Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on *04 April 2024* via video conference.

Present:

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Martin Andrew	CAG Expert Member
Mr Thomas Boby	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Ben Gibbison	CAG Expert Member – (Except item 4c)
Dr Pauline Lyseight-Jones	CAG Lay Member
Mr Andrew Melville	CAG Lay Member
Mrs Sarah Palmer-Edwards	CAG Expert Member
Mr Umar Sabat	CAG Expert Member – (Items 4a & 4b only)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Mr William Lyse	HRA Approval Administrator
Mr Dayheem Sedighi	HRA Approval Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Laura Fairman	Observer - HRA Approval Administrator (Items 4a & 4b only)

Mr Nicholas Longhurst	Observer - HRA audit and risk committee
Ms Claire Edgeworth	Observer - Head of Strategic Information Governance, NECS/NHS England (Item 4c only)
Mr Jamie Webb	Applicant - Project Manager (4a only)
Dr Timothy Jobson	Applicant - liver specialist at Somerset NHS Foundation Trust (4a only)
Ms Rachel Snow-Miller	Applicant - Head of LeDeR (4b only)
Ms Emma Stark	Applicant - Premature Mortality Development Senior Manager, Learning Disability & Autism Programme, NHS England (4b only)
Ms Nicola Easey	Applicant - Head of Health Improvement Learning Disabilities & Autism - NHS England and NHS Improvement (4b only)
Ms Amy Dillon	Applicant - Data Access Lead, GWSDE (4c only)
Mr Charlie Kenward	Applicant – Chief Investigator (4c only)
Mr Henry Ireland	Applicant - Programme Director (4c only)
Ms Amanda Threfall	Applicant - Digital Critical Friend (4c only)
Mr Arron Bernard	Applicant - Chief Investigator (4d only)
Ms Mary Goodwin	Applicant - SID Programme Manager (4d only)
Ms Lindsay Wells	Applicant - Head of Information Governance and Trust Data Protection Officer (4d only)
Mr Jon Elsom	Applicant - SID Data Architect Lead (4d only)

1. APOLOGIES FOR ABSENCE

There were no apologies for absence.

2. DECLARATIONS OF INTEREST

2.1	**24/CAG/0057**	**Great Western SDE**
	Conflict:	CAG Member Dr Ben Gibbison declared an interest for item 4c – as he knows the applicants, although he has had no involvement with the application. The Committee agreed that Dr 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/not yet provided a response to the advice provided by the CAG in relation to the 07 March 2024 meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the 07 March 2024 meeting applications.

Minutes:

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

PS CAG Meeting 01 March 2024
Full CAG Meeting 07 March 2024

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4.a	**24/CAG/0052**	**The Development of a Combined Multi-Modal Non-Invasive Biomarker Screening Approach for High-Risk Undiagnosed Liver Disease**
	Chief Investigator:	Dr Patrick Short
	Sponsor:	Sano Genetics
	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 Sano Genetics set out the purpose of medical research that aims to demonstrate the cost effectiveness and potential utility of a combined population risk stratification approach to identify patients in Somerset, at risk of progressive liver disease, using historical blood tests initially, and then also including ultrasound evaluation of the liver (transient elastography and continuous attenuation parameter scores) and genetic markers of risk of progression. The key outcome for this project is the development of a blueprint

for population-level liver risk-stratification and case identification which could be applied to the whole population.

It is known that many people with long term liver disease are not identified until it is too late for meaningful treatment. These people have no (or very few) symptoms and lack of treatment can lead to irreversible liver damage (cirrhosis), and this can in turn lead to cancer, liver failure and premature death. The true rate of cirrhosis in the population is unknown but it is likely that only 1 in 20 to 1 in 30 people with advanced liver disease are actually known about and being treated or monitored. Identifying at risk patients is challenging and many potential approaches are too costly. Screening of the whole population with interventions such as liver biopsy or MRI scans is not affordable and/or too risky. It is also known that many people ultimately found to have advanced liver disease have had minor changes in many previous blood tests, going back over many years. These blood tests were usually performed as part of routine screens or for investigation or monitoring of other illnesses and the true implications for liver health are not recognised. In addition for many people, progression of liver disease is driven by particular variations in their genes. The understanding of these genetic markers has increased significantly over the last few years, and it is now possible to rapidly identify a panel of genes and therefore an individual's risk for liver disease. Therefore combining a system which scans through millions of historic blood test results, and then including a simple saliva based test for genes relevant to liver disease may be a way to identify the population at high risk of liver disease. If successful, this project will identify a way of risk stratifying the whole population in an affordable way which has the potential to be a key intervention in the prediction and prevention of liver and metabolic disease.

The hepatoSIGHT platform has been developed for longitudinal blood test integration, and is currently in use within Somerset. GP and hospital blood test data which are already processed for direct care purposes are entered into the hepatoSIGHT platform, and the population of Somerset is risk stratified to identify those at risk of liver disease, and are then invited for treatment by the liver team.

This application requires 's251' support in order to disclose identifiers from the hepatoSIGHT clinical platform within Somerset NHS Foundation Trust to the liver team also within Somerset NHS Foundation Trust. This is because the liver team cannot be considered direct care team for all the patients in Somerset, especially if their data originated from one of the GP practices and not the Trust. The National Data Opt Out (NDOO) will be applied at this stage. Data will be disclosed regarding approximately 17,000 25-35 year olds and 29,000 45-55 year olds who have had sufficient blood tests. The liver team will use risk stratification techniques to look at pre-existing blood test results and look for patterns over time that might suggest a risk of future liver disease, to identify potential participants from 4 separate groups. These groups are age 25-35 high risk patients, age 25-35 low risk patients, age 45-55 high risk patients, and age 45-55 low risk patients.

The liver team at Somerset will send invitation letters to patients to invite them

to consent into the study, which will involve providing a saliva test and undergo a liver scan. After the point of consent, no further 's251' support will be required. The study aims to include 85 people from each group in Somerset (a total of 340 people). The applicants will aim to send letters to more people than this, as they do not expect to get 100% response rate, and will send letter in batches until the recruitment target of consented patient is reached.

Confidential information requested

Cohort	All patients in Somerset between 25-35, and 45-55 who have had (Liver Function tests) LFTs on 4 or more occasions with the last being within the last 5 years. Applicant estimates this to be 17,000 younger and 29,000 older patients in database with sufficient LFTs. Invitation letters will be sent out in batches, in order to aim to consent 85 people in each of the following groups: 1) Age 25-35 high risk (maximum of 1275 patients will be sent a letter) 2) Age 25-35 low risk (maximum of 16940 patients will be sent a letter) 3) Age 45-55 high risk (maximum of 2068 patients will be sent a letter) 4) Age 25-35 low risk (maximum of 27476 patients will be sent a letter)
Data sources	Previous blood tests from Medical records at Somerset NHS Foundation Trust, and Somerset GP practices, which are already contained in the hepatoSIGHT clinical system which operates within Somerset NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for sending invitation letters	1. Name 2. Address
Identifiers required for analysis purposes	1. N/A as analysis undertaken with consent

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 noted that there is already a clinical database called the hepatoSIGHT system which operates within Somerset NHS Foundation Trust, since 2020, which is not the subject of this CAG application. The common law legal basis for the current 'Clinical care' risk stratification process using the hepatoSIGHT system within Somerset NHS Foundation Trust was considered originally by the Trust and GPs to not require 's251' as it was originally assessed that this was direct care. The CAG asked the applicant to explain a little bit more about this process, to understand if this was indeed direct care, or if a non research application for 's251' support was needed for this risk stratification process.

The applicant explained that this clinical database contains NHS number, date of birth, and blood results regarding all patients in Somerset with certain blood results. This includes data disclosed from GP practices, even if the patient has never attended the hospital. Patient data is analysed within the hepatoSIGHT system, and any patients with certain combinations of blood results are invited to clinic, by the liver team at the Trust. All relevant data controllers for that data have previously ascertained that this process does not require 's251' support. However the applicant explained that it was now his understanding that this non-research process may require 's251' support, as the liver team are processing identifiers without consent, and are not considered direct care team for many of these patients, as per the reasoning for the current research application. The liver team use a risk stratification tool, and therefore for those most at risk who are identified as requiring treatment, the purpose is direct care at the point they are re-identified and invited to be treated by the liver team. However this would not constitute clinical care for most of the patients whose data is used, and the liver team would be not be considered part of the direct care team for many of these individuals, who do not require treatment, but whose identifiable data has still been processed, without consent.

The CAG asked the applicant to directly confirm whether the liver clinicians were able to see information from patients that they were not directly caring for using the system. The applicant confirmed that the liver clinicians were able to see identifiers regarding patients that were not in their direct care.

The Members agreed that a non-research CAG application for the Somerset NHS Foundation Trust hepatoSIGHT system was likely required, to assure CAG of the common law legal basis for the data source for this research application. The applicant requested if the non-research application could be exempted from the National Data Opt Out (NDOO), and the CAG explained that a supporting paper could be submitted alongside the non-research application

regarding NDOO exemption, and to seek further advice from the Confidentiality Advice Team (CAT). **(Action 3)**

The CAG noted that the majority of patients included in the Patient and Public group were liver disease patients. The CAG asked the applicant to clarify whether they had included patients from other populations, as the risk stratification tool would be used on many people who did not have liver disease. The applicant responded that they had created the Predictive Health Intelligence: Public and Patient Reference Group in 2019, and this has evolved over time. Currently there were 12 regular attenders in this group and they were predominantly general members of public rather than specific liver patients. Going to the next stage the applicant has invited people who had gone through this process to provide feedback for the project. The CAG was satisfied with the response.

The Members noted that in order to inform people of the potential of their data being included in this research, the team would publicise this locally through NHS information channels, as well as local media and project specific websites. Mechanisms for opting out would also be on the NHS Trust and project websites, Local Newspaper and GP practices in poster format. The CAG also commented that the applicant did not provide the draft GP poster and therefore asked the applicant to provide the draft posters for CAG review. **(Action 4a)**

The CAG agreed that the patient notification materials were not clear that the trial would also include a commercial element to the research, which should be included, even though the commercial partners do not process any identifiable data. The CAG requested that the patient notifications were updated to be transparent about the involvement of Sano Genetics, and to be clear therefore that this project also included commercial elements. **(Action 4b)**

The CAG felt strongly about GP engagement/education regarding this study, and noted that the applicant mentioned some GPs have opted to not submit their data into the current hepatoSIGHT system. The CAG asked the applicant to clarify whether that meant the other GPs were aware of the system, and the study. The applicant confirmed that most GPs were engaged with the system and discussions had been underway since 2019. It was also noted that the study would inform GPs at the time point one of their patients consented into the study. The CAG was satisfied with the response.

<u>Confidentiality Advisory Group advice:</u> 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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Security assurances for 2022/23 are outstanding for the following organisations. • *Somerset NHS Foundation Trust* Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	
3.	A non-research CAG application should be submitted and supported, to provide a common law legal basis for the existing processing within the hepatoSIGHT system, as this is the data source for this research study, and a common law legal basis should be in place for each data source prior to the study starting.	
4.	The CAG requests the following regarding patient notification materials: a. As discussed in the meeting please provide the draft poster that is going to be used in GP practices for the purposes of communicating a study specific opt out to the relevant cohort. b. Update the patient notifications to be transparent about commercial elements of the study, and the involvement of commercial companies.	

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

4b	**20/CAG/0067**	**Learning Disability Mortality Review (LeDeR) programme**
	Contact:	Rachel Snow-Miller

	Data controller:	NHS England
	Application type:	Non-research
	Submission type:	NDOO exemption request

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 NDOO exemption request

This is a request to defer the National Data Opt-Out (NDOO) for 20/CAG/0067. The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities and autistic people (aged 4 years and over) in England.

The activity was previously given support under reference 16/CAG/0056. A new application (20/CAG/0067) was given support in May 2020 as the data controller for the application changed from HQIP to NHS England.

LeDeR has existing 's251' support to process confidential patient information as follows;

- For South Central and West Commissioning Support Unit (hosted by NHS England) to receive reports containing personal details about people with learning disabilities who have died. These could come from many sources, and some sources would be patient relatives, and as such that data would not be confidential patient information. 's251' support is in place where the report does come from a health and social care professional, and would constitute confidential patient information.

- To allow a reviewer to collect detailed case information from health or social care case notes, to conduct a review of the death. The reviewer will collect identifiable and clinical information on the deceased person, but also the name of relative/next of kin, their address, and relationship to the deceased. Reviews may be undertaken by ICBs, or by data processors on behalf of ICBs.

- For South Central and West Commissioning Support Unit to internally link to civil registration mortality dataset to identify each person's causes of death.

As part of the request, the applicant provided two core reasons why application of the NDOO would impact the running of LeDeR.

1. Patient safety – loss of data in the form of individual cases will reduce the ability of LeDeR to identify incidents where people with learning disabilities

have been treated poorly, where the poor care contributed to their deaths, which is of great concern regarding patient safety, as this would damage care for all individuals living with a learning disability, under the care of health services.

2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data, and will further exacerbate health inequalities.

Main issues considered, discussed and outcomes

1. Deferral rationale: patient safety

The paper set out a strong argument detailing the potential impacts of a potential loss of information regarding individual cases, on patient safety. LeDeR was set up to ensure that all patient deaths of all people with learning disabilities and autistic people (aged 4 years and over) are investigated, by case review of the entire care pathway, and that learning feeds into improvements in the quality and safety of care regarding those who are living with a learning disability, to prevent future deaths. In doing so, LeDeR aims to improve care, reduce health inequalities and prevent the premature mortality of people with a learning disability and autistic people. LeDeR is an important safeguarding mechanism in identifying specific examples of poor care. There are cases where people with learning disabilities have been mistreated, which have been identified via the LeDeR review. The Care Quality Commission (CQC) has stated that too many hospitals for people with a learning disability or autism are providing poor care which is, at times, undignified and inhumane. This is shown in examples such as Cawston Park, who were found to have staff physically assaulting and failing to meet the healthcare needs of patients with a learning disability and autism. LeDeR received notifications of the deaths of three patients at Cawston Park and, because of learning from these reviews, improvements have been made based on learning from the deaths to improve care for others.

There is longstanding evidence that people with a learning disability experience high rates of health inequalities and premature mortality:

- people with a learning disability die, on average, over 20 years younger than the general population.
- 42% of deaths of people with a learning disability in 2022 were deemed avoidable (i.e. preventable or treatable) compared to 22% for the general population.
- concerns about the overall quality of health or social care were identified by reviewers for 25% of deaths of people with a learning disability in 2022.

LeDeR do not rely on complete national case ascertainment in order to make recommendations. LeDeR is different to other audits, because it does not look for statistical outliers of poor care – these require 100% case ascertainment to be effective. Instead LeDeR looks in detail at individual cases to help ascertain service improvement. Its methodology is qualitative more than quantitative.

LeDeR identify cases of poor care via individual case review, by reviewing information about the health and social care that the deceased individuals received. Each time a single review is missed, this represents a missed opportunity to identify poor care, which impacts on those people who are alive and in the health care system, by removing opportunities to improve care and prevent premature mortality. LeDeR review approximately 3,300 cases annually. If the NDOO was applied (at 5% opt out rate), this would mean LeDeR would miss 165 cases annually. Of these 165 cases, it is expected that 42% of those deaths would have been avoidable, and 25% would have a concern about the quality of care. This would mean 41 individual cases annually, where LeDeR would not be able to identify and rectify poor care in order to prevent future deaths of living people with learning disabilities, and living autistic people. In the Cawston Park example, there were just three cases from one organisation in order for LeDeR to identify mistreatment, (and would have likely been identified from even 1 case review). Application of the NDOO could therefore lead to missing other tragic and avoidable cases of deaths such as those at Cawston Park, which could in turn lead to more avoidable deaths, which is a clear patient safety issue.

The CAG noted that whilst full case ascertainment is important to CAGs considerations regarding NDOO exemption, the 100% mark is not as relevant for LeDeR, as the findings are on an individual case by case basis. The applicant explained in the meeting that as LeDeR is not a mandatory programme, it is not possible for LeDeR to know everyone who dies and has a learning disability or is autistic. There is no national register, and individual GP registers have only approximately one third of patients listed. In addition, the deceased individual may not have been in contact with NHS services at the time of death. Therefore it is important the LeDeR are allowed to continue to review every single death that it is possible for them to do so, and if the NDOO was applied this would further reduce this important data source.

Members were supportive of exempting the NDOO, due to the strong patient safety impact.

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDOO will introduce bias due to non-random opt-out patterns. There may be a differential loss of information about vulnerable groups of people whose safety LeDeR are most concerned about, as is further explained below. Additionally application of the NDOO would undermine any detection of trends – applicants may miss a case in a small sub-group that LeDeR would otherwise have taken action on. Applying the National Data Opt-Out to LeDeR data collection would therefore mean inaccurate reports of any trends in patient deaths, either overall or in specific clinical settings.

For example, certain sub-groups of people with learning disabilities appear to die younger than others: 42% of white British people with learning disabilities die aged over 65, whereas only 7% of Asian people with learning disabilities

die aged over 65, and only 5% of black people with learning disabilities die over aged 65. This is a very starkly disproportionate figure, and needs to be investigated, as looking at the reasons behind this are the only way that services will be improved. Additionally, 94% of deaths reported to LeDeR were white patients, and all other ethnicities are already under-represented. The National data opt-out equality impact assessment identified that NDOO rates were likely to be high among ethnic minorities - where earlier mortality is a particular concern. If the 5.4% average opt out rate was applied to LeDeR data on deaths in 2022, the number of deaths of people from minority ethnic groups reviewed by LeDeR would reduce from the already low figure of 243 to 230 deaths. Looking, for example, at the deaths of Asian or Asian British adults, the numbers with average NDOO rates applied would reduce from 109 reviews to 103 reviews. Given that opt out rates are likely to be higher amongst these groups, the potential to skew findings or render them unreportable could increase significantly, thus thwarting LeDeRs ability to identify and address the significant inequalities faced by people from minority ethnic groups.

Additionally, only 25% of people with a learning disability whose deaths in 2022 were reviewed by LeDeR lived in the most deprived communities in England, and it is known from findings published in the National data opt out statistics (July 2023) that people from the least deprived areas are more likely to opt out than those from most deprived areas. It is therefore possible that LeDeR findings about the impact of deprivation have been skewed by the NDOO, making it hard to identify priority areas for improvement activity.

55% of people with a learning disability whose deaths in 2022 were reviewed by LeDeR were men, and it is known from findings published in the National data opt out statistics (July 2023) that women are more likely to opt out than men. It is therefore possible that LeDeR findings about sex have already been skewed by the NDOO, making it hard to identify priority areas for improvement activity.

Data being skewed in this way has the potential to harm public health rather than improve it, by worsening existing inequalities. Applicants are concerned that applying the NDOO to the LeDeR data collection will introduce bias that could potentially damage the safety of all people with a learning disability, and people with autism, receiving healthcare - with a disproportionate bias in relation to particularly vulnerable groups. Members were supportive of exempting the NDOO, due to the impact of bias, as this would exacerbate already existing health inequalities.

In addition to the non-random nature of the NDOO affecting health inequalities, LeDeR raised an additional concern around the non-random nature of existing objections. The applicant presented repeated evidence, albeit anecdotal, of healthcare professionals and GP practices, opting people out using the NDOO, in some cases all people with a learning disability registered at the practice, without engaging with the people themselves. When family members were engaged with postmortem, they stated that the person was not able to have made that decision themselves and, as next of

kin, they had not been involved in any best interest discussion under the Mental Capacity Act about opting out. Experience from LeDeR suggests that some people may be 'opted out' by people acting on their behalf, or that they have opted out without making an informed decision about what opting out means. Individuals whose data is processed by LeDeR either had a learning disability or were autistic and it is likely that many of them, particularly people with a learning disability, would not have had capacity (under the Mental Capacity Act) to make the decision to opt out via NDOO whilst they were alive. Despite this, LeDeR receives a substantial number of notifications for people who have seemingly opted out via NDOO. Concerns have been raised to LeDeR of instances where an individual lacked capacity to opt out themselves and a decision was made that opting out was in their 'best interest', as well as reports of incidents where someone did not fully understand the implications of opting out. This could hide instances of poor care and mean that systems are unable to learn from mistakes made and improve services to avoid poor care in the future.

Because LeDeR are not currently able to process these individuals' data further, LeDeR have not been able to investigate the circumstances surrounding their opt outs, so it is not known who opted out on their behalf. LeDeR has heard several examples of GPs opting patients with a learning disability out without their knowledge and consent. LeDeR cannot confirm these directly, but they appear to be borne out by the National opt out statistics (July 2023) which show that there are several GP practices across the country for whom a large proportion (up to 78% in July 2023) of their patients have opted out. These anecdotes are not limited to one region of England nor are they in one instance only and LeDeR have heard of cases allegedly where all patients with a learning disability have been opted out where registered in specific GP practices. For LeDeR this means that deceased people with learning difficulties may have been opted out by the very people providing the care that would be reviewed as part of the review process. For this reason, all deaths should be reviewed as part of the LeDeR process, without the NDOO being applied, to determine whether service improvement or indeed safeguarding concerns, where relevant, can be identified in every case. Members were supportive of exempting the NDOO, due to the impact of bias, as this would potentially mask instances of poor care.

Informing the patient population

In order to ensure that the relevant patient population are informed that the NDOO would not be applied, the CAG agreed that it would be critical, as a general principle, for clear communication methods around the deferral to be established. The applicant confirmed that a notification is already in place regarding data is processed under Regulation 5 support.

The applicant provided a draft wording to include in the website patient notification document, regarding informing the population that the NDOO would not be applied, and a communications plan. It is of note that in this cohort there is no application specific opt out available, or notification which

the cohort will see, as they are deceased. This is accepted by CAG. The notification is therefore for transparency, and for the general public. Members were broadly content with the notification wording, although Members felt that the website could be more welcoming in its tone, and suggested that the applicant review the website with a group of people with learning disabilities and/or carers, as this website will be an important resource for information about LeDeR, This is not a condition of support, but the CAG do strongly recommend this.

Members also noted that although a communications plan and webinar presentation were provided, these documents were embedded within the main document and the links did not work. The applicant is therefore requested to send these documents to CAG, for our records. [**Condition 2].** However the communications plan was also described in the body of the document and CAG were content with the proposed actions.

Patient and Public Involvement

LeDeR raised NDOO exemption at meetings of its key stakeholder groups – The LeDeR Independent Advisory Group and NHS England's Learning Disability and Autism Health Improvement Steering Group. These groups have memberships from a variety of interested organisations and include people with lived experience, family carers and representatives from third sector organisations. At these meetings the members were asked to take the debate back to their constituents across their organisations and report back with a view on whether LeDeR should seek exemption from NDOO. The groups consulted were unanimously supportive of the application for NDOO exemption. The CAG noted that it was unclear how many individuals were part of these groups. The applicant responded that there were 26 people in the LeDeR Independent Advisory Group meeting, and that there were 16 constituent members attending the Learning Disability and Autism Health Improvement Steering Group meeting. Each of the members were asked to speak to relevant individuals within their constituent areas, and it is not clear how many individuals were spoken to in each area, as this level of detail was not asked of the constituent members.

The applicants also described in more detail the comments and feedback from the patient involvement undertaken, which included overwhelming support, and a feeling that all deaths should be reviewed, and surprise that LeDeR was not already exempt from application of the NDOO. The CAG were content with these explanations.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDOO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, Members agreed that the patient safety rationale and health inequalities explanations were strong and provided

appropriate rationale for advising why the NDOO should not be applied to this data flow.

CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved, as the Members accepted that application of the NDOO to this application would result in negative patient safety consequences and disadvantage vulnerable groups.

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
1.	This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in 20/CAG/0067
2.	Please provide the communications plan and webinar presentation, within 1 month.

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

4.c	24/CAG/0057	Great Western SDE
	Chief Investigator:	Dr Charlie Kenward
	Sponsor:	NHS Bristol, North Somerset, South Gloucestershire Integrated Care Board (BNSSG ICB)
	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 NHS Bristol, North Somerset, South Gloucestershire Integrated Care Board (BNSSG ICB) sets out the medical purpose to create a research database.

BNSSG ICB are developing and will host the Great Western Secure Data Environment (GWSDE). This is part of a national initiative to move towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy. SDEs across the country will also become interoperable to enable access. Further details on this national initiative and progress to date is here.

BNSSG ICB are linking data from multiple sources to create a deidentified dataset for research use. Support is requested for:

- Processing and sharing of confidential patient information (CPI) from direct care providers (except primary care) to the GWSDE (hosted by BNSSG ICB) by a member of the provider team who is not considered part of the direct care team
- Processing and sharing of CPI for secondary uses from the Shared Care Record to the GWSDE
- Processing and sharing of CPI for secondary uses from the primary care data processor to the GWSDE
- Processing, pseudonymisation and linkage of data within the GWSDE by named members of staff
- Storage of the pseudonymisation key within a separate area of the GWSDE

Requests for data access are governed by the Data Access Committee. The Committee contains a range of members from health and social care providers across the region, including two lay members.

Confidential information requested

Cohort	Approximately 5.15 million patients using health and social care services in the Great Western region (Bristol, Cornwall (including the Isles of Scilly), Devon, Gloucestershire, Somerset and Wiltshire) as well as regionally supported ambulance and not for profit services. This will include those permanently residing, visiting or in the region for specialist tertiary care.
Data sources	1. Primary Care a. Demographic data b. Diagnostic Records c. Prescribing Data d. Referral data e. Appointment information 2. Secondary and Tertiary Care including; a. Electronic Health Record Systems data, including demographic data

	b. Prescribing Data c. Diagnostic Data i.e. Radiology, Pathology, Microbiology etc. d. Specialist Treatment Systems Datasets for example Cardiology, Respiratory, Bariatric, Stroke etc. e. Theatres f. Maternity and Paediatric Systems g. Critical Care Systems h. Community Care i. Outpatient Care j. Operational data 3. Local Authority (Social Care data) 4. Mental Health Trust data, including inpatient and community-based mental health care 5. South West Genomics Medicines Alliance, Genomics data (these are unstructured data) 6. South Western Ambulance Service data for the region (SWAFST)
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital number 4. GP registration 5. Date of birth 6. Date of death 7. Unit level postcode 8. Any geographical information contained in clinical notes, reports, or metadata: for example, the fact that a particular Xray was performed at a particular hospital. 9. Any identifiers, including the names of members of the clinical team responsible for the care of a patient, that may be included in clinical notes or reports.
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Sector level postcode 4. Gender 5. Ethnicity 6. Sex

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 noted that the application mentioned collecting social care data from

local authorities. The members were not clear on what type of social care data was going to be collected for the purposes of this application. The CAG asked the applicant to explain what type of social care data they were going to collect for this project. The applicant responded that they were going to collect basic unit social care activities such as date, time and level of social care but noted that this information was limited to what was available. The applicant stated that this data would flow in the same way as the data flowing from NHS Trusts. The applicant explained that currently there was no information to work out the cost benefits of social care activities and by not knowing simple circumstances of the patients they could not look at linkage and data quality. The CAG was satisfied with the response.

The CAG agreed that the patient notifications were health care data centric and did not mention collection of social care data. The CAG requested that notification materials were updated so the patients were informed that the project was also planning to collect social care data as well as health care data. **(Condition 1)**

The CAG was impressed by the amount of engagement work that had been done with diverse communities. The CAG requested for this work to continue and to be provided with a progress report at annual review. **(Condition 2)**

The CAG requested that the following data flows should be presented to CAG as amendments when the applicant is ready to do so:

- Secondary uses of local ICB data flowing into the SDE.
- Cohort data linkage (health studies) such as ALSPAC and Exter 10,000
- Data flows from disease and civil registries and national datasets

(Condition 3)

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 Health Research Authority, 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 inform patients that the project is also planning to collect social care data as well as health care data within 3 months.	
2.	Continued ongoing PPI is to be undertaken and a progress report should be presented at annual review.	

3.	The CAG requested that the following data flows should be presented to CAG as amendments when the applicant is ready to do so: • Secondary uses of local ICB data flowing into the SDE. • Cohort data linkage (health studies) such as ALSPAC and Exter 10,000 • Data flows from disease and civil registries and national datasets	

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

4.d	**24/CAG/0056**	**Our Care Connected Falls Risk Tool**
	Contact:	Dan Hughes, Programme Director, Our Care Connected Programme
	Data controller:	East Sussex Healthcare NHS Trust (ESHT) as the host organisation for Our Care Connected
	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 application from the East Sussex Healthcare NHS Trust (ESHT) as the host organisation for Our Care Connected, sets out the non-research purpose of using risk stratification techniques to implement a Falls Risk Tool that will help identify patients with ‘the greatest risk’ of falls, to identify patients who may require additional healthcare interventions. Risk stratification is a tool to identify patients that are at high risk of health deterioration and may require use of multiple services. This identification allows GPs to prioritise the management of their care to reduce and prevent poor outcomes.

Sussex is an outlier for injurious falls in vulnerable patients compared to national figures, therefore this activity will directly benefit patients of Sussex, by enabling clinicians to target patients with interventions to directly support their individual

care needs. This application will also enable a better understanding of the implications patients at risk of falls have on hospital admissions, health service and cost.

Risk stratification for falls risk necessitates the use of large scale, whole Sussex area population, use of secondary care data combined with GP data. Support is not requested for the flow of confidential patient information from GP suppliers or ESHT to NHS South, Central and West Commissioning Support Unit (NHS SCW CSU), as alternative common law legal bases are already in place for these flows. 's251' support is requested to link this information together using NHS number. This data is pseudonymised at the point of linkage and during the falls risk tool processing, however the CSU have the ability to re-identify, (and are processing confidential patient information in order to create a pseudonymous dataset and retain the key) and therefore 's251' support is required. The Falls Risk Model produces a score measuring the probability of an injurious fall for each patient in the cohort. Support is not being requested for reidentification, as that is undertaken for direct care purposes. The applicant envisaged this as an ongoing process, with linkages undertaken monthly.

Confidential information requested

Cohort	86,000 Sussex patients over the age of 65 registered with a Sussex GP.
Data sources	1. NHS South, Central and West Commissioning Support Unit (NHS SCW CSU) – • GP data • East Sussex Healthcare NHS Trust (ESHT) data
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	N/A
Additional information	The key to facilitate re-identification of patients will be retained by NHS South, Central and West Commissioning Support Unit during the risk stratification process.

	This process is envisaged to be ongoing, and linkage will be undertaken monthly.

Main issues considered, discussed and outcomes.

This application sets out the non-research purpose of using risk stratification techniques to implement a Falls Risk Tool that will help identify patients with 'the greatest risk' of falls, to identify patients who may require additional healthcare interventions. The CAG remained unclear as to whether this application was for a research or non-research purpose. The applicant informed CAG that this assessment tool was created, tested, and validated by the University of Surrey, amongst a cohort of those over 65 years old. This initial research led the applicant and their study team to look towards implementing a similar model and applying it to community data.

The CAG remained unresolved on whether the scope of the application fell under the definition of non-research. Therefore, the group requested that the applicant verify their rationale by providing CAG with validation from the Research and Development (R&D) department, as well as present a completed copy of 'is my study research' tool, as found on the HRA website. **[Issue 1]**

The CAG requested clarity on why the assessment tool would be measured amongst a cohort older than 85 years. The applicant confirmed that this was a typographical error within the application and that the assessment would be conducted on those above 65 years.

The CAG requested written confirmation for the correct age of the given cohort. **[Issue 2]**

The CAG requested clarification on whether the applicant had sought any clinical input for the study. It was noted that, should the applicant wish to access confidential patient information, they would need to acquire support from the local Integrated Care Board (ICB). The applicant clarified that they regularly engage with a clinical reference group, made up by, GP's, Clinicians, Nurse's, and Physiotherapist's, all of whom have contributed to the development of the study. These insights enabled the study team to directly target where further support could be provided as well as explore how to improve current methods of practice.

The CAG was satisfied with the applicant's response.

The CAG requested clarification on whether the study team received support from the local ICB to conduct any follow-up work post study. The applicant could not confirm however, clarified that conversations were ongoing.

The CAG was content with the applicant's response.

The Committee queried the heavy burden on the GP staff if there was to be a sudden influx of assessments arriving to the practice. The applicant confirmed

that only patient scores would be directly sent to the GP services, with the vision of staff reviewing the data and acting accordingly. The ambition was for GP staff to evaluate which patients required care and then treat them within the community setting.

The CAG was satisfied with the applicant's response.

The CAG stated that the notification materials were too complex for the intended population. The CAG queried whether all participant facing materials had been reviewed by the patient and public involvement and engagement group (PPIE). The applicant clarified that they were working on a new draft of participant facing materials which would be reviewed by the PPIE group.

The CAG requested for all participant facing materials to be reviewed by the PPIE group. **[Issue 3a]** Furthermore, the CAG requested that the information sheets clearly explained how to dissent from the project **[Issue 3b]**, as well as clearly state who and where patient data would be shared with. **[Issue 3c]**

The CAG queried whether the PPIE group discussed the use of confidential patient data without consent. The applicant confirmed that the PPIE group remained positive around the use of data without consent. However, the applicants noted that the PPIE group had asked for confirmation that data was only shared with necessary groups and to ensure that participants had a clear pathway to opt-out of the study.

The CAG was satisfied with the applicant's response.

The CAG requested that the applicant implement a direct queries telephone and postal address for patients to be able to contact. The applicant confirmed that this would be added within the patient notification materials. **[Issue 3d]**

The CAG queried where the notification leaflets would be made available. The applicant clarified that. in addition to being advertised within healthcare waiting rooms, the patient leaflet would also be posted on the GP and NHS website.

The CAG was satisfied with the applicant's response.

The CAG requested confirmation that all the appropriate safety measures were conducted prior to developing the tool. The applicant clarified that the assessment tool had undertaken review from the safety officers and that all further risk assessments had been conducted. Furthermore, the applicant wished to remind the CAG that the development and validation of the tool had been undertaken within the University of Surrey and that the research team were adopting the tool in line with Sussex integrated dataset (SID) to utilise within the community.

The CAG was satisfied with the applicant's response.

The CAG queried whether this assessment tool could be considered a medical device. The CAG requested the applicant to contact and seek advice from the MHRA. **[Issue 4]**

Confidentiality Advisory Group advice: Deferred

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. The CAG noted that the following points should be taken into consideration and addressed prior to resubmitting this application in future.

Number	**Issue:**
1.	The CAG remains unresolved on whether the scope of the application falls under the definition of non-research. Therefore, validation from the Research and Development (R&D) department need to be provided, alongside a completed copy of 'is my study research' tool, as found on the HRA website.
2.	Provide clarity on the correct age of the given cohort that the assessment tool will be undertaken on.
3.	Ensure the following is completed regarding participant facing materials: a. Ensure all participant facing materials are reviewed by the patient and public involvement and engagement group (PPIE). b. Specify a route to dissent from the project. c. Clearly state who and where patient data would be shared. d. Implement a direct queries telephone and postal address for patients to be able to contact.
4.	Seek advice from the MHRA, regarding whether the assessment tool could be considered as a medical device.

5. ANY OTHER BUSINESS

There was no other business for discussion.

Dr Tony Calland MBE	11 April 2024
…….	……..
Signed – Chair	*Date*
Mr Dayheem Sedighi – Approvals Administrator, Mr William Lyse – Approvals Administrator, Ms Caroline Watchurst – Confidentiality Advisor	10 April 2024
…….	……..
Signed – Confidentiality Advisory Team	*Date*