Toward implementation plans for replacement of animal testing for human vaccines

Stakeholder briefing
19 January 2023
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
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.
Current AFSA members
AFSAcollaboration.org

Bill & Melinda Gates Foundation
Unilever
L'Oréal
P&G
LUSH

Firmenich
Johnson & Johnson
AVON
ExxonMobil
Givaudan

IFF
Sasol
Innospec
Symrise
BioMérieux
Lhasa Limited
IVS Institute for In Vitro Sciences

Delphic HSE
TABS
A T A L L Incubation Centre Centre for Cellular & Molecular Biology
GPC
Creme Global
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**)

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**HUMANE SOCIETY INTERNATIONAL**

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# Examples of vaccines and testing

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

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

- **Implementation plan template**
  - HSI will facilitate the creation of implementation plans or roadmaps template that will guide the discussion within working groups and stakeholder meetings

- **Reports**
  - 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

- **Final conference**
  - 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
Thank you!

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