Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 20th July 2023

09:30 – 16:30

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser / Co-Deputy Chair (Chair)
Prof Nicola Fear (NF)	Independent Specialist Academic Adviser
Dr. Imran Khan (IK)	Specialist GP Adviser / Co-Deputy Chair
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Miranda Winram (MW)	Independent Lay Adviser (**Observer – new AGD member)**
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Ian Bullard (IB)	Analytics & Insights, Data and Analytics Directorate (**Presenter**: item 4.2)
Michael Chapman (MCh)	Data and Analytics representative (not in attendance for part of item 5.3)
Garry Coleman (GC)	NHS England SIRO Representative
Dickie Langley (DL)	NHS England DPO Representative (Delegate for Jon Moore)
Karen Myers (KM)	AGD Secretariat Team
Dr Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
Pritpal Rayat (PR)	Analytics & Insights, Data and Analytics Directorate (**Presenter**: item 4.2)
Charlotte Skinner (CS)	Data Access Request Service (DARS) (**Presenter**: item 4.1)
Kimberley Watson (KW)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.1 to 5.5)
Vicki Williams (VW)	AGD Secretariat Team (not in attendance for items 5.2 and 5.3) (**Presenter**: items 9 and 10.1)

INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Claire Delaney-Pope (CDP)	Independent Specialist Adviser (**Observer – new AGD member)**
Dr. Robert French (RF)	Independent Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Jenny Westaway (JW)	Independent Lay Adviser
Dr. Maurice Smith (MS)	Independent Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Jon Moore (JM)	NHS England Data Protection Office Representative

1	**Welcome and Introductions** 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: • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); the Caldicott Guardian; and the SIRO. • Attendees would not be listed as “members” in minutes during the transitional period; • NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting; • It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing. 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. Paul Affleck noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.

2	**Review of previous AGD minutes:** The minutes of the 13th July 2023 AGD meeting were reviewed and subject to a number of amendments were agreed as an accurate record of the meeting.	
3	**Declaration of interests:** Paul Affleck noted professional links to the University of Leeds (NIC-656777-B0V8N) but noted no specific connections with the application and it was agreed that this was not a conflict of interest.	
BRIEFING PAPER(S) / PRESENTATION(S)		
4.1	**Title:** Updates to the National Diabetes Audit Core dataset: prisons and monogenic data Briefing Paper **Presenter:** Charlotte Skinner **SAT Observer:** Kimberley Watson The purpose of the briefing paper was to provide details of a proposal to use data already collected by NHS England via the GP Extraction Service (GPES) relating to individuals in adult and young offender prisons in England with a diagnosis of diabetes for the National Diabetes Audit Core Audit (NDA Core Audit). Prison data is identified in the GPES extract by the organisation site code so that Healthcare Professionals can review service levels so that diabetes care and outcomes in this setting can be assessed. The proposal is also to collect monogenic diabetes data from the Royal Devon University Healthcare NHS Foundation Trust and analyse/link this data to the NDA Core Audit to allow care processes and treatment outcomes from the audit to be used to assess the care of people with monogenic diabetes. There is no change to the data being collected for prison data as this is already collected within GPES, however, there will be a change for the addition of monogenic data to the NDA collection. NHS England were seeking advice on the following points: 1. Confirmation that the group are content for the addition of prison and monogenic data collection to the NDA audit. 2. If the transparency information for the addition of the prisons data and monogenic data to the NDA is sufficient. 3. If the group are satisfied with the controls in place in relation to GPES extracts containing prison site codes (no internal access by other teams and not to be onboarded as a DARS product). Noting that any requests or use cases for internal/external access will be handled in accordance with the	

	Statutory Guidance from Secretary of State under s274A of the Health and Social Care Act 2012. **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: **4.1.1** In respect of point 1 above, the group advised that they were content with the addition of the monogenic data collection to the NDA audit provided, that this was consistent with the legal basis for the collection of the data and the information which has been provided to the patients to whom the data relates, noting the prison data is already collected, subject to the points below. **4.1.2** In respect of point 2 above, the group noted that the briefing paper stated that those individuals who had submitted a National Data Opt-out (NDO), would still have their data shared with NHS England as part of the legal obligation to collect the data under the NDA Directions; however advised that the transparency materials were **not** clear on this point. Independent advisers suggested that the transparency materials were updated to clarify this, in line with Caldicott Principle 8, *"…A range of steps should be taken to ensure no surprises for patients and service users…"*. **4.1.3** The group noted that, prior to the meeting, an independent adviser queried with NHS England where the Royal Devon University Healthcare NHS Foundation Trust collect the data, what the legal basis was for collecting the data and what information was given to patients about the collection and what (if any) opt outs are there from that provision. NHS England advised that they had been unable to seek clarification on the points raised with the Royal Devon University Healthcare NHS Foundation Trust, and that the briefing paper would be updated as may be necessary once this information had been obtained. **4.1.4** In respect of point 3 above, the group noted that the text *"…any requests or uses cases for internal/external access will be handled in accordance with…"* was redundant since there would be no internal access by other teams and it was not to be onboarded as a DARS product. **4.1.5** The group noted that this data collection would **not** be flowing outside NHS England at the current time, however advised that if there were any future updates to the processing of this data, they would welcome a further discussion / information on this. **4.1.6** The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting.	
4.2	**Title:** NHS BSA Direction and NHS BSA dataset - Clarifying use cases for Medicines dispensed in Primary Care data - Presentation **Presenters:** Pritpal Rayat / Ian Bullard **SAT Observer:** Kimberley Watson	

	Observer: Louise Dunn The purpose of the presentation, was in response to a request from AGD on the 23rd March 2023, for NHS England to advise the group on the scope of use for the NHS BSA dataset in line with the relevant Direction authorising the collection. The presentation provided details of the scope of use for the NHS BSA dataset; the aims and objectives, for example, who is using the dataset, constraints and improvements; stakeholder engagement; current and potential use of the dataset; findings so far and next steps. **Outcome of discussion:** The group welcomed the presentation and made the following observations / comments: **4.2.1** Noting the potential to use the NHS BSA dataset beyond the current scope / purpose, it was suggested that NHS England should seek an amendment to the Direction to encompass future processing. **4.2.2** In addition, it was suggested that prior to any update(s) to the Direction, NHS England should ensure that patient and public involvement and engagement (PPIE) was undertaken, for example, with relevant stakeholder groups, such as use MY data. **4.2.3** The group highlighted the importance of transparency on the use of the NHS BSA data, in line with Caldicott Principle 8 *"…A range of steps should be taken to ensure no surprises for patients and service users…"*. **4.2.4** The group noted that if there were any future updates to the processing of the NHS BSA data, they would welcome a further discussion / update on this.	
EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-401935-N9W7P-v0.4 **Applicant:** East Anglian Air Ambulance (EAAA) **Application Title:** NHS England to undertake record linkage of East Anglian Air Ambulance patients to HES APC, Adult Critical Care and ECDS **SAT Observer:** Kimberley Watson **Application:** This was a new application. The purpose of the application is to carry out an audit and evaluation of outcomes of patients treated by East Anglian Air Ambulance (EAAA). Linkage with NHS England datasets will enable EAAA to audit and evaluate their pre-hospital care of the patient in relation to the entire patient pathway, for example, diagnoses, procedures, and the ultimate outcomes of the patient after they have been discharged from their care. The initial phase will test linkage on the 2021/22 cohort (Approx 1600 patients) to test the feasibility and usage of dates with the aim of expanding to further years of data collection.	

	Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **5.1.1** An independent adviser queried the role of the East of England Ambulance Service NHS Trust, and whether they were considered a Data Controller; and, noting that this was not clear in the internal application assessment form or the application, suggested that this was clarified and the internal application assessment form and application were updated as necessary, in line with NHS England's DARS Standard for Data Controllers. **5.1.2** The SIRO representative noted the information within the internal application assessment form in relation to the identifiers, and queried whether the flow of data from NHS England to the EAAA was truly pseudonymised; and asked that further clarification was provided as to which identifiers would be deleted and what the technical and contractual controls were within EAAA to prevent re-identification of individuals. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.1.3** The independent advisers noted that the application was for a one-year data sharing agreement (DSA), and queried how this related to individuals who had been treated by the EAAA; and suggested that the internal application assessment form and the application were updated with clarification. For example, was the purpose of the application only for feasibility or did it expand into an audit. If it was deemed that the purpose of the application was for an audit, it was suggested that the applicant consider any future uses of the data and if this expands beyond audit and into research. **5.1.4** If the scope expanded beyond feasibility, it was queried whether the applicant would require data on those individuals who died before reaching hospital; and suggested that this was clarified, and the application updated as appropriate. **5.1.5** An NHS England representative noted that the internal application assessment form referred to the applicant possibly extending the s251 support; and suggested that this was updated to be clear if this was for the purpose of retaining the data or whether it was referring to the EAAA sending further identifiable data to NHS England, or both. **5.1.6** An NHS England representative noted that Article 6(1)(e) of the UK General Data Protection Regulation (UK GDPR) was cited in the application and privacy notice "*Public task: the processing is necessary for you to perform a task in the public interest or for your official functions, and the task or function has a clear basis in law"*; and queried if this was the correct legal basis, and suggested that this was	

	explored further and the application and privacy notice was updated as may be appropriate. **5.1.7** The independent advisers noted that processing of the data under this data sharing agreement (DSA) could be done remotely; and suggested that further information was added to the application on the remote access arrangements in England and Wales only; and reiterated previous advice that NHS England needs a clear policy on remote access. **ACTION:** NHS England to provide its position to AGD on remote access *(as previously requested and agreed at the AGD meeting on the 2nd February 2023)*. **5.1.8** An independent adviser observer noted in the application that patient and public involvement and engagement (PPIE) had been undertaken; however, suggested that the applicant undertakes **ongoing** PPIE. The HRA guidance on Public Involvement is a useful guide.	NHSE
5.2	**Reference Number:** NIC-10029-G5R2H-v2.3 **Applicant:** Northern Ireland Clinical Trials Unit **Application Title:** Hydroxymethylglutaryl-CoA reductase inhibition with simvastatin in Acute lung injury to Reduce Pulmonary dysfunction (HARP2) **SAT Observer:** Kimberley Watson **Previous Reviews:** The application and relevant supporting documents had previously been discussed at the IGARD BAU meeting on the 3rd March 2022. **Application:** This was an extension application. NHS England were seeking advice on the following point: 1. The outstanding security assurance requirements 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 high-level comments: In respect of point 1 above: **5.2.1** The group noted the ongoing discussions between NHS England and the applicant regarding security assurance. **5.2.2** The SIRO representative provided the group with a verbal update on the background to the audit findings on this application and the subsequent work underway. The group noted and thanked the SIRO representative for the update and noted the importance of the audit findings being actioned in a timely manner to ensure compliance with the contract and security of the data. **5.2.3** In response to the audit findings, an NHS England representative noted the information in the internal application assessment form that all NHS Digital data	

	which was onwardly shared beyond the Data Controllers and Data Processors listed within this data sharing agreement (DSA), and which is not aggregated with small numbers suppressed as per the relevant data set disclosure rules must be destroyed; and queried if this was misleading, noting the data may not be personal data if the individuals are now deceased, and therefore the UK General Data Protection Regulation (UK GDPR) would not apply. **5.2.4** In addition, the independent advisers noted that individuals had provided consent for their data to be processed and that any deletion requirement from NHS England might conflict with such consent. However, it was acknowledged that NHS England needed to act consistently and take action based on audit findings. **5.2.5** Separate to the application, the group suggested that NHS England may wish to amend the description of the flow of the records of deaths data in and out of NHS England, to ensure that this process / flow, and the legal bases, were clearly understood. **ACTION:** NHS England to consider amending the description of the flow of the records of deaths data in and out of NHS England. **5.2.6** Separate to this application, the group suggested that NHS England reconsider / re-evaluate its position on ONS death data, noting an individual's date of death is in the public domain, and, if the individual has consented for this data to be held by another party, it may not be appropriate to put restrictions on how long this data can be retained. **ACTION**: NHS England to reconsider / re-evaluate its position on ONS death data, noting an individual's date of death is in the public domain, and, if the individual has consented for this data to be held by another party, it may not be appropriate to put restrictions on how long this data can be retained. **5.2.7** In respect of the expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care), the independent advisers suggested that this was edited to ensure this only contained benefits and not outcomes; and that any outcomes should be moved to section 5(c) (Specific Outputs Expected) in line with NHS Digital DARS Standard for Expected Outcomes and NHS Digital DARS Standard for Expected Measurable Benefits. **5.2.8** The independent advisers noted that the benefits in section 5(d) were a good example of where a negative outcome from a study can be beneficial.	NHSE NHSE
5.3	**Reference Number:** NIC-655446-P9K9Q-v0.5 **Applicant:** Adelphi Group Limited **Application Title:** A retrospective observational study of patient characteristics, treatment patterns and healthcare resource utilisation for stage II melanoma in England	

	SAT Observer: Kimberley Watson **Application:** This was a new application. The purpose of the application is for a research project, with the aim of **1)** gaining a better understanding of the disease characteristics of patients diagnosed with stage II Melanoma; **2)** to gain a better understanding of the treatments patients with stage II Melanoma receive, and how effective these treatments are; **3)** to better understand the cost of the healthcare provided to stage II melanoma patients; and **4)** to aid in categorising key sub-groups within the stage II melanoma patient population that could benefit from the use of new treatments to improve treatment outcomes. 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 **not** supportive of the application at this time and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting: **5.3.1** The independent advisers noted within the internal application assessment form and the application, stated that *"There is no direct commercial gain for either Adelphi Group Limited or Merck Sharpe and Dohme Limited from the study"*; and noting that this may not be correct, suggested that further information was provided in respect of the medications that Merck Sharpe and Dohme Limited manufacture that relate to the disease being studied, and how this relates to the application. In addition, it was suggested that the internal application assessment form, and section 5(a) (Objective for Processing) and section 5(e) ((Is the Purpose of this Application in Anyway Commercial) in the application were amended to accurately reflect the commercial purpose, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.3.2** It was also suggested by the independent advisers that an assessment was undertaken of the commercial benefits and whether they were proportionate in terms of balancing with public benefits, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.3.3** The independent advisers queried whether the data provided would show pathways via NHS Trusts, noting this may have some commercial applications; and suggested that this was clarified and the application updated as may be appropriate, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.3.4** The group was disappointed that **no** patient and public involvement and engagement (PPIE) had been undertaken. Not least because this could be crucial to determining the balance of benefits (as raised in point 5.3.2 above), and suggested that the applicant undertakes PPIE. The HRA guidance on Public Involvement is a useful guide.	

	5.3.5 The group advised that the applicant was required to have a UK General Data Protection Regulation (UK GDPR) published privacy notice(s) prior to any data flowing from NHS England, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA). **5.3.6** The independent advisers noted that the application was for a fifteen-month (DSA), and suggested that NHS England consider extending this to two-years. In addition, independent advisers suggested that an annual report and an audit at one-year would be an appropriate approach for a new commercial applicant. The independent advisers noted that one of the Data Controllers was a *"new"* applicant for NHS England data, and suggested, in this case, that a two-year as opposed to a three-year DSA was justified. **5.3.7** Separate to this application, the independent advisers suggested that NHS England considered how benefits were captured for "shorter" DSAs and how such benefits were made transparent to the public. **ACTION:** NHS England to consider how benefits are captured and made transparent for shorter DSAs. **5.3.8** The group queried whether the Data Security and Protection Toolkit (DSPT) for Merck Sharpe and Dohme Limited covered the part of the organisation that would be involved with data controllership for this application; and suggested that clarification was provided. **5.3.9** The independent advisers noted in section 5(a) that all of the variables within the datasets would be requested; and suggested that this was reviewed to see if any data minimisation could be undertaken in line with NHS England's DARS standard for data minimisation. **5.3.10** The independent advisers noted the information in section 5(b) (Processing Activities) outlining the processing activities, however suggested that this was updated further with a clear outline of the actual processing activities, in line with NHS Digital DARS Standard for processing activities noting that it was currently not clear. **5.3.11** The independent advisers queried the output in section 5(c) (Specific Outputs Expected) *"A report of findings…"*; and suggested that this was updated with further information as to what this was, in line with the NHS Digital DARS Standard for Expected Outcomes.	NHSE
5.4	**Reference Number:** NIC-682583-Z3V2H-v0.5 **Applicant:** Adelphi Real World **Application Title:** A retrospective observational study of treatment patterns, resource use and outcomes in patients with early-stage Non-Small Cell Lung Cancer (NSCLC) in England	

SAT Observer: Kimberley Watson

Application: This was a new application.

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

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

Outcome of discussion: The group were **not** supportive of the application at this time and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting:

5.4.1 The independent advisers noted within the internal application assessment form and the application, stated that *"There is no direct commercial gain from the study"*; and noting that this may not be correct, suggested that further information was provided in respect of the medications that Merck Sharpe and Dohme Limited manufacture for the disease being studied, and how they relate to the application. It was suggested that the internal application assessment form, and section 5(a) (Objective for Processing) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application, were amended to accurately reflect the commercial purpose, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose.

5.4.2 It was also suggested by the independent advisers that an assessment was undertaken of the commercial benefits and whether they were proportionate in terms of balancing with public benefits, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose.

5.4.3 The independent advisers queried whether the data provided would show pathways via NHS Trusts, noting this may have commercial implications; and suggested that this was clarified and the application updated as may be appropriate, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose.

5.4.4 The group was disappointed that **no** patient and public involvement and engagement (PPIE) had been undertaken. Not least because this could be crucial to determining the balance of benefits (as raised in 5.4.2 above), and suggested that

	the applicant undertakes PPIE. The HRA guidance on Public Involvement is a useful guide. **5.4.5** The group advised that the applicant be required to have a UK General Data Protection Regulation (UK GDPR) published privacy notice(s) prior to any data flowing from NHS England in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA). **5.4.6** The independent advisers noted that the application was for a fifteen-month DSA, and suggested that NHS England consider extending this to two-years. In addition, the independent advisers suggested that an annual report and an audit at one-year would be an appropriate approach for a new commercial applicant. The independent advisers noted that one of the Data Controllers was a *"new"* applicant for NHS England data, and suggested in this case, that a two-year as opposed to a three-year DSA was justified. **5.4.7** Separate to this application, the independent advisers suggested that NHS England considered how benefits were captured for "shorter" DSAs and how such benefits were made transparent to the public. **ACTION:** NHS England to consider how benefits are captured and made transparent for shorter DSAs. **5.4.8** The group queried whether the Data Security and Protection Toolkit (DSPT) for Merck Sharpe and Dohme Limited covered the part of the organisation that would be involved with data controllership for this application; and suggested that clarification was provided. **5.4.9** The independent advisers noted in section 5(a) that all of the variables within the datasets would be requested; and suggested that this was reviewed to see if any data minimisation could be undertaken in line with NHS England's DARS standard for data minimisation. **5.4.10** The independent advisers noted the information in section 5(b) (Processing Activities) outlining the processing activities, however suggested that this was updated further with a clear outline of the actual processing activities, for example, by using some of the information outlined in the protocol; in line with NHS Digital DARS Standard for processing activities. **5.4.11** The independent advisers queried the output in section 5(c) (Specific Outputs Expected) *"A report of findings …"*; and suggested that this was updated with further information as to what this was, in line with NHS Digital DARS Standard for Expected Outcomes. **5.4.12** The independent advisers noted that the applicant had not obtained ethical approval for this application, as the data disseminated under this application was pseudonymised and not considered confidential; however suggested that ethical review/input was sought in line with NHS England's DARS Standard for Ethical Approval(awaiting publication).	NHSE

	5.4.13 The group discussed whether the Data Controller for this application was *"Adelphi Real World"*; or *"Adelphi Group Limited"*, and advised that they were content that that the correct information had been reflected in section 1(b) (Data Controller(s)) to state that *"Adelphi Group Limited"* were the correct Data Controller, but that NHS England check the right entity was identified in all relevant documentation. **5.4.14** The independent advisers noted that the objectives for processing in section 5(a) were correct and aligned with the protocol; however, noted that some of the objectives did not align with the outcomes in section 5(c), for example, the statement that *"the study is not looking at specific treatments and direct outcomes…"*, and that this did not align with the protocol. It was suggested that the application was reviewed in line with the objectives / outcomes outlined in the protocol and updated as may be necessary in line with NHS England's DARS Standards. **5.4.15** The independent advisers advised that the applicant should ensure that all benefits from the project should be published in the public domain in a timely manner, for example, within 18-months, whether they are positive or negative, to inform the wider community. **5.4.16** Noting the statement in section 5(a) *"The study will provide evidence to support ongoing medical strategies, inform the implementation of future clinical trials and support the UK reimbursement process";* it was suggested that further clarity was provided on this and whether there were any commercial implications. **5.4.17** The independent advisers queried whether one of the outputs would be aggregated datasets that could be used for further analysis; and suggested to NHS England that, if this was the case, there would be a risk associated with this since it would fall outside the agreement.	
5.5	**Reference Number:** NIC-667901-T5Z9P-v0.2 **Applicant:** Adelphi Group Limited **Application Title:** A retrospective observational study of treatment patterns, resource use and outcomes in patients with locally advanced, operable gastric cancer or gastro-oesophageal junction adenocarcinoma in a UK registry **SAT Observer:** Kimberley Watson **Application:** This was a new application. The purpose of the application is for a study, with the aim of describing the disease characteristics of patients diagnosed with a specific type of gastric (stomach) cancer or gastro-oesophageal junction cancer, called adenocarcinoma. The study will focus specifically on those patients whose tumour is able to be removed by surgery, and whose tumour has spread to nearby areas; and will describe the treatments they receive, how effective these treatments are and look at the use and costs associated with the healthcare provided to these patients in England. This study will also help	

	inform the use of new treatments that can improve outcomes for patients with locally advanced, operable gastric cancer and gastro-oesophageal junction adenocarcinoma. 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 **not** supportive of the application at this time and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting: **5.5.1** The independent advisers noted within the internal application assessment form and the application, stated that *"There is no direct commercial gain from the study"*; and noting that this may not be correct, suggested that further information was provided in respect of the medications that the Merck Sharpe and Dohme Limited manufacture that relate to the disease being studied, and how this relates to the application. It was also suggested that the internal application assessment form, and section 5(a) (Objective for Processing) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application were amended to accurately reflect the commercial purpose, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.5.2** It was also suggested by the independent advisers, that an assessment was undertaken of the commercial benefits and whether they were proportionate in terms of balancing with public benefits, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.5.3** The independent advisers queried whether the data provided would show pathways via NHS Trusts, noting this may have some commercial applications; and suggested that this was clarified and the application updated, as may be appropriate, in line with NHS England's DARS Standard for Objective for Processing and NHS England's DARS Standard for Commercial Purpose. **5.5.4** The independent advisers were disappointed that there had been no patient and public involvement and engagement (PPIE) undertaken, since this could be crucial in determining the balance of benefits (as raised in point 5.5.2 above), and suggested that the applicant undertakes PPIE. The HRA guidance on Public Involvement is a useful guide. **5.5.5** The group advised that the applicant was required to have a UK General Data Protection Regulation (UK GDPR) published privacy notice(s) prior to any data flowing from NHS England in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA). **5.5.6** The independent advisers noted that the application was for a fifteen-month (DSA), and suggested that NHS England consider extending this to two-years. In	

	addition, independent advisers suggested that an annual report and an audit at one-year would be an appropriate approach. The independent advisers noted that one of the Data Controllers was a *"new"* applicant for NHS England data, and suggested, in this case, that a two-year as opposed to a three-year DSA was justified. **5.4.7** Separate to this application, the independent advisers suggested that NHS England considered how benefits were captured for "shorter" DSAs and how such benefits was made transparent to the public. **ACTION:** NHS England to consider how benefits are captured and made transparent for shorter DSAs. **5.5.8** The group queried whether the Data Security and Protection Toolkit (DSPT) for Merck Sharpe and Dohme Limited, covered the part of the organisation that would be involved with data controllership for this application; and suggested that clarification was provided. **5.5.9** The independent advisers noted in section 5(a) that some data minimisation efforts had been undertaken; and suggested that this was reviewed to see if any further data minimisation could be undertaken in line with NHS England's DARS standard for data minimisation. **5.5.10** The independent advisers noted the information in section 5(b) (Processing Activities) outlining the processing activities, however suggested that this was updated further with a clear outline of the actual processing activities, for example, by using some of the information outlined in the protocol; in line with NHS Digital DARS Standard for processing activities. **5.5.11** The independent advisers queried the output in section 5(c) (Specific Outputs Expected) *"A final study report will be prepared…"*; and suggested that this was updated with further information, in line with NHS Digital DARS Standard for Expected Outcomes. **5.5.12** The independent advisers noted that Public Health England's (PHE) Research Ethics and Governance Group (REGG) had previously reviewed the purpose of the application; however, it was not clear if REGG reviewed the same proposal presented to the group (as outlined in this application) and therefore may not provide as much reassurance as it may appear.	NHSE
EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
6.1	**Reference Number:** NIC-365354-R3M0Q-v11.3 **Applicant:** University of Oxford **Application Title:** R1 (D09) - Data support to COVID-19 RCT (RECOVERY) **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the IGARD meeting on the 11th June 2020,	

	30th July 2020, 3rd September 2020, 12th November 2020, 26th August 2021, 14th October 2021, 27th January 2022, 23rd June 2022, 6th October 2022 and the 12th January 2023. The application and relevant supporting documents had previously been presented / discussed at the IGARD COVID-19 Response meetings on the 21st April 2020, 28th April 2020, 5th May 2020, 12th May 2020, 19th May 2020, 7th July 2020, 21st July 2020, 22nd September 2020, 1st December 2020, 26th January 2021, 28th September 2021 and 5th October 2021. The application and relevant supporting documents had previously been presented / discussed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 4th June 2020, 25th August 2021 and the 20th July 2022. **Application:** The purpose of the application is for a study aiming to compare several different treatments that may be useful for patients with COVID-19. These treatments have been recommended by the expert panel that advises the Chief Medical Officer (CMO) in England. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided. The NHS England SIRO representative thanked the group for their time.	
6.2	**Reference Number:** NIC-656757-J8V9D-v1.7 **Applicant:** London School of Hygiene and Tropical Medicine **Application Title:** Inequalities in Cancer Survival (ODR_1516_050) **Presenter:** No Presenter **Previous Reviews:** 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. **Application:** The purpose of the application is for a study aiming to understand why and how inequalities in cancer survival arise and persist in England, by studying how survival is affected by characteristics of the patient, the tumour, the management and care of the patients and the healthcare system factors. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided:	

	6.2.1 The group expressed concern that the territory of use had not been observed and noted that this gave further weight to NHS England providing a clear position on remote access. The NHS England SIRO representative thanked the group for their time.	
6.3	**Reference Number:** NIC-656777-B0V8N-v1.2 **Applicant:** University of Leeds **Application Title:** Life After Prostate Cancer Diagnosis (LAPCD) **Presenter:** No Presenter **Previous Reviews:** 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. **Application:** The original purpose of the application was to link the data collected by LAPCD as part of the survey of men with prostate cancer, with routine data from PHE. The request under this iteration of the application, is for the applicant to retain the data previously disseminated from PHE; whilst in the process of submitting a new application to NHS England, to use the data they already hold for a different purpose. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided: **6.3.1** It was suggested that it is problematic to state that data is no longer required for its original purpose because it opens the question as to whether there is a UK GDPR basis to continue holding it. However, it is plausible that the data here is being held for the existing purpose of public benefit research, but the new research is not explicitly covered by the existing agreement. The NHS England SIRO representative thanked the group for their time.	
AGD Operations		
7	**Statutory Guidance** The independent advisers again noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were **not** aware of an agreed risk management framework, and requested that NHS England provide further information/ clarity on this, noting this topic had been raised by Lord Hunt in the House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements - UK Parliament. **ACTION:** NHS England SIRO Representative to provide further clarity on the risk management framework.	GC

8	**AGD Terms of Reference (ToR)** Garry Coleman noted that NHS England were still considering comments from stakeholders on the AGD ToR. **ACTION:** The NHS England SIRO Representative noted a previous action to clarify when a revised draft of the AGD ToR would be presented to AGD and when the AGD ToR was scheduled to be considered by the NHS England Board / subcommittee of the Board.	GC
9	**Standard operating procedures** The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
10 **10.1**	**New Operational Actions & those carried forward from previous meetings of AGD:** **Zero Hours contracts for independent advisers** Vicki Williams noted that eight independent advisers had now moved to NHS England zero hours contracts, with just two independent advisers due to move from 1st August 2023. Vicki noted that NHS England were actively working to put the remaining zero hours contracts in place before the end of July 2023.	To note
Any Other Business		
11	**National Data Advisory Group** As discussed at the AGD meeting on the 13th July 2023, the SIRO representative provided a verbal update on the 'National Data Advisory Group' within the recently published '*Data Saves Lives Implementation Update'* (published 27th June 2023); and advised that there were ongoing discussions within NHS England in respect of AGD and the National Data Advisory Group, and that further information would be presented to the group in due course.	
Meeting Closure As there was no further business raised, the Co-Deputy Chair thanked attendees for their time and closed the meeting.		