



## Final Agenda Public Conference:

### Advancing the 3Rs for Regulatory Testing of Medicines

Antwerp, 31<sup>st</sup> January 2024

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#### Opening and Welcome

- 9:00-9:15 Sonja Beken, Coordinator Non-clinical Assessors (FAMHP) – Chair 3Rs Working Party (EMA)
- 9:15-9:30 Sara Rafael Almeida, Policy Officer, DG SANTE (EC)

#### Contribution of the FAMHP to the 3Rs for regulatory testing of medicines

*Chair: Sonja Beken (FAMHP)*

- 09:30-09:50 Advancing the 3Rs at the EMA: a journey from the Joint Expert Group on 3Rs to the new 3Rs Working Party - *Sonja Beken (FAMHP)*
- 09:50-10:10 Non-clinical testing of human medicinal products and 3Rs – Non-clinical Working Party activities - *Karen Van Malderen (FAMHP)*
- 10:10-10:30 The risk-based approach for ATMPs – a new paradigm with 3Rs opportunities – *Claire Beuneu (FAMHP)*

10:30 – 11:00 Coffee Break

- 11:00-11:20 Implementing the 3RS in quality Control and batch release testing – view from the Belgian OMCL - *Morgane Florens (Sciensano)*
- 11:20-11:40 Opportunities for 3Rs implementation in medical device testing - *Pieter Van de Vijver (FAMHP)*
- 11:40-12:00 Q&A

12:00-13:30 Lunch



## Stakeholder initiatives on 3Rs

Chair: *Birgit Mertens (Sciensano)*

- 13:30-13:45 Human medicines industry initiatives on 3Rs - *Kirsty Reid (EFPIA)*
- 13:45-14:00 Stakeholder 3Rs initiatives: a view from the Animal Health industry - *Cat Stirling (AnimalhealthEurope)*
- 14:00-14:15 An NGO view - *Tina Stibbe (PETA Science Consortium International e.V.)*
- 14:15-14:30 View from DG RTD / IHI: 3Rs projects for regulatory testing of human medicinal products - *Christian Desaintes (EC)*

## Panel discussion – fostering the 3Rs

Moderator: *Monica Piergiovanni (JRC EC, EU)*

- 14:30-15:15 Panel:  
Sonja Beken, Karen Van Malderen, Claire Beuneu & Pieter Van De Vijver (FAMHP), Morgane Florens (Sciensano), Kirsty Reid (EFPIA), Cat Stirling (AnimalhealthEurope), Tina Stibbe (PETA Science Consortium International e.V.), Christian Desaintes (EC).

15h15 – 15h45: Coffee Break

## National 3Rs activities

Chair: *Karen Van Malderen (FAMHP)*

- 15:45-16:05 PARERE: a network for discussing the regulatory need and relevance of new testing methods and approaches – *Birgit Mertens (Sciensano)*
- 16:05-16:25 Advancing new approach methodology (NAM) in Belgium through the IC-3Rs platform - *Vera Rogiers & Axelle Cooreman (IC-3Rs, VUB)*
- 16:25-16:45 Exploring the use of New Approach Methodologies in Belgium via the RE-Place database - *Mieke Van Mulders (Sciensano, VUB)*
- 16:45-17:05 3Rs in toxicity testing: initiatives within the Belgian Society of Toxicology and Ecotoxicology - *Steven Van Cruchten (Beltox, UA)*
- 17:05-17:25 Roundtable discussions to progress reduction in animal use - *Eveline Roose (Dept Omgeving, Vlaamse Overheid)*

## Concluding remarks and closing of the public conference

- 17:25-17:40 Hugues Malonne, CEO, Federal Agency for Medicines and Health Products (FAMHP)