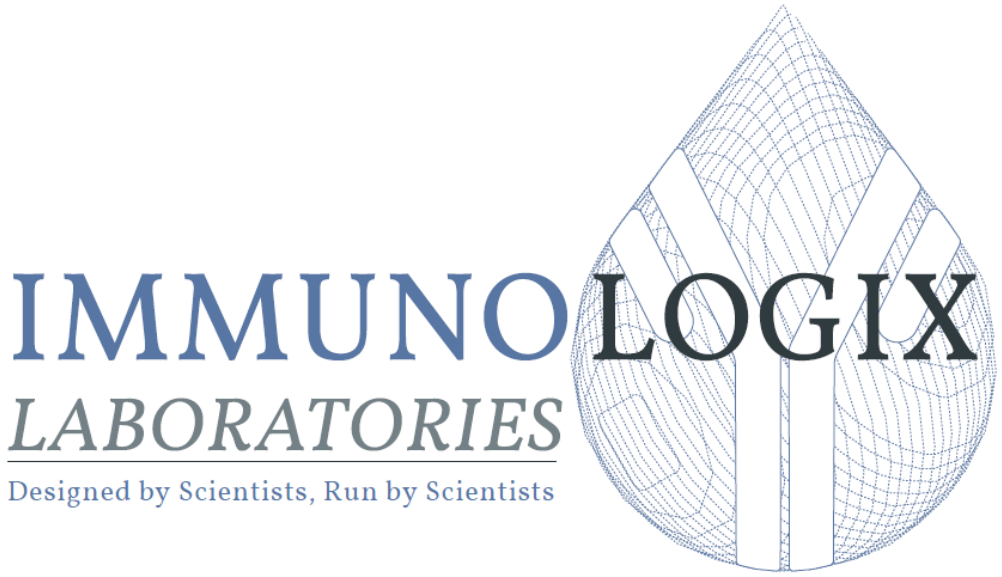


Translational Sciences Division

Designed by drug developers, Run by drug developers

Translational Sciences Division

From Bench to Bedside: Translational Sciences is the interface between basic science and clinical medicine

Customized Translational Sciences Solutions

Translational Strategy

- ❑ Drug Development Biomarker Strategies: Preclinical to Filing
- ❑ Post-market Clinical Research Strategy
- ❑ Large Molecule Bioanalytical Strategy
- ❑ Bioanalytical and Biomarker Assay Life Cycle Management

Scientific Partnership

- ❑ Scientific Guidance and Oversight of PK, Immunogenicity, and Biomarker Projects
- ❑ Critical Reagent Design and Management
- ❑ Data Analysis and Interpretation
- ❑ Scientific Integration with drug development stakeholders

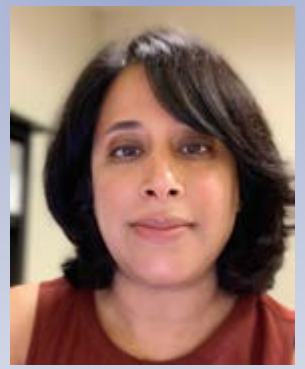
Regulatory Engagement

- ❑ Author and Review Bioanalytical and Biomarker sections for INDs, study protocols & reports, & filing documents
- ❑ Regulatory Q&A
- ❑ Data-driven Influencing of Regulatory Guidance

TS Leadership

Lauren Stevenson, PhD, Vice President of Translations Sciences Division

- Industry-wide thought leader in biomarker development, large molecule BA, and immunogenicity; extensively influences industry best practices and regulatory guidance.
- 20+ years of drug development experience, building and leading scientific teams with expertise in setting biomarker& BA strategies and developing PK, immunogenicity and biomarker assays.
- Her experience spans multiple modalities and disease indications through all stages of development, from discovery to post-market.
- Lauren is passionate about people development, has received certification as a Strengths coach and is active in mentorship and career development programs.



Devangi Mehta, PhD, Executive Director of Translations Sciences Division

- Recognized thought leader in translational sciences and has led scientific teams that deliver biomarker & BA strategies to support internal program decision-making, regulatory submissions, post-marketing and drug-positioning goals.
- 14+ years of drug development experience and developing PK, immunogenicity and biomarker assays to support drug programs from discovery-to-post-market and spanning multiple disease indications.
- Externally, Devangi has special interests in advancing industry-wide best practices for assay development and “fit-for-purpose” validation of ligand-binding and flow cytometry biomarker assays.
- Devangi is passionate about bringing the science to patients through integration of translational research and medical education.

Multiplying Value: Integrated Team Model

<u>Prior experience: Demonstrated Proof-of-Concept</u>

Matrixed Team of 18 Scientists

- ✓ 44 Drug programs – LM, SM, ASO, GT
- ✓ Across multiple therapeutic areas – Immuno, Neuro, Rare Disease, Fibrosis
- ✓ 57 distinct Bioanalytical and Biomarker scientific leader roles
- ✓ Critical reagent generation and resupply for >30 programs
- ✓ Assay life cycle management for ~300 assays
- ✓ Leaders in Bioanalytical and Biomarker Industry – authors of multiple white papers
- ✓ Successfully influenced regulatory guidance – e.g. FDA 2019 Immunogenicity Guidance

Biomarker Strategies to Enable Data-driven Decisions

Research /Pre-Clinical Safety → IND enabling → Phase 1 → Phase 2 → Phase 3 → Post market

Reverse Translation

Building a biomarker strategy and tools to translate preclinical research into the clinic

Selecting the Right Drug and Dose:
- ✓ Target Engagement
- ✓ Pharmacodynamic activity
- ✓ Proof-of-Biology
- ✓ Refine disease subpopulations

Improving the Probability of Success:
- ✓ Modulation of Disease Biomarkers
- ✓ Patient enrichment and selection
- ✓ Safety profiling
- ✓ Product differentiation and label claims

BM assay development:
- Establish Context of Use
- Select right technology
- Fit-for-purpose validation
- Understand clinical Implementation

Post-market Life Cycle Management:
- ✓ Respond to emerging clinical data
- ✓ Medical Affairs translational research
- ✓ Expand to new indications
- ✓ Reverse translation to drug pipeline

Core Expertise in Biomarker Assay Development

- ✓ Ligand Binding Assays (ELISA, MSD, ECL, Gyros)
- ✓ Emerging and High-Sensitivity Technologies (Simoa ™, SMCxPro™, Ella ™)
- ✓ Flow Cytometry
- ✓ Ex-vivo stimulation & cell-based assays
- ✓ Targeted genomic and qRT-PCR assays

Bioanalytical (PK & Immunogenicity) Strategy & Execution

Pre-R2D

- Immunogenicity risk assessment
- Develop initial BA strategy
- Technology platform selection
- Assay format design
- Reagent generation strategy & execution

R2D-Ph2

- GLP Tox assay(s) devel & validation
- Clinical assay(s) devel & validation
- Study sample analysis & data interpretation
- IND filing – first communication of strategy to regulators
- Update strategy/risk assessments based on emerging data
- Develop/validate assays for repro & chronic tox

Ph3-launch

- Clinical assay(s) maintenance
- Study support & data interpretation
- Repro & chronic tox assays/study support if not already done
- Filing readiness & BLA preparation
- Reagent resupplies
- Redevelop/validate assay(s) as needed for evolving Regulatory expectations
- Update strategy

Post -market

- Clinical assay(s) maintenance
- Responses to Regulator questions
- PM study support & data interpretation
- Reagent resupplies
- Patent defense
- MSL/Global Medical support
- Commercial assay development, if needed

Core Expertise in Bioanalytical Assay Development

BA assay development:

- Select right reagents
- Select technology platform & assay format
- GxP validation
- Iterate for multiple species, disease populations & evolving regulations

- ✓ PK assays
- ✓ Anti-drug antibody assays
- ✓ Neutralizing antibody assays
- ✓ Integrated PK, PD, ADA data to inform presence of neutralizing activity
- ✓ Critical reagent generation, inventory & resupply
- ✓ Assay life cycle management
- ✓ Technologies
  - ✓ Ligand Binding Assays (ELISA, MSD, ECL, Gyros)
  - ✓ ImmunoPCR
  - ✓ Flow Cytometry

Partnering with Translational Sciences

Fully Outsourced Partner

- Emerging small and virtual biotechs approaching development
- Flexible and agile TS resourcing for an emerging pipeline

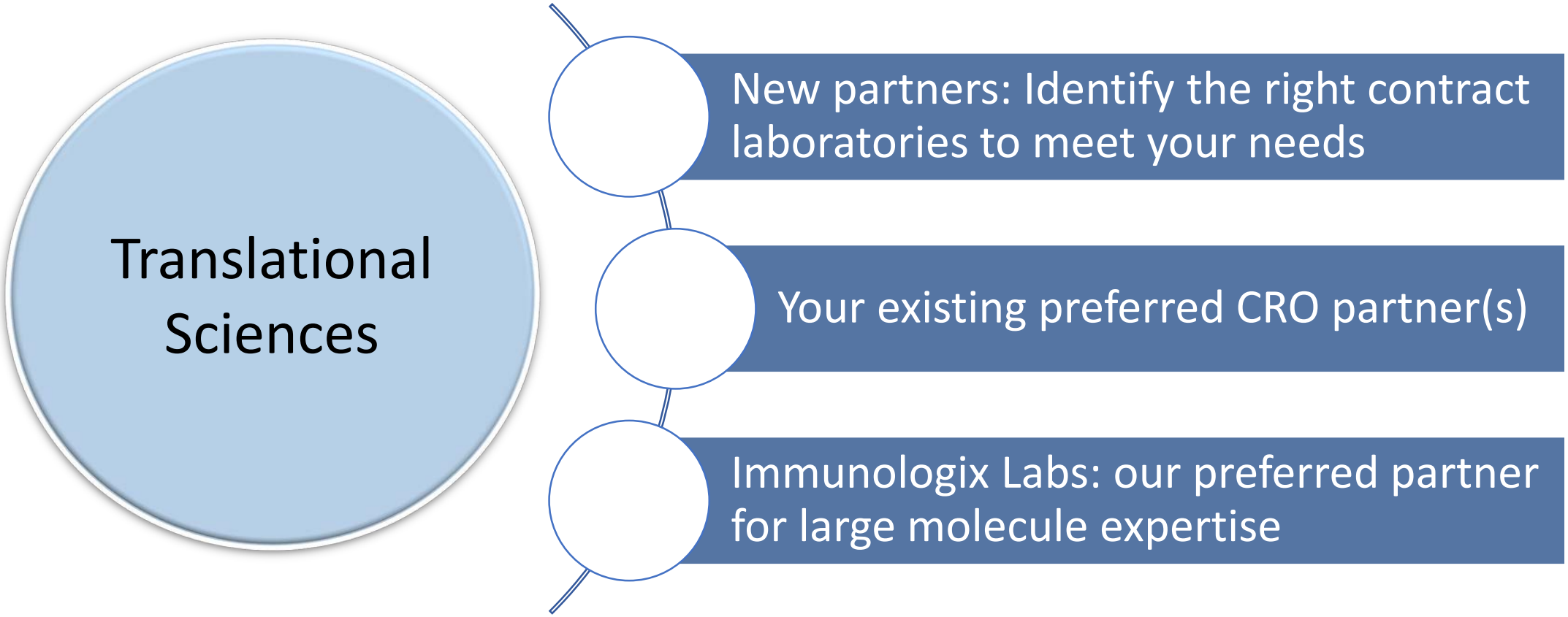
Supplemental Partner

- Mid-Large Biotech/Pharma with Expanding Pipelines
- Maximize limited internal resources by supplementing TS expertise

Fully customizable to meet the needs and working styles of our partners

Execution of translational strategies requires flexibility

TS is committed to providing the best laboratory solutions for your needs



Many projects will require utilization of multiple labs

Synergizing with Immunologix Laboratories Assay Experts

Fully Outsourced Partner

- Emerging small and virtual biotechs approaching development
- TS partners and +/- Lab Operations

Supplemental Partner

- Mid-Large Biotech/Pharma with Expanding Pipelines and Limited Resources
- TS Supplemental Scientists +/- Lab Operations

Immunologix Translational Sciences

- Quantitative PK
- Immunogenicity
- Neutralizing Assays
- Biomarkers
- Reagent Characterization

Immunologix Laboratories

IMMUNOLOGIX LABORATORIES
Designed by Scientists, Run by Scientists

Where to start?

Contact us to schedule an introductory discussion & partnership options

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617-777-4294

dmehta@immunologixlabs.com
617-777-2806

https://www.immunologixlabs.com/translational-sciences/

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