

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

Thursday, 2<sup>nd</sup> May 2024

09:00 – 15:15

*(Remote meeting via videoconference)*

<b>AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role:</b>
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser) (Chair for items 1 to 5.1) (not in attendance for item 11.1)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair) (not in attendance for items 1 to 5.1)
Narissa Leyland (NL)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
Andrew Martin (AM)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser)
<b>NHS ENGLAND STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Garry Coleman (GC)	NHS England SIRO Representative
Thomas Knight (TK)	Product Manager, NHS Notify, Cohorting Pillar - Products and Platforms Directorate ( <b>Presenter:</b> item 5.1)
Abigail Lucas (AL)	Data Access and Partnerships, Data and Analytics ( <b>Observer:</b> items 6.4 and 6.5)

Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics ( <b>Observer:</b> items 6.1 and 6.2)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
<b>AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS <u>NOT</u> IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Prof. Nicola Fear (NF)	AGD independent member (Specialist Academic Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)

<b>1</b>	<b>Welcome and Introductions:</b> The AGD meeting Chair welcomed attendees to the meeting.
<b>2</b>	<b>Review of previous AGD minutes:</b> The minutes of the AGD meeting on the 25 <sup>th</sup> April 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
<b>3</b>	<b>Declaration of interests:</b> Dr. Jonathan Osborn noted a professional link to the National Institute for Health and Care Excellence (NICE) guidelines for bladder cancer treatment and management (NIC-664431-F3G8W). It was agreed this did not preclude Dr. Osborn from taking part in the discussion on this application.  Claire Delaney-Pope noted a professional link to NIC-615981-K2W5D as part of her role within the South-East London Integrated Care System (SEL ICS). It was agreed that Claire would remain in the room, but would not be part of the discussion of this application.
<b>4</b>	<b>AGD Action Log:</b> <i>The action log was not discussed.</i>
<b>5 BRIEFING PAPER(S) / DIRECTIONS:</b>	
<b>5.1</b>	<b>Title:</b> NHS Notify

**Presenter:** Thomas Knight

NHS Notify Programme is an NHS England service that supports NHS healthcare organisations to communicate with patients (including supporting accessibility purposes) simply and easily through a variety of digital (NHS App, Short Message Service (SMS) and email) and physical messaging (letters) individually or as part of a defined patient cohort in a standard way.

The motivation and requirement for development of NHS Notify was to provide a consistent, standardised and centralised approach to sending cost effective communications to patients and citizens using existing technologies with the aim to replace the various existing communications approaches to patients and citizens from NHS England, put into place during times of crisis in different ways by different programmes by NHS England, and also from Primary, Secondary and Tertiary Care NHS organisations.

NHS England were seeking advice on the following points:

1. The scope, position and activities of the NHS Notify Programme and to obtain any insights, recommendations or considerations from AGD that can assist the NHS Notify Programme to potentially be better placed going forwards for the future.

**Outcome of discussion:** AGD welcomed the briefing paper and made the following observations / comments:

In response to point 1:

**5.1.1** In addition to the information provided to AGD prior to the meeting, the Group were also provided with a presentation in-meeting, that provided additional information. AGD thanked NHS England for the additional information provided and requested that the presentation was shared with the Group following the meeting, for future reference and for those AGD members not in attendance.

**ACTION:** NHS England to share a copy of the presentation with AGD (via the AGD Secretariat).

**5.1.2** AGD were advised by NHS England that NHS Notify was for the purpose of direct care **only** and would **not** be used for any direct marketing.

**5.1.3** AGD queried whether the purpose would be expanded beyond direct care in the future, and were advised by NHS England that discussions were ongoing on this point, however, were clear that the restrictions on direct marketing would remain.

**5.1.4** AGD noted concern that if the purpose was expanded beyond direct care, and multiple NHS organisations were using it, there may be an increase in National Data Opt-outs (NDOs) if patients felt that too many messages were being sent. It was suggested that NHS England address this point through patient and public involvement and engagement (PPIE), to carefully test tolerances and preferences so as not to overstep what individuals would want from this service.

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	<p><b>5.1.5</b> AGD noted the risks outlined in the Data Protection Impact Assessment (DPIA) provided as a supporting document; however, suggested that this was updated to also address the wider organisational risks to NHS England, for example, any reputational risks.</p> <p><b>5.1.6</b> AGD also highlighted a further risk in respect of those families / individuals subjected to domestic violence; and noted concern on data protection and confidentiality issues, for example where an s-flag (sensitive restriction) had <b>not</b> been applied; and suggested that this was given careful consideration by NHS England.</p> <p><b>5.1.7</b> AGD queried the process where an error was identified with contact information, and if / how the Personal Demographics Service (PDS) was updated to reflect this; and were advised by the SIRO representative that this point would be picked up outside of the meeting with NHS England colleagues.</p> <p><b>ACTION:</b> The SIRO representative to discuss with NHS England colleagues how PDS could be updated following an error being identified with an individual’s contact details.</p> <p><b>5.1.8</b> AGD suggested that further consideration be given as to how NHS England were supporting groups of people who may be digitally disadvantaged; noting that these groups could benefit most from the service outlined.</p> <p><b>5.1.9</b> AGD advised NHS England that they would welcome further discussions on this area of work as may be required.</p>	SIRO Rep
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**6 EXTERNAL DATA DISSEMINATION REQUESTS:**

6.1	<p><b>Reference Number:</b> NIC-709865-W9X6H-1.4</p> <p><b>Applicant:</b> The Royal College of Surgeons of England</p> <p><b>Application Title:</b> National Cancer Audit Collaborating Centre (NATCAN)</p> <p><b>Observer(s):</b> Jodie Taylor-Brown</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 28<sup>th</sup> September 2023.</p> <p><b>Application:</b> This was an amendment application.</p> <p>The amendment is to streamline six existing data sharing agreements (DSAs) (four related to GICAP, one for lung, and one for prostate) into a single existing DSA. This will add four audits to the single DSA, which will then include all ten NATCAN audits. NHS England were seeking advice on the amendment request (above).</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> AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p>	
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AGD noted that they had only been provided with limited documentation and noted that they would be providing observations based on these documents only.

**In response to point 1:**

**6.1.1** AGD discussed the amendment to the application; and advised that they were supportive of the four existing audits being added into this DSA.

**6.1.2** AGD noted that, prior to the meeting, NHS England had shared some additional information that outlined why each of the four audit teams require the additional data; and suggested that this information was summarised in section 5(a) (Objective for Processing) of the application for transparency.

**6.1.3** AGD noted that the point raised at the AGD meeting on the 28<sup>th</sup> September 2023, in respect of honorary contract holders, had **not** been adequately addressed; and reiterated the point that, noting there were seven honorary contract holders, suggested that NHS England queried this further, for example, in respect of the **proportion** of the team: were there only seven individuals within the team, or are the seven part of a much wider team. It was noted that the response to this query may have implications on data controllership; and suggested that once the point had been clarified that this was assessed in line with the [NHS England DAS Standard for Data Controllers](#); and that the application / internal Data Access Service (DAS) escalation form were updated as may be necessary, to reflect any updates.

**6.1.4 Separate to this application:** AGD reiterated the point made at the AGD meeting on the 28<sup>th</sup> September 2023; that the Group noted and applauded the questions asked by NHS England’s DAS in respect of how many honorary contract holders there were for this application; however, suggested that for future applications, further follow up questions are asked in respect of the **proportion** of the honorary contract holders within the wider team, with a view to whether this impacted the assessment of data controllership.

**ACTION:** DAS to seek further clarity from applicants in respect of the honorary contract holders and proportion of the study team that they represented.

**6.1.5** AGD noted that at the AGD meeting on the 28<sup>th</sup> September 2023, they had queried what the justification was for Local Patient identification (ID), consultant code and general medical practitioner data fields; and noted in the internal DAS escalation form that the inclusion of a Local Patient ID would enable NHS Trusts, to recognise the patient in their own identifiable data and thereby determine potential areas where improvement in practice is required. The Group suggested that further clarification was provided on how this aligned with the purpose of the application and its restrictive statements on re-identification.

**6.1.6** AGD noted the audit purposes outlined in section 1.1 (Summary of Proposed Changes to the DSA) of the internal DAS escalation form; and noting point 3 which states “*Stimulate improvements in cancer detection, treatment and outcomes including survival*”, queried whether this was in fact research and not part of the

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	<p>audit. The Group suggested that NHS England seek further clarification on this point with the applicant and amend the application and internal DAS escalation form as may be necessary. The Group further noted the reference to research in 5(d), which was not permitted for a non-research application without ethical support: <i>"It is hoped that through publication of findings in appropriate media, the findings of this research..."</i></p> <p><b>6.1.7</b> AGD reiterated the point made at the AGD meeting on the 28<sup>th</sup> September 2023, that NHS England remind the applicant that research is <b>not</b> permitted under this DSA, and that processing for the purpose of research would be subject to an amendment to this application or separate application.</p>	
<p><b>6.2</b></p>	<p><b>Reference Number:</b> NIC-91972-S9W9T-v9.3</p> <p><b>Applicant:</b> KCI Medical Ltd (<i>previously 3M United Kingdom PLC</i>)</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>Observer:</b> Jodie Taylor-Brown</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 16<sup>th</sup> November 2023.</p> <p>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> <p><b>Application:</b> This was an extension application.</p> <p>The purpose of the application is to provide software services to clients in the health sector.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> <li>1. The benefits of the processing; and</li> <li>2. The appropriateness of continuing to permit access to data for the stated purpose noting the progress made to date and noting the benefits yielded and expected.</li> </ol> <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> AGD were <b>not</b> supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:</p> <p>AGD noted that they had only been provided with limited documentation and noted that they would be providing observations based on these documents only.</p> <p><b>In response to points 1 and 2:</b></p>	

**6.2.1** AGD noted the outstanding query in the internal Data Access Service (DAS) escalation form in respect of whether or not KCI Medical Ltd has access to the data; and, were advised by NHS England, that following submission of the papers to the Group for review, the applicant has advised that the data continues to be hosted within the secure 3M environment and is covered by a transactional service agreement between 3M and KCI Medical Ltd. The Group also noted that KCI Medical Ltd do **not** have a Data Sharing Framework Contract (DSFC) in place. Noting both of these points, AGD advised that they were in agreement with the assessment made by DAS in the internal DAS escalation form, that there had been a breach of the data sharing agreement (DSA) in that data was being shared with an organisation that was **not** permitted; and, in addition, the necessary security arrangements for that organisation had **not** been met.

**6.2.2** AGD advised that NHS England discuss the apparent breach with 3M United Kingdom PLC and ensure due process was followed in respect of this.

**6.2.3** AGD noted the importance of attention to detail in safe custodianship of NHS data shared through a DSA. They also noted that if an organisation does not pay attention to detail in meeting the conditions of DSAs or DSFCs, then parallels could be drawn re the willingness and/or ability of an organisation to safeguard the data itself. Company acquisitions involve complex legal processes, and AGD expects a data-safe organisation to devote the necessary time to ensure that data contractual commitments are not breached.

**6.2.4** AGD discussed whether it would be appropriate for the applicant to hold / process the data to support the overall objective for processing, once the issues in respect of the breach had been suitably addressed; and it was the view of the majority of the Group that a benefit to health and care was **not** being achieved and it would therefore **not** be appropriate for the applicant to continue to hold / process the data.

**6.2.5** In addition, noting that KCI Medical Ltd had been added as a Data Controller under this iteration of the application, it was noted that they had **not** followed the appropriate procedures required by their DSA / DSFC with NHS England to be a Data Controller.

**6.2.6** AGD also suggested that NHS England satisfied itself that the DSA had been signed by the correct person with appropriate signing authority to bind the correct organisation.

**6.2.7** In addition, the AGD NHS England Caldicott Guardian Team representative who is also a clinician, observed there was no apparent benefit in the case study provided.

**6.2.8** AGD suggested that NHS England consider whether there were any benefits to the health and care system in creating the proposed products, as per the objective of processing under this application.

	<p><b>6.2.9</b> AGD noted that whilst the majority of the Group were <b>not</b> supportive of this application progressing any further, due to the breach issues highlighted and apparent lack of benefits (delivered to date or imminent) to the health and care system, they noted that NHS England had endeavoured to support a new applicant access NHS data over several years. The Group therefore commended NHS England's efforts in ensuring that access to health data for the benefit of health and care was not restricted to a small number of existing market participants.</p> <p><b>6.2.10</b> AGD noted that should NHS England request that the data under this application be destroyed, they would, if requested by NHS England, still review any future applications submitted from this applicant / KCI Medical Ltd, via the usual DAS process; and that any application would be reviewed on its own merit.</p>	
<p><b>6.3</b></p>	<p><b>Reference Number:</b> NIC-321968-S4Q6L-v7.6</p> <p><b>Applicant:</b> University of Cambridge</p> <p><b>Application Title:</b> MR487 - EPIC – European Prospective Investigation into Cancer in Norfolk</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 16<sup>th</sup> July 2020, 28<sup>th</sup> June 2018 and the 24<sup>th</sup> May 2018.</p> <p>The application and relevant supporting documents were previously presented / discussed at the Data Access Advisory Group (DAAG) meetings on the 13<sup>th</sup> August 2015 and the 28<sup>th</sup> July 2015.</p> <p><b>Application:</b> This was an extension, renewal, and amendment application.</p> <p>The amendment is to request National Diabetes Audit (NDA) for 2003/04 - 2025/26 for the linkage of 30,445 EPIC-Norfolk participants of the original cohort.</p> <p>The NDA data will be used to highlight participants treated or diagnosed with diabetes outside of Norfolk to allow accurate analysis of the data. Access to earlier NDA data from 2003/04 onwards is important as it allows for the identification of pre-existing conditions.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> <li>1. That the purpose for using the dataset is clearly justified; and,</li> <li>2. That the common law duty of confidence is addressed.</li> </ol> <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> AGD were supportive of the aspects of the application they were asked to consider and wished to draw to the attention of the SIRO the following advice points:</p>	

	<p>AGD noted that they had only been provided with limited documentation and noted that they would be providing observations based on these documents only.</p> <p><b>In response to point 1:</b></p> <p><b>6.3.1</b> AGD noted the amendment to the application, to request National Diabetes Audit (NDA) for 2003/04 - 2025/26 for linkage with the 30,445 EPIC-Norfolk participants of the original cohort, and advised that there was a clear justification for this.</p> <p><b>6.3.2</b> AGD suggested however, that the applicant maintain ongoing engagement with the EPIC-Norfolk Participant Advisory Panel (EPAP) to explain / seek views on the extended linkage and what this contains; and to ensure the options available to withdraw from the study if participants are not content with the extended linkage (or any other aspect of the study) are well communicated and transparent.</p> <p><b>6.3.3 Separate to this application:</b> AGD noted and commended NHS England on the transparency on their <a href="#">website</a> on the NDA Programme.</p> <p><b>In response to point 2:</b></p> <p><b>6.3.4</b> AGD noted that the s251 Health Research Authority Confidentiality Advisory Group (HRA CAG) support was very broad; and suggested that NHS England satisfies itself that the NDA linkage is covered under the existing s251 support.</p> <p><b>6.3.5</b> AGD noted that the cohort numbers differed between the HRA CAG letter of support and the internal Data Access Service (DAS) escalation form; and suggested that these were reviewed and aligned.</p> <p><b>6.3.6</b> AGD noted the information within section 4.1 (Decision Details and Next Steps) of the internal DAS escalation form, in respect of AGD advice being sought where there is request for a new dataset and where the data is identifiable; and agreed with the proposal of adding this to their internal knowledge base as a reusable decision.</p> <p><b>6.3.7</b> AGD queried the reference to a previous breach, and were informed the applicant had flowed a cohort to NHS Digital that related to a different agreement and so data had flowed back to the applicant that related to the wrong cohort. AGD were reassured that this had been reported to the NHS Digital DPO, who had advised Data Access Request Service (DARS) (predecessor of DAS).</p> <p><b>6.3.8</b> AGD noted and supported the proposal in section 10.1 (Onward sharing / Sublicensing) of the DAS escalation form that an audit be undertaken on this data sharing agreement (DSA).</p>	
<p><b>6.4</b></p>	<p><b>Reference Number:</b> NIC-664431-F3G8W-v0.5</p> <p><b>Applicant:</b> University of Birmingham</p> <p><b>Application Title:</b> BladderPath: Image Directed Redesign of Bladder Cancer Treatment Pathways</p>	

**Observer:** Abigail Lucas

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

The purpose of the application is for a study, aiming to improve staging, accelerate treatment and reduce tumour spread in patients with muscle invasive bladder cancer (MIBC) by avoiding transurethral resection of the bladder tumour (TURBT), ultimately improving clinical outcomes. The hypothesis being tested is that substituting TURBT with magnetic resonance imaging (MRI) will avoid unnecessary surgery and reduce the time to definitive radical treatment for MIBC.

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

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

**6.4.1** AGD noted and commended the work undertaken by NHS England’s Data Access Service (DAS) on the content of the internal consent review, which supported the review of the application.

**6.4.2** AGD noted and commended the applicant on requesting the ethnicity data, for the purpose of assessing the impact of ethnicity on healthcare outcomes and to investigate inclusivity in the trial; however, queried whether the ethnicity fields in the datasets requested were sufficient in terms of quality of data to achieve the aims of the analysis; and suggested that this was explored by NHS England. If the data was not of a sufficient standard, the Group advised that they would be supportive of the addition of an alternate dataset to the data sharing agreement (DSA) that provides the most relevant ethnicity information, with the relevant governance and justifications added to the application.

**6.4.3** AGD noted that the consent review stated that it would be in the reasonable expectations of participants for the applicant to request data up to 2026; and suggested that NHS England clarify this point with the applicant, for example, noting that they may require a refresh of data at a future date, and whether this would be compatible with the current consent materials.

**6.4.4 Separate to the application:** Noting the derived data that would be flowing under this application; AGD noted that there was ongoing work within NHS England, in respect of derived data; and as discussed at the AGD meeting on the 14<sup>th</sup> March 2024, where a number of points / suggestions were made by the Group; AGD asked the AGD NHS England Data and Analytics representative that a further update was provided on this programme of work in due course.

**ACTION:** The AGD NHS England Data and Analytics representative to provide an update on the ongoing derived data programme of work.

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	<p><b>6.4.5</b> AGD noted that the link to the privacy notice in section 4.7 (Transparency) of the internal application assessment form, was <b>not</b> accessible; and suggested that, for ease of reference, this was updated with the correct link.</p>	
<p><b>6.5</b></p>	<p><b>Reference Number:</b> NIC-743681-L8G9L-v0.2</p> <p><b>Applicant:</b> University of Oxford</p> <p><b>Application Title:</b> EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin) - Post-Trial Follow-up (PTFU)</p> <p><b>Observer:</b> Abigail Lucas</p> <p><b>Application:</b> This was a new application.</p> <p>The purpose of the application is for a study, to investigate the effect of empagliflozin on kidney disease progression or cardiovascular death versus placebo on top of standard of care in patients with pre-existing chronic kidney disease (CKD). The main inclusion criterion was participants with CKD who are at risk of their condition progressing.</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> AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p><b>6.5.1</b> AGD noted and commended the work undertaken by NHS England’s Data Access Service (DAS) on the content of the internal application assessment form, which supported the review of the application.</p> <p><b>6.5.2</b> AGD noted that Boehringer Ingelheim International GmbH (BI) were funding the study; and suggested that section 5 (Objective for Processing) was updated to be clear that BI also owned the patent of the drug being studied.</p> <p><b>6.5.3</b> In addition, it was suggested that section 5 be updated as to whether there is a proportionate balance between public and commercial benefit flowing discerning the efficacy and safety of the drug, in line with <a href="#">NHS Digital DAS Standard for Expected Measurable Benefits</a> and the National Data Guardian (NDG) <a href="#">guidance on benefits</a>.</p> <p><b>6.5.4 Separate to this application:</b> AGD noted that there was an ongoing action initially raised at the AGD meeting on the 23<sup>rd</sup> March 2023, in respect of potential updates to the <a href="#">NHS England DAS Standard for Expected Measurable Benefits</a> and <a href="#">NHS England DAS Standard for Commercial Purpose</a>, to align with the NDG <a href="#">guidance on benefits</a>, on enabling better public benefit evaluations when data is to be used in planning, research and innovation; and asked that a further update be provided on this.</p> <p><b>6.5.5</b> In addition, it was noted that any updates could feed into NHS England’s internal Question and Answer (Q&amp;A) document and the internal application assessment form.</p>	

	<p><b>ACTION:</b> AGD NHS England Data and Analytics representative to provide an update on the action raised at the 23<sup>rd</sup> March 2023 AGD meeting, in respect of updates to the <a href="#">NHS England DAS Standard for Expected Measurable Benefits</a> and <a href="#">NHS England DAS Standard for Commercial Purpose</a>, to align with the NDG <a href="#">guidance on benefits</a>.</p> <p><b>6.5.6</b> Noting the statement in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application “<i>The trial is considered a non-commercial trial from the perspective of the National Institute for Health Research (NIHR)</i>”; AGD suggested that this was not used as a justification to regard an application as non-commercial as t the criteria of NIHR may not align with the <a href="#">NHS England DAS Standard for Commercial Purpose</a></p>	D&A Rep
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**7 INTERNAL DATA DISSEMINATION REQUESTS:**

*There were no items discussed*

**8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL**

8.1	<p><b>Reference Number:</b> NIC-148130-46N08-v8.9</p> <p><b>Applicant:</b> University of Oxford</p> <p><b>Application Title:</b> MR261 - ISIS 2: STREPTOKINASE ASPIRIN AFTER MYOCARDIAL INFARCT</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents had previously been presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 13<sup>th</sup> October 2022, 4<sup>th</sup> February 2021 and the 19<sup>th</sup> March 2020.</p> <p>The SIRO approval was for the data to be archived for 3 years. This permits the applicant to hold, and process only to respond to queries in relation to the research, not conduct any additional analysis or research (or other purpose).</p> <p><b>Outcome of discussion:</b> AGD noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this.</p> <p>AGD thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p><b>8.1.1</b> AGD noted that NHS England would carry out any future linkage to General Practice Data for Planning and Research data (if it becomes available) or other follow up data; and noted that it would therefore seem sensible for NHS England to hold the identifiers rather than the Nuffield Department of Population Health (NDPH) Information Governance Team; and queried if this had been considered. The SIRO representative noted the point made, however advised that this was not a service currently offered by NHS England.</p>	
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	The NHS England SIRO representative thanked AGD for their time.	
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## 9 OVERSIGHT AND ASSURANCE

### 9.1 Oversight and Assurance Process

The [Statutory Guidance](#) states that the data advisory group (AGD) should be able to provide NHS England with advice on: *“Precedents for internal and external access, including advising in accordance with an agreed audit framework whether processes for the use of precedents are operating appropriately, to provide ongoing assurance of access processes”*.

In advance of the meeting, the AGD independent members were provided with **1)** nine applications (selected by the AGD Secretariat); **2)** internal application assessment forms for each of the nine applications; and **3)** an oversight and assurance template to complete.

Following review of the applications by the AGD independent members **out of committee**, the completed oversight and assurance templates were sent to the AGD Secretariat prior to the meeting.

It was noted that only **high-level points** would be discussed in meeting (and noted in the minutes); however, the full suite of comments and feedback from AGD independent members on the oversight and assurance templates would be collated by the AGD Secretariat and shared with the SIRO representative and relevant NHS England colleagues as may be appropriate.

Please see **appendix A** for high-level points raised in-meeting on the nine applications.

### 9.2 Oversight and Assurance Conclusion / Review

AGD noted that as the oversight and assurance process had only been in progress since the 21<sup>st</sup> March 2024; this was still being reviewed and that changes to processes would be agreed and updated as may be appropriate.

AGD noted that as agreed at the AGD meeting on the 18<sup>th</sup> March 2024, the oversight and assurance template had been uploaded to the internal AGD SharePoint site by the AGD Secretariat (as opposed to each reviewer filling out individual forms), where AGD independent members were able to note their comments. It was noted that this had worked well and would continue moving forward.

It was noted that further thought would be given to the deadlines for first and second reviewers to review and add comments to the oversight and assurance template.

**ACTION:** AGD and the AGD Secretariat to give consideration to potential deadlines for first and second reviewers to submit comments.

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## 10 AGD OPERATIONS

### 10.1 AGD Standard Operating Procedures (SOPs) (Presenter: Vicki Williams)

	<p>The ongoing forward plan of work for creating the AGD Standard Operating Procedures was discussed; and noting that the AGD Terms of Reference (ToR) had now been approved, it was noted that work was progressing in order to finalise the AGD SOPs in line with the approved AGD ToR.</p> <p>It was noted that a further update would be provided to the Group in due course.</p>	
<b>10.2</b>	<p><b>AGD Stakeholder Engagement</b></p> <p><i>There were no items discussed</i></p>	
<b>10.3</b>	<p><b>AGD Project Work</b></p> <p><i>There were no items discussed</i></p>	
<b>11 Any Other Business</b>		
<b>11.1</b>	<p><b>AGD Training / Learning and Development</b></p> <p>The SIRO representative advised that work was ongoing to identify internal training / learning and development opportunities for AGD independent members; and that a further update would be provided in due course.</p> <p>The AGD independent members noted the update and looked forward to further information on this.</p> <p><b>ACTION:</b> The SIRO representative to provide further information on internal training / learning and development opportunities for AGD independent members.</p>	<p>SIRO Rep</p>
<p><b>Meeting Closure</b></p> <p>As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.</p>		

## Appendix A

### Oversight and Assurance Review – 2<sup>nd</sup> May 2024

Ref:	NIC Number:	Organisation:	Areas to consider:
240502a	NIC-196263-J9Q7Z-v1.4	University College London (UCL)	<ul style="list-style-type: none"> <li>• The role of the academics and whether this had implications for data controllership in line with <a href="#">NHS England DAS Standard for Data Controllers</a></li> <li>• IGARD's previous concerns over the linkage not reflected.</li> <li>• Benefits to health and care to be outlined in section 5(d) in line with <a href="#">NHS England DAS Standard for Expected Measurable Benefits</a></li> <li>• References to PhD student "<i>affiliated with</i>" – to clearly state if a student of UCL or not.</li> <li>• Benefits to be clearly articulated in the Annual Confirmation Report.</li> </ul>
240502b	NIC-97202-W2L3P-v6.3	Portsmouth City Council	<ul style="list-style-type: none"> <li>• Lack of clarity as to what has been removed / replaced in the application.</li> <li>• No internal application assessment form available.</li> </ul>
240502c	NIC-159251-K4Y6Q-v4.6	King's College London	<ul style="list-style-type: none"> <li>• Study title change and has a new protocol – concern over whether this is fully compliant with <a href="#">NHS England DAS Standard for Ethical Approval</a> / whether a further ethical review is required.</li> </ul>

			<ul style="list-style-type: none"> <li>• Unclear on the references to “<i>sensitive</i>” information.</li> <li>• Further clarity on why there was a gap between DSA versions; was there a potential breach?</li> </ul>
240502d	NIC-148267-W26RZ-v6.5	University of Oxford	<ul style="list-style-type: none"> <li>• Not supportive due to previous issues not being addressed.</li> <li>• Precedent cited needs a review as appears outdated.</li> <li>• Complex criteria that need applying consistently across all applications using Precedent 17.</li> <li>• Previous IGARD concerns not taken into account in terms of extending without independent review and s251 concerns.</li> <li>• Concern that risk assessment states that “<i>AGD did not state they wished to see the application on review</i>”.</li> <li>• Ongoing s251 support not evident.</li> </ul>
240502e	NIC-49164-R3G5K-v3.7	University of Leeds	<ul style="list-style-type: none"> <li>• Internal application assessment form clear and easy to link to the precedent applied.</li> <li>• Further clarity on why there was a gap between DSA versions; was there a potential breach?</li> <li>• Needs to be clear that the update to the legal basis is to specify the limb as opposed to legal basis change. Wider suggestion made re updating</li> </ul>

			wording in precedent exclusions to make this point also clear.
240502f	NIC-615981-K2W5D-v1.3	NHS South East London Integrated Care Board (ICB)	<ul style="list-style-type: none"> <li>• Not clear if the correct Precedent had been used.</li> <li>• Unclear if other ICBs should be Data Controllers.</li> <li>• Risk if correct Data Controllers not reflected.</li> <li>• Unclear why application has not been to AGD for independent advice.</li> </ul>
240502g	NIC-148465-PJQ4L-v8.5	UK Health Security Agency	<ul style="list-style-type: none"> <li>• Operation of Precedent route where it is not reliant on subjective review of risk, need more specific exclusion criteria.</li> <li>• IGARD's previous concerns not reflected / addressed.</li> <li>• No recent independent oversight noting the legal basis cited.</li> <li>• Consent review not completed in internal application assessment form.</li> <li>• Confirmation required from Caldicott Guardian panel – unclear how addressed.</li> <li>• Unclear on NHSE position where UKHSA is a Data Processor but not a Data Controller.</li> <li>• Privacy Notice not updated since 2021.</li> </ul>
240502h	NIC-376603-K2J9R-v13.4	NHS England (Quarry House)	No comments
240502i	NIC-656750-K1X5M-v1.2	Imperial College London	<ul style="list-style-type: none"> <li>• Not clear if the correct Precedent had been used.</li> <li>• Confusion how Precedent applied.</li> </ul>

			<ul style="list-style-type: none"><li>• Confusion over opt out options.</li><li>• Need to be clearer what documents have been used to review.</li></ul>
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