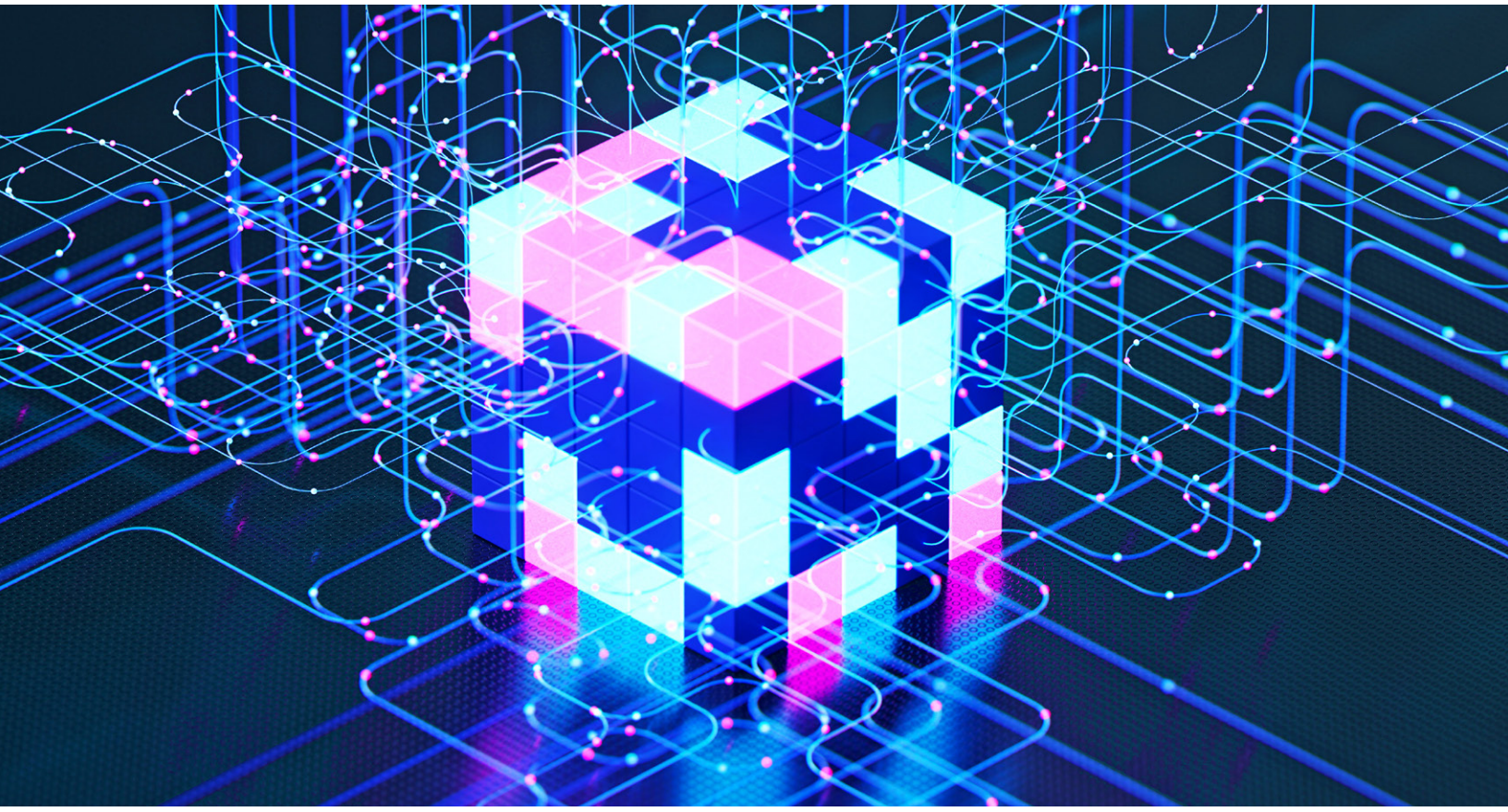
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Life Sciences Practice

Rewiring pharma's regulatory submissions with AI and zero-based design

Six building blocks could help pharma organizations slash filing timelines from months to weeks, potentially unlocking as much as $180 million in net present value for priority assets.

This article is a collaborative effort by Anton Mihic, Gaurav Agrawal, Lotte Berghauser Pont, and Rosa Poetes, with Giulia Ferretti and Ralf Raschke, representing views from McKinsey's Life Sciences Practice.



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Biopharmaceutical companies have set bold ambitions to reduce regulatory-submission timelines for new products. This is part of broader efforts and ambitions over the past decade to compress clinical timelines and revitalize stagnant R&D productivity in the industry. Among the many steps required to deliver new medicines to patients, the often-time-consuming submission process presents an exceptional opportunity to accelerate the drug development period.

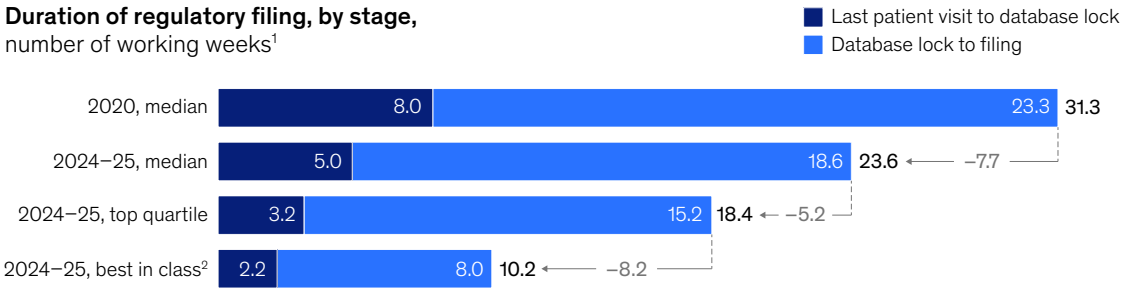
Faster and higher-quality submissions during drug development can provide substantial benefits to patients, pharma companies, and other stakeholders. For example, it would provide patients with earlier access to potentially life-saving therapies. Additionally, per our analysis, a pharma company making an improved submission for a $1 billion asset one month more quickly than typical would unlock roughly $60 million in net present value (NPV).

In the past five years alone, the pharma industry has made impressive progress in reducing filing timelines. Per McKinsey's benchmarking data, some leading companies have accelerated their overall submissions by up to three times over the 2020 industry average, and others are now sustainably delivering filings eight to 12 weeks after database lock (DBL), cutting historical timelines by 50 to 65 percent (Exhibit 1). Our estimates show that companies that achieve this feat could extend patent exclusivity during peak revenue years and, in doing so, obtain roughly $180 million in NPV for a $1 billion peak sales asset.[1]

Almost all top pharma companies have set ambitious filing timeline targets—the most ambitious are aiming to file in fewer than eight weeks. Yet many companies struggle to transform their submission processes at scale. Key obstacles include the complexity of digital integration, diverse therapeutic modalities, and internal capability gaps, all of which have led to inconsistent execution across the industry.

Exhibit 1

Today's leading pharma companies are filing regulatory submissions up to three times faster than the industry average in 2020.



[1]From benchmarking of 62 pharma companies. 2025 data as of Q1.
[2]Speed of top 2 or 3 fastest submissions in benchmarked data set.

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[1] This estimate assumes the acceleration from the median timeline in 2020 to the top quartile's timeline in 2024 (an acceleration of roughly 12 weeks), with an NPV of roughly $60 million per month.

We propose a path forward that draws from our work with several top 20 global pharma companies. This article describes the six building blocks of successful submission excellence transformations—approaches that consistently produce high-quality submissions. It also explores technologies that can enable faster submission, including automation and gen AI, and offers three implementation approaches for companies to revamp their submission journey.

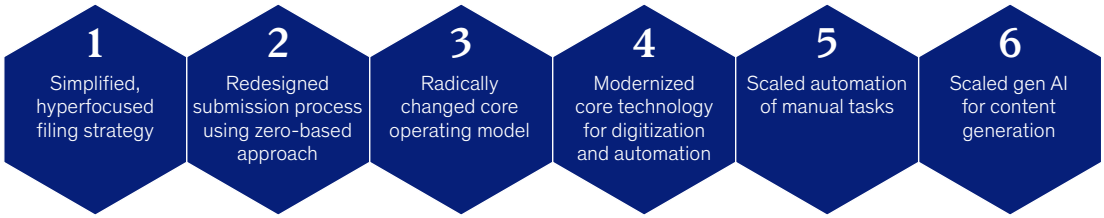
Six building blocks of submission excellence

The six elements of successful submissions span three core areas: strategic and process foundations (simplified filing strategy and redesigned zero-based process), organizational transformation (radically changed operating model), and technology enablement (modernized core systems, scaled task automation, and scaled, AI-enabled content generation). Together, they create a comprehensive approach to achieving sustainable submission transformation (Exhibit 2). Although companies may choose to implement the six building blocks in varying combinations and sequences, the most successful transformations pursue all of them.

Exhibit 2

Pharma companies see faster results from submission excellence transformations when they implement all six building blocks.

6 building blocks of submission excellence



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Block one: Simplification of filing strategy

Organizations should start with a filing strategy that's built on rigorously defining and targeting the desired product label. This approach promotes collaboration across different teams, such as biostatistics, clinical-development, marketing, regulatory, and safety groups. As a result, the study designs meet all requirements while focusing on critical-path activities. Clinical programs designed by regulatory strategists with a laser focus on efficiently demonstrating a product's benefit and risk profiles can be combined with proactive education and engagement from health authorities.

Block two: Zero-based redesign of submission process

Several top pharma companies have taken steps to fundamentally redesign their entire submission process, starting with the last patient's last visit and extending all the way to filing. Some have taken a gradual approach by applying lean principles to improve each step. Others have achieved faster results by conducting a zero-based redesign of core processes and automating key aspects of their operations. They have employed such strategies as bold decision-making, front-loading, "parallelizing," and removing nonessential dossier activities (table).

Although companies may choose to implement the six building blocks in varying combinations and sequences, the most successful transformations pursue all of them.

Table

Pharma companies can accelerate submissions by optimizing processes across seven categories.

Category	Examples
Data preparation optimization	• rigorous and cautious collection of data about and samples of last patients' last visits • unbatched sample analyses for last patients' samples • automated cleaning of data and issuing of queries • preblocked time with principal investigator for sign-off and e-signature
Predrafting of lean clinical reports and chemistry, manufacturing, and control reports, with hyperfocus on label	• early alignment on key messages for studies and label • scenario-based front-loading of draft reports • application of lean writing principles by trained writers across modules
Batch generation and tables, listings, and figures (TLF) standardization	• early alignment on and commitment to key TLF data • fixed number of TLF data sets • preprogramming off the critical path • dry runs executed before database lock (DBL) • standardized templates • prioritized table delivery in batches
Strategic review in 24 hours, with a single round after DBL	• fixed document review time • restricted access to sections • condensed reviewer matrix and training of reviewers • early-stage strategic reviews conducted to allow a single round after DBL
Submission publication around the clock	• around-the-clock publication, using offshore capability • cloud-based publication • rolling publication • sections locked after publication
Clinical-pharmacology-process optimization	• sample analysis prioritization • early release of pharmacokinetic and pharmacodynamic data to clean team • models developed for population pharmacokinetics and pharmacodynamics, based on earlier data • writing of final population pharmacokinetics and "parallelized" summary of clinical pharmacology • Optimized vendor capacity
Automation	• automated and restrictive workflows • collaborative, structured, and gen-AI-enabled content writing • automated checks of TLF quality and writing style

Redesigning core processes can alleviate the substantial workload placed on global regulatory teams caused by inefficiencies in responding to health authority queries (HAQs). These inefficiencies can slow the correspondence between pharma and health authorities and, by extension, the resolution of HAQs. This problem is magnified when companies file submissions simultaneously in multiple countries to reach a larger patient population faster.

Block three: Radical change of core operating model

A successful process redesign requires a fit-for-purpose operating model that aims to deliver faster, more sustainable submissions. As such, organizations should embrace a paradigm shift in their submission process and be prepared to acquire the capabilities needed to scale the adoption of new processes. Lasting success depends on adequate training, focused capability building, strong leadership commitment, and clear expectations across the product portfolio.

Pharma leaders should target these important outcomes for their operating-model overhauls:

— *Autonomous, small cross-functional teams.* The teams should include biostatistics, regulatory, and medical-writing groups and be empowered with clear goals and incentives to work in sync.

— *Rigorous planning and sustainable execution of the filing process.* A submission manager leading the team needs to initiate early filing preparations, have full accountability for the critical paths, and ensure that no detail gets overlooked.

— *Faster, focused decision-making.* Leaders should be able to make bold, early decisions on high-value assets.

— *Culture of bold innovation and collaboration.* Team members should be encouraged to push boundaries within and beyond their functional roles.

— *Stronger vendor partnerships.* There needs to be real-time collaboration with external vendors to provide seamless execution and prevent last-minute delays.

Block four: Modernization of core technology for digitization and automation

Technology is critical in sustainably accelerating regulatory submissions. Modern, integrated core systems, such as regulatory-information-management systems (RIMS), enable seamless workflows, embedded automation, and data-centric approaches that replace document-heavy processes. According to data from McKinsey's 2025 regulatory affairs benchmark, roughly 80 percent of top pharma companies said that they were modernizing their RIMS. Some had automated core processes beyond basic writing tools, quality controls, and publishing by applying structured content and collaborative authoring within a data-centric submission workflow (Exhibit 3).

Exhibit 3

Use of an automated, data-centric submission workflow is crucial for pharma companies to submit faster regulatory filings.

Example of a data-centric submission workflow



1. **Data generation**
   Real-time regulatory intelligence hub knowledge base capability, with latest global and regional health authority requirements; end-to-end digital data flow, from protocol to submission
2. **Data preparation**
   AI-assisted clinical data cleaning, review, query generation, and reconciliation; automated data transformation (eg, study data tabulation model, analysis data model)
3. **TLF[1] generation**
   Predefined, set number and type of TLFs in workflow; gen-AI-assisted TLF programming, generation, formatting, and audit trails
4. **Drafting and labeling**
   Gen-AI-assisted drafting, automated formatting, and style guide checking; structured content management; digitized label platform, including automated propagation of changes from company core data sheet to local template
5. **Review**
   Auto-suggestions for initial drafts and auto-consolidation of comments
6. **Quality control**
   Automated quality control and source data validation of in-text TLFs; automated validation of compliance with controlled terminologies, abbreviations, and CDISC[2] standards
7. **Publication**
   Enhanced, continuous publication, leveraging regulatory intelligence hub and automated publishing tools
8. **Local translation**
   Real-time population of local templates; automated translation for "rest of world" filings from electronic common technical document
9. **HAQ[3] management**
   Real-time population of HAQ repository; integrated HAQ workflow, with AI-assisted response drafting based on HAQ repository

[1]Tables, listings, and figures.
[2]Clinical Data Interchange Standards Consortium.
[3]Health authority query.

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Leading pharma companies are investing in scaled workflow automation and digital data flow, integrating technology from protocol development to submission. Their biggest challenges are navigating the complexity of available solutions, prioritizing high-impact investments, and building internal capabilities to adopt and scale automation. Some industry leaders are laying the groundwork for real-time data updates and automated exchanges with health authorities, thanks to the emergence of next-gen RIMS platforms and external initiatives that have focused on building technology bridges between sponsors and regulators. The widespread adoption of this workflow is still to be fully realized. To achieve the full potential of a data-driven regulatory future, companies should develop a clear strategy, scalable technology road map, and structured implementation plan.

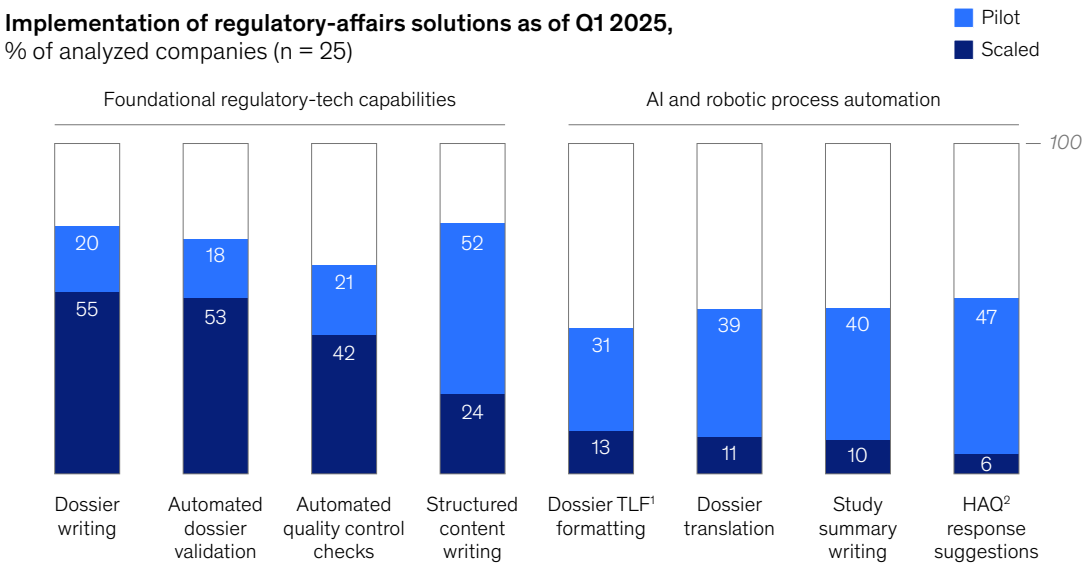
Block five: Scaling of automation for manual tasks

Automation promises to be a game changer for the submission process, yet it remains largely underused beyond core tasks, such as dossier writing and validation (Exhibit 4). For example, internal benchmarking reveals that only 13 percent of companies automate the time-consuming formatting of tables, listings, and figures at scale. Likewise, the global workflow associated with the HAQ process—a major contributor to the workload—remains largely unautomated. The opportunity exists for organizations that successfully scale automation in these areas to make considerable gains in filing speed and workload efficiency.

Exhibit 4

Many pharma companies have yet to scale their automation and AI pilot projects that aim to accelerate filings.

Implementation of regulatory-affairs solutions as of Q1 2025,
% of analyzed companies (n = 25)



[1]Tables, listings, and figures.
[2]Health authority query.

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Block six: Scaling of gen AI for content generation

Gen AI is emerging as a major disruptor in regulatory and medical writing. Early pilots show that gen-AI-assisted medical writing can help reduce the end-to-end cycling time for authoring of clinical-study reports (CSRs) by 40 percent.[2] And more recently, McKinsey and Merck codeveloped an AI-powered platform that reduced first-draft CSR writing time to 80 hours, from 180 hours, and cut errors by 50 percent.[3] Many companies are now expanding into other regulatory document types, including safety and efficacy summaries, labeling, and even clinical pharmacology, to enable further submission timeline compression. Gen AI could also be used to generate HAQ responses, which could streamline that time-consuming task, including for situations when multiple health authorities submit queries simultaneously. Also, we're observing meaningful advances with agentic AI, which could be used as a virtual content challenger alongside a human in the loop who reviews the submissions to anticipate lines of questioning and improve the overall quality of a dossier during the internal review and quality control process.

Leading companies are already developing technology plans and building AI-ready capabilities to stay ahead in this transformation. To overcome scaling challenges and capture gen AI's full benefits across entire pipelines, leaders should prioritize four actions:

2 "Unlocking peak operational performance in clinical development with artificial intelligence," McKinsey, January 9, 2025.
3 *New at McKinsey*, "With gen AI, Merck and McKinsey transform clinical authoring," blog entry, McKinsey, June 27, 2025; "Merck expands innovative internal generative AI solutions helping to deliver medicines to patients faster," Merck press release, June 25, 2025.

— Modernize core clinical-data systems to support AI-driven automation.

— Build state-of-the-art gen AI authoring platforms with reusable components that balance flexibility and precision for high-stakes documents.

— Invest in AI adoption with well-defined workflows that secure compliance and high quality.

— Upskill talent, including by training employees in the effective use of these tools and broader AI adoption strategies.

Submission transformation over three horizons

Although companies choose to take their own approach to accelerating filing, we have observed that successful submission transformations follow a sequence across three discrete horizons. Within each horizon, companies typically choose one to three high-priority assets to hasten through the filing process while they adjust their underlying processes for sustainability. This strategy can yield early, tangible benefits to top-line revenue and resource capacity while systematically addressing fundamental governance, processes, systems, and ways of working.

Horizon one: Revamp the operating model and processes (Exhibit 5A):

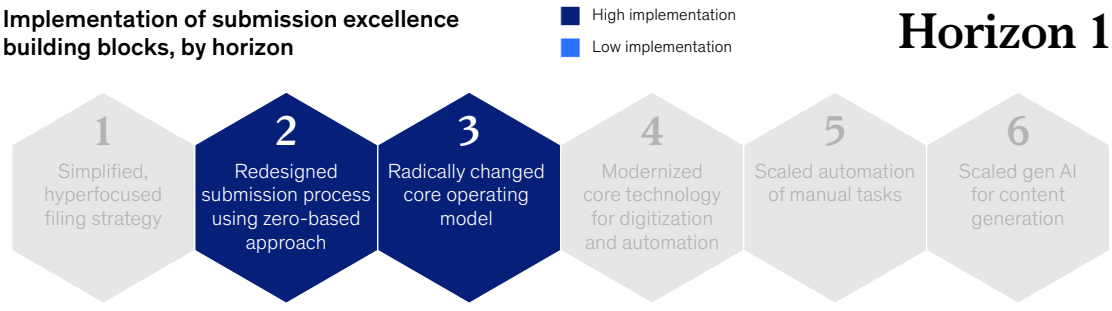
— Using building blocks two and three, this horizon primarily involves the execution of a zero-based redesign of the submission process and radical changes in the core operating model.

— Examples of outcomes include more flexible governance, improved execution rigor, and basic technology improvements, such as workflow automation.

— The DBL-to-filing timing is approximately 12 to 14 weeks.

Exhibit 5A

A staggered approach to submission transformation allows pharma companies to adjust and streamline underlying processes more efficiently.



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Horizon two: Perform a zero-based redesign of the operating model and experimentation with emerging technology (Exhibit 5B):

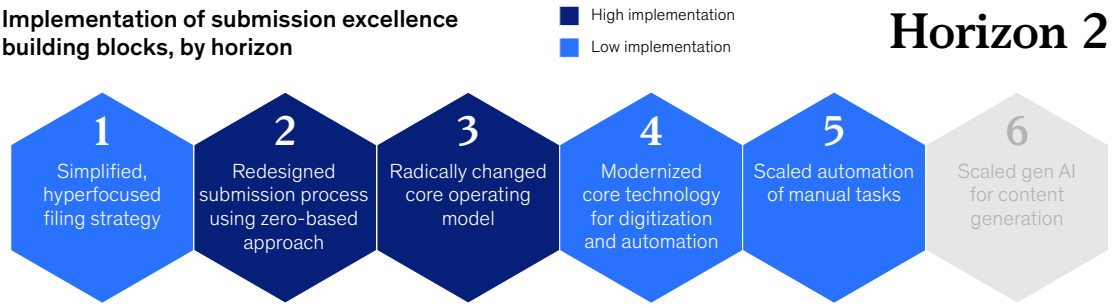
— Using building blocks one through five, this horizon involves the execution of a laser-focused filing strategy and a full revamp of the operating model and processes, including a zero-based design of all core processes and entirely new ways of working.

— Examples of outcomes include automation integration for structured content authoring, source updates, and translations and the use of gen AI for generating content, such as clinical-study reports.

— The DBL-to-filing timing is approximately eight to ten weeks.

Exhibit 5B

A staggered approach to submission transformation allows pharma companies to adjust and streamline underlying processes more efficiently.



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Horizon three: Shift the paradigm from scaling technology to submission (Exhibit 5C):

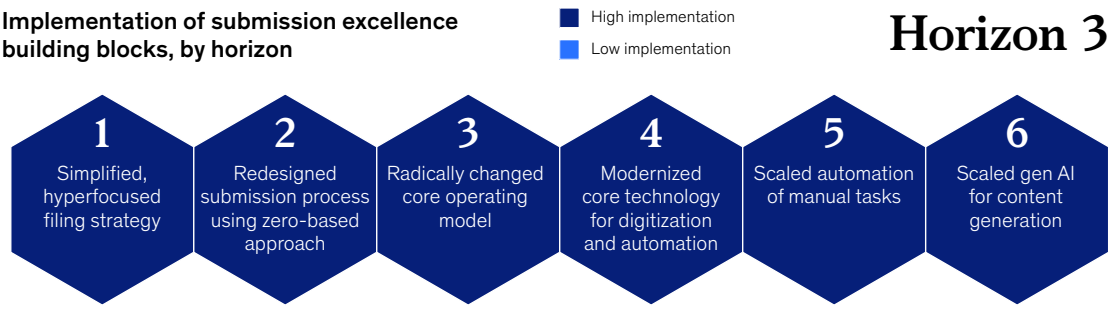
— Using building blocks one through six, this horizon involves a full embrace of all the submission transformation elements, including scaling new technology, such as gen AI, and adopting a human-in-the-loop operating model.

— Examples of outcomes include achieving filing speeds in fewer than six weeks and positioning the organization for such radical changes as fully paperless filings and real-time data sharing with health authorities. A precursor to the latter innovation is the US Food and Drug Administration's real-time oncology review, which aims to accelerate access to safe, effective cancer treatments through streamlined reviews and early communication with applicants.

— The DBL-to-filing time is fewer than six weeks.

Exhibit 5C

A staggered approach to submission transformation allows pharma companies to adjust and streamline underlying processes more efficiently.



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Leading pharma R&D companies are prioritizing faster clinical development and shorter regulatory-filing timelines to capture massive value for their stakeholders. While such companies have made impressive progress, others could achieve ambitious timeline reductions by achieving submission excellence and upgrading their core technology. Leaders of regulatory-affairs teams should make informed decisions, develop winning technology plans, and equip teams with game-changing capabilities. Done correctly, an improved regulatory-filing process could play an outsize role in accelerating the delivery of life-saving medicines to the patients who need them most.

Anton Mihic is a partner in McKinsey's New Jersey office, where **Ralf Raschke** is a senior expert; **Gaurav Agrawal** is a senior partner in the New York office; **Lotte Berghauser Pont** is a partner in the Amsterdam office; **Rosa Poetes** is a partner in the Zurich office; and **Giulia Ferretti** is an associate partner in the Geneva office.

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