

**SESSION OVERVIEW**

**Chair:** Dr. Linda Rhodes

**Speakers:** Dr. Judith-Samson French, Dr. Giovanna Massei, Elaine Lissner, Dr. Linda Rhodes, Dr. Julie Levy

**GETTING INVOLVED IN FIELD TESTING OF NON-SURGICAL STERILANTS:  
LESSONS LEARNED, AND WHAT ORGANIZATIONS AND VETERINARIANS SHOULD  
CONSIDER WHEN GETTING INVOLVED**

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The scope of current field trials with non-surgical sterilants and contraceptives is truly global, with projects currently taking place in Nepal, Northern Canada, Kenya, Oklahoma, Chile, and Mexico. (As defined in this session, “field trials” or “field testing” refers not to the final stage in getting a drug approved, but rather the use of products on an experimental basis in a field rather than laboratory setting.) Field testing can provide extraordinarily valuable information on a product. To achieve this outcome, however, significant care must be given to such factors as study design; expectations, regulations, and potential partners in the community where the study is taking place; and welfare and standards of care for animals taking part in the study.

This session, “Getting involved in field testing of non-surgical sterilants,” addressed these topics through presentations on studies in Canada and Nepal; a presentation on potential to field test the intra-testicular injection of a calcium chloride formulation in the U.S.; and presentations on study design, social, and welfare considerations that should be addressed in order to conduct scientifically valid and ethical research in a field setting.

Dr. Judith Samson-French presented “A trial with deslorelin in free-roaming female dogs on First Nations reserves.” The trial entailed administration of 141 Suprelorin® implants to free-roaming female dogs in First Nations communities in Alberta, Canada. The objective of the three-year study was to evaluate the efficacy of this 12 month contraceptive and improve the short lives of free-roaming dogs in these harsh conditions. In addition to assessing the reproductive outcomes of the implanted dogs, Dr. Samson-French also spoke to broader social and cultural considerations of conducting work among animals in underserved communities.

In “Testing GonaCon® for female dogs in Nepal: preliminary results,” Dr. Giovanna Massei presented results of a study in Sauraha, Nepal, to evaluate the efficacy of a single administration of the immunocontraceptive GonaCon-Canine in combination with rabies vaccine. Dr. Massei’s team conducted the study with support from local officials and Nepal’s preeminent veterinary school, and caretaker interviews suggested a desire for controlling reproduction. Soon after the dogs were treated, the team noticed severe injection site reactions in the overwhelming majority of animals, which were traced to the USDA accidentally shipping a *non*-canine-specific formulation of GonaCon to the study site. Dr. Massei focused much of her presentation on lessons learned from the error, including the need

to have community support prior to launching a field study. She also highlighted the need to have sufficient veterinary resources in place to provide affected animals with high-quality veterinary care and ensure their welfare, a contingency plan whose importance became very evident when this study had unexpected outcomes. (The affected dogs in this study have received treatment and recovered.)

Elaine Lissner, Director of the nonprofit Parsemus Foundation, presented “Could your organization use Calcium Chloride? Nuts and bolts.” She spoke about the potential of calcium chloride formulated for intra-testicular injection to serve as a safe, humane, and affordable injectable chemical sterilant for male dogs and cats. She has facilitated laboratory studies of calcium chloride formulations in both Italy and India, which have shown potential for calcium chloride to cause permanent sterilization with minimal observed discomfort. Parsemus Foundation is supporting this work because of it is not patentable, and therefore not attractive to for-profit groups to develop, and because it might potentially provide a low cost alternative to surgical castration, if it is inexpensively compounded. Ms. Lissner has applied to the Center for Veterinary Medicine to open an Investigational New Drug Application, which could pave the way for next steps including conducting field research.

Drs. Linda Rhodes and Julie Levy concluded the session with “What to consider when undertaking a field trial,” a presentation on the highlights of things to consider when designing a field trial. Dr. Rhodes advised on study protocol and detailed multiple key features of a well-conducted field study—beginning with the need to record every detail. (Study protocol basics are included in the online proceedings). Dr. Levy spoke on “Ethical and welfare considerations in field trials of products destined for underprivileged populations.” She prompted the audience to consider, among other issues, the need for and potential pitfalls of trialing products in developing countries, the standards of care with which research ought to be conducted, and the ways in which researchers can and should protect their subjects.