

The Transfer of Analytical Procedures

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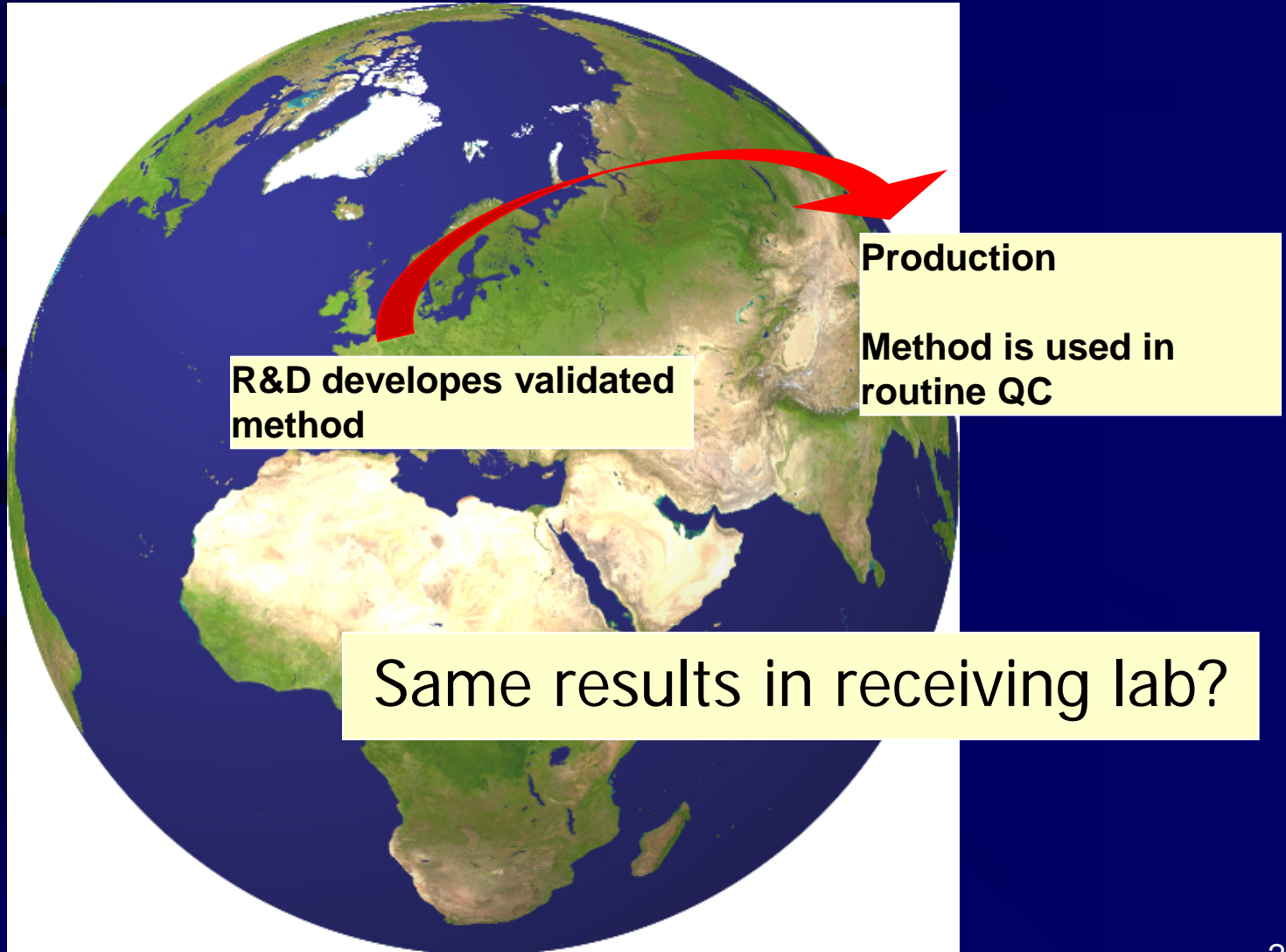
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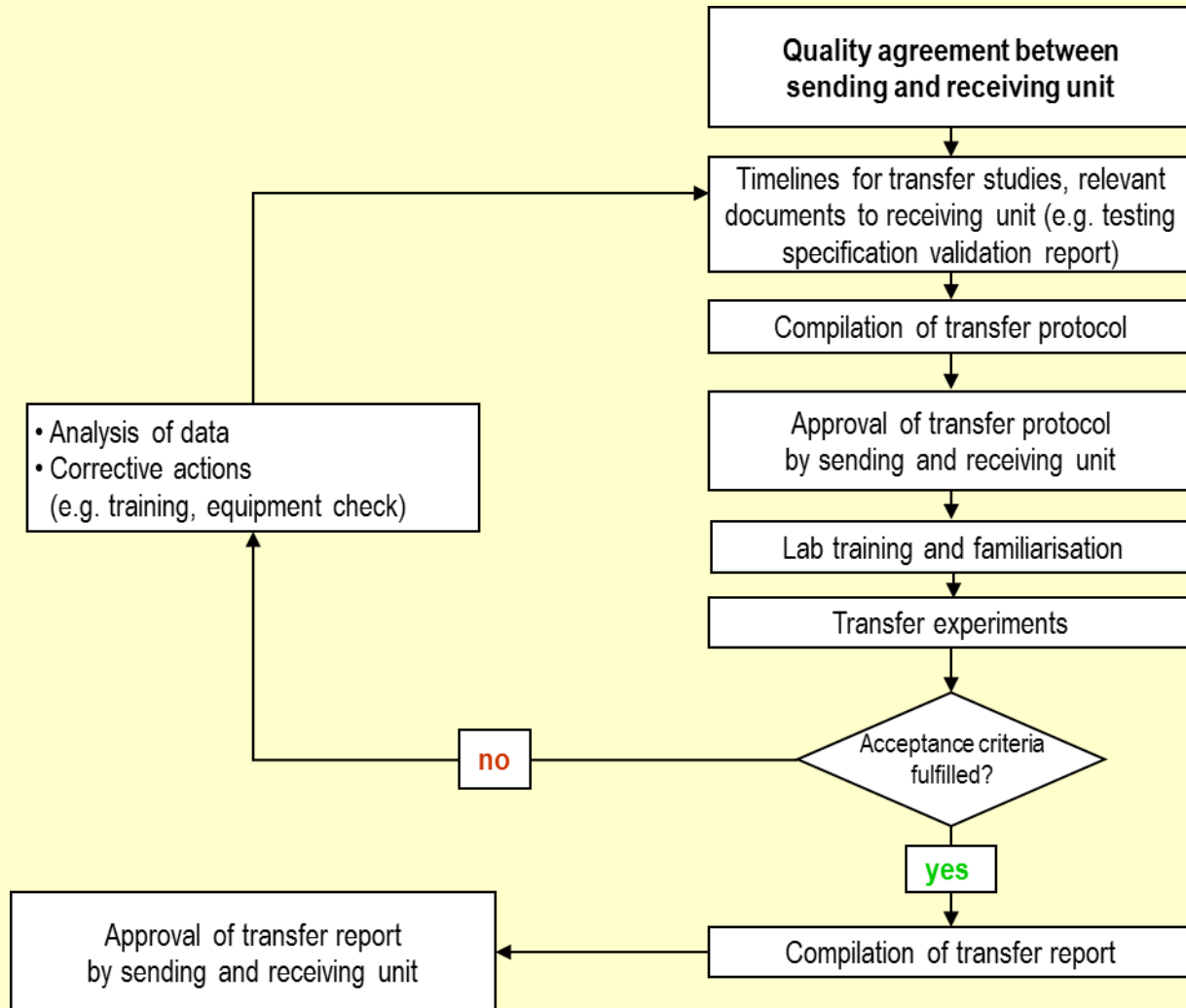


Method transfer



The Transfer of Analytical Procedures

- **Regulatory Overview**
- **Planning**
- **Acceptance criteria, statistics**
- **Avoiding pitfalls**
- **Glossary**



3. Planning method transfers

3.1. Responsibilities

3.2. Success factors

3.3. Documentation and knowledge transfer

3.4. Definition of transfer types

3.5. Familiarization and training

3.6. Transfer samples

3.7. Transfer protocol

3.7.1. Acceptance criteria

3.8. Experimental investigations

3.9. Finalization of the method transfer,
compilation of transfer report

Comparison of results: absolute values

- e.g. means should not differ by more than X units, or by not more than Y%

- However, if calculations are performed this way, neither variability nor number of repetitions are considered

⇒ n muss festgelegt werden

⇒ nur bei geringer Variabilität, die man großzügig nach oben abschätzen kann

**Bei höherer oder
schwer abschätzbarer Streuung:**

Vergleich der Verteilungen

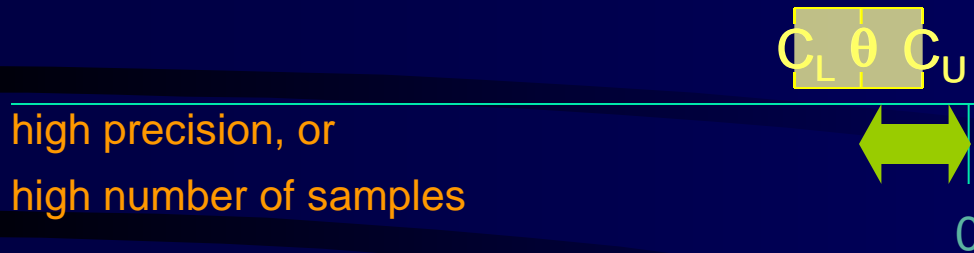
Comparison of results: Student's t-distribution

- t-test

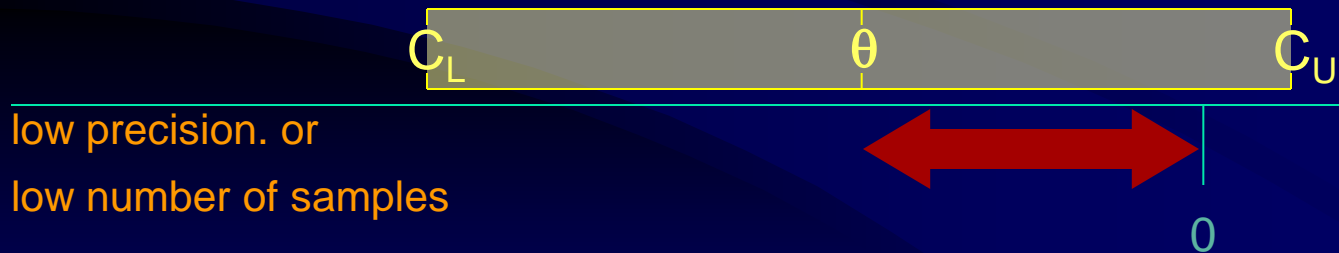
- equivalence tests

the t-test

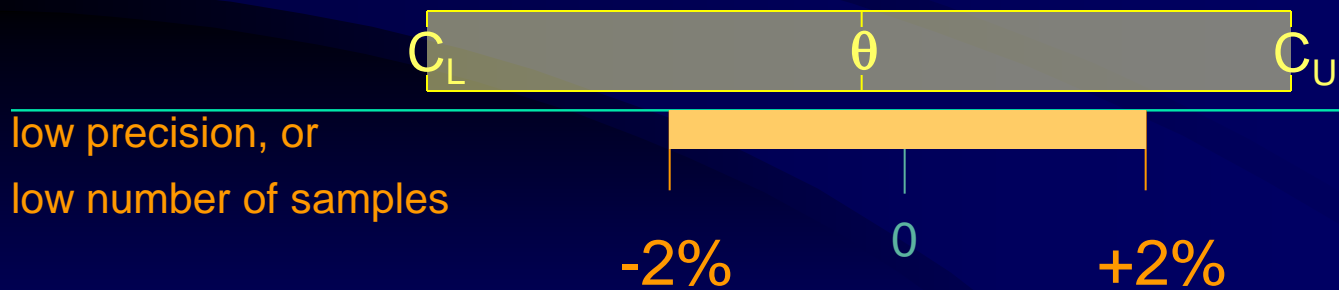
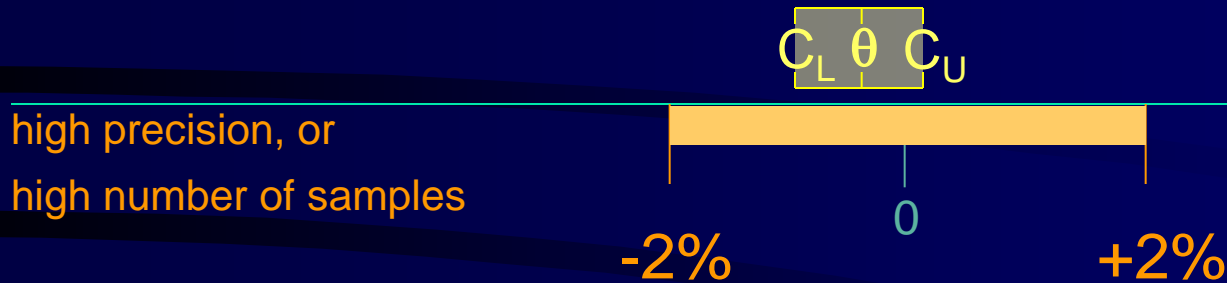
significant, but practically not relevant difference



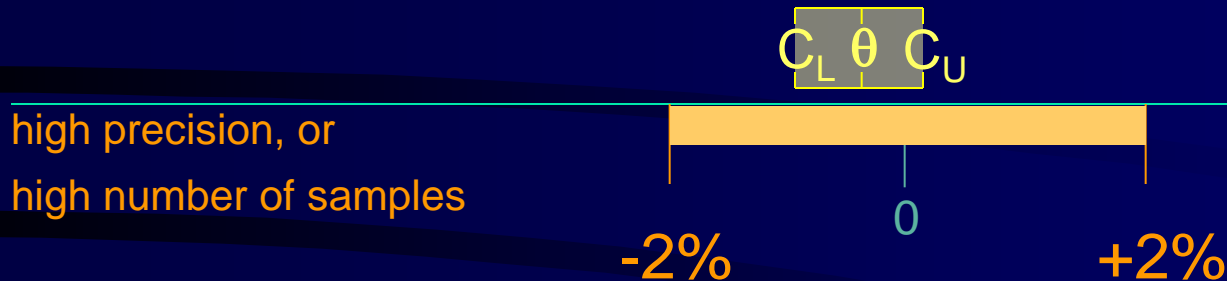
practically relevant, but not statistically significant difference



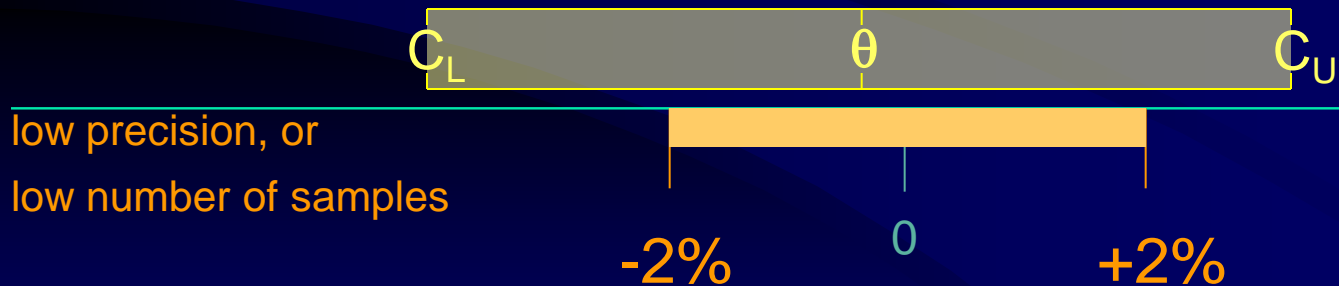
Equivalence test : better properties



Equivalence test : better properties



Comparison of intervals avoids the mentioned paradox!



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Are you interested in more information?

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