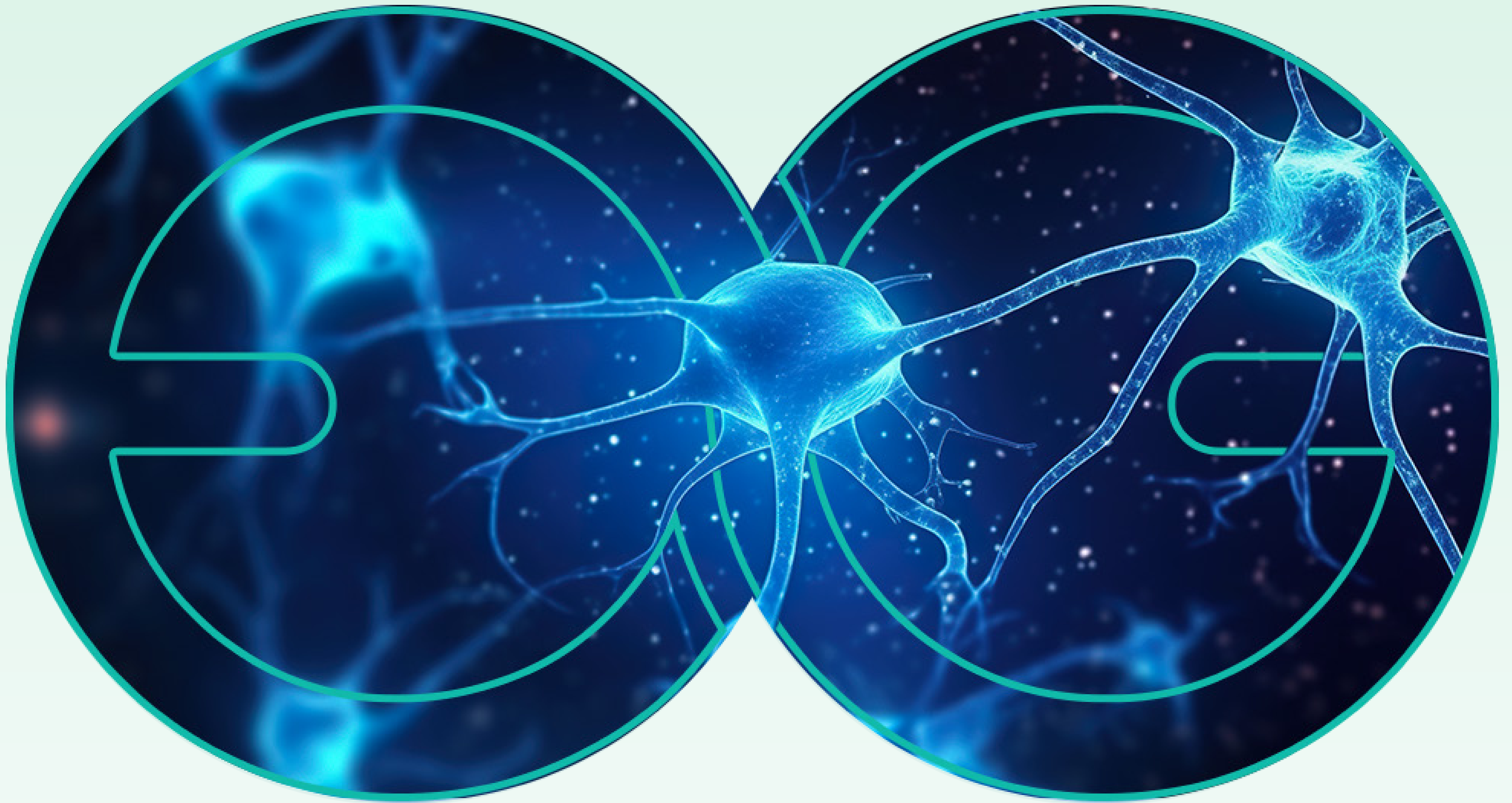




ADVANCING PATIENT SAFETY

Through Developmental Neurotoxicity & Neuropathology Expertise

Background

A Europe-based chemical company partnered with Veeda Lifesciences to conduct an Extended One-Generation Reproductive Toxicity (EOGRT) Study in rats, integrated with comprehensive neuropathology assessment in accordance with OECD 443 guidelines.

The study was designed to support regulatory safety evaluation for a chemical entity with a focus on developmental neurotoxicity (DNT) risk assessment and neuropathological evaluation.

Regulatory Context

Developmental neurotoxicity is a critical component of nonclinical safety assessment, as exposure to certain chemicals and xenobiotics has been associated with developmental and neurological disorders in children.

Global regulatory agencies require developmental neurotoxicity evaluation as part of the safety package for new chemical entities and industrial chemicals. Depending on the study design and regulatory requirements, DNT assessments may be conducted as:

- Standalone studies
- Integrated reproductive toxicity studies
- Adult neurotoxicity studies
- Prenatal developmental toxicity studies

Neuropathology assessment plays a vital role in identifying structural and microscopic changes within the nervous system through:

- Multi-level brain sectioning
- Evaluation of anatomically sensitive brain regions
- Morphometric analysis of specific neural structures
- Detection of neurotoxicant-induced alterations

Project Scope

- Extended One-Generation Reproductive Toxicity Study (EOGRT) in rats
- Neuropathology assessment in Cohort 2
- GLP-compliant study execution aligned with OECD 443 guidelines
- Histopathological and morphometric evaluation of brain tissues
- Preparation of regulatory-ready study documentation

Challenges

Study Design & Execution

- | Complex study design and cohort management
- | Specialized neuropathology expertise
- | Precise brain sectioning across multiple anatomical levels
- | Detailed morphometric and histopathological evaluation
- | Strict adherence to GLP and OECD regulatory expectations



Veeda Lifesciences' Solution

Veeda Lifesciences leveraged its experienced reproductive toxicology and pathology teams to successfully execute the EOGRT study and integrated neuropathology evaluation.

The study included:

- GLP-compliant reproductive toxicity assessment
- Comprehensive neuropathology evaluation across multiple brain regions
- Detailed microscopic examination and morphometric analysis
- Regulatory-aligned documentation and reporting

Our expert pathologists ensured high-quality interpretation of neuropathological findings while maintaining compliance with international regulatory standards.

Outcome

- Successful completion of the EOGRT study with integrated neuropathology assessment
- GLP-compliant neuropathology evaluation delivered within regulatory timelines
- Regulatory-ready reports submitted to European regulatory authorities
- Supported the sponsor's nonclinical safety evaluation requirements



Scientific Highlights

- Expertise in developmental neurotoxicity assessment
- Integrated reproductive toxicology and neuropathology capabilities
- GLP-compliant nonclinical safety studies
- Advanced histopathological and morphometric evaluation expertise
- Strong regulatory alignment with OECD guidelines

Key Guidelines & References

- Grandjean P, Landrigan PJ. *Developmental neurotoxicity of industrial chemicals*. The Lancet. 2006; 368(9553):2167–2178.
- OECD TG 416: Two-Generation Reproduction Toxicity Study
- OECD TG 424: Neurotoxicity Study in Rodents
- OECD TG 426: Developmental Neurotoxicity Study
- OECD TG 443: Extended One-Generation Reproductive Toxicity Study



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