

YEAR IN REVIEW 2021

SETTING THE STAGE 2021 saw a global shift toward responding to the SARS-CoV2 pandemic, with a greater focus on vaccine and antiviral R&D.

The FDA grants an EUA (Emergency Use Authorization) for the first SARS-CoV2 vaccines in December of 2020, with approval and rollout beginning early 2021.

According to The Center for Biosimilars, many clinical trials stalled and drugs with recent FDA approvals failed to launch due to hospitals being overwhelmed.

Negotiations at the WTO about the waiving of COVID-19 vaccine intellectual property begin amid talks to speed up global vaccine distribution.

The WHO, Vaccine Alliance, and Coalition for Epidemic Preparedness Innovations form Covax to supply free COVID-19 vaccines to the world's 92 poorest countries.

Merck's oral antiviral pill Molnupiravir and Pfizer's Paxlovid are endorsed by the FDA as a treatment for those who have contracted COVID-19.

AT A GLANCE

The FDA approves Pfizer and Moderna mRNA vaccines and Johnson & Johnson viral vector vaccine in the U.S.

Pfizer redesigns its logo to include a helix-like icon, potentially hinting at a future in biotechnology.

Vyera Pharmaceuticals and its parent company Phoenixus to make Daraprim available to any generic competitor for the cost of making the drug, and pay up to \$40 million in settlement for the 2015 4,000% price hike and anticompetitive restrictions.

The 2020-21 influenza season is unusually mild, with credit given to the COVID-19 precautions in place.

Globally, "testing," "vaccine," and ways to stay entertained at home dominated search trends.

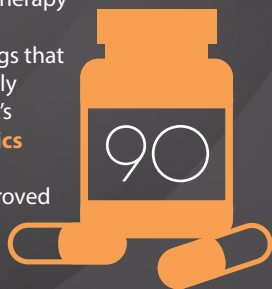
Gig work and remote work, in general, have increased in 2021 as COVID-19 concerns, advisories and restrictions guide many to socially distance.

U.S. v. Elizabeth Holmes, et al. trial begins, deciding whether Holmes' company, Theranos, defrauded doctors and patients by false claims and omitted information about its capabilities.

NEW DRUGS

The FDA approved **50** novel drug and therapeutic biological products in 2021.

Including vaccines, allergenic products, blood products, plasma derivatives, cellular and gene therapy products, and new indications for drugs that had been previously approved, the FDA's **Center for Biologics Evaluation and Research** has approved closer to **90** new drugs in 2021.



TRENDS

Supply chain delays and other issues are leading to innovations in production technology and digitization processes like **Electronic Data Capture** and **Electronic Clinical Outcome Assessment** to circumvent reliance on less-certain avenues.

Greater spend on R&D – in-house and via CROs.

An increase in clinical trials launched in 2020 and 2021 suggests greater focus on studies relating to the pandemic and COVID-19.



MERGERS & ACQUISITIONS

Under an expanded strategic partnership deal, **Samsung Biologics** produced **AstraZeneca's** COVID-19 antibody cocktail and will begin production on a cancer immunotherapy product in the coming year.

Thermo Fisher Scientific acquired Pharmaceutical Product Development.

Humana acquired Kindred Healthcare.

Pfizer acquired Arena Pharmaceuticals.

Merck acquired Acceleron Pharma.

Danaher acquired Aldevron.

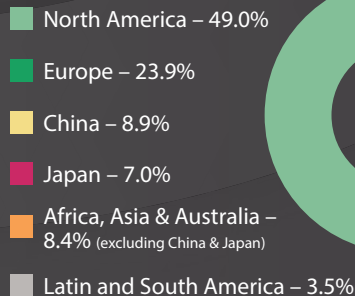


SALES & FINANCIALS

In 2018, the biopharmaceutical market was recorded at around \$1.2 trillion; the IQVIA Institute forecasts that number will exceed **\$1.5 trillion** by 2023.

Clinical trials market size value in 2021 is roughly **\$47 billion**.

BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET SALES (AS OF 2021)



CLINICAL TRIALS

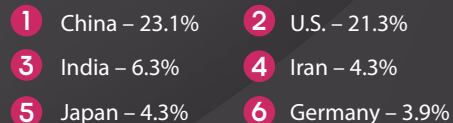
35,584 clinical trials launched in 2021 – down from 2020's total, but higher than 2019 and previous years. This suggests a greater focus on pandemic-related studies and deprioritization of other trials.

Many trial sites became unavailable as hospitals tended to COVID-19 patients.

67.3% of trials affected by the pandemic are due to **suspension of trial enrollment**.

AMA subsidiary Health2047 created **SiteBridge Research** to help increase clinical trial access and accelerate time to market and product access in underrepresented communities.

PERCENTAGE OF TOTAL CLINICAL TRIALS INITIATED IN THE TOP SEVEN COUNTRIES, 2021



YEAR IN REVIEW 2021 SOURCES

AT A GLANCE

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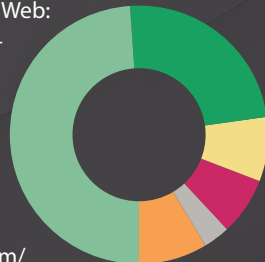


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