Insights Guide

Cutting Time, Not Corners

Accelerating clinical entry through regulatory efficiency

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Executive summary

Traditional development programs often accumulate studies out of caution or convention, rather than demonstrable regulatory need. In today's environment, regulators welcome targeted, phase-appropriate packages (the 'right studies at the right time') provided the rationale is well supported and include explicit patient safety protections.

Sponsors face increasing pressure to reach the clinic faster, but on restrictive budgets. By prioritizing more informative studies, cost savings are maximized without compromising patient safety or regulatory rigor. This Insights Guide outlines a science-driven strategy to evaluate non-clinical and clinical regulatory study requirements that helps to eliminate redundancies, right-size evidence packages, and adopt phase-appropriate, risk-based testing.

The approach leverages prior knowledge and historical data, robust scientific rationale, and innovative methodologies (e.g., modeling and simulation, platform read-across, adaptive and seamless designs) to meet global regulatory expectations while trimming unnecessary work.

The result: earlier first-in-human (FIH) trials, streamlined progression across clinical phases, and lower total development costs through transparent engagement with regulators and fit-for-purpose evidence.

A structured, question-based assessment of every proposed study is central to this approach. For each non-clinical or clinical activity, sponsors should evaluate whether the study materially contributes to patient safety assurance, informs clinical or regulatory decision-making, or is necessary for phase-appropriate progression of the program. Studies that do not clearly answer a critical development or regulatory question should be redesigned, deferred, replaced, or eliminated, while maintaining alignment with global regulatory expectations.

Introduction

The case for leaner, smarter evidence

Leaner evidence plans can help de-risk timelines by:

1. **Avoiding duplicative non-clinical investigations** when well-characterized platforms or prior-knowledge dossiers exist

2. **Replacing or re-sizing studies** with validated modeling, simulation, or in vitro/in silico methods where scientifically justified

3. **Designing clinical programs that maximize learning per patient** through adaptive features, master protocols, and intelligent data reuse.

Increasingly, regulatory agencies expect sponsors to justify not only what studies are conducted, but why they are needed at a given point in development. IQVIA supports sponsors by reframing development planning around explicit regulatory questions, such as whether a study meaningfully reduces residual safety uncertainty, enables dose selection, or impacts go/no-go decisions. This evidence-driven approach enables programs to meet regulatory standards with more targeted, informative, and phase-appropriate evidence packages.

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A framework for regulatory efficiency

Sponsors often submit regulatory packages to FDA with extensive testing and study designs based on historical precedent and perceived agency expectations for specific modalities and patient populations. Drawing on IQVIA's cumulative experience, we recognize that many pre-clinical studies, clinical assays, and trial designs might be redundant, provide limited incremental value to the safety profile, or are rarely utilized in clinical decision-making.

Application of a consistent, structured decision framework to evaluate each proposed study against regulatory expectations and overall development objectives supports fit-for-purpose evidence generation, and the development of regulatory strategies tailored to patient needs, sponsor expectations, product characteristics, and program goals. Through this lens, sponsors can distinguish between studies that are required, informative but deferrable, and non-decision-driving.

The key principles outlined below clarify how this framework is applied in practice. These define the regulatory intelligence, strategic planning, expert evaluation, evidence design, and agency engagement methods that allow sponsors to assess the necessity, value, and regulatory impact of each proposed study.

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Key principles

- **Regulatory intelligence (know what's necessary and what's not):** Monitor global precedents, guidance documents, and reviews to identify where agencies have accepted condensed non-clinical packages, prior-knowledge arguments, or alternative methodologies, **particularly where specific studies were shown not to materially influence safety or regulatory decisions**.
- **Regulatory strategy (align business and benefit–risk)**: Translate intelligence into a plan that evaluates planned studies, explicitly tying each proposed study to the regulatory question it is intended to answer, patient safety considerations, and program objectives.
- **SME-based pre-clinical and clinical expertise**: Apply the expertise of former FDA/NIH professionals skilled at strategizing minimum phase-appropriate study designs and requirements to meet regulatory requirements.
- **Evidence planning (fit-for-purpose, phase-appropriate)**: Build an integrated evidence plan that right-sizes non-clinical and clinical activities by phase, **ensuring that each study has a clear role in safety assessment, clinical decision-making, or enabling the next development milestone**.
- **Regulator interaction (engage early and often, document transparently)**: Secure alignment via early scientific advice meetings with briefing packages that clearly present the risk-based rationale, **articulating which regulatory questions are being addressed, how remaining uncertainties are managed, and why certain studies are not necessary at that time**.

Similarly, the focus areas below translate these principles into the specific domains where disciplined, phase-appropriate decision-making is most critical across development. They highlight where targeted optimization can reduce unnecessary work, strengthen regulatory confidence, and accelerate progress from pre-clinical activities to global clinical execution.

Areas of focus

- **Pre-clinical testing optimization**: optimizing both pharmacology and toxicology studies, while reducing overall and large animal testing in-line with FDA's New Approach Methodologies (NAMs)
- **Non-clinical assays**: phase-appropriate development and necessity, and considerations for biobanking/ sample retention for retrospective assessment.
- **CMC development**: process and phase-appropriate sample optimization, such as stability testing, retains, etc., and utilization of toxicology versus clinical grade material.
- **Clinical development**: generate new or leverage existing real world evidence (including, where appropriate, to support reduced pre-clinical testing requirements), use validated clinical versus exploratory endpoints, potentially reduce clinical study size, minimizing patient burden, and apply phase-appropriate data collection to ultimately reduce time to clinic and market.
- **Global regulatory harmonization**: understand global regulatory requirements and client needs to maintain a streamlined path to clinic and market, while ensuring sustainability and rigor across global regulatory bodies.

Across each area, application of a consistent question-driven evaluation determines whether proposed activities meaningfully contribute to safety assurance, clinical interpretation, or phase-appropriate development versus adding confirmatory data with limited regulatory or decision-making value.

Application of a consistent, structured decision framework to evaluate each proposed study against regulatory expectations and overall development objectives supports fit-for-purpose evidence generation, and the development of regulatory strategies tailored to patient needs, sponsor expectations, product characteristics, and program goals.

Phase-appropriate, risk-based examples

The examples illustrate how applying explicit regulatory and development questions can enable study minimization while preserving scientific and regulatory rigor:

Non-clinical study minimization: evidence that can be applied across a platform and exposure-driven bridging supported by Physiologically Based Pharmacokinetic (PBPK) modeling, consolidation of repeat-dose studies, and in silico/in vitro alternatives.

Clinical acceleration: Seamless Single Ascending Dose (SAD)/Multiple Ascending Dose (MAD) designs, adaptive Phase 1b/2 protocols, master protocols, and intelligent reuse of biomarker and exposure–response data (e.g., assessing early safety, PK, and biomarker questions in a single, integrated protocol).

Sponsors can responsibly minimize regulatory study requirements and accelerate time to clinic by applying disciplined regulatory science, fit-for-purpose evidence planning, and early, transparent regulator engagement.

Operational readiness: making 'lean' work

Establishing regulatory efficiency through all phases of product development requires organizational readiness, processes, templates, governance, and training that normalize decisions across phases and enable cross-functional alignment throughout the product development lifecycle.

IQVIA supports governance models that require justification of each proposed or anticipated study against predefined safety and decision-making criteria, normalizing challenge of legacy expectations across functions.

Faster, more efficient clinical entry

Time to FIH: Months saved by deferring or substituting low-value non-clinical work.

Protocol optimization: Streamlining designs, reducing patient burden, minimizing exploratory endpoints, etc.

Evidence economics: Cost avoided by leveraging prior knowledge and modeling.

Regulatory clarity: Number of key uncertainties resolved at early advice meetings.

Patient protection metrics: Event-driven safety thresholds and audit findings.

Conclusion

Sponsors can responsibly minimize regulatory study requirements and accelerate time to clinic by applying disciplined regulatory science, fit-for-purpose evidence planning, and early, transparent regulator engagement.

By integrating regulatory intelligence, modeling and simulation, and prior knowledge and expertise, we can help redesign, defer, or eliminate activities that do not meaningfully impact benefit–risk assessment or regulatory outcomes. This approach can help streamline global regulatory submissions, reduce time to first in human studies, derisk early development, support efficient transitions through clinical phases, and align programs with global regulatory expectations. This enables opportunities for commercialization or partnerships.

Applying a disciplined, question-based evaluation of safety, decision impact, and phase appropriateness allows sponsors, supported by IQVIA, to accelerate development responsibly while maintaining regulatory confidence.

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