# Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 19th October 2023

09:30 – 15:00

*(Remote meeting via videoconference)*

| **INDEPENDENT ADVISERS IN ATTENDANCE:** | |
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| **Name:** | **Role:** |
| Paul Affleck (PA) | Specialist Ethics Adviser (Chair) |
| Claire Delaney-Pope (CDP) | Specialist Information Governance Adviser |
| Dr. Imran Khan (IK) | Specialist GP Adviser |
| Jenny Westaway (JW) | Lay Adviser |
| **NHS ENGLAND STAFF IN ATTENDANCE:** | |
| **Name:** | **Role / Area:** |
| Angela Blakeney (AB) | Senior information Governance Manager, Data Governance, Delivery Directorate (**Observer:** item 4.1) |
| Michael Chapman (MC) | Data and Analytics representative (**Presenter**: item 10) (not in attendance for items 7 to 9) |
| Garry Coleman (GC) | NHS England SIRO Representative (**Presenter**: items 7 and 8) |
| Rick Cooper (RC) | Vaccine Digital Services, Transformation Directorate (**Presenter**: item 4.1) |
| Dave Cronin (DC) | Assurance Team, Data Access Request Service (DARS) (**Observer**: item 5.1) |
| Louise Dunn (LD) | Assurance Team, Data Access Request Service (DARS) (**Observer**: item 4.3) |
| Duncan Easton (DE) | Assurance Team, Data Access Request Service (DARS) (**Observer**: items 5.1 to 5.5) |
| Jon Moore (JM) | NHS England Data Protection Office Representative |
| Karen Myers (KM) | AGD Secretariat Team |

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| Laura Norris (LN) | Director of Transformation, Vaccination and Screening Directorate (**Observer:** item 4.1) |
| Jonathan Osborn (JO) | NHS England Caldicott Guardian Team Representative |
| Deep Patel (DP) | Strategy, Vaccine Deployment Programme, Vaccination Digital Services (**Observer:** item 4.1) |
| James Watts (JW) | Data Access Request Service (**Observer**: items 5.3 to 5.5) |
| Emma Whale (EW) | Data Access Request Service (DARS) (**Observer**: item 5.2) |
| Vicki Williams (VW) | AGD Secretariat Team (**Presenter**: item 9) |
| Tom Wright (TW) | Data Governance and Assurance, Data Access and Partnerships Directorate (**Presenter**: item 4.2 to 4.3) (**Observer**: item 4.4) |
| **INDEPENDENT ADVISERS NOT IN ATTENDANCE:** | |
| Prof. Nicola Fear (NF) | Specialist Academic Adviser |
| Dr. Robert French (RF) | Specialist Academic / Statistician Adviser |
| Kirsty Irvine (KI) | Chair |
| Dr. Geoffrey Schrecker (GS) | Specialist GP Adviser |
| Dr. Maurice Smith (MS) | Specialist GP Adviser |
| Miranda Winram (MW) | Lay Adviser |

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| **1** | **Welcome and Introductions**<br>The NHS England Senior Information Risk Owner (SIRO) Representative, noting the Advisory Group for Data (AGD) Terms of Reference (ToR) had not yet been agreed, proposed that:<br>• Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings;<br>• The meeting will be minuted, with advice and minutes published;<br>• 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; Data and Analytics; and the SIRO.<br>• Attendees would not be listed as “members” in minutes during the transitional period;<br>• 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; |

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| | • It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing.<br><br>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.<br><br>Paul Affleck noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting. |
| **2** | **Review of previous AGD minutes:**<br><br>The minutes of the 12th October 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. |
| **3** | **Declaration of interests:**<br><br>Claire Delaney-Pope noted a professional link to King's College London (NIC-264102-D2X7J) as part of her role at South London and Maudsley NHS Foundation Trust. It was agreed this did not preclude Claire from taking part in the discussion on this application. |
| **BRIEFING PAPER(S):** | |
| **4.1** | **Title:** Framework Legal Directions for NHS public health functions (section 7A) – Briefing Paper<br><br>**Presenter:** Rick Cooper<br><br>**Observers:** Angela Blakeney, Laura Norris, Deep Patel<br><br>In response to the National Vaccination Strategy (publication imminent), NHS England's Vaccination Digital Services (VDS) Team are seeking to support the Vaccination and Screening Directorate in a series of changes that will enable improved delivery of the NHS Act 2006, Section 7a delegated Public Health Functions for national vaccination programmes, utilising national digital capabilities.<br><br>The Vaccination Programme, supported by VDS is seeking a Legal Direction to enable expansion of current digital capabilities in COVID to all Section 7a vaccination programmes, to support NHS England to fulfil their delegated obligations.<br><br>NHS England were seeking advice on the following points:<br><br>1. The approach in seeking a Direction from the Secretary of State, aligned with the one already in place for COVID-19, and to provide additional assurance that all processing for the purposes of all vaccinations programmes is done transparently and lawfully.<br>2. The planned consultation process to support the submission to DHSC that will focus primarily on consulting with representative bodies of the GP profession (i.e. BMA and RCGP) as the development of the strategy has already engaged heavily with the public and profession. |

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| | **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments:<br><br>In response to point 1:<br><br>**4.1.1** The independent advisers queried what the Direction will deliver that Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002 (COPI) does not already provide; and noting the verbal response that was provided in-meeting from NHS England, suggested that further information was provided within the briefing paper.<br><br>**4.1.2** The NHS England DPO Representative noted a potential risk to NHS England in that if COPI was relied on for purposes beyond the direction, it could undermine transparency and cause confusion and that this might be allayed by careful drafting of the Direction. The group noted the comments by the DPO representative and suggested that this was given more consideration by NHS England as to how this would be managed.<br><br>**4.1.3** The independent advisers noted a potential risk in that the draft Direction was broader than the current vaccination strategy, and highlighted the importance of engagement with the profession (such as the British Medical Council (BMA) and Royal College of GPs (RCGP)), including, but not limited to, consideration of the "broadness" of the Direction, and the transparency of the use of General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (COVID-19) (GDPPR) data. NHS England noted that they had engaged with a variety of stakeholders including the profession and primary care organisations and that further engagement would be undertaken in due course. The group noted the verbal update in meeting, and suggested any discussions with the profession were **prior** to the draft Direction being finalised.<br><br>**4.1.4** The independent advisers noted point 2.10 in the draft Direction, in respect of sending vaccination information to GPs so that clinical records can be updated; and stressed the importance of ensuing this was done correctly.<br><br>**4.1.5** The independent advisers noted that point 2.15 in the draft Direction, in respect of ensuring that systems used to record vaccinations are able to obtain and display a person's relevant immunisation history, could be read as restricting access to clinicians and suggested a less restrictive term was used that would encompass all staff who would need access to the record to enable delivery of care.<br><br>In response to point 2:<br><br>**4.1.6** The group noted the verbal update from NHS England on the engagement to date, for example, primary care engagement; and that there were ongoing discussions about all future engagement. The independent stressed the importance of ongoing engagement before the Direction was finalised.<br><br>In addition, the group made the following observations on the briefing paper and / or supporting documentation provided as part of the review. |

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| | **4.1.7** The group had a discussion on Type 1 opt-outs and National Data Opt-out (NDO), and whether these would be applied; and suggested that further clarification was included in the briefing paper.<br><br>**4.1.8** It was also suggested by the group that transparency information about and policy documents relating to the Type 1 opt-outs and NDOs were reviewed to ensure that this aligned with the work outlined and the Direction.<br><br>**4.1.9** The group noted the verbal update from NHS England that the draft briefing paper required further work and looked forward to receiving a further updated briefing paper for discussion at a future meeting. |
| **4.2** | **Title:** Hertfordshire and West Essex Integrated Care Board (ICB) request to replace Arden and Greater East Midlands (AGEM) Commissioning Support Unit (CSU) with Cerner as their principal Data Processor – Briefing Paper<br><br>**Presenter:** Tom Wright<br><br>Hertfordshire and West Essex (HWE) ICB is requesting to amend its data sharing agreement (DSA) to use a new Data Processor, Oracle Cerner (Cerner) whose offshore engineers will have access to the system from Ireland, Sweden, India and the USA. This is a first-of-a-kind request and any advice provided will be used as a guide for other ICBs.<br><br>HWE ICB have a current DSA in place for the purposes of commissioning, risk stratification and invoice validation. At present commissioning activities are carried out by Arden and Greater East Midlands (AGEM) Commissioning Support Unit (CSU) using pseudonymised data from Greater East Midlands (GEM) Data Services for Commissioners Regional Office (DSCRO).<br><br>NHS England were seeking advice on the following points:<br><br>1. Whether they would be supportive of the proposed amendment to the DSA naming Cerner as a principal data processor for HWE.<br>2. Whether NHS England has done enough to ensure that we are assured that HWE is compliant with GDPR as per our own obligations when sharing data with HWE.<br>3. What the group feels would be a minimum assurance standard or criteria for similar cases, and how they might use this amendment as a precedent.<br><br>**Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments:<br><br>In response to points 1 to 3 above:<br><br>**4.2.1** NHS England advised that the Cerner offshore engineers provide ‘around the sun’ support for example, if there is an issue in the middle of the night UK time, they can access the platform so as to restart jobs and implement fixes.<br><br>**4.2.2** It was noted by the independent advisers that Cerner are currently providing a similar service to other NHS Trusts in England, and there was therefore a precedent. However, the |

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| | independent advisers queried if 'around the sun' support was required for this specific use case.<br><br>**4.2.3** NHS England advised that the data will not leave the UK, and that the engineers based in Ireland, Sweden, India and the USA **would** be able to access data as part of troubleshooting and ad-hoc support.<br><br>**4.2.4** The independent advisers noted the arrangements outlined in the briefing paper are not uncommon in the commercial world, and that this can be done safely.<br><br>**4.2.5** The independent advisers queried whether patients in the UK would object to their data being accessed by an organisation outside of the UK; and suggested that this could be explored further and that it be clearly articulated for transparency that individuals outside of the UK could see a patient's record.<br><br>**4.2.6** The SIRO representative outlined to the group the benefits of having Cerner as a Data Processor to the ICB, including, but not limited to, cheaper running costs and round the clock support.<br><br>**4.2.7** The independent advisers queried what the implications would be on NHS Trusts, if this particular use case request was not approved by NHS England, noting that other NHS Trusts are already working with Cerner.<br><br>**4.2.8** The independent advisers recognised allowing access from outside the UK could raise public concerns. However, if there are public benefits to such access, and any risks are managed, those public concerns should be assuaged via transparency.<br><br>**4.2.9** The group noted the benefits of the use case outlined in the meeting and it was emphasised that, going forward, these requests should be undertaken on a case-by-case assessment of the benefits and risks.<br><br>**4.2.10** The independent advisers noted that it was not the interim group's remit to confirm UK General Data Protection Regulation (UK GDPR) compliance. The Data Protection Office (DPO) representative advised the group that colleagues within the Privacy, Transparency, Ethics and Legal (PTEL) would be able to provide further support on the specific query on HWE being UK GDPR compliant; and to ensure transfers comply with the legal requirements.<br><br>**4.2.11** The DPO representative also noted the importance of the group reviewing this proposal, following the advice from PTEL, in terms of transparency.<br><br>**4.2.12** The group stated they would support this request when: there was a robust benefit case; sufficient controls were in place, and UK GDPR had been met.<br><br>**4.2.13** The DPO representative and the SIRO representative advised that they would discuss a clear framework for future requests, including, but not limited to, inclusion and exclusion criteria.<br><br>**4.2.14** The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting. |

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| **4.3** | **Title:** Post COVID assessment service data collection Briefing<br><br>**Presenter:** Tom Wright<br><br>**Observer:** Louise Dunn<br><br>**Previous Reviews:** The briefing paper was previously presented at the AGD meeting on the 21st September 2023 and 27th July 2023.<br><br>The purpose of the original briefing paper was to inform the group about the post-COVID assessment service data collection, which is required to support the response to long-COVID, one of the most pressing ongoing national public health challenges. It enables the capture of critical unified data from post-COVID assessment services spanning a range of care settings and organisational formats, which cannot be obtained from other sources or standard commissioning datasets.<br><br>NHS England were seeking **further** advice on the following point:<br><br>1. The internal transfer and the analysis of the Post COVID assessment service patient data as detailed in an internal data flow request (IDFR) form.<br><br>**Outcome of discussion:** The group welcomed the finalised briefing paper and made the following observations / comments:<br><br>**4.3.1** The group noted the content of the finalised briefing paper and confirmed that they had **no** further comments to make.<br><br>In response to point 1 above:<br><br>**4.3.2** The independent advisers queried the origin of the IDFR form and its underpinning processes.<br><br>**4.3.3** The independent advisers noted that they were supportive of the use of the internal use of the data to advance COVID-19 and COVID-19 related purposes, and that it aligned with the purpose of the COVID-19 data store.<br><br>**4.3.4** The group noted that some of the data was already flowing, and queried whether it was needed, and what it would add, and suggested that further clarification was provided<br><br>**4.3.5** The Caldicott Guardian Team representative noted that the use case had been discussed with the wider Caldicott Guardian Team; and confirmed that the Caldicott Guardian Team were broadly supportive.<br><br>**4.3.6** The group discussed the additional processes outlined in the IDFR form, and noted it was a sensible approach and an appropriate use of the data; however, suggested that further clarification was provided as to how the additional purposes fitted into the wider process.<br><br>**4.3.7** It was noted that there was significantly less information provided for the internal flow of data compared to the information provided within an external application; and the group suggested that NHS England provide more information if the intention is to have the same level of scrutiny for internal data flows as for external data flows. |

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| | **4.3.8** In respect of transparency, the NHS England representatives advised that NHS England's Internal Data Uses Register is used to record all internal data flows. The independent advisers noted the verbal update from NHS England.<br><br>**4.3.9** In respect of the transparency on the COVID-19 datastore, the independent advisers noted that the current published information may give the impression that this has been decommissioned; and suggested that the wording was reviewed and updated as may be appropriate.<br><br>**4.3.10 Separate to this briefing paper:** the independent advisers suggested that the 'internal data flow request template' for the AGD advice, submitted alongside the AGD cover note template, was brought to a future meeting for further discussion on content, including, but not limited to, the section on reputational risks.<br><br>**ACTION:** NHS England to submit a copy of the IDFR form for discussion at a future meeting, to discuss the content, including, but not limited to, the section on reputational risks. |
| **4.4** | **Title:** Clinical Registries for Commissioners Briefing Paper<br><br>**Observer:** Tom Wright<br><br>**Previous Reviews:** The Briefing Paper was previously discussed as part of the review for NIC-627119-M2CF Class Action (ICB Clinical Registries) at the AGD meeting on the 4th May 2023.<br><br>The Briefing Paper was previously presented / discussed at the IGARD meetings on the 16th June 2022, 7th April 2022 and the 11th July 2019.<br><br>The purpose of the original briefing paper was to inform IGARD about that Commissioners are requesting to receive the pseudonymised Clinical Registry data already approved to flow to NHS England; in order to fulfil their functions as set out in the Health and Social Care Act 2012.<br><br>The updated briefing paper was submitted to the group, following a request at the AGD meeting on the 4th May 2023 as part of NIC-627119-M2CF.<br><br>**Outcome of discussion:** The group welcomed the finalised briefing paper and made the following observations / comments:<br><br>**4.4.1** The group noted that the points raised at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meeting on the 16th June 2022 had been addressed and were content with the responses / updates provided, and confirmed that they had **no** further comments to make.<br><br>In addition, the group made the following observations:<br><br>**4.4.2** The independent advisers noted that each of the clinical registries will have its own transparency arrangements and artefacts, which could include physical patient information leaflets, online privacy or transparency notices, and had committed to updating these; and noted that work still needed to be done in this area and that one of the clinical registries did not appear to have an online privacy notice. |

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| | **4.4.3** The independent advisers noted the commitments to ensuring that the diversity of restrictions on the different datasets from different registries is understood by the Integrated Care Boards (ICB); and suggested that NHS England give further consideration as to how they could support ICBs with this. | |
| **EXTERNAL DATA DISSEMINATION REQUESTS:** | | |
| **5.1** | **Reference Number:** NIC-373563-N8Z9J-v11.8<br><br>**Applicant:** IQVIA Ltd<br><br>**Application Title:** Analytical Services<br><br>**Assurance Team Observers:** Dave Cronin, Duncan Easton<br><br>**Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 28th September 2023 and the 18th May 2023.<br><br>The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 24th November 2022, 28th January 2021, 6th February 2020 and the 7th February 2019.<br><br>The application and relevant supporting documents were previously presented / discussed at the DAAG meetings on the 10th January 2017, 18th October 2016, 27th September 2016 and the 13th September 2016.<br><br>**Linked applications:** This application is linked to NIC-315134-L9Z6B and NIC-210151-K9C7G.<br><br>**Application:** This was an amendment application.<br><br>The amendment is to amend the purpose of the application in section 5(a) (Objective for Processing).<br><br>The purpose of the application is for IQVIA Ltd to provide commercial services to clients in the health sector or clients that support the Health Sector.<br><br>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.<br><br>**Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:<br><br>**5.1.1** The independent advisers noted and commended the work undertaken by NHS England's Data Access Request Service (DARS) on the internal application assessment form and application following the review on the 28th September 2023.<br><br>**5.1.2** The group noted the responses in the internal application assessment form, in respect of the points raised on the 28th September 2023, and advised that the points had been adequately addressed and that they had **no** further comments to make in respect of these. | |

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| | **5.1.3** The independent advisers suggested that NHS England should consider undertaking an audit of this DSA, noting the history of the application, the volume of data flowing and its commercial aspects. | |
| **5.2** | **Reference Number:** NIC-148471-FR43L-v4.11<br><br>**Applicant:** Newcastle University<br><br>**Application Title:** MR1032 - The Newcastle 85+ Study: Biological, Clinical & Psychological Factors Associated with Healthy Ageing<br><br>**Assurance Team Observer:** Duncan Easton<br><br>**Observer:** Emma Whale<br><br>**Previous Reviews:** The application and relevant supporting documents were previously presented at the IGARD meetings on the 20th December 2017.<br><br>**Application:** This was an extension application.<br><br>The purpose of the application is for a research project, to **1)** determine the full spectrum of health within an inception cohort of 85-year-olds, irrespective of health status, and establish the distribution and variability of a broad range of health measures within this age group; and **2)** to examine in unprecedented detail, the health trajectories and outcomes as the cohort aged and the associations with underlying biological, medical and social factors.<br><br>NHS England were seeking advice on the following points:<br><br>1. To determine whether the Department of Health and Social Care (DHSC) are considered a joint Data Controller.<br>2. Although the Research Ethics Committee (REC) support references a study end date of 30th September 2020, AGD advice is being sought on whether REC support should be obtained for continued follow up, given that the support was granted in conjunction with the study protocol which describes the 10 year follow up until 2026.<br><br>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.<br><br>**Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:<br><br>In response to points 1 and 2:<br><br>**5.2.1** The group discussed whether DHSC should be considered a joint Data Controller, in line with NHS England's DARS Standard for Data Controllers, and agreed that, based on the evidence provided, it was a reasonable position that they are **not** a joint Data Controller. It was also noted that there wasn't clear Information Commissioner's Office (ICO) guidance on when a commissioner becomes a Data Controller, and this was therefore an area of ambiguity. | |

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| | **5.2.2** The independent advisers discussed whether on-going Research Ethics Committee (REC) support was required, and advised that the applicant should approach their REC for advice. However, if the project has not ended it would seem REC support is still required. Any additional supporting documentation should be uploaded to NHS England's customer relationship management (CRM) system for future reference.<br><br>**5.2.3** In respect of the consent, the independent advisers noted that the follow-up consent forms did **not** appear to contain the same information as the original consent materials (the original patient consent was not provided as a supporting document, but was found on-line) in relation to follow-up; and there was therefore a mismatch. However, the independent advisers suggested that the applicant could rely on the consent originally taken from the cohort, because they state there will be a follow up on health status from central records.<br><br>**5.2.4** Noting that the NHS England consent review provided as a supporting document was on a different template than usual, the independent advisers suggested that, for consistency, NHS England's DARS ensure that all consent reviews provided to the group are on the same template.<br><br>**ACTION:** DARS to ensure that all consent reviews provided to the group as supporting documents, are on the usual template for consistency.<br><br>**5.2.5** In addition, the independent advisers noted the information within the consent review in respect of the privacy notice, and advised that this information would **not** usually be relevant as part of the consent review, and instead focus on the documents upon which the participant gave consent.<br><br>**5.2.6** The independent advisers noted the information in section 5(d) (Benefits) (ii) (Expected Measurable Benefits) in relation to the yielded benefits; however, noting the significant impact / wide ranging scope of the project benefits, suggested that this section was reviewed and updated as appropriate, to ensure that further information was provided in terms of the actual policy impacts, in line with NHS England's DARS Standard for Expected Measurable Benefits.<br><br>**5.2.7** The independent advisers noted within the application that the funding expires before the DSA end date, and that the applicant will seek funding on an ongoing basis; and suggested that assurance was provided that Newcastle University can continue to support the research and researchers, should further funding **not** be available.<br><br>**5.2.8 Separate to the application**: the independent advisers reiterated advice from the 5th October 2023 meeting, that NHS England DARS update the internal Q&A document to ensure that assurance is provided that where the funding expires before the end of the DSA, the relevant institution / organisation has sufficient resources to support the research and researchers, or end the project. | DARS |

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| | **ACTION:** NHS England DARS to update the Q&A document, to ensure that questions are asked about what will happen if funding expires before the end of the DSA and renewed funding is not granted; for example, will the relevant institution / organisation be able to support the research and researchers, or will data be deleted, should further funding not be available. | DARS |
| **5.3** | **Reference Number:** NIC-655446-P9K9Q-v0.7<br><br>**Applicant:** Adelphi Group Limited<br><br>**Application Title:** A retrospective observational study of patient characteristics, treatment patterns and healthcare resource utilisation for stage II melanoma in England<br><br>**Assurance Team Observer:** Duncan Easton<br><br>**Observer:** James Watts<br><br>**Previous Reviews:** The application and relevant supporting documents were previously presented at the AGD meeting on the 20th July 2023.<br><br>**Application:** This was a new application.<br><br>The purpose of the application is for a research project, with the aim of **1)** gaining a better understanding of the disease characteristics of patients diagnosed with stage II Melanoma; **2)** to gain a better understanding of the treatments patients with stage II Melanoma receive, and how effective these treatments are; **3)** to better understand the cost of the healthcare provided to stage II melanoma patients; and **4)** to aid in categorising key sub-groups within the stage II melanoma patient population that could benefit from the use of new treatments to improve treatment outcomes.<br><br>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.<br><br>**Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:<br><br>**5.3.1** The independent advisers reiterated a previous point from the review on the 20th July 2023, that further information was provided in respect of the medications that Merck Sharpe and Dohme Limited manufacture that relate to the disease being studied, and how this relates to the application. In addition, it was suggested that the internal application assessment form, and section 5(a) (Objective for Processing) and section 5(e) ((Is the Purpose of this Application in Anyway Commercial) in the application were amended to more accurately and fully reflect the commercial purpose, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose.<br><br>**5.3.2** To further support the applicant, the independent advisers suggested that further text be added to section 5(a) for example "*The study will not evaluate or capture the outcomes of any specific treatments (including MSD's* | |

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| | *treatments). However, this study will provide analysis of a care pathway in which Merck Sharp and Dohme have a commercial interest as they produce a drug that is used in this area. The potential commercial benefit to Merck Sharp & Dohme Limited of better understanding this care pathway, is proportionate to the potential public benefits of increased understanding of this area of care and appropriate use of drugs approved for patients with stage II melanoma. There is a direct commercial gain from the study to Adelphi, which will be paid for carrying out this work".*<br><br>**5.3.3** Independent advisers also suggested that when NHS England are working with commercial applicants to ensure clear and accurate information about commercial interests are included within an application, the Data Access Service might ask applicants to articulate how they would describe the value of a project to their shareholders,<br><br>**5.3.4** The independent advisers reiterated a previous point from the review on the 20th July 2023, that the group was disappointed that **no** patient and public involvement and engagement (PPIE) had been undertaken. Not least because this could be crucial to determining the balance of benefits, and suggested that the applicant undertakes **ongoing** PPIE, not just at the end of the project to support the drafting of lay summaries of findings. The HRA guidance on Public Involvement is a useful guide.<br><br>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:<br><br>**5.3.5** The group noted that they had previously queried whether the Data Security and Protection Toolkit (DSPT) for Merck Sharpe and Dohme Limited covered the part of the organisation that would be involved with data controllership for this application; and had suggested that clarification was provided. Noting that the DSPT had been updated to reflect the specific part of the organisation, it was also suggested that this information was reflected in section 5(a) of the application for transparency and accountability.<br><br>**5.3.6** The group noted the intention to publish the findings / outcomes of the study, and were keen to ensure that this should happen. It was recognised that this is difficult to enforce, and advised NHS England that failure to publish results (without appropriate, robust justification) ought to affect the likelihood of future applications being successful. | |
| **5.4** | **Reference Number:** NIC-682583-Z3V2H-v0.7<br><br>**Applicant:** Adelphi Real World<br><br>**Application Title:** A retrospective observational study of treatment patterns, resource use and outcomes in patients with early-stage Non-Small Cell Lung Cancer (NSCLC) in England<br><br>**Assurance Team Observer:** Duncan Easton | |

**Observer:** James Watts

**Previous Reviews:** The application and relevant supporting documents were previously presented at the AGD meeting on the 20th July 2023.

**Application:** This was a new application.

The purpose of the application is for a research project with the aim of **1)** describing the demographics and clinical characteristics of patients diagnosed with early stage or locally advanced NSCLC, stratified by stage at diagnosis and first-line treatment modality; **2)** to describe the pharmacological and other interventional (i.e. surgery, radiotherapy) treatment utilization patterns of patients diagnosed with early stage or locally advanced NSCLC, stratified by stage at diagnosis, first-line treatment modality and referral type; and **3)** to describe the all-cause and NSCLC-related healthcare resource utilisation and direct medical costs, for patients diagnosed with early stage or locally advanced NSCLC for different disease states, stratified by stage at diagnosis and first-line treatment modality.

Should an application be approved by NHS England, further details would be made available within the Data Uses Register.

**Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:

**5.4.1** The independent advisers reiterated a previous point from the review on the 20th July 2023, that further information was provided in respect of the medications that Merck Sharpe and Dohme Limited manufacture that relate to the disease being studied, and how this relates to the application. In addition, it was suggested that the internal application assessment form, and section 5(a) (Objective for Processing) and section 5(e) ((Is the Purpose of this Application in Anyway Commercial) in the application were amended to accurately reflect the commercial purpose, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose.

**5.4.2** To further support the applicant, the independent advisers suggested that, to make clear the potential commercial benefit to Merck, Sharpe and Dohme, section 5(a) be updated with the following additional information (highlighted in bold): "*Results may also be used to supplement health technology assessment (HTA) reimbursement proposals (such as NICE) as MSD has several clinical trials in the early-stage NSCLC setting, in which Marketing Authorisation Application (MAA) has been submitted.* ***This may contribute to Merck Sharpe and Dohme's drugs being approved for early-stage NSCLC patients and thus commercial gain for Merck Sharpe and Dohme".***

**5.4.3** Independent advisers also suggested that when NHS England are working with commercial applicants to ensure clear and accurate information about commercial interests are included within an application, the Data Access Service

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| | might ask applicants to articulate how they would describe the value of a project to their shareholders,<br><br>**5.4.4** The independent advisers reiterated a previous point from the review on the 20th July 2023, that the group was disappointed that **no** patient and public involvement and engagement (PPIE) had been undertaken. Not least because this could be crucial to determining the balance of benefits, and suggested that the applicant undertakes **ongoing** PPIE not just at the end of the project to support the drafting of lay summaries of findings. The HRA guidance on Public Involvement is a useful guide.<br><br>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:<br><br>**5.4.5** The group noted that they had previously queried whether the Data Security and Protection Toolkit (DSPT) for Merck Sharpe and Dohme Limited covered the part of the organisation that would be involved with data controllership for this application; and had suggested that clarification was provided. Noting that the DSPT had been updated to reflect the specific part of the organisation, it was also suggested that this information was reflected in section 5(a) of the application for transparency and accountability.<br><br>**5.4.6** The group noted the intention to publish the findings / outcomes of the study, and were keen to ensure that this should happen. It was recognised that this is difficult to enforce, and advised NHS England that failure to publish results (without appropriate robust justification) ought to affect the likelihood of future applications being successful. | |
| **5.5** | **Reference Number:** NIC-264102-D2X7J-v1.8<br><br>**Applicant:** King's College London (KCL)<br><br>**Application Title:** Investigating the association between X-ray guided endovascular aortic aneurysm repair and incidence of cancer<br><br>**Assurance Team Observer:** Duncan Easton<br><br>**Observer:** James Watts<br><br>**Previous Reviews:** The application and relevant supporting documents were previously presented at the IGARD meeting on the 3rd June 2021.<br><br>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 3rd June 2021.<br><br>**Linked Applications:** This application is linked to NIC-467721-N7C0L<br><br>*(The National Disease Registration Service (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)*. | |

**Application:** This was an amendment application.

The amendment is linkage of both Data Access Request Service (DARS) business as usual (BAU) and NDRS data products; previously this request was split between two NIC numbers NIC-264102-D2X7J and NIC-467721-N7C0L.

The purpose of the application is for a research project, with the aim of comparing the incidence of radiation-related cancer for patients who underwent endovascular aneurysm repair (EVAR) versus open aneurysm repair.

Should an application be approved by NHS England, further details would be made available within the Data Uses Register.

**Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:

**5.5.1** The group noted the information in section 1.8 of the internal application assessment form that stated the Radiation Epidemiology Group at UK Health Security Agency (UKHSA) would be conducting the statistical and epidemiological analysis of the data, and why they are listed a Data Processor in the application. Noting that UKHSA were also the funder, the group discussed whether UKHSA could be both a Data Processor and funder, and noted that although this was possible, this needs to be borne of the facts, and that there needed to be clear boundaries to ensure they do not become a Data Controller. It was suggested that further clarification be provided in the internal application form and the application as may be necessary, to confirm how UKHSA would take instructions from the Data Controller, who was overseeing this, and what the relationships are, and in line with NHS Digital DARS Standard for Data Controllers.

**5.5.2** In addition, the group noted that it was unclear what role UKHSA had in the project, and what expertise they were bringing; and suggested that the further clarification was provided in section 5 (Purpose / Methods / Outputs) of the application as may be necessary.

**5.5.3** The group queried how the data would flow to UKHSA, and noting that this was currently unclear, suggested that further clarification was provided in section 5 of the application; with a clear rationale for this process.

**5.5.4 Subsequent to the meeting:** the independent advisers noted that UKHSA were noted in the protocol (SD4) as a “sponsoring” organisation, noting that the Director of Privacy, Transparency and Ethics, had confirmed to the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) in early 2021, that HRA guidance states that study sponsors are automatically deemed data controllers and if they are not, then NHS England should include a rebuttal statement in section 1 (Abstract) and section 5 of the application detailing the analysis undertaken by NHS England that the study sponsor is not undertaking any data controllership activities, if supported by the facts.

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| | **ACTION: Separate to the application:** as previously suggested by IGARD on the 26th January 2023 and 11th August 2022, NHS England should update their internal processes to ensure that where sponsors are **not** deemed to be carrying out data controllership activities, this analysis and justification is addressed in section 1 and section 5 of the application, as a matter of course; as per the NHS Health Research Authority (HRA) guidance on 'Controllers and personal data in health and care research'<br><br>In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:<br><br>**5.5.5** The independent advisers noted the reference in the internal application assessment form to Article 6(1)(f) of the UK General Data Protection Regulation (UK GDPR); and noting this appeared to be incorrect, suggested that this was reviewed and removed / updated to reflect the correct Article 6 legal basis.<br><br>**5.5.6** The independent advisers queried the number of PhD students that would have access to the data, noting that the application and internal application assessment form were unclear on this point; and that the application referred to *"student"* and *"Students"*; and suggested that the application was updated with confirmation of the number of PhD student(s) involved.<br><br>**5.5.7** The independent advisers queried the statement in section 5(b) (Processing Activities) *"Access is restricted to employees, students and **agents** of King's College London"*; and suggested that further information was provided as to what was meant by "*agents*", and whether this aligned with the Data Sharing Framework Contract (DSFC).<br><br>**5.5.8** The independent advisers suggested that section 5(d) (Benefits) be updated to use a form of wording such as "*it **may** be beneficial* …", rather than "*it **will** be beneficial…*", in line with NHS Digital DARS Standard for Expected Measurable Benefits. | DARS |
| **EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL** | | |
| **6.1** | **Reference Number:** NIC-663539-G7F9X-v2.3<br><br>**Applicant:** The Royal College of Surgeons of England<br><br>**Application Title:** National Lung Cancer Audit - NCRAS data request<br><br>**Previous Reviews:** The application and relevant supporting documents had previously been presented and discussed at the IGARD meeting on the 15th September 2022.<br><br>**Application:** The purpose of the application is to evaluate the performance of NHS lung cancer services against established standards of care, and to encourage NHS hospitals with unexplained variation in areas of clinical practice or patient outcomes | |

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| | to examine their lung cancer service and formulate action plans to improve their clinical performance.<br><br>The SIRO approval was for a 12-week extension.<br><br>**Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval.<br><br>The group thanked NHS England for the written update and made the following observations on the documentation provided:<br><br>**6.1.1** The independent advisers noted that the Article 9 UK General Data Protection Regulation (UK GDPR) legal basis cited in the internal application assessment form and the application were not consistent and suggested that these were reviewed and updated to reflect the correct information.<br><br>**6.1.2** The independent advisers noted that the purpose of the application in the e-mail provided to the group from NHS England, and the applicant's privacy notice were not aligned; and suggested that the purpose of the application was reviewed.<br><br>**6.1.3** The independent advisers noted that section 5(a) (Objective for Processing) stated *"The ODR was responsible for providing a common governance framework for responding to requests to access PHE datasets for secondary purposes, including service improvement, surveillance and ethically approved research"*; and suggested that this was reviewed and updated if not relevant / correct.<br><br>The NHS England SIRO representative thanked the group for their time. | |
| **AGD Operations** | | |
| **7** | **Statutory Guidance**<br><br>The independent advisers again noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were **not** aware of an agreed risk management framework, and requested that NHS England provide further information/ clarity on this, noting this topic had been raised by Lord Hunt in the House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements – UK Parliament.<br><br>The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the group, which confirmed that NHS England were asking the interim data advisory group to use the NHS England DARS Standards and Precedents model to assess the risk factors in relation to items presented to the interim data advisory group for advice; however the independent advisers noted that the wording in the in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is **separate** | |

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| | to the DARS Standards and Precedents, and asked that this be clarified by NHS England.<br><br>It had been noted previously that an Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework.<br><br>**ACTION:** NHS England SIRO representative to provide a written response addressed to AGD with further clarity on the risk management framework. | GC |
| **8** | **AGD Terms of Reference (ToR)**<br><br>The independent advisers noted that nearly five months had passed since the Statutory Guidance had been published, requiring a ToR to be agreed and published, and queried whether there was any further update on the progress of the AGD ToR.<br><br>The SIRO representative noted that NHS England were still considering comments from stakeholders on the AGD ToR.<br><br>**ACTION:** The NHS England SIRO representative noted a previous action to clarify when a revised draft of the AGD ToR would be presented to AGD and when the AGD ToR was scheduled to be considered by the NHS England Board / subcommittee of the Board. | GC |
| **9** | **Standard operating procedures**<br><br>Vicki Williams noted that of the 37 SOPs currently highlighted as required (noting this figure could increase when the TOR was finalised and cross referenced with the Statutory Guidance); 21 were in "final draft" awaiting the finalised TOR to ensure they aligned, 8 were in first draft and progressing to "final draft", and 8 required further discussion because they related to recruitment and the future programmes of work initially outlined in a previous draft TOR (this figure may go up or down dependent on the finalised TOR).<br><br>The group thanked Vicki for the update and noted the ongoing forward plan of work for creating Standard Operating Procedures that it continued to be difficult to progress further without sight of the final ToR. | To note |
| **Any Other Business** | | |
| **10** | **Data Access update**<br><br>The group noted that at the meeting on the 10th August 2023, it had been agreed that a monthly update would be provided on the current applications in progress within NHS England's Data Access Request Service (DARS) and at what stage the applications were at within NHS England's customer relationship management (CRM) system. | |

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| | This was the second update from Michael Chapman and provided information on the number of applications in the system and time to approval; an update on team structures, and progress on automation of data production.<br><br>The group thanked Michael Chapman for providing this information in advance of the meeting and noted the content of the paper.<br><br>**ACTION:** it was agreed in meeting that the Head of Secure Data Environments and Head of Digi-Trials would be invited to a future meeting to provide updates on their areas of work. |

**Meeting Closure**

As there was no further business raised, the Chair of the meeting thanked attendees for their time and closed the meeting.