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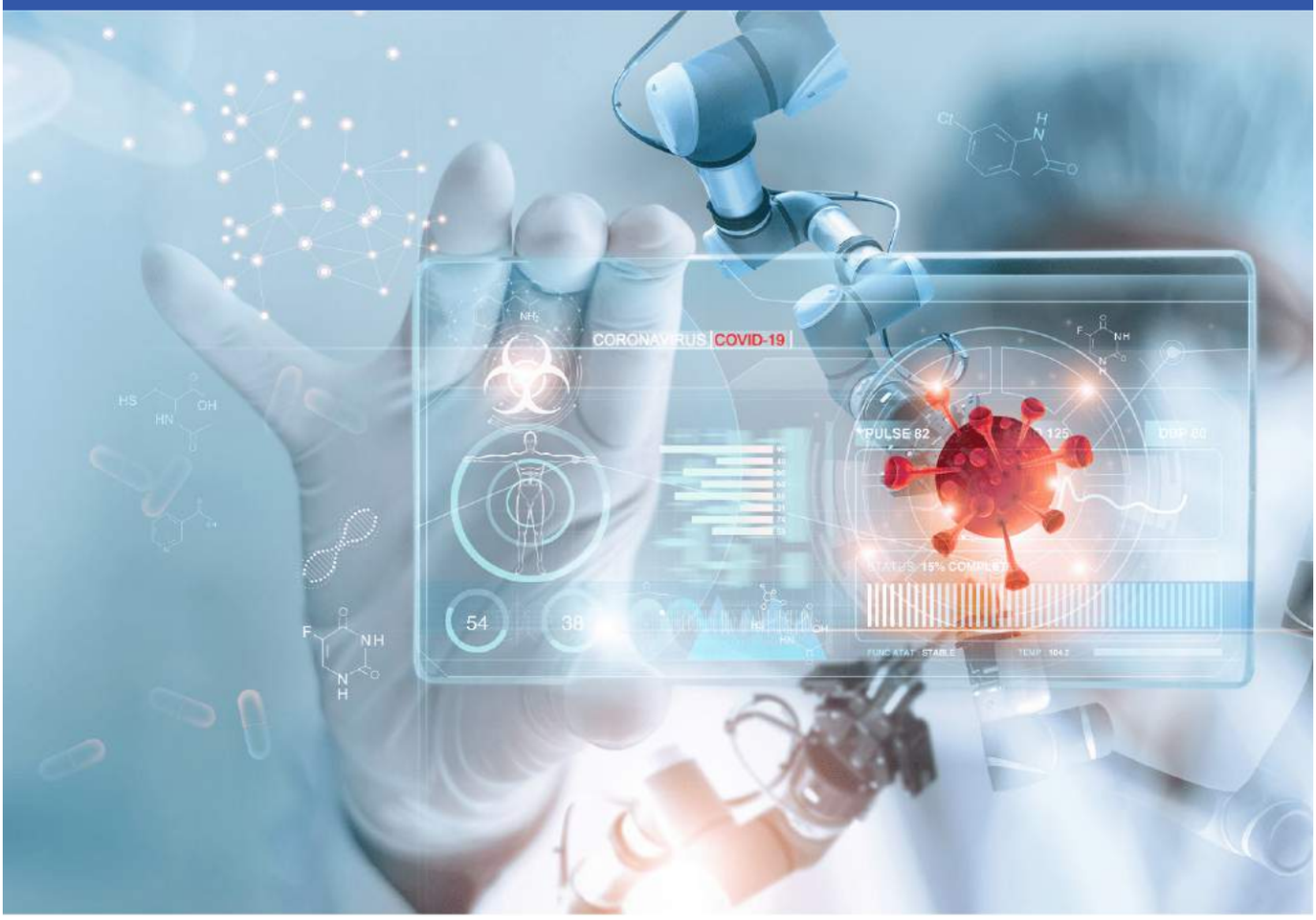

KEEPING CLINICAL TRIALS MOVING BEYOND THE PANDEMIC

Regulatory

FDA Proposes New Rule on Reporting Requirements

Financial

Indian pharma market contracts nearly 6% in Q1FY21

Clinical Research

NIH launches clinical trials network to test COVID-19 vaccines and other prevention

Merger and Acquisition

Grifols to Acquire GC Pharma's Plasma Facilities for $460M

Indian Pharma

Indian pharma compliance standards improving, regulatory risks here to stay

Webinar

We conducted a webinar for our new offering on 'Statistics and Data Modeling'

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EMA starts review of dexamethasone for treating adults with COVID-19 requiring respiratory support

EMA is reviewing results from the recovery study arm that involved the use of dexamethasone in the treatment of patients with COVID-19 admitted to hospital. This part of the study looked into the effects of adding dexamethasone to usual care in adults receiving invasive ventilation, those given oxygen (e.g. through a mask) or those receiving no oxygen.

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FDA Proposes New Rule on Reporting Requirements

Today, the U.S. Food and Drug Administration published the proposed rule, Annual Summary Reporting Requirements Under the Right to Try Act, that when finalized, will implement a statutory requirement for sponsors and manufacturers to provide an annual summary to the FDA for any eligible investigational drug they provide to eligible patients under the Right to Try Act.

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EMA sets up infrastructure for real-world monitoring of treatments and vaccines

EMA has now set up an infrastructure to support the monitoring of the efficacy and safety of COVID-19 treatments and vaccines when used in day-to-day clinical practice. This is underpinned by three contracts for observational research that EMA has signed with academic and private partners over recent month.

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US FDA approves Quest COVID-19 test for 'pooled' sample use

The Food and Drug Administration has given emergency approval to a new approach to coronavirus testing that combines test samples in batches instead of running them one by one, speeding up the process. The FDA said Saturday that it reissued an emergency use authorization to Quest Diagnostics to use its COVID-19 test with pooled samples. It is the first test to be authorized to be used in this way.

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US FDA working to restart on-site inspections during week of July 20

The US Food and Drug Administration recently announced that it will resume prioritized domestic inspections of FDA-regulated facilities and other associated activities since it first announced postponement in March due to the COVID-19 pandemic.

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Indian Pharma Market registers 2.4% growth in June 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 2.4% for the month of June 2020, due to significant revival in some therapies. The COVID crisis had impacted the IPM and the trend of negative growth in April–May 2020 comes to an end in June 2020 with growth of 2.4%.

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Improved 4th Quarter Profitability and Deleveraging to Strengthen Indian Pharma's Flexibility

Indian pharmaceuticals companies' improved profitability on growth in key markets and cost-cutting efforts in the fourth quarter of the financial year ended March 2020 (4QFY19-20) and their deleveraging efforts will strengthen financial flexibility ahead of the full impact of the coronavirus, says Fitch Ratings.

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Indian pharma market contracts nearly 6% in Q1FY21

Indian pharmaceutical market contracted 5.9 percent in first quarter of FY21. The contraction was largely due to supply chain disruption on account of COVID-19 lockdown and steep fall in the sales for acute therapies such as anti-infective drugs, gastrointestinal and pain and fever medications, according to data released by market research firm AIOCD.

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U.S. sets global benchmark for COVID-19 vaccine price at around the cost of a flu shot

The U.S. government has set a benchmark for COVID-19 vaccine pricing in a $2 billion deal announced on Wednesday with Pfizer Inc and German biotech BioNTech SE that will likely pressure other manufacturers to set similar prices, industry analysts told Reuters.

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DoP notifies Rs. 10,000 crore scheme for promoting bulk drug parks & making India self-reliant in producing 53 key APIs

The Department of Pharmaceuticals (DoP) has come out with notification for Rs, 3,000 crore bulk drug parks' promotion scheme and Rs. 6,940 crore production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical key starting materials (KSMs)/ drug intermediates (DIs) and active pharmaceutical ingredients (APIs) in India.

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AIIMS begins phase-1 clinical trials for Covaxin

The subject, who was monitored for two hours at the hospital, has been discharged and will be under medical supervision for the next two weeks, said doctors at AIIMS. Speaking to The Hindu, Professor at the Centre for Community Medicine, AIIMS, and Sanjay Rai said: “The screening process has been on for voluntary participants who wanted to be enrolled for the first phase of human clinical trial of Covaxin.

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Clinical trials rebound after COVID-19 crash, but can enrollment gains continue?

For the hundreds of thousands of people enrolling in clinical trials every year—and for whom experimental therapies can offer a last hope—a new report provides some welcome news: Enrollment in clinical studies in the United States is on the rebound after disruptions caused by the COVID-19 pandemic. But a fresh surge of coronavirus cases could once again scramble studies aimed at testing disease treatments.

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3 ways digital technology can help drug makers fight COVID-19

The pharma industry has played a vital part in fighting the COVID-19 pandemic, supplying life-saving drugs that can help patients recover from coronavirus. However, the pandemic has also posed severe challenges to drug makers. It has disrupted global supply chains, laid bare the sector’s vulnerability and highlighted the need for greater resilience and flexibility.

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Managing uncertainty: Regulatory reporting in multinational trials during COVID-19

This article discusses regulatory reporting challenges for multinational clinical trials during the COVID-19 pandemic. The author covers the pandemic’s impact on clinical research, national guidelines, and harmonization, as well as the challenge of assessing what is reportable and how to submit COVID-19 risk mitigation measures.

Read More

NIH launches clinical trials network to test COVID-19 vaccines and other prevention tools

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has established a new clinical trials network that aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines and monoclonal antibodies intended to protect people from COVID-19.

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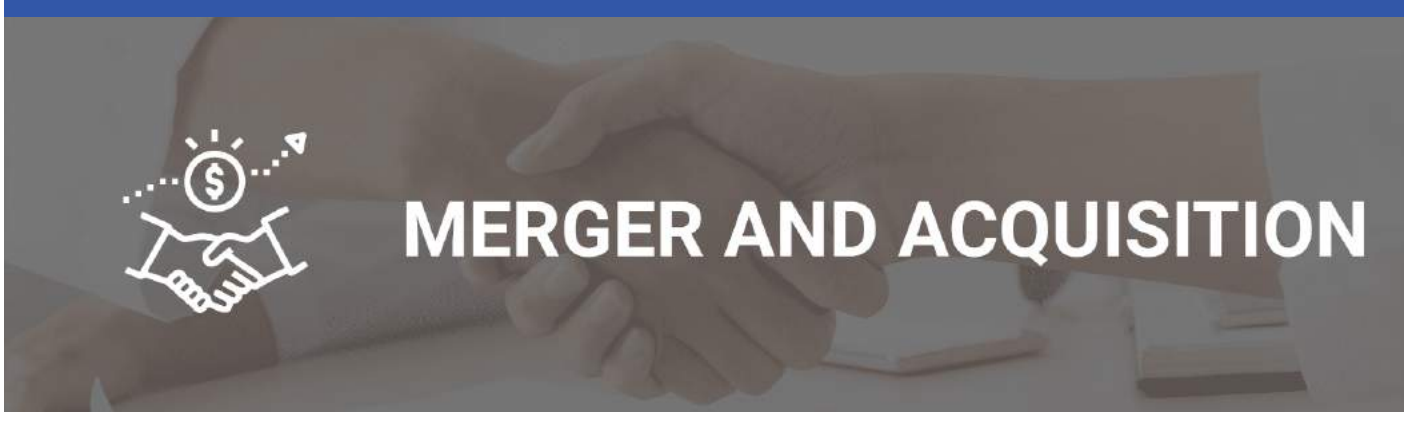

Grifols to Acquire GC Pharma's Plasma Facilities for $460M

Grifols, one of world's top producers of plasma-derived medicines, has entered an agreement to acquire GC Pharma Group's Montreal-based plasma fractionation facility and two purification facilities, along with 11 U.S.-based plasma collection centers for $460 million.

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MGC Pharmaceuticals moves to acquire one of Australia's leading medicinal cannabis clinics

MGC Pharmaceuticals Ltd intends to acquire 100% of the operating clinic-based assets, data and intellectual property of Medicinal Cannabis Clinic Pty Ltd (MCC). MGC Pharma, a European-based bio-pharma company specialising in the production and development of EU-GMP phytocannabinoid-derived medicines, has signed a binding term sheet with Cannvalate Pty Ltd to acquire its wholly-owned subsidiary MCC.

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Curi Bio Acquires Dana Solutions

Curi Bio, a leading developer of human iPSC-based platforms for drug discovery, has acquired Dana Solutions, a pioneer in the application of artificial intelligence and machine learning to in vitro cell-based assays.

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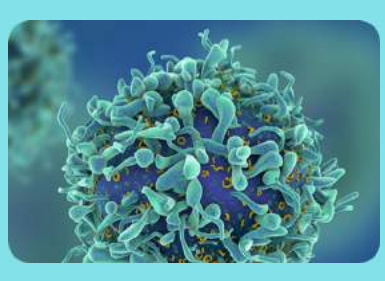
Oncology Venture Acquires PARP Inhibitor Program



Oncology Venture A/S has secured the remaining 16% ownership in its priority PARP inhibitor (2X-121) program along with its 2X-111 program, by acquiring all outstanding shares in Oncology Venture US Inc. for $1.75 million. The company now has full ownership of 2X-121, which is being clinically developed as an anti-cancer therapeutic, as well as being tested as an anti-viral agent against COVID-19.

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ANI Pharma (ANIP) Announces Acquisition of Fluconazole Tablets

ANI Pharmaceuticals, Inc. ("ANI") (Nasdaq: ANIP) today announced the acquisition of Fluconazole Tablets USP, 50mg, 100mg, 150mg, and 200mg from a private company for $3.0 million. The current annual U.S. market for this product is approximately $40 million, according to IQVIA/IMS Health.

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Indian Pharma Company get regulatory nod to launch COVID-19 drug

India's Cipla has received regulatory approval to launch favipiravir 200 mg at 0.91 U.S. dollar per tablet to treat patients from mild to moderate COVID-19, a company statement said on Friday. Cipla will be the second Indian company to launch the drug, which has been developed jointly with state-owned Council of Scientific and Industrial Research (CSIR)-Indian Institute of Chemical Technology (IICT).

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Oxford drug gives hope; Serum Institute to seek human trials in India soon

The race to find an effective coronavirus vaccine has drawn encouraging results with researchers across the world and in India making significant strides. In what was seen as a positive breakthrough, a COVID-19 vaccine candidate developed by Oxford University induced a strong immune response in over a thousand people who got the shot in early human trials. The preliminary findings were published on Monday in the Lancet medical journal.

Read More

Seven Indian pharma players race to develop vaccine for deadly coronavirus

At least seven Indian pharma companies are working to develop a vaccine against coronavirus as they join global efforts to find a preventive to check the spread of the deadly virus that has already infected more than 14 million globally. Bharat Biotech, Serum Institute, Zydus Cadila, Panacea Biotec, Indian Immunologicals, Mynvax and Biological E are among the domestic pharma firms working on the coronavirus vaccines in India.

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Indian pharma industry capable of producing vaccines for entire world: Bill Gates

India's pharmaceutical industry will be able to produce COVID-19 vaccines not just for the country but also for the entire world, according to Microsoft co-founder and philanthropist.

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Indian pharma compliance standards improving, regulatory risks here to stay

Indian pharmaceutical companies have built a strong abbreviated new drug application (ANDA) pipeline since FY12 through scaling-up of investments in R&D but this will increase the inspection intensity, India Ratings and Research (Ind-Ra) said on Tuesday. Ind-Ra said there will be an increase in the number of inspections and re-inspections of pharma facilities to clear the overall backlog.

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We are delighted to offer to our global pharmaceutical clients a comprehensive new service under "Statistics and Data Modeling" that will cover statistics, biostatistics, and data modeling applications across the pharmaceutical development life cycle.

We are glad to announce the appointment of Dr. Ghanshyam Patel to lead this initiative. Dr. Ghanshyam Patel is a Ph.D. in Statistics and has over 16 years of industry experience. Dr. Patel has worked with major Indian Pharmaceutical companies like Sun Pharmaceuticals and Cadila Healthcare and has managed various pharmaceutical and consumer healthcare assignments for CROs. Dr. Patel has served as an honorary lecturer at various Clinical Research Academic Institutes and has participated in various national and international seminars and conferences as a speaker. Dr. Patel is also a member of the Board of Studies for Academic Institutes at St. Xavier's College, Ahmedabad.

To present an overview of the portfolio of statistical and data modeling applications that we would be able to support we recently conducted an inaugural webinar which will be further followed up by a series of webinars covering specific applications in details.

Glimpse of our Inaugural webinar

Access Password: !bEm7na7

We look forward to your participation in these discussions and to the opportunity to extend our valued relationship to include our Statistics and Data Modeling service capabilities.

For any further information contact us at info@veedacr.com.

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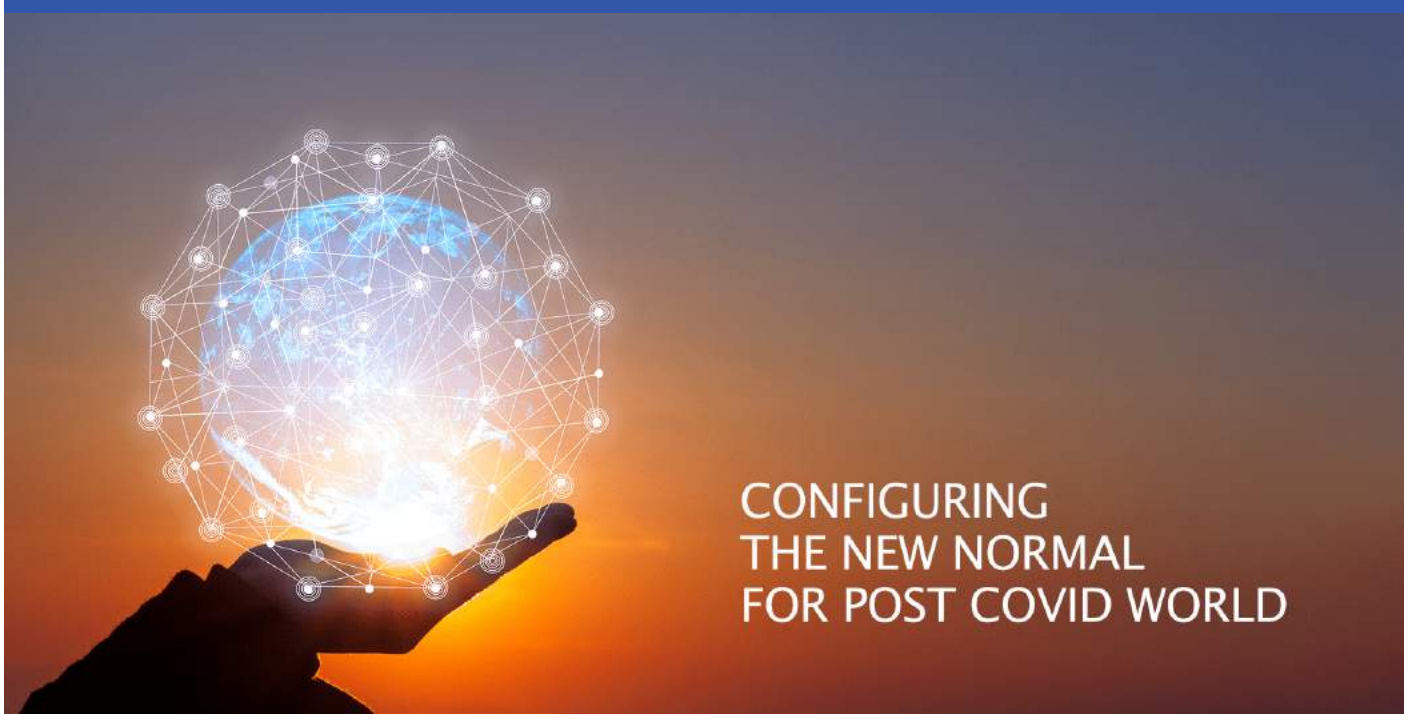

For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

VEEDA CLINICAL RESEARCH® PVT. LTD.
Veeda House, Beside YMCA club S.G. Highway, Vejalpur, Ahmedabad- 380015, Gujarat, India

ADDRESS:

Registered Office

- Shivalik Plaza-A, Near IIM Ambawadi, Ahmedabad- 380015, Gujarat, India. CIN No. U73100GJ2004PTC044023
- Insignia, Besides Auda Garden, Opp. Zenobia Residency, Sindhu Bhavan Road, Off. S. G. Highway, Bodakdev, Ahmedabad- 380059, Gujarat, India
- Radhe Palladium, Floor 1st (Shop No 9, 10 & 11), 2nd & 3rd Floor Panchot, Nr. Panchot Bypass Circle, N. H. No. 6, Mehsana, Gujarat – 384002