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The Veeda Newsletter

ISSUE 05: MAY 2020

WE ARE ALL IN THIS TOGETHER.

EVEN IN ISOLATION, WE CAN ALL STAND UNITED!

Regulatory

FDA updates guidance on clinical trials amid COVID-19

Financial

Pharma emerges the star of the market in April 2020

Clinical Research

ICMR approves 21 institutions for participating in clinical trials of convalescent plasma therapy

Merger and Acquisition

Merck to Acquire Themis

Indian Pharma

High-level panel to reform drug regulatory system as Modi govt works to fast-track approvals

Webinar

We conducted a webinar on The New Normal: An Operational and Regulatory Perspective

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WHO and UNHCR join forces to improve health services for refugees, displaced and stateless people

The World Health Organization (WHO) and UNHCR, the UN Refugee Agency today signed a new agreement to strengthen and advance public health services for the millions of forcibly displaced people around the world.

UNHCR
The UN Refugee Agency

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MHRA regulatory flexibilities resulting from coronavirus (COVID-19)

We are working closely with the Department of Health and Social Care (DHSC) and other healthcare partners and stakeholders to rapidly identify where flexibilities in the regulation of medicines and medical devices may be possible. This is with a view to supporting the healthcare products supply chain and wider response to the coronavirus (COVID-19) outbreak in the UK.

Medicines & Healthcare products Regulatory Agency

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Global regulators commit to cooperate on observational research in the context of COVID-19

Regulators from around the world have agreed three priority areas for cooperation on observational research during COVID-19. They will collaborate on pregnancy research, on medicines used in clinical practice and on vaccine safety and effectiveness monitoring.

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With drugmakers clamoring, FDA looks to restart facility inspections delayed by COVID-19

The FDA abruptly shut down its on-site facility inspections in March, hoping to keep its employees safe during the novel coronavirus pandemic. More than two months into that moratorium, drugmakers are calling for relief—and with some new guidance, the FDA shows it might be willing to accommodate.

FDA

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FDA updates guidance on clinical trials amid COVID-19

The US Food and Drug Administration (FDA) this week updated its guidance on conducting clinical trials amid the coronavirus disease (COVID-19) pandemic to address new questions, including the use of alternate laboratory or imaging centers, video conferencing and postmarketing requirements.

FDA U.S. FOOD & DRUG ADMINISTRATION

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PE firms chase Indian API makers amid covid-19 disruptions

Private equity (PE) investors are betting on Indian drug makers that manufacture active pharmaceutical ingredients (APIs), even as uncertainty over covid-19 has slowed down investments. This as the government looks to push local manufacturing of pharmaceutical ingredients, making India an alternative supplier to global drug makers hit by factory shutdowns in China.

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Price drives Indian pharmaceutical market growth to five-year high in FY20

For the first time in at least five years, price is the key factor driving the Rs 1.4-trillion Indian pharmaceutical market (IPM). During FY20, price accounted for over 55 per cent of growth in the sector.

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Zydus Cadila launches generic prostate cancer drug at nearly 70% less price in India

Drug firm Zydus Cadila on Friday said it has launched generic Enzalutamide capsules used for the treatment of prostate cancer which costs nearly 70 per cent less than the currently available similar products in India.

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Pharma emerges the star of the market in April 2020

The markets were sharply up in the month of April. Whether it was short covering or fresh buying is something that will be confirmed in the coming weeks. Nifty returns were extremely attractive at 29.56%. Most of the sectors gained around that much, but two sectors actually stood out as shown below.

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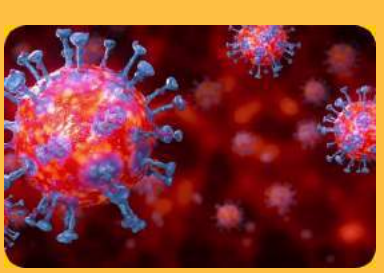
Seven post-Covid insights India must operationalize



The Covid-lockdown has exposed seven key insights that India must operationalize for accelerated economic growth, post-pandemic. India may be the only large economy with positive growth in FY'21 and beyond, provided we deploy the right strategies.

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Recruiting for a COVID-19 clinical trial?

Recently, the UK's Secretary of State for Health and Social Care, Matt Hancock, appealed for more volunteers for COVID-19 clinical trials. He explained that "the bigger the trials, the better the data and the faster we can roll-out the treatments". With 50% of preCOVID-19 clinical trials delayed due to patient recruitment and early Chinese COVID-19 trials facing similar issues, it was a pragmatic move – but not a complete solution.

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Trials and Tribulations: Turning Clinical Trials Virtual During COVID-19

COVID-19, however, threw a wrench in the traditional method of clinical trials, in which participants usually travel to a clinical site for an in-person evaluation. This is causing principal investigators and research staff to find other ways to keep participants connected with studies.

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The Expanding Role of Artificial Intelligence in Clinical Research

In recent years, access to patient medical information, coupled with rapid advancements in data analytics tools and technologies, has significantly altered many areas of healthcare, from early-stage discovery and research to patient treatment. One of the most significant applications of new technology is in efforts to streamline and advance clinical research.

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Amid the COVID-19 Crisis, Clinical Research is experiencing a Renaissance of Collaboration and Speed

More than ever before, collaboration and efficiency are critical in scientific research as the world seeks solutions to the Coronavirus Pandemic. In recent weeks, pharma, financial and federal organizations made deliberate shifts, changing several facets of clinical trials to allow research to proceed at an unprecedented pace.

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ICMR approves 21 institutions for participating in clinical trials of convalescent plasma therapy

The Indian Council of Medical Research (ICMR) has approved 21 institutions for participating in a randomised controlled study to assess the safety and efficacy of convalescent plasma to limit complications associated with COVID-19.

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SERB Announces the Acquisition of Veriton Pharma

SERB expands presence in UK specialty pharmaceuticals and strengthens its neurology and rare disease franchise with the acquisition of Veriton Pharma

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KKR leads race to buy majority stake in JB Chemicals for ₹2500-3000 crore

US private equity giant KKR & Co. Inc. has emerged as the front-runner to buy a 51% stake in JB Chemicals and Pharmaceuticals Ltd, which manufactures popular over-the-counter drugs rantac and metrogyl. Two persons confirmed that the companies are in discussion.

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THC Global Acquires Tetra Health

Tetra Health provides support to patients and medical practitioners. In terms of the latter, the network has more than 600 referring physicians across the country and 30 that can prescribe medicinal cannabis. It makes its money primarily though patient consultation fees and data that assists healthcare providers in making evidence-based treatment decisions.

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AbbVie completes acquisition of Allergan

According to the firm, the move significantly expands and diversifies AbbVie's revenue base and complements existing leadership positions in immunology, with Humira (adalimumab), and recently launched Skyrizi (risankizumab) and Rinvoq (upadacitinib), and haematologic oncology, with Imbruvica (ibrutinib) and Venclexta (venetoclax).

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Merck to Acquire Themis

Merck and Themis, a company focused on vaccines and immune-modulation therapies for infectious diseases and cancer, have entered into a definitive agreement under which Merck, through a subsidiary, will acquire privately-held Themis.

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From Disruptive Covid Chaos, Comes an Opportunity for India's Pharmaceutical Industry

COVID 19 has brought to the fore and fused the subjects of science, sustainability, and social issues. On May 14, 2020 the Indian Council for Medical Research (ICMR) announced that it would partner with the World Health Organization (WHO) on the Global Solidarity Trial for Treatment of the COVID-19 disease and fast-track trials to help in finding an effective treatment.

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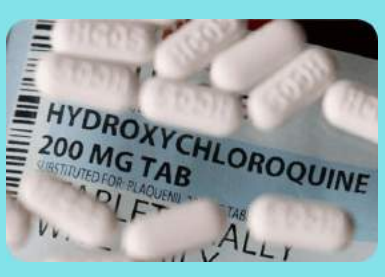
ICMR issues revised advisory on use of hydroxychloroquine



A revised government advisory has recommended use of hydroxychloroquine as a preventive medication for asymptomatic healthcare workers working in non-Covid-19 hospitals, frontline staff on surveillance duty in containment zones and paramilitary/police personnel involved in coronavirus infection related activities.

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Understanding the coming challenges to India's pharma sector

By the end of January 2020, the world slowly began to accept that COVID-19 is a reality that each country would have to learn to live with. With the alarming speed with which it consumed the lives of its patients, COVID-19 engulfed one country after another without providing any opportunities for production of a vaccine or medicine to treat it.

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High-level panel to reform drug regulatory system as Modi govt works to fast-track approvals

The Narendra Modi government has constituted a high-level committee to "simplify and expedite" the drug approval process in India, ThePrint has learnt, as the country continues to fight the Covid-19 pandemic.

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Huge scope for Indian pharma as FDA eases drug scrutiny over shortage in US

Most Indian pharma plants that were inspected by the US drug regulator in the last few months or so have received positive outcomes. As drug majors in the country have gradually improved compliance, against the backdrop of high shortages in the US, analysts see this as a positive sign for pharma exports.

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COVID-19 has forced a reckoning in how we conduct all aspects of our lives, and clinical trials are no exception. Patient safety is the foundational principle of any trial, and suddenly we have a situation where having patients come into clinical sites for their scheduled visits poses a significant risk to their health and well-being. We conducted a webinar on The New Normal: An Operational and Regulatory Perspective on 18th May with industry experts to talk about how clinical trials will be affected in the short term, as we now emerge from the lockdown phase and take steps towards gradually resuming operations, our team at Veeda Clinical Research would like to apprise you of the current operational and regulatory perspective for clinical studies in India and of the various steps being taken to address the safety and well-being of our volunteers and staff and ensure business continuity in these uncertain times. If you did not get the chance to attend it live, below is the recording of the webinar.

Watch Now

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