Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 7th September 2023

09:30 – 14:30

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
Miranda Winram (MW)	Independent Lay Adviser **(Observer – new AGD member)**
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Noela Almeida (NA)	NHS England Data Protection Office Representative (Delegate for Jon Moore)
Garry Coleman (GC)	NHS England SIRO Representative (**Presenter**: item 8)
Cath Day (CD)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.1, 5.2 to 5.3)
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: item 5.1)
Kate Fleming (KF)	NHS England Data & Analytics Representative (Delegate for Michael Chapman)
James Gray (JG)	Digi-Trials Team (**Observer**: item 5.1)
Karen Myers (KM)	AGD Secretariat Team
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
France Perry (FP)	Digi-Trials Team (**Observer**: item 5.1)
Andy Rees (AR)	Digi-Trials Team (**Observer**: item 5.1)

INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Paul Affleck (PA)	Specialist Ethics Adviser
Claire Delaney-Pope (CDP)	Independent Specialist Adviser **(Observer – new AGD member)**
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Michael Chapman (MC)	Data and Analytics representative
Jon Moore (JM)	NHS England Data Protection Office Representative

1	**Welcome and Introductions** The NHS England Senior Information Risk Owner (SIRO) Representative, noting the Advisory Group for Data (AGD) Terms of Reference (ToR) had not yet been agreed, proposed that: • 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; Data and Analytics; 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. Kirsty Irvine 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 24th August 2023 meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.
3	**Declaration of interests:** Jenny Westaway noted that she had undertaken some paid contract work for Templar Executives to contribute to the development of a general e-learning course on data protection for Our Future Health. It was agreed this did not preclude the Jenny from taking part in the discussion about the Our Future Health application (NIC-411795-X5N2V). Kate Fleming noted a professional link to the National Disease Registration Service (NDRS) (NIC-656816-Z3N6R, NIC-656851-D6M5H, NIC-656886-D8H1H, NIC-656887-Q7M1C). It was agreed this was not a conflict of interest.
BRIEFING PAPER(S):	
4.1	**Title:** COVID Therapeutics Blueteq Briefing Paper **Presenter:** None **SAT Observer:** Cath Day **Previous Reviews:** The COVID Therapeutics Blueteq Briefing Paper was previously presented at the AGD meeting on the 10th August 2023. The purpose of the original briefing paper was to inform the group about this shell onboarded product to support an urgent application by Imperial College London and NHS Blood and Transplant requesting COVID-19 Therapeutics data, for the 'Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people' (MELODY Study). This request has support from the Secretary of State for Health and Social Care. **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: **4.1.1** The group noted that it was not possible to identify where updates had been made to the briefing paper, following the review on the 10th August 2023 and suggested that NHS England provide further information to the group, that clearly outlines what updates have been made and how the previous points have been addressed. The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting.
EXTERNAL DATA DISSEMINATION REQUESTS:	
5.1	**Reference Number:** NIC-411795-X5N2V-v0.8 **Applicant:** Our Future Health (OFH) **Application Title:** Our Future Health Outcomes TRE Data Linkage Application with Sublicencing

SAT Observer: Louise Dunn

Observers: Andy Rees, Frances Perry, James Gray

Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 13th July 2023.

The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meeting on the 22nd September 2022.

Linked applications: This application is linked to NIC-414067-K8R6J.

Application: This was a new application.

The purpose of the application is to **1)** obtain identifiable personal record-level data linked to a cohort of consenting participants held by OFH. Linkage to health records is a central component of the OFH programme, forming part of the core cohort dataset. To enable the high priority data linkages that will include secondary care, cancer data, and death data; and **2)** sub-licence the linked data with the global research community within the Our Future Health Trusted Research Environment (TRE).

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 The independent advisers noted that this application had previously been brought for advice to the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 22nd September 2022; and that the following **key point** from this review had not been comprehensively addressed:

> **5.1.2** The minutes from the 22nd September stated that *"It was noted that although the applicant had consent to hold the genomic data, further thought should be given to describing this as "pseudonymised" data, noting that unless this data had been partially redacted or further refined, current thinking in this area is that the data would in fact be identifiable".*

5.1.3 The group discussed this point; and agreed that although they were not offering a formal view as to whether the genomic data in this instance was identifiable; they did advise that in the majority of cases the genomic data **would** be deemed to be identifying data, as per the University of Cambridge report on the General Data Protection Regulation (GDPR) and genomic data.

5.1.4 In addition, the group discussed whether there was a legal gateway in consent for researchers accessing the data in the TRE, to view identifying genomic data (if it is deemed to be identifying); and noted concerns with any future amendments to the application, that may include the sharing of genomic data outside the TRE in numerous worldwide jurisdictions in respect of the identifiability of the data.

	In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.1.5** The group advised that they had assessed the application, with a view to **only** aggregated data leaving the Trusted Research Environment (TRE). **5.1.6** The group noted from NHS England that a future amendment application would be submitted, which would address potential dissemination of row level data. The group noted the verbal update from NHS England, however, advised that if the amendment was to be submitted to the group for review, there were significant issues and concerns that would need addressing. The NHS England SIRO representative confirmed that any future amendment to the application, would be subject to a review by the group. **5.1.7** The group discussed the *"worldwide"* sharing of the data, and agreed that the consent materials provided a clear indication that worldwide sharing of personal (pseudonymised) data was permitted; and were content that participants had consented to their personal (pseudonymised) data being disseminated worldwide. **5.1.8** Noting that there would be an assessment process for the granting of any sub-licences to applicants in jurisdictions that are not deemed *"adequate"* under UK GDPR; the group suggested that the criteria and process for this assessment was clarified and published; and advised that the group would welcome the opportunity to review the criteria and process **prior** to this being published. **5.1.9** The group noted that before researchers could export results data from the TRE, they would need to go through a *"statistical disclosure control process"*; and advised that this appeared to lack sufficient detail compared with other controllers of data of a similar magnitude. It was suggested that this was reviewed, expanded further, and made transparent to the public. **5.1.10** In respect of the competitive model, it was suggested by the group, that the procedure for this was more explicit and that OFH referred back to NHS England's DARS. **5.1.11** The independent advisers noted that this application had previously been brought for advice to the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 22nd September 2022; and reiterated the following points from this review: **5.1.12** *"NHS Digital* (now NHS England) *should review the model for sub-licences for TRE access, for example, noting that NHS England would presumably not need to audit the sublicensee if data was only accessed via the OFH TRE, as any data removed from that environment would be aggregated data".* **5.1.13** *"…noted concern on the enormous volume of possible sub-licence applicants, i.e. "200 – 1000 over a five-year period", most of whom would be based outside of the UK, it was suggested that NHS Digital* (now NHS	

	England) *gave this further consideration from a policy and practicality perspective. It was also queried how NHS Digital* (now NHS England) ***and*** *the applicant would maintain appropriate oversight of so many sublicensees, and asked that further consideration was given to this".* **5.1.14** The independent advisers discussed these points; and suggested that NHS England utilise their powers to audit the sublicensing arrangements within the first year of the data flowing t. In addition, it was also suggested that NHS England should also audit the applicant's process for considering applications to access data in its TRE and how this was working. **5.1.15** The group also noted concern about the proposed breadth of activity of the sub-licences, and queried how OFH would assess the benefits to the public versus the commercial benefits, for example in the context of *"data mining"*. **5.1.16** In addition, it was suggested by the independent advisers that the group had sight of and were able to comment on the applicant's annual report; and that this was a general point of advice and suggestion to NHS England in respect of **ALL** sub-licensors of NHS England data. **ACTION:** NHS England to consider submitting all NHS England data sub-licensors' annual reviews to the group for review / comments. **5.1.17** The group noted that they had provided advice on this on the 13th July 2023, and noted that following this review NHS England had made some suggestions to OFH in response to the points raised, as highlighted in the internal application assessment form. The group advised that they endorsed the comments / suggestions put forward by NHS England. **5.1.18** Notwithstanding the progress on the application since the last review, the group reiterated the following points from the 13th July 2023 that had not been sufficiently addressed:**5.1.20** *"In addition, an NHS England representative noted the geographical location of participants on the OFH Access Board, and queried whether they were representative of the cohort and that further information be provided".* **5.1.19** *"In respect of the OFH Access Board Standard Work Instructions, provided as a supporting document, the independent advisers noted that it was unclear when the Access Team and / or OFH Access Board provided approval, and suggested that further clarification be sought".* **5.1.20** *"It was also noted in the OFH Access Board Standard Work Instructions that the OFH Access Board does* ***not*** *seem to have the function/role to* ***balance*** *the public benefit against the commercial benefit and that this be further clarified".* **5.1.21** In respect of point 5.1.22, the independent advisers suggested that it may be helpful to add additional questions for the Access Board to consider to the 'Public Benefit Assessment in the Access Process' provided as a supporting document for	NHSE

example including: **1)** *"Are any commercial interests transparently described"*; and **2)** *"Is the board's assessment that commercial/private benefits are proportionately balanced with the benefits to the public"*.

5.1.22 The group noted that the OFH Access Board would be considering in detail approximately eight applications per week; and expressed concern regarding the capacity and depth of expertise on the Board, noting that there only appeared to be a minimum of one lay member and one expert member for quoracy. Concern was also noted that if the lay member or expertise on the Board expressed any concerns, that this may be overruled by the rest / majority of the Board, and queried what checks and balances were in place to ensure there was a balanced view on the Board.

5.1.23 It was also queried by the group, whether the OFH Access Team would be assessing the potential public benefit of applications, to determine whether this would be proportionate to the commercial benefit in line with the National Data Guardian guidance on benefits, or whether this would be considered by the OFH Access Board.

5.1.24 It was suggested by the group that OFH may benefit from consulting more widely with other organisations with experience of assessing complex applications of a similar nature; and to ensure that there is a robust review and sufficient input from a researcher perspective.

5.1.25 It was also noted by the group that if there is high initial interest, there could be a potential for a backlog of applications waiting for review to develop by the OFH Access Board, and that this should not influence the rigour / sufficient checks and review of the applications. In addition, it was queried how the OFH Access Board would prioritise applications if there was a backlog, and suggested that there was further transparency on this process.

> **5.1.26** *"In respect of the OFH Data Access Register, it was noted in section 5(a) (Objective for Processing) that this would include a "public benefit statement"; and it was suggested by the independent advisers that this the public benefits were assessed in line with the National Data Guardian (NDG) guidance on benefits; and that the commercial benefits accruing to the commercial organisation(s) were proportionate to the benefit to health and social care".*

5.1.27 It was also noted in section 5(a) of the application that the OFH Data Access Register would have a recommended seven minimum required fields; and it was suggested by the group that there should be more than seven minimum required fields.

5.1.28 It was also noted by the group that the OFH Data Access Register would need to be ready in parallel with the first applications to the OFH Access Board.

	5.1.29 *"The independent advisers noted the intention to link the data with other datasets, for example, the Office for National Statistics data; and suggested that this was reviewed to ensure that **all** data linkage was compatible with the consent".* **5.1.30** In respect of point 5.1.31, the group noted and supported NHS England's review on this point, as outlined in the internal application assessment form, in that there was concern that the point raised could have been interpreted in such a broad manner by OFH; and suggested that a special condition was added to section 6 (Special Conditions), to state that OFH are permitted to link NHS England data **solely** with other personal health-related datasets; and that this excludes for example, linkage with other administrative datasets such as education or employment data (but permits combining data with anonymous data). **5.1.31** In addition, the group noted that the consent covered **only** linkage with health related datasets; and would welcome the opportunity to provide advice on any proposals from OFH for a specific approach to expand their consent to cover such linkage. **5.1.32** The group noted that s261(4) of the Health and Social Care Act 2012 had been cited in the application; and were advised by NHS England, that this was an error and the application would need updating to reflect the correct legal basis of s261(2)(c). The group noted the verbal update. **5.1.33** In respect of the Data Protection Impact Assessment (DPIA), the group noted the importance of maintaining and ensuring this document was kept up to date with the most recent information, including but not limited to, an accurate record of any concerns and mitigating factors and that consideration was given to publishing the DPIA for transparency. **5.1.34** The group noted the information in various sections of 5(a) in respect of the funding arrangements; however, suggested that for ease of reference, this was updated to ensure that all funding information was grouped together under one heading. **5.1.35** The independent advisers advised that when this application returns for a future review; OFH should ensure that it was clear in the application and the supporting documents what data is to be accessed within the TRE and what data is for onward sharing.	
5.2	**Reference Number:** NIC-297783-V4P6H-v3.4 **Applicant:** GlaxoSmithKline R&D Ltd **Application Title:** Investigation of TRELEGY Effectiveness: Usual Practice Design (INTREPID) Exploratory data set **SAT Observer:** Cath Day	

	Previous Reviews: The application and relevant supporting documents were previously presented / discussed under "*Ignite Data Limited*" at the IGARD meetings on the 3rd September 2020, 1st October 2020, 7th October 2021 and the 10th February 2022. **Application:** This was an extension application. The purpose of the application is for an exploratory outcome for the Phase 4 study entitled 'INTREPID: Investigation of TRELEGY Effectiveness: Usual PractIce Design'. The main study has been completed but the exploratory outcome work continues as the feasibility of using national centralised healthcare records to reduce the burden of data collection at research sites is looked at. 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: **5.2.1** The independent advisers noted that this application had previously been reviewed by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 10th February 2022; and reiterated the following key point from this review that had not adequately been addressed: **5.2.2** The independent advisers *"noted the potential benefit of having publicly available information on the applicant's website, along with a paper copy of patient information provided at consent, to support public trust and confidence in pharmaceutical company use of health data. Noting that the applicant only provides a paper copy of the privacy notice at consent, it was suggested that an online notice would have the additional benefit of keeping the cohort updated on developments, since they may not be attending GP practices".* **5.2.3** The group advised that the applicant was required to maintain a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice(s) for the lifetime of the agreement, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA). **5.2.4** The independent members of the group reiterated their advice to NHS England that it would be helpful if applicants applying for an extension, renewal or submitting an annual report were asked to provide a web link to a UK GDPR published transparency notice(s), notwithstanding that it would remain the applicant's responsibility, not NHS England's, to ensure that it was UK GDPR-compliant. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.2.5** The independent advisers noted that the objective for processing as outlined in section 5(a) (Objective for Processing), did not align with the expected outputs in	

	section 5(c) (Specific Outputs Expected); however noted that the expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) did contain some expected outputs, and suggested these were reviewed and moved to section 5(c) as may be appropriate, in line with NHS England's DARS Standard for Expected Outcomes. In addition, it was suggested that section 5(c) was reviewed throughout to ensure that section 5(c) was clear as to what outputs are expected or have been achieved, for example, in relation to the cost assessment. **5.2.6** It was noted by the independent advisers that neither the application nor the internal application assessment form was clear as to whether an analysis / assessment had been undertaken, in respect of whether the commercial benefit accruing to the commercial organisation was proportionate to the benefit to health and social care, in line with NHS England's DARS Standard for Commercial Purpose. Noting that this had **not** been addressed it was advised that this would **not** currently align with the NDG guidance on benefits. It was suggested by the independent advisers that this was reviewed, and that section 5(e) (Is the Purpose of this Application in Anyway Commercial) and section 5(a) were updated as necessary, in line with NHS England's DARS Standard for Commercial Purpose and NHS England's DARS Standard for Objective for Processing.	
5.3	**Reference Number:** NIC-656816-Z3N6R-v1.4 **Applicant:** University of Oxford **Application Title:** Study to investigate the accuracy with which breast cancer recurrence can be identified in women registered with invasive breast cancer using routinely collected data compared with recurrence information collected by the AZURE trial (ODR1718_364) **SAT Observer:** Cath Day **Previous Reviews:** The National Disease Registration Service (NDRS) datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review. **Application:** This was an extension and amendment application. The amendments are to **1)** add NHS England as joint Data Controller to reflect joint working arrangements with the NDRS analysis; and **2)** to seek permission to utilise honorary contract working arrangement's during the term of the data sharing agreement (DSA). The purpose of the application is for a data-linkage study, that will use data from the AZURE Trial and link it to routinely collected data sources within NHS England to help evaluate the accuracy of an algorithm to identify breast cancer recurrences and serious adverse events using routinely collected data.	

	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 to the extent they were able to review (see 5.3.1 below) and wished to draw to the attention of the SIRO the following comments: **5.3.1** The group noted that the consent materials / NHS England consent review for this study had not been provided as supporting documents, and they were therefore **unable** to provide any comments on this aspect of the application. The independent advisers and the NHS England Caldicott Guardian Team Representative advised that sight of the consent materials and / or consent review would have been helpful to support the review of this application. **5.3.2** The independent advisers suggested that section 5(a) (Objective for Processing) was updated with clarification that PHE had previously undertaken a consent review, and that the use of the data was consistent with the original consent. **5.3.3** Separate to this application, the independent advisers advised NHS England that in order to support comprehensive reviews of such applications, it would be helpful to have the consent materials / NHS England consent review provided as supporting documents. **ACTION:** NHS England to ensure that consent materials / NHS England consent review are provided as supporting documents for all applications where consent has been provided. **5.3.4** Noting the amendment to add NHS England as a Data Controller, the independent advisers suggested that, separate to this application, NHS England should consider updating the ODR Precedent to exclude the need for an AGD review where the only substantive change is to add NHS England as a Data Controller. **ACTION:** NHS England should consider updating the ODR Precedent to reflect the process where NHS England are a Data Controller. **5.3.5** The group advised that the applicant was required to maintain a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice(s) for the lifetime of the agreement, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA).	DARS DARS
EXTERNAL DATA DISSEMINATION – SIRO APPROVED / SEEKING SIRO APPROVAL		
6.1	**Reference Number:** NIC-656851-D6M5H-v3.3 **Applicant:** NHS England & Health Quality Improvement Partnership (HQIP) **Application Title:** National Prostate Cancer Audit (ODR1920_024)	

	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 an audit, to assess the care process and its outcomes in men diagnosed with prostate cancer in England and Wales (this data sharing agreement (DSA) covers patients who are residents of England only). By auditing the care delivered by cancer services, we can highlight areas where hospitals are doing well and areas where the quality of care can be improved. The Audit produces performance indicators for all NHS providers, it allows cancer services to compare themselves with others in England and Wales, and share examples of good practice. The SIRO approval was for a 12-month extension. **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-656886-D8H1H-v1.3 **Applicant:** Adelphi Group Limited **Application Title:** Patient characteristics, treatment patterns and healthcare resource utilization of newly diagnosed locally advanced head and neck squamous cell carcinoma: an observational retrospective cohort analysis of real-world data in England (ODR2021_255) **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents were previously discussed at the IGARD meeting on the 13th October 2022. 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 to harness real world data from a nationwide registry to describe the characteristics of patients newly diagnosed with locally advanced head and neck squamous cell carcinoma (LAHNSCC) in England, including treatment patterns, clinical outcomes and healthcare resource utilisation. The SIRO approval was for a 6-month extension The data will be destroyed upon the 6- month extension ending.	

	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 independent advisers noted that there would be a commercial purpose to this application – noting that the pharmaceutical company involved in the application manufactured a drug used in treating LAHNSCC, and queried whether NHS England should review the process for commercial applications proceeding down the NHS England Precedent route, that have not had a previous independent review. **6.2.2** It was also suggested by the independent advisers, that the application should be more explicitly clear on the extent of commercial purpose, in line with NHS England's DARS Standard for Commercial Purpose. The NHS England SIRO representative thanked the group for their time.	
6.3	**Reference Number:** NIC-656887-Q7M1C-v1.3 **Applicant:** Adelphi Group Limited **Application Title:** Patient characteristics, treatment patterns and healthcare resource utilization of newly diagnosed Triple Negative Breast Cancer Patients: an observational retrospective cohort analysis of real-world data in England (ODR2021_259) **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents were previously discussed at the IGARD meeting on the 13th October 2022. 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 to harness real-world data using cancer registration and secondary care data in England, to characterise the treatment patterns, clinical outcomes and health care resource utilisation of locally advanced non-metastatic triple negative breast cancer patients, in the adult population. The SIRO approval was for a 6-month extension The data will be destroyed upon the 6- month extension ending. **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** The group noted the importance of the study.	

	6.3.2 The independent advisers noted that there would be a commercial purpose to this application, and queried whether NHS England should review the process for commercial applications proceeding down the NHS England Precedent route, that have not had a previous independent review. **6.3.3** It was also suggested by the independent advisers, that the application should be more explicitly clear on the extent of commercial purpose, in line with NHS England's DARS Standard for Commercial Purpose 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. The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the group, which confirmed that NHS England were asking the interim data advisory group to use the NHS England DARS Standards and Precedent model to assess the risk factors in relation to items presented to the interim data advisory group for advice; however the independent advisers noted that the wording in the in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is **separate** to the DARS Standards and Precedents, and asked that this be clarified by NHS England. **ACTION:** NHS England SIRO Representative to provide a written response addressed to AGD with further clarity on the risk management framework.	GC
8	**AGD Terms of Reference (ToR)** 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
Any Other Business		
10	**Data Access KPI Dashboard** The group noted that at the meeting on the 10th August 2023, it had been agreed that a monthly update would be provided on the current applications in progress within NHS England's Data Access Request Service (DARS) and at what stage the applications were at within NHS England's customer relationship management (CRM) system. The group thanked Michael Chapman for providing this information in advance of the meeting, and noted the content of the paper.	
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.		