Compass Carter Osborne

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What is the next big innovation *coming to the Life Sciences sector?*

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Introduction

"Despite new investment funding remaining below pre-pandemic level, the global life science sector continues to evolve at pace, embracing new technologies and innovative solutions. As this dynamic industry moves forward, what roles could new and emerging technologies such as AI drug discovery and quantum computing play and how might it impact patient outcome improvement?

Investors, directors, and other key stakeholders from across the life sciences sector were brought together by Compass Carter Osborne at a recent round table event to discuss the next innovations and trends that are set to have the biggest positive impact on the life sciences sector around the globe over the next several years. Our panel represented a rich mix of insight, diversity of perspective and experience from around the globe.

In a wide-ranging discussion, we explored how innovation really works; the multiple stages and many parties involved; how risks are considered, managed, and regulated; and the timescales and quantum of investment. We talked about the importance of focusing on real applications and not dreams of changing the world with one technology. We explored the extensive scope for computing and AI in discovery stage research, clinical trial data collection and post launch surveillance. We considered how the industry needs to operate during a time when investment levels are low and what might be the most important predictors of an upturn. We concluded with a conversation about the factors influencing decisions about product launch.

This insightful discussion was energising and informative for me, and I sensed how others felt similarly. I hope that you enjoy reading this report and find something here useful to you and your business."

Geoff Dobson
Discussion Chair

Key Areas of Discussion

- Which innovation might have the biggest positive impact on the life science sector in the next 5 years?
- Investors: which innovative technologies are you most likely to invest in and why?
- Quantum computing for life sciences – hype or hope?
- How can the life science sector best appreciate the potential for innovation through computing?
- Is it too soon to predict a biotech funding cycle bounce back?
- If you were launching a new therapeutic or device in 2025, what market(s) would you target first and why?

Artificial intelligence – adoption, opportunities, and the regulatory environment

The role of artificial intelligence (AI) and machine learning has the capacity to change the way life science companies operate. It was agreed that the life sciences sector has historically been a slow adopter of new technologies, including AI. As one participant remarked: “We are not quite there yet.”

The advancement of life sciences research drives multiple studies that generate data, often in huge volume. Processes such as high-throughput sequencing are now the norm. As well as automating data collection in the discovery stage in the lab, the importance of protocol designs and having more focus on data analytics in clinical trials and post-launch surveillance should also be noted.

> *“To become a truly data-enabled industry, we need to prioritize research that is evidence based, not eminence based.”*

As one participant argued, “there may never be a single real gamechanger in life sciences, and this include AI.” The data in drug discovery is much more complex, heterogeneous, and much more difficult to capture than the way data is manipulated in other AI applications. Each study is exploring a new frontier of research, so it is not surprising that these data are not easy to curate. While advocates of AI publish and promote stories of the predictive power of AI for drug discovery, our panel of industry experts suggested these stories need to be treated with caution. As one person observed, “while AI technology for specific use cases has already been implemented in various health systems, systematic AI use will get there but not in the next five years, maybe the next decade.”

Another participant emphasised that valued added versus the cost of change is an important consideration. Life science businesses must be cautious about change. It almost always costly (in cash and time) so process innovation must produce a significant improvement, not a marginal effect.

The danger of over-exuberant promotion of AI may even be detrimental. One panellist, who has considerable insight into the US market reported that stateside, there is a sense of fatigue with the slow progress of AI. This has led to led to a lot of “waiting and seeing” in a market that is not known for its patience. “I think the enthusiasm may be wearing off a little bit.”

The discussion also surfaced areas where surprising progress is being made, and other areas where challenges still exist. One participant highlighted how small-molecule chemistry had historically been constrained by rigid adherence to Lepinski rules, but advances in computing have stimulated new and more flexible approaches. However, there was broad agreement that there was little evidence yet about how AI or quantum computing could best address the challenges of translational medicine.

> *“Translational research is vital, it’s not just about the chemical mechanism or biological action.”*

Another innovation discussed was the use of data analysis to create “semi-personalised medicine” by using big data to look at common denominators in patient populations, bio markers and other indicators for effective new treatments. For example, a study that examined cancer patients discovered that amongst patients with colorectal cancer and oesophageal cancer, 80% of the patients had specific, identifiable epitopes. Rather than highly specified, personalised immune therapies, it may be that a “semi-personalised” approach is both clinically and economically a more effective approach to oncology drug development “That is quite good enough”, one participant said, “I think semi-personalised medicine may take the mainstream.”

> *“Discovery alone is never enough; innovations need applications to progress and to attract investment”*

Computing and different therapeutic areas

Harvesting, storage, and curation of the huge amounts of medical data from past, current and future studies will be an immense task, and our round table participants could envisage ways in which AI may enable insights and breakthroughs. While this is potential applicable to all diseases, during the time available we focused on a small number of therapeutic areas.

> *“The industry should look through the lens of global healthcare need. Preventative treatments in cardiovascular and metabolic disease can make life-altering and life-saving impact.”*

Obesity and co-morbidity

Expert and generalist observers would probably all be aware of the excitement around the metabolic area, and what is commonly referred to as “anti-obesity drugs”. The demand for these new compounds is notable. Novo Nordisk’s Wegovy® currently generates sales of $1.4bn per quarter. Lilly’s comparable GLP-1 agonist product is also generating around $1bn per quarter. Amgen, Pfizer and Roche all have new compounds in development. The global market for GLP-1 agonists is forecast to hit upwards of $100bn by 2030.

In our discussion, we moved beyond consideration of these new products as anti-obesity treatments and considered the wider perspective of their potential positive impact in reducing cardiovascular disease, diabetes, and other metabolic diseases. The exciting potential here is for improvement in general health and a reduction of co-morbidities thus saving millions to healthcare systems around the world. Our round table discussed the potential for AI and computing innovations in patient and general population surveillance. Panel members also make connections between the treatment of obesity and data insights from osteoarthritis and Alzheimer's. “This is also consistent”, one participant observed, “with a shift from focussing on increasing the longevity of people’s lives, to managing and enhancing quality of lives.”

Neurological disease and neurodegeneration

One panel member highlighted that there are currently 684 new drugs in development for Alzheimer’s and dementia, 43% of which are already in Phase II or Phase III. While neurology has been an exceedingly difficult area for innovation, this volume of activity suggests some will hopefully soon come to market. However, patients are often diagnosed in medium to late onset of the disease, which presents problems. It currently seems extremely difficult to identify the best treatments for early onset.

Concurrently, there are companies researching potential screening tools and protocols for dementia. Improvements in surveillance, RWE data collection and improved analytics could be the keys to optimising neurological therapies.

> *“This screening using AI, using affordable methods, I think will revolutionise the healthcare and wellbeing of people.”*

As with other challenging diseases, current treatments may be limited to slowing the onset or reducing the impact of certain neurodegenerative conditions. However, our round table saw hope for the use of AI and machine learning to accelerate the development treatments and move us towards breakthrough curative drugs.

> *“A move from single agent AI to multiple agent models will accelerate this process and lead to better defined data outcomes.”*

A brave new world for regulators?

Our round table also debated the potential for utilising AI by regulatory bodies. While AI’s use in the development phase might result in efficiencies, both the US Federal Drug Agency (FDA) and EMA, European Medicines Agency, may require separate clinical studies – with and without AI – and this duplication adds cost and delay. While the inherent and understandable cautious nature of regulatory bodies remains evident, our panel expressed hope that societal, political and industry pressure will encourage change. As one panellist remarked: “My hope in the next few years is that we will be able to get over the hump where things like organ chips and more efficient data use will be more accepted.”

Industry and investor appetite for digital innovation

The life science industry has historically been a slow adopter of digitalising processes. The panel agreed that there was more work to do in this area ahead of implementing systems such as AI or quantum computing. There remains considerable scope to analyse and utilise data that has already been the gathered. Improvements in this area should inform future data capture and analysis and be preconditions for further successful innovation.

> *"Through digital innovation, there is so much more data generated. It is how we can get this data captured and updated in a way that we can apply to the next layer of AI."*

The quality of existing data was highlighted as a concern, with drug discovery data being described as variable. Digitising every stage of discovery processes, clinical trials and post launch surveillance was seen as essential, as well as identifying errors and learning from them. This may not be something that AI cannot easily resolve. As one participant said, "If you cannot resolve the data, you cannot generate information."

Another panellist added: "This is back to quality of data, and it's about learning and interrogating data. It all comes back to fundamentally being a data-driven business. The right data with the right story will get you funding." Another panellist added: "This is back to quality of data, and it's about learning and interrogating data. It all comes back to fundamentally being a data-driven business. The right data with the right story will get you funding."

> *"We need end-to-end data collection that can be analysed in real time."*

The investment community: pharma partnerships, M&A, new investment

Despite optimists reporting the sighting of proverbial "green shoots," our round table participants await a broad pick up in life science investment. VC funding is hard to come by, and the IPO market has only shown occasional sparks of action.

Some private equity investors, who have historically focused on revenue generating businesses were beginning to explore the early-stage life science market before COVID. However, PE investors may yet have more of a role to play by enabling M&A transactions in the short-term.

Progressively over the past 30 years, global pharmaceutical companies, and to a lesser extent speciality pharma businesses have enabled and supported the growth of early-stage biotechnology companies through licensing deals and co-development partnerships. Several participants cautioned against an overly optimistic view that big pharma "money chests" would be deployed in a mutually supportive manner that funded smaller, development stage businesses while enhancing hollowed-out big pharma product pipelines. One participant, drawing on career experience described how a major European company known to be "cash rich" and in a position to invest in co-development, had to meet shareholder expectations and found great and more certain returns from other deployment of funds including investments in gold, other precious metals, and currency hedging transactions.

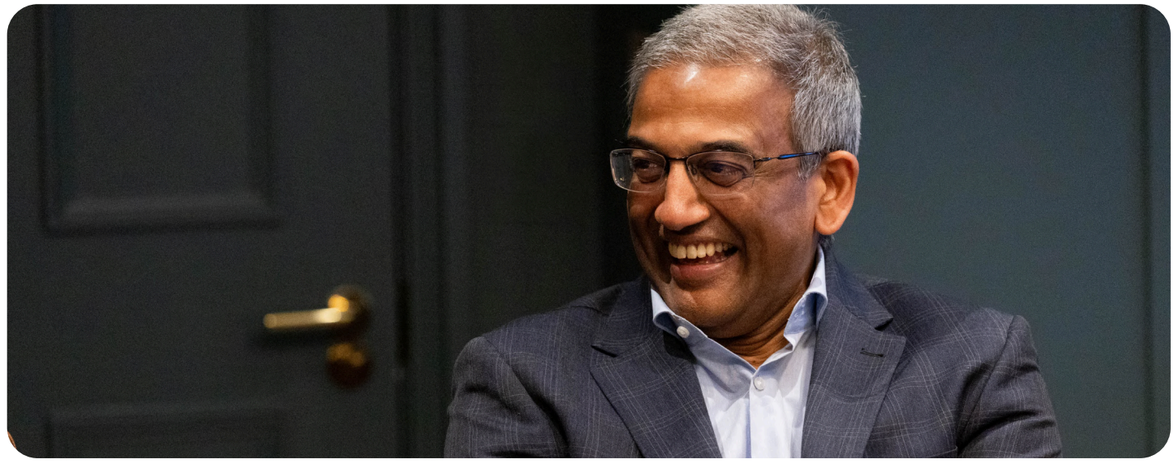
> *"Industry partnerships make commercial sense for technology validation, although the big pharma industry partners may now have more power over smaller companies than before."*

While there was general agreement that it was naïve to assume that big pharma would fill a gap left behind by VC caution, there remains a mutual interest between big pharma and the largest medical device companies and development stage businesses. As one participant described, research and new product

development is more-or-less outsourced to development stage companies, and there is a dependency relationship where funding must support innovation.

> *"It seems illogical and frustrating, but it's currently easier to begin a conversation about raising a really big new fund than to find three to five million pounds for an existing project".*

Drawing on macro-economic analysis, one contributor focused our minds on the likely impact of a progressive period of reducing interest rates, beginning in the US market. It is worth noting that within 7 days of the round table event, the US rate was reduced by 50 basis points. Ultimately, one of the biggest drivers of investment into higher risk discovery research is a reduced rate of return on more cautious investment.



Harnessing the power of quantum computing

Quantum computing is another trend that has been touted as having the capability to transform life sciences, but how does the sector best harness this technology?

Quantum computers - although currently few in full operation around the world with only six operational in the UK – are extremely hot property. They have the potential to be far more powerful than even the fastest conventional super computers. A classical computer solves problems sequentially. A quantum computer can address multiple questions in parallel, like reading every page of a book at the same time. If solving a puzzle or looking for a route from one point to another, quantum computers can be highly effective – rapid and accurate at predicting solutions. This is, albeit an oversimplified summary of the scope, the hope, and the real impact of quantum computing for life science discovery research, clinical trials, post launch surveillance, patient conditions and behavioural analysis. It is about harnessing computing capacity, matching it to research, clinical and patient populations, and making the best predictions to optimise products and treatment regimes for specified patient groups. As one participant said: “If you can analyse a biological system using AI and you can make predictions, then you are likely to get a rational business model from that.”

Quantum computing is also being used to digitise the workflow and looking around failure within the discovery process. By using AI to examine why something failed and then reversing it back and make those modifications, new products and even new business models are opening. One panellist described the potential for quantum analysis for repurposing drugs including new indications for successful compounds, and recovery of a compound which may have failed for its original indication. Another contributor also reminded the round table that engagement of regulators with such innovations in repurposing is often a challenge, and the industry needs to help regulators assess risk within these models.

Preconditions for future growth

Another possible factor inhibiting growth is the psychological impact of the current holding pattern that the early-stage biotech and med tech funding cycle finds itself in. The round table was told that the situation is the same across the board from concept to commercialisation, and across geographic territories. “Everyone is just looking at everyone else wondering what’s happening, when it is going to open back up again?,” one participant commented.

Companies are becoming extremely capital efficient in this constrained environment. Companies are being rewarded for low FTEs. The current trend is for smaller, leaner research teams.

> *“The dominant investment thesis of this time is to look for shorter routes to market, and to work with more experienced management teams.”*

The funding cycle is also limiting the number of US businesses coming to Europe, the panel heard. Unless companies have a product pipeline of substance and considerable cash reserves, they are not coming over from North America to Europe. As one participant remarked: “You traditionally see 20 or 30 coming across the Atlantic and setting up here every year. In my business, we see this. I have talked to 150 different firms over the last 12 months. I know of just five that are coming to Europe.”

We discussed how when times are good, people find reasons to invest, and the reverse is true. There are many current concerns that are acting as a brake on investment, on decision making, or even considering an investment. Current military conflicts around Europe and the Middle East are problematic. 2024 has also been a year of political uncertainty. Sixty countries, two billion people, or to put it another way, half the world began this year knowing that it faced an election.

Even though the UK has now passed its election phase with a clear result, the panel explored how uncertainty about budget and taxation changes could either inhibit decision making cycles or have absolute impacts. Attracting and retaining talent in the life science sector may face short-term adverse impacts in people issues, even if the Government is making decisions that are aimed at longer-term revival of the economy.

This difficult investment environment is forcing life science companies to have to compromise. “A business might have 5 or more clinical programmes that they can realistically pursue, but with cash constraints, they are forced to focus on one. From a leadership perspective, it has been a big mental challenge.” one person observed.

We also noted how the Covid-19 pandemic has had an impact on life sciences real estate. One panel member commented “It is a virtual world now in terms of the real estate landscape, especially in North America. It has changed drastically; empty labs, empty offices, empty vivarium.”

Another source of uncertainty and potential instability is the prospective introduction of the US Biosecure Act 2024, that could prohibit federal agencies or others from procuring or obtaining any biotechnology equipment or service produced or provided by a biotechnology company of concern to the US Government. It was suggested that this is leading to investors in China seeking to get their assets out the country. The round table also discussed how in the recent past, the trend has been to outsource aspects of clinical research and volume production of clinical grade material to China, India and elsewhere. However, a change in US legislation may lead to a complete reverse of this pattern, and even impact upon decisions made by European companies that will need to access the North American markets.

Another panellist revealed: “We have decided not to go with (name of major Chinese Company) for all these reasons, we have gone for a European manufacturer. We would have gone for (the Chinese market leader) had it not been for the uncertainty surrounding biosecurity. For a small biotech this is a ten-million-euro problem. The business risk if it all collapses is catastrophic to the programme and possibly to the company. We thought it was just too big a risk.”

New product launch 2025, where and why?

Economic potential, regulatory environments and data collection were all highlighted as key considerations when deciding which markets to target when launching a new therapeutic treatment or device.

You cannot ignore North America when making this critical choice as it is the biggest market, the round table heard. However, some participants cautioned that there were aspects of data collection during the launch period where the US might not be the right market for data.

> *“Product launch in the USA nearly always makes commercial sense, but we often need to look to Europe for the best data generation, capture and analysis”*

Life science companies are also becoming much more discerning about where they do their studies. “There is a lot more strategic thinking about the feasibility of clinical studies and late-stage development to launch a product now than there was 10-15 years ago”, one panellist said. He added: “From my perspective, which is oncology, you can still get away with approvals in the US with minimal US data because of the population dynamics and the numbers. However, if you look at recruitment for clinical trials and the data you can collect from a given trial, in Spain, France and Belgium, it is phenomenal for oncology. If you extrapolate that to the other hot potato which is autoimmune disease, you are going to find a similar picture.”

Another consideration involves collaborating with pharmaceutical firms to determine where the trial sites should be; a conversation would not have happened 10 to 15 years ago.

“What I haven’t figured out is the role of China in all of this”, one panellist said. The patient volumes are still there so we can’t ignore it but if you look at the pure numbers, China has underdelivered from a commercial perspective. It keeps firms going back to the US.”

China has become the second biggest market for AstraZeneca in terms of revenue. Each year it will have a double-digit growth. However, if you want to launch your product in China, you must conduct a country specific clinical trial. “You shouldn’t ignore China and India, after the US but you need to manoeuvre how you are going to operate”, one panellist said. “Localisation is the key to that success.”

Another panellist commented that China and Japan are commercially significant but culturally so different that few UK or European companies want to go there alone without a supportive local partner.

Europe’s status as a launch destination is under threat from the GCC (Gulf Co-operation Council), Japan and China, in the view of several panellists. Some companies are looking at Middle East and Saudi Arabia before Europe.

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