

Break out group 3



The Use of LLNA

For The Development of Next Generation Tests

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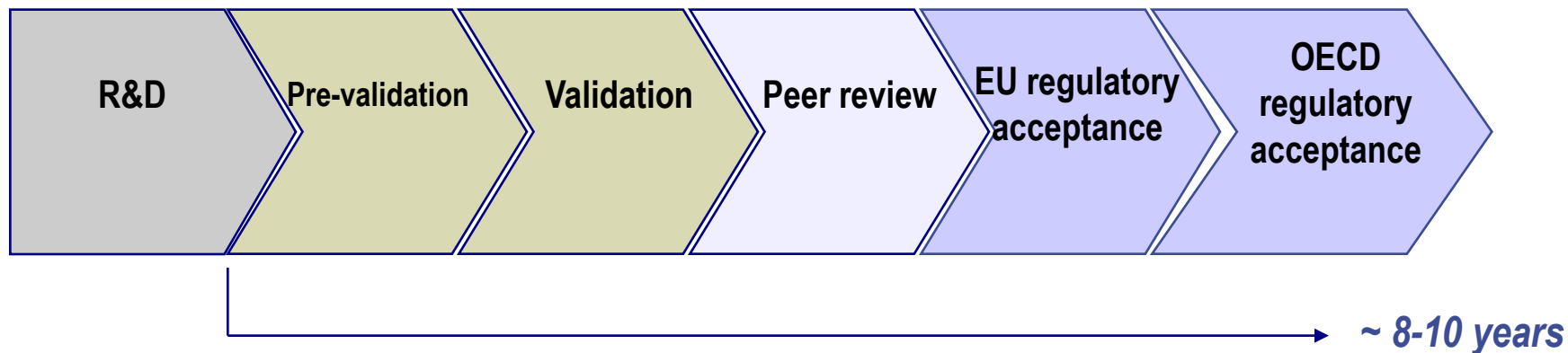
ECVAM, In Vitro Methods Unit

European Commission

Institute for Health and Consumer Protection (IHCP)

JRC Ispra (Italy)

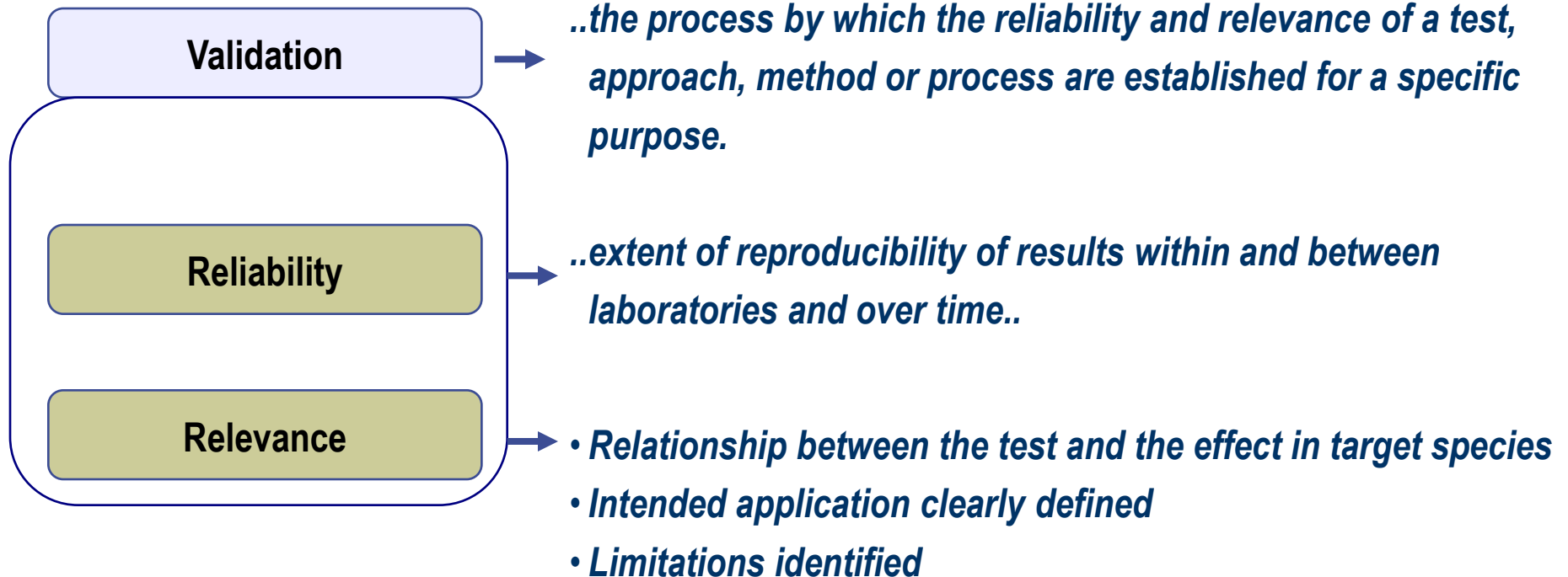
Alternative Methods: From Development to Regulatory Acceptance



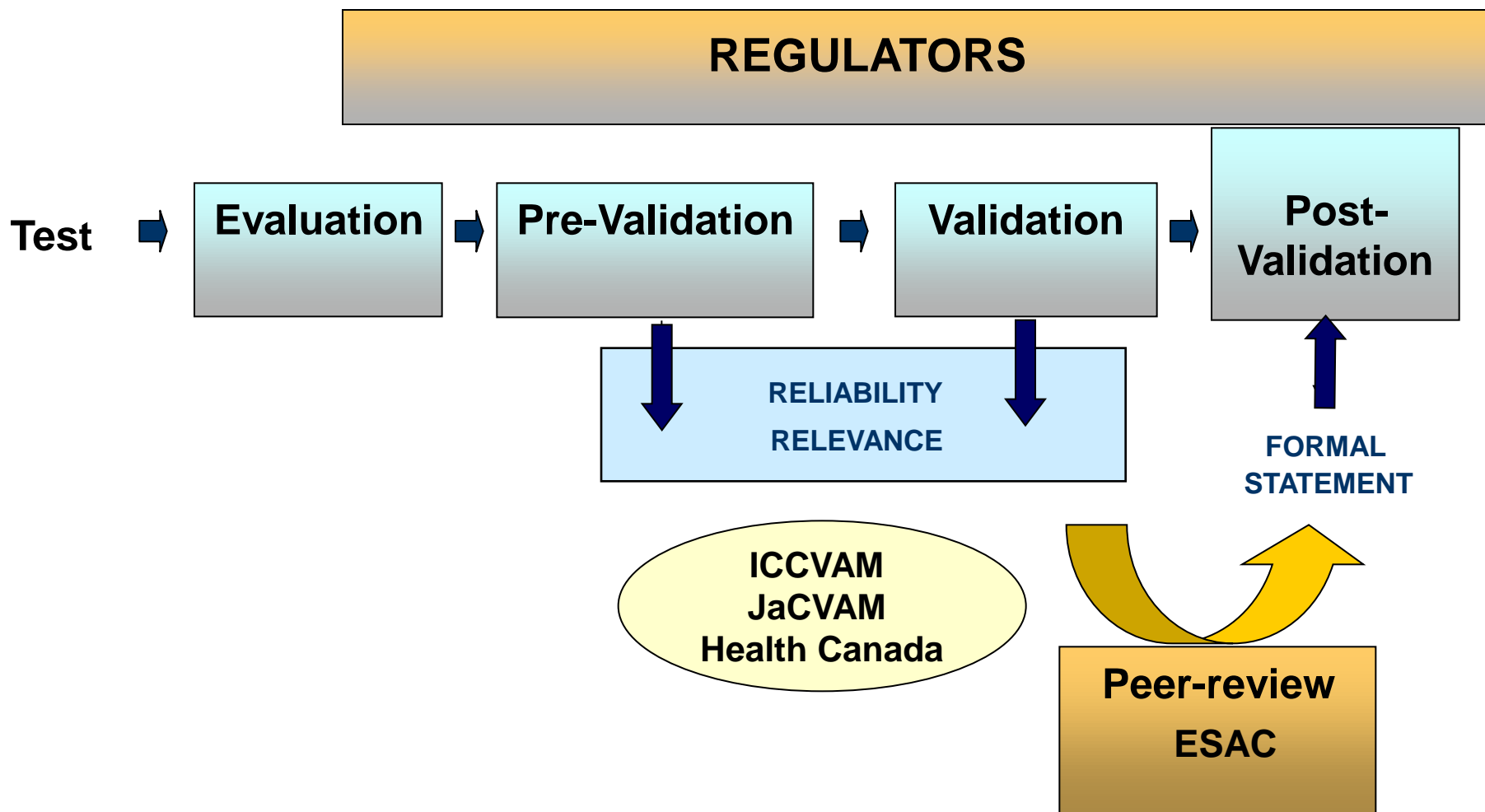
*Alternative (Non-Animal) methods for Cosmetic Testing:
Current Status and Future Prospects.*

ATLA , 2005

Test Method Validation



The ECVAM Validation Process



Validation: Considerations

- The extent of validation a test method needs to undergo (e.g. number of chemicals) depends on its proposed application (i.e. stand alone full replacement/ building block of a testing strategy)

- One of the crucial aspect in validation is the selection of the relevant chemicals which are used to judge the performance of the test. These must:
 - be supported by *relevant an reliable in vivo* data
 - be readily available from commercial sources
 - cover the range of toxic effects /potencies observed in vivo
 - represent the relevant classes of chemicals
 - cover a wide range of physical chemical parameter

However, different criteria might be used depending on the scope of validation

Break out group 3: proposed discussion items

- What are alternative test methods for skin sensitisation designed for? Should they be 1:1 replacement for the LLNA?
- Is the LLNA the gold standard for development/validation of alternative methods?
- What use should we make of other in vivo data (guinea-pig, human data)?
- Are potency information to be considered for development /validation purposes?
- How to interpret alternative testing results which are not concordant with LLNA classifications?
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