research studies. This ensures that they have been given clear information about how their data will be used before deciding to take part, meaning there is a sound legal basis to satisfy the duty of confidence before NHS Digital provides data. This activity was particularly important when studies and trials were being set up rapidly in 2020 in response to the COVID-19 pandemic[45].

Changing ways of working

Two key themes emerged in the public consultation[46] about the creation of IGARD carried out in 2015.

That an independent oversight group with lay representation was needed to strengthen public confidence in NHS Digital's data sharing governance. And also, that data users were frustrated and concerned about difficulties accessing data, with many respondents complaining that NHS Digital's approach was too 'risk averse'. In its response to the consultation the NHS Digital board was clear that because IGARD would be an advisory group, with NHS Digital retaining responsibility for processing applications and making decisions, it would be NHS Digital to lead on the response to these anxieties.

Since then, NHS Digital invested significant resources in developing its Data Access Request Service (DARS)[47]. Nonetheless, data applicants are understandably looking for efficient access to data to support their work to find new insights and improve health and care and IGARD is aware most applications still take many months.

Where IGARD is involved to assure the consistency and quality of an application, this typically comes at the end of the process after an applicant has been working with DARS to submit an application (apart from the instances where DARS brings an application earlier in the process for advice). IGARD members receive

[41] https://www.england.nhs.uk/publication/integrated-care-boards-in-england/
[42] https://ico.org.uk/for-organisations/accountability-framework/transparency/
[43] See for instance advice to the Office of National Statistics: https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---16-june-2022---final.pdf
[44] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-minutes-2022/igard-minutes---27-october-2022-finalv2.pdf
[45] file:///C:/Users/jenny/Downloads/IGARD+Minutes+-+3rd+June+2021+final.pdf
[46] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/appendix_b_to_daag_closure_report_-_you_said_we_did_%28igard_consultation%29.pdf
[47] https://digital.nhs.uk/services/data-access-request-service-dars

applications on a Friday afternoon before the weekly Thursday IGARD meeting at which the applications are discussed and recommendations given. Draft minutes are reviewed by all members who were present and discussed at the next meeting where they are ratified, published no later than 10 days from the meeting.

Where IGARD identifies ethical, legal or policy challenges within applications, it may make recommendations the applicant needs time to address. Depending on the nature of the changes, these may return for review within a subsequent IGARD meeting, be approved through email, or be ratified by NHS Digital without further review by the group.

The challenge for IGARD and DARS has always been on the one hand to find ways to reduce the burden on applicants, while on the other hand ensuring that sufficient checks and balances remain, so that IGARD stays true to its underlying objectives and so that the public can trust the processes were sufficiently robust.

The introduction of Precedents and Standards

A key reform in the way that IGARD and DARS work together came in May 2019 when NHS Digital introduced Precedents and Standards. IGARD's primary purpose remained the same - to have oversight of all requests for dissemination. However, experienced and senior staff in NHS Digital's DARS could now approve an application if they judged it to align with a precedent and to meet the required standards (which cover issues such as data security, legal basis, and expected benefits of the project).

There are exclusion criteria that prevent the use of a Precedent. Exclusion criteria include: a new application; a substantial amendment to a previously approved application (such as a new purpose for using data); the first application from an applicant following a substantial breach of an agreement, and applications which previously came to IGARD but were not recommended for approval. However, one Precedent - the NHS Digital SIRO precedent – does not have any specific exclusion criteria, meaning that the SIRO can approve any application without an IGARD review. Where the SIRO does this, IGARD is informed at its next meeting and has a chance to feedback and this is noted in the published minutes. The SIRO will also on occasion seek IGARD views before such approvals, particularly where there are complex issues, in order to help identify risks and relevant considerations.

One of the benefits of the new Standards has been greater clarity for applicants about what is expected of their application - for instance, what they need to do to explain the benefits of their data use or the purpose of their application. The Standards have also enhanced the reviews undertaken by IGARD and DARS by providing a clear, objective framework for assessing an application and for providing feedback to applicants.

The changes in May 2019 meant that IGARD reviews could focus on novel, contentious or repercussive applications. At the same time, IGARD's remit was extended to include helping NHS Digital develop, review, and approve the Standards and Precedents by which applications were developed and assessed. This has been an ongoing process of dialogue and refinement, with IGARD members asked to help develop and refresh some of the standards, for instance, the ethics standard.

Since the introduction of the Precedent system, an additional IGARD activity has been to regularly review a handful of the applications that have gone down a precedent route. The applications are picked at random for this 'oversight and assurance' process by the IGARD Secretariat Manager who can download any application which has progressed under Precedent, with four to eight applications coming fortnightly. Four key high-level objectives of the oversight and assurance process are to:

a) Define the objectives and the process to be followed;

b) Inspect the outputs to assess compliance with, and suitability of, the processes;

c) Adjust the processes to ensure the objectives are met;

d) Increase the speed of processing larger volumes of applications whilst maintaining transparency and public trust.

In undertaking the oversight and assurance role, IGARD is to:

a) Provide oversight and assurance of the process to ensure Precedents and Standards are correctly applied;

b) Receive a copy of Audit Reports via the Internal Audit Team;

c) Be furnished with all the evidence required to do their oversight role;

d) Focus its review on whether the Precedent process has been followed correctly;

e) Review applications against approved and published Precedents and Standards;

f) Have read access, via the secretariat, to NHS Digital's dashboard of internally reviewed applications; and

g) Ascertain that the assurance system is tested before being finalised and information included within published minutes.

For transparency, all applications reviewed via this process were included in IGARD's published minutes, including feedback given to NHS Digital on key themes or concerns.

At the outset of the move to a Precedent system, the ambition was to reduce the number of applications that would come to IGARD for review. It is certainly the case that fewer applications have come, allowing for attention to be focussed on the most complex. And it is also the case that the Precedents have simplified the system for less contentious applications.

However, the move to using Precedents has not reduced the number of applications coming to IGARD to the degree that was originally envisaged. This may have been appropriate as IGARD was still regularly finding issues with the way that Precedents were applied in 2022, three years after their piloting and introduction in 2019. After the initial Precedent piloting period, between March 2020 and December 2022, IGARD reviewed 191 applications that had been down the Precedent route, around 15 per cent of all the applications that had progressed down this route. Of these, IGARD judged that in more than one in four instances, the Precedent had not been applied correctly (52 out of 191 applications reviewed) and in 85 per cent of applications, significant issues were reported by IGARD reviewers.

It has appeared to IGARD that the reliable and effective running of the Precedent system has been threatened by the challenges NHS Digital has faced in recruiting and retaining experienced staff. Conversely, IGARD's experience is that where staff have the time, experience, and support to prepare data applications, the IGARD and post-IGARD timeframe is considerably shortened. The need to invest in and support staff working in data access will continue (see also the Challenges and opportunities section).

Supporting the pandemic response

IGARD also changed its way of working to support NHS Digital's response to the COVID-19 pandemic. From March 2020 to December 2021, IGARD added a half-day Tuesday meeting to its schedule, in addition to its business-as-usual Thursday meeting. During this time, members and the secretariat worked on even tighter timescales than usual to ensure rapid responses were given to urgent and emergent issues so that data could be used in the pandemic response. For example, the secretariat provided notes to the COVID-19 response meeting within three working days of the meeting and added a COVID-19 slot to the business-as-usual meeting agenda for urgent COVID-19 items.

IGARD also worked with the Health Research Authority's Confidentiality Advisory Group[48] to agree on expedited application processes and supported work to create the Shielded Patient List, which enabled clinically extremely vulnerable individuals at high risk to be identified and offered guidance and support.

IGARD was also charged with providing assurance of the COVID-19 (non-DARS) data release register, published on the NHS Digital website[49]. This contains details of releases approved through a process separate from the usual DARS application route. In practice, applications were instead considered by NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL) directorate for COVID-19 purposes. IGARD was not able to provide assurance on the disseminations as they only received a copy of the register and no further details about the data request. Therefore, the group provided comments on the information provided in the register and has suggested improvements to the register content to the Executive Director of PTEL. IGARD was also charged via the Executive Director of PTEL to provide a 'deep dive' of the releases to support continuous improvement and quality in the PTEL team. IGARD provided feedback on two deep dive requests to NHS Digital for the period March 2020 to December 2022.

Collaborative service improvement

A summary report will be appended to the final IGARD minutes in January 2023 detailing the service improvement process undertaken since summer 2018 in relation to NHS Digital and IGARD working together.

In addition to changing ways of working and providing additional capacity as outlined above, IGARD worked collaboratively with NHS Digital staff to improve the service that IGARD provided to NHS Digital and the service that NHS Digital provided to data applicants. Regular service reviews and a planned service improvement programme were built into IGARD's work. Examples of service improvements over the last four years include:

- Introduction of a new process whereby IGARD members would raise substantive issues before a meeting to enable NHS Digital staff to explore issues and solutions ahead of the weekly IGARD meeting;
- Design of a briefing note template to support DARS to present information to IGARD before bringing an application, enabling key issues to be dealt with earlier in the process;
- Providing support at earlier stages of the application process, by speaking to applicants or NHS Digital in advance of an application being submitted to IGARD;
- Improvements to the IGARD website to make information clearer to the public and data applicants;
- Bespoke advice to DARS on a range of issues to enable staff to deal with these complexities before bringing an application for advice. Subjects included the use of date of death information; risk stratification in relation to automated decision making and the application of the National Data Opt-out; and the application of S-flags in data;
- Bespoke support from individual IGARD members to improve privacy notices across a number of NHS, local authority, commercial and academic organisations;
- Bespoke advice with regard to a range of GDPR/UK GDPR issues including: automated decision making; definition of a 'natural person'; multi-party/joint controller issues; European Data Protection Board working party guidance; legal basis for a variety of organisational types; data controller and processor determinations; and digital ethics in GDPR;

[48] https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/
[49] https://digital.nhs.uk/services/data-access-request-service-dars/data-uses-register#covid-19-non-dars-data-release-register

- Bespoke advice on a range of other issues including use of cloud computing; research ethics; anonymisation and (re)identification; sharing data for genomic medicine and research; and sharing data for commercial purposes;
- Support to NHS Digital about using language which is intelligible to all, lay or otherwise, respectful to diverse populations and acknowledges the experiences of patients.

IGARD members also, with the support and agreement of NHS Digital, joined other groups to offer expertise and support a joined-up approach. These include:

- NHS Digital's Research Advisory Group[50];
- NHS Digital's Expert Advisory Group regarding the use of an algorithm (the QCovid model) to expand the list of clinically extremely vulnerable individuals who received support and guidance to shield from COVID-19[51];
- The National Data Guardian's oversight panel for its project on public benefit[52];
- NHS Digital's working group on a GDPR Article 40 Code of Conduct on data sharing;
- The IGARD secretariat supported NHSE London in their development of an independent information access group.

IGARD members engaged with external groups to exchange learning. These included:

- The IGARD Chair met regularly with HDRUK[53] and spoke at their conferences in 2021 and 2022;
- IGARD Chair presented twice at the NHS Higher Education Information Governance working group.

IGARD member reflections

Some IGARD members have provided their own reflections on their experience of being part of the group for this report.

Maria Clark (IGARD Lay Member 2019-2023)

"My time with IGARD has been a real journey of learning and reflection. To work within such complex legal structures and frameworks of course brings with it challenges but IGARD members together with the secretariat team were always on hand to provide guidance and support. The role has enabled me to continue in my work with both community groups and third sector organisations, locally and nationally and really champion the needs of patients and the public. Raising social injustice and highlighting health and social inequity was always on my agenda and to see this followed through in the work of those using patient data felt like a real win - not for me personally but for those harmed by structural inequalities and data bias. I sincerely hope this continues with the new group and in any new ways of working. Equity and justice, diversity and inclusion must be a golden thread running through the work of those taking on public roles such as this."

Dr Rob French (IGARD Specialist Member 2022-2023)

"As a researcher, most of my training was on statistics, however in practice, most of my time is actually spent accessing and linking data to run those models. As part of that work, I've learned about the challenges in sharing data, the technical and legal safeguards, the precious trust from the public that permits that data sharing, and the need for real-world benefits that the public can see resulting from this sharing. Being a member of IGARD has provided me with the opportunity to support and give feedback to

[50] https://digital.nhs.uk/services/research-advisory-group
[51] https://digital.nhs.uk/coronavirus/risk-assessment/population
[52] https://www.gov.uk/government/publications/putting-good-into-practice-a-public-dialogue-on-making-public-benefit-assessments-when-using-health-and-care-data
[53] https://www.hdruk.ac.uk/

research applications for NHS Digital data, and contribute a research perspective to the range of data uses further from my day-to-day experience such as the commercial applications and Integrated Care Board applications (though the boundaries between these different usages are becoming less clear cut). The diversity of the IGARD membership has provided such a range of perspectives on data sharing that has given me a much richer understanding of the challenges and opportunities in this data ecosystem, it has been an absolute privilege to have been involved."

Dr Imran Khan (IGARD GP Specialist Member 2020-2023)

"I have found being a member of IGARD incredibly rewarding and it has been a privilege to be part of a team and process that helps ensure patient data is used appropriately. The experience gained from IGARD has allowed me to deepen and inform my understanding of information governance. It has enabled me to better advocate for patients interests at a national level through my informatics role with the Royal College of General Practitioners. Most of all, it has been a pleasure to work with such enthusiastic and knowledgeable IGARD members, NHS Digital staff and Secretariat."

Dr Maurice Smith (IGARD GP Specialist Member 2019-2023)

"I've found working on IGARD to be an extremely rewarding and educational experience. I've learnt a huge amount and it's been a genuine privilege to work with colleagues who bring such a range of experience, expertise and enthusiasm to the group. I've been able to use knowledge gained during my time on IGARD to inform my role as Chief Clinical Information Officer (CCIO) and Caldicott Guardian for Liverpool Clinical Commissioning Group (CCG) and now as CCIO within Cheshire & Merseyside Integrated Care Board (ICB)."

IGARD accountability and governance

Accountability

IGARD's TOR provides that members do not represent any employing organisations, professional bodies, or any group or organisation but bring individual experience and knowledge. Members are either "specialist" or "lay", from a range of backgrounds with a variety of interests, specialist knowledge and expertise[54]. Details of IGARD members[55] and their declarations of interest are published on the NHS Digital website[56].

The IGARD Chair is responsible for the proper conduct and functioning of IGARD and reports to the NHS Digital Board via the NHS Digital SIRO. The IGARD Chair reports in person annually to the Information Assurance and Cyber Security Committee (IACSC), which is a sub-committee of the NHS Digital Board[57]. Accountability for all decisions about data dissemination rest with the SIRO and the Board. IGARD, or its Chair, considers and responds in a timely manner to any issues raised by the Board.

Where NHS Digital, on occasion, chooses not to follow IGARD's advice, IGARD is informed by the NHS Digital SIRO. This allows the group to make any comments, or consider whether Standards or Precedents need to be revised, whether IGARD wishes to reaffirm their original recommendation, or whether they wish to make any additional observations. For transparency, any such NHS Digital SIRO notifications are noted in published IGARD minutes.

[54] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-statements/igard-member-skills-and-expertise-sop-v0.3---final.pdf
[55] https://digital.nhs.uk/binaries/content/assets/legacy/pdf/8/a/igard_member_v0.3_final.pdf
[56] https://digital.nhs.uk/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/igard-declarations-of-interests-october-2018-v2.4-final.pdf
[57] https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/nhs-digital-s-annual-reports-and-accounts/nhs-digital-annual-report-and-accounts-2021-22/accountability-report

The terms of reference set out that IGARD's Chair and/or Deputy Chair can take advice from the NHS Digital Caldicott Guardian or their deputy, the Health Research Authority's Confidentiality Advisory Group[58] and the National Data Guardian[59]. The NHS Digital Caldicott Guardian is the senior responsible officer for IGARD.

Transparency of IGARD work

Transparency is a fundamental principle running through IGARD's terms of reference and how it operates. A great deal of care is taken to track recommendations across each data application - some agreements came to IGARD multiple times over many years, for instance where an applicant has received data but now wants to develop the aims of their project, receive different datasets, or involve a new partner in their work. In all cases, IGARD's advice is tracked both on internal systems and also in its published minutes, which always highlight where an application has previously been to IGARD or its predecessor committees.

IGARD minutes are published within 10 days of the meeting on the NHS Digital website so that they are open to scrutiny. The minutes also make clear when a recommendation was made "out of committee" by the Chair, or quorum of IGARD members, outside a regular meeting. The rules and instances of this happening are included in the published out of committee report, appended weekly to the published minutes for transparency.

Standard operating procedures

Standard operating procedures underpin IGARD's accountability, governance, operations, and processes.

Most of the standard operating procedures are published on the IGARD webpage for transparency including: IGARD member profiles; declarations of interest; authority of the IGARD Chair; COVID-19 response meeting; IGARD glossary of terms; IGARD terms of reference; member skills & expertise; out of committee procedures; IGARD appeals and service improvement process; whether the applicant is a member of IGARD; IGARD clinicians as members; history of IGARD; IGARD meeting content; and recommendation type procedure.

There are a small number of unpublished internal standard operating procedures which support the operational side of IGARD, outlining the IGARD member payment process and briefing note template.

All standard operating procedures mapped, where relevant, to any internal and external NHS Digital policies and procedures.

Membership and remuneration

The pay rates for IGARD members are set by NHS Digital and have remained unchanged from 2017 to 2023. IGARD members can claim for expenses, in line with NHS Digital policy. Remuneration was:

- £650 per day for the IGARD Chair, plus expenses
- £500 per day for a specialist member, plus expenses, and
- £350 per day for a lay member, plus expenses.

All IGARD members are independent external contractors and sourced by NHS Digital through open recruitment. The duration of any appointment is usually three and a half years (three years as a full member with the potential to be extended by NHS Digital beyond this term, with three months observation and three months built-in at the end for handover and 'buddying' of new members), or as agreed with NHS Digital. Appointments are staggered so that the overall change in membership is usually one third in a

[58] https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/
[59] https://www.gov.uk/government/organisations/national-data-guardian

given year. IGARD's last recruitment, in 2021, resulted in two members starting in 2022 and two being scheduled to start in 2023.

Members of IGARD 2017-2022

Name of IGARD member	Date of IGARD appointment (including observation period)	Planned IGARD replacement month / year
Dr Eve Sariyianndou (SM)	2014	2019
Dr James Wilson (SM)	2015	2018
Dr Joanne Bailey (SM)	2015	2019
Chris Carrigan (Chair)	2016	Resigned 2019
Anomika Bedi (SM)	2017	2020
Sarah Baalham (LM)	2017	2020
Debby Lennard (LM)	2017	Resigned 2017
Jon Fistein (SM)	2017	Resigned 2019
Priscilla McGuire (LM)	2019	Resigned 2019
Maria Clark (LM)	1 January 2019 (observed from w/c 5 November 2017)	March 2023
Dr. Maurice Smith (SM)	1 April 2019 (observed from w/c 18 February 2019)	August 2023
Dr. Geoff Schrecker (SM)	1 April 2019 (observed from w/c 18 February 2019)	August 2023
Kirsty Irvine **(Chair and lay member)**	1 October 2018 (Appointed 1 February 2017 as lay member) (observed from 1 November 2016)	March 2024
Professor Nicola Fear (SM)	1 February 2017 (observed from 1 November 2016)	March 2024
Paul Affleck (SM) **(Co-Deputy Chair)**	1 April 2020 (observed from w/c 3 February 2020)	June 2024
Dr. Imran Khan (SM) **(Co-Deputy Chair)**	17 March 2020 (observed from w/c 3 February 2020)	June 2024
Jenny Westaway (LM)	1 April 2022 (observed from w/c 3 January 2022	June 2025
Dr. Robert French (SM)	1 April 2022 (observed from w/c 3 January 2022)	June 2025

Claire Delaney Pope (SM – to replace specialist vacancy)	April 2023 (TBC)	March 2026
Miranda Winram (LM – to replace Maria Clark)	April 2023 (TBC)	March 2026

Key: SM – Specialist member / LM – Lay member

Budget

The budget for IGARD in 2022/23 was £497,517. This covers the cost of time and expenses for all the independent members (£366,240) and staff costs (£131,277). It also includes additional budget for NHS Digital overhead costs, for instance, finance and HR support.

IGARD Secretariat

Since IGARD's creation, the secretariat has consisted of two core members: IGARD Manager and a Senior Support Officer. The IGARD secretariat sits within NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL) team. However, as the work undertaken by the secretariat is quite different in nature to that undertaken by the rest of PTEL, support for IGARD has only ever been provided by the two core staff members. This was also the case when DAAG was in operation. This has resulted in resource pressures for the secretariat team, in particular where there are additional requirements over and above the already demanding business-as-usual activities. Due to the specialised nature of the Secretariat's work, it was not possible to smooth out workloads by drafting in additional resources from the wider PTEL team.

For example, from March 2020 to December 2021 NHS Digital asked that an additional half-day weekly meeting be put in place for IGARD to provide observations on COVID-19 applications, supported by the secretariat team. Increased pressure also occurred at times of additional projects or discrete work, such as the overhaul of the IGARD webpages, work needed on the internal SharePoint site, or recruiting new IGARD members. Attempts to recruit an additional member of staff to the secretariat were made but were not successful.

Despite the resource pressures, the IGARD secretariat consistently delivers their work to the agreed weekly timescales for IGARD meetings. This includes issuing meeting pack papers every Friday ahead of the following Thursday meeting, producing draft outcomes for NHS Digital within one working day of the meeting, producing draft minutes to a high quality standard within two working days of each meeting so that they can be reviewed and ratified within a week, and publishing all documentation within agreed timescales.

IGARD's secretariat works to an internal standard operating procedure to ensure continuity and consistency in the event of staff absence, new staff training or similar eventualities.

Management information

IGARD also collated and provided quarterly management information to the Senior Responsible Officer for IGARD (the Caldicott Guardian), the Executive Director PTEL, Director for Clinical Trials, and other key senior NHS Digital colleagues alongside IGARD members. This is attached in **Appendix A** –

IGARD Management Information – (February 2017 – January 2023)Appendix A – IGARD Management Information – (February 2017 – January 2023).

IGARD in numbers

From February 2017 to January 2023:

- 222.5 IGARD meetings were held.
- 1719 applications were reviewed.
- 77% of applications were either recommended for approval or recommended for approval with conditions.

For the final year of IGARD (February 2022 to January 2023):

- 44 IGARD meetings were held.
- 214 applications were reviewed.
- 84% of applications were either recommended for approval or recommended for approval with conditions.

Year-by-year summary of IGARD activities and development

2017

The Data Access Advisory Group was replaced by IGARD on the 1st February 2017[60]. Three former DAAG specialist members (Dr James Wilson, Dr Joanne Bailey and Dr Eve Sariyiannidou) were asked to join IGARD to provide stability and institutional memory for the newly formed group.

As a result of NHS Digital's recruitment campaign in 2016, new specialist members joining in February 2017 were Anomika Bedi, Jon Fistein and Nicola Fear. The new independent Chair and lay representative was Chris Carrigan. Other new lay members joining the group were Kirsty Irvine, Sarah Baalham and Debby Lennard. Debby resigned from IGARD later that summer. The inclusion of lay members was a key output from the consultation with the public in 2015.

Policies, procedures, and processes were still in their infancy at this stage and were developed rapidly in order to support good functioning of the group. During that first year, IGARD slowly found its footing and set its own course, with a particular focus on ensuring collaborative, solution-focused working.

2018

As IGARD moved into year two, it was clear that changes were required to its remit and work parameters as part of a larger end-to-end review of the data dissemination process.

Following the departure in summer 2018 of Dr James Wilson and the IGARD Chair, Chris Carrigan, NHS Digital undertook another round of recruitment. Two new lay members joined IGARD in late 2018: Priscilla McGuire and Maria Clark. Following open recruitment and a successful interview, lay member Kirsty Irvine moved to be the new Chair of IGARD. Priscilla and Maria filled the two current vacant roles at that time.

In 2018 the secretariat embarked on service improvement and transformation in its processes, procedures and policies, engaging with key stakeholders across NHS Digital to ensure that IGARD meetings were a welcoming, supportive and solution-based environment for NHS Digital presenters. IGARD moved to providing more solution-focused commentary on applications and advice on alternative approaches,

[60] https://nhs-prod.global.ssl.fastly.net/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/daag_closure_report_2017.pdf

recognising that presenters to IGARD changed often and were at differing stages of their own learning and development cycle.

Work started with IGARD and NHS Digital to define what was meant by a condition (a positive recommendation may be conditional on changes that IGARD judges satisfactory) and an amendment (a change which IGARD has requested but where IGARD judging the change to be satisfactory is not a condition of its positive recommendation). The IGARD secretariat included these definitions in a new standard operating procedure[61], designed to support NHS Digital and applicants and to ensure consistency of recommendations across all applications. This was published in May 2019.

Work started on clearly defining the process for appeals where IGARD has advised that it is not able to recommend an application. In May 2019, IGARD published the 'IGARD appeals, complaints and service improvement procedure'[62] which outlined how applicants can appeal against an IGARD 'unable to recommend for approval' outcome, raise a complaint about an IGARD member to NHS Digital, and offer service improvement or issues which are part of IGARD's service improvement cycle.

2019

During 2019, NHS Digital embarked on an overhaul of the end-to-end data dissemination process. This took into account the DARS online system, the way in which NHS Digital reviews applications, and the applications that are submitted to IGARD. In particular, this process aimed to put in place clearly defined, documented and transparent Standards and Precedents. Instead of IGARD being involved only at the final stage of an application review, IGARD's remit was extended to encompass helping NHS Digital develop, review and approve the Standards and processes by which future applications are developed and assessed.

The volume, types and complexities of new datasets being managed by NHS Digital and the number of customers and requests was increasing. Accordingly, the role of both NHS Digital and IGARD needed to change to respond to the additional demand, reduce timescales for applicants, and maintain IGARD's independent oversight role.

NHS Digital updated the remit for IGARD with the aim of retaining and protecting the scrutiny, controls and transparency but also allowing a greater quantity of applications to move through the system at pace. The updated role of IGARD from 1 May 2019 included:

- Advising on a (potential) solution, or otherwise advise on an alternative way forward for an applicant;
- Discussing and advising on difficult, new types or new feature requests for data for example novel, contentious and repercussive applications;
- In conjunction with the NHS Digital data dissemination service, developing the Precedents and Standards by which policy and procedure can be viewed to have been met in the data dissemination or disclosure assurance function;
- Supporting the induction of new staff in information governance and data dissemination;
- Receiving written feedback from NHS Digital if IGARD advice is not accepted and being able to highlight concerns to NHS Digital's data protection officer;
- Advising on disseminations when customers have breached the terms of agreements, had Information Commissioner's Office action taken against them, or had adverse audits by NHS Digital;

[61] https://digital.nhs.uk/binaries/content/assets/website-assets/corporate-information/corporate-information-and-documents/igard/meeting-content--rec-type-sop-v0.7---final.pdf
[62] https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data/appeals-complaints-and-service-improvement-procedure

This new way of working between NHS Digital and IGARD, as described in IGARD's updated Terms of Reference, was intended to improve the experience of applicants.

In late 2018 specialist member Dr Jon Fistein stepped down and the following March specialist member Dr Joanne Bailey left as part of a planned departure. At the time, NHS Digital was working on a proposal to establish a national GP data collection and so the next round of recruitment had a particular focus on recruiting GPs. Dr Geoff Schrecker and Dr Maurice Smith, both GPs, joined IGARD in April 2019. Dr Imran Khan, also a GP, and specialist ethics member Paul Affleck were also recruited in this round and later joined in early 2020. In late 2019 lay member Priscilla McGuire resigned from IGARD and recruitment to that vacant role was put on hold until the next round of recruitment.

IGARD was asked to have an increased focus on new, first-of-type datasets and applications, discussing with and advising NHS Digital at an early stage. IGARD has encouraged early-stage applications to come for advice.

Service improvement continued via the secretariat who focused attention on agenda timings and encouraged members to raise complex issues prior to meetings to enable the NHS Digital presenter to discuss with the applicant. NHS Digital's values and behaviours policy was integrated into IGARD's standard operating procedure and meetings between the IGARD Chair and key NHS Digital colleagues continued to ensure the IGARD environment remained open, honest and constructive.

In line with the new Precedent route, by which not every application for data would come to IGARD for review, IGARD embarked on designing and implementing an oversight and assurance programme to assure a proportion of those applications that had gone down the precedent route (signed off internally by NHS Digital without independent oversight).

2020

In January 2020, the IGARD secretariat embarked on another round of service improvement. This included reducing the number of applications brought to the weekly meeting from a maximum of 14, with 20 minutes of discussion each, down to five or six applications, with 40 minutes of discussion each. Service improvement also saw work to ensure the oversight and assurance work was continuing to be rigorous and to encourage partnership working. The secretariat strove to facilitate a solution-focused approach, with applications being brought for advice ahead of a formal recommendation, allocation of sufficient time for complex discussions and other supportive activities.

IGARD specialist members Dr Eve Sariyiannidou and Anomika Bedi left IGARD in March 2020 along with lay member Sarah Baalham. At that time Paul Affleck and Dr Imran Khan, who had been recruited the previous year, joined IGARD bringing specialisms respectively in ethics and as a GP.

Amid the global pandemic, IGARD adapted to support NHS Digital's response. Weekly business-as-usual meetings switched seamlessly to take place online, alongside a new COVID-19 weekly meeting. The business-as-usual meetings tended to run 60-90 minutes longer to accommodate the additional work from NHS Digital, as applications coming to IGARD had increased by one per week, to seven on average. IGARD members continued to provide comments on complex applications prior to the start of the meeting. In addition, IGARD provided additional support to applicants and NHS Digital presenters after the meeting, meeting with applicants and providing further information and advice on particular points. COVID-19 work included IGARD's review of the RECOVERY trial suite of consent materials, providing comments to support NHS DigiTrials[63] and the applicant.

As well as administering one complex business-as-usual meeting per week, the IGARD secretariat was now administering an additional half day per week COVID-19 meeting to support NHS Digital in its pandemic response. This meant producing an additional agenda, agenda pack, action note and

63 https://digital.nhs.uk/services/nhs-digitrials

undertaking in-meeting clerking. The weekly COVID-19 meeting had three members in attendance, which was not quorate according to IGARD's terms of reference. This meant the meeting outcomes were in the form of observations rather than recommendations. As papers were only received the day before the meeting, members were unable to provide a full review of the documentation.

A new General Practitioner Extraction Service (GPES) Profession Advisory Group (PAG)[64] was formed in early 2020 to support the dissemination of the GP data for pandemic planning and research (GDPPR)[65]. PAG was set up at the request of the British Medical Association (BMA) and Royal College of General Practitioners (RCGP) and representatives of those two organisations are independent members of PAG.

Chaired by NHS Digital's Caldicott Guardian or their deputy, PAG reviews applications for access to the GDPPR dataset. It meets as and when required and provides advice to NHS Digital. PAG feedback is provided to IGARD when they consider the relevant application. The feedback note is also appended to the IGARD minutes and published for transparency. IGARD continued to build productive relationships with PAG throughout 2020.

2021

With the global pandemic continuing into 2021, IGARD continued to meet remotely for business-as-usual and COVID-19 meetings weekly. The business-as-usual meetings continued to have the ability to flex to increase application capacity with a new standing item of the "CV19 application slot" to allow for urgent applications that could not be presented at the COVID-19 response meeting, or which required an urgent IGARD recommendation. In order to support NHS Digital, the deadline for the CV19 slot on the Thursday business-as-usual meeting was shortened so that papers could be provided as late as midday on the Wednesday before the Thursday meeting. In December 2021, IGARD agreed with NHS Digital that the COVID-19 meetings would not continue and the last such meeting was held on Tuesday 14 December 2021.

The IGARD Chair and IGARD Secretariat Manager presented to the IACSC committee on 19 July and 14 December 2021, to update the sub-committee of the NHS Digital Board of work undertaken to date by IGARD.

IGARD secretariat undertook another round of service improvement in June 2021 looking in particular at collaborative working, timings and structures of the IGARD meetings, encouraging NHS Digital case officers and case managers to attend with presenters, and ensuring internal processes continued to work well. IGARD continued to provide positive solution-based feedback on applications in-meeting and appreciated NHS Digital observers attending with presenters, particularly where they were the members of staff engaging with the applicant.

IGARD members led three learning and development sessions during 2021 for NHS Digital staff: overview of IGARD, data controllership, and benefits.

The IGARD secretariat also project managed the creation of new IGARD pages on the NHS Digital website, which were easier to navigate and updated to provide further information for internal and external stakeholders.

2022

Noting that IGARD still carried vacancies, it was agreed by NHS Digital that recruitment for up to three new members should start in summer 2021 to take IGARD up to its maximum membership of ten members. The focus was to be on specialists from an academic or information governance background, plus a lay

[64] https://digital.nhs.uk/coronavirus/gpes-data-for-pandemic-planning-and-research/gpes-data-for-pandemic-planning-and-research-profession-advisory-group-terms-of-reference
[65] https://digital.nhs.uk/coronavirus/gpes-data-for-pandemic-planning-and-research

member to replace the vacant lay post. To that end, Dr Robert French and Jenny Westaway joined IGARD in April 2022, with Claire Delaney-Pope and Miranda Winram also recruited with a view to joining in 2023 (Claire filling a vacancy and Miranda replacing Maria Clark).

The secretariat undertook two rounds of service improvement in January and August 2022. These looked at improving working relationships after the two years of home working, welcoming the introduction of a Senior Approvals Team (SAT) in DARS, welcoming the pro-active approach by DARS to seek advice in advance of a recommendation for complex applications (for example the PANORAMIC trial, real world effectiveness of the safety of the COVID-19 vaccine in England[66]), and welcoming SAT as observers to the presentation of applications at IGARD.

The IGARD Chair, IGARD secretariat Team and SAT set up meetings every other month from the start of the year, which focused on addressing the findings from a service improvement consultation exercise in December 2021 and maintaining good working collaborative relationships.

The secretariat, on behalf of the IGARD Chair, undertook to send to the Head of Data Access and SAT Team a weekly email following the IGARD Meeting, with exemplars of good practice, actions, process or improvement suggestions in order to support the DARS team and improve the learning and development for staff.

IGARD held their first plenary (face-to-face) meeting in Leeds after nearly two years online on Thursday 17 March 2022. Some members travelled to the NHS Digital offices in Leeds and others joined via MS Teams. IGARD held their next plenary meeting on the 24 November 2022, again in NHS Digital Leeds office, with members attending face-to-face and or via an MS Teams dial-in.

IGARD continued to be solution-focused and held a workshop with NHS Digital's Data Services for Commissioners team[67] in May 2022 with regard to the changes from Clinical Commissioning Groups to Integrated Care Boards from 1 July 2022[68]. This workshop was a useful first step in the work that IGARD then undertook with DARS to develop a template for data sharing agreements with the 42 new integrated care boards.

In September, and ahead of the NHS Digital and NHS England merger, IGARD adopted a new oversight process in relation to NHS England applications. Instead of making a recommendation about whether data should be shared, IGARD would provide advice, note any risks or areas of concern, and provide either a positive statement of support or not. In addition, NHS England colleagues would be invited to attend, in order for IGARD to ask questions of the subject matter experts on the application.

The IGARD Chair and IGARD Secretariat Manager presented to the IACSC committee on 5 December 2022, to provide the annual update to the sub-committee of the NHS Digital Board of work undertaken to date by IGARD.

[66] https://digital.nhs.uk/coronavirus/panoramic-trial

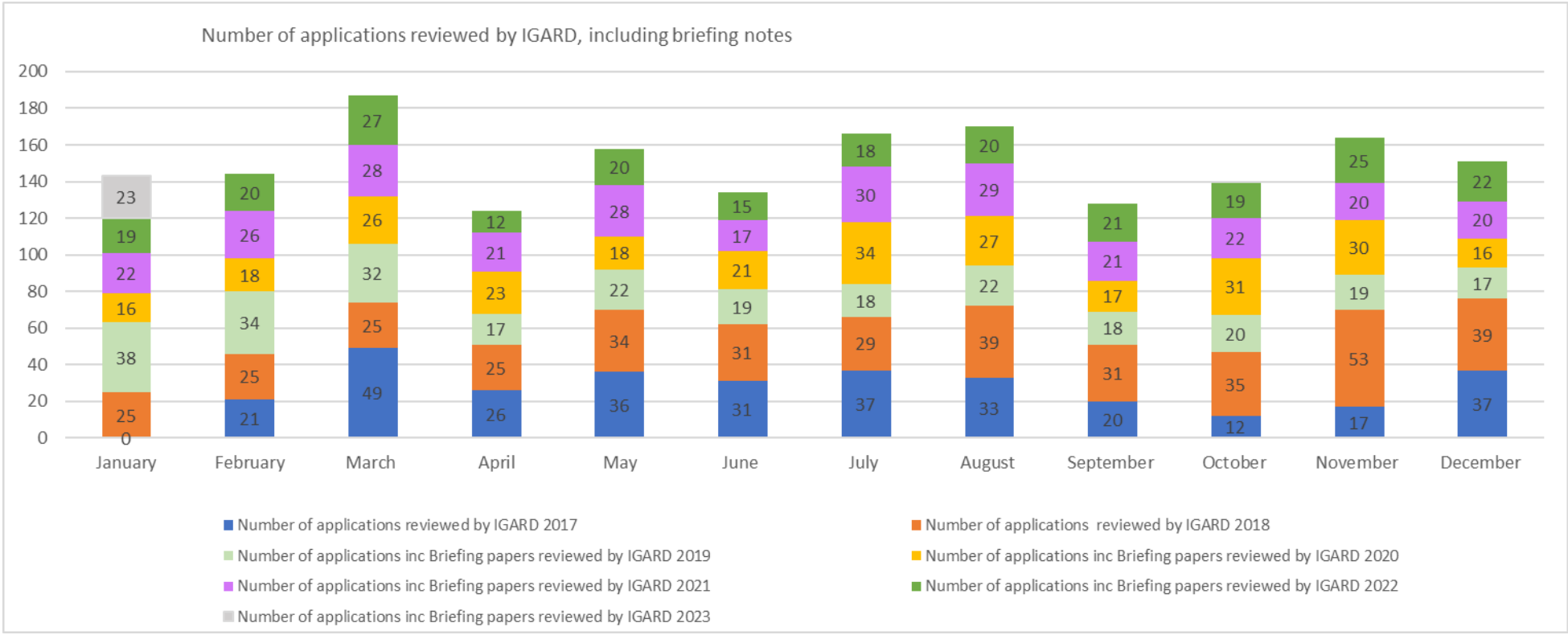
[68] https://www.england.nhs.uk/publication/integrated-care-boards-in-england/

Appendix A – IGARD Management Information – (February 2017 – January 2023)

Number of applications / briefing papers presented

- In January 2019 DARS introduced the concept of "Precedents" into the approval process to enable senior NHS Digital staff to confirm data release based on previous similar IGARD recommendations, so where a precedent is used, the application would not go to IGARD for review. Prior to the precedent process, most applications for data (as defined above) would be considered by IGARD.
- It is important to remember that not all applications on an agenda are "new" to the meeting since some may have been previously deferred, withdrawn, or unable to recommend, so for operational reasons every time an application comes to IGARD it is counted as "1 unit of activity" in order to cost IGARD accurately, so the figures show each presentation of every application to IGARD, even if presented multiple times.
- IGARD transitioned to its new way of working on 1st May 2019 with the number of slots per agenda decreasing from a maximum of 14 application "units" (20 minute slots), to a maximum of 5 application "units" per meeting (40 minute slots) although since transition this number has been consistently higher (6-7 "units" per meeting), noting the complexity of the applications presented and them being more contentious or novel in order to fully utilise the IGARD expertise, plus additional COVID-19 related urgent applications.
- The number of applications to IGARD from April 2019 significantly dropped and then levelled out since moving to the new way of working on the 1st May 2019, and since precedents have been in use since January 2019, with the expectation that this figure will continue to remain constant at approximately 6-7 applications / briefing papers per meeting, notwithstanding the increase in complex and novel applications due to COVID-19 related urgent applications.
- The complexity of applications to IGARD has increased including COVID-19 related applications, and the length of some applications can be in excess of 30 pages, noting that IGARD members also are given a number of additional supporting documents as part of the pack.
- In order to support NHS England (up to the end of August 2022), several applications to IGARD from ICBs are grouped onto one application 'group application' or alternatively all England ICBs are included in the one application, which will also include additional supporting documentation for each ICB to be appended to the one application presented. Although it may be seen as reviewing one application to IGARD, each applicant and their associated supporting documentation must be reviewed by IGARD to ensure the purposes and data requested applies to that ICB and as such, they are clearly marked in published minutes with the footer including the relevant NIC numbers and organisations.
- Moving forward from September 2022, templated application wording for ICBs has been agreed between IGARD, NHS Digital SIRO and NHS Digital DARS to support ICBs and the application process.
- Moving forward from September 2022, IGARD suggested that, in the absence of a process for how NHS England will assure internal flows of data once NHS Digital is no longer a legal entity, it conducts a pilot whereby they would start advising what they think would be key elements of a data flow and process flow which NHS England should provide transparency to the public. NHS England applications would still be presented at a single slot advice

session and IGARD, instead of providing a recommendation, would give a positive statement of support or unable to support focusing on key elements about transparency in the public domain, possible risk, areas of improvement, issues to focus on, whether further assurance was required and a timeframe. The NHS England application would proceed under NHS Digital's SIRO precedent.



Type of recommendation made by IGARD

- IGARD transitioned to its new way of working on the 1st May 2019 and each recommendation captured is per "unit of activity", not per application, since an application may be presented several times (see below).
- It is important to remember that not all applications on an agenda are "new" to the meeting since some may have been previously deferred, withdrawn, or unable to recommend, so for operational reasons every time an application comes to IGARD it is counted as "1 unit of activity" in order to cost IGARD accurately, so the figures show each presentation of every application to IGARD, even if presented multiple times.

78% of applications that have been presented to IGARD have been recommended for approval (or recommendation for approval with conditions, recommendation for approval from such time as ONS was onboarded or a positive statement of support made due to lack of quoracy) for the period February 2017 to April 2021 (this figure may include previously deferred, unable, or withdrawn applications as noted above).

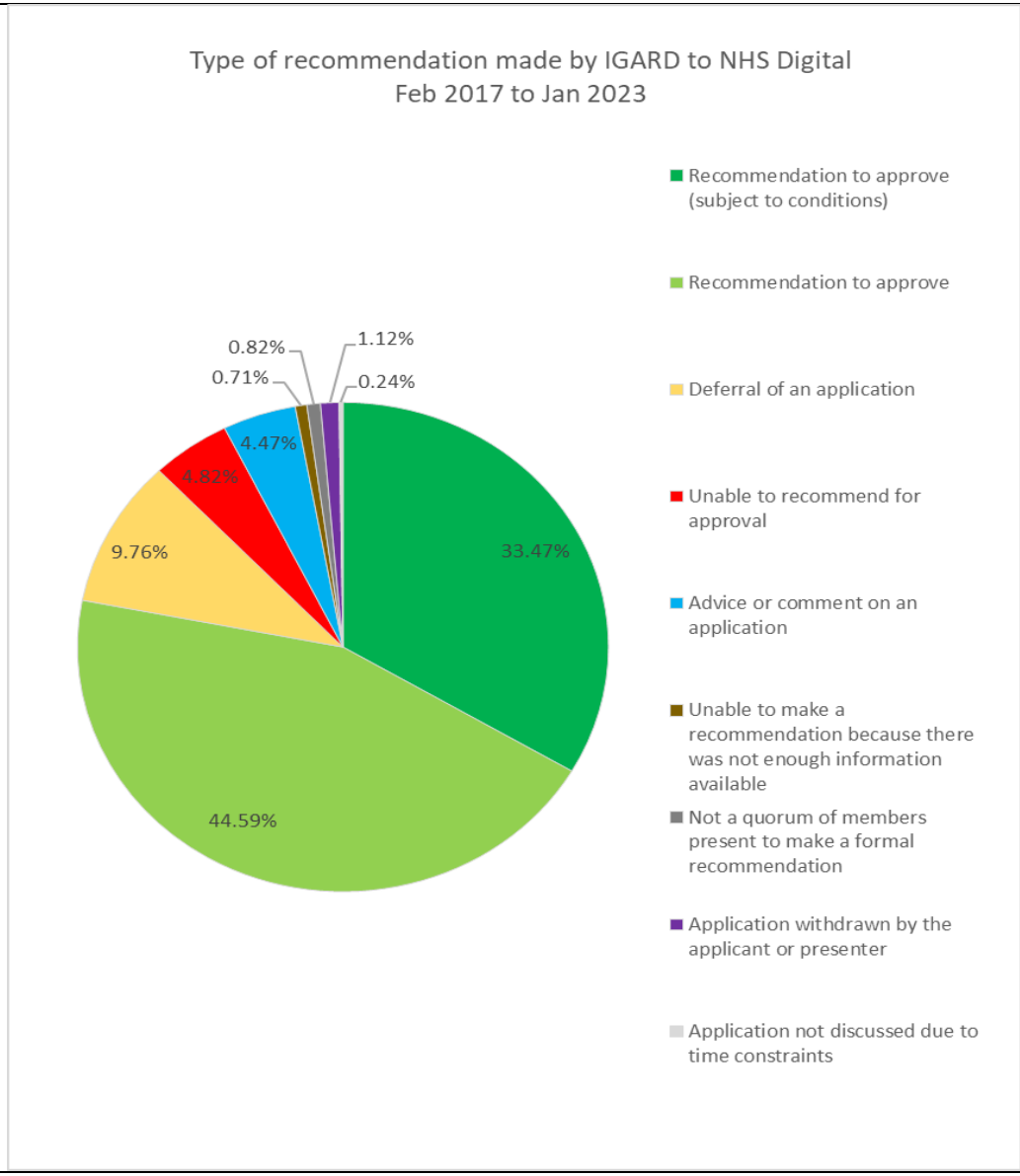
11.5% of applications to IGARD were 'deferred', 'unable to make a recommendation due to not enough information being available' as part of the review, 'not discussed due to time constraints' or not a quorum of members present to make a formal recommendation – these applications should return to IGARD for full review and move to a recommendation to approve.

5% of applications to IGARD have been 'unable to recommend for approval' for the same period.

5.5% of applications to IGARD came for advice, or were withdrawn by the presenter or applicant or not discussed due to time constraints for the same period.

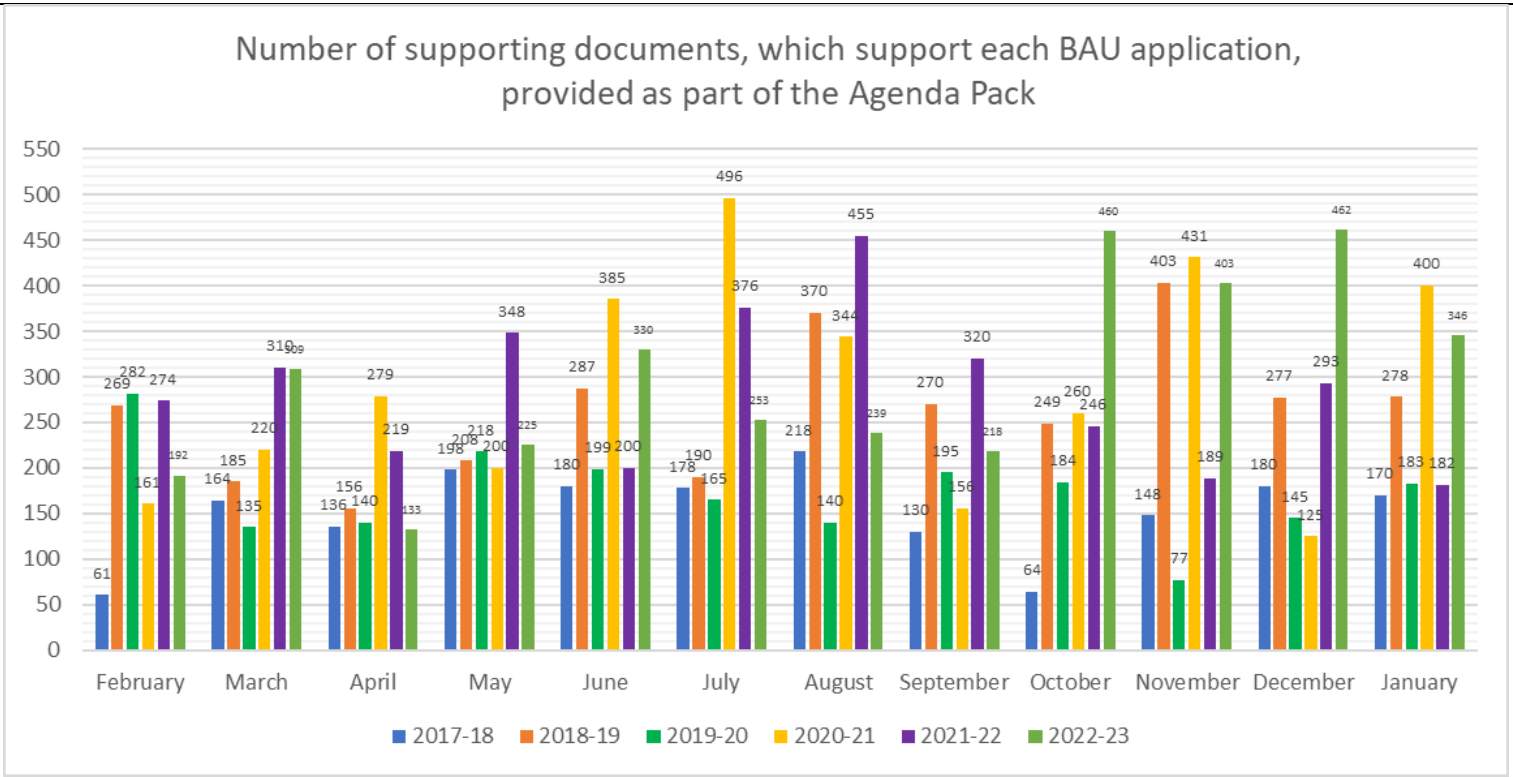
Briefing papers to IGARD

- **95 briefing papers** have been submitted to IGARD for the period February 2017 to January 2023 (this figure includes new briefings and re-submitted briefings)
- A briefing paper is submitted to IGARD ahead of, for example, a first of type application or newly onboarded dataset, and is designed so that first of type applications are not unduly delayed while the details of the newly onboarded dataset or collection are worked out and documented.
- Briefings are submitted on an agreed template, however if a briefing has been submitted to NHS Digital's EMT or Board, that documentation must be forwarded to IGARD as the briefing note.
- The briefing paper will include an executive summary, data controllers and processors, purpose of processing, types of processing activities, any restrictions on processing activities, background and context, the nature and type of data requested, data flows, all actors involved, the legal bases for the requirement, the legal bases for the processing, transparency requirements, other requirements, data retention, questions.


Type of recommendation made by IGARD to NHS Digital
Feb 2017 to Jan 2023
33.47%
44.59%
9.76%
4.82%
4.47%
0.71%
0.82%
1.12%
0.24%
Recommendation to approve (subject to conditions)
Recommendation to approve
Deferral of an application
Unable to recommend for approval
Advice or comment on an application
Unable to make a recommendation because there was not enough information available
Not a quorum of members present to make a formal recommendation
Application withdrawn by the applicant or presenter
Application not discussed due to time constraints

Number of supporting documents presented to an IGARD business as usual meetings

- Since the transition to new ways of working, the agenda has had to flex up to 9 applications and associated documents per meeting due to the number in the DARS system awaiting independent review, plus additional work due to COVID-19 urgent work.
- Since the complexity of applications to IGARD has increased, including COVID-19 related applications, the number of supporting documentation for review per application has stayed consistently high in some months compared to previous years.
- A supporting document provides additional background information and detail to enable IGARD to make a recommendation i.e., consent forms, patient information sheets, s251 support letters, ethics documentation etc.
- Dependent on the type of application being reviewed, the number of supporting documents can vary per application, on average each application to IGARD has 10.2 supporting documents of varying complexity and length.

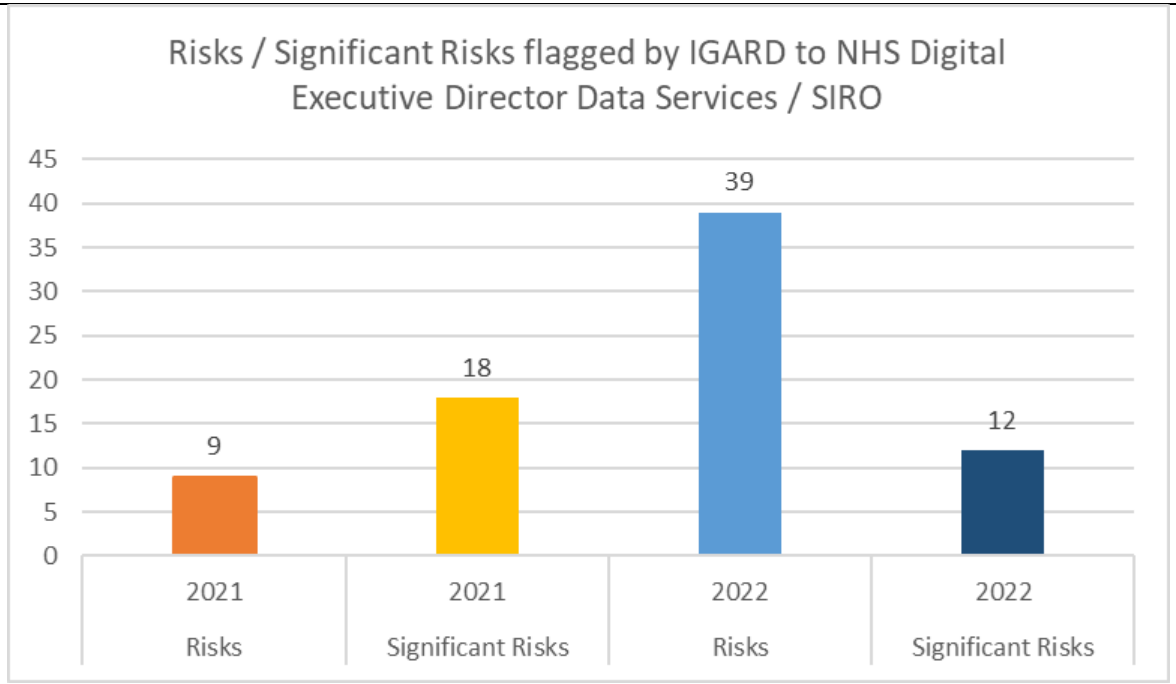


Please note: When a class action CCG application is presented to IGARD which may include more than 1 CCG or all English CCGs, the application is counted as "1 unit"

Please note: IGARD moved to its new ways of working on the 1st May 2019, prior to that the agenda had 20 min slots x 14 applications / briefing notes, after it had 40 mins slots x 5-7 applications / briefings. In addition from 1st May 2019 IGARD reviewed applications via the O&A slot (up to 10 applications at least monthly, usually fortnightly)

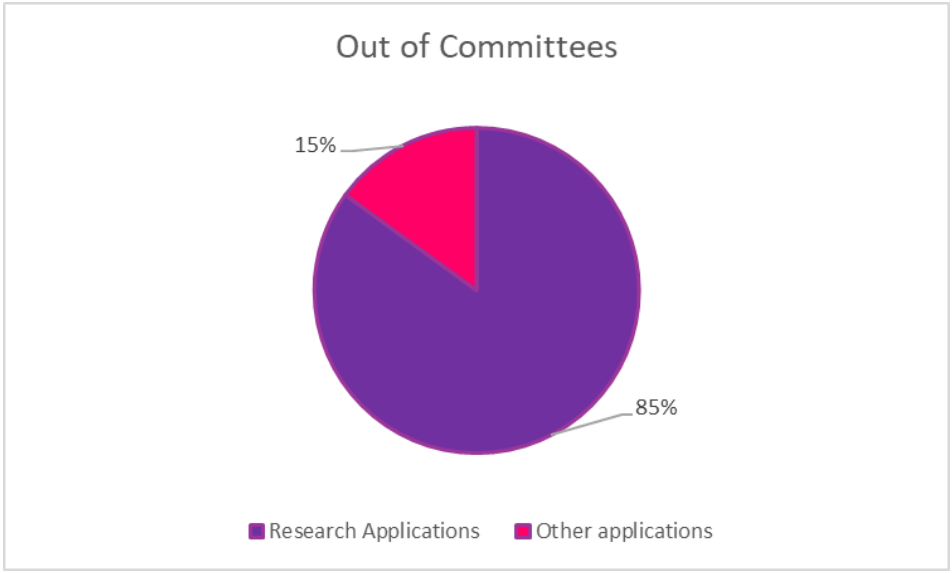
Risk areas / significant risk areas notified to NHS Digital

- From the 23rd September 2021 meeting of IGARD onwards, IGARD notified NHS Digital SIRO and NHS Digital Executive Director Data following ratification of the minutes via email of risk areas or significant risk areas, as noted in the published minutes of IGARD associated with applications presented to IGARD.


Risks / Significant Risks flagged by IGARD to NHS Digital
Executive Director Data Services / SIRO
45
40
35
30
25
20
15
10
5
0
9
18
39
12
2021
Risks
2021
Significant Risks
2022
Risks
2022
Significant Risks

Number of Out of Committee (OOC) approvals

- IGARD transitioned to its new way of working on the 1st May 2019. Since then the number of applications to IGARD has reduced and the group has moved to a more solution focused approach to recommendations. Hence the number of out of committee applications has significantly reduced, due to the reduction in the number of applications considered at each meeting.
- However, due to the complexity of outcomes, it is evident that although the number of OOCs has reduced, the OOCs are taking significantly more time to review OOC by IGARD members and more queries are being returned to DARS for additional background information or supporting documentation. This may have had an impact on the DARS elapsed time from application to agreement for those complex, contentious, and novel applications and mitigations have included additional bespoke advice from the Caldicott Guardian.
- The OOC email contains a copy of the updated application, any additional supporting documents, and a deadline for IGARD members to note their contentment, or not, including narrative as to why an OOC does or does not provide contentment. KPIs are in place between the Secretariat and Members to ensure a timely response to OOCs.
- Approval of OOCs by the IGARD Chair and / or IGARD Members subsequently produces several “sign off emails” to the Associate Director Data Access which signifies that the IGARD end-to-end process has concluded and that the application is at 4c on the CRM system for Associate Director Data Access / IAO sign off and progression within DARS.
- Approximately 85% of out of committees are research applications.



Additional summary:

IGARD meets weekly and the number of meetings of IGARD remains similar year on year at approximately 44, noting five meetings were cancelled[69] in 2017, four cancelled in 2018, five cancelled in 2019, six meetings cancelled in 2020, six cancelled in 2021 and seven cancelled in 2022 (including the extended Queen's Platinum jubilee weekend). Cancellations were always in agreement with the Associate Director Data Access / Caldicott Guardian / IGARD Chair. No meetings were cancelled in September 2022 due to the death of HM The Queen and the additional bank holiday for her funeral, IGARD Secretariat mitigated the impact by implementing established business continuity processes.

Number of applications and supporting documents presented to an IGARD business as usual (BAU) meeting per month (yearly stats run February to January)

- IGARD receive the BAU application pack late afternoon on the Friday before a Thursday meeting, giving three working days between the dissemination of the agenda pack and the BAU meeting.
- In an average year, IGARD review six applications and briefing papers per BAU meeting.
- On average, the length of an application summary or briefing paper to IGARD is approximately nine pages in length.
- In an average year, IGARD review 63 supporting documents per BAU meeting, which are 7.5 hours in duration on average.
- On average the supporting documents at a BAU meeting are six x A4 pages in length.
- IGARD have a work package allowance of half a working day per week to review the BAU agenda pack which includes applications, supporting documents, briefing papers and other items added to the agenda.
- On average, an IGARD member has approximately 55 seconds per A4 side of paper to read, review, digest and form an opinion on the application, supporting documentation or briefing paper.

The above averages and approximations are based on 500 words per A4 side of paper, 12-point text (standard font size), single spacing, with an average reading speed of 130 words per minute (slow is 100 wpm / fast is 160 wpm).

69 *Cancelled definition for this MI report: at the request of the Associate Director Data Access and in consultation with the Caldicott Guardian, IGARD Chair, IGARD Deputy Chair and IGARD Secretariat Team Line Manager, the IGARD BAU meeting in the week following a bank holiday week is usually cancelled due to the impact on DARS staff getting applications ready for IGARD in a bank holiday week due to staff absences, in addition the Maundy / Holiday Thursday (Easter) BAU meeting is also cancelled due to the impact on the Secretariat team before a 4-day bank holiday and the processing of BAU outputs.

Appendix C

IGARD and NHS Digital Partnership Working and Service Improvements

Service Improvement Closure Report: January 2023

Prepared by: Karen Myers, IGARD Secretariat

Between Autumn of 2018 and January 2023, the IGARD Secretariat undertook a number of consultation exercises with NHS Digital colleagues, to identify and understand where processes were working well, and where additional service improvements could be made and to ensure a positive and productive experience for all at IGARD meetings.

Following the consultation exercises during the period Autumn 2018 and January 2020, a number of changes were implemented, including, but not limited to: the introduction of 'big picture' pre-meeting queries from IGARD to NHS Digital, to support the meeting discussion and progression of applications; IGARD members providing feedback in-meeting, in a more 'solution focussed' manner to support NHS Digital colleagues and the applicant; the introduction of joint (IGARD and NHS Digital) Education Sessions which supports learning and development for all; collaboration on, and the implementation of NHS Digital's Standards and Precedents and the implementation of the oversight and assurance process for applications that have proceeded via the NHS Digital Precedent route.

As a result of the COVID-19 pandemic, the consultation exercises were temporarily paused from March 2020, noting the pressures that IGARD and NHS Digital were under, in supporting NHS Digital and the wider NHS with the response to the COVID-19 pandemic, including, but not limited to the additional weekly IGARD meeting that focussed specifically on COVID-19 applications.

The consultation exercises commenced again from October 2020 where the IGARD Secretariat sought feedback from NHS Digital, mainly focussing on the changes to IGARD's processes and procedures in reaction to the COVID-19 pandemic. The way in which IGARD and NHS Digital worked collaboratively and successfully adapted their processes from March 2020 was widely acknowledged; this included: IGARD and NHS Digital colleagues dialling in to the weekly meetings remotely; amending the meeting agenda to ensure business continuity, but to also support external pressures for colleagues at home, for example, those with caring responsibilities; and mitigations for colleagues who became unwell from COVID-19 to ensure that work did not stop.

From June 2021, and noting the significant progress with the service improvement remit of work, the IGARD Secretariat began engaging with IGARD members, in addition to NHS Digital as part of the consultation exercises. This was to add a more

holistic view; and to ensure the views of all were sought, thus creating a more ‘partnership working’ element to the service improvement work.

Following feedback from the consultation exercises, in March 2022 IGARD and NHS Digital held the first face-to-face IGARD meetings since the start of the COVID-19 pandemic in March 2020. This was followed with another face to face meeting in November 2022. The meetings were welcomed by all who attended and supported the ongoing relationship between IGARD and NHS Digital.

In addition to some of the examples provided above, the service improvement remit of work has also resulted in a number of positive changes to the internal logistics, including, but not limited to: the IGARD meeting agenda providing the full history of the application, which supports the review of applications by members; and the number of NHS Digital observers attending meetings has increased, which supports learning and development.

It was also identified that the public facing information had improved, this included, but was not limited to: the update to the IGARD webpage in 2021; the minutes from the IGARD business as usual meetings being published on the IGARD webpage within 24 hours of being ratified; the publication of the IGARD – NHS Digital COVID-19 Response meeting notes; and the content of the IGARD minutes, which now provides further, more succinct information of in-meeting discussions.

The IGARD Secretariat have ensured that the outcomes of all the consultation exercises have been documented and shared with NHS Digital colleagues and IGARD members, and recommends that ongoing service improvement forms part of the new committee secretariat’s remit following the merger of NHS Digital with NHS England on the 1st February 2023.