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Integration and innovation: reshaping the NHS

Gala Events

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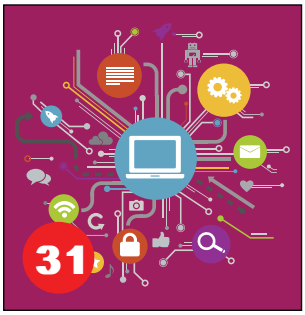

Integration and innovation: reshaping the NHS

Integration and innovation: reshaping the NHS Oli Hudson, of Wilmington Healthcare, explores the government's new white paper, which proposes some of the most important reforms for health and social care for nearly ten year

The government's legislative proposals for a new Health and Care Bill incorporate many of NHS England's formal requests and reflect key changes that have occurred in recent years, particularly with regard to joined-up care.

Indeed, the Integration and Innovation: working together to improve health and social care for all white paper marks a clear shift away from competition towards a new model of collaborative working.

However, it has attracted some controversy since it proposes to strengthen government powers over local reconfigurations and also the work of NHS England (NHSE).

This article explores the key elements of the document, including its plans for integrated care, the potential impact of more central government intervention and the proposed introduction of national medicines registries.

Integrated care

The white paper solidifies and codifies much of what has been happening in health policy around integration over the past five years as reflected in the NHS Long Term Plan and its predecessor, the Five Year Forward View.

It confirms that NHSE is backing legislation to abolish Clinical Commissioning Groups (CCGs) – a move that could see the core statutory functions of CCGs absorbed into Integrated Care Systems (ICSs), which will ultimately become statutory bodies. Alternatively, CCGs may merge to become ICS-sized structures.

The changes in CCGs are likely to affect Area Prescribing Committees (APCs). For example, if two or three CCGs that currently have separate APCs merge to ft the size of an ICS, or are absorbed into the system, then the number of APCs could decline.

Other changes needed to facilitate joined-up working include integrated finances with 'a single pot' of money shared between ICSs or groups of providers, and the introduction of provider collaborative that span multiple systems. Of particular note in the white paper is the inclusion of NHSE's recommendation for a reserve power to set a capital spending limit on

Foundation Trusts, which currently have additional freedoms to borrow from commercial lenders and spend surpluses on capital projects, such as new buildings, equipment or IT. This move underlines the system-level approach and the 'all in it together' ethos that lies at the heart of it.

The structural changes that are required to facilitate integrated care will have major implications for territory and account planning for pharma. Key stakeholder maps will need to be constantly updated as the move towards ICSs continues apace, and CCGs are expected to merge at scale and pace.

In finance, industry will need to identify the payers in the new organizations that are emerging, including the people who control rebates, and track how APCs are operating and on whose behalf.

Government control

An unexpected measure within the white paper, and one that has been particularly controversial, is the bid to award more power to ministers to intervene in decisions made about healthcare services at both NHSE and local levels.

'The establishment of medicines registries could provide an opportunity for pharma to be proactive in gathering real-world data around patient experience"

Under the proposals, the government would be able to get involved in decisions on local 'reconfigurations' – i.e. the work undertaken by each part of the system. In many areas, this may involve plans to close or downgrade hospitals as more services are moved out of secondary care – decisions that are, of course, likely to be highly contentious within the local communities these hospitals serve.

As some critics have pointed out, the new proposed central powers could, therefore, come at a price for the government since the public would be likely to blame it generally for unpopular decisions around services or setbacks rather than local healthcare system leaders.

On a national scale, the government also wants powers to intervene in, direct and oversee the work of NHSE itself, which threatens to remove its current independence in making decisions about the future of services.

If these moves were implemented in this form, the white paper would largely undo the legacy of the 2012 Health and Social Care Act, placing integration and ICSs centrally, and returning accountability to government instead of what was previously essentially, a 'handsof' approach.

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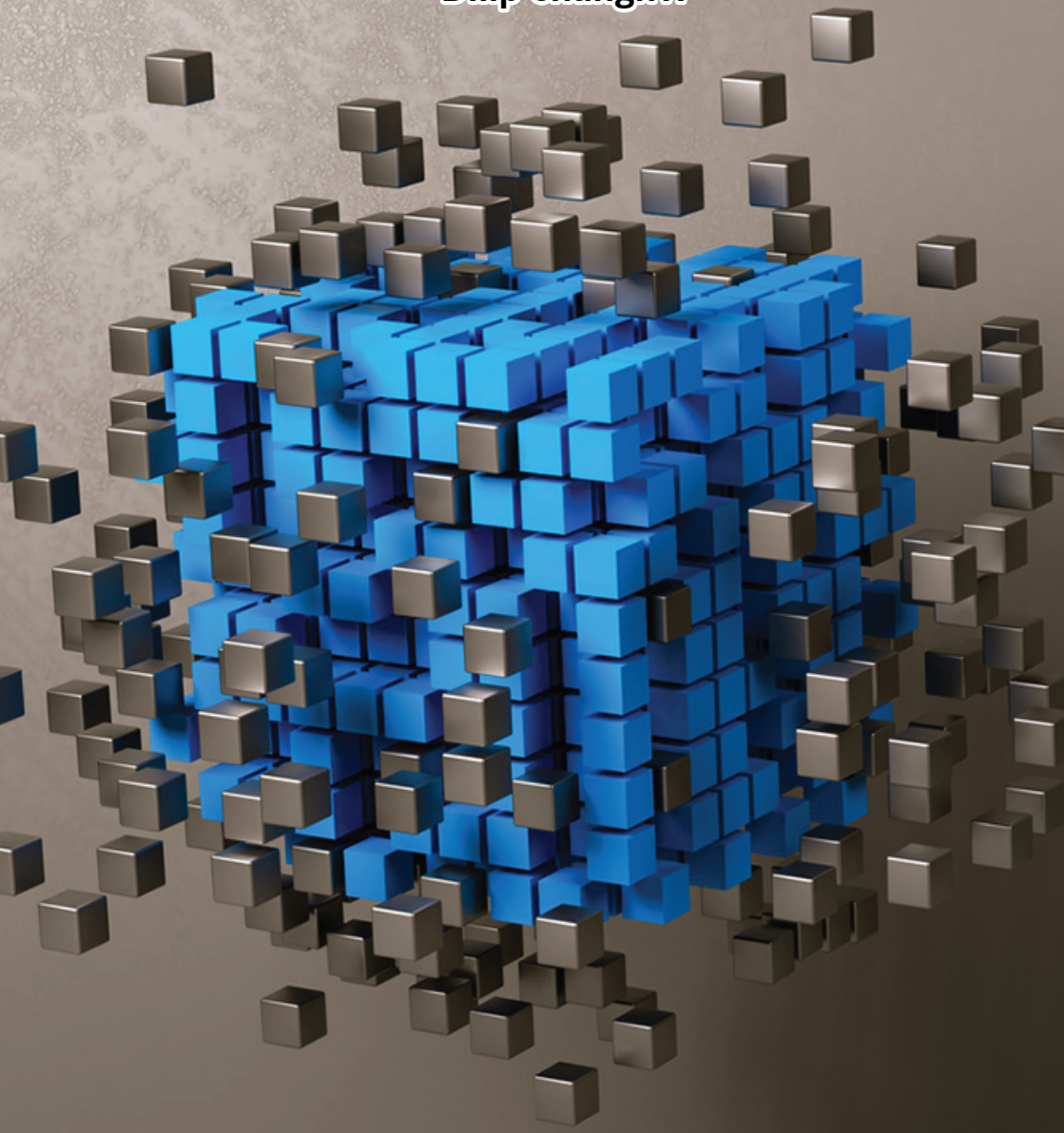
Medicines registries

One area mentioned in the white paper that is of particular significance for industry is the proposed introduction of national medicines registries. Under the scheme, the Medicines and Healthcare products Regulatory Agency (MHRA) would develop and maintain publicly funded and operated medicines registries and work with the NHS to populate and maintain them where there is a clear patient safety or other important clinical interest.

According to the white paper: 'Registries would be established for a medicine where the public need is clear and the benefits of a publicly held national registry that can access routinely collected data where it is available are required. For example, where we know risks of a medicine can result in serious adverse health outcomes and consistent adherence to risk minimization measures is critical, or where there are

If a company is not doing well, it doesn't necessarily mean that it is not a good company

-Dilip shanghvi



substantive unknowns about the safety or effectiveness of a medicine in a population and urgent evidence is required to support safe access to it'.

The medicines registries would provide patients and their prescribers, as well as regulators and the NHS, with the information they need to make evidence-based decisions. They could consolidate prescribing data for specific medicines with data from clinical care and other databases and be further developed to capture more detailed and bespoke data on the cohorts of patients receiving these medicines.
Currently, the MHRA receives data from pharma companies when there is a knowledge gap, or when it is needed to make a decision on efficacy or safety, however, the new medicines registries would give a more joined-up view. the local communities these hospitals serve.

With the new registries, there would also be an element of patient reported outcome measures – i.e. feedback from patients about particular drugs and whether they are enhancing their quality of life, which is a very important part of the data picture that does not currently exist.world data around patient experience.

Access to all kinds of data around patient care and outcomes is, of course, essential for the NHS to capitalize on innovations and continue to drive improvements and it is a key area in which pharma could provide support. Hence, the establishment of medicines registries could provide an opportunity for pharma to be proactive in gathering real-world data around patient experience.

This could help back up clinical trial results and inform industry's value propositions, particularly around high cost drugs. 'handsof' approach.

Conclusion

While the prospect of more central government control places a question mark over the autonomy of decision-making at both local and NHSE levels, the white paper makes it clear that the government is committed to delivering integrated care.

Consequently, this year, we expect to see the move towards population-based healthcare, joint accountability for patients in systems and shared local budgeting, continue to gather pace, prior to ICSs being given statutory powers. This is going to bring major changes for pharma from the need to regularly review its key stakeholder maps to the ability to fully embrace the whole system approach and ensure that its value propositions help the NHS to improve patient outcomes and also deliver on wider priorities.

By thinking broadly and innovatively about how it can provide support and gathering and analyzing relevant data to back up its proposals, industry can seize opportunities to work in partnership with the NHS as the move towards integrated care looks set to continue to underpin major changes in the way services are designed and delivered.

Training the next generation of healthcare leaders

The global COVID pandemic has highlighted the need for expert leadership in global healthcare. Oxford University is rising to the challenge, pulling together specialists from business and medical departments to launch an MSc in Global Healthcare Leadership

"The COVID pandemic has taught us that you can't just sit on your hands when you've got no evidence. You still have to make decisions. You still have to act," says Professor John Powell, Professor of Digital Health Care, Nuffield Department of Primary Care Health Sciences. "There is this argument, do we save public health or do we save the economy, but actually it's a compromise between the two. If you get the public health right, you support the economy."

It all comes down to healthcare leadership. And in the current pandemic, the challenge for healthcare leaders has been huge. "What the virus has done is illustrate the very important interplay necessary for dealing with a pandemic between leaders in different organizational structures and it has illustrated some of the skill sets we naturally believe are essential for leading organizations but it also illustrates that the modern healthcare leader needs an advanced skill set in many areas that traditionally we wouldn't have thought were necessary," notes Professor Richard Hobbs, Head of the Nuffield Department of Primary Care Health Sciences.

It couldn't be better timing for the University to launch an MSc in Global Healthcare Leadership, which begins in October. While planning for the new Masters programme pre-dated COVID, the pandemic has highlighted the need for expert leadership in global

healthcare. The part-time programme – which will be directed by Professor Powell – covers policy, healthcare innovation and the challenges facing leaders in healthcare nationally and globally, as they confront change and uncertainty and respond by setting effective strategies. It also provides insight into some essential tools of the trade such as methods used in evidence-based medicine, fundamental in informing health care policies. The programme pulls together expertise from across Oxford University's Nuffield Department of Primary Care Health Services and the University's Said Business School to teach a skill set that is not routinely available in other leadership programmes.

The new programme comes at a time when the pandemic has shown a very public spotlight on the challenges facing healthcare leaders and the differences in approach across the globe. One area in particular has been whether or not healthcare leaders in different global organizations are enabled to influence healthcare policy. "In countries that have done well, there does seem to be a tendency that scientists or people with more understanding of science issues are in political roles and decision-making roles, and they have done better than those countries where those skills are lacking in the political leaders," says Powell. This highlights the need for more medical or health literacy among policy makers or, indeed, structural change at higher levels, he says.

However, Dr Eleanor Murray, Senior Fellow in Management Practice, Saïd Business School, points to a possible shortfall in healthcare leaders' skill sets. "We've seen the issues over the period of COVID of the challenges scientists have had in being able to convey the evidence to persuade politicians to take a different approach. Influencing is an important leadership skill and being able to communicate healthcare challenges to politicians."

Hobbs agrees but adds this also highlights another challenge. Politicians are more focused on short-term drivers while healthcare leaders are more focused on mid to long-term drivers. Bringing the two sides together to articulate messages is something all leaders need to consider, he says. Perhaps one of the biggest challenges facing healthcare leaders has been the response to the pandemic within their own organizations because their decisions may not only affect patients but their staff as well, says Hobbs. For instance, the sourcing of PPE, where to use it, to what grade and how frequently it needs to be changed, alongside staff working at pace for a year while continuing to provide high-quality service to patients, against a backdrop of increasing proportions of the workforce being sick or coming to the end of their battery life.

To this end, fostering resilience has been a big theme for healthcare leaders during the pandemic, says Murray. "Research shows you develop resilience as you encounter and overcome crises so just the fact that healthcare professionals will have had to work through and deal with the challenges of the pandemic will have helped develop their personal resilience, as well as developing strong support networks with family and friends and peer support networks in the workplace. The more people in organizations who have strong support networks and who can build on them with their colleagues are more likely to create strong resilience across the whole organization." From a leadership perspective, building these strong supportive cultures within an organization and encouraging a learning mindset are critical to help build organizational resilience, she says.

'Given that Oxford University has been central to research around COVID and vaccines, it makes sense it hosts a Masters in Global Healthcare Leadership"

Of course, COVID has also caused great change and disruption to healthcare systems, virtually overnight. According to Hobbs, prior to COVID just 3% of consultations with GPs were online. Within two to three weeks of the pandemic that had jumped to 60%. "That's an absolutely unbelievable penetration of something there would have been huge resistance to, but it had to happen and the impact of digital health is going to be transformative. We really need leaders thinking about how that sort of innovation can transform the way they run their organisations and design their clinical services.

Murray agrees, noting that the response to the pandemic has enabled the removal of structural barriers, which no longer appear to be the impediment they had previously seemed to be. The new challenge for healthcare leaders moving forward, she says, will be maintaining the removal of these barriers and not seeing that as a potential threat. Digital transformation is just one challenge alongside the pandemic facing healthcare leaders, but there are many others that are not pandemic related. Climate change, health system costs, engaging empowered patients, countering misinformation and health conspiracy theories, improving communication and infuence on policies, dealing with antimicrobial resistance, just to name a few. All of these require unique leadership skills to navigate the future healthcare space.

"Leadership in healthcare and policy making is going through such a tremendous series of changes," says Kathy Harvey, Associate Dean, MBA and Executive Degrees, Saïd Business School. "No one knows how our health systems or health leaders will emerge at the end of this pandemic." Given that Oxford University has been central to research around COVID and vaccines, it makes sense it hosts a Masters in Global Healthcare Leadership, she says. The programme is aiming for a broad international reach across commercial, research sectors, policy, healthcare providers and politics. "We want to create a community of healthcare leaders across the public and private sectors that will really make a difference," Harvey says. The pandemic has exposed the gaps in global healthcare leadership. Oxford University is drawing on its expertise to plug those gaps and prepare today's healthcare leaders for tomorrow's healthcare challenges.

The market access challenge

Digital health technologies are failing to reach their potential to boost the quality and effciency of healthcare systems, largely because of a lack of dedicated access pathways or value assessment processes

Digital health is an emerging and rapidly developing fled with the potential to increase the quality and efficiency of healthcare systems. The rise of digital health technologies (DHTs) has been driven by an increase in non-communicable diseases and a desire by patients to take a more active role in the management of their condition and is now being accelerated by the COVID-19 pandemic. DHTs have the potential to allow payers and manufacturers to track patient outcomes and adherence better, faster and more accurately and hence support wider adoption of value-based healthcare models.

While there are several barriers to the evolution of DHTs, one of the key issues is funding. This is challenging because there are no dedicated access pathways or value assessment processes, and funding flows are driven in silos. DHT suppliers must therefore often battle with a fragmented marketplace with no clear route to market.

However, recent examples show that more national and local reimbursement systems are starting to tackle this issue, and the COVID-19 crisis is likely to act as a catalyst. The potential of DHTs has been observed during the COVID-19 pandemic, where the integration of digital technology into pandemic policy and response could be one of several characteristic features of countries that have better managed to fatten their COVID-19 incidence waves and maintained low mortality rates.

Market access challenges for DHTs

1.Lack of standardized and dedicated value assessment

Emerging technologies such as DHTs will need new approaches to value assessment as currently there is little consensus on what defines value and a lack of clarity on evidence requirements. Manufacturers and payers should cooperate to develop a standardized, objective, rigorous and transparent process describing what evidence should be submitted and how it needs to be collected, depending on the indication and the device's target.

Several countries worldwide are developing more standardized value assessment frameworks for DHTs but their progress varies greatly. In the US, the FDA created a Digital Health Center of Excel

lence to provide technical advice and advance best practices. In Japan, government initiatives like the Healthcare Innovation Hub support companies developing innovative devices to address the issues of an ageing society.

The situation is more complex in Europe where, for example, there remains a great deal of uncertainty in Italy but where a new, advanced approach has been developed in Germany with the Digital Healthcare Act. In countries with a degree of regional autonomy and lack of overarching national approach, interim solutions can be seen such as regional assessment of apps or regional level approaches being adopted on a national level. In the UK, for example, the National Institute for Health and Care Excellence (NICE) Medtech Innovation briefings aim to ease local decision-making by providing a factual overview but do not ultimately make recommendations; in Andalucía, Spain, apps can be awarded a quality seal and subsequently included in a database of recommended apps.

'Value assessment methodologies have been designed to support the evaluation of pharmaceutical products, but these are not well-suited to DHTs'

As the value assessment of DHTs becomes more standardized and transparent, the process will become easier to navigate. Manufacturers should become more targeted in their development and testing of DHTs, keeping in mind payer value drivers to increase the likelihood of reimbursement/coverage and achievement of a value-based price.

2. Evidence of DHT value at launch will inevitably below

Reimbursement of DHTs is predicated on achieving quality outcomes against evidence-based standards, but health technology assessment (HTA) in this domain is embryonic and only now developing in line with the sector. HTA often adopts a strict adherence to the hierarchy of evidence, demanding that technologies be supported by evidence from robust, randomized controlled trials (RCTs). However, for many DHTs, there is uncertainty about their clinical and economic outcomes. Evidence from robust RCTs is often limited or unavailable at the time of launch as data covering medical device experience is routinely collected in the course of treatment through real-world evidence. Adopting anything like a pharmaceutical paradigm, based on an expectation of multiple RCTs being available at the time of launch, creates hurdles to access for many DHTs. Lack of confidence in clinical evidence at launch reduces the likelihood of reimbursement or coverage by public or private insurance and leads to payer reluctance to provide additional budget and higher price points.

Consequently, providers of DHTs should work with payers and clinical stakeholders to understand the best indication-specific approach to generate value evidence at launch, or in the real-world setting.

3. No dedicated reimbursement and funding pathways

Efforts to integrate DHTs have resulted in a mix of nationally run access schemes and regionally funded programmes. Access and coverage often vary by private and government payers within each country, depending on the healthcare landscape. Each payer is likely to have its own guidelines for DHT adoption. Even in the absence of a definitive policy, public as well as private insurers reimburse for DHTs only when there is a strong rationale for their use.

In the US, the Prescription Digital Therapeutics to Support Recovery Act aims to change Social Security to support the use of DHTs, and individual insurance plans roll out specific programmes like the digital health programme 'Level2' by UnitedHealth for type 2 diabetes patients. In Latin America, the situation is more complex due to the mix of private insurers and high share of patients paying out of pocket, but there are examples of public/private digital health partnerships aimed at supporting access to medical services in rural areas using DHTs. In Europe, funding sources for DHTs are country dependent: in the UK, the NHS England's Innovation and Technology Tarif (ITT) and the Innovation and Technology Payment (ITP) are available at the national level and clinical commissioning funding at the regional level, whereas, in Germany, the Digital Healthcare Act allows doctors to prescribe health apps to patients which are reimbursed by the statutory health insurance.

Approved and reimbursed DHTs show that private insurers and hospitals are willing to reimburse apps when they provide value. DIGITAL HEALTH TECH From a public health perspective, a standardized reimbursement and funding pathway for DHTs needs to be created to encourage their development and appropriate utilization; this need offers an opportunity for leadership from the industry.

Conclusion :

Value assessment methodologies have been designed to support the evaluation of pharmaceutical products, but these are not well-suited to DHTs. Although progress is being made in some markets, there is a long way to go for market access pathways to become easier to navigate for DHT manufacturers.

It will take time to address these challenges but until these are resolved, financial constraints will continue to limit DHT-supported care for patients. In the meantime, we suggest leveraging the strategies below to boost the value perception of DHTs and mitigate possible objections:

Identify influential stakeholders and develop stakeholder engagement strategies; develop a robust evidence programme informed by up-to-date indication-specific payer evidence guidance; and explore and priorities reimbursement pathways and opportunities

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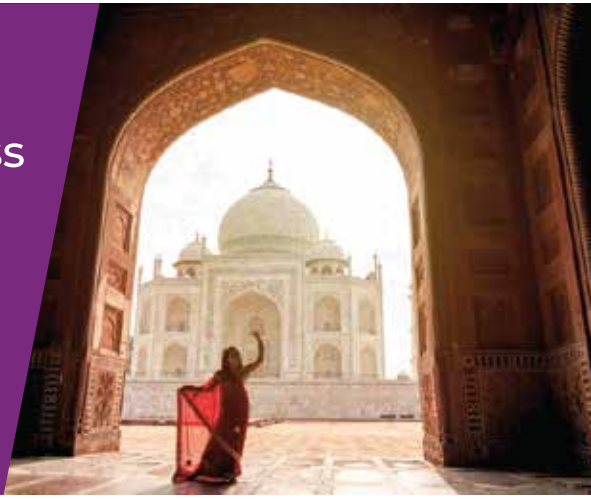

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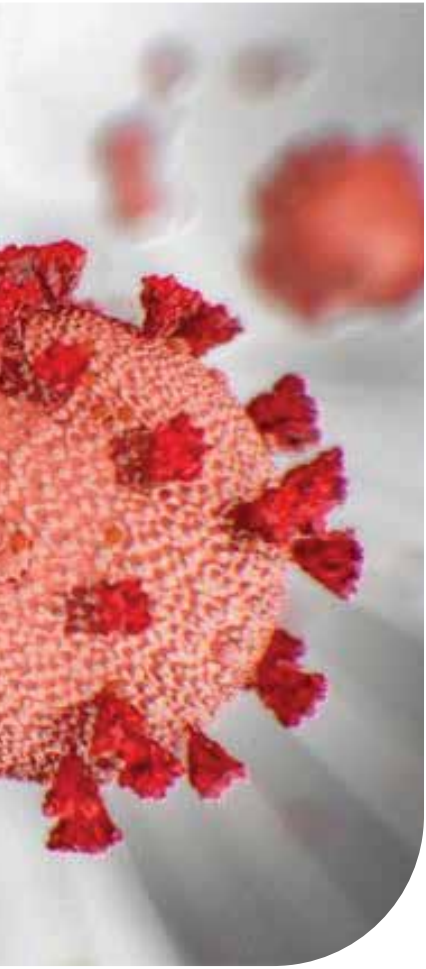
Antiviral drug Molnupiravir showing promise in trials against coronavirus

Molnupiravir is currently in clinical trials and could be a promising tool against coronavirus.



Over the last year, several drugs have either been developed or tested to treat coronavirus. Now there's another that's showing some promise.

Molnupiravir is an antiviral drug in clinical trials.

We talked with molecular epidemiologist Dr. Jill Roberts about it being a treatment for COVID-19.

She says the way that it works is it messes up viral replication. It's shown some use against other viruses such as SARS and MERS.

Dr. Roberts says during an animal study on ferrets, they tried to get coronavirus to spread, and it wouldn't. So while it's a treatment designed to prevent hospitalizations and deaths, it also seems to prevent transmission.

While there is no timetable about when this would be available, it could be promising for future viruses or pandemics.

"This is a great tool to have to be able to know for future viruses maybe if we get a mutant that actually circumvents the vaccines, this drug will still work."

Dr. Roberts says now that Merck is behind it, it has the resources to do a big enough trial to send to the FDA to get Emergency Use Authorization or even full authorization.

A couple of other positives she pointed out with this drug: it can also be used for people who do not want to get a vaccine or don't have the resources to get shots. And, this is a pill, unlike other treatments right now that are IVs and have to be given at a treatment center.

Bharat Biotech, ICMR announce interim results from Phase 3 trials of COVAXIN

It demonstrates overall interim clinical efficacy of 78 per cent and 100 per cent efficacy against severe COVID-19 disease

Bharat Biotech announced phase 3 interim analysis results of COVAXIN. The second interim analysis is based on accruing more than 87 symptomatic cases of COVID-19. Due to the recent surge in cases, 127 symptomatic cases were recorded, resulting in a point estimate of vaccine efficacy of 78 per cent (95%CI: 61-88) against mild, moderate, and severe COVID-19 disease.

The efficacy against severe COVID-19 disease was 100 per cent (95%CI: 60-100), with an impact on reduction in hospitalisations. The efficacy against asymptomatic COVID-19 infection was 70 per cent, suggesting decreased transmission in COVAXIN recipients.Safety and efficacy results from the final analysis will be available in June, and the final report will be submitted to a peer-reviewed publication. Based on the achievement of the success criteria, placebo recipients have now become eligible to receive two doses of COVAXIN.

The Phase 3 study enrolled 25,800 participants between 18-98 years of age, including 10 per cent over the age of 60, with analysis conducted 14 days post-second dose. COVAXIN was developed with seed strains received from the National Institute of Virology, and the phase 3 clinical trial was co-funded by the Indian Council of Medical Research.

Prof Balram Bhargava, Secretary Dept. of Health Research & Director General, Indian Council of Medical Research, said, "I am very pleased to state that COVAXIN, the first indigenous COVID-19 vaccine developed by ICMR and BBIL, has shown the efficacy of 78 per cent in the second interim analysis. The tireless efforts of our scientists at ICMR and BBIL have resulted in a truly effective international vaccine of the highest standards and efficacy. I am also happy to note that COVAXIN works well against most variants of SARS-CoV-2. These findings together consolidate the position of our indigenous vaccine in the global vaccine landscape."

Suchitra Ella, Joint Managing Director, Bharat Biotech, said, "COVAXIN's evidence-based development has proved its suitability for global access, with excellent efficacy results against symptomatic, asymptomatic, and severe disease. The interest from countries worldwide has quietly validated our efforts. We thank our Volunteers, Principal Investigators, Partners and team Bharat Biotech for their contribution to this project towards improving Global Public Health."

The company's development efforts have been published in six peer-reviewed journals, with additional publications in process.

SEC of CDSCO recommends approval to Sputnik V for EUA in India

The DCGI will take a final call on the recommendation. If approved, it will be the third COVID-19 vaccine to be available in India

An expert panel of India's central drug authority has recommended granting approval to Russian COVID-19 vaccine Sputnik V for emergency use in the country with certain conditions, sources said.

The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO) took up the application of Dr Reddy's Laboratories seeking emergency use authorisation for Sputnik V.

The Drugs Controller General of India (DCGI) will take a final call on the recommendation. If approved, it will be the third COVID-19 vaccine to be available in India.

The vaccine would be imported from Russia for emergency use in the country, they said.

In September last year, Dr Reddy's partnered with the Russian Direct Investment Fund (RDIF) to conduct clinical trials of Sputnik V and for its distribution rights in India.

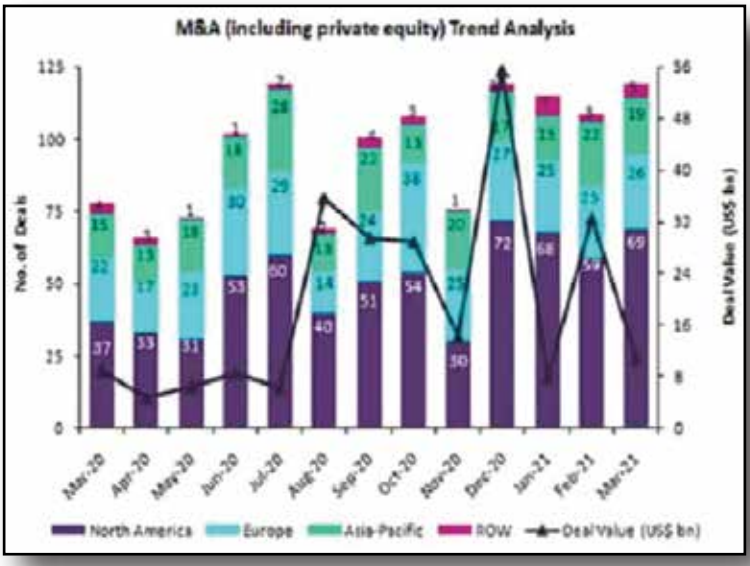
Sputnik V has demonstrated an efficacy rate of 91.6 per cent in the interim analysis of phase 3 clinical trial, which included data on 19,866 volunteers in Russia.

Healthcare industry reported 119 deals worth $10.8 billion in March 2021

Deal value decreased by 66.7 per cent in March 2021, compared to February 2021

In March 2021, the healthcare industry reported 119 deals worth $10.8 billion as compared to the last 12-month average (March 2020 to February 2021) of 94 deals worth $20 billion.

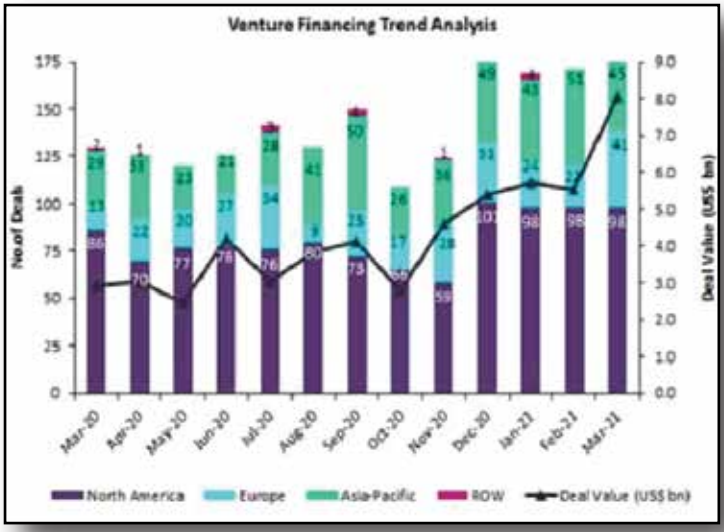
Amgen Inc, a biopharmaceutical company, to acquire Five Prime Therapeutics Inc, a clinical-stage biotechnology company for $38 per share in cash, representing an equity value of approximately $1,900 million; Altaris Capital Partners, LLC, a private equity firm, to acquire Generic Rx Pharmaceuticals business of Perrigo Company plc for $1,550 million in cash; and Abu Dhabi Developmental Holding Company PJSC to acquire Amoun Pharmaceutical Company S.A.E., a company engaged in the development, manufacturing, marketing, distribution, and export of human pharmaceutical and animal health products for $740 million are the three major deals reported in March 2021.



Deal Date	Acquirer (s)	Target	Deal Value ($ m)
4-Mar-21	Amgen Inc (US)	Five Prime Therapeutics Inc (US)	1,900.0
1-Mar-21	Altaris Capital Partners LLC (US)	Generic Rx Pharma Business (Ireland)	1,550.0
24-Mar-21	Abu Dhabi Developmental Holding Company PJSC (United Arab Emirates)	Amoun Pharmaceutical Company SAE (Egypt)	740.0
31-Mar-21	Amgen Inc (US)	Rodeo Therapeutics Corp (US)	721.0
30-Mar-21	Nordic Capital Ltd (United Kingdom)	Leo Pharma AS (Denmark)	536.0

Venture Capital Investments Increased by 45.9 per cent in March 2021, compared to February 2021

The healthcare industry reported 187 venture capital (VC) deals worth $8.1billion in March 2021, compared to the last 12-month average (March 2020 to February 2021) of 140 deals worth $4 billion. ElevateBio LLC, raising $525 million in series C round of financing to expand and advance its technology to accelerate the production and development of life-saving cell and gene therapies; Insitro Inc, raising $400 million in series C round of financing to reshape drug discovery and development of transformative medicine; and AffaMed Therapeutics Shanghai Ltd, raising $170 million in series B round of financing to further develop its Ophthalmic and Neuroscience pipeline are the major VC deals reported in March 2021.



Deal Date	Acquirer (s)	Target	Deal Value ($ m)
15-Mar-21	F2 Ventures Limited; Itochu Technology Ventures, Inc.; Invus Group LLC; EcoR1 Capital LLC; Redmile Group LLC; Fidelity Management & Research Company; EDBI Pte Ltd; Emerson Collective LLC; Vertex Ventures HC; MPM Capital Inc; Matrix Capital Management Fund LP; SoftBank Vision Fund LP; Samsara BioCapital LLC; Surveyor Capital Ltd; Undisclosed	ElevateBio LLC (US)	525.0
15-Mar-21	BlackRock Inc; Canada Pension Plan Investment Board; Undisclosed; Third Rock Ventures LLC; Alexandria Venture Investments; Temasek Holdings (HK) Limited; ARCH Venture Partners LP; Andreessen Horowitz LLC; Foresite Capital Management LLC; Two Sigma Ventures LP; Casdin Capital LLC; HOF Capital; GV Management Co LLC; T Rowe Price Associates Inc; SoftBank Investment Advisors	Insitro Inc (US)	400.0
30-Mar-21	Central Bottling Company, Ltd.; Partners Investment; Fountainhead Investment Partners, LLC; Lake Bleu Capital; Superstring Capital Management LP; Orion Science Capital	AffaMed Therapeutics Shanghai Ltd (China)	170.0
17-Mar-21	M&G Investment Management Ltd; Tencent Holdings Ltd; Gilead Sciences Inc; Oxford Sciences Innovation Plc; Future Planet Capital; Fonds de Reserve Constitutionnel	Vaccitech Ltd (United Kingdom)	168.0
3-Mar-21	Orbimed Advisors LLC; RA Capital Management LP; Marshall Wace LLP; Fidelity Management & Research Company; Versant Venture Management LLC; Qatar Investment Authority; Federated Kaufmann Fund; Octagon Capital Group LLC; Casdin Capital LLC; Leaps by Bayer; Logos Global Management LLC; Avidity Partners LLC	Century Therapeutics Inc (US)	160.0

Source: GlobalData

OTC Drugs and E-Pharmacies: High time for regulation?

Renuka Abraham, Senior Associate and Priya Venkatesan, Associate with Spice Route Legal's corporate practice group explain that there is a necessity to regulate the sale of OTC drugs and e-pharmacies, but also caution that lawmakers need to tread carefully to avoid excessive regulation in these areas which are poised for innovation and change

It is not an uncommon trend in India to self-medicate for minor bodily discomforts. The COVID-19 pandemic has in all probability only served to exacerbate this trend. Online sales of medicinal drugs have also seen a major uptick in the past year. Self-medicating with half-baked knowledge, or consuming a drug at higher dosages for recreational purposes, can have extremely serious consequences. How do current Indian regulations keep a check on such activities, especially insofar as they apply to OTC drugs and the online sale of drugs, through e-pharmacies?

Manufacturing and sale of drugs fall under the Concurrent List of the Indian Constitution, and hence, is regulated by both central and state governments. As a result, both the central licensing authority (Central Drugs Standard Control Organisation) and the relevant state licensing authority (Food and Drug Administrations of various states) are responsible for testing and licensing drugs in India. The primary central legislation governing drugs in India is the Drugs and Cosmetics Act, 1940 (Act) and the corresponding rules – Drugs and Cosmetic Rules, 1945 (Rules).

Medicinal drugs can be categorised into two types – prescription drugs (for example, Hepatitis B. Vaccine, Insulin Human), and over-the-counter (OTC)drugs (such as Paracetamol). The purchase of a prescription drug is only allowed with a valid prescription from a registered medical practitioner; this requirement is however waived for the purchase of OTC drugs. The drugs consultative committee (formed under the Act to advise the central and state governments and drugs technical advisory board), has acknowledged this lacuna in the regulations and has contemplated bringing laws to govern OTC drugs.

In 2019, the drugs consultative committee was appraised of the recommendations made by a sub-committee led by Ravi Shankar (Shankar Committee). The drugs consultative committee formed another sub-committee under the chairmanship of NK Ahooja to review the recommendations of the Shankar Committee (Ahooja Committee). The Ahooja Committee proposed that OTC drugs should be categorised into OTC-1 and OTC-2 based on multiple factors including the drug's therapeutic index, need for accessibility to patients, the extent of safety, availability, non-habit-forming nature, its present supply-chain mechanism, and even socio-economic conditions of the country. The Ahooja Committee also recommended regulating the sale and advertisement of OTC drugs in India. However, two years on, these recommendations are yet to be adopted.

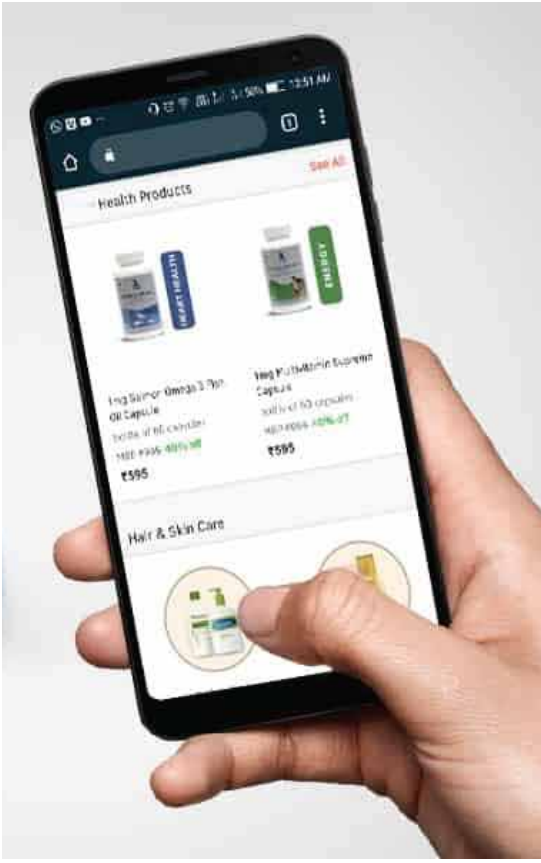
India does not currently have any specific regulations governing e-pharmacies. Online sale of medicines is not covered under any specific law and is instead governed by the Act, the Rules, and the Information Technology Act, 2000, among various other laws. Coupled with the lack of strict laws governing OTC drugs, we believe concerns around the misuse of e-pharmacies for online purchases for prescriptive drugs are well-founded.

With the rise in online demand for the purchase of medicinal drugs, the Ministry of Health and Family Welfare had published a draft regulation in 2018 to amend the Rules. The proposed draft amendment would add 'Part VIB'to the Rules, explicitly governing the sale of drugs by e-pharmacies. It defines the term "e-pharmacy" as "the business of distribution or sale, stock, exhibit or offer for sale of drugs through a web portal or any other electronic

mode." The draft amendment proposes that e-pharmacies must be registered with the central licensing authority and also lays down the procedure to sell medicines online, including that all e-pharmacy business activities must be conducted through an "e-pharmacy portal". Under the application for registration, as per this proposed amendment, e-pharmacies would also be restricted from selling narcotic and psychotropic substances as defined under the Narcotic Drugs and Psychotropic Substances Act, 1985, as well as tranquilisers and those drugs specified in Schedule X of the Rules.

In the meanwhile, the Delhi High Court passed an order in Zaheer Ahmed v. Union of India, prohibiting the online sale of drugs pending the enactment of proper rules to govern e-pharmacies and their business activities. Complying with this order, on 4 December 2019, the drugs control department of the Government of NCT, Delhi released an advisory addressing the All Chemists Association of Delhi, directing that 'no person shall engage in an activity associated with online sales of drugs without a licence'. Given that the legislature is yet to pass any amendment to the Rules, including those discussed above, it is not clear whether this direction would in any manner restrict the online sale of drugs, in other states.

The lack of adequate regulations governing the sale of OTC drugs is a significant concern that needs the urgent attention of the Indian regulators. Additionally, given the general shift of the urban Indian population towards purchasing drugs from e-pharmacies over traditional 'Kirana shop' chemists, Indian lawmakers should also separately legislate on the regulation of e-pharmacies and the online sale of drugs. While there is a necessity to regulate the sale of drugs and e-pharmacies, our lawmakers must tread carefully to avoid excessive regulation in an industry which is poised for innovation and change.



Mankind Pharma seeks CDSCO approval for Phase 1 Clinical Trials of patented anti-diabetic molecule

MKP10241 is a potent and orally administered small molecule, GPR119 agonist

Mankind Pharma has submitted its first Investigational New Drug (IND) application for approval to Central Drugs Standard Control Organisation (CDSCO) for MKP10241, a patented novel anti-diabetic molecule.

"MKP10241 is a potent and orally administered small molecule, GPR119 agonist," informed the company through a statement. GPR 119 is highly expressed in pancreatic beta cells and intestinal enter endocrine cells.

"What makes MKP10241unique is its mechanism of action. GPR119 elevates intracellular secondary messengers such as cAMP inside the cells and promotes postprandial insulin and incretin secretion (GLP-1) in a glucose-dependent manner. This dual mechanism by GPR119 in mediating glucose-dependent insulin secretion is distinct from the currently available therapeutic options for Type 2 diabetes and thus becomes a promising new approach for the treatment of type 2 diabetes and related metabolic disorders," informed the company statement.

It added, "The small molecules with GPR119 agonist property would help the Indian pharma industry to provide a new therapeutic option in the anti-diabetic armamentarium for the clinicians in the management of type 2 diabetes."

The new drug was tested in multiple preclinical models of Type 2 diabetes to understand the mechanism of action and efficacy, and has shown effective results in reducing blood sugar levels and glycated haemoglobin. MKP10241 elevates plasma insulin as well as plasma GLP-1 levels ultimately leading to reduced plasma glucose in preclinical models validating the dual mechanism of action associated with GPR119.

MKP10241 has been granted patents worldwide till 2037.

RC Juneja, Executive Chairman, Mankind Pharma said, "Our team of scientists have worked tirelessly and with immense passion to develop this novel drug to benefit the people, and it will be affordable for patients. Mankind Pharma is committed to expanding its portfolio of products in the Indian market in all major therapeutic areas for the benefit of patients, prescribers and the healthcare system."

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Industry forecast

for the Indian pharmaceutical market

Expanding Medicine Manufacturing

Indian medicine manufacturing will continue to expand. The country's changing epidemiological profile will continue to drive investment within the pharmaceutical sector.

Key destination for investment

India will continue to attract multinational drugmaker investment, underpinning its long-term growth potential with a large and fast-growing population.

8%

3-year compound annual growth rate (CAGR).

Developing a research-based pharma industry

India is a global leader in the production of quality generic medicines and is gradually realising its potential to develop a strong, research-based pharmaceutical industry.

Economic

India's pharmaceutical sector will remain a key destination for foreign direct investment (FDI). Domestic pharmaceutical manufacturers, occupying 77% market share in India, continue to enter into international alliances with multinational companies in order to import skills, finance and knowledge, which are not always locally available, giving Indian companies a route to upgrading their ability to conduct R&D.

Political

The Indian government has been very active in boosting growth and investment in the Indian pharma industry. It allows 100% FDI under automatic route (without prior permission) in the pharmaceuticals sector and also a weighted tax deduction at a rate of 150% for the R&D expenditure incurred.

Social

Rising incomes, better health infrastructure and an ageing population are contributing to a greater demand for pharmaceuticals

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India Expo Center, Greater Noida, Delhi NCR, India

Source: Fitch Solutions - India Pharmaceuticals & Healthcare Report - Q1 2021

Key Stats - India's Pharmaceutical Market

A future powerhouse for R&D and manufacturers of pharmaceuticals

World's largest
provider of generic medicines

200+
Largest number
of US FDA-approved pharmaceutical units outside US

Imports growth
USD2.9bn by 2024

70-80%
of branded generics in the retail market

250m Indians – Phase 1
Mass Covid-19 vaccination programme in 2021

Key foreign players:
Pfizer, GlaxoSmithKline, Novartis, Sanofi, Abbott Laboratories, MSD and Roche.

Exports to more than 200 countries. *Top destinations:*

1. *USA*
2. *UK*
3. *Australia*
4. *Germany*
5. *France*
6. *The Netherlands*
7. *Canada*
8. *Belgium*

Indian Pharma Market *value*

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Sources:
India Pharma 2020, Propelling access and acceptance, realising true potential, McKinsey & Company
Fitch Solutions - India Pharmaceuticals & Healthcare Report - Q1 2021

The five biggest data challenges for life sciences

Vimal Venkatram, Country Manager, Snowflake India explains that to be prepared for the future, all types of life sciences organisations from biopharma to medtech companies will need to find new ways to create value along with new metrics that will help them make sense of today's wealth of data

The life sciences industry is at a turning point. To prepare for the future and remain relevant in the ever-evolving business landscape, biopharma companies and medical technology businesses are looking for new ways to create value and make sense of today's wealth of data. Many companies are looking to leverage new-age technologies such as Artificial Intelligence (AI), Machine Learning (ML), and automation to accelerate the discovery and development of treatments. In the wake of the COVID-19 pandemic, organisations rushed to analyse unprecedented volumes of data in the race to develop the COVID-19 vaccine. As per Precedence Research, the Life Science Analytics market had a global value of $7.57 billion in 2019 and is projected to reach an estimated value of $18.12 Billion by 2030, expanding at a CAGR of 8.25 per cent.

Precedence Research also states that the rising penetration of big data usage in healthcare has boosted the life science care analytics segment. Data standardisation has become key in life science analytics.

To be prepared for the future, all types of life sciences organisations from biopharma to medtech companies will need to find new ways to create value along with new metrics that will help them make sense of today's wealth of data. The exploding volume and variety of data pose significant management and security challenges for life sciences companies using outdated legacy on-premises and cloud database systems. Additionally, these legacy systems hinder life sciences organisations from attaining the level of data diversity they need to improve business processes and make critical decisions.

Here are five common challenges life sciences companies face in leveraging data for better therapeutic and business outcomes:

Data quality

To conduct R&D and clinical trials and manage day-to-day business, life sciences companies need to process a vast amount of real-world data that comes in a wide variety of formats. Life sciences companies futilely spend precious time ingesting, cleaning, and organising the data, but legacy data warehouses cannot deliver data in a way that enables fast accurate analysis and insights. In addition, the data often sits in two silos: commercial, for data such as sales and marketing records, and regulated, for data such as clinical trial and laboratory reports.

Data performance

To reach actionable insights quickly, life sciences companies must be able to process massive amounts of data quickly and easily. For example, efficient integration, validation, and mining of clinical trial data is crucial for drug development. Time-to-insight is also critical in conducting successful sales and marketing campaigns as well as optimizing inventory management and supply chain logistics. However, many companies still rely on slow legacy systems that exacerbate the issues created by data silos, deliver poor and inconsistent user experiences, and produce fragmented insights generated by much manual effort. Such systems do not easily scale to accommodate a larger volume of data or number of users, which could be critical when a pharmaceutical company needs to act quickly during a public health crisis, as just one example.

Data exchange and collaboration

Access to a diverse and varied source of data enhances informed decision-making. To achieve data diversity, life sciences companies must exchange vast volumes of sensitive data with other entities, often requiring back-and-forth collaboration. During a clinical trial, for example, data about the therapies, patients, and lab results must be exchanged between a pharmaceutical company and a variety of partners throughout the process. But disparate, legacy systems hinder the fast, easy, and secure transfer of data, causing companies to rely on manual, insecure processes such as FTP.

Data management and scaling

A data platform that is easy and cost-effective to manage and scale is a key part of that success. Legacy platforms, whether on-premises or in the cloud, can be complex and costly to maintain and grow. Instead of making data-driven decisions, data scientists and analysts waste time managing the platform and worrying about its cost.

Regulatory compliance

In the life sciences industry, companies must comply with stringent regulations and quality guidelines, including GxP requirements, which regulate practices in manufacturing, laboratories, and clinical settings to ensure medical products are safe for consumers. In addition, life sciences companies must comply

with strict regulations on the use, storage, and disposal of sensitive data.

To stay ahead of the seismic shifts in the industry, today's life sciences organizations need to harness the power of the cloud and its ability to deliver performance, speed, and flexibility. Companies can leverage data from any source to deliver better therapeutic and business outcomes for patients, customers, partners, and care providers. They can manage, scale, share, and exchange data in a secure and governed manner leading to faster actionable insights in clinical trials and reducing time to market.

In addition, they can work with a technology platform that ensures GxP compatibility, security, and data privacy requirements.

In conclusion, to discover, collaborate, and generate value from data regardless of where it resides and turn data into mission-critical insights, life science companies need to leverage the compute power and flexibility offered by the Data Cloud. Moreover, with accessibility and ease of data integration, life science companies can forge new partnerships and tighter data connections across business ecosystems. With the help of technology and through a truly data-driven approach, life science organisations can focus on developing and delivering life-saving treatments and devices, which could help address the ever-increasing medical and pharmaceutical costs and improve the quality of care.

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Research identifies nine potential new COVID-19 treatments

Three already have FDA approval — the transplant-rejection drug cyclosporine, the cancer drug dacomitinib, and the antibiotic salinomycin

A team of researchers has identified nine potential new COVID-19 treatments, including three, that were already approved by the US Food and Drug Administration (FDA) for treating other diseases.

The study, published in the journal Cell Reports, screened thousands of existing drugs and drug-like molecules for their ability to inhibit the replication of the Covid-19-causing coronavirus, SARS-CoV-2.

Of the nine drugs found to reduce SARS-CoV-2 replication in respiratory cells, three already have FDA approval — the transplant-rejection drug cyclosporine, the cancer drug dacomitinib, and the antibiotic salinomycin.

"Our discoveries here suggest new avenues for therapeutic interventions against Covid-19, and also underscore the importance of testing candidate drugs in respiratory cells," said researcher Sara Cherry from the University of Pennsylvania.

For the study, the researchers assembled a library of 3,059 compounds, including about 1,000 FDA-approved drugs and more than 2,000 drug-like molecules that have shown activity against defined biological targets.

They then tested all of these for their ability to significantly inhibit SARS-CoV-2 replication in infected cells, without causing much toxicity.

Initially, they performed antiviral screens using cell types that could grow easily in the lab and infect with SARS-CoV-2, namely African Green Monkey kidney cells, and a cell line derived from human liver cells.

With these screens, they identified and validated several compounds that worked in the monkey kidney cells, and 23 that worked in the human liver cells. Hydroxychloroquine, which is used as a malaria drug, and remdesivir, were effective in both cell types.

Since SARS-CoV-2 is mainly a respiratory virus and is thought to initiate infections via airway-lining cells, the researchers sought a respiratory cell type that they could infect experimentally with the virus.

They eventually identified a suitable cell line, Calu-3, that is derived from human airway-lining cells.

They used these respiratory-derived cells to test the antiviral compounds identified through the human liver cell screen, and found that only nine had activity in the new cells. The nine did not include hydroxychloroquine.

The nine antivirals active in respiratory cells did include salinomycin, a veterinary antibiotic that is also being investigated as an anticancer drug; the kinase enzyme inhibitor dacomitinib, an anticancer drug; bemcentinib, another kinase inhibitor now being tested against cancers; the antihistamine drug ebastine; and cyclosporine, an immune-suppressing drug commonly used to prevent the immune rejection of transplanted organs.

Research identifies novel peptoids with potent antiviral activity against HSV-1 and SARS-CoV-2

Antiviral peptoids are being developed by Maxwell Biosciences to treat recurrent herpes labialis

Maxwell Biosciences, a preclinical stage biotechnology company developing CLAROMER brand anti-infectives, announced that the peer-reviewed, open-access journal Pharmaceuticals (MDPI) has published new scientific research findings co-authored by Scientific Advisory Board Member Gill Diamond, University of Louisville, Department of Oral Microbiology and Infectious Diseases and eleven other collaborating academic researchers. Titled Potent Antiviral Activity against HSV-1 and SARS-CoV-2 by Antimicrobial Peptoids, the research findings demonstrate that several peptoids exhibit potent in vitro antiviral activity against both HSV-1 and SARS-CoV-2.

As outlined in the paper's abstract, viral infections, such as those caused by Herpes Simplex Virus-1 (HSV-1) and SARS-CoV-2, affect millions of people each year. However, there are few drugs that treat viral infections effectively, and no vaccine to prevent HSV-1 infections exists.

"There's a huge need for new antiviral agents and whereas new vaccines are now available for SARS-CoV-2, treatments can help those who become infected and develop Covid-19 illness. This paper constitutes the first report of biomimetic antiviral peptoids—stable mimics of natural antiviral peptides—that effectively inactivate two different enveloped viruses, utilizing a mechanism of action similar to that of natural innate immunity. Recurrent HSV-1 infections affect around 177M adult Americans; and of course, SARS-CoV-2 affects us all," said Dr Diamond.

As detailed in the body of the paper and visualised by cryo-EM images the researchers showed experimentally that antiviral peptoids disrupt the phospholipid envelopes of the viruses by a mechanism similar to that observed for natural human antiviral peptides.

Dr Diamond stated, "The entire research team involved in this study deserves tremendous praise, as interdisciplinary research of this nature is critical to the development of new therapies that are effective against viral infections, while also being safe for human use." Dr Diamond is continuing to study these promising peptoids now as topical treatments in a rodent model of Herpes Labialis.

Key observations and findings

• The antiviral peptoids were synthesised at the DOE-sponsored Molecular Foundry. Their antiviral activity was studied and tested at the University of Louisville with financial support from Maxwell Biosciences. They were designed to function as mimics of natural biological antiviral peptides. Antiviral peptoids have the distinct advantage of being insensitive to the proteases that quickly degrade biological peptides, and thus offer increased bioavailability and stability in the body.

• Herpes simplex virus type-1 (HSV-1) infections cause recurrent oral lesions and affect millions in the developed world. HSV-1 is also a major cause of infectious blindness and genital infections worldwide. HSV-1 infections are life-threatening in immunocompromised individuals. Furthermore, there is recent evidence that HSV-1 infections are associated with the pathogenesis of Alzheimer's disease, magnifying the importance of treating these infections early. HSV-1 virus is transmitted readily through oral secretions. It is estimated that up to 80 per cent of the population is infected with this virus, depending on age and socioeconomic status.

• The innate immune system is one of the primary mechanisms for recognising and eliminating viruses and other pathogens from mucosal surfaces.

• Challenges of using natural antimicrobial peptides as therapeutics spurred the development of non-natural peptidomimetics such as 'peptoids', which are a class of biostable, sequence-specific N-substituted glycine oligomers.

• Based on the prior results demonstrating the inactivation of enveloped viruses by antiviral peptides via membrane-disruption mechanisms, Drs Diamond and Barron hypothesised that antimicrobial peptoids designed to mimic natural antiviral peptides could inactivate an enveloped virus such as HSV-1. And since the recently emerged virus SARS-CoV-2 (the etiological agent of COVID-19) is similarly enveloped, they further believed that these peptoids might exhibit activity against this devastating virus.

• A library of ten different biomimetic peptoids was tested, by comparison to the natural human host defense peptide LL-37 (the only human form of cathelicidin antimicrobial peptides) for activity against HSV-1. LL-37 is a broad-spectrum antiviral peptide.

• The researchers' previous results demonstrated that the natural human antimicrobial peptide LL-37 disrupts the membrane of Kaposi's Sarcoma Herpes Virus (KSHV). Thus, they hypothesized that these peptoids, which are simplified structural mimics of natural antimicrobial peptides, could act through a similar biophysical mechanism.

• To determine whether the peptoids exhibited activity against enveloped viruses, the researchers tested the in vitro inhibitory activity of peptoids MXB-4 and MXB-9 against SARS-CoV-2. When incubated with virus for 1 h

at 37 °C at increasing concentrations, they observed virus inactivation with IC50 values of 20 µg/mL and 7 µg/mL, respectively. These two different peptoids were also well tolerated by human cells.

• To determine whether the peptoids acted against SARS-CoV-2 by a membrane-dependent mechanism as with HSV-1, the researchers treated SARS-CoV-2 with the active antiviral peptoids (MXB-4 and MXB-9), followed by visualisation by Cryo-EM, and confirmed that this was the case; direct disruption of the viral membrane was observed.

• To provide further evidence to support the development of antiviral peptoids as potential therapeutics, Dr Diamond et al. assayed peptoid cytotoxicity against cultured human cells, and observed excellent tolerability up to 500 µg/mL. Thus, these antiviral peptoids offer an apparently excellent therapeutic window.

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Indigital Technologies launches Indigital Mentor League, an initiative for pharma marketers

Three already have FDA approval — the transplant-rejection drug cyclosporine, the cancer drug dacomitinib, and the antibiotic salinomycin

Indigital Technologies announced the launch of Indigital Mentor League (IML), a Social Media Outreach program starting from April 19, 2021, for pharma marketers with the help of mentors having industry experience of more than 30 years, through this campaign.

Indigital Mentor League is a continuous program where subject matter experts Dr Ulhas Ganu-CEO, Advisors in Medico-marketing and Management; Rajendra Dhandhukia- Strategy and Leadership Coach; Dr VK Sharma-CEO, Dezin Consulting & Visiting Professor, NMIMS; Prabhakar Bethi- CEO, Zesla Solutions; Deepak Verma, General Manager – Zuventus Healthcare and National VP – Society of Pharmaceutical Education & Research (SPER) would be selecting trending topics like New Product Launch, New Trends in Patient Education, Digital Transformation for Pharma companies, Importance of CPD – Continuous Professional Development, Telehealth & Telemedicine etc. and sharing their knowledge with the pharma product managers.

Speaking about the launch of the IML, Hiren Dhuvad, CEO, Indigital Technologies, said, "Indigital Mentor League is a path-breaking initiative from Indigital Technologies, we are sure this continuous professional development program by the pharma experts will empower the pharma product managers further."

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