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Accelerating Generic Drug Time-To-Market: Integrative Review of Operational Excellence, Strategic Knowledge Management and Cross-Functional Bottlenecks

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ABSTRACT: A generic drug can achieve all its technical milestones on time and still get to patients late. Time is seldom lost within a single department, but it gathers up in the intervals between them. The relevant literature is spread across pharmaceutical development, knowledge management, organizational learning, business-process management, cross-functional integration, project scheduling and operational excellence, and has not yet been synthesized. This review combines that work, giving priority to generic and broader pharmaceutical development and using studies from other settings only where their mechanisms are transferable. It draws on 65 sources, from empirical studies to regulatory guidance, identified through database searches and reference tracking. There are three interrelated processes. When a decision must be made, technical and regulatory experience must be at hand. Recurring management processes and handovers must be defined so that they are predictable. The project schedule must separate avoidable waiting and preventable rework from the necessary science and the unavoidable waiting that no management system can shorten. Whether a local delay then shifts the launch date depends on concurrency, dependencies and available float. The proposed framework links strategic knowledge management to process harmonization and handover reliability, and these in turn to lower operational loss and shorter time-to-market. Evidence on generic development from the laboratory to the market is still limited, and the proposed relationships have not yet been tested empirically. The review provides a basis for reducing preventable launch delay without weakening scientific rigor, product quality or regulatory compliance.

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1. INTRODUCTION

Generic drugs increase the treatment accessibility, and the creation of a generic takes longer than the production of an already-established formulation. A company needs to achieve pharmaceutical quality, standardized product and process, demonstrate that its analytical methods are fit for purpose, demonstrate manufacturing preparedness and produce evidence of substitution to meet the regulatory pathway it has selected before a program is viable. Guidelines from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the World Health Organization (WHO) put knowledge, risk management, quality systems and lifecycle learning at the center of that work (ICH, 2008, 2009, 2019, 2023a, 2023b, 2023c, 2024; World Health Organization, 2024). The Egyptian Drug Authority (EDA) specifies the registration requirements in Egypt, e.g., the Common Technical Document (CTD), bioequivalence, sampling, and release (Egyptian Drug Authority, 2025a, 2025b, 2026a, 2026b).

What follows from these requirements is a coordination problem as much as a scientific one. Formulation and analytical development, matching suppliers and materials to the required specifications, manufacturing, validation, comparative studies, dossier preparation, responses to authority requirements, release, and launch each depend on outputs produced elsewhere in the organization. Studying generic pharmaceutical companies, Prašnikar and Škerlj (2006) tied development speed to organizational design, the management of concurrent activities, functional integration, sourcing, project and capacity management, and measurement practice. Testas et al. (2021) later described an industrial generic-development case in which a structured quality by design (QbD) approach cut development and validation time.

The time-to-market thus has both strategic weight, and technical weight. The advantage of early entry is that it lengthens the timeframe within which a generic medicine has a good competitive position. A meta-analysis relates the speed of new product development (NPD) with product performance (Cankurtaran et al., 2013), and the research of generic markets indicates that early entry can be rewarded in specific market circumstances (Hollis, 2002; Wattal, 2025). All of this is not unconditional. Market share is influenced by the pricing, distribution, availability, promotion, prescribing behavior, and the competitive field. Knowing TTM thus implies posing the question of where time is accrued and what bottleneck activities can be controlled in order to reduce the total time.

The evidence needed to address that question is dispersed across research disciplines. The concern of pharmaceutical operational excellence is quality, compliance, and continuous improvement. Knowledge management and organizational learning give us reasons as to how experience can help us to avoid wasting time. Business-process research studies end-to-end flow, while cross-functional integration (CFI) research examines how specialist functions coordinate to achieve a common purpose. Project scheduling refers to the duration of the project in terms of task dependency, overlapping activity and available float. One aspect of the problem is well explained by each field. Not many research projects combine them and implement them to a specific project in generic-development (Ramy et al., 2022; Dongo et al., 2025). This fragmentation is the gap this review addresses.

The paper examines how Operational Excellence, Strategic Knowledge Management and coordination across functions could enhance TTM across the generic-development lifecycle. The synthesis is directed by four questions. Where do bottlenecks and delays occur? What are the OE mechanisms that can minimize time wastage and rework? What is the benefit of knowledge reuse in coordination? And what could be the interaction of these mechanisms to enhance TTM? The resulting framework distinguishes necessary duration from operational loss, treats handover reliability as something to observe rather than assume, and separates product and regulatory complexity from performance.

2. REVIEW APPROACH AND SCOPE

In this review, preference is given to direct evidence on generic pharmaceutical development. Broad pharmaceutical research is encompassed where it is related to regulated development, technology transfer, quality systems, or lifecycle management. The transferable mechanisms are explained using new product development (NPD) and process-management studies of other industries and a definite distinction is made between the industry settings. Empirical research, systematic reviews, conceptual research, selected doctoral theses, and regulatory guidance form part of the literature reviewed. Regulatory guidance has no purpose as evidence of managerial effectiveness, but rather as setting industry expectations.

Sources were identified through searches of Scopus, Web of Science, PubMed and Business Source Complete, with Google Scholar used to trace doctoral theses. The searches covered 2000 to August 2026 and combined three groups of terms: generic

or pharmaceutical development (for example, generic drug, pharmaceutical development, technology transfer); knowledge and coordination (knowledge management, organizational learning, process orientation, cross-functional integration, handover); and time outcomes (time-to-market, development speed, cycle time, delay, rework). The reference lists of retained papers were also checked, and this is how older foundational work on the knowledge-based view and organizational learning entered the review. Regulatory documents were taken directly from the ICH, WHO and EDA websites.

A source was kept when it met at least one of three conditions: it reported evidence on generic or wider pharmaceutical development; it explained a mechanism linking knowledge, coordination or process design to development time, rework or performance; or it set a regulatory expectation that shapes the development timeline. Studies that dealt only with clinical efficacy or safety were left out, as were market studies with no link to development timing or entry. Evidence from other industries was used only when the mechanism behind it, such as knowledge transfer between functions or delay spreading through task dependencies, also operates in regulated pharmaceutical work and does not rely on something that work lacks, such as the freedom to modify a product after launch without regulatory approval. The final synthesis draws on 65 sources.

All sources were evaluated based on their relevancy to generic drug development, study design, the mechanisms studied, the results reported, and limitations. The analysis also makes a distinction differentiating between the subjective measures, including employee-reported performance, and objective data, including time-to-market records. It further decouples correlation and causation, and broad organizational outcomes and project outcomes. These distinctions determine the interpretive weight assigned to each study. Table 1 outlines the primary evidence domains and their proposed impact on development performance.

Table 1. Evidence domains and performance logic synthesized in the review

Domain	Core mechanism	Performance implication	Representative evidence
Regulated lifecycle	Interdependent technical, regulatory, quality, supply, manufacturing, and commercial work	Performance depends on flow across functions, not local completion alone	(ICH, 2008, 2009; World Health Organization, 2024; Prašnikar and Škerlj, 2006)
Operational Excellence	Reliable, compliant, right-first-time and continually improving execution	Reduce avoidable loss without weakening quality or compliance	(Eich and Friedli, 2021; Jalundhwala and Londhe, 2023; Duarte et al., 2025)
Strategic Knowledge Management	Capture, organize, retrieve, transfer, reuse and apply context-rich knowledge	Convert prior experience into current decision and execution capability	(Ramy et al., 2022; Dongo et al., 2025; Alavi and Leidner, 2001)
Organizational learning / reuse	Experience is contextualized, adapted, institutionalized and fed back	Reduce recurrence of known failure modes and repeated discovery	(Crossan et al., 1999; Zollo and Winter, 2002; Dowson et al., 2024)
Process harmonization	Common management definitions, inputs, outputs, decision rules and escalation	Reduce omission and non-value-adding management variation while preserving technical flexibility	(Škrinjar et al., 2008; Kohlbacher and Reijers, 2013; Brenner et al., 2026)

Domain	Core mechanism	Performance implication	Representative evidence
Cross-functional handovers	Complete, accurate, approved, usable and timely transfer across dependencies	Reduce clarification cycles, late starts, returns and corrective repetition	(Cummings and Teng, 2003; Sherman et al., 2005; Moore et al., 2025)
Operational loss / project flow	Necessary work and waiting distinguished from avoidable loss; overlap and dependencies assessed separately	Reduce preventable delay; identify which losses affect completion	(Testas et al., 2021; Project Management Institute, 2019; Campbell et al., 2025)
Time-to-Market	Explicit start/end milestones plus decomposition into phases and dependencies	Primary end-to-end project outcome; possible commercial timing implications	(Prašnikar and Škerlj, 2006; Cankurtaran et al., 2013; Hollis, 2002; Wattal, 2025)
Product/regulatory complexity	Multidimensional legitimate technical and evidence burden	Protect benchmarking from confusing difficult science with poor execution	(ICH, 2019, 2023a, 2024; Egyptian Drug Authority, 2026a; Sreedevi et al., 2025)

3. GENERIC DRUG DEVELOPMENT AS A REGULATED CROSS-FUNCTIONAL LIFECYCLE

The initial stages of generic development are often not accompanied by new discovery and what is left may not be easy, both scientifically and organizationally. The work continues to cover regulatory feasibility, commercial priority, formulation, analytical methods, supplier qualification, material availability, manufacturing process, packaging, validation, comparative in vitro or in vivo studies, dossier evaluation, release and launch.

What one department finishes becomes the input to the next activity in the sequence. That output may arrive incomplete, unapproved, or simply unusable in the form it takes.

The lifecycle is knowledge-intensive by design. ICH Q8(R2) emphasizes product and process understanding, and ICH Q10 names KM and quality risk management as enablers of an effective pharmaceutical quality system across the lifecycle (ICH, 2008, 2009). Pharmaceutical KM research arrives at much the same conclusion from an organizational direction: development knowledge has to survive the transitions between stages and functions if it is to support lifecycle decisions, technology transfer, and continual improvement (Ramy et al., 2022; Rathore et al., 2017; Lipa et al., 2021). On this reading, knowledge continuity and coordination belong to execution quality itself.

The pathway depends on the product. Evidence of substitution rests on in vivo studies, on in vitro dissolution studies, or on an eligible biowaiver, according to the requirements that apply. ICH M9 covers biopharmaceutics classification system (BCS)-based biowaivers, and M13A covers bioequivalence for immediate-release solid oral dosage forms within its scope. WHO and EDA guidance add international and Egyptian context (ICH, 2019, 2024; World Health Organization, 2024; Egyptian Drug Authority, 2026a).

The effectiveness of generic medicines is also under the protection of regulation. Clinical trials, stability testing, analytical and process validation, quality review, comparative testing, authority assessment and release can take a lot of time and all the stages have to be included in the schedule. Time is conserved through prior identification of prerequisites and the start of each activity only after the necessary data, materials, studies and approvals have been received. The most common causes of launch delay include missing inputs, incomplete transfers of information and multiple requests to clarify.

The development of generic drugs does not have a straight path. Decision gates when required are placed with work streams which may progress in parallel and the two may not necessarily co-exist comfortably. Stage-Gate models remain useful in this case, primarily due to their ability to explain the manner and timing of decisions made by management (Cooper, 2008). What they often fail to notice is that there is overlap between stages which is often intentional and not accidental and dependencies that bind the schedule together under it. The question whether a lag in an activity really shifts the completion date or not is a different question, and it is the critical-path analysis which answers it (Project Management Institute, 2019). This should be followed by performance evaluation. The crossings of the functional interfaces are what is worth tracing; they include knowledge, decisions, materials, evidence, and responsibility (Cummings and Teng, 2003; Hirunyawipada et al., 2010). **Figure 1** shows all stages of generic drug development, with the responsible functions, parallel workstreams, decision gates, and outputs passed between stages.

4. OPERATIONAL EXCELLENCE IN PHARMACEUTICAL DEVELOPMENT

Lean, Six Sigma, and continuous improvement are three approaches to pursue Operational Excellence in pharmaceutical manufacturing. The techniques strive to ensure the processes are reliable, efficient, and predictable and maintain productivity, quality, data integrity and regulatory compliance. They are meant to ensure that failures do not occur again (by doing a job correctly the first time), and this is achieved by analysing the manner in which a task is executed and also making it better in order to ensure that the same issue does not arise. Consistent application helps stabilize processes, an important consideration in pharmaceutical production, where quality and safety are paramount.

This is supported by empirical work. Jalundhwala and Londhe (2023) have discovered that there is no necessity of improvement conflicting with compliance. Eich and Friedli (2021) have discovered that companies that were more successful in the implementation of Operational Excellence were more likely to excel in inspections in pharmaceutical locations. Grangeia et al. (2020) demonstrated how structured quality by design approach assists organizations to comprehend and manage their processes. Duarte et al. (2025) applied the same reasoning to research, development, manufacturing, and quality assurance, including the knowledge, risk management, and systematic development throughout the lifecycle.

The same direction is taken by regulatory guidance. The ICH Q10 focuses on knowledge management, quality risk management, responsibility of management, process performance, corrective and preventive action, change management and continuous improvement (ICH, 2008). ICH Q9(R1) stipulates that risk-based decision-making must be done in a more or less formal manner depending on the risk (ICH, 2023b). Read together, these guidelines suggest two goals for improvement: necessary work must be performed reliably, and the avoidable losses around it must be minimized.

Operational Excellence is visible on multiple levels: the quality of the performance, the ratio of the work performed without errors, the dependability of handovers, unnecessary waiting, unnecessary rework, consistency in the processes, use of resources, and learning. To add all these into a single score, there must be measures that are established to make sense and even then, the score must not take over the detail behind the score. According to Tran (2021), it is challenging to pick and read right measures to Operational Excellence. These things are all about definition: adding up the times of activities that run simultaneously will give a bloated total, and including planned experiments as rework will be the wrong thing to do to represent the scientific work underway.

The framework here divides capabilities, mechanisms and outcomes. Strategic Knowledge Management is a capability in an organization. The way work is coordinated is referred to as process harmonization and handover reliability. Unnecessary waiting and avoidable rework is an operational loss. Time-to-market is the end-to-end project outcome. Operational Excellence is the broader performance objective above these elements, with quality and compliance maintained throughout.

5. STRATEGIC KNOWLEDGE MANAGEMENT, KNOWLEDGE REUSE, AND ORGANIZATIONAL LEARNING

Knowledge management involves the development or acquiring, storing, recalling, sharing and using of knowledge. Alavi and Leidner (2001) divide these processes into creation, storage and retrieval, transfer and application. Gold et al. (2001) differentiate knowledge infrastructure and process capability and Lee and Choi (2003) analyze KM enablers, knowledge creation, and organizational performance. SKM in this article refers to intentionally integrating such processes with the priorities and decisions of development. A repository contributes to this capability only if its contents can inform the work someone is doing today.

The knowledge-based perspective is what makes this ability a strategic as opposed to administrative ability. Grant (1996) refers to the firm as a mechanism of combining specialized knowledge and Nonaka (1994) elaborates on the creation of knowledge by interaction of tacit and explicit forms. The explicit side of pharmaceutical development contains protocols, methods, specifications, reports, record of validation, correspondence with authorities and documented decisions. The tacit aspect is expert judgment: the way that a material will act, whether an analytical method will remain reliable under demanding conditions, what the history of a supplier points to, and how to interpret evidence that is not yet clear.

Pharmaceutical studies show these processes at work in different settings. Bierly and Chakrabarti (1996) identified distinct knowledge strategies from longitudinal data on 21 pharmaceutical firms in the United States. Rathore et al. (2017) examine KM across biopharmaceutical development and lifecycle management, and Lipa et al. (2021) discuss enhanced knowledge transfer as an enabler of the pharmaceutical quality system. Ramy et al. (2022) identify a gap between academic KM research and pharmaceutical regulatory expectations. Recent reviews return to the organizational, managerial, and technological conditions that implementation requires (Dongo et al., 2025; Henz and Oliveira, 2024).

Structured knowledge shapes regulatory assessment as well. Wang et al. (2026) describe the implementation by the United States Food and Drug Administration (FDA) of Knowledge-aided Assessment and Structured Application (KASA) for the assessment of non-sterile solid oral dosage-form products submitted as abbreviated new drug applications (ANDAs). The case illustrates how much regulators gain when product and process knowledge is organized. It does not, on its own, establish that company-side KM reduces TTM.

In Egypt, evidence is starting to build up. In a survey of over 370 employees in five pharmaceutical firms in Cairo, Mahmoud et al. (2025) established that when KM practices were effectively implemented, they were related to enhanced efficiency and increased innovation. These results are unique to the organizations under research and cannot be generalized to the Egyptian industry. Ueda and Tanaka (2026) focused on the issue of converting tacit knowledge of senior researchers into explicit and made available to other individuals, a question that is of most interest in the situations when the development schedule is lengthy and complicated.

Knowledge is strategically useful at the juncture where it can be reused. Argote and Ingram (2000) consider knowledge transfer as a source of competitive advantage, and Walsh and Ungson (1991) conceptualize organization memory in terms of acquisition, retention and retrieval. Learning is depicted as the different levels that it passes through individual, group, and organization as outlined by Crossan et al. (1999) and experience accumulation, articulation and codification of knowledge in developing capability as outlined by Zollo and Winter (2002). Absorptive-capacity theory adds a condition: an organization's existing knowledge shapes what it can recognize, assimilate, transform, and use (Cohen and Levinthal, 1990; Zahra and George, 2002).

Project research concurs with the same regarding captured experience. Dowson et al. (2024) discuss the connections between personal, project and organizational learning. Bredell and Tshuma (2025) take into account the way the lessons learnt can inform the risks of future projects. Igoa-Iraola and Díez (2024) overview knowledge transfer in the context of organizational change through generational change, retention, communication and tacit knowledge. The themes of acquisition, sharing, and application are recurrent in KM and NPD studies as Idrees et al. (2023) define.

When creating a new product, an organization uses the knowledge it has gained: how previous problems were solved, how a method was tested, what a supplier provided, what an authority requested during assessment, how a problem was solved previously and what previous efforts have shown. The knowledge that is available cannot just be shifted without changes. It must be evaluated in its applicability to the task at hand and it must be adjusted where the fit is not perfect and what is learned by the application must be documented. Reuse is thus a process; past work is analyzed and what is learnt is used to create new work. This cycle is established in **Figure 2**, starting with the analysis of previous projects up to new learning.

6. PROCESS HARMONIZATION AND CROSS-FUNCTIONAL HANDOVER RELIABILITY

Process harmonization means managing recurring work consistently: roles, inputs, outputs, decision criteria, documentation, handover requirements, escalation paths, milestones, and measurement conventions. It leaves room for genuine differences in formulation, analytical strategy, manufacturing, suppliers, equivalence requirements, and regulatory pathway. The aim is to make coordination predictable without constraining product-specific technical judgment.

This stance is supported by business research. Škrinjar et al. (2008) discovered that an orientation towards business operations can enhance non-financial performance. As demonstrated by Kohlbacher and Reijers (2013), it is possible to design an organization around processes to enhance its quality, speed and overall performance. Harjanto and Mahendrawathi (2023) discovered that process orientation does not imply following one process per se but a group of related practices that encompass process definition, documentation, performance measurement, whole-organization view and technology utilization. Brenner et al. (2026) believed that formal rules are best applied along with open communication and a culture that tolerates exceptions. Practically, this translates into clear guidelines and the ability to have a discussion and escalate where necessary with exceptions that are justified.

Technical interfaces are also supported by standardization. Lorenz et al. (2019) considered the concept of standardization in biotechnology and discovered that standardization reduces uncertainty and simplifies combining products and processes. The common feature in both is the underlying system: a manner of structuring information as well as a clear anticipation of how work should be transmitted, and expert and risk-based judgment is maintained. Harmonization can have various practical forms, including common milestone definitions, stated input requirements, controlled templates, transfer checklists, preparedness criteria, escalation triggers, and decision records. Such arrangements bring omissions to light earlier and include past lessons in the regular work. They also render project data comparable, which is more than it might seem: a delay measure will be meaningless when two teams conceptualize the same milestone differently.

CFI is the greater organization capacity wherein specialized functions align interdependent work. Sherman et al. (2005) look at the interaction of CFI and KM in NPD and Hirunyawipada et al. (2010) conceptualize integration as a knowledge-transforming process. Troy et al. (2008) discover that the correlation between CFI and new-product success is significant but contingent upon the circumstances, which is a warning against thinking that increased interaction is necessarily effective.

Handover reliability concerns how well work is transferred at a particular interface. A good handover is one which leaves the receiving individual or team with all that they need to continue: the output itself, supporting evidence, the status of decisions made, the responsible owner, and the timing of the next step. There are multiple characteristics that are relevant to each other. A handover should be complete, accurate, approved, usable, accessible and timely and all those involved must have the same understanding of a handover. Handover quality and transfer duration are two dimensions, which are different yet important. An accurate and full handover remains an issue when it is late and a fast handover that has to be corrected is not entirely trustworthy.

Many delays arise at the interface between knowledge transfer and handover. Cummings and Teng (2003) found that the transferability of knowledge in research and development depends on the nature of the knowledge, its source, its recipient, the mode of transfer, and the surrounding context. Lipa et al. (2021) similarly indicate that a structured approach to knowledge transfer matters across the pharmaceutical lifecycle. Communication and process definition recur as difficulties in technology-transfer research. Wu et al. (2024) examined this in manufacturing and found that it can influence new-product development, while also noting the limits of the relationship.

Integration should reflect actual task dependencies rather than the organizational chart. Anyone who holds relevant knowledge, grants approval, provides resources, or makes decisions affecting the next step should be involved at the appropriate time. Lack of coordination usually leads to issues being brought up late and incompleteness of transfers. Too much coordination results in a number of meetings that water down accountability. All that is needed is ownership and prompt coordination where it is needed, so that everybody knows what is expected of him or her and at what time and the process proceeds more efficiently.

7. BOTTLENECKS, WAITING, REWORK, PARALLEL WORK, AND CRITICAL-PATH CONTRIBUTION

In practice, a bottleneck is not simply the longest activity or the busiest department. It is something that holds back the entire project. It may occur anywhere, depending on the project's current circumstances: waiting for critical information, a decision, or a particular material, or encountering a technical problem. It can also be a capacity, quality standards, a supplier or a regulatory requirement that must be worked through. A bottleneck is not permanent; it may change as the project continues. Detecting it thus involves analyzing dependencies between parts of the project and their downstream effects. A bottleneck cannot be identified from activity duration alone.

Waiting refers to the failure to proceed with an activity due to a lack of input, resource, decision, approval, material or clarification. Rework is a correctional or repetitive work performed after a previous product has been produced that does not

meet the requirements when it is used. Neither is automatically preventable. Some waiting reflects a required technical interval or external assessment, and some remedial action is a consequence of uncertainty which could not reasonably have been addressed earlier. Both classifications require evidence about cause and preventability.

The practical implications of this difference are in validation, formulation, analytical development, regulatory response, and equivalence research. Batches required under an approved process-validation strategy are planned work. In the case that the initial three batches of production are also validation batches, then they are the same three batches, and they should not be counted twice as separate production activity. An additional batch required after a preventable failure may count as rework, subject to root-cause review. An intended formulation trial, by the same reasoning, is a development work, not a symptom of operational failure.

A workable diagnostic sorts time into necessary processing, mandatory technical or regulatory waiting, avoidable organizational waiting, and preventable rework. Scientifically justified iteration belongs with necessary work, and where the position is uncertain, cases are better left unclassified until the evidence supports a judgment. Concurrency is a scheduling attribute rather than a fifth category of time, since work in any category may overlap with other work. Keeping the two apart prevents the reason time was consumed from being confused with where that time sat in the schedule.

Table 2 turns these categories into working definitions and shows where the evidence for each can usually be found in project records. The unit of analysis is the interval between two dated events, for example the date an analytical method was sent to QC and the date QC accepted it. Each interval is assigned to one category according to its documented cause, not its length. When the records do not show the cause, the interval stays unclassified, as noted above, and a second reviewer can classify a sample of intervals independently to check that the rules are applied in the same way. Totals are read on the calendar timeline, so overlapping work is not counted twice, and critical-path analysis then shows which avoidable intervals actually moved the launch date (Project Management Institute, 2019).

Table 2. Operational definitions of the time categories and how each can be measured from project records

Category	Working definition	Example in generic development	Evidence in project records
Necessary processing	Active work that the product or the regulations require, including scientifically justified iteration	Validating the analytical method; manufacturing the validation batches; planned formulation optimization trials; compiling the CTD	Start and end dates in protocols, batch records, trial logs and reports
Mandatory waiting	Elapsed time fixed by science or regulation that management cannot shorten	Stability intervals required before filing; the authority's assessment period	Stability protocol time points; submission and authority letter dates
Avoidable waiting	Time an activity stands idle for an input, decision or resource that could have been ready	QC waiting for reference standards or columns after method transfer; an approval waiting in a queue; material ordered late	Request, receipt and handover-acceptance dates; clarification e-mails
Preventable rework	Repeated or corrective work caused by an error, an omission or a known risk that was not acted on	Repeating a batch after a failure with a known cause; resubmitting a dossier section because a document was missing	Deviation, CAPA and root-cause records; resubmission letters

Category	Working definition	Example in generic development	Evidence in project records
Concurrency (a scheduling attribute, not a category)	Overlap between activities that run at the same time	Stability studies running while the dossier is written	Overlapping start and end dates of parallel activities

Two quantities matter in any project: the time taken by each task and the time taken by the project as a whole. Consider two tasks that each take 30 days. Performed concurrently, they occupy 30 days of the schedule; performed one after the other, they occupy 60 days; with partial overlap, the total falls between the two. Prašnikar and Škerlj (2006) pointed out that managing activities that run in parallel is important to shortening development. Summing the duration of each task therefore does not describe the project as a whole, and it misses one of the largest available sources of time saving.

The effect of a delay on project completion is determined by its impact on the overall timeline, and this is based on the relationship between tasks, the resources available, as well as the flexibility of the schedule. In a standard project plan, any delay on a non-critical path task does not shift the project completion date, so long as there is sufficient available time, or float to absorb the delay. When the float is used up and the activity postponed becomes a bottleneck, the completion date shifts unless recovery measures are undertaken. Activities that are adjacent to the critical path, but not part of it, may also cause the completion to be slowed down in case they are not completed in time. On the other hand, a slight delay to an approval may turn into a major hitch where the approval must be obtained prior to the commencement of other work and it may then dictate the date of completion by itself.

The research of pharmaceutical cycle-time emphasizes the significance of prerequisites and dependency structure. Among the drivers of cycle time singled out by Campbell et al. (2025) are the material readiness and timely initiation, which occur in early drug-product development. They are in the innovative early development environment as opposed to the generic launch, and, hence, evidence transfers as opposed to applies directly. The process remains unchanged: the time that has elapsed is determined by the presence of the enabling conditions at the moment of the work start. Testas et al. (2021) provide generic evidence of the case in another environment where the structured development and process knowledge were associated with shorter development and validation period.

The recorded start and finish dates, the handovers, the dependencies and the overlaps should be rebuilt in a diagnostic review. There it can distinguish between elapsed time and summed effort and the question to ask is whether a given wait or repetition moved the completion date. **Figure 3** illustrates the importance of having a schedule with time classification and dependency analysis. Where the records are not sufficient to determine a dependency or a cause, such uncertainty must remain apparent instead of being resolved by assumption.

8. TIME-TO-MARKET AS THE PRIMARY PROJECT OUTCOME

The definitions of TTM differ with the literature with some being concept-to-launch and development start-to-launch to smaller ones like submission-to-approval. A comparison is meaningful only when its start and end milestones are explicit. Cankurtaran et al. (2013) discuss the relationship between NPD speed and the product outcomes, and later studies consider knowledge integration, organizational capabilities, and launch readiness to the product development speed (Lyu et al., 2024; Mota et al., 2025). These broader findings provide context for generic medicines rather than direct estimates.

The research by Prašnikar and Škerlj (2006) is still significant in terms of knowledge on project development. They investigated 34 projects started in 2002 in four large pharmaceutical firms in Central and Eastern Europe and what they managed to discover about the organizational and process factors that influence the development duration remains useful. Regulation and competition have changed substantially since then, but the study retains value because it examines the projects themselves and how they operate. This is especially relevant to the development of generic versions of existing medicines. Testas et al. (2021) provide complementary information regarding a single generic oral-solid development case, reporting that overall development and validation time had reduced by 30% as compared to a traditional method. It is a case-specific comparison: it advocates the possible worth of structured product and process knowledge without providing a pooled impact or a guaranteed saving on

other products. Katz (2020) views TTM and research and development cost in pharmaceutical productivity and Campbell et al. (2025) looks at cycle-time drivers in early drug product development.

The project being studied must have milestones which are reproducible and that are applicable to the goals and the site under consideration. A project in Egypt could start with the EDA Action Letter, provided this starting milestone is applied consistently across all projects studied. The endpoint might be the date of the first recorded product sale, supported by a dated transaction record. It is a suggested method of measuring progress and not a definition mandated by the EDA. It also does not cover the initial phases of project selection and feasibility analysis, and it might also incorporate waiting time subsequent to the project being technically ready, therefore these limits need to be mentioned each time the measure is applied. Under this definition of milestones, project managers will be in a better position to track the progress and make sound decisions, and the method can be used in other projects, as long as the milestones are adjusted to the local environment. The objective is a stable and dependable method of gauging progress that assists the projects to remain on schedule.

The duration, in which a business takes to enter the market, can have a significant impact on the business stance. Hollis (2002) discovered that the initial generic form of a medicine to the market in Canada is likely to hold a dominant portion. Wattal (2025) discovered that in India where branded generic medicine are sold, the companies that entered the market earlier than their competitors could be able to gain a larger market share. These results imply that the influence of the entry time on business success can be researched, considering the price, distribution, and competition. Developing a product quickly does not guarantee first entry, because some other company can have initiated a project of like nature before.

9. PRODUCT AND REGULATORY COMPLEXITY AS CONTEXT, NOT WASTE

Not all projects involving generic-drug are equally challenging. The product itself, regulatory requirements and the necessity of further scientific research or evidence can make a given project complicated. These complexities will be because of factors like formulation, analytical specifications, raw materials, manufacturing, packaging and the regulatory pathway. A longer project can be confused as an inefficient project without taking them into account. Having them on the view facilitates more valuable comparisons among the projects and a better understanding of areas where improvement is possible.

A number of factors do normally interact. The complicated formulation may amplify the analytical effort; the involvement of a new supplier may bring extra obstacles in the qualification process and material preparation; certain equivalence routes must be coordinated with third parties or an extended time of evidence gathering. The regulatory questions also differ with the product and its history, as well as, changing needs. Sreedevi et al. (2025) outline the numerous difficulties on complex generic medicines, such as formulation, analytical, manufacturing, equivalence and approval problems. They concentrate on complex generics, although their results provide a good case of considering complexity as a multidimensional property, and not a single attribute, and of studying the interactions between its dimensions.

A number of resources define technical load. ICH Q8(R2) and Q9(R1) (ICH, 2009, 2023b) help in understanding product and processes and developing them based on risks. ICH Q14 and Q2(R2) (ICH, 2023a, 2023c) provide expectations of development and validation of the analytical procedures throughout the lifecycle. ICH M9 (ICH, 2019) gives the requirements of BCS-based biowaivers and M13A (ICH, 2024) gives bioequivalence principles in its scope. In more general terms, the principles of interchangeability are advised by the World Health Organization (2024), and the Egyptian Drug Authority (2025a, 2025b, 2026a, 2026b) issue a guide on registration, the CTD, comparative equivalence and the release context. All these documents are a set of standards that a product should have.

It is the context of complexity that gives the interpretation of duration. A long equivalence pathway, a justified stability requirement, or a necessary optimization cycle may take lots of time without signalling of inefficiency, and this work may be directly on the critical path during this period. The necessity and schedule-controlling are not in tension. The improvement question is more specific: did preventable failure or poor coordination add avoidable delay to work that had to be done anyway? These complexity dimensions are preferably not collapsed into some arbitrary composite score unless a validated weighting scheme can be justified. A multidimensional profile maintains the causes of the dissimilarity in projects and provides benchmarking with a stronger ground. It also reduces the chances of the common mistake where work that is technically challenging is documented as bad operational performance.

10. INTEGRATED THEORETICAL SYNTHESIS

The model is a mixture of four perspectives that are complementary. The knowledge-based perspective and organizational learning describe how special experience of a company can be converted to a dependable capacity that can be replicated throughout the entire organization. Process orientation and CFI detail the coordination and management of that capability. The timeline of the project is then used to ascertain the ability to meet the deadline. The principles of pharmaceutical quality-system demand that such improvement should be acceptable and in compliance. Combined, the framework explains how an organization converts specialized experience into a repeatable, coordinated, and on-time, delivered capability, whilst quality standards are upheld.

Knowledge-based perspective considers specialized knowledge as a key resource to the success of a company. A company must share the knowledge across regulatory affairs, formulation, analytical development, quality control, manufacturing, planning, supply chain and sales to grow and develop. The way it handles that knowledge, a term that SKM defines, is important since it links the appropriate information to appropriate individuals in the appropriate time, and therefore makes decision-making and handovers more efficient. SKM thus contributes towards making sure that the right knowledge is employed when the need arises whether in making a big decision or in conveying information to another employee.

When a project ends and the team moves on, the experience and knowledge gained need not be lost. This is where organizational learning applies: it is concerned with keeping experience usable and applying it in future work. Walsh and Ungson (1991), Nonaka (1994), Crossan et al. (1999), and Zollo and Winter (2002) have studied how organizations learn from their experience, and have identified the processes that make experience a usable resource: creating knowledge, retaining it, interpreting it, articulating it, codifying it, and reusing it. In short, experience becomes a genuine organizational resource when someone else can find it, understand it, and use it.

Process orientation shifts the focus from departmental optimization to end-to-end flow, and empirical research links process-oriented design with quality, time, and organizational performance (Škrinjar et al., 2008; Kohlbacher and Reijers, 2013; Harjanto and Mahendrawathi, 2023). Cross-functional integration studies provide a complementary account of how specialized expertise is brought together during NPD (Sherman et al., 2005; Hirunyawipada et al., 2010; Troy et al., 2008). Project-flow theory contributes the scheduling conditions that determine whether a local delay propagates to completion: dependencies, concurrency, float, and critical-path position (Project Management Institute, 2019). Pharmaceutical lifecycle principles set the outer boundary, keeping any acceleration inside validated science, risk management, quality systems, and regulatory compliance (ICH, 2008, 2009, 2023b).

The argument is that a sound structure such as SKM can streamline management processes and make handovers more reliable. When everyone knows what they are expected to do and when, errors and misunderstandings become less frequent. Distributing information in a form that is accessible and usable, and getting it to the right people at the right time, avoids a considerable amount of back-and-forth and delay. That in turn reduces waiting time and rework, which shortens the timeline. Improvements of this kind can affect overall performance across quality, compliance, learning, and growth. Cost savings may well follow, but that requires evidence of its own rather than a count of elapsed days.

Four propositions follow. SKM is expected to be positively associated with process harmonization and handover reliability. Process harmonization is expected to be negatively associated with avoidable waiting and preventable rework. Handover reliability is expected to be negatively associated with TTM. Schedule-relevant operational loss is expected to be positively associated with TTM. **Figure 4** summarizes these proposed mechanisms. Testing them will require attention to temporal ordering, project complexity, shared resources, and the distinction between organizational and project-level measures.

The four propositions are the review's own proposals and have not yet been tested together. The evidence behind the individual links is uneven. At the level of the firm, knowledge management has been associated with performance and efficiency (Lee and Choi, 2003; Mahmoud et al., 2025), and cross-functional integration with new-product performance, although the strength of that link depends on the setting (Sherman et al., 2005; Troy et al., 2008; Wu et al., 2024). Process-oriented design has also been linked with better performance in other industries (Škrinjar et al., 2008; Kohlbacher and Reijers, 2013). Within generic development itself, direct evidence is limited to a project-level study of development duration and a single case in which structured product and process knowledge shortened development and validation (Prašnikar and Škerlj, 2006; Testas et al.,

2021). The full chain, from SKM through harmonization and handover reliability to avoidable waiting, rework and TTM, should therefore be read as a framework to be tested, not as an established result.

11. RESEARCH GAPS AND FUTURE RESEARCH AGENDA

The gaps below concern what current evidence cannot yet answer, and they set directions for future studies. Practical challenges for companies are discussed separately in the Challenges, Limitations and Future Trends section.

The first gap is theoretical. Knowledge management, organizational learning, process orientation, cross-functional integration, and project scheduling each carry their own insights, but these are usually examined separately. What is missing is an account of how the mechanisms work together within a single setting, rather than an attempt to connect the findings of separate studies after the fact. Research is needed that examines how the pieces fit together, so that their interaction becomes visible.

The second gap involves the aspect of generic drug development. Most existing studies concern innovative pharmaceuticals, biopharmaceutical technology, manufacturing, or product development in other industries. These results can be used to develop theory, but do not eliminate the necessity of current, practical evidence of generic development. The findings of Prašnikar and Škerlj (2006) and Testas et al. (2021) are relevant, yet more recent empirical evidence is needed to clarify generic development.

The third gap concerns measurement. Relationships may be demonstrated by a single cross-sectional view or a set of overall results, but they cannot reveal how the activities intersect, how the work is transferred between the functions, and how delays impact the end result. In making the matching of survey responses of organizations to project outcomes, future research ought to employ clear measures of capability, look at the records of the project, and the reasons behind the events recorded and state in plain terms what is being analyzed.

The fourth gap is the time categorization. The necessary processing, mandatory waiting, avoidable waiting, justified iteration, and preventable rework require definitions of their own, and the concurrency is recorded separately as a scheduling attribute. In the absence of these distinctions, a study has the propensity to capture scientific rigor as a waste of operation.

The fifth gap concerns measuring handover reliability. Studies need to be done to determine whether or not a handover is complete, usable, approved and delivered in a timely manner and whether clarification is requested after the handover. Transfer time is also to be noted. The measurement of these attributes will allow determining whether a handover helped the following step of the process and what distorted it and provide a more accurate understanding of what is functioning and what is not.

The sixth gap concerns product and regulatory complexity, which makes comparison between projects difficult. The projects can vary in the way they are formulated, analytical needs, suppliers, production process, packaging, equivalence pathways, and stability needs, as well as regulatory evidence. Unless these differences are made explicit, fair comparison is difficult and technically demanding work may be recorded as an organizational loss rather than a scientific requirement.

The seventh gap is related to Egypt. There is emerging evidence on how knowledge management works in this regard, but its impact on generic drug development is yet to be identified. Specifically, there is still more to be learned about the impact of KM on schedule, handovers, and bottlenecks in the development process, and in the context of the regulatory framework created by the Egyptian Drug Authority. It is a field that is open to exploration and it cannot be presumed that what works in the United States or Europe will automatically transfer to other countries. The specific characteristics of the Egyptian context must be considered.

The eighth gap is related to the commercial translation. The existing studies of TTM indicate that timing could be a critical issue in competitiveness but development-process studies seldom relate internal operational performance to market-entry position or entry gap. Subsequent market position is rarely thought of even though there are other commercial determinants. This is best treated as an exploratory extension, rather than a direct causal chain from development speed to market share.

Taken as a whole, the agenda requires establishing where time was consumed, why it was lost, whether that loss was avoidable, and how it affected project completion. Fully analyzed projects can be used to identify patterns and compare cases, but confirming those patterns requires a larger, independent sample. A small number of examples drawn from the same products cannot be treated as independent cases. Table 3 summarizes these priorities.

Table 3. Research gaps and priorities for future generic-drug development research

Gap	Evidence deficiency	Priority for future research
1. Theoretical integration	Knowledge, process, coordination and project-flow mechanisms remain fragmented across literatures.	Test integrated pathways linking SKM, harmonization, handovers, operational loss and TTM.
2. Generic-specific evidence	Few contemporary end-to-end empirical studies directly examine generic-development TTM.	Use detailed project records for diagnosis and adequately sized independent samples for confirmatory testing.
3. Diagnostic measurement	High-level or perceptual outcomes often cannot locate where calendar time is created.	Combine capability measures with objective dates, dependencies, overlaps and critical-path analysis.
4. Necessary vs avoidable time	Long mandatory work may be mislabeled as waste; legitimate iteration may be mislabeled as rework.	Classify causes and preventability; record concurrency separately.
5. Handover reliability	Interface quality is rarely measured directly in generic-development research.	Measure completeness, usability, approval status, timeliness, clarification cycles and lead time.
6. Complexity context	Technical and regulatory differences can distort TTM comparisons.	Retain multidimensional complexity profiles and avoid arbitrary weighting.
7. Context-specific evidence	Integrated evidence remains limited in the Egyptian generic-development and EDA context.	Test mechanisms using traceable project records under the local regulatory pathway.
8. Commercial translation	Internal operational performance is rarely linked carefully to entry timing and later market position.	Explore entry rank/entry gap and market outcomes while controlling for non-TTM commercial determinants.

12. MANAGERIAL AND REGULATORY IMPLICATIONS

The managers must be able to visualize the links between the departmental outputs and the project progress. A common project record is one of the viable starting points: prerequisite status, the owner in charge, handover acceptance, downstream preparedness, and the outstanding decisions. Local completion measures retain their value, but must be interpreted with respect to a simpler question, namely, whether the receiving function can actually proceed.

The use of SKM in decision making should be evaluated. Reports, authority responses, root causes, experience with the supplier, and corrective actions all require sufficient context that a team reviewing them later can use to decide whether it is pertinent. A helpful record is the one that records what has taken place, why a certain decision has been made, what were the circumstances at the time, and what has been learned out of it. This focus is in line with systematic knowledge transfer as well as the orientation that regulatory assessment is taking.

The process of aligning can be started off with minor steps like agreeing the major milestones, the information needed at each stage, decision makers, and the escalation of problems. This provides a standard platform on which teams can be based and yet enables the approach that in different contexts is necessary, and the research of process orientation and risk-based quality principles justifies such a balance between reliability and adaptability.

The suggested diagnostic process consists of five steps that were described as follows: define the project boundaries; rebuild the dated activities and handovers; establish dependencies and overlap; categorize the cause and preventability of interruptions; and evaluate what each of them added to the completion time. Causes are then documented and improvement actions are made to address them with an owner and a recurrence measure. This is a proposed sequence, derived from this synthesis, that future studies can validate.

Separate descriptors are required by benchmarking to be used on the factors that vary across projects including formulation difficulty, change in suppliers, manufacturing requirements, equivalence requirements, and regulatory evidence. These descriptors help explain differences in project duration and keep rankings fair. In the case of missing information, it is preferable to indicate the uncertainty than make an assumption or give a score which the evidence fails to back up. In this way, a more accurate reflection of what is measured is provided.

The approach that results is to safeguard the required work by enhancing its preparation and more reliable coordination. Teams should start with usable knowledge, available materials, required approvals, and clearly defined responsibilities, and document what each interruption taught them. The improvement of TTM should then be evaluated in comparison with quality and compliance, and only under these circumstances, it is possible to define whether the quicker performance is also trustworthy.

13. CHALLENGES, LIMITATIONS AND FUTURE TRENDS

The literature identifies several recurring challenges in managing generic drug development as a cross-functional process. First, critical know-how is often linked with expert R&D pharmacists and the organization loses this asset when such pharmacists leave, while knowledge management can become focused on storing documents rather than preserving the reasoning behind decisions; therefore, decision rationales, lessons learned, and contextual knowledge should be captured during the work, with planned knowledge transfer when responsibilities change and KM integrated into the quality system (ICH, 2008; Dongo et al., 2025; Lipa et al., 2021; Nonaka, 1994; Bredell and Tshuma, 2025; Igoa-Iraola and Díez, 2024). A second challenge occurs at functional interfaces, where each department may focus on completing its own activities while transferring outputs that are incomplete, unapproved, or not immediately usable, resulting in clarification loops and rework. This can be reduced through defined handover checklists, clear acceptance criteria, named ownership at each interface, and a shared project record that identifies prerequisites and confirms handover acceptance (Cummings and Teng, 2003; Sherman et al., 2005; Lipa et al., 2021; Hirunyawipada et al., 2010). At the same time, excessive harmonization can become counterproductive by restricting product-specific judgment or creating unnecessary meetings that dilute accountability. A more balanced approach is to harmonize the management layer—including milestones, required inputs, decision rights, and escalation routes—while allowing technical decisions to remain risk-based and permitting justified exceptions where appropriate (ICH, 2023b; Brenner et al., 2026; Troy et al., 2008). Another important challenge is the pressure to shorten time to market (TTM), which may lead to essential studies such as stability studies, bioequivalence, validation, or regulatory review being treated as avoidable delays. Instead, development time should be separated into necessary time, unavoidable waiting, and avoidable waiting or rework, with extra efforts directed toward the avoidable component while using quality-by-design principles to prevent failures (ICH, 2008, 2009, 2023b; Testas et al., 2021). Measuring delays is also difficult because organizations may define TTM differently, parallel activities can hide the actual duration of development, and project records are often designed primarily for compliance rather than for explaining how time was spent. Consistent start and end milestones, dated handovers, documented dependencies, and critical-path analysis can therefore provide a clearer understanding of which delays actually affect the final release date (Prašnikar and Škerlj, 2006; Cankurtaran et al., 2013; Project Management Institute, 2019; Lyu et al., 2024; Mota et al., 2025). Attribution is a related problem: when several delays overlap, it is hard to say which one actually moved the launch date, so the cause of each delay should be recorded when it happens and checked later against the critical path (Project Management Institute, 2019). Direct evidence from generic development is also scarce, and many of the practices discussed here were first described in innovative pharmaceuticals or in other industries. A company can deal with this by trying a practice on a few of its own projects and checking the effect in dated records before using it more widely. Organizations and regulatory environments differ as well. What works under one authority's procedures, or in a large multi-site company, may not work the same way elsewhere, so comparisons are fairer between projects that share a regulatory pathway and a similar organizational setting. Finally, generic development projects vary significantly in complexity because of factors such as formulation challenges, supplier requirements, the choice between bioequivalence and biowaiver pathways, and regulatory authority requirements. Meaningful performance analysis therefore requires a multifactor complexity profile for each project, comparison of projects with similar characteristics,

and systematic reuse of previous regulatory requirements and experience to anticipate issues in subsequent dossiers (ICH, 2019, 2024; Egyptian Drug Authority, 2026a; Sreedevi et al., 2025). There are a number of trends, though, indicating that the problem is becoming more manageable. Product and process knowledge is more and more anticipated to be presented in a structured and machine-readable form by the regulator (Wang et al., 2026), which makes the organization of internal knowledge a submission requirement instead of an efficiency option. Generative artificial intelligence is used to encode tacit knowledge of experienced researchers into explicit form (Ueda and Tanaka, 2026), addressing the layer that document repositories had not captured. Lifecycle-management expectations are redefining knowledge continuity as a demonstrable capability (Lipa et al., 2021). Harmonized bioequivalence and analytical lifecycle guidance is lowering the inter-jurisdiction variation in pathways (ICH, 2023a, 2023c, 2024) and this makes inter-project comparison more justifiable. Transfer of technology is becoming a standard process as opposed to a local practice (Moore et al., 2025; Singh et al., 2025), and collaborative cycle-time benchmarking is now being implemented in early product development (Campbell et al., 2025), but there is nothing similar with generic products. Quality by design on the other hand is evolving into a generator of reusable process knowledge instead of a documentary process (Duarte et al., 2025; Grangeia et al., 2020). The dated event trail that project-level diagnosis requires is increasingly becoming data, as the records of development are transferred to validated electronic systems, which may eventually render reconstruction on a portfolio scale possible.

14. CONCLUSION

The effectiveness of a generic development program is determined by how smoothly the program's functions work together. That work encompasses scientific inquiry, regulatory adherence and informed decision making, and in all of them the knowledge and experience sharing is at the heart of the matter. In teams where information sharing is consistently present, and teams work together in getting better results, then the experience gained over time can be converted to improved results, since each of the functions can depend on the other to perform their role and can be confident that the work has been done properly.

The diagnosis of TTM requires clear project boundaries and a working distinction between work that is needed and operational loss that is avoidable. Parallel tasks must be read with respect to their calendar overlap, and local delays with their dependencies and available float. It is the product and regulatory complexity that provides the context that enables fair comparison.

The research reviewed in this paper suggests that these relationships deserve more attention, but the evidence does not yet provide a comprehensive description of the interactions between the mechanisms involved in the development of generic drugs. Future studies should relate what organizations can do to events that happen in projects and should test whether making knowledge usable and handovers reliable would help minimize delay and rework without quality and compliance being compromised. That would determine whether those changes would make the project timeline better and still have the standards met. For practice, the priority is to make knowledge usable, handovers dependable, and preventable delay visible, so that necessary scientific and regulatory work can continue without interruption.

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AUTHOR CONTRIBUTIONS

Kyrillos M. Sami: Conceived the study, designed the synthesis, conducted the literature review, developed the conceptual framework and figures, and prepared the original draft.

Samir Y. Marzouk: Supervised the work, contributed to the conceptual and methodological development, and critically reviewed and revised the manuscript.

Mai S. Mabrouk: Supervised the work, contributed to the conceptual and methodological development, and critically reviewed and revised the manuscript.

All authors read and approved the final manuscript and accept responsibility for the work.

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The authors declare that they have no competing interests.

ETHICS STATEMENT

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DATA AVAILABILITY STATEMENT

Not applicable. No new data were generated or analyzed for this review. All sources used are listed in the references.

USE OF ARTIFICIAL INTELLIGENCE

During the preparation of this manuscript, we used generative artificial intelligence tools to improve the readability and language of the text. We reviewed and edited all resulting content and take full responsibility for the content of the published article.

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FIGURE LEGENDS

Figure 1. Generic drug development as a regulated cross-functional lifecycle.

Figure 2. Strategic knowledge reuse and organizational learning cycle

Figure 3. Illustrative parallel activities, available float, and the effect of delay on project completion

Figure 4. Proposed relationships between knowledge management, execution mechanisms, and time-to-market

FIGURES

Figure 1



Figure 2



Figure 3

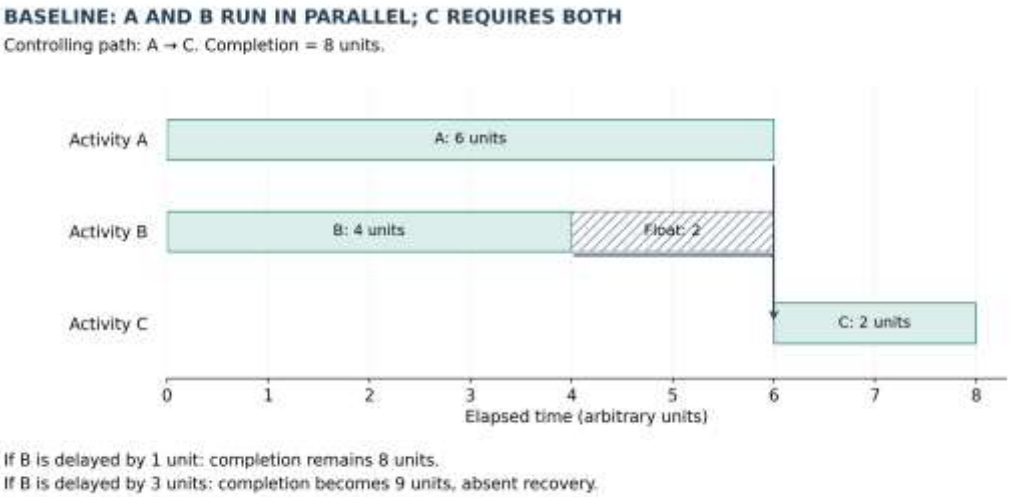


Figure 4

