Turner et al.:

Incorporating New Approach Methodologies into Regulatory Nonclinical Pharmaceutical Safety Assessment

Supplementary Data

Overarching category	Sub-categories
Advantages of NAMs	Predictive
	Regulatory confidence in some NAMs
	Insight into mechanisms
	Representation of human variability
	Human-relevant disease models
	Ability to conduct long-term studies
	Ability to do high-throughput screening
Factors discouraging uptake of NAMs	Cell quality and standardization issues
	Inability to represent whole organism or measure higher level endpoints
	Not tailored to regulatory needs
	Lack of clarity from regulators
	Some companies not yet sufficiently confident to jettison animal tests
	Benefits of NAMs not publicized
	Lack of reference data
	Cost
Factors likely to increase adoption of NAMs	Collaboration, especially with regulators
	Learn from other regulated sectors
	Use NAMs to assess developmental and reproductive toxicology
	Describe NAMs conducted in-house when making submission to regulators
	Rewording of ICH guidelines
	Use battery of tests
	Make NAMs commercially available
	Understand purpose of *in vivo* studies
	Bridging studies from animal to human

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