DESSI TURNER, MS, DABT

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EDUCATION

DABT	Diplomat *American Board of Toxicology*	October 2022
MS	Pharmacology and Toxicology *Michigan State University*	May 2018
BS	Animal Science *University of Connecticut*	May 2012

WORK EXPERIENCE

Bulletproof Consulting Apr 2022 - Present

Fractional Head of Nonclinical Development

- Serve as embedded, fractional Head of Nonclinical Development for early-stage and growth-stage biotech companies, owning end-to-end nonclinical development from discovery through IND and into early clinical development.
- Own execution of the full nonclinical program — pharmacology, DMPK, toxicology, safety pharmacology, and CMC coordination — aligning with regulatory strategy and corporate milestones.
- Direct the design, execution, and oversight of nonclinical safety programs, including study strategy, CRO selection and management, on-site monitoring, timeline control, and budget accountability.
- Set regulatory strategy and author/manage submissions and interactions, including pre-INDs, INDs, CTAs, and regulatory briefing packages, with a focus on defensible interpretation and regulatory clarity.
- Build the development narrative that anchors investor decks, board materials, and diligence packages — translating complex nonclinical data into a story non-scientists can evaluate and fund.
- Support fundraising as the development lead, including non-GLP toxicology plans and cost estimates for SBIR/STTR and other grant applications, plus data-room preparation and direct investor engagement as programs advance toward equity financing.
- Lead nonclinical programs across diverse modalities — small molecules, biologics, ADCs, vaccines, nanoparticles, and radiopharmaceuticals — and therapeutic areas including oncology, immunology, rare disease, endocrinology, cardiovascular, and CNS.

Immugen BioPharma, Inc. Mar 2026 - Present

Chief Development Officer (CDO) and Board Member

- Serve as Chief Development Officer for a clinical-stage biopharmaceutical company developing a non-psychoactive THC derivative as a non-hormonal treatment for genitourinary syndrome of menopause (GSM), targeting FDA approval
- Lead end-to-end drug development strategy spanning nonclinical safety, CMC, regulatory affairs, and IND-enabling program execution
- Direct CRO identification, qualification, and oversight across toxicology, pharmacology, and formulation development programs
- Author and oversee regulatory submissions and interactions including pre-IND strategy, briefing documents, and IND preparation
- Lead fundraising strategy and investor engagement, including preparation of investor decks, data room documentation, and Seed/Series A planning
- Collaborate with CEO and executive team on program prioritization, milestone planning, and operational execution
- Represent the company's scientific and development programs to prospective investors, partners, and collaborators
- Serve as a voting member of the Board of Directors, contributing to governance, strategic direction, and major operational decisions
- Provide executive oversight on fundraising, equity structure, key partnerships, and program advancement criteria
- Participate in review/approval of budgets, agreements, and corporate strategy

Mimicry Solutions May 2023 – Feb 2024

Founder and CEO

- Founded and lead a biotechnology innovation venture focused on applying AI-driven translational modeling to turn animal predictions of drug safety into human predictions through a proprietary computational platform called ARTEMIS™.
- Defined company vision and built business strategy around reducing animal testing and accelerating drug candidate safety prediction through computational toxicology and data harmonization.
- Designed and oversaw development of proprietary data integration algorithms to identify mechanistic patterns across multi-modal toxicology datasets.
- Managed scientific partnerships and collaborations with academic, pharma, and AI/ML teams to validate and benchmark model performance against regulatory datasets.
- Authored investor materials and pitch decks articulating Mimicry's scientific rationale, business potential, and alignment with 3Rs and regulatory innovation frameworks.
- Authored and filed patent applications covering Mimicry's proprietary computational platform architecture, data integration algorithms, and predictive toxicology modeling framework.
- Authored and secured SBIR grant application invitation to advance development and validation of Mimicry's AI-driven computational toxicology platform, including full preparation of technical, commercial, and budget documentation.
- Represented Mimicry Solutions at industry conferences and regulatory workshops, highlighting advancements in AI-enabled safety science and translational toxicology.
- Oversaw all operational, legal, and financial aspects of company establishment, including corporate formation, equity structure, and strategic partnerships.

Q32 Bio Apr 2022 – Feb 2025

Associate Director of Toxicology

- Direct nonclinical safety programs to support development candidate nomination, regulatory submissions, and clinical development of large molecule therapeutics targeting autoimmune diseases.
- Manage the outsourcing and execution of nonclinical studies, including study design, species and dose selection, endpoint determination, CRO selection, study monitoring, protocol review, data analysis, safety assessments, and report finalization.
- Evaluate test articles to identify additional study needs or endpoints, ensuring comprehensive characterization of safety, toxicological, and pharmacological profiles to support human clinical trials.
- Lead IND/CTA submission projects, overseeing timelines, managing cross-functional review processes, coordinating advisory boards, and serving as liaison with medical writers and quality control teams.
- Author nonclinical sections of regulatory submissions ensuring compliance and scientific rigor; experience includes but is not limited to INDs, CTAs, pINDs, Type D Meetings, Briefing Books, Investigational Brochures, and Waivers.
- Provide strategic input on toxicology program feasibility, leveraging data from nonclinical studies to guide decision-making and program design.
- Oversee SEND dataset requirements, ensuring compliance and submission readiness.

Epizyme, Inc. Feb 2021 – Apr 2022

Nonclinical Safety Lead

- Directed nonclinical safety programs to support development candidate nomination, regulatory submissions, and clinical development of small molecule oncologic drugs targeting blood cancers.
- Oversaw all nonclinical safety studies including Toxicology, Safety Pharmacology, and DART studies; responsibilities included study design, species/dose selection, endpoint determination, CRO selection, monitoring, protocol finalization, data analysis, safety assessments, report review, and presentation of findings to project teams.
- Managed preclinical assessments, including in silico (DEREK/Sarah Nexus), in vitro (hERG assays, kinase profiles, off-target activity assays), and in vivo (mutagenicity and phospholipidosis evaluations) studies to support development candidate nomination.
- Evaluated test articles to identify additional study needs, endpoints, or assessments to comprehensively characterize safety and toxicological profiles for human clinical trials.
- Led collaborations with external research institutions, including review of research proposals, material transfer agreements, and scientific research agreements to advance initiatives.
- Served as nonclinical representative on project teams, contributing scientific expertise and ensuring alignment of safety strategies with program goals.
- Acted as Project Lead for IND submissions, managing timelines, coordinating cross-functional reviews, overseeing advisory boards, and liaising with medical writers and quality control teams.
- Authored key sections of IND packages, including Toxicology, Secondary Pharmacodynamic, and Safety Pharmacology sections, as well as NCOs, Co-Protocol Elements, and the Investigator's Brochure.
- Oversaw the creation, review, and implementation of departmental SOPs and qualified CROs for GLP study outsourcing to ensure compliance and quality.

Instem Jun 2018 – Feb 2021

Senior Information Scientist

- Oversaw the conversion and review of nonclinical Toxicology and Safety Pharmacology data into SEND datasets, ensuring compliance with regulatory standards and policies (SENDIG, TCG, CoDEx, CDER, CBER) for FDA submission packages.
- Interpreted study reports and raw data to accurately populate SEND datasets, ensuring alignment with sponsor submission packages and supporting the safety assessment of test articles.
- Extensive experience with a wide range of study designs, including all nonclinical species, dose routes, and endpoints, ensuring comprehensive data collection and reporting.
- Actively participated as a member of the CDISC Core Team and CDISC Safety Pharm Subteams, contributing to the development and implementation of industry-wide standards for SEND datasets.
- Led multiple process development and implementation projects, including converting Safety Pharmacology data into SEND format in response to new SEND Igs, revamping work instructions, and managing client projects involving up to 400 dataset conversions.
- Served as a trainer and mentor, providing guidance on dataset conversions, reviews, Microsoft Office applications, and industry best practices, while supporting professional development and data collection methods.

Pfizer, Inc. May 2012 – Jun 2018

In Vivo Study Scientist

- Led the execution and oversight of nonGLP and GLP Toxicology, Safety Pharmacology, and DART studies, managing all aspects from pre-planning to reporting across various species (mouse, rat, dog, rabbit, monkey).
- Conducted in vivo studies involving diverse dosing routes (oral gavage, subcutaneous, intravenous, intraperitoneal, intramuscular), blood collection techniques (central ear artery, saphenous vein, femoral vein, etc.), various clinical observations, and specialized technical work including necropsy, ophthalmic exams, telemetry, ECG, and urine collection.
- Managed study endpoints for Toxicology, Safety Pharmacology, and DART studies, interpreting data related to ADA, cytokines, immunophenotyping, FOBs, respiratory assessments, and clinical pathology, ensuring accurate results and conclusions.
- Provided input on study design, dose selection, endpoints, resourcing, and scheduling, ensuring alignment with regulatory and scientific goals.
- Oversaw data collection systems, ensuring accurate protocol entry and management of cardiovascular, toxicokinetic, and study data.
- Reviewed and authored protocols, amendments, deviations, and final reports, ensuring clarity and scientific rigor.
- Developed, validated, and implemented in vivo methods to enhance animal welfare, data quality, and toxicology interpretation, such as stress biomarker urine collection and a flush system for intravenous dosing.
- Authored and reviewed departmental SOPs for nonGLP and GLP studies, ensuring compliance and best practices in study execution.
- Presented complex data and methodologies to team leaders and executives, demonstrating the effectiveness of evaluation techniques in assessing toxicity and test article-related effects.
- Trained and mentored teams in in vivo skills, ensuring high standards in nonclinical studies related to test article safety.

PUBLICATIONS

Abstract Publications

Galand et al. (2025). Bempikibart, a Novel Human IL-7Ra Antagonist Inhibiting IL-7 and TSLP Signaling, Demonstrated Robust Impact on T-cell Maintenance and Th2 Responses in T-cell Driven Skin Disease. 6th *Inflammatory Skin Disease Summit (ISDS).*

Journal Publications

McEntee D, Borg K, Markiewicz V. (2016). Establishment of a Home-cage, In Vivo Method of New Zealand White Rabbit Urine Collection. *Laboratory Animal Science Professional.*

Book Publications

McEntee, D. (2025). *Data Is Not Strategy: Why Interpretation, Not Volume, Drives Nonclinical Decisions*. ISBN 979-8241480118.

Courses and Educational Programs

McEntee, D. (2025). *The Complete Guide to Nonclinical Development.* Nonclinical Academy. Online professional course covering nonclinical drug development through IND.

PRESENTATIONS AND INVITED LECTURES

Webinar, "Regulatory Pathways: Navigating FDA and PMDA for Global Approval", BioLabs and Astellas, August 2026

Panel Discussion, "Single-Track CRO Process Automates Generation of Study Report & SEND", SOT Annual Meeting, March 2026

Panel Discussion, "Empowering Toxicologists with Access to Near-Real Time Study Data through Interim Study Monitoring: The Sponsor's Perspective", SOT Annual Meeting, March 2022

Webinar, "Interim Study Monitoring and Generation of Analysis-Ready, Submission Quality SEND Datasets", PointCross Life Sciences, October 2021

PROFESSIONAL AFFILIATIONS

Roundtable of Toxicology Consultants (RTC)
Member, 2025-Present

American College of Toxicology (ACT)
Podcast Subcommittee, 2021-Present
Member, 2014-Present

Society of Toxicology (SOT)
Member, 2014-Present

American Society for Cellular and Computational Toxicology (ASCCT)
Member, 2022-Present

Clinical Data Interchange Standards Consortium (CDISC)
Core Team Member, 2019-Present
Safety Pharmacology Subteam Member, 2019-Present