Driving launch excellence with agile transformation

Examining the key risks and opportunities that biopharma asset teams should prioritise during R&D and launch

By Aleksandar Ruzicic and André Moa

Launching a biopharmaceutical product globally always involves significant uncertainty – especially before pivotal clinical trial results confirm efficacy. Risks arise at every stage: R&D setbacks, unclear healthcare demand, unpredictable competitors and commercial or financial challenges.

As we discussed in our previous PME article 'Product launches: making the most of your one shot', traditional launch planning focuses on three pillars: shape the market; shape the product; shape the organisation. Early in the process, many assumptions remain uncertain – but this is also when there's the most flexibility to address risks, reduce uncertainty and capture new opportunities.

Consider a real-world biopharma case. After phase 2 results showed disappointing efficacy, questions arose about pursuing a rare disease follow-on indication. Despite significant unmet need, high annual treatment costs and cheaper off-label alternatives threatened its commercial viability.

Applying agile thinking, the asset lead sought early input from the US affiliate – especially on market access and pricing – before committing more R&D funding. The US team warned that the much higher dose required for this indication would push annual therapy costs into the high six figures. Even as the only approved product for this rare disease, payers could still enforce use of cheaper, off-label drugs with similar mechanisms (which the US team referred to as 'step edits of hell'). This could shrink the addressable patient pool by tenfold or more. The global team concluded the indication wasn't viable in the US and chose not to pursue it further.

This case study illustrates how top cross-functional biopharmaceutical launch teams thrive amid uncertainty – turning risks and opportunities into advantages through agile project management. By leveraging optionality in R&D and launch preparation, as discussed in *'Capturing value from optionality in pharma R&D'*, they enhance launch excellence.

Like leading tech companies, they use approaches such as design thinking to accelerate and deepen learning. Successful teams focus on maximising learning on investment (LOI) and increase assumption certainty over time – through competitor monitoring, insight generation, KOL engagement, evidence generation and other critical launch activities (see Figure 1).

In general, agile project management runs in structured sprints of two to four weeks – similar to other industries – although in biopharma these may extend longer to meet industry-specific needs. Leading companies embed GxP regulations, quality assurance and compliance/medical review requirements directly into their sprint cycles:

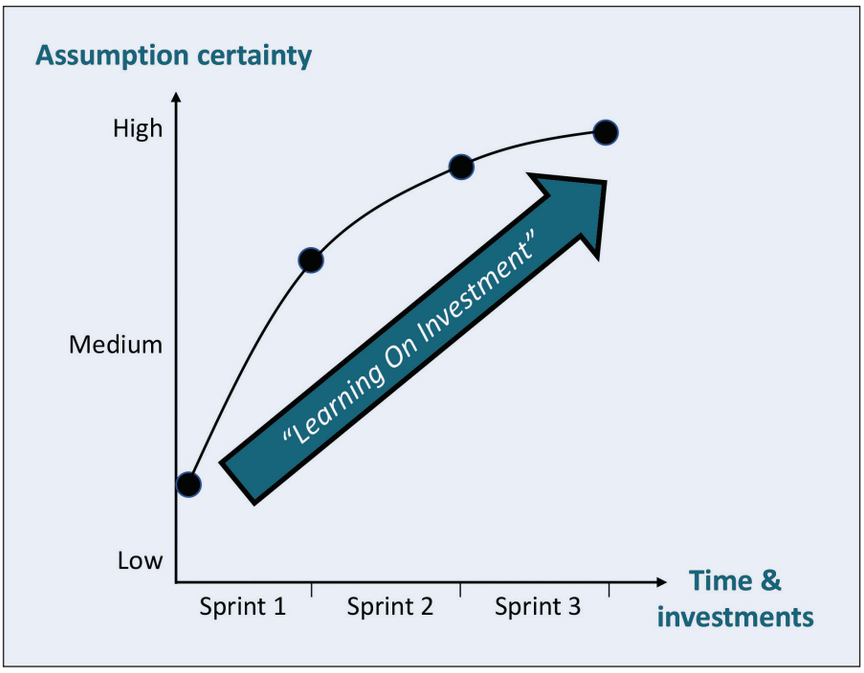

Figure 1: Assumption certainty vs time & investments

1. **Planning** – identify the uncertainties and key risks/opportunities we aim to address.
2. **Implementation** – coordinate, align and prioritise activities to focus on the most critical work.
3. **Review** – capture learnings and assess their implications for the next sprint.
4. **Retrospective** – evaluate what worked, what didn't and how to improve processes and resources.

What uncertainties and key risks or opportunities should a biopharma asset team prioritise during R&D and launch? In our previous article on launch excellence, we introduced a comprehensive Launch Excellence Framework. Below are selected examples of how agile sprints can address each area:

Shape the market:
- **Insights generation** – identify a specific uncertainty, risk or opportunity and investigate it in the next sprint (leveraging existing contracts with external experts)
- **KOL/expert engagement** – set a clear engagement objective and connect with key opinion leaders or experts via medical affairs in the upcoming sprint
- **Expert centre collaboration** – co-develop an initiative with one expert centre and validate interest with others through medical affairs during the next sprint.

Shape the product:
- **Evidence generation** – compile new evidence for cross-functional review in the next sprint to guide prioritisation and sequencing of launch plan updates
- **Brand vision** – gather fresh insights that may require adapting the brand vision and initiate updates with clear implications during the next sprint
- **Multichannel strategy** – use design thinking to address a specific multichannel objective in the next sprint, especially for digital initiatives.

Shape the organisation:
- **Resource forecasting** – identify new information and update existing resource forecasts in the next sprint (only for material changes)

'The integration of AI with robotics is enabling closed-loop discovery systems that automate and continuously optimise the drug discovery process'

- **Organisational evolution** – confirm a predefined trigger point and adjust the organisational set-up based on new insights (with only a few trigger points set in advance)
- **Performance tracking** – choose a specific value driver to brainstorm and prioritise a KPI in the next sprint, including defining data sources and calculation methods.

The systematic adoption of AI and data science across all functions in biopharma is accelerating the need for agile transformation – just as it has already done in drug discovery.

The integration of AI with robotics is enabling closed-loop discovery systems that automate and continuously optimise the drug discovery process. These platforms execute iterative cycles of hypothesis generation, automated experimentation, data analysis and refinement, significantly enhancing the speed, scale and consistency of research.

In the future, cross-functional teams will have access to more data than ever – enabling them to form (often uncertain) hypotheses and rapidly validate or discard them. Still unsure whether agile project management is right for your cross-functional launch team? Ask yourself these three questions to assess whether agile is the right fit in an environment defined by uncertainty and the need for flexibility:

1. Can your team align around a clear value objective?
In biopharma, cross-functional teams typically focus on external stakeholders – patients, prescribers, providers, payers, policymakers and others – making it likely that a tangible value objective exists. Centring efforts around a 'minimum viable product' (MVP) helps reduce uncertainty through early engagement and feedback from these stakeholders. More broadly, a shared value objective drives the team to learn, adapt and reduce uncertainty collaboratively.

2. Can your team adapt the end-to-end workflow?
In most biopharma companies, cross-functional launch teams don't operate within a rigid, fully defined end-to-end workflow.

Instead, their activities are typically guided by stage-gate processes during R&D, long-range launch planning and periodic management reviews tied to budget and strategic decisions. Within this framework, teams often have the flexibility to self-organise – as long as they meet company-defined milestones. This flexibility makes agile practices particularly relevant.

3. Can you gather feedback to improve future outcomes?

Agile ways of working enable rapid feedback from both internal and external stakeholders through early testing of an MVP. This approach surfaces critical value drivers and potential barriers to adoption early in the process. Engaging stakeholders upfront not only improves product quality but also builds trust and buy-in – essential in biopharma, where companies must often collaborate with healthcare systems and other partners to deliver value effectively.

Once a cross-functional team in a biopharma company opts for agile project management, it must undergo a broader agile transformation, significantly adapting its operating model. In addition to redesigning the organisation and processes, this shift requires the right collaboration tools. A modern agile launch execution platform, such as SmartLaunch from TRiBECA Knowledge, provides the structured environment needed to manage launch activities and sprints, track uncertainties, surface insights and drive cross-functional alignment and collaboration. The programme enables teams to visualise progress and launch readiness in real time, integrate KPIs and sprint learnings directly into launch plans and embed agility within day-to-day workflows across affiliates and functions (see figure 2).

'The systematic adoption of AI and data science across all functions in biopharma is accelerating the need for agile transformation'

As in other industries, agile project management offers substantial benefits for cross-functional teams in biopharma – driving both qualitative and quantitative impact.

The most important qualitative benefit is a stronger, more consistent focus on external stakeholders and customers. Early, systematic and iterative engagement with these stakeholders leads to higher-quality decision-making. Agile ways of working also empower team members (often organised into cross-functional 'squads') by fostering ownership and adaptability – provided that supporting changes in business planning and budgeting are in place.

On the quantitative side, biopharma companies adopting agile practices often see tangible gains, including faster launches, higher success rates, lower costs and overall improvements in productivity.

Agile methodologies are gaining ground in biopharma – already transforming areas like drug discovery, omnichannel engagement and digital health solutions. Now, the time has come to extend this transformation to product launches. Future launch excellence will depend on three core capabilities: a sustained focus on stakeholder value; iterative end-to-end workflows and a culture of continuous learning and risk management. Agile is no longer optional – it's essential. First movers will not only improve the outcomes of individual launches, but also build institutional 'learning on investment' that compounds across their entire portfolio – creating a lasting competitive edge.

References are available on request.

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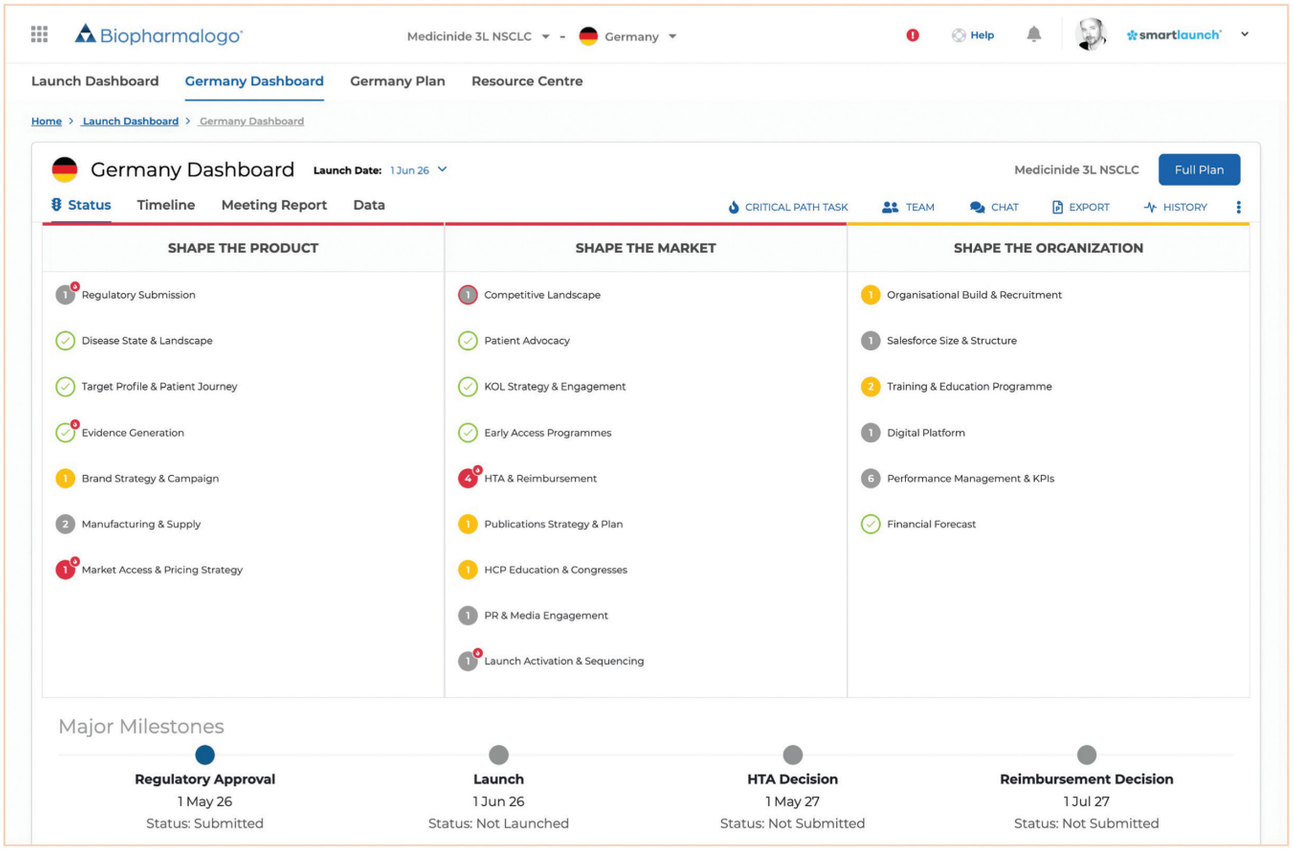

Figure 2: SmartLaunch country dashboard