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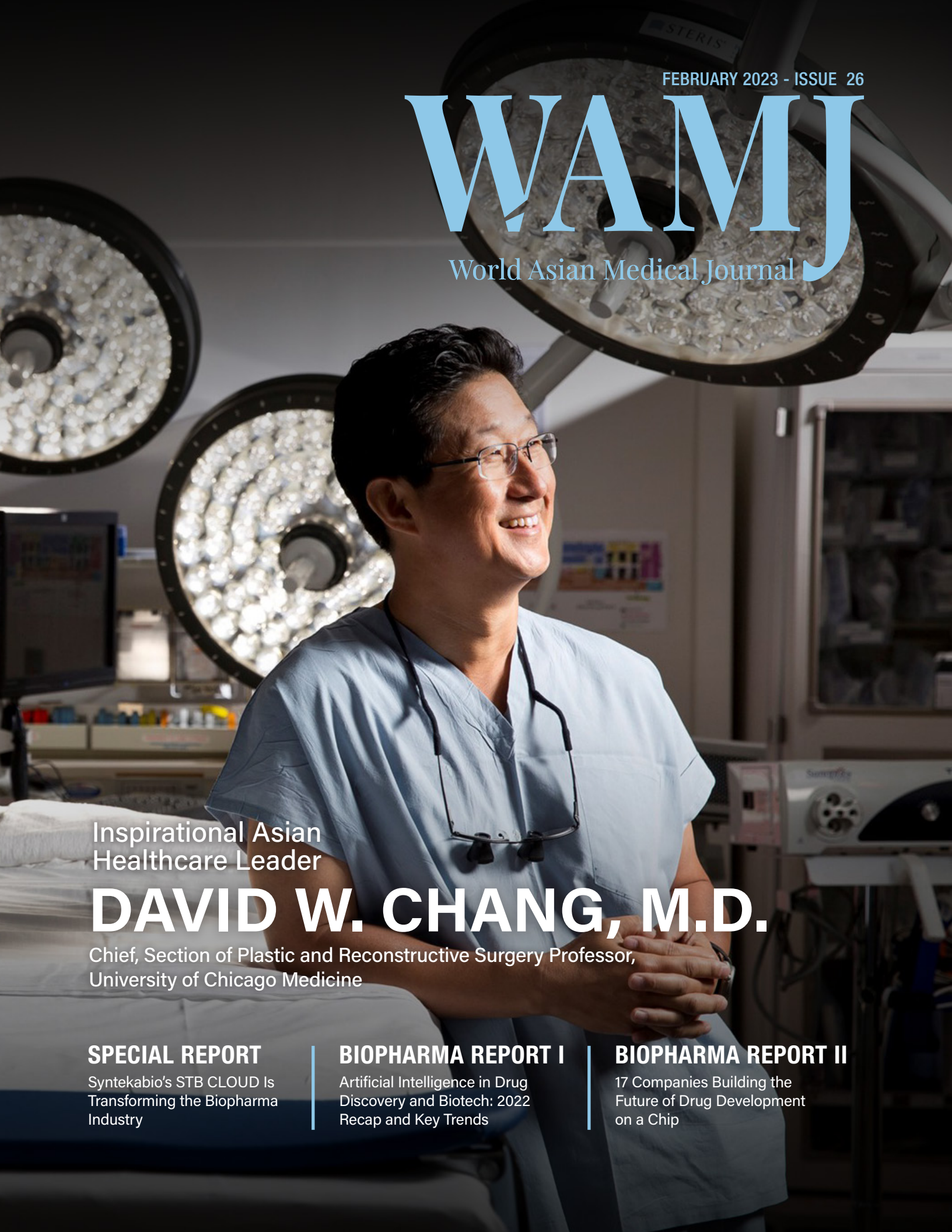
World Asian Medical Journal



Inspirational Asian Healthcare Leader

DAVID W. CHANG, M.D.

Chief, Section of Plastic and Reconstructive Surgery Professor, University of Chicago Medicine

SPECIAL REPORT

Syntekabio's STB CLOUD Is Transforming the Biopharma Industry

BIOPHARMA REPORT I

Artificial Intelligence in Drug Discovery and Biotech: 2022 Recap and Key Trends

BIOPHARMA REPORT II

17 Companies Building the Future of Drug Development on a Chip

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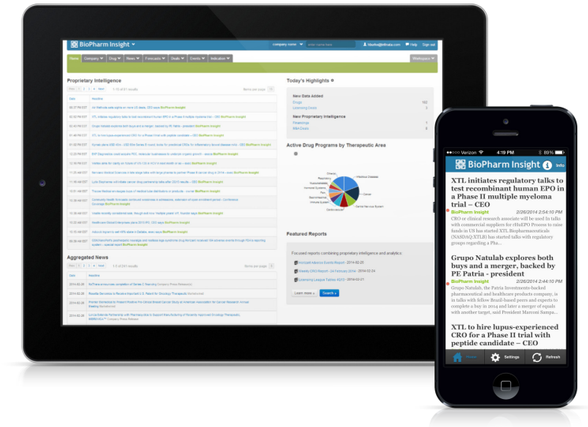

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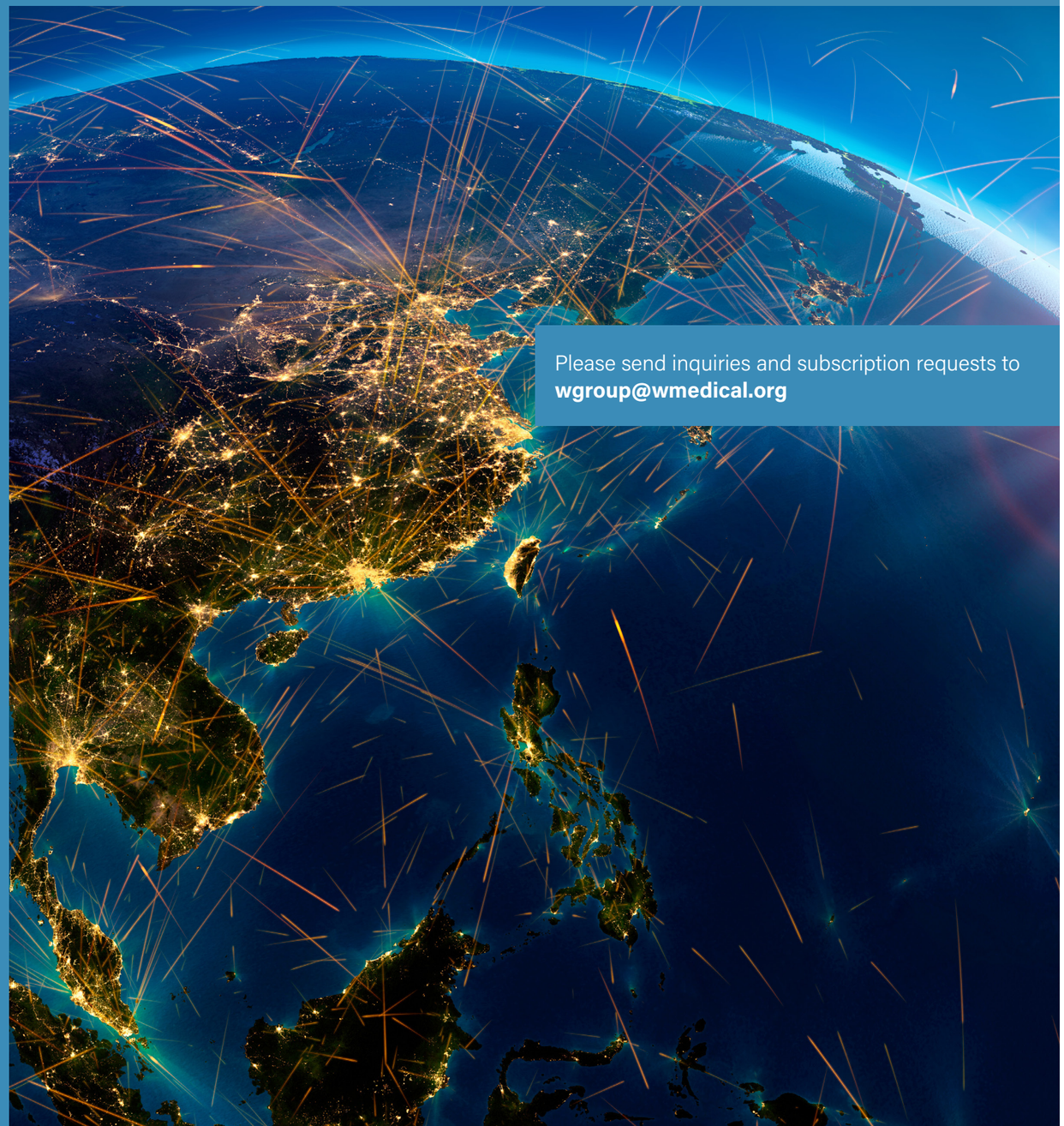
World Asian Medical Journal



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Cover Story

Inspirational Asian Healthcare Leader
David W. Chang, M.D., F.A.C.S., Chief, Section of Plastic and Reconstructive Surgery Professor, University of Chicago Medicine

Special Report

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Biopharma Report

Artificial Intelligence in Drug Discovery and Biotech: 2022 Recap and Key Trends

17 Companies Building the Future of Drug Development on a Chip

From the Publisher

For the current issue of World Asian Medical Journal (WAMJ), I'm excited to share our cover story about Dr. David Chang, a leading expert in the field of reconstructive surgery and a true innovator in the treatment of lymphedema. As you may already know, lymphedema is a chronic condition that results in the swelling of body parts, particularly the limbs, due to a buildup of lymphatic fluid. It's a painful and debilitating disease he understands well and has valuable insights for our readers.

Dr. Chang's passion for his work and dedication to improving the lives of his patients knows no bounds. During the interview, he spoke about how he managed to develop microsurgical techniques for the treatment of lymphedema despite many difficult challenges emphasizing the importance of early diagnosis and treatment, and the role of multidisciplinary care in achieving the best outcomes for patients.

We believe that this interview with Dr. Chang provides valuable insights into the challenges and opportunities in the field of reconstructive surgery and lymphedema treatment. We are proud to have had the opportunity to speak with such a knowledgeable and dedicated expert and to share his insights with our readers.

In the February issue, we focus on the bio-health industry's new trends, including insightful POVs published by BiopharmaTrend.com, a specialized digital hub for news, articles, business intelligence and market research in the pharmaceutical, biotechnology and healthcare technology industries. We're delighted to welcome BiophamaTrend as our content partner and invite our readers to explore emerging topics and opportunities in life sciences with us.

Thank you for your continued support for World Asian Medical Journal.

DoHyun Cho, PhD
Publisher
President & CEO of W Medical Strategy Group
Chairman of New York Health Forum

From the Editor-in-Chief

This month's cover story features David Chang, MD, a reconstructive surgeon at the University of Chicago and a pioneer in lymphedema microsurgery. An immigrant to the United States at age 12, Dr. Chang decided early on that, to reach his goal of helping others, medicine was the most attractive road. In medical school, he discovered the joys of surgery, with its quite literal hands-on approach to "fixing things." When during his general surgery residency, he realized that plastic surgery offered much more than purely aesthetic procedures, he found his niche, and has been enthusiastically pursuing it ever since.

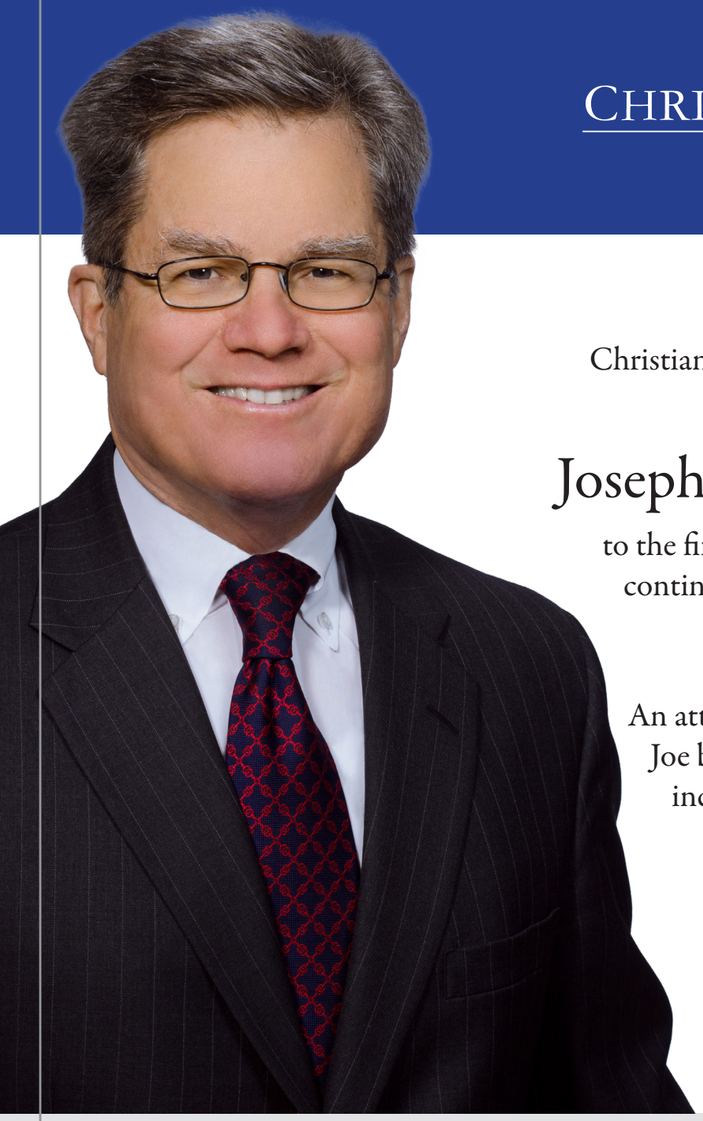
Dr. Chang teaches that lymphedema afflicts far more patients than most of us realize--an estimated 250 million people worldwide. Here in the US and in many other nations in the temperate zones, the cause is often cancer, and more specifically cancer surgery, which often entails removal of lymph nodes and thus disruption of the pathways for lymphatic drainage. The technical challenges in operating on lymph vessels are enormous: these structures are both tiny (as small as 0.2 mm in diameter) and transparent, requiring microscopes to see. But mastery of these techniques paves the way for transplantation of tissue of substantially every kind, and with it the reconstruction of almost any structure.

Following surgery for lymphedema, distortions in patients' anatomy are corrected. Although complete restoration of pre-morbid anatomy may not be possible, patients can once again wear rings, watches, normal clothing, and so forth, just as they could pre-operatively. Even more important, lymphedema-associated inflammation, pain, and susceptibility to infection abate substantially, reducing morbidity and mortality

If as a young boy Dr. Chang wanted to help people, he has achieved his goal.

We hope you enjoy Dr. Chang's interview, and all our other stories in this issue.

Joseph P. McMenamin, MD, JD, FCLM
Editor in Chief
EVP of W Medical Strategy Group



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Christian & Barton, LLP is pleased to welcome WAMJ's Editor-in-Chief

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to the firm's Health Law Group where he will continue his practice focused on health law, telehealth and AI in health care.

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WAMJ Recap of the Last Issue

COVER STORY

Eul-Sik Yoon, M.D., Ph.D., chairman and board of director at the Korean Society of Plastic and Reconstructive Surgeons

Dr. Eul-Sik Yoon is a highly esteemed plastic and reconstructive surgeon with more than 35 years of surgical practice. His list of accolades and titles is just as long as his celebrated career. With his unparalleled skills achieved through his years of training, he has successfully performed numerous plastic and reconstructive surgeries. He proves to be an inspirational healthcare leader, serving as president of Korea University Anam Hospital, and as a distinguished member of the International Plastic Reconstructive Surgery (IP), Plastic Surgery Research Council (PSRC), American Society of Plastic Surgery (ASPS), Korean Medical Association, Korean Association of Microsurgery Association, Korean Association of Aesthetic Plastic Surgery, and the Korean Association of Plastic and Reconstructive Surgeons. He has also worked internationally as an associate professor and visiting laboratory researcher of Tissue Engineering and Regenerative Medicine at the University of California, Irvine. Our dynamic interview with Dr. Yoon is WAMJ's cover story for issue 25.

SPECIAL REPORT II

Latest Update for Surgical Treatment of Lymphedema

Lymphedema requires a systematic approach from diagnosis to surgery to rehabilitation due to the nature of the disease. Korea's medical system is highly competent and experienced, possessing the wide ranging skills and facilities to treat lymphedema. Korean plastic surgeons are well known for their microsurgery skills, consistently showing highly satisfactory outcomes. To learn more, refer to the full article published in issue 25.

BIOPHARMA REPORT I

Innovative Value-Based Price Programs Back in the Spotlight

Value-based plans are emerging as particularly attractive coverage options for therapies that become available after an FDA accelerated approval. The smaller amount of evidence that underscores such an approval provides an impetus to attempt alternative payment models. "Value-based arrangements can help manage high-risk categories where there is an uncertainty about the economic impact. However, they need to be used selectively such that they reach patients in an effective way", said Ed Schoonveld, managing principle of Value & Access, ZS Associates. A detailed insight provided by Manasi Vaidya is featured in issue 25.

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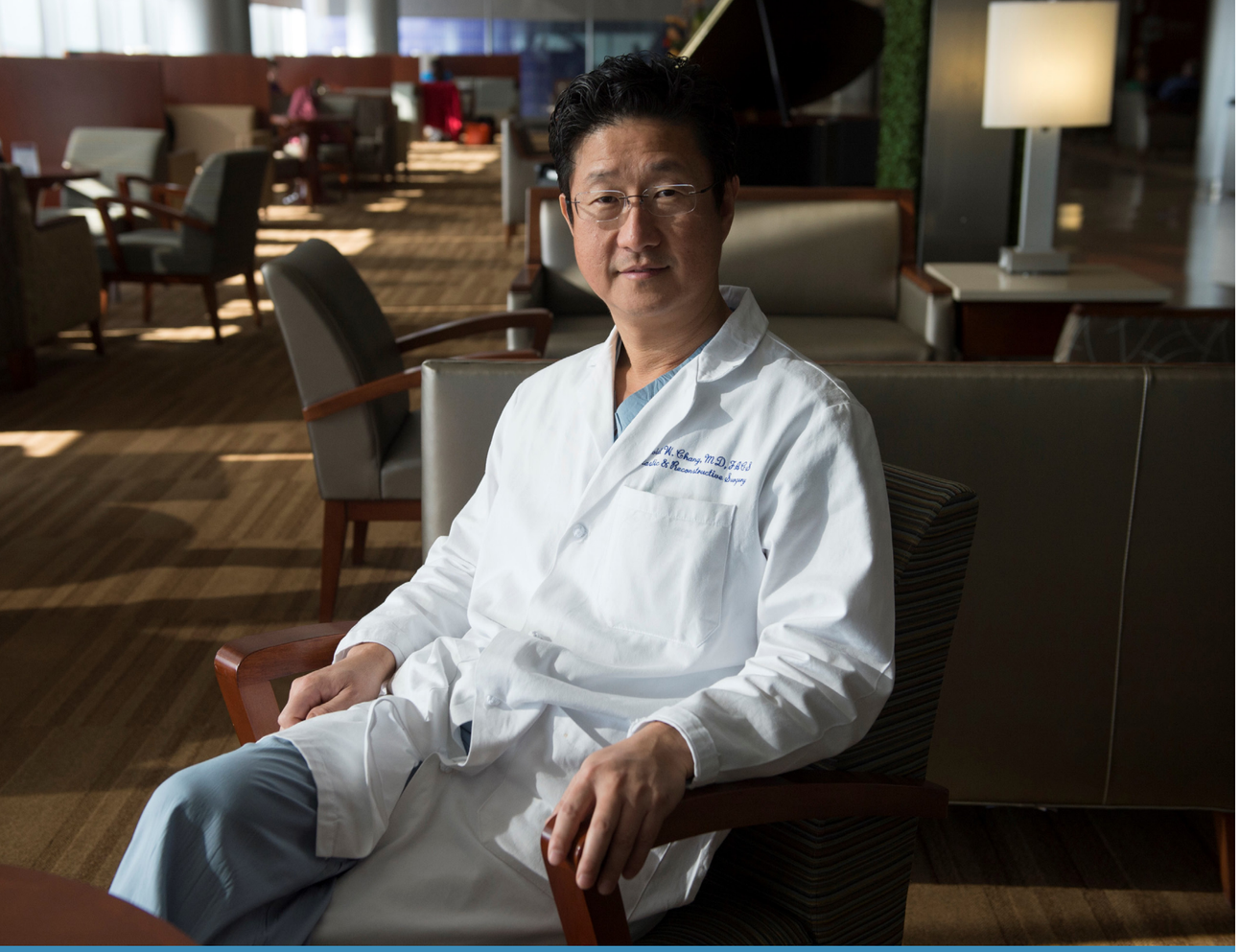

COVER STORY

Inspirational Asian Healthcare Leader

David W. Chang, M.D.

Chief, Section of Plastic and Reconstructive Surgery Professor, University of Chicago Medicine

1. As a world-renowned plastic and reconstructive surgeon, can you reflect on your reasons and motivations that pushed you to apply to medical school and pursue a career in medicine? After entering med school, was there a pivotal moment in your education or training that cemented your decision to specialize in plastic surgery?

This may sound like a cliché, but I wanted to have a career helping others. After my family and I immigrated to the US when I was 12, I thought about becoming a physician, specifically a medical missionary.

I wanted to be a surgeon but was not sure what kind. During GS [general surgery] residency, I became exposed to PS [plastic surgery] and how PS reconstructed patients, and then I knew right away that is what I wanted to do. I was intrigued by PS because many people view plastic surgery as simple cosmetic alterations, but in fact it requires imagination for problem solving, repairing things, and reconstructing defects to restore patients' function and appearance. Every case is unique and different, and we work all over the body from head to toe. I liked the variety in PS and how it was not limited to one particular anatomic area. I also found it incredibly fun to repair and solve problems for patients and for our physicians as well. So, after the GS residency, I did PS residency and then a fellowship in Microsurgery.

2. How common is lymphedema, and what problems does it cause patients? As a pioneer in lymphedema microsurgery, can you explain in more detail the innovative procedures you helped in developing and promoting such as lymphovenous bypass and vascularized lymph node transfers? Why are these surgical procedures so complex and important and in what way do they significantly improve the quality of life for lymphedema patients?

Lymphedema is more common than people realize. Over 250 million people worldwide suffer from it. Common causes are parasites/cancer/congenital. Lymphedema causes pain, discomfort, infection, an inability to wear proper clothes, and physical

disfigurement. It can have a significant impact on quality of life as it can interfere with work, social and daily personal activities.

Lymphovenous bypass (LVB) is a procedure in which an obstructed or damaged lymphatic system is diverted to an open venous system, allowing trapped lymphatic fluid to be drained. VLNT [vascularized lymph node transfer] is transplanting a patient's own healthy, functioning lymph nodes to a site of lymphedema to promote generation of new lymphatic vessels to reestablish lymphatic function.

Lymphatic vessels are very small, usually much smaller than 1 mm. So, they are very difficult to identify and then suture together, even under the microscope. Compared to other systems in our body, the lymphatic anatomy and physiology have not been well studied and understood.

The procedures we perform do not cure lymphedema, but have been shown to help reduce the severity of the lymphedema, reduce the incidence of infection, and improve quality of life for the patients. Also, they help reduce the progression of lymphedema, an important benefit, as the natural history of lymphedema is that it usually becomes worse over time.

3. As an innovator in various areas of plastic surgery such as breast reconstruction and microsurgical treatment of lymphedema, what are some of the current major innovations and growing trends in reconstructive surgery? How do you see the field of reconstructive surgery advancing in the next few years and what are some changes in practice you would like to see happen?

The utilization of microsurgery for cancer reconstruction has become standard world-wide, so it's no longer limited to only a few selected centers. It is a tool that allows us to reconstruct almost any defect, anywhere in the body, whether it be soft tissue, bone, nerve, or lymphatics. In addition, these advances in reconstruction allow our oncologic surgeons to perform more definitive ablative surgery, facilitating chemotherapy and radiation therapy which can perhaps lead to better survival of these patients.

And our approach to reconstruction continues to improve, with creation of more innovative techniques, the incorporation of new technology, and a better understanding of our bodies. Rather than just reconstructing the defect, there's growing emphasis on better functional restoration and better aesthetic outcomes.

This field is already evolving rapidly with incorporation of new and state-of-the-art technology. For example, we are now incorporating advanced imaging systems to help plan for safer and more efficient surgery. We also have better equipment and instruments, including robotics to facilitate surgery. We have already seen advances in face and hand transplants, and this progress will expand to other parts of the body. We will see advances in tissue engineering that will allow us to grow various tissues which we can use for reconstruction. I envision advances in robotics and AI that may alter how we do reconstructive surgery. The future of reconstructive surgery is very exciting and we will be on the forefront of these new innovations.

4. Given the complexity of cancer reconstructive surgery, can you describe the process of coming up with personalized treatment plans for a diverse set of cancer patients? How do you work with each patient to develop the optimal reconstructive surgical plan for her particular needs and are there any personal philosophies and principles that you incorporate into your patient care?

Every patient is different. Each has a different body type and shape, and different medical conditions, lifestyle, expectations etc. Thus, it is critical that in offering reconstructive options we customize our approach to meet each patient's needs. One size does not fit all. Foremost, communication and patient education is critical. Patients need to know what the options are, what the pros and cons of each option are, what to expect after the surgery, so that they can make educated, informed decisions about the type of reconstruction to accept. Also, their expectations of what the surgery will be like and what types of outcomes they can expect are very important. In most cases, patients may have several options, so they need to make the decision that is best for them.

5. Having published more than 175 peer-reviewed research articles and serving as a principal investigator on several clinical research studies, can you describe some of your key research projects and their findings? How important has research been in your career and why do you find it important in the field of reconstructive surgery? How do you find the right balance between patient care and research?

I have been fortunate to work in leading academic centers such as at the MD Anderson Cancer Center and now at the University of Chicago. And it is exciting that I have had opportunities to do research to advance our field. Research is essential in making improvements and coming up with new, better ideas that can help our patients. Research is not only done within the lab setting but also in the clinical setting. We can critically evaluate our data outcomes to evaluate which approach works best. We need to continue to make investments in research that can lead to innovations and advances in caring for our patients. We cannot improve, innovate, and advance without research.

I am currently conducting an NIH clinical trial that is studying a new collagen-based medical device that is inserted under the skin during a lymph node transplant. It acts as a scaffold to promote the growth of lymph nodes. It's an ongoing study that will require another 3-4 years for outcomes.

Finding balance between patient care and research does not need to be difficult because, for clinical research, they compliment each other. For example, critically analyzing outcomes data from our own patient care is essential for us to continue to find ways to provide better and improved patient care. Also, it is critical that we collaborate with experts from other areas to work as a team to do research. In my mind, research can be done most effectively when we collaborate with others.

6. Can you explain to our readers what microsurgery entails and why it is important in the field of plastic and reconstructive surgery?

In microsurgery, surgeons use microscopes to operate on small structures that are difficult to see and manipulate because they are so tiny, such as little blood vessels, nerves, and lymphatics. A common application of microsurgery is transplantation of tissues. Large organs such as the kidney, liver and

heart have larger vessels, so microscopes are not necessary. Other tissues, however, such as muscle, skin, fat, bone etc. have blood vessels that are 1-2 mm or even smaller and require the use of a microscope. Microsurgery is a very useful tool that allows surgeons to transplant virtually any type of tissue from a patient's own body to another location of defect or damage, allowing reconstruction and restoration of virtually any defects, whether caused by such factors as cancer resection, or trauma, or in even in cases of congenital defects. These transplants can be done anywhere in the body: the scalp, nose, jaw, tongue, throat, breasts, arms, hand, genitals, legs, etc.

7. What are some final remarks and advice you would like to leave for aspiring physicians and plastic surgeons? Are there any key characteristics/qualities that you believe all medical professionals should possess or activities that all should engage in?

In one word, passion. You need to love what you do. It is hard work, and the training is long and rigorous. But if you love what you do and if you are passionate about your work, then it is not work. I am very grateful that I found a profession that I love. It continues to be a huge privilege and a joy to help reconstruct patients' lives for better.

David W. Chang, M.D., F.A.C.S.

Chief, Section of Plastic and Reconstructive Surgery Professor, University of Chicago Medicine

David W. Chang, MD, specializes in complex microsurgical reconstructive surgery in cancer patients, and has an international reputation as a pioneer and an innovator in the field of breast reconstruction, head and neck reconstruction, extremity reconstruction and microsurgical treatment of lymphedema. Dr. Chang has published more than 175 peer-reviewed research articles in high-impact journals as well as numerous book chapters. Dr. Chang is the Chief of Plastic Surgery and the program director of the prestigious UChicago Medicine Microsurgery Fellowship. He previously served as the president of the American Society for Reconstructive Microsurgery and the vice president of the World Society for Reconstructive Microsurgery.

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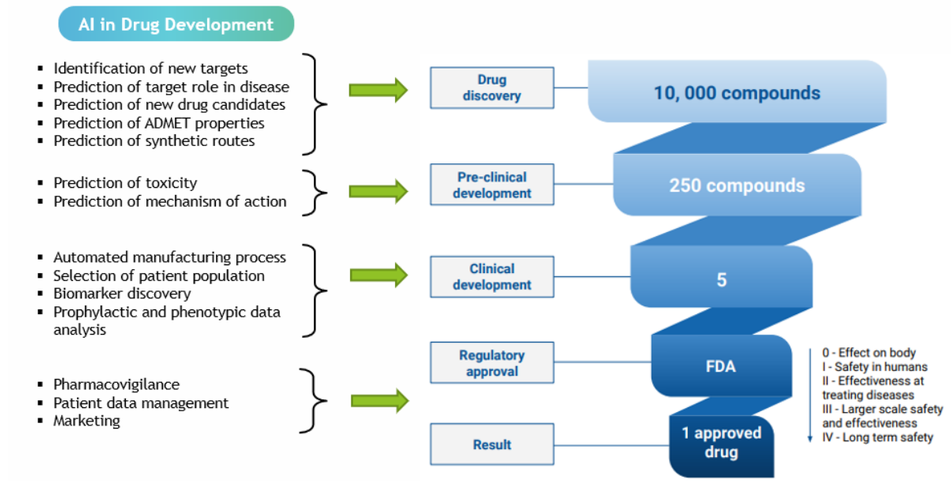
Syntekabio's STB CLOUD is Transforming the Biopharma Industry

BY **SABINA LEE**

BiopharmaTrend.com, one of the top 10 biopharma online news sites, published a timely interview with Syntekabio CEO Jongson Jung about the state of artificial intelligence (AI) in drug discovery and development on Jan. 17, 2023. The full article is available on the BiopharmaTrend site.

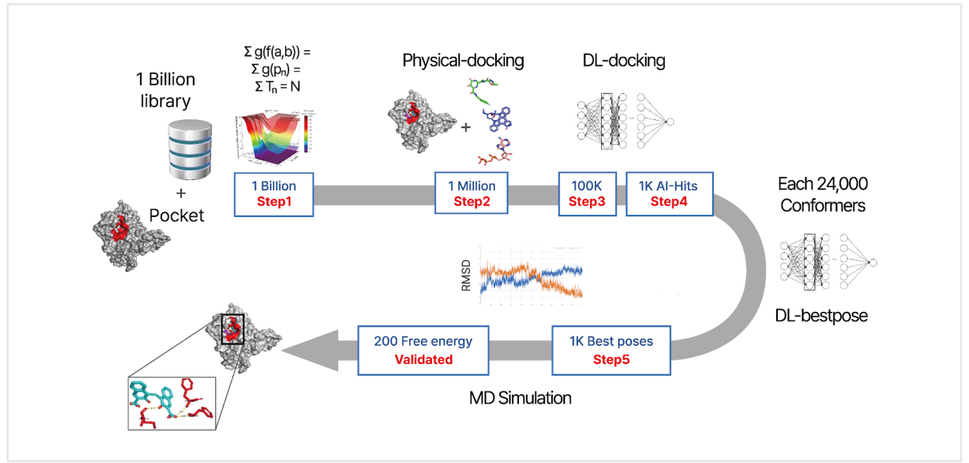
The drug discovery market has been on an exponential growth trajectory. The expected market value is poised to reach 71 billion U.S. dollars by 2025. Korean companies are on the beat to discover new drugs, fiercely competing to capture their market share in this colossal global market. Prioritization of AI in R&D is expected to produce a fully AI-based preclinical candidate in 2023.

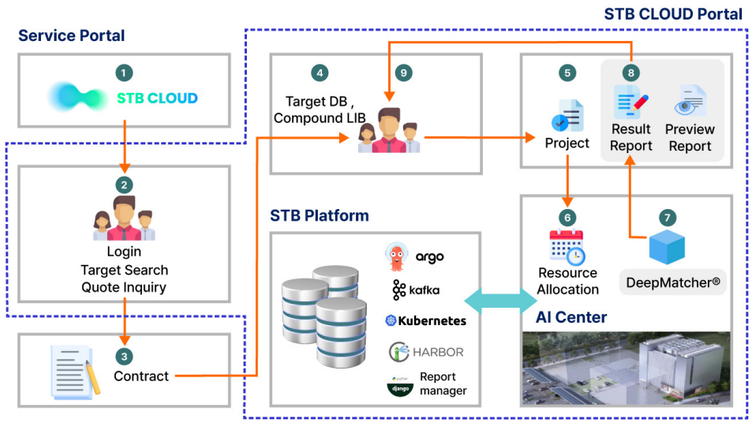
CEO Jongsun Jung stands by Syntekabio's company mission



Syntekabio (226330:KS) is the only AI drug discovery biotech company listed on KOSDAQ among 645 artificial intelligence startups in South Korea. The company revealed its latest AI drug development platform STB CLOUD following the 2022 launch of its U.S. operations based in New York. Enabling systematic small molecule and biomarker discovery, it's creating a buzz in the competitive drug discovery industry by cutting through vast swaths of data to speed the discovery and development of new drugs.

Since its founding in 2009, Syntekabio has built advanced AI drug discovery technology, supercomputing infrastructure and genomic big database. Using deep learning algorithms, Syntekabio developed a proprietary small molecule drug discovery technology called DeepMatcher®. It applies advanced data parsing algorithms with its own database to provide new drug candidates with high probability of success rate.





By integrating DeepMatcher®—Syntekabio's patented AI-driven small molecule drug discovery technology—STB CLOUD has automated AI computing function within its own supercomputing hardware environment and database into a single cloud system. Delivering standardization, simplification and automation of the existing computer-aided drug discovery (CADD) process, STB CLOUD optimizes the drug discovery and development process far better in terms of time, cost, accuracy and resources to accelerate drug development feasibility and accurate prediction of drug candidates.

Syntekabio's CEO Jongsun Jung, Ph.D., a biochemical computational scientist with extensive academic and industrial experience, has been instrumental in evolving Syntekabio's big genome data analysis technology. According to Jung, STB CLOUD can give clinical stage pharmaceutical companies with limited drug discovery capability an ideal solution for fully automatic drug discovery. It creates their market advantage by increasing their asset from new pipeline projects for predicted drug candidates.

From bench to bedside, AI has transformed the industry beyond recognition. AI is at the center of rational drug design. It can discover and predict effective and safe drug candidates and assist in decision making to determine the right development pathway, including personalized medicine discovery.

Syntekabio welcomes opportunities to join hands with other biotech companies and institutes interested in the initiation of new drug pipelines. The future of innovation is bright for Syntekabio.

Sabina Lee, M.A.

Senior Consultant, W Medical Strategy Group

Building on her international experience, she helps clients navigate complex issues management and cross-cultural PR and marcomms in the global environments. She has worked with a range of clients in varied sectors, including high-profile institutions, government agencies and corporations in New York, Washington D.C., Beijing, Paris and Seoul. Sabina previously served as chief media strategist for the Pulitzer Prizes and senior public affairs officer for Cornell and Columbia Universities. A graduate of Pratt Institute in New York, she attended the Middlebury Institute of International Studies in California for her M.A. in International Policy and Development.

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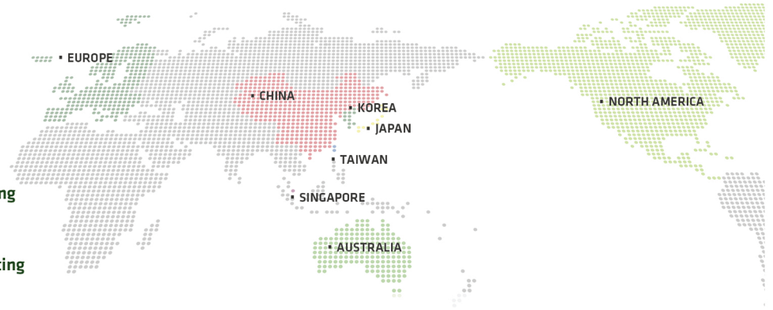

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Artificial Intelligence in Drug Discovery and Biotech: 2022 Recap and Key Trends

BY **ANDRII BUVAILO**

The advent of AI in drug discovery at a glance

The current advent of artificial intelligence (AI) is shaping the evolution of entire industries, including the pharmaceutical and biotech industries. Unsurprisingly, almost every large and small Life Science organization has shown keen interest in adopting AI-driven discovery platforms in the hope of streamlining R&D efforts, reducing discovery timelines and costs, and improving efficiency.

All of the largest pharmaceutical companies, such as J&J, GSK, AstraZeneca, Novartis, Pfizer, Sanofi, Eli Lilly, and others, have made significant investments in AI technology, including equity investments, acquisitions of, or partnerships with, AI-focused companies, building internal capabilities, or a combination of approaches.

At the same time, there is a wave of new kinds of drug discovery and biotech companies built as AI-centric organizations, often from day one. Having been founded, for the most part, within the last decade, such companies have already built and tested specialized AI-driven drug discovery platforms -- often including dozens of machine learning models -- and now are starting to reap the rewards in the form of fast and cost-effective target discovery and drug design capabilities, yielding preclinical and clinical drug candidates in a fast manner. Below we will be discussing a cohort of AI-developed drug candidates -- small molecules, biologics, and other modalities -- which have already entered clinical trials or are about to do so.

Other AI companies can model biology using complex multimodal data at scales not imaginable some twenty years ago. Yet another group of companies developed AI-driven platforms to boost operational efficiency and experiment design of clinical trials or real-world data analysis (e.g., pharmacovigilance).

Big-tech companies, such as Alphabet, Microsoft, Amazon, IBM, and Tencent, which have competency and expertise in AI and big data technologies, are also making a foray into the drug discovery space -- by investing, founding startups, partnering with life science companies, experimenting, innovating...

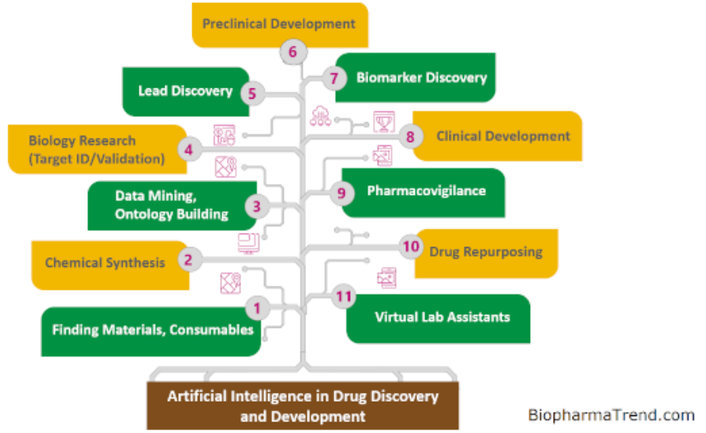
Finally, there is significant progress in other cutting-edge technologies -- quantum computing, Cryo-EM, DNA-encoded libraries, etc.-- which are converging with the artificial intelligence trend to output not only new types of tools, products, and services but also a wave of new startups and even novel business models.

What is AI, and how can it boost drug research?

Artificial intelligence is a relatively old concept, formalized at a famous Dartmouth College conference in 1956. The AI technologies in drug discovery have evolved from earlier machine learning (ML), cheminformatics, and bioinformatics concepts and approaches. For example, the application of machine learning to developing quantitative structure-activity relationship (QSAR) models and expert systems for toxicity prediction has a long history.

However, the rapid (in some cases -- "exponential") advent of big data, advanced analytics, minimizing the cost of computation, GPU acceleration, cloud computing, algorithm development (e.g., deep neural nets and large language models), and the "democratization" of AI technology -- all led to a synergistic "boom" in commercializing and industrializing artificial intelligence, in particular, in the pharmaceutical and biotech industries.

In this white paper, we use the collective term "artificial intelligence" to refer to any sophisticated computational and modeling systems which can



automatically learn insights and derive practical suggestions from "big data," structured and unstructured data, also multimodal data.

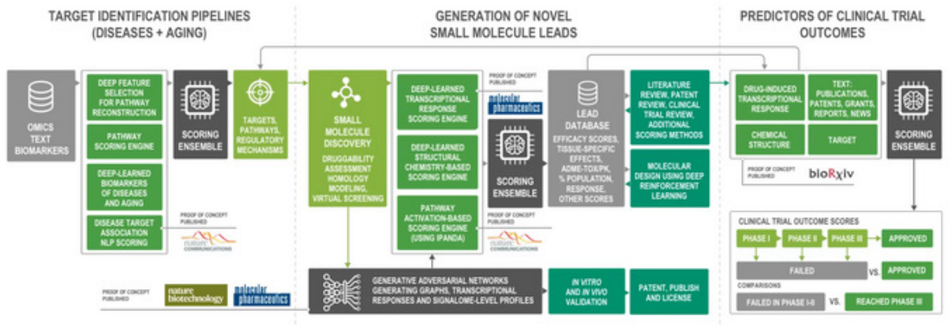
While there is no limit to a particular family of algorithms that we refer to as "artificial intelligence," we, in most cases, imply various flavors of machine learning-based systems (primarily deep neural networks) and large natural language processing (NLP) models. Modern AI systems can learn without being explicitly instructed (in contrast to traditional cheminformatics software within "if-then" logic), they can improve accuracy after new learning cycles and when more data is fed to the system, and -- most notably -- they can process high dimensionality multimodal data of enormous size. All such attributes are what significantly differentiate modern-day artificial intelligence systems from legacy cheminformatics and bioinformatics software packages. Such abilities are at the center of what drives the ongoing excitement about AI (and hype).

While some components of what we call "artificial intelligence" -- e.g., machine learning tools and language models -- are used by pretty much every pharmaceutical organization and academic lab, some companies managed to build sophisticated computational and modeling pipelines, research "AI platforms," which include automated workflows across dozens and even hundreds of various models and systems (deep learning, language models), and hundreds of various public and proprietary data sources.

The high sophistication and automation of some AI platforms led to their "commoditization" to the point they have trademarked commercial names. At the same time, some of them are offered as software-as-a-service to other companies. Examples include mRNA DESIGN STUDIO™ by Moderna, Centaur Chemist® by Exscientia, Guardian Angel™ by AI Therapeutics, ConVERGE™ by Verge Genomics, Taxonomy3® by C4X Discovery, and many others.

Below is an example of Pharma.AI by Insilico Medicine, a modular system for end-to-end drug discovery that comprises hundreds of different sub-systems and machine learning models -- altogether controlled by yet other algorithms of higher modeling abstraction (via a principle of "ensemble learning").

Artificial intelligence is widely used in almost every aspect of pharmaceutical research, from data mining, biology modeling, and target discovery to lead identification and preclinical and clinical research. It is also used for synthesis planning,



A scheme of Pharma.AI end-to-end platform.

intelligent search for reagents and research consumables, and auxiliary tasks such as smart laboratory notebooks and virtual assistants.

The Life Science ecosystem of AI adopters includes the following major categories of players:

400+ AI-driven companies (startups/scaleups), offering a wide array of AI-driven platforms and services -- from classical Software as a Service model to custom data science services, drug discovery ("Drug candidate-as as service"), and clinical trial support/management resources.

Domain-specific software providers (e.g., KNIME, ChemAxon, Dotmatics, MolSoft, and others) primarily focus on cheminformatics/bioinformatics software but also provide machine learning-powered tools.

Top-tier pharmaceutical and biotech companies developing in-house AI expertise as part of their R&D strategy. Such players often collaborate with external AI vendors and AI-driven biotech startups to explore pilot programs in drug discovery/basic biology/clinical trial analytics.

Top-tier technology companies like Google, Amazon, and Tencent entering the pharmaceutical space, leveraging cutting-edge AI technologies and big data infrastructures.

Contract research organizations (CROs) developing expertise in AI to augment their value offering to pharma/biotech customers.

Academic labs in pharma/biotech space, conducting AI research and developing specialized frameworks and tools relevant to the industry (usually a cradle for future AI startups/spin-outs).

Non-domain-specific software providers developing AI-as-a-service packages and models suitable for application in pharmaceutical research (e.g., "out of the box AI").

Open-source machine learning tools and frameworks, widely exploited by life science professionals in their research projects.

AI drug discovery investment landscape, 2022

After 2021, the anomalously successful year for the biotech industry in terms of the amount of venture capital deals, the record number of initial public offerings, an abundance of successful exits, and a generally very positive climate in the stock market, the year 2022 demonstrated significant cooling down of financial activity and outright poor performance of the stock market.

However, artificial intelligence in the drug discovery sector demonstrated certain resilience, at least in the private equity transactions landscape, with several companies raising hundreds of millions in venture capital. Some examples include Beijing-based MegaRobo Technologies ($300 million Series C), Massachusetts-based ConcertAI ($150 million Series C) and Celsius Therapeutics ($83 million Series A), Hong Kong-based Insilico Medicine ($95 million Series D), California-based BigHat Biosciences ($75 million Series B) and DeepCell ($73 million Series B), and several others -- read "Major VC Rounds For AI Companies in Drug Discovery and Biotech in 2022".

A merger and acquisition (M&A) landscape was marked by a recent notable deal involving a biotech giant Ginkgo Bioworks acquiring Zymergen in a transaction valuing Zymergen at $300 million. The acquisition brings Zymergen's machine learning and data science capabilities together with Ginkgo's synthetic biology platform.

Key industry observations and trends

The advent of AI and data technologies, as well as novel computational tools and infrastructural solutions (databases, cloud services, etc.), are all redefining the way the pharmaceutical industry is operating -- on research, clinical, and business levels. Below let us review some of the trends and observations in the AI for drug discovery space and illustrative industry developments in 2022.

AI-enabled biology modeling and target discovery

In drug discovery research, identifying novel drug targets is critical for developing novel first-in-class therapeutic drugs -- potential "blockbusters." Drug discovery efforts over several past decades centered, traditionally, around targeting specific proteins with suitable "pockets" to be influenced by a ligand molecule (often, a small molecule). But out of the entirety of all human proteins (aka "proteome"), a small number of proteins were explored as targets. There are currently 20,360 human proteins in Swiss-Prot, of which approximately 4,600 are known to be involved in disease mechanisms according to the OMIM database, representing around 22% of human proteins with roles in disease. These proteins are the obvious region of the human proteome likely to contain viable drug targets. However, as of 2017, only around 890 human and pathogen-derived biomolecules (mostly proteins) were actually utilized by the existing FDA-approved drugs. These biomolecules included 667 human-genome-derived proteins targeted by drugs for human disease. Things are not much different today, so there is still a lot of room for identifying novel targets in this pool. Novel computational approaches based on artificial intelligence technologies allow for identifying new druggable protein pockets at scale, sometimes allowing for proteome-wide virtual screens.

But what is even more exciting, advanced modeling tools help identify and modulate novel types of targets, such as protein-protein interactions, targets with large contact areas, protein-nucleic acid interactions, and next-generation targets, such as exploiting the cell's protein degradation machinery.

A lot of AI-driven companies are focused on modeling biology, discovering and validating novel targets and offering "disease model-as-a-service" or "target-discovery-as-a-service" to other organizations. Demand for this kind of contract research services is rising which is reflected in the growing number of target discovery partnerships.

For example, in September 2022, an Israeli-based biology modeling company CytoReason announced an expanded $110 million collaboration with Pfizer. The two companies started working together in 2019 when Pfizer started using CytoReason's biological models in research aimed at developing new drugs for immune-mediated diseases and cancer immunotherapies.

In May 2022, AstraZeneca announced that it collected a second pulmonary fibrosis target from its collaboration with BenevolentAI, a UK-based leader in AI-driven drug discovery. The milestone marked a third novel target discovered by BenevolentAI for AstraZeneca since the collaboration started in 2019. Just several months later, in October 2022, BenevolentAI managed to deliver two additional AI-generated targets for AstraZeneca's R&D portfolio, aimed at chronic kidney disease and idiopathic pulmonary fibrosis.

In November 2022, Hong Kong-based Insilico Medicine signed a potentially $1.2 billion-worth deal with Sanofi for discovering up to six new targets leveraging Insilico Medicine's "Pharma.AI" platform.

While such cutting-edge algorithms as deep neural networks require large volumes of data to properly model biology, there are targets with a little amount of data available. A Canada-based Cyclica developed an AI-driven platform for polypharmacology and proteome-wide screening, capable of working with "low-data" targets. In November 2022, Cyclica received a $1.8 million grant from Bill & Melinda Gates Foundation to apply its AI-enabled drug discovery platform to discover new non-hormonal contracts, leveraging multiple low-data biological targets.

As per the BiopharmaTrend report, there are at least 182 other AI companies in the target discovery space, including leading well-funded companies with cutting-edge R&D platforms, such as Insitro, Relay Therapeutics, Valo Health, and others.

New "AI-native" startups are constantly emerging in the biology modeling space. For example, CardiaTec Biosciences, WhiteLab Genomics, Degron Therapeutics to name a few.

All in all, advanced modeling methods based on artificial intelligence help redefine the very definition of biological targets, as we try to link drug response to genetic variation, understand stratified clinical efficacy and safety, rationalize the differences between drugs in the same therapeutic class and predict drug utility in patient subgroups.

Cracking structural biology with AI

One of the most discussed AI-related topics in the Life Sciences community this year was the recent success of Alphabet's UK-based subsidiary DeepMind, which received widespread coverage for its success in cracking protein folding problem, a half-century-old biological problem.

In July 2022, DeepMind's deep learning software AlphaFold predicted and publicly shared protein structures of over 200 million proteins, having demonstrated the astonishing ability of its AI system to accurately predict 3D structures just from its 1D amino acid sequence. While some argue that this discovery may not (just yet) have such a transformative role in drug discovery as one may assume, and that AlphaFold did not perform much better than chance when predicting bacterial protein-antibacterial compound interactions, the discovery is certainly paradigm-changing for both structural biology and illustrating the potential of AI in basic biology research.

In November 2022, DeepMind's groundbreaking success in modeling the proteome was rivaled by researchers at Meta (formerly Facebook, headquartered in Menlo Park, California). It used AI to predict the structures of some 600 million proteins from bacteria, viruses, and other microorganisms that haven't been characterized.

The scientists at Meta used an entirely different AI approach -- using a 'large language model', a type of AI that can predict text from just a few letters or words. Natural language models (NLPs) are usually trained on large volumes of text. However, 1D protein sequences are essentially strings of letters, so NLPs can be applied to such problems similarly to working with human languages.

Interestingly, such major technological leaps in protein folding might turn out to be more useful for de novo protein design, than simply modeling structures of existing proteins for drug discovery. Time will tell where the impact will be the biggest, but the above successes by DeepMind and Meta are not the only exciting development for structural biologists in 2022.

Recently, the rapid advancements in cryo-EM, coupled with AI technologies, gave birth to a new wave of biotech startups such as Gandeeva Therapeutics, Septerna, and MOMA Therapeutics.

The cryo-EM field is heating up with biotech start-ups attracting the attention of a wide range of investors, from the smaller venture organizations to the owner of TikTok and internet tech giant ByteDance, investing in Shuimu BioSciences. The interest is driven not only by the revolutionary Nobel prize-winning technology but also by the active recruitment of AI into the process. The recent publication "An AI-assisted cryo-EM pipeline for structural studies of cellular extracts" highlighted the non-replaceable role of AI in complex cryo-EM pipelines, including AI-driven atomic model prediction to rapidly and simultaneously investigate the structure of multiple protein community members de novo. Machine learning helps not only speed up and optimize the cryo-EM pipeline but to also avoid user bias pitfalls.

Gandeeva Therapeutics, founded in 2021, raised $40M at the beginning of this year to develop novel therapies based on the precision imaging of protein-drug interactions. Their Target-Selection Engine together with the Cryo-EM Engine can help to "steer away from discovery dead ends", as the company stated. At the same time, launched in 2020 cryo-EM biotech MOMA Therapeutics raised a whooping $236M in just two years, having an ambitious goal of releasing to clinic novel precision drugs for cancer. MOMA is focused on a unique class of biological targets -- "molecular machines."

Developing small molecules using AI

After disease modeling and target discovery, designing chemical or biological molecules is the second most abundant use case for applying artificial intelligence in drug discovery. More than 130 artificial intelligence-driven companies out of 384 companies in the BiopharmaTrend AI Report apply artificial intelligence for designing drug candidates, among other use cases.

AI-driven drug design falls mainly into three major categories: de novo (e.g., generative) drug design, virtual screening of existing databases, and drug repurposing.

De novo drug design is mostly enabled by deep learning models, such as generative adversarial neural networks (GANs). Some examples of generative AI platforms include Chemistry42 software by Insilico Medicine, Makya by Iktos, and De Novo Platform by Ro5. Other player in this category include Recursion Pharmaceuticals, Deep Cure, Standigm, and others.

The application of artificial intelligence-enabled ultra-large-scale virtual screening, sifting through billions of molecules to find successful hits. In August 2022, Sanofi partnered with Atomwise in a drug design deal worth potentially up to $1.2 billion. The deal, which will see Sanofi pay $20 million upfront, centers on leveraging the U.S. company's AtomNet platform to research small molecules for up to five drug targets selected by Sanofi. A convolutional neural network-based AtomNet excels at structure-based drug design, enabling "the rapid, AI-powered search of Atomwise's proprietary library of more than 3 trillion synthesizable compounds," according to the announcement.

Earlier in 2019, Atomwise collaborated with Ukraine-based chemical leader Enamine to conduct the "world's first and largest 10 billion compounds virtual screen," aiming at identifying hits for pediatric oncology.

Finally, a number of companies are using repurposing strategies for AI-enabled drug discovery. Companies in this category, including Healx, BenevolentAI, BioXcel Therapeutics, are largely using natural language processing (NLP) models and machine learning and operate via analyzing massive amounts of unstructured textual data -- research articles and patents, electronic health records (EHRs), as well as other data types -- to build and search "knowledge graphs." Such AI-enabled searchable ontologies allow picking novel indications or patient populations for previously known drug candidates or even approved drugs.

For example, Lantern Pharma, a US-based clinical-stage biotechnology company, focused on innovating the cancer drug development process by using advanced genomics, machine learning, and artificial intelligence. The company's AI platform, RADR®, currently includes more than 25 billion data points and uses big data analytics and machine learning to rapidly uncover biologically relevant genomic signatures correlated to drug response, and then to identify relevant cancer patient subgroups to benefit from Lantern's drug candidates. RADR ® is also used by Lantern and its collaborators to develop and position new drugs as well as for drug repurposing.

AI meets DNA-encoded libraries

A somewhat unique approach to drug design consists in using DNA-encoded libraries (DELs) as a source of novel molecules to search through. Since DEL technology offers access to essentially the largest chemical space available on the market, this big data technology is a natural fit for AI-based tools.

A notable deal took place in 2020, when Insitro, one of the notable players in the application of machine learning for drug discovery, founded by Daphne Koller, acquired Haystack Sciences. Haystack's machine learning-based platform combined multiple elements of their DEL technology, including the capability to synthesize broad, diverse, small molecule collections, the ability to execute iterative follow-up, and a proprietary semi-quantitative screening technology called nDexer™, that generates higher resolution datasets.

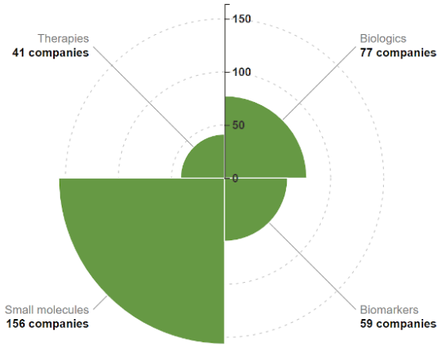
In its turn, ZebiAI was acquired in 2021 by another notable developer of an artificial intelligence-powered drug discovery platform, a clinical-stage biotech Relay Therapeutics, where Relay paid $85 million up-front. This acquisition allowed Relay to incorporate ZebiAI's machine-learning-based DEL technology into their protein targeting platform Dynamo.

In October 2021, X-Chem acquired Glamorous AI, a developer of a modular multifaceted artificial intelligence solution for drug discovery RosalindAI, including capabilities of data engineering and featurization, predictive analytics, high-performance computing, and de-novo drug design.

AI-driven drug design beyond small molecules

Considering that modern-day artificial intelligence tools applied for drug discovery have deep historical roots in cheminformatics and early machine learning-based QSAR models of the past century, it is not surprising that the overwhelming majority of AI startups in drug discovery are focused on small molecules.

However, biomolecule drugs (aka "biologics") and novel chemical modalities are increasingly abundant in the pharmaceutical space, and so are the new biotech companies applying AI-based methods to discover those. After scientists cracked the human genome in 2003, the druggability and developability space rapidly evolved. In the past century, Lipinski's rule-of-five (Ro5) used to serve as a "guiding light"



Distribution of AI drug discovery companies by product category

for drug-like molecule design for oral delivery in the "traditional" druggable target space.

In contrast, novel types of targets, such as protein-protein interactions, targets with large contact areas, protein-nucleic acid interactions, and next-generation targets, such as exploiting cell's protein degradation machinery, are driving the advent of a variety of emerging molecular modalities, namely beyond the Ro5 (bRo5) small molecules (such as protein-protein interaction modulators, protein-targeted chimeras (PROTACs), monoclonal antibodies (mAbs), peptides and peptidomimetics, and nucleic acid-based modalities (RNA and DNA-based), have become a key focus in drug discovery.

For instance, there is a growing number of companies applying AI methods to discover novel monoclonal antibodies -- the most commercially successful biologics modality so far. Notably, in April 2022, Israel-based Biolojic Design announced their first ever computationally designed antibody entered the clinical trial. The company leverages a structure-based design strategy. Its AI model is trained on millions of antibody-antigen pairs to identify a template antibody against the target of interest from existing human antibodies. An additional machine learning model is used to predict mutations and guide the optimization of the template to improve its properties.

In November 2022, Canada-based AbCellera Biologics announced that Regeneron elected to exercise its right to advance the first of AbCellera's therapeutic antibody candidates targeting an undisclosed G-protein coupled receptor (GPCR) into further preclinical development. The partnership, which commenced in March 2020 and allows for four discovery programs selected by Regeneron, leverages AbCellera's AI-based antibody discovery engine and Regeneron's VelocImmune® mice to identify novel therapeutic antibodies.

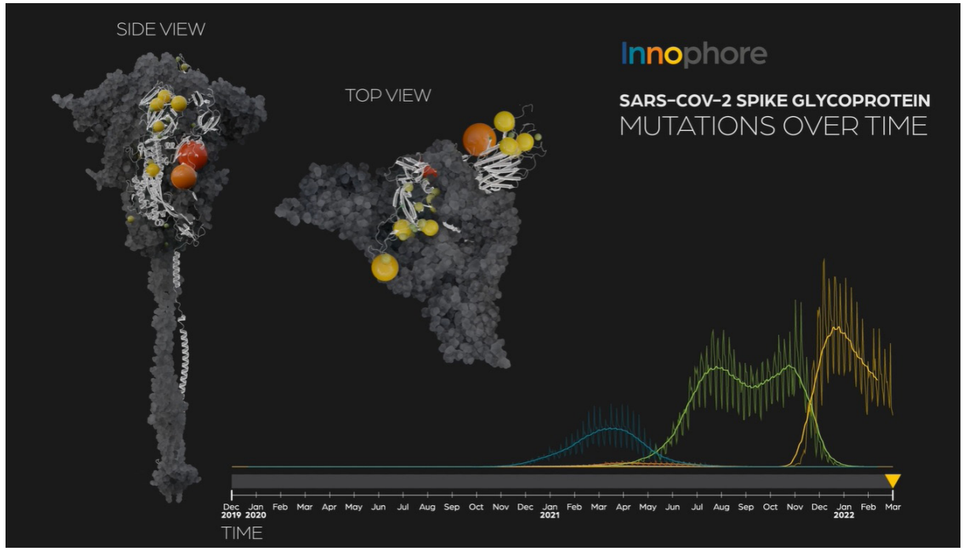
Two dozen other antibody-discovering companies are using AI, including US-based AbSci, BigHat Biosciences, Totient, Nabla Bio, and Generate Biomedicine; Canada-based Deep Biologics; China-based NeoX; EU-based Deep CDR, Natural Antibody, and MabSilico, etc.

US-based company with a catchy name Creyon Bio applies an engineering approach to creating new oligonucleotide-based medicines (OBMs). The company was founded in 2019 and raised $40M in funding in March 2022. Founded in 2014 as a spinout of Cold Spring Harbor Laboratory, Envisagenics is a New York-based company focusing on discovering RNA therapeutics. According to their stated mission, they aim to reduce the complexity of biomedical data with the help of AI/ML technologies. Just recently, in August 2022, they received a grant from the National Cancer Institute, resulting in a total raised funding of $27.1M.

Envisagenics's AI-driven technology, SpliceCore, is a cloud-based platform experimentally validated to predict drug targets and biomarkers through splicing discovery from RNA-sequencing data. According to the company, it ensures higher precision and speed compared to traditional methods.

Innophore's AI-driven strategy to design novel therapeutic enzymes is realized by coupling their patented Catalophore™ technology to state-of-the-art conventional bioinformatics approaches and artificial intelligence. Innophore can mine structural and sequence databases using three-dimensional (3D) search templates called "catalophores" (i.e., carrier of the catalytic function) defined by point clouds of physicochemical features. Novel enzymes identified by this technique do not necessarily share a common structure or sequence basis with their employed counterparts. Therefore, they potentially feature altered protein properties, such as thermostability, robustness, substrate spectrum, selectivity, and specificity.

Besides designing novel enzymes, Innophore's technology can potentially be a game changer for epidemiologic applications, protecting potentially dangerous mutations in viruses. In 2021, Innophore started the virus.watch project in cooperation with



Tracking the evolving virus over time using Innophore technology and AWS shows a high rate of mutations arising with the Omicron variant. Spheres depict alpha-C-atoms of the corresponding amino acid residue. Both color and size correlate with the number of mutations at each position

the AWS Diagnostic Development Initiative. The goal of this project was the implementation of a monitoring and evaluation system for emerging drug and disease-relevant Coronavirus (SARS-CoV-2) variants. The first joint paper, published in Nature in August 2022, describes bioinformatics analysis of SARS-CoV-2 variants revealing higher hACE2 receptor binding affinity for Omicron B.1.1.529 spike RBD compared to a wild-type reference.

Founded in 2008, Denmark-based Evaxion Biotech is an AI-driven company, devoted to developing vaccines against cancer and infectious diseases. They own a clinical-stage AI-Immunology platform, combining AI technology with their engineering expertise to generate predictive models, helping to identify unique immunotherapies for patients. Evaxion Biotech attracted a total of $57M, entering the post-IPO equity funding round in June 2022 worth $40M, led by a single investor Lincoln Park Capital Fund.

Some AI companies from the "chemical modalities club," like Exscientia, are now expanding into biologics discovery. In November 2022, the company announced its AI platform would include the design of human antibodies. Exscientia is also establishing an automated biologics laboratory in Oxford to internally generate and profile novel antibodies.

A growing trend is to exploit the protein degradation system of human cells to get rid of malignant proteins and cure diseases. One modality here that is rising in popularity is proteolysis targeting chimera (PROTAC) was introduced in 2001, and it consists of two ligands connected by a flexible linker. The primary chemical architecture of modern PROTACs is the same: one ligand targets the E3 enzyme, which is a component that sends outdated proteins

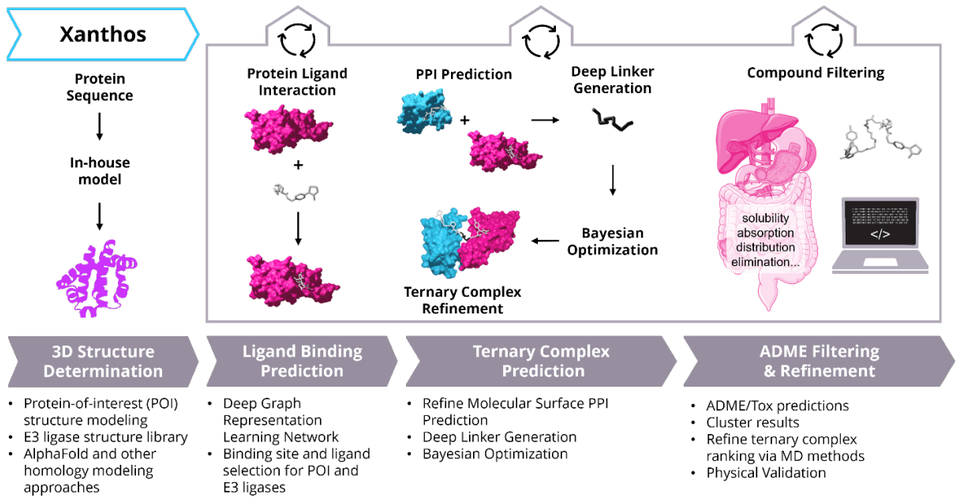
to the proteasome, and another ligand targets a protein of interest (POI) that has to be degraded. A PROTAC binds E3 and POI, bringing them closer to form an induced proximity complex. In some cases, when the proteins align appropriately, the POI gets ubiquitinated, which marks it for degradation by the proteasome.

Another broad approach to protein degradation includes so-called "molecular glues," an actively growing area of research. In contrast to PROTACs, being relatively large bifunctional small molecules with two active sites and a linker, molecular glues are smaller and more drug-like molecules. The latter bind to an aggregate protein pocket resulting from two separate proteins coming into proximity due to the effect of the molecular glue molecule.

There is a wave of companies within the protein degradation (and, more broadly -- modulation) space, including Arvinas, Nurix Therapeutics, Kymera Therapeutics, C4 Therapeutics, Roivant Discovery, Cedilla Therapeutics, and Lycia Therapeutics, to name a few.

Some companies are applying cutting-edge AI algorithms to design proximity-inducing compounds. For instance, Austria and US-based Celeris Therapeutics has built Celeris One platform, including three work zone systems: Xanthos, Hephaistos, and Hades. The systems incorporate graph neural networks to predict interactions and generative models to create new chemical matter, such as linker and multi-objective optimization to improve molecular properties, molecular dynamics, and free-energy calculations. The workflow also employs geometric deep learning and machine learning-driven retrosynthesis capabilities. Celeris Therapeutics runs an automated lab to generate biology data and conduct custom chemical synthesis.

We have recently published a broad overview of the protein degradation market in a post Protein Degraders Take Industry By Storm, including several case studies with a technical overview of the computational platforms involved.



The dry lab workflow of Celeris Therapeutics' AI-driven platform Xanthos

The first wave of AI-developed drug candidates goes clinical

While it is probably early to say that AI adoption in the pharmaceutical industry revolutionized drug discovery altogether, several "AI-native" companies did manage to gain notable efficiency in building their therapeutic pipelines quickly. What is one common feature of such companies? Each built a specialized, highly integrated AI platform, including many models and data sources. Some platforms are also available as software-as-a-service to external R&D partners, such as Chemistry42.

One of the most vivid examples of benefiting from a "digital-first" strategy the industry has seen is Moderna Therapeutics, which not only managed to incorporate cutting-edge AI analytics in its research but digitalized and integrated every aspect of its R&D workflow, including production and distribution. When the COVID-19 pandemic struck the world at the beginning of 2020, Moderna was among the first companies to be able to come up with an efficient mRNA-based vaccine within just 2 days (!) and bring it to the market within a year.

A wave of therapeutics discovery successes enabled by AI demonstrates the ability of AI-native companies to come up with drug candidates faster than it typically used to take for similar programs.

AbCellera's monoclonal antibody LY-CoV555 was developed within three months and obtained emergency use authorization by the FDA.

BenevolentAI's Knowledge Graph helped the company identify Baricitinib as an efficient COVID-19 antiviral within a matter of days (now approved for use by the FDA). Another small molecule BEN-8744, a novel inhibitor to treat Ulcerative colitis and Dermatitis, was advanced to late preclinical studies within less than 24 months.

Exscientia's small molecule inhibitor EXS-21546 marked the first AI-designed molecule for immuno-oncology to enter human clinical trials (now in Phase I) and was discovered in just eight months. The company has several other molecules in clinical trials.

Insilico Medicine's small molecule inhibitor ISM001-055, to treat Idiopathic Pulmonary Fibrosis, was de novo designed and advanced into late preclinical studies within 18 months (now in Phase I).

New York-based Schrodinger developed a small molecule SGR-1505 to treat B-cell lymphoma within ten months and is now in the process of IND application.

Salt Lake City-based Recursion Pharmaceuticals developed a drug candidate for an unspecified rare disease within 18 months. The company has a

large and diverse portfolio of preclinical and clinical drug candidates designed with the help of its digital biology platform.

Toronto-based Deep Genomics used its AI Workbench platform to develop a novel genetic target and a corresponding oligonucleotide drug candidate DG12P1 to treat a rare inherited Wilson's disease.

To keep track of the leading AI-developed clinical drug candidates, we have created "The Roadmap of Drug Candidates Designed by AI," which will be updated regularly.

Twenty most "productive" AI companies in the drug discovery space

Having shortlisted around 130 companies from more than 380 AI companies in the BiopharmaTrend AI Report, we have further selected 20 companies -- using a simple but robust evaluation formula taking into account clinical and preclinical pipelines of companies, the ability for target discovery, and the time in business. The 20 selected companies formed the BPT20: Artificial Intelligence in Drug Discovery Productivity Index -- the industry's first point of reference to highlight companies championing the application of AI for de novo drug design, virtual screening, or drug repurposing.

AI and robotized labs of the future

Deep learning models (e.g., based on deep neural nets) are extremely "data-hungry," meaning that no matter how good AI is, it is the quality and size of data that is equally important for meaningful research predictions. The most efficient way to generate high-quality biology data is by using robotics. If we consider the modern AI-driven transformation of drug discovery as a step-by-step process, widely available and relatively cost-efficient robotics-as-a-service would be the final and critical piece in the AI-enabled industrialization of pharma and biotech research. As per a report by Arctoris, "Robotics is key to allowing the paradigm of closed-loop discovery to become a reality - which will be an exciting space to watch over the coming years."

Some companies are building standardized, highly automated, scalable, and increasingly compatible laboratory facilities guided by AI-based experiment control systems and supplemented by AI-driven data mining and analytics capabilities. Such "next-gen" lab facilities are becoming available remotely to preclinical drug research experimentalists, making preclinical experimentation a more scalable and standardized routine. The leading remote lab providers on the list are Automata Labs, Strateos, Emerald Labs, and Culture Biosciences, to name a few.

The space is attracting venture funding and clients. For example, in February 2022, UK-based Automata Labs raised $50 million to automate the lab research process. In July 2021, Strateos raised $56 million for further improving its SmartLab platform and its remote robotized, automated technology, available to preclinical researchers across the globe. Culture Biosciences raised a total of more than $100 million, with the latest $80 million Series B announced in November 2021. San Francisco-based Emerald Cloud Labs (ECL) raised more than $90 million over the years. Early users of ECL's remove robotic platform reported 300% to 700% improvements in research productivity. In June 2022, Beijing-based MegaRobo raised $300 million to expand its diverse range of automated AI-driven remote lab services and robotized facilities.

The rise of remote robotized labs is a long-term industry trend, a new way to offer contract research services that would be extremely beneficial for the long-term adoption of data-centric "AI-first" research strategies.

Several AI-driven drug discovery companies, such as Arctoris, Recursion Pharmaceuticals, Insitro, and Generative Bio, are approaching this trend via a different business model -- they have built internal robotized lab facilities to improve their in-house data generation capacities for training their AI models and building pipelines of therapeutic drug candidates.

For example, Oxford-based Arctoris, founded in 2016, built a fully automated wet lab that generates superior quality data at scale, feeding into Arctoris's data lake and powering the company's AI-driven decision-making platform Ulysses that is powering the company's research from target to hit, lead, and to IND application stage.

Arctoris's pipeline now includes several preclinical programs in Oncology and Neurology. Arctoris raised a total of $10.3 million in several rounds from investors, including Future Planet Capital, RT Ventures, and Formic Ventures.

Some leading AI drug discovery companies, such as Exscientia and Insilico Medicine, are now also building in-house robotized labs for building their internal data generation "muscles."

Salt Lake City-based Recursion Pharmaceuticals is among the leaders in robotized biology experimentation space. The company's AI-driven infrastructure, called Recursion Operation System, is an integrated closed-loop system combining proprietary in-house data generation and advanced computational tools to generate novel insights to initiate or accelerate therapeutic programs. The company is automating preclinical biology experimentation at scale. For instance, cellular microscopy images capture composite changes in cellular morphology and are processed by the company's AI-powered computer vision systems. Since 2017, Recursion Pharmaceuticals has approximately doubled the capacity of the phenomics platform each year and scaled the number of executed phenomic experiments to up to 2.2 million every week, resulting in ~19 petabytes of proprietary high-dimensional data.

Navigating clinical trial bottlenecks with AI

The clinical trial is a critical stage of drug development workflow, with an estimated average success rate of about 11% for drug candidates moving from Phase 1 towards approval. Even if the drug candidate is safe and efficacious, clinical trials might fail due to insufficient financing, insufficient enrollment, or poor study design.

Artificial Intelligence (AI) is increasingly perceived as a source of opportunities to improve the operational efficiency of clinical trials and minimize clinical development costs. Typically AI vendors offer their services and expertise in three main areas. AI start-ups in the first area help to unlock information from disparate data sources, such as scientific papers, medical records, disease registries, and even medical claims, by applying Natural Language Processing (NLP). This can support patient recruitment and stratification, site selection, and improve clinical study design and understanding of disease mechanisms. As an example, about 18 % of clinical studies fail due to insufficient recruitment, as a 2015 study reported.

Another aspect of success in clinical trials is improved patient stratification. Since trial patients are expensive - the average cost of enrolling one patient was $15,700-26,000 in 2017 -- it is essential

to be able to predict which patient will have more significant benefit or risk from treatment. AI-driven companies operate with multiple data types, such as Electronic Health Records (EHR), omics, and imaging data, to reduce population heterogeneity and increase clinical study power. Vendors could use speech biomarkers to identify neurological disease progression, imaging analyses to track treatment progression, or genetic biomarkers to identify patients with more severe symptoms.

AI is also streamlining the operational processes of clinical trials. AI vendors help to track patient health from their homes, monitor treatment response, and patient adherence to the trial procedures. By doing that, AI companies decrease the risk of patient dropouts, which accounted for 30% on average. Usually, the Phase 3 clinical study stage requires 1000-3000 participants, with a part of them taking a placebo. That's why the development of synthetic control arms - AI models that could replace the placebo-control groups of individuals, thus reducing the number of individuals required for clinical trials - might become a novel trend.

There are more than 80 companies in all three categories, as per BiopharmaTrend AI Report, including Owkin, PathAI, GNS Healthcare, Neurcuit, AICure, and Unlearn.ai.

The demand for AI-enabled clinical trial platforms is high, as well as investments in this area, despite the overall cold investment climate in biotech.

In March 2022, ConcertAI got a valuation of $1.9 billion after banking a $150 million series C round to scale its software and real-world data (RWD) solutions for cancer research.

Saama is a Silicon Valley-based company founded in 1997, but it raised its first venture capital in 2015. The company has raised more than $500 million in venture capital, including the latest mega-round of $430 million in August 2022 -- from Carlyle and venture funds from Merck, Pfizer, Amgen, McKesson, and others.

Saama is one of the leading players in the AI-driven clinical trial analytics space, offering a diverse suite of solutions: accelerated clinical trials via centralized data analytics and control center, including real-time data processing capabilities; automated data quality capabilities; streamlined regulatory submission capabilities, including pharmacovigilance analytics and submissions.

In April 2022, Unlearn.AI, a startup developing a 'digital twin' service for clinical trials, raised $50 million.

In June 2022, Bristol Myers Squib invested $80 million in OWKIN – to help enhance the design of cardiovascular drug trials, with improvements to endpoint definitions, identifying patient subgroups, and estimating treatment effects. Paris and New York-based "unicorn" OWKIN is leveraging our high-quality multimodal data access and state-of-the-art machine learning to accurately predict various treatment effects on patient sub-populations to improve clinical trial experiment design and outcomes. OWKIN is also applying its AI platform for drug discovery.

In August 2022, Bristol Myers Squibb also announced a multi-year expanded collaboration agreement with AI pathology specialist PathAI. The initial work within this extended agreement will focus on key translational research in oncology, fibrosis, and immunology, with an overall goal of forwarding these into clinical trials. Two months earlier, PathAI struck a strategic multi-year partnership with GlaxoSmithKline to accelerate scientific research and drug development programs in oncology and non-alcoholic steatohepatitis (NASH) by leveraging PathAI's technologies in digital pathology, including the use of PathAI's AIM-NASH tool.

Notably, Dublin's Akkure Genomics just announced it crowdfunded €1 million in one week to support clinical trials via its AI platform, which helps people participate in the most relevant clinical trials based on data about themselves and their condition.

AI in the contract research industry

The emergence of novel AI-native contract research companies in pre-clinical and clinical spaces challenges the status quo of major well-established contract research organizations (CROs). They respond by incorporating AI in their service offerings to pharma or partnering with AI companies to complement their research capacity.

For example, Charles River Labs, a US-based early-stage contract research organization, is diving deeper into AI by establishing a multiyear partnership with Valo Health. Charles River adds Valo's Opal technology that actively learns as programs are developed. Charles River hopes its use of the Opal deep learning platform will result in a faster and more effective process from de novo molecule design through lead optimization. Last year, Charles River established a strategic partnership with Valence Discovery that lent the CRO's clients access to Valence's artificial intelligence platform for molecular property prediction, generative chemistry, and multiparameter optimization.

IQVIA has been investing in AI capabilities for years to add value to clinical trials and commercial activities it is offering to customers. To improve clinical trials, for example, IQVIA launched Avacare Clinical Research Network™ in 2020, which allowed sites to match patients for the trials faster and more efficiently. The platform is powered by AI algorithms and can operate across 19 disease areas. Earlier, another IQVIA's Linguamatics Natural Language Processing (NLP) platform won Questex's 2019 Fierce Innovation Awards. The platform can have vast applications in healthcare and life sciences, including target identification, gene mapping, predicting patient outcomes, and so on.

A significant trend in the clinical research industry is running virtual clinical trials, a market worth $8 billion. The COVID-19 pandemic forced pharma companies to switch to remote monitoring, improved patient enrollment, apps to track patient engagement, telemedicine, decentralization, and other measures to keep trials running. Since the demand for such solutions grew significantly, CROs rushed to add virtual and decentralized capabilities to their service offerings. AI technology proved invaluable in creating and running such projects to help synthesize data and speed up clinical trial processes.

Technology giants go after drug discovery and biotech

The earlier mentioned successes of the Alphabet's DeepMind and Meta in solving basic biology research riddles, like predicting protein structures at scale using deep learning and language models, are just the tip of the iceberg: almost every leading technological giant is now in the life sciences business, somehow.

Alphabet (a parent company of Google) has dozens of investments in life science projects, including AI-based reagent search engine BenchSci, China-based AI and quantum physics in drug discovery company XtalPi, personal genomics company 23andMe, and AI-driven drug development unicorn OWKIN to name a few. In 2021, Alphabet, together with DeepMind, launched Isomorphic Labs to focus on applying artificial intelligence to crack basic biology and drug discovery.

Apart from multiple other projects and activities in pharmaceutical research and biotech, Alphabet has a full-scale entity, Verily, dedicated to Life Sciences and MedTech.

Microsoft, a global software developer, has a deep footprint in Life Sciences, with dozens of research collaborations with big pharma, providing its infrastructures to handle big data using large-scale machine learning models. Among the latest Microsoft initiatives is MoLeR model, a new tool being developed by the company's generative chemistry team in collaboration with Novartis. The MoLeR model – unlike other generative tools – uses deep learning to come up with new structures based on a given scaffold that acts as an initial base for the generative process. Another example is AI4Science, a new Microsoft venture combining computational

chemistry, quantum physics, machine learning, molecular biology, fluid dynamics, and software engineering to realize a vision of the so-called "fifth paradigm" of science.

A particularly active company in this context is a hardware producer for the gaming industry and personal computers, NVIDIA. This tech company has launched Clara Discovery, which is a collection of frameworks, applications, and AI models enabling GPU-accelerated drug discovery, with support for research in genomics, proteomics, microscopy, virtual screening, computational chemistry, visualization, clinical imaging, and natural language processing (NLP). And in March 2022, the company introduced Clara Holoscan MGX™, a platform for the medical device industry to develop and deploy real-time AI applications at the edge, specifically designed to meet required regulatory standards. Clara Holoscan aims for an all-in-one, medical-grade reference architecture, as well as long-term software support, to accelerate innovation in the medical device industry.

The future of AI in drug discovery: all things "quantum"

Most software tools used for drug discovery and biology research rely on molecular mechanics -- a simplified representation of molecules, essentially reducing them to "balls and sticks": atoms and bonds between them. This way, it is easier to compute, but accuracy suffers greatly. To gain adequate accuracy, one has to account for the electronic behavior of atoms and molecules, i.e., consider subatomic particles -- electrons and protons. This is what quantum mechanical (QM) methods are all about -- and the theory is not new, dating back to the early decades of the 20th century.

However, quantum methods are exceptionally computationally costly -- and until recent decades, it was a prohibitive barrier for quantum theory to influence the practical side of things. Due to the exponential growth of available computing power, quantum methods are finally becoming valuable tools in scientists' hands.

Several companies are merging machine learning and quantum theory to improve the modeling capabilities of their drug discovery systems substantially. For example, scientists at XtalPi, a China and US-based tech company backed by Sequoia China, Tencent, and Google, have built their Intelligent Digital Drug Discovery and Development (ID4) platform, incorporating quantum mechanics, artificial intelligence, and high-performance cloud computing algorithms. ID4 allows predicting with high precision the physiochemical and pharmaceutical properties of small-molecule drug candidates, as well as their crystal structures -- critical elements in drug R&D.

Another company moving this field forward is Paris-based Aqemia. The company focuses on de novo, structure-based design of lead-like molecules by combining quantum and artificial intelligence (AI). A unique quantum-inspired statistical mechanics algorithm that predicts the affinity between a compound and a therapeutic target accurately and 10,000 times faster than the competition. Aqemia's AI can generate compounds with increasing accuracy by getting feedback from the affinity predictor.

Finally, there is Barcelona-based Pharmacelera, a computational company applying quantum theory to boost drug design via their two primary software packages: PharmScreen and PharmQSAR. The first tool allows for an accurate ligand-based virtual screening using a high-precision 3D ligand-alignment algorithm based on the interaction fields. It can generate a higher diversity rate among leads than classical methods and tools. The second one -- PharmQSAR, is a 3D quantitative structure-activity relationship (QSAR) tool that enables a combination of multiple fields of interaction to perform CoMFA/CoMSIA studies.

Another -- a more futuristic -- technological trend, exploiting quantum theory, deals with creating a quantum computer. With several decades of advances in quantum theory and simultaneous progress in several software and hardware fields, we are finally entering the era of quantum computers becoming practically viable.

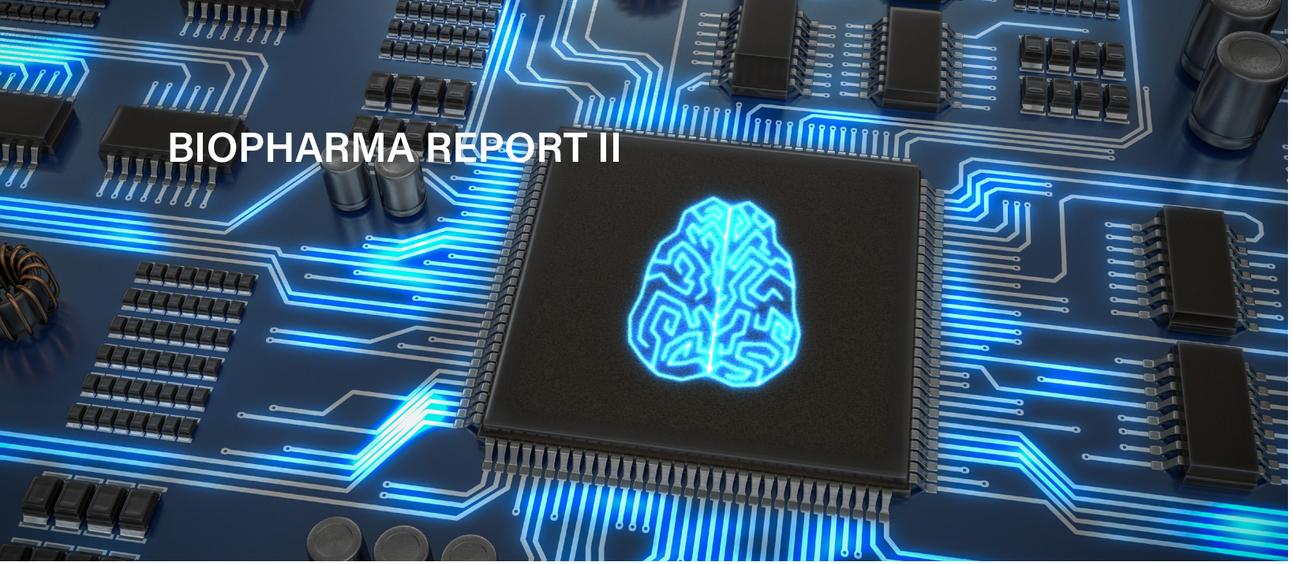
While we are in the early days of quantum computing, several companies are already integrating elements of quantum computing into computational drug discovery.

For instance, POLARISqb is a UK-based developer of the world's first drug discovery software built for quantum computers, combining artificial intelligence and a quantum approach. At the heart of POLARISqb technology is the Tachyon drug design platform, used for executing distributed molecular design work across the cloud, managed by an automated process that allows searching large chemical libraries while running multiple projects in parallel. By developing proprietary software for quantum systems, the company claims it can substantially accelerate drug design and get leads of higher quality. Due to the inherent "agnosticism" of the Tachyon system, it can work in multiple diseases and indications.

Menten AI is a Canadian start-up founded in 2018 that develops a software platform for protein design powered by machine learning and quantum computing. The company uses proprietary quantum optimization algorithms, which it believes can significantly improve the accuracy of drug discovery while reducing cost and development time.

To summarize this post, let's refer to a prediction by Dr. Christopher Savoie, Co-founder, and CEO at Zapata Computing, an American quantum software company, on cutting-edge research in this area, that he expressed in an interview for BiopharmaTrend:

> "Quantum will be a part of every, or almost every, data science and machine learning workflow in biopharma in the future. I do believe it will be an integral part of it. If you can get a more accurate model by using quantum tech -- why wouldn't you do that, after all?"
>
> - Dr. Christopher Savoie



17 Companies Building the Future of Drug Development on a Chip

BY **ANDRII BUVAILO**

In the early 2000s, the concept of organ-on-a-chip technology, also known as microphysiological systems, emerged as a way to replicate the structure and function of human organs in a laboratory setting. Donald E. Ingber, a bioengineer at Harvard University, was a key early player in this field, developing the first organ-on-a-chip models using microfabrication techniques. The National Institutes of Health (NIH) established the Tissue Chip for Drug Screening program in 2012, which stimulated the development of organ-on-a-chip technology. This program brought together researchers from various disciplines, such as biology, engineering, and materials science, to create organ-on-a-chip models for drug discovery and toxicity testing. In 2012, researchers at Harvard University's Wyss Institute for Biologically Inspired Engineering created a "human-on-a-chip" platform that integrated multiple organ-on-a-chip models, including the lung, heart, liver, and blood-brain barrier. This system was able to simulate how different organs in the human body work together. This gave a more accurate picture of how the human body works.

In 2017, the FDA announced a collaboration with the Wyss Institute to evaluate organ-on-a-chip technology for drug development and toxicity testing. This was a notable milestone when the FDA acknowledged organ-on-a-chip technology as a legitimate tool for drug development. Many companies, including MIMETAS, InSphero, and TARA Biosystems, have emerged in recent years to develop and commercialize organ-on-a-chip technology. These firms have created a variety of organ-on-a-chip models for a variety of applications, including drug development, disease research, and toxicity testing. Overall, organ-on-a-chip technology has progressed from simple 2D cell culture systems to more complex 3D systems capable of replicating the structure and function of multiple human organs. Even though the technology is still in its early stages, it has the potential to revolutionize drug development and disease research by creating more accurate and reliable models of how the human body works.

Convergence of technologies

Tissue engineering and microfabrication have converged to aid in the development of organ-on-a-chip technology. Early 2D monocultures have given way to more sophisticated 3D co-culture systems. By manipulating the cellular microenvironment and geometrical arrangement, researchers can now achieve cell polarization, direct cell-cell interaction, and the propagation of chemical and electrical signaling.

In addition, the handling of primary cell sources and the integration of these cells into artificial structures to promote organ-like functions have improved. The use of induced pluripotent stem cells (iPSCs) promises personalization of organ-chips for patient-specific clinical trials and research on disease phenotypes and drug responses.

Microsystems technology, adapted from the integrated circuit industry, has also played a major role in the success of organ-on-a-chip tech. By transferring lithographic patterns, researchers can now fabricate nanoscale and microscale structures, resulting in a change in the way in vitro bioreactors and cell biological systems are conceived, run, and monitored.

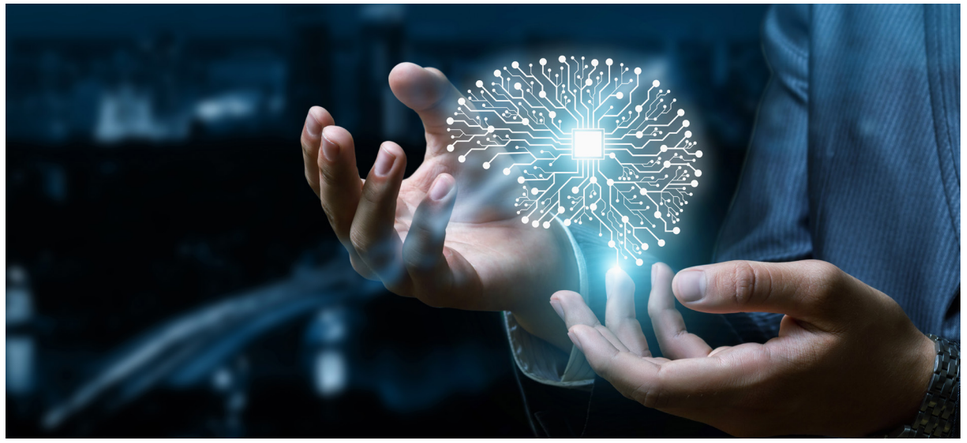
Organ function in vitro can now be studied using organ-specific chips. Designed to mimic the organ's cellular and extracellular features in response to biochemical and physical cues, these chips maintain and simulate organ function.

Organ-on-chip systems are very important because they allow for multi-parametric readouts of organ function.

Artificial intelligence (AI). can play a significant role in organ-on-a-chip systems by analyzing large amounts of data generated by these systems and providing insights that would be difficult to obtain through manual methods. AI techniques such as machine learning, deep learning, and computer vision can be used to analyze images of cells and tissues on the chips, predict cellular behavior, and identify patterns and trends in the data.

One application of AI in organ-chip systems is in the development and optimization of the microfabrication techniques used to create the chips. AI algorithms can be used to design and optimize the microscale structures on the chips, such as the size and shape of the channels and the distribution of cells.

AI can also be used to monitor and control the conditions on the chips, such as temperature, pH, and nutrient levels. This can help to ensure that the cells on the chips are kept in the optimal environment for growth and function. AI methods are essential for processing complex multimodal data obtainable from organ-on-a-chip systems.



Below, let's have a look at the **17 most innovative companies** engineering organ-on-a-chip systems and related technologies in the United States, European countries, and Israel.

1) Bi/ond

The company is based in the Netherlands and develops custom organ-on-a-chip solutions for in vitro testing, including their key products, inCHIPit and comPLATE. For instance, inCHIPit has an open well for tissues, a porous membrane, and a bottom compartment for oxygen and nutrient-delivering microchannels. This enables the longitudinal evaluation of organoid tissue cultures using microscope-compatible instruments.

2) InSephero

Based in Switzerland, this company offers 3D-cell-based assay solutions as well as scaffold-free 3D organ-on-a-chip technology for in vitro testing that yields biologically relevant insights. The technology developed by InSphero aids in the early detection of pharmaceuticals and toxic risks, allowing the pharmaceutical and biotechnology industries to reduce the use of animals in testing.

3) AlveoliX

Another Swiss biotech in this field, which created in-vitro lung products for drug testing. The products of the company aid in simulating the biophysical properties of lungs, predicting the effects of respiratory drug candidates in humans, and reducing the number of candidates tested in clinical trials.

4) Mimetas

Mimetas is a Dutch company that develops organ-on-a-chip products for compound testing, screening, and basic research. Mimetas' product enables clinicians to test compounds in high throughput on miniaturized organ models using 3D cell culture with continuous perfusion.

5) MesoBioTech

This French company offers integrative solutions for research, education, and large-scale applications. Their primary focus is on advanced stem cell technologies based on the fabrication of artificial basement membranes composed of a monolayer of gelatin nanofibers and functional proteins (culture patches). The patches could then be reversibly combined with microfluidic devices to create organs-on-a-chip and microphysiological systems, which are important for disease modeling, toxicity testing, drug screening, and regenerative medicine research.

6) Cherry Biotech

Another company out of France is focused on the development of a new generation of cell environment control suitable for organs-on-a-chip. They can culture and replicate any human organ in a physiological and pathological state using their patented microfluidic technique.

7) 4Dcell

This France-based biotech, has created an innovative 3D cell culture system that mimics in vivo conditions and, eventually, organ function through extensive regulation of the cell microenvironment. This system enables the acquisition of more physiologically relevant readouts.

8) TissUse

TissUse was founded in Germany and is focused on creating a one-of-a-kind "Multi-Organ-Chip" platform that uses human tissues to deliver exceptional preclinical knowledge on a systemic level. This multi-organ-on-chip contains four organs as well as a variety of organs-on-chip. It is currently developing a "human on a chip" with a dozen organs.

9) BEOnchip

This biotech company based in Spain creates innovative cell culture equipment to make the cells' environment as bioimetic as possible. Their goal is to use this technology to improve drug testing, accelerate the development of new treatments, and reduce the cost of drug development.

10) Emulate

Boston-based Emulate created an automated bio-emulation platform for studying neuronal and vascular endothelial cells in a micro-engineered living environment. This platform is a new living system that combines micro-engineering with living human cells to better understand how diseases, medicines, chemicals, and foods affect human health.

11) Hurel

This US-based company specializes in advanced micro-liver tissue with a focus on microfluidic cell-based test systems. The company's micro-liver tissue is metabolically active and can live in a cell culture for a long time. This lets clinicians recreate how drugs move through different tissues and organs.

12) AxoSim

This US-based biotech has created a platform for neurological drug discovery that focuses on preclinical pharmaceutical development. By simulating the in vivo nervous system in vitro, the platform offers an alternative to costly animal testing and ineffective 2D models.

13) Altis Biosystems

US-based Altis Biosystems is working on a stem cell platform for regenerating the human intestinal epithelium. RepliGut is a stem and differentiated cell organ-on-a-chip technology with a patent-pending biomimetic framework that allows the small intestine and colon to be customized based on geographic specificity from different donors.

14) TARA Biosystems

TARA created a biotech platform that leverages human biology and data to transform cardiac medication discovery. The platform generates heart cells from stem cells, allowing for the measurement of changes in human cardiac function without requiring human testing. This allows for the development of pharmaceuticals.

15) Nortis

This US-based biotech company has developed in-vitro technology to aid in the discovery of new medicin`es. By creating human tissues and organs in vitro on a disposable chip-like device, the company's technology allows physicians to accelerate research.

16) BioIVT

The OrganDOT platform, developed by BioIVT in the United States, combines high-quality primary cultures with a stable air-liquid interface to recreate tissue architecture and functions. This technology has been used to create well-known models like pancreatic islets and lung airway epithelium.

17) Tissue Dynamics

Based in Israel, Tissue Dynamics is integrating advanced data science technologies into the organ-on-a-chip realm. This is an AI-driven bionic human organoid drug development company with human-related disease models and a sensor-illuminated drug discovery and development platform.

Andrii Buvailo, Ph.D.

Co-Founder, Director, BiopharmaTrend

Andrii Buvailo is a pharmaceutical industry analyst and writer, focusing on emerging companies (startups), technologies and trends in drug discovery, and R&D outsourcing. He received a master's degree in Inorganic Chemistry and a PhD in Physical Chemistry from Kyiv National Taras Shevchenko University. His articles were published on Forbes.com, and market research reports were referenced by some of the leading life science organizations. He also participated in numerous scientific projects in Ukraine, Belgium, Germany, and the United States (DAAD, Horizon 2020, NATO, CRDF grants), and published in high-impact research journals.

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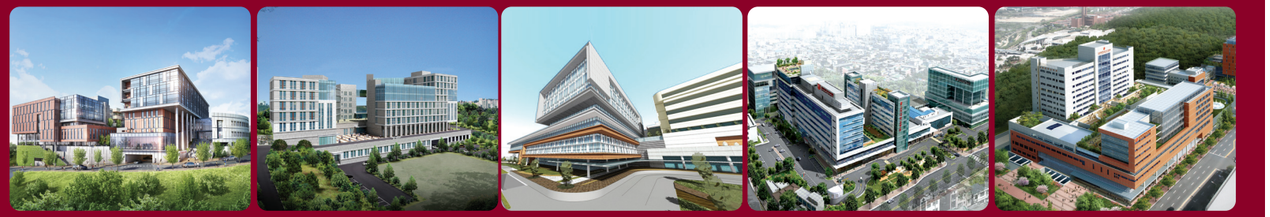

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Conference Alerts

NORTH AMERICA

36th Annual AHA Rural Health Care Leadership Conference

Feb 19-22, 2023 | San Antonio, Texas, USA

Website: https://www.aha.org/education-events/2023-aha-rural-health-care-leadership-conference
Contact: ruralregistration@aha.org
The 2023 AHA Rural Health Care Leadership Conference, February 19-22, in San Antonio, brings together top practitioners and thinkers to share strategies and resources for accelerating the shift to a more integrated and sustainable rural health system. We'll examine the most significant operational, financial and environmental challenges and present innovative approaches that will enable you to transform your organization's care delivery model and business practices.

Joint US FDA Health Canada ICH Public Meeting

Feb 24, 2023 | Virtual Conference

Website: https://www.fda.gov/drugs/news-events-human-drugs/joint-us-fda-health-canada-ich-public-meeting-02242023
Contact: info@sbiaevents.com
FDA and Health Canada will be co-hosting a regional public meeting to provide information to stakeholders and solicit input prior to the next ICH biannual Assembly meeting scheduled for June 12-13, 2023. The public meeting will include presentations by FDA, Health Canada, and PhRMA experts on ICH guidelines recently reaching significant ICH milestones. For example, guidelines recently released for public consultation include a harmonized clinical trial protocol and viral safety evaluation of biotechnology products derived from cell lines of human or animal origin. Recently finalized ICH guidelines include continuous manufacturing and bioanalytical method validation.

World Health Summit Regional Meeting 2023

April 13, 2023 | Washington, DC, USA | Virtual & In-Person Conference

Website: https://www.worldhealthsummit.org/regional-meeting/2023-usa.html
Contact: WHSDC@gwu.edu
The Regional Meeting 2023 will be held in partnership with the Annual Conference of the Consortium of Universities for Global Health (CUGH) CUGH 2023 and the Global Innovation Forum organized by the Association of Academic Health Centers International (AAHCI). Hosted by the US-based members of the M8 Alliance, the academic backbone of the World Health Summit, this collaboration strives to join forces for global health and create a unique opportunity for knowledge exchange and partnership building.

INTERPHEX 2023

April 25-27, 2023 | New York, New York USA

Website: https://www.interphex.com/
Contact: inquiry@interphex.com
INTERPHEX is the leading global event that fuses industry innovation with expert-led technical conferences. It's where the newest ideas are shared, technology is unveiled, and the power of science though commercialization comes to life. No matter where you are in the pharmaceutical supply chain, INTERPHEX delivers relevant solutions through curated education sessions, networking and over 500 global suppliers to source quality products and services. The future of pharma, through the power of experience.

CPHI North America 2023

April 25-27, 2023 | Philadelphia, Pennsylvania, USA | Virtual & In-Person Conference

Website: https://www.cphi.com/northamerica/en/home.html
Contact: cphiregistration@informa.com
CPHI North America is the premier event connecting the entire US pharmaceutical drug development and manufacturing supply chain. Part of the CPHI global network, the event brings together over 3,000 attendees from over 70 countries for 3 days of engaging and inspirational program content and unrivaled networking opportunities.

2023 ASCO Annual Meeting

June 2-6, 2023 | Chicago, Illinois, USA | Virtual & In-Person Conference

Website: https://conferences.asco.org/am/attend
Contact: ascoregistration@spargoinc.com
Join more than 40,000 oncology professionals from around the world at the 2023 ASCO Annual Meeting. Stay up to date on new clinical cancer advances in every area of cancer research, gain real-time insights from world-renowned faculty, and connect with one of the largest, most diverse audiences in global oncology—in person or online.

BIO International Convention 2033

June 5-8, 2023 | Boston, Massachusetts, USA

Website: https://www.bio.org/events/bio-international-convention
Contact: CustomerCare@bio.org
The BIO International Convention attracts 14,000+ biotechnology and pharma leaders for one week of intensive networking to discover new opportunities and promising partnerships. It will deliver four days of BIO One-on-One Partnering for business development, networking events, along with expert-level programming content focused on the most pressing industry topics including COVID-19, Infectious Diseases, Oncology, Business Development, Financing Trends, Cell, and Gene Therapy, Digital Health, and more. There will be a variety of panels and presentations across all four days.

EUROPE

ICPP 2023 International Conference on Pharmacy and Pharmacology

February 16-17, 2023 | Barcelona, Spain

Website: https://waset.org/pharmacy-and-pharmacology-conference-in-february-2023-in-barcelona
Contact: https://waset.org/login
International Conference on Pharmacy and Pharmacology aims to bring together leading academic scientists, researchers and research scholars to exchange and share their experiences and research results on all aspects of Pharmacy and Pharmacology. It also provides a premier interdisciplinary platform for researchers, practitioners and educators to present and discuss the most recent innovations, trends, and concerns as well as practical challenges encountered and solutions adopted in the fields of Pharmacy and Pharmacology.

Conference Alerts

Bio-Europe Spring 2023 Reconnecting and Facilitating Global Partnerships

March 20-30, 2023 | Basel, Switzerland | Virtual & In-Person Conference

Website: https://informaconnect.com/bioeurope-spring/
Contact: EBDcustomerservice@ebdgroup.com
A major theme of the BIO-Europe program is innovation, a major strength of Switzerland in general and Basel especially. Novartis and Roche will lead the program in a joint opening keynote.

DIA Europe 2023

March 22-24, 2023 | Basel, Switzerland

Website: https://www.diaglobal.org/en/flagship/dia-europe-2023
Contact: Basel@DIAglobal.org
Dia Europe 2023 is designed to drive insights into action by connecting key policy discussions to real-world knowledge that you need for your everyday job. Your participation will accelerate your growth and your organization's performance in the drug development ecosystem.

AMP 2023 Europe Congress

June 18-20, 2023 | Milan, Italy

Website: https://amp-europe-congress.com/#
Contact: amp-europe@wearemci.com
AMP is the leading organization in the field of molecular diagnostics, and our Europe Congress is a premier meeting of molecular professionals around the globe. As always, we will explore how cutting-edge technology and developments in molecular testing and diagnostics continue to have a major impact on patient care. Please be sure to check back for all the latest information. This year's Congress will be held in conjunction with the 37th Congress of the Italian Society of Pathology and Translational Medicine (SIPMeT). We are delighted to have our Italian colleagues participate in this prominent event.

ASIA

Medical Korea 2023 The 13th Global Healthcare & Medical Tourism Conference

March 23-24, 2023 | Seoul, South Korea

Website: https://www.mkconf.org/fairDash.do
Contact: mkconf2023@gmail.com
Medical Korea 2023 conference exchanges international medical trends and expands global networks. It exchanges information on the latest healthcare industry trends and prospects by holding a global healthcare conference which is combined with topicality and professionalism. Medical Korea 2022 aims to build a global network of industry with participating health and medical field's global experts.

Healthcare Asia Summit 2023

March 28, 2023 | Singapore, Singapore

Website: https://healthcareasiamagazine.com/event/healthcare-asia-summit-2023
Contact: businessconference@charltonmediamail.com
In March 2023, join senior executives from hospital and healthcare firms, subject-matter experts from top consultancies, business leaders, and regulators of the healthcare sector in Asia. Healthcare Asia Summit will explore a plethora of topics through industry presentations, case study presentations, and panel discussions. Topics and discussions range from the role of the private and public sectors in expanding health access to factors that influence the increase in the popularity of healthcare services.

CPHI Japan 2023

April 19-21, 2023 | Tokyo, Japan

Website: https://www.cphi.com/japan/en/home.html
Contact: https://www.cphi.com/japan/en/about/contact-us.html
CPHI Japan is the ideal business platform for international pharma professionals to join in order to grow their business in the rapidly evolving Japanese pharma market. Hosting over 200 exhibitors from ingredients, contract services and biopharma through to technology, packaging and machinery – CPHI Japan is your ultimate one-stop-shop to find the latest Japanese pharma solutions.

18th Asia Conference on Healthcare and Healthcare Insurance

May 10-11, 2023 | Singapore, Singapore

Website: https://www.asiainsurancereview.com/Events/Home/Asia/airhc2023
Contact: loga@asiainsurancereview.com
In its 18th year, this conference will aim to offer a slew of information and potential solutions to address the region's health insurance challenges. Insurers need to modify their business strategies immediately for sustainability and profitability. Changes in health insurance have highlighted issues such as the need for better coverage, innovative products, addressing mental health issues, and an all-rounded wellness approach for both the healthcare and insurance industry.

2023 BioKorea International Convention

May 10-12, 2023 | Seoul, South Korea

Website: https://www.biokorea.org/index.asp
Contact: biokorea@biokorea.org
Since 2006, BIO KOREA has been holding the International Convention every year for invigorating and growing the global bio-health industry. Through various programs of BIO KOREA 2023 including conferences, business partnering, exhibition, and invest fair, exchange the newest bio-health trends and technology as well as get the global expansion business opportunity with various international academics, professionals, and CEOs of the global bio-health field.

Latest Healthcare Industry News

January 2023 - February 2023

1 J&J's Latest Data for Nipocalimab in Fetal Disorder Suggests Momenta Acquisition May Still Pay Off

When Johnson & Johnson acquired nipocalimab as part of the $6.5 billion takeover of Momenta Pharmaceuticals, the hype surrounding the therapy was focused on its potential as a treatment for the hot disease area of myasthenia gravis. But a top-line phase 2 readout for the drug in a fetal disorder is a reminder that nipocalimab could have a far broader reach. Nipocalimab is the only therapy in clinical development for the treatment of alloimmunized pregnant adults at risk of severe hemolytic disease of the fetus and newborn. Over the roughly 20-week treatment period, nipocalimab's safety profile supported further development of the drug in this fetal indication, J&J said in a release Monday morning.

https://www.fiercebiotech.com/biotech/jj-latest-data-nipocalimab-fetal-disorder-suggests-momenta-buy-may-pay

2 Boarding Priority Review Track, Biogen and Sage Get August Decision Date for Depression Drug Approval

Add Aug. 5 to your diaries. That is the FDA's decision date for the approval of Biogen and Sage Therapeutics' zuranolone, which the agency has accepted for priority review as an oral treatment of major depressive disorder (MDD) and postpartum depression (PPD). The FDA's acceptance of the submission is the latest milestone in Sage's bid to recover from the failure of a phase 3 clinical trial of zuranolone in MDD in 2019. Biogen came on board in 2020, and, together, the pair executed a three-pronged R&D program that was originally designed to get the molecule to market in 2022. While the partners missed that target, they now have the finish line in sight.

https://www.fiercebiotech.com/biotech/boarding-priority-review-track-biogen-and-sage-get-august-pdufa-date-oral-depression-drug

3 FDA Approves Gilead's Trodelvy for Expanded Use in Breast Cancer

Gilead has secured an expanded U.S. approval for its breast cancer medicine Trodelvy, announcing Friday the Food and Drug Administration cleared the antibody treatment for the most commonly occurring form of the tumor type. Previously approved only for rarer, "triple-negative" breast tumors, Trodelvy can now be used to treat patients with metastatic breast cancer that's hormone receptor, or HR, positive, but negative for a protein called HER2. This type of breast cancer accounts for an estimated 70% of all new cases, according to Gilead. The FDA's decision is a win for Gilead, which gained Trodelvy when it paid $21 billion to acquire Immunomedics in 2020. But clinical trial results showed the drug's benefit was modest, and Gilead will face competition from a rival drug sold by AstraZeneca and Daiichi Sankyo.

https://www.biopharmadive.com/news/gilead-fda-approval-trodelvy-hr-breast-cancer/641968/

4 How CAR-T Therapies are Revolutionizing Cancer Treatments

One of the most significant advancements made in treating disease in recent years is the development and commercialization of CAR-T therapy, which weaponizes a patient's own white blood cells to attack certain types of blood cancer cells. For some cancer patients, CAR-T therapy hope holds the promise of a cure. Something that could open more options for CAR-T treatments is a shift from autologous (unique to a single patient) to allogeneic CAR-T treatments, which are off-the-shelf options that can be used by many patients.

https://www.biopharmadive.com/spons/how-car-t-therapies-are-revolutionizing-cancer-treatments/640134

5 Baxter Links Up With Miromatrix to Test Bioengineered Liver Replacement Therapy

Baxter has teamed up with the xenotransplant developer Miromatrix Medical to help advance bioengineered replacement organs for patients suffering from acute liver failure.The medtech signed on while Miromatrix's work is currently in a holding pattern. The company is awaiting a green light from the FDA to launch a phase 1 human study after the agency delivered a clinical hold and requested additional data before participants could be treated.

https://www.fiercebiotech.com/medtech/baxter-links-miromatrix-test-bioengineered-liver-replacement-therapy

6 N.Y.U. Langone Withdraws From Type 1 Diabetes Vaccine Trial in Adolescents

The B.C.G. vaccine, more than a century old, has shown some promise against diabetes. The university's move left parents and outside investigators concerned. Researchers at N.Y.U. Langone Health have pulled out of a trial investigating the use of an old tuberculosis vaccine to treat children with Type 1 diabetes only months after they began enrolling participants on Long Island.The lead investigators of the pediatric trial, who are at Massachusetts General Hospital in Boston, are proceeding with the study, but N.Y.U. Langone's abrupt withdrawal could potentially jeopardize its viability if they are unable to collect data on the children at the N.Y.U. site.

https://www.nytimes.com/2023/01/20/health/diabetes-bcg-nyu.html

7 AAHI Awarded a $9.9 Million Project to Develop Prototype Intranasal Bivalent Influenza RNA Vaccine Candidate

The Access to Advanced Health Institute (AAHI) announced today that it has been awarded a project agreement worth up to $9.9 million through the Medical CBRN Defense Consortium (MCDC) Other Transaction Authority (OTA) to develop a prototype intranasal bivalent influenza RNA vaccine candidate based on AAHI's self-amplifying RNA (saRNA) platform that targets both pandemic A(H5N1) and A(H7N9) influenza virus pathogens.This prototype project was awarded on behalf of the U.S. Department of Defense's (DoD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services. AAHI's innovative RNA platform, which delivers saRNA bound to the exterior of a nanostructured lipid carrier (NLC), entered first-in-human clinical trials in May 2022 with Phase 1/2 clinical trials of the "AAHI-SC2" COVID-19 vaccine candidate (NCT05370040).

https://www.news-medical.net/news/20230206/AAHI-awarded-a-2499-million-project-to-develop-prototype-intranasal-bivalent-influenza-RNA-vaccine-candidate.aspx

8 BeiGene Wins Expanded Approval for Leukemia Drug, Intensifying Battle with AbbVie, AstraZeneca

The Food and Drug Administration has approved BeiGene's targeted cancer drug Brukinsa for use in a type of leukemia, the company said Thursday. The decision expands the treatment's market and puts it in a battle with AbbVie and Johnson & Johnson's Imbruvica and AstraZeneca's Calquence in the most common form of the disease. BeiGene hopes data from a clinical trial testing Brukinsa head to head against Imbruvica will give it an edge in chronic lymphocytic leukemia, a condition in which Brukinsa outperformed the AbbVie and J&J drug in delaying disease progression or death in the ALPINE trial.

https://www.biopharmadive.com/news/beigene-brukinsa-cll-leukemia-abbvie-astrazeneca/640851

9 An FDA Committee Votes to Roll Out a New COVID Vaccination Strategy

A committee of advisers to the Food and Drug Administration voted unanimously on a proposal to simplify the nation's strategy for vaccinating people against COVID-19. The recommendation is that future COVID-19 vaccines should be interchangeable: no matter whether you're getting your first dose or a booster, the vaccines would all have the same formulation targeting the same viral strain or strains, regardless of the manufacturer. In addition, the committee considered (but didn't vote on) proposals to have an annual COVID vaccination schedule, much like the U.S. has for the flu. The ultimate goal would be to get more people vaccinated.

https://www.npr.org/sections/health-shots/2023/01/26/1151810765/fda-committee-votes-to-roll-out-new-covid-vaccination-strategy

10 Fledgling Digital Health Companies Take Complex Fertility Process Out of the Clinic and Into the Home

The time-sensitive process of getting pregnant through in vitro fertilization (IVF) could not wait for stay-at-home orders to end. As the pandemic wanes, health tech companies are bringing the IVF process into the home while providing support to the patients who largely coordinate the process themselves. Women's health company Proov provides an at-home ovulation testing kit and boasts the only FDA-cleared and CE-marked at-home ovulation diagnostic platform. The startup nabbed $9.7 million in series A funding in December 2021 to continue building out its product pipeline in women's health.

https://www.fiercehealthcare.com/digital-health/fledgling-digital-fertility-companies-are-bringing-new-fashion-baby-making-process

11 LymeX Diagnostics Prize Launches Phase 2 with a Virtual Accelerator

The U.S. Department of Health and Human Services (HHS) and the Steven & Alexandra Cohen Foundation (the Foundation) have launched Phase 2 of the LymeX Diagnostics Prize , inviting the ten Phase 1 winners to participate in a virtual accelerator. Through September 2023, the virtual accelerator cohort will refine their concepts for detecting active Lyme disease infections in people.The goal of the multiphase LymeX Diagnostic Prize (LymeX) competition is to nurture the development of diagnostics toward Food and Drug Administration review.

https://www.hhs.gov/about/news/2023/02/02/lymex-diagnostics-prize-launches-phase-2-with-a-virtual-accelerator.html

12 EzriCare Eye Drops Recalled After CDC Linked to Infections, One Death

Federal health officials urged people to stop using a brand of nonprescription eye drops that they said could be responsible for a spate of infections and at least one death. At least 55 patients in 12 states have been diagnosed with multidrug-resistant bacterial infections possibly linked to EzriCare Artificial Tears, the Centers for Disease Control and Prevention said. The infections have caused one death, permanent vision loss and hospitalization, the CDC said in a health alert on its website. At least five patients have experienced vision loss, the CDC said Thursday.

https://www.wsj.com/articles/eye-drops-linked-to-infections-and-one-death-cdc-says-11675301856

13 Amazon Doubles Down on Generic Drugs with New RxPass Subscription

Amazon is launching a generic drug discount program for Prime members, beefing up its pharmacy offering as the ecommerce giant continues its push into healthcare. The subscription service, called RxPass, is $5 per month for customers with Prime to fill as many prescriptions as needed from a list of about 50 generic medications, including delivery to their doorstep.RxPass does not accept insurance, including Medicare and Medicaid coverage. It is available in 42 states.

https://www.healthcaredive.com/news/amazon-prime-generic-drug-subscription-rxpass/641042/

14 What to Know About Paxlovid, the COVID Antiviral That Keeps People Out of the Hospital

The antiviral Paxlovid has changed the battle against COVID-19. It's so effective that more than 85% of people at risk for severe disease can avoid a bad outcome with a five-day course of the prescription medication given within five days of symptoms starting. But word of its effectiveness has been slow to catch on. Only about 7.6 million Americans have taken the medication, with nearly 1.6 million doses currently available nationwide.

https://news.yahoo.com/know-paxlovid-covid-antiviral-keeps-120008895.html

15 Gilead's Trodelvy Snags Vital Breast Cancer Nod. But AZ , Daiichi's Enhertu Casts Long Shadow

Thanks to a new FDA approval, Gilead Sciences' Trodelvy has entered a breast cancer arena that's crucial to the drug's commercial success—as well as the company's larger oncology ambitions. The FDA has approved Trodelvy for previously treated HR-positive, HER2-negative breast cancer, Gilead said Friday. To be eligible for the therapy, patients must have tried endocrine therapy and at least two additional therapies in the metastatic setting. Meaningful penetration in HR-positive, HER-2 negative breast cancer could give Trodelvy a major sales boost. But a recent market shift, pioneered by AstraZeneca and Daiichi Sankyo's Enhertu, casts a layer of uncertainty over the opportunity.

https://www.fiercepharma.com/marketing/gileads-trodelvy-snags-vital-breast-cancer-nod-az-daiichis-enhertu-casts-long-shadow

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