intox
an aragen company

aragen

Comprehensive, GLP Compliant Developmental and Reproductive Toxicology (DART) Studies

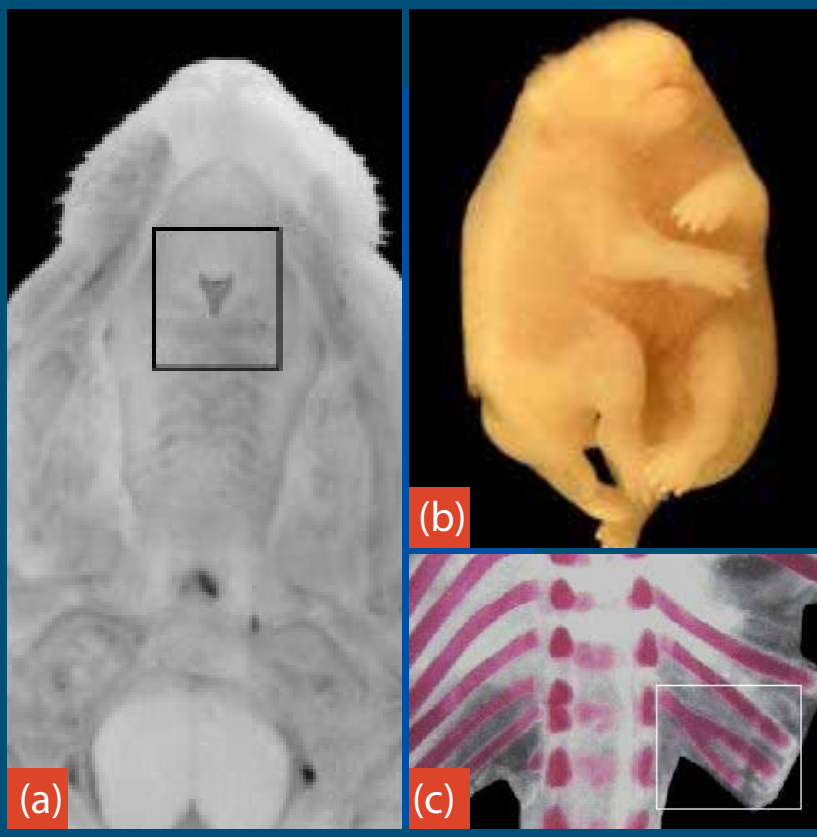
Focused expertise in conducting DART and specialized reproductive toxicology studies supported by immaculate bioanalytical capabilities for small and large molecule pharmaceuticals, including vaccines and biomarkers.

Developmental and reproductive toxicology studies (DART) are an essential part of the non-clinical dossier for a regulatory submission.

Intox, a subsidiary of Aragen Life Science, offers an extensive range of services in developmental and reproductive toxicology (DART) to advance your candidate products. Our expertise encompasses in-depth investigations in to the adverse effects of test items on various aspects of fertility, early embryonic development, embryo-fetal development and pre/postnatal development .

For such studies, we also specialize in conducting advanced assessments such as neurotoxicity, endocrine toxicity and immunotoxicity to provide in-depth insights into the induced effects.

We offer studies on rodent and nonrodent species, employing routes of administration such as oral (gavage/ dietary admixture), parenteral, topical and inhalation. Our well equipped laboratory facilities and experienced Study Directors are supported by our team of expert regulatory toxicologists.



(a) Fissure of Palate (b) Congenital Twins (c) Branched Ribs

DART Studies Offered at Intox

- Preliminary dose range finding studies
- Fertility and early embryonic development studies in Rats (FEED/Segment I).
- Embryo fetal developmental toxicity studies in Rats/Rabbits (EFD/Teratology/ Segment II).
- Pre and postnatal developmental toxicity studies in Rats (PPND/Segment III); Multi-generation studies.
- Combined repeated dose toxicity studies with the reproduction/developmental toxicity screening test in Rats.
- Extended one-generation reproductive toxicity study in Rat.

DART for Vaccines

- Pre and postnatal developmental toxicity studies on vaccine candidates, including mRNA/DNA vaccines.
- Biodistribution studies.
- Immunogenicity studies – humoral & cell mediated immunity.

Comprehensive Historical Control Data with Long Experience of Testing

Small / large Molecule Pharmaceuticals, Vaccines, Cell based therapies, Industrial chemicals, Pesticides, Nutraceuticals/Herbal Extracts, Medical devices

Testing programs are designed to support applications as per the requirements of

INDIA:

- CDSCO (Pharma/Biotech, Devices)
- CIB (Pesticides)

INTERNATIONAL:

- US–FDA, US-EPA
- EMA, UK, Australia, Japan
- OECD, EFSA, Redbook 2000, ICH, ISO
- WHO

Reporting time (including range finding studies, if any) for DART studies:

Fertility and early embryonic development study in Rats (Segment I)	5-6 Months
Embryo fetal developmental toxicity (Teratology) studies in Rats/Rabbits (Segment II)	4-6 Months (Rat) and 10-12 Months (Rabbit)
Pre and postnatal developmental toxicity studies in Rats (Segment III)	15-18 Months
Reproductive/Developmental toxicity screening test (OECD 421/422)	5-6 Months
Extended one generation reproductive toxicity/ Two generation reproductive toxicity studies	15-18 Months

Well Established Protocols for Single and Double Staining for Skeletal Evaluations

Single Staining
(Alizarin Red S)

Double Staining
(Alizarin Red S and Alcian Blue):

Enhanced Capabilities: High-Resolution Sperm Motility and Morphology Analysis through SMAS system

Sperm Motility and Morphology Analysis (SMAS) System is an advanced CASA System for precise sperm studies. With its user-friendly interface, high-resolution analysis, and an innovative sperm identification algorithm, SMAS accurately measures motility, morphology, and concentration of sperms. Equipped with a 5-megapixel camera, it eliminates measurement errors during semen examination, offering a remarkable edge in assessing spermatozoa.

Case Studies of performing DART studies on vaccines and other molecules:

Study Title	Guideline Followed
Prenatal and Postnatal Developmental Toxicity Study in Rats with Assessment of Immunogenicity and Bio-distribution (Covid DNA Vaccine)	WHO Technical Report Series, No. 927, 2005
Prenatal and Postnatal Developmental Toxicity Study in Rat (TdaP2 Vaccine)	WHO Technical Report Series, No. 927, 2005
Prenatal Developmental Toxicity Rabies Vaccine (inactivated); H1N1 inactivated / attenuated Vaccine	OECD/ICH/WHO
Prenatal Developmental Toxicity of EX-Vivo cultured human mesenchymal stem cell in Rat	OECD/ICH/WHO
Reproduction / Developmental Toxicity Screening Test of an implantable medical device	OECD No. 421, ISO10993-Part 3 and ISO10993 Part 12

About Intox:

Intox Pvt Ltd. is a subsidiary of Aragen Life Sciences, a leading R&D and manufacturing solutions provider, for the global life sciences industries offering integrated or standalone solutions for small and large molecules. Its OECD GLP-certified and AAALAC-accredited test facility has conducted over 17,000 GLP studies and has a successful track record of data submission to global regulatory authorities in USA, Canada, EU, UK, Brazil, Argentina, Japan, India, Australia, and China.

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