**Confidentiality Advisory Group**

Minutes of the meeting of the Confidentiality Advisory Group held on *01 February 2024* via video conference.

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**Present:**

| Name | Capacity |
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| Dr Tony Calland MBE | CAG Chair |
| Dr Patrick Coyle | CAG Vice Chair |
| Dr Martin Andrew | CAG Member (Expert) |
| Dr Joanne Bailey | CAG Member (Expert) |
| Professor Lorna Fraser | CAG Member (Expert) |
| Mr Anthony Kane | CAG Member (Lay) |
| Dr Rachel Knowles | CAG Member (Expert) |
| Mrs Sarah Palmer-Edwards | CAG Member (Expert) |
| Mr Dan Roulstone | CAG Member (Lay) – Items 4a and 4b |
| Mr Thomas Boby | CAG Member (Expert) – Item 4c only |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Ms Katy Cassidy | HRA Confidentiality Advisor |
| Dr Paul Mills | HRA Confidentiality Advice Service Manager – Items 4b and 4c |
| Mr Will Lyse | HRA Approvals Administrator – Minuted items 4b and 4d |
| Mr Dayheem Sedighi | HRA Approvals Administrator – Minuted items 4 5a, 4a and 4c |

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| Ms Ruth Ryder | Research Midwife at Medway Maritime Hospital (Observer) |
| Ms Claire Edgeworth | Head of Strategic Information Governance, NECS/NHS England (Observer) – Item 4c only |
| Mr Ben Wilczynski | Data Protection Officer and Strategic IG Lead, Innovate Healthcare Services – Item 4a |
| Ms Queenie Goredema | Population Health Management Communications & Engagement Manager, NHS Coventry and Warwickshire Integrated Care Board – Item 4a |
| Mr Stephen Thirkell | Senior Platform Architect, Oracle Cerner, Item 4a |
| Professor Saad Shakir | Director of the Drug Safety Research Unit (DSRU) and named Controller for the application – Item 4b |
| Dr Elizabeth Lynn | Head of Scientific & Educational Development at the DSRU and contact person for the application – Item 4b |
| Mr Shayne Freemantle | Former Head of Data Management at the DSRU and current data management consultant to the DSRU – Item 4b |
| Professor Elizabeth Sapey | Co-lead for WM-SDE ethics and governance, medical consultant in acute and respiratory medicine and Professor of acute and Respiratory medicine at the University of Birmingham – Item 4c |
| Ms Suzy Gallier | Head of Research Informatics at University Hospital Birmingham, Technical Director of PIONEER, HDRUK Hub in acute care, technical theme for WM-SDE – Item 4c |
| Ms Amy Gosling | Programme Manager for WM-SDE – Item 4c |
| Ms Amelia Jewell | Members of the CRIS team who are facilitating the linkage – Item 4d |
| Ms Hannah Woods | Members of the CRIS team who are facilitating the linkage – Item 4d |
| Ms Alice Wickersham | Researcher attending on behalf of Johnny Downs (lead applicant) – Item 4d |
| Dr Johnny Downs | Applicant – Item 4d |

## 1. APOLOGIES FOR ABSENCE

Apologies for absence was received from CAG Member Dr Harvey Marcovitch

## 2. DECLARATIONS OF INTEREST

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| **2.1** | **24/CAG/0017** | **CRIS Linkage with the Police National Computer (PNC)** |
| | Conflict: | CAG Member Mr Anthony Kane declared an interest in this item as a previous employee of Greater Manchester Police he had access to the Police National Computer. He has not been involved in the design or development of the system or had any involvement in the application. The Committee agreed this did not constitute a conflict of interest and they could participate in the full study discussion. |

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| **2.1** | **24/CAG/0017** | **CRIS Linkage with the Police National Computer (PNC)** |
| | Conflict: | CAG Member Professor Lorna Fraser declared an interest in this item as they are employed by the same organisation as the lead individual, but they have no connection to the applicant or the application. The Committee agreed this did not constitute a conflict of interest and they could participate in the full study discussion. |

## 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 with the advice provided by the CAG in relation to the **07 December 2023** meeting applications.

### Health Research Authority (HRA) Decisions

There were no applications requiring a decision by the Health Research Authority in relation to the **07 December 2023** meeting applications.

### Minutes:

No meeting minutes have been ratified and published on the website since the last CAG meeting.

## 4. NEW APPLICATIONS FOR CAG CONSIDERATION

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| **4.a** | **24/CAG/0010** | **Coventry and Warwickshire Population Health Management** |
| | Contact: | Ben Wilczynski |
| | Data controller: | Coventry and Warwickshire Integrated Care Board |

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| | 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.

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 Coventry and Warwickshire Integrated Care Board set out the purpose of collecting patient data for use in population health management.

Embedding Population Health Management (PHM) in patient care and decision making throughout Coventry and Warwickshire Integrated Care System (ICS) is a key goal of the ICS as it works to improve patient care and to improve preventative care. Having access to high quality data through a PHM approach is also a key system capability outlined in NHS England's national ICS planning guidance. The PHM Programme seeks to improve understanding of the population's health to provide insights into the health and social care needs and wider determinants of health of the population now, as well as their needs for the future, the impact of services that we put in place and bringing data together to provide a holistic view of individual people in the population.

The data collected will include Primary Care from GP Practices, Acute Hospital Care, and Community and Mental Health care, from GP practices within the ICB area, George Elliot Hospital, South Warwickshire Foundation Trust, University Hospital Coventry & Warwickshire and Coventry and Warwickshire Partnership Trust. The data will be disclosed to HealtheIntent, within Oracle Cerner, for linkage. Linked confidential patient information will be made available to members of the direct care team from the organisations that supplied the data. Anonymised data will be made available to supporting team members.

**Confidential information requested**

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| **Cohort** | Patients and service users of partner organisations who are residents in Coventry and Warwickshire.<br><br>Inclusion Criteria:<br>• Patient has an active registration with a GP practice.<br>• OR a patient has a post code in Coventry and Warwickshire.<br>• OR patient has been treated at one of the data controller's and has a homeless/no fixed abode code. |

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| | Exclusion Criteria:<br>• Patient has objected (either through a type 1 opt-out with their GP practice or through the centralised objection process)<br>• National Data Opt-Out |
| **Data sources** | 1. Primary Care data supplied by GP Practices in Coventry & Warwickshire ICB<br>2. Acute Hospital Care, supplied by George Elliot Hospital NHS Trust, South Warwickshire University NHS Foundation Trust, University Hospitals Coventry and Warwickshire NHS Trust and Coventry and Warwickshire Partnership Trust |
| **Identifiers required for linkage purposes** | 1. Given Name/First Name/Nickname<br>2. Middle Name/Initial<br>3. Last Name/Surname/Family Name<br>4. NHS Number<br>5. Date of Birth<br>6. MRN (and other aliases such as local hospital or social care record id's)<br>7. Addresses<br>8. Telephone Numbers<br>9. Email Addresses<br>10. Gender<br>11. Race<br>12. Ethnicity |
| **Identifiers required for analysis purposes** | Patient's' Postcodes, Dates of Birth, Gender and Ethnicity may be used may be used for risk stratification. |
| **Additional information** | Identifiers, such as Name and NHS Numbers, are not used for analysis but displayed back to users (who have a legitimate relationship with the patient) to ensure that to the correct patient is identified for direct care purposes.<br><br>Regarding the number of data items required to identify patients and link their data, the applicants advised that most patients will be linked via their NHS number. However, the applicants anticipate that local authorities within the Coventry and Warwickshire will also join the program and further data items will be required for linkage to social care data. The applicants note that an amendment will be submitted before these linkages take place. |

**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 application mentioned that one of the secondary uses of de-identified data was risk stratification for early intervention and prevention. The CAG asked the applicant to clarify whether section 251 support was required for risk stratification purposes as well as population health management. The applicant confirmed that they were planning to use risk stratification for early intervention and prevention purposes. The CAG stated that further clarification on how the data collected would be used for risk stratification purposes would be requested. **(Condition 1)**

The CAG noted the application stated that all confidential patient information would be deleted by the end of 2031. The CAG explained that information should be retained in line with the NHS records management code of practice and it need to be deleted once the retention periods are met. The CAG recommended ‘s251’ support for 5 years, in line with other applications of this type. **(Condition 2)**

The CAG noted that the CAT asked the applicants to provide postal, email and telephone contacts for local Opt-out. The CAG noted that the Opt-out option on the QR link contained telephone, email and a postal address but the revised “How we are using your data” leaflet only contained the telephone number and email address, and postal address was not included. The CAG requested that the leaflet was updated to include a postal address for patients who didn’t have access to the internet and want to opt-out in writing. **(Condition 3a)**

The CAG noted that the data flow diagram mentioned other sources of data flowing in this application. The CAG asked the applicant to clarify what other data sources they meant by that. The applicant responded that the phase 1 would include GP practices and acute hospitals. In phase 2 they were going to include the Mental Health Trust and in future the local authorities. The applicant explained at the point of including local authorities they were going to submit a new application as this application did not include the local authority data. The CAG was satisfied with the response.

The CAG requested that the applicant to provide clarification on the data flow diagram to explain where Reg 5 support was required. **(Condition 3b)**

The CAG asked the applicant to include a statement in the patient notifications to explain that section 251 support was requested to allow access to patient confidential information without consent to reassure patients that there was a legal basis for accessing their data. **(Condition 3c)**

The CAG noted the patient and public involvement undertaken was adequate but queried whether the use of confidential patient information without consent was discussed within these sessions, as it was not clear from the application. The CAG requested information on any feedback the applicant sought and received on the use of confidential information without consent. **(Condition 4)**

The CAG noted that the application would require two separate opt-out mechanisms for the purposes of Health population management and Risk stratification as the opt out process for risk stratification may impact the care patients receive. The CAG requested that the applicant to develop 2 separate opt-out mechanisms for the purposes of Health population management and Risk stratification. **(Condition 3d)**

The CAG noted that the application should utilise caution if using a Type 1 opt out approach for risk stratification opt out and patient notification should highlight to patients that opting out may affect the care received. **(Condition 3e)**

**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. | Provide further clarification on how the data collected would be used for risk stratification purposes. | |
| 2. | Support under s251 will be given for 5 years from the issue of the final outcome letter. A duration amendment will be required at that time if 's251' support is still required once the 5 year time period has elapsed. | |
| 3. | Please revise the following with regards to the patient notification materials and provide to CAG within 2 months.:<br><br>a. Update the leaflet to include a postal address for patients who don't have access to the Internet and want to opt-out in writing.<br><br>b. Provide clarification on the data flow | |

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| | diagram to explain where Reg 5 support is required.<br><br>c. State that the activity is undertaken under 'section 251 support' provided by the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG).<br><br>d. Develop 2 separate opt-out mechanisms for the purposes of Health population management and Risk stratification.<br><br>e. Add a statement to include that using a Type 1 opt out approach for risk stratification opt out may impact the care they receive. | |
| 4. | Please provide detailed feedback within two months on the outcomes of the recommendations that were discussed by representatives group, specifically the discussions around the use of confidential patient information without consent. | |

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

| **4.b** | **24/CAG/0003** | **Prescription Event Monitoring** |
|---|---|---|
| | Contact: | Dr Elizabeth Lynn |
| | Data controller: | Professor Saad Shakir |
| | 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 Drug Safety Research Unit set out the purpose of post-market surveillance, using Prescription-Event Monitoring methodology to monitor newly approved medicines.

New medicines are tested in clinical trials to determine safety and efficacy before licensed for use in humans. Participants in clinical trials are usually healthy men between 18 and 45 years of age. Women of child-bearing age, children, people with illnesses and those taking other medications are typically excluded from clinical trials. Clinical trials are also conducted for a limited time and involve a smaller number of patients relative to the size of the patient population. As clinical trials are not conducted under real-life conditions and may not detect side effects that develop over a longer time period or very rare side effects or side effects specific to the populations who are excluded from clinical trials. Due to the limitations of clinical trials, it is essential that post-marketing evaluations are conducted to check the safety of medicines once licenced and in use in the general population.

In the Prescription-Event monitoring methodology, the DSRU notifies the NHS Business Services Authority (BSA) of the study drug. NHS BSA will then send confidential patient data from GP dispensed NHS prescriptions in England from the date the drug was made available on the NHS to the DSRU, where it is stored in the OSIRIS database. At intervals (usually 3, 6, and 12 months) after the patient's first prescription, Prescription Event Monitoring (PEM) Data Collection Forms (DCF) will be sent to the prescribing GP for completion. The DCFs will be returned, and the information entered into the DSRU database. Further information may be sought from the GP if a patient has experienced an adverse drug reaction, pregnancy or death with an unknown cause. The data is then analysed by the DSRU research team. Support is needed for the disclosure of confidential patient information from the NHS BSA to the DSRU, the storage of this confidential patient information in the OSIRIS database, and the disclosure to and return of confidential patient information to the relevant GP practices.

**Confidential information requested**

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| **Cohort** | Patients who have dispensed NHS primary care prescriptions for the named medicine, written by any GPs in England and supplied in confidence to the DSRU by the NHS BSA for England.<br><br>Patients for whom a study DCF containing useful information has been returned, will be included in the study cohort regardless of the dose or frequency of administration of the named medicine, and irrespective of whether any medicines are concurrently administered. |
| **Data sources** | 1. Electronic Prescription Service (EPS) data provided by the NHS BSA.<br><br>2. Data provided by GP practice records |

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| | 3. OSIRIS database, held by DSRU |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. GP Registration<br>4. Date of birth<br>5. Postcode – unit level |
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Gender<br>3. Year of birth |
| **Additional information** | |

**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 asked the applicant to justify the number of identifiers collected. The applicant clarified that these identifiers would be used to identify patients to their GP (General Practitioner). The applicants noted that they could explore whether the number of identifiers could be reduced. The CAG requested that the research team explore the possibility of reducing the number of identifiers collected **[Condition 1]**

The study specific opt-out was implemented after the breach in the common law duty of confidentiality had occurred. The CAG queried whether the opt-out could be applied prior to the breach through the NHS Business Services Authority. The applicant clarified that they would display their patient poster within GP surgeries, which would clearly outline the opt-out process. The applicant also suggested including a section about opt-out within the study questionnaire. The CAG requested that the research team consider and action the best route forward. **[Condition 2]**

The CAG queried whether a type 1 Opt-Out, which prevents information being shared outside a GP practice for purposes other than direct care, would be applied at GP practices The applicant was not certain, however, reassured the Group that the opt-out would be explained within the patient poster. The CAG requested that the applicant confirm whether the type 1 opt-out would be applied. **[Condition 3]**

The CAG requested for wider distribution of the patient poster to increase attraction and engagement from the population. The CAG suggested signposting the poster through stakeholder websites. The applicant stated that this would be achieved with one option being the university and other websites. **[Condition 4]**

The CAG noted that the demographic within the patient and public engagement and involvement group (PPIE) did not accurately reflect the studied population. The CAG requested that the applicant extend the demographic of those involved to include the relevant patient population and ensure the further activity includes discussion of the use of confidential patient information without consent. The applicant confirmed that this would be undertaken. **[Condition 5]**

Furthermore, the CAG queried whether specific PPIE could be conducted around the use of highly sensitive drugs. The applicant clarified that this had not been conducted before, however, should the CAG request this, then the research team would look to action it.

The CAG queried whether the team would assess participants status of the National Data Opt-Out each time they linked back to confidential patient information. Members noted that a patient may apply the National Data Opt-Out whilst enrolled within the study and without the research team's knowledge. The applicant stated that they would need to revisit this with the wider team and determine how this would be actioned. **[Condition 6]**

The CAG highlighted the data flow diagram and queried whether the flow of data to GP practices would require section 251 support. The applicant clarified that the data would only flow towards the practice. The applicant reassured the CAG that the data flow diagram would be amended to clearly reflect the flow of data and specify which flows require s251 Support. **[Condition 7]**

The CAG requested the applicant to confirm whether the pseudonymisation key was kept separate to the clinical data. The applicant confirmed this was correct and stated that although the key was stored within the same database, it was within a separate location to the clinical data and that the two would not be seen together. The CAG was satisfied with the applicant's response.

**<u>Confidentiality Advisory Group advice:</u> 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. | Explore the possibility of reducing the number of identifiers collected. | |

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| 2. | Clarify whether NHS BSA can apply the National Data Opt-Out prior to the breach in the common law duty occurring. | |
| 3. | Clarify whether a type one opt-out will be applied within the GP sites. | |
| 4. | Explore further ways of promoting the study. | |
| 5. | Extend the demographic of those involved to include the relevant patient population and ensure the further activity includes discussion of the use of confidential patient information without consent. | |
| 6. | Ensure that patients National Data Opt-Out statis is re-assessed each time further linkages of confidential patient information are undertaken. | |
| 7. | Amend the data flow diagram to clearly reflect the flow of data and specify which flows require s251 Support. | |
| 8. | The support given under application ECC 5-07 (b)/2009 will be expired and superseded by this application from the date of the issuing of the conditionally supported outcome letter. | |

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

| **4.c** | **24/CAG/0025** | **West Midlands Secure Data Environment** |
|---|---|---|
| | Chief Investigator: | Dr Elizabeth Sapey |
| | Sponsor: | University Hospitals Birmingham 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 University Hospitals Birmingham NHS Foundation Trust, sets out the medical purpose to create a research database.

University Hospitals Birmingham NHS Foundation Trust are developing the West Midlands sub-national Secure Data Environment (SNSDE). 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. SNSDEs across the country will also become interoperable to enable access. Further details on this national initiative and progress to date is here.

The West Midlands SDE will consist of different areas. One area will allow for patient information to flow into the SDE environment from participating organisations, where approved staff will support the temporary reidentification and linkage process to create the research database. A Trusted Research Environment area will enable approved researchers to access the data relevant for their research in a non-identifiable form.

Support is requested for all primary and secondary care organisations to share confidential patient information with University Hospitals Birmingham NHS Foundation Trust. Depending on the organisation this may be in a pseudonymised or identifiable form. Support is also requested for University Hospitals Birmingham NHS Foundation Trust to temporarily reidentify the information to enable linkage across organisations, and for retention within the SDE environment.

The data will consist of structured and unstructured data from each organisation. This includes unstructured images, clinic letters and radiology/pathology reports, plus structured data from free text medical records from GPs. A number of highly sensitive types of data relevant to health are excluded, notably data on religion or sexual orientation.
West Midlands SDE will be used to enable research that will improve the health and wellbeing of WM residents and have outputs of both national and global relevance across a broad range of clinical areas. A separate research use case document is provided for CAG review. There is a 4-stage process to consider requests to access data, with stage 3 being the Data Trust Committee (DTC). This is a public advisory body that will provide public advice on the application to the SDE. Whilst advisory, no application will be approved if the DTC does not support it.

The SDE will be set up in stages depending on the maturity of the organisation. However, support is sought for all organisations to contribute to the SDE.

**Confidential information requested**

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| **Cohort** | All patients within the West Midlands SDE footprint (Black Country ICB, Birmingham and Solihull ICB, Coventry and Warwickshire ICB, Staffordshire & Stoke-on-Trent ICB, Herefordshire and Worcestershire ICB), unless opted out |
| **Data sources** | 1. All NHS primary and secondary care organisations within the West Midlands SDE footprint |
| **Identifiers required for linkage purposes** | 1. NHS Number<br>2. Date of Birth<br>3. Postcode |
| **Identifiers required for analysis purposes** | 1. Age<br>2. Postcode (sub-sector level)<br>3. Ethnicity<br>4. Sex |
| **Additional information** | Where NHS organisations are able to data will be flowed in a pseudonymised form to University Hospitals Birmingham NHS Foundation Trust, though it is expected a number will flow this in an identifiable manner. For all organisations, University Hospitals Birmingham NHS Foundation Trust will reidentify for a limited period to enable linkage. |

**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 scope of support was slightly unclear as the applicant mentioned in the page 61 of the protocol that staff preparing data at some of the organisations contributing data may not be part of the care team and that the section 251 support would need to cover this. This did not align with other sections of the application, such as the point at which the National Data Opt-Out would be applied. Therefore, the CAG asked the applicant to clarify who were the contributors that were not in the direct care team and whether they required section 251 support. The applicant responded that majority of people working across the SDE program were from healthcare organisations making data available for the SDE; and the processing of the data within the SDE would be NHS staff who work within the hospitals and usually access this data within their daily life. The applicant explained that they recognised that some of the people who work with NHS organisations would move away from their direct care role to work fully within the SDE because of the volume of the data that they were expecting. Therefore, as they were recruited by SDE the applicants wanted to be clear that they would not be processing data as part of their daily

roles as the direct care team. The applicant confirmed for this purpose they would require section 251 support. The CAG was satisfied with the response.

The CAG noted that the IRAS form mentioned using HES data as part of this application, however it was not mentioned in other documents the use of HES data. The CAG asked the applicant to clarify whether they were planning to use HES data as part of this application. The applicant responded that the primary source of data that they were getting for West Midlands SDE would be from health care organisations within West midlands. The applicant explained that they acknowledged that there were different levels of digital maturity in terms of healthcare organisation across the West Midlands patch and they wanted to adjust the access to research so that all areas were represented. Therefore, the applicants were in discussion with NHS England to see whether it was possible to gain access to HES data from organisations that agreed to be part of the West midlands SDE to remove some of the burden of making their own data available for the research. The CAG was satisfied with the response.

The CAG noted that the application was heavily promoting the National Data Opt-out rather than the study specific opt out which could result in more patients opting out of wider national data use with other implications. Therefore, the CAG asked that the notifications promote the use of application specific opt-out, whilst still stating the National Data Opt-Out would be respected. **(Condition 1)**

The applicant also explained that they were working with patient and public involvement groups to come up with wording for local opt-out that was accessible to their population. Once they were happy with the wording, they were going to interpret it to different languages prevalence to West Midlands regent to make it even more accessible to their population. The CAG asked the applicant to clarify whether all patient facing documents were going to be translated to those languages. The applicant confirmed that they were going to translate all patient facing documents to 5 languages which were prevalent to the most majority of their population. The CAG was satisfied with the response.

The CAG also noted that the National Data Opt-out (NDOO) was only going to be applied by the SDE on receipt of the data. The application explained this was to ensure that the NDOO was applied. Whilst the members agreed a local opt out was harder to implement pre-flow in these cases, the provider would be non-compliant with the NDOO if they flowed the data covered by ‘s251’ support without applying it first. The CAG asked the applicant to clarify whether the NDOO was going to be applied after the breach of confidentiality. The applicant responded that large organisations had the facilities to apply their own Opt-out beforehand and then send the data once the Opt-out was applied. The applicant explained that they would check the information at two stages, once when the data came through and secondly at the point were cut off data was made available in order to go to Trust for research. The applicant explained that smaller practices did not have the facility to apply the Opt-out mechanism themselves. In discussion with GPs regarding applying the Opt-out directly they were told that they would essentially be losing smaller practices from being part of this research. Therefore, they were looking at how they could get system suppliers to apply the Opt-out instead of the GP practices applying the Opt-out

directly. The applicant reassured the CAG that they would explore how to get the Opt-out applied as early as possible at source to avoid the breach of confidentiality, however in some instances it would not be possible unless completely excluding those practices which was a disadvantage for those smaller practices. The CAG requested to provide an update on progress on applying the national data opt out as early as possible, within 3 months. **(Condition 2)**

The CAG noted that the applicant wishes to use free text data from medical records, including GPs. CAG have had concerns about this in the past, but this appeared to be set up differently, in that no raw free text enters the SDE. The CAG asked the applicant to clarify what was going to happen to free text once it had the code extracted from it. The applicant responded that they would keep the data in a secure environment if a researcher wanted to use that information, then they could re-run to extract any data that might not have been extracted the first time. The applicant explained that the secure environment was under the control of the healthcare organisation providing the source data. The CAG was satisfied with the response.

The CAG noted that the applicant had an existing research database with CAG at the moment (PIONEER – 20/CAG/0084). The CAG asked the applicant to clarify whether the data would be returning to PIONEER. The applicant responded that the data would not be returned to PIONEER as this was an entirely separate application. The only data that could be returned after the research would be the data that was retained as part of their record for re-productivity. The CAG was satisfied with the response.

**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. | The CAG asked that the notifications be updated to promote the use of application specific opt-out, whilst still stating the National Data Opt-Out would be respected. Feedback should be provided in 3 months. | |
| 2. | The CAG requested an update on progress on applying the National Data Opt-Out as early as possible. Feedback should be provided in 3 months. | |

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

| **4.d** | **24/CAG/0017** | **CRIS Linkage with the Police National Computer (PNC)** |
|---|---|---|
| | Chief Investigator: | Alice Wickersham |
| | Sponsor: | South London and Maudsley 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.

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 South London and Maudsley NHS Foundation Trust set out the purpose of creating a research database, containing linked data from the CRIS dataset at South London and Maudsley NHS Foundation Trust and the Police National Computer dataset, held by the Ministry of Justice.

One in seven adults in the UK is an offender or ex-offender, and a large proportion will suffer from at least one mental health disorder. Surveys of offenders within the court, prison, and probation services reveal far higher rates of psychiatric disorders compared to the general population. Despite the burden and complexity of mental health issues experienced by offender populations, resources dedicated to understanding and responding to these needs is limited. The creation of the proposed database will be used in research to provide evidence to help patients, their families, treating clinicians, and health and justice policy makers understand the offender related risk factors for poor outcomes for major mental illness throughout the life course.

Support is required to allow the South London and Maudsley NHS Foundation Trust (SLaM) to create a SLaM Patient Identifiers table for all patients within SLaMs clinical records. SLaM's Clinical Data Linkage Service (CDLS) will disclose the Patient Identifiers table to the Ministry of Justice (MoJ) for linkage to the Police National Computer (PNC) database. The MoJ will match the SLaM Patient Identifiers against their PNC identifiers. Matches will be extracted and the SLaM BRCID pseudonym will be added. The resultant table, the CRIS cases, will be stripped of all identifiers other than the BRCID and sent to the CDLS. Researchers seeking to use the dataset will apply to the CRIS Oversight Committee. Applications will be evaluated on three points - research value;

research governance; likelihood of identification of cases, e.g. due to rare conditions and/ or combined rare demographic. Researchers will compile clinical data from CRIS for approved analyses and send to the CDLS who will link CRIS and PNC data using the BRCID. CDLS will fully anonymise resultant tables by replacing the BRCID with a one-way encrypted project specific anonym and send linked tables back to researchers for analysis.

**Confidential information requested**

| | |
|---|---|
| **Cohort** | Approximately 470,000 individuals, approximately 40,000 of whom will be under the age of 18, who had contact with SLaM and held within CRIS between 01/01/2008-the date of extraction. |
| **Data sources** | 1. CRIS dataset at South London and Maudsley NHS Foundation Trust<br>2. Police National Computer dataset, held by the Ministry of Justice |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of birth<br>3. Postcode – unit level |
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Postcode – sector level<br>3. Gender<br>4. Ethnicity<br>5. Month of birth |
| **Additional information** | The applicants advised that as new patients are continually added, the cut-off date will be date of data extraction, so that the dataset is as up to date as possible. |

**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 step seven was missing from the submitted data flow diagram. The applicant apologised for this error and reassured the Committee that the diagram would be amended and resubmitted. **[Condition 1]**

The CAG noted that the REC approval for the study was issued on 31 July 2020. The CAG sought reassurance from the applicant that the REC outcome was still in date as well as a justification as to the delay in submitting to CAG. The applicant confirmed that REC approval was still valid, and the study was temporarily paused due to Covid-19 and staff delays. The Group was satisfied

with the applicant's response.

The CAG noted that the patient and public involvement and engagement (PPIE) was conducted in 2020 and queried whether there had been any recent engagement. The applicant clarified that the PPIE had been undertaken in 2020 and 2021, with engagement continuing after REC approval. However, there had been no recent PPIE due to the delays, as previously stated. The CAG accepted the applicant's justification, however, requested for further recent PPIE to be undertaken. **[Condition 2]**

The Committee sought clarification over the amount of people involved within the PPIE groups. The applicant clarified that there had been 6 or 7 engagement sessions over 8 years with an average of 10 people per group. However, unfortunately they had not been able to gain access to engage with offenders who display mental health disorders. The CAG queried whether engagement had been undertaken with youth groups. The applicant clarified that the research team engaged with a youth advisory panel, however, struggled to access younger aged offenders with mental health disorders. The CAG requested for the research team to access engagement with youth offenders through charities. **[Condition 3]**

The CAG requested further details on how the data received from the Ministry of Justice (MoJ) would be handled. The applicant clarified that the research team would receive individual level data from the Police National Computer (PNC) and that they would only receive data for patients who the MoJ had identified in the PNC. The applicant stated that the research team may receive aggregate reports for comparison but no individual level data from PNC for non-SLaM patients. The committee was satisfied with the applicant's response.

The CAG requested that the patient leaflet include links and QR codes to further sources of information. The applicant was content with the CAG's request. **[Condition 4]**

The CAG highlighted specific wording on the patient leaflet around mental health patients and caseworkers. The CAG noted that some patients, such as those with autism or endocrine conditions, may not view themselves as mental health patients. The CAG asked that the applicant clarify whether these patients would be in scope of the study and, if so, whether they were aware and given the opportunity to opt-out. The applicant stated that anyone referred to South London and Maudsley NHS Foundation Trust would be aware that they are under a trust specialising in the treatment of mental health conditions. The CAG asked that the materials were amended to make the inclusion criteria clear. Members also asked that other views of promoting the study were explored. **[Condition 5]**

The CAG requested clarification around whether new patients always received the CRIS leaflet explaining the overall project. The applicant confirmed that this was not always the case and advises that they would explore this request further with the research team. **[Condition 6]**

The CAG requested clarification on whether the MoJ records would be flagged to state that the patient was on a CRIS system and whether any flags would remain on the PNC system. The applicant clarified that the research team would not send any mental health information to the MoJ and no information would flow to practitioners or custody sergeants, The applicant also confirmed that the flag would not remain on the PNC system. The CAG was satisfied with the applicant's response.

**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. | Amend the data flow diagram to include step seven. | |
| 2. | Undertake further patient and public engagement and involvement. | |
| 3. | Explore engagement with youth offenders, for example by contacting relevant charities. | |
| 4. | Revise the patient information leaflet to include links and QR codes to further sources of information. | |
| 5. | Explore further ways of promoting the study, so that patients who don't receive the leaflet will be aware of the study. | |
| 6. | Clarify what efforts the research team will make to help ensure that all new patients receive the CRIS leaflet, or a link, explaining the overall project. | |

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

## 5. CONSIDERATION ITEMS

## 5.1 Annual review

| 5.a | 21/CAG/0008 | Clinical Practice Research Datalink (CPRD) |
|---|---|---|
| | Chief Investigator: | Dr Puja Myles |
| | Sponsor: | MHRA |
| | Application type: | Research |
| | Submission type: | Annual review |

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

**Summary of annual review**

This application from the MHRA sets out the purpose of medical research to linkage data from numerous sources in order to establish a research database. The Clinical Practice Research Datalink (CPRD) has been operating for about 30 years and has established support under Regulation 5 for NHS England to act as a trusted third party in order to link data from numerous sources.
The CPRD is a government research service, jointly supported by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR), as part of the Department of Health and Social Care. CPRD collects de-identified data from participating GP practices to establish the research database and to date includes over 50million patient lives. Deidentified data is shared with research teams whose applications are reviewed by the CPRD's data governance review process. CPRD also provides other services to researchers, such as patient recruitment, support with interventional research and study planning/feasibility. Note that the activities undertaken by the CPRD do not require Regulation 5 support as the data that CPRD process is not identifiable.
However, about 75% of approved research protocols use linked data to provide more depth to the data. External data custodians (the organisations holding the data) will provide NHS England with NHS number, gender, date of birth and postcode and a pseudonym. NHS England matches the identifiers to those provided by the GP system suppliers to generate a linker file (links GP system pseudonym with external dataset pseudonym). Deidentified data is then sent by the external data custodians to CPRD who link the data with the primary care data on pseudonyms alone.

Some linkages are undertaken on routine basis, where there is sufficient demand for the, whilst others may be undertaken on a study specific basis.

The CPRD has long been established and the data has been used in many peer-reviewed publications, for example confirming the safety of MMR vaccine, informing NICE cancer guidance, safeguarding use of pertussis vaccine in pregnancy and influencing the management of hypertension in diabetics. CPRD data are also being used to monitor COVID-19 vaccine safety.

**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 it was not clear whether it was possible to opt-out other than via the National Data Opt-Out or type 1. The CAG requested that the website was updated to clearly describe the study specific Opt-Out process and make it easily accessible to the patients. **(Condition 1)**

The CAG noted that they had laid out patient and public involvement activity for the next 3 years which seem worthwhile but raising wider awareness seems important given the increasing size of the population covered. The CAG was concerned whether there were sufficient patient and public involvement representatives considering the scale of the cohort for this application. Members were also concerned whether proportionate number of lay members were routinely involved in the discussions. Therefore, the CAG made requests for changes listed in the table below. **(Condition 2)**

The CAG noted that the annual review form stated that research in response to ministerial requests, such as research in support of security, intelligence, prosecution and international relations, were exempt from patient and public involvement due to the additional time constraint imposed in these situations. The CAG noted that the medical purpose of these ministerial requests was not clear and requested assurance that anything resulting from these has medical purpose. **(Condition 3)**

The CAG requested that the applicant provide an update on the progress towards their Trusted Research Environment. **(Condition 4)**

**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. | The CAG requested that the website should clearly describe the study specific Opt-Out process and make it easily accessible to patients. Feedback should be | |

| | | |
|---|---|---|
| | provided in 6 months. | |
| 2. | Patient and public involvement needs to be carried out, and feedback provided to CAG within 6 months. The feedback should include:<br><br>a. A routine inclusion of lay members in all levels of patient and public involvement.<br><br>b. increase the number of representative individuals in the patient and public involvement group, and ensure the use of confidential patient information without consent, and outside the direct care team is discussed.<br><br>c. Explain what ad-hoc reviewers mean.<br><br>d. There needs to be a better inclusion of practice participation groups. | |
| 3. | Provide assurance that research in response to ministerial requests, such as research in support of security, intelligence, prosecution and international relations, has a medical purpose. | |
| 4. | Provide an update on the progress towards their Trusted Research Environment | |

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

## 6. ANY OTHER BUSINESS

There was no other business for discussion.

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|---|---|
| Dr Tony Calland MBE & Dr Patrick Coyle | 13 February 2024 |
| ……. | …….. |
| *Signed – Chair* | *Date* |
| | |
| *Dayheem Sedighi* | *06 February 2024* |
| ……. | …….. |
| *Signed – HRA Approvals Administrator* | *Date* |