

Course Objective

This course, held annually, will provide attendees with a foundation of developmental and reproductive biology and its practical applications for safety assessment. Attendees will gain a solid understanding of the principles and methodologies used in nonclinical safety assessments across a variety of industries (i.e., pharmaceuticals, food additives, pesticides, and industrial chemicals).

Course Description

This hybrid course includes a 3-day foundational component conducted in a virtual setting and a 2-day, in-person case study-based component. The in-person content will be rotated annually, with an emphasis on either pharmaceutical drug development or pesticide and industrial chemical development/registration in alternating years. Course content will be refreshed and revitalized as needed to reflect new developments and technologies.

Specific topics covered during the virtual course modules include history of DART and an introduction to DART testing, embryology and comparative organ system development, male and female reproductive physiology, fertility and reproduction, embryo/fetal development and fetal morphology, postnatal development, developmental immunotoxicity and neurotoxicity, NAMs, dose formulation considerations, and study conduct and monitoring.

Topics covered in the 2026 in-person module focus on pharmaceutical drug development include study timing, species and route selection, strategies for small molecules, biologics, and new modalities, pediatric plans (including weight-of-evidence approaches), impact of DART data on clinical programs, contraception, global labelling, and post-marketing surveillance. In addition, vaccine development, novel routes of administration, and TK, PK, ADME, and related approaches will be discussed with case studies and interactive breakout group exercises.

In fall 2027, the in-person module will focus on pesticide and industrial chemical development, including global registration and regulatory frameworks, hazard identification, and risk assessment.

Course Modules

Virtual Module 1

Friday, September 25, 2026
10:00 AM–3:00 PM ET

Virtual Module 2

Friday, October 2, 2026
10:00 AM–3:00 PM ET

Virtual Module 3

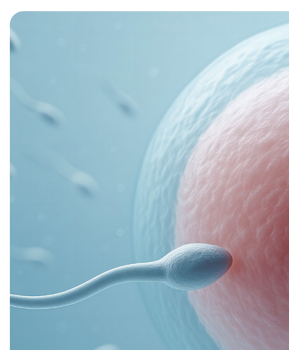
Friday, October 9, 2026
10:00 AM–3:30 PM ET

Access to the downloadable course materials and virtual module access information will be provided in advance.

Pharma-Focused In-Person Module 4

Thursday, October 15, 2026
7:30 AM–4:20 PM ET

Friday, October 16, 2026
7:30 AM–4:00 PM ET



Reproductive and Developmental Toxicology

for Industrial and Regulatory Scientists

An Interactive Hybrid Course

Three Foundational Modules (Live-Virtual)

September 25, October 2, and October 9, 2026

Pharma-Focused Module (In-Person)

October 15–16, 2026
Cambridge, MA

REGISTRATION OPEN

For more course information and registration, visit

www.birthdefectsresearch.org/rdt

Course Organizers

- Prägati S. Coder, *Co-Chair*, Charles River
- Kary E. Thompson, *Co-Chair*, Johnson & Johnson
- Christopher J. Bowman, Pfizer Inc.
- Bethany R. Hannas, Eli Lilly and Company
- Joshua F. Robinson, University of California, San Francisco
- Justin D. Vidal, Charles River
- Leah M. Zorrilla, Bayer Crop Science

Course Registration

Virtual Only (Modules 1–3)

Member	\$500.00
Member Group*	\$450.00
Nonmember	\$700.00
Nonmember Group*	\$630.00
Trainee**	\$200.00

Full Course (Modules 1–4)

Member	\$795.00
Member Group*	\$715.50
Nonmember	\$995.00
Nonmember Group*	\$895.50
Trainee**	\$500.00

*Three or more individuals from the same organization who register together with a single payment.

**A letter of verification from a Major Professor, Program Director, or Department Chair must accompany trainee registration.

Cancellation Policy

A written request for cancellation must be received by BDRP Headquarters no later than August 28, 2026. The registration fee will be refunded less a \$75 processing fee. No refunds will be issued after August 28, 2026. BDRP reserves the right to cancel the course, in which case all registrants will receive a full refund.

Questions and Special Accommodations

If you have any questions or require special accommodations, please contact Becca Isakower at becca@bdrp.org.

Visit www.birthdefectsresearch.org/courses-webinars-lectures.asp
for updated course information and registration.



2026 AGENDA

Agenda subject to change.

Live-Virtual Module 1

Live-Virtual Module 2

Live-Virtual Module 3

Friday, September 25, 2026
10:00 AM to 3:00 PM ET

- **Welcome and Introductions**
 - Kary E. Thompson, *Johnson & Johnson*
- **History of DART Testing**
 - Robert M. Cabrera, *Baylor College of Medicine*
- **Introduction to DART Testing**
 - Bethany R. Hannas, *Eli Lilly and Company*
- **Embryology and Abnormal Development**
 - Robert M. Cabrera, *Baylor College of Medicine*
- **Female Reproductive System**
 - Justin D. Vidal, *Charles River*
- **Male Reproductive System**
 - Justin D. Vidal, *Charles River*
- **Module 1 Panel Q&A and Wrap-Up**
 - Kary E. Thompson, *Johnson & Johnson*

Friday, October 2, 2026
10:00 AM to 3:00 PM ET

- **Welcome Back**
 - Prägati S. Coder, *Charles River*
- **Fertility and Reproduction**
 - Kristen A. Roosa-Beck, *Merck & Co., Inc.*
- **Estrous and Sperm Evaluation**
 - Prägati S. Coder, *Charles River*
- **Embryo/Fetal (Prenatal) Development**
 - Sara T. Humes, *Charles River*
- **Fetal Morphology**
 - Natasha Catlin, *Pfizer, Inc.*
- **Pre/Postnatal Development**
 - Curtis E. Grace, *Merck*
- **Neurobehavioral Assessments**
 - LaRonda L. Morford, *Eli Lilly and Company*
- **Module 2 Panel Q&A and Wrap-Up**
 - Prägati S. Coder, *Charles River*

Friday, October 9, 2026
10:00 AM to 3:30 PM ET

- **Welcome Back**
 - Prägati S. Coder, *Charles River*
- **Comparative Organ System Development: Pre/Postnatal Developmental**
 - Steven J. Van Cruchten, *Antwerp University*
- **Juvenile Toxicity Studies**
 - Elise M. Lewis, *Charles River*
- **Placental Transfer, Prewaning, Weaning, and Lactational Exposures**
 - Ellen A. Cannady, *Eli Lilly and Company*
- **Developmental Immunotoxicity**
 - Jamie C. DeWitt, *Oregon State University*
- **Developmental Neurotoxicity**
 - Brad Bolon, *GEMpath, Inc.*
- **Study Formulation Considerations**
 - Bryan Fennell, *Charles River*
- **Study Conduct and Monitoring**
 - Teresita A. Olitan, *TAO DART Consulting*
- **Module 3 Panel Q&A and Wrap-Up**
 - Kary E. Thompson, *Johnson & Johnson*

Pharma-Focused In-Person Module 4

Thursday, October 15, 2026 | 7:30 AM to 4:20 PM ET

- **Introduction to In-Person Course**
 - Kary E. Thompson, *Johnson & Johnson*
- **DART Guidance: ICH S5(R3) and M3(R2)**
 - Bethany R. Hannas, *Eli Lilly and Company*
- **Case Study 1 and Exercise 1**
- **DART Guidance: ICH S11**
 - Sarah Campion, *Pfizer, Inc.*
- **Case Study 2 and Exercise 2**
- **Influence of DART Data on Clinical Programs**
 - Katie J. Turner, *Johnson & Johnson*
- **Contraception**
 - Natasha Catlin, *Pfizer, Inc.*
- **Global Labelling and Post-Marketing Surveillance**
 - Tacey E.K. White, *Tacey White Toxicology Consulting, LLC*
- **Case Study 3 and Exercise 3**
- **DART Safety Assessments of Vaccines**
 - Christopher J. Bowman, *Pfizer, Inc.*
- **New Approach Methodologies (NAMs) for DART**
 - Joshua F. Robinson, *University of California, San Francisco*
- **Wrap-Up**
 - Prägati S. Coder, *Charles River*

Friday, October 16, 2026 | 7:30 AM to 4:00 PM ET

- **Welcome Back**
 - Prägati S. Coder, *Charles River*
- **DART Guidance: ICH S6**
 - Wendy Halpern, *Genentech*
- **Case Study 4 and Exercise 4**
- **DART Guidance: ICHS9**
 - Chris Sheth, *Aclairo Pharmaceutical Development Group, Inc.*
- **Case Study 5 and Exercise 5**
- **Considerations for Oligonucleotide-Based Therapeutics**
 - Ron Wange, *Aclairo Pharmaceutical Development Group, Inc.*
- **DART Guidance: ICH S12**
 - Rachel Goldsmith, *Madrigal Pharmaceuticals*
- **New/Novel Routes of Administration**
 - Stefania Cinquino, *Charles River*
- **Case Study 6 and Exercise 6**
- **Pharma-Focused Course Wrap-Up**
 - Kary E. Thompson, *Johnson & Johnson*

The in-person module will take place at Kendall Square in Cambridge, MA. Daily continental breakfast and lunch included.

Join Us in Fall 2027 for the In-Person Chemicals Focused Module