Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on *07 March 2024* via video conference.

Present:

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Martin Andrew	CAG Member (Expert)
Mr Thomas Boby	CAG Member (Expert)
Dr Sandra Duggan	CAG Member (Lay)
Mr David Evans	CAG Member (Expert) – (Item 4a only)
Professor Lorna Fraser	CAG Member (Expert)
Dr Ben Gibbison	CAG Member (Expert) – (Except item 4e)
Mr Andrew Melville	CAG Member (Lay)
Professor Sara Randall	CAG Member (Lay) – (Except item 4e)

Also in attendance:

Name	Position (or reason for attending)
Mr Paul Mills	Confidentiality Advice Service Manager
Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Mr William Lyse	HRA approvals Administrator
Mr Dayheem Sedighi	HRA approvals Administrator
Ms Sandra Eismann	Observer - Chair of the Social Care Research Ethics Committee – (Items 4a & 4b only)

Ms Frances Burns	Observer - Responsible for setting up a “CAG equivalent”, based on Northern Ireland legislation once it is passed – (Except Item 4d)
Dr Sadiyah Hand	Applicant - Respiratory Consultant & CI (4a only)
Dr Ash Sinha	Applicant - Respiratory registrar (4a only)
Dr Linxin Li	Applicant - CI (4b only)
Mr Redouane Serroukh	Applicant - Head of Information Governance and Risk (4c only)
Ms Trudi Mount	Applicant - Head of Primary Care Digital (4c only)
Mr Carl Bates	Applicant - Head of Business Intelligence (4c only)
Ms Suzanne Wright	Applicant - Technical/Systems product owner, intelligence & research lead, Public Health Commissioning and Operations (4d only)
Ms Rachel Fernandez	Applicant - Senior IG Manager, IG Delivery (Digital and Operations) (4d only)
Ms Catherine Walker	Applicant - Project Manager, National Cancer Programme (4d only)
Ms Debbie Robinson	Applicant - Transformation Lead (4d only)
Ms Christy Burden	Applicant - CI (4e only)
Mr Andy Judge	Applicant - Deputy CI (4e only)
Mr Stefan Lewandowski	Applicant - Trial Manager (4e only)

1. APOLOGIES FOR ABSENCE

Apologies for absence was received from: Dr Rachel Knowles

2. DECLARATIONS OF INTEREST

2.1	**24/CAG/0047 (item 4c) & 24/CAG/0037 (item 4d)**	**H&WE ICB PHM & NHSE Multi-Cancer Blood Test Programme (pilot programme)**
	Conflict:	CAG Member Mr David Evans declared an interest in items 4c & 4d. These are non-research applications, and David works in the same team as the CAG non-research decision maker. The Committee agreed that Mr David Evans should leave the meeting for the review of these applications.

2.2	**24/CAG/0035 (item 4e)**	**The PARTNER Trial**
	Conflict:	CAG Member Dr Ben Gibbison declared an interest in item 4e. The study sponsor is his employer, and the applicants are known to him. The Committee agreed that Dr Ben Gibbison should leave the meeting for the review of this application.

3. SUPPORT DECISIONS

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has agreed to the advice provided by the CAG in relation to the **01 February 2024** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **01 February 2024** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- **26 January PS**
- **01 February full**

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4.a	**24/CAG/0031**	**Retrospective study investigating the clinical characteristic of patients with acute presentation for asthma to the A+E department in a busy acute hospital in England UK in Era of biological therapy for asthma between January 2019 and January 2024**
	Chief Investigator:	Dr Sadiyah Hand
	Sponsor:	Norfolk and Norwich University Hospitals NHS Foundation Trust
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

The Chair informed the applicants that there were observers in attendance at the meeting and the applicants confirmed that they had no objection to the observers being present.

Summary of application

This application from Norfolk and Norwich University Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to develop a better understanding of why patients present to A+E with asthma attacks.

The applicants seek to explore why patients present recurrently to A+E with asthma. This will include investigating whether recurrent presentations are due to TH2 low cases which cannot be treated with biological therapy or because secondary care does not have the capacity to appropriately manage their treatment and being biological therapy, and whether poor inhaler compliance is a factor in re-presentation to A&E.

The applicants will obtain a list of patients discharged or referred to medicine from A+E at Norfolk and Norwich University Hospitals NHS Foundation Trust with a discharge diagnosis of asthma. Support is not required for this as the researchers are part of the direct care team. Support under s251 is required to allow the researchers to obtain primary care data from the NHS Summary Care Record without patient consent, for linkage to the data obtained from Trust records. The linked dataset will then be anonymised before analysis.

Confidential information requested

Cohort	All patients aged 16 years and over with asthma as diagnosis on discharge from A+E who presented to A+E in the month of January of each year – between 2017 and 2023. The applicants anticipate that 400 patients will be included.
Data sources	1. Patient records at Norfolk and Norwich University Hospitals NHS Foundation Trust 2. GP records, obtained via the Summary Care Record
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID Number 4. Date of birth 5. Postcode – district level
Identifiers required for analysis purposes	1. Gender 2. Ethnicity

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG was concerned about the transfer of data by 'secure email' to a personal computer, especially if the de-identification process meant that re-identification could be undertaken quite easily. The CAG asked the applicant to justify why they were going to use a personal computer to process the data. The applicant responded that the NHS did not have the license for SPSS which was the statistics package used on computers, and it was not feasible to obtain this package on an NHS computer as it would cost a lot of money. Therefore they would require using personal computer to access university license for processing the statistics of the data. The applicants also reassured the members that data would be completely anonymised by the time it was transferred to the personal computer.

The CAG asked the applicant to explain how the data was going to be transferred from NHS computer to the university computer. The applicant responded that they would use an end to end encryption so that the data would not go anywhere or be lost. The CAG was satisfied with the response.

The CAG asked the applicant to explain whether it would be possible to process the data on a university server given that the license for SPSS was from university. The applicant responded that they were happy to use a university server instead of a personal computer. The CAG requested that protocol was updated to state that the data would be stored on the university server using an end-to-end encryption. **(Action 1)**

The CAG noted that the protocol mentioned contacting patients who they believed were at high-risk to inform them regarding available treatments. The CAG recommended that the patients were contacted by their GP who they were familiar with rather than getting an unexpected call from hospital. **(Action 2)**

The CAG was unclear about the data range as 5 or 6 years were both referenced with different start/end dates. The CAG asked the applicant to explain whether they were collecting the data just in consecutive Januarys or each January for the previous 12 months. The applicant responded that as part of their service development they had gathered asthma patient's information who had come through A&E for the past 5 years. The applicant explained that they did not have the resources to look at every single patient and therefore they would take a month each year to see how the services were doing since they had biologics. The CAG was satisfied with the response.

The CAG noted the GP data that they were looking at also included the treatment for psychological problems (mental health medication or social referral for support). The CAG asked the applicant to clarify why they needed to

include mental health problems. The applicant responded that an audit in 2024 had found, if a patient had mental health issues, then there were more likely to die from asthma. Therefore, it would be important to collect that data to see if they were getting more patients with mental health issues in case they needed to support people in that area. The CAG was satisfied with the response.

The members were not clear if the project was aiming to identify whether people with different phenotypes receive the proper treatment or to find out why the people go to A&E rather than GP. The CAG asked the applicant to clarify. The applicant responded that the aim of the study was to find out both of those objectives. The CAG requested that the applicant update the patient notifications to clearly explain the purposes of the project in terms of whether this application was exploring the consequences of an increase in referrals to A&E by looking at insufficient resources in general practices or whether the purpose was about improvements overall in patient compliance with the medication that was available. **(Action 3)**

The CAG asked the applicant to explain how they were going to manage the local opt-out. The applicant responded that they were informed that their IT team had a list of people who have already opted-out and those patients who have opted-out would be removed from the list. The CAG noted that the applicant described the National Data Opt-Out instead of study specific opt-out. The CAG explained that they would need a study specific opt-out mechanism in place to prevent patients using National Data Opt-Out to exclude themselves from future projects. Therefore, the CAG asked the applicant to create a study specific opt-out which was clearly separated from the National Data Opt-Out and was easily accessible, by including a phone number, email and postal address. **(Action 4)**

The CAG noted that the application did not undertake full public involvement for this study as no patients or member of the public was involved in design of the study. The CAG requested that specific patient and public involvement to be undertaken with proportionate representative groups, to discuss the use of confidential patient information, without consent, for the purpose of this application. **(Action 5a)**

The CAG also requested that the applicant to provide the result of public involvement input in the rewording of the patient notification materials. **(Action 5b)**

The CAG recommended that the applicants to get advice from a recognised statistician before proceeding with the project and read the guidance on CAG website. **(Recommendation 1)**

The CAG agreed that there needs to be clarity about the process of anonymisation. The CAG requested a clear description of the anonymisation process to include how it was going to be undertaken, the identifiers to be removed and what would happen to the identifiers once they were removed. **(Action 6)**

The CAG requested a communication plan including any actual notification materials that the applicant was planning to use to inform the population. **(Action 7)**

The CAG recommended that the applicants to get advice from the Information Governance team and cyber security regarding the anonymisation process to make sure that data was anonymised properly for transfer. **(Recommendation 2)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Update the protocol to state that the data will be stored on the university server using an end-to-end encryption.	
2.	Update the protocol to state that patients who are believed to be at high-risk will be contacted by their GP to be informed about the risks and available treatments.	
3.	Update the patient notifications to clearly explain the purposes of the project in terms of whether this application was exploring the consequences of an increase in referrals to A&E by looking at insufficient resources in general practices or whether the purpose was about improvements overall in patient compliance with the medication that was available.	
3.	Create a study specific opt-out which is clearly separated from the National Data Opt-Out and is easily accessible, by including a phone number, email and postal address.	

4.	Patient and public involvement needs to be carried out, and feedback provided to CAG: a. Specific patient and public involvement needs to be undertaken with representative group reflecting the size of the cohort, to discuss the use of confidential patient information, without consent, for the purpose of this application. b. All developed patient notification materials should be reviewed by the patient and public involvement group. For further guidance in respect of the Patient and Public involvement requirements, please refer to: Guidance for CAG applicants - Health Research Authority (hra.nhs.uk) and Public Involvement - Health Research Authority (hra.nhs.uk)	
5.	Provide clear description of the anonymisation process to include how it is going to be undertaken, what identifiers are going to be removed and what will happen to the identifiers once they are removed.	
6.	Provide an updated communication plan, including any materials that are going to be used to inform the cohort.	
Recommendation(s):		
1.	The CAG recommends getting advice from a recognised statistician before proceeding with the project.	
2.	The CAG recommends getting advice from the Information Governance team and cyber security regarding the anonymisation process to make sure that data is anonymised properly for transfer.	

The Group delegated authority to confirm its final opinion on the application to

the Chair and reviewers.

4.b	**24/CAG/0028**	The National Young Stroke Study
	Chief Investigator:	Dr Linxin Li
	Sponsor:	University of Oxford
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application

This application from University of Oxford set out the purpose of medical research that aims to understand why stroke is increasing at younger ages and to better inform preventative measures. The study will provide estimates of the associations of young stroke with traditional modifiable risk factors (such as high blood pressure, diabetes, high cholesterol level, smoking, alcohol and obesity) and emerging risk factors (such as mental health conditions, stress, long working hours, and oral health). The study will then compare frequencies of these traditional and emerging risk factors in young stroke patients and in stroke-free controls, to understand if these risk factors are more often found in young stroke patients.

The number of new stroke cases diagnosed yearly has declined at older ages. However, over the last 10 to 20 years, the incidence has been doubling in those aged less than 55 years (“young stroke”). There are now 20,000 new “young stroke” cases every year in the UK. Unfortunately, the reasons behind this increase are not known. There is, therefore, an urgent need to better understand the causes and routes to prevention of stroke at younger ages.

Eligible patients will be identified at 30 participating English sites by either the direct care team, or NIHR researchers. Eligible patients will be approached for consent, or consultee opinion, either whilst inpatients or in clinics. Where patients are identified and approached for consent by individuals who are not direct care team, ‘s251’ support is required. Data collected on emerging risk factors, via questionnaire, will always be with consent, and is therefore out of scope for ‘s251’ support. Linkage to NHS England outcome data (HES & civil registration mortality data) will be with consent, if consent was able to be sought. However there will be a sub-set of patients where consent or consultee advice was not able to be sought – those who are discharged quickly. These patients will receive an invitation letter from the participating site. ‘s251’ support is required for those who are not direct care team to send these invitation

letters. The letters will invite them to participate in the questionnaire element of the study, and inform them that if no action is taken, their confidential patient information alongside clinical data will be extracted from participating sites, disclosed to Oxford University, and linked to NHS England data. Identifiers will be sent to NHS England once recruitment is completed and NHS England will retain a flag for these individuals. Record-linkage will be annual for the first 5 years and then every 5 years until the end of follow-up (i.e. death or 30 years). Identifiers are retained by Oxford University for 30 years. Patients are able to opt out of this linkage if they wish. Non responders will be included into the study, with 's251' support, as direct consent for this linkage is not sought in the invitations, merely consent to the questionnaire element of the study.

Confidential information requested

Cohort	The study aims to recruit approximately 2000 (or more) young adult patients (18-54 years) with ischaemic stroke or intracerebral haemorrhage in England in total over the next 2 years. CAG cohort regarding data collection and retention covers only those who do not respond to letters – Applicant estimates this will be approximately 10-20% - (200-400 patients).
Data sources	1. NHS England – HES & civil registration mortality data 2. English Trusts – medical records - >30 participating Trusts 3. Data regarding mental health conditions, stress, long working hours, and oral health appear to be out of scope as are collected by a questionnaire and therefore with consent
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. sex 5. Unique study ID
Identifiers required for analysis purposes	1. Date of birth – modified to age in years 2. Date of death – modified to age in years and time from index event to death 3. Unit level postcode – modified to deprivation index and then first three digits retained only. 4. Gender 5. Occupation 6. Ethnicity 7. Unique study ID

	This is pseudonymous for analysis.
Additional information	Data will be retained in pseudonymised fashion using a unique study ID on the encrypted central database. However, the key will also be retained by the study, to enable linkage. The name, NHS number, DOB and sex will be only accessible by the PI (LL) and the Co-PI (PMR) with a separate encryption layer. Record-linkage will be annual for the first 5 years and then every 5 years until the end of follow-up (i.e. death or 30 years).

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG requested a justification for the 30-year retention period of participant data being kept. The applicant clarified that the study would be reviewing the long-term outcomes of stroke patients aged 18-54. The applicant stated that currently, there was a research gap in long term outcomes and therefore would like to continue following up with participants up to 30 years post study. The CAG considered the retention to be justified, however a condition will be provided to state that 's251' support will be provided for 5 years, at which time an amendment can be completed to extend the duration of 's251 support'. **[Condition 1]**

The CAG requested clarification on the exit strategy, specifically, the timepoint date of death will be deleted. The applicant clarified that date of death would be received after linkage, and the last linkage would be in 30 years. Once received, the applicant would calculate age, and time to death, and any other calculations required. Once modified, the full date of death would be deleted, and the applicant confirmed this would be undertaken as soon as they received it. The CAG was satisfied with the applicant's response.

The CAG requested clarification on the different groups of patients consulted with, as it was not clear if the Stroke Prevention Advisory Group (SPRAG) and the Stroke Prevention and Research Volunteer Advisory Group (SPaRVAG) are separate to the Wolfson Centre for Prevention of Stroke and Dementia (CPSD) patient and public involvement (PPI) group, which the applicant has consulted with. The CAG queried the size and makeup of these groups as well as the topics discussed and outcomes. The applicant stated that they conducted

patient involvement via the CPSD PPI group, comprising of 6 members, made up of previous stroke victims, families, and ambassadors from the stroke association, who are varying ages, ethnicities and socioeconomic backgrounds. This group has quarterly discussions, which occur in person or via email and were focussed on reviewing the study process and documents. The applicant stated that this group were supportive of the use of confidential patient information without consent, and also reviewed the patient notification materials.

The CAG queried whether the PPI groups voiced a preference regarding de-identification to be conducted earlier. The applicant confirmed that this was not the case, and no issues had been raised regarding this point.

The applicant also mentioned that she had undertaken less formal discussions with other patients who represent the cohort. The applicant also consents patients into a different study called 'Thames young stroke study', and had asked these patients informally about retaining identifiers for record linkage at 30 years. These patients were happy for identifiable data to be held lifelong, for continued access to their records. The CAG was satisfied with the applicant's comments.

The CAG requested for regular ongoing patient involvement to ensure that attitudes towards 30 year retention do not change, and for feedback to be provided to CAG at annual review. **[Condition 2]**

The CAG discussed the invitation materials with the applicant, as CAG felt that the letter could be made much clearer. The applicant confirmed all materials had been reviewed by the patient involvement group already. The CAG requested for the invitation letter to be further revised, simplified, and ensure it clearly outlines the study process and use of identifiable patient data. The CAG requested that the invitation letter should make it clearer that if the patient does nothing, their data will be used and retained for 30 years, for linkage. This is already on the invitation letter, but it is towards the end, and is not very explicit. The CAG commented that the distinction between the invitation to take part in the study, which involves completing a questionnaire, and the linkage which is undertaken with 's251' support needs to be more explicit. **[Action 1]**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Revise the invitation letter in line with advice, and provide an updated version to CAG. This should clearly outline the study	

	processes, provide a clearer statement that if the patient does nothing, their data will be retained for 30 years for linkage, and ensure the differences between consenting into the questionnaire, doing nothing, and opting out are clearly explained.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition
1.	's251 support' is in place for 5 years from the date of a supported outcome, which can be extended via duration amendment.
2.	Continue regular ongoing patient involvement and submit feedback at annual review
3	Favourable opinion from a Research Ethics Committee **Confirmed 23 January 2024**
4	Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:** The NHS England **22/23** DSPT reviews for **University of Oxford - Medical Sciences Division (8HM11) & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 12 March 2024) Due to the number of participating organisations involved it is the responsibility of University of Oxford, as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

4.c	**24/CAG/0047**	**Hertfordshire and West Essex Integrated Care Board Population Health Management**
	Contact:	Mr Alan Pond
	Data controller:	Hertfordshire and West Essex Integrated Care Board
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

The Chair informed the applicants that there was an observer in attendance at the meeting and the applicants confirmed that they had no objection to the observer being present.

Summary of application

This is a non-research application from Hertfordshire and West Essex Integrated Care Board (ICB) for the purpose of population health management.

Population Health Management involves using data to identify local 'at risk' populations to enable planning and targeting of interventions of the population to prevent ill-health and improve care for the local population. It allows commissioners to design appropriate care pathways for the population which can in turn reduce health inequalities and improve the health of the population.

Population Health Management necessitates the use of large scale, whole ICB population, use of national datasets combined with GP data. Support is requested for the flow of confidential patient information from GP suppliers to the risk stratification supplier for pseudonymisation, and to link this information with national datasets through pseudonymised NHS number. Support is not being requested for the flow of national datasets as this is sent in a pseudonymised form. Population Health Management analysis will be undertaken on anonymised or aggregated data and does not require support.

Confidential information requested

Cohort	All GP-registered patients in the Hertfordshire and West Essex Integrated Care Board area.
Data sources	1. GP data 2. National commissioning datasets
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	1. None

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that the patient notification was very similar to one submitted to CAG in response to conditions for their risk stratification application. On review of the document related to both purposes the CAG felt that the differences between risk stratification and population health management were unclear and requested that the privacy notice was reviewed and updated to make it clearer to patients. **(Condition 1a)**

Whilst understanding that the patient leaflet was recently approved by CAG under risk stratification purposes, the CAG agree that the leaflet could be further improved to ensure it is in a language that is accessible for patients. The CAG requested that the patient notifications were reviewed and updated to be written in language suitable for a lay reader. Members suggested that public feedback into the leaflet could support this development **(Condition 1b)**

The CAG noted that the Type 1 Opt-out mechanism is relied upon for the project specific opt out. Members agreed that this approach should proceed with caution given that this route would prevent information being shared outside a GP practice for purposes other than direct care and may have broader consequences. This caution should be added to the information leaflet. **(Condition 1c)**

Whilst mindful of the current difficulties that ICBs are experiencing in implementing a project specific opt out, members also requested that ICB look into further whether alternative arrangements for a project specific opt out could in time be made and asked the applicant to explore and report back a first annual review. **(condition 2)**

The CAG recommended that the posters and waiting room screen slides used in GPs for the purpose of patient notifications were made clear about the options of opt-out that were available to the patients. **(Recommendation 1)**

Confidentiality Advisory Group advice: Conditionally supported

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition	Response from the applicant
1.	Update the patient notifications to CAG within 6 months with the following: a. Update the Privacy notice to make it	

	clearer the differences between risk stratification purposes and Health population management. b. Patient notifications should be reviewed and written in language suitable for a lay reader. CAG suggested review by a public involvement group may help. c. Add a statement to the patient notifications to explain using a Type 1 opt out approach may impact the care patients receive.	
2.	Explore alternative arrangements for a project specific opt out, reporting back at first annual review.	
Recommendation:		
1.	The CAG recommended that the posters and waiting room screen slides used in GPs for the purpose of patient notifications to be made clear about the options of opt-out that are available to the patients.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

4.d	**24/CAG/0037**	**NHS England Multi-Cancer Blood Test Programme (pilot programme)**
	Contact:	Debbie Robinson, Transformation Lead Cancer Programme
	Data controller:	NHS England
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application

This is an application from NHS England to pilot a new screening programme for cancer with a view for future national roll-out.

The NHS Long Term Plan details the ambitions for improving cancer outcomes and by 2028, the aim is that 75% of people will be diagnosed at an earlier stage. The Multi-Cancer Blood Test Programme is piloting a blood test as a new way to screen for cancers and find them early. The pilot programme will invite people aged 50-77 years across 13 cancer alliance areas to book an appointment at an NHS clinic to provide a blood sample, which will be tested with the Galleri test. This follows from on 21/CAG/0056, a research application to support the invitation procedure to test the efficacy of the Multi-Cancer Blood Test (Galleri test) from GRAIL LLC.

This application requests support for the invitation procedure. The NHS England 'Cohorting as a service' (CaaS) provision will identify the cohort and provides a daily demographics file to the NHS England Galleri Pilot System. The National Disease Registration Service (NDRS) will provide information on participants within 21/CAG/0056 to the CaaS to remove any trial participants prior to transfer to the NHS England Galleri Pilot System. The NHS number and participant ID of those to be invited will be shared with NHS Notify (part of NHS England) who will collect name and address from the personal demographics service and send an invite.

Confidential information requested

Cohort	Aged 50 to 77 years of age and reside within the cancer alliance pilot areas. Those with a diagnosis of cancer, or previously participated in the GRAIL application will be excluded.
Data sources	1. National Disease Registration Service (NHS England) 2. Cohorting as a Service (NHS England) 3. Personal Demographics Service (NHS England)
Identifiers required for linkage purposes	1. Full name (including name prefix) 2. Full address, including postcode. 3. Telephone number (home and mobile) 4. Email address 5. Date of birth 6. NHS number (included any superseded NHS numbers) 7. GP Practice Name and Postal Code 8. Date of death
Identifiers required for analysis purposes	1. NHS Number

Main issues considered, discussed and outcomes

The CAG discussed that the application potentially had a high public interest and has the potential to bring significant benefits to patients. Noting that the efficacy of the test itself is subject to a separate ongoing research study the CAG asked the applicant what the purpose of this pilot application is. The applicant stated it was to test the roll out of a new screening programme in the real world and whether the NHS was able to manage potentially an increase in further tests as a result of any positive tests from the pilot. The research on the test itself is ongoing and this pilot would only start once an independent evaluation of the first-year data from the test was analysed and assessed as positive. NHS England has also commissioned a second independent evaluation of the screening pilot that is yet to begin and will be subject to a separate ethics application. This approach, to begin the screening pilot before final results of the tests are available, was part of a drive to shorten the time between clinical trial and implementation.

Whilst CAG members supported the initiative to move research to implementation quickly members noted that this application was pre-emptive and would only begin once NHS England confirmed the test itself can be used in the pilot, based on an independent evaluation of the first year data. As such, the CAG requested as a condition of support to be provided with the minutes of the meeting to give the go ahead of the pilot in order to have reassurance that the identification and invite procedure, undertaken under Regulation 5 support, has a public interest. **(Condition 1)**

Members also further discussed the position of NHS England that this is a non-research activity, terming it a ‘large in-service evaluation’. CAG members were of the opinion that the pilot to be undertaken was more reflective of research under the HRA definition. This was due to the fact that the Galleri test was not yet fully validated. Further the test was not being provided as standard of care given that it is only being undertaken in 13 out of 21 cancer alliance areas, and 1 million screening tests were available in an eligible population of 10 million, with a best-case scenario of sending 2.5 million invites. The applicant also indicated that purposive sampling will be used to over invite hard to reach groups to ensure the population screened was balanced. Members also noted that the applicants indicated a research evaluation application will be submitted to the research ethics committee at a later date.

Given the strength of views from the CAG, expert advice was sought from the Health Research Authority (HRA). The HRA confirmed it was ultimately the sponsor decision (NHS England) as to whether the activity was research or not. Following this advice members agreed to accept the position that the screening invite procedure could proceed as non-research but requested an update on progress towards the research evaluation at annual review **(Condition 2).**

Following the meeting, and given there was no review by a research ethics committee, members reviewed the patient information leaflet to ensure that patients were made aware that this is a pilot and that the risks and benefits were adequately explained. Whilst members were broadly content with the

information within the leaflet it was noted the risks focussed on the potential for false positives. There was no information for patients on the potential for false negatives and the associated risks. As such, the CAG requested that the patient information leaflet is updated to include information on the risks associated with false negative results **(Action 1a).**

The CAG noted that the communication leaflet felt too complex to read. The group queried whether all notification materials had been reviewed by the public involvement group. The applicant confirmed that the notification materials were still in draft and had not yet been signed off for use. The applicant reassured the CAG that the notification materials will also be reviewed by the public involvement group prior to release.

The CAG requested for all final notification materials to be reviewed by public involvement group, to ensure that content and written language was appropriate for the intended target audience. **[Action 1b]**

The CAG requested for clarification on how the pilot would be advertised to the public. The applicant clarified that promotion would be held via a national press release as well as displaying notification materials on each alliance and NHS website. The applicant continued, stating that each alliance would be provided with the materials and centrally agreed messaging, though it would their decision on how to promote the study locally.

The CAG was satisfied with the applicant's response.

The CAG requested clarification on how the research team intended to stage the roll out of invitations across the cancer alliances. The applicant stated that the invitations would be staggered, starting with one alliance, and when satisfied would proceed to others. The applicant also planned to over-invite certain populations to gain a balanced representation. The applicant anticipated that all 13 alliances will have started recruitment after 3 months.

The CAG was content with the applicant's response.

Regarding the identification procedure, the CAG questioned why information from the National Disease Registration Service was required in order to remove those participating in the current Galleri research trial, as this pilot is being undertaken in different cancer alliances from the research trial. The applicant stated that people may have moved across cancer alliances and therefore requested this data flow to ensure removal of all Galleri research participants.

Whilst CAG were satisfied with the applicant's rationale in principle, members also discussed whether, given the number of trial patients moving across cancer alliances is likely to be relatively low, the applicant could instead add this exclusion to the patient invitation letter for patients to be aware of and not respond. This is similar to the invited participants who are not eligible for this activity due to pregnancy, had cancer within the past 3 years or undergoing tests for suspected cancer. Doing so would lessen the breach in confidentiality

and CAG requested further justification as to why this is not an option **(Action 2)**

The CAG queried the applicant on whether they felt enough public involvement had been undertaken, as well as whether the numbers and representation of the engagement groups were proportionate to the size of breach that would be occurring. The applicant stated that they felt they had gained sufficient numbers within their engagement groups and had achieved a broad representation from minority ethic groups. The applicant clarified that they would also continue to engage with public involvement groups and campaigns alongside the ongoing pilot.

Whilst the CAG was content with the applicant's response, members noted that to date there was no evidence that patient and public involvement had been undertaken specifically on the use of confidential patient information without consent to identify and invite patients for screening. Members agreed that the applicants should, as a condition of support, undertake further work on this area and report back to CAG within 6 months. **(Condition 3).**

The CAG queried whether any identifiable patient data was being transferred outside of the England and Wales. The applicant clarified that only anonymous data was being transferred to the United States of America, to be processed by GRAIL.

The CAG was satisfied with the applicant's response.

The applicant requested exemption from applying the National Data Opt-Out (NDOO). The CAG requested the applicant to provide a justification as to why exemption from the NDOO was necessary.

The applicant stated that by exempting the NDOO all patients would have the opportunity to participate and would therefore reduce health inequalities, and the applicant did not want to disadvantage access to screening for those that applied their NDOO. The pilot is being undertaken to make sure that it can be run in the real world and applying the NDOO would introduce bias and could impact the evaluation on NHS delivery of a screening programme. Lastly the applicant felt that patients would have a reasonable expectation to be invited given that the applicant asserted that this was not considered to be research or planning.

The CAG challenged the applicants whether they are creating their own bias given they are not inviting the whole eligible population. The applicant responded that they are carefully considering the invitation procedure to take account of all groups in society.

The CAG queried whether the applicant had specifically sought views from public involvement groups on the acceptability of exempting the NDOO for this application. The applicant clarified that patients raised no concerns about the NDOO, though this exemption was not specifically discussed.

Members reflected that all activities under Regulation 5 Support are expected to apply the NDOO, as per the Department for Health and Social Care policy. Whilst the CAG has the ability to exempt the NDOO this is only agreed to in exceptional and limited circumstances. The CAG noted that previous exemptions have relied heavily on the applicant making a strong case that applying the NDOO will have a profound impact on patient safety, supported by strong evidence of public support through public involvement. The CAG also mentioned that an exemption might be considered if there was evidence of a detrimental effect on addressing health inequalities. Whilst the applicants mentioned the health inequalities issue, they also discussed the steps taken to address this by over-inviting the ”hard to reach “groups who are known to feature disproportionately in the NDOO cohort. Members agreed that the threshold to exempt the NDOO had not been met and agreed that the request was declined. The National Data Opt Out should be applied to this application.

Confidentiality Advisory Group advice: Provisionally supported.

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Update the patient leaflet to: a. provide information to patients on the risks associated with false negative results. b. ensure it is in lay language for patients, including a review by the public involvement group. Final versions should be provided to CAG.	
2.	CAG were unclear why there was a need for a flow of information from the National Disease Registration Service to remove participants from the Galleri trial when the numbers moving across cancer alliances is likely to be small. The applicants are asked to justify why instead information for Galleri participants to self-exclude cannot be added to the invitation letter to reduce the flow of confidential patient information, as already happens with those who are pregnant, had cancer within the past 3 years or undergoing tests for suspected cancer.	

The CAG also agreed that the following specific conditions should be added to the final support outcome on satisfactory review of the provisional response.

Number	Condition	Response from the applicant
1.	Provide, by June 2024, CAG with the minutes of the meeting that agrees to proceed with the pilot, on satisfactory advice that the independent evaluation of the Galleri trial first year data is sufficiently positive.	
2.	At annual review provide an update on progress towards the research evaluation.	
3.	Within six months of the supported outcome provide an update on further public involvement specifically on the acceptability of using confidential patient information without consent for the purposes of this pilot screening invite.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

4.e	**24/CAG/0035**	**PregnAncy Risk assessmenT aNd dEcision suppoRt (PARTNER): A Clinical Decision Tool To Reduce Placental Disorders and Preterm birth in Pregnancy**
	Chief Investigator:	Dr Christy Burden
	Sponsor:	University of Bristol
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

The Chair informed the applicants that there was an observer in attendance at the meeting and the applicants confirmed that they had no objection to the

observer being present.

Summary of application

This application from the University of Bristol set out the purpose of medical research that seeks to assess the effectiveness of the Clinical Decision Support Tool on reducing incidences of hypertensive disorders compared with standard care.

There are 25,000 cases of pre-eclampsia, 3000 stillbirths and 60,000 preterm births per year in the UK. The rates of stillbirth and preterm birth vary widely between hospitals, even when adjusted for population socio-economic and demographic characteristics. This demonstrates that poor pregnancy outcomes are principally a consequence of local variations in risk assessment and inconsistency in delivery of maternity healthcare pathways. Recent national reports have identified that staff struggle with a lack of information, support and resources to provide best care, and that guidelines and best practice are not always followed. Targeted use of these interventions relies on accurate identification of women and pregnant people with at-risk pregnancies, which at present, is undertaken using a checklist of risk factors first adopted into antenatal care 50-years ago. The checklist does not weight risk factors, account for interaction between risk factors, or even include risk reduction for absence of any risks. With this in mind, Tommy's Pathway: a Clinical Decision Support Tool has been developed by the Tommy's National Centre for Maternity Improvement. The Clinical Decision Support Tool processes data already gathered at antenatal appointments as well as information directly entered by patients.

The PARTNER Trial aims to evaluate the effect of the 'real world' implementation of the Tommy's Pathway: a Clinical Decision Support Tool within the NHS. Maternity units that join the study will be put into one of two groups. One intervention group will follow risk assessments and interventions as per the Clinical Decision Support Tool. The usual care/control group will carry on using their risk assessments and interventions as per local care pathways. At the intervention sites, staff will input personal information into the Tool and the MIS systems they use as normal. Patients will also use the Tool so that they can actively participate in their own care. The site uses the Tool and the personal information entered into it to provide maternity care recommendations.

The information collected through the Tool is the same information routinely collected by maternity care providers during maternity care. At control sites, the usual MIS system will be used to collect data. Quarterly extracts will be sent from both intervention and control sites to the University of Bristol for monitoring purposes. Extracts from the same system (e.g. the multiple quarterly extracts from MIS) will need to be linked with each other using patient identifiers. For intervention sites, the Tool extracts will be linked to the MIS extracts to compare the data collected on each, also whether the recommendations by the Tool were acted on and the Tool used as intended and the extent to which the Tool is used within the population it is intended for.

Confidential information requested

Cohort	Women giving birth within participating NHS Trusts. The applicants anticipate that up to 62400 patients will be included. 13 – 30 maternity units will participate.
Data sources	1. Electronic maternity records and scan viewing systems, and data entered on to the Clinical Decision Support Tool, at participating trusts.
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Ethnicity

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG was not clear why support was needed for parts of the data flow. Members agreed that transfer of data to the tool and access by the device manufacturer was for the purposes of direct care. It was also unclear why linkage was required for linking Maternity Information System (MIS) data to MIS data from the same system and why no pseudonymised or internal identifier could be found to be entered into the tool for linkage. The CAG asked the applicant to explain whether it was possible to use the hospital number that came from the same institution to prevent asking everyone to provide a full set of identifiers to complete the linkage. The applicant responded that due to the process of collecting data from this tool at the moment, the data for that tool was not going to be stored in an MIS and would be stored on an NHS England server instead. However, the data flow diagram shows that the Hospital number is flowing in the tool and available in the hospital records. The CAG requested that the applicant explore practicable alternatives with NHS England to see whether they could minimise the information flow to avoid section 251 support. **(Issue 1)**

The CAG noted that the applicants plan to store confidential patient information

and other study documentation securely until the youngest child born during the recruitment period turns 25. This was in case the child wanted to make a claim to the University of Bristol regarding their participation in the trial, which could be made until the child turns 25. After this time paper and electronic records would be destroyed by secure and confidential means. Members agreed that this was a very long time for personal data to be kept and that section 251 support could not be provided for the retention of personal data for 25 years. Members asked that the applicants explore whether the data held by the University could be pseudonymised to allow re-identification should a participant raise a claim specifically about the study. The CAG requested that the notification material to be updated to reflect that the personal data would no longer be retained for 25 years. **(Issue 2)**

The CAG asked the applicant to clarify how many people were involved in the Patient and Public Involvement group. The applicant responded that there were a variety of members with different lived experience in maternity. The applicant explained that they were involved in reviewing posters and privacy statements. There were also discussions around data arrangements and what was going to happen to the data. The CAG was satisfied with the response.

The CAG noted that the application explained that there may be instances where the device Digital Developers (Apadmi) and the device manufacturer (RCOG) would require access to individual level patient identifiable data (i.e. a specific user profile) to investigate and resolve errors, issues or bugs. Members agreed that section 251 support was not appropriate for this as it was outside the purpose of medical research. The CAG asked the applicant to clarify whether they had discussed the legal basis for this processing with NHS England. The applicant responded that after processing the data the maintenance would become the applicant's responsibility. The CAG suggested that applicant discuss this issue with NHS England to seek a legal basis to provide developers to personal data. **(Issue 3)**

The CAG requested that the patient notification was revised to make sure the terms "anonymised" and "pseudonymised" were used in a consistent way. **(Issue 4)**

<u>Confidentiality Advisory Group advice:</u> Deferred

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received. The CAG noted that the following points should be taken into consideration and addressed prior to resubmitting this application in future.

Number	**Issue:**

1.	Explore practicable alternatives with NHS England to see whether the flow of confidential patient information can be altered to minimise the support under s251 required.
2.	Section 251 support cannot be provided for the retention of personal data for 25 years. Explore whether the data held by the University can be pseudonymised to allow re-identification should a participant raise a claim specifically about the study. The notification materials need to be updated to reflect that the personal data will no longer be retained for 25 years.
3.	Section 251 support is not an appropriate legal basis for Digital Developers (Apadmi) and the device manufacturer (RCOG) to access individual level patient identifiable data.
4.	The patient notification needs to be revised to make sure the terms “anonymised” and “pseudonymised” are used in a consistent way.

5. CONSIDERATION ITEMS

There were no items for consideration.

6. ANY OTHER BUSINESS

There was no other business for discussion.

Insert name of member that chaired the meeting

Dr Tony Calland MBE
Dr Murat Soncul — Agreed via correspondence 15 March 2024

…… ……..
Signed – Chair *Date*

Dr Paul Mills
Ms Caroline Watchurst
Ms Kathleen Cassidy
Mr William Lyse
Mr Dayheem Sedighi — 22 March 2024

…… ……..
Signed – Insert job title *Date*