

# The Sooner, The Better: 3 Reasons to Run More ADME Testing During Preclinical Research

These days, sponsors are modernizing protocols for faster go-to-market. In their haste, many forgo extensive preclinical ADME screening.<sup>1</sup> That's a bad idea, and here's why.



## Preclinical ADME Saves Time, Money, and Lives

Absorption, distribution, metabolism, and excretion (ADME) studies explore a compound's journey through the body.

Incorporating drug metabolism and pharmacokinetics (DMPK) plus drug-to-drug interaction (DDI), preclinical ADME testing reveals safety problems that can:



Delay Launch



Drive up costs



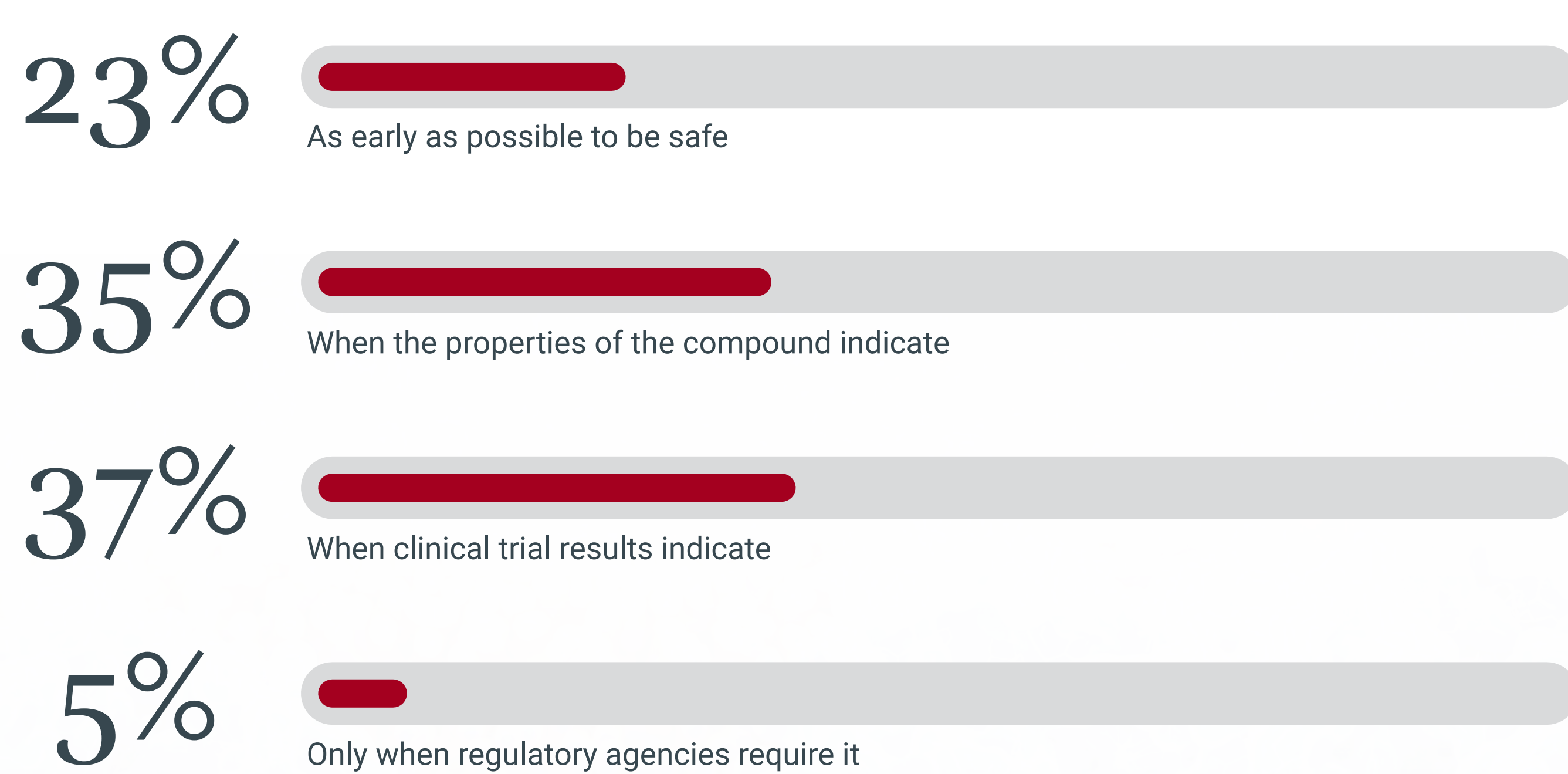
Risk outcomes

## And yet...

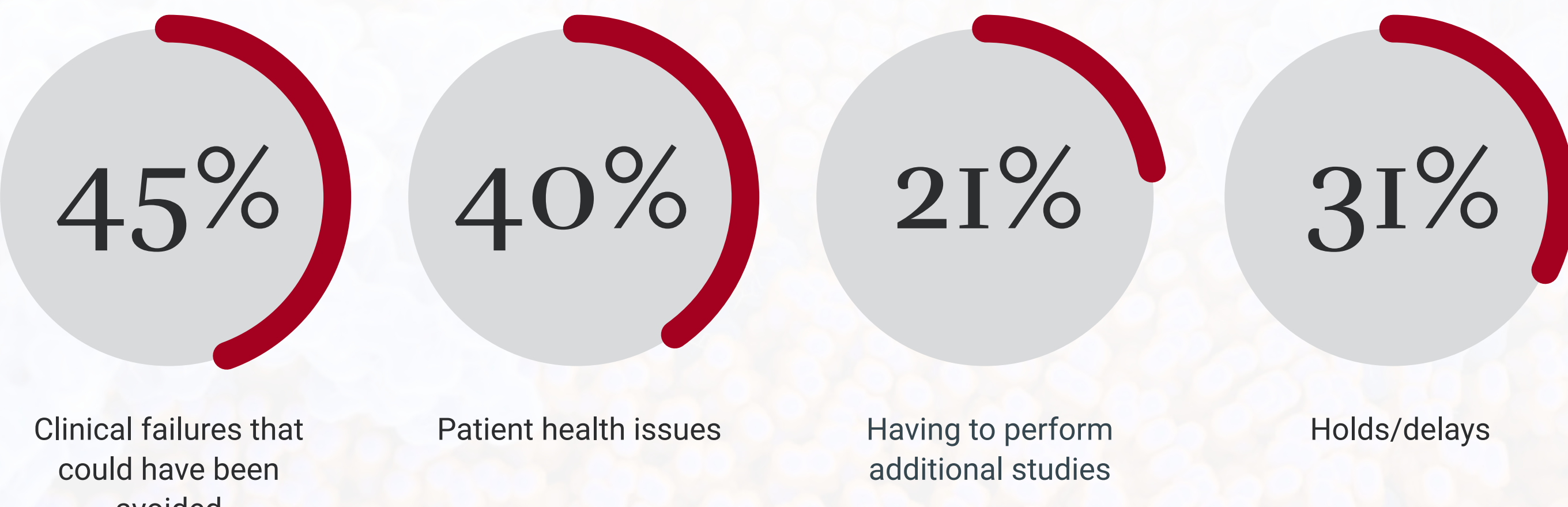
When we asked sponsors when they conduct ADME studies, many said they wait until the last possible opportunity—even though **only 4% of respondents** said they had never experienced any repercussions from postponing!



## When do you perform ADME/PK & DDI testing?



## Top 4 risks of delaying ADME/PK & DDI studies



A prevailing myth is that in vitro ADME studies are too expensive and take too long. In the long run, it's just the opposite.

## 3 Benefits of Early-Stage ADME

Doing in vitro ADME studies with a trusted expert adds value, reduces risk, bolsters pipelines, and strengthens approval odds.<sup>2</sup>

1

**Call Go or No-Go Faster: Between 1991 and 2008, access to early ADME testing reduced PK failures from 40% to less than 1%.<sup>3</sup> And yet, 9 in 10 trials still fail today.<sup>4</sup> Avoid clinical failures by knowing when to:**

- Go: Move forward with confidence and the data to justify it.
- No-Go: Find red flags earlier before investing further.

2

**Preempt Regulatory Problems: 50% of IND filings fail because of insufficient ADME.<sup>5</sup>**

- Build a program that weathers FDA scrutiny by catching problems before regulators do.

3

**Avoid Unnecessary Studies: Avoiding or postponing ADME studies can delay timelines. When delays occur, 6 in 10 sponsors report impacts of six months or longer.<sup>6</sup>**

- Apply mechanistic insights from ADME done in drug development.
- That way, you don't have to run these studies during clinical phases, when they get costly and complex.<sup>7-9</sup>



## Get Confidence Inspired by Quality

Sponsors need high-quality ADME data with high-quality interpretation. Get both with a custom ADME plan from SEKISUI XenoTech.

Visit [www.xenotech.com/contact](http://www.xenotech.com/contact) to learn more.

<sup>1</sup> <https://ascpt.onlinelibrary.wiley.com/doi/10.1002/psp4.12466>

<sup>2</sup> <https://www.xenotech.com/nonclinical-studies/timing-invitro-invivo/>

<sup>3</sup> <https://doi.org/10.1016/B978-0-12-803752-2.00007-7>

<sup>4</sup> <https://blogs.sciencemag.org/pipeline/archives/2019/05/09/the-latest-on-drug-failure-and-approval-rates>

<sup>5</sup> <https://pubmed.ncbi.nlm.nih.gov/12769701/>

<sup>6</sup> 2021 Industry Survey Conducted by SEKISUI XenoTech

<sup>7</sup> <https://www.fda.gov/drugs/cder-small-business-industry-assistance-frequently-asked-questions-pre-investigational-new-drug-ind>

<sup>8</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3691435/>

<sup>9</sup> [https://jpharmsci.org/article/S0022-3549\(17\)30249-6/fulltext](https://jpharmsci.org/article/S0022-3549(17)30249-6/fulltext)