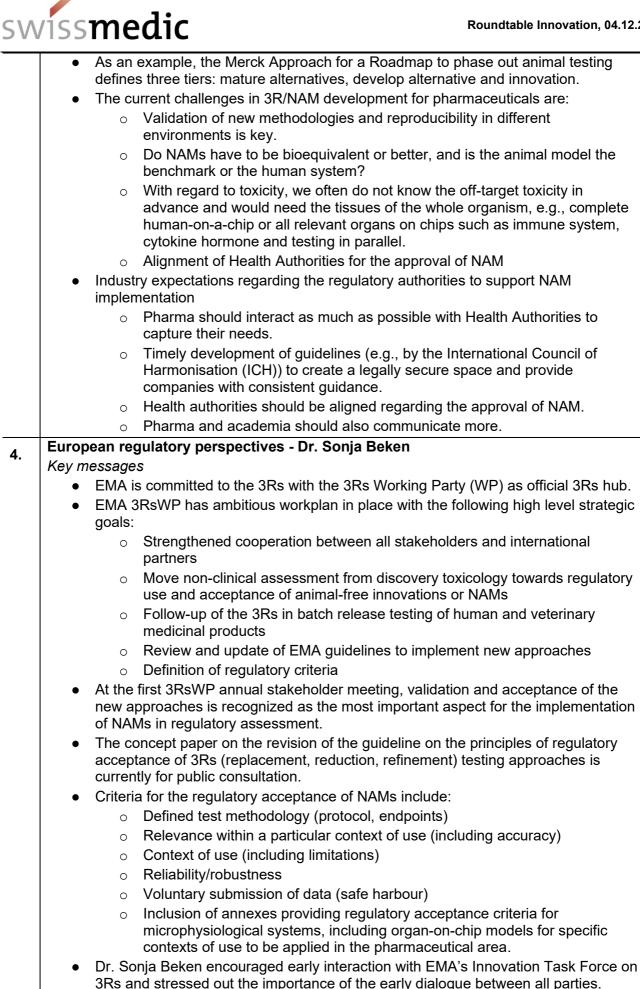


Summary Report

3rd Swissmedic Roundtable Innovation (RTI) 3R Regulatory Implementation: Status of New Approach Methodologies (NAMs) in Drug Safety

Monday, 04 December 2023 10.00 –12.00

1.	Welcome and Introductions
	• Dr. Elisabeth Klenke, Head Sector Authorisation a. i., Head Nonclinical Assessment
	& GLP Inspectorate, welcomes all participants on site as well as online.
	She briefly introduced the presenters:
	 Dr. Johannes Mosbacher from the School of Life Sciences, FHNW, to provide insight from academia perspective
	 Dr. Birgit Ledermann, 3R Leader of Novartis Biomedical Research representing the industry perspective, and
	 Dr. Sonja Beken, Chair of the EMA 3R Working Party as regulatory representative.
	 She encourages the participants to extent their network and interact.
	 One of the key questions to be addressed is to discuss the expectations regarding the regulatory authorities in general and from Swissmedic in particular with regard to support the implementation of NAM.
2.	Academic perspectives on NAMs in drug safety - Prof. Johannes Mosbacher
۷.	Key messages
	 Academia provides "enabling science" for NAMs, and is specifically in Switzerland well positioned to enable NAMs.
	 However, there is an inverse relationship between academic reward (for discovery and innovative models) and society needs (for validated, predictive models for routine use). This translational gap needs to be overcome.
	Steps to get academia into a productive NAM development include
	 Reward "implementation-inspired" research
	 Foster academia – manufacturer incubators
	 Define and ask concrete scientific questions
	 Advance in vitro and in silico NAMs together
	 Teach how to do NAM assay validation and quality control
	 Sensitize for risk assessment attitude
	 Keep such Roundtables for exchange with industry and authorities
3.	Industry perspectives - Dr. Birgit Ledermann
	Key messages
	 NAMs have been integrated into drug development and regulatory safety assessment for a long time and have led to a reduction of experimental animals.
	They are gaining scientific and regulatory acceptance.
	 Any non-animal method must be scientifically based. The new test must be
	validated that it adequately addresses the safety or efficacy questions that the animal test was previously used for.
	• The presentation includes the industry perspective in general as well as the current status of the 3R/NAM research related to the drug safety.





5.	Open discussion - Dr. Tatjana Petkovic (Moderation)
0.	Dr. Tatjana Petkovic outlined how Swissmedic is going to address questions with regard to NAMs. The agency follows the trends, supports the implementation of NAMs in drug
	development and assessment, and is currently establishing national and international
	networks.
	Various aspects concerning the implementation of NAMs in the drug development were
	discussed, including: Developing NAMs
	 Validation vs. qualification vs. standardisation: Terminology and requirements for regulatory acceptance should be clarified.
	Funding of method development (e.g., InnoSuisse)
	Definition the "gold standard" for each endpoint/system – animals or clinical data?
	Interaction between academia, industry and regulators Implementing NAMs
	 From industry perspective, early collaboration with regard to the build-up of new methods and the harmonization of the regulatory authorities is very important. Industry seeks the use of routine methods.
	 It is unlikely to replace one animal model with one NAM. A suite of assays will be required for regulatory decision.
	 NAMs are already used by industry for evaluation for drug safety when testing in animals is not an option or as part of a weight of evidence approach.
	All participants agreed that complete replacement of animal studies for drug testing within the next years is not realistic. However, there was consensus about the potential to reduce and refine of animal tests.
	Dr. Tatjana Petkovic closed the discussion round with the conclusion that collaboration between all parties and the harmonisation between regulatory agencies are important for the further steps in NAMs implementation. From the regulatory point of view, reliable methods are needed that support regulators in the decision-making process either for the license of the FIH trials or for the marketing authorization.
6.	Closing remarks and next steps – Dr. Elisabeth Klenke
	Dr. Elisabeth Klenke thanked the speakers for their presentations and all participants for the fruitful discussion. The roundtable clearly showed that sharing of information, harmonisation and collaboration are key to advance new approach methodologies. Communication to stakeholders and management of expectations regarding the capabilities of NAMs in context of drug development also play a pivotal role. Approaches focusing on "reduce" and "refine" may be a first step to improve animal research. A follow-up Roundtable Innovation is in planning for 2024/2025.