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Dear Regulators,

We understand you are aware of press reports and public concern regarding Google DeepMind's agreement with the Royal Free London NHS Trust.

The attached timeline contains our understanding of relevant events. As this raises complex questions, involving multiple Regulatory bodies, we have provided a single but segmented list of questions to assist in a coordinated discussion. While we have attempted to identify the lead agencies for each part, it is clear the answers are deeply interrelated.

MHRA

1. Is the dedicated device running the Streams app subject to MHRA regulation?[1]

2. Is the implementation of the AKI algorithm auditable to the standards required for the exceptions to MHRA approval?[2]
    a. To what extent was the "AI toolkit" used to build a decision tree?
    b. To what extent are decisions verifiable?

3. According to the PM interview,[3] the Streams app has a mechanism to "provide an immediate alerts to doctors, **the right doctors, in the right way, synthesise the data**".[4] Is there a "Notice of No Concern" regarding the "small scale testing" of this feature?[5]

4. Has it been confirmed that no patients were harmed by the unapproved tests of this application?

[1] See timeline, including paragraphs 5, 12, 18, 20.

[2] See timeline, including paragraphs 18,19,20, 23, 25.

[3] See timeline, paragraph 17.

[4] See timeline, paragraph 20.

[5] See timeline, including paragraphs 18, 19, 20, 50.

a. What would best practice in this case have been?

5. Regarding Google's statement that "We sought all the approvals we believed to be necessary",[6] is this the standard MHRA expects device manufacturers to uphold?
    a. How can MHRA reassure the public that future reviews of unregulated tools in use by a hospital will not require whistleblower investigations?

ICO

6. What are the consequences for providing "false or misleading information"[7] on an IG Toolkit?

7. Have the Data Protection principles been breached, either for direct care or for "development work"[8] (a secondary use), according to the current public understanding of this project?

8. Is the ICO satisfied there is a legal and appropriate basis for Google receiving the data of patients who never had a blood test when they were at RFH A&E, and who will never return to the RFH?

9. Is the Information Sharing Agreement signed by both parties an appropriate document? Is it internally consistent? What is the heritage of the various parts of the document? Who created it, for what purpose, and when?

10. When did the Caldicott Guardian first see the Agreement? Was this appropriate?

11. If relevant, given the answers to other questions, who determined the manner of the processing of the data by the decision making software within DeepMind's app?[9]

[6] See timeline, paragraph 53.
[7] http://www.legislation.gov.uk/ukpga/2014/23/section/92/enacted

[8] See timeline, including paragraph 34.

[9] See timeline, including paragraphs 5, 18,19, 20, 50-53.

HSCIC / NDG / DH

12. As the basis for the piece in the Guardian,[10] and given other questions in these documents, has HSCIC audited DeepMind to verify that the IG Toolkit answers provided to HSCIC were fully accurate?[11]
    a. Will the findings of any audit be published?

13. The app was designed by an external agency.[12] What data was used in the design and iterative testing? What agreements were in place?

14. What are the consequences for providing false or misleading information on an IG Toolkit submission?

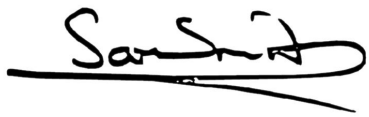
15. One article[13] makes reference to the "1500 data sharing agreements" – a figure taken from a medConfidential discussion, which we sourced from the HSCIC's Data Release Register.[14] Does the Royal Free / DeepMind Information Sharing Agreement meet the standards and processes required to be met for HSCIC projects in that Register?

16. Should all care provider level agreements / contracts, and data flows, be published in a publicly available Register?

17. Having looked at this project in detail, does it raise any new issues about the definition of "direct care"?

We are happy to meet with any organisation looking at this in more details.

Yours sincerely,



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[10] See timeline, including paragraphs 28.

[11] See timeline, including paragraphs 29, 30.

[12] See timeline, including paragraphs 47.

[13] See timeline, paragraph 32, footnote 15.

[14] http://www.hscic.gov.uk/dataregister