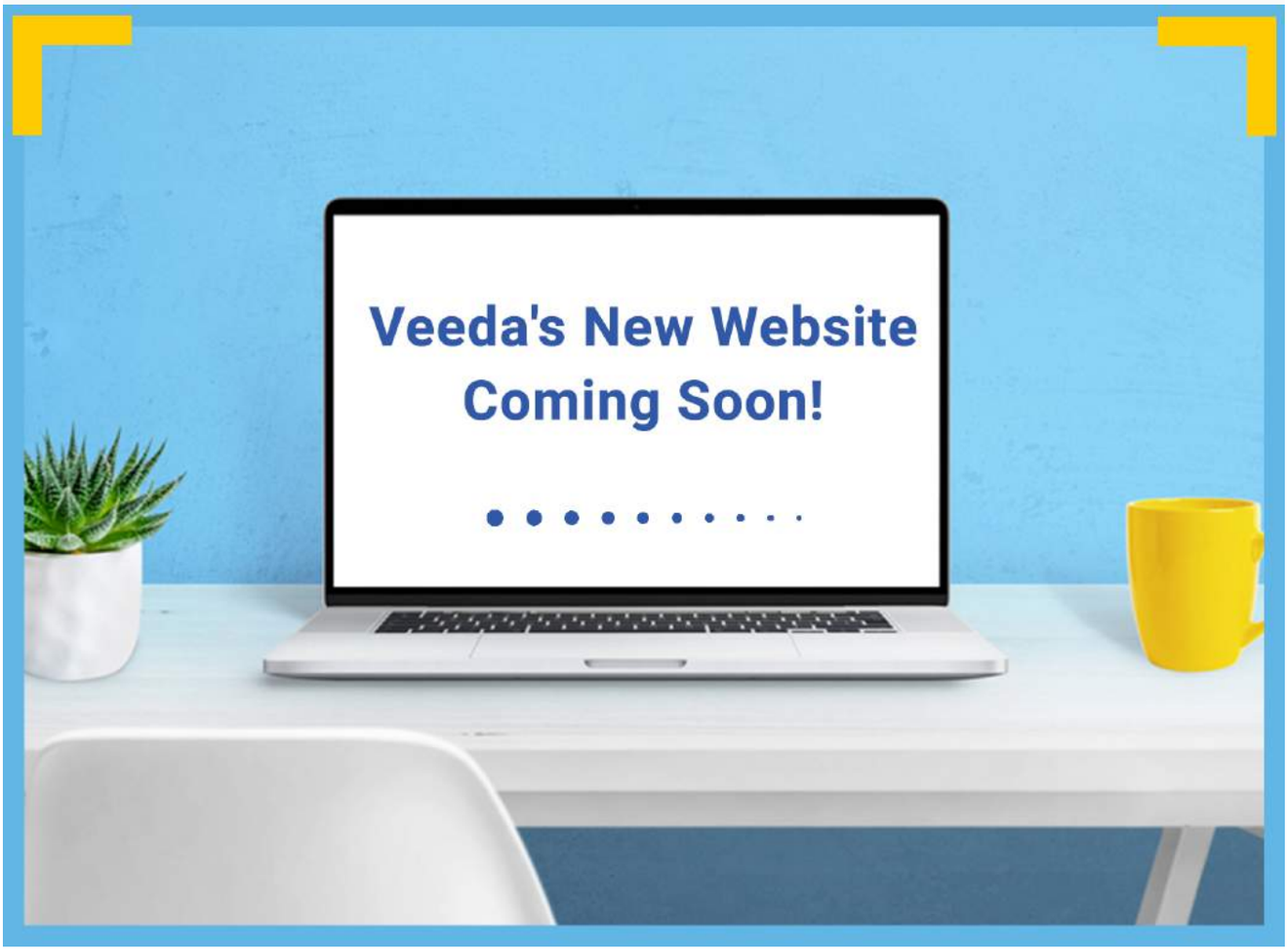
The Veeda Newsletter

APRIL 2021: ISSUE 04



16 YEARS
OF DELIVERING EXCELLENCE

Veeda News
Glimpse of our inaugural event for Ingenuity BioSciences

Regulatory
EMA and ECDC join forces for enhanced post-marketing monitoring of COVID-19 vaccines in Europe

Financial
India's pharmaceutical businesses and trademark growing rapidly

Clinical Research
New Dimensions of Clinical Trial Optimization

Merger and Acquisition
Merger and acquisitions jump over 17 per cent to USD 25.3 billion in Q1

Indian Pharma
How much vaccines can India make? And the catch...

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For the last 16 years, our goal has always been to deliver quality clinical research solutions to our clients. We strive to deliver Quality in everything that we do every single day and hence reinforcing a common understanding of Quality across our organisation is imperative in synchronising our efforts to accomplish our Vision & Mission."

Here's a video of our Managing Director Mr Tandon, Ajay explaining "QUALITY" at Veeda, how do we assess quality and how quality impacts our entire organisation.

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FDA Authorizes Marketing of Device to Facilitate Muscle Rehabilitation in Stroke PatientsFDA Authorizes Marketing of Device to Facilitate Muscle Rehabilitation in Stroke Patients

Today, the U.S. Food and Drug Administration authorized marketing of a new device indicated for use in patients 18 and older undergoing stroke rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion. The Neurolutions IpsiHand Upper Extremity Rehabilitation System (IpsiHand System) is a Brain-Computer-Interface (BCI) device that assists in rehabilitation for stroke patients with upper extremity or hand, wrist and arm disability.

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FDA Continues Important Steps to Ensure Quality, Safety and Effectiveness of Authorized COVID-19 Vaccines

The U.S. Food and Drug Administration takes its responsibility to ensure medical product quality, safety and effectiveness very seriously. The American public puts its trust in the agency to ensure that all medical products, including COVID-19 vaccines, meet the agency's standards for quality, safety and effectiveness.

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EMA board confirms the EU clinical trial portal and database is fit for purpose

The European Medicines Agency (EMA)'s Management Board has announced that the clinical trial EU portal and database is now fully functional and on track to go live by 31 January 2022. This was confirmed during an extraordinary meeting held on 21 April, following an independent audit of the new system. The portal and database are one of the main deliverables of the 2014 Clinical Trial Regulation (Regulation (EU) No 536/2014).

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Update of the WHO guidance on the treatment of drug susceptible tuberculosis

The World Health Organization (WHO) is convening a Guideline Development Group (GDG) to advice on updates needed to its recommendations on the treatment of drug susceptible tuberculosis (TB). Drug susceptible TB affects approximately 7 million people annually.

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EMA and ECDC join forces for enhanced post-marketing monitoring of COVID-19 vaccines in Europe

The European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) today kicked off a new initiative aimed at strengthening post-marketing monitoring of the safety, effectiveness and impact of COVID-19 vaccines in the European Union (EU) and the European economic Area (EEA).

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veeda clinical research

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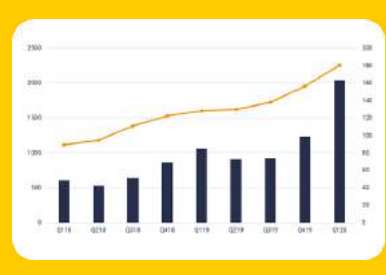
Digitization changes face of healthcare market in wake of Covid-19 crisis

With digitalization and technology advancement, health application strategies are now being devised to align with real-time sales information in Covid-19 pandemic era. For example, a skincare brand has launched a digital diary that allows doctors to use selfies of patients to analyze possible treatment areas. Pandemic has encouraged stakeholders of the health and wellness industry to adopt digitization to cater to needs of customers which has led to a substantial increase in their revenue, said Sanjeev Singhai, founder, Wellnesta.



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Fair Pricing Forum ends with good intentions and new undertakings from WHO

The third WHO Fair Pricing Forum on reaching fairer prices of medicines and health tools ended on Thursday 22 April after six days of intense conversations held virtually with over 700 participants. The Forum this year was supported by the Government of Argentina and attended by the main stakeholders in the access to health products area, chief among them governments, civil society and the pharmaceutical industry.

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Pharma index hits record high as Govt launches phase 3 of Covid vaccination

Shares of pharmaceutical companies are in demand at the bourses with Nifty Pharma and the S&P BSE Healthcare indices gaining 2 per cent each and hitting their respective all-time highs on Tuesday as a significant resurge in Covid-19 cases across India led to spike in demand for Covid-related drugs.

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Indian pharma exports up 18% to a record $24.44 bn in pandemic year

Indian pharmaceutical exports have registered a record growth in the pandemic year (2020-21), bucking the global trend of 1-2 per cent negative growth in 2020. As per the quick estimates of the Department of Commerce, drugs and pharmaceutical exports for the FY-21 (Apr 2020 - Mar 2021) touched $24.44 billion, a record growth of 18.07 per cent.

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India’s pharmaceutical businesses and trademark growing rapidly

The pharmaceutical business in India has developed and shown a great rise and rapid growth in its present situation and this is apparently due to the fact that Indian Pharmaceutical meets approximately up to 50% of the different types of Vaccine demand of the World, 40% demand for generic in USA and in UK there is demand of 25% for all Indian Pharmaceutical medicines as per the findings of IBEF.

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New Dimensions of Clinical Trial Optimization

For much of the past three decades, even as methodologies for clinical trial design have advanced and refined, the idea of the optimized clinical trial has centered on optimal patient samples, target enrollment rates, and generally the most efficient uses of scarce resources in the form of patients. Yet anyone who has had to design and optimize a clinical trial, knows that trial optimization occurs within an ecosystem of choices.

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How to Ensure Clinical Trial Success in Asia and Europe

Innovative and personalized treatments are transforming the face of modern medicine. As patient populations become more targeted, clinical trial organizers are using strict criteria to precisely capture therapeutic effects in these populations. Successful study planning requires operational expertise, market understanding, contingency planning, and the right partners. The global pandemic in 2020 brought many industrial sectors to a standstill.

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Large clinical trial to study repurposed drugs to treat COVID-19 symptoms

The National Institutes of Health will fund a large, randomized, placebo controlled Phase 3 clinical trial to test several existing prescription and over-the-counter medications for people to self-administer to treat symptoms of COVID-19. Part of the Accelerating COVID 19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership.

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How digital platforms provide a bigger picture for patients in clinical trials

Patient burden in clinical trials remains one of the biggest challenges for the life sciences industry to address. Patient retention and adherence are crucial in the clinical trial process and can dramatically impact the outcome of the trial. Dropout rates are sometimes over 30%, leading to trial delay, additional costs, risk to the validity of the study, and potential failure of the trial.

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How eConsent empowers more participant engagement in clinical trials

The chances are high that you have signed at least one consent document in your life. Consents are embedded into every part of our culture. Consent to use your photograph, consent to assume the risks of skydiving, or consent for the use of cookies on the internet. Many of you have also consented for an approved medical procedure. You were running, fell, and hurt your leg. Your doctor needed an X-ray or CT scan to assess the damage. First stop – “sign here.” That is consent.

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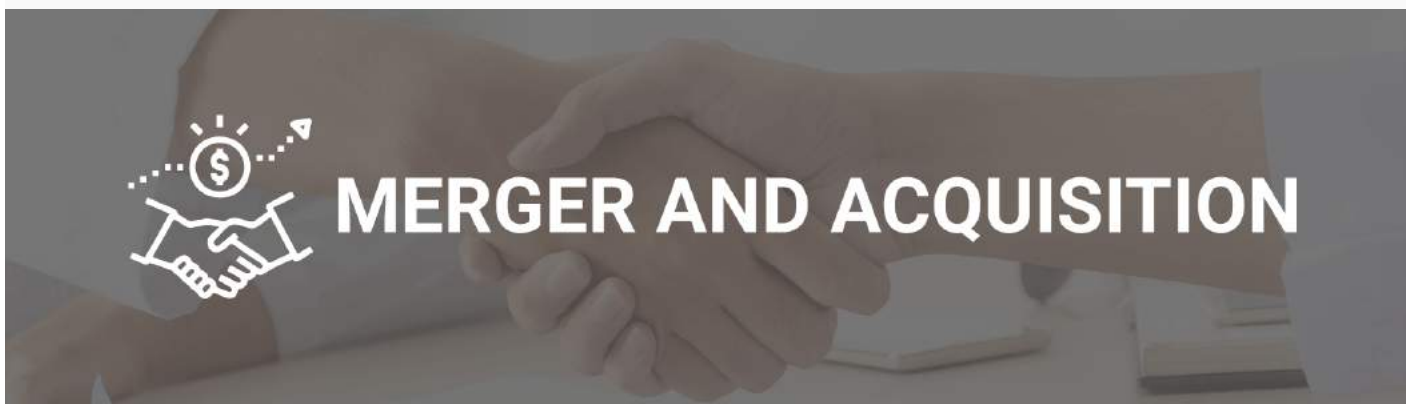

Merger and acquisitions jump over 17 per cent to USD 25.3 billion in Q1

Merger and acquisitions surged 17.4 per cent in the March quarter to USD 25.3 billion across 97 deals, according to a report. According to the report collated by Merger market, relaxation in the pandemic restrictions as well as investor optimism due to vaccines roll-out and government stimulus have helped the delay activities.

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MGC Pharma acquires clinical trials research company MediCaNL

Medicinal cannabis company MGC Pharmaceuticals (ASX:MXC) is expanding its business with the acquisition of worldwide pharmaceutical clinical research company MediCanNL for about $6m. The Israel-based research company will design, manage and run all of MGC Pharma's clinical trials for its cannabinoid medical treatments in line with European, Israeli and US health regulations.

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Thermo Fisher Scientific Plans $17.4 Billion PPD Acquisition

Thermo Fisher Scientific Inc. has reached a definitive agreement to acquire PPD Inc., a leading clinical research service provider. Thermo Fisher's shares gained 3.46% after it was confirmed that the two companies' boards had approved the proposed $20.9 billion cash and debt acquisition. Thermo Fisher will buy PDD at $47.50 a share; paying $17.4 billion in cash and will take over an estimated debt of $3.5 billion.

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KD Pharma expands CBD manufacturing capability with acquisition

The new development will be tightly focused on supply active pharmaceutical ingredients for new drug development, said Adam Ismail, chief strategy officer for the company. To some degree it's a statement about how the uncertain regulatory framework for hemp/CBD nutritional products in the United States, Europe and elsewhere is inhibiting innovation.

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Sanofi pays $160m upfront to acquire Tidal Therapeutics

Tidal's mRNA-based research platform has potential in a number of disease areas – including oncology and immunology – according to Sanofi. Sanofi has paid $160m upfront to acquire Tidal, with up to $310m contingent on the achievement of future milestones. Following the acquisition, Sanofi will gain access to Tidal's novel mRNA-based approach to in vivo reprogramming of immune cells.

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Merck working closely with leading Indian Pharma giant to develop pill that can eliminate coronavirus

Amidst all the bad Covid news coming out of India there could be a glimmer of hope. As reported previously American Pharma major Merck has developed a drug called Molnupiravir – a 200 mg capsule. This oral treatment has to be taken at home for 5 days and works to completely eliminate the new Coronavirus from the body.

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ISCR to focus on digital adoption in clinical trials

The Indian Society for Clinical Research (ISCR) will increase focus on digital adoption in clinical trials and foster greater collaboration among all stakeholders, the newly elected ISCR president Dr Sanish Davis said. Dr Davis, stated, “The lessons from clinical trials during the pandemic will act as a catalyst to transform how we do clinical trials in the future and I am excited about the possibilities.

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How much vaccines can India make? And the catch...

As coronavirus cases continue to rise in the country, the focus has shifted to vaccination. India has administered over 10.45 crore doses of COVID-19 vaccines cumulatively as of Monday morning. But in the clamour against vaccine shortage, the question is what is the total vaccine production capacity and how many COVID-19 vaccines can India produce? The Department of Biotechnology had recently informed the Parliamentary Standing Committee on Science and Technology, Environment, Forests and Climate Change that the estimated manufacturing capacity of Covishield is 70-100 million doses every month.

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IPC and USP India to cooperate for setting drug standards, developing reference standards

The Indian Pharmacopoeia Commission (IPC) and United States Pharmacopoeia (USP) India recently held discussions in Hyderabad on areas of mutual cooperation for setting drug standards and development of reference standards. Ghaziabad-based IPC provides Indian Pharmacopoeia Reference Substances (IPRS) which act as a fingerprint for the identification of an article under test and its purity as prescribed in Indian Pharmacopoeia (IP).

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Pharma Manufacturing is Focusing on Automation

Milan Patel, President, Gujarat State Board Chapter, IDMA, and Joint Managing Director, Troikaa Pharmaceuticals Ltd spoke to PrathibaRaju on how the segment is focusing more on automation and getting data driven. Pivotal role heading the state chapter will be on laying emphasis on the current regulatory landscape, compliance issues, raise their level of understanding and implementing international norms of cGMP.

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