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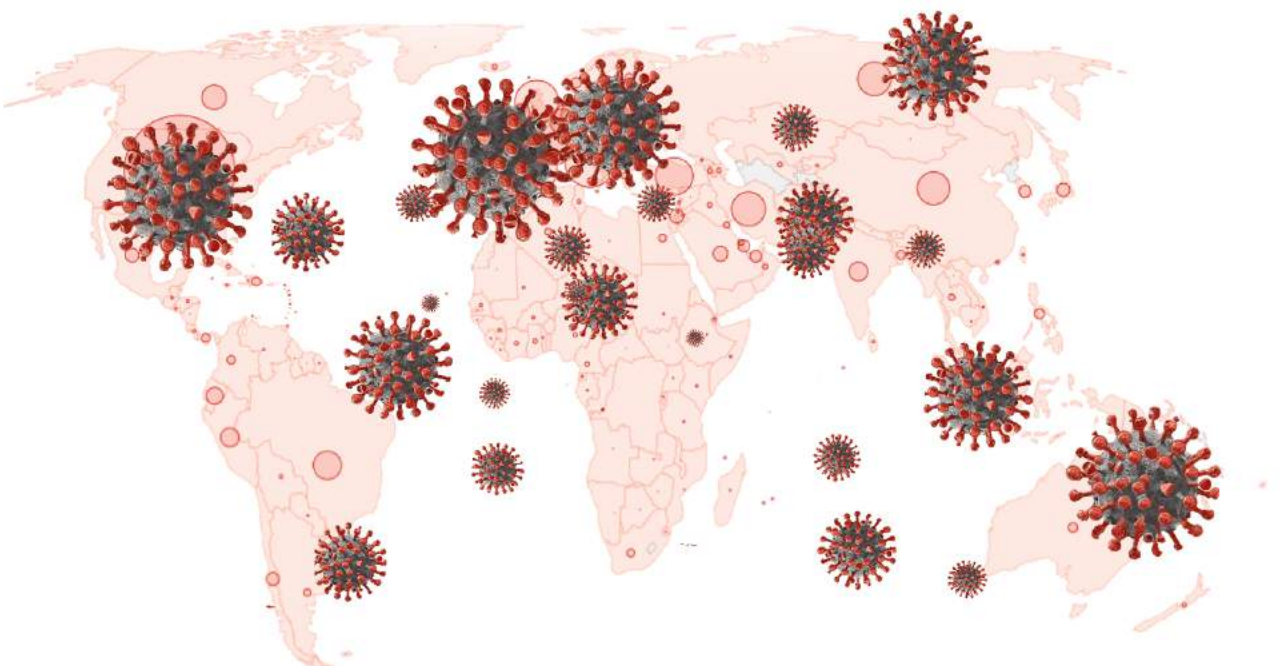
STAY SAFE & AT HOME



LET'S FIGHT THE PANDEMIC TOGETHER

Regulatory

WHO guidance helps detect iron deficiency and protect brain development

Financial

Pune firm first in India to get govt funding for COVID-19 vaccine

Clinical Research

Clinical Trials during COVID-19: Updates from FDA, MHRA and TGA

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Pharma giant acquires Phoenix-based startup developing eye treatments

Indian Pharma

Indian Pharmaceuticals Boost Production of Anti-malaria Drug Hydroxychloroquine to Deal with Rising Demands

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MHRA approves new life-saving breathing aid to help keep coronavirus (COVID-19) patients out of intensive care

The MHRA has provided regulatory guidance to a team of University College London (UCL) and Mercedes Formula One engineers and clinicians to build an adapted Continuous Positive Airway Pressure (CPAP) device that delivers oxygen to the lungs without needing a ventilator.

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US FDA authorizes use of new two-minute test kit for coronavirus

The US Food and Drug Administration has authorized the emergency use of Bodysphere Inc's test that can detect the coronavirus in nearly two minutes, the privately held company said on Tuesday.

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FDA Requests Removal of All Ranitidine Products (Zantac) from the Market

The U.S. Food and Drug Administration today announced it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac).

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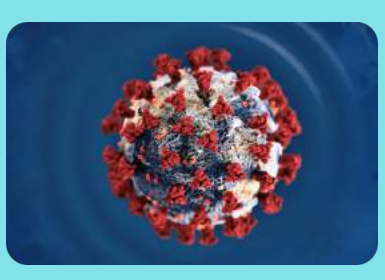
Guidance on regulatory requirements in the context of the COVID-19 pandemic

The European Commission, EMA and the European medicines regulatory network have developed a question-and-answer (Q&A) document to provide guidance to stakeholders on adaptations to the regulatory framework to address challenges arising from the COVID-19 pandemic, with a particular focus on crucial medicines for use in COVID-19 patients.



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WHO guidance helps detect iron deficiency and protect brain development

Detecting iron deficiency early during pregnancy and in young children is crucial. Iron deficiency in children under two years of age can have significant and irreversible effects on brain development. This can lead to negative consequences on learning and school performance later in life.

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Beaten-down pharma stocks turn healthy bets for investors

India’s emergence as the biggest supplier of hydroxychloroquine to the US drug market for treating Covid-19 has triggered investor interest in Indian pharma stocks.

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Coronavirus impact| Pharma companies to see earnings growth

The COVID-19 pandemic is likely to benefit pharma companies as they will witness improvement in business and return on equity which may further lead to earnings growth and a sector re-rating, Aditya Khemka, Fund Manager of DSP Healthcare Fund, said in a webinar on investment opportunities in the healthcare sector.

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Pune firm first in India to get govt funding for COVID-19 vaccine

The Union science and technology ministry will fund a Pune-based firm to develop a vaccine for Covid-19 which is expected to enter phase-1 trial in 18-20 months. Seagull Biosolutions is the first company the government is financially backing for coronavirus vaccine efforts.

Read More

Natco launches cut-price copies of AstraZeneca's patented anti-diabetes drug

Amid serious global attention on Covid-19 pandemic, India's Natco PharmaNSE 1.22 % has quietly launched the generic versions of AstraZenecaNSE 2.61 %'s patented anti-diabetes brand Farxiga. Natco named its brand Dapnat, which will be available in 5mg and 10mg strengths. These products will be priced significantly lower than the two strengths of Farxiga (dapagliflozin) sold in India.

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Pharma attractive again for investors

Pharmaceutical companies have re-emerged as the safer bets for investors in the ongoing market turmoil. With valuations at multi-year lows and the sector expected to remain resilient in the current downturn, investors are opting for larger pharma firms such as Dr Reddy’s Laboratories (DRL), Sun PharmaNSE 1.72 % and CiplaNSE 2.61 %, among others.

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Clinical Trials Set To Determine If Anti-Malaria Drug Effective Against COVID-19

A nationwide trial is underway to see if the drug hydroxychloroquine can prevent disease in people exposed to the novel coronavirus. A second trial will test to see if the drug can prevent severe disease in people who are already showing COVID-19 symptoms.

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How to Combine Quality Management with Risk-Based Monitoring In Clinical Trials

The research community was introduced to risk-based monitoring (RBM) in 2013, when the FDA published its industry guidance, “Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring.” This guidance tasked industry sponsors with adopting a formal approach to quality management by embracing technology and leveraging access to real-time information to drive a more structured approach to risk in study conduct, of which monitoring is a critical element.

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Clinical research versus patient care: Access to experimental treatment

An outbreak of pandemic disease for which there is no known effective therapy can create a climate of fear and uncertainty that may lead patients, and their physicians, to be willing to take risks they would not consider under normal circumstances.

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Clinical Trials during COVID-19: Updates from FDA, MHRA and TGA

The US Food and Drug Administration (FDA) last week updated its guidance from earlier this month on conducting clinical trials during the coronavirus disease (COVID-19) pandemic.

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Global group calls for Covid-19 clinical research in poor nations

A team of scientists, physicians, funders and policymakers from over 70 organisations across the world has called for acceleration of research on Covid-19 in poor and middle-income countries where the disease can wreak havoc.

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Zealand Pharma completes the acquisition of Valeritas

Zealand Pharma A/S (“Zealand” or the “Company”) (NASDAQ: ZEAL) (CVR-no. 20045078), a Copenhagen-based biotechnology company focused on the discovery and development of innovative peptide-based medicines, announces that the acquisition of substantially all assets of Valeritas Holdings, Inc. (NASDAQ: VLRX) has been completed for the cash purchase price of $23 million and the assumption of certain liabilities related to the ongoing business.

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UCB Completes the Acquisition of Ra Pharmaceuticals - to Deliver Differentiated Therapies to Patients

The transaction, which was announced October 10, 2019, will enhance UCB's potential to be a leader in myasthenia gravis by adding zilucoplan, a peptide inhibitor of complement component 5 (C5) currently in phase 3, to the UCB pipeline alongside rozanolixizumab, UCB's FcRn targeting antibody which is also in phase 3

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Orgenesis to Acquire Tamir Bio Assets

Orgenesis Inc., a global biotech company working to transform the delivery of cell and gene therapies (CGTs), has entered into an agreement to acquire the assets of Tamir Biotechnology, Inc., including ranpirnase, TamirBio’s broad spectrum anti-viral platform. The acquisition will be completed for total consideration of approximately $16.8 million.

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Astellas Pharma Acquires Nanna Therapeutics

Astellas Pharma Inc. and Nanna Therapeutics Limited have announced that Astellas has acquired Nanna, a biotech company headquartered in the United Kingdom that is focused on addressing age-related diseases with high unmet medical need including mitochondria-related diseases.

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Pharma giant acquires Phoenix-based startup developing eye treatments

A Phoenix-based digital therapeutics company that has been developing treatments for lazy eye and other ocular disorders has announced its acquisition by New Jersey pharmaceutical giant Novartis.

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India mulls relaxing clinical trial rules to develop COVID-19 vaccine

The Centre is looking at relaxing clinical trial rules in the country temporarily to let pharmaceutical companies attempt to develop a vaccine for the deadly novel coronavirus. The pathogen has killed over 42,000 people across the globe and infected more than 8,00,000 people.

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Taiwan shares coronavirus response strategy with 14,000 Indian medical staff

Taiwan is sharing its best practices to deal with the COVID-19 crisis with 14,000 Indian medical staff, of which 9,000 have already been done on April 2 via video conference. The second video conference is scheduled on April 14. Around 5,000 Indian medical staff are participating.

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Indian Pharmaceuticals Boost Production of Anti-malaria Drug Hydroxychloroquine to Deal with Rising Demands

The demand for anti-malaria drug hydroxychloroquine (HCQ) has increased in India and worldwide to treat COVID-19 patients. To deal with the growing demand, two of the leading pharmaceutical companies for HCQ in India – Zydus Cadila and IPCA laboratories – have boosted the production 10 times on government orders.

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India ready for clinical trial of plasma treatment for critical Covid-19 patients

India will soon begin clinical trials of a plasma treatment for critical Covid-19 patients, according to the Indian Council of Medical Research (ICMR), the country's apex body in the field. The treatment includes injecting patients with plasma from people who have recovered from the infection, and whose bodies have therefore generated the antibodies required to fight the virus.

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India sets up high-level task force to develop vaccine for coronavirus; to co-ordinate with global researchers

India has formed a high level task force to research on coronavirus and develop a vaccine. The task force will also coordinate with international community on vaccine development process for coronavirus.

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