

**NETVAL
laboratories**

**ICATM
cooperation**

**Stakeholder
dialogue**

**EURL ECVAM
Validation Process**

**Key
documents**

ICATM: Exchange Information on promising submissions. Select mode of collaborative activity.

Relevance assessment:

- PARERE: regulatory relevance
- ESTAF: user relevance

1. Assessment of test method submission
Scientific and regulatory aspects.
Stakeholder relevance (priority setting).

Test Submission *Submission Assessment Report*

NETVAL: Participation of NETVAL laboratories in validation ring trials coordinated by EURL ECVAM

ICATM: Technical aspects of VS. Propose VMG members. Second liaison members (=observers).

Public input on planned Validation Study. Submission of existing information.

2. Planning and conduct of Validation Study (VS). → Test method evaluation.

Validation Project Plan (VPP) *Validation Report (VR)*

ICATM: Proposal of experts for the ESAC WG supporting the ESAC peer review.

3. ESAC review of (1) VS conduct (2) VS conclusions → **ESAC opinion** on test method's validity for purpose.

ESAC Request *ESAC Reports & Opinion*

ICATM: Harmonised recommendations of validated test methods (if feasible).

Comments on draft recommendation:

- PARERE
- ESTAF

4. ECVAM Recommendation on validated test method.
4.1. 'Right to be heard' process.

Draft ECVAM Recommendation

Public input on draft ECVAM recommendations

4.2. Public Commenting on EURL ECVAM draft recommendation

4.3. Publication of final ECVAM recommendation (together with ESAC opinion and VSR).

ECVAM Recommendation *Protocol in DbALM*