

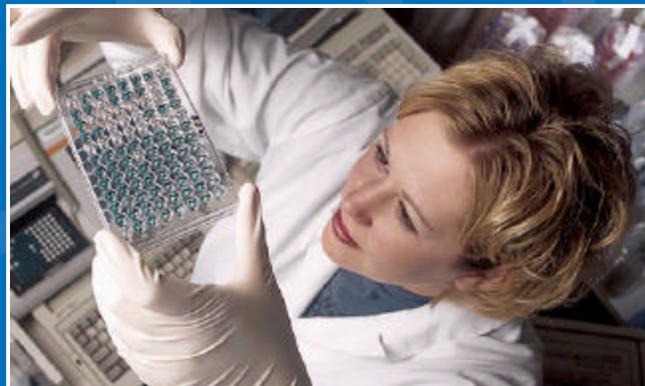


Guidance for Immunosuppression Risk Assessment

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Objectives

- Develop a framework for conducting risk assessments on immunological endpoints
- Inform risk assessors on the components and functions of the immune system
- Improve transparency and consistency of agency documents



Milestones

- 2004 Initiation of the project
- 2006 Review of draft guidance document
- 2007 “Nexus” workshop
- 2008 Revised draft to RAF
- 2008 Internal review
- 2009 External review
- 2010 Completion



Issues

- Biological vs. statistical significance
- Sensitive life stages/populations
- Gender differences
- Changes in humoral vs. cellular immunity
- Animal model data vs. epidemiological/clinical studies



Document Organization

1. Overview
2. Relationship between Immunosuppression and Adverse Effects
3. Problem Formulation
4. Hazard Characterization
5. Quantitative Dose-Response Analysis
6. Exposure Assessment
7. Risk Characterization
8. Appendix – Endpoints for Evaluating Systemic Immunosuppression in Humans and Test Species