

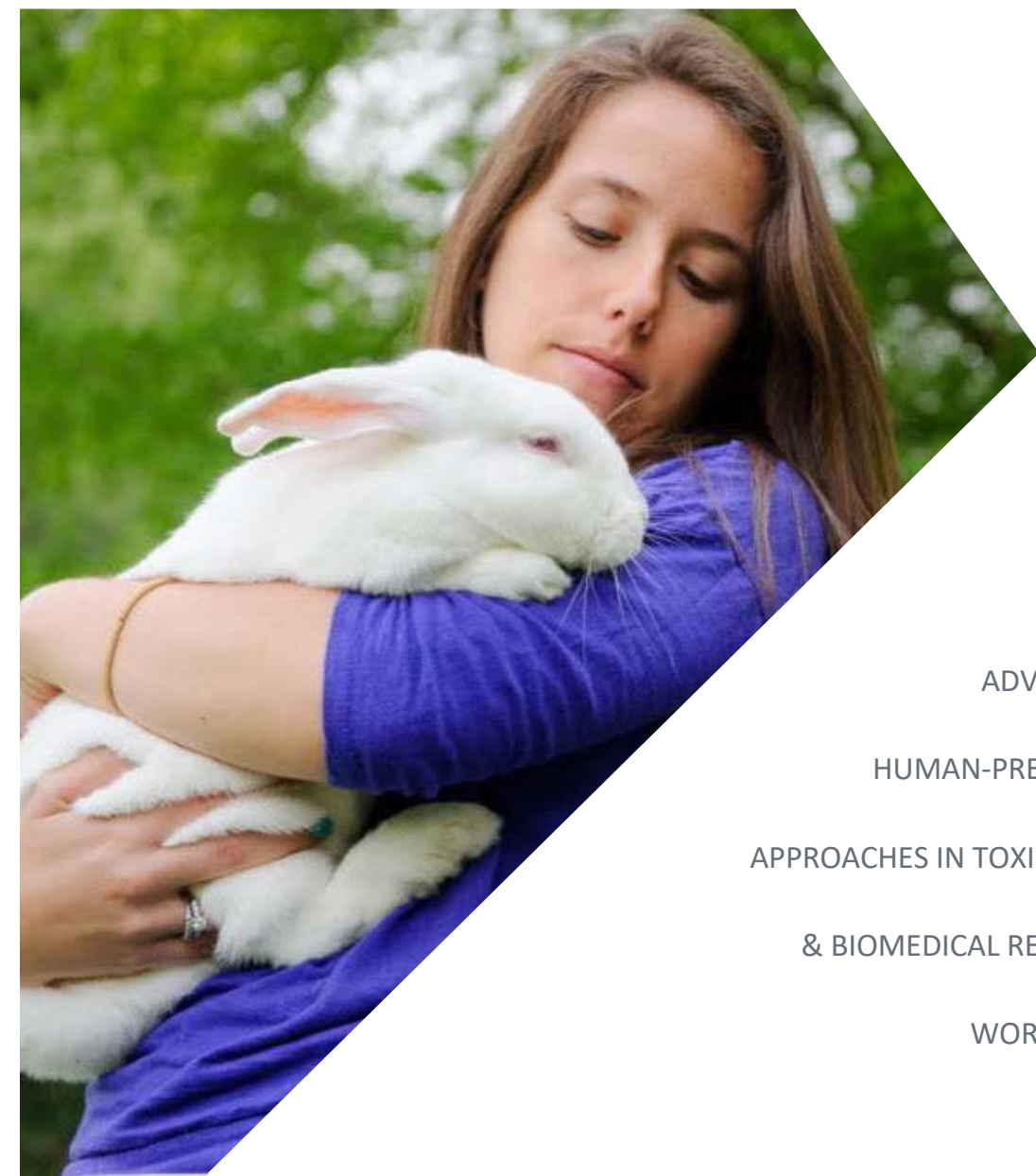
Global harmonization of vaccine testing requirements

MAKING ELIMINATION OF
THE ATT & TABST A CONCRETE
GLOBAL ACHIEVEMENT



HUMANE SOCIETY
INTERNATIONAL





ADVANCING
HUMAN-PREDICTIVE
APPROACHES IN TOXICOLOGY
& BIOMEDICAL RESEARCH
WORLDWIDE

ABOUT HSI

- Humane Society International is active on the ground in >60 countries across Europe, Asia-Pacific & the Americas
- Our Research & Toxicology Department brings together experts in human & environmental toxicology, biologicals, regulatory science, biomedicine, public policy, etc.
- Working with research institutes, companies, government regulators, policy-makers & other stakeholders
- United Nations, OECD & other inter-governmental forums, national government advisory bodies on alternative methods & product safety, etc.



HSI PRESENCE ON EXTERNAL BODIES

- OECD Joint Meeting & subsidiary bodies (test guidelines, chemical, etc.)
- US EPA Science Advisory Committee on Chemicals
- US EPA Pesticide Program Dialogue Committee
- United States Trade Representative
- EU Member State Working Group on Cosmetics
- European Medicines Agency (interested party status)
- European Chemicals Agency Member State, Risk Assessment & Biocidal Products Committees
- Committee on REACH & CLP (CARACAL)
- EURL-ECVAM Stakeholder Advisory Forum
- China SOT Translational Toxicology Committee
- Brazilian Commission of Chemical Safety Advisory Committee
- Canadian Council on Animal Care Ethics Committee
- Alternatives Congress Trust (World Congress)
- CAAT US & EU Boards of Directors
- ... and others

HSI CORPORATE COLLABORATIONS

Advancing a human pathway paradigm
in chemical safety assessment
HumanToxicologyProject.org



HUMAN
TOXICOLOGY
PROJECT

NON-ANIMAL
COSMETIC SAFETY
ASSESSMENT
COLLABORATION
hsi.org/nacsa



L'ORÉAL



ExxonMobil.



HESI



ATT & TABST

A LONG JOURNEY

- The elimination of ATT & TABST has seen many years of data collection and assessment, stakeholders engagement and discussions. The journey started already in the 1980s & 90s
- The contribution of many regulatory authorities, vaccines manufacturers, international organizations & public-private partnerships accomplished the removal of ATT & TABST from some regulations and products
- From the great work of those stakeholders, we seek the final steps to make their elimination a concrete global achievement & use this example to bring more arguments in favor of a harmonized approach to an animal-free vaccines batch-release testing strategy



ATT & TABST

The European success story,
told by Klaus Cussler & Lukas Bruckner

A COMMON APPROACH

Working session to establish key characteristics
of a global roadmap

Agenda

- 9:00 HSI opening remarks
- 9:15 **ATT and TABST elimination:
The European success**
- 9:15 Klaus Cussler (PEI): Abnormal Toxicity
Testing: Origin, propagation and abolition
in Europe
- 10:00 Lukas Bruckner: The target animal batch
safety test: A non-suitable tool to demon-
strate the safety of veterinary vaccines
- 10:45 Coffee break
- 11:00 **ATT and TABST: Where we are in
other regions**
- 13:00 Lunch and break
- 14:00 **Working session: Building a
common approach**
- 16:00 Coffee break
- 16:15 **Working session: Drafting the roadmap**
- 17:15 **Closing remarks and next steps**
- 17:15 Review of the working session
outcomes and closing remarks
- 17:50 Presentation of IABS/Vac2Vac global
congress in Bangkok, Dec 2019
- 18:00 Closure of the symposium

WHERE WE ARE

Round-table, where we will begin to make the
change

DRAFTING THE ROADMAP

Structuring and writing the global roadmap

WHO WE ARE TODAY



A **global** perspective from key stakeholders

- The group gathered here represents a wide spectrum of expertise, experiences & viewpoints
- Together, we aim to change for the better the current reality of human & veterinary vaccine batch-release testing field

PLEASE DON'T HESITATE TO
ASK QUESTIONS & PROPOSE
SOLUTIONS



OBJECTIVES

OUR PLANNED WORK FOR TODAY

1. Leverage success stories
2. Lay out a possible common strategy
3. Enumerate & discuss the barriers/difficulties for the elimination of ATT & TABST
4. Define a concrete roadmap & assign proper actions to the stakeholders

OUR FOCUS



DATA

Which kind of dataset
can be considered
adequate for
regulatory purposes?



PROCESS

Detail an appropriate
process model –
including actions,
stakeholders & data –
for the elimination of
the ATT & TABST



PLANNING

What does an
effective planning for
the process entail?

DESIRED OUTCOMES

Flash Report

To provide a summary of the event to all the stakeholders in our network

Roadmap

To be shared among stakeholders globally

Scientific publication

To officially present the roadmap & underlying working model

Strengthen current collaborations

To keep alive & healthy the collaboration between the participants

Engage new stakeholder collaborations

To engage new stakeholders interested in initiating the work on those tests' elimination

Harmonization

Export this working model to other alternative methods & foster the harmonization of animal-free vaccine testing requirements