Case study | Preclinical integrated solutions optimize and accelerate drug development

# Accelerator™ Drug Development:

## Streamlining preclinical pathways for a fast transition to First-in-Human trials

### How an integrated approach saved $1M and shortened timelines

For biotech companies racing to bring novel therapies to patients, the gap between preclinical development and first-in-human (FIH) trials can mean the difference between progress and stagnation. Regulatory complexities, underdeveloped characterization methods, and inefficient study design can stall momentum, costing millions and delaying life-changing treatments. Without the right strategy, early-stage biotech innovators risk missing key clinical milestones and losing investor confidence.

One biotech sponsor faced this reality while advancing a novel therapeutic to clinical testing. Their API characterization and release methods were insufficiently defined, creating the potential for an 18-month delay—a setback that could require costly rework and additional GMP manufacturing runs, adding more than $1M in expenses. At the same time, the FIH study design and site selection process introduced inefficiencies, threatening to extend timelines even more. They needed a strategic partner to optimize these critical preclinical elements and ensure a seamless transition to clinical trials.

They found what they needed in Thermo Fisher Scientific's Accelerator™ Drug Development solution—a unique, fully integrated approach that ensured collaboration across early development and preclinical processes, helping to enable greater speed, simplicity, and scalability across their drug development journey.

**Speed**
Time to FIH accelerated by 12 months

**Simplicity**
Scalable framework mitigated risk, streamlined future programs

**Savings**
$1M saved by eliminating unneeded API runs

## Integrated preclinical solutions help to reduce risk and drive efficiency

Thermo Fisher Scientific's development experts worked closely with the customer to resolve these challenges with an integrated approach that streamlined preclinical processes and minimized risk.

### The team:

- Defined alternative API specifications based on toxicology data, enabling a faster Quality Assurance (QA) release process.
- Optimized the FIH study design by incorporating on-site compounding and refining site selection for greater efficiency.
- Integrated timelines across formulation, lab services, and regulatory consulting to proactively resolve bottlenecks before they could impact development.

## Delivering speed, simplicity, and cost savings

By addressing key bottlenecks early, the customer avoided an 18-month delay and accelerated the transition to FIH trials by 12 months. Without intervention, unresolved API characterization and inefficient study design could have significantly delayed their progress.

### As a result of Thermo Fisher's proactive strategy:

- The customer saved $1M by eliminating unnecessary GMP manufacturing runs of additional API batches.
- Development timelines were reduced by 12 months through data-driven, optimized trial design and site selection. Thermo Fisher Scientific's strategic development CMC consultants optimized API assay tests, and the customer did not have to procure materials nor remake the API batch.
- A scalable framework was established to mitigate risk and streamline future clinical programs.

By preventing delays and mitigating costly risks, this integrated approach transformed the sponsor's development strategy, positioning them to advance future programs with greater speed, efficiency, and confidence.

Learn how **Accelerator™ Drug Development** can streamline your path to First-in-Human trials.