COLUMNS

Emerging Biotech and Biopharma Trends to Watch for in 2023

by Dr Senthil Sockalingam

The majority of biomedical innovation right now is coming from the emerging biotech and emerging biopharma (EBP) industry. EBPs now represent 65% of the total drug development pipeline globally with an additional 7% being developed by EBPs in partnership with larger firms.

Below are some key trends that EBPs should keep an eye out for in 2023:

1. Economic realities likely to force some strategic re-alignment of development pipelines to maximize efficiencies

The current economic climate is causing those EBPs with restricted financial flexibility to strategically reassess their priorities. Funding is not flowing as freely as 18 months ago and requests for extended program development come under additional scrutiny. EBPs are likely to spend more time working with partners to critically assess their indication prioritisation, and evaluate the target product profile against the current market to make the right decisions for the business. When looking for a good third-party partner, working with global clinical research organisations to run pivotal trials and handle regulatory submissions will be an increasingly attractive option to cost-constrained EBPs.

2. Funding and deal-making in EBPs will continue to follow innovation

Early EBPs are recipients of VC or angel investment funding, at the early stages of drug development. The funding flow for early emerging biopharma companies, which saw a dramatic increase during the pandemic, with venture capital deal activity and investment flows doubling, has returned to pre-pandemic levels in 2022. This is not surprising given the global macroeconomic context. Deals between EBPs represent 62% of deals in the health sector, up from 49% five years ago, increasingly driven by EBPs or tech companies with platforms or services to provide to other EBPs. In the Asia-Pacific region, lots of opportunity remains for funding for innovative molecules and approaches. The biggest funding rounds in 2022 were linked to EBPs employing highly advanced approaches such as robotic and AI-led drug design. The biopharma market size in China is predicted to be almost double that of 2019 in 2023 and there will be a continued focus on biopharma investment and capability building in Singapore, Taiwan, Australia and New Zealand.

3. More EBPs will bring their product to market by themselves

Over the past decade, more than half of all global launches of novel active substances (NAS) were originated by EBPs and there has been a growing trend for EBPs to “go it alone” as opposed to partnering with a larger organisation to overcome market access and commercialisation challenges. However, it is becoming increasingly difficult for JAPAC EBPs to raise funding through traditional channels and there is an increasing interest in monetising some of their clinical development assets through out-licensing to bigger pharmaceutical companies. Traditionally, business development has not been a core competency for these EBPs and so more JAPAC EBPs, especially those EBPs headquartered in China, are seeking help to find out-licensing partners. The EBPs have promising, innovative science to offer and there is an opportunity for a win-win; with pharma companies getting access to innovative products and EBPs generating a revenue stream.

4. The cell, gene and RNA therapy advance continues apace

The continued shift towards advanced therapies and the unique potential of cell, gene and RNA therapies means this sector remains robust and lucrative, with over 3,500 pipeline therapies in testing and over 5,000 active clinical trials. The therapeutic focus of these therapies continues to expand from a focus on oncology to infectious disease and vaccines and towards potential indications in neurology and immunology.

RNA technology is not new, but in many ways, the COVID-19 pandemic unlocked the power of RNA vaccines and generated broader interest in the field of RNA therapies. The significant medical and commercial success of the COVID-19 mRNA vaccines has in addition accelerated the development and distribution models for this technology. There is an expanding breadth of RNA technologies, including antisense oligonucleotides, mRNA and siRNA therapies in development and trials for a plethora of therapeutic indications.

There are, however, challenges in the approval and commercialisation of new cell, gene and RNA therapies. Small addressable patient populations and high manufacturing and operational costs due to the highly personalised nature of the therapies. A sophisticated and highly-organised approach to clinical trial implementation is vital to bringing these therapies to life whilst ensuring patient safety. Scaling manufacturing remains difficult despite great progress and finding appropriate and sustainable market access and funding models continues to be extremely challenging, with major shifts from current practice required to enable broader access to approved therapies.

5. Broader impact of Project Optimus on early-stage oncology

39% of the EBP pipeline is in oncology and we have seen a fundamental change in the approach to dosage design and optimisation for oncology drugs entering trials. With the continued implementation of Project Optimus, we will see more pharmacokinetic and pharmacodynamic model-informed dose-finding and earlier involvement in the FDA in oncology trial design to select registration trial doses with a more suitable benefit-risk profile. This approach, a huge positive for patients and trial

participants, theoretically reducing the rate of dose reductions, intolerable toxicities and premature trial discontinuations requires enhanced communication and education between sponsors, agencies, and patients on clinical trial activity.

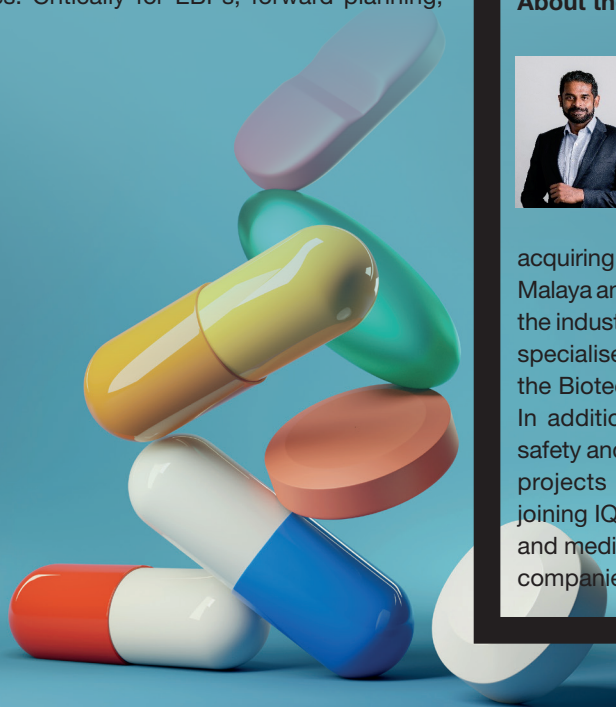
6. Decentralised Clinical Trials will continue to play a more important role

Decentralised clinical trials (DCTs) using virtual platforms, telehealth applications, remote monitoring technology, wearable devices, online patient portals, and other technology, have delivered cost and time efficiencies compared to conventional trials. Decentralised approaches open participation to a broader, more diverse patient population, significantly reducing the time it takes to recruit. Although each study saw different results based on the type of trial, size and location, our 2022 analysis of over 12 studies demonstrated benefits, including a 49% reduction in time to first patient in, a 54% reduction in protocol deviations, and 78% reduction in overall recruiting time. DCTs also offer lower dropout rates due to decreased travel burden by study patients, improved compliance, and patient engagement. There are additional factors that had a positive impact on these, specifically start-up timelines and recruitment during the COVID-19 period.

Expect the rate of adoption of DCTs to continue to grow, largely through hybrid trials that combine site visits with technology-enabled data collection and home-based services. Critically for EBPs, forward planning, prospectively designing and planning for decentralised approaches from the outset will glean better efficiencies than retrofitting existing trials with decentralised elements after the protocol has been finalised. With the highly competitive, ultra-time-sensitive backdrop, EBPs cannot afford to ignore the value add of well-planned DCTs moving forwards. IQVIA is currently managing 300+ DCTs across 30+ indications in more than 50 countries. APBN

Relevant Links

1. IQVIA APAC's CAGT solutions: https://www.iqvia.com/locations/asia-pacific/solutions/cell-and-gene-therapy-coe
2. Project Optimus: https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus
3. Benefits of DCTs: https://www.iqvia.com/library/white-papers/dcts-deliver-big-roi
4. For more information on IQVIA's biotech solutions, please visit https://www.iqviabiotech.com/



About the Author

Dr. Senthil Sockalingam is Head of IQVIA Biotech in Japan-Asia Pacific as well as Chief Medical Officer for IQVIA Asia Pacific based in Singapore. Senthil is a physician by training, acquiring a MBBS degree from the University of Malaya and practicing in Malaysia prior to joining the industry. In his current role, he leads IQVIA's specialised clinical development services for the Biotech sector across Japan-Asia Pacific. In addition, he is overall responsible for the safety and ethics of IQVIA clinical development projects in the Asia Pacific region. Prior to joining IQVIA, Senthil led clinical development and medical affairs for several pharmaceutical companies in the region.