

Advancing Safety Pharmacology for ICH S7A(R1): From Workshop Insights to Future Frameworks

*A 17-manuscript collection exploring the science, practice
and regulatory future of safety pharmacology*



WHY NOW? ICH S7A (2000) must adapt to a changing landscape including:

- New therapeutic modalities
- New technologies
- New approach methodologies (NAM)
- Evolving clinical expectations
- Global regulatory complexity

***What should come next for ICH S7A?
This collection provides insights and
answers***

FIVE PILLARS SHAPING S7A(R1)

01	WEIGHT OF EVIDENCE	How can a structured WoE approach improve consistency & transparency in safety pharmacology strategy?
02	SECONDARY PHARMACOLOGY	How should secondary pharmacology evolve across increasingly diverse therapeutic modalities?
03	SAFETY PHARMACOLOGY INTEGRATION IN TOXICOLOGY STUDIES	How can functional endpoints be integrated into toxicology studies to increase efficiency, safety value & interpretability?
04	NEW APPROACH METHODOLOGIES	Where can NAMs add value & what challenges must be addressed to enable confident use for safety pharmacology?
05	ADVERSITY	How can clearer definitions of adversity and NOAEL improve harmonization in safety pharmacology?

ONE COLLECTION. MANY PERSPECTIVES.

SCIENCE	CLINICAL	REGULATORY	INDUSTRY	CRO	NGO / 3Rs	STAKEHOLDERS
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Academia, industry, CROs, regulators, NGOs, and other stakeholders examine what has changed since the ICH S7A guideline was established, how safety pharmacology supports today's development decisions, where global expectations align, and what the community wants from the next generation of ICH S7A.

The conversation starts here: *Where have we been? Where are we now? What needs to change? What should S7A(R1) look like?*

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