



H E S I

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## Key Features of Testing Paradigm as Proposed by the HESI ACSA Technical Committee

### Base Set (Tier 1)

- Integrated approach to evaluating systemic toxicity including reproductive and life stage effects
- Pivotal 28-day rat study
- Dosing based on kinetics and physiology
- Evaluation of relative sensitivity of rat v. dog
- Full utilization of animals in each study via thorough analysis of clinical chemistry, histopath, etc.
- Reduces/refines animal usage
- Emphasis on effects of concern

### Tier 2:

- Testing focused on endpoints identified in Tier 1
- Flexible study designs
- Mechanistic data explored



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