Toward implementation plans for *replacement* of animal testing for human vaccines

Stakeholder briefing

19 January 2023

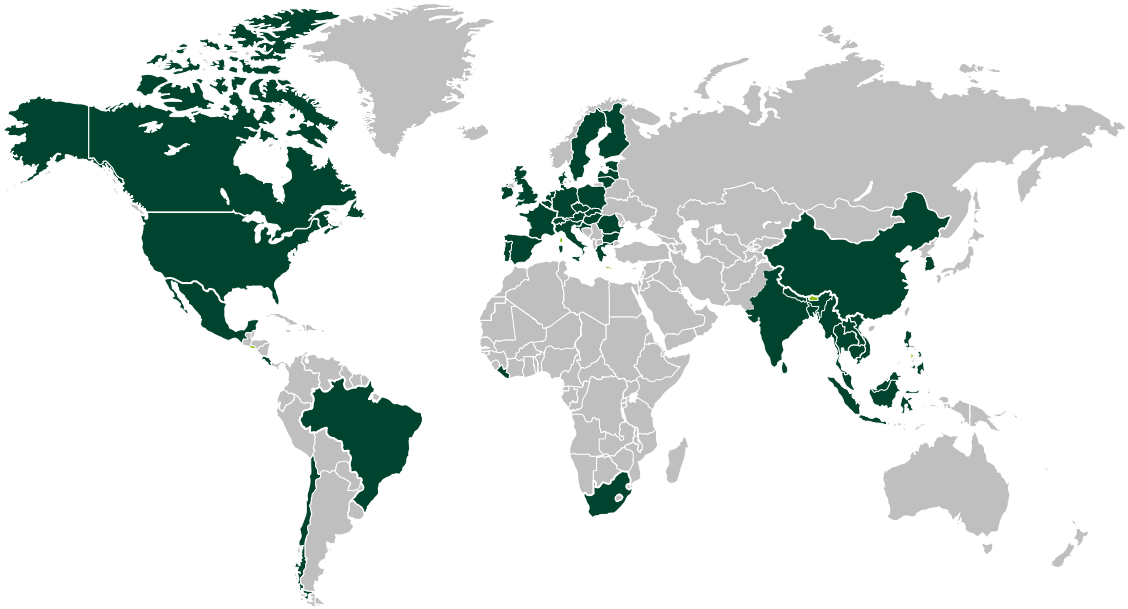
HUMANE SOCIETY INTERNATIONAL

Agenda

- **Overview:** HSI Research & Toxicology program and biologicals work
- **New project:** "Promoting implementation plans for replacement of animal testing for human vaccines"
- Questions & discussion

HSI Research & Toxicology program

- HSI's R&T team includes experts in regulatory science, biomedicine, government and corporate relations, advocacy and science communications
- Working cooperatively with industry, regulators, lawmakers, researchers, funding bodies, and other stakeholders to achieve lasting change
- Working for animals and science in more than 50 countries



Countries with R&T staff &/or program activity

HSI's strategic approach

"Building partnerships for progress"

Increase science funding for human-centric, non-animal technologies and predictive models

Build stakeholder capacity and confidence in animal-free safety assessment and human-centric research design

Accelerate regulatory acceptance, global alignment, and mainstream use of animal-free approaches

Promote use of objective tools to evaluate the validity and translational value of models of human biology and disease

Overcome animal reliance bias in publication

Modernize laws and regulations to lay the foundation for a paradigm shift away from reliance on animals for testing and research

AFSA COLLABORATION

The HSI-coordinated Animal-Free Safety Assessment (AFSA) Collaboration works to accelerate global adoption of a modern, species-relevant approach to safety assessment that will better protect people and our planet and hasten the replacement of animal testing.

Cosmetics

Chemicals

Medicines

Current AFSA members

AFSAcollaboration.org

Biologicals

- Products made by living organisms (e.g. vaccines, antibodies, blood, gene therapy, etc.)
- Many countries still require animal-testing of *each batch* of a product, consuming millions of animals
- New products follow strict manufacturing practices & assessed with non-animal approaches
- Shifting old vaccines to new tests is the challenge

Tests prioritized for replacement/ deletion from regulatory frameworks

Abnormal toxicity test

Target animal batch safety test

Pyrogenicity test

Potency tests

Implementation plans for replacement of animal testing for human vaccines

Goal

- Accelerate the implementation and regulatory acceptance of non-animal approaches for human vaccine batch-release testing with a specific focus on developing countries,
- Advance the dialogue toward global regulatory alignment while generating local competencies together with direct experience and confidence in change

Approach

- Creation of stakeholder- and/or country-specific implementation plans, or roadmaps, to include non-animal testing opportunities in the regulations, pharmacopoeias, and in the human vaccine manufacturers' quality-control routine testing

Why now?

Global community of engaged experts

- We are a truly global community and every year we have new experts and new interested stakeholders willing to contribute to the challenges

Scientific and technical experience

- International projects and studies (like VAC2VAC, DCVMN PSPT, EDQM BSPs, etc.) demonstrated the concrete opportunities to use methodologies to replace, reduce and refine animal testing

Regulatory and policy readiness

- Increased number of international agencies and initiatives, regulatory agencies, pharmacopoeias and legislations are now actively including alternatives methods or are in the process to include them

Project pillars

- Increase the knowledge and opportunities for first hand-experience on newly-developed methods, further supporting the deletion of obsolete tests (**awareness**)
- Increase local and international business opportunities to secure a sustainable industry and regulatory ecosystem where raw materials, reagents and equipment are available and affordable (**readiness**)
- Strengthen local regulatory capacity, understanding, and acceptance of the newly developed methods (**adoption**), empowering local regulatory authorities with first-hand experience of change, fostering a mindset of trust in innovation and in local capabilities
- Facilitate the implementation of novel approaches for vaccine manufacturers and national control laboratories or relevant regulatory bodies (**implementation**)
- Allow a fruitful continuation of the dialogue on global regulatory alignment to improve timely and affordable access to life-saving vaccines (**global alignment**)
- Bring about a reduction of costs and increase access to life-saving vaccines in LMICs (**public health**)

Examples of vaccines and testing

Tests \ Vaccines	Tetanus Diphtheria Pertussis (whole-cell, acellular)	Rabies	Hepatitis B/A	IPV
Potency replacement opportunities (*in vivo* – min 100 up to 300 animals per batch)	Serology *In vitro* (ELISA; multiplex)	*In vitro* (ELISA)	*In vitro* (ELISA)	*In vitro* (D-Antigen)
Safety removal (*in vivo* – between 3-10 animals per batch)	Removal of abnormal and specific toxicity	Removal of abnormal toxicity test	Removal of abnormal toxicity test	Removal of abnormal toxicity test
Pyrogenicity	Replacement of the rabbit pyrogenicity test with monocyte activation test (MAT)			
Bacterial endotoxin test	Replacement of LAL with MAT or recombinant Factor C			

Geographic scope

- Primary focus: Brazil, India, China, South Korea, Indonesia
- Secondary focus: Mexico, Argentina, Thailand, South Africa and others based on stakeholder interest on the project

Goals & timelines

Output	Target countries	Target completion date
Establish international project steering committee	Global	June 2023
3 webinars (technical knowledge sharing)	Global and regional	August 2023
3 local working group face to face meetings	TBD	August 2023
Country specific meetings/ discussions	All countries in scope	2023-2025
Yearly interim reports published on afsacollaboration.org		December (2023, 2024, 2025)
5 implementation plans or roadmaps for 5 target countries	Countries in scope	December 2025
Final conference	Global	December 2025

Reaching our goals

- This group of international experts will provide guidance to the implementation of local strategies, including the establishment and support of local working groups in priority countries as they are established

- HSI will prepare and deliver free-access webinars (translations in target countries' main languages will be available) to disseminate the status of the latest removal and replacement of animal testing opportunities

- HSI will organize wherever possible local working groups and facilitate meetings with country-specific stakeholders as soon as possible during the first year of the project, which will strengthen the collaboration among the various working group members and define a working plan for the group

Reaching our goals

- HSI will facilitate the creation of implementation plans or roadmaps template that will guide the discussion within working groups and stakeholder meetings
- At the end of each year, HSI will prepare, translate and disseminate interim reports summarizing the ongoing work and status of the creation of the roadmaps or implementation plans, sharing problem-solving approaches across the stakeholders and working groups
- At the end of the project, a final meeting will present the results of the project, including the implementation plans or roadmap developed in each country; a summary report will be published in a peer-reviewed journal

Why participate?

HSI offers:

- The opportunity to participate in a global change and be part of international and local discussions
- Access to experts and expertise via webinars, *ad hoc* meetings, documentation and materials (translated)

HSI invites:

- Your expertise and wish to participate to a local and global transformation, time to join calls, meetings and webinars as in-kind contribution

How can I participate?

International steering committee

- Open to experts with experience in methods development, optimization, validation, regulatory and policy, methods review and acceptance to provide guidance and technical support

National/regional stakeholders

- Representatives from industry, regulatory agencies, control laboratories, academia, research organizations, etc. to participate in local-level discussions and development of implementation plans

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Thank you!

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