

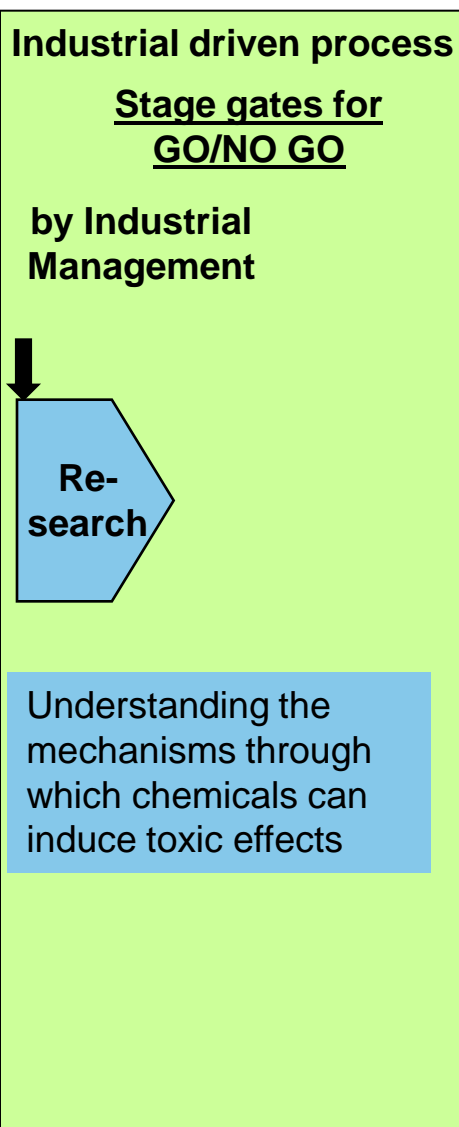


The process of validation: the point of view of the industry

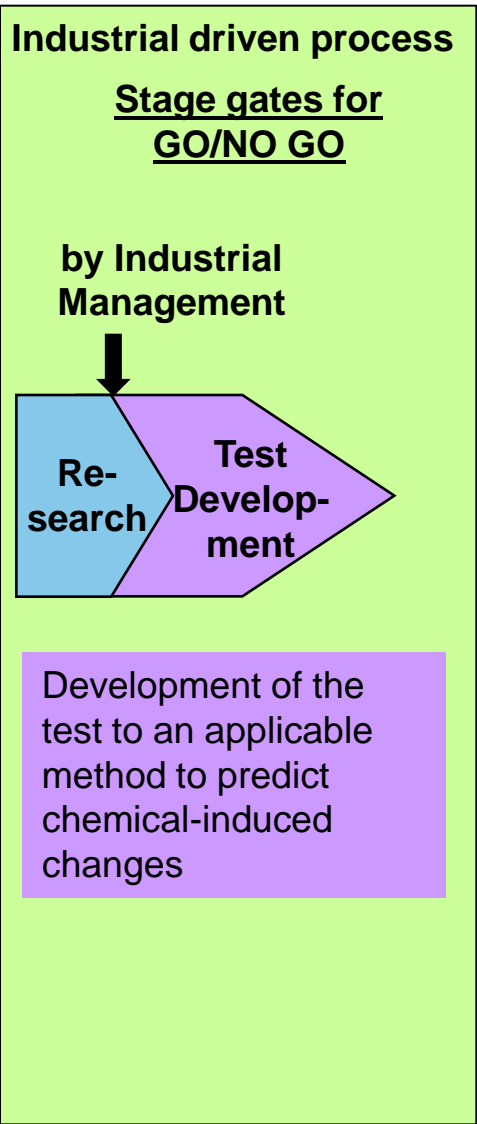
Philippe Vanparys

A personal interpretation on the process of validation on basis of information and experience

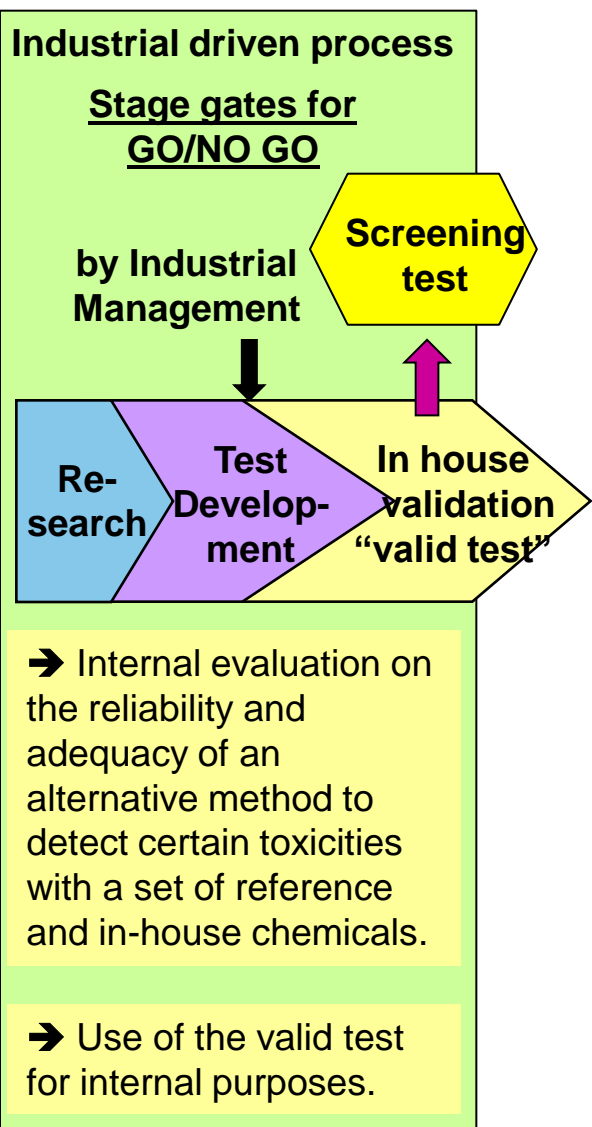
Process from research to a regulatory test



Process from research to a regulatory test



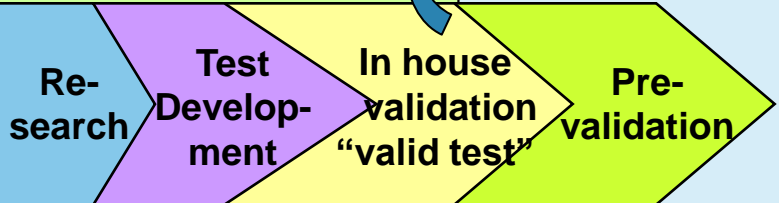
Process from research to a regulatory test



Process from research to a regulatory test

Industrial driven process

Industrial and regulatory driven process



Stage gates for GO/NO GO

Industry

- Submit all data to ECVAM through the Test Presubmission Form (**TPF**) and the Test Submission Template (**TST**)
- ➔ 2-step ECVAM test submission process which is mandatory to have a test method eventually entering the ECVAM validation process

Small scale study essential for a good validation

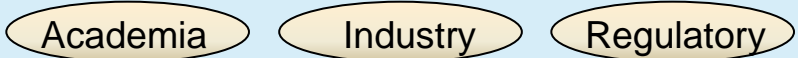
- According to the Modular Approach (Hartung et al. 2004)

↑ ?
PARERE
ESTAF
ICATM

PARERE (Preliminary Assessment of Regulatory Relevance)
ESTAF (ECVAM Stakeholders Forum)

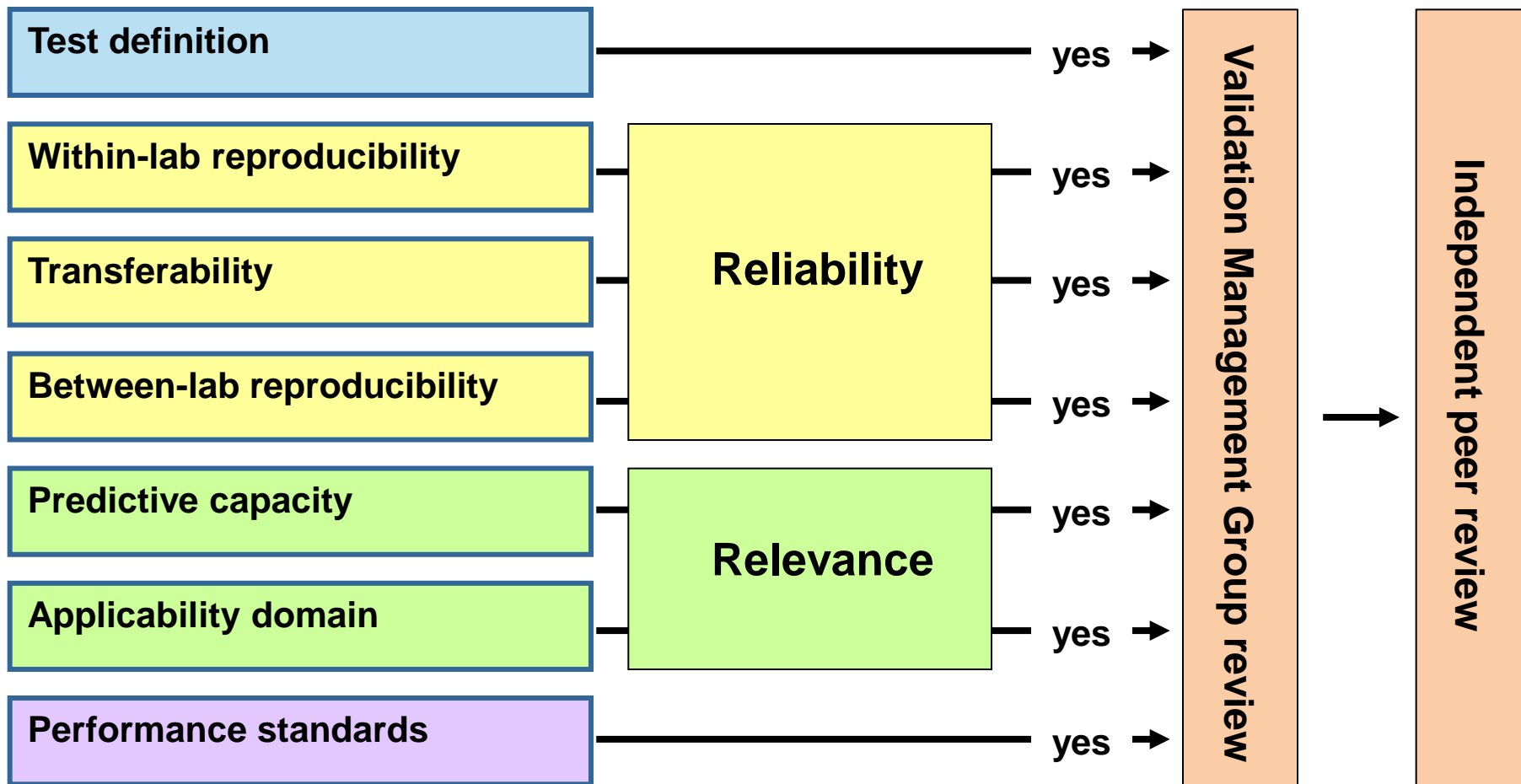
ICATM (International Cooperation on Alternative Test Methods)

- Input at an early stage on the relevance of the proposed method
- Define regulatory need of the new method



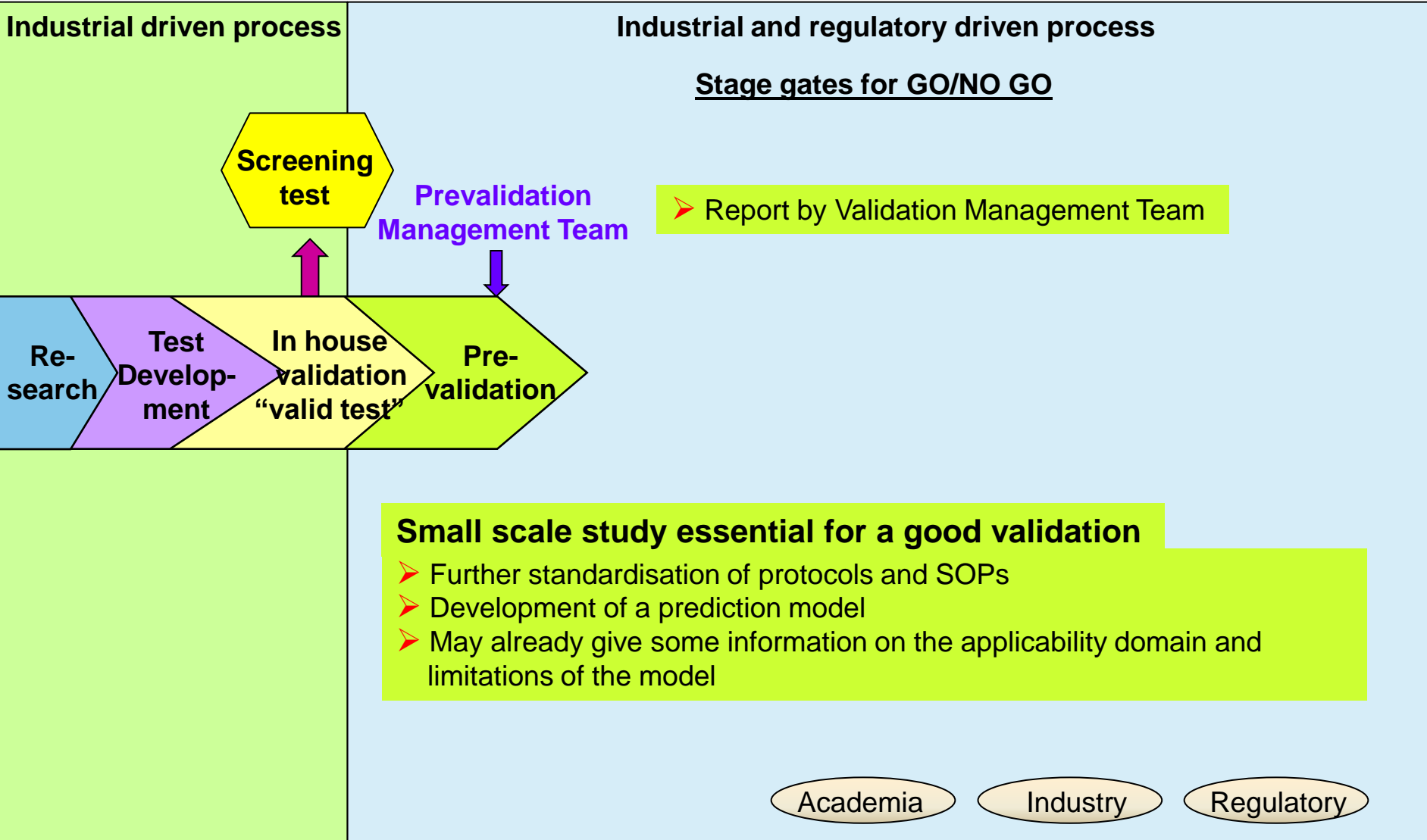
Process from research to a regulatory test

The ECVAM Modular Approach



Hartung et al., 2004

Process from research to a regulatory test

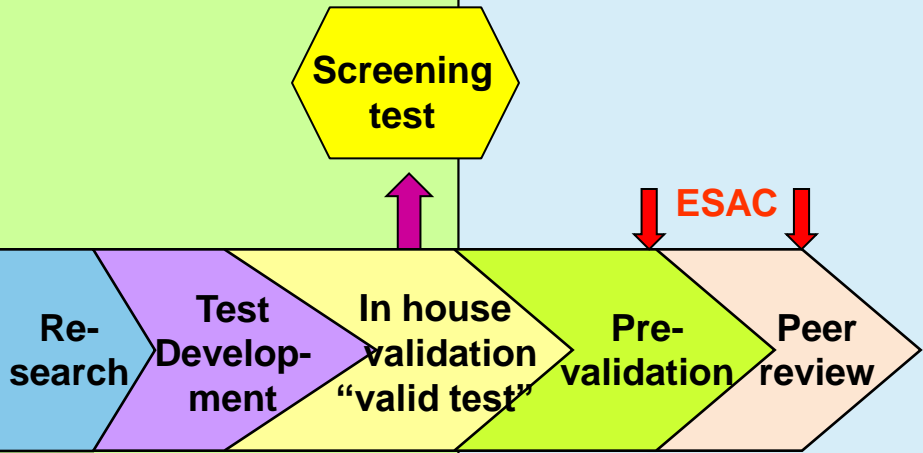


Process from research to a regulatory test

Industrial driven process

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Stage gates for GO/NO GO

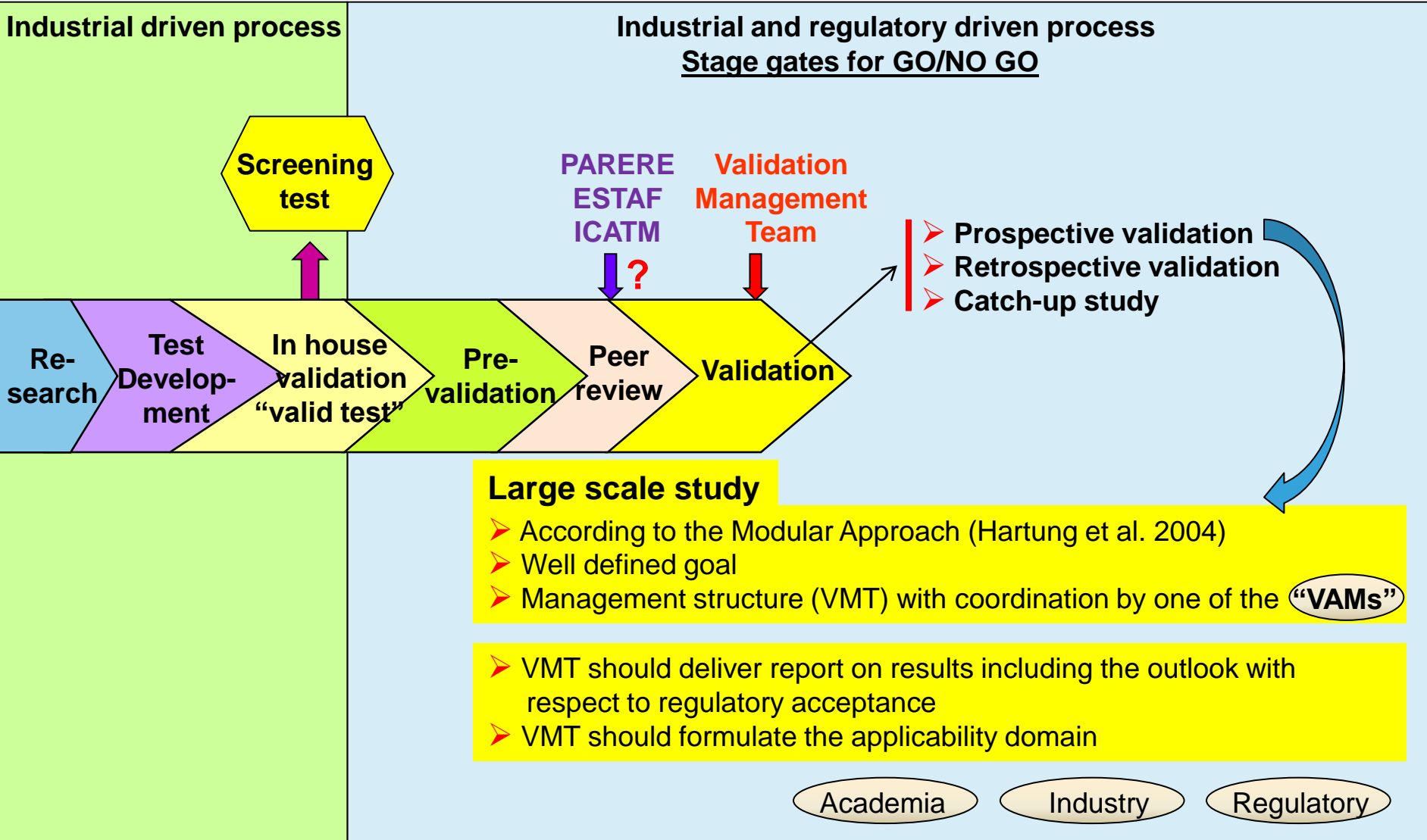


ESAC (ECVAM Scientific Advisory Committee)

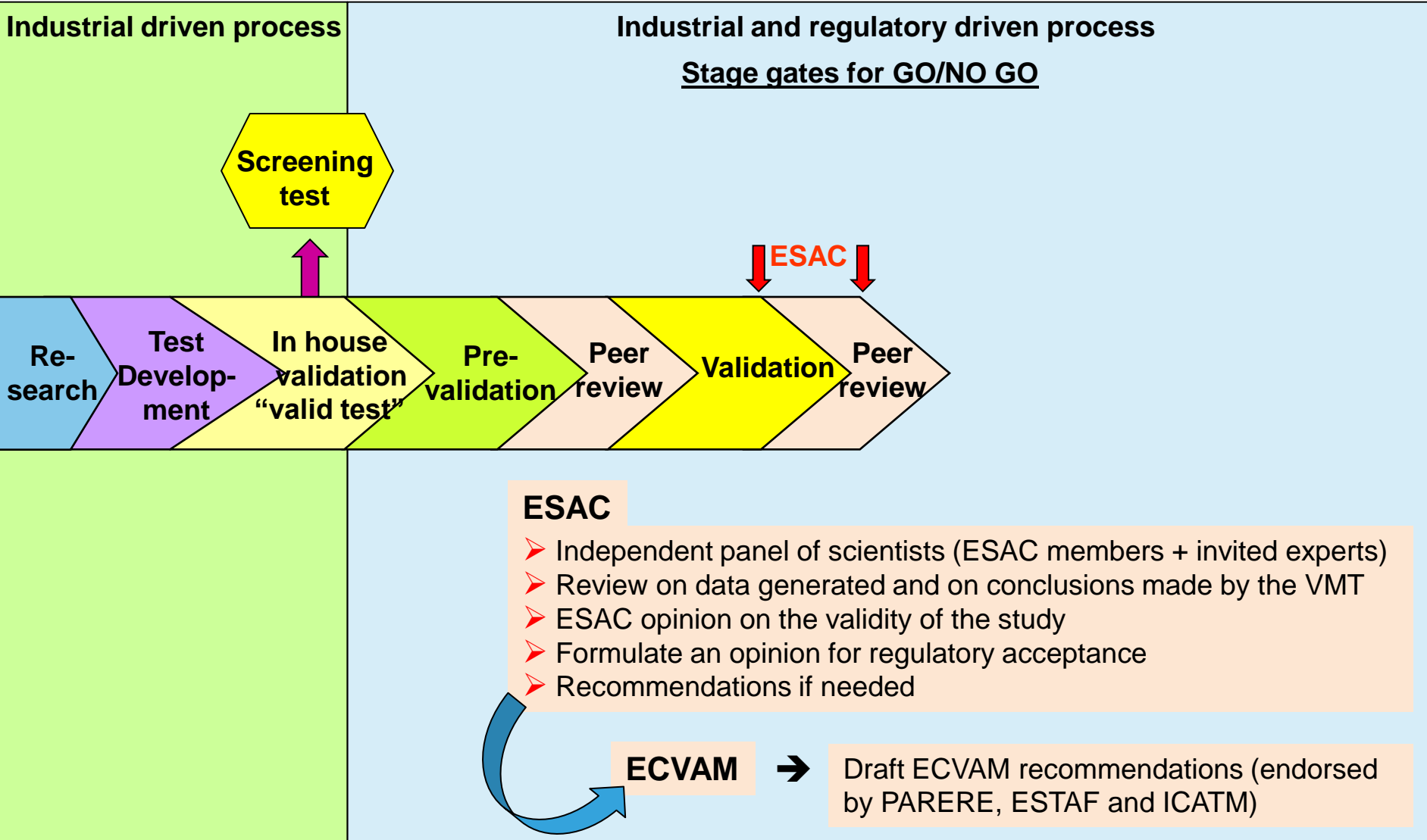
- Independent panel of scientists (ESAC members + invited experts)
- Review on data generated and on conclusions made by the VMT
- ESAC opinion on the validity of the study
- Recommendations if needed



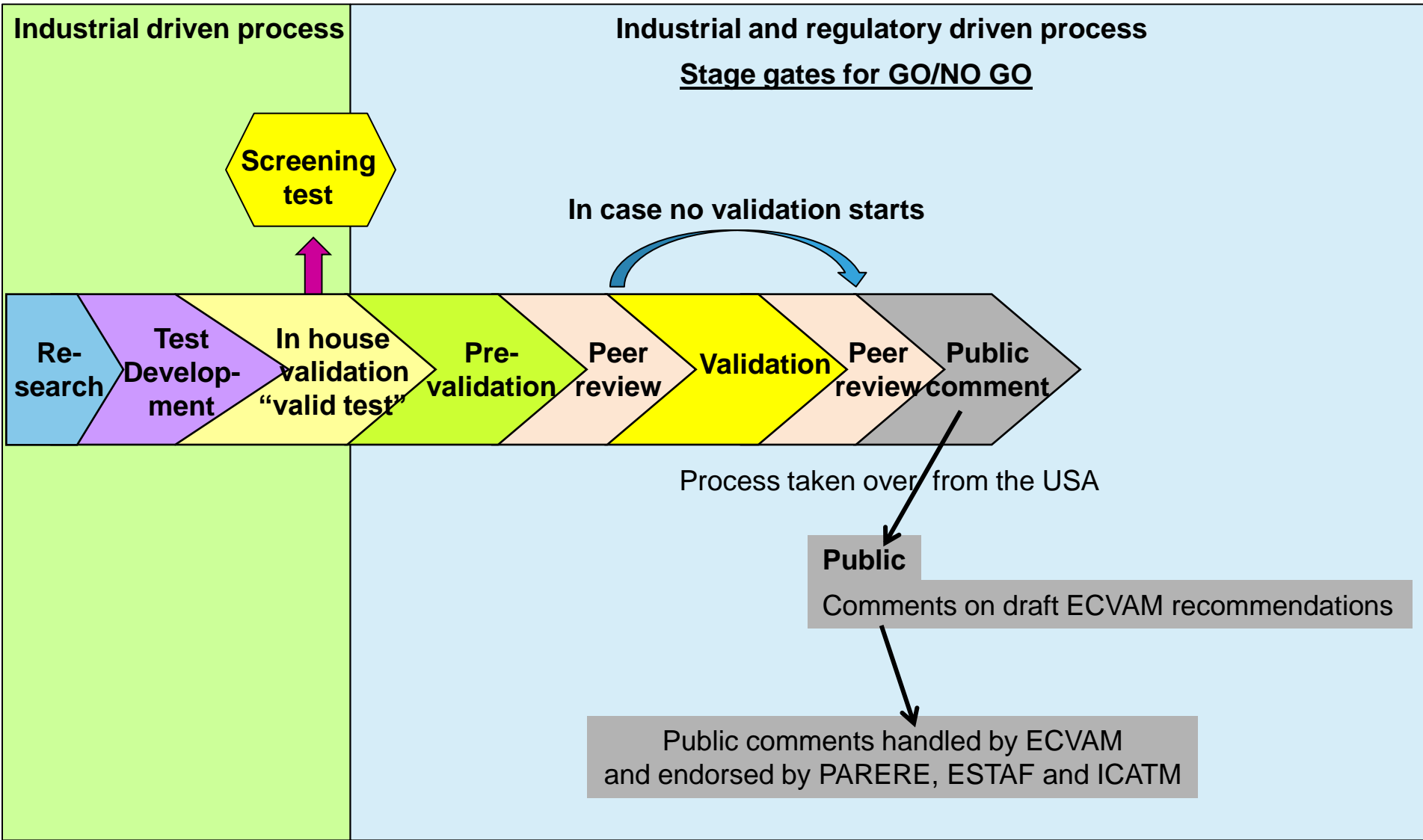
Process from research to a regulatory test



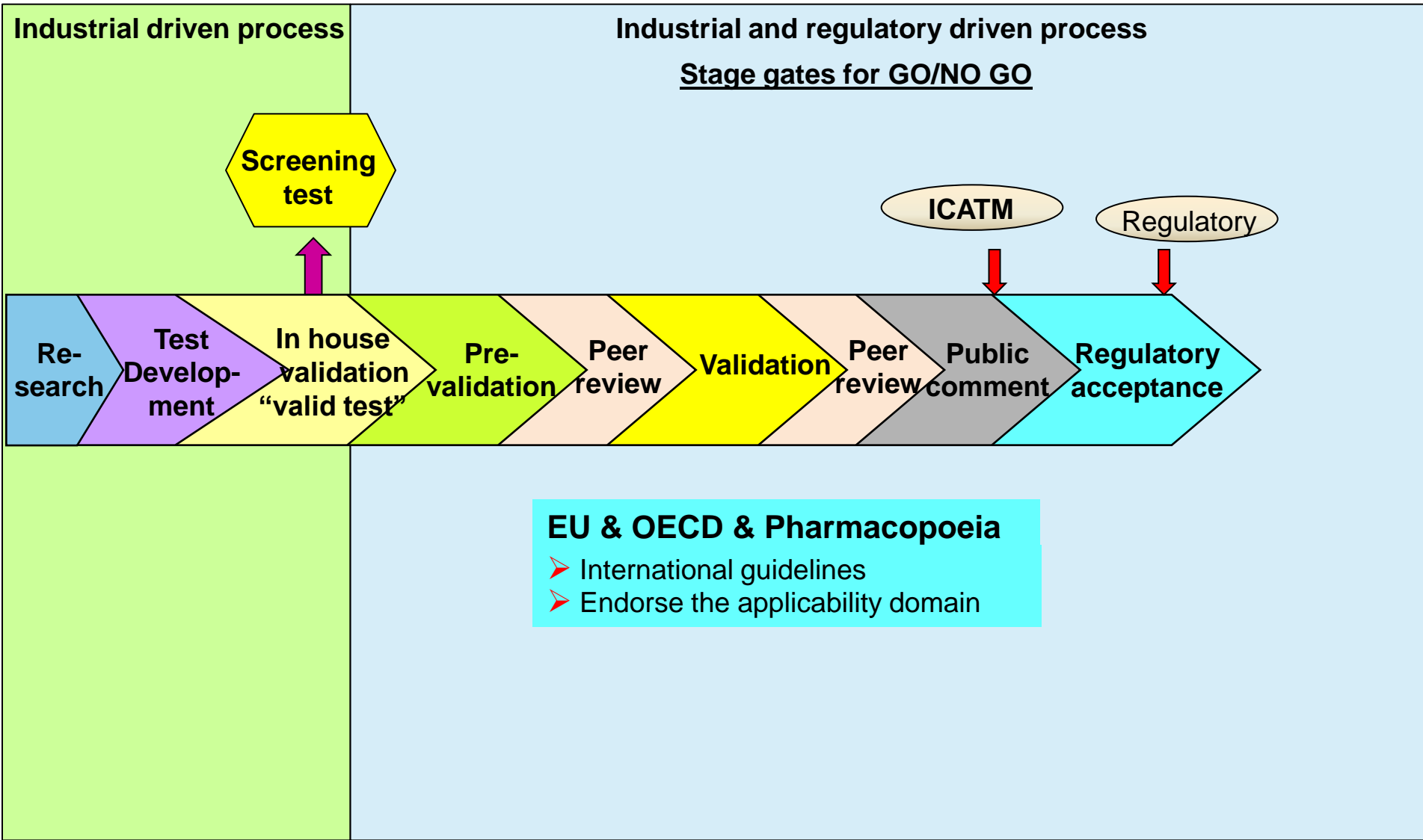
Process from research to a regulatory test



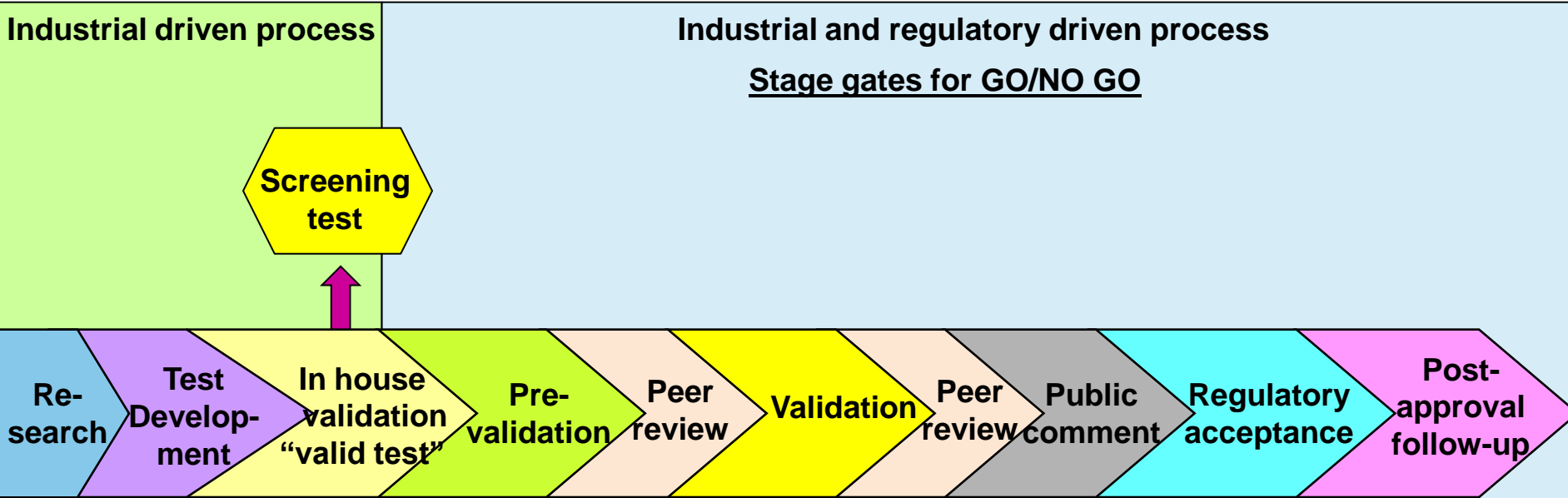
Process from research to a regulatory test



Process from research to a regulatory test



Process from research to a regulatory test

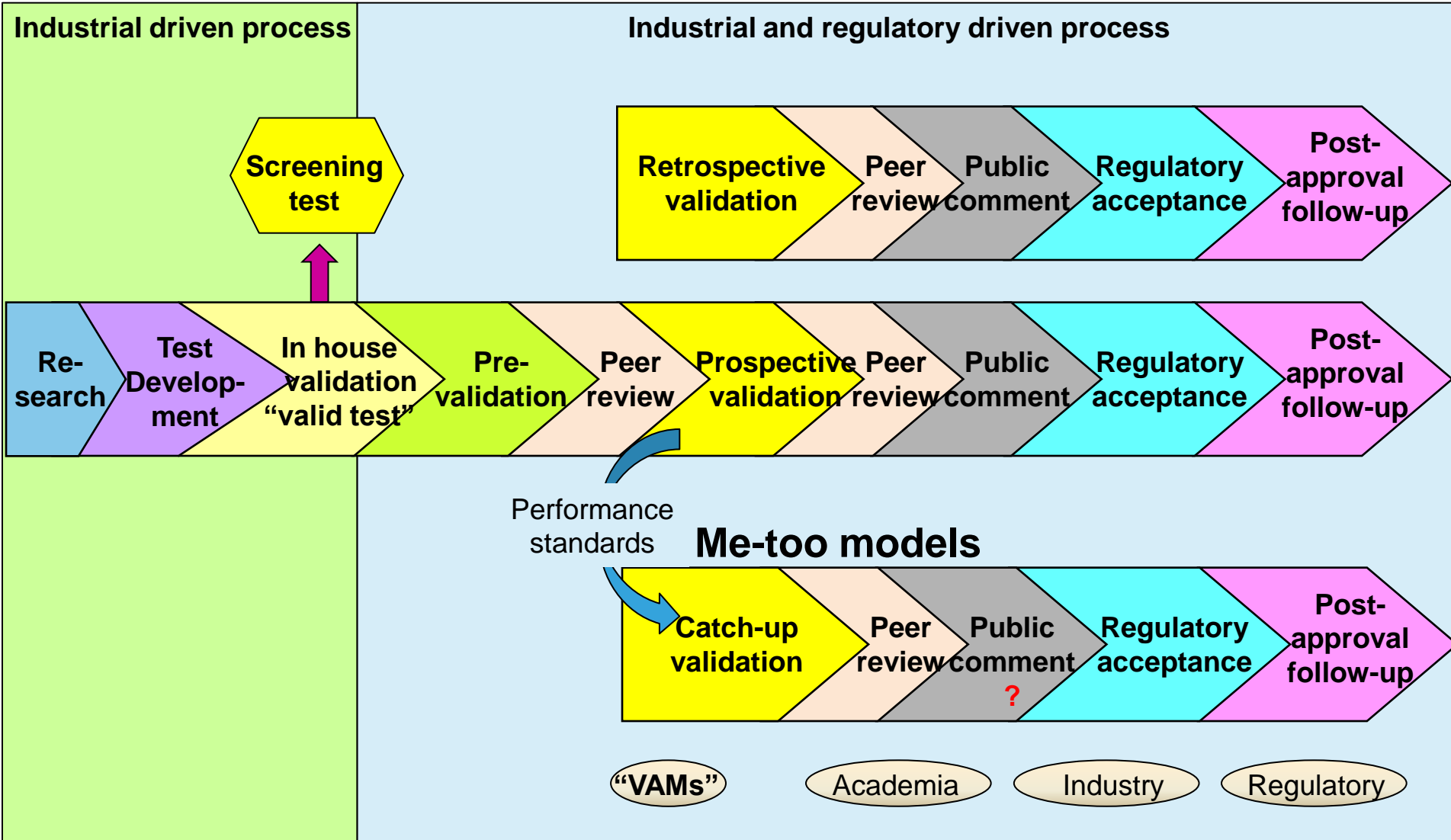


Currently missing phase but crucial for "survival" of alternative methods

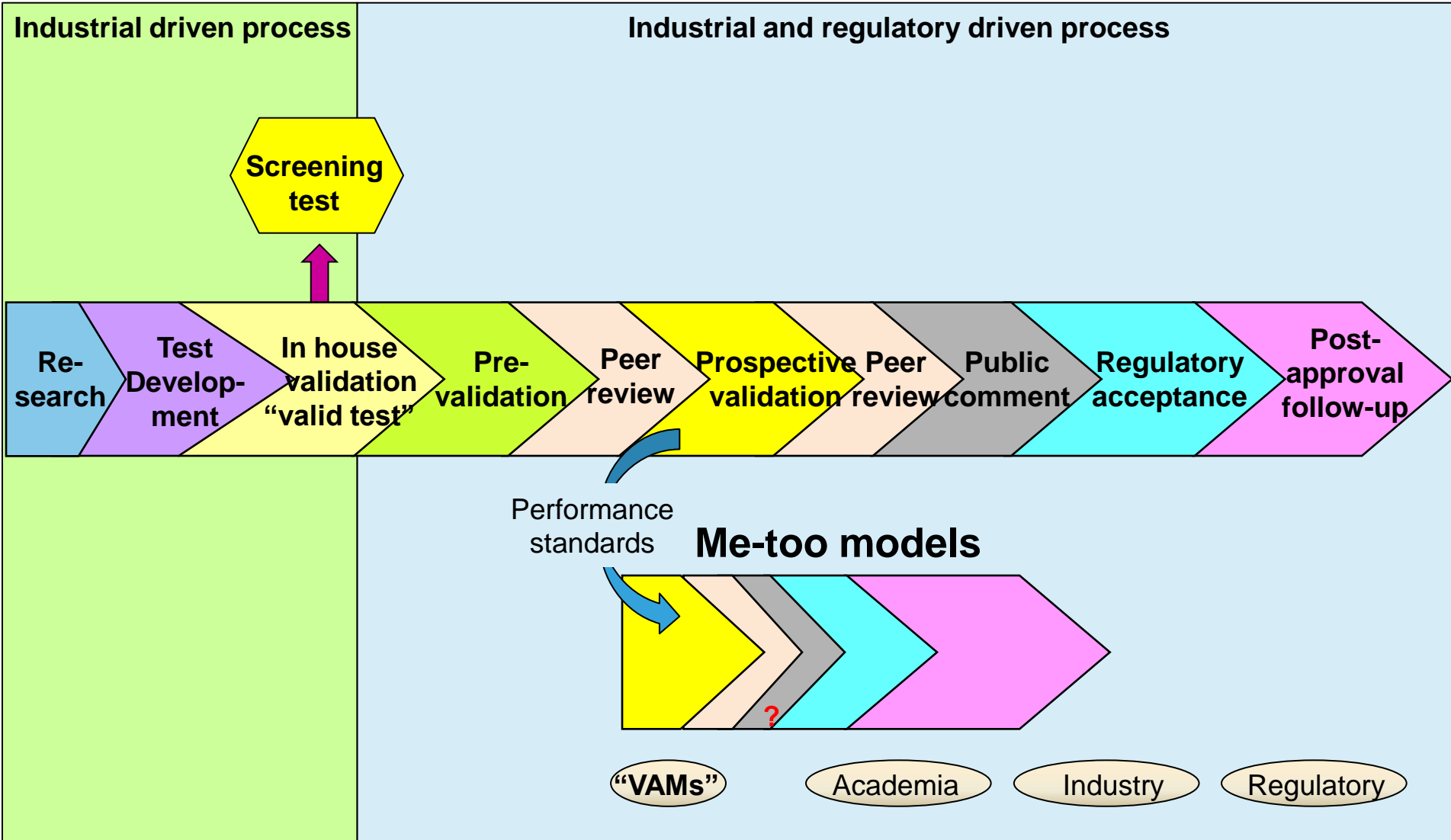
- Data generated leading to misclassifications should be centrally stored
- Task for the "VAMs" to coordinate
- The coordinating group should formulate adaptations to the guidelines and address the findings to the EU, OECD, Pharmacopoeia

Academia Industry Regulatory

Process from research to a regulatory test



Process from research to a regulatory test

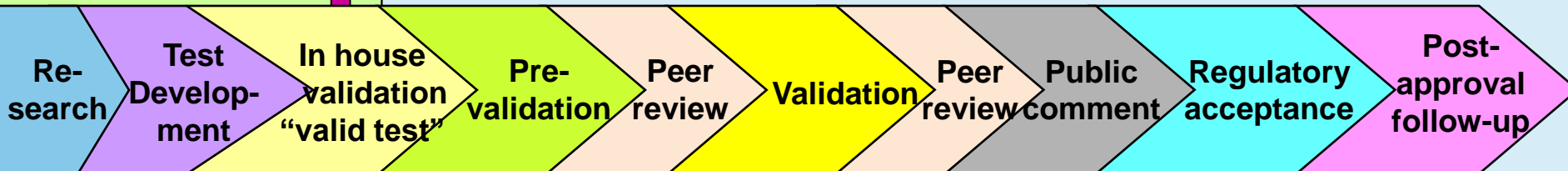
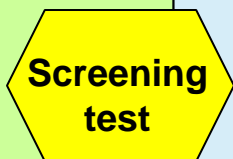


Process from research to a regulatory test

Time lines

Industrial driven process

Industrial and regulatory driven process



← > 10 years →

← > 8 - 12 years →

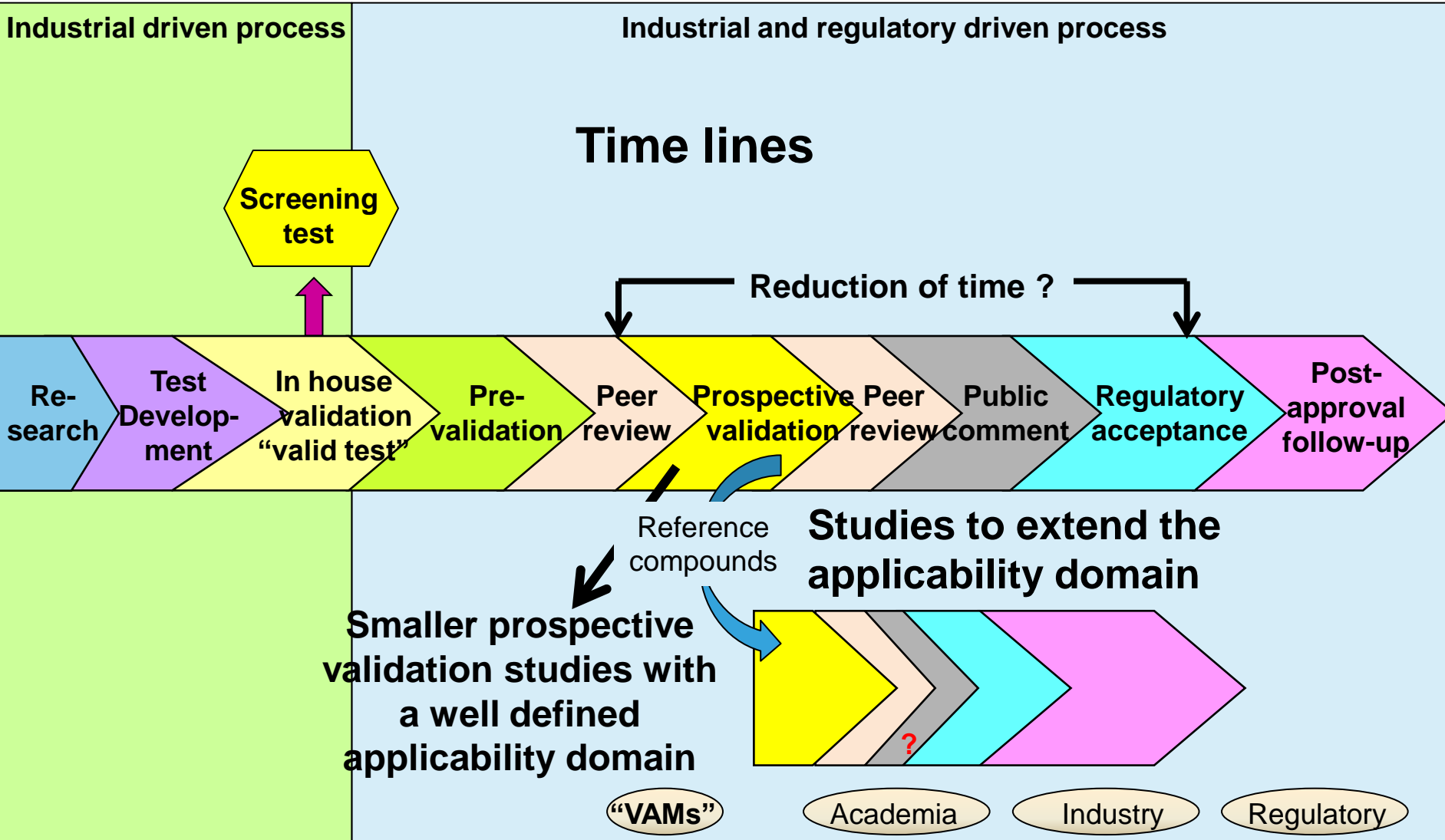
Most positive view of estimated timelines for entry into prevalidation

Toxicokinetics	> 5-7 years
Skin sensitisation	7-9 years
Repeated dose toxicity	no estimate
Carcinogenicity	no estimate
Reproduction toxicity	> 10 years

(Adler et al., 2011)

(Alternative (Non-Animal) methods for Cosmetic Testing: Current Status and Future Prospects. ATLA , 2005)

Process from research to a regulatory test



***In vivo studies can be painful for animals,
but time necessary to go through the validation process
is nowadays painful for man***

Thanks for your attention