

27 April 2023 ICB Board Meeting - Questions received in advance

All questions raised to the Board will be answered in writing to the individual who raised them and published on the ICB website.

Question Received and Answers Provided	Raised by
<p>Protection of patient information</p> <p>Background Board paper ICB/04/27/12 asks the ICB to extend current funding for Graphnet, C2Ai, and System P for two years while preparing for rationalisation and alignment with national data frameworks including the Federated Data Platform. The FDP is expected to adopt the Foundry platform, designed and operated for NHS England by US spy-tech firm Palantir which is bidding for the FDP contract.</p> <p>The paper signals the intent to ensure the ICB's data Architecture and approach is designed to fit as part of a national NHS data architecture as continues to develop and ensure that as a system with a relative mature capability around population analytics is well place to take advantage of any products provided nationally. The procurement nationally is not expected to complete until autumn this year and specifications for that specification are supplier agnostic. There is not currently an obligation to adopt national products, but the design work locally is intended to ensure that the ICB is in a position to integrate at that point if it chooses to do so based a detailed evaluations and normal due diligence work.</p> <p>C2-Ai has been included as part of the IECCP NHSE programme in other regions and has integrated the PTL risk stratification analysis within the Foundry system (i.e., FDP-ready) should C&M ICS require it.</p> <p>C2Ai (https://c2-ai.net/about-us/) is Copeland Clinical Ai, limited., has its HQinCambridge and offices in other countries. The parent company is registered in the UK as Crab Clinical Informatics Ltd which trades as C2-Ai.</p> <p>A pilot study co-authored by ICB Executive Medical Director Prof. Rowan Pritchard-Jones evaluated the C2Ai artificial intelligence tool for risk stratification in elective surgery. The ICB proposes to roll out C2Ai across the 10 acute Trusts, supporting risk-adjusted triage and prioritisation of the Patient Treatment List (PTL).</p> <p>NHS England publishes a list of risk stratification approved organisations. Graphnet is authorised for Cheshire & Merseyside ICB, but neither C2Ai nor Copeland nor Crab are authorised, nor are they mentioned in Confidential Advisory Group spreadsheets for approved research or non-research applications.</p> <p>The ICB says that "A critical aspect of this work is maintaining patient confidence in use of personal data" and refers to an NHS England review of ICB compliance with risk stratification control published in March 2023.</p>	<p>Greg Dropkin</p>

The Board paper ICB 04/27/12 describes the anticipated required budget to maintain existing capabilities. The core capabilities around the Graphnet solutions are supported under an existing contract which runs until March 2025. Other elements of the analytics will be subject to appropriate procurement rules under the ICB's SFI's.

The confirmation of a supplier to support specific work at an ICB level around waiting lists has not been conducted yet. The pilot work funded and evaluated by NHSE that has given us health economic and operational evaluation of the C2-Ai tool and an indicative cost for which support in principle is sought but it is planned to conduct an appropriate procurement process to commission waiting list analytics capability and any supplier chosen would need to satisfy a range of assurance question including data handling protocols.

The work with C2Ai done to date has been carried out at individual Trust level where the Trusts are data controllers. Data has not been aggregated with wider data from the system or been processed at an ICB level. The work has been done by individual Trusts to support direct care.

Questions

1. Please supply a web address for the full "NHS England review of ICB compliance with risk stratification control published in March 2023".

The report titled. ***S251 Risk Stratification Assurance Report*** was commissioned for the NHS England Confidentiality Advisory Group (CAG) and has been shared with ICB. It is not formally published externally.

2. The ICB states that "The full specification of the C2AI work is given in Appendix Three." None of the three appendices mention C2AI. Please supply the full specification of the C2AI work.

Unfortunately, that reference was included in the report in error and should not have been referenced.

3. Why is the ICB proposing to fund risk stratification work by a company which is not authorised to do so by the relevant authorities?

Any additional suppliers and products brought into the ICB' Data analytics capability would be subject to the same governance checks and process which have been worked through a part of the submission to NHS under the review of ICB compliance with risk stratification control.

C2-Ai is DCB 129 and ISO 9001 accredited. The C2-Ai PTL risk stratification tool is pending Class IIa medical device registration. The C2-Ai PTL risk stratification tool has been included in the GIRFT best practice guidance in 2021 https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/12/GIRFT_HVLC_Guide_Edition_2_FINAL.pdf .

4. The NHS Digital Data Uses Registers show data releases. For the Data Controller Crab Clinical Informatics, FILE0152598 concerns anonymised, "Sensitive", Admitted Patient Care data released for commercial purposes in June 2022 with no Patient Opt-Outs applied. Such Opt-Outs have been available since 2018. How does the release of anonymised sensitive patient data for commercial purposes without provision for patient opt-out, maintain patient confidence in the use of personal data?

<p>The lawful basis is the STHK NHS Trust and assigned NHS Trusts' public authority for the support of the provision of care, and public health processing under Articles 6(1)(e) and 9(2)(h) and 9(2)(i) GDPR respectively. NHS Digital data is not used as part of the analysis provided to STHK as C2Ai receive data directly from the Trust and have a dedicated DSA acting as the data processor on behalf of the Trust</p> <p>5. The ICB states that the C2Ai PTL Risk stratification tool includes “automated data input from Trust upload to C2-Ai and download of PTL analysis back to Trust”. PTL data is pseudonymised personal data as it must be capable of re-identification to enable individual clinical decisions. How can the ICB ensure that automated Trust uploads to C2-Ai will not be available to the C2-Ai headquarters in Florida? How would such assurances be validated in practice?</p> <p>C2-Ai / L2S2 adhere to ISO 27001 and ISO 13485 business resilience protocols. L2S2 as the sub-processor to C2-Ai is DSP Toolkit compliant (“standards Met”). Data is retained unless otherwise instructed by the data owner (Healthcare Organisation). Data would therefore remain in the secure, encrypted database for the duration of any C2-Ai’s contract with a Healthcare Organisation within the HSCS environment within the UK; and thereafter until a formal destruct notice is received from The Healthcare Organisation. In any case, as a matter of good practice, C2-Ai and L2S2 would review the ongoing requirement to retain data on an annual basis</p> <p>C2-Ai headquarters are in Cambridge, UK. The parent company CRAB Clinical Informatics Limited is registered in the UK. Company number 06601066</p>	
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