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EQALM Symposium 2024

Presentation of the COMET project

Vincent DELATOUR

Vienna, October 17th, 2024

(Regulatory) Context

EU regulation 2017/746 on in vitro diagnostic medical devices (IVDR)

Metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order

The main goals of the project are to :

- ✓ Help the IVD industry **meet requirements of the IVDR** regarding metrological traceability and post-market surveillance
- ✓ Provide a **coordinated response** to needs that were expressed during the 2021 JCTLM / IFCC / ICHCLR workshop that was organized to identify & overcome challenges to global standardization of clinical laboratory testing.
- ✓ **Improve the availability of commutable CRMs & EQA materials** for high priority IVD tests for which there is an urgent need to properly establish results metrological traceability and/or better monitor results accuracy and harmonization : neonatal bilirubin, cyclosporine, PTH, hCMV, estradiol, glucose.


Clin Chem Lab Med 2023; 61(1): 48–54 DE GRUYTER

Guidelines and Recommendations

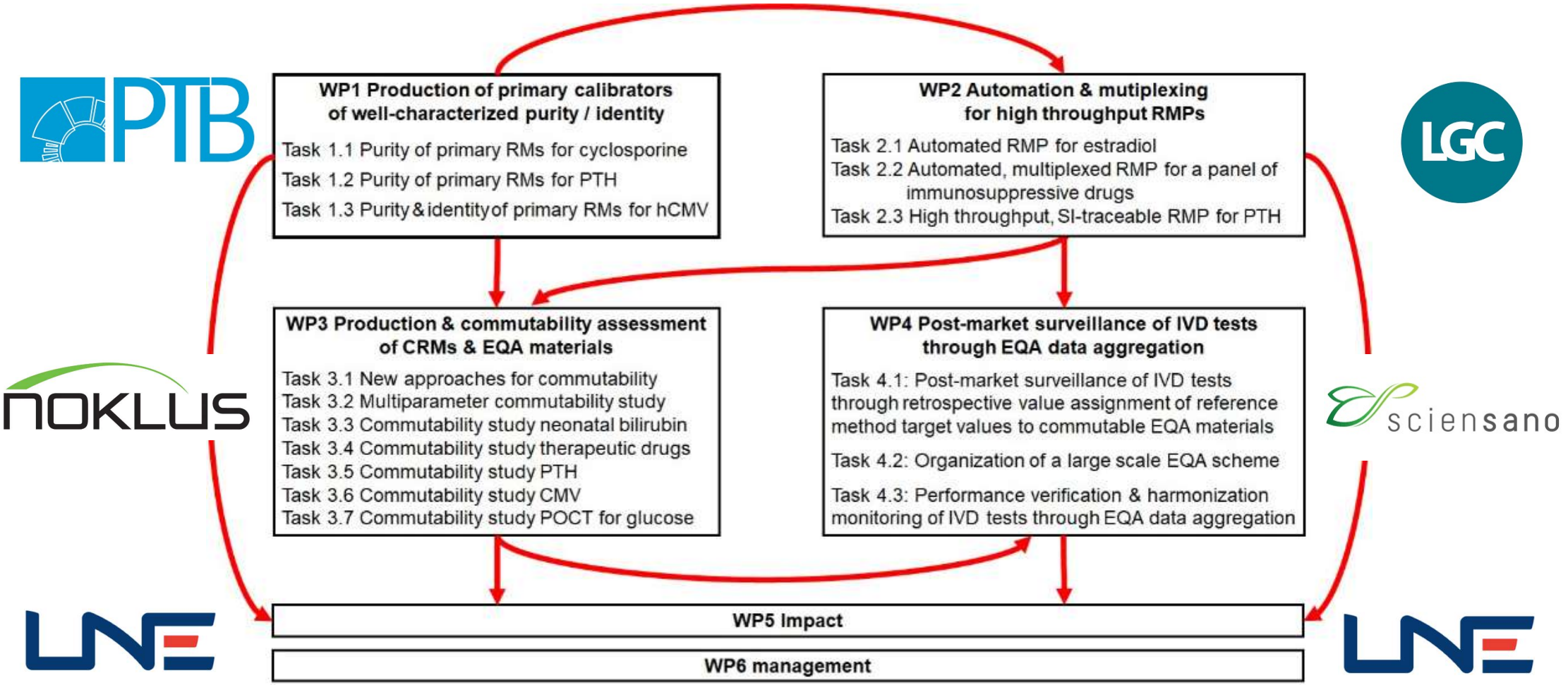
W. Greg Miller*, Gary Myers, Christa M. Cobbaert, Ian S. Young, Elvar Theodorsson, Robert I. Wielgosz, Steven Westwood, Stephanie Maniguet and Philippe Gillery

Overcoming challenges regarding reference materials and regulations that influence global standardization of medical laboratory testing results

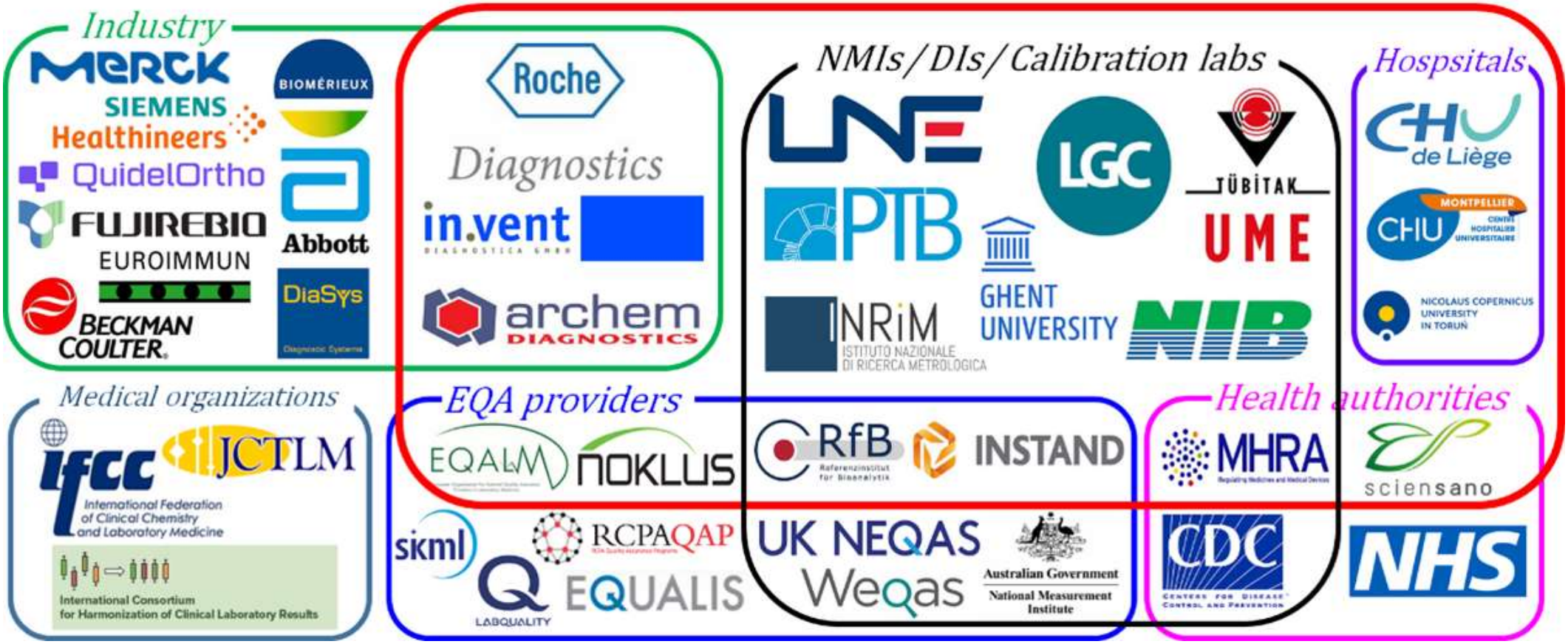
Objectives of the COMET project

- ✓ **Primary CRMs** of well characterized purity and identity will be developed to calibrate **high throughput RMPs** that will be used to value assign target values to secondary CRMs and EQA materials of proven commutability
- ✓ **Commutability** of various CRMs and EQA materials will be evaluated and compared with the objective to **identify key common causes affecting materials commutability** and the most suitable matrices / formats of material.
- ✓ **Commutability** evaluation being cumbersome, more efficient and cost-effective ways of conducting commutability studies will be developed.
- ✓ **Post-market surveillance** will be performed by :
  - ✓ aggregating EQA data using commutable EQA materials to which reference method target values will be retrospectively assigned by a coordinated network of calibration laboratories;
  - ✓ Organizing large-scale EQAS in which commutable EQA materials value assigned with Reference Methods will be distributed to a large number of medical laboratories from multiple European countries.

WP Flowchart



Partners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Weqas
Australian Government
National Measurement Institute
Health authorities
MHRA
sciensano
CDC
NHS

Post-market surveillance

Different tools are available to evaluate the performance of IVD tests

✓ **IQC materials can help detecting errors but as they are not meant to be commutable, they can't be used to evaluate results trueness**

ISO 15189

b. The laboratory shall select IQC material that is fit for its intended purpose. When selecting IQC material, factors to be considered shall include:

1. stability with regard to the properties of interest;
2. the matrix is as close as possible to that of patient samples;
3. the IQC material reacts to the examination method in a manner as close as possible to patient samples;
4. the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.

Post-market surveillance

Different tools are available to evaluate the performance of IVD tests

- ✓ IQC materials can help detecting errors but as they are not meant to be commutable, they can't be used to evaluate results trueness
- ✓ **EQA materials can be used to evaluate results trueness in condition that :**
  - materials commutability has been properly assessed and is adequate
  - target values are assigned with a reference method

ISO 15189

e) When selecting EQA programme(s), the laboratory should consider the type of target value offered.

Target values are:

1) independently set by a reference method, or
2) set by overall consensus data, and/or
3) set by method peer group consensus data, or
4) set by a panel of experts.

NOTE 1 When method-independent target values are not available, consensus values can be used to determine whether deviations are laboratory- or method-specific.

NOTE 2 Where lack of commutability of EQA materials can hamper comparison between some methods, it can still be useful for comparisons to be made between methods for which it is commutable, rather than relying only on within-method comparisons.

Different types of External Quality Assessment Schemes

Table 3. Evaluation capabilities of PT/EQA related to scheme design.

Miller et al. Clin Chem. 2011;57(12):1670-80

				Evaluation capability						
				Accuracy						
				Individual laboratory					Standardization or harmonization[b]	
	Sample characteristics				Relative to participant results		Reproducibility		Measurement procedure calibration traceability	
Category	Commutable	Value assigned with RMP[a] or CRM	Replicate samples in survey	Absolute vs RMP or CRM	Overall	Peer group	Individual laboratory intralab CV	Measurement procedure interlab CV	Absolute vs RMP or CRM	Relative to participant results
1	Yes	Yes	Yes	X	X	X	X	X	X	X
2	Yes	Yes	No	X	X	X		X	X	X
3	Yes	No	Yes		X	X	X	X		X
4	Yes	No	No		X	X		X		X
5	No	No	Yes			X	X	X		
6	No	No	No			X		X		

- EQAS relying on non-commutable materials don't make it possible to assess comparability of results between different peer groups
- EQAS relying samples which target values have not been value assigned with a reference method don't make it possible to assess absolute bias

Post-market surveillance

Different tools are available to evaluate the performance of IVD tests

- ✓ IQC materials can help detecting errors but as they are not meant to be commutable, they can't be used to evaluate results trueness
- ✓ **EQA materials can be used to evaluate results trueness in condition that :**
  - materials commutability has been properly assessed and is adequate
  - target values are assigned with a reference method

f. When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness.

NOTE : Acceptable alternatives include:

participation in sample exchanges with other laboratories;

interlaboratory comparisons of the results of the examination of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material;

analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material;

analysis of microbiological organisms using split/ blind testing of the same sample by at least two persons, or on at least two analyzers, or by at least two methods;

analysis of reference materials considered to be commutable with patient samples;

Post-market surveillance

Different tools are available to evaluate the performance of IVD tests

- ✓ IQC materials can help detecting errors but as they are not meant to be commutable, they can't be used to evaluate results trueness
- ✓ EQA materials can be used to evaluate results trueness in condition that :
  - materials commutability has been properly assessed and is adequate
  - target values are assigned with a reference method
- ✓ **Secondary CRMs can be used as trueness verifiers but commutability assessment is cumbersome, which limits their availability**

Post-market surveillance

Different tools are available to evaluate the performance of IVD tests

- ✓ IQC materials can help detecting errors but as they are not meant to be commutable, they can't be used to evaluate results trueness
- ✓ EQA materials can be used to evaluate results trueness in condition that :
  - materials commutability has been properly assessed and is adequate
  - target values are assigned with a reference method
- ✓ Secondary CRMs can be used as trueness verifiers but commutability assessment is cumbersome, which limits their availability
- ✓ **Comparison studies : panels of (fresh) patient samples (commutable by definition) are measured with an IVD-MD and a reference method : costly!**

1. **RMPs are not available for many measurands and/or are too costly and/or do not meet adequate analytical performance specification**
2. **Commutability evaluation of EQA materials and of secondary CRMs is cumbersome**

Current issues … and possible solutions

RMPs are not available for many measurands and/or are too costly and/or do not meet adequate analytical performance specifications

- **Possible causes :**
  1. **Lack of primary CRMs to calibrate RMPs**
  2. **Validating RMPs of high accuracy with sufficiently small measurement uncertainty to meet the clinical need can be challenging when it comes to measure large and/or low abundant measurands in complex matrices**
  3. **IDMS-based RMPs usually have low throughput due to high hands-on time**
  4. **There are too many measurands for which RMPs are needed**

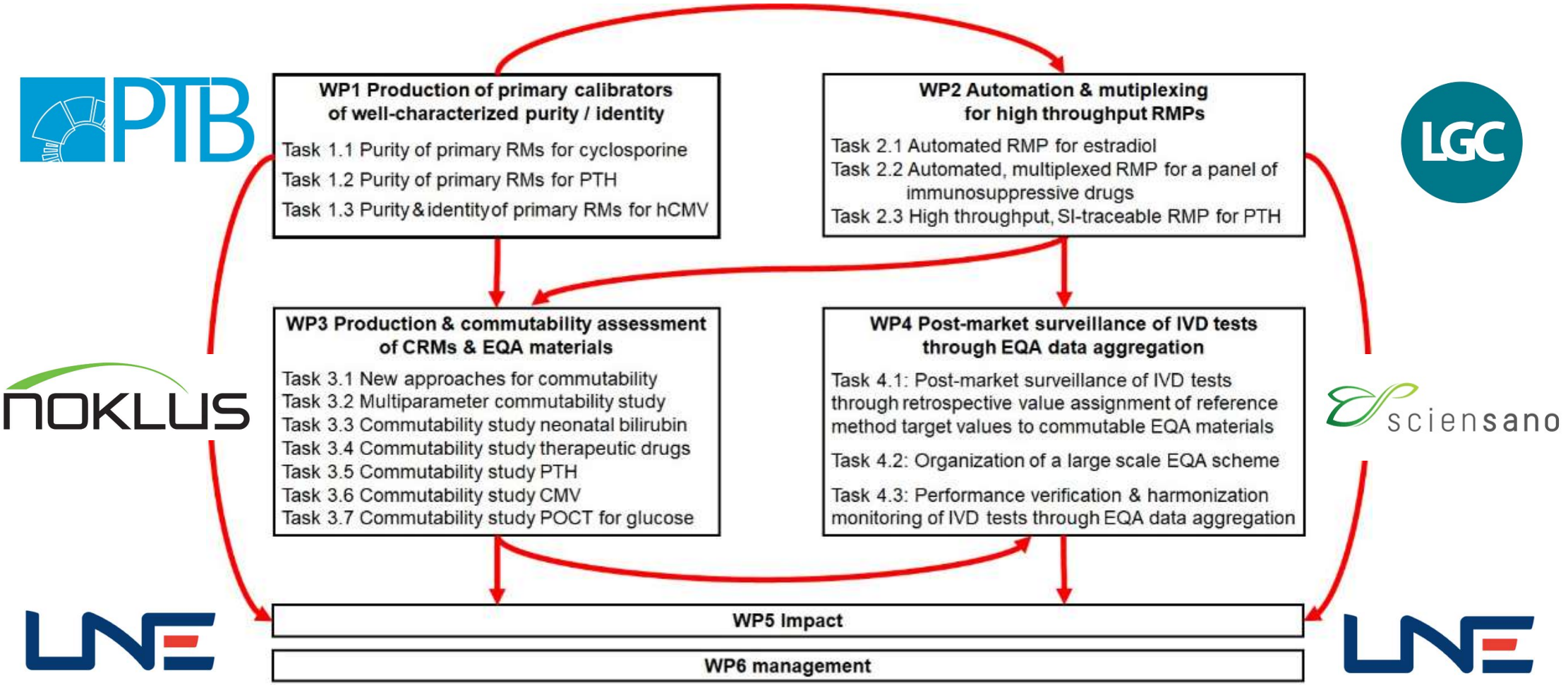
Current issues … and possible solutions

RMPs are not available for many measurands and/or are too costly and/or do not meet adequate analytical performance specifications

- **Possible causes :**
  1. **Lack of primary CRMs to calibrate RMPs**

- **Possible solutions:**
  1. **New purity assessment techniques to identify and quantify impurities faster**

WP Flowchart



Current issues … and possible solutions

RMPs are not available for many measurands and/or are too costly and/or do not meet adequate analytical performance specifications

- **Possible causes :**
  2. **Validating RMPs of high accuracy with sufficiently small measurement uncertainty to meet the clinical need can be challenging when it comes to measure large and/or low abundant measurands in complex matrices**

- **Possible solutions:**
  2. **Better consider measurement uncertainty at each level of the calibration hierarchy and its impact on the overall quality of laboratory tests.**

     → **JCTLM Task Force on Reference Measurement Systems Implementation**

Current issues … and possible solutions

Clin Chem Lab Med 2021; 59(8): 1362–1368 DE GRUYTER

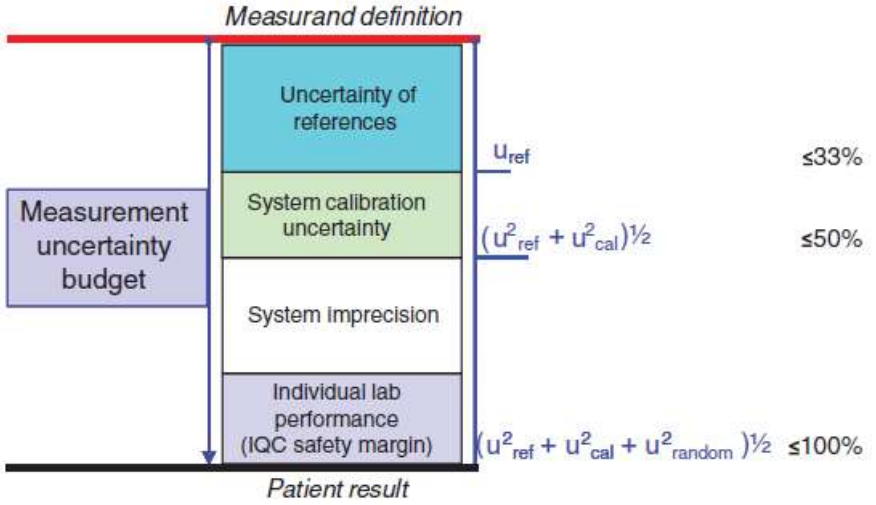
Opinion Paper

Federica Braga* and Mauro Panteghini

Performance specifications for measurement uncertainty of common biochemical measurands according to Milan models

Conclusions

. We recommend that no more than one third of the total uncertainty budget, established by appropriate analytical performance specifications, is consumed by the uncertainty of references and approximately 50% of the total budget consumed by the manufacturer's calibration and value transfer protocol. The remaining 50% should be available for the commercial system imprecision and individual laboratory performance as a safety margin



Current issues … and possible solutions

Objective 1: Improved availability of commutable CRMs & EQA materials for high priority biomarkers

Commutable CRMs and EQA materials will be developed for high priority IVD tests for which there is an urgent need to properly establish results metrological traceability and/or better monitor results accuracy and harmonisation (neonatal bilirubin, cyclosporine, PTH, hCMV, estradiol, glucose). Primary calibrators of well characterised purity and identity will be developed for estradiol, cyclosporine and PTH. These will be used to calibrate automated and/or multiplexed RMPs delivering SI-traceable results with fit for purpose uncertainties ($U < 7.6\ \%$ for cyclosporine, $U < 5.2\ \%$ for PTH, and $U < 4\ \%$ for estradiol).

Objective 2: Identification of manufacturing processes leading to high commutability levels

As the causes for a material's non-commutability remain largely unknown, various calibration and quality control materials will be sourced and/or prepared according to different manufacturing processes. Their commutability will be evaluated and compared with the objective to identify critical quality attributes of materials and key common causes limiting commutability. To define commutability acceptance criteria, measurement uncertainty will be considered at each level of the calibration hierarchy, as well as its impact on the quality of laboratory tests.

Current issues … and possible solutions

Clinical Chemistry 67:12
1590–1605 (2021)

Special Report

Optimizing Available Tools for Achieving Result Standardization: Value Added by Joint Committee on Traceability in Laboratory Medicine (JCTLM)

Mauro Panteghini,[a,*] Federica Braga ,[a] Johanna E. Camara,[b] Vincent Delatour,[c] Katleen Van Uytfanghe ,[d] Hubert W. Vesper,[e] and Tianjiao Zhang,[f] for the JCTLM Task Force on Reference Measurement System Implementation

SUMMARY: We produced a synopsis of JCTLM-listed higher-order CRMs and RMPs for the selected measurands, including their main characteristics for implementing traceability and fulfilling (or not) the APS for suitable MU. Results showed that traceability to higher-order references can be established by IVD manufacturers within the defined APS for most of the 13 selected measurands. However, some measurands do not yet have suitable CRMs for use as common calibrators. For these measurands, splitting clinical samples with a laboratory performing the RMP may provide a practical alternative for establishing a calibration hierarchy.

Current issues … and possible solutions

RMPs are not available for many measurands and/or are too costly and/or do not meet adequate analytical performance specifications

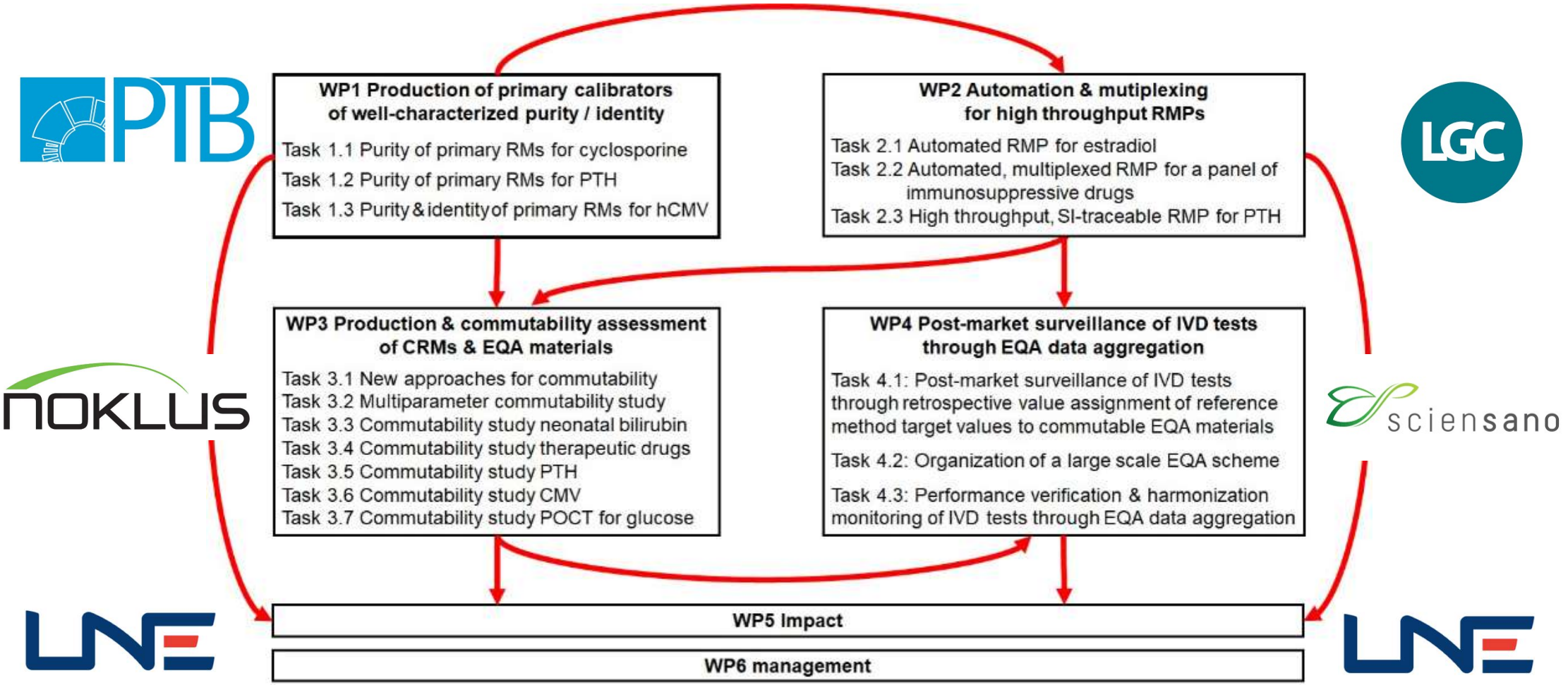
- **Possible causes :**
  3. **IDMS-based RMPs usually have low throughput due to high hands-on time**

- **Possible solutions:**
  3. **Develop high throughput RMPs**

     → Automation can help decreasing hands-on time

     → Measuring a panel of measurands simultaneously can also help providing more cost-effective calibration services

WP Flowchart



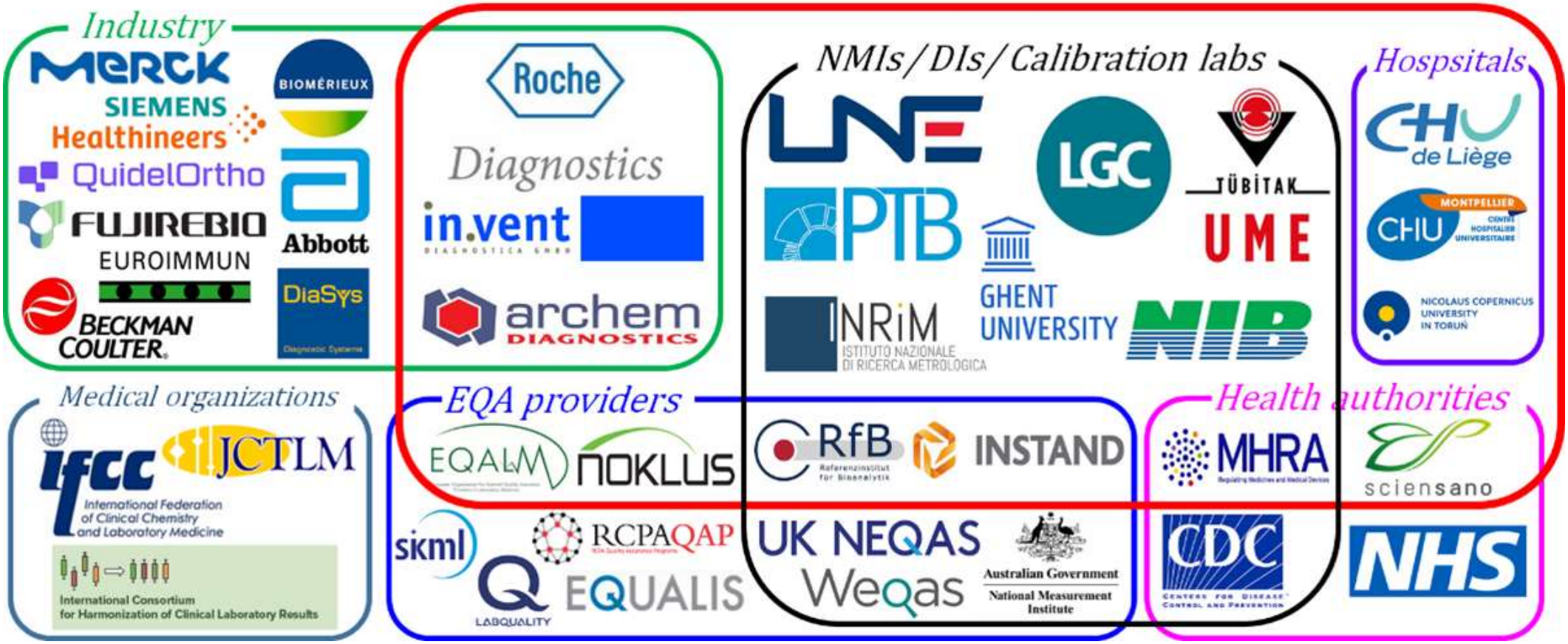
Current issues … and possible solutions

RMPs are not available for many measurands and/or are too costly and/or do not meet adequate analytical performance specifications

- **Possible causes :**
  4. There are too many measurands for which RMPs are needed

- **Possible solutions:**
  4. Better coordinate & prioritize activities of NMIs and reference laboratories
     → Focus NMIs activities on measurands in real need for metrology input
     →Improve collaboration between NMIs and assays providers & EQA providers

Partners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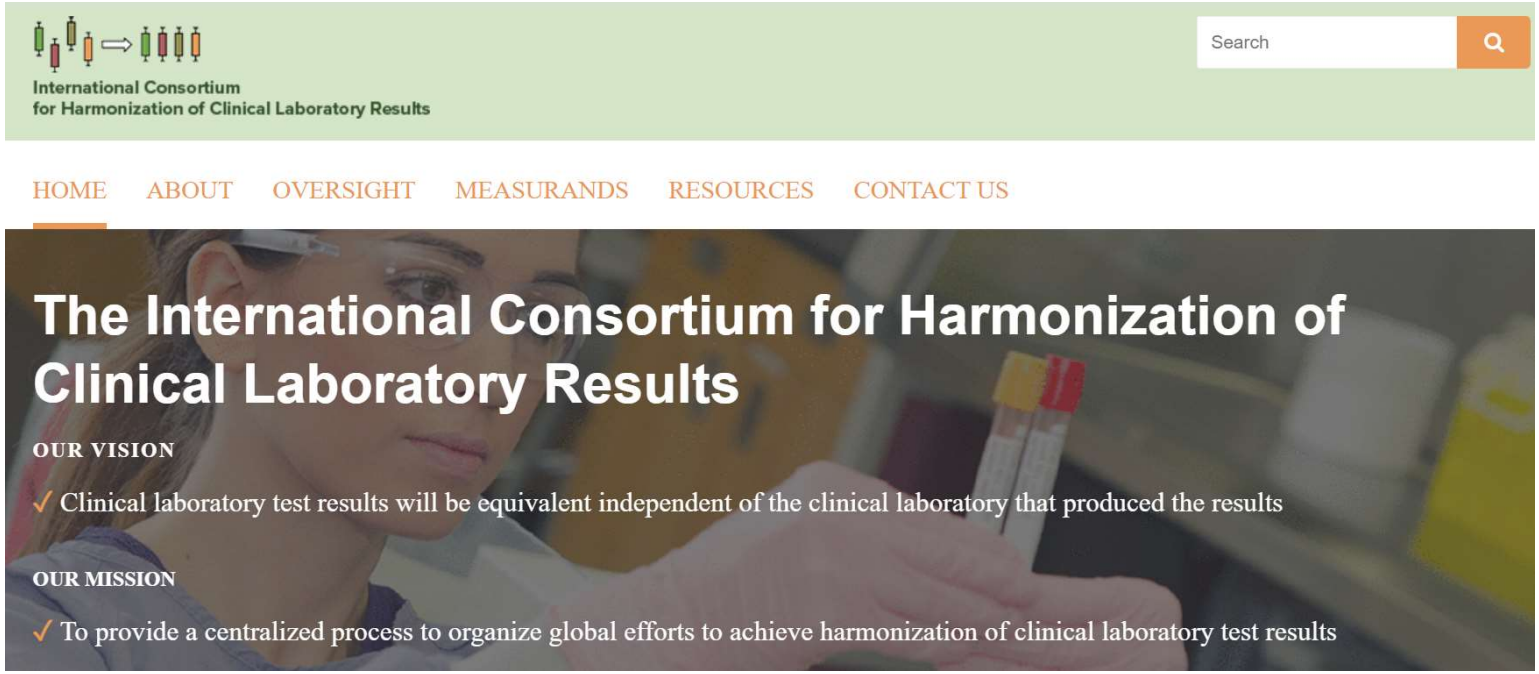
Current issues … and possible solutions



Measurand	Matrix	Medical Impact of Harmonization	Harmonization Status	Resources	Organization
Pregnancy-Associated Plasma Protein A	Plasma		Active		IFCC
Anti-Hepatitis B Surface Antigen (Anti-HBsAg)	Serum, Heparin Plasma	High	Needed	WHO	
Anti-myeloperoxidase (MPO) antibody, IgG	Serum	High	Needed	JCTLM	IFCC
B-type Natriuretic Peptide (BNP)	Serum	High	Needed		

An elephant in the room?

Current issues … and possible solutions

Commutability evaluation of EQA materials and of secondary CRMs is cumbersome

- **Consequences :**

1. **Standardization is compromised and/or a calibration bias is introduced**

   → **results are not standardized and/or inaccurate**

2. **Results comparability across different platforms cannot be evaluated**

   → **the effectiveness of standardization programs cannot be monitored**

   → **EQA data cannot be aggregated (cf. HALMA project)**

   → **the suitability of using common reference ranges cannot be evaluated**

3. **Target values assigned to EQA materials are consensus means**

   → **results trueness cannot be evaluated**

IFCC recommendations on commutability

Clinical Chemistry

Clinical Chemistry 64:3
447–454 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 1: General Experimental Design

W. Greg Miller,[1*] Heinz Schimmel,[2] Robert Rej,[3] Neil Greenberg,[4] Ferruccio Ceriotti,[5] Chris Burns,[6] Jeffrey R. Budd,[7] Cas Weykamp,[8] Vincent Delatour,[9] Göran Nilsson,[10] Finlay MacKenzie,[11] Mauro Panteghini,[12] Thomas Keller,[13] Johanna E. Camara,[14] Ingrid Zegers,[2] and Hubert W. Vesper,[15] for the IFCC Working Group on Commutability

Clinical Chemistry 64:3
455–464 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 2: Using the Difference in Bias between a Reference Material and Clinical Samples

Göran Nilsson,[1] Jeffrey R. Budd,[2] Neil Greenberg,[3] Vincent Delatour,[4] Robert Rej,[5] Mauro Panteghini,[6] Ferruccio Ceriotti,[7] Heinz Schimmel,[8] Cas Weykamp,[9] Thomas Keller,[10] Johanna E. Camara,[11] Chris Burns,[12] Hubert W. Vesper,[13] Finlay MacKenzie,[14] and W. Greg Miller,[15*] for the IFCC Working Group on Commutability

Clinical Chemistry 64:3
465–474 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 3: Using the Calibration Effectiveness of a Reference Material

Jeffrey R. Budd,[1] Cas Weykamp,[2] Robert Rej,[3] Finlay MacKenzie,[4] Ferruccio Ceriotti,[5] Neil Greenberg,[6] Johanna E. Camara,[7] Heinz Schimmel,[8] Hubert W. Vesper,[9] Thomas Keller,[10] Vincent Delatour,[11] Mauro Panteghini,[12] Chris Burns,[13] and W. Greg Miller,[14*] for the IFCC Working Group on Commutability

Clinical Chemistry 0:0
1–10 (2020)

Special Reports

IFCC Working Group Recommendations for Correction of Bias Caused by Noncommutability of a Certified Reference Material Used in the Calibration Hierarchy of an End-User Measurement Procedure

W. Greg Miller,[a,*] Jeffrey Budd,[b] Neil Greenberg,[c] Cas Weykamp,[d] Harald Althaus,[e] Heinz Schimmel,[f] Mauro Panteghini,[g] Vincent Delatour,[h] Ferruccio Ceriotti,[i] Thomas Keller,[j] Douglas Hawkins,[k] Chris Burns,[l] Robert Rej,[m] Johanna E. Camara,[n] Finlay MacKenzie,[o] Eline van der Hagen,[d] Hubert Vesper,[p] for the IFCC Working Group on Commutability

IFCC recommendations on commutability

Clinical Chemistry 00:0
1–10 (2023)

Special Report

Recommendations for Setting a Criterion for Assessing Commutability of Secondary Calibrator Certified Reference Materials

W. Greg Miller,[a,*] Thomas Keller,[b] Jeffrey Budd,[c] Jesper V. Johansen,[d] Mauro Panteghini,[e] Neil Greenberg,[f] Vincent Delatour,[g] Ferruccio Ceriotti,[h] Liesbet Deprez,[i] Robert Rej,[j] Johanna E. Camara,[k] Finlay MacKenzie,[l] Alicia N. Lyle,[m] Eline van der Hagen,[n] Chris Burns,[o] Pernille Fauskanger,[p] and Sverre Sandberg,[p,q,r] for the IFCC Working Group on Commutability in Metrological Traceability

Clinical Chemistry 00:0
1–11 (2023)

Special Report

Recommendations for Setting a Criterion and Assessing Commutability of Sample Materials Used in External Quality Assessment/Proficiency Testing Schemes

Sverre Sandberg,[a,b,c,*] Pernille Fauskanger,[a] Jesper V. Johansen,[d] Thomas Keller,[e] Jeffrey Budd,[f] Neil Greenberg,[g] Robert Rej,[h] Mauro Panteghini,[i] Vincent Delatour,[j] Ferruccio Ceriotti,[k] Liesbet Deprez,[l] Johanna E. Camara,[m] Finlay MacKenzie,[n] Alicia N. Lyle,[o] Eline van der Hagen,[p] Chris Burns,[q] and W. Greg Miller;[r] for the IFCC Working Group on Commutability in Metrological Traceability

COMET Objective 2

Objective 2: Identification of manufacturing processes leading to high commutability levels

As the causes for a material's non-commutability remain largely unknown, various calibration and quality control materials will be sourced and/or prepared according to different manufacturing processes. Their commutability will be evaluated and compared with the objective to identify critical quality attributes of materials and key common causes limiting commutability. To define commutability acceptance criteria, measurement uncertainty will be considered at each level of the calibration hierarchy, as well as its impact on the quality of laboratory tests.

- Organization of a series of commutability studies to assess commutability of different types of CRMs & EQA materials → identify manufacturing processes consistently leading to high commutability levels
- Materials will consist of frozen, lyophilized spiked or not with exogenous substances such as preservatives, cryoprotectants, purified compounds to increase measurand's final concentration

EQA providers and producers of EQA Materials will be invited sharing their materials for inclusion in the commutability studies

Current issues … and possible solutions

Commutability evaluation of EQA materials and of secondary CRMs is cumbersome

➢ **Develop new approaches for making commutability evaluation easier**

Objective 3: Development of more efficient and cost-effective ways of conducting commutability studies

As commutability evaluation is cumbersome, the project will develop more efficient and cost-effective ways of conducting commutability studies, including simplified commutability studies involving a reduced number of patient samples and/or a comparison with a material which commutability was successfully established in a previous study; multiparameter commutability studies in which commutability of a large number of CRMs and EQA materials will be evaluated simultaneously for a panel of measurands; use of commutability panels consisting of frozen pools which commutability was qualified beforehand; use high-throughput RMPs that are automated and/or multiplexed; mutualising the resources and capabilities of a coordinated network of reference laboratories that will share the work to jointly assign reference method target values to all study materials; development of a software for automated data analysis.

Current issues … and possible solutions

Commutability evaluation of EQA materials and of secondary CRMs is cumbersome

- **Develop new approaches for making commutability evaluation easier**

1. **simplified commutability studies involving a reduced number of patient samples and/or a comparison with a material which commutability was successfully proven in a previous commutability study;**
2. **multiparameter commutability studies in which commutability of a large number of CRMs and EQA materials will be evaluated simultaneously for a panel of measurands;**
3. **use of commutability panels consisting of frozen pools which commutability was qualified against a panel of fresh clinical specimens in a first study;**
4. **Use of high-throughput RMPs;**
5. **Development of automated data analysis**
6. **Invite EQA providers join commutability studies organized by RM producers**
7. **Mutualize the resources and capabilities of a coordinated network of reference laboratories that will share the work to jointly assign reference method target values to all study materials;**

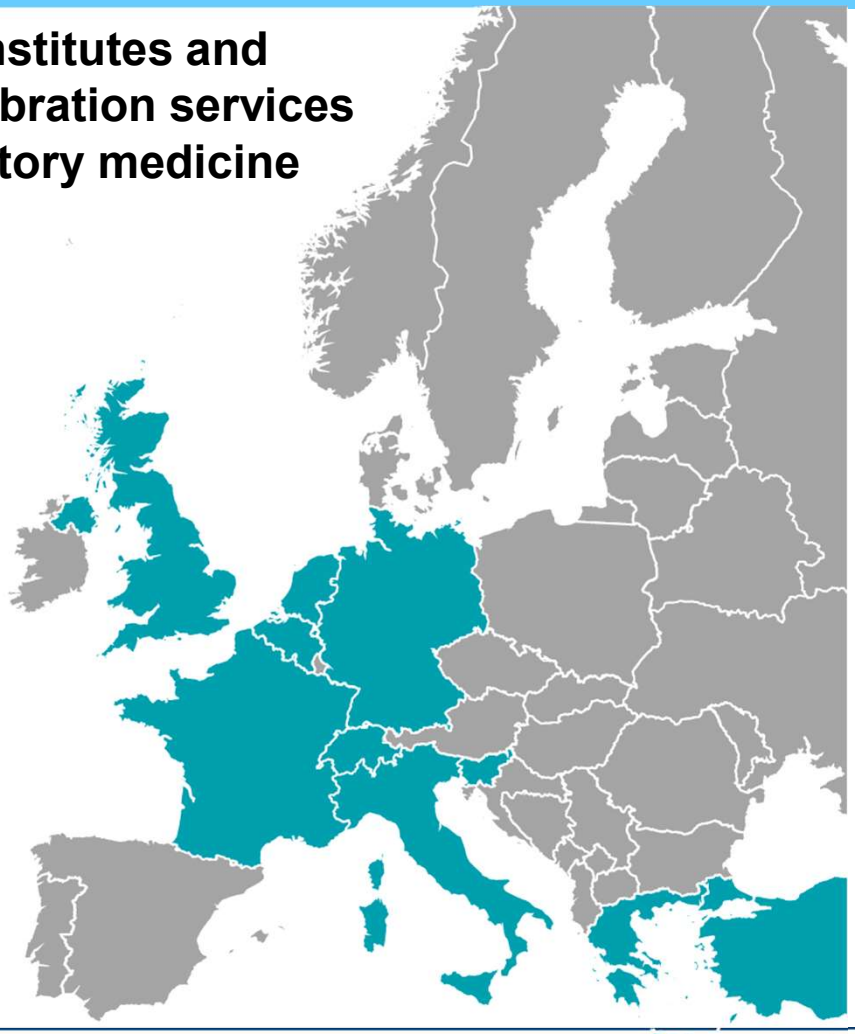
European Metrology Network TraceLabMed

Network of National Metrology Institutes and reference laboratories providing calibration services and reference standards in laboratory medicine

TRACE LAB MED

In 2024:

14 NMIs/DIs &
4 Partners from
10 Countries



WP4 Post-market surveillance of IVD tests through EQA data aggregation

DE GRUYTER Clin Chem Lab Med 2021; 59(1): 117–125

Eline A. E. van der Hagen, Cas Weykamp, Sverre Sandberg, Anne V. Stavelin, Finlay MacKenzie and W. Greg Miller*

Feasibility for aggregation of commutable external quality assessment results to evaluate metrological traceability and agreement among results

DE GRUYTER Clin Chem Lab Med 2024; 62(1): 77–84

Gro Gidske*, Sverre Sandberg, Pernille Fauskanger, Jonna Pelanti, Mette C. Tollånes, Anne E. Solsvik, Una Ø. Sølvik, Wenche S. Vie and Anne Stavelin

Aggregated data from the same laboratories participating in two glucose external quality assessment schemes show that commutability and transfers of values to control materials are decisive for the biases found

WP4 Post-market surveillance of IVD tests through EQA data aggregation

C4 WP4: European metrology infrastructure supporting the organisation of accuracy-based programs and EQA data aggregation for improved post-market surveillance of IVD tests

The aim of this work package is to support a coordinated European metrology infrastructure (EMN TraceLabMed) supporting continuous post-market surveillance of IVD tests by supporting or organising accuracy-based programs relying on commutable EQA materials with reference method target values.

In Task 4.1, reference method target values will be retrospectively assigned to EQA materials that were shown to be commutable (Task 3.2).

In Task 4.2, a large-scale EQAS will be organised for which 2 EQA materials will be tested for commutability and value assigned with RMPs by calibration laboratories.

In Task 4.3, a framework for performance verification of IVD tests and harmonisation monitoring of clinical measurements through EQA data aggregation will be developed.

Acknowledgements

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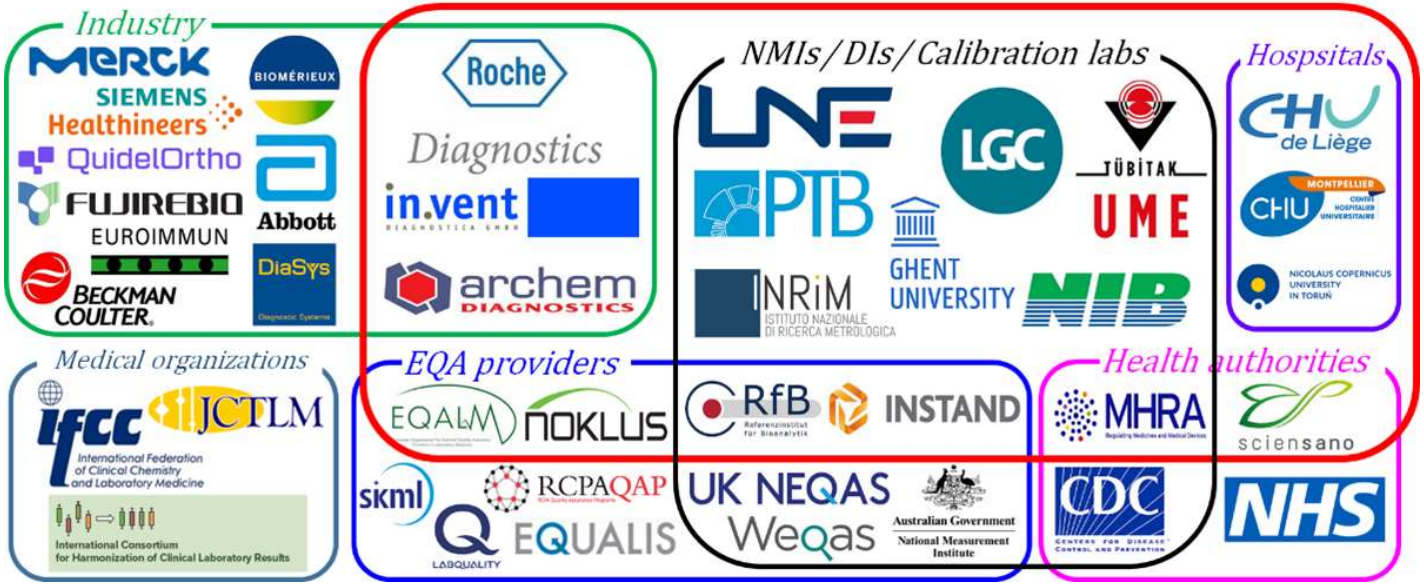
Acknowledgements



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EUROPEAN PARTNERSHIP

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METROLOGY PARTNERSHIP

EURAMET

Acknowledgements

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