AAA launch excellence – agile, adaptive and agentic

Over time, the use of AI agents will support a broader range of launch processes and workflows, enabling teams to move faster, make more informed decisions and operate with greater efficiency

By Aleksandar Ruzicic

In 2025, uncertainty surrounding the global launch of biopharmaceutical products has intensified, driven in part by the introduction of the US Most Favored Nations (MFN) drug pricing model for therapies overseen by the Centers for Medicare & Medicaid Services (CMS).

On 23 December 2025, proposed rules were released outlining GLOBE (Global Benchmark for Efficient Drug Pricing) for Medicare Part B and GUARD (Guarding US Medicare Against Rising Drug Costs) for Medicare Part D. Earlier that month, on 11 December 2025, the European Parliament and the Council of the European Union reached a political agreement on reforming EU pharmaceutical legislation, also including launch and supply obligations.

Accelerating agile transformation

Biopharma companies must therefore accelerate their agile transformation to achieve launch excellence – see our previous article in September 2025 PME, Driving launch excellence through agile transformation. However, this alone is no longer sufficient. Many organisations have already begun integrating AI into select pre-launch and launch processes.

The companies that will lead going forward are aiming for 'AAA launch excellence' – agile, adaptive, and agentic. They are evolving towards continuous learning models characterised by real-time sensing, faster decision-making and swift execution. This approach helps reduce uncertainty, enhance learning on investment (LOI) and capture value from optionality in an increasingly complex and unpredictable environment.

'Biopharma companies need a robust, integrated solutions architecture with an agile launch execution platform at its core'

Imagine a future where a launch plan is no longer static, but a living system – one that incorporates event-driven workflows, self-adjusting sequences and, over time, an increasing number of AI agent-triggered actions. Event-driven workflows may respond to external signals, such as competitor product data performing better than anticipated, or to internal developments, such as evidence for follow-on indications diverging from the base case assumptions.

Ensuring robust, agile workflow systems

Historically, planning for these contingencies in detail has been challenging due to the sheer number of possible permutations. With robust agile workflow systems in place, however, it becomes far more feasible to embed adaptive processes that support self-adjusting sequences – for example, recalibrating supply and demand plans or sales forecasts in response to approval delays.

AI agent-triggered actions represent the next frontier. Real-time insights from healthcare professionals (HCPs), for instance, can dynamically inform risks or upsides relative to the base case, enabling continuous refinement of forecasts and more responsive decision-making.

Such a bold vision cannot be realised overnight. Biopharma companies need to take a stepwise approach to building launch excellence capabilities. The foundation layer focuses on establishing clear processes and workflows, with defined dependencies, deliverables and decision points. This enables the creation of an agile launch plan, where major processes are broken down into work packages or sprints – allowing teams to learn from each step and reduce uncertainty for those that follow.

Identifying key triggers and responses

Building on this agile foundation, companies can introduce an adaptive layer that identifies key triggers and corresponding responses. Achieving this requires a sufficiently robust agile workflow system – one that supports the definition of event-driven actions and enables automated replanning when trigger events occur.

The final layer involves the systematic integration of AI agents across launch-related processes and workflows. Most companies have already begun adopting modular AI agents for specific activities. Real-time AI monitoring for signal detection is increasingly available – not only during launch, but also for in-market brands – for example, through social listening among HCPs and patients.

Biopharma companies are also rolling out AI agents, often starting with in-market brands, such as those used for dynamic sales forecasting and HCP targeting. Over time, AI agents will support a broader range of launch processes and workflows, enabling teams to move faster, make more informed decisions and operate with greater efficiency (see Figure 1).

Implementing key enablers

A successful biopharma launch excellence transformation depends on several key enablers, including standardisation where appropriate, access to historical launch data, robust governance frameworks and strong regulatory discipline. Standardisation can involve creating ready-to-use launch processes and workflows tailored to different scenarios – such as a novel compound, a new indication or additional evidence generated through life cycle management. These common situations lend themselves to reusable frameworks that streamline planning and execution.

While launch teams can and should tailor these frameworks to their specific needs, having a standardised starting point avoids the need to build plans from scratch, as is often the case today. Deliverables should also be standardised wherever possible. For example, a target product profile can serve as a consistent framework to articulate the core value proposition, evolving over time to incorporate key market insights and emerging product evidence.

'With robust agile workflow systems in place, it's far more feasible to embed adaptive processes that support self-adjusting sequences'

Data from historical launches should capture not only key deliverables, but also how they evolved over time – along with the underlying reasons for changes. This includes elements such as sales forecasts, demand and supply plans, and their subsequent adjustments. Such data is invaluable for identifying likely external and internal triggers that may require adaptive, event-driven workflows in future launches. In addition, granular historical data is essential for training AI agents, including dynamic sales forecasting models.

A robust governance framework is equally critical, clearly defining accountability and decision rights throughout the launch process. This encompasses established decision-making bodies, such as cross-functional launch teams, functional sub-teams and senior leadership. It should also anticipate trigger-based responses and AI agent-initiated actions, typically incorporating a human-in-the-loop approach given the high stakes involved. Finally, regulatory rigour must be embedded from the outset. This includes ensuring GxP compliance for key deliverables – such as regulatory submissions – as well as maintaining auditability of critical decisions and traceability of any adaptations made during the launch process.

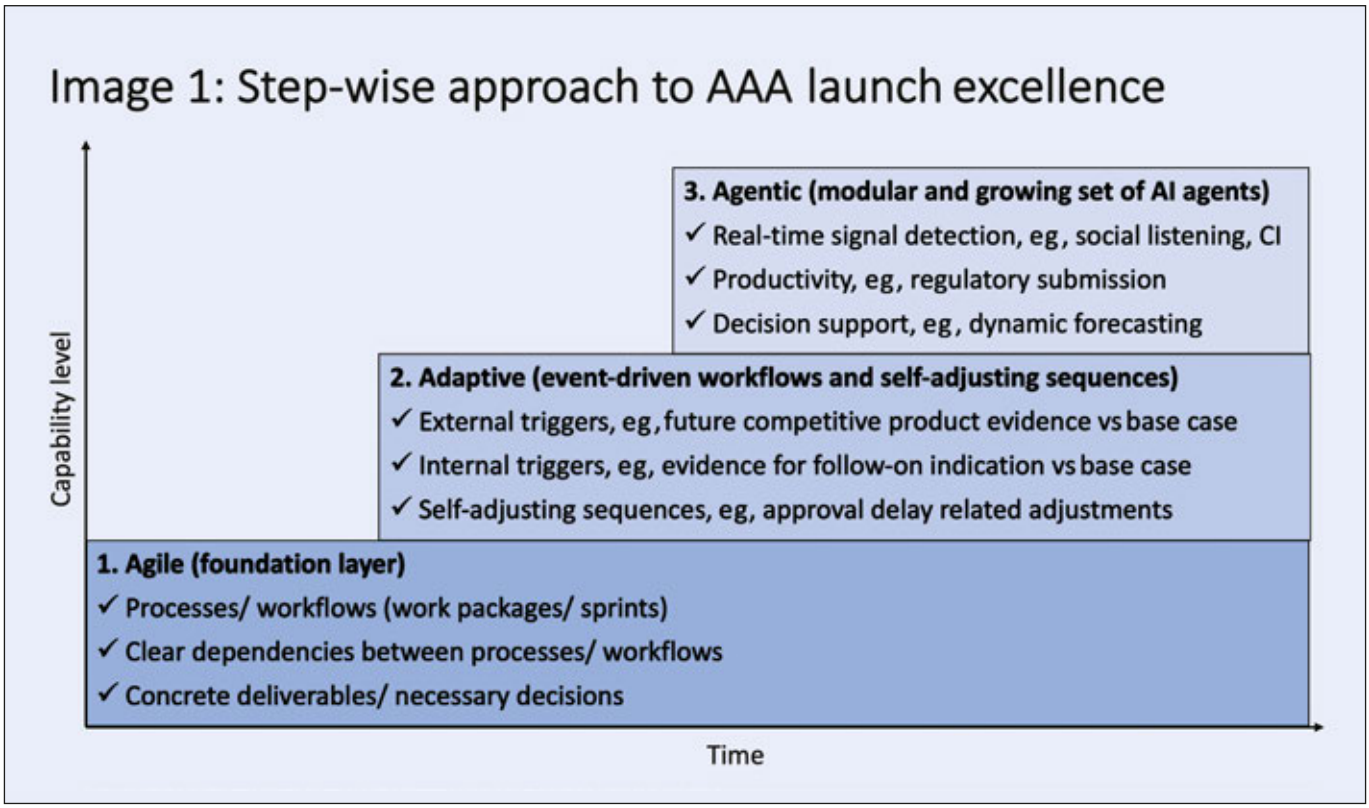
Adopting integrated solutions architecture

To meet these success factors, biopharma companies need a robust, integrated solutions architecture. At its core should be an agile launch execution platform that enables the desired level of standardisation – such as ready-to-use processes and workflows with defined dependencies, pre-built deliverables and centralised document repositories with version control.

Many organisations, from top 20 pharma companies to emerging biotechs, have adopted solutions that can be readily configured to fit specific launch processes and workflows, while remaining flexible enough to evolve towards more agile and adaptive models over time.

Beyond the core platform, companies must equip launch teams with a growing suite of modular AI agents. Many of these are initially developed for post-launch commercial use cases – such as account and HCP segmentation, resource sizing and sales forecasting – but are increasingly being applied earlier in the launch life cycle.

Image 1: Step-wise approach to AAA launch excellence



A range of specialised vendors offer both off-the-shelf products and customised solutions, typically encompassing a vast pool of proven AI agents.

Building future-ready capabilities

Biotechs launching their first product – without the constraints of legacy systems – are well positioned to leapfrog large pharma companies. They can build future-ready capabilities from the outset, without needing to redesign entrenched ways of working. As a result, they may be the fastest to achieve AAA launch excellence, operating in an agile, adaptive and agentic manner from day one.

Leading biopharma companies will gain speed as lead times shrink, while also increasing flexibility in subsequent steps. This allows them to delay certain decisions until critical insights or deliverables from earlier investments are available – then act quickly and decisively, often faster than competitors. In doing so, they reduce overall launch risk by accelerating insight generation and responding more rapidly to emerging developments.

Ensuring quality, consistency and scalability

At the same time, quality and consistency will improve across launches and geographies, driven by fewer inconsistencies, more systematic challenge and stronger alignment. Productivity within launch teams will also increase, enhancing scalability – for example, enabling experts to manage more assets or indications, boosting efficiency in smaller affiliates and driving an overall uplift in quality.

'Launch teams need a growing suite of modular AI agents that are increasingly being applied earlier in the launch life cycle'

Ultimately, a successful transformation depends on empowering launch teams with the autonomy to operate in agile and adaptive ways, while effectively leveraging AI agents.

AAA launch excellence will enable fast-learning launch teams to make decisions jointly as soon as new information emerges. These teams will need to learn how to involve management early – for example, by validating external and internal triggers for event-driven workflows upfront.

Empowering launch teams

As launch teams increasingly leverage AI agents, it will become more challenging to keep top and functional line management continuously informed and aligned. At the same time, top and line management will take on crucial new responsibilities: shaping the evolving portfolio of AI agents; unlocking investments for their development and validation, and approving their use for both in-market and launch teams. In the long run, AAA launch excellence will require top and line management to empower launch teams even further, enabling continuous learning, real-time sensing, immediate decision-making and rapid execution.

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