

Letter via email

For the attention of Dr Ian Hudson, Chief Executive, Medicines & Healthcare products
Regulatory Agency

Dear Dr Hudson

The Royal Free Hospital's sharing of data with Google DeepMind

I am writing to you following work that my panel of independent experts, who advise me in my role as National Data Guardian, and I have undertaken to consider the Royal Free's recent sharing of patient data with Google DeepMind.

Representatives from the Royal Free and Google DeepMind attended a meeting of my advisory panel in May 2016, and have also provided useful follow-up information through an exchange of correspondence.

When my advisory panel last met on 19th September, we reviewed all the information that we have received on this and discussed our next steps. We think that there are a number of issues of concern about the way in which the Royal Free shared this patient data with Google DeepMind, and I believe that it would be helpful for me to convey these to the trust.

However, before I take this course of action, I wanted to write to you to ensure that in doing this I would not impact on any work that you may have underway with the Royal Free or Google DeepMind. I am aware that most of the issues that we have identified may well not be within the purview of the MHRA, however, I thought it would be helpful to share them all with you. Please note that I have sent a similar correspondence to the ICO, with whom my team have kept in close contact as we have undertaken this work.

The first issue, which is most pertinent to the reviews I have carried out for the current and previous governments, is that the Royal Free has stated that they shared the patient data with Google DeepMind on the legal basis of 'implied consent for direct care', as the Streams application is intended to be used by clinicians to provide direct care to patients. However, the Royal Free has also informed us that the Streams application is not currently in use at Royal Free Hospital (RFH) and that only small scale testing of the pre-production prototype version of Streams has taken place to date, with a focus on refining the design and functionality of the application. From this it appears clear that the application has not yet been used by clinicians to provide direct care. Therefore 'implied consent for direct care' is not an appropriate legal basis for the sharing of this data.

It is also our opinion that the Royal Free did not make sufficient effort to make information available to patients about the sharing of data with Google DeepMind, or enable them to object to that.

The panel also raised concerns about the Information Sharing Agreement between the Royal Free and Google DeepMind. The Royal Free has stated that the contract they have in place with Google DeepMind is a Data Controller to Data Processor agreement. However, the published contract appears to contain elements of a data sharing agreement (i.e. Data Controller to Data Controller), and therefore does not provide all of the necessary controls for the sharing of this data.

Further, although the Royal Free has stated in correspondence to us that GP blood test results have been shared with Google DeepMind, this is not covered in the published data sharing contract. We also intend to ask the Royal Free if they have put the appropriate data sharing agreements in place with the GPs, as they are the Data Controllers for this data.

Finally, the panel also felt that the Royal Free should have performed a Privacy Impact Assessment (PIA) at the start of this programme of work, as this would have helped them to identify and mitigate many of the issues that have subsequently occurred.

Given the intended functionality of the Streams application, we also believe that it should be classed as a medical device and that the Royal Free should not deploy the Streams application until Google DeepMind have achieved the appropriate compliance for a medical device as defined by the MHRA. We understand that Google DeepMind is now seeking to achieve this compliance for the Streams application.

Given that my role, of the National Data Guardian, is not yet on a statutory footing, I do not have the 'formal advice giving' powers which the government intends to see placed into legislation. However, given that we have engaged with the Royal Free, and colleagues have been forthcoming in answering our questions, I do feel inclined to share my thoughts with those concerned there.

In writing to the Royal Free, my intention would be to raise the issues listed above and recommend that resolution of them should take place prior to progressing any further with this programme. I would also like to suggest that they consider retrieving the patient data that has already been shared with Google DeepMind, given that they are not currently using the application, and that they suspend any ongoing monthly updates to that data.

Lastly, I would like to say that my panel and I fully appreciate the benefits to patients of the development and deployment of applications such as those being developed by Google DeepMind. However, as with all uses of patient data, it is absolutely paramount that this is undertaken in a transparent and secure manner, which helps to build public trust, otherwise the full benefits of such developments will not be realised, and indeed harm may be done.

Yours sincerely



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National Data Guardian