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The opportunities and challenges for antibody-based drugs

Reece Armstrong,
Editor, Drug Discovery World

Therapeutic antibodies have evolved from passive serum treatments to the types of targeted approaches we're now seeing in diseases such as cancer, changing the landscape of how clinicians approach diseases.

As science has developed, market approvals for therapeutic antibodies have risen drastically, making them one of the biggest successes in biologic medicines. There are now over 150 approved therapeutic antibodies and with research continuing at pace, we can expect to see more effective treatments make it to market in the coming years.

As it currently stands, cancer has been the main target for therapeutic antibodies due to these therapies' ability to target specific tumour proteins, making them more effective and reducing side effects compared to traditional treatments such as chemotherapy. This targeted approach has also enabled the delivery of cytotoxic therapies to tumours, giving clinicians access to a wider arsenal of cancer fighting drugs.

Autoimmunity and inflammatory conditions are also popular targets for therapeutic antibody developers but we're also seeing strong research emerge within neuroscience and infectious diseases.

This report covers some of the emerging research that are driving advancements within the sector, also outlining the strengths of the therapeutic antibody market, its geographical competitiveness and investment within the market. And though there are challenges such as price relating to antibody development, what this report largely points to is a market that is burgeoning with both investor and scientific confidence.

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An overview of the therapeutic antibody market

Antibody-based therapies have become somewhat ubiquitous and promising medicines that harness the body's immune system to fight a range of diseases such as cancer, infectious diseases and other disorders that affect the immune system. A decades old sector, antibody-based therapies have been advancing both scientifically and financially since their inception, becoming a major market within the pharmaceutical landscape. Here, DDW assesses the antibody therapeutic market, including the global powerhouses, key players and recent market developments in the field.

The market

In 2025 the global market for antibody therapies was valued at $351 billion according to a report by Precedence Research. The report also states that the market is expanding at a CAGR of 12% and that by 2034, will be valued at $973 billion.

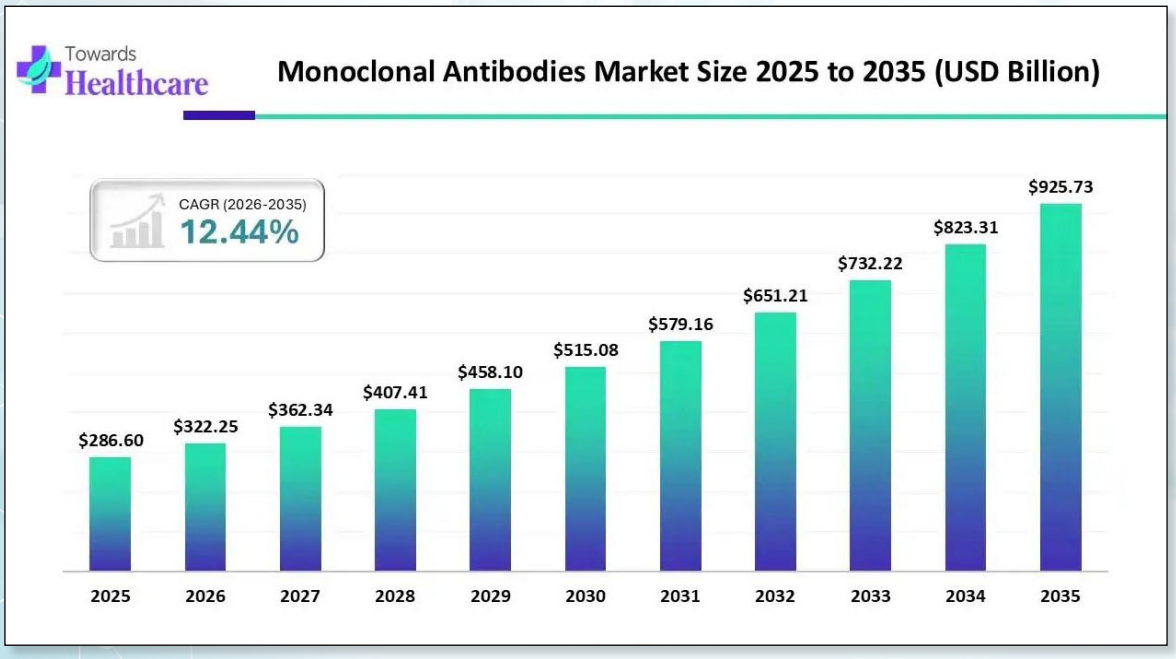
This expected growth can be attributed to the rise in approved therapies across numerous diseases, made possible by advancements in drug discovery and development processes which have helped enable more efficient antibody-based therapies.

Expanding clinical indications is also accelerating adoption of these therapies. In recent years, the market has seen developments into multiple cancer types, automimmune diseases, Parkinson's disease, Alzheimer's, obesity and more.

More so, strong regulatory backing has given drug developers expanded and accelerated access to global markets. For instance, the use of antibody-based therapies across rare diseases means they are often granted orphan drug designation (ODD) by the FDA.

Market by type

In 2024 there were 1,308 companies operating within the antibody therapy market, with a total of 12,553 assets in some form of development, according to a report by Inpart Insights. Among these assets, monoclonal antibodies (mAbs) made up the majority,



Source: www.towardshealthcare.com

Source: www.towardshealthcare.com

with 7,269 candidates in development. This was followed by antibody-based therapies at 3,230, antibody-drug conjugates at 1,357, and CAR-T NK cell therapies at 168. Other assets such as multivalent antibodies, humanised antibodies and chimeric antibodies featured below the 100 range.

According to FutureMarketInsights, monoclonal antibodies have held such a large share of the market due to their widespread clinical usage, high therapeutic efficacy and regulatory backing. In terms of safety, monoclonal antibodies have high specificity when targeting antigens and are generally considered to be safer than some traditional therapies.

Indeed in total, the global mAbs market was estimated to be worth $322.25 in 2026 and is projected to reach a value of around $925.73 billion by 2035, according to Towards Healthcare. The strong growth seen by mAbs can be linked to advances in genetic engineering, which have helped lead to greater efficacy for these drugs, and have also helped reduce side effects.

Market by region

US

Globally, the US holds the largest market for antibody therapies, being valued at around $93 billion in 2025 and expecting to reach a value of $265 billion by 2034. In terms of market share, the US sits at the top of the market with a 34% market share reported in 2024. You can understand why the US remains a market leader in antibody therapies when you consider how many are currently in development. According to the Antibody Societies' Database for Therapeutic Antibodies, the number of therapeutic antibodies that have been in some form of form of development (whether approved or terminated) in the US is 1,257. China is the second largest competitor on this database, having had 759 therapeutic antibodies in some form of development from 2000.

China

In total, China's antibody market is expected to reach $184.3 billion by 2031 and currently sits with a market value of $92.6 billion. A rising demand for precision medicine, better oncology therapeutics and further approvals on mAbs are some of the factors helping to drive China's antibody market.

> "Much like other global markets, the rising prevalence of chronic diseases is driving the demand for advanced and effective treatments."

Other aspects driving growth include the growing prevalence of chronic diseases, including cancer, rheumatoid arthritis, psoriasis, inflammatory bowel disease, and asthma. These conditions, especially in ageing populations means that healthcare sectors are in need of therapies which can more effectively treat these diseases.

According to a survey conducted by ICON of 100 small pharma / biotech companies in China, 39% of them state that antibody-drug conjugates (ADCs) were the most prominent modality in their pipeline,

behind only cell therapies and microbiome-based drugs. These figures align with the industry's overall focus on precision medicine strategies, placing antibody-based therapies in a good position for growth in the coming years.

However, speaking about the position of ADCs in China, Wu Jie, Wu Jie Head of APAC at MPM BioImpact said that the crowded ADC market means that "many Chinese biotechs are having doubts right now."

"The way out for them is to get out-licenced or through licencing or M&A with a large pharma," Jie continued. Given the activity in the industry though, Jie says that pharma is in a position where it can wait to acquire biotechs with the best clinical data. As such we can expect to see some possible acquisitions in the space in the coming years but there seems to be no rush as of right now.

"One of the largest challenges facing therapeutic antibodies comes from how costly they are to produce, which could result in the market expanding at a slower rate."

Europe

Europe's antibody therapy market has been valued at $43.95 billion and is expected to reach $104.32 billion by 2033. The region has been supported by the likes of the European Medicine Agency's (EMA's) adaptive pathways and multi-nation trials which have helped speed up clinical trials throughout Europe by removing requirements to submit individual applications per country for multi-nation trials.

Much like other global markets, the rising prevalence of chronic diseases is driving the demand for advanced and effective treatments. We can see this demand correlating to the usage and approvals of new biologics. In 2024, biologics made up the majority of new drug approvals in Europe and were also the major therapeutic candidate in company pipelines.

Key players

The therapeutic antibody sector, whilst seeing a lot of activity in the biotech / small pharma space, is dominated by some of the usual suspects in big pharma. These include Roche, Abbvie, Johnson & Johnson, AstraZeneca, Novartis, Pfizer, Amgen, and Merck & Co. Roche for instance has had several key mAb therapies make it to market for the treatment of cancer and has a well-developed pipeline of early and late-stage therapeutic antibodies mostly targeting cancer and immunological conditions.

Last year Roche entered in a multi-year collaboration with Oxford Biotherapeutics to discover novel targets for antibody-based therapies in cancer. The deal, which could see Oxford Biotherapeutics receive up to $1 billion in milestone payments, further cements Roche's dedication to the therapeutic antibody space.

The collaboration combines the drug discovery capabilities of Oxford Biotherapeutics with Roche's expertise in development and commercialisation.

"We are excited to enter into this strategic collaboration with Oxford Biotherapeutics. By combining Roche's expertise in discovering and developing transformative therapeutics with Oxford Biotherapeutics' innovative target discovery platform, we aim to unlock new possibilities in cancer treatment", said Boris L. Zaïtra, Head of Corporate Business Development at Roche. "This partnership underscores our commitment to advancing potentially first-in-class antibody-based therapeutics. Together, we aim to accelerate the development of innovative therapies that address major unmet patient needs in oncology."

Roche's activity in the sector is rather impressive considering how much of a market share the company holds. For instance, Future Market Insights placed Roche's share of the global antibody therapy market at 25% in 2025, with the remaining three quarters being taken up by the remaining key players.

Challenges

One of the largest challenges facing therapeutic antibodies comes from how costly they are to produce, which could result in the market expanding at a slower rate, especially as the industry looks towards methods that can reduce costs and development timelines. Precedence Research quotes the average price for a mAb to be around $100,000, meaning that affordability, for both private and public healthcare systems is a major consideration. These high prices can be attributed to discovery and development costs, which for a mAb, can range from $750 million to $2 billion. However, this is an area which, as you will see below, makes for an interesting opportunity for costs to be reduced. As *Chen et al* writes, the cost of goods (COGs) for mAbs has dropped significantly over the past decades due to advances in manufacturing technologies. Cost per gram

for instance has dropped from the $1,000s to the $10s-$100s, with the authors stating that there is huge potential for the cost of therapeutic antibodies to be reduced.

Investment developments

In 2025 The Gates Foundation and LifeArc awarded several new projects designed to reduce the production costs for monoclonal antibodies. The $5 million partnership between the two organisations was designed to improve affordability for mAbs, which can often be out of reach in resource-limited settings due to high costs and supply chain limitations.

> "That pharma is in a position where it can wait to acquire biotechs with the best clinical data."

Projects funded by the organisations include:

- A continuous flow platform that could enable large amounts of antibodies to be produced on small local sites.
- The pioneering of low-cost, high-throughput technology using engineered fusion proteins to replace chromatography, reduce timelines and costs.
- The use of cells from filamentous fungus to possibly produce more mAbs in less time and at a lower cost.
- A continuous manufacturing platform for monoclonal antibody production.
- a low-cost biomanufacturing platform for the antimalarial antibody MAM01 by combining a fungal expression system with nanofiber-bound peptide purification.
- A low cost all-membrane process to Purify MAM01 Antibodies from C1 Cell Lines.
- A project to develop a low-cost platform for producing the antimalarial antibody MAM01 using the photosynthetic cyanobacterium Synechococcus.

Last September, Eli Lilly announced it would build a $5 billion manufacturing facility in the US to support its bioconjugate platform and monoclonal antibody portfolio. The plans form part of the company's plans to bolster domestic medicine production by developing four new pharmaceutical manufacturing sites. This Virginia facility, will enable Eli Lilly to boost its manufacturing capabilities for antibody-drug conjugates (ADCs).

Speaking about the investment David A. Ricks, Lilly chair and CEO said: "Our investment in Virginia underscores our commitment to US innovation and manufacturing – creating high-quality jobs, strengthening communities and advancing the health and well-being of Americans nationwide. "By expanding our domestic capacity, we're building a secure, resilient supply chain that delivers for patients today and supports the breakthrough medicines of tomorrow."

Asset management company Novo Holdings participated in a $187 million Series A launch financing for the biotechnology company Callio Therapeutics. The company is developing multi-payload antibody-drug conjugates (ADCs) to improve cancer therapies and has recently entered into an exclusive licensing agreement with Hummingbird Bioscience.

The Series A financing was led by Frazier Life Sciences and saw participation from Novo Holdings, Jeito Capital, Omega Funds, Norwest, ClavystBio, EDBI, Platanus, Pureos Bioventures and SEEDS Capital.

Callio Therapeutics will use the funding to achieve clinical proof-of-concept for its HER2-targeted dual-payload ADC and a second undisclosed ADC programme.

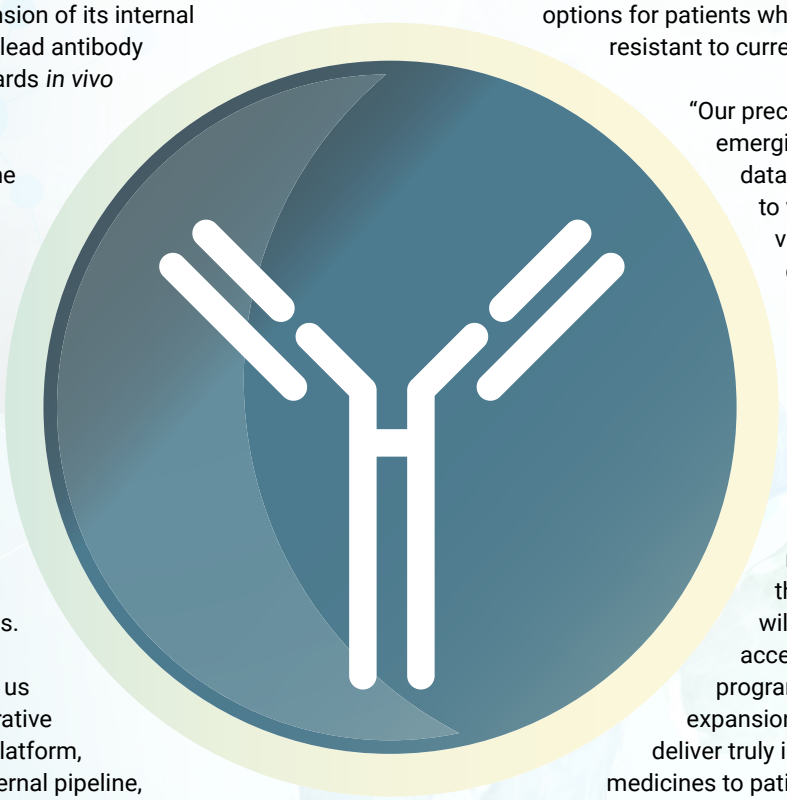
Novo Holdings participated in the financing as Callio Therapeutics' company goal aligns with Novo Holdings' commitment to advancing innovative ADC technologies and builds on its existing portfolio to support the next generation of precision cancer therapies.

> "The global mAbs market was estimated to be worth $322.25 in 2026 and is projected to reach a value of around $925.73 billion by 2035."

Piers Ingram, PhD, co-founder and Chief Executive Officer, Callio Therapeutics, said: "We are delighted to be launching Callio Therapeutics with the support of Frazier Life Sciences and this syndicate of investors. Multi-payload ADCs have the potential to enable the targeted delivery of rational drug combinations to

cancer cells and may provide significantly enhanced efficacy. This new generation of ADC therapies may meaningfully improve outcomes for patients."

In March, UK-based biotech Antiverse raised £7 million in a series A funding round bringing the total capital raised by the company to $20 million. The company states the funding will enable it to scale its AI-powered antibody discovery platform and also support the expansion of its internal drug pipeline and lead antibody programmes towards *in vivo* efficacy studies.



Speaking about the funding, Murat Tunaboylu, Co-Founder and CEO of Antiverse, said: "Many biologically important targets have remained difficult to drug using conventional antibody discovery methods. This Series A financing enables us to scale our generative antibody design platform, accelerate our internal pipeline, and expand strategic collaborations such as our work with the Cystic Fibrosis Foundation, where our technology is applied to explore challenging targets like extracellular CFTR. Together, these efforts help inform future research efforts and allow Antiverse to continue advancing our own therapeutic programs for patients."

Antibody-drug conjugate company Phrontline Biopharma closed a $60 million financing round led by Lapam Investment.

Phrontline is focused on bispecific antibody ADCs (BsAb-ADCs) and dual-payload ADCs – a strategy it states reflects recent investor confidence. The company will use the investment to advance its clinical-stage and preclinical ADC programmes, expand its global clinical operations, and strengthen existing strategic partnerships. The company has signed a global strategic collaboration with Samsung Bioepis in which the two companies will jointly develop two next-generation bispecific, dual-payload ADC candidates.
It has also entered in an exclusive license agreement with Sino Biopharmaceutical which the company says represents its transition into accelerated global clinical development.

Speaking about the investment Tony Chen, Founder and Chief Executive Officer of Phrontline Biopharma said: "From the beginning, our strategy has been guided by biology and translational science. We believe that dual-target synergy and complementary payload mechanisms can unlock new therapeutic options for patients whose tumours are resistant to current therapies.

"Our preclinical and emerging clinical data are beginning to validate this vision. We are deeply grateful to both our new and existing investors for their continued confidence in Phrontline. This financing marks an important milestone for the company and will allow us to accelerate our clinical programs and global expansion as we work to deliver truly innovative ADC medicines to patients around the world."

In one of the larger funding rounds last year, oncology company Tubulis closed a second Series C financing round totalling $401 million.

Tubulis intends to use the funds to accelerate its lead antibody-drug conjugate (ADC) candidate TUB-040 into pivotal trials. It will also explore earlier lines of treatment in ovarian cancer and expand into combination regimens and new solid tumour indications. The company also says the funds will help advance its current pipeline and preclinical programmes.

Dr Dominik Schumacher, Chief Executive Officer and Co-founder of Tubulis said: "We are expanding our syndicate with prestigious investors who all have significant track-records and a strategic long-term focus. The combined group of funds enables us to accelerate our clinical development plans and further expand our global footprint. We are now in a strong position to deliver on our goal – realising the full potential of the ADC drug class for more patients."

Why mAbs are at the heart of phasing out animal testing

DDW Editor Reece Armstrong speaks to Lorna Ewart, Chief Scientific Officer at Emulate, about regulations to phase out animal testing, and why monoclonal antibodies (mAbs) and technologies such as organ-on-a-chip are so important in these goals.

RA: How realistic is phasing out animal studies by 2030?

LE: Phasing out all animal studies by 2030 is a very ambitious target but the opportunity to reduce animal studies by 2030 is achievable. The FDA roadmap published in April 2025 and the subsequent NHP guidance released in December 2025 highlights real opportunities to reduce six-month chronic NHP toxicity studies for monoclonal antibody programmes. This can be done by incorporating human-relevant models, such as organ-on-a-chip technology together with other *in vivo* toxicity studies and existing toxicity from similar antibodies. Other global initiatives, such as the roadmap released by the UK government in November 2025 provides a path towards reducing dogs and NHPs in PK or cardiovascular safety studies by 35% by 2030, once more referencing the significant performance of *in vitro* and *in silico* models in the field. Other opportunities to reduce animal use include using validated models such as Liver-Chip[1] for predicting drug-induced liver injury (DILI) prior to the maximum tolerated dose/dose range finding in vivo studies. If the Liver-Chip flagged a candidate as toxic, they have the option not to progress it to the animal studies thus reducing animals used as well as providing them with greater confidence in the candidate they do progress to clinical trial. Moderna has also used the Liver-Chip to pre-screen lipid nanoparticles (LNPs) for its pro-fibrotic potential ahead of progressing into a NHP study. In so doing, it can substantially reduce the number of NHPs that are needed to identify the optimal LNP candidates to deliver their mRNA cargo.

RA: Why are monoclonal antibodies (mAbs) the starting point for this programme and how can this inform future therapy areas?

LE: Let's start with the science. Not all human antigens are conserved in primates; binding affinity can be different and in some cases the target is absent. In such cases it is possible to raise an antibody homologue to the animal antigen, but ultimately this is not working with the "real" antigen and immunogenicity remains a challenge. Then, there is the very high financial cost of primate studies, which can take up to 36 months from study design to execution and of course there is an ethical consideration as these studies use large numbers of NHPs per programme. mAbs are among the most established biologic drug classes, used widely in oncology, autoimmune disease, and infectious diseases. There is a large amount of clinical and post-marketing safety data available and thus using this, there is sufficient evidence to support alternative testing approaches. Compared to small molecules, monoclonal antibodies have a high target specificity, exhibit predictable PK and follow well characterised mechanisms including target binding and immune modulation. Because of this their safety can be predicted by tools like organ-on-a-chip. For example, Roche were developing a bi-specific antibody for the folate 1 receptor which led to a severe inflammatory response in the lungs of NHPs. A human alveolus-chip exposed to the same antibody reproduced these findings[2] and thus if it had been available prior to the NHP study and shown such a result, it may have stopped the candidate prior to entering an NHP. For future modalities this is likely to inform firstly other biologics such as antibody-drug conjugates and recombinant proteins.

RA: Are you expecting to see better patient-relevant data

LE: As organ-on-a-chip technology is used more frequently by academics and biopharma, there has been a steady increase in the number of publications highlighting their ability to generate patient-relevant data. More recently a publication by Dr Lorenzo Ferri at the Research Institute of the McGill University Health Center eloquently reproduced a person's cancer on an organ-chip and moreover showed across eight patients this model could predict treatment response with high precision[3]. This ultimately opens the potential for the advancement of personalised medicine.

RA: What are the practical issues of utilising animal models in drug development? What are the scientific limitations of animal models in pre-clinical research?

LE: One of the biggest limitations is the species differences between pre-clinical animal models and humans. More specifically, this can be categorised at a genetic, environmental, physiological (functional) and drug metabolism level. Most widely shared is the statistic that for every 10 drugs that enter Phase I clinical trials, only one reaches the marketplace thus making the case for an improvement in pre-clinical testing strategies. However, for diseases such as Alzheimer's disease or cancer, the statistic is typically higher, highlighting that animal models are not a good surrogate for human response. These statistics form a strong ethical argument, especially as human relevant technologies are on the ascendance.

Maintaining animal facilities is an expensive endeavour requiring dedicated housing, veterinary oversight, regulatory compliance and in some cases, specialised equipment. Laboratory animals are favoured for their genetic uniformity, but such a trait compounds the ability to study human variability in response and together with their sterile housing environment, the impact of environmental factors particularly on the microbiome, are missing. Lastly, it has been extensively described that animal model experiments are poorly reproducible. Amgen are acknowledged as taking the lead in this space with their landmark publication in 2012[4]. Here they found that out of 53 preclinical cancer studies, only six (or 11%) could be reproduced. This sets the benchmark for organ-on-a-chip studies going forward and reproducibility increasingly asked for by the biopharma industry and regulators when considering a model for qualification.

RA: What challenges will research teams face when implementing NAMs over animal models?

LE: Beyond scientific validation and regulatory qualification, research teams will need to ensure operational and ecosystem readiness. For example, their workforce needs to be trained in the operating platforms and interpretation of high-dimensional, multi-modal datasets. In parallel, laboratory infrastructure will likely evolve to support scalable deployment through automation, robotics and standardised device handling compatible with industrial drug discovery workflows. Lastly, interoperable data architectures will also be critical.

RA: What preparations has Emulate taken in consideration of the FDA's roadmap?

LE: For organ-on-a-chip technology to influence regulatory decision making as a drug development tool, the model should be qualified. Emulate entered the FDA's ISTAND qualification programme to achieve qualification for the Liver-Chip model to predict DILI. ISTAND is a three-step programme that involves writing a letter of intent, followed by a qualification plan and then submitting a full qualification package. In September 2024, Emulate became the first organ-on-a-chip to be accepted into the ISTAND programme and is currently one of only two companies to have an accepted qualification plan.

RA: We've seen rapid advancement of AI and machine learning in recent years. How can these technologies be used to improve pre-clinical research?

LE: Thinking about organ-on-a-chip technologies, there are several major ways that AI and machine learning, already is or could, improve pre-clinical research; (1) phenotypic profiling and mechanism of action discovery, (2) creation of digital twins to support PBPK/PD frameworks, (3) optimisation of experimental design, (4) quality control of cell seeding and (5) performance modelling.

RA: We've seen other countries implement similar goals. How should companies be approaching global regulatory alignment?

LE: This is an area that the IQ MPS affiliate, a group of pharmaceutical companies who work in a pre-competitive manner, are actively working on. For example, at the upcoming MPS World Summitt in Washington DC in May 2026 they are organising a workshop to bring global regulators together to discuss and share ideas on how they can align with the regulatory policy updates that are shaping the field.

Biography
Lorna Ewart is Chief Scientific Officer at Emulate where she plays a pivotal role in advancing regulatory science. She worked in the pharmaceutical industry for 20 years where she gained deep expertise across drug discovery, development, and translational science. Ewart serves on the board of the international MPS society.

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The structural data bottleneck in AI antibody discovery

Dan Benjamin, PhD, Co-Founder & Chief Technology Officer of Immuto Scientific, examines why limited antibody–antigen co-structure datasets may be constraining AI model performance—and how high-throughput structural generation could reshape the field.

Artificial intelligence now plays a central role in antibody discovery. Machine learning models assist in sequence design, paratope prediction, affinity maturation, and developability screening. Yet despite increasingly sophisticated architectures, model performance often degrades when applied to novel antibody sequences or previously uncharacterised targets.

The limitation may not be algorithmic. It may be structural.

The scale problem in antibody training data

Most AI systems for antibody discovery rely heavily on publicly available structural data—primarily antibody–antigen co-crystal and cryo-EM structures deposited in the Protein Data Bank (PDB). While invaluable, the number of unique antibody–antigen complexes remains relatively small—on the order of only a few thousand nonredundant structures.

For a field attempting to generalise across immense antibody sequence diversity, this represents a narrow sampling of interaction space.

Antibody repertoires span millions to billions of possible sequences. Yet structural training data captures only a tiny fraction of that diversity. When models trained on this limited structural universe are asked to predict binding for novel antibodies—particularly those far from known scaffolds—they often struggle to accurately model interaction geometry.

The issue is not that existing structures are flawed. It is that there are not enough of them.

Generalisation requires interaction diversity

AI models in antibody discovery are often evaluated on their ability to predict properties within known sequence families. However, real-world discovery requires generalisation beyond previously observed binders.

Failure modes frequently emerge when models encounter:

- Novel CDR loop geometries
- Unseen epitope topologies
- Unusual binding interactions
- Rare scaffold architectures

These are precisely the cases where additional co-structural examples would improve model learning. Expanding the diversity of antibody–antigen interaction geometries—rather than only refining model architecture—may be essential for building truly generalisable systems.

In this sense, structural data functions as infrastructure. Without sufficient interaction diversity, model sophistication alone cannot compensate.

The limitations of traditional structure generation

X-ray crystallography and cryo-electron microscopy have defined structural biology for decades. They provide atomic-resolution insight and remain foundational tools.

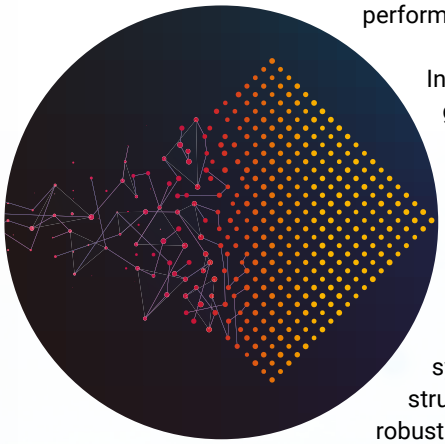
> "Antibody sequence space is vast. Our structural training sets are comparatively small."

However, they are not optimised for scale. Structure determination through crystallography or cryo-EM requires significant time, protein engineering, purification, stabilisation, and iterative optimisation. As a result, structural datasets accumulate slowly. Certain protein classes are overrepresented, while others remain sparsely characterised. Many antibody–antigen interactions are never structurally resolved due to throughput

constraints rather than scientific irrelevance.

Additionally, these approaches typically capture a single stabilised conformation. While high resolution, they do not readily capture interaction dynamics in solution.

For AI systems attempting to learn the rules of molecular recognition, both diversity and dynamic representation matter.



Toward high-throughput, in-solution structural generation

Recent advances in structural mapping technologies now enable antibody–antigen complexes to be characterised in solution at substantially higher throughput. By integrating empirical interaction data with computational modeling, it is possible to generate full PDB-format co-structures constrained by experimental measurements.

Importantly, these workflows are compatible with scale.

> "Model architecture matters. But training-set size and diversity may matter more."

Rather than solving tens of structures per year, structural generation can expand into the thousands—and potentially far beyond. Increasing the size of structural training datasets from approximately 2,000 public co-structures to 10,000, 50,000, or even 100,000 diverse examples would meaningfully alter the landscape for AI antibody design.

Such expansion does not replace computational modeling; it strengthens it. Empirical constraints reduce structural ambiguity and anchor models in experimentally derived interaction data.

Structural data as competitive infrastructure

In AI-driven antibody discovery, competitive advantage is often framed in terms of proprietary models. Yet models trained on similar public datasets inevitably converge toward similar performance ceilings.

Industrialised structural generation enables the creation of proprietary, high-diversity antibody–antigen interaction datasets. These datasets can serve as the foundation for internal model training, fine-tuning, and validation. Over time, organisations capable of systematically expanding their structural libraries may achieve more robust generalisation across novel targets and binders.

This reframes structural biology from a validation tool to a data engine.

Rather than asking which architecture performs best on a fixed dataset, the field may increasingly ask which organisations can generate the richest structural training datasets.

Redefining what limits AI in antibody discovery

The past decade has focused heavily on algorithmic innovation. The next phase may focus on dataset expansion.

Antibodies recognise three-dimensional structure through highly specific geometric complementarity. Training AI systems to predict and design these interactions requires exposure to broad and diverse examples of that geometry.

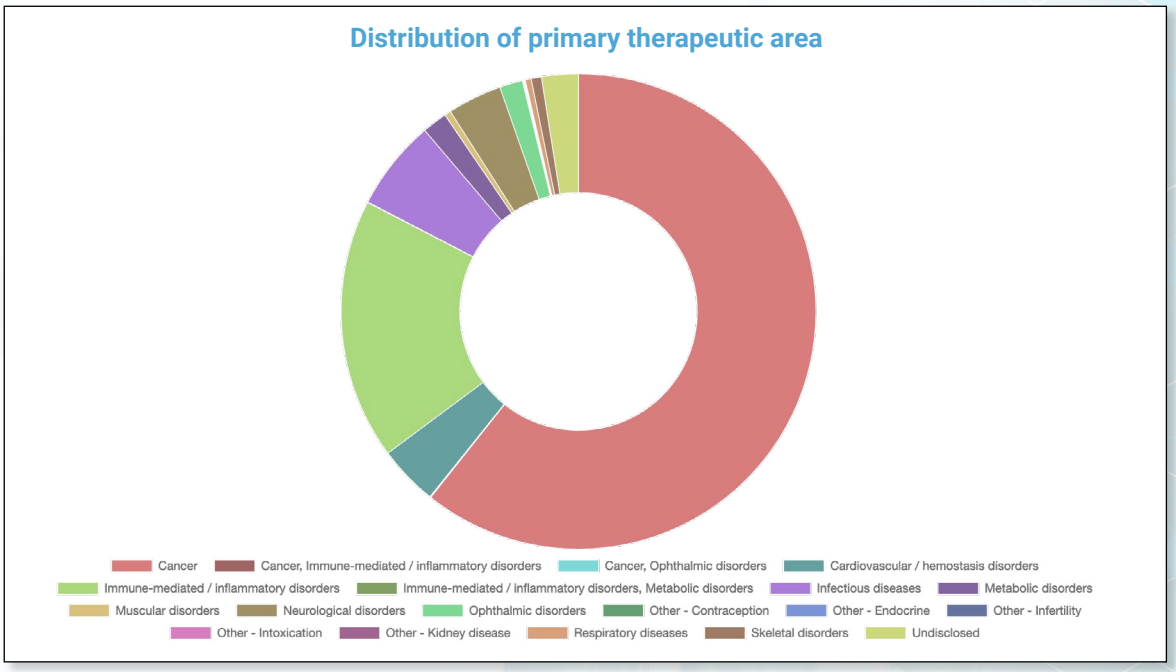
Expanding antibody–antigen structural datasets—particularly with scalable, in-solution methods—offers a pathway to improve generalisation, robustness, and predictive accuracy across novel sequence space.

In antibody AI, the bottleneck may no longer be compute—it may be structural data volume.

About the author
A structural biologist and technology developer, Daniel Benjamin leads the company's high-throughput structural proteomics and AI integration efforts for antibody discovery. His doctoral research focused on advancing mass spectrometry–based approaches for studying protein structure in biopharmaceutical research.

The scientific developments driving therapeutic antibodies

DDW explores the latest industry developments seen throughout the therapeutic antibodies sector.



Source: antibodysociety.org

Clinical outlook of therapeutic antibodies

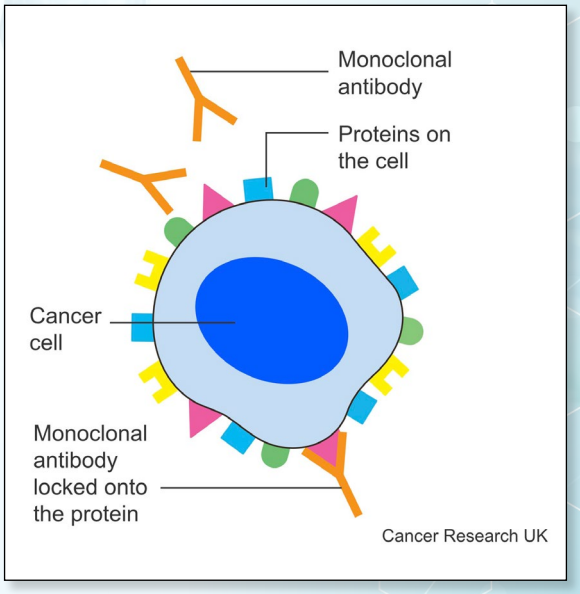
According to the Database for Therapeutic Antibodies, oncology is the most prominent clinical target for therapeutic antibodies. This is unsurprising given the potential that therapeutic antibodies hold as targeted and effective treatments for many cancers. Data from the Antibody Society show that there are 1,819 therapeutic antibodies targeting cancer, that are either approved, in clinical trials or that have been terminated since the year 2,000. The next largest clinical target is immune-mediated / inflammatory disorders (532), followed by infectious diseases (185).

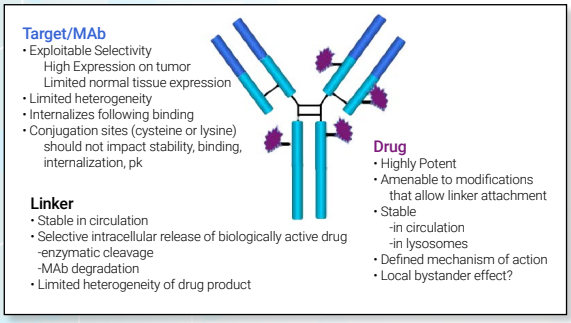
Types of therapeutic antibodies

Monoclonal antibodies

Monoclonal antibodies stick to a target marker or antigen in a specific manner, blocking the action of proteins that can help cancer cells survive in various manners including by:

- Blocking the signals that tell cancer cells to divide and grow
- Carrying drugs to cancer cells
- Blocking proteins that enable cancer cells to hide from the immune system
- Blocking the signals that develop blood supplies for cancer cells





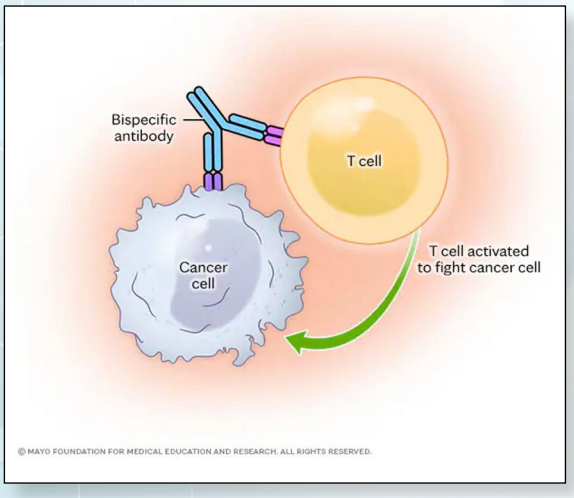
Source: Trail, Pamela. (2013). Antibody Drug Conjugates as Cancer Therapeutics. Antibodies. 2. 113-129. 10.3390/antib2010113

Antibody Drug Conjugates

Antibody drug conjugates (ADCs) will combine an mAb with a chemotherapy drug via a linker agent. These drugs works by having the mAb bind to a specific protein on a cancer cell, which can then release a cytotoxic drug directly into a cancer cell – minimising damage to healthy cells.

Bi-specific antibodies

Bi-specific antibodies are able to bind to two distinct biological domains, letting them target two different antigens or epitopes on the same antigen. This gives bi-specific antibody treatments a wider range of applications against disease such as blocking multiple signalling pathways, targeting dual drivers of disease and delivering therapeutic payloads to dual targets.



Oncology

Solid tumours

Biotechnology company Hutchmed is focused on the development of targeted therapies and immunotherapies for cancer and immunological diseases. The company is utilising its Antibody-Targeted Therapy Conjugate (ATTC) platform that enables the delivery of therapies with dual mechanism of actions through the conjugation of a monoclonal antibody with small-molecule inhibitor payloads via cleavable linkers.

Recently, the company initiated a Phase I/IIa clinical trial of its HMPL-A580 candidate – its second novel ATTC in patients unresectable, advanced or metastatic solid tumours.

HMPL-A580 is comprised of a highly selective and potent PI3K/PIKK small-molecule inhibitor payload linked to an anti-EGFR antibody via a cleavable linker. EGFR is highly expressed in multiple types of solid tumours and is well recognised as a driving force in tumourigenesis and disease progression.

The PI3K/AKT/mTOR ("PAM") pathway is a critical intracellular network involved in cell growth, survival, and division. Alterations in the PAM pathway are frequently associated with poor prognosis and resistance to treatment across various cancers. However, existing PAM-targeted drugs face significant challenges, including on-target toxicities that restrict dosing, feedback loops that enable pathway reactivation, and insufficient tumour-specific delivery.

Hutchmed hopes that by delivering HMPL-A580 into EGFR-expressing tumour cells, it can overcome the systemic toxicity and narrow therapeutic index historically associated with PI3K/PIKK inhibitors.

The study will assess the safety, tolerability, pharmacokinetics, immunogenicity and preliminary efficacy of HMPL-A580, as well as the maximum tolerated dose and recommended dose for expansion.

Pancreatic tumours

A team of scientists at Northwestern Medicine: Feinberg School of Medicine has developed an antibody therapy that blocks how pancreatic tumours use a sugar-based disguise to hide from the immune system. The scientists' study in preclinical mouse models details how the sugar disguise works and shows that blocking it with a monoclonal antibody can reawaken immune cells to attack the tumour.

The study shows that pancreatic tumours hijack a natural safety system used by healthy cells, in which they express sialic acid on their surface so that the immune system doesn't target them.

The scientists found that pancreatic tumours exploit that system by loading the same kind of sugar onto the surface protein integrin α3β1, enabling them to bind to sensor on immune cells, disguising them from attack.

By using monoclonal antibodies that block this mechanism, the scientists found that immune cells woke up and began attacking cancer cells.

The team's next step is to combine the antibody

with current chemotherapy and immunotherapy treatments.

Study senior author Mohamed Abdel-Mohsen, PhD, the Margaret Gray Morton Professor of Medicine in the Division of Infectious Diseases, said: "There's a strong scientific rationale to believe combination therapy will allow us to reach our ultimate goal: a full remission," he said. "We don't want only a 40% tumour reduction or slowing down. We want to remove the cancer altogether."

The team is now fine-tuning the antibody for human use and states it may take about five years before the therapy could reach patients if progress continues successfully.

Breast cancer

Scientists at King's College London have developed a new antibody therapy strategy which could provide new treatment options for aggressive forms of breast cancer.

The team have developed an antibody that both attacks tumours cells directly and harnesses the immune system to attack the cancer cells at the same time. This 'triple-engineered antibody' attaches onto cancer cells on one end and draws in immune cells on the other.

In the team's study, lab experiments and animals models showed the modified antibody could bind immune cells more strongly compared to current treatments. This enabled immune cells already present in the tumour to attack it, limiting their growth in triple-negative and treatment-resistant breast cancers. The team also discovered that the treatment was able to activate immune cells in the bloodstream, potentially boosting the body's ability to fight cancer.

First author Dr Alicia Chenoweth, from the Faculty of Life Sciences & Medicine at King's College London, said: "By making a few key changes in the structure of the antibody, we found that it could activate the immune system much more powerfully than an unmodified antibody currently used in breast cancer treatment.

"Many of the immune cells in breast tumours are in a 'suppressed' state, difficult to activate with unmodified antibodies. We found our triple-engineered antibodies were not only able to activate these immune cells to kill the cancer cells, but shifted these immune cells to a more 'activated' state overall."

Neuroscience

Biotechnology SciNeuro Pharmaceuticals is focused on developing a pipeline of candidates targeting mechanistic drivers of neurodegenerative conditions. The company has multiple antibody candidates targeting proteinopathy and immune response.

The company has developed a platform that enables deep brain delivery of therapeutics, overcoming traditional challenges that prevented therapies from crossing the blood-brain barrier (BBB). The company's BBB shuttle platform was developed to enable cargo such as antibodies to be effectively delivered to the central nervous system (CNS).

This year, SciNeuro signed a collaboration with Novartis Pharma to advance SciNeuro's novel amyloid beta targeted antibody programme for the treatment of Alzheimer's disease.

The programme will incorporate SciNeuro's BBB shuttle technology with de novo antibody candidates that the company hopes will offer differentiation from existing amyloid beta targeted agents.

"The anti-amyloid programme represents one of SciNeuro's key strategic R&D priorities to target neurodegenerative disease. We are thrilled to collaborate with Novartis to continue its development, given their preeminent capabilities and commitment to next generation therapies for neurodegenerative diseases," said Min Li, Founder and CEO of SciNeuro. "This collaboration delivers an optimal synergy, combining our expertise in disease biology and early development with Novartis' global leadership in clinical development and commercialisation."

SciNeuro's says that its anti-amyloid candidate (SNP234) has exceptional potency and selectivity for toxic aggregated species over non-pathogenic monomeric forms. The candidate is targeting proteinopathy, which sees the accumulation of misfolded and toxic proteins build up in the brain, disrupting neuron structure and key cellular function. By removing pathogenic aggregates and preventing their further deposition, SciNeuro hopes its SNP234 candidate will have promise as a disease-modifying therapy.

ALS

VectorY Therapeutics is developing a vectorised antibody targeting a common pathological hallmark of amyotrophic lateral sclerosis (ALS). The company's VTx-001 and VTx-002 candidates are targeting TDP-43 pathology, a misfolded protein that builds up in the cytoplasm of motor neuron cells and which is seen in the majority of ALS cases.

Vectorised antibodies contain a transgene that delivers the instructions for a cell to create the therapeutic antibody, and a vector in which the transgene is packaged and delivered to the brain cells. This year saw the company dose its first patient with

VTx-002 in a Phase I/II PIONEER-ALS clinical trial of VTx-002 in people with ALS. VTx-002 was granted FDA Fast Track Designation for expedited review earlier this year.

Olga Uspenskaya-Cadoz, Chief Medical Officer of VectorY, said : "This trial marks the first ever clinical evaluation of a therapy designed to holistically target TDP-43 pathology in ALS, and thereby reduce TDP-43 aggregation, correct mis-splicing abnormalities, and restore normal nuclear function, and we are excited to advance this novel potential therapeutic strategy to a community of patients who are actively looking for hope."

Autoimmune diseases

Last year, preclinical data for Arialys Therapeutics demonstrated that its lead drug candidate, ART5803 was able to effectively block the underlying disease mechanism in anti-NMDA receptor encephalitis (ANRE).

ANRE is an autoimmune disease in which the body creates antibodies targeting the brain's NMDA receptors, disrupting normal brain signalling and causing encephalitis.

ART5803 is a humanised, monovalent IgG1 antibody engineered to selectively bind the GluN1 subunit of the NMDA receptor without disrupting receptor function or causing internalisation.

In data published in nature, ART5803 demonstrated the ability to potently block NMDA receptor internalisation in cellular and neuronal models and reversed both molecular and behavioural hallmarks of disease in a novel marmoset model of ANRE.

In addition to demonstrating the therapeutic potential of ART5803, the study revealed a potential link between infections – specifically Toxoplasma gondii and certain bacterial pathogens – and the generation of pathogenic anti-NMDA receptor autoantibodies. Toxoplasmosis and bacterial infections are well-established risk factors for a range of neuropsychiatric conditions.

In September 2025, the company received Rare Pediatric Disease Designation from the FDA for ART5803.

Speaking about the decision, Peter Flynn, Ph.D., President and CEO of Arialys Therapeutics said: "The Rare Pediatric Disease Designation recognises the severity of ANRE as well as the potential of ART5803, a precision medicine specifically designed to rapidly reverse the symptoms of anti-NMDA receptor autoimmunity, to meet a significant unmet medical need for these rare paediatric patients."

Fibrosis

This year, drug company Abalone Bio announced preclinical data showcasing the first characterisation of antibody agonists of CB2 in data which it states could lead to significant milestones in G protein–coupled receptor (GPCR) and antibody drug development.

The study reported that antibody agonists, AB120 and AB150 exhibit robust anti-inflammatory and anti-fibrotic activities, including potent suppression of pro-inflammatory cytokine secretion and significant reductions in collagen expression in a model of liver fibrosis.

Abalone Bio states that the study highlights the specificity and potency of AB120 and AB150 for CB2 over CB1, giving them an advantage over traditional small molecules to avoid unwanted CB1 receptor activation. This reduces a source of psychotropic and pro-inflammatory or pro-fibrotic side effects and the exclusion of large molecule drugs like antibodies from the CNS can reduce further side effects.

"The anti-inflammatory and anti-fibrotic activities produced by Abalone Bio's CB2 agonist antibodies in precision-cut human liver slices represent a mechanism of action distinct from—and potentially complementary with—existing therapies, and point the way to improved therapies for advanced liver fibrosis," said Scott L. Friedman, MD, Dean for Collaborative Research and Partnerships and Director of the Mount Sinai Institute for Liver Research at the Icahn School of Medicine at Mount Sinai; Co-Investigator and paid consultant to Abalone Bio.

Vaccines

Last year researchers at Vanderbilt Health isolated two monoclonal antibodies in a project that could lead to antibody therapies for those suffering from the flu. The research could also lead to vaccines that are broadly protective against evolving influenza.

The team isolated two monoclonal antibodies that recognise three subtypes of influenza type A virus. By binding to the active site of neuraminidase (NA) glycoprotein on the surface on the type A virus, the antibodies inhibited the virus' ability to infect cells and spread through the respiratory system. NA-specific monoclonal antibodies are also able to recruit immune cells to destroy infected cells.

"The discovery of these antibodies identifies potential new medicines to prevent or treat influenza and also informs vaccine developers of a vulnerable site on the virus that can be targeted by new vaccines," said James Crowe Jr., MD, director of the Vanderbilt Center for Antibody Therapeutics.

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