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Life Sciences Sector Incubates Its Next Growth Phase

Pharma and biotech companies are focusing their tech investments on personalized medicine, clinical trials, safety, and other key areas.

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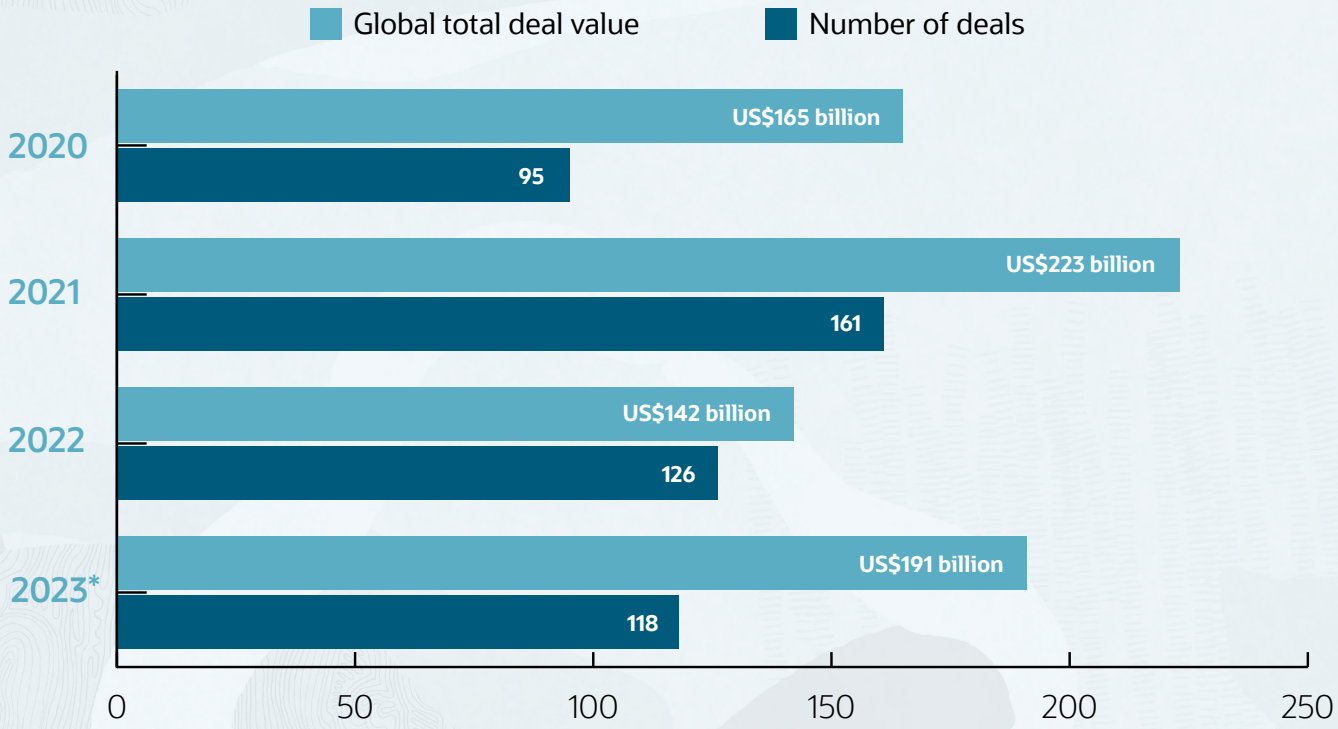
As the COVID vaccine boom years recede, the life sciences sector is starting to break out of its market slump on the back of gene therapy breakthroughs, AI-enhanced drug discoveries, clinical trial reforms, and other advances. Global pharmaceutical companies and drug development–focused biotechs will need to place their technology bets carefully to support those efforts.

Dogging the sector have been low success rates for developing new drugs, expiring patent protections for existing ones, regulatory pressure to keep prices down, and difficulty sharing and analyzing data because of developing formats, paper-based processes, and national boundaries.

Life Sciences Sector M&A Activity



* Deals through December 10, 2023. Source: EY

"With cloud computing and much faster processors, now you can do many more tests in a much shorter time, and that analytical capability has exploded the imagination of the people who are doing the experiments," says Liliana Brown, director of the genomics and advanced

technologies office at the US National Institute of Allergy and Infectious Diseases (NIAID).

Gene expression analysis has become sophisticated enough to let scientists see single-cell differences between cancerous and normal tissue, bolstering understanding of diseases at the molecular level, Brown notes. What's lacking are standardized pipelines to get information into data lakes and warehouses where peers can benefit. "We don't have the right data science habits," she says. "We still haven't digitized everything."

Pharmaceutical companies see 92% of drug candidates fail in clinical trials, according to Citi Global Insights. Drugs that do succeed often take a decade to get approved. Shortening the window would add more years of profitable patent protection.

Companies are trying new tactics to assemble better panels for their trials, including mining electronic health records to expand the pool of qualified participants beyond the mostly affluent ones who live near academic hospitals. The goal is to get a better read on how drugs will perform once they're broadly available.

Drug prices are also under increased regulatory scrutiny. Starting in 2026, the US Inflation Reduction Act will authorize Medicare to negotiate prices for some medicines for which there are no alternatives, a measure that will likely reduce drug makers' returns. The US Food and Drug Administration has begun letting Florida import cheaper drugs from Canada, and other states may follow, though the pharma industry's main lobbying group is expected to sue to block the plan. In the European Union, beginning in 2025 for cancer treatments and gene therapies, pharma companies will need to comply with EU-wide reviews of new drugs and medical devices, influencing member states' pricing and reimbursement decisions. Pressure on revenues is especially high as drug companies face falling demand for COVID-19 vaccines and antiviral drugs.

Nonetheless, life sciences companies are making strides in a number of areas. Advances in

genomic medicine have yielded powerful chimeric antigen receptor (CAR) T-cell therapies, in which cancer patients' immune cells are modified in a lab with a gene that lets them better attack tumors, sending the disease into remission after a single dose. New treatments for the debilitating sickle cell blood disease are based on the gene-editing technology CRISPR and a viral vector approach that delivers patients a transplant of their own genetically modified stem cells.

Pharma companies are also developing new vaccines using messenger RNA instructions—the technique that helped fight COVID-19—which could one day treat cancer, cardiovascular disease, and other conditions. And they're applying AI across the therapeutic spectrum. For example, pharma companies are partnering with AI-focused startups to sift molecular libraries to find compounds that potentially could become medicines—or synthesize entirely new ones. They're also using AI to design clinical trials and select patients, clean up redundant or inconsistent EHR data, and summarize drug safety information.

Acquisition activity has ramped up as industry leaders look to expand their product portfolios to boost sales amid a coming falloff in patent-protected revenue. Life sciences M&A spending rose 34% to US$191 billion through December 10, 2023, compared with the previous year, as 11 companies signed at least one deal worth US$1 billion or more, according to consultancy EY. The largest was Pfizer's US$43 billion acquisition of cancer specialist Seagen. AstraZeneca in March 2024 said it would buy targeted chemotherapy company Fusion Pharmaceuticals for US$2.4 billion. The sector still has US$700 billion in cash and debt that can be used for acquisitions, which could help offset US$230 billion in potential lost revenue by 2030 as patent protections expire, according to Goldman Sachs.

To reinvigorate growth and make the most of emerging therapies, here are six areas where big pharma companies and biotechs need to focus their tech investments.

1 Unlock EHRs to combine clinical and genomic data

Modern electronic health records based on graphical interfaces and internet protocols debuted in the 1990s as scheduling and billing tools for large academic hospitals. Since then, they've become more sharable and secure. Now, doctors, patients, and researchers want to pack in new kinds of information—and get fresh insights out.

Clinical researchers, genomics testing labs, and technology companies are combining data from patients' gene sequences that show disease proclivity and drug tolerance with EHR data about their medical exams, lab tests, demographics, and lifestyles. Genetic analysis can help doctors prescribe more precise treatments. Yet it's been hampered by the cost and complexity of connecting myriad databases and applications and by immature industry standards for doing so.

The genome, a person's set of DNA molecules, contains roughly 30,000 genes with instructions for making proteins, the building blocks of life. Variants in people's genome sequences can reveal risk factors for disease or show how they experience symptoms and respond to drugs.

Today's sequencing machines can produce results in less than a day for about US$600, and the industry is aiming for US$200 sequences, putting genetic tests within reach of many more people. EHRs contain a trove of so-called "real-world data" on diagnoses, symptoms, and vital stats. What's been missing is a comprehensive view to help physicians pinpoint which medications to prescribe or avoid—without wading through reports or searching the

> "Life sciences companies need those electronic medical records to develop innovative new therapeutics. There's information known about you that could be pertinent."

Frank Baitman
Healthcare Technology Adviser
Oaklins DeSilva+Phillips

internet. Biotechs could see why some people are more prone to, say, cancer or heart disease, aiding drug development.

"Life sciences companies need those records to develop innovative new therapeutics," says Frank Baitman, former CIO for the US Department of Health and Human Services and now a senior healthcare technology adviser to investment bank Oaklins DeSilva+Phillips. "There's information known about you that could be pertinent, like your genetic proclivity for a particular therapeutic. Is there a way to integrate that into the EMR? It's really hard to stretch the electronic medical record for all these use cases. We need a different architecture, or to use AI to do the integration."

The FHIR Genomics Operations data format, part of an industry standard for exchanging health information called Fast Healthcare Interoperability Resources, lets developers create applications that include genome variant analysis in a way that's useful to doctors. It can integrate genomics databases with EHRs and handle dynamic, complex data with standardized APIs so that developers don't need to understand bioinformatics calculations. Applications include matching cancer patients to available clinical trials, screening for treatable hereditary conditions, and identifying risks of medication reactions, which involve computing across databases.

But the broader FHIR standard hasn't been rapidly adopted worldwide. And interoperability standards alone may not be enough. The workflows hospitals, universities, and commercial researchers want to build also require data repositories of variants, drug dosing information, and relationships between drugs and genes. Algorithms need to run atop those databases to turn gene variants into information about drug response, and decision support software in EHRs and patient portals has to offer suggestions doctors can act on. Other standards based on FHIR, such as CDS Hooks, can show doctors electronic "cards" with suggestions and links based on the drug they've prescribed.

2 Deliver on the promise of personalized medicine

Oncologists are banishing cancers into remission by infusing patients with their own genetically engineered white blood cells that contain tumor-fighting properties. Sufferers of painful blood disorders are getting infusions of edited bone marrow stem cells, putting decades of symptoms behind them. The treatments—which can cost millions of dollars for a one-time dose—will require hospitals, pharma companies, and insurers to track patients' progress over years, which is changing business models and data-sharing requirements.

Annual spending on gene therapies in the US could increase from US$5.15 billion in 2020 to US$25.3 billion in 2026, according to the private National Bureau for Economics Research. Policy researcher Economist Impact estimates that by 2031, the US will have 100 approved cell and gene therapies, the EU 70, and China 50.

CAR T-cell therapies work by extracting immune cells from patients with blood cancers, then modifying them in a lab to bind to proteins on tumor cells and kill them. The customized treatment is reinfused into patients, where engineered T cells attack cancer and multiply on their own. A one-time dose can cost hundreds of thousands of dollars to US$1 million.

Meanwhile, the FDA in December 2023 approved the first two gene therapies for sickle cell disease, an inherited blood disorder, while UK regulators and the European Union have also

approved the CRISPR approach. Those drugs cost US$2 million and US$3 million, respectively. A Novartis gene therapy for spinal muscular atrophy in children costs US$2 million.

The prices may still be less than the millions of dollars it costs to treat these diseases over the course of a patient's life, leading health insurers and pharma companies to create reimbursement models based on how patients fare over time. Tying payments to outcomes means EHRs need to track patients' progress over a decade or more, demanding more of the databases behind them.

Other aspects of personalized medicine are also compelling data sharing. CAR T-cell therapies could one day be used against lung, kidney, and bone cancer, and CRISPR therapies could treat cancer, diabetes, heart disease, and HIV. As the patient pool widens and usage expands from specialized centers to general hospitals, pharmas, insurers, and medical centers will need to share more information via EHRs.

More data will need to go to regulators, too, since the treatments raise new safety flags. The FDA said in November 2023 it was investigating a "serious" risk that CAR T-cell therapies could lead to new malignancies.

Programs designed to speed cell and gene therapy authorizations, including the FDA's Regenerative Medicine Advanced Therapy Designation, EMA's PRIME, and Japan's Sakigake, will require drug developers to collect evidence over many years for approvals, safety monitoring, and insurance coverage.

3 Create more effective clinical trials

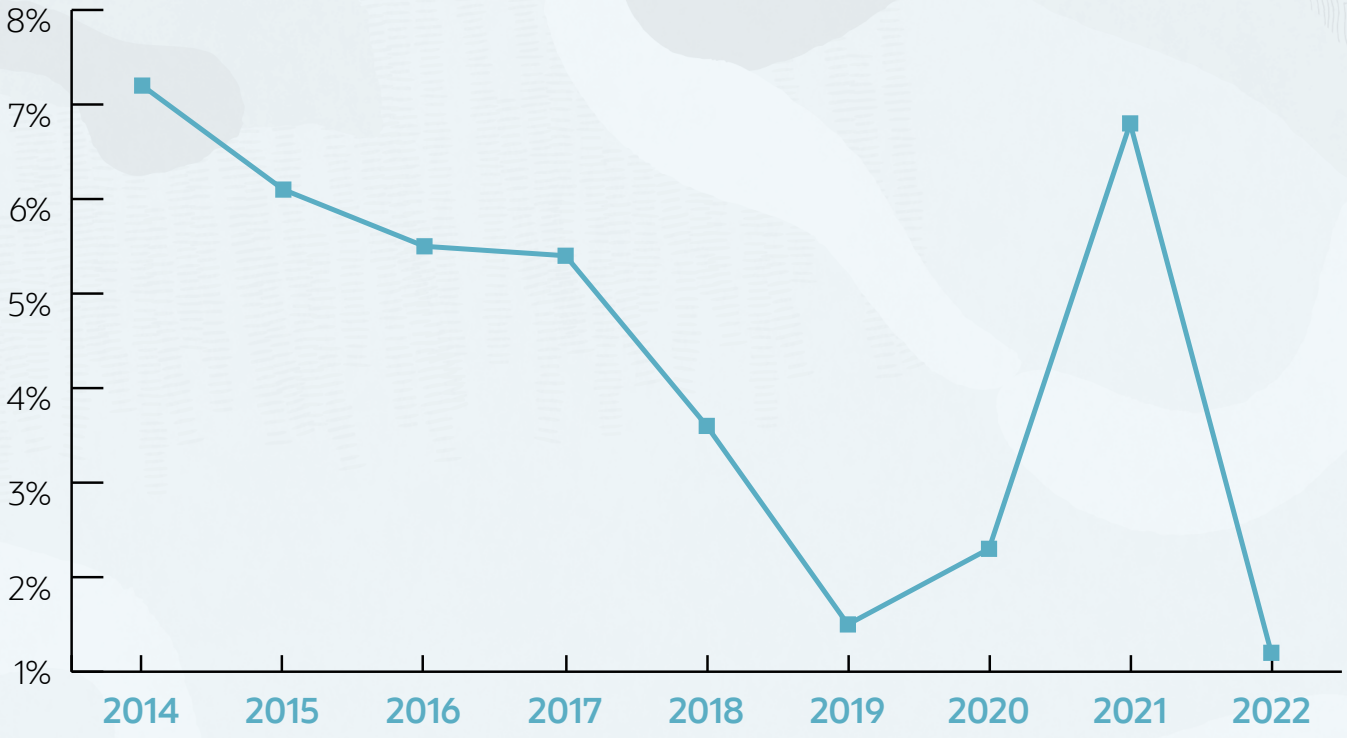
Rising development costs and lower returns are prompting pharma companies to redesign their drug studies. It costs an average of US$2.3 billion to get from clinical testing to usable medicine, according to consultancy Deloitte. Misses can hurt a company's stock price. "Often clinical studies fail not because of the drug, but because they couldn't assemble the population in the time they needed to, or patients drop out," says Oaklins' Baitman.

Recruiting and retaining patients who belong to ethnic groups or live far from urban study sites could boost success rates by making panels more diverse and better reflecting how drugs affect populations once they're widely prescribed.

Most potential study participants live more than a two-hour drive from research hospitals, and 78% of US clinical trial participants are white, according to Deloitte. Asian Americans

Diminishing Returns

Rising pharma R&D costs contribute to lower internal rates of return for late-stage drug pipelines.



Source: Deloitte 2023 Global Life Sciences Outlook

make up more than 6% of the US population but only 3% of cancer study participants, even though the disease is the demographic group's leading cause of death. In Europe, eastern countries are underrepresented. About 80% of clinical trials are delayed because of recruitment problems; a third of participants drop out before trials' completion.

Pharma companies are scouring EHRs for real-world data on health outcomes and demographics to find recruits, including those for decentralized clinical trials in which participants can show up at a drug or grocery store for tests, or transmit results from home.

Decentralized clinical trials in phases II and III, which prove drugs' efficacy and benchmark them against current standards, can yield seven times the return on investment per drug compared with trials in which participants need to regularly check in at a medical center or other healthcare facility, according to the Tufts Center for the Study of Drug Development.

During the pandemic, real-world data stored in EHRs aided vaccine development when patients didn't want to enter hospitals for checkups, and doctors didn't want them there. Now pharma companies, regulators, and government agencies are promoting its use for a range of approval and safety scenarios.

The US government's Advanced Research Projects Agency for Health (ARPA-H) launched a clinical trial program in October 2023 urging hospitals, universities, pharmacies, and tech companies to develop tools to speed clinical trial enrollment by letting people participate

remotely and improving IT interoperability. “The lack of shared data makes it difficult to cast a wide net for candidates,” the agency said.

The FDA’s Real-World Evidence program stems from the US 21st Century Cures Act of 2016, which required the administration to evaluate information about drugs’ usage and potential benefits, including in clinical trial design, in part by drawing on EHR information and medical claims.

Syneos Health, a pharmaceutical research organization that contracts with drugmakers, is mining data from hospitals to try to recruit study panels faster, increase diversity, and get patients to stay longer in trials. Freenome, which develops blood tests that look for signs of pancreatic and lung cancer before tumors form, is running an 8,000-person study that analyzes EHR data to find newly diagnosed cancer patients who’ll contribute a blood sample before they start chemotherapy.

Assembling decentralized clinical trials can be difficult. Disadvantaged groups are less likely than affluent ones to get the current standard of care for a disease, a requirement for participation in control groups that are compared to those receiving experimental treatment. They’re also less liable to have reliable Wi-Fi and command of mobile devices needed to transmit results from home.

4 Tap AI for faster drug development

Life sciences companies aren't just trying to wring costs from clinical studies. They're also tapping AI to accelerate preclinical work that ushers drug candidates from the lab to human trials.

Pharma companies are teaming with tech startups to apply AI-based analytics to computerized libraries containing hundreds of thousands of chemical compounds to find molecules that can potentially bind with target proteins in the body to fight diseases. AI models can test whether a compound is soluble in bodily tissue and able to be transported to cells. Companies are also using AI to summarize scientific literature, clinical trial data, and patents more quickly.

AI a Boon to Pharma

Estimated industry value to be produced by generative AI

Commercial	$18B to $30B
Research, early drug discovery	$15B to $28B
Clinical development	$13B to $25B
Enterprise	$8B to $16B
Operations	$4B to $7B
Medical	$3B to $5B
Total value	**$60B to $110B**

Source: McKinsey & Co. Estimates in US dollars.

The market for AI-assisted drug discovery could be worth US$50 billion by 2032, according to Morgan Stanley, which forecasts that even modest improvements in early-stage drug development assisted by AI could yield as many as 50 new therapies within a decade. McKinsey & Co. estimates that generative AI could contribute US$15 billion to US$28 billion a year in value in the research and early discovery phases of drug development and another US$13 billion to US$25 billion in clinical development, including trial management and regulatory submissions.

AstraZeneca, Pfizer, Novartis, Roche, and Bayer are among the pharma companies partnering with AI drug discovery concerns. BioNTech, inventor of a COVID-19 mRNA vaccine, acquired London's InstaDeep in 2023 to design and test large numbers of drug candidates via AI.

Eli Lilly works with Chinese AI drug discovery company XtalPi, while Pfizer has partnered with XtalPi to develop its COVID-19 vaccine and antiviral pill. Both were approved by the FDA in less than two years. "It's early stages but super promising," says Seema Verma, executive vice president for healthcare and life sciences at Oracle and the former head of the US Centers for Medicare and Medicaid Services, which spends more than $1 trillion annually on health programs benefitting 160 million Americans. "A lot of the work requires cloud and GPUs."

Computer-aided drug discovery, including database searches, gained widespread adoption in the 1990s and early 2000s. The adoption of AI is more recent, driven by advances in multimodal models that can understand language, images, gene and protein sequences, and other types of data relevant to diseases. They can also see weaker signals and patterns during experiments than human scientists can, exploring avenues pharma companies may have previously discarded.

5 Secure drug safety

Harmful drug reactions kill about 100,000 Americans and 200,000 Europeans alone each year. Clinical trials screen for safety, but other side effects may crop up after more people worldwide start using a drug, and adverse reactions have risen as patients take more medications in combination than in decades past.

Pharma companies rely on reports from doctors and patients, often sent through online forms. But only a fraction of adverse events get reported. And making sure those that do yield high-quality data showing when their medicines triggered reactions is paramount.

Health authorities and the industry are trying to make it easier for patients and providers to report adverse events, including right from patient healthcare portals and EHRs. Large drug companies processing millions of reports a year are adopting AI techniques, including entity

recognition, to turn text into internationally recognized medical terms. They're also using generative AI to summarize cases for doctors.

Another industry goal is linking drug reaction databases to data in EHRs to explain medications' risks to individual patients better than generic package inserts can. Proactively identifying patient populations that may have a higher risk of adverse events can lead to faster drug approvals.

Further complicating drug safety are the complex manufacturing processes and intricate supply chains needed to deliver CAR T-cell therapy and other genetic treatments. CAR T-cell infusions need to be transported at extremely cold temperatures and shipped back to treatment sites quickly. Drug companies are developing meticulous identity systems to ensure that treatments sent back to patients for reinfusion are the ones customized exactly for their cells. "You're a manufacturing company, whether you know it or not," Bluebird Bio CEO Andrew Obenshain told attendees of the J.P. Morgan Healthcare Conference in San Francisco in January 2024.

6 Break down data boundaries to accelerate insights

Data sharing and interoperability are taking on new urgency as falling gene sequencing costs, more powerful imaging techniques, and faster processors in the cloud put pressure on companies and government labs to make their datasets easier to find and use inside and outside their walls.

Many bench scientists aren't trained on structuring data so that peers can use it immediately for their own computing, and in many cases experiments are recorded on paper rather than in digital notebooks. Even during the pandemic, the NIAID was handling paper reports from US state and local labs. The agency ties funding to recipients' efforts to make data usable across different software tools.

Biomedical research repositories are also ballooning in size, driven by more powerful gene sequencing machines and the falling cost of sequencing DNA. In some cases, the volume of observable data is outpacing the ability to analyze it.

Data sharing in life sciences is also affected by geopolitics. Flu vaccines for North America, Europe, and China depend on the previous year's infection data from the southern hemisphere. But the early data providers don't share in the profits. African countries that sounded early warnings on the COVID Omicron variant were hit with travel bans.

Some countries in South America, Africa, and Southeast Asia have been attaching licenses to flu, COVID, and other disease data, though adding bureaucracy can slow public health

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authorities' reaction times during an outbreak or epidemic. "In pathogen genomics, this is one of the biggest concerns that we have," the NIAID's Brown says. "Our field is still struggling with the right approach."

Limits on where genomics data can be stored and processed are also changing cloud computing strategies for software makers, especially in the Middle East. Governments in Saudi Arabia and the United Arab Emirates are investing in gene sequencing of residents to fight inherited diseases while ensuring that sequencing files, which can consist of petabytes of raw data, stay within those countries' borders.

"The question is then: What to do with that data?" says Tommi Kaasalainen, CEO of Euformatics, whose software lets hospital laboratories analyze how patients' genome variants affect the efficacy of cancer drugs and other medicines. Genomics software vendors are gravitating to cloud providers with local data centers, which let them comply with data boundary rules while scaling more easily than on-premises computing as the numbers of genetic samples supplied by their customers grow.

"You want to transfer the computing to where the data resides," Kaasalainen says. "It's really kind of an evolving field."

How can Oracle help?

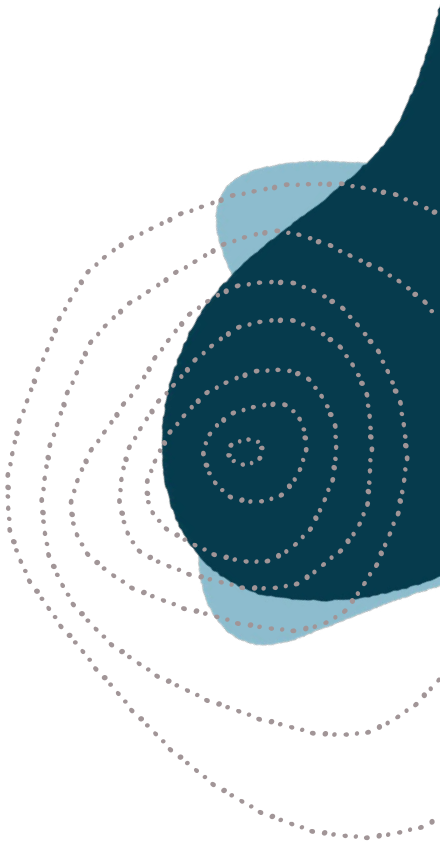
Help accelerate the development and launch of new drugs and therapies, and monitor their safety, with Oracle life sciences applications.

- **Oracle's clinical study startup solutions** streamline clinical trial study planning, initiation, site identification, and activation to get needed therapies to patients sooner.
- **Oracle's Siebel Clinical Trial Management System (CTMS)** manages clinical trial operational planning, startup, conduct, and closure. That includes tracking patient enrollment, managing study sites, monitoring budgets, ensuring regulatory compliance, and facilitating data management and reporting.
- **Oracle Health Sciences Clinical One Randomization and Trial Supplies Management (RTSM)** supports complex study designs. It lets pharmas and contract research organizations set study timelines, quickly respond to protocol changes, and better control trials.
- **Oracle Argus safety case management** supports pharma companies' drug safety requirements by helping collect, report, and analyze adverse events. It covers medications, vaccines, and medical devices.

Run genomics applications and clinical development on Oracle Cloud Infrastructure

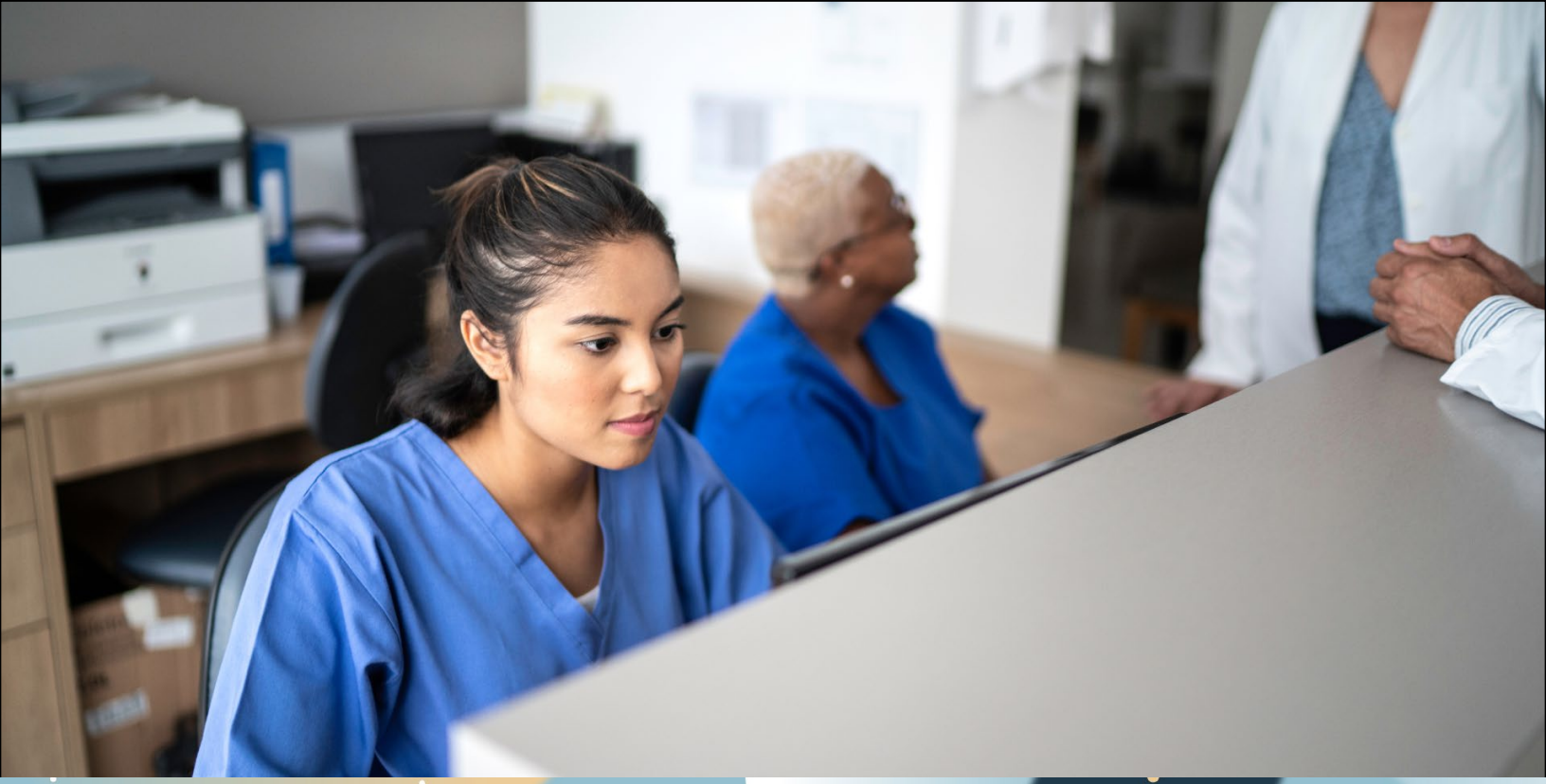
- **Oracle Cloud Infrastructure (OCI)** can support drug development workflows with high performance computing, data science tools, and built-in security features. OCI helps life sciences companies collect and integrate data enterprisewide for clinical research, as well as run molecular dynamics and genomic simulations quickly and at scale.
- **OCI Generative AI Service** lets organizations run large language models and includes tools for managing dedicated GPU clusters.

OCI Compute bare metal and virtual machine instances, powered by **NVIDIA GPUs**, let life sciences companies accelerate simulation software for drug research and discovery. NVIDIA Parabricks software running on OCI turns genetic sequence files into compressed binary alignment map (BAM) files and variant call format (VCF) files that compare particular genomes to a reference genome.



Manage complex supply chains and financial reporting with Oracle Cloud Applications

- **Oracle Fusion Cloud Supply Chain & Manufacturing (SCM)** helps life sciences companies make better decisions with a planning model that allows for uninterrupted delivery of medications. Better understand the relationships between supplier risk, patient demand, and potential supply chain disruptions, and manage outsourced manufacturing and complex global supply chains to get drugs and devices to patients faster.
- **Oracle Fusion Cloud Enterprise Resource Planning** applications contain modules for supply chain management and financial reporting that can help pharmaceutical companies, biotechs, and clinical research organizations coordinate increasingly complex supply chains and stay regulatory compliant. Drive accurate plans across finance and lines of business, analyze profitability, and improve operational decision-making.
- **Oracle Fusion Cloud Financials**, part of the Oracle Cloud ERP suite, helps life sciences companies consolidate financial data from complex product mixes and transactions conducted worldwide to help make better decisions. Oracle can also help life sciences companies address the FDA's GxP good practice guidelines for computerized systems used in clinical trials.



Oracle Life Sciences: Get drugs, devices, and therapies to market faster

Oracle Cloud applications and infrastructure are helping pharma companies and biotechs accelerate drug development, improve clinical trials, track drugs' safety, enhance their effectiveness, and ultimately improve health outcomes.

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