



Transval is a software dedicated to the confirmation that an analytical method could be transferred based on Total Error concept.

An analytical transfer is a complete process that consists in transferring a validated analytical method from a sending laboratory (called sender) to a receiving laboratory (called receiver) after having experimentally demonstrated that it also masters the method. The experiments performed in such a transfer and the methodology used to accept or reject it should be fitted for purpose. It is highly critical to have all the guarantees that the method is mastered by the receiver in order to avoid problems in the future.

As it is for method validation, "Total Error" based approach should be also considered in method transfer. Indeed the classical approaches based on the separate evaluation of bias and precision (Hypothesis tests such as Student t-tests, or equivalence tests like TOST for bias, ...) do not allow to make the adequate risk based decision. The b-expectation tolerance interval similar to the one used in method validation is calculated and then compared to acceptance limits around the estimate of the true value.

This approach is about checking whether most of the results produced by the receiver will be close enough to the average result of the sender.

Transval is dedicated to the transfer of quantitative analytical methods in these highly critical situations.

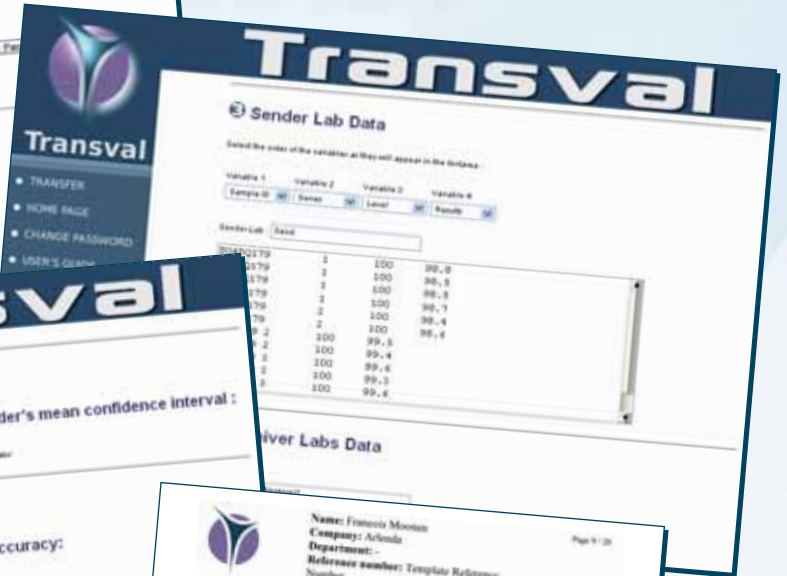
Features:

The objective of **Transval** is to allow users to apply easily the statistical methodology for the transfer of any quantitative analytical methods, and to provide them with a ready to file transfer report.

- **Transfer design:** **Transval** allows the evaluation of the transfer towards up to 5 laboratories and can evaluate different concentration levels.
- **Transfer Profile:** For every receiving laboratory, the corresponding transfer profile based on Total Error is calculated (graphical representation) and serves as **decision tool**.
- **Estimation of trueness, precision and accuracy:** The optimal estimation of the main criteria required for the transfer in accordance with regulatory documents such as ICH Q2R1 and ISO.
- **Risk estimation:** The risk of having Out Of Specifications results at each receiving lab is known.
- **Reporting:** A transfer report containing the whole information required to judge the acceptability of the method transfer.
- **Web-based Application:** **Transval** is an Internet based application on a secured website (<https://>). No installation and maintenance cost. Always the latest version available.

If you want to try it for 1 month, just fill the application form on <http://www.arlenda.com/login/demoform.html>

Example of screenshots from Transval



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4. Precision

Precision is the closeness of agreement among measurements from multiple sampling of an homogeneous sample under the recommended conditions. It gives some information on random errors and it can be evaluated at two-levels: repeatability and intermediate precision. This criterion is only evaluated for the receiver laboratory.

As shown in Table IV, precision is expressed in terms of relative standard deviation (RSD) values for repeatability and intermediate precision of the receiving laboratory. The upper 95% confidence limit of the intermediate precision RSD is also computed.

The estimates of variance components are obtained by the intuitive approach of restricted maximum likelihood (REML).

Table IV - Relative Precision Table

Laboratory	Concentration level (±)	Repeatability RSD (%)	Intermediate Precision RSD (%)	95% Upper Confidence Limit of RSD (%)
Receiver	100.0	1.10	1.70	1.90
Receiver	100.0	0.410	0.510	0.60
Receiver	100.0	0.470	0.590	0.68
Receiver	100.0	0.480	0.60	0.70

Table V - Absolute Precision Table

Laboratory	Concentration level (±)	Repeatability (SD - Conc)	Between-Series (SD - Conc)	Ratio of Variance Components (Receiver/Reference)	Relative Error (%)
Receiver	100.0	1.10	1.70	1.50	1.50
Receiver	100.0	0.410	0.510	0.37	0.217
Receiver	100.0	0.470	0.590	0.48	0.48
Receiver	100.0	0.480	0.60	0.51	0.50

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Transfer Profile

Figure 1 - Transfer Profile

The red dashed lines are the adjusted acceptance limits; the black continuous segments are the β -expectation tolerance region of the receiver. The colored dots (one color per series) are the results of the receiver laboratory.

Table VI - Transfer profile legend

Laboratory number	Laboratory name
1	Receiver
2	Receiver
3	Receiver
4	Receiver

Table VIII shows the effective risk of having future measurement at the receiving laboratory exceeding the adjusted acceptance limits.

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