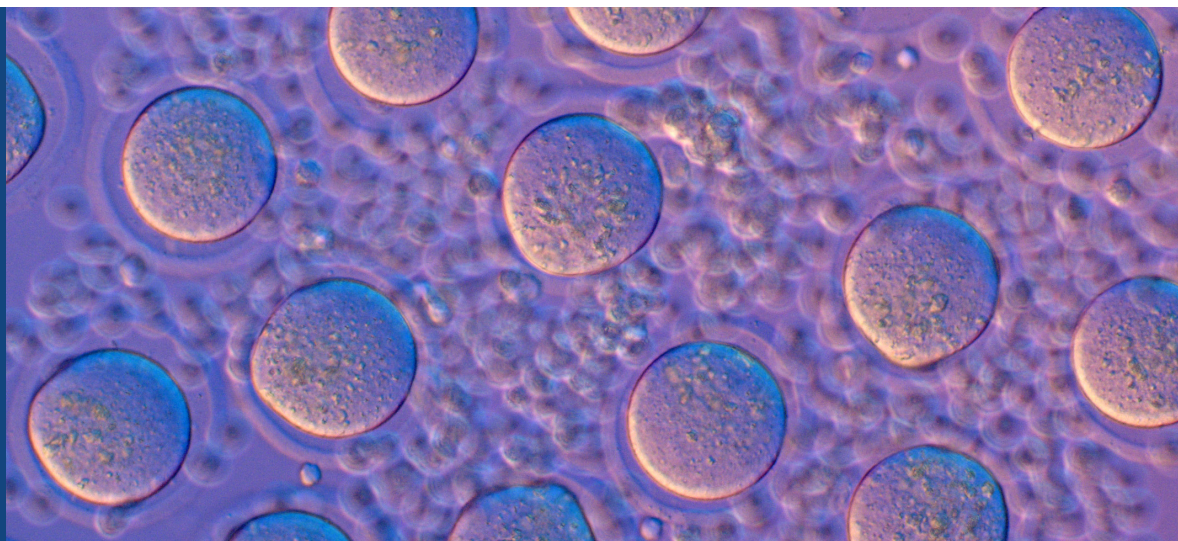


## Summary

Charles River can incorporate a range of specialized functional evaluations into DART study designs to maximize the data generated. All studies are supported by our own laboratory and regulatory experts.



SAFETY ASSESSMENT

# Specialty Endpoints in Developmental and Reproductive Toxicology

Charles River offers overall [developmental and reproductive toxicology](#) (DART) program planning and individual study design to conduct product safety assessments according to internationally recognized guidelines, including ICH and OECD.

We conduct male and female fertility, developmental toxicity (embryo-fetal development), pre- and postnatal development and multigenerational studies to assess the potential effects of novel products on the entire reproductive spectrum. Our expertise includes pharmaceuticals (including vaccines, biopharmaceuticals, veterinary and medical devices), agrochemicals, industrial chemicals and food additives.

We offer an extensive range of specialized endpoints to evaluate the effects on all organ systems, as well as reproductive functionality and skeletal growth.

## Behavioral Endpoints

Observing a model's behavior can provide valuable information to enhance and support more objective chemical and biological data. In addition to functional observational battery (FOB) testing, we perform assessments of pre- and post-weaning behavior, learning and memory, startle habituation and locomotor activity and can evaluate a complete set of physical, sensory and reflexological endpoints.

EVERY STEP OF THE WAY

## Reproductive Endpoints

Reproductive endpoints provide data on a product's impact on a subject's fertility, reproductive anatomy and function. We provide a range of endpoints to suit the unique aspects of male and female reproductive organs and systems.

### Male

- Sperm count/concentration
- Viability and motility
- Sperm morphology
- Spermatid count
- Histopathological evaluation and staging of the testes
- LH, FSH, testosterone, and inhibin hormones
- Preputial separation

### Female

- Estrous cycling/vaginal cytology
- Reproductive senescence
- Oocyte counts
- Estradiol, LH, FSH, progesterone and prolactin hormones
- Vaginal opening

In addition, our IRFM-accredited staff morphologists offer complete fetal examinations for the assessment of external features, fresh and frozen sections of viscera and skeletal structure.

## Biological Endpoints

Our integrated, multidisciplinary team provides focused expertise in immunology, metabolism, neurology, and endocrinology, further enriching studies with comprehensive biological data. Our tiered immunology assessments collect basic hematology, organ weights and immunohistopathology endpoints, as well as advanced phenotyping and antibody and NK cell response data. In addition to *in vivo* and *in vitro* endocrine disruptor screening assays, we can perform a complete assessment of thyroid hormone function using T3, T4, and TSH assays. We are also able to perform neuropathology and specialized reproductive pathology testing as well as skeletal densitometry and histomorphometry.

## Specialty Investigations

When required or desired, we can suggest and perform additional targeted assessments to extend a study's dataset.

- Critical window studies
- Nonrodent male reproductive assessments
- Gravid telemetry measurement
- Postnatal skeletal development
- Cross-fostering studies
- Mechanistic studies
- Semen transfer