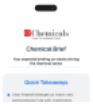
ET Pharma.com
From The Economic Times
Get App
ET Pharma.com
From The Economic Times
News Exclusives Leaders Speak Events Webinars Brand Solutions More
Regulatory Update | Drug Approvals & Launches | Financial Performance | Policy & Regulations | R & D | Mergers & Acquisitions | Pharma Industry
India Inc On The Move 2026
AI-led manufacturing insights from industry leaders on sustainability,...
ETPharma Newsletter
Explore and subscribe to our Daily newsletters
RE-Pharma A
As the ET Re-
enters its 5th
celebrate the
From The Economic Times
Get sharp, essential insights in Chemicals — focused, timely, actionable.
Join the newsletter

Get sharp, essential insights in Chemicals — focused, timely, actionable.
Join the newsletter



Exclusive Pharma Industry 3 Min Read

Integrated translational research models reshape early drug development strategi

As drug development grows more complex and failure rates in early clinical stages rer high, pharmaceutical companies are increasingly turning to integrated translational r models to de-risk programmes before first-in-human studies.

Rashmi Mabiyan • ET Pharma
Updated On Jan 8, 2026 at 03:53 PM IST

New Delhi: As drug development becomes increasingly complex, pharmaceutical companies are re-evaluating how early-stage clinical

programmes are designed, with a growing emphasis on translational science to reduce failure risks before compounds enter human trials.

Traditionally, clinical development teams have been brought in only after preclinical work is completed, often inheriting programmes with limited scientific context. “In these models, data moves sequentially across organisational boundaries, which can lead to a loss of context and risks emerging late in development,” said Dr Mrinal Kammili, Head of Translational & Clinical Research at Syngene International Ltd.

Advt

To address these challenges, integrated translational and clinical research models are gaining traction. These approaches embed clinical strategy development alongside discovery, toxicology, pharmacokinetics and manufacturing, allowing continuous scientific evaluation as

molecules progress toward the clinic.

Dr. Kammili added that having discovery, preclinical, clinical and manufacturing capabilities within a single framework allows scientific insights to “travel with the molecule” rather than being fragmented across handovers.

According to Dr. Kammili, early access to mechanism-of-action data, pharmacokinetic and pharmacodynamic understanding, toxicology signals and formulation readiness helps clinical teams design more predictable first-in-human and early-phase studies. “By the time a molecule reaches the clinical team, it arrives with a deep scientific narrative and a manufacturing pathway that supports smooth progression,” he said.

EVENT

RE-Pharma Summit 2026

Fri, 13 Feb 2026
Mumbai

Fri, 13 Feb 2026
Mumbai

Register Now

AWARD

RE-Pharma Awards 2026

Join us in applauding the

Nominations till Tue, 20 Jan 2026

Nominations till Tue, 20 Jan 2026

Nominate Now

A central goal of translational science is to de-risk programmes before human dosing. One key strategy, Dr. Kammili noted, is rigorous exposure–response modelling to better understand therapeutic windows and assess the likelihood of human relevance. Another is the use of biomarkers as early decision gates. “We identify measurable indicators that allow us to assess biological activity with confidence during first-in-human studies, rather than relying on uncertainty,” he said.

Multidisciplinary collaboration is also critical. Translational teams increasingly bring together toxicology, drug metabolism, bioanalytical and clinical experts to identify potential red flags early, refine dose selection and streamline trial design. Such integration, Dr Kammili said, helps reduce late-stage surprises as compounds transition into human studies.

Advt

Globally, oncology, immunology and cardiometabolic diseases are driving much of the demand for translational and early clinical research, as these areas lend themselves to biomarker-driven development. At the same time, the industry is seeing a shift toward complex modalities such as biologics, antibody–drug conjugates, RNA-based therapies, and cell and gene therapies. “These programmes require deeper translational insight and advanced bioanalytical platforms,” Dr Kammili added.

Precision medicine has further accelerated the need for early biomarker integration. According to Dr Kammili, biomarker discovery and validation are now being incorporated as early as the discovery phase, with the aim of supporting patient stratification, dose optimisation and early proof of concept. “By the time a programme reaches the clinic, there should be clarity on which biomarkers are robust and how they will be used to generate meaningful biological readouts,” he said.

India is emerging as an increasingly important geography for early-phase clinical research. Regulatory reforms such as the New Drugs and Clinical Trials (NDCT) Rules, 2019, have brought greater transparency to approval pathways, while the country's growing network of multi-speciality hospitals and experienced investigators is strengthening execution capabilities.

"India is no longer just a place to execute studies efficiently; it is becoming a place to shape early clinical development strategies," Dr Kammili said, while noting that scaling capacity for complex, biomarker-intensive trials remains an ongoing challenge.

Looking ahead, the contract research market is expected to shift further toward integrated development partners rather than fragmented service providers. "Clients are looking for continuity, scientific alignment and speed," Dr Kammili said. He added that translational intelligence will play an increasingly central role as pipelines move toward advanced biologics and gene-modifying therapies.

Ultimately, he said, the objective is to enable earlier, better-informed development decisions that improve efficiency and help innovative therapies reach patients with greater certainty.

Most Read in Pharma Industry

Novo Nordisk recalls weight-loss drug Wegovy in US

Generic Semaglutide patent expiry opens over Rs 50,000 Cr opportunity for drugmakers: Report

Biocon to introduce Keytruda among three new oncology biosimilars at JPM 2026

Budget for 'pharmacy of the world': What Sitharaman & Co can do to make medicines more affordable in India