Frontage has a highly comprehensive range of services supporting customers' drug-development programs beyond IND and into NDA-enabling toxicology studies.

Regulated preclinical developmental and reproductive toxicity (DART) studies using mammalian research models are an important step to take before initiating clinical trials. These studies provide important information regarding the effects of drug exposures prior to and during parental mating, as well as evaluating maternal and fetal changes during gestation and identifying any alterations in the development of the offspring following birth.

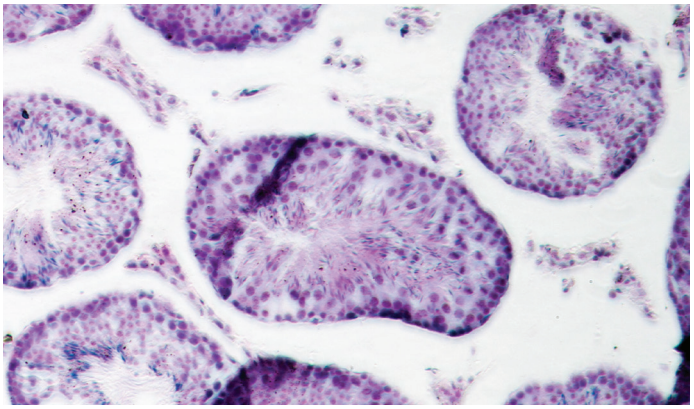
Scientists with Focused DART Expertise

Conducting DART studies is a more complex process than standard toxicology studies, which is why having the right expertise is key for successful studies. Frontage's scientists have over 20 years of experience running DART studies with knowledge of accurately estimating test doses, showing formulation stability, and expertise in animal handling. Our labs have the extensive capacity to run many studies, helping our sponsors meet their timelines with uncompromising quality.

Study Types

Frontage has the capability to run the following studies following the ICH S5 (R3) Guideline:

- Fertility and Early Embryonic Development (FEED) Study: Evaluates the effects on mating, estrous cyclicity, spermatogenesis, and ability to produce a viable implant. Sperm count, motility, and morphology are assessed with a Hamilton-Thorne Analyzer.
- Embryofetal Development (EFD) Study: Demonstrates the effects of gestational exposure on the pregnant female and the developing fetus during the organogenesis period.
- Pre- and Post-natal (PPND) Study: Quantifies the effect of gestational and lactational maternal exposure on embryonic development, the process of parturition, and the development of the offspring.
- Single- and multi-generation studies are also available.



The typical species for DART studies include rats and rabbits via multiple routes of administration.

Advantages of Choosing Frontage

- Comprehensive toxicology services
- AAALAC-accredited for commitment to animal welfare
- Specialized regulatory and scientific expertise in toxicology
- Speed and flexibility
- Access to historical data
- Exceptional bioanalytical support for small molecules, large molecules and biomarkers

Supporting Services

- Chronic toxicity
- Investigative toxicology
- Neurotoxicity
- Carcinogenicity studies (routine and transgenic)
- In-house histology, diagnostic pathology, clinical pathology and analytical chemistry services

THE FRONTAGE COMMITMENT

For many sponsors who rely on service partners to help develop and commercialize their products, good science is not enough. For more than 20 years, Frontage has earned a reputation for collaboration, responsiveness and the ability to customize services and deliverables that are aligned with the needs of our clients.

Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, science-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of molecules through development and file regulatory submissions in the United States, China, and other countries.

FOR MORE INFORMATION, CONTACT US AT: *sales@frontagelab.com* **OR VISIT US AT:** *frontagelab.com*