

## **Advisory Group for Data (AGD) – Meeting Minutes**

Thursday, 16<sup>th</sup> November 2023

09:30 – 15:30

*(Remote meeting via videoconference)*

<b>INDEPENDENT ADVISERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role:</b>
Paul Affleck (PA)	Specialist Ethics Adviser (Items 9.1 and 9.2)
Claire Delaney-Pope (CDP)	Specialist Information Governance Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser (Items 9.1 and 9.2)
Jenny Westaway (JW)	Lay Adviser
<b>NHS ENGLAND STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Garry Coleman (GC)	NHS England SIRO Representative ( <b>Presenter:</b> item 7)
Dave Cronin (DC)	NHS England Data and Analytics Representative (Delegate for Michael Chapman)
Mujiba Ejaz (ME)	Applications Team, Data Access Request Service (DARS) ( <b>Observer:</b> item 4.2)
Jackie Gray (JG)	Solicitor and Director of Privacy, Transparency, and Trust (PTT) (Items 9.1 and 9.2)
Suzanne Hartley (SH)	Data Access Team Manager, Data Access Request Service (DARS) ( <b>Observer:</b> item 4.4)
Andrew Martin (AM)	NHS England Data Protection Office Representative (Delegate for Jon Moore)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative (Items 1 to 4.4, 7, 9.1, 9.2 and 9.4)

Frances Perry (FP)	Applications Team, Data Access Request Service (DARS) ( <b>Observer:</b> item 4.5)
Steve Russell (SR)	Chief Delivery Officer, National Director for Vaccinations and Screening and Senior Information Risk Owner (SIRO) (Items 4.3, 9.1 and 9.2)
Suzanne Shallcross (SS)	Applications Team, Data Access Request Service (DARS) ( <b>Observer:</b> item 4.4)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate ( <b>Presenter:</b> Item 8)
Clare Wright (CW)	Applications Team, Data Access Request Service (DARS) ( <b>Observer:</b> item 4.3)
<b>INDEPENDENT ADVISERS NOT IN ATTENDANCE:</b>	
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Miranda Winram (MW)	Lay Adviser
<b>NHS ENGLAND STAFF NOT IN ATTENDANCE:</b>	
Michael Chapman (MC)	Data and Analytics Representative
Jon Moore (JM)	NHS England Data Protection Office Representative
<b>DEPARTMENT OF HEALTH AND SOCIAL CARE STAFF IN ATTENDANCE:</b>	
Gareth James (GJ)	Data Policy, Joint Digital Policy Unit (Item 9.2)
Katy Lindfield (KL)	Data Policy, Joint Digital Policy Unit (Item 9.2)
Osman Sabir (OS)	Data Policy, Transformation Directorate (Item 9.2)

<b>1</b>	<p><b>Welcome and Introductions</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings;</li> </ul>
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	<ul style="list-style-type: none"> <li>• The meeting will be minuted, with advice and minutes published;</li> <li>• 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.</li> <li>• Attendees would not be listed as “members” in minutes during the transitional period;</li> <li>• 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;</li> <li>• It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing.</li> </ul> <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><b>Review of previous AGD minutes:</b></p> <p>The minutes of the 9<sup>th</sup> November 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><b>Declaration of interests:</b></p> <p>Dr. Imran Khan noted a potential conflict with NIC-561357-X0F3N-v1.3 Evidera Ltd, as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussion on this application, however it was agreed that he would not form part of the group’s advice to the NHS England SIRO Representative.</p> <p>Dr. Imran Khan noted a potential conflict with NIC-707577-H0F4Z University of Leeds, noting that he continues to be contracted by a direct competitor of The Phoenix Partnership (TPP). It was agreed this did not preclude Dr. Khan from taking part in the discussion on this application.</p>
<b>EXTERNAL DATA DISSEMINATION REQUESTS:</b>	
4.1	<p><b>Reference Number:</b> NIC-16016-Y9H1D-v14.2</p> <p><b>Applicant:</b> Wilmington Healthcare</p> <p><b>Application Title:</b> Hospital Episode Statistics (HES), ECDS, Diagnostic Imaging Dataset (DIDs) and sensitive Mental Health data to assist disease awareness, commissioning, and help to produce longitudinal rare disease analysis and reports</p>

**Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 21<sup>st</sup> September 2023.

The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 4<sup>th</sup> August 2022, 7<sup>th</sup> July 2022, 5<sup>th</sup> November 2020, 16<sup>th</sup> May 2019, 26<sup>th</sup> July 2018, 11<sup>th</sup> January 2018, 21<sup>st</sup> December 2017, 19<sup>th</sup> October 2017 and the 5<sup>th</sup> October 2017.

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

The purpose of the application is to **1)** raise disease awareness, management and diagnosis through analysing data and publishing reports and tabulations; **2)** to support the commissioning, healthcare and service improvement cycle and enhancing patient outcomes through understanding disease progression and applying it to the continual improvement of service development; and **3)** to produce longitudinal rare disease analysis and reports that enable patients to receive the correct treatment for a condition that had not yet been diagnosed, e.g. no testing available, and no definitive diagnosis reached by the clinician.

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 comments:

**4.1.1** The group noted that they were supportive of the three-year term of the data sharing agreement (DSA).

**4.1.2** The Data Protection Office (DPO) representative noted the content of the Legitimate Interest Assessment (LIA) provided as a supporting document (SD5) and the benefits outlined to the NHS, however suggested, as a point of advice to the applicant only, that this was updated with further information of the benefits to Wilmington Healthcare, as a commercial company, from the work outlined in the application. The DPO representative noted this information would usually be captured in the LIA to show the balance and assessment made between the interests of the Data Controller and the interests of third parties and the data subjects.

**4.1.3** Noting the information in section 5.3 of the internal application assessment form that Wilmington Healthcare Advisory Board considers ethical considerations during its approval process; it was noted that the Board's Terms of Reference (ToR), which were provided as a supporting document (SD2.3), did **not** specify this. It was therefore suggested by the independent advisers that NHS England liaise with the applicant and suggest that the ToR were updated to expressly refer to the Board having ethical considerations as part of their remit.

**4.1.4** It was suggested by the SIRO representative that a special condition be added to section 6 (Special Conditions) of the application, that permits an NHS England

observer to attend any meeting(s) of the Wilmington Healthcare Advisory Board, in line with the approach now being taken for sub-licensing. The group advised that they were supportive of this.

**4.1.5** The independent advisers noted under 'Accountability' in the Wilmington Healthcare Advisory Board's ToR that "*Projects are not approved by the Advisory Board unless at least 2 Wilmington members along with 1 lay member having reviewed and approved the purpose statement*" and questioned whether this meant that a project could be approved in this way, in the instance that the other 6 members of the Board / majority of the Board disagreed, and queried what checks and balances were in place to prevent this. It was suggested that the ToR / governance arrangements of the Board be reviewed and updated as may be necessary to address this point, since it is usual practice to have half plus one for a consensus of a Board.

**4.1.6** The independent advisers also suggested that the published Wilmington Healthcare Advisory Board ToR were updated to include a link to the relevant privacy notice, as opposed to replicating text from the privacy notice within the ToR.

**4.1.7** In addition, it was suggested that the lay members of the Wilmington Healthcare Advisory Board review the privacy notice to ensure, for example, this was clear and transparent to a lay reader; and suggested that this could be done in line with the [Information Commissioner's Office \(ICO\)](#) and NHS England templates.

**4.1.8** Noting the information within the application and internal application assessment form in respect of 'honorary contracts', it was suggested that this was reviewed and updated as may be necessary to accurately reflect the contractual arrangements (noting honorary contracts were most typically used for visiting academics or clinicians working at universities or hospital trusts other than their home institution). The independent advisers noted that if this term was referring to an intra group movement of a small number of employees, then it was suggested that a secondment or employment contract amendment may be more appropriate. If the use of 'honorary contracts' raises wider Data Controller or Data Processor issues, then it was suggested that NHS England explore this further in line with [NHS England's DARS Standard for Data Controllers](#) and [NHS England's DARS Standard for Data Processors](#) to whether any additional parties needed to be added to the DSA.

**4.1.9** The independent advisers suggested the honorary contract special condition in section 6 of the application was reviewed and either amended as may be necessary; or removed from the application if not relevant.

**4.1.10** The independent advisers commended NHS England / the applicant on the information provided in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application, on the commercial aspect of the application; however suggested that paragraphs 3,4 and 5 were also replicated for transparency

	<p>in section 5(a) (Objective for Processing), in line with <a href="#">NHS England's DARS Standard for Objective for Processing</a>.</p> <p><b>4.1.11</b> The group noted and commended the applicant on the benefits outlined in section 5(d) (Benefits) of the application.</p> <p><b>4.1.12</b> Noting the statement in section 5(d) (iii) (Yielded Benefits) of the application, in respect of MS Emergency Admissions “<i>These admissions are estimated to cost the NHS over £40k per year...</i>”; and suggested that this figure was reviewed and updated as may be necessary, for example, is it £40,000 <b>per patient</b>.</p> <p><b>4.1.13</b> The independent advisers noted the statement in section 5.3 of the internal application form that “<i>...the data request is beneficial to NHS England...</i>”; and it was suggested that the Data and Analytics representative discuss this further with colleagues in DARS, to ensure that colleagues / the applicant are aware that the data request does <b>not</b> require a benefit to NHS England as an organisation; and that all stated benefits should be in line with <a href="#">NHS England's DARS Standard for Expected Measurable Benefits</a>.</p> <p><b>4.1.14 Separate to this application:</b> the independent advisers noted that NHS England were in the process of reviewing the operation of the annual confirmation report mechanism; and it was agreed that a further discussion would be held at the AGD meeting on the 14<sup>th</sup> December 2023 in respect of this.</p> <p><b>ACTION:</b> NHS England to provide further information on the operation of the annual confirmation report mechanism, at the AGD meeting on the 14<sup>th</sup> December 2023.</p>	NHSE
4.2	<p><b>Reference Number:</b> NIC-561357-X0F3N-v1.3</p> <p><b>Applicant:</b> Evidera Ltd</p> <p><b>Application Title:</b> Health Burden of COVID-19 and Healthcare Resource Utilisation in England - INvestigation oF cOvid-19 Risk among iMmunocompromised populations</p> <p><b>Observer:</b> Mujiba Ejaz</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 20<sup>th</sup> October 2022 and the 16<sup>th</sup> June 2022.</p> <p>The application was previously presented at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 15<sup>th</sup> October 2022 and the 9<sup>th</sup> February 2022.</p> <p><b>Application:</b> This was an amendment and renewal application.</p> <p>The amendment is to widen the cohort of interest from 25% of the English population to 100% of the English population. (<i>Please note that this amendment request was withdrawn by NHS England; please refer to point 4.2.5 below</i>)</p>	

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

**Outcome of discussion:** It was noted that one GP specialist adviser present was not participating in the advice due to a potential conflict of interest. The group were **not** supportive of the application, and wished to draw to the attention of the SIRO the following substantive points, and suggested that the application be brought back to a future meeting:

**4.2.1** The group noted the feedback was restricted to significant / high-level points only and they were **not** providing in-depth comments on the application and / or supporting documents.

**4.2.2** The group noted that the application included a request for additional General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (COVID-19) (GDPPR) data. *(Please note that this amendment request was withdrawn by NHS England; please refer to point 4.2.5 below)*

**4.2.3** The Caldicott Guardian Team representative (and PAG Chair) advised the group that there was ongoing work within NHS England to support the ongoing operation of PAG following the merger between NHS Digital and NHS England; and that as a result of this, PAG were unable to review this application at the current time.

**4.2.4** NHS England advised the group that the PAG process discussed at the AGD meeting on the 27<sup>th</sup> July 2023 had been followed, up to a point, prior to this application being submitted to the group for review.

**4.2.5** Noting that PAG had not opined on the request for the additional GDPPR data, NHS England withdrew the request for that amendment, and for the widening of the cohort to 100% in-meeting, and asked that the application be considered as a 'renewal' only. NHS England confirmed that the amendment could be progressed once PAG were operational and were able to provide a review on the GDPPR aspect of the application, and as per the required process. The group noted the request.

**4.2.6 Separate to the application:** noting the discussion in respect of the operational aspect of PAG, AGD suggested that NHS England may wish to consider whether the valuable input from PAG, could be incorporated into the structure of AGD, in respect of the potential cost savings, use of existing or shared resources (for example, Secretariat) and efficiency of deployment of senior staff etc. The independent advisers noted that this had been suggested, and previously agreed, in respect of incorporating PAG into IGARD; and that the point had been expressly raised during the drafting of the AGD Terms of Reference.

**ACTION:** NHS England to consider incorporating PAG advice into the existing meeting structure of AGD and revert to AGD on this point.

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**4.2.7** The independent advisers noted the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had raised issues around transparency at their meetings on the 20<sup>th</sup> October 2022 **and** the 16<sup>th</sup> June 2022, and in addition the group noted the contractual statement in section 4 (Privacy Notice) of the data sharing agreement (DSA), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. The group were very disappointed that transparency remained an outstanding issue.

**4.2.8** The independent advisers also noted the request from IGARD on the 20<sup>th</sup> October 2022, that in line with [NHS Digital's \(now NHS England\) DARS Standard for Transparency \(fair processing\)](#), that a special condition be inserted in section 6 (Special Conditions) that draws the applicant's attention to the contractual statement in section 4 of the data sharing agreement (DSA) and Article 12 of the UK GDPR, whereby individuals have the right to be informed about the collection and use of their personal data. The group noted that the applicant did **not** appear to have complied with these contractual obligations set out in both section 4 and section 6 of the DSA.

**4.2.9** The group reviewed the Data Protection Impact Assessment (DPIA), which had been provided as a supporting document following circulation of the meeting papers pack; and noted the statement in this document that although there was an overarching privacy notice on the AstraZeneca website "*...we do not think it would be proportionate to provide a privacy notice to individuals...*". As a result of this, the group advised that they were **not** supportive of a renewal to the application at this time; and suggested that there was **no** further access to the data was given until such time as the contractual and legal obligations to furnish a UK GDPR compliant, publicly accessible transparency notice(s) for the lifetime of the agreement were complied with.

**4.2.10** In addition, the group noted concerns that the tenor of the comments within the DPIA suggested that AstraZeneca UK Limited were **not** taking full responsibility of its data controllership obligations, for example, the emphasis laid on the fact that they were not handling the data, which is not determinative of data controllership or their responsibilities as a Data Controller.

**4.2.11** Based on the discussion, the SIRO representative noted that the Data Controller has **not** met the contractual requirement in section 4 of the application; nor the special condition in section 6, and noted the importance emphasised by AGD with regards to that transparency (and the length of time that had elapsed since IGARD had first drawn this issue to the Data Controller's attention). The SIRO representative noted that on that basis NHS England would **not** be minded to support a renewal, nor an extension. Noting that NHS England would usually look in such circumstances to permit the applicant to "*hold but not otherwise process*", the SIRO representative noted that in this case, processing of the data was done within a Secure Data Environment (SDE), and that this would equate to removing access.



	<p>Subject to confirming that the Data Controller / Data Processor does <b>not</b> hold any data that would be covered under a data sharing agreement (DSA), it was advised that NHS England would therefore cease that access until the DSA special conditions are met. The SIRO representative agreed to work with NHS England's Data Access Request Service (DARS) to ensure that the applicant is aware of the obligation and requirement.</p>	
<p><b>4.3</b></p>	<p><b>Reference Number:</b> NIC-568980-P9W7B-v0.7</p> <p><b>Applicant:</b> University of Edinburgh</p> <p><b>Application Title:</b> Rates, Risks and Routes to Reduce Vascular Dementia</p> <p><b>Observer:</b> Steve Russell, Clare Wright</p> <p><b>Application:</b> This was a new application.</p> <p>The purpose of the application is for a UK-wide observational study of cognitive, physical and neuropsychiatric complications after stroke. Patients can experience memory, thinking or mood changes, or dementia, after a stroke but enough is not yet known about how to treat these conditions. The study are looking at these conditions to help more people to make a better recovery.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:</p> <p><b>4.3.1</b> The group noted that a 'consent waiver' had been used to add seven participants who did not have capacity to consent during the COVID-19 pandemic when visitors were not permitted in hospitals thus consultee advice could not be sought. It was noted that neither consent nor consultee advice had been obtained for these seven individuals subsequently. The group queried what the legal basis was to address Common Law Duty of Confidentiality (CLDoC) in respect of these seven individuals and advised the SIRO that if this could not be answered, then the data should not flow.</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><b>4.3.2</b> The Data Protection Office (DPO) representative noted that the patient information sheet, provided as a supporting document (SD3.0), referred to the limited right of data subjects; but noted that this was <b>not</b> reflected in the privacy notice (link provided in SD3.0). It was suggested that the privacy notice was updated to ensure there was transparency on the limited right of data subjects.</p> <p><b>4.3.3</b> The group noted in the internal application assessment form the queries raised by NHS England with the applicant, in respect of data controllership; and advised that whilst they were content with the responses received from the applicant, they</p>	

did note in the privacy notice, that the sponsor's DPO was listed as a contact for further information. The group queried whether this was appropriate and suggested that NHS England may wish to explore this further with the applicant and in line with the [NHS England DARS Standard for Data Controllers](#).

**4.3.4** The independent advisers noted that the standard special condition had been added to section 6 (Special Conditions) of the application, setting out the restraints of the Medicines dispensed in Primary Care (NHSBSA) data as per the [NHS Business Services Authority \(NHSBSA\) medicines data Direction](#); however, noting that at the AGD meeting on the 2<sup>nd</sup> November 2023 (as part of the discussion for NIC-08472-V9S6K UK Biobank), the SIRO representative had advised that although the [Direction](#) did set out constraints of the use of data, it was not the only legal gateway that NHS England had to share data. It was therefore suggested that NHS England consider whether the NHSBSA special condition was required, dependant on which legal basis was being relied on for the processing of this data, and that the application was updated as may be appropriate.

**4.3.5 Separate to the application:** the group reiterated the point made at the AGD meeting on the 2<sup>nd</sup> November 2023, that for transparency and public trust, NHS England should explore how this could be explained, since the public may take at face value the constraints as set out in a Direction and as published on the website, and may not envisage NHS England using other legal powers to set aside restrictions in a Direction.

**4.3.6 Separate to the application:** Noting the NHS BSA presentation to the group on the 20<sup>th</sup> July 2023, and that the SIRO representative at AGD on the 24<sup>th</sup> August 2023 had noted that the [Direction](#) was being reviewed and would be presented back to the group in due course; the group also reiterated a request made at the AGD meeting on the 2<sup>nd</sup> November 2023 for a note setting out the work undertaken to reach the position set out in 4.3.4 above, alongside the work to review the [Direction](#) be presented to AGD as soon as practicable. In addition to the transparency and public trust points raised in 4.3.5, the group queried whether this view would have retrospective or prospective impact on other applications using this dataset, or indeed any other applications where there were restrictions on use or dissemination of data due to wording in Directions.

**ACTION:** NHS England to provide a note outlining the work undertaken to allow the applicant to use the data as outlined in the DSA, and to provide a copy of the work undertaken to review the [Direction](#).

**4.3.7** Noting the final statement in section 5(a) (Objective for Processing) "*A sub-studies sub-Committee of the R4VaD SSC considers proposals for sub-studies*"; the independent advisers noted that any sub-studies would need to be within the parameters of the purpose outlined elsewhere in section 5(a). It was suggested that NHS England discuss this further with the applicant and either update section 5(a) to be clear that any sub-studies must be within the parameters of the purpose already outlined, or that clarification of the sub-studies were added to section 5(a); and that

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	<p>NHS England may wish to seek a further review from the group on this aspect of the application.</p> <p><b>4.3.8</b> The group commended the applicant on the excellent patient and public involvement and engagement (PPIE).</p> <p><b>4.3.9</b> The independent advisers noted the information in the internal application assessment form to the “<i>remote access standard</i>”; and were advised by NHS England that some standard wording in respect of remote access had been developed.</p> <p><b>4.3.10 Separate to the application:</b> it was suggested by the independent advisers that the group are provided with the remote access standard wording to review; and queried whether this could be developed into an NHS England DARS Remote Access Standard.</p> <p><b>ACTION:</b> NHS England DARS to provide the group with the remote access standard wording for the group to review.</p> <p><b>ACTION:</b> NHS England to consider whether the remote access standard wording could be developed into an NHS England DARS Remote Access Standard.</p>	<p>NHSE</p> <p>NHSE</p>
<p><b>4.4</b></p>	<p><b>Reference Number:</b> NIC-707577-H0F4Z-v0.9</p> <p><b>Applicant:</b> University of Leeds</p> <p><b>Application Title:</b> Penicillin allergy status and its effect on antibiotic prescribing, patient outcomes, and antimicrobial resistance</p> <p><b>Observers:</b> Suzanne Shallcross, Suzanne Hartley</p> <p><b>Application:</b> This was a new application.</p> <p>The purpose of the application is for a research project, where the primary objective is to determine whether the Penicillin allergy assessment pathway (PAAP) intervention is clinically effective in increasing the proportion of patients prescribed penicillin to treat conditions where a penicillin is the first-line recommended antibiotic.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> The group were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p><b>4.4.1</b> The independent advisers noted and commended the work undertaken by NHS England’s Data Access Request Service (DARS) on the content of the internal application assessment form, which supported the review of the application.</p> <p><b>4.4.2</b> The group queried whether the applicant would also benefit from receiving <a href="#">Electronic Prescribing and Medicines Administration (EPMA) Data</a>, which would provide richer information with regard to medicines actually dispensed in secondary</p>	

care, as opposed to just what a GP had prescribed (access to GP data) and dispensed (access to NHSBSA data); and noted that they would be supportive of this data flowing without a further review from the group for this amendment, and subject to any amendment put forward by the applicant to the application.

**4.4.3** The independent advisers noted that the standard special condition had been added to section 6 (Special Conditions) of the application, setting out the restraints of the Medicines dispensed in Primary Care (NHSBSA) data as per the [NHS Business Services Authority \(NHSBSA\) medicines data Direction](#); however, noting that at the AGD meeting on the 2<sup>nd</sup> November 2023 (as part of the discussion for NIC-08472-V9S6K UK Biobank), the SIRO representative had advised that although the [Direction](#) did set out constraints of the use of data, it was not the only legal gateway that NHS England had to share data. It was therefore suggested that NHS England consider whether the NHSBSA special condition was required dependent on which legal basis was being relied on for the processing of this data, and that the application was updated as may be appropriate.

**4.4.4 Separate to the application:** the group reiterated the point made at the AGD meeting on the 2<sup>nd</sup> November 2023, that for transparency and public trust, NHS England should explore how this could be explained, since the public may take at face value the constraints as set out in a Direction and as published on the website, and may not envisage NHS England using other legal powers to set aside restrictions in a Direction.

**4.4.5 Separate to the application:** noting the NHS BSA presentation to the group on the 20<sup>th</sup> July 2023, and that the SIRO representative at AGD on the 24<sup>th</sup> August 2023 had noted that the [Direction](#) was being reviewed and would be presented back to the group in due course; the group also reiterated a request made at the AGD meeting on the 2<sup>nd</sup> November 2023, for a note setting out the work undertaken to reach the position set out in 4.4.3 above, alongside the work to review the [Direction](#) be presented to AGD as soon as practicable. In addition to the transparency and public trust points raised in 4.4.4, the group queried whether this view would have retrospective or prospective impact on other applications using this dataset, or indeed any other applications where there were restrictions on use or dissemination of data due to wording in Directions.

**ACTION:** NHS England to provide a note outlining the work undertaken to allow the applicant to use the data as outlined in the DSA, and to provide a copy of the work undertaken to review the [Direction](#).

**4.4.6** Noting the content of the privacy notice, the Data Protection Office (DPO) representative suggested that this was reviewed and updated to ensure the references to “*information from NHS England*” were updated to align with the text elsewhere in the document that more accurately refers to “*data from NHS England*”.

**4.4.7** In addition, it was suggested by the independent advisers that the privacy notice was reviewed and updated as may be necessary to ensure that the language

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	<p>was retrospective as opposed to prospective, to avoid any confusion for cohort members who had already provided consent.</p> <p><b>4.4.8</b> The group suggested that for clarity, section 5 (Purpose / Methods / Outputs) of the application be updated to be explicitly clear as to which organisations are receiving what data, and when; noting that this was currently unclear.</p> <p><b>4.4.9</b> In respect of the data minimisation outlined in section 5(a) (Objective for Processing) of the application, the SIRO representative asked that this be updated to remove the text outlining how the applicant would minimise the data; and update to be clear that NHS England would be minimising the data by cohort, participant and data randomisation.</p> <p><b>4.4.10</b> The independent advisers noted the information in respect of The Phoenix Partnership (TPP) in section 5(e) (Is the Purpose of this Application in Anyway Commercial of the application; and suggested that this was replicated for transparency in section 5(a), in line with <a href="#">NHS England's DARS Standard for Objective for Processing</a>.</p> <p><b>4.4.11</b> The Data and Analytics Representative queried the special condition in section 6 of the application in relation to data destruction, noting the potentially restrictive date; and following a further discussion by the group, it was suggested that the special condition was removed, noting that the data would be destroyed at the end of the term of the data sharing agreement (DSA), and therefore did not require further specification via a special condition.</p> <p><b>4.4.12</b> NHS England advised the group, that following submission of the application, the applicant had updated their privacy notice to include details of the identifiers to be shared with NHS England. The group noted the update.</p> <p><b>4.4.13</b> In addition, NHS England noted that the statement in section 5(b) (Processing Activities) "<i>The University of Leeds stores Data on the Cloud provided by <b>The University of Leeds</b></i>" was incorrect and should state that Cloud was provided by "<i>Microsoft</i>", and that this would be updated. The group noted the update.</p>	
<p><b>4.5</b></p>	<p><b>Reference Number:</b> NIC-446852-L0T4R-v0.2</p> <p><b>Applicant:</b> University College London (UCL)</p> <p><b>Application Title:</b> RESOLVE UK - Randomised Evaluation of Sodium dialysate Levels on Vascular Events</p> <p><b>Observer:</b> Frances Perry</p> <p><b>Application:</b> This was a new application.</p> <p>The purpose of the application is for a study to assess the efficacy of a strategy of adopting a default dialysate sodium of 137 mmol/l compared with a default dialysate sodium of 140 mmol/l in reducing major cardiovascular events and death in recipients of maintenance dialysis. The primary outcome is a safety and efficacy</p>	

endpoint and is the composite of hospitalised myocardial infarction, hospitalised stroke, and all-cause death.

NHS England were seeking advice on the following points:

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:

**4.5.1** The independent advisers queried the role of the University of Sydney, noting the content of the protocol provided as a supporting document (SD1.0) that appeared to have been dictated by the University of Sydney; and suggested that NHS England seek assurance from the applicant that the University of Sydney are **not** responsible for determining the purpose and means of processing, and are therefore **not** carrying out any data controllership activities, in line with the [NHS England's DARS Standard for Data Controllers](#).

**4.5.2** If the University of Sydney are considered a joint / sole Data Controller, then the internal application assessment form and the application should be updated as may be necessary to reflect the factual scenario.

**4.5.3** Noting that it seemed that all patients at a specific unit would receive the same intervention, whether or not they opted out of their confidential information being included in the study, the independent advisers queried the content of the transparency materials, and noted that the poster provided as a supporting document (SD4.2) and the leaflet (SD4.0) appeared to be incorrect in respect of the reference to participation being "*voluntary*"; and suggested that the applicant review these as soon as practicable and update to ensure the details were factually correct.

**4.5.4** The independent advisers queried whether, from an ethical perspective, s251 was the preferable basis for the flow of data, noting that consent may have been viable since the applicant appeared to be in regular contact with the cohort; however the group did note that the reasoning put forward by the applicant and that this had been considered by Health Research Authority Confidentiality Advisory Group (HRA CAG) when considering the s251 support.

In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:

**4.5.5** In respect of further updates to the transparency materials, the independent advisers suggested that the applicant refer to the HRA CAG process and Regulation 5 of The Health Service (Control of Patient Information Regulations (COPI) 2002.

**4.5.6** The independent advisers noted the references to "*fully anonymised study data*" being shared with the University of Sydney in the transparency materials; and noting that it was unclear what this meant, suggested that further clarification was provided in the transparency materials.

	<p><b>4.5.7</b> The independent advisers noted the technical language and acronyms in section 5 (Purpose / Methods / Outputs) of the application; and suggested that this was updated to ensure it was written in a manner suitable for a lay reader.</p> <p><b>4.5.8</b> Noting the references to “<i>consent forms</i>” in section 5(a) (Objective for Processing) of the application, it was suggested that the independent advisers that these were reviewed and amended, or removed if they were not relevant because s251 was being relied on for the legal basis.</p> <p><b>4.5.9</b> The independent advisers queried if there was another route for this study to obtain the information they required, for example via the renal registry, noting that all the participants would be in this registry; and suggested that NHS England give this further consideration.</p>	
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**EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL**

<p><b>5.1</b></p>	<p><b>Reference Number:</b> NIC-147750-8GS7S-v4.6</p> <p><b>Applicant:</b> University of Cambridge</p> <p><b>Application Title:</b> ADDITION: Anglo-Dutch-Danish study of Intensive Treatment In peOple with screenN-detected diabetes (MR798)</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 17<sup>th</sup> February 2022 and the 10<sup>th</sup> January 2019</p> <p>The SIRO approval was for a six-month extension.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval.</p> <p>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>	
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<p><b>5.2</b></p>	<p><b>Reference Number:</b> NIC-91972-S9W9T-v8.2 3M United Kingdom Plc</p> <p><b>Applicant:</b> NIC-91972-S9W9T-v8.2 3M United Kingdom Plc</p> <p><b>Application Title:</b> Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 27<sup>th</sup> October 2022, 3<sup>rd</sup> February 2022, 17<sup>th</sup> June 2021, 21<sup>st</sup> May 2020, 30<sup>th</sup> April 2020, 9<sup>th</sup> April 2020, 14<sup>th</sup> March 2019, 17<sup>th</sup> January 2019, 1<sup>st</sup> November 2018 and the 1<sup>st</sup> February 2018.</p>	
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	<p>The SIRO approval was for a three-month extension, with a request for the application to be brought back to a future AGD meeting.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval.</p> <p>The group thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p><b>5.2.1</b> The independent advisers noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and supported the SIRO view that these required further development, in line with <a href="#">NHS England’s DARS Standard for Expected Measurable Benefits</a>.</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>AGD Operations</b>		
6	<p><b>Statutory Guidance</b></p> <p>The independent advisers again noted the reference to reviewing materials in accordance with “<i>a clearly understood risk management framework</i>” within the published <a href="#">Statutory Guidance</a> and advised that they were <b>not</b> 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 26<sup>th</sup> June 2023, and was answered by Lord Markham on the 5<sup>th</sup> July 2023: <a href="#">Written questions, answers and statements – UK Parliament</a>.</p> <p>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 “...<i>using a clearly understood risk management framework, precedent approaches and standards that requests must meet...</i>”, suggested that the risk management framework is <b>separate</b> to the DARS Standards and Precedents, and asked that this be clarified by NHS England.</p> <p>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.</p> <p><b>ACTION:</b> NHS England SIRO representative to provide a written response addressed to AGD with further clarity on the risk management framework.</p>	GC
7	<b>AGD Terms of Reference (ToR)</b>	



	<p>The independent advisers noted that over-five months had passed since the <a href="#">Statutory Guidance</a> had been published, requiring a ToR to be agreed and published.</p> <p>Jackie Gray, Director of Privacy, Transparency, and Trust (PTT) (formally Privacy, Transparency, Ethics and Legal) attended the meeting, to advise the group that the draft AGD ToR had been updated following feedback from stakeholders and comment previously made by AGD back in June 2023; and that an updated version of the ToR would be available on Monday 20<sup>th</sup> November 2023; with a stakeholder workshop, that would include representatives from AGD and AGD Secretariat taking place on Monday 27<sup>th</sup> November, to discuss this document and any further suggested updates and amendments to the draft ToR.</p> <p>The group noted and thanked Jackie for the update, and looked forward to receiving the updated ToR document on Monday, 20<sup>th</sup> November 2023, and the subsequent workshop.</p> <p>In addition, the group noted that they looked forward to further information on the timeline for progressing the ToR, including when this would be considered by the NHS England Board / subcommittee of the Board.</p> <p><b>ACTION:</b> The SIRO representative to provide further information to the group on the timeline for progressing the draft ToR, including when this would be considered by the NHS England Board / subcommittee of the Board, following the workshop on the 27<sup>th</sup> November 2023.</p>	GC
8	<p><b>Standard operating procedures</b></p> <p>The ongoing forward plan of work for creating Standard Operating Procedures was discussed and noted that this could not progress further without sight of the final ToR.</p>	To note
<b>Any Other Business</b>		
9.1	<p><b>Steve Russell – Welcome</b></p> <p>The group noted that the NHS England Chief Delivery Officer, National Director for Vaccinations and Screening and Senior Information Risk Owner (SIRO), Steve Russell, had attended part of the meeting to meet the group; and to observe meeting discussions.</p> <p>On behalf of the NHS England Board, Steve thanked the group for their work to date as part of the interim advisory group for data.</p> <p>The group thanked Steve for attending and looked forward to seeing him again at a future AGD meeting.</p>	
9.2	<p><b>Reviewing The Health Service (Control of Patient Information) Regulations 2002</b></p>	

The independent advisers discussed the updated COPI proposal document that had been shared with them on the 30<sup>th</sup> October 2023 for comments, from the Department of Health and Social Care (DHSC) in respect of the 'Responsible use of information to support the delivery of health and care: reviewing The Health Service (Control of Patient Information) Regulations 2002'.

It was noted that comments on this document were due back to DHSC on the 24<sup>th</sup> November 2023, and that a further / final discussion on the comments / feedback on this document from the independent advisers would take place at the AGD meeting on the 23<sup>rd</sup> November 2023.

The group noted that colleagues from DHSC had attend the meeting to listen to initial high-level thoughts / comments from the independent advisers, prior to receiving the formal feedback on the 24<sup>th</sup> November 2023. The group thanked DHSC colleagues for attending.

### 9.3 UK Biobank

The independent advisers noted the recent [article](#) in The Guardian, raising concerns around de-identified data being shared with insurance companies; and were advised by the SIRO representative that NHS England were aware of the article and were considering the implications, if any, for NHS England and that he would update the group in due course.

The independent advisers noted and thanked the SIRO representative for the update.

### 9.4 Independent adviser recruitment / day rate

The independent advisers reiterated concerns with the Chief Delivery Officer, National Director for Vaccinations and Screening and SIRO and the Director of Privacy, Transparency, and Trust (PTT) that were raised with the SIRO representative at the AGD meeting on the 9<sup>th</sup> November 2023, in respect a number of recruitment / day rate issues remained outstanding following the move from the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) to the interim data advisory group (NHS England); and wished to note to NHS England the frustration for current independent advisers; and that this may be a risk to NHS England for future recruitment to the independent adviser roles.

The Chief Delivery Officer, National Director for Vaccinations and Screening and SIRO and the Director of Privacy, Transparency, and Trust (PTT), noted the concerns raised, and advised that work was ongoing, and that an update would be provided as soon as possible.

### Meeting Closure

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