EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Non-clinical domain work plan: Priorities for 2024

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Priorities for 2024

1. Tactical goals: activities/projects to deliver the strategic goals

1.1. *Guideline activities*

1.1.1. ICH new/revision

NcWP in the lead

- Support to ICH Q3E guideline for extractables and leachables (E&L)
- ICH guideline on non-clinical safety studies for oligonucleotides-based therapeutics

1.1.2. Non-ICH new/revision

Joint NcWP 3RsWP activities

- Drafting of 'Reflection paper on the alternatives to the use of non-human primates (NHPs)'
- Revision of the guideline on non-clinical local tolerance testing of medicinal products EMA/CHMP/SWP/2145/2000

NcWP in the lead

- Finalisation of 'Guideline on environmental risk assessment (ERA) of medicinal products for human use' EMEA/CHMP/SWP/4447/00 (public consultation ended on 30 June 2019)
- Annex to guideline on 'Excipients in the labelling and package leaflet of medicines for human use': Finalisation of the 2 drafts information for the package leaflet: dextrans (EMA/CHMP/187129/2016) and lactose (EMA/CHMP/186428/2016) (public consultations ended on 31 May 2019) and revision of benzyl alcohol
- Finalisation of 'Guideline on the non-clinical requirements for radiopharmaceuticals' EMA/CHMP/SWP/686140/2018 (public consultation ended on 30 June 2019)
- Finalisation of 'Reflection paper on the qualification of non-genotoxic impurities' EMA/CHMP/SWP/545588/2017 (public consultation ended on 30 September 2019)
- Drafting of 'Reflection paper on lessons learnt from Covid19 about preclinical data for product development'
- Contribution to the revision of the guideline on the investigation of medicinal products in the term and preterm neonate EMEA/536810/2008
- Contribution to the revision of the guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling EMEA/CHMP/203927/2005
- Contribution to recommendation paper on GLP requirements for CTs for NC studies conducted in OECD non-MAD countries

For any 3Rs aspects in relation to the above guidance papers, the 3RsWP will be consulted for input and comments.

3RsWP in the lead

- Revision of 'Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs' EMA/CHMP/CVMP/3Rs/742466/2015
- Revision of 'Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs' EMA/CHMP/CVMP/3Rs/164002/2016
- Drafting of 'Concept paper on the revision of the Guideline on the principles of regulatory acceptance of 3Rs testing approaches' EMA/CHMP/CVMP/JEG-3Rs/450091/2012
- Revision of the 'Guideline on the principles of regulatory acceptance of 3Rs testing approaches' EMA/CHMP/CVMP/JEG-3Rs/450091/2012
- Contribute to the revision of the 'Guideline on user safety of topically administered veterinary medicinal products' EMA/CVMP/SWP/721059/2014
- Contribute to the revision of the 'Guideline on user safety for pharmaceutical veterinary medicinal products' EMA/CVMP/543/03-Rev.1

1.2. *Training activities*

Joint NcWP 3RsWP activities

- Develop network training activities for implementation of the Q&A ICH S7B

NcWP in the lead

- Contribute to the pre-clinical assessor meeting (PAM) in Ireland Q1 2024
- Develop training modules for implementing the new approaches for nitrosamine assessment (including CPCA and EAT)
- Develop training on the implementation of the revised environmental risk assessment (ERA) guideline and, if necessary, organise a workshop for industry on the revised guideline
- Develop courses on other topics prioritised for training by the NcWP

3RsWP in the lead

- Develop training activities on 3Rs methods and best 3Rs practices across the EU network to promote their regulatory acceptance, as stated in the RSS 2025

1.3. *Communication and Stakeholder activities*

1.3.1. European level

NcWP in the lead

- Organise the annual Non-clinical WP stakeholders meeting
- Organise brainstorming sessions on emerging non-clinical topics with EFPIA in the margins of the annual pre-clinical assessors meeting
- Co-operation with the EU institutions and agencies on non-clinical safety issues

- Organise 2-3 meetings per year with interested parties on nitrosamines
- Retrospective review of the regulatory efficiency of the WoE approach in ICH S11

3RsWP in the lead

- Organise annual 3RsWP brainstorming sessions on emerging 3Rs topics with interested parties and relevant 3Rs stakeholders
- Publish biennial report on the application of the 3Rs in regulatory testing of medicinal products
- Establishment of an accessible database of qualified/validated NAMs (in collaboration with JRC and EDQM)
- Investigation of potential actions related to alternatives to the development and production of animal-derived antibodies
- Brainstorming on best practices for the application of 3Rs principles in models used for the demonstration of primary pharmacology (including animal models of disease)

1.3.2. International level

Joint NcWP 3RsWP activities

- Collaboration with relevant stakeholders on opportunities for use of a single species in regulatory safety studies

NcWP in the lead

- EMA-FDA Non-clinical Oncology cluster (3 meetings per year)
- EMA-FDA paediatric medicines cluster (support for NC safety issues)
- Co-operation with international regulators on nitrosamines, including contribution to ICH discussions on potential harmonisation activities
- Strengthening of global approach in paediatric non-clinical requirements through FDA and Swissmedic participation to NcWP meetings and sharing outcomes of PIP/SA assessments

3RsWP in the lead

- Creation of a worldwide cluster of regulators to establish regulatory acceptance criteria for new approach methodologies (3Rs, e.g. organ-on-chips) and to harmonise views and acceptance criteria between the EU and worldwide NCAs
- Mapping of current and future co-operations with European and international stakeholders involved in fostering new approach methodologies (3Rs)
- Collaborate with relevant international stakeholders to investigate batch testing requirements for human and veterinary vaccines with regards to the application of the 3Rs

1.4. *Multidisciplinary collaboration*

NcWP in the lead

- Collaborate with the veterinary ERA WP, in particular with regard to interactions with the European Commission where EMA/network input is required, e.g. PIE strategic approach, review of watchlists under water framework directive etc.
- Collaborate with the Quality domain for activities related to the safety evaluation of impurities and excipients
- Collaborate with SAWP and PDCO for selection of PIPs and SAs that require assessment
- Collaborate with CTCG regarding harmonisation of non-clinical, 3Rs and GLP-related recommendations
- Foster collaboration on non-clinical issues with the Committee for Advanced Therapies (CAT)

3RsWP in the lead

- Collaborate with the veterinary domain and the human quality domain for the review of product batch testing requirements with regards to the application of the 3Rs in batch release testing of human vaccines and biotechnology-derived pharmaceuticals (including botulinum-neurotoxin containing products), and veterinary vaccines and biological medicinal products
- With respect to modelling and simulation, foster collaboration with the Methodology domain to support the integration of methods adhering to the 3Rs principle in the regulatory framework
- Collaborate with the veterinary safety working party (SWP-V) on topics relevant to 3Rs
- Contribute to a working group to examine practical implications of the application of Section I.1.7 of Annex II to Regulation (EU) 2019/6 (on veterinary medicinal products) in collaboration with CVMP and CMDv

2. Operational goals: medicinal product-specific activities

2.1. *Pre-Authorisation activities*

2.1.1. Support to SAWP

- Support to Scientific Advice and Protocol Assistance procedures on paediatric, general non-clinical safety issues and on 3Rs-related matters

NcWP in the lead

- Support to the implementation of the ICH S1B(R1) addendum via Scientific Advice procedures and participation to the ICH S1B(R1) implementation working group

3RsWP in the lead

- Support to the qualification advice/opinion for new approach methodologies (3Rs) procedure

2.1.2. Support to PDCO

NcWP in the lead

- Support to PDCO for PIPs evaluations on paediatric non-clinical requirements

2.1.3. Other

- Support to Innovation Task Force (ITF) for non-clinical aspects and regulatory acceptance of new approach methodologies including those related to 3Rs principles

3RsWP in the lead

- ICH S5[R3] related activities: foster qualification of EFD in vitro/ex vivo/other 3Rs approaches

2.2. *Evaluation and supervision activities*

2.2.1. Support to CHMP and CVMP

- Address requests from CHMP and CVMP for input on evaluation activities
- Contribute to product-related assessment post-authorisation following specific CHMP requests

2.2.2. Support to other committees (CAT, PRAC, HMPC and CMDh) and WPs

- Address requests on product related issues. Support to other committees (CAT, PRAC, HMPC and CMDh) and WPs

2.2.3. Support to expert groups

NcWP in the lead

- Oversight and maintenance of the Nitrosamines Operational Expert Group (NS OEG)
- Oversight and maintenance of the ICH S1B Operational Expert Group (NS OEG)

3RsWP in the lead

- Oversight and maintenance of the Non-clinical and New Approach Methodologies European Specialised Expert Community (NC NAMs ESEC)
- Oversight and maintenance of the Batch Release Testing Operational Expert Group (BRT OEG)