**APPENDIX TWO: SUGGESTED QUESTIONS**

**Theme 1: GOVERNANCE**

**1.1 Overall structure**

Q: Which boards, committees, sub-committees and working groups across the ICS play a role in the ICS’s *collection, processing, sharing, and use* of patients’ data?

Q: Which boards, committees, sub-committees and working groups across the ICS play a role in *governing* the ICS’s use of patients’ data?

Q: Please explain

1. the role and membership of each of Board, committee, sub-committee and group that deals with patient data, and to whom they are accountable, or direct us to where this information can be found;[[1]](#footnote-2)
2. how these Boards, committees, sub-committees and groups relate to or engage with the public, which of these are open to the public, and how the public can access their papers,
3. if none of these are open to the public, and the papers are unpublished, how is accountability to the public to be established?

Q: What access do the various bodies across the ICS have to social care data, and how is this access governed?

**1.2 The Digital Board**

Q: Please provide the Terms of Reference for the Digital Board. (If not available, please provide details of the Board’s responsibilities and membership.) Please provide details of any representatives on the Board from private companies or the ICS’s commercial ‘partners’.

Q: How are the interests of patients and the public represented at the Digital Board? Are meetings of the Digital Board open to the public? Are the Board’s papers made available to the public and if so, where can they be found?[[2]](#footnote-3)

**1.3 The Information Governance sub-committee**

Q: Which private companies – including technology, commercial or research ‘partners’ - are represented on the Sub-Committee, what is the rationale for their membership, and how does the sub-committee deal with conflicts of interest?

Q: The SEL ICB’s Governance Handbook states that the IGSC’s responsibilities include reviewing internal and external flows of data, including those flows transferring personal data abroad.

1. What personal data may be transferred abroad (i.e. nature of content), to whom is it sent, and for what purposes?
2. What form does this data take (e.g. anonymised, pseudonymised, aggregated)?
3. What safeguards are in place to prevent the further selling on, or out of contract/unconsented processing of patient data that is transferred abroad?
4. What processes are in place to ensure patients’ informed consent for this transfer?

Q: How are the interests of patients and the public represented at the IGSC? Are meetings of the sub-committee open to the public? Are the Board’s papers made available to the public and if so, where can they be found?

**1.4 THE Digital Transformation Board**

Q: What are the terms of reference of the Digital Transformation Board?

Q: Please provide details of any representatives on the Board from private companies or industrial, technology, commercial or research ‘partners’.

**1.5 The Data Usage Committee**

Q: Please supply the Data Usage Committee’s terms of reference. If these are not yet published in final form, please explain:

* to whom is the DUC accountable?
* what are its responsibilities?
* which ICS and non-ICS bodies, groups or committees does the DUC relate to?
* which roles are represented on the DUC?
* which external bodies or organisations, including private companies or the ICS’s industrial, technology, commercial or research ‘partners’, are represented on the DUC?
* how is the public represented on the DUC, beyond Healthwatch?

Q: How does the Data Usage Committee fit within the ICB’s system of governance (for example, what is the relationship between the Committee and the ICB’s Business Intelligence Unit)?

Q: The NHS Digital Independent Group Advising on the Release of Data (IGARD) provided a model of good practice: detailed minutes of their meetings, for example, provided transparency and demonstrated the robustness of decision making. In contrast, the DUC does not publish its minutes, and the list of Approved Data Usage Requests provides scant information.

What steps will the ICB take to make the work of the DUC and its decision making more transparent?

**1.6 The Business Intelligence Committee**

Q: Please provide details of the work of the Business Intelligence Unit, including its core responsibilities, to whom it is accountable, and its relationship to any external partners. What access does it have to confidential patient information (CPI) and on what legal basis?

Q: Which organisation is providing risk stratification services to the ICB? Are they on NHSE’s List of Risk Stratification Approved Organisations?

Q: Which organisation/s is providing population health analytic services to the ICB? Are they listed on the Risk Stratification Register? What was the process for approval?

Q: How has the ICB informed patients whose CPI has been obtained following CAG approval that they have the option to opt-out of the planned data processing.

As the nature of Population Health Management requires individual CPI to provide what is felt to be appropriate care, can you please tell us home many people have opted out of this particular use of their data following your application of section 251?

Q: Who has or will be undertaking the review to consider the preferred model for analytical services, on what basis (e.g. scope and cost of contract) and when will it report. If already completed, what are its findings?

**1.7 The Population Health Management and Inequalities Board**

Q: Please provide the terms of reference for the PHMIB. If these are not yet published in final form, please explain:

* to whom is the Board accountable?
* which ICS and non-ICS bodies, groups or committees does the Board relate to?
* which roles are represented on the Board?
* which external bodies (including private companies, industrial, technology, commercial or research ‘partners’) have representatives on the Board and what is the rationale for this?
* how is the public represented on the Board, including but also beyond Healthwatch?

Q: Which service suppliers does the ICB use to process data for population health analytics and how did they gain approval?

Q: The ICB’s Digital Strategy refers to the need for a review of the requirements that the ICB will need to implement and embed its PHM programme across Borough Partnerships. Who has been charged with undertaking this review, on what basis (e.g. scope and cost of contract) and what are its findings?

**THEME 2: USE OF PATIENTS’ DATA**

**2.1 Discovery Data Survey**

Q: Which are the different supplier systems that currently publish data sets to the DDS and who controls the data that they publish? Does the data controller of each supplier carry out a Data Protection Impact Assessment, and where can the public access these?

Q: Is the DDS categorised as an ‘NHS accredited secure data environment” as described by the Department of Health and Social Care’s *Secure data environment for health and social care data – policy guidelines*?[[3]](#footnote-4) If not, how does it fit with DHSC policy for SDEs to become the default way to access NHS health and social care data for research and analysis?

Q: What is the relationship of the DDS to the NHS Digital Regional Office?

Q: We understand that disclosure of anonymised or aggregated data to the DDS by GPs, hospital trusts and other data controllers is lawful provided that anonymisation takes place at source. What steps has the ICB taken to ensure that the anonymisation of the data that it draws on for analytic purposes has been undertaken at source?

Q: Does the DDS share patient identifiable data with third parties? If so, for what purposes and what is the legal basis for sharing such information?

Q: If the DDS shares patient identifiable data with third parties, do these include private companies (including those such as technology, industry, and research companies working in partnership within the ICS)?

Q: The National Data Guardian and Caldicott Guardian Chair of Council have recently expressed concerns that sharing information from local record sharing programmes with SDEs for purposes other than direct care may be happening without ensuring that their activities do not breach confidentiality. Please explain:

* How does the DDS ensure confidentiality during this process?
* Is it correct to say that disclosure of confidential patient information for direct care purposes at the end of a processing chain cannot legitimise prior, unlawful disclosure and processing (e.g. if processing takes place within the London Care Record without proper authorisation?[[4]](#footnote-5)

Q: Have any applications been made to the CAG for support under Section 251 of the NHS Act 2006 to share confidential patient information from the London Care Record with the Discovery Data Service? If so, what are the CAG reference numbers?

Q: Which occupational groups are trained and authorised to conduct dataset linking within the DDS? What form of training is recognised, and what is the process for authorising/verifying those who are carrying out dataset linking? What degree of probity is legally required contractually?

Q: Which occupational groups are trained and authorised to have access to data within the DDS?

What form of training is recognised, and what is the process for authorising/verifying those who are accessing data?

Q: We understand that there is local governance for projects that are given approval to access data held by the Discovery Data Service (DDS), but what are the overall governance arrangements for the Discovery Data Service itself? To whom is the DDS accountable?

Q: What Data Sharing Agreements, signed in the past 18 months, underpin the use of, and access to, patients’ personal data via the Discovery Data Service? Please give details of the particular projects and the specific policies in place in respect of people’s rights and consent.

Q: When and how are patients proactively informed about their right to opt out of their data being collected and shared at local and national levels? What information, including the numbers of those who have chosen to opt out, is kept that shows patients have been given a choice by all SEL organisations?

**2.2 Population Health Management and risk stratification**

Q: According to NHS England, population health management uses joined up information from across health and care partners to understand the factors driving health inequalities and to tackle the underlying causes of ill health.[[5]](#footnote-6)

* Which underlying causes of ill health is the ICB currently tackling using population health management?
* Which data sets are being used?
* How is the ICB tackling these causes of ill health? and
* What new funding been secured for tackling these inequalities, and if no new funding, which existing services are losing funding in order to finance these activities?

Q: How does the ICB ensure that the public understands the proposed use of their data for risk stratification purposes? At what point in the collection of a patient’s data are they given an explanation of risk stratification, information about who the data controllers and processors are, the type of data used, and the individual’s rights, e.g. to access the data or to object.

Q: What are the conditions set by the CAG allowing the ICB to carry out risk stratification? Please provide a copy of the Risk Stratification Assurance Statement.

**THEME THREE: THE LEGAL BASIS FOR THE USE OF PATIENTS’ DATA**

**3.1 The common law duty of confidentiality**

Q: Please provide evidence to demonstrate that the ICB has complied with the existing section 251 exemption conditions and controls in all its use of confidential patient information for all purposes that do not constitute direct patient care, including

* risk stratification and
* Population Health analytics.

Plus, if linked social care data has been used, please provide evidence of the necessary legal basis relied on for such use.

Q: Please inform us how many patients’ data were excluded from risk stratification and analysis due to their opting out? If none, then has a specific exclusion been applied, and if so, by which authorized body?

Q: Population Health Management requires identifiable patient level data. To be lawful, this requires an application the Confidentiality Advisory Group for support under Section 251 of the NHS Act 2006 to lift the Common Law Duty of Confidentiality. Has the ICB made an application/s for this specific purpose and if so, what are the CAG reference numbers?

**3.2 The UK GDPR and right to know**

Q: A key transparency requirement under the UK GDPR[[6]](#footnote-7) gives individuals the right to be informed about the collection and use of their personal data when the data is being collected.

How is the ICB ensuring that patients and other individuals are made aware, *at the point of data collection*, that their personal data is to be collected for non-direct patient care, and informed about the purposes for which it may be used? Will it be made clear that their data will be used not only by the SEL ICB, but other organisations as well, such as other ICBs? (The SEL ICB Data Service Privacy Notice does not explain this.)

**3.3 The Data Protection Act (DPA 2018) and ‘substantial public interest’**

Q: If the ICS or DDS is relying on substantial public interest conditions set out in the DPA (2018) to process special category data, please identify which of the DPA’s conditions reflect the ICS’s purpose, and what specific arguments are they providing to justify that such processing is in the public interest.

Q: In what way is the disclosure, without consent, of patients’ data in the ICB’s use of “risk stratification and providers’ administrative purposes” (<https://www.selondonics.org/wp-content/uploads/SEL-ICB-Privacy-Notice-Data-Service-v2.0.pdf>) in the public interest?

Q: If the ICS or DDS is relying on substantial public interest conditions set out in the DPA (2018) to process special category data, please identify which of the DPA’s conditions reflect the ICS’s purpose, and what specific arguments are they providing to justify that such processing is in the public interest.

**3.4 Data confidentiality and the SEL context**

Q: How is the ICB ensuring independent oversight of the way it uses confidential patient information?

Q: We note that the ICS’s Privacy Notice draws on Article 6 (1) (e) as the lawful basis for processing personal data. While Article 6 (1) (e) states that “processing shall be lawful when it is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller”, the ICO clarifies this by saying that “the *task or function* has a clear basis in law” (our emphasis). Further, Section 8 of the Data Protection Act (2018) says that the underlying legal basis of such tasks or functions must be identified.

Which *tasks or functions* as laid down by law are being performed when the ICB (or its suppliers) processes patients’ data for:

 a) risk stratification, and

 b) providers’ administrative purposes?

Q: Patients’ medical records often contain special category data that is subject to additional protections. How does the DDS’s or ICS’s processing of special category data comply with Article 9 (3) of the UK GDPR, requiring such data to be processed by a professional who is subject to an obligation of professional secrecy (such as a doctor, nurse or clinical scientist) or others owing a legal duty of confidentiality?

Q. Please provide the DDS’s Appropriate Policy Document covering the processing of special category data.

Q: The ICB’s Privacy Notice[[7]](#footnote-8) states that individuals have a right to raise an objection to some or all of their information being processed for the DDS and to do so they must contact the relevant Controller, at least where the objection is specifically about local information (e.g. concerning a specific health and social care provider).

1. How does the ICS ensure that individuals are aware that they may raise an objection to their data being processed (this is not made clear by the Privacy Statement) and informed about how they can do this?
2. Where the objection concerns a specific health and social care provider, how are individuals supported in finding the relevant Controller to contact?

**THEME FOUR: PATIENT AND CITIZENS’ ENGAGEMENT**

Q: Please explain how the public is represented, beyond Healthwatch, in ICB decision-making on digital and data matters, and how the public can get involved. What methods are used to consult and engage with a diverse range of citizens?

Q: Which committees, sub-committees and groups dealing with patients’ data have a representative from Healthwatch?

Q: When and how are patients proactively informed about their right to opt out of their data being collected and shared at local and national levels? What information, including the numbers of those who have chosen to opt out, is kept that shows patients have been given a choice by all SEL organisations?

**THEME FIVE: PRIVATE COMPANY INVOLVEMENT**

Q: Do the different companies such as EMIS or TPP SystemOne that supply data sets derived from primary and hospital care to the Discovery Data Service have access to the detail of individual patient records?

If so,

* what requirements are placed on them to ensure that they do not use this data for their own purposes, and
* what monitoring takes place to ensure they comply with any such requirements?

Q: Do the different companies involved in processing or otherwise dealing with data for risk stratification, Population Health Management and other analytics have access to the detail of individual patient records?

If so:

* what requirements are placed on them to ensure that they do not use this data for their own purposes, and
* what monitoring takes place to ensure they comply with any such requirements?

Q: A significant number of companies listed on the HSSF for ‘Informatics, Analytics and PHM Digital Tools’ have parent companies that have been required to pay colossal fines for violations of contracts. For example, EMIS and Optum are both owned by UnitedHealth, which since 2000 has been fined $469,099,518 for ‘customer protection-related offences’, and $131,539,180 for ‘government contracting-related offences’.

What processes has the ICB put in place to ensure that it does not procure services from companies with a history of customer protection and contract violations?

1. An ICS’s Governance Handbook may contain some of this information so it’s worth checking first. [↑](#footnote-ref-2)
2. The Digital Board is not mentioned in SEL ICS’s list of bodies and their terms of reference. [↑](#footnote-ref-3)
3. <https://www.gov.uk/government/publications/secure-data-environment-policy-guidelines/secure-data-environment-for-nhs-health-and-social-care-data-policy-guidelines> [↑](#footnote-ref-4)
4. <https://www.nhsdatasharing.info/CLoC/DDSdataflow.pdf> [↑](#footnote-ref-5)
5. <https://www.england.nhs.uk/about/equality/equality-hub/case-studies/reducing-healthcare-inequalities-using-population-health-management/>. [↑](#footnote-ref-6)
6. https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-be-informed/ [↑](#footnote-ref-7)
7. <https://www.selondonics.org/wp-content/uploads/SEL-ICB-Privacy-Notice-Data-Service-v2.0.pdf> [↑](#footnote-ref-8)