

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

Thursday, 11<sup>th</sup> May 2023

09:30 – 17:00

*(Remote meeting via videoconference)*

<b>INDEPENDENT ADVISERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role:</b>
Paul Affleck (PA)	Specialist Ethics Adviser
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser (in attendance for item 7 only)
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser (not in attendance for item 10)
Jenny Westaway (JW)	Lay Adviser
<b>NHS ENGLAND STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Michael Chapman (MCh)	Data and Analytics representative ( <b>Presenter:</b> item 10)
Garry Coleman (GC)	Senior Information Risk Owner (SIRO) representative
Cath Day (CD)	Data Access Request Service Senior Approval Team (DARS SAT) ( <b>SAT Observer:</b> items 5.4 to 5.5)
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) ( <b>SAT Observer:</b> items 5.1 to 5.3)
Dan Goodwin (DG)	Data Access Request Service (DARS) ( <b>Presenter:</b> item 5.5)
Dr Phil Koczan (PK)	Deputy Caldicott Guardian ( <b>Observer:</b> items 1, 7 and 10)
Dickie Langley (DL)	Data Protection Officer (DPO) representative (Delegate for Jon Moore) ( <b>Presenter:</b> item 7)
Jon Moore (JM)	NHS England Data Protection Office Representative (attending as the DPO Representative for item 7 only)
Karen Myers (KM)	Secretariat Team
Dr. Jonathan Osborn (JO)	Caldicott Guardian Team representative
Terry Service (TS)	Data Access Request Service ( <b>Presenter:</b> item 10)

Eva Simmonds (ES)	Programme Director, Digital Primary Care, Transformation Directorate ( <b>Observer:</b> item 7)
Ming Tang (MT)	Chief Data and Analytics Officer, Data & Analytics Directorate (In attendance for item 1) ( <b>Presenter:</b> item 7)
James Watts (JW)	Data Access Request Service (DARS) ( <b>Presenter:</b> items 5.1 to 5.3)
Vicki Williams (VW)	AGD Secretariat Team ( <b>Presenter:</b> items 8 and 9.1)
Clare Wright (CW)	Data Access Request Service (DARS) ( <b>Presenter:</b> item 5.4)
<b>INDEPENDENT ADVISERS NOT IN ATTENDANCE:</b>	
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser

<b>1</b>	<p><b>Welcome and Introductions</b></p> <p>The NHS England Senior Information Risk Owner (SIRO) Representative advised attendees that, noting the statutory guidance and the AGD Terms of Reference (ToR) had not yet been agreed, the meeting could not be held under the draft ToR, until they have been approved, and recognised that the draft ToR may change as the statutory guidance evolves. As NHS England would like to seek advice on a number of areas, the NHS England SIRO Representative therefore proposed that:</p> <ul style="list-style-type: none"> <li>• Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings;</li> <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; 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>
<b>2</b>	<b>Review of previous AGD minutes:</b>

	The minutes of the 4 <sup>th</sup> May 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.
<b>3</b>	<p><b>Declaration of interests:</b></p> <p>Paul Affleck noted a professional link to the University of Leeds (NIC-656830-C3F5S) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Prof Nicola Fear noted a professional link to the team at the University of Leeds (NIC-656830-C3F5S), but noted no specific connections with the application and it was agreed that this was not a conflict of interest.</p> <p>Dr. Geoffrey Schrecker noted a professional link to Q-Research (NIC-656839-K5V9L) and would not be part of the discussion. It was agreed that Dr. Schrecker would <b>not</b> remain in the room for the discussion of that application.</p> <p>Michael Chapman noted professional links to the Cancer Research's Data Advisory Group (NIC-656849-P9M6C, NIC-656839-K5V9L, NIC-334952-R5M7K) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p>
<b>BRIEFING PAPER(S):</b>	
<b>4.1</b>	<p><b>Title:</b> Secondary Care ePMA Data Collection 2023</p> <p><b>Presenter:</b> None</p> <p><b>Previous Reviews:</b> The Community Services Data Set (CSDS) briefing papers were previously presented at the AGD meeting on the 30<sup>th</sup> March 2023.</p> <p>The updated briefing paper provided details of the proposal to collect patient-level (identifiable) data for medicines prescribed and administered to patients by secondary care providers in England, when this is recorded on electronic Prescribing and Medicines Administration (ePMA) systems. NHS England aim to make the data comparable and make it available for analysis purposes to organisations with a lawful basis.</p> <p><b>Outcome of discussion:</b> The group welcomed the updated briefing paper and made the following observations / comments:</p> <p><b>4.1.1</b> The independent advisers noted, from NHS England representatives in the meeting, that colleagues within NHS England's Privacy, Transparency and Ethics (PTE) were not aware that this updated briefing paper was being discussed at AGD; and that the legal basis was currently being discussed with the Department of Health and Social Care (DHSC).</p> <p><b>4.1.2</b> The independent advisers reiterated a point made previously by the group with regard to the content of the draft NHS England privacy notice in respect of this data collection. Noting that the draft privacy notice had been updated, it was suggested by the independent advisers, that this was amended further to either remove or update the existing examples provided, to provide further information on how the data is used.</p> <p><b>4.1.3</b> The independent advisers noted the information within the draft privacy notice, in respect of opt-outs; and suggested that this was potentially giving a misleading impression, noting that the data was received under a Direction, and therefore a National Data Opt-out (NDO) would <b>not</b> apply to data flowing to NHS England. The independent advisers suggested that this should be made clear.</p>

	<p><b>4.1.4</b> Separate to the briefing paper, the independent advisers reiterated the point made previously, that in relation to the standard wording in the Data Protection Impact Assessment (DPIA) in respect of the NDO that had been suggested by NHS England's Caldicott Guardian Team representative; that the group would liaise with the Caldicott Guardian Team representative separately in respect of some suggested amendments.</p> <p><b>ACTION:</b> AGD to liaise with the Caldicott Guardian Team in respect of the NDO text within the DPIA.</p> <p><b>4.1.5</b> The independent advisers reiterated their points made previously, with regard to references to "gender" within the transparency materials and DPIA. Noting the response from NHS England on this point, it was noted that the definition was confused and suggested to NHS England that this should be transparent.</p> <p><b>4.1.6</b> The independent advisors reiterated their points made previously, that it was the intention of NHS England to publish the DPIA; and had queried the restriction on sending identifiable data back to the NHS Trust who originally flowed the data to NHS England, as per the advice from NHS England's PTE. The independent advisers noted the response from NHS England that in respect of the specific restriction highlighted, PTE had advised that there were general statutory dissemination powers, that would overrule this. The independent advisers, with the support of the NHS England DPO representative in attendance, queried whether a general dissemination power could, or should, overrule a specific restriction.</p> <p><b>4.1.7</b> Separate to this application, the independent advisers advised NHS England that Directions should <b>not</b> contain restrictions if they can be overruled by general dissemination powers, or, alternatively, such general dissemination powers should be noted in the Direction or transparency materials.</p> <p><b>4.1.8</b> In respect of the previous point raised in respect of the linkage, which currently restricted it to NHS England datasets, the independent advisers queried the response from NHS England's PTE on this point and advised that they would encourage the ability to linkage to other non-NHS England datasets and suggested that there should <b>not</b> be a restriction on linkage.</p> <p><b>4.1.9</b> The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by AGD).</p>
<b>EXTERNAL DATA DISSEMINATION REQUESTS:</b>	
5.1	<p><b>Reference Number:</b> NIC-656849-P9M6C-v1.6</p> <p><b>Applicant:</b> University of Oxford</p> <p><b>Application Title:</b> Hodgkin and Non-Hodgkin Lymphoma: Using routine data to identify recurrence, and variation in the use of radiotherapy (ODR1920_011)</p> <p><b>Presenter:</b> James Watts</p> <p><b>SAT Observer:</b> Louise Dunn</p> <p><b>Previous Reviews:</b> The NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure; and therefore, had not had a previous independent review.</p> <p><b>Application:</b> This was an extension and renewal application.</p>

	<p>The purpose of the application is for a research project, to help improve the understanding into the use of radiotherapy, recurrence rates of lymphoma, and late toxicity of Hodgkin and Non-Hodgkin Lymphoma.</p> <p>Should the 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>5.1.1</b> The independent advisers queried if the applicant had a privacy notice, noting that they had been unable to locate one online; and were advised by NHS England that they had discussed this with the applicant, who had confirmed that they have an organisational privacy notice, but <b>not</b> a study specific privacy notice. NHS England had advised the applicant of the contractual requirement to have a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice throughout the life of the data sharing agreement (DSA). The independent advisers noted the verbal update from NHS England and advised that they were supportive of the feedback already provided to the applicant, noting that the data requested was <i>personal data</i>.</p> <p><b>5.1.2</b> In addition, the independent advisers suggested that a special condition was added to section 6 (Special Conditions), that a UK GDPR compliant, publicly accessible transparency notice was maintained, throughout the life of the DSA.</p> <p><b>5.1.3</b> Separate to the application, the SIRO representative advised that they would engage with the University of Oxford Information Governance (IG) Team, to ensure there was clarity, around the privacy notice requirements.</p> <p><b>5.1.4</b> NHS England advised the group, that the text used in section 3(c) (Patient Objections) in respect of opt-outs would be reviewed and updated, to ensure that it aligned with the text used in other NDRS applications. The group noted the verbal update from NHS England, however queried the content of the proposed wording (shared in-meeting), particularly the reference to the “<i>Health and Social Care Act 2012</i>” as the Act containing the relevant data definition for the purposes of application of the National Data Opt-out (NDO) ; and suggested that this should be clarified with NHS England’s Privacy, Transparency and Ethics (PTE) and updated to reflect the correct statutory reference (the definition of Confidential Patient Information (CPI) in the 2006 NHS Act). In addition, the independent advisers noted that the definition of CPI in the 2006 Act, does <b>not</b> include all instances when the duty of confidence applies and so care should be taken with statements, such as that in the proposed wording, that information is not subject to a duty of confidence it does not fall within a statutory definition.</p> <p><b>5.1.5</b> In addition, and notwithstanding the verbal update from NHS England in respect of section 3(c) being updated to align with the <i>correct</i> text used in other applications; the independent advisers suggested that it was made clear that the National Data Opt-out would <b>not</b> be applied.</p> <p><b>5.1.6</b> The independent advisers suggested that, for transparency, section 5 (Purpose / Methods / Outputs) was updated to include details of the special features of the National Disease Registration Service (NDRS) opt-out, with a link to the relevant <a href="#">online information</a>.</p>	
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	<p><b>ACTION:</b> (Noting the reference to homeworking in section 5(b)), NHS England to provide its position to AGD on remote access (<i>as previously requested and agreed at the AGD meeting on the 2<sup>nd</sup> February 2023</i>).</p> <p><b>5.1.17</b> The independent advisers also suggested that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) were updated to reflect how the benefits would impact on patients and the public, in line with <a href="#">NHS England's DARS Standard for Expected Measurable Benefits</a>.</p>	NHSE
5.2	<p><b>Reference Number:</b> NIC-656830-C3F5S-v1.2</p> <p><b>Applicant:</b> University of Leeds</p> <p><b>Application Title:</b> Is the survival of teenagers and young adults with cancer associated with the dose and intensity of chemotherapy that they receive? (ODR1819_148)</p> <p><b>Presenter:</b> James Watts</p> <p><b>SAT Observer:</b> Louise Dunn</p> <p><b>Previous Reviews:</b> The NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure; and therefore, had not had a previous independent review.</p> <p><b>Application:</b> This was an extension application.</p> <p>The purpose of the application is for a study, to investigate whether the dose intensity of systemic anticancer agents (chemotherapy) received by Teenagers and Young Adults (TYA) with cancer impacts on their survival. It will also determine whether any factors exist which influence a patient's ability to receive the ideal amount of chemotherapy.</p> <p>Should the 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>5.2.1</b> The independent advisers queried if the applicant had a privacy notice, noting that they had been unable to locate one online.</p> <p><b>5.2.2</b> The independent advisers suggested that a special condition was added to section 6 (Special Conditions), that a UK GDPR compliant, publicly accessible transparency notice was maintained, throughout the life of the DSA.</p> <p><b>5.2.3</b> NHS England advised the group, that the text used in section 3(c) (Patient Objections) in respect of opt-outs would be reviewed and updated as necessary.</p> <p><b>5.2.4</b> In addition, and notwithstanding the verbal update from NHS England in respect of section 3(c) being updated to align with the correct text used in other applications; the independent advisers suggested that it was made clear that the National Data Opt-out would <b>not</b> be applied.</p> <p><b>5.2.5</b> The independent advisers suggested that, for transparency, section 5 (Purpose / Methods / Outputs) was updated to include details of the special features of the National Disease Registration Service (NDRS) opt-out, with a link to the relevant <a href="#">online information</a>.</p>	

	<p><b>5.2.6</b> Separate to this application, the independent advisers suggested that all DARS applications requesting NDRS data, contain information within section 5, in respect of the special features of the NDRS opt-out.</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>5.2.7</b> The group welcomed the application and noted the importance of the study.</p> <p><b>5.2.8</b> Noting the conflicting information in section 5(b) (Processing Activities) in respect of data linkage, the independent advisers suggested that this was reviewed and update with clarification of what data is being linked and with what datasets, in line with <a href="#">NHS England's DARS Standard for processing activities</a>.</p> <p><b>5.2.9</b> Separate to this application, NHS England advised, that is respect of the linkage query, the questions posed to the applicant, to support the completion of the internal application assessment form, should be updated, to ensure that clarity of the linkage is determined as part of this process.</p> <p><b>5.2.10</b> The independent advisers queried the special condition in section 6, in relation to the Cloud provider, in particular the statement that “<i>An amendment must be submitted...</i>”; and suggested that this was updated to reflect that the amendment must also be approved before the change in data processor.</p>	
<b>5.3</b>	<p><b>Reference Number:</b> NIC-656839-K5V9L-v1.7</p> <p><b>Applicant:</b> University of Oxford</p> <p><b>Application Title:</b> QResearch and Q-Covid (ODR1819_247)</p> <p><b>Presenter:</b> James Watts</p> <p><b>SAT Observer:</b> Louise Dunn</p> <p><b>Linked applications:</b> This application is linked to NIC-382794-T3L3M.</p> <p><b>Previous Reviews:</b> The NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure; and therefore, had not had a previous independent review.</p> <p><b>Application:</b> This was a renewal, extension and amendment application.</p> <p>The amendments are to <b>1)</b> use the NDRS National Radiotherapy Dataset (RTDS) and NDRS Systemic Anti-Cancer Therapy Dataset (SACT) data for Q-Research; and, onward share the RTDS and SACT data via the Q-Research database with other UK Universities; and <b>2)</b> to expand the temporality of the RTDS and SACT data, receiving data from 2010 onwards.</p> <p>Should the 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>5.3.1</b> NHS England advised the group, that the text used in section 3(c) (Patient Objections) in respect of opt-outs would be reviewed and updated as necessary.</p> <p><b>5.3.2</b> An NHS England representative noted the information in the application that stated the National Data Opt-out (NDO) <b>would not</b> be applied conflicted with the QResearch <a href="#">website</a> that</p>	



	<p>states NDO <b>would</b> be applied; and suggested that this was discussed with the applicant, and that the application or the website was updated to ensure they were aligned in respect of the NDO.</p> <p><b>5.3.3</b> In addition, the independent advisers noted that the QResearch <a href="#">website</a> stated that the data was “<i>anonymised</i>”, and advised that they did not support this description of the data; and suggested that NHS England discuss this further with the applicant.</p> <p><b>5.3.4</b> The independent advisers suggested that for transparency, section 5 (Purpose / Methods / Outputs) was updated to include details of the special features of the National Disease Registration Service (NDRS) opt-out, with a link to the relevant <a href="#">online information</a>.</p> <p><b>5.3.5</b> Separate to this application, the independent advisers suggested that all DARS applications requesting NDRS data, contain information within section 5, in respect of the special features of the NDRS opt-out.</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>5.3.6</b> The SIRO representative noted that the linked application NIC-382794-T3L3M had been audited, and suggested that this application should align with NIC-382794-T3L3M in respect of the sub-licensing arrangements / information.</p> <p><b>5.3.7</b> The independent advisers noted the content of the sub-licensing agreement provided as a supporting document, and suggested that this was updated, to <i>require outputs to use the NDRS citation</i>.</p> <p><b>5.3.8</b> The independent advisers noted and supported the advice to the applicant from NHS England, as outlined in the internal application assessment form, in respect of the benefit of having patient and public involvement and engagement (PPIE) on the QResearch Scientific Committee.</p> <p><b>5.3.9</b> The independent advisers noted that they could not see from the application or information online about the QResearch Scientific Committee, whether there was a transparent assessment made of whether sub-licensing applications might have commercial benefit, as well as public benefit. The independent advisers suggested that NHS England draw the applicant's attention to the recently published <a href="#">National Data Guardian guidance on benefits</a>, so that they could ensure their approval processes took this into account.</p>	
<b>5.4</b>	<p><b>Reference Number:</b> NIC-403429-N2X9B-v0.16</p> <p><b>Applicant:</b> Medway NHS FT</p> <p><b>Application Title:</b> inflammatory bowel disease (IBD) surgical care during the COVID19 outbreak: a retrospective analysis of the practice and outcomes described in the Hospital Episode Statistics database</p> <p><b>Presenter:</b> Clare Wright</p> <p><b>SAT Observer:</b> Cath Day</p> <p><b>Application:</b> This was a new application.</p> <p>The purpose of the application is for a study, to retrospectively analyse the practice and surgical outcomes of Inflammatory bowel disease (IBD) patients during the COVID-19 pandemic. The data would also allow the study to analyse any trends or patterns between</p>	

	<p>geographical areas and to identify any regions which had disproportionately poorer / better surgical outcomes than others.</p> <p>Should the 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>5.4.1</b> The independent advisers commended NHS England on the work undertaken on the application.</p> <p><b>5.4.2</b> NHS England advised the group that the application and internal application assessment form were inconsistent when referring to the funding sources; and advised that they would be revised and updated to reflect that Medway NHS FT were the funder. The group noted the verbal update by NHS England.</p> <p><b>5.4.3</b> The independent advisers noted, within the internal application assessment form, that there had been some discussions with the applicant in respect of the honorary contract; and advised that, as per usual process / advice, the honorary contract should be counter-signed by the individual's substantive employer. The independent advisers suggested that NHS England ensure that written confirmation was received from the applicant that the document had been counter-signed by the employing body; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p><b>5.4.4</b> Separate to this application, the SIRO representative noted that the length of this data sharing agreement (DSA) had been assessed in line with <a href="#">NHS England's DARS Standard Term of Data Sharing Agreement</a>; however, advised that this DARS Standard would be reviewed with a view to offering longer agreements now that NHS England have an annual review statement in DSAs.</p> <p><b>ACTION:</b> NHS England SIRO representative to review the <a href="#">NHS England's DARS Standard Term of Data Sharing Agreement</a>; to ensure the NHS England annual review is reflected.</p> <p><b>5.4.5</b> Separate to this application, the independent advisers suggested that the internal application assessment form be updated, to reflect why data is being disseminated and not accessed in a Trusted Research Environment (TRE).</p> <p><b>ACTION:</b> NHS England to consider updating the internal application assessment form, to reflect why data is being disseminated and not accessed in a TRE.</p> <p><b>5.4.6</b> The independent advisers advised that, as part of the review for this application, they had noted a similar <a href="#">study</a> '<i>The use of, and outcomes for, inflammatory bowel disease services during the COVID-19 pandemic: a nationwide observational study</i>'; and suggested that NHS England shared this information with the applicant, and ask that they briefly outline how the research under this application differed from the study already undertaken.</p> <p><b>5.4.7</b> The independent advisers queried the statement in section 5(a) (Objective for Processing) "<i>There has been no direct patient and public involvement and engagement (PPIE) for this study</i>"; and were also advised in-meeting, that the applicant had advised NHS England that there were no current plans to undertake any PPIE. The independent advisers suggested that the applicant undertakes <b>ongoing</b> PPIE. The <a href="#">HRA guidance on Public Involvement is a useful guide</a>.</p>	<p>SIRO</p> <p>DARS</p>
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5.5	<p><b>Reference Number:</b> NIC-334952-R5M7K-v7.6 University College London (UCL)</p> <p><b>Applicant:</b> NIC-334952-R5M7K-v7.6 University College London (UCL)</p> <p><b>Application Title:</b> MR740 - United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS)</p> <p><b>Presenter:</b> Dan Goodwin</p> <p><b>SAT Observer:</b> Cath Day</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented at the DAAG meetings on the 16<sup>th</sup> February 2016.</p> <p>The application and relevant supporting documents had previously been discussed at the IGARD meetings on the 17<sup>th</sup> February 2022.</p> <p><b>Application:</b> This was an extension application.</p> <p>The UKCTOCS was a multicentre randomised control trial which aimed to assess the impact of screening on ovarian cancer mortality while comprehensively evaluating physical and psychological morbidity, compliance and resource implications of screening and performance characteristics of a serum CA125 (cancer antigen 125) versus ultrasound-based screening strategy.</p> <p>The purpose of the application is to support the secondary objective, to create a bioresource of data and samples for ethically approved secondary studies with a focus on the early detection and treatment of disease.</p> <p>Should the 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>5.5.1</b> The group welcomed the application and noted the importance of the study as highlighted in the yielded benefits.</p> <p><b>5.5.2</b> NHS England advised the group that, as originally discussed at the AGD meeting on the 4<sup>th</sup> May 2023, in addition to the amendments outlined in the application, there would be an additional amendment to add Amazon Web Services (AWS) as a Data Processor. It was advised that the omission of AWS in UCL data sharing agreements (DSA) had been identified via an audit that had been undertaken by NHS England on another UCL DSA; and that, as a result, <b>all</b> UCL applications were in the process of being reviewed by NHS England, to ensure that AWS were listed as a Data Processor. The group noted the verbal update by NHS England.</p> <p><b>5.5.3</b> NHS England advised the group that the Health Research Authority Confidentiality Advisory Group (HRA CAG) register had been updated to reflect ongoing s251 support for this application to 2024. The group noted the verbal update by NHS England.</p> <p><b>5.5.4</b> The independent advisers noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) provided details of the commercial purpose of the application; however, suggested that section 5(a) (Objective for Processing) was updated further to include details of</p>	
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	<p>the commercial benefits, in line with <a href="#">NHS Digital DARS Standard for Objective for Processing</a> and <a href="#">NHS Digital DARS Standard for Commercial Purpose</a>.</p> <p><b>5.5.5</b> The independent advisers noted that, when reviewing the internal application assessment form for this application, it was not clear how points raised when the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had reviewed the application on the 17<sup>th</sup> February 2022 as part of 'oversight and assurance' had been addressed; and suggested that, separate to this application, the internal application assessment form clearly reflects any oversight and assurance review, and how any points raised from this have been addressed.</p> <p><b>ACTION:</b> NHS England to ensure any previous IGARD oversight and assurance review and how comments have been addressed, is reflected in the internal application assessment form.</p> <p><b>5.5.6</b> In addition, and separate to this application, the independent advisers advised that where there has been a previous 'oversight and assurance' review by IGARD; in addition to this being noted in the internal application assessment form, this was also clear when submitting applications for approval via NHS England's Precedent and SIRO approvals route; including how any points have been addressed.</p> <p><b>ACTION:</b> NHS England to ensure that applications proceeding via NHS England's Precedent and SIRO approvals are clear on any previous IGARD oversight and assurance review.</p>	<p>DARS</p> <p>DARS</p>
<b>EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL</b>		
6.1	<p><b>Reference Number:</b> NIC-400304-S1P1B-v5.9</p> <p><b>Applicant:</b> Office for National Statistics (ONS)</p> <p><b>Application Title:</b> Investigating COVID-19</p> <p><b>Presenter:</b> No Presenter</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 17<sup>th</sup> September 2020, 19<sup>th</sup> November 2020, 26<sup>th</sup> November 2020, 3<sup>rd</sup> December 2020, 18<sup>th</sup> February 2021, 15<sup>th</sup> April 2021, 27<sup>th</sup> January 2022, 10<sup>th</sup> February 2022, 3<sup>rd</sup> March 2022, 17<sup>th</sup> March 2022 and 27<sup>th</sup> October 2022.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 8<sup>th</sup> September 2020 and 15<sup>th</sup> September 2020.</p> <p>The application was previously presented at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9<sup>th</sup> September 2020 and 18<sup>th</sup> November 2020.</p> <p><b>Application:</b> The purpose of the application is to support the national response to the COVID-19 pandemic; by supporting the production of official national statistics.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided:</p>	

	<p><b>6.1.1</b> The independent advisers queried the length of the extension approved by NHS England's SIRO, noting that the supporting information provided was conflicting in terms of four months and one-year; and expressed concern over a one-year extension.</p> <p><b>6.1.2</b> The SIRO representative noted the query raised and advised that this would be reviewed, however advised that it was a four-month extension.</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>6.2</b>	<p><b>Reference Number:</b> NIC-147901-2XMLG-v5.11</p> <p><b>Applicant:</b> University Hospitals Bristol and Weston NHS FT</p> <p><b>Application Title:</b> MR1240 - Evaluation of centralisation in head and neck cancer</p> <p><b>Presenter:</b> No Presenter</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 29<sup>th</sup> August 2019 and 2<sup>nd</sup> February 2022.</p> <p><b>Application:</b> The purpose of the application is for a study, with the aim of evaluating the outcome of centralisation in Head and Neck cancer, identify prognostic indicators for head and neck cancer and to create a resource for translational and applied research in head and neck cancer.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided.</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>6.3</b>	<p><b>Reference Number:</b> NIC-414067-K8R6J-v2.2</p> <p><b>Applicant:</b> Our Future Health</p> <p><b>Application Title:</b> Our Future Health Recruitment Programme</p> <p><b>Presenter:</b> No Presenter</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the AGD meetings on the 2<sup>nd</sup> March 2023 and 30<sup>th</sup> March 2023.</p> <p>The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 5<sup>th</sup> May 2022, 26<sup>th</sup> May 2022, 17<sup>th</sup> November and 1<sup>st</sup> December 2022.</p> <p><b>Application:</b> The purpose of the application is for a research programme to support people living healthier lives for longer through better prevention, earlier detection and improved treatment of diseases. The programme will aim to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early when outcomes are usually better.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided.</p>	

	The NHS England SIRO representative thanked the group for their time.	
6.4	<p><b>Reference Number:</b> NIC-656874-T3L9D-v1.2</p> <p><b>Applicant:</b> University College London (UCL)</p> <p><b>Application Title:</b> Using Large-scale Routine Data to Monitor and Improve Ethnic Inequalities in Cancer and Cardiovascular Disease (ODR1920_301)</p> <p><b>Presenter:</b> No Presenter</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been discussed at the IGARD BAU meeting on the 3<sup>rd</sup> November 2022.</p> <p><b>Application:</b> The purpose of the application is for a project, which aims to 1) investigate ethnicity reporting in cancer and cardiovascular diseases (CVD) data; and 2) characterise the burden of coexisting cancer and CVD in Black Minority Ethnic (BME) groups.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p><b>6.4.1</b> The NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review.</p> <p><b>6.4.2</b> The independent advisers noted that the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had reviewed the application on the 3<sup>rd</sup> November 2022 as part of 'oversight and assurance'; and queried if the SIRO representative had been made aware of this when reviewing for progression via the SIRO approval route. The SIRO representative advised the group that he had not been made aware.</p> <p><b>6.4.3</b> The independent advisers reiterated advice provided under item 5.5 (NIC-334952-R5M7K-v7.6 University College London (UCL)), and suggested that, separate to this application, NHS England ensure that applications proceeding via NHS England's Precedent and SIRO approvals route, are clear on any previous IGARD oversight and assurance review.</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
6.5	<p><b>Reference Number:</b> NIC-656773-F5L2T-v0.2</p> <p><b>Applicant:</b> Queen Mary University of London</p> <p><b>Application Title:</b> National Interval Cancer Reporting (ODR1617_011)</p> <p><b>Presenter:</b> No Presenter</p> <p><b>Application:</b> The purpose of the application is for the Cancer Screening Programmes (operated by UKHSA), which are required to carry out quality assurance of their screening activities and to evaluate long-term outcomes. This project is part of an on-going process to analyse breast interval cancers which are a key indicator of the performance the screening units and of the programme as a whole.</p> <p><b>Outcome of discussion:</b> The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided:</p>	



	<p><b>6.5.1</b> The NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review.</p> <p><b>6.5.2</b> The independent advisers noted that the application was not clear, on the data controllership arrangements and what data was flowing.</p> <p><b>6.5.3</b> The independent advisers noted that some of the text in sections 5a and 5b did not relate to the application and expressed concern that it would be confusing to include it on the public release register.</p> <p>The NHS England SIRO representative thanked the group for their time.</p>	
<b>7</b>	<p><b>OpenSAFELY</b></p> <p>Following the verbal update at the AGD meeting on the 4<sup>th</sup> May 2023; Ming Tang and Dickie Langley provided the group with an update on the ongoing work within NHS England, in respect of OpenSAFELY.</p> <p>The independent advisers noted the verbal update from NHS England and provided the following comments / advice:</p> <p><b>7.1</b> NHS England were advised by the independent advisers that data controllership at the various stages of processing data needs to be clear.</p> <p><b>7.2</b> It was noted by the independent advisers that some of the risks with OpenSAFELY will be quite different to the risks with centralised data collection.</p> <p><b>7.3</b> To support the GP profession to meet their responsibilities to inform data subjects about the processing, the independent advisers suggested that materials were provided that can be shared with patients, for example, text for websites.</p> <p><b>7.4</b> In addition, it was suggested by the independent advisers that clear and transparent materials were provided, to help reassure GP practices about their responsibilities.</p> <p><b>7.5</b> It was suggested by the independent advisers that transparency was essential, and, to maintain public trust, NHS England should be clear and up-front about how OpenSAFELY has ensured data has been used safely and will continue to be used safely for public good. This should include being transparent about any future plans for OpenSAFELY at the earliest opportunity.</p> <p><b>7.6</b> The independent advisers suggested that it was important that there was appropriate transparency with the public about any commercial arrangements underpinning OpenSAFELY, for instance with GP system suppliers or partners.</p> <p><b>7.7</b> The independent advisers recognised the advantages of the OpenSAFELY approach to using data, and the benefits in using data this way.</p> <p><b>7.8</b> The independent advisers suggested that further engagement should be undertaken with key stakeholders, particularly with patients and the public, on whether Type 1 opt-outs should now be applied.</p> <p><b>7.9</b> It was suggested by the independent advisers that the data use (project/study) approval process be aligned with standard NHS England governance processes.</p>	
<b>AGD Operations</b>		

<b>8</b>	<b>Standard operating procedures</b> The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
<b>9</b>	<b>New Operational Actions &amp; those carried forward from previous meetings of AGD:</b>	
<b>9.1</b>	<b>IR35 / Zero Hours contracts for independent advisers</b>  Vicki Williams noted that NHS England were actively working on putting zero hours contracts in place for all independent advisers.	To note
<b>Any Other Business</b>		
<b>10.1</b>	<b>Assurance approach for extensions, renewals and amendments</b>  As advised at the AGD meeting on the 4 <sup>th</sup> May 2023, Michael Chapman and Terry Service provided a paper to the group on behalf of NHS England; and were seeking advice from AGD on changes to the assurance approach for low-risk changes to previously approved applications. Applications where NHS England is already sharing data and where the change is not increasing risk will progress more rapidly, which will allow staff and advisers to focus attention on the areas of greater risk to patients and to NHS England.  The group were advised that the process outlined in the supporting documents was a result of consultation and engagement with NHS England colleagues; and outlined the urgency of implementing an assurance approach, to prevent a backlog of applications in the system.  The independent advisers made a number of points on the assurance approach outlined in the paper provided, including, but not limited to: <ul style="list-style-type: none"> <li>• confirming the types of applications that would / would not proceed via the Precedent route;</li> <li>• providing a clear process of extending the length of DSAs and the benefits / restrictions of this;</li> <li>• ensuring where IGARD have previously asked for independent oversight, this is still appropriate and looking at this holistically in line with the full minutes;</li> <li>• the transparency for how an application proceeds, regardless of which route this is;</li> <li>• to further explore the exclusion criteria for example, the territory of use.</li> </ul> The independent advisers thanked NHS England colleagues for the information provided in advance of the meeting, and for engagement on this issue; and looked forward to further discussions at future AGD meetings.	
	<b>Meeting Closure</b>  As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.	