EARLY PHASE DEVELOPMENT SOLUTIONS

Real-world case studies – demonstrating accelerated timelines, risk reduction and measurable cost savings are possible

Early Phase Development Solutions is a unique drug development model proven to save time, mitigate risk and help drive down costs in drug development. The following real-world case studies highlight how sponsors leveraged Early Phase Development Solutions scientific expertise, operational efficiency and disciplined program management to streamline their drug development journey and unlock new efficiencies.

labcorp
Drug Development

Meet Aggressive Timelines

Sponsors often need expedited studies to meet imminent regulatory filing dates. The following examples demonstrate how clients leveraged Early Phase Development Solutions to meet their aggressive timelines.

CASE STUDY 1

Responding to a global health crisis with urgency

A biopharmaceutical company developing a novel treatment for a highly contagious disease was driven by an urgent health crisis to deliver an IND package on an aggressive timeline.

Our Solution

- A risk-assessed, integrated development plan with studies conducted in parallel to accelerate and meet the challenging IND filing date
- Partnership between the client and a highly motivated Labcorp Drug Development team of scientific experts with extensive experience running similar programs to deliver on time

The Results

- The sponsor filed their IND only 5 months after program initiation – an estimated time savings of ~50%
- The client moved swiftly into Phase I to determine safety, tolerability and pharmacokinetics
- In parallel to Phase I study, the client was allowed to treat patients

"The Early Phase Development Solutions team worked out individual timelines for each study and delivered on its plan to expedite our urgent program."

CASE STUDY 2

Dedicated project management to integrate vendor activities and expedite program

An emerging biopharmaceutical company with a lead compound targeting a range of solid tumors chose Labcorp as their partner to accommodate their need for an aggressive timeline vs their prior CRO.

Our Solution

- Proactive project management of parallel studies at Labcorp and management of activities at another vendor to integrate the project plan
- Active escalation of key risks to ensure timeline commitments were met

The Results

- The IND program was completed within 6.5 months (versus 9–12 months industry average): the sponsor's regulatory filing date was achieved
- The sponsor successfully progressed to clinic
- Second IND enabling program now underway with Labcorp

"Ease of communication and organization provided by the Labcorp Early Phase Development Solutions team far exceeded our previous experiences with our former CRO."

Manage Potential Risks and Mitigate Unexpected Findings

Unexpected scientific results can occur in any program – requiring additional work and placing immediate strain on timeline and resource. The following examples demonstrate effective partnering strategies to mitigate these risks.

CASE STUDY 3

Resolving critical issues to deliver on time

A virtual biotech company had in-licensed a molecule with a first-in-class mechanism for treatment of a neurological disease. To avoid losing rights to the molecule, they needed to gain regulatory approval for a First-in-Human (FIH) study within an aggressive timeframe: 9 months from start of manufacture to regulatory submission.

Our Solution

- Dynamic development plan created; balancing cost, scientific risk mitigation and time
- Early engagement of Labcorp regulatory and clinical teams enabled seamless and expedited transition to clinical trial approval and Phase I study start
- Informal discussions with regulatory assessor to agree to clinical dose escalation plans in light of toxicology findings

The Results

- Multiple, unexpected scientific issues were resolved creatively, which included the need to conduct additional work while still achieving the client's goals
- The client gained regulatory approval, retained rights to the asset and has since progressed to Phase II with Labcorp

"We were delighted and compliment the Labcorp team that acted as a 'well-oiled machine' and worked closely to resolve issues."

CASE STUDY 4

Designing a joint plan to address and overcome risks

An emerging biopharmaceutical company needed an immuno-oncology IND-enabling program with an expedited timeline. The client was targeting a regulatory submission 6 months after initiation of the first toxicology study.

Our Solution

- Strong collaboration with sponsor's team and their consultant
- A mutually agreed risk management strategy
- An aggressive project plan with contingencies to balance risks and time, including conduct of parallel studies
- Expert scientific assessment and management of exaggerated pharmacological effects

The Results

- The prospective risk assessment enabled team to address emerging data effectively
- Completed expedited program in 6 months, on time

"The full IND-enabling program assumed a high degree of risk but ultimately we were able to meet the compressed timeline of 6 months vs. the typical 9 months to keep our program moving forward."

Get Sound Scientific Advice for Continuity in the Clinic

Facilitating a successful transition to the clinic requires scientific and operational continuity. The following examples demonstrate how clients experienced the impact of rich institutional knowledge, access to experts and insightful advice at key decision points to smoothly advance their development.

CASE STUDY 5

Creating an innovative development strategy

A mid-sized pharmaceutical company needed scientific and regulatory expertise to address a significant development challenge for their innovative biological medicine.

Our Solution

- Assessment of the client's data and preparation of a scientific and regulatory development strategy to address the issue: no apparent, relevant toxicology species
- A plan to conduct a program of in vivo and in vitro immunotoxicology studies to enable progression to the clinic

The Results

- Studies in progress
- Formal regulatory authority scientific feedback confirmed that the proposed nonclinical testing program was acceptable

"The help and advice provided by the team at Labcorp to develop the molecule is greatly appreciated."

CASE STUDY 6

Resolving critical issues to deliver on time

A biopharmaceutical company identified a siRNA candidate for treatment of a rare disease in children, but faced issues with the toxicology program design and execution. They needed expert guidance on the most efficient strategy to deliver their IND package.

Our Solution

- A multidisciplinary program team including subject matter experts in toxicology, clinical pathology and animal medicine provided scientific input into complex study designs and data interpretation

The Results

- A scientific strategy that kept the project on the critical path
- Study results delivered quickly within 5.5 months

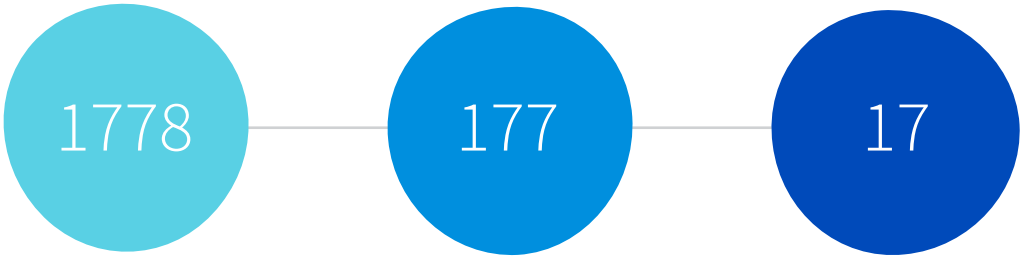
"The work set a new precedent for us. Based on the success, we asked the Labcorp team to run 5 more Early Phase Development Solutions programs for us."

Explore How Early Phase Development Solutions Can Trim Your Timelines, Reduce Risks and Cut Costs

Minimizing development time, mitigating risks and leveraging scientific expertise are all key factors to enable a seamless transition to the clinic. Count on Early Phase Development Solutions to deliver strategic insights and execute the most efficient program, saving time and maximizing your asset's value.

The reach of early phase development solutions

In less than three years, more than 170 companies have adopted this unique approach and have initiated:



Studies

IND/CTA-Enabling Packages

FIH Studies

Ready to accelerate your journey through drug development? Take the clear path forward with Early Phase Development Solutions.

Learn more at drugdevelopment.labcorp.com/epds

labcorp Drug Development