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Rawen Kader
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Life Sciences

The road to recovery

Covid-19 has put the life sciences industry in the spotlight.

The sector has pulled together to care for those impacted by the virus and in the race to find a vaccine. There have been collaborations between major players in the sector not seen before and an advancement of the use of technology which will have a lasting impact.

In our report we look at how the pandemic has remodelled the life sciences sector through changing regulation to allow the accelerated approval of medicines to the use of big data and advancements in digital health.

We also speak to Rawen Kader, Clinical Research Fellow, Faculty of Medical Sciences who is currently researching the use of artificial intelligence to try to improve the quality of colonoscopy and how the pandemic has impacted his research.

If you have any questions please do not hesitate to get in touch.

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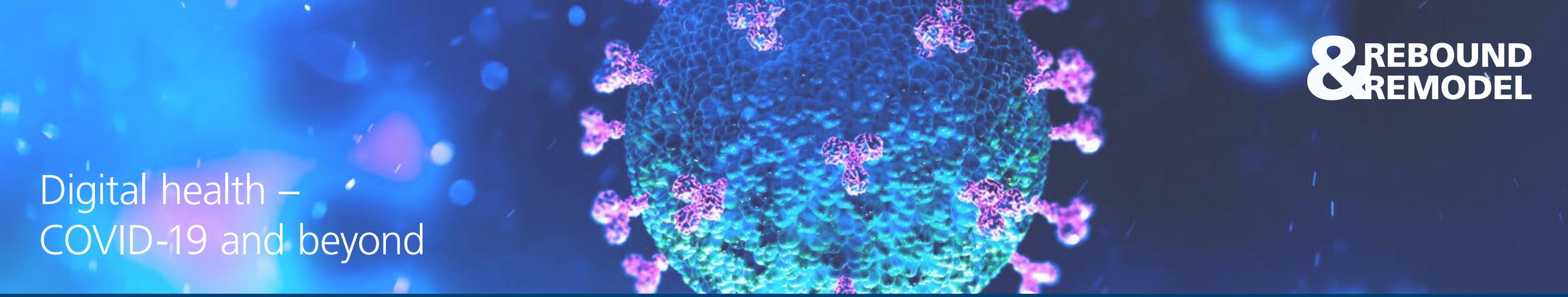

Digital health – COVID-19 and beyond

The COVID-19 pandemic, now a year in, has created unique opportunities for digital health platforms and the use of technology for home-based care. As front-line services have struggled with capacity and changes in the way patients are using healthcare services, the market has looked towards technology to fill the gap.

Impact of COVID-19 on healthcare services

The outbreak of COVID-19 has intensified pressure within areas of the NHS that were already under-resourced prior to the pandemic, for example investment in equipment and social care. As the NHS looks to get back on its feet, there is a backlog in postponed elective treatment which may continue for some time.

The new patient experience

With the government's 'stay home' policy, healthcare has had to adapt to reduce contact, transforming the patient experience. DrDoctor, the appointment booking and patient interaction app in use across 30 trusts, has used the pandemic to innovate and create remote consultation tools and a tool for broadcasting cancellations or changes to large volumes of non-essential appointments. As a result, they were recently awarded the AI in Health and Care Award by the NHS AI Lab. Babylon Health, the platform for remote consultations with doctors and health care professionals, launched a COVID-19 Care Assistant to help patients check symptoms, order home-test kits, track their illness and chat with trained staff and doctors. Globally, AI chatbots, such as Berlin-based Ada Health are providing access to healthcare in countries such as Tanzania where there is only one doctor per 25,000 citizens.

The prescription management app Echo, part of the LloydsPharmacy group, has reported a 300% revenue rise compared to pre-pandemic figures. Other remote prescription services such as Pharmacy2U and Amazon's Pillpack have also seen huge increases in use.

Efficiency and capacity

A number of apps addressing under-resourcing in the NHS have seen rapid uptake during the pandemic. GoodSAM, which allows emergency services to access their video camera at the scene of an emergency, expanded its offering to connect community volunteers with individuals who have contracted COVID-19 or even to recruit vaccine volunteers to assist with the governments ambitious plan to vaccinate the most vulnerable groups by mid-February 2021. Patchwork, an app that allows healthcare workers to access flexible shifts, has reduced NHS reliance on agencies, through assisting in the creation of collaborative staff banks across London and regional trusts. Similarly, Hospify, a secure messaging platform for medical professionals, has seen an increase in use during the pandemic as more individuals work remotely.

A changing environment for healthtech

The unique challenges posed by the pandemic have catapulted the NHS into a new phase where innovation is being implemented quickly and led by NHSX, the innovation arm of the NHS. Hospitals have been proactive with change management, with some experts predicting that 1 in 3 healthcare visits will be conducted digitally in the future. In addition, in March 2020 the UK government launched a £500,000 fund to identify digital ways to support people who need help during the crisis, with a focus on remote social care and mental health support.

Mental health in particular is a growth area within the Digital Health space, and COVID-19 has highlighted the importance of active management of mental health. NHS England and NHS Improvement have worked with three providers to waive costs for NHS workers dealing with the COVID-19 outbreak. They include Unmind, a platform that provides a range of tools to help with stress, sleep, connection and nutrition; Headspace, a mindfulness and meditation app aimed at reducing stress and building resilience; Big Health's Sleepio, a clinically-evaluated sleep improvement programme, and Daylight, a cognitive behavioural technique to manage worry and anxiety.

Vaccines

With three vaccines having now been approved for use in the UK, and although in the height of the second wave (and a third national lockdown), there is optimism the roll out will allow us to return to normality. A coalition of organisations including Microsoft, Oracle and Mayo Clinic are working together to establish standards to verify whether a person has been vaccinated under a "digital vaccination passport". With new variants of the COVID-19 virus emerging across the world, there is likely to be substantial interest in these solutions but it is yet to be seen whether technology can keep up with the rapidly evolving virus.

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Accelerated approval

As a result of the COVID-19 crisis, regulatory procedures in the UK have been adjusted to allow for quicker product approvals. This has implications for approval post-COVID for non-COVID medicines. The very recent emergence of new and effective COVID-19 vaccines has led to a focus on the drug approval process.

Given the medical emergency, the European Medicines Agency (EMA) indicated in early October that it was conducting a rolling review of Oxford University/ AstraZeneca's COVID-19 vaccine, the so called "Oxford vaccine". A rolling review means that the EMA's human medicines committee (CHMP) evaluates data as it is being generated, whereas normally all data on a medicine's effectiveness, safety and quality and all required documents must be submitted at the start of the evaluation in a formal application for marketing authorisation. The rolling review carries on until sufficient data has been obtained to allow the grant of a formal marketing authorisation application. As a result, the approval process should be shorter than a regular evaluation, due to the time gained during this rolling review.

It subsequently turned out that the first vaccine to be approved in the UK was Pfizer and BioNTech's mRNA vaccine, also approved based on a rolling review, as was the COVID-19 repurposed medicine Veklury (remdesivir) used for hospitalised patients.

Use of this regulatory tool does not speed up the clinical trial, nor compromise safety or quality of assessment, but it should speed up the assessment of a promising medicine or vaccine during a public health emergency to allow more rapid product deployment.

Fast track approval

In another development the UK Government recently used Regulation 174 of the Human Medicine Regulations to rapidly approve the Pfizer vaccine on a temporary basis, allowing roll out before a full product license has been granted. These measures were necessary because, during the Brexit transition period, a new potential COVID-19 vaccine must be granted a licence by the EMA.

Rolling review

It is clear that the various regulatory bodies and governments in general are looking to speed up access to COVID-19 products. Whilst temporary product approvals will not f other (non-pandemic, non-COVID) medicines. Arguably there is a pressing medical need for many drugs, and the regulatory authorities will have more experience of the rolling review process post-COVID. We might now expect to see companies lobbying for a more regular use of the rolling review process, to allow quicker product launch.

The temporary approval of the Pfizer/BioNTech vaccine led to a curt exchange of comments between UK politicians and members of the EMA and FDA about the speed of the authorisation. Whilst the Leader of the UK House of Commons tweeted that "We could only approve this vaccine so quickly because we have left the EU", in fact all of the EU member states have the same temporary authorisation option open to them. European Commission spokesman Eric Mamer quite sensibly stated "we are definitely not in the game of comparing regulators across countries, nor on commenting on claims as to who is better".

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Big Data and Life Sciences

COVID-19 has forced us all to re-think the way in which we work, collaborate and communicate. Perhaps none more so than those in organisations which can take advantage of the massive amount of information which big data provides. During the pandemic we have seen non-conventional collaborators and even competitors pool resources and data to facilitate more informed decisions in connection with the fight against the COVID-19 virus, demonstrating the value of its application in the sector more broadly.

Precision medicine

Precision medicine, being medical care designed to optimize efficiency or therapeutic benefit for groups of patients, and in particular a gene-centric approach to medicine, has been promoted as the future. We know that different people present with different symptoms and it is thought that pre-existing conditions can only be part of this story. Capturing the vast sets of data needed to apply this care is beyond what can be achieved within the timescales of the current pandemic but we have certainly seen its application accelerate during the course of 2020 through collaborations such as that between Bayer and Tempus.

Value-based healthcare

Healthcare professionals and providers worldwide strive to recognise and refine the most cost-effective care delivery, so patients receive the right care, first time, every time. Combining patient outcome data with resource allocation identifies where unnecessary waste is expended and machine learning technologies can assist in the management of supply chains and the adoption of clinical best practice. The acceleration of telemedicine, increased focus on operating expenses and decline in low-value care during the pandemic have all lead to an increased acceleration in the adoption of value-based care models which will hopefully continue post-pandemic.

R&D

The combination of traditional patient data, such as information sourced from audits, patient-reported outcomes, medical claims and patient records, with additional data streams from mobile phones, fitness wearables, social media activity and online purchases are helping life sciences and healthcare companies overcome the unique challenges posed by COVID-19. It is predicted that the use of such data alongside data science to understand the impact of COVID-19 will instigate the combination of big data alongside traditional R&D in the industry on a wider basis post-pandemic.

Artificial intelligence

Big data is critical to the next generation of programmes loosely grouped under the "AI" banner. Large quantities of good quality data are critical to train these programs to a point where they can make assessments and predictions on their own. This is already making an impact in the life sciences and healthcare sector and has huge potential to change the sector. In the context of the pandemic, AI has been used to harness the huge amounts of publicly available information to better model the progress of the disease and make predictions to help combat the spread.

Online purchases

Data collection from the purchase of consumer products is well established. The increase in online purchases of pharmaceutical products and prescription renewals catalysed by the pandemic brings with it the opportunity for the collection of data in the field of life sciences and healthcare. Insight into supply chains, an increased ability to manage fraud and the potential to price reactively will all lead to a more personalised experience for the patient.

Summary

Not only is the potential of big data to continually track the virus's effect on a global basis and create innovation in the medical field huge, the pandemic itself has accelerated the application and impact of big data in the sector more broadly. Big data has the potential to model outcomes and roads to recovery and, surely, the potential demonstrated during 2020 is good reason for its application to continue at this increased pace.

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Collaborating for good

Collaboration between healthcare companies during the pandemic has been vital for society. The sharing of data and information has helped maintain supply chains for medical establishments taking care of patients whether suffering from COVID-19 or other illnesses.

Even while the sector pulls together for a common goal, it is important to be aware of the competition law rules which are policed by the Competition & Markets Authority (CMA) and the limits of any flexibility that may be applied with respect to those rules in supporting the fight against COVID-19.

Greater flexibility

Our recent rebound article 'UK competition law after the pandemic – The end of the COVID excuse' outlined the CMA's flexibility during the pandemic to engage in targeted cross-competitor cooperation to guarantee the supply of essential products.

However, those that have benefitted from the CMA's leeway must ensure their cooperation does not become inappropriately used in the long term in a way that breaches the competition rules.

A look back

In the spring of 2020, the UK government issued a series of sector- specific orders excluding agreements from the scope of competition law under particular conditions. For the healthcare sector this included independent healthcare providers and NHS bodies:

"information sharing in relation to capacity […] including information regarding staff and facilities" as well as "the joint purchasing of goods, materials, vehicles, plant, apparatus, facilities or services".

Such sharing has been required to be for the purpose of assisting the NHS in addressing the effects or likely effects of coronavirus on the provision of health services to patients and cannot concern costs or pricing.

As industries are now learning to cope with the pandemic and looking to rebound in the months ahead, these exceptions are being gradually withdrawn. While the exclusion linked to healthcare currently remains in place, it is likely to be withdrawn over the coming months.

Investigations

The CMA has noted that most business have not taken advantage of the sector-specific orders. Furthermore, its investigations into alleged anticompetitive behaviour during the pandemic shows it has stayed extremely vigilant to detect and address bad behaviour. Two specific examples stand out in the healthcare space:

Case Study 1

On the 18 June 2020, the CMA launched four investigations under Chapter II of the Competition Act 1998 into suspected breaches of competition law by four pharmacies and convenience stores. The investigations related to suspected charging of excessive and unfair prices for hand sanitiser products during the pandemic. The CMA eventually closed its investigations noting that after a review of the evidence (including wholesale costs and volume of hand sanitiser sold) it was unlikely that the retailers' prices infringed competition law.

Case Study 2

The CMA published a joint letter with the General Pharmaceutical Council, in which the CMA urged pharmacies to ensure that prices for essential products do not include higher than usual mark-ups when compared to pre-coronavirus mark-ups.

Comment

Whilst there have been investigations into allegations of excessive pricing, in general the sector has worked together appropriately to help the UK through the pandemic. Since the order relating to healthcare will eventually be withdrawn, returning competition law obligations to their even stricter pre-pandemic standards, healthcare providers who have got used to collaborating must keep a close eye on the CMA's guidelines and the status of the order. They will need to unwind cooperation at the appropriate time to ensure that they do not inadvertently breach their competition law obligations.

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Rawen Kader
Clinical Research Fellow, Faculty of Medical Sciences

"It is quite beautiful when you have two completely different specialists coming together and using their expertise for the greater good of everyone."

Please outline your background and the projects you are currently working on

I am a Gastroenterology Registrar, currently researching the use of artificial intelligence (AI) to try to improve the quality of colonoscopy. Colonoscopy is not a perfect procedure as it is done by a human so there are a lot of ways to improve it. One of the main reasons we do a colonoscopy is to remove polyps (precancerous lesions) and we miss up to a quarter of these through human error. There are many reasons why they could be missed, for example fatigue towards the end of the day increases the chances of a missed polyp. My research is to try to assist humans improve their performance and detect polyps using AI.

The second project I am working on is optical diagnosis of polyps which looks at assessing the histology of a polyp in real time. We usually remove a polyp then send it to the lab for analysis to confirm if it is a harmful or harmless polyp. The research we are doing is to use AI to give the diagnosis in real time, which would avoid removing harmless polyps, improve workflow, decrease anxiety and save money for the NHS.

Rawen Kader

Aside from improving the patient experience, saving money and increasing efficiency, are there are any other benefits that you can anticipate from the database you are creating?
The first benefit of the database is the additional uses of the data aside from optical diagnosis. We could use AI to measure time spent examining the colon and measure the speed of withdrawing the colonoscope to alert the clinician if they are going too quickly and may therefore miss a polyp or lesion. If a patient has inflammatory bowel disease, such as Crohn's or Ulcerative Colitis, we score them using a criteria, however often two endoscopists in the same procedure will give totally different scores. You can train an AI device to be impartial and give a more standardized platform of this diagnosis.

The second benefit is to overcome bias in AI. One of the difficulties we have in the research community is the size of the data sets – you can only train your AI system on the data you have. This introduces bias to which AI is very susceptible. If the AI system was trained on one age group it will be completely biased to certain characteristics within that cohort. The idea of this project is to create a big database which will continue to grow and which all research academics can access to advance the AI technology and also provide separate data for others to test their AI system against.

How has the pandemic affected your work?
When COVID-19 hit the UK all endoscopies were put on a complete hold. It took a few months until we able to establish a new workflow of how to do a safe endoscopy in the context of the pandemic.

My project has been impacted in three ways:
— From the research database perspective, there was no more data coming in as endoscopies had stopped.

— I am setting up a clinical trial to evaluate our AI polyp detection and AI polyp optical diagnosis software, as you need to evaluate these systems in real life to confirm your preclinical results. This was also paused as the national priority for research from NIHR (National Institute for Health Research) was for COVID-19 only. This has delayed the start of my trial by at least 6 to 12 months.

— During the peak of the pandemic the NHS was under a lot of strain and there was a call out to researchers to help hospitals. I spent three months between March to May away from my research and supported my local hospital treating COVID-19 patients.

Please can you explain how you have adapted to deal with the pandemic?
I have had to be innovative about how to spend time doing research – you have to accept new data is not coming in and the trial has been put on hold so you have to think about other ways to progress your project. I spent the time annotating my data as this is one of the most laborious aspects of the project and a task I can do on my own which is needed when working from home. The other aspects have been transitioning from working in an office to at home – virtual meetings etc.!

What do you think the key priorities will be for the life sciences sector as a whole in the next few years?
The potential is so big in AI so it will be hard to narrow it down in priority. I feel that AI researchers will be at the forefront of developments because there are so many different fields that AI can help us with. Two of the most common fields are 'computer vision' which is the kind of the work I am doing where it is looking at visual characteristics and training in the AI system to recognise them. The second piece of work is using 'natural language processing'. This is where the AI system scans your data in terms of text and words (e.g. clinical notes) and quickly learns pattern recognition to identify new ways of diagnosing disease and how to spot it earlier. We have a goldmine of clinical notes in our healthcare systems – millions of documents which it would be very time consuming for a human to review. You can train an AI system to do this very quickly. I wouldn't say there is any one priority but I suspect computer vision would lead the forefront of AI as it is at the moment. The next transition would be using natural language processing to be able to process data in terms of written texts for further uses.

Do you see the collaboration between the tech sector and the life sciences sector becoming more prominent?
Yes, absolutely. On a personal note what I have enjoyed the most about this project is being able to collaborate with computer scientists rather than working solely in lab-based environments where doctors and clinicians tend to work. When we collaborate, we work on all aspects of the project and you learn from one another. It is quite beautiful when you have two completely different specialists coming together and using their expertise for the greater good of everyone.

It is also exciting as you are doing your research as part of a much wider team – you are easily working with up to 20 people on a project which has many benefits. Not only do you learn from one another you also have the opportunity to learn leadership skills and develop these earlier than working alone.
I find the collaboration fascinating and it seems the penny has only dropped in the last couple of years that we should be working hand in hand.

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