DESSI MCENTEE, 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

Toxistrategy LLC Apr 2022 - Present
Fractional Head of Toxicology

- Serve as embedded, fractional Head of Toxicology for early-stage and growth-stage biotech companies, providing senior nonclinical leadership from discovery through IND and early clinical development.
- Own nonclinical safety strategy and decision-making, ensuring alignment across toxicology, pharmacology, DMPK, CMC, clinical plans, and regulatory objectives.
- Lead nonclinical programs across diverse modalities, including small molecules, biologics, ADCs, vaccines, nanoparticles, and radiopharmaceuticals, and across therapeutic areas such as oncology, immunology, rare disease, endocrinology, cardiovascular, and CNS.
- Advise and guide discovery and preclinical activities, including target risk assessment, off-target screening strategies, efficacy models, DMPK integration, and CMC considerations to support IND-ready development paths.
- 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.
- Author, review, and manage regulatory submissions and interactions, including INDs, pre-INDs, CTAs, and regulatory briefing packages, with a focus on defensible interpretation and regulatory clarity.
- Provide strategic oversight of SEND datasets, including compliance assessment, dataset review, and development of efficient, submission-ready SEND strategies aligned with regulatory expectations.

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 nonclinical collaborations with external research institutions, including review of research proposals, material transfer agreements, and scientific research agreements to advance program 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.

McEntee, D. (2024). *Thank an Animal: A tribute to the animals who gave us the greatest medicines in history.* Ferae Projects LLC. ISBN 9798218365059.

McEntee, D. (2024). *Thank an Animal: Oncology.* Ferae Projects LLC. ISBN 9798340263438.

PRESENTATIONS AND INVITED LECTURES

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 TRAINING

Leadership Bootcamp
The Quad Symposium, Mohegan Sun, 2016

Business of Science Certification
Pfizer, 2016

AIM (Accelerating Implementation Methodology) Workshop
Pfizer, 2015

ADME Workshop
Pfizer, 2015

RLAT Certification, AALAS, 2014

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)
Volunteer, 2019-Present
Core Team Member, 2019-Present
Safety Pharmacology Subteam Member, 2019-Present

PHUSE
Member, 2022-Present