Coronavirus treatment

UK plans to use AI to process adverse reactions to Covid vaccines

Software deal reveals high level of reported side-effects expected in inoculation programme

The types of vaccine being developed by many of the pharmaceutical companies are relatively new, making it hard to predict how they will interact with millions of people's immune systems when they leave clinical trials © REUTERS

Anna Gross in London NOVEMBER 1 2020

The UK drugs regulator is planning to use artificial intelligence to sift through the "high volume" of reports of adverse reactions to Covid-19 vaccines in the coming months, as it prepares for an inoculation programme of groundbreaking scale.

A government contract shows the Medicines and Healthcare Regulatory Authority has paid a software company called Genpact UK £1.5m to develop an AI tool to "process the expected high volume of Covid-19 vaccine adverse drug reaction (ADRs) and ensure that no details . . . are missed".

The need for a powerful tool to sort through what are forecast to be a huge numbers of adverse reactions, speaks to the scale of the vaccination programme in the months ahead.

The types of vaccine being developed by many of the pharmaceutical companies are also relatively new, such as the MRNA and chimpanzee adenovirus vectors, making it hard to predict how they will interact with millions of people's immune systems when they leave clinical trials.

“You’re talking about vaccines that have potential liabilities, it’s an unknown unknown,” said Gary Nabel, chief scientific officer at pharmaceutical company Sanofi, which is currently working on two Covid-19 vaccine candidates. “As big as a 30,000-person trial is, when these go out into the world of millions of people, things will happen.”

Mr Nabel recalled the famous vaccine developer Maurice Hilleman telling him, “every time I launch a new vaccine, I hold my breath for the first 30m doses”.

The MHRA told the Financial Times that, based on previous vaccination campaigns, there would be between 50,000 and 100,000 reports of suspected side effects for every 100m doses over a 6-12 month period.

However, it added that all vaccines, including for Covid-19, underwent rigorous testing and that most reactions would be mild and short term.

The AI tool will be employed as part of the MHRA’s yellow card scheme for coronavirus, through which patients and healthcare professionals report suspected side effects and negative reactions. These are then evaluated to identify where updated advice or regulatory interventions are needed to protect the public.

The contract terms stated, “it is not possible to retrofit the MHRA’s legacy systems to handle the volume of ADRs that will be generated by a Covid-19 vaccine”. It added that the absence of an AI tool would “hinder its ability to rapidly identify any potential safety issues . . . and represents a direct threat to patient life and public health”.

The MHRA said that the scale of the Covid-19 vaccination campaign would be much larger than any adult programme seen in the past.

It added that the reporting of side effects and adverse reactions could be influenced by “media attention, public concern and anti-vaccine social media activity and lobbying.” This would be “highly prevalent in relation to a Covid-19 vaccination campaign”.

“It is important to note that a report of a suspected ADR is not proof of a side effect occurring due to the vaccine but a suspicion by the reporter that the vaccine may have caused the side effect,” it added.

Mr Nabel and other experts thought that the move by the MHRA was a positive sign of proactivity by the UK’s regulator.

“I’m happy to hear there’s such a programme and AI is a great way to do it,” he said. “Why not use our most advanced technologies to get at these important questions.”

Kate Bingham, chair of the UK's vaccine task force, said the use of AI was "just what the MHRA should be doing", adding that the UK is "incredibly well set up to do this given we all have NHS records which are electronic and connected".

In the US, where the health system is more fragmented, experts are not aware of there being a similar initiative.

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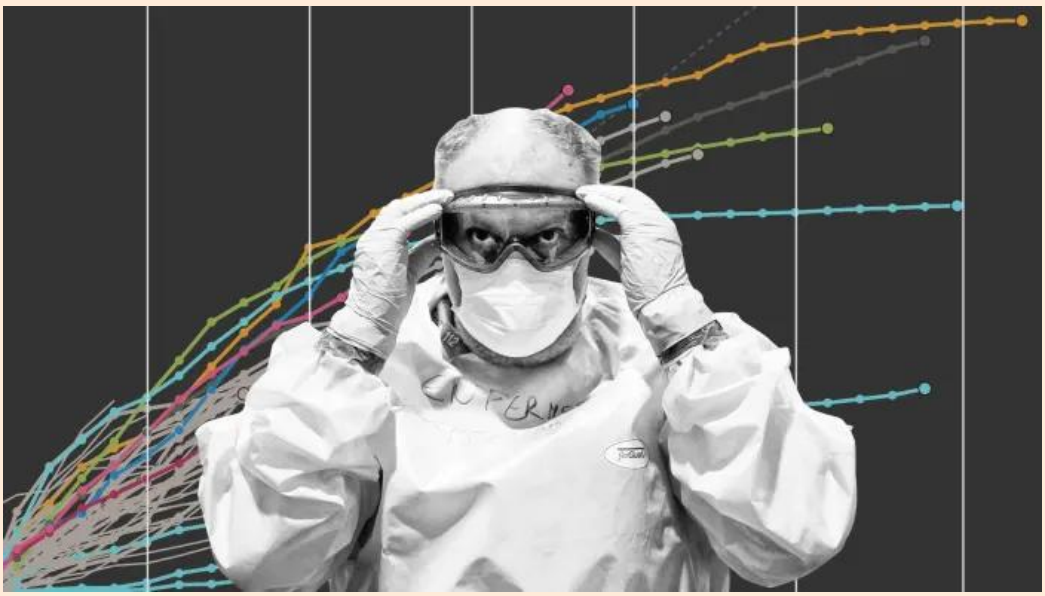

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