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.[1] 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?

- 23% — As early as possible to be safe
- 35% — When the properties of the compound indicate
- 37% — When clinical trial results indicate
- 5% — Only when regulatory agencies require it

Top 4 risks of delaying ADME/PK & DDI studies

- 45% — Clinical failures that could have been avoided
- 40% — Patient health issues
- 21% — Having to perform additional studies
- 31% — Holds/delays

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.[2]

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%.[3] And yet, 9 in 10 trials still fail today.[4] 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.[5]

- 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.[6]

- 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.[7-9]

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** to learn more.

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

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

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

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

5 https://pubmed.ncbi.nlm.nih.gov/12769701/

6 2021 Industry Survey Conducted by SEKISUI XenoTech

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

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

9 https://jpharmsci.org/article/S0022-3549(17)30249-6/fulltext

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