# PK assay Cross validation process

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# Cross validation process

**WHEN**

| 1 Laboratory<br>2 different validated Assays | 2 Laboratories<br>1 or 2 different validated Assays |
|---|---|

**HOW**

**Samples**

QC set (L,M,H)

≥ 30 clinical samples

- Closed trial
- Samples should represent the expected range

**Analytical plan**

QC's: - 3 inter and intra precision runs
Clin Samples: 1 analysis / sample

**Analytical report**

- Inter/intra precision
- sample results
- % difference
- Correlation graph

- Inter/intra precision
- sample results

# Cross validation process

| | 1 Laboratory<br>2 different validated Assays | 2 Laboratories<br>1 or 2 different validated Assays |
|---|---|---|
| **Analytical report** |  <br>• Inter/intra precision<br>• sample results<br>• % difference<br>• Correlation plot |  <br>• Inter/intra precision<br>• sample results |
| **Biostats report** |  <br>• Bland Altmann<br>• Deming Regression |  <br>• % Difference<br>• Bland Altmann<br>• Deming Regression |

# Cross validation process – Internal stakeholder interaction

**Samples**

QC set (L,M,H)

≥ 30 clinical samples

**Biostatistics:** sample size evaluation

**Biostats report**

**Biostatistics:** Supportive statistical analysis

**Clinical Pharmacology**

- Evaluate the impact on PK/PD model
- Describe impact in the 2.7.2 module: "Summary of Clinical Pharmacology Studies"

# Acknowledgement


- Bioanalytical team
- Biostats team
- Clinical Pharmacology