

The power of aggregation of EQA/PT results

in the monitoring of traceability of test results in the medical laboratory

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Missions of EQA

- Comparing a laboratory's results with those of other laboratories.
- Ideally, informs the participants if their measurement procedure has a bias from a true value.

Missions of EQA

We know:

- There are systematic differences between measurement methods.
- Information about bias needs to be communicated to the IVD industry and to the users so they can take actions to harmonize results.
- But: We need evidence.

Question 1 (poll)

For how many **standardized** measurements in your laboratory do you feel standardization/traceability needs to be optimized by the manufacturer?

- a) None
- b) Some
- c) A fair amount
- d) (Nearly) all

The Aggregation project

Aggregate results from EQA providers for the same measurand to:

- 1) Get more results (and more power).
- 2) See if the results are similar from different schemes and different regions.
- 3) Provide the data to the IVD industry.

Pilot – aggregation of creatinine results

Results from:

- CAP (USA)
 - Noklus/Labquality (Norway)
 - SKML (the Netherlands)
 - UK-NEQAS (UK)
-
- 4 EQA organizations: 1011 results.
 - Creatinine concentrations ~ 70 $\mu\text{mol/L}$ (0.8 mg/dL).

Question 2

What were the requirements we used to be able to aggregate (a combination of answers is possible)?

- a) Target values and uncertainty using a Reference Method Procedure/Reference Material.
- b) The material is commutable.
- c) Samples must not contain known potential interfering substances, e.g. glucose or total protein.
- d) The samples were measured at the same time.

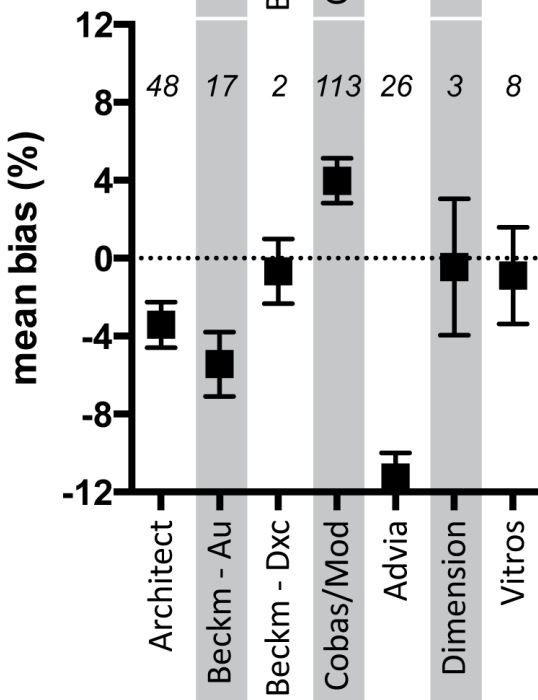
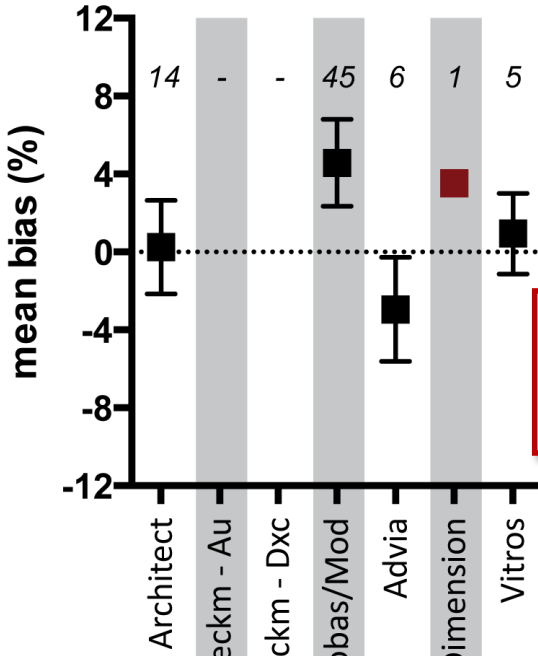
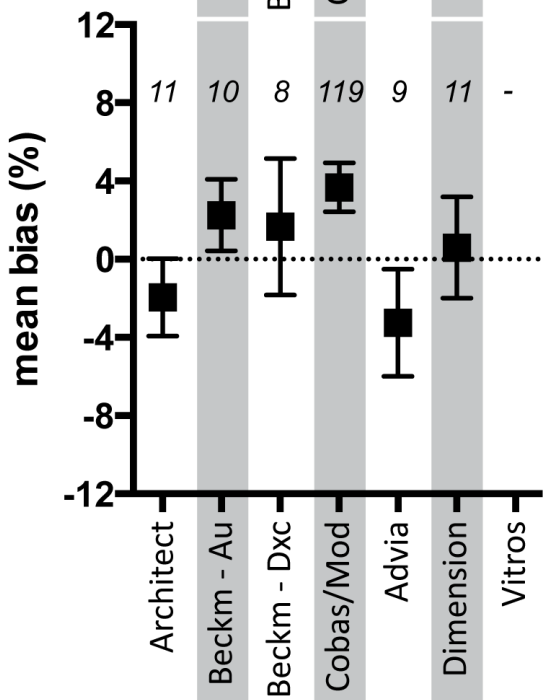
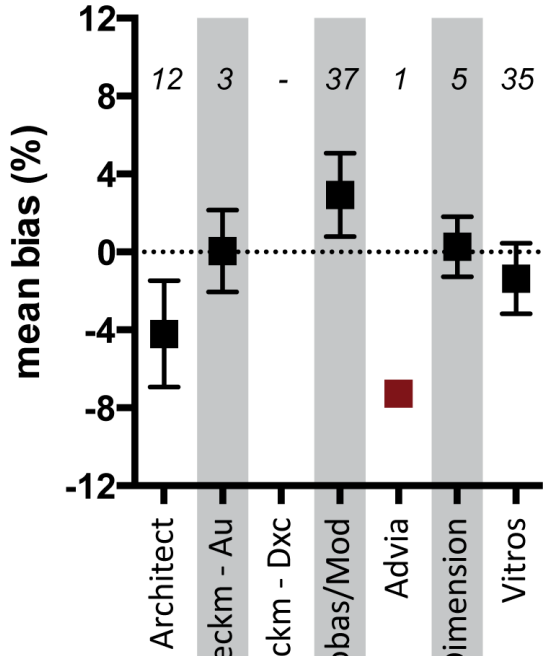
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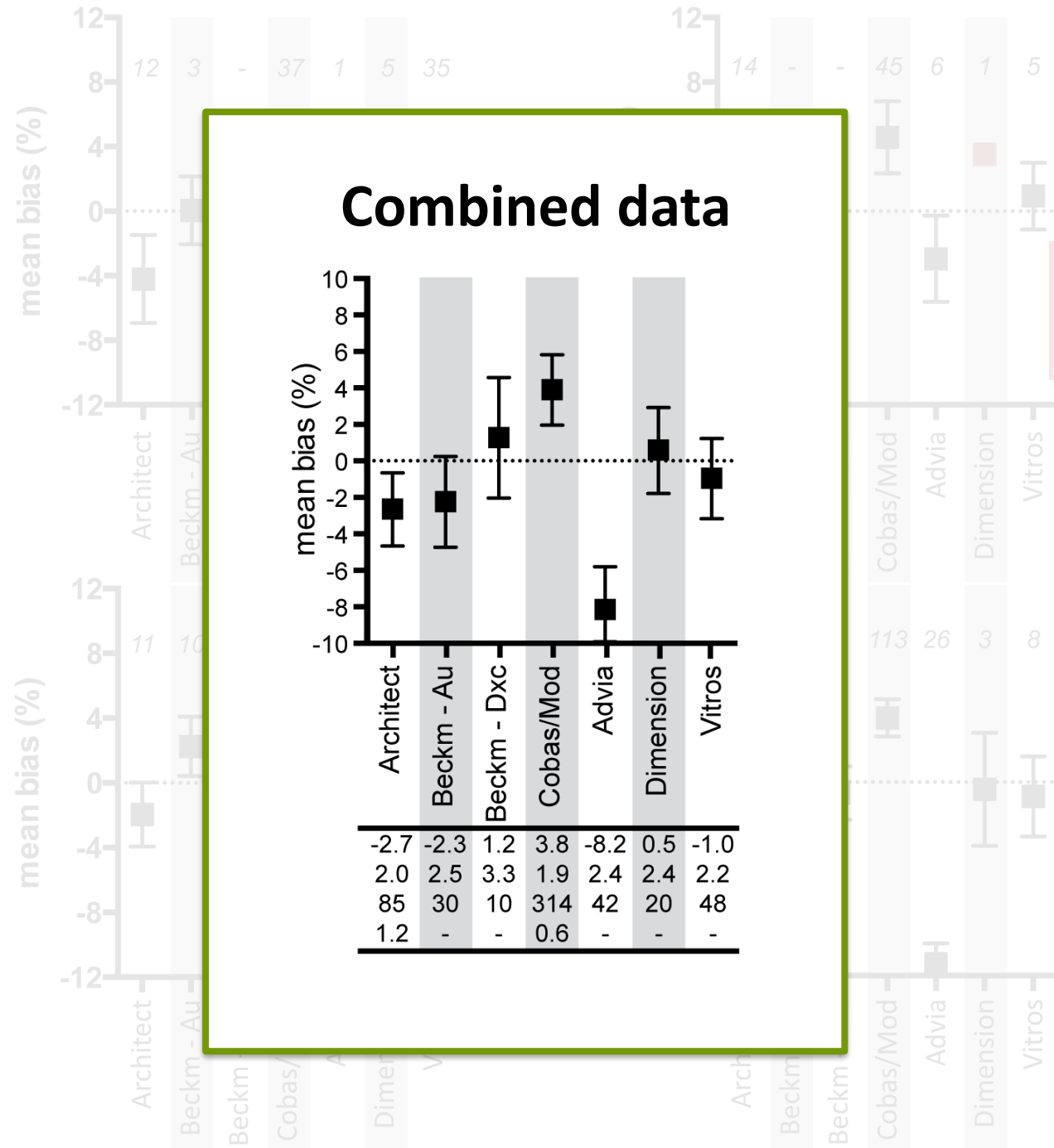
Pilot – aggregation of creatinine results

- Important aspects for aggregating results:
 - Definition of methods: e.g. compensated vs kinetic Jaffe
 - Definition of instruments:
 - Differences in naming: e.g. Ortho Clinical Diagnostics vs. Vitros
 - Differences on details of instruments: e.g. Cobas/Modular vs. c501

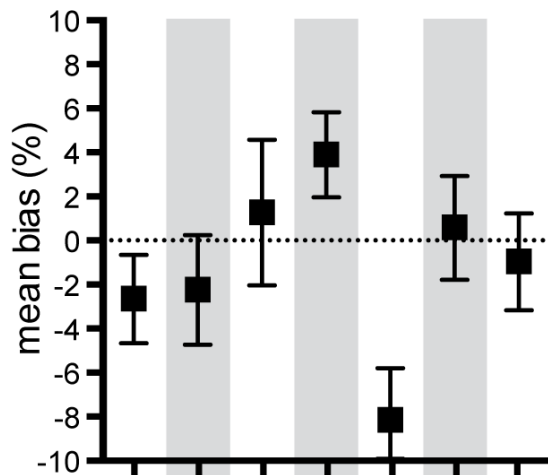


Results are quite similar between EQAS.





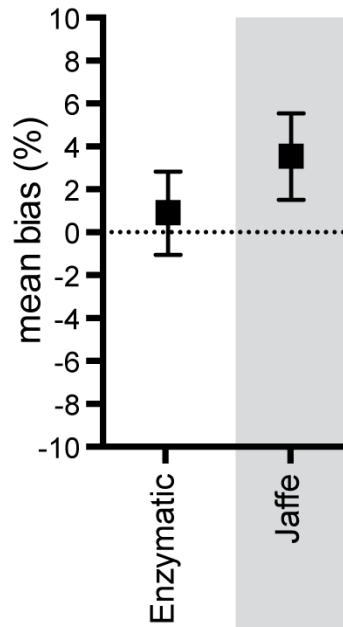
Combined data



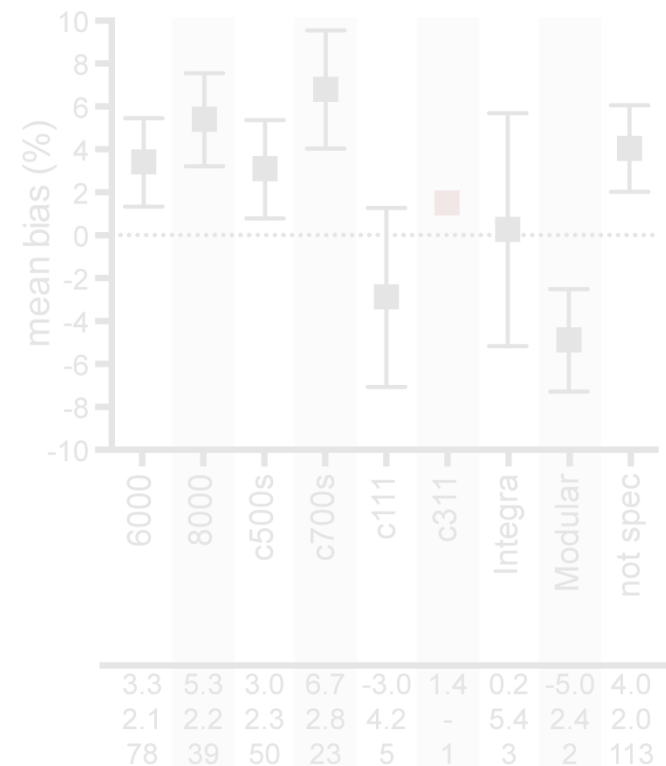
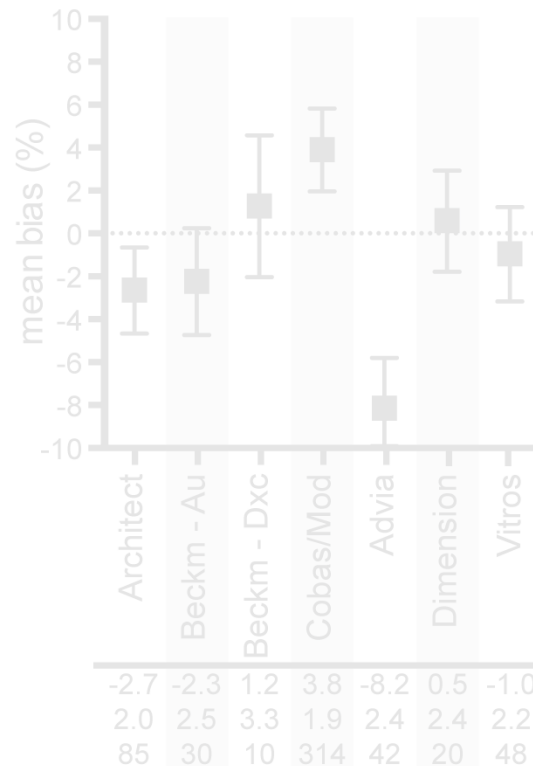
-2.7	-2.3	1.2	3.8	-8.2	0.5	-1.0
2.0	2.5	3.3	1.9	2.4	2.4	2.2
85	30	10	314	42	20	48
1.2	-	-	0.6	-	-	-

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Pilot – challenges in aggregation of creatinine results

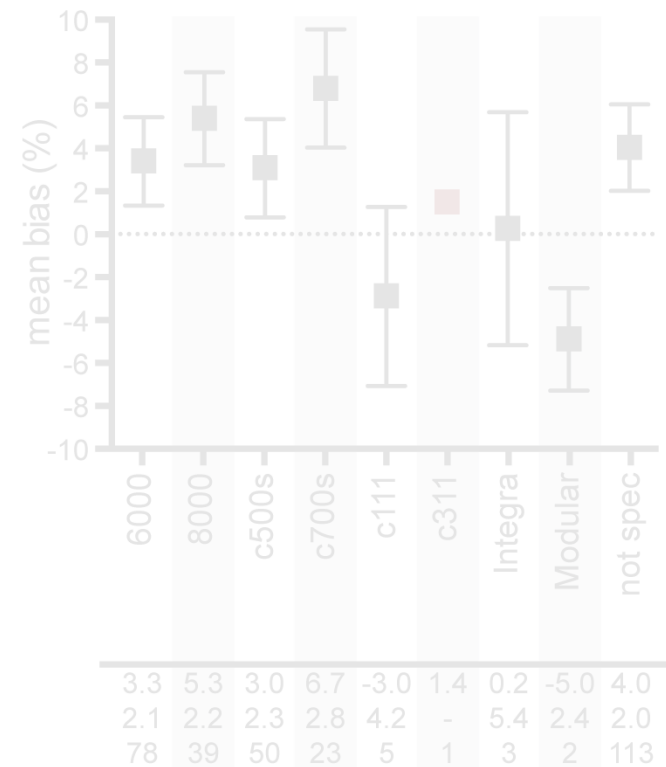
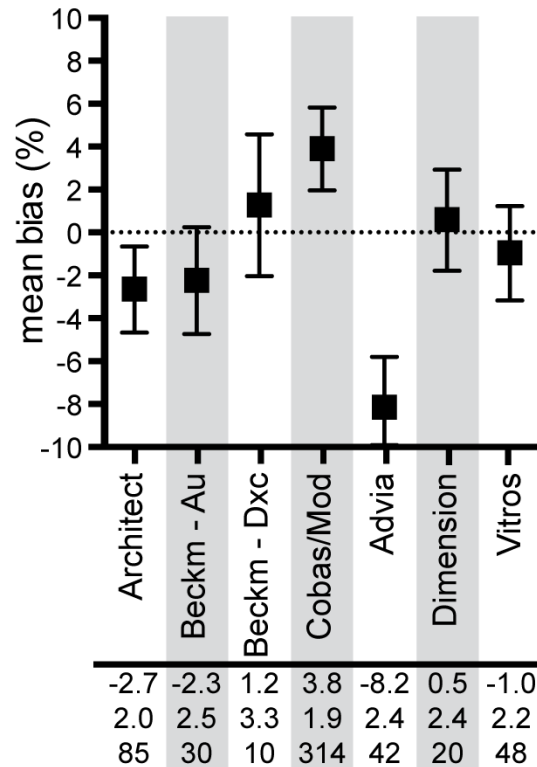
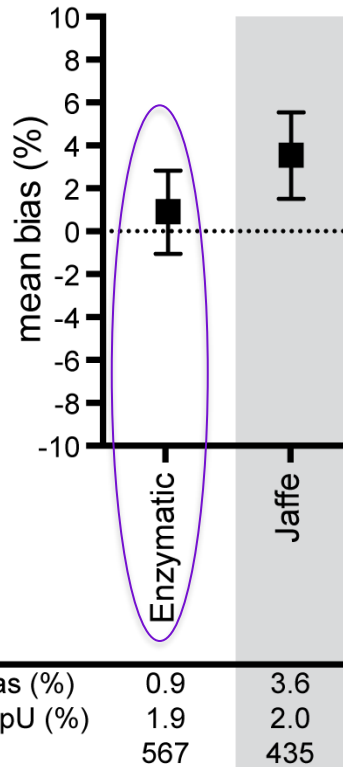


Bias (%)	0.9	3.6
ExpU (%)	1.9	2.0
n	567	435



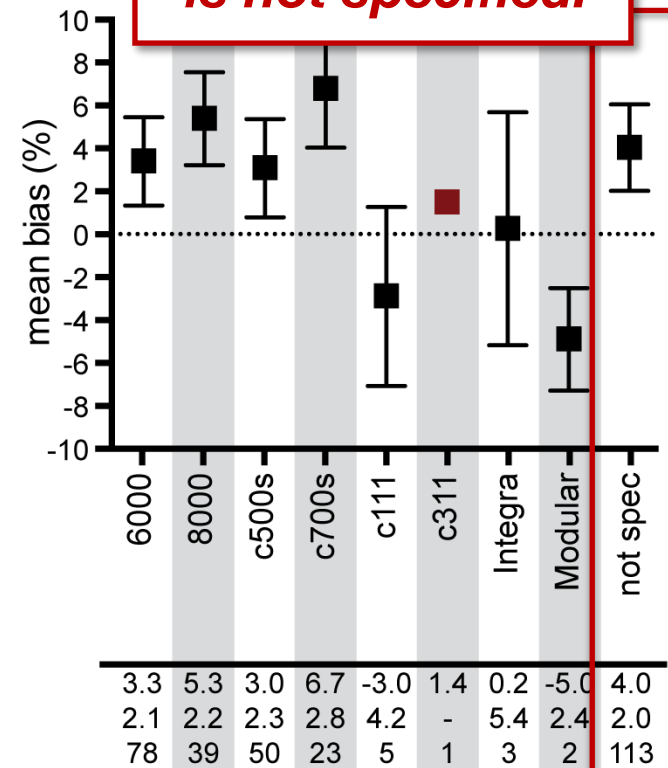
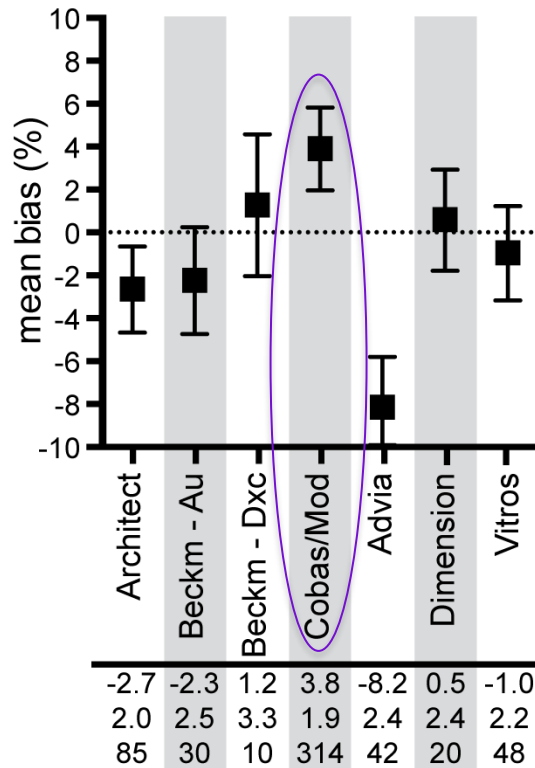
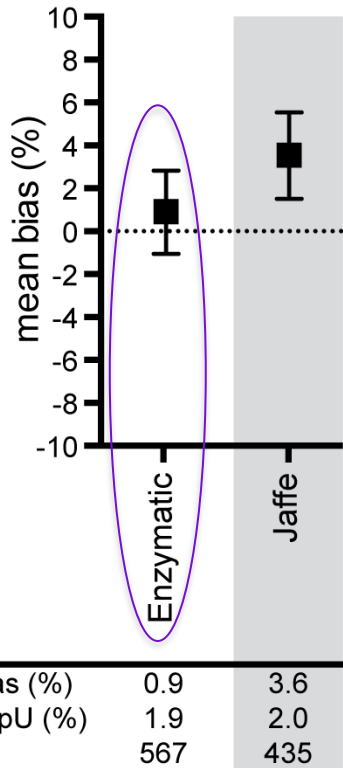
* ExpU = combined Uncertainty of the target and Interlab SD.

Pilot – challenges in aggregation of creatinine results



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Pilot – challenges in aggregation of creatinine results



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Conclusions

- Aggregation of results is feasible with currently available data.
- Results strengthen conclusions regarding specific IVDs/Methods.
 - **Jaffe vs Enzymatic**, mean bias 2.3 vs 0.8 $\mu\text{mol/L}$.
 - **Clear biases can be observed** e.g. Siemens Advia all EQA demonstrate similar negative biases, ***mean bias -5.9 $\mu\text{mol/L}$*** with 42 instruments, ExpU 0.9 $\mu\text{mol/L}$.
 - **Large amounts of data** e.g. Roche Cobas/Modular mean bias is 2.7 $\mu\text{mol/L}$ with ***314 instruments***, ExpU 0.8 $\mu\text{mol/L}$.

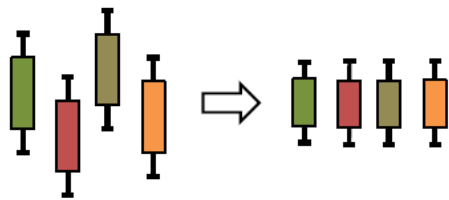
Challenges

- Harmonization of Method/Instrument definitions, especially on instrument details.
 - This can be taken even further by including calibrator/reagent types/lot numbers.
- How to prove commutability?

Future directions

This pilot project is continued in the HALMA initiative of ICHCLR and EQALM: <http://www.eqalm.org/site/halma/halma.php>

HArmonization of measurands in **L**aboratory **M**edicine through data **A**ggregation



International Consortium
for Harmonization of Clinical Laboratory Results



Thank you for your attention!

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- UK-NEQAS

MCA Laboratory team

Publication: Feasibility for aggregation of commutable external quality assessment results to evaluate metrological traceability and agreement among results. PMID: 32759402.