

Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 8th June 2023

09:30 – 17:15

(Remote meeting via videoconference)

| INDEPENDENT ADVISERS IN ATTENDANCE: | |
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| Name: | Role: |
| Paul Affleck (PA) | Specialist Ethics Adviser / Co-Deputy Chair |
| Dr. Robert French (RF) | Specialist Academic / Statistician Adviser |
| Kirsty Irvine (KI) | Chair |
| Dr. Geoffrey Schrecker (GS) | Specialist GP Adviser |
| Jenny Westaway (JW) | Lay Adviser (not in attendance for item 5.1) |
| NHS ENGLAND STAFF IN ATTENDANCE: | |
| Name: | Role / Area: |
| Vicky Byrne-Watts (VBW) | Data Access Request Service Senior Approval Team (DARS SAT) (SAT Observer: items 5.1, 5.2 and 5.4) |
| Michael Chapman (MCh) | Data and Analytics representative (In attendance for items 1, 4.1, 5.1, 8 and 11.3) |
| Garry Coleman (GC) | NHS England SIRO Representative (Presenter: items 10.1, 11.4 and 11.5) |
| Ben Cromack (BC) | Data Access Request Service (DARS) (Presenter: item 5.5) |
| Dave Cronin (DC) | Data Access Request Service Senior Approval Team (DARS SAT) (Presenter: item 11.1) |
| Cath Day (CD) | Data Access Request Service Senior Approval Team (DARS SAT) (SAT Observer: item 5.3) |
| Mujiba Ejaz (ME) | Data Access Request Service (DARS) (Presenter: item 5.1) |
| Forrest Frankovitch (FF) | NHS England Data & Analytics (Delegate for Michael Chapman) (not in attendance for items 4.1 and 5.1) |
| Jackie Gray (JG) | Executive Director, Privacy, Transparency, Ethics & Legal (PTEL) (Attending for items 1 and 8) |
| Nicola Jennings (NJ) | Data Access Request Service (DARS) (Observer: item 5.4) |

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| Shaista Majid (SM) | Data Access Request Service (DARS) (Presenter: item 5.2) |
| Andrew Martin (AM) | Data Protection Officer (DPO) representative (Delegate for Jon Moore) |
| Karen Myers (KM) | AGD Secretariat Team |
| Dr. Jonathan Osborn (JO) | Caldicott Guardian Team representative |
| Denise Pine (DP) | Data Access Request Service (DARS) (Presenter: items 5.3 to 5.4) |
| Kimberley Watson (KW) | Data Access Request Service Senior Approval Team (DARS SAT) (Presenter: items 5.5 and 11.2) |
| Tom Wright (TW) | Head of Service, Data Services for Commissioners (DSfC) (Presenter: item 4.1) |
| INDEPENDENT ADVISERS NOT IN ATTENDANCE: | |
| Prof. Nicola Fear (NF) | Specialist Academic Adviser |
| Dr. Imran Khan (IK) | Specialist GP Adviser / Co-Deputy Chair (Chair) |
| Dr. Maurice Smith (MS) | Specialist GP Adviser |
| NHS ENGLAND STAFF NOT IN ATTENDANCE: | |
| Jon Moore (JM) | NHS England Data Protection Office Representative |
| OFFICE OF THE NATIONAL DATA GUARDIAN: | |
| Ryan Avison | Head of Office (Observer: items 1 and 8) |

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| 1 | <p>Welcome and Introductions</p> <p>The NHS England Senior Information Risk Owner (SIRO) Representative advised attendees that, noting the statutory guidance and the AGD Terms of Reference (ToR) had not yet been agreed, the meeting could not be held under the draft ToR, until they have been approved, and recognised that the draft ToR may change as the statutory guidance evolves. As NHS England would like to seek advice on a number of areas, the NHS England SIRO Representative therefore proposed that:</p> <ul style="list-style-type: none"> • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); the Caldicott Guardian; and the SIRO. • Attendees would not be listed as “members” in minutes during the transitional period; |
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| | <ul style="list-style-type: none"> NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting; It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing. <p>The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis.</p> <p>Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.</p> |
| 2 | <p>Review of previous AGD minutes:</p> <p>The minutes of the 25th May 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> |
| 3 | <p>Declaration of interests:</p> <p>There were no declarations of interest</p> |
| BRIEFING PAPER(S) | |
| 4.1 | <p>Title: Faster Data Flows for Integrated Care Boards (ICBs)</p> <p>Presenter: Tom Wright</p> <p>Previous Reviews: The Faster Data Flow Acute Patient Activity Briefing Paper was previously presented at the IGARD meeting on the 18th August 2022.</p> <p>The application (NIC-616043-S9R4P) and relevant supporting documents were previously presented / discussed at the IGARD meeting on the 18th August 2022.</p> <p>Prior to the NHS Digital and NHS England merger, NHS England was permitted to receive and link the faster data flows data via NIC-616043-S9R4P; which also allowed NHS England to sub-license the data to ICBs.</p> <p>Following the merger, the sub-licensing element is no longer fit for purpose; and, therefore, any sharing of NHS England data should be processed via the established NHS England Data Access Request Service (DARS) process.</p> <p>The purpose of the briefing paper is to request that the faster data flows product (Acute Activity Dataset) is permitted to be disseminated to the ICBs via the NHS England DARS process.</p> <p>Outcome of discussion: The group welcomed the updated briefing paper and made the following observations / comments:</p> <p>4.1.1 The independent advisers noted that the Faster Data Flow Acute Patient Activity Briefing Paper was reviewed by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 18th August 2022, and that points raised by IGARD had not been addressed in this updated paper; including, but not limited to 1) the points raised on transparency; and 2) engagement with stakeholders. The independent advisers suggested that the briefing paper was reviewed in line with the previous IGARD points raised and updated accordingly.</p> |

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| | <p>4.1.2 The independent advisers suggested that the first of type application was submitted to AGD for review / advice.</p> <p>The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by AGD).</p> |
| EXTERNAL DATA DISSEMINATION REQUESTS: | |
| 5.1 | <p>Reference Number: NIC-445543-W0D4N-v4.4</p> <p>Applicant: AstraZeneca UK Limited</p> <p>Application Title: Real-world effectiveness of the Oxford/AstraZeneca covid-19 vaccine and investigation of the epidemiology of thrombotic thrombocytopenia and other adverse events of interest following COVID-19 vaccination in England - SDE Analysis</p> <p>Presenter: Mujiba Ejaz</p> <p>SAT Observer: Vicky Byrne-Watts</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 1st July 2021, 30th September 2021 and the 25th November 2021.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 25th May 2021, 15th June 2021 and the 22nd June 2021.</p> <p>The application was previously presented at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 26th May 2021 and the 16th June 2021.</p> <p>Linked applications: This application is linked to NIC-459114-J3C1F.</p> <p>Application: This was an application coming for advice.</p> <ol style="list-style-type: none"> 1. Advice was being sought on the inclusion of ‘purpose 3’: To report the vaccine effectiveness of booster doses (3rd dose) of COVID-19 vaccine and investigate their risk of developing thrombotic thrombocytopenia, thromboembolism and thrombocytopenia within a pre-defined time interval (these analyses may include other MHRA-approved vaccines other than Pfizer-BioNTech and ChAdOx1). <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:</p> <p>5.1.1 The independent advisers noted that the application was reviewed by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 30th September 2021, and advised that several substantive points raised by IGARD had not been referenced or addressed in the internal application assessment form, including, but not limited to, the points raised on transparency and providing further clarity on the “<i>artificial intelligence (AI)-based approaches</i>”; and suggested that this was updated to adequately address all of the previous points.</p> |

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| <p>5.1.2 In relation to the outstanding points raised on the applicant's transparency, the SIRO representative advised NHS England that this would be discussed further outside of the meeting, noting the contractual obligation in section 4 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. The independent advisers noted and supported the update from the SIRO representative.</p> <p>5.1.3 Noting that some of the previous points had been outstanding since 2021, the independent advisers confirmed that they would be supportive of a future audit on this data sharing agreement (DSA) by NHS England.</p> <p>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>In response to point 1</p> <p>5.1.4 The independent advisers noted the addition of purpose 3 in the application; and queried whether this had sought and received ethical support, noting that this was unclear in the application and supporting documents provided. NHS England advised that it was their understanding that the applicant had received ethical support for the additional purpose, however noted that evidence of this had not been provided by the applicant. The independent advisers noted the verbal update from NHS England and suggested that the application was updated to reflect that ethical support had been received for the additional purpose, and that confirmation of the ethical approval was provided by the applicant, and that, once received, this was uploaded to NHS England's customer relationships management (CRM) system for future reference.</p> <p>5.1.5 The independent advisers noted and were supportive of the data under this data sharing agreement now being accessed and processed within NHS England's Controlled Environment.</p> <p>5.1.6 NHS England advised that prior to the meeting, further discussions had been ongoing internally to determine whether the COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2) was "<i>identifiable</i>" as stated in the application. The SIRO representative requested that further clarification be provided on this outstanding query once confirmed, and that the relevant updates were made to the application to reflect the correct information.</p> <p>5.1.7 The independent advisers noted the reference to 'National Institute of Standards and Technology' (NIST) in both the internal application assessment form and the application, when referring to acceptable security assurance; and suggested that notwithstanding the review by NHS England's Security Adviser, this was a potential risk to NHS England, noting that NIST was not a direct equivalent of the Data Security and Protection Toolkit (DSPT) as it is not externally assessed or audited.</p> <p>5.1.8 Noting the request in the application for the Uncurated Low Latency Hospital Data Sets, the independent advisers queried why this dataset was required, and why the applicant was unable to wait several weeks for the datasets which would provide properly curated information to the applicant; and suggested that NHS England discussed this further with the applicant.</p> <p>5.1.9 The independent advisers noted that at the AGD meeting on the 11th May 2023, NHS England had advised that the text used in section 3(c) (Patient Objections) in respect of opt-outs would be reviewed and updated as necessary; and suggested that section 3(c) in this</p> | |
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| | <p>application was aligned with the correct / most recent text used in other applications, and that it was made clear that the National Data Opt-out would not be applied.</p> <p>5.1.10 The independent advisers noted the expected benefits outlined in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care), however suggested that this was reviewed to ensure that it was up to date and contained the most recent information, for example, removing the historical dates; and that it was clear which benefits related to which purpose as outlined in section 5(a) (Objective for Processing); and in line with NHS England's DARS Standard for Expected Measurable Benefits.</p> <p>5.1.11 Noting the PAG special conditions in section 6 (Special Conditions), the independent advisers suggested that NHS England confirmed with the applicant that the special conditions had been complied with; and suggested that all the PAG special conditions were reviewed, and if no longer necessary / appropriate, were removed from the application. The Caldicott Guardian Team representative confirmed his support for this approach, and advised that he was content to have a further discussion about this issue outside of the meeting with the presenter / DARS SAT observer.</p> <p>5.1.12 The independent advisers noted the addition of the COVID-19 datasets; and noting they were restricted to COVID-19 related research only, suggested that a special condition outlining any restrictions was inserted in section 6, in line with NHS England's DARS Standard for Special Conditions.</p> <p>5.1.13 The independent advisers noted that the citation special condition had been added in section 6, however suggested that this was updated, to state that, where practicable, outputs cite the source of the data as <i>"This work uses data provided by patients and collected by the NHS as part of their care and support"</i>.</p> | |
| 5.2 | <p>Reference Number: NIC-14709-Z2H2R-v7.13 i5</p> <p>Applicant: i5 Health Limited</p> <p>Application Title: NHS Commissioning Support</p> <p>Presenter: Shaista Majid</p> <p>SAT Observer: Vicky Byrne-Watts</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 28th June 2018, 27th August 2020 and the 12th August 2021.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 6th October 2020.</p> <p>Application: This was a renewal, extension and amendment application.</p> <p>The amendments are 1) the addition of Community Services Data Set (CSDS); and 2) to amend the special condition regarding data retention.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> | |

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| <p>5.2.1 NHS England advised the group that the application incorrectly stated that this was a three-year data sharing agreement; and that this would be updated to correctly state that this was a one-year agreement, in line with the current funding. The group noted the verbal update.</p> <p>5.2.2 The independent advisers noted that the application was previously reviewed by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 12th August 2021, where IGARD had noted that there were ethical issues relating to research and development of algorithms and suggested that the applicant may wish to seek independent ethical review in respect of their processes. The independent advisers queried the response from the applicant on this point, that “...it was deemed that an independent ethical review was not required for this DSA as the applicant utilised the *HRA research project decision tool” (*Health Research Authority); noting that the point made by IGARD was not specifically about obtaining an ethical review from the HRA. Notwithstanding this, it was noted that effort had been made in the application to address some ethical issues, for example, as part of the request for an increased quantum of data; and in addition, NHS England advised that further information had been provided verbally by the applicant in respect of addressing ethical issues. The independent advisers suggested that section 5(a) (Objective for Processing) was updated further to address that there are ethical issues and how they are being addressed.</p> <p>5.2.3 Noting that the NHS England DARS Ethical Review Standard was still in draft, the independent advisers suggested that NHS England may wish to share this with the applicant (in confidence) to further support the progress with the ethical issues raised and how these are being, or could be, addressed.</p> <p>5.2.4 The independent advisers noted that as part of the audit on this data sharing agreement (DSA), it had been recommended that the applicant produce a Data Protection Impact Assessment (DPIA); and advised that they were supportive of this, noting the scale and nature of the processing. In addition, the independent advisers suggested that the ethical issues discussed could be addressed as part of the DPIA.</p> <p>5.2.5 The independent advisers advised that the applicant’s published privacy notice contained a large volume of information, and that some of the information may not be suitable for a lay reader and there appeared to be some inaccuracies; and suggested that this was reviewed and edited as appropriate in a manner suitable for a lay audience.</p> <p>5.2.6 Noting the volume of historical data requested, i.e. five / ten years; the independent advisers suggested that section 5(a) was updated with further examples of why this volume of historical data was required.</p> <p>5.2.7 In addition, the independent advisers suggested that if the historical data was required to avoid bias, as indicated within the application, then this should also be linked to the ethical issues raised.</p> <p>5.2.8 The independent advisers suggested that NHS England may wish to consider where the use of new technologies, such as Artificial Intelligence (AI), have implications for the way that applications are assessed. For instance, how the Data Minimisation standard should be applied where greater volumes of data could result in more effective AI insights.</p> | |
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| | <p>5.2.9 Noting the references in the application to “AI”, the independent advisers suggested that NHS England clarify with the applicant that the development of AI was being carried out within the permitted territory of use.</p> <p>5.2.10 The independent advisers queried the benefits in section 5(d) (Benefits), including, but not limited to, the statement that <i>“The increased number of, in particular, nurses who are able to prescribe will accelerate patient treatment, and free up doctors to spend more time with patients who need appointments”</i>; and suggested that section 5(d) was updated throughout to ensure that all statements can be supported with evidence; in line with NHS England’s DARS Standard for Expected Measurable Benefits.</p> <p>5.2.11 The independent advisers noted that some of the benefits in section 5(d) (iii) (Yielded Benefits) were expected benefits and not yielded benefits; and suggested that this was reviewed and edited as appropriate, to ensure the correct information was in the relevant section, in line with NHS England’s DARS Standard for Expected Measurable Benefits.</p> <p>5.2.12 Noting the yielded benefit in section 5(d) (iii) relating to the <i>“avoidance of mass screening in primary care and community settings...”</i>; the independent advisers suggested that this may raise queries on automated processing; and suggested that this could be addressed as part of the DPIA.</p> | |
| 5.3 | <p>Reference Number: NIC-700125-B2Z7J-v0.5</p> <p>Applicant: Young Epilepsy</p> <p>Application Title: Turning6 - A Clinical and Neurodevelopmental follow up of ‘Epilepsy in infancy: relating phenotype to genotype’ (EPIPEG) participants at 60 months</p> <p>Presenter: Denise Pine</p> <p>SAT Observer: Cath Day</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for research project to 1) establish up-to-date address information of children who participated in the EPIPEG study to enable Young Epilepsy to send parents/carers invitations for their children to participate in the Turning6 study; and 2) to establish whether any children who participated in the EPIPEG study have died, so parents/carers of those children are not invited to participate in the Turning6 study, therefore reducing the likelihood of causing potential distress to those parents/carers.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:</p> <p>5.3.1 The independent advisers queried the data controllership arrangements, in light of the research undertaken previously, and the anticipated research once the study team have a new cohort. Noting the involvement of UCL and Great Ormond Street Hospital (GOSH) in the EPIPEG study, it was advised that it was difficult to delineate their involvement with the purpose and means of processing under this application. It was suggested that NHS England explore this further, and update the application and the relevant supporting</p> | |

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| <p>documents as may be appropriate to reflect the factual scenario; and in line with NHS England's DARS Standard for Data Controllers.</p> <p>5.3.2 In addition, if UCL and / or GOSH are deemed to be joint Data Controllers, the independent advisers advised that the application would need to be updated with the correct legal basis for each organisation to undertake this role.</p> <p>5.3.3 In respect of the invitation letter, provided as a supporting document, the independent advisers noted that Health Research Authority Confidentiality Advisory Group (HRA CAG) had asked that the typo "<i>metal</i>" was corrected to state "<i>mental</i>"; and noting that this was a HRA CAG condition of support that had not yet been actioned, suggested that this was corrected as soon as possible.</p> <p>5.3.4 In addition, the independent advisers suggested that the information within the invitation letter in respect of the HRA CAG support, was made more visible, i.e. not in a smaller font.</p> <p>5.3.5 The independent advisers also noted concern over some of the language within the invitation letter, which appeared to have been taken from a research funding application or scientific literature, for example, "<i>...their life chances are significantly diminished</i>" and "<i>They rarely progress at the same rate as their peers in school...</i>"; and suggested that, while factually true, it may be advisable for this not to form part of the invitation letter, noting the potential upset / impact this could have on parents / carers. In addition, it was suggested that the applicant should undertake patient and public involvement and engagement (PPIE), to ensure the letter was written in a more sensitive manner.</p> <p>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>5.3.6 The independent advisers noted the statement in section 5(b) (Processing Activities) "<i>Analysts from Young Epilepsy will process the data...</i>"; and suggested that further information was provided on the type of analysis they will be undertaking, and if the analysts were substantive employees of Young Epilepsy. If the analysts were not substantive employees of Young Epilepsy, it was suggested that clarification was sought as to whether they were on honorary contracts (if this was relevant dependent on the outcome of the data controllership point raised).</p> <p>5.3.7 Noting that Young Epilepsy was a new recipient of NHS England data, the independent advisers queried, what, if any, due diligence had been undertaken by NHS England on this organisation, beyond the usual NHS England checks.</p> <p>5.3.8 Separate to this application, if NHS England do not currently undertake any due diligence on new applicants, the independent advisers suggested that this was given further consideration.</p> <p>ACTION: NHS England to consider undertaking additional due diligence for new recipients of NHS England data; or providing an update to the group (for information) on what due diligence was undertaken.</p> <p>5.3.9 NHS England's SIRO representative noted the amendment to the application, to establish whether any children who participated in the EPIPEG study have died, so parents/carers of those children were not invited to participate in the Turning 6 study; and queried whether this included formal and informal deaths. NHS England advised that the</p> | <p>NHSE</p> |
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| | <p>original request was for Civil Registration (deaths) data, which would have provided formal and informal deaths data; however, Demographics as requested under this application only provides formal deaths data. The independent advisers advised that they would be supportive of the dataset flowing that provided the greatest volume of information to support the applicant / study to minimise the risk of distress.</p> <p>5.3.10 The independent advisers queried the information in section 3(c) (Patient Objections) that stated patient objections would be applied, noting that the HRA CAG letter dated the 13th October 2022 states that patient objections do not need to be applied. It was therefore suggested that section 3(c) was updated to reflect the correct information.</p> <p>5.3.11 The independent advisers queried what the data deletion approach would be, noting that this was unclear, and suggested that section 5(a) (Objective for Processing) was updated with clarification, noting that the applicant should be processing and retaining the minimum volume of data as possible, in line with the HRA CAG support.</p> <p>5.3.12 The independent advisers noted that the next phase of the study would be commercially funded, and suggested that this should be made clear within the application, i.e. creating a cohort for a commercially funded study; in line with NHS England's DARS Standard for Commercial Purpose.</p> | |
| 5.4 | <p>Reference Number: NIC-667040-B5T1X-v0.12</p> <p>Applicant: University of York</p> <p>Application Title: Centre for Health Economics, University of York, Programme Level Agreement</p> <p>Presenter: Denise Pine</p> <p>SAT Observer: Vicky Byrne-Watts</p> <p>Observers: Nicola Jennings</p> <p>Linked applications: This application is linked to NIC-84254-J2G1Q.</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for the purpose of research to help inform health and social care policy and practice by identifying the effectiveness, efficiency, distribution, and quality of a wide range of services provided to the population. It produces insights that allows the maximisation of health gain and other measures of benefit from limited healthcare budgets, along with information on how health and health care is/can be distributed equally to meet the health needs of varying demographics. It may potentially provide a view of health care utilisation to understand how effective delivery of care is distributed both nationally and locally, contributing to the delivery of new healthcare policy aimed at improving the quality of care.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were not supportive of the application and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting:</p> | |

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| | <p>5.4.1 The independent advisers advised NHS England that the application, as it currently stands, would be ceding too much control to the applicant without ensuring that suitable governance over data access would be in place, however, would be content to review a further iteration of the application if suitable governance structures were in place; there was suitable transparency; and the application was in accordance with other programmatic access arrangements.</p> <p>5.4.2 The independent advisers noted and acknowledged the skills and expertise of those involved with the research.</p> <p>5.4.3 The independent advisers noted that this was an application for programmatic access, however advised that, as currently presented, it did not align with other similar applications, including, but not limited to, the governance in respect of how projects were selected, for example, there were no Terms of Reference for a governance group, which would cover a number of issues, including, but not limited to, the assessment of benefits to health and social care; an assessment of the commercial benefits and proportionate balancing with public benefits; an oversight of the nature of the funding; data minimisation; purpose limitation; compliance with UK General Data Protection Regulation (UK GDPR) principles; and compliance with the NHS England data sharing agreement (DSA).</p> <p>5.4.4 In addition, it was suggested by the independent advisers that the objective for processing in section 5(a) (Objective for Processing) should be more restrictive in terms of developing broader themes by which the internal governance group could determine whether the application for data could comply.</p> <p>5.4.5 The independent advisers noted that another significant feature of programmatic access should be lay involvement; however, in this case, it was noted within the application, that there was patient and public involvement and engagement (PPIE) panels, and it was positively noted that this could be an effective mechanism if linked with the oversight of access to the programme.</p> <p>5.4.5 It was also noted by the independent advisers that, for programmatic access, there would usually be transparency on the projects that had been approved, in line with UK GDPR; and further information of how the benefits had been assessed in line with the National Data Guardian (NDG) guidance on benefits. There did not appear to be any plans addressing this point.</p> <p>5.4.6 The independent advisers noted that the Community Services Data Set (CSDS) and Improving Access to Psychological Therapies (IAPT) dataset had been requested under this application; and noting the significant volume of data within these datasets, suggested that a justification for this request was made clear within section 5 (Purpose / Methods / Outputs).</p> <p>5.4.7 The independent advisers queried the statement in section 5(a) <i>“*CHE has determined that no moral or ethical issues are raised by its processing of HES or other patient data sets...”</i> (*The Centre for Health Economics (CHE)); and suggested that this statement was removed, as it was incorrect.</p> <p>5.4.8 Noting the information within section 5(a) on the <i>“scoping analysis”</i>, the independent advisers queried whether this could be carried out internally, as opposed to allowing access to the whole dataset.</p> <p>5.4.9 In respect of the benefits in section 5(d) (Benefits), the independent advisers suggested that this was edited to ensure this only contained yielded benefits and not</p> | |
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| | <p>outcomes; and that any outcomes should be moved to section 5(c) (Specific Outputs Expected) in line with NHS England's DARS Standard for Expected Outcomes and NHS England's DARS Standard for Expected Measurable Benefits.</p> <p>5.4.10 The independent advisers noted that at the AGD meeting on the 11th May 2023, NHS England had advised that the text used in section 3(c) (Patient Objections) in respect of opt-outs would be reviewed and updated as necessary; and suggested that section 3(c) in this application was aligned with the correct / most recent text used in other applications, and that it was made clear that the National Data Opt-out would not be applied.</p> | |
| 5.5 | <p>Reference Number: NIC-396095-H1P1D-v3.4</p> <p>Applicant: NHS Cheshire and Merseyside Integrated Care Board (ICB)</p> <p>Application Title: DSfC - CIPHA - CV19</p> <p>Presenter: Kimberley Watson / Ben Cromack</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 10th February 2022.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 29th September 2020, 6th October 2020 and the 20th October 2020.</p> <p>Application: This was an amendment application.</p> <p>The amendments are to 1) to reflect that CCGs have been abolished and replaced with Cheshire and Merseyside ICB; 2) to reflect that the Local Authorities are no longer Data Controllers; 3) to reflect that the Local Authorities have only received aggregated data with small numbers suppressed data, therefore data destruction is not required; 4) to remove the locations in line with the new ICB applications; 5) to update the legal basis from relying on the COVID-19 specific COPI notice to Regulation 3 of COPI; 6) to reflect relevant updates in line with the ICB commissioning template and outcomes of NIC-361618-Y2W1Y-v0.2.</p> <p>Should the application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p>5.5.1 The NHS England SIRO representative provided a verbal update on the previous breach that had occurred under this data sharing agreement, and as discussed by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 10th February 2022. In addition, and as advised by IGARD, the SIRO representative noted that an audit had been undertaken on this data sharing agreement (DSA), and that there had been a delay in producing the audit report due to ongoing discussions between NHS England and NHS Cheshire and Merseyside ICB, however confirmed that an agreement had been reached on the outcome of the audit, and that this had now been published on NHS England's website.</p> <p>5.5.2 The independent advisers noted the verbal update from the SIRO representative, however suggested that NHS England may wish to consider the implications for other ICBs and their obligations in ensuring the relevant parties had sight of the DSA.</p> | |

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| | <p>5.5.3 The SIRO representative also highlighted to the independent advisers the unusual method outlined in this DSA, of the processing method for re-identification rather than doing this via the Data Services for Commissioners Regional Office (DSCRO); and the additional governance requirements required for this method. The independent advisers noted the verbal update and suggested that NHS England confirm, and note within the application, that they were satisfied with this approach and any associated risks, including but not limited to, confirmation from the Privacy, Transparent, Ethics & Legal (PTEL) team that the re-identification process is acceptable in terms of the risks and governance.</p> <p>5.5.4 The independent advisers note that the legal basis had been changed from relying on the COVID-19 specific Health Service (Control of Patient Information (COPI)) Regulations 2002 to Regulation 3 of COPI; and noted that the legal advice provided by NHS England's PTEL team was subject to legal privilege, and they had therefore not had sight of this.</p> <p>5.5.5 The independent advisers noted that when the IGARD had reviewed the application on the 10th February 2022, they had asked that the yielded benefits were updated in line with NHS Digital (now NHS England) DARS Standard for Expected Measurable Benefits and that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (Benefits) (iii) (Yielded Benefits) and to ensure these are clear about the benefits to both patients and the health care system more generally. The independent advisers noted that some amendments had been made, however, suggested that this could be further strengthened and therefore reiterated the previous IGARD advice.</p> <p>5.5.6 The independent advisers noted that at the AGD meeting on the 11th May 2023 NHS England had advised that the text used in section 3(c) (Patient Objections) in respect of opt-outs would be reviewed and updated as necessary; and suggested that section 3(c) in this application was aligned with the correct / most recent text used in other applications, and that it was made clear that the National Data Opt-out would not be applied.</p> | |
| EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL | | |
| 6.1 | <p>Reference Number: NIC-365354-R3M0Q-v11.2</p> <p>Applicant: University of Oxford</p> <p>Application Title: R1 (D09) - Data support to COVID-19 RCT (RECOVERY)</p> <p>Presenter: No Presenter</p> <p>Previous Reviews: The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 11th June 2020, 30th July 2020, 12th November 2020, 26th August 2021, 14th October 2021, 27th January 2022, 23rd June 2022, 6th October 2022 and the 12th January 2023.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 5th May 2020, 12th May 2020, 21st July 2020, 28th April 2021, 21st June 2020, 28th September 2021 and the 5th October 2021.</p> <p>The application was previously presented at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 4th June 2020, 25th August 2021 and the 20th July 2022.</p> <p>Application: The purpose of the application is for a study aiming to compare several different treatments that may be useful for patients with COVID-19. These treatments have</p> | |

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| | <p>been recommended by the expert panel that advises the Chief Medical Officer (CMO) in England.</p> <p>Outcome of discussion: The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided.</p> <p>The NHS England SIRO representative thanked the group for their time.</p> | |
| 6.2 | <p>Reference Number: NIC-148101-R7RSL-v7.4</p> <p>Applicant: University College London (UCL)</p> <p>Application Title: Regional Heart Study (Female Cohort)</p> <p>Presenter: No Presenter</p> <p>Previous Reviews: The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 9th November 2017, 1st March 2018 and the 20th May 2021.</p> <p>Application: The purpose of the application is for a prospective cohort study of cardiovascular disease in women aged over 60 years, in England, Scotland and Wales. The study was set up in 1999 to complement the British Regional Heart Study (BRHS), to describe and establish risk factors and the differences in their impact in women compared to the men followed up by the BRHS.</p> <p>Outcome of discussion: The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p>6.2.1 The independent advisers noted the SIRO approval form stated that there were “no” risks with the extension; and suggested that this was not factually correct, and that there are risks that are being appropriately managed.</p> <p>The NHS England SIRO representative thanked the group for their time.</p> | |
| 6.3 | <p>Reference Number: NIC-433629-H3M0G-v3.4</p> <p>Applicant: NHS England (Quarry House)</p> <p>Application Title: SMI Comprehensive Physical Health Checks (PHSMI) GPES Extract</p> <p>Presenter: No Presenter</p> <p>Previous Reviews: The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 22nd July 2021, 4th November 2021, 20th January 2022 and the 11th August 2022.</p> <p>Application: The purpose of the application is to permit NHS England, to continue to use the Physical Health Checks for people with Severe Mental Illness (PHSMI) data which was collected via the General Practice Extraction Service in order to monitor the delivery of the NHS Long Term Plan ambition to ensure that 390 thousand people with Severe Mental Illness have their physical health needs met by receiving a comprehensive PHSMI and follow-up intervention by 2023/24 and beyond.</p> | |

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| | <p>Outcome of discussion: The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p>6.3.1 The independent advisers noted that section 1 (Abstract) of the application referred to a breach that had been referred to the Information Commissioner's Office (ICO), however queried why this had not been acknowledged in the SIRO form. The SIRO representative advised that this been brought to his attention by the AGD Chair prior to the meeting, and that this was being investigate further internally. The independent advisers noted the verbal update from the SIRO representative.</p> <p>The NHS England SIRO representative thanked the group for their time.</p> | |
| 6.4 | <p>Reference Number: NIC-656861-S5H3R-v1.2</p> <p>Applicant: London School of Hygiene and Tropical Medicine</p> <p>Application Title: Updating trends in the cancer survival index for England and Wales (ODR1920_179)</p> <p>Presenter: No Presenter</p> <p>Application: The purpose of the application is for a project, to assess progress in an index of cancer survival up to 10 years after diagnosis for patients diagnosed with a cancer in England or Wales.</p> <p>Outcome of discussion: The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided.</p> <p>6.4.1 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 independent review.</p> <p>The NHS England SIRO representative thanked the group for their time.</p> | |
| AGD Operations | | |
| 7 | <p>Statutory Guidance</p> <p>The independent advisers queried the reference to "<i>agreed audit framework</i>" within the published Statutory Guidance and advised that they were not aware of an agreed audit framework, and requested that NHS England provide further information/ clarity on this.</p> <p>ACTION: NHS England to provide further clarity on the audit framework.</p> | NHSE |
| 8 | <p>AGD Terms of Reference</p> <p>The independent advisers noted that the latest draft AGD Terms of Reference had been circulated on the 30th May 2023; and that NHS England has requested that comments were received by the 16th June 2023.</p> <p>The Executive Director, Privacy, Transparency, Ethics & Legal (PTEL) attended the meeting to receive initial high-level thoughts / comments on the draft AGD Terms of Reference document.</p> <p>The group thanked Jackie for attending, and it was noted the independent advisers would return formal comments / feedback on the draft ToR by the 16th June 2023 as requested.</p> | |

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| 9 | Standard operating procedures The ongoing forward plan of work for creating Standard Operating Procedures was discussed. | To note |
| 10 10.1 | New Operational Actions & those carried forward from previous meetings of AGD: IR35 / Zero Hours contracts for independent advisers Garry Coleman noted that NHS England were actively working on putting zero hours contracts in place for all independent advisers. | To note |
| Any Other Business | | |
| 11.1 | Title: NHS England DARS Honorary Contracts Standard Presenter: Dave Cronin Dave Cronin attended the meeting to discuss comments and suggestions on the draft NHS England DARS Honorary Contracts Standard; that were provided out of committee in May 2023, by the AGD independent advisers; this was following a discussion with NHS England at the AGD meeting on the 23 rd March 2023. It was agreed that following the final updates to the NHS England DARS Ethical Review Standard; this should be sent to the SIRO representative for sign-off; should be published on NHS England's website; and sent to the AGD Secretariat for information. | |
| 11.2 | Title: NHS England DARS Ethical Review Standard Presenter: Kimberley Watson The group noted that at the AGD meeting on the 30 th March 2023, it was outlined that there was an ongoing issue with the National Disease Registration Service (NDRS) applications that were novated from Public Health England (PHE) following its cessation in 2021; and the issues with obtaining Health Research Authority ethics approval for these applications, which was previously required by PHE. The group noted that prior to the AGD meeting on the 27 th April 2023, an updated draft copy of NHS England DARS Ethical Review Standard had been provided as part of the meeting pack, which had been brought to the group for advice on the proposed amendments. Kimberley Watson attended the meeting to discuss any further suggested updates to the NHS England DARS Ethical Review Standard with AGD independent advisers. The independent advisers thanked NHS England for the updates already made to the document; and made some additional suggestion in respect of minor refinements to the Standard for consideration. It was agreed that following the final updates to the NHS England DARS Ethical Review Standard; this should be sent to the SIRO representative for sign-off; should be published on NHS England's website; and sent to the AGD Secretariat for information. | |
| 11.3 | Title: NHS England DARS Term of Data Sharing Agreement Standard Presenter: Michael Chapman / Garry Coleman | |

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| | <p>The group noted that at the AGD meeting on the 11th May 2023, there was an action for the SIRO representative to review the NHS England's DARS Standard Term of Data Sharing Agreement; to ensure the NHS England annual review is reflected.</p> <p>Michael Chapman and Garry Coleman shared an updated version of the NHS England's DARS Standard Term of Data Sharing Agreement with the independent advisers, who made some additional suggestion in respect of minor refinements to the Standard for consideration.</p> <p>It was agreed that following the final updates to the NHS England DARS Ethical Review Standard; this should be sent to the SIRO representative for sign-off; should be published on NHS England's website; and sent to the AGD Secretariat for information.</p> |
| 11.4 | <p>Reference Number: NIC-175120-W5G2X</p> <p>Applicant: Office for National Statistics (ONS)</p> <p>Application Title: D5 - Office for National Statistics requirements for NHS-Digital data, for the purposes of Statistics and Statistical Research, under section 45 of the Statistics and Registration Services Act 2007 as amended by the Digital Economy Act 2017</p> <p>The SIRO representative updated AGD on a SIRO approval which will be tabled at the AGD meeting on the 15th June 2023.</p> |
| 11.5 | <p>NHS England statement on Capita cyber incident</p> <p>The SIRO representative advised the group that NHS England has reported a data breach to the Information Commissioners' Office following a recent cyber incident involving Capita; and that further information could be found on the NHS England website.</p> <p>The independent advisers noted and thanked the SIRO representative for highlighting this information.</p> |
| <p>Meeting Closure</p> <p>As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.</p> | |