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Maximize your asset value across the biopharma value chain

How to overcome the challenges of biotech companies to successfully maximize your asset value from clinical development to commercialization

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Demonstrating asset value is becoming more complex across therapeutic areas and impacting biotech, specialty, and larger pharma alike. Key stakeholders involved in the ultimate success of a drug, and their evidence needs, continue to evolve as the marketplace transforms from volume- to value-based performance.

With non-COVID post-pandemic launches underperforming by nearly 20% compared to pre-pandemic levels in the major markets[1] and a tightening of payer budgets, biotech companies need to get savvier with their asset development and commercial readiness – even if they plan not to self-commercialize their product. How can biotech stakeholders define and build an actionable plan to maximize their asset value? Is an integrated evidence generation plan a mandatory requirement? Is self-commercialization the best way to retain value? Is omnichannel sales & marketing an imperative in the post-pandemic environment?
This article summarizes key insights from a panel discussion of biotech and biopharma executives during the Swiss Biotech Insight event co-organized by IQVIA Switzerland and the Swiss Biotech Association on 30th September 2022. Included in the discussion 5 panelists across functions and including Biotech and biopharma executives, investor, and commercial and market access experts (The names and titles of the panelists are on the left side of this page)
Tom Baker, Senior Vice President, and General Manager at IQVIA Switzerland was the panel moderator.
This article also includes some global trends presented by Aurelio Arias and Tom Baker during the event and relevant insights from IQVIA whitepapers.

Maximizing an asset value: Multiple perspectives across biotech key stakeholders

2021 marked a peak in venture capital funding that has not seen similar levels so far in 2022[1]. As asset valuations and deal sizes normalize, biotech companies may look to the US as a model in which they increasingly self-commercialize their products. At any rate, there is an increased need to focus on commercial readiness, whether it is through preparing an asset for sale, to fully self-commercialize or a model that sits somewhere in the middle.

"Usually, companies are financed for two years roughly and then you find another financing, this [last] funding is gone […] there is only a few funds left in Europe with substantial money [..] that's going to be a challenge. If you are a company today and someone is offering you cash, take it!" said Thomas

From an investor's point of view, biotech companies funded by venture capitals, there is a pressure to sell after phase I or latest Phase IIb, as many investors do not want to bear the commercial risk until uptake. In the current market environment with raising interest rates, the valuation of non-profitable biotech companies is under pressure, providing an opportunity for takeovers.

"[…] investors hope that there is a takeout on phase I or after Phase IIb, latest moment where you make money. If you go further and you must fund that, you have a problem […] we hope that someone loves it, acquires it, and fixes it down the road," said Thomas.

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Integrated evidence plan (IEP), an accelerator for drug development

Most big pharma and biotech companies believe they already do the right amount and type of clinical research to frame their product development strategies or that little or none is needed assuming their science will speak for itself. Without knowing what evidence is required to differentiate the product, poor clinical development decisions are often made and are executed at great cost.

"Are we overweight with science? Asked Tom […] No, as long as the science demonstrates an unmet need [..] however I would say yes, we need payer's and patient's relevant endpoints" answered Jennifer.

As data and evidence capabilities mature across healthcare systems around the world, drug developers need to prove the value of their drugs by running trials with payer- and patient-centered endpoints alongside traditional clinical ones. Time is critical as any delays can hamper a launch. IQVIA research across several decades of launches shows that any course correction must be done withing the first six months[4] or risk a shallower sales trajectory than forecasts, and that RWE as part of a submission has a positive impact on reimbursement success in Europe.

To get the most value from RWE (real world evidence), developers should stop just seeing it as an ad hoc solution to solve a specific need and start treating RWE as an integral component of evidence strategy that affects every key milestone, from early research, through commercialization.

"One way to fix [the pricing and market access strategy], it is to use the time between data readout and approval and run phase IIIb trial and start systemically filling those gaps […] and build a value story that works across different markets," said Christoph

Before sharing key insights and considerations, we must define what is an integrated evidence plan. Integrated evidence plans (IEP) catalog all existing and planned evidence, and seek to identify unmet evidence requirements, dependencies, and common themes across different categories of evidence.

"[IEP definition] Before you get to the price and to the access, you need to get into an integrated access strategy that starts with R&D and shapes the whole development program, evidence package and then determine the value of the drug to set the price and then good access to patients," said Marco.

What does it mean for Biotech companies and to what extent having an integrated evidence plan early on is important?

Many examples exist of clinical development teams that continue to limit their clinical plan and activity to focus on the first clinical hurdle of demonstrating safety and efficacy to meet the historical needs of the regulator. This results in "legacy thinking" around how to drive value in clinical development: minimize timeline and cost while gathering data focused on minimizing risk for regulatory approval.

"What I consistently see in the business of acquisitions, those [Biotech] companies do nothing with price, market access and evidence generation […] if you acquired something in early development, they just focus on R&D maybe phase I data and they even did not think what it comes next. If you see something complemented with an access and pricing strategy and commercial model, it will make your life easier when you evaluate the deal and would have more confidence with the company," said Marco

Clinical-commercial convergence, now more than ever, is central to the success of the drug development team. This convergence needs to deliver an integrated and agile understanding of the situation-based product value proposition, and then plan, design, and efficiently collect and communicate the value evidence.

"When we go for late-stage assets, there is probably less risk for clinical and regulatory perspective but there is an enormous market access risk. One asset we acquired end phase III, we knew that we have no chance to get the price anywhere outside the US and even in the US […] The best spot to entering a program for us, before or shortly after the clinical proof of concept, because that's the moment you can still shape the data generation plan required for getting value from those assets," said Christoph

When IEP is integrated into the clinical development early on, developers can draw more value from the data they collect and acquire while reducing redundant data collection efforts and avoiding evidence gaps. Experience shows that in order to optimize the full set of strategies through clinical development, stakeholder focus needs to include at a minimum the regulator, the provider, the payer and the patient. Increasingly this must also include a more diverse, and asset specific set of key influencers, partners, policymakers, manufacturers, laboratories and site of care facilities.

"In general, you try to go with patient relevant outcomes […] for example, impact on the quality of life of patients, caregivers […] PROs are relevant […]" said Marco

IQVIA predict that the rapid adoption of eCOAs[a] (Electronic Clinical Outcomes Assessments), including ePRO[b] (electronic patient reported outcomes) will continue to

[a] *An electronic Clinical Outcome Assessment (eCOA) is a method of capturing patient experience data electronically in clinical trials and real-world studies.*

[b] *ePRO refers to information provided directly from the patient about symptoms, side effects, drug timing, etc.*

grow, as sponsors acknowledge how useful these tools have become in decentralized clinical trial (DCT) settings.

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Specialty and rare diseases growth driven by Biotech companies with more mature assets

Specialty and rare disease medicines continue to drive growth and more of these are being developed by biotech, who own 64% of the global pipeline (Phase II and above)[1]. For new launches, Europe remains the largest market behind the US, contributing 21% of a new active substance's sales in the first 2 years[2].

Many upcoming launches in the next 5 years are in the rare disease and specialist areas, and patient journeys in this segment are longer and more complex[3]. Therefore, it's going to be increasingly important for companies to focus on what has changed, and how to accelerate the improvement in care pathways.

"We are still recovering from COVID [...] COVID impacted on our ability to recruit mostly in rare diseases" said Djordje.

In rare diseases, engaging with patients is key. A patient engagement through patient advocacy groups could be part of the IEP as patient registries is relevant for data collection, mostly for rare diseases[5]. Data from registries can significantly benefit early-stage drug development, and potentially serve as a starting point for multi-arm, multi-company clinical trials. Registries can help address many challenges inherent in rare disease trials, allowing for a more complete understanding of the disease course and variability; guiding the development of endpoint measures, patient reported outcomes (PROs).

"From a small biotech perspective, when you develop rare disease assets, you need patient perspective in addition to payer endpoints," said Jennifer

For new launches, Europe remains the largest market behind the US, contributing 21% of a new active substance's sales in the first 2 years.

Launching a new product in Europe: Challenges for Biotech companies and differences between US and Europe

Launching a product is a daunting prospect for any company and even more so for biotech companies, most of which lack any prior launch experience. Furthermore, the European healthcare environment is very different from the U.S., in terms of stakeholder dynamics and the approach to assessing, and rewarding, innovation.

Understanding the specific challenges for commercializing in Europe, especially as a biotech company, is a crucial first step towards achieving success.

Health Technology Assessments (HTA) play an important part in Europe to inform market access decisions. Unlike the Institute for Clinical and Economic Review (ICER) in the U.S., European HTA agencies are public bodies with a formal remit and

role in the healthcare system. However, different HTA bodies use different criteria for assessing 'value'. For example, Germany's IQWiG/G-BA and France's HAS tend to focus on added clinical benefit against a comparator, while England's NICE focuses on cost-effectiveness using cost per QALY (Quality-Adjusted-Life-Year).

"With [upcoming] EU/HTA legislation [changes] clock is ticking, there is upside and downside and especially for biotech companies […] I have seen that we were able to decrease time to access, that's represent an opportunity for small biotech companies […] as the first component of the HTA will be done centrally and will allow to save resources," said Jennifer

Such an environment presents unique challenges for anyone wishing to commercialize in Europe. Success will depend on careful market prioritization and launch country sequencing, with international reference pricing implications firmly in mind. It also follows that a one-size-fits-all commercialization approach will not work, and that instead country-specific commercial models are needed that reflect local market dynamics and stakeholder requirements.

Many biotech companies have never launched a product before and find themselves at an inflection point of transitioning from a development-stage company to a commercial-stage enterprise. As such, they have to fundamentally change their organizational mindset, from focus on science and clinical development to driving business results. This means building new requisite capabilities, which often involves bringing in external talent, especially with commercial experience, while executing launch preparations, all without the comfort of legacy launch processes, infrastructure, or experience to fall back on. Rapid scaling up of headcount presents a particular challenge, and risk to stability, which can see a biotech's organization double or triple in size over a short period of time, without key supporting processes and functions yet being fully established.

Biotech companies usually lack existing relationships with key European healthcare stakeholders, especially payers. Where relationships do exist, these are typically limited to a small number of investigators involved in their clinical trials.

"In general, it is not the same people who creates the company and have the idea and who brings the product to market […] overtime, you change the board and management team […]" said Thomas

This situation is often compounded by U.S.-centric development programmes, driven by the importance of the U.S. market, resulting in the dominance of U.S. trial sites and U.S.-based investigators. This U.S. bias may also manifest itself in the choice of trial endpoints that do not reflect the evidence requirements of ex-U.S. stakeholders, such as European payers or HTA bodies.
For example, they would expect comparators based on the relevant European standard of care, some may even want to see local data.
"When you look at various companies you have Boards and Management (often with scientific background) … and may be scientific advisory committee. One way to compensate for limited RWE expertise, could be a dedicated RWE advisory committee" said Djordje

Key considerations for building the right commercial model at the right time

It is not uncommon for commercialization to be low on the list of priorities that biotech companies tackle during most of their early existence, with budgets often very limited prior to Phase III readout. Consequently, biotechs tend to be late in starting key commercialization activities and often find themselves having to catch up and deliver against compressed timelines. These challenges set up biotech-specific success factors for commercializing in Europe, such as the need for

flexible cost structures, the ability to ramp up resource fast to plug capability gaps, and the fundamental question of the commercial model (i.e., commercialization with or without a commercial partner or full exit).

Scientific advisory board is the first committee in place for most biotech companies. There is an opportunity for an access/RWE advisory committee

Successful biotech companies invest at risk in early market preparation, to create awareness and build advocacy with key European stakeholders, including regulators, payers, KOLs and patient advocacy groups.

"Even if they [biotech companies] missed to have an exit at the clinical proof of concept, there is still some advice that I will give to biotechs that you increase your value dramatically if even at that stage [clinical proof of concept] you have already solved the end stage and designed your clinical proof of concept that supports your value proposition that will be validated in phase III"

"There is another element that is important, and it is very often overlooked [...] we filed for conditional approval at phase II data [...] we failed twice [..] because CMC was not ready," said Christoph

Launch readiness has very distinctive ramifications for biotechs. Unlike big pharma, biotech companies must do this while being resource and budget constrained, with a need for flexible cost structures and without the benefit of a legacy 'launch playbook', a deep market insight foundation or prior launch experience to draw on. Even so, the marketplace is unforgiving and does not distinguish between types of companies; they all compete for the attention of HCPs, for funding from payers and, ultimately, for patients being treated with their products.

Commercial success in Europe is contingent on addressing stakeholders' evidence needs, especially the ability to demonstrate differential value. Therefore, the careful design of pivotal trials and the choice of relevant endpoints, control arms and patient populations for European stakeholders, particularly payers, is key for launch success. This extends to generating relevant RWE to address stakeholder needs along the product lifecycle, from pre-launch through maturity. Given the typical lead times for generating evidence, launching in Europe must be considered early on as part of a biotech commercial ambitions, including what it takes to do so successfully.

"Investments into CMC are large, and it is not possible to catch up and compensate for delays. ... and you might lose time to market ... or end up ready for commercialization but not being able to deliver the product at the end" said Djordje

Working with a clinical and/or commercial partner is a viable option for biotech companies for partnering on both selective capabilities and end-to-end. It offers local market knowledge and presence, well-established relationships with key healthcare stakeholders and a broad range of critical capabilities, such as clinical, regulatory, medical, market access and commercial, including contract medical, sales and patient-supporting in-field teams, all available for immediate deployment. It can also provide access to cutting edge technology and analytics infrastructure, for example to power commercial operations.

Unlike the option of out-licensing or working with a distribution partner, in this partnering arrangement biotech companies retain full control of their assets and commercial strategy, while reducing complexity and benefiting from speed, scale and a flexible cost structure to mitigate financial risk.

References:

1. *A Big Deal: Strategic Rejuvenation for Post-Pandemic Realities – click here*
2. *Realising The Commercial Promise Of Europe For Emerging Biopharma – click here*
3. *Orphan Medicines Launch Excellence – click here*
4. *Launch Excellence VII – click here*
5. *Registries for rare diseases – click here*
6. *Making Real World Evidence meaningful and actionable – click here*
7. *Excellent launches are winning the evidence battle – click here*
8. *Emerging Biopharma's Contribution to Innovation – click here*
9. *Riding Out the Storm: The Future of Post-Pandemic Customer Engagement – click here*
10. *Finding All the Needles in the Haystack: Technology-Enabled Patient Identification for Clinical Trials – click here*

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