OECD STAKEHOLDERS' SURVEY AND WORKSHOP ON OPERATIONAL AND FINANCIAL ASPECTS OF VALIDATION

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EC workshop on roadmap to phasing out animal testing
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BETTER POLICIES FOR BETTER LIVES

RECAP OF RECENT DISCUSSIONS AT THE OECD - CHEMICAL SAFETY PROGRAMME

- In 2022, Chemicals and Biotechnology Committee:
  - discussed the future of chemicals assessment
  - supported evolutions proposed, incl.
    - Having a framework/guidance for the validation of New Approach Methods (NAMs)
    - Standardised reporting templates to facilitate regulatory use (QSAR models and predictions, IATAs, omics, etc.)
    - Emphasis on new methods for exposure assessment
    - Considerations of the technical readiness of NAMs

CURRENT STATE-OF-PLAY ON VALIDATION

Years reflecting on validation practices and principles

- Consensus today:
  - Validation principles are universal (relevance/reliability)
    - but context has changed (↓ standalone methods)
  - Validation is needed to facilitate regulatory acceptance
  - Validation practices should evolve (multiple reasons)

- Meanwhile, validation practitioners evolved and new issues have emerged
  - Validation centres, small innovative companies, large chemical producers, academia
  - Originating from public or private or public-private partnerships
  - Different needs and challenges (operational, financial, regulatory,…)

Update of GD 34

OECD proposed to facilitate discussions on concrete actions that would ease operational aspects of the validation and the sourcing of financial support for validation studies.

2023: ENGAGING TOGETHER IN CONCRETE ACTIONS

- 2023:
  - Jan: Call for increased public funding into methods validation to allow new standard methods based on emerging science and technologies and allow broad accessibility and use in countries

  - Project started to update OECD Guidance Document 34 on Validation (collaboration EC-JRC, US, NL)

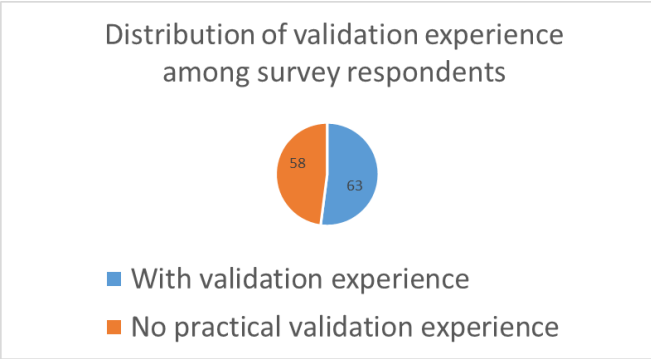
  Survey of validation practitioners on practical and financial aspects of validation
    - collect insight on specific issues and identify opportunities to work more cost efficiently on methods validation

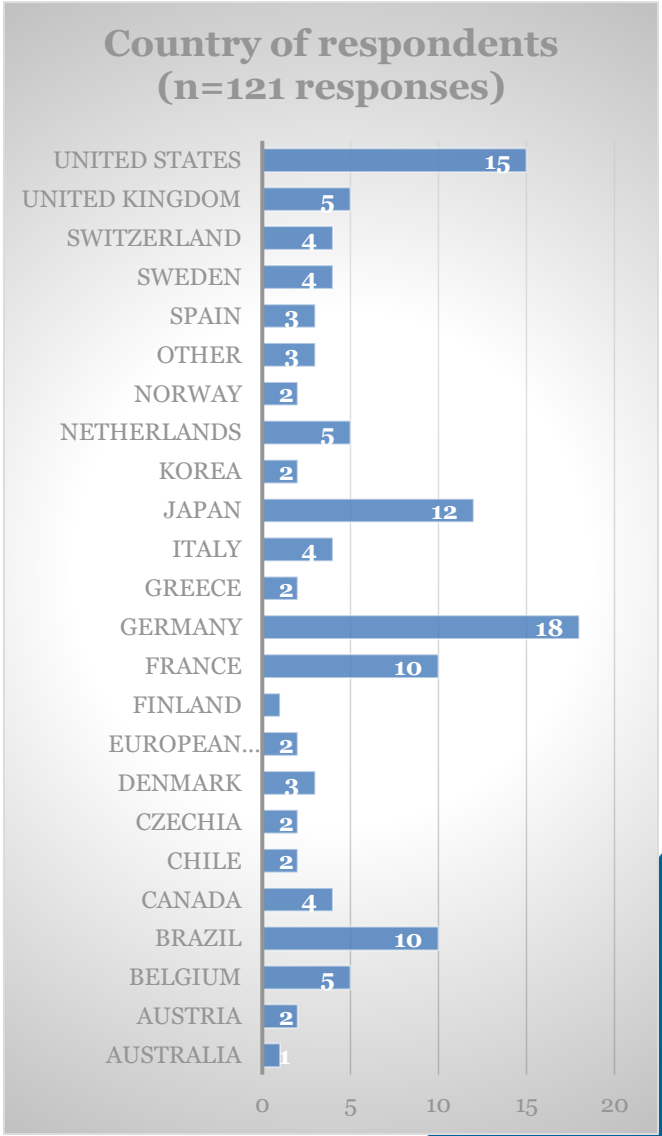
  - Workshop with validation practitioners on 14-15 Dec. 2023 to explore options and solutions together

STAKEHOLDERS' SURVEY

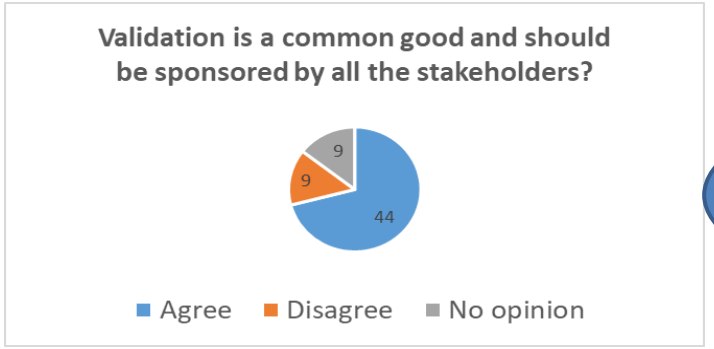
Objective: develop an overview of the validation landscape, document experience, identify challenges and what solutions may come from practitioners

- 35 questions to collect feedback in the following areas:
  - Practical experience with validation
  - Level of interaction with other stakeholders in the field
  - Perspectives on practices and processes and where efficiency gains might be
  - Interest and incentives to take part in validation studies in future
  - Financial aspects of validation: collect cost figures, who funds? who should fund? what is costly and where efficiency gains are possible
  - Organisational support for funding (parts of) validation?
  - Good practices that should be promoted (funding and operational aspects)
  - Different models for organising and funding validation studies?

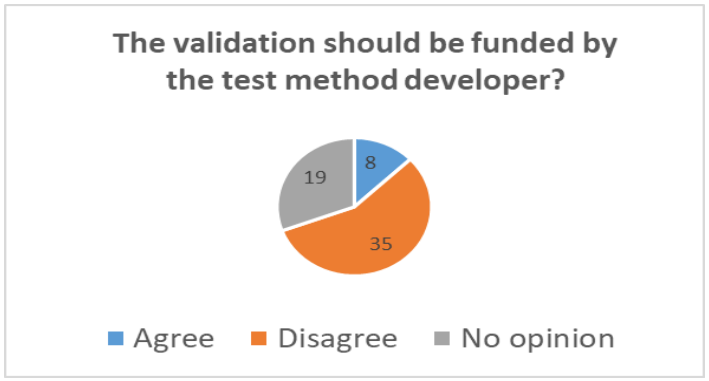




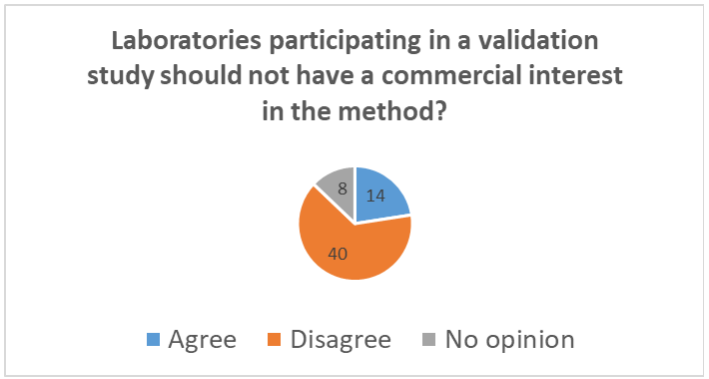
FINANCIAL ASPECTS



A large majority agrees **all stakeholders should financially support validation** activities



Funding of validation should **not** be left to the method developer only



It is **acceptable that commercial laboratories take part in a validation study** to acquire skills, but bias should be avoided.

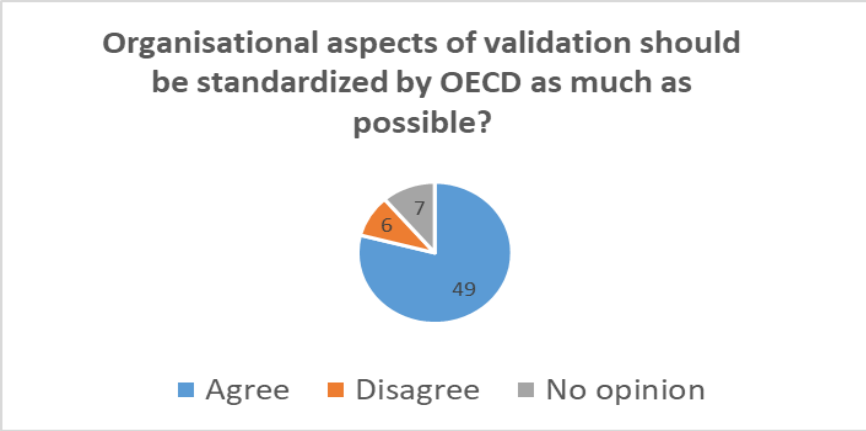
Costing validation

Item	Min. resources (EUR/USD)	Max resources (EUR/USD)
Cell line/reagents		
Within lab reproducibility		
Between lab reproducibility (e.g. 3 labs)		
Chemicals procurement		
Coding/blinding		
Analytical chemistry		
Training/transfer		
Statistical analysis and report drafting		
Miscellaneous		
TOTAL		

From ~200 KEUR to ~500KEUR, depending on the complexity/costing of the assay

"The main drivers of the costs include technology transfer and training, between laboratory reproducibility, chemicals procurement, coding, blinding and shipment".

ORGANISATIONAL ASPECTS



Guidance on organizational aspects could be **standardized by OECD**, but **maintaining flexibility** to accommodate different situations

Respondents are willing to support validation through participation, peer review, funding, and dissemination.

Many feel the validation process should be streamlined and accelerated. Suggestions include more funding, guidance, training, **stronger engagement of stakeholders**, and **separating technical from regulatory validation**.

Potential efficiency gains include **better planning**, **training**, chemical selection, data sharing, and **separating reproducibility from regulatory assessments**.

Good practices for **integrity and transparency** should be promoted when commercial interests are involved in organizing/funding validation.

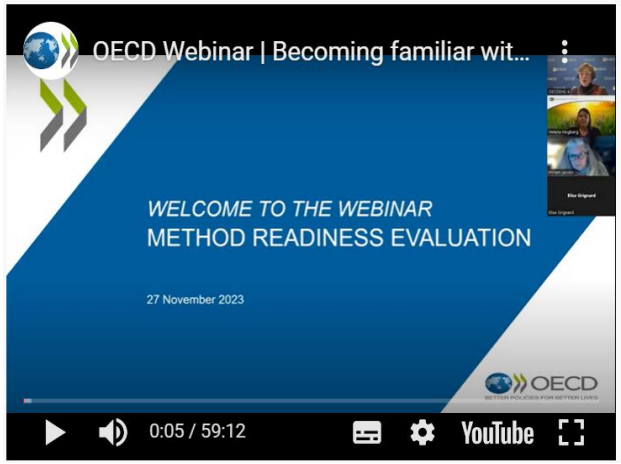
Specific suggestions include **optimizing protocols before validation**, **limiting chemicals and labs needed for reproducibility**, **engaging regulators early**, and **timely data sharing**.

Workshop expectations: finding solutions, sharing responsibilities and taking action for implementation

- Clear explanation why validation needs to be adequately funded by all stakeholders
  - common good, shared responsibility;
- Finding actionable solutions for each target group;
- Facilitating communication between funding bodies and project proponents;
- Making available resources/competencies more visible;
- Clarifying what “streamlined validation” means;
- Identifying any remaining gaps:
  - Which target group is left out with no role to play?
  - Which action/solution has not met an operator?

THANK YOU FOR LISTENING!

RECENT WEBINARS WITH REPLAYS AVAILABLE:



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