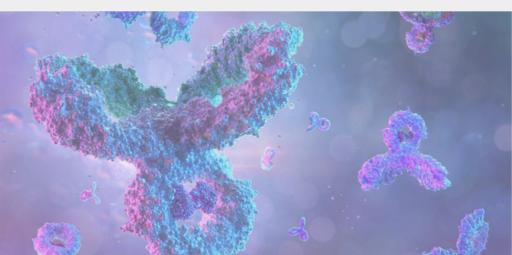


## DEEP DIVE ARTICLE

# THE IMMUNOLOGIX DIFFERENCE

BIOANALYTICAL INTAKE PROCESS: A COMPREHENSIVE APPROACH TO LARGE MOLECULE PROGRAM SUPPORT

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# WHAT MAKES A LABORATORY SERVICES PARTNER TRULY DIFFERENT?

#### Introduction

In the intricate world of drug development, the intake process represents a critical transition point where scientific potential meets strategic execution. As a specialized contract research organization delivering advanced bioanalytical and biomarker laboratory services, our approach goes far beyond a simple administrative procedure, serving as a sophisticated bridge that connects initial project concepts with robust, scientifically rigorous analytical programs.

At Immunologix Laboratories, we've built our project initiation framework on a foundation of integrated scientific expertise and strategic drug development knowledge. Our intake process exemplifies our commitment to bringing together laboratory excellence with comprehensive translational understanding, ensuring each project begins with the right foundation for success.

#### The Scientific Triad: A Collaborative Approach to Expertise

Every project that enters our laboratory is supported by three dedicated scientists working in seamless collaboration, bringing a minimum of 30 years of combined assay development expertise to your project. This triad model ensures that both strategic insight and technical excellence inform your project from its inception.

**Principal Investigator (PI):** The PI serves as your scientific point of contact, leading project communication and oversight through weekly or bi-weekly meetings. While serving as your primary interface, the PI works in close coordination with two other key scientists to ensure comprehensive project support.



**Translational Scientist:** Each PI works directly with a member of our Translational Sciences team, ensuring that every project benefits from both strategic and practical drug development experience. Our Translational Scientists each bring more than 15 years of direct drug development experience from the sponsor side, understanding the strategic, scientific, and technical landscape from late research through post-market, including regulatory interactions.

**Lead Method Developer:** The Lead Method Developer designs and executes bench work with support from an assigned backup developer, ensuring continuous project progression. This technical team works in daily collaboration with the PI and Translational Scientist, sharing insights and addressing any challenges in real time.

Unlike traditional linear project management, our triad model creates a dynamic, interconnected support system that addresses scientific challenges from multiple perspectives.

#### **Strategic Information Collection**

Our intake process is meticulously designed to gather and distribute critical information across multiple organizational dimensions. Unlike traditional approaches that might silo information, we create a comprehensive intelligence network that ensures each project component receives precisely the insights it requires.

Through this coordinated approach, the Method Development team accesses the strategic and technical details essential for comprehensive project planning and execution, ensuring a strong foundation for analytical success. Working in parallel, our Business Development team utilizes critical project parameters to optimize resource allocation and develop precise timeline planning.

The Translational Sciences team plays a crucial role in this information network, obtaining strategic insights that guide program development and address regulatory considerations from the outset. Completing this comprehensive approach, our sample management team focuses on specific requirements for handling and processing, with particular attention to the precise timing needs that can be especially critical for animal studies and cohort by cohort data delivery for early clinical studies.



This orchestrated flow of information ensures each team not only receives the specific details they need but also understands how their work connects to the broader project objectives and specific needs and preferences of our Sponsor organizations.

#### Scientific Office Hours: Real-Time Collaborative Support

A distinguishing feature of our intake process is the integration of daily scientific consultation sessions. These meetings represent more than routine check-ins; they are dynamic knowledge exchange platforms that bring together our entire translational sciences team. In addition to supporting our internal project teams, we also offer our Sponsors the opportunity to utilize these sessions to gain direct access to over 100 years of combined translational experience, transforming potential challenges into collaborative problem-solving opportunities.

During these sessions, sponsors can address a wide range of scientific topics. From specific assay development challenges to broader biomarker strategies, from regulatory response crafting to exploring complex drug development implications, these consultations provide unprecedented access to expert scientific guidance.

#### **Advanced Support Infrastructure**

Our commitment to comprehensive project support extends beyond the core scientific triad. Senior-level laboratory supervisors maintain a constant boots-onthe ground presence in our laboratories, providing real-time collaborative consultation and oversight. Integrated Quality Control teams work seamlessly with data systems, while our independent Quality Assurance team maintains rigorous compliance standards. We provide access to FDA 21 CFR Part 11 compliant systems, ensuring both operational excellence and regulatory adherence.

### **Tailoring to Project Complexity**

Recognizing the diverse landscape of drug development, our intake process is designed with remarkable flexibility. We support a balanced portfolio, equally serving large biotech and pharmaceutical companies as well as small to mediumsized enterprises. This provides us with a dynamic landscape of projects, keeping us at the leading edge of scientific advancement while also ensuring we possess a strong understanding of the varied working styles and organizational demands of



our diverse Sponsors. With these integrated perspectives we provide true partnership and superior customer service that delivers tailored solutions for even the most complex projects. Our specialized expertise, enhanced scientific oversight, and innovative problem-solving approaches all contribute to our ability to deliver an unparalleled scientific partnership experience.

#### Transforming Potential into Scientific Achievement

Our intake process is more than an administrative procedure; it is a strategic foundation for successful drug development. By combining integrated scientific expertise, comprehensive information gathering, and a collaborative team structure, we ensure that each project begins with the optimal framework for success.

We don't just manage projects—we cultivate scientific potential, transforming initial concepts into groundbreaking analytical solutions that respond to the needs of the evolving drug development industry.

#### Contact

Our scientific team welcomes detailed discussions about how our integrated approach can support your drug development programs. Whether you're facing complex analytical challenges or seeking a long-term laboratory partner, we're prepared to advance your programs with scientific rigor and strategic insight.

<u>Contact us</u> today to start a conversation.

