

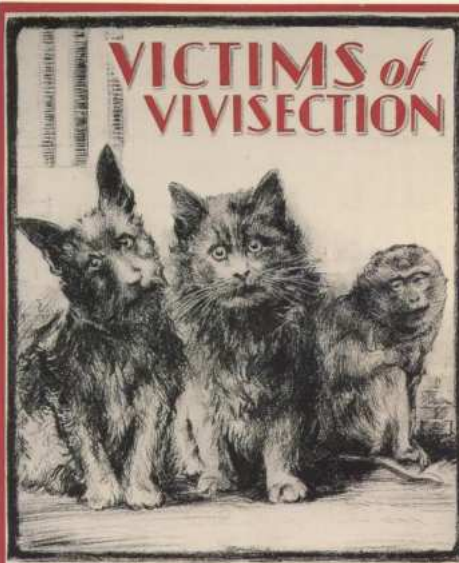


HUMANE SOCIETY
INTERNATIONAL

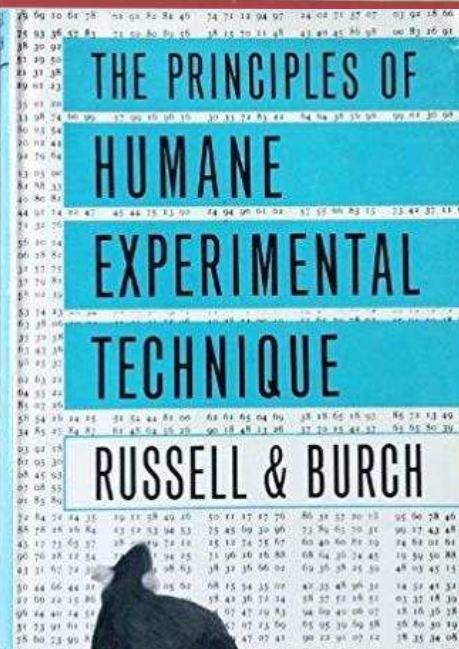
INDIA

Landscape of the Animal Testing Issue

2021



Write for free literature to
**THE LONDON & PROVINCIAL
 ANTI-VIVISECTION SOCIETY**
 76 VICTORIA STREET, LONDON, S.W.1

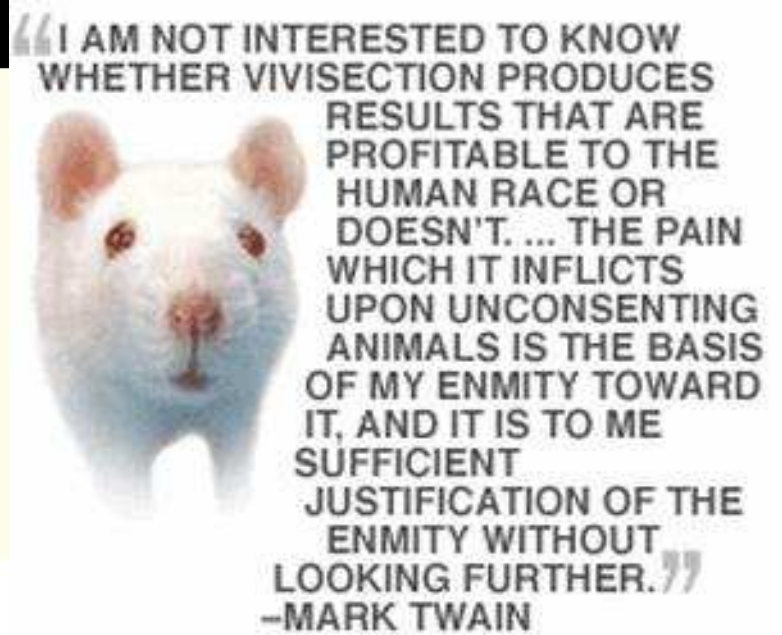


DOCTORS AGAINST VIVISECTION

Dr Herbert Stiller MD & Dr Margot Stiller MD:
"Practically all animal experiments are untenable on a statistical scientific basis, for they possess no scientific validity or reliability. They merely perform an alibi for pharmaceutical companies, who hope to protect themselves thereby."

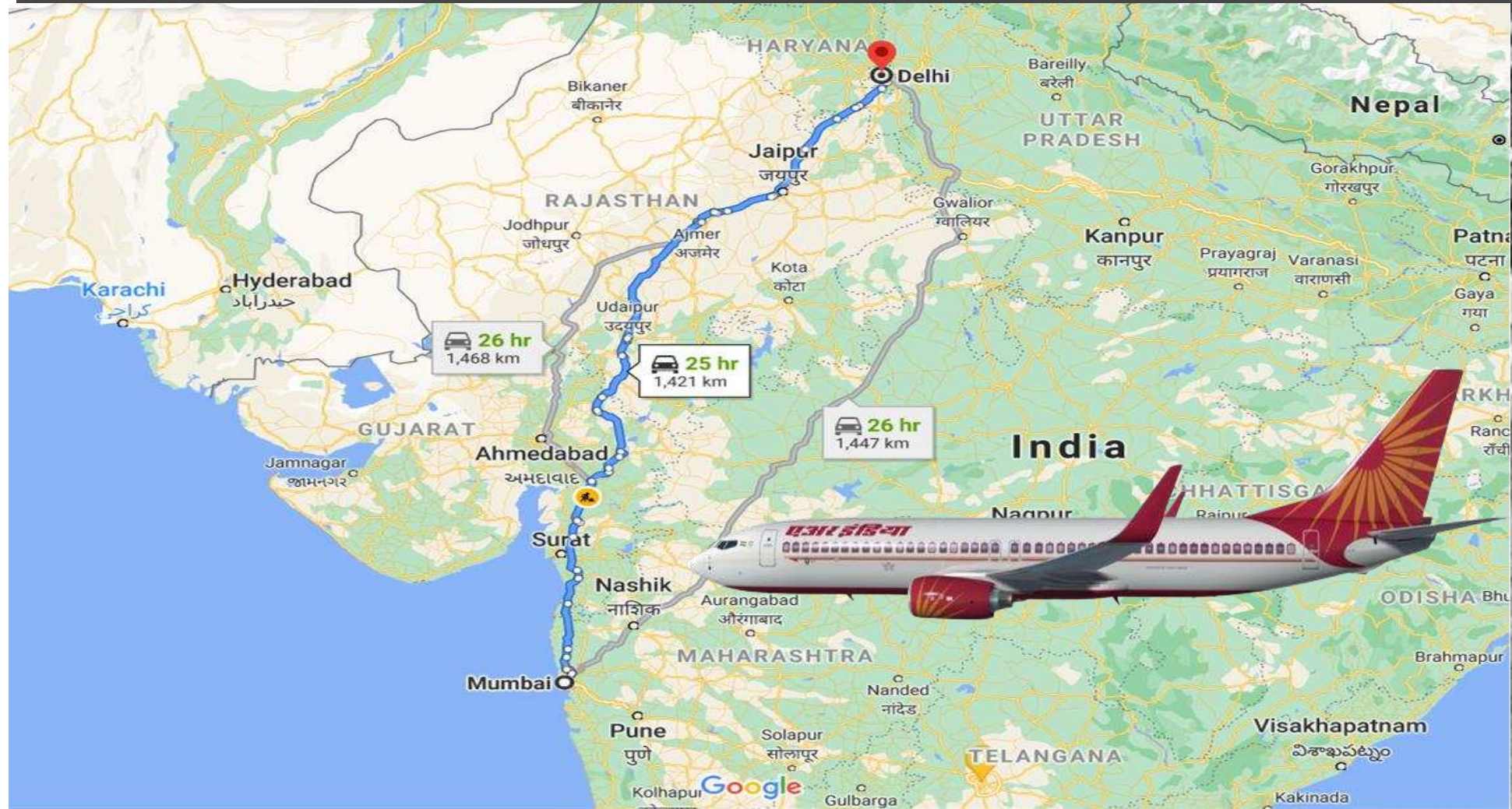
The Stillers were a married couple who resided in Germany. They were specialists in neurology, psychiatry, & psychotherapy. They authored numerous articles & books such as "Deadly Tests: Experiments with Animals and Humans" and founded a German organisation whose name translates to "Doctors Against Animal Experiments" Reference: https://de.wikipedia.org/wiki/Herbert_Stiller

Quote from the book *1000 Doctors Against Vivisection* - available as a free PDF via: www.MedicineKillsMillions.com
 Doctors report on how orthodox medicine is a leading cause of death & injury.



Evolution vs. Revolution

replacing parts one by one vs. building something new



Understanding the problem 'testing' vs. 'research'

TESTING (regulatory)



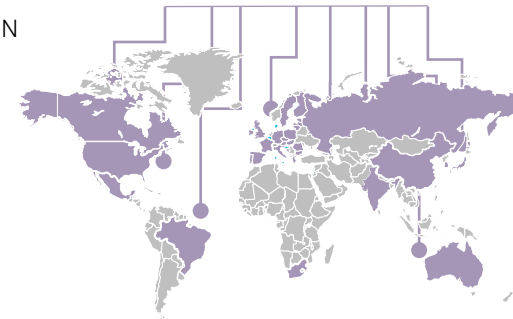
Test data
required by
government
authorities
prior to
marketing

IS IT SAFE?
DOES IT WORK?

Requirements may include:

- ☐ ACUTE TOXICITY - ORAL
- ☐ ACUTE TOXICITY - SKIN
- ☐ ACUTE TOXICITY - INHALATION
- ☐ EYE IRRITATION
- ☐ SKIN IRRITATION
- ☐ SKIN ALLERGY
- ☐ GENETIC TOXICITY
- ☐ REPEATED DOSE TOXICITY
- ☐ REPRODUCTIVE TOXICITY
- ☐ DEVELOPMENTAL TOXICITY
- ☐ CARCINOGENICITY
- ☐ ...

Authorities in key countries
must all agree to a change
→ even 1 holdout means
animal testing will continue



COMPANIES
TEST
ACCORDING
TO THE
REGULATION

RESEARCH (fundamental & biomedical)

Research funding body
(government, charity,
etc.) decides funding
priorities & publishes
funding call



e.g. \$100M for lung
cancer:
improved **animal models**
– OR –
lung cancer-on-a-chip
using **human tissue**

Scientists seeking
funding prepare
proposals
according to
funding body
criteria

Animal use
protocol
application

Human-based
approach

Animal
care
cmtee.
review

APPROVED
ANIMAL
RESEARCH
STUDY

Legislative reforms

>> enacting 'mandatory alternatives' laws

European Union

- Requirement to use available alternatives established in 1986 Animal Experiments Directive and subsequent regulations

Brazil

- 2014 CONCEA Resolution establishes 5-year mandatory phase-out for animal tests with government-recognized replacement

United States

- 2016 revision of Toxic Substances Control Act introduced unprecedented animal protective language in a US national chemical law

South Korea

- 2017 'K-REACH' Reform Bill introduced established first-in-Asia animal protective language in a national chemical law

India

Chapter 17 (2) (d) under Prevention of Cruelty to Animals Act and CPCSEA but



South Korean politicians propose K-REACH animal testing reduction principles

Environment ministry sees amendment as positive

12 October 2017 / Alternatives assessment & substitution, K-REACH, South Korea, Test methods



3 Strategic Pillars



Cosmetics

#BeCrueltyFree

To outlaw
cosmetic animal
testing & trade in
50+ key global
beauty markets
by the end of
2023



Toxicology

Tox21

To supplant
animal testing
with next-
generation risk
assessment in
toxicology



Research

BioMed21

Toward a
human-based
paradigm in
health research

Education



HUMANE SOCIETY
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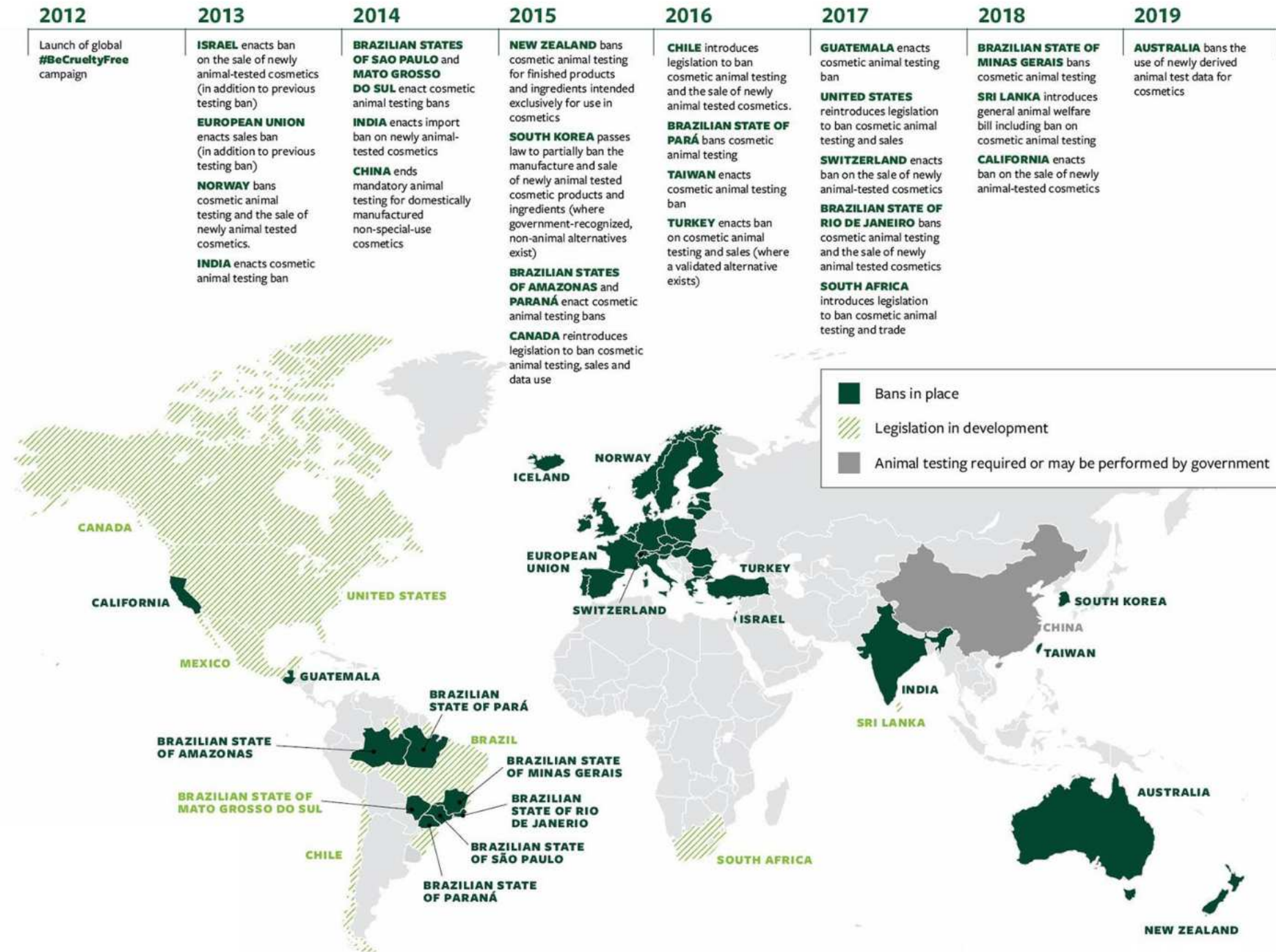
Countries with active RTD programs or personnel



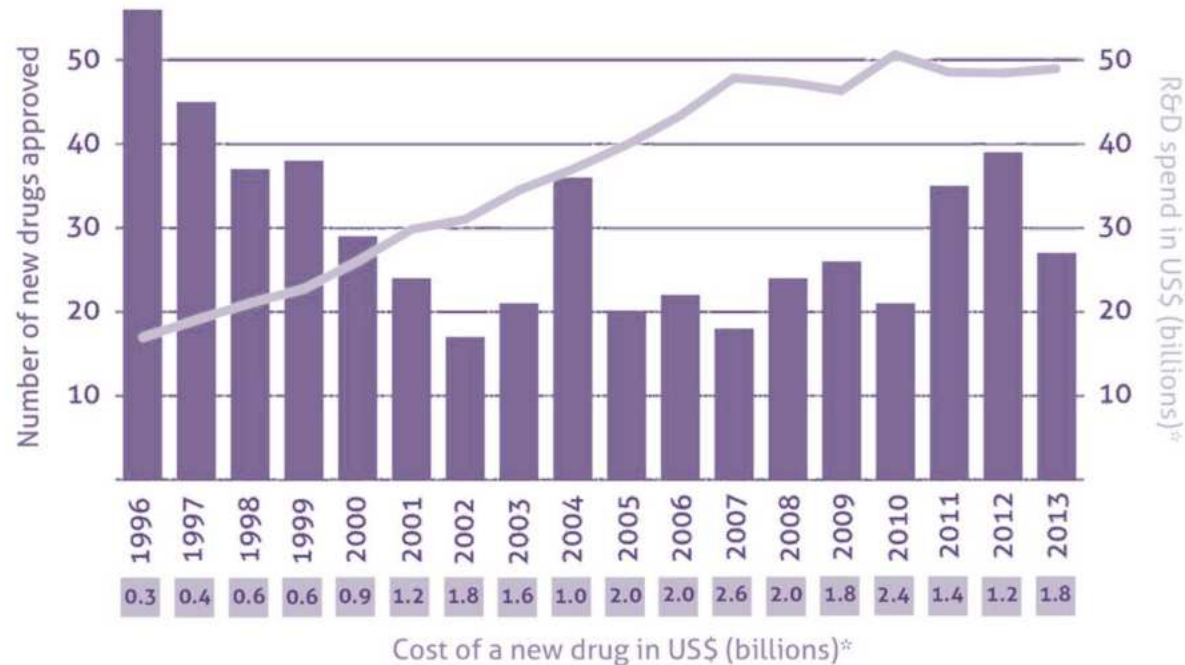
‘Enactment of EU-concordant cosmetic animal testing & sales bans in 50+ key beauty markets by the end of 2023’

→ 39 national (+9 state) measures already in force, achieved despite industry opposition

**BE
CRUELTY
FREE**



High failure rates for candidate drugs that appear safe & effective in animals



Data: USFDA, PhRMA

Up to
\$2.5 billion

13.5 years

Thousands of animals



“Most of this failure is due to the **limited predictive value** of preclinical models.”

PLENGE ET AL. NAT REV DRUG DISCOV. 2013; 12: 581-94; KOLA & LANDIS. NAT REV DRUG DISCOV. 2004; 3: 711-15

“We have moved away from studying human disease in humans...
The problem is that **it hasn't worked**, and it's time we stopped
dancing around the problem... We need to refocus and
adopt new methodologies for use in humans,
to understand disease biology in humans.”

-Elias Zerhouni, MD
Former Director
National Institutes
of Health, USA



CREDIT: SHUTTERSTOCK

HSI's BioMed21 Collaboration

>> critical reviews & consensus-building



Funded reviews have identified poorly predictive models & suggested novel roadmaps

- Alzheimer's disease
- Amyotrophic lateral sclerosis
- Asthma
- Autism spectrum disorder
- Autoimmune disorders
- Cardiovascular disease
- Diabetes type II
- Liver disease
- Parkinson's disease
- Tuberculosis
- Zika virus
- ... others in development



International workshop series

- Asia:
 - India (, South Korea
- Europe (Brussels, Dec. 2015)
 - Langley et al. Drug Discov. Today 2017
- Latin America (Brazil, May 2017)
 - Triunfol et al. Drug Discov. Today 2018
- North America (Bethesda, June 2017)
 - Marshall et al. Drug Discov. Today 2018

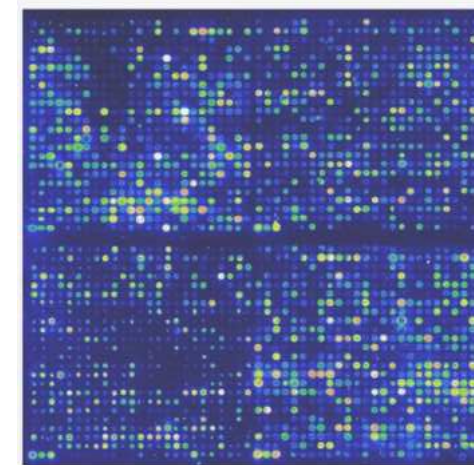
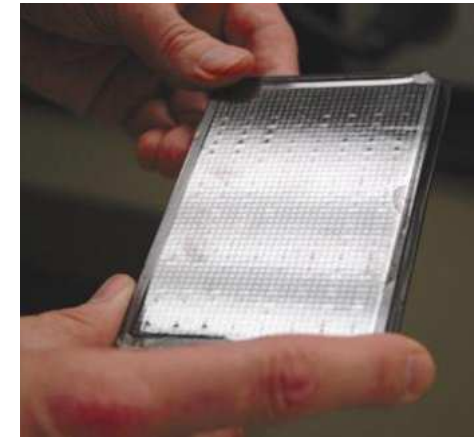


Modern, human-relevant tools

>> high-throughput / high-content in vitro



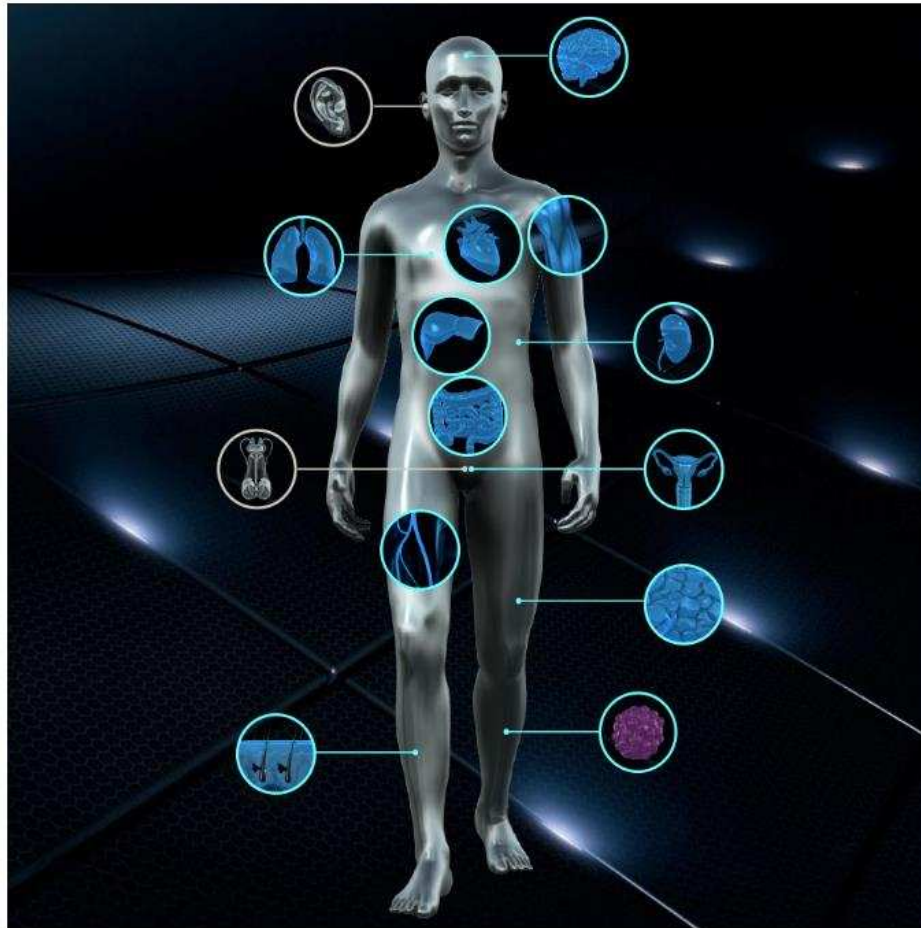
CREDIT: NIH / NATIONAL CHEMICAL GENOMICS CENTER



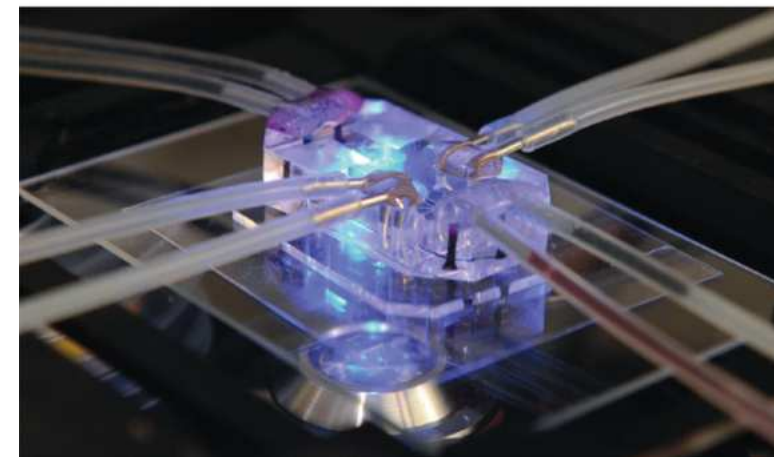
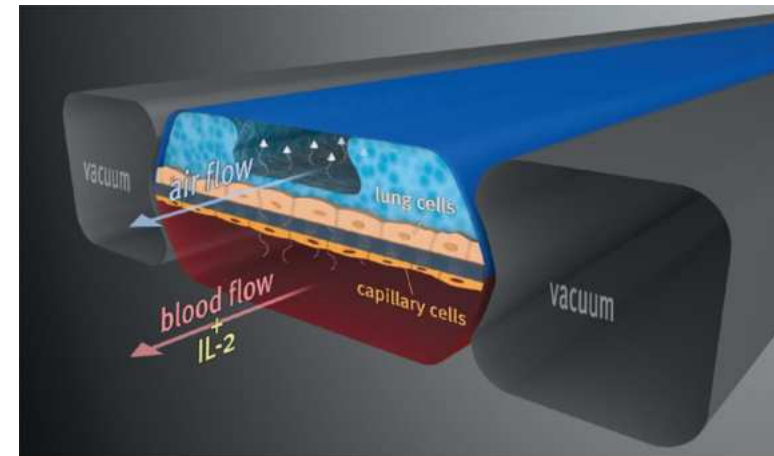
CREDIT: P&G

Modern, human-relevant tools

>> organ-on-a-chip



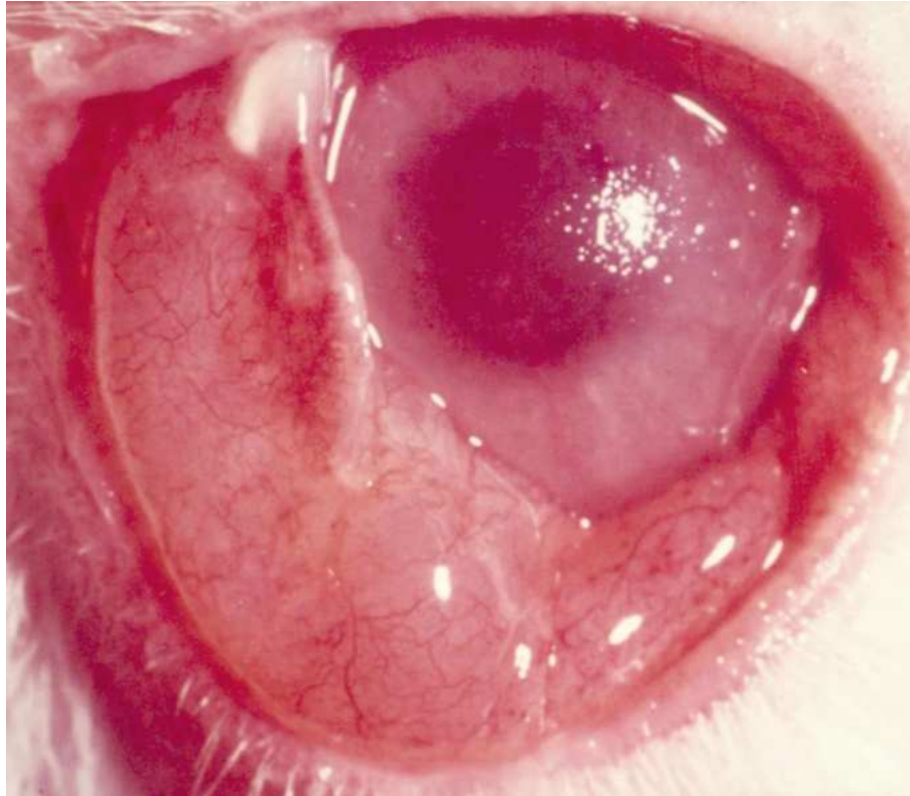
CREDIT: NIH / NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES



CREDIT: WYSS INSTITUTE / HARVARD UNIVERSITY

Modern, human-relevant tools

>> organ-on-a-chip



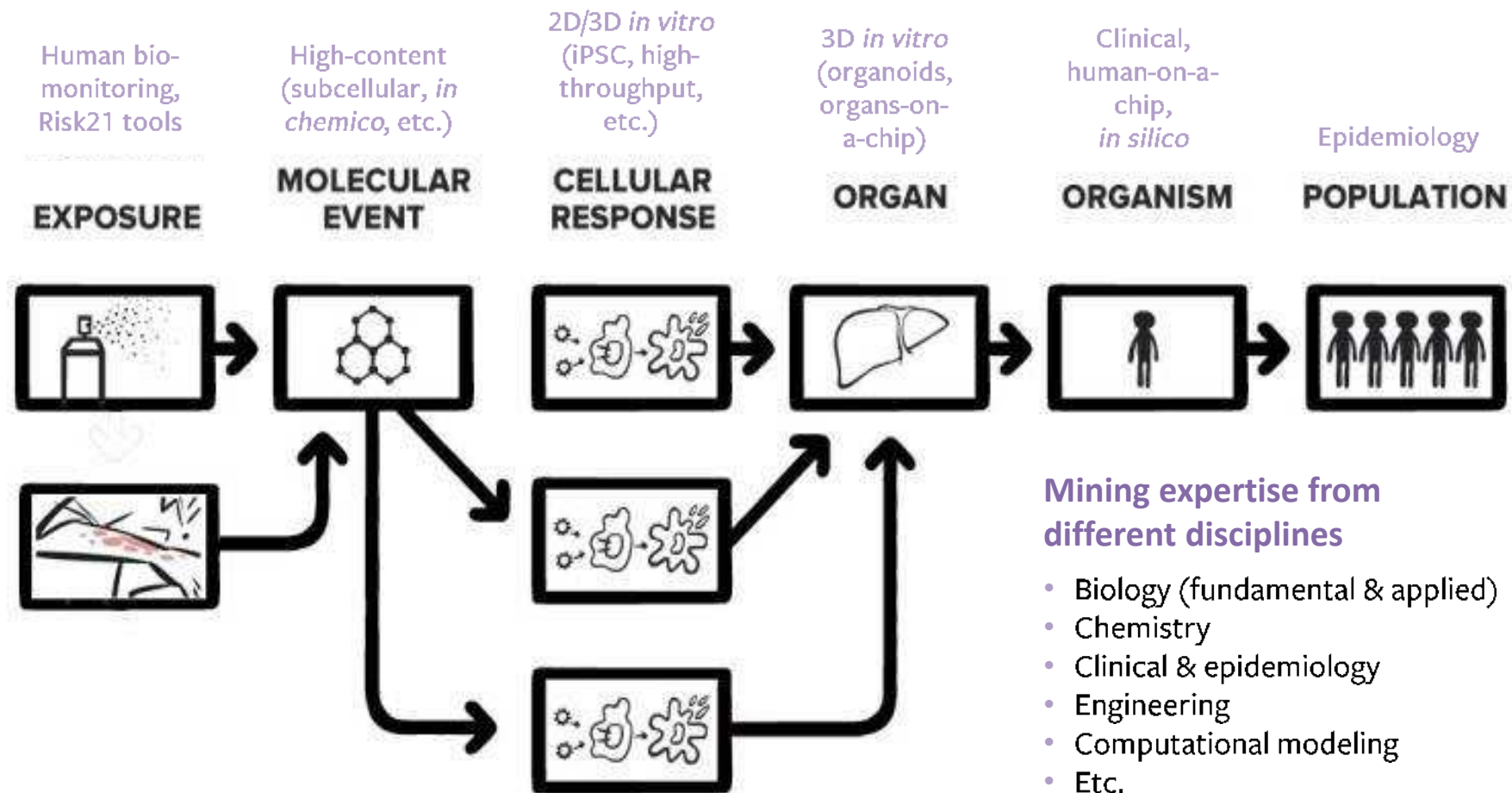
CREDIT: PETA



CREDIT: D. HUH / UNIVERSITY OF PITTSBURGH

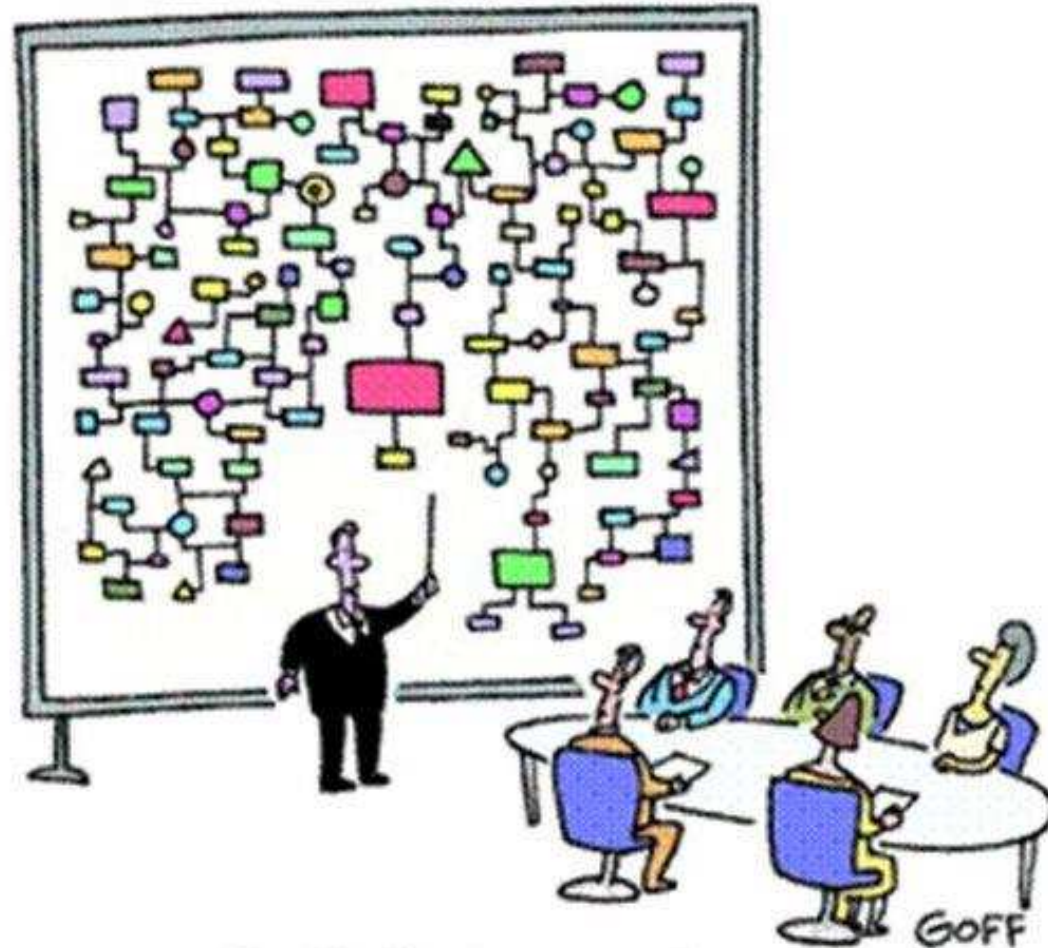
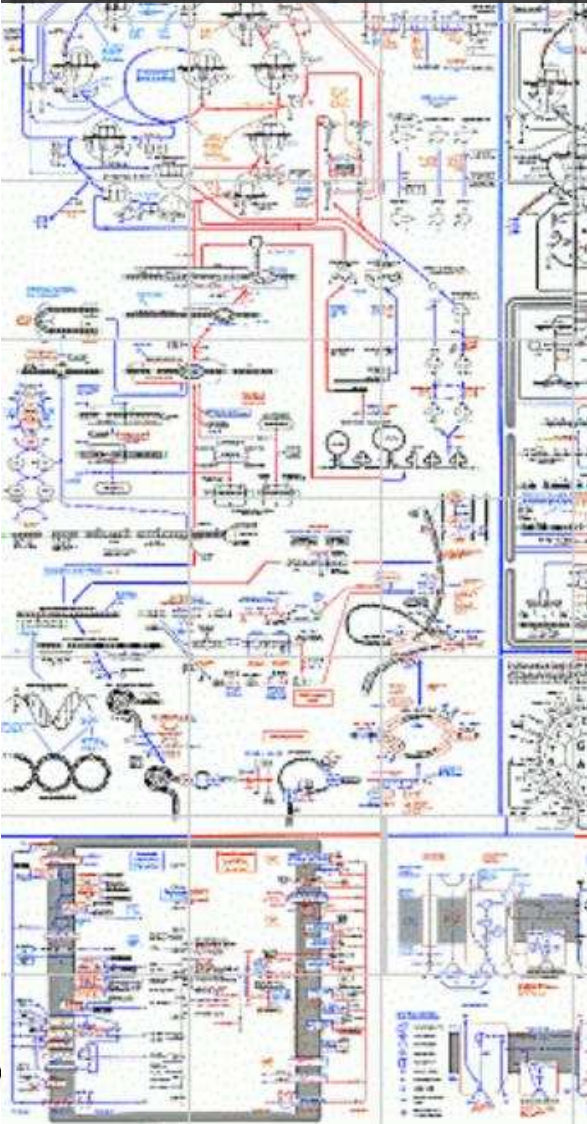
Modern, human-relevant tools

>> understanding complex disease biology



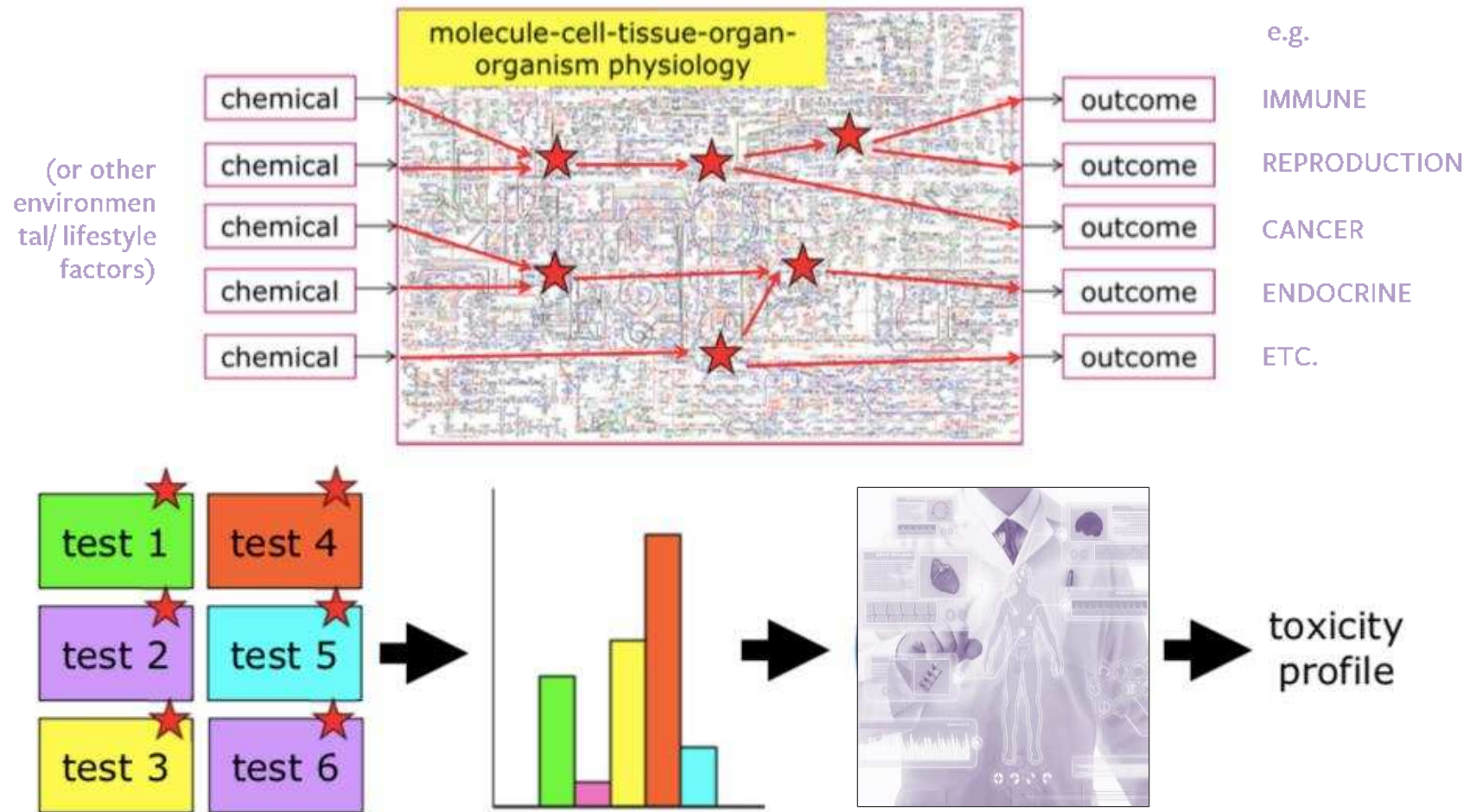
Modern, human-relevant tools

>> computational modeling

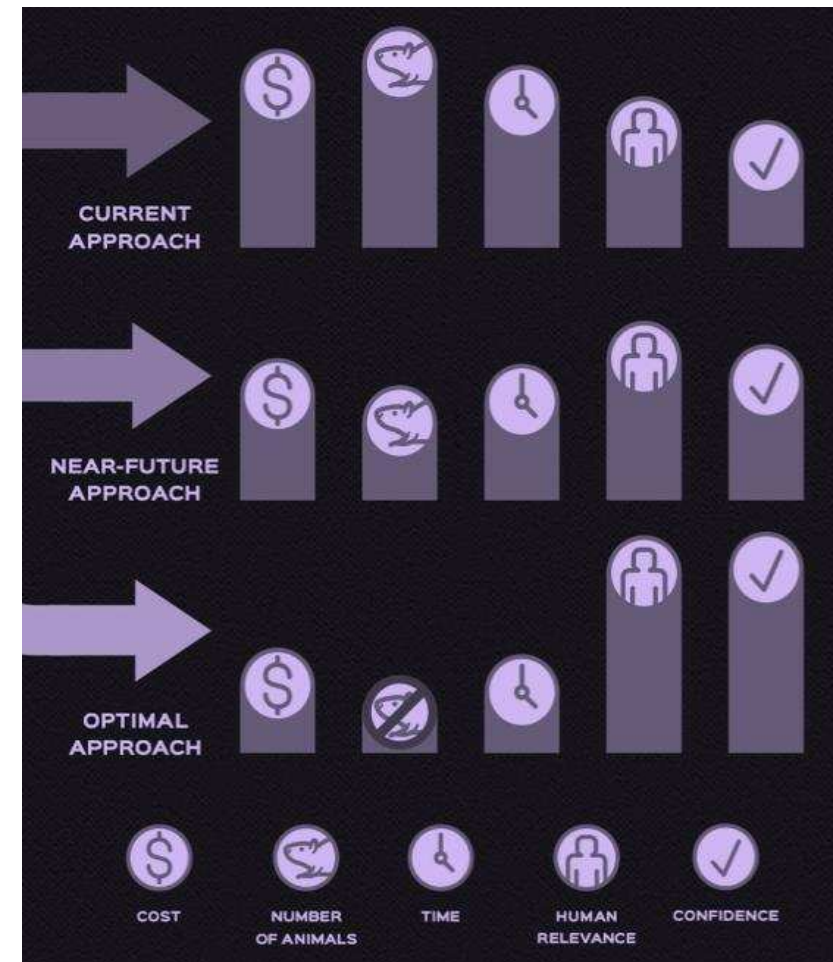
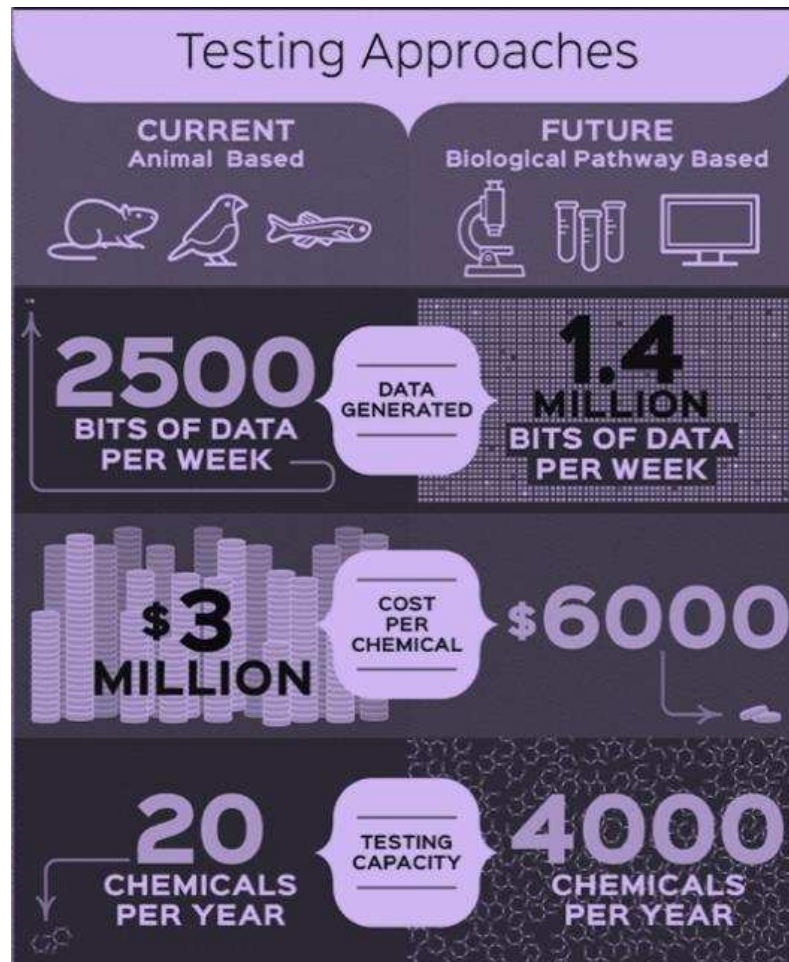


"And that's why we need a computer"

Combining human-relevant tools to fully replace animal testing/research



Combining human-relevant tools saves animals, money, time & better predictions



Bringing it all together

>> adopting strategies that work

REGULATORY TESTING



Test data
required by
government
authorities
prior to
marketing

IS IT SAFE?
DOES IT WORK?

- ☐ ACUTE TOXICITY - ORAL
- ☐ ACUTE TOXICITY - SKIN
- ☐ ACUTE TOXICITY - INHALATION
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- ☐ CARCINOGENICITY
- ☐ ...

Authorities in key countries
must **ALL** agree to the change

→ even 1 holdout means
animal testing will continue

**Mandatory
alternatives
laws globally
& multilateral
harmonization
frameworks**

COMPANIES
TEST
ACCORDING
TO THE
REGULATION

FUNDAMENTAL & BIOMEDICAL RESEARCH

**Redirect
research
funding**



e.g. \$50M for lung cancer:
improved **animal models**
– OR –
lung cancer-on-a-chip
using **human tissue**

Scientists seeking
funding prepare
proposals
according to
funding body
criteria

Animal use
protocol
application

Animal
care
cmtee.
review

**APPROVED
ANIMAL
RESEARCH
STUDY**

**Human-based
approach**



RTD INDIA

To enable RTD India to function within
HSI India and for HSI India to remain
functioning, more collaborations needed

FUTURE OF RTD INDIA

Breaking silos, building partnerships

80%
BIOMED

10%
TOX21

10%
VACCINES

PESTICIDES

Photo by Brian Gunn/IAAPEA

First regulatory acceptance of non – animal methodologies apart from cosmetics

Tedious, long campaign of 3 years

Industry & HSI/India agreed on most things but the Govt. didn't

Poor scientific knowledge of the regulators

Access to an important Ministry, potential of maintaining dialogue

Political Environment & Bureaucracy

Eye Irritation & Corrosion

OLD TEST

Rabbits are locked in restraints and a chemical is applied to one eye. They may experience redness, swelling, ulcers and even bleeding and blindness. Pain relief is rarely provided.

MODERN APPROACH

Alternative tests use reconstructed human corneas made from donated eye tissue or abattoir-sourced cow and chicken eyes instead of live animals.

SAVES UP TO

3 
per test



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INDIA

TAKE ACTION hsi.org/dirtydozen

DRUGS



Prohibition on Draize test

Repeat Animal Testing

Harmonization with ICH (International Council for Harmonization)

VACCINES

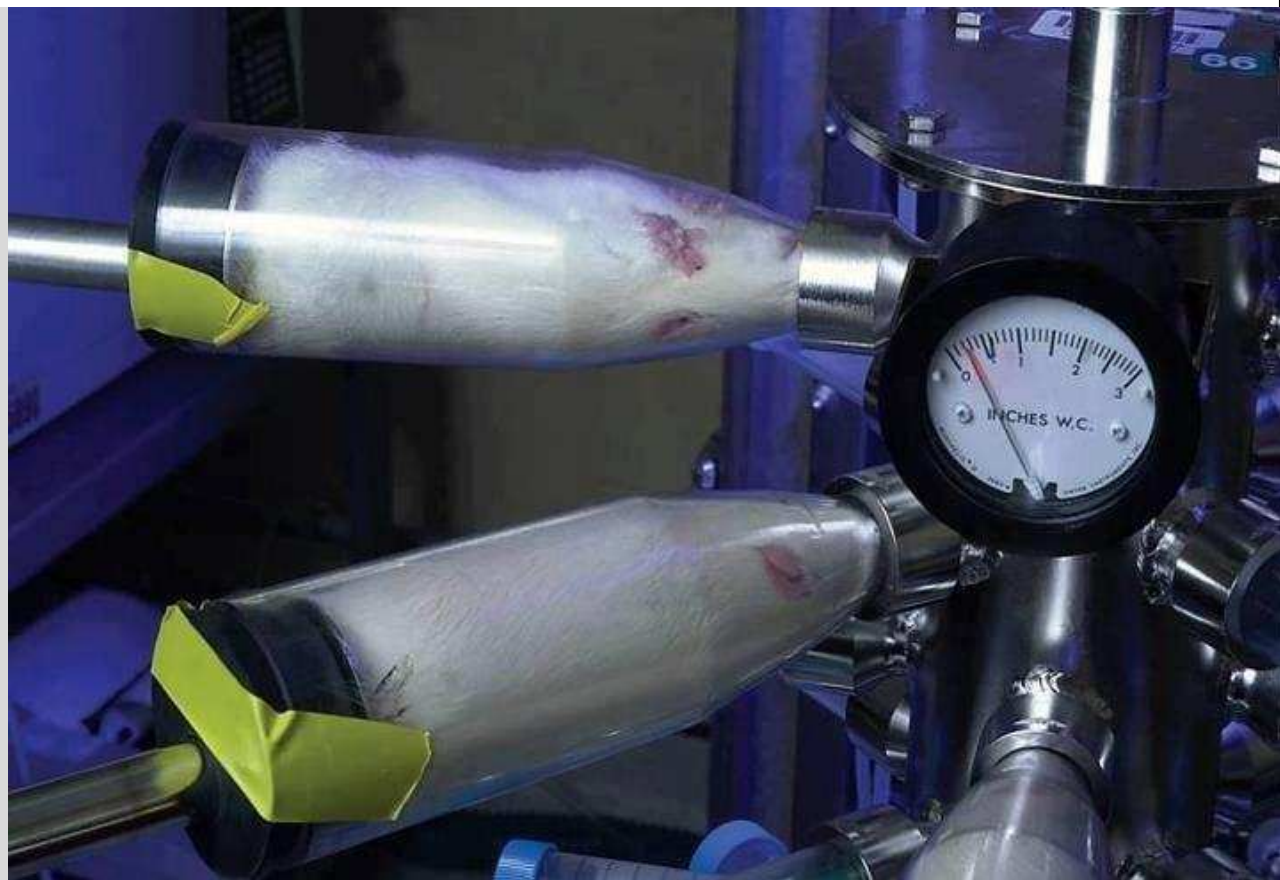
Removal of Abnormal Toxicity Testing in 2020

LABST/TABST in the process of being deleted

Replicating progress other countries
& regulators are making
e.g. Removal of rabbit pyrogen testing



CHEMICALS



- National Chemical Policy in the pipeline for 10 years

- India continues to be a country without chemical legislation

- 2011-2012 recommendations by HSI India were included in the 2nd draft

- No update since 2014

- Regulatory work difficult in this political scenario

- No direct access to ministry or previous industry contacts



ATAL INCUBATION CENTRE
CENTRE FOR CELLULAR
& MOLECULAR BIOLOGY

Supported by Atal Innovation Mission, NITI Aayog



**HUMANE SOCIETY
INTERNATIONAL**
INDIA

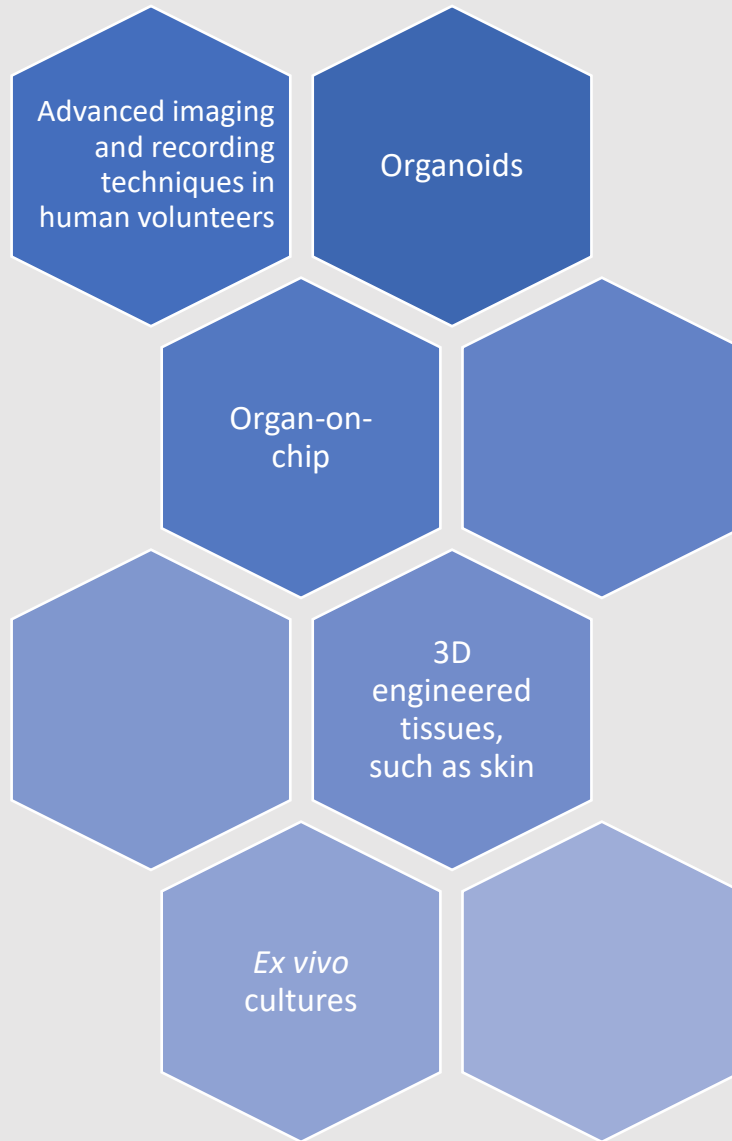
Centre for Predictive Human Model Systems

Atal Incubation Centre-CCMB

Surat Parvatam, PhD
Senior Research Associate



Human-relevant model systems



Can generate “human – relevant” data that can capture subtleties of human biology

Our work



Increasing awareness

Popular articles, reviews
webinars

THE HINDU

SCIENCE

Of mice and SARS-CoV-2



Surat Parvatam

nature india

Why infection research in India must become relevant to humans

What works in mice may not work in humans, especially in infectious diseases, argue Surat Parvatam* and Karishma Kaushik**.



Education/ Training

AOP Workshops,
Monthly webinars,
EMBO India Lecture
Series



India | EMBO Lecture Courses



Policy initiatives

- White papers
- Multi-stakeholder roundtable meeting to provide recommendations to government bodies
- Global collaborations



Call for a national strategy to make biomedical research more human-relevant
P Surat



EU SCIENCE HUB

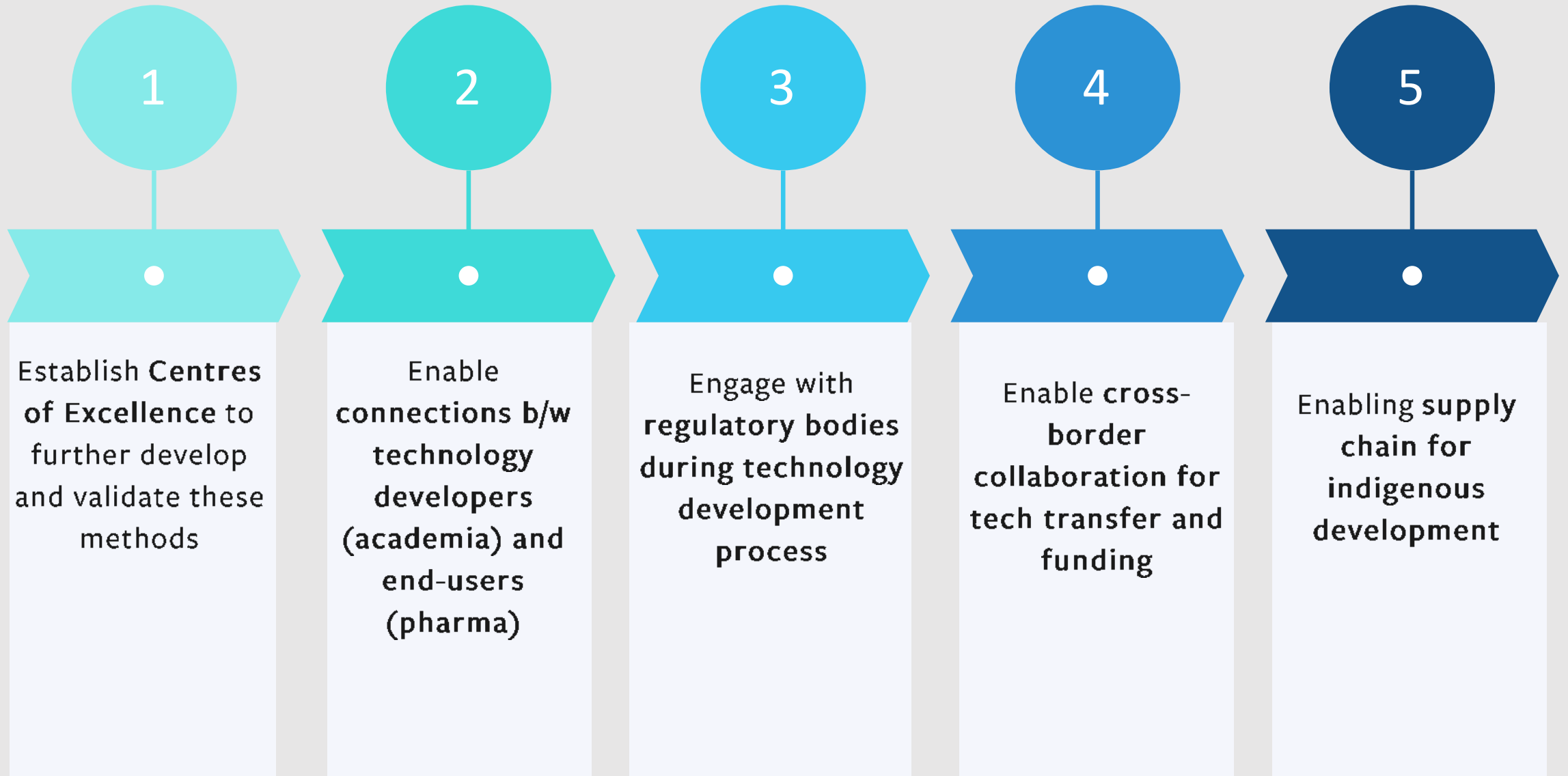
The European Commission's science and knowledge service



Funding

Grant provided to two Indian scientists to develop an AOP in the field of cancer

Roadmap to enable human-relevant research in India



BIOMED21 INDIA STRATEGY

Objective: To de-fund
animal experimentation
by 2050



1 INCREASING PUBLICATIONS

- 4 white papers per year.
- 2020 - Microphysiological Systems, Systems Biology, AOP; disease model whitepaper on Diabetes.
- 2021 - 2 disease papers, 2 generic papers
- Work with institutions and reputed scientists to collaborate on publications.



2 DIALOGUE WITH KEY STAKEHOLDERS

- 2 workshops with scientists on status and need for development and funding into NAMs.
- 2 round-table meetings with ICMR, CSIR, DBT, DST, and NITI Aayog to discuss investment in NAMs.

Messaging:

1. Factsheets/infographics from our publications.
2. Presentations by HSI and scientists on efficacy of NAMs and current status of development and use in India
3. Failing animal models in India and globally, emphasizing the significance of 21st century toolbox



3 REGULATION

- Draft proposals to Ministry of Health and Family Welfare, Ministry of Science and Technology, NITI Aayog to increase funding into NAMs and set a timeline for it (30% per decade).
- To establish support from Members of Parliament.

Messaging:

1. Use EPA as precedent.
2. ICMR's roadmap and perspectives paper on NAMs.
3. Make-in-India argument, and economic importance.
4. Flash reports from workshops and round-tables.
5. Petitions from public outreach.



4 PUBLIC OUTREACH

- Press releases for the publications and events using more animal-centered messaging.
- Regular posts, share-graphics, infographics (animals used for testing/NAMs), drawbacks, way ahead in layman terms.
- Petitions for the public to sign to de-fund animal tests.



- First paper by a regulator on need of non animal methodologies published by Indian Council of Medical Research (ICMR)
- ICMR agreed to divert funds from NARF – BR to a Centre of Excellence for Human – Based Pathway
- Call for proposals for white papers on review of animal models in specific diseases
- Call for proposals for Adverse Outcome Pathways for them to be included in OECD Wiki
- Roundtables held with scientists, regulatory roundtable to be held in September, 2021
- Future plan to propose legislation on increasing funding towards NAMs – encouragement received from parliamentary standing committee

Questions?

