News from CARE Research, LLC

Combining Compassion and Quality

Pre-clinical Expertise

Efficient | Accurate | Responsive

Jan-Feb 2013

Message from the President

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As we kick off 2013 at CARE we look forward to continuing to provide our clients with the high quality service and expertise they have become accustomed to expect from us. In addition to our competence in conducting IND and NDA enabling studies, we also offer comprehensive Developmental and Reproductive Toxicology (DART) services. CARE's close association with Colorado Histo-Prep (CHP), our sister company with in-house hematology, clinical chemistry and statistical analyses capabilities assures that we are able to accelerate project timelines. CHP recently expanded its services by adding tissue culturing capabilities.

In February, I will be participating in a Polio re-vaccination program for children in India through the Rotary International organization. PolioPlus is recognized worldwide as a model of public-private cooperation in pursuit of a humanitarian goal. In addition, CARE & CHP are sponsoring a 'Purple Pins Bowling' event on February 10th in conjunction with the Rotary Club of Fort Collins, CO. Please consider joining us to raise money to continue the battle to eradicate polio in the remaining 3 polio stricken countries in the world.

Sincerely,
Rajan Bawa, Ph.D
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President, Colorado Histo-Prep
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DART Expertise

CARE's Developmental and Reproductive Toxicology (DART) services provide clients with the highest level of expertise. These FDA mandated studies test the teratogenicity of New Chemical Entities (NCE) and are critical to assuring that the drug does not cause any birth defects in the developing fetuses or early termination of pregnancy.

These studies are typically conducted in rats and rabbits and are composed of 3 phases. The dose finding studies, followed by the developmental toxicity studies. Our highly trained staff manages each project efficiently with a primary point of responsibility.

(continue)

DART Expertise

About CARE

22 Acre Facility

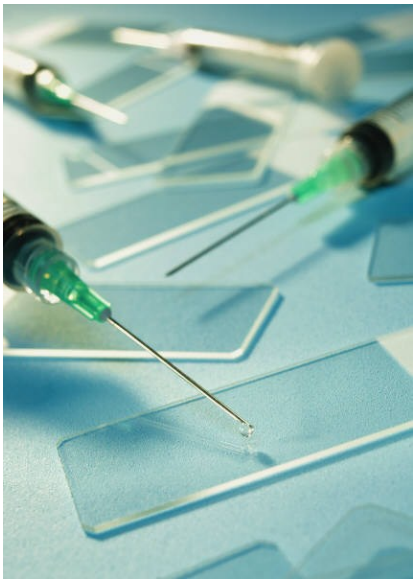
Acute & Chronic Toxicology

ADME Studies

Toxicology, Feed, Range Finding

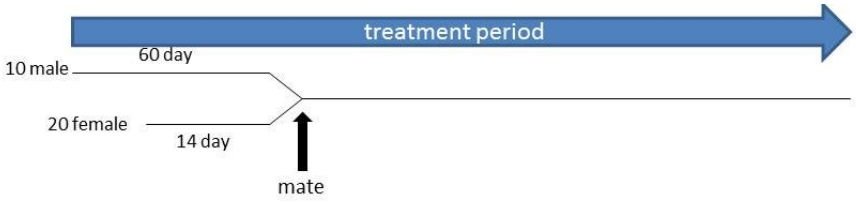
Multispecies TK & PK

Developmental & Reproductive Toxicology

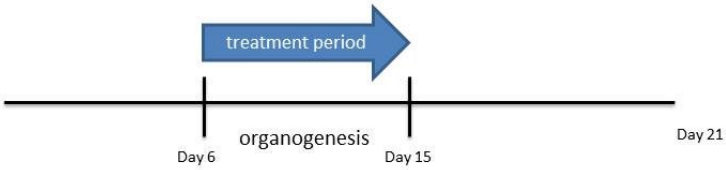


- Fertility and Early Embryonic Development (SEG I) studies detect toxic effects resulting from treatment before mating, through the mating and the implantation process.
- Embryofetal Development (SEG II) testing is designed to determine adverse effects on the development of the embryo and fetus by focusing on the identification of external, visceral and skeletal anomalies.
- SEG III studies are designed to evaluated adverse effects on Prenatal and Postnatal Development.

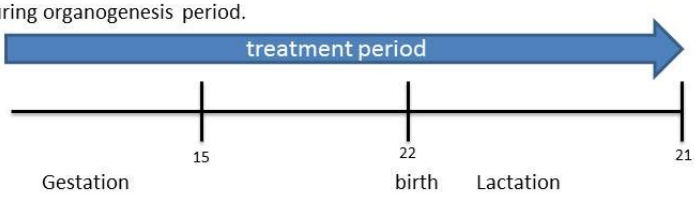
Click here for images of testing



Phase I. General fertility and reproductive performance. Measure of pre- and postimplatation death



Phase II. Teratology study basic design for mice. 20 insemminated females are treated during organogenesis period.



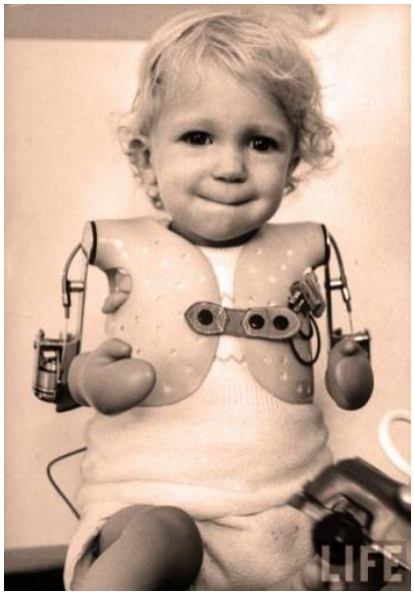
Phase III. Perinatal/postnatal studies.

Chart source: Pharmaceutical Intelligence

Why CARE?

- Complete FDA audit - No 483 issued with accolades to documentation and procedures
- Exceptional team with proven integrity and accountability
- Expertise in protocol development and regulatory guidance

The Thalidomide Tragedy



A hazard of not performing DART testing is exemplified by the sale of thalidomide that led to birth defects of a tragic and unprecedented nature in the 1950s.

Doctors in Europe first prescribed thalidomide in the late 1950s to treat anxiety, insomnia and, in pregnant women, morning sickness. It was marketed in Europe as well as in Japan, Australia and Canada. It was withdrawn from the market in the early 1960s when doctors learned that it caused devastating birth defects. About 10,000 children around the world were born with major malformations because their mothers had taken the drug during early pregnancy.

Until 1998, thalidomide was not approved in the United States. This was largely due to the skepticism of FDA medical officer Frances Kelsey, MD, PhD. Dr. Kelsey wanted proof that thalidomide was safe for humans, particularly for the embryo. By late 1961, the drug's unique ability to cause serious human malformations was becoming clear.

The worldwide thalidomide tragedy changed the way drugs are developed, tested and regulated in the United States, significantly broadening FDA authority. Dr. Kelsey often is credited with sealing the FDA's reputation as the world's premier authority on food and drug safety.

www.marchofdimes.com/pregnancy/alcohol_thalidomide.html

Tissue Culturing

COLORADO Histo-Prep

Integrating Histopathology
and
Clinical Pathology

Colorado Histo-Prep (CHP) recently expanded its services by adding tissue culturing capabilities. This equipment will enable us to offer cytotoxicity testing for drugs and devices. At CHP we are continually working to expand our services to provide a full range of preclinical research. This allows our sponsors to focus their point of contact to a single study director throughout the project at CHP/CARE versus placing the project at several different CROs with limited service offerings.

www.histoprep.com