DESSI MCENTEE

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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
Owner & Consultant

- Nonclinical consulting services for companies developing new therapeutics in the large and small molecule space
- Preclinical/discovery consulting on off-target screening assays, efficacy models, DMPK and CMC recommendations from a nonclinical standpoint
- Nonclinical safety and development consulting on toxicology, safety pharmacology and DART studies to support packages for clinical trials and marketing
- Regulatory consulting and authoring of IND, CTA, IB, BB and other regulatory submissions to ensure proper and accurate nonclinical interpretation
- SEND consulting on regulatory submission requirements, review of datasets and submission packages, and CDISC updates/guidances

Q32 Bio Apr 2022 - Present
Associate Director of Toxicology

- Manage strategy related to nonclinical development of large molecules targeting the complement system and other autoimmune disorders
- Outsourcing and oversight of all nonclinical studies including study design, species selection, dose selection, study endpoints, CRO selection, study monitoring, protocol review/finalization, analysis and interpretation of study data in the assessment of test article safety and program viability, report review/finalization, presentation of results to project teams
- Assessment of test articles based on nonclinical studies and data to determine need for additional studies, endpoints, or other evaluations to thoroughly characterize the safety, toxicological and pharmacological profile to support human clinical trials
- Toxicology representative on project teams
- Project Contact for IND/CTA submissions including timeline management, review management, advisory board management, liaison for medical writers and QC
- Authorship of IND/CTA packages including NCO, IBs, IMPDs, PIPs, etc.
- Input on toxicology strategy and program feasibility based on results from nonclinical studies and data
- Overview of all SEND datasets and requirements

Epizyme Feb 2021 – Apr 2022
Nonclinical Study Manager and Operations Lead

- Outsourcing and oversight of all nonclinical safety studies (nonGLP and GLP; Toxicology, Safety Pharmacology and DART) including study design, species selection, dose selection, study endpoints, CRO selection, study monitoring, protocol review/finalization, analysis and interpretation of study data in the assessment of test article safety and program viability, report review/finalization, presentation of results to project teams
- Outsourcing and oversight of preclinical in silico (DEREK/Sarah Nexus), in vitro (hERG assays, kinase profiles, off-target activity assays) and in vivo (mutagenicity evaluation, phospholipidosis evaluation) assessments to support development candidate nomination
- Assessment of test articles based on nonclinical studies and data to determine need for additional studies, endpoints, or other evaluations to thoroughly characterize the safety and toxicological profile to support human clinical trials
- Management of nonclinical collaborations with external research institutions to progress program initiatives including review of research proposals, material transfer agreements and scientific research agreements
- Nonclinical representative on project teams
- Project Lead for IND submission including timeline management, review management, advisory board management, liaison for medical writers and QC
- Authorship of IND packages including Toxicology, Secondary Pharmacodynamic, and Safety Pharmacology sections of the NCO, Co-Protocol Elements, Investigational Brochure
- Input on toxicology strategy and program feasibility based on results from nonclinical studies and data
- Oversight, creation and review of departmental SOPs as well as the qualification of CROs for utilization in GLP study outsourcing

Instem Jun 2018 - Feb 2021
Senior Information Scientist

- Responsible for the oversight, conversion and review of nonclinical Toxicology and Safety Pharmacology data into SEND datasets and for the review/interpretation of data in created SEND datasets for various sponsor submission packages to the FDA, including but not limited to compliance for all regulatory standards/policies (SENDIG, TCG, CoDEx, CDER, CBER, etc.)
- Interpretation of study reports and study data to accurately populate datasets that will align with sponsor submission packages and support the assessment of the safety of test articles
- Experience with countless number of study designs that utilize all nonclinical species, all nonclinical dose routes and all study endpoints
- Active participation and representation on CDISC Core Team and CDISC Safety Pharm Subteams which develops, implements and reviews industry wide standards for SEND datasets and packages
- Team Leader of several process development and implementation projects, including Safety Pharmacology conversions into SEND datasets in response to new SEND IGs, full revamp of all work instructions and related processes, and client projects of up to 400 dataset conversions

- Trainer and mentor in dataset conversions, dataset reviews, use of all systems, use of all Microsoft Office applications, professional and industry development, and data collection methods and analysis
- Vast experience in communication with clients/companies worldwide, allowing for advanced knowledge of numerous nonclinical data collection processes, data reporting types, and nonclinical data collection systems

Pfizer, Inc. May 2012 - Jun 2018

In Vivo Study Scientist

- Complete oversight and execution of nonGLP and GLP Toxicology, Safety Pharmacology and DART studies from pre-planning to reporting
- In vivo execution of nonGLP and GLP Toxicology, Safety Pharmacology and DART studies in various species (mouse, rat, dog, rabbit, monkey) including dosing (oral gavage, subcutaneous, intravenous, intraperitoneal, intramuscular), blood collection (central ear artery, saphenous vein, femoral vein, jugular vein, tail vein, sublingual vein, brachial vein, cardiac puncture, abdominal aorta, vena cava), euthanasia (drug- induced, gas-induced, exsanguination), necropsy, clinical sign observation and collection, bodyweight collection, food consumption collection, ophthalmic examination, telemetry acquisition (implanted and jacketed external telemetry), ECG collection (wired leads), interventions (alleviation of tremors, seizures, morbidity), vaginal smears, urine collection
- Execution of Toxicology, Safety Pharmacology and DART endpoints and their relation to the overall conduct and interpretation of the study (ADA, cytokines, immunophenotyping, FOBs, respiratory assessment, ECG/telemetry, ophthalmic examination, estrus cycle monitoring, clinical pathology, histopathology, Draize scoring)
- Input on study design, dose selection, study endpoints, study resourcing and schedule
- Oversight of data collection systems including protocol entry and management for main study data, cardiovascular data, and toxicokinetic data
- Review and authorship of protocols, amendments, deviations and reports
- Development, validation and implementation of in vivo methods to enhance animal welfare, data quality, and toxicology interpretation/findings (rabbit urine collection to assess stress biomarkers; pre- and post-dose flush system for intravenous dosing to minimize unnecessary test article related effects at the injection site)
- Authorship and review of departmental SOPs for the conduct of nonGLP and GLP Toxicology, Safety Pharmacology and DART studies
- Presentation of data and/or methodologies to team leaders and executives to properly relay effectiveness in evaluation of toxicity and test article related effects
- Trainer of all in vivo skills utilized in nonclinical studies in support of the assessment of the safety of test articles

PUBLICATIONS

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.*

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

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