

Report from the International Workshop on Alternative Methods for *Leptospira* Vaccine Potency Testing

Background Material:

- Report on the international workshop on alternative methods for *Leptospira* vaccine potency testing: State of the science and the way forward. *Biologicals* in press
- Opportunities and strategies to further reduce animal use for *Leptospira* vaccine potency testing. *Biologicals* in press
- Webpage for Workshop on Alternatives for *Leptospira* Vaccine Testing

NICEATM and ICCVAM organized a September 2012 workshop on alternative methods for *Leptospira* vaccine potency testing. Workshop participants reviewed available alternative methods and defined efforts necessary to achieve their global acceptance and implementation. Specific actions were identified that should be taken by both regulators and industry to facilitate broader use of USDA-validated ELISA antigen quantification methods, which would replace animal use. Where use of the ELISA methods is not appropriate, approaches to reduce and refine animal use were identified, including serological assays, use of analgesics and humane endpoints, potential elimination of back-titrations for calculation of LD₅₀, and harmonization of regulatory requirements for the number of animals used for testing.