Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 30 July 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair (2.4 & 2.6-2.8)
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair (2.1, 2.2, 2.3 & 2.5)
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Paul Brown	Medicines Data Programme
Garry Coleman	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS) (Observer: item 2.3)
Fintan Grant	Medicines Data Programme
Ross Jenkins	Clinical Audit and Registries Management Service
Steve Marks	Medicines Data Programme
Karen Myers	IGARD Secretariat
Pritpal Rayat	Medicines Data Programme
Alison Roe	Clinical Audit and Registries Management Service
Kimberley Watson	Data Access Request Service (DARS)
Vicky Byrne-Watts	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Access Request Service (DARS)

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Nicola Fear noted a professional link to the team at the University College London (NIC-372269-N8D7Z), but noted no specific connection with the application, and it was agreed this was not a conflict of interest. Maurice Smith noted that as a GP, he may submit prescriptions as a prescribing doctor in England for medicines personally administered in England, and in a partnership which GP partners do likewise, therefore, he noted a professional link to item 2.5 Patient-Level Medicines data from the NHS Business Services Authority, however this was not considered a conflict of interest. **Review of previous minutes and actions:** The minutes of the 23rd July 2020 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	**Data Applications**
2.1	<u>Breast and Cosmetic Implant Registry (BCIR) Briefing Paper (Presenters: Alison Roe / Ross Jenkins)</u> The briefing paper was to inform IGARD about the BCIR, which records the details of any individual who has had breast implant surgery, for any reason, so they can be traced in the event of a product recall or other safety concern relating to a specific type of implant. It also allows the identification of possible trends and complications relating to specific implants. NHS Digital is directed to use the data to analyse outliers and potential issues at hospital and manufacturer level. The BCIR has been running in England since October 2016, and Scottish participation commenced in March 2019. The Clinical Audit and Registries Management Service produces an Annual Report on activity and data quality. At present there are three broad types of customers with potential interest in this data set: 1) statutory bodies requiring data to support a statutory function, 2) hospitals undertaking clinical audit or research, and 3) commercial organisations undertaking post market surveillance. IGARD were supportive of this important work and made the following comments on the briefing note: • To ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader, for example, but not limited to, 'CHI' number. • IGARD suggested the paragraph under 'purpose for processing' which includes the text "…*it is the responsibility of the surgical team providing the impact surgery to inform patients of this processing activity*…" be revised to reflect that while the surgical team may have the direct contact with patients, it remains the Data Controller's **responsibility** to inform patients.

	• IGARD suggested removing the sentence under 'transparency requirements' which starts "*there is a reasonable expectation that the patient is informed about the processing of their data…*" since it is not relevant under this legal basis. **Observations**: • IGARD noted that data could not be linked, but suggested that further exploration with the relevant professional bodies be sought due to the valuable research that could be undertaken if the data could be linked (and if deemed a useful development the relevant Direction expanded to cover such linkage). • IGARD noted the overwhelming public interest in collecting this data. Notwithstanding this, and noting the potential commercial interest in this data, IGARD noted that future applicants for the data would need to clearly establish how use of the data would be for the benefit of health or social care. • IGARD members suggested that as the registry onboards different forms of implants, (and noting that not all breast implants are for cosmetic purposes), that thought be given to the registry's name and sensitivities around implants as a whole. IGARD welcomed the briefing paper and looked forward to receiving an updated finalised briefing paper as a supporting document alongside the first application for BCIR.
2.2	<u>University College London: Virus Watch: Understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour (Presenter: Kimberley Watson) NIC-372269-N8D7Z</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Civil Registration, Emergency Care Data Set (ECDS) and COVID-19 Second Generation Surveillance System datasets (SGSS). There is currently a lack of understanding of COVID-19 community incidence, symptom profile, severity, infectious period, risk factors, strength and duration of immunity, genetic differences in immune response, asymptomatic infection and viral shedding, household and community transmission risk and population behaviours during periods of wellness and illness (including social contact and movement and respiratory hygiene). This information can only be gathered accurately through large scale community-based studies. Virus Watch is one of the largest of such studies anywhere in the world and will help to inform NHS planning and the national public health response. NHS Digital noted that following discussion at a Tuesday meeting, the applicant had updated their legal basis and that their consent materials had been revised accordingly. NHS Digital also noted that there was a discrepancy across the cohort figures provided across the application and supporting documentation. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 26th May and 30th June 2020. IGARD noted NHS Digital's comment with regard to discrepancy across the cohort figures and asked that the correct cohort numbers were reflected throughout the application. In addition, IGARD suggested that the applicant revise their study website to reflect that there was no upper limit on recruitment in reference to cohort numbers. IGARD noted that the consent and assent materials had been updated in line with comments made at the COVID-19 response meetings on the 26th May and 30th June 2020, however there were still a number of outstanding issues which need to be addressed on the children's assent materials including, but not limited to, ensuring they were written in a language suitable for the

	young reader such as removing reference to "*paying legal costs*" and appropriate language for **assent** materials eg changing "*I consent to…*" to "*I agree*…". IGARD also noted that the children's assent materials were limited to the respiratory information only but that the adult consent materials required access to all health records and suggested that further clarification be sought, and that **if** data for children was being limited to respiratory infection only to reflect this restrictions in the data minimisation column in table 3(b) (Additional Data Sets Requested) accordingly. Conversely, if additional health records were being sought for children then the materials would need to be expanded to address this. The children's assent materials also noted that data details would be used "…*for up to 5 years from joining the study…"* however, the application stated '…*follow up to 5 years after the end of the study*…". IGARD asked that the period required was clearly defined across all documentation. IGARD noted that "*Persons from Poland would also be oversample[sic]…*" and noting that "*oversample*" should be updated to read "*oversampled*" were unclear why the Polish community were being oversampled other than the statement "…*Polish is also the second most common language spoken in the UK…*" and asked this be updated to state that it is "…*the second equal most frequently spoken language…*" and that an explicit justification be included in section 5 (Purpose / Methods / Outputs) detailing why the applicant had a focus on Polish people as an oversampled group. IGARD also noted that reference to 'Poland' as a group of particular interest was not included in the protocol provided as a supporting document. IGARD noted reference in version 7 of the protocol, provided as a supporting document, to recruitment via social media, however, this was not part of the application presented and that further information should be included in section 5 of the application. Noting the above points and that Ethics approval had been granted for version 3 of the protocol by the Research Ethics Committee (REC), IGARD were unclear if REC had had sight of version 7 of the protocol and asked that the applicant confirm that they had secured ethics amendment approval which also addressed, inter alia, the above key points. In addition, IGARD noted that the application should be updated to accurately reflect the latest version of the protocol, version 7. IGARD noted the inconsistencies within the application and supporting documentation to everyone in the household taken part and suggested that a brief sentence be included in section 5(a) (Objective for Processing) that information will be gathered on **all** members of the participating household. In addition, IGARD also noted the individual's right to withdraw at any time suggested that the applicant may wish to give consideration of a withdrawal form or other mechanism for tracking withdrawals and thus taking a layered approach. IGARD also reiterated their comments from the COVID-19 response meeting on the 26th May 2020: "*…if identifiable data is required to flow to NHS Digital for each collection of pseudonymised data, NHS Digital discuss with the applicant their plan to reconsent children who reach 16 years of age, since recruitment was ongoing until 2021 and follow up for a further five years… IGARD members raised a query with regard to those households which are 'split', where a child lives part of the week with each parent or another caregiver, and suggested that the applicant may wish to consider if both households would need to consent to be part of the study or other such considerations."* IGARD members also reiterated their comments with regard to data minimisation made at the COVID-19 response meeting on the 26th May 2020: "…*It was noted that a substantial amount of data was being requested a cohort of approximately 25,000 households and that the applicant may wish to consider appropriate rationale for the quantum of data requested, and in*

	line with NHS Digital's relevant data minimisation standard…" and that the table 3(b) be updated. In addition it was noted that the table should be updated to consistently reflect 'participants' for each data set, to provide an outline of the data minimisation efforts undertaken for HES Admitted Patient Care (SPC), to clarify what data alongside the "*geographical variables*" was being disseminated for SGSS, IGARD noted reference in section 5(a) point (k) "to measure COVID19 clinical profiles" and asked that a clear explanation be provided as to what was being undertaken. IGARD noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader including '…*systematic sampling by selecting every k-th address*…" and suggested since section 5 was publishable, that this be updated in terms accessible by a lay person and an explanation of the term be provided. IGARD reiterated they comment made at 30th June COVID-19 response meeting that section 5 should be further updated to include the accessibility of the study including the barriers presented by language since invitation postcards were provided in six languages (Urdu, Bengali, Punjabi, Portuguese, French and Polish) but that the lead householder "…*will need to be proficient in English in order to answer the weekly and monthly surveys which will be in English only*…" and access to technology since "…*in order for the household to be enrolled they must have an internet connection and email address*…" and that other avenues should be considered for obtaining consent such as by telephone. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested a study-specific privacy notice may be helpful, particularly if recruitment is extended via social media. Given the long running nature of this study, IGARD suggested the applicant consider further plans for patient and public involvement (PPI). **Outcome:** recommendation to approve subject to the following conditions: 1. To confirm the applicant has successfully secured ethics amendment approval, which addresses, inter alia: a) social media recruitment; b) children's assent materials limited to respiratory infections only or (if relevant) revised materials covering a wider range of reference points; c) the reference to *"5-years"* in the children's assent materials*;* d) the oversampling of the Polish community; and e) that REC have seen and approved version 7 of the protocol. 2. In respect of Data Minimisation: a) To address the data minimisation points raised in the IGARD – NHS Digital COVID-19 Response meeting on the 26th May 2020. b) To update the table in 3(b) accordingly. The following amendments were requested: 1. In respect of the children's assent materials a) To address the reference to follow up for "5 years". b) To ensure the language is appropriate for the age range. c) To address the internal inconsistency with regard to everyone in the household taking part vs an individual withdrawing at any time. 2. In respect of the table in section 3(b): a) To refer to the "participants" in the data minimisation column for each data set. b) Outline the data minimisation for HES APC.

	c) To clarify what data alongside geographical is being disseminated for SGSS. d) **If** data for children is being limited to respiratory infections only, to reflect this restriction in the data minimisation column. 3. To update section 5(a) to include a brief sentence that information will be gathered on **all** members of the participating household(s). 4. To update references in paragraphs 2-3 section 5(a) to "oversample**d**". 5. To ensure the correct cohort numbers are reflected throughout the application, and to revise the website to reflect that there is no upper limit on recruitment. 6. To update section 5(a) to provide a rationale for the oversampling of the Polish community. 7. To explain how the researchers can "measure the COVID-19 clinical profile". 8. To update section 5 to give further consideration of accessibility of the study, including barriers presented by language and access to technology and consider other avenues for obtaining consent, such as telephone. 9. To update paragraph one section 5(b) to explain in terms accessible to a layperson what is meant by "systematic sampling by selecting every k-th address". 10. Ensure the application reflects the latest version of the protocol. 11. To update section 5 to reflect that Polish is the second equal most frequently spoken language in the UK. The following advice was given: 1. IGARD suggested consideration of a withdrawal form or other mechanism for tracking withdrawals, taking a layered approach. 2. IGARD suggested a study-specific privacy notice may be helpful, particularly if recruitment is extended via social media. 3. IGARD suggested that, particularly given long-running nature of the study, the applicant considers plans for PPI. It was agreed the conditions would be approved OOC by IGARD Members.
2.3	<u>CCG Group Class Action Application and SHMI Briefing Paper: An amendment for CCGs to receive: Summary Hospital-Level Mortality Indicator (SHMI) - Underlying record-level data (Presenters: Stuart Gunson / Tom Wright / Duncan Easton) NIC-380714-D3R8F</u> **Application:** This was Class Action application for all CCGs in England to receive underlying record-level pseudonymised data for the Summary Hospital-Level Mortality Indicator (SHMI). The SHMI is the ratio between the actual number of patients who die following hospitalisation at the trust and the number that would be expected to die on the basis of average England figures, given the characteristics of the patients treated there. It covers all deaths reported of patients who were admitted to non-specialist acute trusts in England and died either while in hospital or within 30 days of discharge. Bandings indicating whether the SHMI is 'higher than expected', 'as expected' or 'lower than expected' are also provided. Commissioners will use pseudonymised data 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 CCG area. **Discussion:** IGARD welcomed the briefing paper, which on this occasion had been brought at the same time as an application and owing to the fact that SHMI data was not a new onboarded dataset. IGARD made the following comments:

- To update paragraph 13.1 to clearly articulate the data retention period since it was unclear across the documentation provided for review if this was 'up to 3 years' or 'at least 3 years'.
- To update the privacy notice published on NHS Digital's website, where appropriate, to correctly reference the data retention period.
- To update paragraph 6.3 in line with comments made around re-identification / pseudonymisation.
- To append a copy of the written information governance (IG) advice from NHS Digital's Information Governance (IG) Directorate in relation to the legal basis for disseminating SHMI data and ensure the legal basis for dissemination stated briefing paper aligned with the stated legal basis for dissemination in the application.

IGARD looked forward to receiving an updated finalised briefing paper as a supporting document, alongside future applications for SHMI.

With reference to the class application provided for all English CCG's, IGARD noted that some of the text, although relevant to CCG purposes, was not relevant to the SHMI specific purpose and asked that section 5 (Purpose / Methods / Outputs) be updated to clearly reflect the activities and outputs relating to the SHMI data, since this also related to the legal basis for collecting and disseminating the SHMI data. In addition, IGARD noted that the Data Access Request Service (DARS) team has sought IG advice from the IG Team and asked that a copy of that written IG advice be uploaded to CRM and provided as a future supporting document in relation to the legal basis for disseminating SHMI data.

IGARD noted reference to the statement in section 5 "*Patient stratification and predictive modelling - **to identify specific patients** at risk of requiring hospital admission and other avoidable factors such as risk of falls, computed using algorithms executed against linked de-identified data, and identification of future service delivery models"* and asked that a further explanation was provided since paragraph 6.3 of the briefing note and section 3 (Datasets Held / Requested) of the application stated the data was pseudonymised, and if this did involve the re-identification of an individual that it be clearly set out in section 5, including the appropriate security measures and legal basis relied upon to do so.

IGARD noted reference within the application to 'STPs' but since 'sustainable and transformation partnerships' were not legal entities and therefore could not be considered as joint or sole Data Controllers, this reference should be removed.

IGARD noted that section 1 (Abstract) and throughout the application that where referencing 'the CCG' this should read 'each CCG' for example updating reference to *"**Each** CCG has a Caldicott Guardian…",* since this was a class action applying to all English CCGs.

IGARD queried the inconsistences within the application and asked that this was revised to ensure that where appropriate the term '*gender*' was replaced with the term '*sex*', if '*sex*' was the data set held by NHS Digital.

IGARD noted that in section 3(b) (Data Requested) that reference was made to Common Law Duty of Confidentiality and suggested this reference was removed, since it was not relevant to this application, because the data was pseudonymised.

Outcome: recommendation to approve subject to the following condition:

1. To provide further explanation of the statement in section 5 "…*to identify specific patients…"* and if this does involve re-identifying individuals, to set out the appropriate security measures and legal basis that is being relied on to do so.

The following amendments were requested:

	1. To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"*. 2. To amend the reference is section 1 to *"**Each** CCG has a Caldicott Guardian…".* 3. To remove reference to the Common Law duty of Confidentiality in section 3. 4. To update section 5 to make clear which of the activities and outputs relate to SHMI. 5. To provide and upload a copy of the IG advice with regard to the legal basis for disseminating SHMI. 6. To remove reference to 'STPs' It was agreed the conditions would be approved OOC by the IGARD Chair. **Subsequent to the meeting:** IGARD noted the update from IG in relation to the IG advice given to the DARS team with regard to the SHMI data dissemination.
2.4	<u>University of Oxford: R1 (D09) - Data support to COVID-19 RCT (Presenter: Vicky Byrne-Watts / Heather Pinches) NIC-365354-R3M0Q</u> **Application:** This was an amendment application to add University of Bristol as an additional Data Processor. The purpose is for a study entitled Randomised Evaluation of COVid-19 thERapY (RECOVERY). This study aims to compare several different treatments that may be useful for patients with COVID-19, that have been recommended by an expert panel that advises the Chief Medical Officer in England. This trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19. NHS Digital noted that the application had been updated since last reviewed including noting that a number of the trials had now closed and papers published. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st April, 28th April, 5th May, 12th May, 19th May, 7th July and the 21st July 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 4th June 2020, and that notes from this meeting had been attached to the IGARD minutes from the 11th June 2020. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and supported the PAG's comments from the 4th June *"The Group would recommend that the transparency material is updated to be in line with the detail within the application, including the fact that Primary Care data would not be shared outside the University".* IGARD asked that a special condition be inserted into section 6 (Special Conditions) that clearly stated that within 1-month of signing the NHS Digital Data Sharing Agreement (DSA) that a General Data Protection Regulation (GDPR) compliant privacy notice be published, and as assessed by NHS Digital. IGARD also supported PAG's comment from the 4th June in relation to whether PCD would leave the University of Oxford and PAG's comment "…*including the fact that Primary Care data would not be shared outside the University"* and asked that clarification be sought as to whether or not the Professor at the University of Bristol, who was undertaking the statistical analysis, would have access to PCD outlined in the application. IGARD noted that reference to the precedent route being 'not applicable' should be updated to be 'not appropriate' in section 1. In addition, IGARD noted a typo throughout the application which referred to '*care **alon**g*' which should be updated to '*care **alone***' since it altered the meaning of the statement(s).

	IGARD noted that the processing and storage location addresses in section 2(a) (Processing Locations) and 2(b) (Storage Locations) in relation to the University of Bristol were 'TBC' and asked that these be updated to ensure the location of the server was reflected. IGARD noted that they had been provided with two supporting document (SD) '12' and suggested that one of them be updated to correction reference 'SD20' and be uploaded to the Customer Relationship Management (CRM) system. IGARD noted a number of acronyms were noted in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example 'GPES' (General Practice Extraction Service). IGARD noted that the text in section 5(a) (Objective to Processing) was outdated and should be updated to accurately reflect the current scale of the COVID-19 pandemic and asked that the information be brought up to date. IGARD queried in section 5(a) reference to "…*Data from routine healthcare records (including linkage to medical databases held by organisations such as NHS Digital) and relevant from relevant research studies (such as UK Biobank and Genomics England) will allow subsidiary analysis…*" and asked that further clarification be provided as to any data linkage to other applications or Data Sharing Agreements (DSAs). If data linkage was being undertaken IGARD noted that this should be covered in the study materials provided and further narrative be provided in section 5b (Processing Activities). IGARD noted the very good work undertaken by the applicant including the tangible benefits and outputs provided, however asked that section 5(d) (Benefits) be updated to reflect **how** the benefit can accrue to the whole population. IGARD noted that the Health Service (Control of Patient Information) Regulations 2002 (COPI) Notice had been extended to March 2021 and that sections 1 and 5 should be updated to reflect this information. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route. **Outcome:** recommendation to approve subject to the following conditions: 1. IGARD endorsed the comments made by PAG and suggested: a) To confirm whether or not the Professor at the University of Bristol will have access to the primary care data. b) To insert a special condition in section 6 stating that within 1-month a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. 2. To clarify in section 5(a) if the data is being linked to any other application, and if so if this is covered in the study materials and processing activities. The following amendments were requested: 1. To update section 2 to ensure the location of the server is reflected. 2. To update section 5(a) to ensure the scale of the COVID-19 pandemic is accurately reflected and the information set out is brought up to date. 3. To update section 5(d) to reflect *how* the benefits can accrue to the whole population. 4. To amend section 1 and section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader, for example *"GPES"*.

	5. To update section 1 and section 5 to reflect the COPI Notice extension to the end of March 2021. 6. To correctly supply supporting document 20 in CRM. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved OOC by IGARD Members.
2.5	<u>Patient-level Medicines data from the NHS Business Services Authority (NHSBSA) Briefing Paper (Presenters: Fintan Grant / Garry Coleman)</u> The briefing paper was to inform IGARD about a collection of patient-level data about medicines dispensed and claimed for in community settings (predominantly community pharmacy). It is taken from electronic and paper prescriptions submitted to the NHS Business Services Authority (NHSBSA) for reimbursement each month. The data comprises prescriptions for medicines that are dispensed or supplied by community pharmacists, appliance contractors and dispensing doctors and prescriptions submitted by prescribing doctors in England for medicines personally administered in England. Since the outbreak of COVID-19 there has been a huge amount of interest in using this data to support the response to the pandemic e.g. clinical trials and via NHS Digital's Trusted Research Environments This data, particularly when linked with other data held by NHS Digital, will enable appropriate secondary uses, such as: informing and supporting prescribing behaviour, planning and research, supporting national priorities, and life sciences purposes. IGARD noted that the presentation had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 7th July 2020. IGARD made the additional following comment: • IGARD noted the important work and suggested that for all applications presented, a supporting document be provided that outlines the data minimisation efforts undertaken and as described in the presentation. IGARD welcomed the presentation and looked forward to receiving the finalised paper as a supporting document alongside the first application for Patient-level Medicines data.
2.6	<u>LA-SER Europe Ltd: Clinical Characteristics of Adult Haematological Cancer Patients with Veno-Occlusive Disease and Their Health Resource Utilisation and Cost Burden in England (Presenter: Louise Dunn) NIC-301834-K0S2Y</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration data, for the purpose of a study, which will assist in obtaining valuable information on haematological cancer patients, especially those with leukaemia, who developed veno-occlusive disease (VOD), which is a rare but serious disorder of the liver. The Primary Objective of the study is to 1) describe the demographic and clinical characteristics of haematological cancer patients who developed VOD by applying an algorithm using ICD-10 codes, adapted Baltimore and Seattle and other clinical criteria for diagnosis of VOD among haematological cancers; and the secondary objectives are to 1) describe the mortality rate

	among haematological cancer patients with VOD; and 2) to describe the resource utilisation and cost burden for haematological cancer patients who developed VOD. The application had been previously considered on the 18th June 2020 when IGARD had deferred pending: Given the complicated clinical and scientific aspects of the study and given the volume of data requested, stated projected aims, the nature of the rare disease, to set out a clear case that there is sufficient expertise and appropriate data available to enable the design of an algorithm, which is relevant to the UK health environment; to clarify whether the study should involve a hepatologist alongside the haematologist; to clarify that the haematologist is able to carry out the stated work with only aggregated data with small numbers suppressed; to clarify how the study will validate the algorithm when there is currently no 'gold standard' for diagnosis of this very rare disease. To accurately describe within section 5 **all** the **potential** benefits accruing to both the applicant and the funder and in addition to direct benefits, to transparently outline any potential declarations of interest or indirect benefits that may accrue now or in the future to either the applicant or funder. To confirm if the study is adapting a USA algorithm for UK use, or developing a novel algorithm for UK use, and to consistently describe this throughout the application. Due to the current pandemic and the large volume and sensitivity of the data requested: to consider whether storing this data on one laptop in a London based office is a practical solution, particularly with potential home working; to provide written confirmation that home working is permitted under this DSA. To insert a special condition in section 6 that all the results will be made public simultaneously with outputs distributed to funder. To update the current wording in section 5 to state that the funder will not have influence on the outcomes nor suppress any of the findings of the research. To update the data minimisation columns in section 3b to accurately reflect that every data entry should refer to data being filtered by ICD10 code. To clearly explain in section 5 approximately how many patients will be covered by the filtering of ICD10 codes. Since it appears other data is being fed into the study, to confirm where the applicant is accessing this data from. The disease outlined in the application is a very rare complication in the UK and not a high cost issue per se: the application should be reviewed to make clear what the outputs are and the benefits that would accrue to health and social care in England and Wales, and how they are proportionate to the data being obtained and processed. The applicant should work with NHS Digital on a Privacy Notice that is GDPR compliant and that no data will flow until such time as a GDPR-compliant Privacy Notice, as assessed by NHS Digital, has been published; which relates to the specific processing as set out in this DSA. **Discussion:** IGARD welcomed and supported the application and noted the importance of the study. IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD reiterated their deferral point 1(d) and queried how the study would validate the algorithm when there was currently no 'gold standard' of this very rare disease, and asked for further clarity. In addition IGARD queried in section 5 (Purpose / Methods / Outputs) if the algorithm they were producing was a written procedure / paper trail or software tool and asked that further clarification was provided in section 5(a) (Objective for Processing). IGARD reiterated their deferral point 2 and what benefits would accrue from this study, and in particular for the applicant and the funder and to describe all the potential benefits accruing to both the applicant and the funder, and in addition to the direct benefits to transparently outline any potential declarations of interest or indirect benefits that may accrue now or in the future to the applicant or funder. IGARD asked that an explicit statement be included in section 5 (Purpose / Methods / Outputs) detailing the relationship between the drug being used, the role of the funder, the condition being studies and the focus of this project.

	IGARD reiterated their deferral point 5, however noting the applicant's request to share a draft copy of the report with the funder prior to publication, asked that a special condition be inserted in section 6 (Special Conditions) stated that all findings would be made public and within 3-months of the funder receiving them. IGARD reiterated their deferral point 10 that the disease outlined within the application was a very rare complication in the UK and not a high cost issue per se, and asked that the application should be reviewed to provide further emphasis on the very rare condition rather than the cost. IGARD reiterated their deferral point 11 that the applicant should work with NHS Digital on a Privacy Notice that is General Data Protection Regulation (GDPR) compliant and that no data would flow until such time as a GDPR-compliant Privacy Notice, as assessed by NHS Digital, had been published; which relates to the specific processing as set out in the Data Sharing Agreement (DSA) IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide an explicit statement in section 5 with regard to the relationship between the drug being used, the role of the funder, the condition being studied and the focus of this project. 2. To insert a special condition in section 6 that the findings will be made public within 3-months of the funder receiving them. 3. The applicant should publish a GDPR compliant privacy notice and before any data flows. The following amendments were requested: 1. To clarify how the study will validate the algorithm when there is currently no 'gold standard' for diagnosis of this very rare disease. 2. To provide further emphasis on the condition and not on the cost. 3. To clarify in section 5 if the algorithm is a paper trail or a software tool. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved OOC by IGARD Members.
2.7	<u>Royal College of Physicians of London: National Asthma and COPD Audit Programme (NACAP): Outcomes of patients included in the adult asthma clinical audit (patients with asthma attacks discharged from hospitals between 1/11/18 -31/03/19 and 1/04/19 - 31/03/20) (Presenter: Louise Dunn) NIC-357479-S6C7T</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration data, for the purpose of linking data collected in the Adult Asthma that will form an outcomes report for the programme and allow organisations to consider what happens to patients in the period after discharge from hospital. The Adult Asthma Audit has been running since 1st November 2018 and reports on care processes provided in the acute hospital setting such as: oxygen prescription, specialist respiratory review, Peak Expiratory

	Flow (PEF), the administration of systemic steroids and/or Beta 2 agonists and treatment at discharge. There were two rounds of national outcome reporting for the adult asthma audit covering the two cohorts: 30- and 90-day outcomes of patients that arrived in hospital on or after the 1 November 2018 and were discharged by the 31 March 2019; and 30- and 90-day outcomes of patients that were discharged from hospital between 1 April 2019 and 31 March 2020. **Discussion:** IGARD noted that cohorts were not consistently described throughout the application and supporting documentation, provided as part of the review, and suggested that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) be updated to reflect the correct details. In addition it was not clear if there was an additional cohort as supporting document (SD) 2.1, the data flow diagram May 2020, described "*sensitive data for patients with adult asthma codes not in the codes (case ascertainment) and send to Imperial*" and asked that this be further clarified, and if there was found to be a '*3rd cohort'* that the application be updated throughout to reflect. IGARD noted that SD1.6, the Health Research Authority Confidentiality Advisory Group (HRA CAG) amendment letter dated 4 February 2020 for the National Asthma and COPD Audit Programme clearly stated in point 3(c) under 'Amendment Request' that "*NHS Digital and NWIS pseudonymise the linked data at source as follows:…date of death changes to survival at X days (Yes/No)*" but it was not clear to IGARD if the date of death was covered by the HRA CAG approval and that clarification be sought. IGARD were unclear if those that were part of cohort 1 but discharged during the cohort 2 time period or those that had multiple admissions were included in the cohorts, and asked that further detail was provided to ensure that no cohort members were lost to the study. IGARD noted that the Data Protection Act (DPA) organisation name for the Royal College of Physicians of London was listed as the '*National Asthma and COPD Audit Programme*' and that this should be updated in section 1(c) (Data Processors). In addition, IGARD noted that Health Quality Improvement Partnership (HQIP) System Level Security Policy (SLSP) was due for review in August 2020. In addition IGARD noted reference to 'research' throughout the application and since this application was for audit, suggested that the word 'research' be removed. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and asked that the table in section 1 be updated to clearly reference the points not met. In addition IGARD noted that NACAP's privacy notice should be updated, to include, but not limited to, being clear about National Data Opt-Outs, and in reference to s251 to remove reference to "breach". **Outcome:** recommendation to approve subject to the following condition: 1. To confirm if date of death data is covered by HRA CAG approval. The following amendments were requested: 1. To update the privacy notice table in section 1. 2. In respect of the cohorts: a) To ensure the cohorts are consistently described throughout the application. b) Where multiple admissions are included, to ensure that no cohort members are lost. c) To provide clarification that there is / isn't a third cohort. 3. To update the RCP DPA organisation name in section 1. 4. To remove reference to "research" throughout the application.

	The following advice was given: 1. IGARD suggested that NACAP's privacy notice is updated, including (but not limited to) to be clear about National Data Opt Outs, and in reference to s251, remove reference to "breach". 2. IGARD noted that the SLSP for HQIP is due to be reviewed in August 2020. It was agreed the condition would be approved OOC by the IGARD Alternate Deputy Chair.
2.8	<u>Department for Transport: HES and STATS19 One-to-one linkage project (Presenter: Catherine Day) NIC-381383-Z9F2P</u> **Application:** This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Accident & Emergency (A&E) data; and an amendment to the purpose, to allow an additional use of the data to investigate the number of admissions to hospital following a road traffic accident during the COVID-19 lockdown period. The purpose of the application is to understand the types of injuries sustained by people injured in road traffic accidents; and to use the analysis to show the number of patients admitted to hospital following a road accident, in the first few months of the year of 2020. This will support policy colleagues in understanding road safety during the COVID-19 period so far and in preparing for users to return to roads. **Discussion:** IGARD noted that the legal basis cited in section 1 (Abstract) was Article 9(2)(j) (*processing is necessary for archiving purposes in the public interest, scientific, or historical* ***research*** *purpose or statistical purposes….*) and asked that further justification be provided of the General Data Protection Regulation (GDPR) legal basis since it did not appear to tally with the legal basis outlined to the Health Research Authority Confidentiality Advisory Group (HRA CAG) supporting documentation provided, as part of the review. IGAR queried why the applicant was requesting HES APC and HES A&E data for a COVID-19 purposes back to 2017, since the purpose of the application was clearly articulated in section 5 which was to understand road safety during the COVID-19 period so far and preparing for users return to the roads. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD asked that a special condition be inserted into section 6 (Special Conditions) that clearly stated that within 1-month of signing the NHS Digital Data Sharing Agreement (DSA) that a GDPR compliant privacy notice be published, and as assessed by NHS Digital. Since the applicant already held this data under this Data Sharing Agreement (DSA) to study and understand the types of injuries sustained by people in road traffic accidents, IGARD queried why the applicant had put forward an amendment application specially relating to COVID-19? IGARD suggested that confirmation be sought if the additional COVID-19 purpose needed to be included within the application, and if it was a distinct / novel purpose, noted that an amendment application would need to be submitted to HRA CAG detailing this major amendment to their s251 support. Subsequently, if an amendment application is submitted to HRA CAG for this additional distinct / novel amendment, that appropriate written evidence be provided that such amendment application has been submitted. IGARD noted a number of acronyms in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) and asked that this public acing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader.

	IGARD noted that the web link in section 5(c) (Specific Outputs Expected Including Target Date) was not working correctly and these should be updated prior to publication of section 5 on the data release register. Noting the information in 5(c) IGARD suggested that this section be updated further to accurately reflect the sources used for the data and information, such as the Hospital Episode Statistics (HES) data from NHS Digital. Given the clear public health benefits of this study, IGARD suggested the applicant consider further plans for patient and public involvement (PPI), noting that SD1.9 of the May 2002 CAG Annual Review, in response to the question with regard to 'user involvement' the applicant had answered 'none', however previously in 2017 had indicated they were in the process of setting up a consultation group. IGARD noted in section 5(a) "…*with over 700 thousand people estimated to being injured on the roads in Britain a year*…" and suggested that this reference be updated and brought into line with current published Government figures. **Outcome:** recommendation for approval subject to the following conditions: 1. In respect of the additional COVID-19 purpose: a) To provide confirmation if the additional COVID-19 purpose needs to be expressly included in the application. b) If the additional COVID-19 purpose is distinct, to submit an amendment application to HRA CAG. c) (If condition 1(b) is actioned): To provide appropriate evidence that the HRA CAG amendment application has been submitted. 2. To insert a special condition in section 6 stating that within 1-month a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. The following amendments were requested: 1. To update section 1 to provide further justification of the stated GDPR legal basis. 2. To update section 5(a) to review the reference to "700,000" people being injured on the roads each year, and in line with government figures. 3. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. 4. To update section 5(c) to acknowledge the sources used for data. 5. To ensure that all web links within the application are working correctly. The following advice was given: 1. IGARD suggested that the applicant may wish to consider PPI involvement. It was agreed the conditions would be approved OOC by IGARD Members.
3	<u>Returning Applications</u> Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
4	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part

	of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 28th July can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
5 **5.1**	<u>AOB:</u> IGARD members noted and endorsed the two AOB items raised in the COVID-19 response meeting on the 28th July 2020, namely: **Documentation addressed to IGARD** IGARD members noted to NHS Digital that should any documentation be addressed for the attention of IGARD, that these should be forwarded to IGARD@NHS.net so that they could be dealt with appropriately and acknowledged where necessary. **Supporting documentation for the business as usual (BAU) Thursday IGARD meeting** Noting that an application for consideration at IGARD on Thursday had 96 supporting documents of varying page lengths, IGARD members asked that NHS Digital investigate how to ensure that all documentation relevant for review was forwarded to IGARD but that thought be given as how this was divided, such as creating sub-folders of 'for background information', 'for this application review' etc.
5.2	There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 24/07/20

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-15814-C6W9R -	Monitor (NHS England / NHS Improvement)	02/07/2020	1. NHS Improvement to furnish an appropriate DPIA, which addresses the risk of unsuppressed data being received and contains a further analyses of the further onward sharing and inclusion of exception basis conditions for sharing of unsuppressed data / metrics with restricted organisations under additional IG controls.	IGARD members	Quorum of IGARD members	*"the applicant may want to consider publication of the DPIA (or a summary) in the interests of transparency, as they have done for the NHS COVID-19 Data Store.* *It would be helpful to see examples from the register where data has been released with small numbers unsuppressed when the application is up for renewal / extension / amendment."*
NIC-07289-G8J6C	Northgate Public Services (UK) Limited	09/07/2020	1. To provide written confirmation that HRA CAG have been notified that there is a cohort of patients who did not give consent to be added to the Registry but are not aware that their data is being held for other purposes; and that any subsequent guidance from HRA CAG is followed in respect of this cohort. 2. To provide clear justification in section 1 and section 5(b) as to why the University of Bristol is currently holding approximately 20 years of NHS Digital data; and if a justification cannot be provided to outline a	IGARD members	Quorum of IGARD members	None

			suitable data deletion programme for the older years of historical data.			

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 notified to IGARD

Appendix B

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 28 July 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (Special GP Member)
In attendance (NHS Digital):	Vicky Byrne-Watts (DARS – item 2.1 & 2.2)
	Louise Dunn (DARS – item 2.1 & 2.2)
	Liz Gaffney (DARS)
	Karen Myers (IGARD Secretariat – Observer)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	NIC-390154-Z4M0F Public Health England (PHE) **Background:** This was an update to the verbal presentation to the COVID-19 response meeting on the 7 July 2020. This was a new application for GPES Data for Pandemic Planning & Research (GDPPR) and is a priority request with a legal basis of the Health Service (Control of Patient Information Regulations) 2002 (COPI). The broad aim is understanding COVID-19 and risks to public health, trends in COVID-19 and such risks, and controlling and preventing the spread of COVID-19 and such risks, for research and planning purposes. NHS Digital noted that this was an update of an application which would be presented to both the Profession Advisory Group (PAG) before submission to a business as usual (BAU) Thursday IGARD meeting for a recommendation. **IGARD Observations:** IGARD members noted that when previously presented to the COVID-19 response meeting, it had been agreed that the application would be presented to the Profession Advisory Group (PAG) before submission to a business as usual (BAU) Thursday IGARD meeting for a recommendation. IGARD members noted the update from NHS Digital with regard to points previously made and welcomed sight of the early stage version of the application and supporting documents.

	IGARD members noted and supported the efforts undertaken by NHS Digital to work with the applicant to ensure appropriate honorary contracts were in place to allow for researchers to access any data under this agreement via the appropriate route and that these would apply to those working "for and on behalf of" PHE. However, it was not clear to IGARD members how many honorary contracts could be issued and how many external analysts / researchers would be working in this manner and suggested that more information be provided. In addition, IGARD members suggested that to ensure transparency of any internal projects that are taking place with a potentially large number of external analysts / researchers that thought be given by the applicant as to how to publish this on an external facing website. Noting that the applicant is aware of the restrictions of receiving data under the COPI notice and the applicant's reliance on this as a legal basis, IGARD suggested that section 1 (Abstract) be updated to correctly reference how the common law duty of confidence was satisfied. IGARD members were, however, unclear as to how all aspects of the application were covered even under a wide interpretation of COPI Regulation 3, specifically with regard to '*service use and specific populations groups*' such as '*changes over time in GP provision of reproductive health services by type of contraception and by inequality of breakdowns, including rural / urban*' and that DARS request specific IG advice as to the suitability of Reg 3 COPI for all aspects of the proposed research. IGARD members supported the steps undertaken by NHS Digital with regard to evidencing appropriate ethical approval and suggested that PHE should expressly state whether Research Ethics Committee (REC) approval was required or not. In addition, IGARD members suggested that NHS Digital and the applicant explore obtaining '*research database*' approval via a REC who have a specific interest in this arena. IGARD members endorsed comments made by NHS Digital with regard to asking questions around PHE's advisory board, their terms of reference, the work they were undertaking and suggested that PHE ensure they are utilising internal committees with specific GP membership particularly because they are dealing with GP data. In addition, thought should be given as to how this application interplays with the previously-approved PHE application for NHS health check data (NIC-201243-R7L2M) and any potential overlaps to ensure that analysts could not access GP data for the health check research project avoiding the appropriate internal checks. IGARD noted that the Office for National Statistics (ONS) had recently applied for GDPPR data (NIC-388794-Z9P3J) and that the application should note any potential overlap with the statistical research being undertaken by ONS and establish how the proposed statistical work will be distinct from, and avoid overlap with, that being carried out by ONS. In line with NHS Digital's DARS Standard: Data Minimisation, IGARD members suggested that s1 should provide a more robust narrative to be clear that the subsequent data minimisation undertaken by PHE does not address the requirement for NHS Digital to consider data minimisation and suggested more explanation be provided as to why no data minimisation was being applied before the data flowed to PHE. IGARD members also suggested that PHE carry out a Data Protection Impact Assessment (DPIA) for this bespoke but highly valuable GDPPR dataset and the measures taken to protect the data.
2.2	<u>NIC-372791-X0H3Q NHS Blood & Transplant (NHSBT)</u> **Background:** This was a verbal update about planned amendments to an existing agreement to provide for additional weekly GPES Data for Pandemic Planning & Research (GDPPR) data disseminations. Previous data releases under v0 and v1 of this this agreement have been

	facilitated and finalised by signed letters from the NHS Digital Information Governance (IG) directorate. The initial request approved under v0 and v1, was to provide contact details for individuals who fit the criteria for collection of convalescent plasma which is being explored as a possible treatment for COVID-19. NHSBT routinely collects plasma from donors who have registered directly as part of their statutory function. The new amendment is to request the GDPPR data to support outbound calling to contact individuals who have been given a diagnosis of COVID-19 to discuss with the individual if they wish to donate Convalescent Plasma, whether the individual is eligible to donate plasma and to book an appointment. NHSBT is already in receipt of pillar 1 and pillar 2 data. This work will continue to support the REMAP-CAP and RECOVERY Trials. NHS Digital noted that a draft application and supporting documentation was available, but had not been provided for review. The following observations are made on the basis of the verbal briefing only. NHS Digital noted that the amended application would be presented to both the Profession Advisory Group (PAG) before submission to a business as usual (BAU) Thursday IGARD meeting for a recommendation. **IGARD Observation:** NHS Digital noted that a data processor called 'Teleperformance' was undertaking the task of contacting potential plasma donors on behalf of NHSBT and that the applicant was relying on Health Service (Control of Patient Information Regulations) 2002 (COPI). Teleperformance was processing confidential patient information (CPI) and Regulation 7(2) COPI stipulates that anyone processing CPI under COPI must be a health professional or person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional. Accordingly, IGARD suggested that the application set out how 'Teleperformance', as a processor of CPI satisfies that requirement in Regulation 7(2) COPI. IGARD members queried why the applicant was applying for GDPPR data and noting NHS Digital's explanation that this was to prepare for any potential wave 2 of COVID-19, were surprised that the applicant had exhausted the utility of the current data it held, since SGSS data contained all positive (and negative) cases of COVID-19, from both hospital and community settings. IGARD members suggested that a clear justification be provided as to what added value GDPPR data would add to data already held. IGARD members noted that potential donors would be contacted by letter and phone call, however noting the number of scams and fraudulent calls being undertaken during the pandemic, suggested that the applicant consider sending a letter out first to potential donors and prior to any call from Teleperformance, since 'cold calling' may distress or worry people unduly. This also tied into National Data Opt-Outs which should be applied to this data since a patient who had opted out of research would not necessarily want to be contacted to ask if they wanted to be part of research. Noting that giving plasma was a more arduous process than giving blood, IGARD members suggested that the applicant ensure that this was appropriately explained and to ensure that all appropriate ethic approval was in place. IGARD noted that the application would be presented to the Profession Advisory Group (PAG) before submission to a business as usual (BAU) Thursday IGARD meeting for a recommendation, but would welcome an update at next week's COVID-19 response meeting

	prior to those submissions and a copy of the documentation which had not been available to review at this meeting.
3	Triage & Prioritisation IGARD noted their support of NHS Digital in their triaging and prioritisation of applications through the system and during the pandemic and offered their continuing support to DARS, should it be required, via this meeting to discuss any early stage applications or queries. Noting that this meeting was primarily for COVID-19 related applications any re-prioritisation of this meeting, after the pandemic, for other non-COVID-19 related work would need appropriate agreement within NHS Digital. NHS Digital noted that work was still being undertaken with regard to service improvement within DARS and asked that a standing item be included on the agenda each Tuesday to discuss this improvement work and any next steps. IGARD welcomed this approach and the service improvement work being undertaken in DARS.
4 **4.1** **4.2**	AOB **Documentation addressed to IGARD** IGARD members noted to NHS Digital that should any documentation be addressed for the attention of IGARD, that these should be forwarded to IGARD@NHS.net so that they could be dealt with appropriately and acknowledged where necessary. **Supporting documentation for the business as usual (BAU) Thursday IGARD meeting** Noting that an application for consideration at IGARD on Thursday had 96 supporting documents of varying page lengths, IGARD members asked that NHS Digital investigate how to ensure that all documentation relevant for review was forwarded to IGARD but that thought be given as how this was divided, such as creating sub-folders of ‘for background information’, ‘for this application review’ etc. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.