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Best Practices for Using Humane Endpoints and Tiered Testing Strategies to Refine, Reduce, and Replace Animal Use in Toxicological Research and Testing

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Animal care and use regulations, guidelines, and policies require consideration of alternatives prior to the use of animals for research and testing. Toxicology studies using animals should therefore incorporate methods and approaches consistent with study objectives that minimize the use of animals and that reduce or avoid potential pain and distress. Several new and recently revised regulatory testing guidelines for acute local and systemic toxicity now recommend the use of humane endpoints and tiered testing strategies. The guidelines allow for hazard identification to be accomplished in some situations with reduced or no animal use. This approach involves an initial review of all available relevant information and data on the test and related substances. If further information is needed, this is generated in a stepwise manner and may include determination of physical/chemical properties, structure-activity relationship evaluations, and *in vitro* studies. A weight-of-evidence evaluation is made at each stage to determine if there is sufficient information for determination of hazard or if additional data is needed. If animal studies are deemed necessary, the use of sequential testing can often reduce the total number required, especially for those chemicals causing severe effects. The establishment of humane endpoints prior to the initiation of animal studies can also provide a basis for appropriate interventions to reduce the severity and/or duration of pain and distress. This involves anticipating possible toxic effects and establishing appropriate criteria that can serve as the basis for ending a procedure before or when pain and distress become apparent. Appropriate consideration and incorporation of best practices in toxicology studies can be expected to refine, reduce, and/or replace animal use while supporting the attainment of study objectives.

SOT Itinerary Information:

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Session: Toxicological Research and Testing: Best Practices and Opportunities for Laboratory Animal Refinement, Reduction, and Replacement