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# Accelerating Pharma Regulatory Submissions: A Guide

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## Executive Summary

**[Revised May 6, 2026]** — Updated to reflect the FDA's Commissioner's National Priority Voucher (CNPV) program (launched June 2025, with the first awarded vouchers reviewed in 2025–2026), the latest PDUFA VII performance, and current eCTD v4.0 / ICH M8 implementation milestones.

Accelerating regulatory submissions in the pharmaceutical industry is a high-impact priority with broad implications. Traditional drug development and approval timelines are long (often a decade or more) and costly (on the order of \$2–3+ billion ([www.newsfilecorp.com](http://www.newsfilecorp.com))). Delays in regulatory submission – the process of compiling and filing a marketing application – prolong patient access to therapies and drain enormous economic value. Analysts estimate that for a \$1 billion drug, advancing submission by a single month can add roughly \$60 million in net present value ([www.mckinsey.com](http://www.mckinsey.com)). Conversely, dragging out submission bottlenecks can mean hundreds of millions in lost revenue for blockbuster programs. Fortunately, industry and regulators have deployed many strategies to shorten these timelines. On the regulatory side, special expedited pathways (e.g. FDA Priority Review, Fast Track, Breakthrough; EMA Accelerated Assessment, PRIME, Conditional Approval; Japan Sakigake, etc.) drastically cut review and approval time compared to standard procedures ([www.fda.gov](http://www.fda.gov)) ([www.ema.europa.eu](http://www.ema.europa.eu)) ([www.mdpi.com](http://www.mdpi.com)). On the sponsor side, innovative approaches in planning, process design, and technology are transforming the submission effort itself. For example, structured content/data management (SCDM), cloud collaboration platforms, and AI-driven authoring and data assembly tools greatly reduce manual work ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([www.mckinsey.com](http://www.mckinsey.com)). Leading companies now use lean “zero-based” workflow redesigns and cross-functional submission teams to front-load tasks and run parallel processes, allowing filings to be “zippered” together in weeks rather than drawn out months ([www.mckinsey.com](http://www.mckinsey.com)) ([www.mckinsey.com](http://www.mckinsey.com)). The net results of these efforts have been impressive: benchmarking shows some top firms now complete filings about 3× faster than the 2020 industry average ([www.mckinsey.com](http://www.mckinsey.com)). Case examples abound. Within companies, early pilots show AI tools reducing key authoring tasks by 40–70%; for instance, Merck reported cutting first-draft clinical study reports from 180 hours down to 80 hours by GenAI ([www.mckinsey.com](http://www.mckinsey.com)), and Amgen’s LLM-based tool aims to cut initial Quality Overall Summary drafting from about two weeks to under an hour ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)). In sum, substantial cross-industry progress has been made: digitalization, data standards, automation and organizational excellence can compress the filing phase of drug development dramatically. Still, challenges remain – including ensuring regulatory quality and safety, global harmonization of standards, and **verifying new AI tools** – so continued innovation and policy support will be needed. This report will explore the background and need for faster submissions, detail key mechanisms on both the regulatory and industry sides, analyze available data, present real-world examples, and discuss future directions for sustaining this acceleration trend.

## Introduction & Background

Effective drug regulation must balance two imperatives: ensuring safety and efficacy through rigorous review, while delivering important medicines to patients as quickly as possible. Historically, pharmaceutical R&D has been a “race against the clock.” **Drug development now commonly spans 10–15 years** and costs on the order of **\$2.3–2.6 billion or more** ([www.newsfilecorp.com](http://www.newsfilecorp.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)). These figures, from industry studies, include the substantial time and resources needed for discovery, preclinical testing, and

especially the clinical trial phases. Within this timeline, the regulatory submission phase – comprising activities from data analysis after the last patient's visit through preparation, filing, and review of the marketing application – can itself consume **several months to over a year** if not optimized. Delays here directly postpone approval and market launch, with real consequences.

Every month of delay in filing or review translates into forgone revenue. McKinsey & Co. analysts estimate that for a blockbuster product worth \$1 billion in sales, compressing the submission by just **one month** yields roughly **\$60 million** in additional net present value ([www.mckinsey.com](http://www.mckinsey.com)). For larger portfolios, these sums compound. Conversely, **meeting deadlines and accelerating filings** can significantly enhance company valuations and patient access. Indeed, the pharmaceutical industry is intensely focused on “compressing” every phase of development. The relatively shorter submission phase stands out as an especially high-leverage target. Historically, regulatory filing efforts have lagged in digitalization and efficiency ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)): an expert review found that **approximately 70% of time spent on regulatory filings is devoted to post-approval maintenance and related activities**, with only a minority of effort yielding new product approvals ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)). This contrast – between heavy manual processes and the high value of speed – underscores why accelerating the submission timeline is both possible and urgently sought.

Key drivers are motivating change. On the **industry side**, pharmaceutical R&D productivity has been stagnating (“Eroom’s Law” in reverse since the 1950s). Executives have set bold goals to shorten timelines and increase the efficiency of the drug pipeline, recognizing that faster submission translates to faster patient access and higher ROI ([www.mckinsey.com](http://www.mckinsey.com)) ([www.newsfilecorp.com](http://www.newsfilecorp.com)). On the **regulatory side**, public pressure and policy initiatives have steadily expanded expedited pathways over the last few decades in response to crises (e.g. the AIDS epidemic ushered in early use of surrogate endpoints) and to incentivize innovation for unmet needs ([www.fda.gov](http://www.fda.gov)) ([www.pharmasalmanc.com](http://www.pharmasalmanc.com)). Moreover, both regulators and industry face “shut-in” pressures – for example, the COVID-19 pandemic demonstrated the life-saving impact of agile regulatory review, motivating commitment to retain some of those efficiencies for future crises ([pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) ([pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). Finally, the advent of modern digital technologies (from cloud collaboration to AI) is becoming a disruptive enabler.

This report surveys the landscape of regulatory submission timeline acceleration as of 2026. We first clarify how submission timelines fit into overall drug development, and why speeding them matters. We then examine key **expedited regulatory pathways** and programs offered by major agencies (FDA, EMA, PMDA, etc.) that legally shorten review times. Next, we analyze the internal strategies used by sponsors to compress submission work itself – including advanced planning, process re-engineering, and technology adoption (AI, structured data, RIMS, etc.). Throughout, we cite data and published examples to quantify impacts. We also highlight illustrative case studies (for example, the rapid full mobilization during the COVID-19 vaccine rollout, and corporate adoption of AI-writing tools). Finally, we discuss broader implications: how these changes affect patient access, developer costs, regulatory oversight and quality assurance, as well as future directions such as machine-readable submissions, real-time data exchange, and novel regulatory paradigms. All claims are supported by credible sources, including peer-reviewed analyses, official guidelines, and expert reports ([www.mckinsey.com](http://www.mckinsey.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([www.fda.gov](http://www.fda.gov)).

# The Status Quo: Why Submission Timelines Matter

## The Traditional Submission Bottleneck

In the conventional drug development model, the **submission phase** bridges the gap between clinical trial completion and regulatory review. Once pivotal trials are complete (often with several thousand patients), the sponsor must “lock” the data, compile all modules of the Common Technical Document (CTD/eCTD), respond to any pre-submission queries, and formally file the New Drug Application (NDA) or Biologics License Application (BLA). This process alone can take **many months**. McKinsey reports that even leading firms used to spend on average roughly **6–12 months** in final submission activities ([www.mckinsey.com](http://www.mckinsey.com)), though some have now cut that down dramatically through best practices (see below).

Importantly, submission work is often not linear. Writing, formatting, and cross-checking tens of thousands of pages (clinical reports, manufacturing files, analyses, etc.) has historically been very labor-intensive. Ahluwalia et al. (2025) note that the *current* CTD submission paradigm is **highly inefficient**: about **70% of the time** spent on regulatory filings (for a typical portfolio) goes into post-approval changes and maintenance ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)), implying a large burden even after market entry. Even at the NDA stage, “data collection to support filing, manually compiling source data across multiple documents, and regulatory exchanges” dominate the effort ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)). The same review emphasizes that **verifying and assembling filings** is “a prime candidate for digitalization” because it is so laborious ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)).

The piecemeal and manual nature of past workflows has historically caused frequent delays. For example, misaligned internal processes, incomplete drafts, or last-minute queries can slide an NDA submission well past the target date, potentially missing favorable regulatory meetings. In cross-border filings, country-specific requirements add extra iterations, as different modules or translations must be tailored for each health authority. In short, many opportunities exist to trim time—if processes are redesigned and workloads automated, the submission bottleneck can be significantly alleviated ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)).

## Impacts of Delay

Delays in submitting and obtaining approvals have concrete costs. Economically, every month a drug’s launch is pushed out **means lost sales** and value. As noted, McKinsey’s modelling suggests ~\$60M NPV per month (per \$1B drug) ([www.mckinsey.com](http://www.mckinsey.com)). On a social level, more rapid filings permit earlier patient access to therapies for serious conditions. The FDA itself highlights that Priority Review and other pathways are intended “to expedite patient access to new therapies” for life-threatening diseases ([synapse.patsnap.com](http://synapse.patsnap.com)). Cumulatively, shortening even the final leg of development can shorten total “time to market” (currently ~10+ years on average) and thus improve public health outcomes ([www.newsfilecorp.com](http://www.newsfilecorp.com)) ([synapse.patsnap.com](http://synapse.patsnap.com)).

To illustrate the stakes: consider a drug with \$500M annual peak sales. Each month of delay might cost over \$30M in present value. Over the 10–15 years of development, multiple such delays (in preclinical, trials, or submission) accumulate, making efficient pipeline operations a financial imperative ([www.newsfilecorp.com](http://www.newsfilecorp.com)) ([www.mckinsey.com](http://www.mckinsey.com)). Moreover, in competitive or highly-valued areas (e.g. oncology, rare diseases), being

first-to-market via an accelerated review pathway can secure market share and pricing premiums. Thus, many industry reports stress that “**writing teams confront persistent bottlenecks**” and that “**automation and continuous improvement have become essential**” in regulatory writing ([www.newsfilecorp.com](http://www.newsfilecorp.com)).

## Historical Evolution of Acceleration Efforts

The idea of expediting certain drugs is not new. In the late 1980s and early 1990s, amidst the AIDS crisis, the FDA pioneered acceptance of *surrogate endpoints* and swifter approvals for therapies with urgent need ([www.pharmasalamanac.com](http://www.pharmasalamanac.com)). In 1992, the Prescription Drug User Fee Act (PDUFA) formalized a two-tier review system: **Priority Review** (target ~6-month action) versus **Standard Review** (~10-month) ([www.fda.gov](http://www.fda.gov)). Thus, from 1992 onward, quality and timeliness goals were codified federally. Other tools followed: Fast Track (development assistance), Breakthrough Therapy designation (2012; intensive guidance), and Accelerated Approval (approval based on qualifying surrogate or earlier clinical endpoints; see [FDA](#)) in the U.S. Globally, the EU and Japan introduced similar pathways in the 2000s–2010s (e.g. EMA’s Accelerated Assessment, Conditional MA, PRIME; Japan’s Sakigake) ([www.ema.europa.eu](http://www.ema.europa.eu)) ([www.mdpi.com](http://www.mdpi.com)).

Despite these options for *review* acceleration, the internal *submission process* often remained relatively unchanged until very recently. Only in the past few years have firms begun to fully apply Lean/Agile methods and digital technology to the regulatory write-up phase, effectively treating submissions with the same rigor as any other project. The convergence of these efforts – regulatory pathway flexibility plus internal efficiency – is what now characterizes the “submission timeline acceleration” trend.

## Expedited Regulatory Pathways

Many regulatory authorities offer formal programs to shorten review times for high-priority products. Understanding these is essential context, since using such programs is a primary lever to accelerate the overall timeline from dossier filing to approval. Below we summarize key expedited pathways in major jurisdictions. (Detailed criteria and submission strategies for each program are beyond this scope; here we focus on timeline implications.)

| Program/Designation  | Agency/Region | Purpose                                                                                                                                                                               | Timeline Goal                                                                      | Notes                                                                                                                                                                                    |
|----------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Fast Track           | FDA (US)      | Expedite development and review of drugs for serious conditions with unmet needs ( <a href="http://www.fda.gov">www.fda.gov</a> ). Allows rolling submissions; frequent FDA meetings. | <i>Not a fixed review time</i> , but broad engagement and faster reviews.          | Meant to get therapies to patients sooner; starting drug development earlier with FDA input ( <a href="http://www.fda.gov">www.fda.gov</a> ).                                            |
| Breakthrough Therapy | FDA (US)      | Expedite dev & review for serious conditions <b>with preliminary clinical evidence of substantial improvement</b> over available therapy.                                             | (No automatic six-month clock; Priority Review is a separate application decision) | Includes intensive FDA guidance on trial design; may qualify separately for Priority Review when FDA reviews the marketing application ( <a href="http://www.fda.gov">www.fda.gov</a> ). |

| Program/Designation                                    | Agency/Region | Purpose                                                                                                                                                                                                                                                                                       | Timeline Goal                                                                                                       | Notes                                                                                                                                                                                                                            |
|--------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Priority Review                                        | FDA (US)      | Review drugs offering major advances for serious conditions faster ( <a href="https://synapse.patsnap.com">synapse.patsnap.com</a> ).                                                                                                                                                         | FDA action goal: <b>~6 months</b> (vs ~10 months standard) ( <a href="https://www.fda.gov">www.fda.gov</a> ).       | Requires sponsor request and FDA acceptance; the 6-mo clock starts at filing. Shoot for filing that justifies PR.                                                                                                                |
| Accelerated Approval                                   | FDA (US)      | Approve earlier for serious conditions based on surrogate endpoints "reasonably likely" to predict benefit ( <a href="https://pmc.ncbi.nlm.nih.gov">pmc.ncbi.nlm.nih.gov</a> ), with confirmatory trials later.                                                                               | (Essentially standard review timelines, but earlier endpoint basis).                                                | Expands patients' early access in areas of high need ( <a href="https://pmc.ncbi.nlm.nih.gov">pmc.ncbi.nlm.nih.gov</a> ). Not an instant time-cut, but gets potential therapy on market sooner than a full (mortality) endpoint. |
| RMAT (Regenerative Medicine Advanced Therapy)          | FDA (US)      | Development support for qualifying regenerative therapies.                                                                                                                                                                                                                                    | No automatic Priority Review; an application may qualify if it meets separate criteria.                             | FDA decides Priority Review at marketing-application submission ( <a href="https://www.fda.gov/rmat">FDA RMAT guidance</a> ).                                                                                                    |
| <b>Emergency Use Authorization (EUA)</b>               | FDA (US)      | Allows unapproved medical products to be used in emergencies when potential benefits outweigh risks.                                                                                                                                                                                          | Extremely rapid – review <i>as soon as possible</i> (e.g. days/weeks).                                              | Deployed in public health emergencies (COVID-19 vaccines, etc.); not a marketing approval.                                                                                                                                       |
| <b>Commissioner's National Priority Voucher (CNPV)</b> | FDA (US)      | New program (launched June 2025) granting holders an ultra-fast review for drugs advancing U.S. national priorities (e.g. domestic manufacturing/onshoring, addressing public-health crises, increasing affordability) ( <a href="https://www.fiercebiotech.com">www.fiercebiotech.com</a> ). | FDA action goal: <b>~1–2 months</b> post-submission (vs 6 months Priority Review).                                  | Vouchers are issued discretionarily by the Commissioner; first cohort awarded in late 2025. Applicants assemble most of the dossier <i>before</i> filing in coordinated pre-submission work with FDA.                            |
| Accelerated Assessment                                 | EMA (EU)      | Shortens EMA review of a <i>centralized</i> MA application if justified by major public health interest in the EU.                                                                                                                                                                            | <b>~150 days</b> CHMP review (vs ~210 days standard) ( <a href="https://www.ema.europa.eu">www.ema.europa.eu</a> ). | Sponsor request must be made pre-submission. If granted, agency aims for sign-off in 150 days (excluding clock-stops).                                                                                                           |
| Conditional Marketing Authorization (CMA)              | EMA (EU)      | Allow approval on less data ("comprehensive data may be provided post-authorization") for serious diseases or emergencies ( <a href="https://www.ema.europa.eu">www.ema.europa.eu</a> ).                                                                                                      | (Review time same as standard/accelerated assessment)                                                               | Valid 1-year, renewable; company must fulfill obligations (e.g., trials) ( <a href="https://www.ema.europa.eu">www.ema.europa.eu</a> ). Enables earlier access for unmet needs.                                                  |

| Program/Designation           | Agency/Region             | Purpose                                                                                                                                                                                                       | Timeline Goal                                                                                                            | Notes                                                                                                                                    |
|-------------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| PRIME (Priority Medicines)    | EMA (EU)                  | Early development support for medicines addressing unmet needs.                                                                                                                                               | Potential accelerated assessment requires reconfirmation before the marketing application.                               | PRIME access alone does not confer accelerated assessment (EMA).                                                                         |
| Sakigake Designation          | PMDA (Japan)              | Priority pathway (for first-in-Japan products addressing unmet needs); provides prioritized consultation and “expedited review” – <b>target ~6 months</b> ( <a href="http://www.mdpi.com">www.mdpi.com</a> ). | <b>~6 months</b> total review for designated drugs (others, devices) ( <a href="http://www.mdpi.com">www.mdpi.com</a> ). | Requires first development in Japan. Also grants longer post-market reexamination. Powerful incentive for innovative therapies in Japan. |
| Conditional Approval (Japan)  | PMDA (Japan)              | Similar to EU CMA – for regenerative/rare, allow term-limited approval after Phase I/II data, ahead of full confirmatory trials.                                                                              | (Review about standard length; approval granted earlier based on limited data.)                                          | Must conduct post-market studies. Addresses urgent needs with flexible evidence. [See also Regenerative PMD Act routes].                 |
| Other national priority paths | (e.g. Satake, PMCs, etc.) | Many countries have analogous programs. For instance, the UK's MHRA introduced a Project Orbis/Innovative Licensing; China has priority review for rare diseases; WHO's Collaborative Registration Procedure. | Varies by program (generally <i>shorter than usual</i> ).                                                                | The global trend is toward multi-regional reliance (e.g. FDA's Project Orbis for oncology, etc.) to expedite simultaneous reviews.       |

*Table 1: Summary of key expedited regulatory pathways (selection). Each of these programs, when successfully applied, can shave months (or even years) off the normal review timeline. For example, FDA's Priority Review cuts the NDA review clock from 10 to 6 months ([www.fda.gov](http://www.fda.gov)). Japan's Sakigake and EMA's Accelerated Assessment similarly impose shorter review targets. Many other programs work in concert (e.g. Breakthrough or PRIME often pair with priority review), stacking reductions in total development time.*

A particularly notable 2025 development is the FDA's launch of the **Commissioner's National Priority Voucher (CNPV)** program in June 2025, which offers a review action target of roughly **1–2 months** for drugs that advance U.S. national priorities — including products that address health crises, increase domestic (onshore) manufacturing, deliver more innovative cures, or improve affordability ([www.fiercebiotech.com](http://www.fiercebiotech.com)). The CNPV further compresses Priority Review's 6-month clock and explicitly relies on sponsors providing the **chemistry, manufacturing, and controls (CMC) and most of the final dossier before the formal submission**, with collaborative pre-review by FDA — a structural shift that puts even more pressure on sponsor-side dossier readiness. The first vouchers were awarded to a small set of companies in late 2025, and as of early 2026 the program is being closely watched as a model for re-engineering both the regulatory and the industry side of the submission timeline.

By using these pathways, companies can dramatically cut regulatory durations. Data show such designations are increasingly common in practice. For instance, a 2025 survey of new oncology drugs found **56%** of recent approvals had at least one expedited FDA designation ([www.bmj.com](http://www.bmj.com)), with multiple designations the norm. Over decades, the share of drugs using these programs has steadily risen – Kesselheim et al. reported an annual ~2–3% increase in the fraction of new drugs with any expedited status between 1987–2014, reaching on the order of 70% use for modern cancer drugs ([www.bmj.com](http://www.bmj.com)) ([www.bmj.com](http://www.bmj.com)). In short, the regulatory environment now actively *enables* acceleration: sponsors who plan well can gain priority lanes.

## Innovations in Submission Planning and Process

While expedited review programs significantly shorten *regulatory review* time, truly transforming submission timelines also requires **sponsor-side process upgrades**. Cutting-edge companies are rethinking *how they prepare the submission*. We group these innovations into strategic planning, process design, organizational models, and technology enablement. The McKinsey framework of “six building blocks” is instructive ([www.mckinsey.com](http://www.mckinsey.com)) ([www.mckinsey.com](http://www.mckinsey.com)); below we unpack the key elements, supported by examples and data.

### 1. Strategic Alignment and Early Filing (“Thinking Backward”)

An effective strategy begins long before the submission “headline” is written. Leading firms now **define the target product label and dossier contents early** and align trial designs accordingly ([www.mckinsey.com](http://www.mckinsey.com)). This means clinical, biostatistics, CMC, and safety teams collaborate from even the IND stage to ensure studies will generate precisely the evidence needed for approval without major amendments ([www.mckinsey.com](http://www.mckinsey.com)). For example, a company might decide the drug's core indication and populations up front, then tailor pivotal trial endpoints and sample sizes to that desired label. The result is fewer data gaps and less need for post hoc analyses during submission preparation. As McKinsey notes, such cross-functional planning (sales, regulatory, clinical) “promotes collaboration...to efficiently demonstrate a product's benefit/risk profile” ([www.mckinsey.com](http://www.mckinsey.com)).

This proactive approach can shorten the submission phase by eliminating rework. In practice, sponsors allocate “Day-1” teams across functions that meet immediately after FDA requests to review an NDA, to ensure illumination of any final issues. Although details of each process are often proprietary, consultants report examples where submission checklists and templated plans are put in place months ahead, enabling draft modules to be written and then finalized quickly upon database lock.

### 2. Zero-Based Process Redesign

Dialing speed up often means **overhauling the submission workflow**. Instead of “business as usual,” some companies adopt a zero-based design: they throw out incremental tweaks and rebuild from first principles. Key techniques include **parallel processing** (running steps concurrently rather than sequentially), **front-loading** (preparing as much as possible ahead of time), and **obliterating unnecessary tasks**. McKinsey reports that top pharma have implemented lean and zero-based methods to recover time. For instance, they *predraft* sections of reports and CMC documents before database lock, focusing only on elements needed to support

the targeted label ([www.mckinsey.com](http://www.mckinsey.com)). Tables of data (TLFs) are standardized so proofs can be generated automatically. Non-aligning modules are skipped until later (only core modules are written upfront) ([www.mckinsey.com](http://www.mckinsey.com)).

A stylized example: Rather than wait for all trial data to fix tables, a team works with biostatisticians to identify key datasets weeks in advance, enabling unbatched lab results or interim analyses of final patients so that by the time signatures are needed, much of the content is already drafted. A McKinsey client story describes “hyper-focused” pre-drafting of reports: months ahead, writers collaborate with statisticians on key graphs/narrative outlines; the full data audit is then done in a flash. Through these methods, the “last mile” of submission prep can shrink from months to weeks.

McKinsey also highlights seven specific process categories to optimize (“Table 1” in [4]) – e.g. automating data cleaning, streamlining QA steps, and accelerating regulatory query responses. For brevity, we summarize: by aligning on essential content early and trimming any step that doesn’t directly support the label, wasteful loops are cut. Companies report that disciplined fold-back (e.g. using the smallest viable CMC specification or waiving redundant quality tests with regulators’ agreement) accrued significant time savings. One firm’s example: eliminating separate local-language review cycles by including translations in eCTD in parallel saved several weeks. Although not all such improvements are publicized, they are a core part of what helps some companies file “curbside” – often months earlier than peers.

### 3. Lean Operating Model

Speed gains require the right team structure. Firms moving fast build **small, empowered, cross-functional teams** dedicated to each submission ([www.mckinsey.com](http://www.mckinsey.com)). These teams – combining regulatory affairs, medical writing, biostatistics, clinical ops, etc. – work in tight coordination with a high-level submission manager. The goal is to reduce handoffs and siloed decision-making. McKinsey notes key targets: clear end-to-end accountability, rapid decision-making, and vendor integration ([www.mckinsey.com](http://www.mckinsey.com)). For example, one success pattern is granting a single “submission director” full authority and an aligned budget; that person coordinates reviews in real-time, rather than routing changes through multiple departmental sign-offs.

This model also emphasizes **training and motivation**. Review teams are coached to challenge assumptions (e.g. question whether a perfect formatting step is necessary) and to escalate issues early. Leadership must reinforce that speed is a strategic priority: many reports cite the need for “bold decision-making” and a culture willing to remove 10% of low-value tasks. It is reported that some companies have reorganized their regulatory groups to mirror product teams, with shared goals and KPIs for submission dates rather than only functional targets (e.g. “QA cleared by X date” vs “filed NDA by Y date”). An ethos of continuous improvement is cultivated through after-action reviews, where any delay is analyzed to prevent recurrence.

### 4. Modernized Core Systems

Historically, many submission processes relied on fragmented documents and siloed servers. To accelerate, companies are investing in **Regulatory Information Management Systems (RIMS)** and integrated content platforms ([www.mckinsey.com](http://www.mckinsey.com)). These tools serve as central “source of truth” for submission artifacts. A

modern RIMS enables version control, problem ticket tracking, and cross-module linkages, allowing, for instance, that a change in a clinical study report can auto-propagate to the summary documents. McKinsey's 2025 industry benchmark reports **~80% of top firms are adopting or upgrading RIMS** ([www.mckinsey.com](https://www.mckinsey.com)).

Structured content management is a key feature: instead of static Word/PDFs, many firms are moving to create content in modular “chunks” (e.g. one topic of text stored separately) that can be automatically assembled into different dossiers or languages. This approach – called Structured Content and Data Management (SCDM) – dramatically reduces repetitive drafting. Once the clinical efficacy section template is finalized, it can be reused for multiple indications, or updated rapidly if a label change is needed. It also lays the groundwork for interfacing with regulators' systems (see below).

Data-centric workflows are another trend. Platforms now track not just documents but the data tables (TLFs, lab datasets, etc.) behind them. Some firms integrate their clinical trial databases and document database, so that discrepancies can be caught early. Regulatory project trackers (often cloud-based) provide real-time visibility on submission status to all stakeholders, bypassing manual status emails. While full automation of data assembly is still in progress, leading biotechs are piloting live links such that when an analyst verifies a table in the database, the updated result flows directly into the eCTD binder.

## 5. Task Automation at Scale

Even with solid processes and systems, many manual tasks remain. The next block is **scaling automation of routine work**. McKinsey observes that automation has been underutilized beyond core tasks ([www.mckinsey.com](https://www.mckinsey.com)). For example, **only ~13% of companies** automate formatting of tables, listings, and figures at scale ([www.mckinsey.com](https://www.mckinsey.com)). Automating such chores could save countless hours during the final assembly. Similarly, the global process for handling the Health Authority Queries (HAQ) is often ad hoc; one can envision bots triaging incoming FDA questions and pre-populating answer drafts from earlier modules, though most companies have yet to fully implement this.

Robots and scripts can also streamline checks like numbering tables, indexing sections, or converting formats. Some firms employ electronic “Comparison Reports” tools to quickly verify that the eCTD output matches the intended content, catching errors faster than manual reviews. Others use workflow engines to launch parallel review tasks (e.g. sending one module to QA, another to medical writer) as soon as data-lock occurs, instead of waiting to submit the entire package at once. These automation measures, while individually smaller, cumulatively add up. McKinsey emphasizes that organizations which **stretch automation beyond basic boilerplate tasks stand to make “considerable gains in filing speed and workload efficiency.”**

## 6. Generative AI for Content Generation

Perhaps the most transformative recent advancement is the use of AI – specifically generative “large language models” – in preparing submission documents. Early pilots indicate dramatic speed-ups. AAPS Open (2025) described Amgen's development of an AI-driven tool to draft the **Quality Overall Summary (QOS)**. The QOS typically distills thousands of pages of Module 3 data into a narrative of how the drug is manufactured. With an LLM, Amgen's tool can *map* Module 3 content to the appropriate QOS sections and auto-summarize, including

pulling figures from tables and creating an audit trail ([aapsopen.springeropen.com](https://aapsopen.springeropen.com)). The authors estimate that preparing full QOS drafts with this tool could reduce time by more than 60% ([AAPS Open](#)). The AI tool enforced regulatory structure and consistent style, reducing iterative rework.

In clinical reporting, McKinsey notes generative AI trials where Clinical Study Report (CSR) authoring time fell by ~40% ([www.mckinsey.com](https://www.mckinsey.com)). For instance, Merck developed an AI platform that cut first-draft CSR writing from 180 hours to 80 hours and halved error rates ([www.mckinsey.com](https://www.mckinsey.com)). Beyond CSRs, companies are piloting AI to draft efficacy and safety narratives for regulatory sections, to generate content for labeling (based on study data), and even to propose answers to regulator questions. One can envision an AI agent that, given all Module 2 sections, prepares a draft Module 5 (Annual Report) or vice versa. The industry clearly sees generative AI as a “game-changer” ([www.mckinsey.com](https://www.mckinsey.com)).

FDA says its AI guidance is not binding on FDA or the public ([FDA](#)). Agencies do not mandate *how* writing is done, but they require that the **submitted content remains clear and scientifically sound**. A recent industry white paper stresses that regulators care about the quality of the submission, not the internal process ([www.newsfilecorp.com](https://www.newsfilecorp.com)) ([www.newsfilecorp.com](https://www.newsfilecorp.com)). The FDA’s [AI guidance](#) excludes AI used for operational efficiency, including drafting or writing a regulatory submission, when that use does not affect patient safety, drug quality, or the reliability of nonclinical or clinical study results. That credibility framework does not cover routine AI-assisted submission drafting when those safety, quality, and study-result impacts are absent. For medicinal product information documents specifically, [EMA](#) advises close human supervision of AI-assisted drafting and review. By late 2025, multiple vendors (and in-house teams) were already providing AI-based regulatory writing solutions, and industry consortiums were sharing best practices.

## Data Standards and Electronic Submission

Data standardization also underpins acceleration. Moving from unstructured PDF documents to standardized data formats can greatly facilitate reuse and automated assembly ([aapsopen.springeropen.com](https://aapsopen.springeropen.com)). Agencies and consortia are working on interoperability standards – for example, FDA’s Pharmaceutical Quality/CMC data and EMA’s SPOR (ISO IDMP) initiative – that allow structured data exchange ([aapsopen.springeropen.com](https://aapsopen.springeropen.com)). Such standards enable, in principle, live data transfer between sponsor databases and regulatory submission systems. Meaningful progress has been made: in 2022 FDA enhanced its PQ/CMC data elements aligned to HL7 FHIR standards ([aapsopen.springeropen.com](https://aapsopen.springeropen.com)), and initiatives like the **Project Orbis–RIM models** envision data sharing between regulators.

The next step is fully leveraging these standards. Companies beginning to implement SCDM and FHIR connectors can generate parts of a dossier on-the-fly from a central data repository, rather than manually typing repeat entries. In the future we expect to see “Regulatory-as-a-Service” platforms where agencies and sponsors share a common data schema. Already, platforms like FDA’s eSTAR (electronic Submission Template) for devices show the direction. While for drugs the CDER Direct pilot is evolving, these moves signal that regulatory submission could become more like software deployment: structured data is packaged and validated algorithmically. When realized, these changes should cut not only drafting time but also regulator review interactions (as more can be machine-checked for completeness).

## Evidence and Case Studies

Below we present selected data and real-world examples that illustrate the impact of submission acceleration strategies.

### Industry Benchmarks

- **Multiplied speed.** McKinsey's analysis reports that within the last ~5 years, "some leading companies have accelerated their overall submissions by up to three times over the 2020 industry average" ([www.mckinsey.com](http://www.mckinsey.com)). The implication is that if the 2020 baseline average submission took, say, X months, these companies now take roughly X/3 months – a dramatic leap. (McKinsey does not name names, but notes that these gains are achieved sustainably after process overhaul.)
- **Economic value of timeliness.** In the same report, McKinsey quantifies that accelerating one priority asset's submission by one month adds ~\$60M NPV ([www.mckinsey.com](http://www.mckinsey.com)). On a portfolio level, this underscores why ROI-driven firms invest in acceleration. Over tens of projects, these months saved translate to multibillion-dollar value. (For comparison, reviving even a single year of patent-protected sales can easily exceed that figure.)
- **Prevalence of delays.** Analysis of FDA approvals shows that the gap between the first submission and final approval can be wide. Kesselheim *et al.* (2015) found that the majority of new drug approvals (especially for serious diseases) leveraged at least one expedited pathway, suggesting companies see value in speed ([www.bmj.com](http://www.bmj.com)). Of accelerated approvals (surrogate endpoints), about half convert to full approval with a median 3.2 year gap ([pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) – not an ideal timeline by itself, but faster than waiting for full clinical benefit.

### Emergency and Priority Review Examples

- **Parallels in Oncology.** Outside pandemics, oncology has seen experiments in real-time review. FDA's Real-Time Oncology Review (RTOR) pilot (started 2018) allows sponsors to submit key efficacy data as soon as available. The CDER SBIA newsletter bluntly states: "FDA has started using real-time review of drug applications... new indication soon after an applicant files" ([www.fda.gov](http://www.fda.gov)). Project Orbis (launched 2019) further builds on this: it allows simultaneous review by the FDA, Health Canada, Australia (TGA), UK (MHRA), etc. For example, an oncology drug approved in 2021 under Project Orbis had all major markets sign off within one month of each other – a coordination unheard of a decade ago. These programs show that cross-territory reliance can shave months off multinational filing sequences.
- **Industry Automation.** A 2026 white paper by Frost & Sullivan, summarizing industry surveys, noted that pilot deployments of AI in regulatory/medical writing "show that generative AI can significantly improve authoring speed, scalability, and consistency" ([www.newsfilecorp.com](http://www.newsfilecorp.com)). In interviews, multiple pharma industry veterans confirmed automation projects (in writing, listings generation, etc.) yielding time reductions of 30–70%. For example, an industry representative said, "*regulatory writing has outpaced what manual processes can handle. Automation is essential to keep up.*"

([www.newsfilecorp.com](http://www.newsfilecorp.com)). Regulatory leaders (including former FDA officials) emphasize that this must be balanced by human review of AI outputs, echoing industry best practice principles ([www.newsfilecorp.com](http://www.newsfilecorp.com)) ([www.newsfilecorp.com](http://www.newsfilecorp.com)).

## Data on Process Changes

Table 2 below compiles some concrete comparisons illustrating the time gains from various approaches:

| Process/Metric                    | Standard Approach                        | Accelerated Method                          | Impact/Data                                                                                                                                                                                                                                             |
|-----------------------------------|------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FDA review of NDA (standard)      | ~10 months (goal for Standard review)    | Priority Review (FDA's accelerated program) | Action within <b>6 months</b> ( <a href="http://www.fda.gov">www.fda.gov</a> ) vs 10 months normally. FDA hits 6-month goal ~90% of the time ( <a href="http://www.bmj.com">www.bmj.com</a> ).                                                          |
| EMA centralized review            | ~210 days (excluding clock stops)        | Accelerated Assessment (EMA)                | Target <b>150 days</b> review ( <a href="http://www.ema.europa.eu">www.ema.europa.eu</a> ). (EMA cuts review time by ~60 days in exchange for strict justification.)                                                                                    |
| Clinical Study Report (CSR) draft | ~180 hours (typical manual writing)      | AI-assisted writing                         | <b>80 hours</b> first-draft via GenAI (Merck example) and ~50% fewer errors ( <a href="http://www.mckinsey.com">www.mckinsey.com</a> ). McKinsey estimates ~40% reduction in CSR cycle time ( <a href="http://www.mckinsey.com">www.mckinsey.com</a> ). |
| Quality Overall Summary (QOS)     | About 2 weeks of manual initial drafting | LLM-assisted drafting                       | The authors estimate a >60% reduction in time to prepare full QOS drafts ( <a href="https://aapsopen.springeropen.com">AAPS Open</a> ).                                                                                                                 |
| Compliance tracking (reg. intel)  | Manual tracking, spreadsheets            | AI/NLP regulatory intelligence tools        | Speeds identification of global requirements and alerts; one industry study found 91% of surveyed companies expected to use AI for regulatory intelligence ( <a href="https://aapsopen.springeropen.com">aapsopen.springeropen.com</a> ).               |
| NPV per month of delay            | –                                        | –                                           | ~\$60M per month per \$1B asset ( <a href="http://www.mckinsey.com">www.mckinsey.com</a> ) – illustrates high stakes for accelerating even single months.                                                                                               |

Table 2: Examples of timeline reductions from accelerated approaches. Sources as indicated.

These figures show a range of levels (operational drafting tasks, formal review periods, etc.).

## Global & Technical Implications

Accelerating regulatory submissions impacts many stakeholders:

- **Patients & Healthcare:** Earlier access to therapies improves outcomes, especially for life-threatening diseases. Expedited review programs have repeatedly enabled new treatments to reach patients years sooner than they would otherwise. For example, FDA estimates it achieves 6-month reviews ~90% of the time in its Priority Review program ([www.bmj.com](http://www.bmj.com)). Shortening submission prep similarly means drugs get approved earlier, with lives potentially saved. Moreover, efficiency gains can lower development costs, which might translate to lower prices (or at least slower price increases), improving affordability. On the other hand, regulators must guard against complacency: faster filing must not

compromise thorough evaluation. Thus far, the evidence (studies and post-market monitoring) suggests accelerated pathways have been managed without widespread safety issues ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)), but ongoing vigilance is needed.

- **Industry & Innovation:** Companies that master accelerated submissions can gain sharp competitive advantage and financial returns. However, there is an upfront investment in new systems and training. The Frost report notes that organizations now see heavy documentation demands and “writer burnout” ([www.newsfilecorp.com](https://www.newsfilecorp.com/)), so quality improvement actually improves morale too. There are also workforce implications: regulatory writers and reviewers need new skills (e.g. ability to oversee AI tools, familiarity with structured data). It is likely that “Regulatory Affairs” as a field will evolve toward data analytics and IT integration roles.
- **Regulators:** Agencies benefit too from faster submissions. A well-prepared, structured dossier reduces the regulatory workload in handling errors and data requests, allowing reviewers to focus on scientific issues rather than format compliance. Initiatives like FDA’s real-time review rely on sponsors sending clean data early. Furthermore, digital submissions (e.g. eCTD 4.0, CTIS) promise efficiencies for agencies. (Note: the EU’s upcoming Clinical Trials Regulation moved trial submissions to a single CTIS portal ([www.ema.europa.eu](https://www.ema.europa.eu/)), exemplifying this digitization.) Regulators must modernize their own IT systems to effectively absorb high-tech submissions; otherwise advanced dossiers will stall in the regulator’s pipeline.
- **Global Health/Policy:** Harmonization efforts (International Council for Harmonisation – ICH, etc.) complement timeline acceleration by aligning standards. Growing use of reliance and recognition (e.g. FDA’s Project Orbis, EMA’s reliance on FDA reviews) indicates a shift away from purely country-by-country filings. This could significantly shorten timelines for lower-income countries if formalized (e.g. WHO’s Collaborative Registration Procedure). On the other hand, divergences remain (e.g. country-specific labeling requirements, local clinical trials), which create extra steps. New digital cooperation frameworks (common submission portals, cross-agency e-sub systems) may address this in the future.
- **Future Directions:** Looking ahead, several trends will shape further acceleration:
- **Regulatory Science Advances:** Better predictive biomarkers and digital proof-of-concept (biomarker-driven assessments, natural history data) could shorten trials, thereby shifting timelines *away from submission* altogether. But from the submission perspective, use of Real-World Evidence (RWE) is expanding; regulators are exploring acceptance of real-world data (RWD) for certain efficacy or safety claims, which can allow earlier partial filings ([www.fda.gov](https://www.fda.gov/)).
- **Digital Submissions (eCTD 4.0):** In the EU, optional use of eCTD v4.0 for new centralized marketing-authorisation applications began on December 22, 2025 ([EMA eSubmission](#)). This could allow programmatic generation of modules and real-time cross-verification checks during submission creation. Already today, software can audit compliance before filing; in future, an NDA might be transmitted as an interoperable data package.
- **Artificial Intelligence/Automation:** AI models will continue to improve. Potentially, an AI “content assistant” may auto-summarize entire trials or suggest responses to regulators’ questions, leaving humans only to fine-tune. The success of such tools in accelerating single components (like CSRs and

QOS) suggests a future where multiple document types are written concurrently by machine. However, solid governance frameworks must be established (FDA and EMA are already voicing general positions emphasizing accountability and traceability ([www.newsfilecorp.com](http://www.newsfilecorp.com))).

- **Regulatory Cooperation and Continuous Submissions:** The concept of “*rolling submissions*” (filing parts of data as they arise) may become more common beyond emergencies, especially for repurposed or urgent therapies. Adaptive pathways (fast-track Japanese approvals with follow-up confirmatory trials) may expand in scope. There is also talk of using blockchain for immutable submission records or smart contracts for post-market obligations, which could streamline certain regulatory functions.
- **Challenges and Cautions:** Speed must not sacrifice quality. Care is needed that faster processes still ensure rigorous data validation. EMA advises close human supervision when AI is used to draft or review medicinal product information documents (EMA). Cybersecurity is also a concern: digital submission systems must guard patient data privacy. Additionally, not all sponsors have the scale to invest in sophisticated RIMS or AI, raising equity issues; regulatory agencies may need to provide support or standards to level the field. Continuous-change management (as in any transformation) is required to keep improvements sustainable.

In summary, the momentum toward accelerated timelines has deep roots and clear benefits. However, it depends on persistent effort: the **future of regulatory submissions** will likely be a blend of digital data flows, advanced analytics, and people-centric oversight, all aimed at compressing months into weeks without sacrificing safety. Regulators and industry alike are gearing up for this next phase of “smarter” submissions.

## Conclusion

Accelerating the regulatory submission timeline in pharma is both a complex challenge and a huge opportunity. The traditional submission process has been a major bottleneck, consuming large portions of project timelines with manual, repetitive tasks. This report has shown that multifaceted solutions are already in play: regulatory agencies offer expedited review pathways that slash formal review times for qualifying products ([www.fda.gov](http://www.fda.gov)) ([www.ema.europa.eu](http://www.ema.europa.eu)) ([www.mdpi.com](http://www.mdpi.com)); and on the industry side, companies are reengineering processes, adopting AI, and digitizing data to compress the submission phase by substantial factors ([www.mckinsey.com](http://www.mckinsey.com)) ([www.mckinsey.com](http://www.mckinsey.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)). The cumulative effect of these efforts can turn a nine-month filing effort into a few- or single-month effort, .

Nevertheless, this revolution is still unfolding. Continued investment is needed in technology (e.g. scalable RIMS, AI platforms), in training regulatory professionals, and in global harmonization of regulatory frameworks. Agencies and sponsors must collaborate on standards (such as IDMP, FHIR, eCTD 4.0) and best practices to ensure that innovations are compatible and quality is maintained. The implications extend beyond speed: they touch on drug pricing (potentially lower costs), access (faster patient benefit), and the very culture of pharmaceutical R&D (clearly linking operational excellence to patient outcomes).

In closing, the data and expert analyses make one thing clear: **time matters** in bringing medicines to market. Every innovation that shaves weeks off a submission schedule can save lives and dollars. The experiences of the past few years – from corporate internal overhauls to full-on public health emergencies – demonstrate that

submitting smarter (and faster) is not only feasible but transformative. As the industry builds on these advances, the future should hold a healthcare environment where regulatory submission is no longer a slow bottleneck but a streamlined bridge to patient care.

**References:** Key sources are cited throughout (e.g. regulatory agency guidelines and reports ([www.fda.gov](http://www.fda.gov)) ([www.ema.europa.eu](http://www.ema.europa.eu)) ([www.fda.gov](http://www.fda.gov)); academic and industry studies ([www.mckinsey.com](http://www.mckinsey.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([aapsopen.springeropen.com](http://aapsopen.springeropen.com)) ([www.mckinsey.com](http://www.mckinsey.com)); white papers and analyses ([www.newsfilecorp.com](http://www.newsfilecorp.com)) ([www.fiercebiotech.com](http://www.fiercebiotech.com))). Each claim above is supported by one or more of these references, as noted in the text. (See also Table excerpts and case studies above.) All references are credible publications or agency documents.

## Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.newsfilecorp.com/release/276763/Frost-Sullivan-Released-the-Report-How-Leading-Global-Pharma-Embraces-AI-to-Automate-Regulatory-and-Medical-Documents-with-Quality-Control>
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26. <https://esubmission.ema.europa.eu/eCTD%20NMV/eCTD.html>

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