



## **Annual Report**

**2021**

Dear colleagues and friends, dear EQALM members!

Again, we are experiencing a very special year; again, we had no face-to-face Symposium and no General Assembly in the presence of representatives of all member organizations. Nevertheless, EQALM has not been inactive, but proceeded very well with several projects.

This Annual Report summarizes activities of EQALM in the year 2021.

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## Activity report of the board 2021

As usual, the executive board held monthly videoconferences for EQALM's agendas; face-to-face meetings that usually take place twice a year were cancelled.

The board's work in 2021 focused on

- organization of the operational office of EQALM including Swiss Chamber of Commerce and Bank account issues
- arrangement of a new server to be used for EQALM documents including a host for the EQALM database (see below)
- preparation of several scientific projects (see below)
- preparation of a template for agreements for cooperation with third parties
- pre-launching work for a new EQALM website

## Reports from EQALM cooperation with other organizations and other activities with EQALM participation

### EEE (Stéphanie Albarède, Erika Sarkani)

The EA-EUROLAB-EURACHEM Working Group „Proficiency Testing in Accreditation“ (EEE-PT) had a virtual meeting in November 2020 and May 2021.

The Eurachem PT guide - Selection, Use and Interpretation of Proficiency Testing (PT) Schemes was published at the beginning of 2021

The working group still works on the Revision of EA-4/18 - Guidance on the level and frequency of proficiency testing participation.

### EFLM - WG POST (Rachel Marrington and Piet Meijer)

Up to now there were 3 online meetings of the EFLM/EQALM Working Group Post. Ongoing projects were discussed. The major focus was on two projects:

[1] *Survey on Reflex/Reflective Testing in Clinical Chemistry and Endocrinology laboratories.* The questionnaire is now finished and ready for distribution.

[2] *LabReport 2.0 Project.* An experimental study is ongoing. Different laboratory reports developed have been presented by Teams to physicians, nurses and medical students to study how the results and change of results are perceived when presented in different formats. Interviews are finished and result interpretation are ongoing. A project on eye tracking during presentation of laboratory reports are under planning.

## ICHCLR (Gitte Henriksen)

In the beginning of 2021 EQALM and the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) signed an updated memorandum of understanding (MoU) for the joint task force to monitor harmonization of measurands in laboratory medicine through data aggregation (HALMA).

*The two organizations recognize the benefits of working together to join forces and agree to:*

- *collaborate on assessing harmonization of agreed measurands in laboratory medicine*
- *use the EQALM central database for the project*
- *collect EQA data from EQA providers worldwide*
- *recruit steering committee members and support working groups*
- *jointly publish results and communicate the findings*

The HALMA task force consists of a steering committee with members from both ICHCLR and EQALM and at the moment there are three working groups (WG) – a WG on commutability, a WG on description of methods and a working group for measurands. Terms of references for the WGs have been written and can be found on the EQALM website. The commutability and description WGs were established first, chairs and members have been found and the work in these WGs have started. It was decided by the HALMA steering committee to start with the measurands Creatinine and Calcium and a WG with dedicated people with expertise in these measurands is being established. The EQALM central database will be used, for providing EQA data that will be used in the HALMA projects.

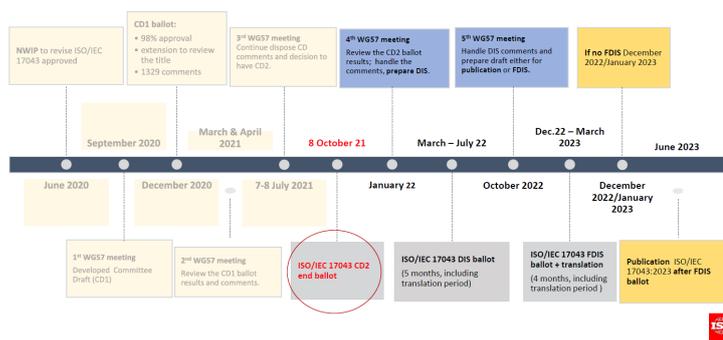
## ISO/CASCO (Stéphanie Albarède)

The WG57 received at the CD1 ballot (December 2020) 1329 comments including 520 technical comments and 297 general comments (the rest is editorial comments). This comments concerned in majority (1052) the main body. The rest concerned annex A (67), annex B (143) annex C (53) and bibliography (14). Regarding the high number of comments, a small drafting group (including EQALM) discussed them for preparing the second meeting of WG57 (21/01/22 to 21/01/24).

The full WG57 which met for 4 days in March had to increase its working time due to the high number of comments by having two more meetings (3 days in April 2021 (19 to 21 April) and 2 days in July 2021). To be more efficient, some works was made by different Task groups during the meetings in March and April. Tasks group also meet them between meetings. EQALM participated at the meeting drafting group for Annex A (April 6<sup>th</sup>).

The next steps are shown in the following figure presented at the information session of WG57 on 17<sup>th</sup> of September were members of EQALM were invited. The 17043 standard Publication should occur between December 2022 and June 2023.

## Next steps & publication



### JCTLM (Piet Meijer)

EQALM is involved in the planning group of the JCTLM Workshop 2023 entitled: “EQA schemes supporting metrological traceability in Laboratory Medicine“. The programme is still under development and will include different topics related the role of EQA in traceability and harmonization in laboratory medicine.

## Report from the Scientific Committee and Working Groups

The major topics discussed within the SC were ongoing projects and initiatives of the Working Groups, the development of a central EQALM database for EQA data collection and evaluation and how to structure scientific collaborations with third parties.

## Latest News from the Working Groups

### Frequency (Wim Coucke)

A study was performed investigating the role of correlation between EQA data obtained by the same laboratories for different samples in determining optimal frequency. It was found that it reducing the number of samples may have a beneficial effect. There is no evidence that a frequency of a survey every two weeks would be too frequent.

### Haematology (Joan-Luis Vives Corrons, Stéphanie Albarède, Barabra De la Salle)

Two new works were proposed at the meeting in Ljubljana in 2019 (survey on Reference Ranges used in Hematology and post-analytical EQA). This two works are postponed in 2021 due to the disruption of everyone's schedules by the current pandemic. However, the steering committee did not remain inactive in 2020. He participated all along the year in the project EQALM Virtual Microscopy Sharing Platform as the pilot operation will concern the differentiation of leukocytes on blood smears.

Concerning the European pilot survey on PK Deficiency pilot: There have been two distributions (1 in 2018 and 1 in 2019), as presented in Ljubljana in 2019. UK NEQAS Haematology had planned a further

two distributions in 2020 but these have been delayed because of the impact of the Covid-19 pandemic on the EQA staff, the courier services and the participant laboratories. The organisers have started plans to send a survey in 2020 and another early in 2021. They have worked with the EuroBloodNet project to develop a questionnaire on the diagnosis and management of PK deficiency and hope that additional testing sites can be recruited through the EuroBloodNet project.

### Microbiology (Sanjiv Rughooputh)

(not yet submitted)

### Virtual Microscopy (István Juhos)

#### Surveys

This section is about surveys among WG members.

Year	Surveys/Pilots
2021	<ul style="list-style-type: none"> <li>EQALM VM Sharing Platform Pilot 1</li> </ul>

#### WG Steering Committee

This section is about the activity and the number of the members of the WG steering committee

Year	Activity
2021	<p>12 participants from 8 EQALM members represented in the VM WG Steering Committee this year supporting ongoing WG projects:</p> <ul style="list-style-type: none"> <li>Brazil, France, Germany, Hungary, Portugal, Spain, Switzerland, UK</li> </ul>

#### EQALM Symposium WG Session

Ongoing project activities was discussed and the following EQALM members gave talks during the session.

Year	Talks
2021	<p>6 members: Belgium (Sciensano), France (CTCB), Germany (Instand), Hungary (QualiCont-University of Szeged), Switzerland (CSCQ), UK (UK NEQAS)</p>

#### Projects

This section is about the status of WG projects.

Year	Status
2021	<ul style="list-style-type: none"> <li>• WG Steering Committee has finalised the EQALM Digital Blood Smear Analysis Scheme in cooperation with the Haematology WG.</li> <li>• EQALM VM Sharing Platform Pilot 1 has been finished and evaluated, pilot 2 will be start soon.</li> <li>• VM image database for the next platform pilot has been extended by the WG steering committee.</li> </ul>

### Scientific activities

This section is about the scientific activities related to the WG.

Year	Scientific activity
2021	<ul style="list-style-type: none"> <li>• WG steering committee has collected references and scientific bibliography for reports and papers about ongoing projects.</li> <li>• EQALM Guideline for Digital Blood Smear Analysis Poster, EQALM Symposium</li> <li>• EQALM VM Sharing Platform talk, EQALM Symposium</li> </ul>

### Haemostasis (Ann Helen Kristoffersen)

#### Short overview of projects:

- New pre-analytical questionnaire in preparation in 2020-21. Routine coagulation tests and interferences of hemolysis, icterus (bilirubinemia) and lipemia. Plan to send questionnaire to EQALM Office to distribute to EQAs (which distribute to their laboratories) in November 2021. Responsible: Ann Helen Kristoffersen
- APTT post-analytical project: Joint project with EFLM WG post-analytical. Samples with prolonged APTT results were sent to laboratories performing APTT mixing. Feedback report almost finalized, to be sent to the laboratories. Manuscripts are written, to be circulated within the WG post-analytical. Responsible: Piet Meijer
- Inventory of the current EQA POCT practice in haemostasis: Questionnaire sent in 2017 to EQA organisations to ask for current types of POCT EQA programmes in haemostasis. Based on results, the WG started to make a questionnaire for EQA organizers on POCT D-dimer. This work has however been delayed and it should be discussed if it is still a project which the group should perform.
- A new project discussed on APTT/PT performance evaluation. Will start planning the questionnaire to EQA organisers when some of the tasks above are finished. Responsible: Piet Meijer

- Projects will be discussed at the WG Haemostasis meeting the 21<sup>st</sup> of October, and the annual report with more information will be updated in the end of the year.

### Performance Specifications (Dalius Vitkus)

Activities of the Working Group Performance Specifications were very limited due to COVID-19 crisis. Terms of Reference were set up in 2020. Suggestions for the questionnaire to be prepared and distributed to EQALM members on Performance Specifications have been discussed during January meeting of the Scientific Committee. It was planned to prepare questionnaire by the end of March. Unfortunately only pre-draft has been set up which is planned to be finalised by the end of the year.

## Latest News from Task and Finish Groups

### Immunohaematology (Christoph Buchta; terminated in October 2021)

The project to investigate the impact of national regulatory and economic conditions and of EQA providers' services on performance of immunohaematology laboratories in EQA came to a good end in 2021. The results of this study were published with the participation of 26 EQA providers:

Buchta C, Coucke W, Huf W, Griesmacher A, Müller MM, Mayr WR, Flesland Ø, Politis C, Wiersum-Osselton J, Aburto A, Badrick T, Bouacida L, Budina M, Duenas JA, Geilenkeuser WJ, Guimarães AVP, Hecimovic A, Jutzi M, Lee CK, Lim YA, Mammen J, Molnár PM, Mokhtari A, Morabito G, Muñoz-Diaz E, Niekerk T, Pakkanen A, Pezzati P, Popa R, Sárkány E, Siest JP, Suvagandha D, Thelen M, Ullhagen J, Vitkus D, Körmöczi GF. **External quality assessment providers' services appear to more impact the immunohaematology performance of laboratories than national regulatory and economic conditions.** Clin Chem Lab Med. 2022 Jan 19;60(3):361-369. doi: 10.1515/cclm-2021-1219. PMID: 35041777.

### Immunology (Dina Patel)

The aim of the Immunology Task and Finish Group is to collaborate with other EQALM members to try to understand how immunology practices/tests are utilised within member countries in the following areas:

- ANA ICAP harmonisation and nomenclature initiative
- ANCA-best practice following the release of updated guidelines
- Phospholipid antibodies- challenges with standardisation of assays

As an initial starting point we met via teleconference in 2020 to decide on the terms of reference of the group. We decided to produce a survey that would be circulated to EQALM members to determine the impact of the ANA ICAP harmonisation initiative and whether changes in technology are reducing or improving skills within the workforce of immunofluorescence testing. Unfortunately no further progress has been made due to the ongoing limitations resulting from the COVID-

19 pandemic. We hope to continue our work in preparing the survey and then circulate it to members in 2022.

### **ISO 17043 revision** (Stéphanie Albarède)

(see above)

### **Performance of laboratories and EQA providers during Covid-19 Pandemic** (Rachel Marrington, Paola Pezzati)

Results presented at the EQALM Symposium 2021; to be published in a manuscript in 2022.

### **Study on the harmonization and performance of anti-SARS-CoV-2 antibody detection and quantification assays in EQALM members' EQA schemes** (Christoph Buchta)

This study is one further international collaboration of EQALM member organisations. With great commitment and providing all his expertise, Prof. Lukas Weseslindtner from the Center for Virology at the Medical University, together with Christoph Buchta from ÖQUASTA, Austria, launched a project to compare the analytical performance of participants in anti-SARS-CoV-2 antibody schemes called to life. Sixteen EQA providers will send the same samples to their participants in the first half of 2022 and we expect results from around 2500 laboratories. This study will provide a good overview of assays used and their performance in many European and non-European countries.

## **Activity plan 2022**

- Start operations of the EQALM central database
- Preparation of the EQALM Symposium 2022 in Athens; this is a very special pleasure after the distance experiences of 2020 and 2021
- Preparation of a manuscript on “Behind the scenes of EQA” (working title) to present to laboratories and other interested parties in EQA what happens before EQA samples arrive, what happens between submission of results and the arrival of an assessment report, and what can be done with and read out from EQA results
- EQALM study on SARS-CoV-2 antibody detection including participants in relevant schemes of 16 EQA providers using the same samples for their EQA rounds included in their studies
- Evaluation of data collected in the EQALM study on performance of laboratories during Covid-19 pandemic
- Study on SARS-CoV-2 assays used in countries with/without official recommendations on IVDs to be / not to be used
- Optimizing and documentation (EQALM manual) of internal routines; internal routines are quite well, but using opportunities for optimization is never wrong

- Annual report; this report of activities, events and decisions during the year is a requirement in the EQALM constitution and summarizes all relevant information
- Regular meetings of the Working Groups and Task-and-Finish-Groups for content-related work on projects
- Regular meetings of the EQALM board to advance projects