



Annual Report

2022

Dear colleagues and friends, dear EQALM members!

After two tough years due to the COVID-19 pandemic, the return to what we used to call "normality" began in 2022. For some of us, however, new, previously unknown challenges arose in 2022 and we wish those who cannot live and work in peace a change for the better.

This Annual Report summarises activities of EQALM in the year 2022.

The EQALM Executive Board 2022

Stéphanie Albarède, Treasurer

Christoph Buchta, Chairman

Gro Gidske, Member

Gitte Marie Henriksen, Member, Chair of the Scientific Committee

Rachel Marrington, Secretary

Pierre-Alain Morandi, Member

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Activity report of the board 2022

As usual, the executive board held monthly videoconferences for EQALM's agendas. Unlike in pre-pandemic times, only one face-to-face meeting was held, namely as part of the EQALM Symposium in October 2022 in Athens.

The board's work in 2022 focused on

- organization of the Annual Symposium
- preparation of several scientific projects (see below)
- pre-launching work for a new EQALM website
- organization of the operational office of EQALM Bank account issues

Status of members in 2023

28 full members

1 individual member

4 non-European members

2 associate members

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

EA-EUROLAB-EURACHEM Working Group: 'Proficiency Testing in Accreditation' (EEE-PT) (Stéphanie Albarede)

There were two meetings in 2022: a meeting via Microsoft Teams in May and a face to face meeting hosted at the CTCB (an EQALM member) in Toulouse.

Several projects from 2021-2022 have been completed, therefore the WG has discussed new topics specifically:

- the need for further guidance on flexible scopes for PT providers. A survey carried out in 2022 showed a lack of standardization in Europe.

- discussion on the structure of an impact study on the revised ISO/IEC 17043. As the EEE-PT WG only has 2 meetings per year, it was decided in November 2022 not to undertake this work. Indeed, to be useful this project is required to be done more quickly.

The next meeting will be held in April or May 2023 in Kempten (Germany). EQALM has two representatives, Erika Sarkani and Stéphanie Albarede. But the WG asks for a third one. A request for volunteering will be made to EQALM members by the EQALM board in 2023.

EFLM - WG POST (Rachel Marrington and Piet Meijer)

In 2022 there were 2 online meetings and one hybrid meeting of the EFLM/EQALM Working Group Post. Ongoing projects were discussed. The major focus has been on several projects:

- Survey on Reflex/Reflective Testing in Clinical Chemistry and Endocrinology laboratories. The survey is complete and two manuscripts are in preparation, which it is hoped will form the basis of forming national recommendations which can be presented to the National Societies.
- APTT reporting in Europe, is ratio better than seconds?

Several publications from the WG-POST appear in 2022:

Cadamuro J, Winzer J, Perkhofer L, von Meyer A, Bauca JM, Plekhanova O, et al. Efficiency, efficacy and subjective user satisfaction of alternative laboratory report formats. An investigation on behalf of the Working Group for Postanalytical Phase (WG-POST), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). *Clin Chem Lab Med.* 2022;60:1356-64.

Bauca JM, Ajzner E, Cadamuro J, Hillarp A, Kristoffersen AH, Meijer P, et al. An international study on activated partial thromboplastin time prolongation. Part 1: Analytical results. *Clinica chimica acta; international journal of clinical chemistry.* 2022;535:167-73.

Bauca JM, Ajzner E, Cadamuro J, Hillarp A, Kristoffersen AH, Meijer P, et al. An international study on activated partial thromboplastin time prolongation. Part 2: Interpretative commenting. *Clinica chimica acta; international journal of clinical chemistry.* 2022;535:174-9.

Mid 2022 Piet Meijer retired as representative of EQALM in the WG POST. He continues his activities in the working group as expert/consultant.

EFLM - WG-PRE (Gunn Berit Berge Kristensen and Barbara De la Salle)

The 6th EFLM Conference on Preanalytical Phase "Preanalytical Quality: an interdisciplinary journey" was arranged on-line, 15-18 March 2022.

There have been two working group meetings in 2022:

Joint EFLM WG-PRE and WG-POST Zoom meeting 8.03.22

The following topics were discussed:

- QI harmonization
- APTT reporting in Europe survey
- EFLM stability project – 3 parts:
- Blood collection guideline for emergency departments in collaboration with EUSEM - European Society for Emergency Medicine
- Hemolyses frequency - "Proof-of-Concept" study
- IV-catheter blood collection
- Questionnaire on lactate/ammonia and anion gap
- Opinion paper on defining and designing electronic ordering systems
- Up to date publication about how to prepare icteric, lipemic and haemolysed samples.

Joint EFLM WG-PRE and WG-POST meeting in Munich 11.11.22

The following topics were discussed:

- EFLM stability project
- Harmonization of extraanalytical Qis
- Opinion paper on defining and designing electronic ordering systems
- GIRFT proposal for writing guidelines for transporting samples to the laboratory
- Urine acidification study II
- Blood collection guideline for emergency departments in collaboration with EUSEM - European Society for Emergency Medicine
- EFLM recommendation on tube validation – CLSI will incorporate EFLM ideas in their document
- 7th Preanalytical Conference & 1st Post-Analytical Conference 2024

- o Status: The executive board of the EFLM is not in favor of a joint Congress or an adjacent Congress (1,5 days WG-PRE and directly thereafter 1,5 days WG-AI) 22.12.22.
- IV-catheter blood collection – postponed
- Questionnaire on lactate/ammonia and anion gap – postponed

Concerning EFLM stability project:

Part 1 - How to evaluate stability studies – Published in CCLM: *The CRESS checklist for reporting stability studies: on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE) Volume 59 (2021): Issue 1 (Jan 2021)*

Part 2 - How to perform a stability study – *Recommendation for the design of stability studies on clinical specimens* – the manuscript is sent for review by the EFLM scientific committee in January 2023.

Part 3 – Stability database – this part has just started.

ICHCLR (Gitte Henriksen)

HALMA is “the joint task force to monitor harmonization of measurands in laboratory medicine through data aggregation” and is a collaboration between EQALM and the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR).

Besides the steering committee there are currently three specific working groups (WG) in HALMA; WG on Measurands for creatinine, calcium and albumin, WG on Commutability and WG on Description of Methods. All WG’s have been active in 2022 with different tasks.

In 2022 the HALMA steering committee and working group (WG) chairs had several virtual meetings to discuss how to move forward with the project thus being able to aggregate data from different EQA providers. A questionnaire regarding method information was made and first sent as a pilot study to a few EQA providers with the purpose of asking if they could understand the questions in the questionnaire. The questionnaire was revised according to the received comments and suggestions. Furthermore, a question regarding commutability was added to the questionnaire. The questionnaire was sent to all the EQALM members and three non-members and 12 EQA providers replied from different locations around the world. If the EQA provider answered yes to having commutable samples, a commutability checklist (prepared by the HALMA Commutability WG) was sent to determine if their EQA samples

are suitable for inclusion in data aggregation for the specified measurands. The Commutability WG reviewed the information given by the EQA providers and identified 11 programs using commutable samples. A template was developed for retrieving data and will be sent to the EQA providers that use commutable samples in the beginning of 2023. Data will be stored in the EQALM Central Database. HALMA welcomes data from additional EQA providers. For more information on HALMA please see EQALM.org

The HALMA steering committee consists of the following people

From ICHCLR: Greg Miller, Gary Myers and Sverre Sandberg

From EQALM: Piet Meijer, Wim Coucke and Gitte Henriksen

ISO/CASCO (Stéphanie Albarède)

As presented in 2021 at the EQALM meeting, it was decided in July 2021 to have a CD2. The BALLOT on this CD2 ended in October 2021. A drafting group (DG) met in November to help convenors and secretariat prepare the comments for the full meeting of WG57 which took place in January 2022; The TFG17043 steering committee of EQALM have established comments for preparing the discussion of the DG. The DG role is to pre-scan/sort out the CD2 comments (768 comments), clean out the editorials and non-controversial comments, draft proposals (where possible) and group more complex comments for WG discussion. EQALM was not represented in January at the full meeting for health reasons.

The ballot of the Draft International Standard (DIS) ISO/IEC 17043, “conformity assessment – general requirements for the competence of proficiency testing providers” opened from 27th April 2022 to 20th July 2022. The draft was approved by 100% of ISO/CASCO members (72 voting) and by 100% of IEC members (32 voting). The 542 comments collated were pre-analyzed by the drafting group in September (6 days meeting) where the EQALM participated. The final decision on the comments have been taken and the workplan and next development steps have been discussed at the series of WG57 meetings planned for November 2022. The ballot of the FDIS will open in December 2022 and will be closed in March 2023. The ISO/IEC 17043 should be published at the first semester of 2023.

During the EQALM meeting in Athens (October 2022), a presentation of the primordial changes was made by a member of the WG57, Olivier Pearson (AFNOR, FRANCE). The TFG17043 have discussed the last version of the DIS (propositions issued from the DG

meeting in September 2022). The members of the EQALM working group decided to postpone the closing date of the TFG in order to prepare an impact study of the new version in order to distribute it to members interested in the topic. The TFG also discussed the possibility of the revisions of the standard EN 14136:2004 ("Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures"). In case the revision will be voted, the TFG members are interested in a new TFG on this topic.

JCTLM (Piet Meijer)

EQALM is involved in the planning group of the JCTLM Workshop 2023 entitled: "EQA/PT Harmonisation; EQA schemes elucidating the clinical suitability of laboratory results" During 2022 the programme for this workshop has been finalised. A variety of topics related to harmonization of laboratory results and the role of EQA will be discussed. The dates for the JCTLM Workshop 2023 are Monday and Tuesday, December 4 & 5. It will be a hybrid meeting at the BIPM (*Bureau international des poids et mesures*, International Bureau of Weights and Measures) with up to 80 participants on site.

Report of the Chair of the Scientific Committee

The Scientific Committee had 4 virtual meetings in 2022 and one face to face meeting at the EQALM Symposium in Athens. At the meetings the chairs shared the progress of ongoing projects within the working groups (WG)/task and finish groups (TFG) and received announcements from the EQALM board.

In 2022 it was decided that chairs of TFGs should also join the Scientific Committee. Three WG's were established: EQALM Central Database, Virology and EQA for POCT which makes it a total of 10 EQALM WG's. Most of the terms of references for the different WG's were updated and posted on the EQALM website.

News from the Working Groups

Frequency (Wim Coucke since 2017)

Realized in 2022

- Application of the framework for evaluating frequency of EQA results by examining correlation between EQA data: the framework has been applied to data from aPTT from ECAT and have been presented at the 2022 EQALM symposium.
- Evaluating frequency based on the detection of the risk of making a laboratory error. A first thought experiment has been presented on the frequency working group meeting at the 2022 EQALM symposium

Planned for 2023

- Another application of the framework for evaluating frequency of EQA results by examining correlation between EQA data
- Defining lower limits for frequency of EQA programs based on the detection of the risk of making a laboratory error.

Haematology (Barabra De la Salle since 2020)

Works in progress

1. Article on the Analytical Performance Specifications for Blood Smear Interpretation in Haematology

The text of this manuscript is in final review prior to submission for publication.

2. Survey on Reference Ranges in Haematology Cell Counting

The questions for this survey have been finalised by the Steering Committee, for distribution by the EQALM Central Office after the Athens meeting. The outcomes of the questionnaire will be used as the basis for a publication.

3. Collaboration with the VM WG

Steering committee members have contributed a substantial amount of expertise and time to the development and completion of the VM WG publication.

Works proposed but still to be started

1. **Post-analytical EQA in Haematology**
2. **Rare disease EQA in PK deficiency**
3. **Standardisation of NGS interpretation in Haematology (new proposal)**

Questions and items to be raised to the Scientific Committee

1. The Haematology WG Steering Committee needs to recruit additional members and requests the contact details of those attending the WG meetings to appeal directly to members by email if necessary.
2. The Haematology WG Steering Committee would like additional information on the establishment of the POCT EQA WG. The Haematology WG supports the formation of the new WG but is concerned on the potential impact on the work of the Haematology WG, the decision-making process behind the formation of the POCT WG and the decision to appoint the chair from a non-European EQA provider organisation.

Virtual Microscopy (István Juhos since 2016)

WG Steering Committee

12 participants from 8 EQALM members represented in the VM WG Steering Committee this year supporting ongoing WG projects:

- Brazil, France, Germany, Hungary, Portugal, Spain, Switzerland, UK

WG Terms of Reference

EQALM VM WG Terms of Reference have been established and approved by the EQALM Scientific Committee and the EQALM Board.

EQALM Symposium WG Session

Ongoing project activities have been discussed. Several new opportunities for the use of the EQALM Sharing Platform have been identified.

Grants

The following grant application has been submitted:

EU Interreg Danube Region Programme.

Budget: 1,4 million EUR.

Project lead partner: University of Szeged

Project partners: EQALM members from Austria, Croatia, Hungary, Romania, Slovenia, moreover the Fraunhofer Institute and its partner, Germany.

Project Strategic Partner: EQALM

Projects

- **EQALM VM Guidelines**
 - EQALM Digital Blood Smear Analysis Scheme Draft has been discussed in several steering committee meetings. A steering committee consensual DRAFT document has been presented to the EQALM Scientific Committee and will be shared with the EQALM members.
- **EQALM VM Sharing Platform**
 - Evaluation and Report module has been established and is under review. External samples from external VM systems can be included in the EQALM VM Sharing Platform as well as digital samples of the platform can be embedded into EQA providers own IT solutions.
 - EQALM VM Sharing Platform possible service cases has been submitted to the EQALM Scientific Committee and the EQALM Board for discussion.
 - Collaboration has been initiated with the Erasmus Medical Centre, Netherlands. The aim of the collaboration is to use the EQALM VM Sharing Platform in the field of parasitology.
 - Collaboration has been discussed with EQA providers, Öquasta, Austria and CTCB, France. The aim of the collaboration is to use the EQALM VM Sharing Platform in the field of haematology.
- **EQALM VM Image Database**
 - Physical slide scanning possibilities have been collected and tested.
 - Creation of VM image database has been started.

Scientific activities

- EQALM VM Sharing Platform and Database talk, EQALM Symposium, Athens, Greece

Haemostasis (Ann Helen Kristoffersen since 2017)

Ongoing projects and responsibilities, Status 2022

APTT post-analytical project - Josep Bauca/Eva Ajzner/Ann Helen Kristoffersen/ Piet Meijer & others from WG-Post (EFLM)

Joint projects with EFLM: Laboratories were invited to participate by measuring APTT and APTT mix in 2 real samples prepared by ECAT and answer a questionnaire about APTT mixing routines and their comments on the results. Samples and questionnaire were sent to the laboratories by email with a link to SurveyMonkey.

Two papers published in 2022. “An international study on activated partial thromboplastin time prolongation.”

Part 1: Analytical results. Clin Chim Acta 2022;535:167-173. PMID: 36041550

Part 2: Interpretative commenting. Clin Chim Acta 2022;535:174-179. PMID: 36055391

APTT/PT performance evaluation - Meijer/ Stavelin/ Kristoffersen

New questionnaire in preparation. Project was discussed at the EQALM meeting in the WG Haemostasis.

APTT seconds/ratio project - Meijer/Kristoffersen/Hillarp/Cadamuro

Project cooperation with the EFLM WG-PRE/POST. Project was discussed at the EQALM meeting in the WG Haemostasis. Data evaluation is ongoing.

New project on pre-analytical variables in haemostasis - Kristoffersen/Meijer and project group

Questionnaire regarding HIL indices (hemolysis, icterus, lipemia) and interference in coagulation tests finalized and distributed by EQALM in June-September 2022. Preliminary results were presented at the EQALM meeting (WG Haemostasis Symposium & main meeting). Data evaluation started.

EQA POCT: D-dimer - Meijer/Kristoffersen

A questionnaire sent to the EQA organisations indicated that they were interested in working with POCT for D-dimer. Questionnaire for EQA organisers in preparation and possible projects on POCT D-dimer discussed. Postponed.

D-dimer - Kristoffersen/Meijer/ van Essen-Hollestelle

Which type of EQA samples are available? Is there commutable material available for D-dimer? Both large instruments and POCT.

To be discussed in the WG Haemostasis.

EQATH cooperation - Kristoffersen/Meijer/Jennings (chair EQATH)

Agreed to cooperate when useful for both EQALM and EQATH (International organizations for External Quality Assessment in Thrombosis and Haemostasis).

Performance Specifications (Dalius Vitkus since 2019)

The main objectives of the WG Performance Specifications are:

- To look which performance specifications are used by different EQA organizations;
- The rationale behind different performance specifications in use;
- The pros and cons of the use of common performance specifications;

- To set-up cooperation with EFLM Science Committee Task Groups “Performance Specifications Based on Outcome Studies” (TG-PSOS) and “Biological Variation Database” (TG-BVD);
- To propose performance specifications for EQA organizations in cooperation with TG-PSOS and TG-BVD.

Revised draft of Questionnaire for EQA organisations regarding performance specifications in use to be sent 1st quarter of 2023.

Questionnaire to Lithuanian laboratories on PS considered when choosing EQA programs (17 questions) sent out in March 2022 to 80 labs (public and private). Target participants - laboratory professionals involved in the selection of EQA organizer. Results were used in preparation of MS thesis at Vilnius University. Scientific paper in preparation.

Closed WG meeting held in Athens on 12-10-2022. Open WG meeting held in Athens during the annual symposium of EQALM attended by 35 participants held 12-10-2022. Constructive discussion on current status of performance specifications used by different EQA providers during the meeting.

Immunology (Dina Patel since 2019)

The aim of the Immunology Working 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

The group has met several times during 2022 via teleconference to confirm the terms of reference of the group. The group has 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. The survey is currently being reviewed by the group with the aim to circulate it to members in 2023.

Immunohaematology (Richard Haggas since 2022)

The aim of the Immunohaematology Group is to collaborate with other EQALM members looking at comparison of results and best practice within the field. Work by Wim Coucke on a comparison of false negative and false positive results for Rh phenotyping was presented at the meeting in Athens and discussion has taken place about possibly comparing errors in DAT testing. The group is now chaired by Richard Haggas (UK NEQAS Blood Transfusion).

EQALM Central Database (Wim Coucke, Piet Meijer since 2022)

Since 2019 the development of an EQALM Central Database for EQA results is ongoing. Because this central database also plays a role in the HALMA initiative (see for details the section on HALMA) and other initiatives for the use of this database are under development the board has decided to establish a special working group for the Central Database project. This working group is chaired by Piet Meijer. Gitte Henriksen and Wim Coucke are members of the steering committee. During the EQALM symposium in Athens a first meeting of the steering committee took place. The major focus has been on extension of the steering committee and setting up the terms of reference and working procedures. In the meantime Stephanie Albaredo and Razvan Popa have agreed to participate in the steering committee.

In addition, a lot of attention has been paid on the involvement of the EQALM Central database in an European project proposal ReMeSys (REference MEasurement SYStems for clinically relevant biomarkers to support the effective implementation of the In Vitro Diagnostic Regulation) which was initiated by Vincent Delatour (France). Unfortunately this project proposal has not been accepted. A new attempt will be undertaken in 2023.

Virology / Pandemic Preparedness (Christoph Buchta since 2022)

Ongoing projects

- Status analysis of pandemic readiness of EQA providers and their schemes (in preparation);
- project based on these results to identify and implement potentials for pandemic preparedness (in planning);

- achievements to be verified in an “EQALM super-challenge”, a feasibility study for the central control of several national and regional coordinated EQA rounds with different specific goals (in planning)

EQA for POCT (Tony Badrick since 2022)

This Working Group started at the EQALM meeting in Athens and had their first meeting there and a steering committee has been established.

News from Task and Finish Groups

ISO 17043 revision (Stéphanie Albarède)

(see above); maybe to be continued by a TaF Group of revision of ISO 14136.

Study on the harmonisation 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 participated and used the same samples in their schemes in the first half of 2022. The results will be published in 2023. The work of this Task and Finish Group will be continued in The Working Group Virology / Pandemic Preparedness.

Activity plan for 2023

- Start operations of the EQALM central database
- Update the content of the website www.eqalm.org
- Preparation of the EQALM Symposium 2023 in Lyon
- Completion and submission 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
- Completion of the evaluation of data collected in the EQALM study on performance of laboratories during Covid-19 pandemic
- Signing of a Memorandum of Understanding with IFCC
- Optimizing and documentation (EQALM manual) of internal routines; internal routines are quite well, but using opportunities for optimization is never wrong
- 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
- Follow up on whether EQALM should be developed from an European to an International organisation
- Follow up on whether EQALM should be moved from Switzerland to an EU member country.