TOXISTRATEGY LLC

NONCLINICAL SAFETY AND TOXICOLOGY CONSULTING

www.toxistrategy.com

TRANSFORMING SCIENTIFIC EXPERTISE INTO BREAKTHROUGH MEDICINES

EXPERIENCE IN YOUR CORNER

From discovery to the clinic, Toxistrategy delivers tailored nonclinical safety solutions to meet your program's unique challenges. Whether navigating toxicology strategy, IND-enabling packages or regulatory authoring, we provide unmatched expertise to ensure your therapeutic reaches its full potential.

SERVICES

- Nonclinical Management
- Regulatory Oversight
- SEND Datasets

NONCLINICAL SAFETY PROGRAM MANAGEMENT

STRATEGY MANAGEMENT

Consultation and oversight of nonclinical safety programs from discovery to clinic including strategic timelines, budgeting, data room management and investor relations.

STUDY MANAGEMENT

Management and execution of nonclinical and toxicology studies including study design, protocol development, study monitoring (off- and on-site), and reporting.

CRO MANAGEMENT

Point of contact for CRO outsourcing of nonclinical studies and assays including SOW generation, timelines, budgeting, and contract management. CRO vetting and auditing services.

ON-SITE STUDY MONITORING

Travel to CROs for site visits to oversee conduct of nonclinical studies. Site visits include review of protocols, SOPs, personnel, study activities, and GLP compliance. All site visits are completed with an official report.

EARLY DISCOVERY TOXICOLOGY

Insights to early toxicology and its translation to nonclinical and clinical implications. This includes TGI and PK studies and oversight of early toxicology assays (eg, Safety44, Kinase Panels).

REGULATORY OVERSIGHT

DOCUMENT AUTHORING

Authorship of regulatory documents including INDs, NDA/BLAs, IBs, BBs, meeting requests, and more. Review and QC of regulatory documents.

TIMELINE MANAGEMENT

Oversight of timelines for completion of regulatory documents and submissions including liaising with cross-functional areas for authorship, review and finalization.

REGULATORY RESPONSES

Insights and interpretation of regulatory responses including strategizing next steps, understanding regulatory needs, and drafting responses.

SUBMISSION PACKAGE PREPARATION

Prepare and review full regulatory submission packages such as INDs, CTAs, DSURs. Review and ensure compliance of SEND datasets.

SEND DATASETS

DATASET MANAGEMENT

Complete management of all SEND datasets including liaising with SEND provider and managing dataset storage and submissions.

DATASET REVIEW

Review and QC of SEND datasets to ensure consistency with study data, compliance with SEND regulations, and alignment with SEND requirements.

REGULATORY COMPLIANCE

Audit of nonclinical program and SEND dataset alignment to prevent rejection of regulatory submissions.

EXPERIENCED IN:

MOLECULES

- small molecule
- large molecule/biologics
- ADCs
- vaccines
- nanoparticles
- radiopharmaceuticals
- gene and cell therapies
- oligonucleotides

INDICATIONS

- oncology
- immunology/autoimmune
- immuno-oncology
- epigenetics
- rare disease
- endocrine
- cardiovascular
- CNS/neuro

WHO WE ARE

DESSI MCENTEE, MS, DABT

OWNER + CONSULTANT

Dessi is a board-certified toxicologist with a rare blend of expertise that places her among the leading nonclinical safety professionals in the industry. With over a decade of hands-on experience in exploratory and GLP nonclinical sciences across the pharmaceutical and biotech sectors, she has successfully led Toxicology, Safety Pharmacology, and DART strategies across a wide range of therapeutics. Her leadership has been instrumental in advancing numerous critical medicines to the clinic, and her track record in regulatory submissions is flawless.

Toxistrategy is not a big consulting firm—it's a one-woman powerhouse. When you work with Dessi, you get direct access to a dedicated expert who delivers a tailored, high-touch service designed to drive your program forward. No bloated teams, no wasted hours—just smart, strategic guidance to turn your breakthrough into reality.

TESTIMONIALS

"I have worked closely with Dessi for many years, both at small molecule and protein biologics companies. What has impressed me the most about her skill sets and experiences is that she is very diligent in not only designing the studies, executing them to the highest standards but she also makes a concerted effort to understand the science behind the programs she has been involved with. In an area that seems to be changing in the requirements for nonclinical safety and drug development, Dessi is extremely up-to-date on this morphing landscape. This has been comforting for me and my teams in that we know that she will ensure compliance with the changing times. Even after our times together at the same organizations I continue to reach out and recommend Dessi as my go-to nonclinical colleague. Besides her immense knowledge base in the areas of safety and nonclinical drug development, Dessi is one of the kindest, hard-working individuals I know and would be a benefit to any organization/team. I have worked with Dessi for years and look forward to continuing any opportunity where we can work together again."

Principal at TranslationalBio LLC

TESTIMONIALS

★★★★★

Dessi is an excellent toxicologist who provides useful and practical guidance related to the development of both large and small molecules. Her extensive knowledge base of compound characteristics, study design and in vivo observations allows her to provide perspective on both how to design toxicology studies and how to interpret the results. I particularly appreciate her ability to separate “signals” from “noise” allowing companies to determine whether the findings will impact development, whether additional studies are warranted and what a path forward might look like. Her pragmatism is invaluable in executing a successful toxicology program. I highly recommend Dessi to any company needing toxicology input.

CEO of Biopharma

TESTIMONIALS

I was fortunate to work with Dessi while she consulted for a couple of pre-clinical, small molecule programs. She was able to succinctly summarize recommendations for studies that aligned with company budget and R&D needs to progress the programs. She was also able to adjust studies, plans and work with vendors to make immediate adjustments if plans changed, which is critical for start-ups. She interfaced with other consultants and CROs to ensure a seamless execution of planned studies, and was always a pleasure to work with.

Director of Business Development

TESTIMONIALS

It was a pleasure to work with Dessi both as a colleague and manager. Dessi is among the most innovative scientists I've known, with broad expertise in molecular techniques, drug discovery, toxicology, SEND datasets, and mechanisms of drug toxicity. She consistently delivered high-quality, well-reviewed data and was instrumental in interpreting results to advance projects.

Dessi's collaborative approach, reliability, and exceptional time management truly set her apart. She's an excellent communicator, a quick learner, and a thoughtful leader, blending technical, scientific, business, and interpersonal skills seamlessly. As a manager, she is supportive, fair, and a strong mentor.

I highly recommend Dessi as an invaluable leader for any organization.

VP, Head of Toxicology

TOXISTRATEGY

CONTACT US

We appreciate the opportunity to work with you and help your business achieve its goals.

Visit www.toxistrategy.com to schedule a free consultation or reach out using a method below:

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