

ALTERNATIEVE METHODEN VOOR DIERPROEVEN

(Inter)nationale context

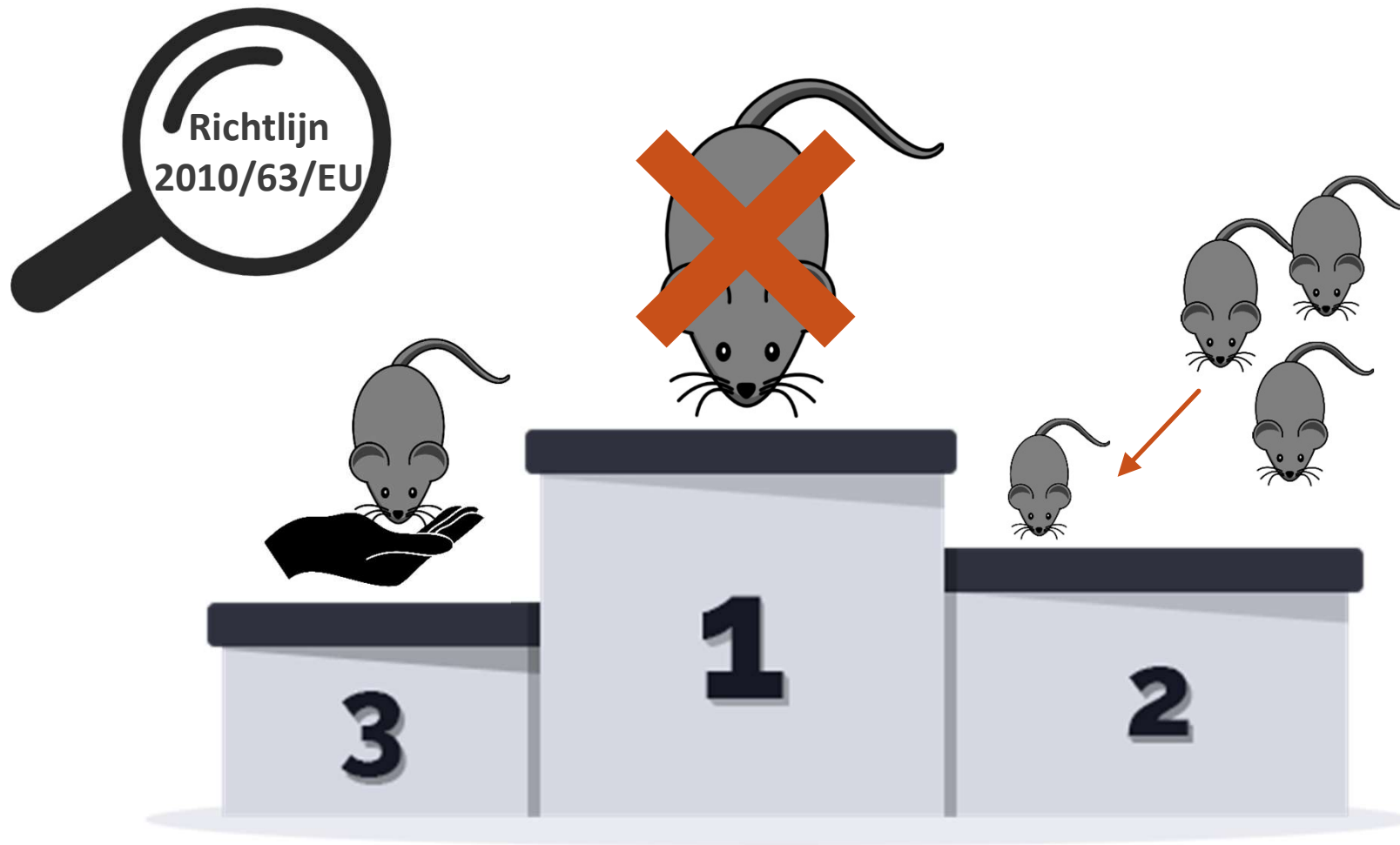
Dr. B. Mertens

Hoorzitting Dierproeven, Vlaams Parlement

22/09/2021

.be

Europese wetgeving



➔ Oprichting van EURL-ECVAM en verschillende Europese netwerken

EURL ECVAM

'European Union Reference Laboratory for Alternatives to Animal Testing'



VALIDATIE

Betrouwbaarheid - Relevantie - Doel



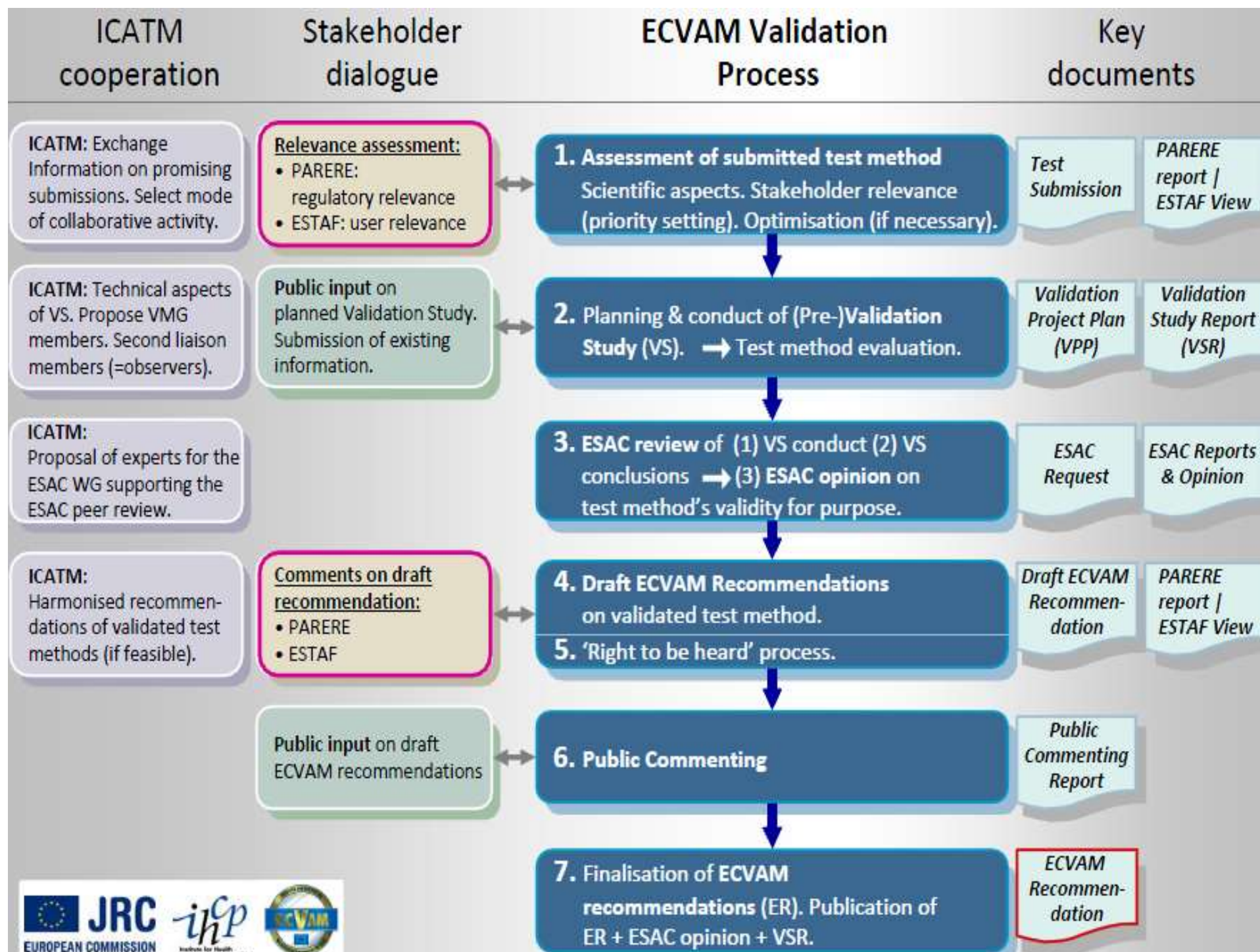
COMMUNICATIE

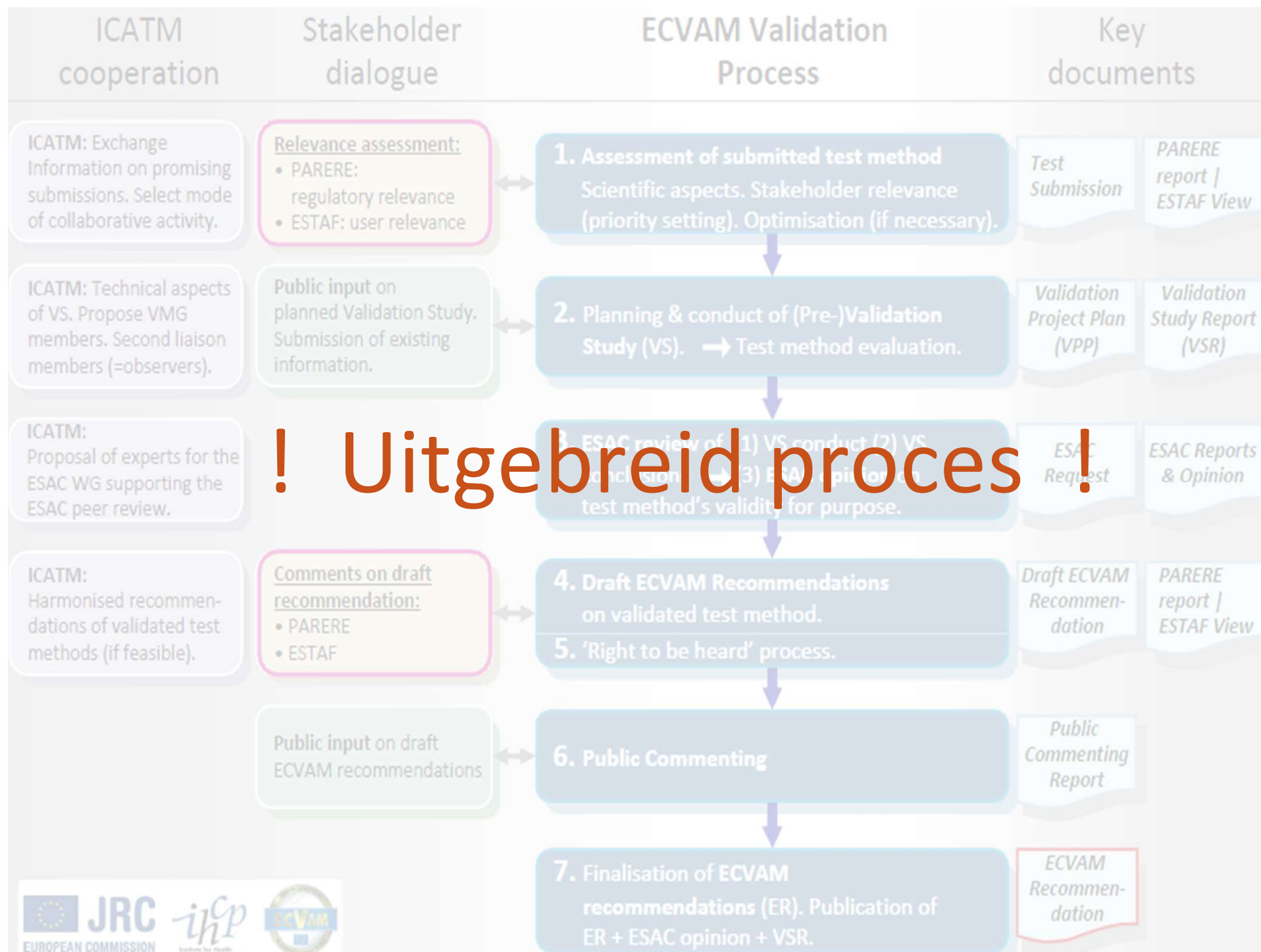
Tussen verschillende stakeholders



DISSEMINATIE

Actief verspreiden van informatie





! Uitgebreid proces !

EU-NETVAL

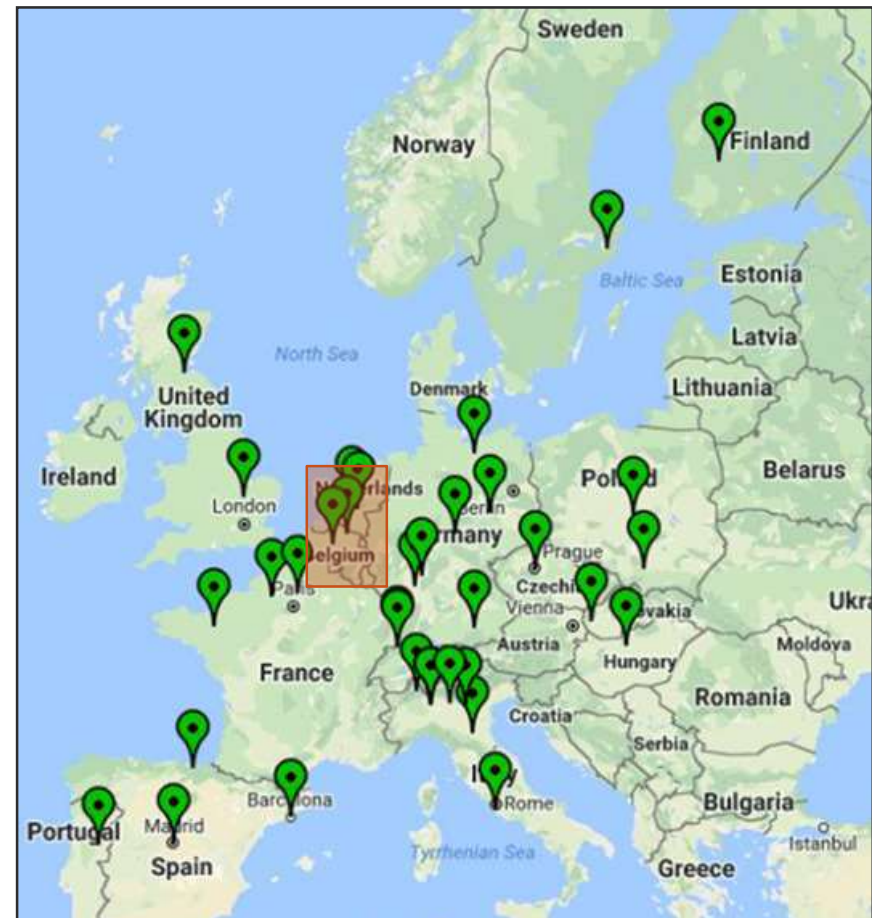
‘EU Network of Laboratories for the Validation of Alternative Methods’

DOEL: Ondersteunen van EURL ECVAM validatiestudies

COORDINATIE: EURL ECVAM samen met ‘DG Environment’ en de NCPs

LEDEN: 35 (laatste oproep 09/2015)

1. Sciensano – Kwaliteit van Vaccins & bloedproducten
2. VITO-ABS – Toegepaste Bio & Moleculaire Systemen



PARERE-netwerk

‘Network for Preliminary Assessment of Regulatory Relevance of alternative methods and approaches’



PARERE vertegenwoordiger in
30 EU lidstaten
(BE: *Sciensano*)



Regelgevende instanties nauwer betrekken bij ontwikkeling van
alternatieve methoden en benaderingen

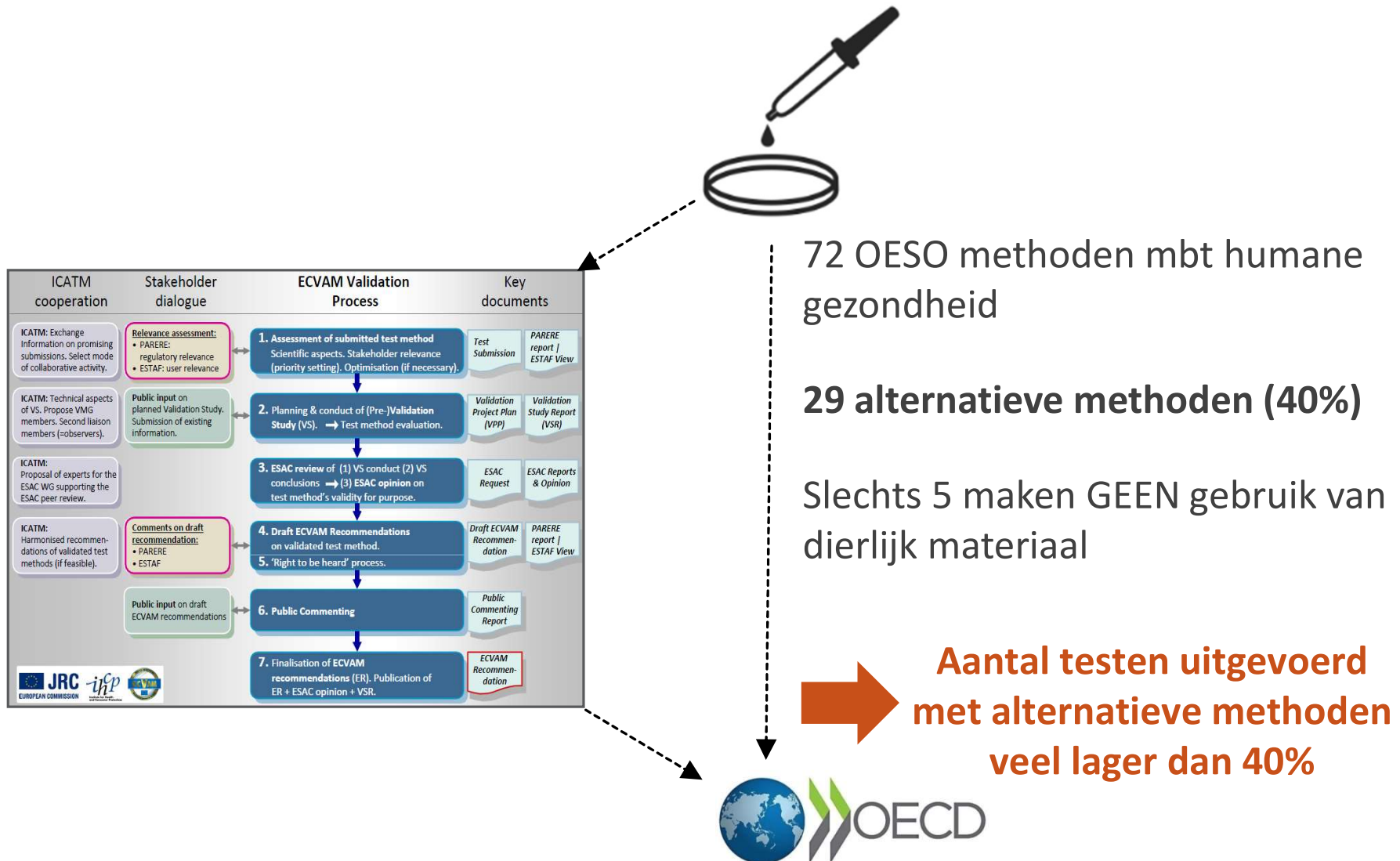
BE PARERE-netwerk

BE experten uit verschillende regelgevende domeinen

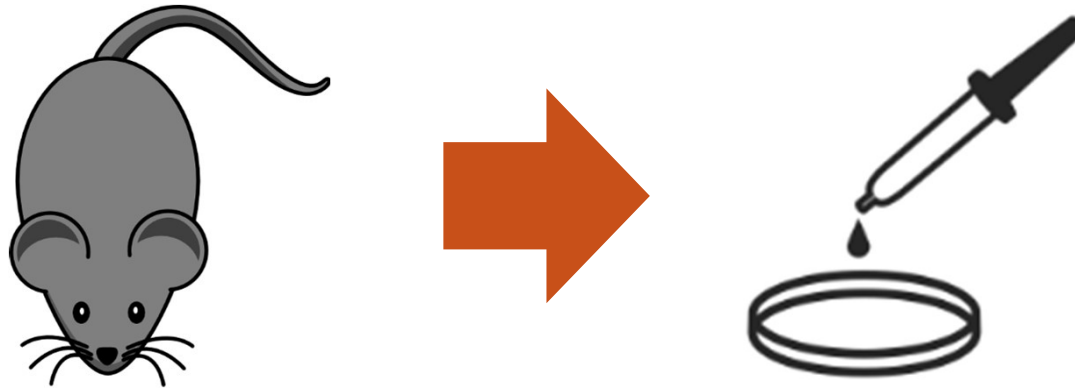


2x/jaar meeting met workshop over alternatieve methoden

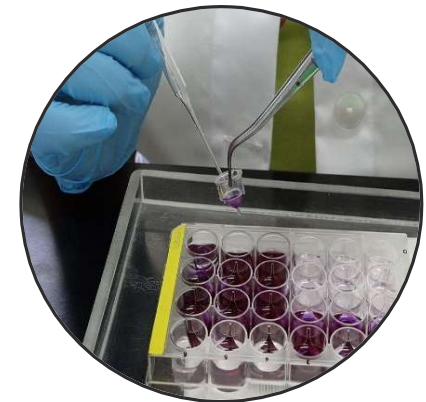
OESO Programma van de testmethoden



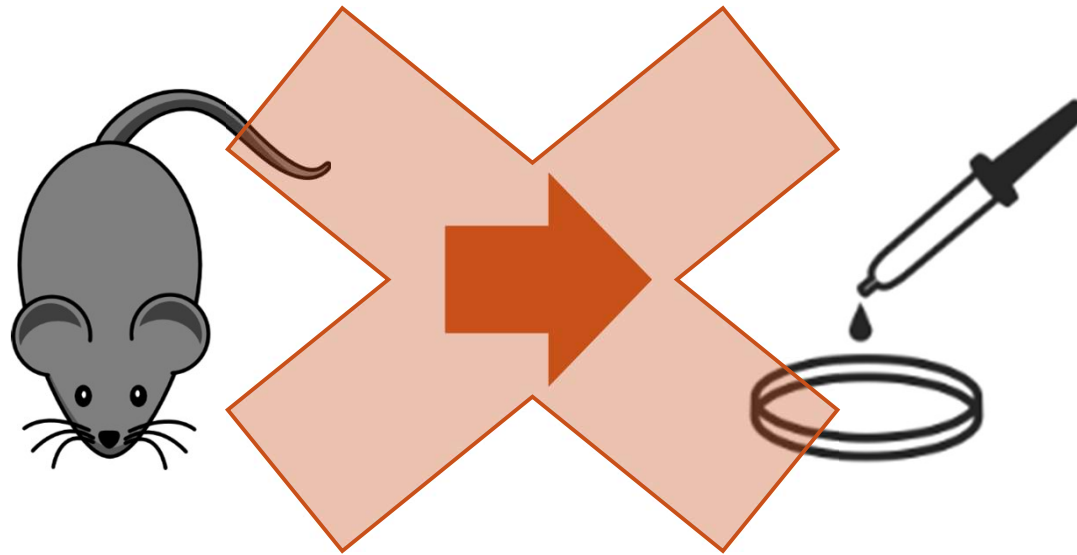
1:1 Vervanging



- **Absorptie door de huid**
(*ex vivo* methode)
- **Huidcorrosie en irritatie**
(*ex vivo* methoden + *in vitro* methoden
gebaseerd op gereconstrueerd humaan
huidweefsel)



1:1 Vervanging



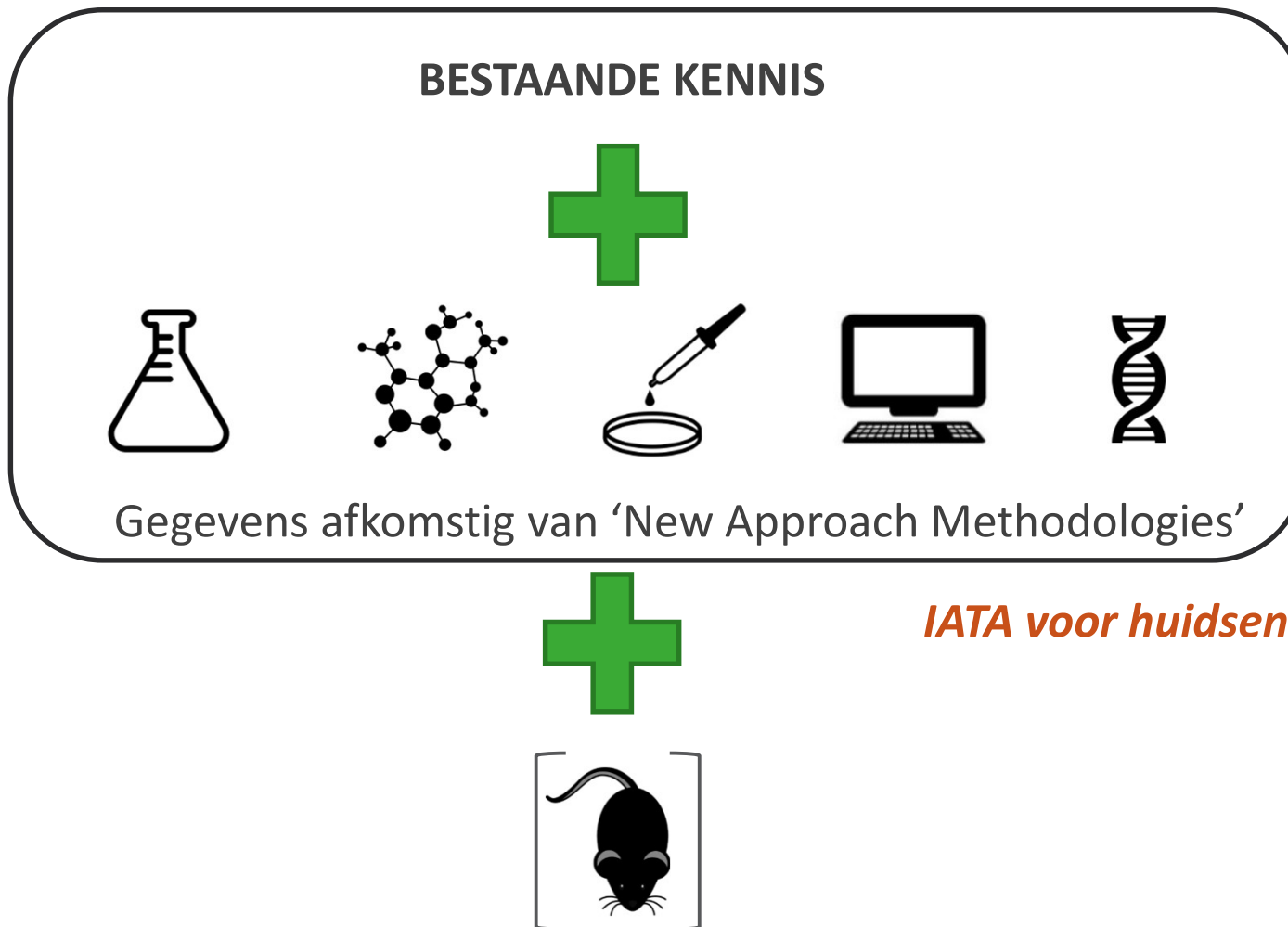
1:1 vervanging NIET MOGELIJK in meeste gevallen



IATA: Integrated Approaches to Testing and Assessment

IATA

'Integrated Approaches to Testing and Assessment'



PARC

‘Partnership for the Assessment of Risk from Chemicals’

Draft proposal for a European Partnership under
Horizon Europe
Partnership for the Assessment of Risk from Chemicals
(PARC)
Version 03/06/2020

About this draft

In autumn 2019 the Commission services asked potential partners to further elaborate proposals for the candidate European Partnerships identified during the strategic planning of Horizon Europe. These proposals have been developed by potential partners based on common guidance and template, taking into account the initial concepts developed by the Commission and feedback received from Member States during early consultation¹. The Commission Services have guided revisions during drafting to facilitate alignment with the overall EU political ambition and compliance with the criteria for Partnerships.

This document is a stable draft of the partnership proposal, released for the purpose of ensuring transparency of information on the current status of preparation (including on the process for developing the Strategic Research and Innovation Agenda). As such, it aims to contribute to further collaboration, synergies and alignment between partnership candidates, as well as more broadly with related R&I stakeholders in the EU, and beyond where relevant.

This informal document does not reflect the final views of the Commission, nor pre-empt the formal decision-making (comitology or legislative procedure) on the establishment of European Partnerships.

In the next steps of preparations, the Commission Services will further assess these proposals against the selection criteria for European Partnerships. The final decision on launching a Partnership will depend on progress in their preparation (incl. compliance with selection criteria) and the formal decisions on European Partnerships (linked with the adoption of Strategic Plan, work programmes, and legislative procedures, depending on the form). Key precondition is the existence of an agreed Strategic Research and Innovation Agenda / Roadmap. The launch of a Partnership is also conditional to partners signing up to final, commonly agreed objectives and committing the resources and investments needed from their side to achieve them.

The remaining issues will be addressed in the context of the development of the Strategic Research and Innovation Agendas/ Roadmaps, and as part of the overall policy (notably in the respective legal frameworks). In particular, it is important that all Partnerships further develop their framework of objectives. All Partnerships need to have a well-developed logical framework with concrete objectives and targets and with a set of Key Performance Indicators to monitor achievement of objectives and the resources that are invested.

Aspects related to implementation, programme design, monitoring and evaluation system will be streamlined and harmonised at a later stage across initiatives to ensure compliance with the implementation criteria, comparability across initiatives and to simplify the overall landscape.

¹ https://www.era-learn.eu/documents/final_report_ms_partnerships.pdf

Horizon Europe

THE NEXT EU RESEARCH & INNOVATION
PROGRAMME (2021 – 2027)



- Public-public partnership
- Start: voorjaar 2022 (7 jaar)
- Doel: ondersteunen transitie naar ‘**Next Generation Risk Assessment**’
- Veel BE instellingen betrokken bij project (*Sciensano Taakleider voor IATAs*)

New Approach Methodologies (NAMs)

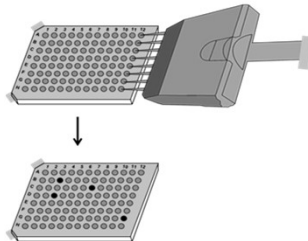
Diverse nieuwe technologieën ontwikkeld in de levenswetenschappen

Bioengineering



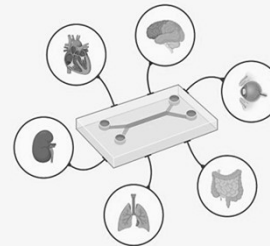
Moleculaire technieken

Celculturen
2D, high throughput



3D, sferoïden

Organ-on-chip



Human-on-chip

Computer modellering



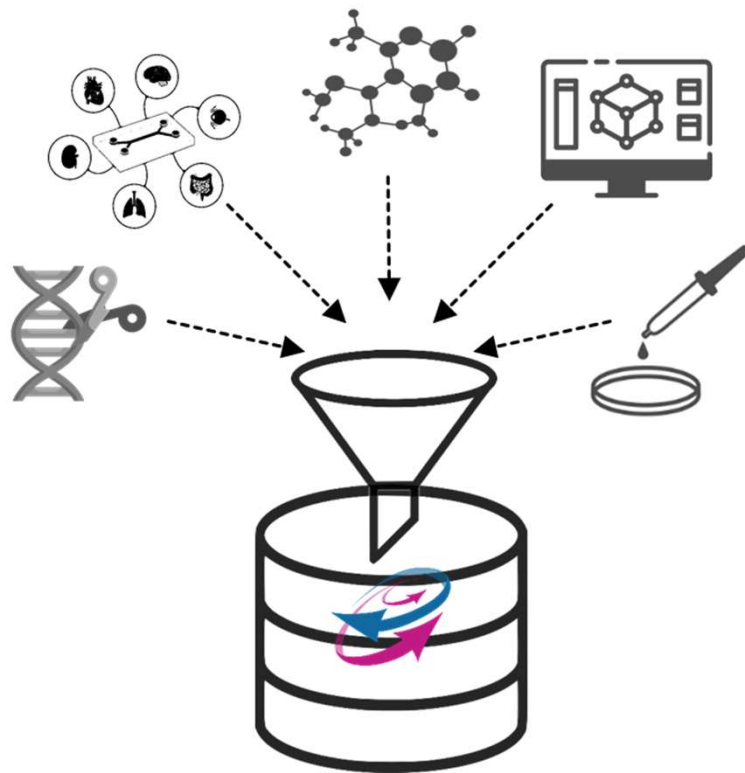
Artificiële intelligentie



Bij voorkeur gebaseerd op humaan lichaamsmateriaal, niet noodzakelijk als stand-alone, maar ook in combinatie met andere NAMs/dieren

RE-Place project

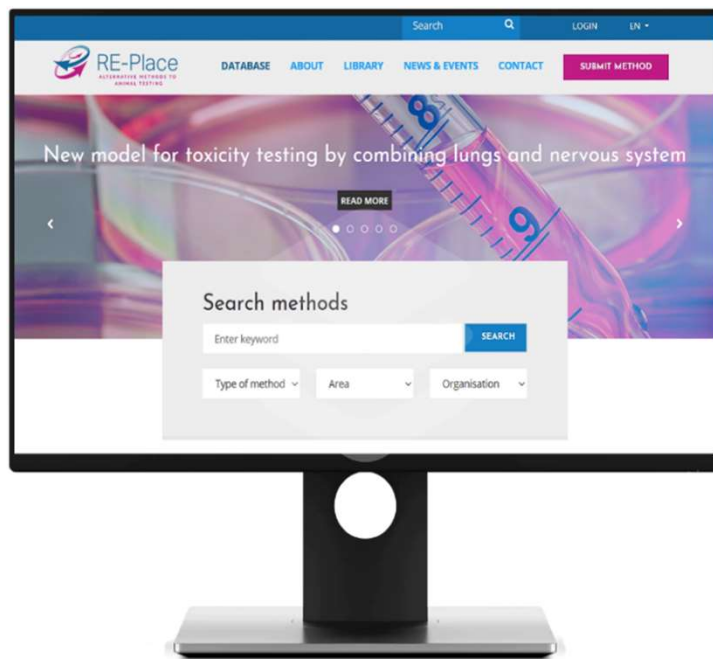
Bestaande EXPERTISE over NAMs in VL en BR verzamelen
in EEN CENTRALE DATABANK



- Gefinancierd door Vlaanderen en Brussel
- Coördinatie door Sciensano en VUB
- Databank en online tool geïntegreerd in website

www.RE-Place.be

RE-Place project



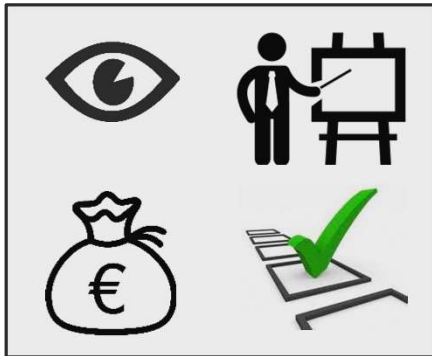
www.RE-Place.be

> 160 methoden

- Ingediend door 115 experts
- Van 17 verschillende instellingen

**Najaar 2021: lancering geoptimaliseerde versie van RE-Place online tool
(+ promotiecampagne om zichtbaarheid te stimuleren)**

Conclusie



Contact

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