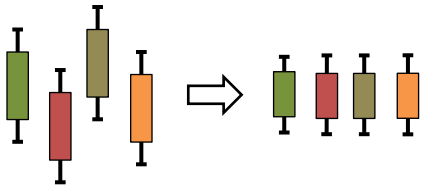

International Consortium for Harmonization of Clinical Laboratory Results

Annual report 2021

This Annual Report is to inform stakeholders of the activities and progress made by the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) for the period November 2020 – December 2021.

Introduction:

The ICHCLR was created in 2013 to fulfil the recommendations from an international conference that discussed the status and challenges to achieve harmonized results from clinical laboratories on a global basis. See the www.harmonization.net website and the Resources tab for more information on the creation and activities of the ICHCLR.

The ***vision*** of the ICHCLR is that clinical laboratory test results will be equivalent independent of the clinical laboratory that produced the results

The ***mission*** of the ICHCLR is to provide a centralized process to organize global efforts to achieve harmonization of clinical laboratory test results.

The major activities of the ICHCLR are:

1. Prioritize measurands in need of harmonization based on medical importance,
2. Identify harmonization and standardization activities by organizations around the world to promote cooperation and avoid duplication of effort,
3. Promote development of technical processes to achieve harmonization when there is no reference measurement procedure or certified reference material,
4. Promote advances in regulatory components of harmonization processes,
5. Promote surveillance of the success of harmonization.

The minutes of all joint Council/HOG conference calls and meetings are posted to the "Resources" tab under "Meeting Summaries" on the www.harmonization.net website. All previous Stakeholder member updates are also posted on the website.

Council update:

The Council provides governance and financial oversight for the ICHCLR. Current member organizations in 2020 and their representatives are:

- The International Federation of Clinical Chemistry and Laboratory Medicine – *Sverre Sandberg, MD, PhD (chair)*
- The American Association for Clinical Chemistry – *Gary L. Myers, PhD*
- The College of American Pathologists – *Anthony Killeen, MD, PhD*
- The Korean Society for Laboratory Medicine – *Gye Chol Kwon, MD, PhD*

In 2021 the Japanese Committee for Clinical Laboratory Standards unfortunately decided to withdraw from the council.

The council has approved the below proposals:

1. Establishing WGs that can accomplish harmonisation activities
ICHCLR has established a long list of measurands that need harmonisation. ICHCLR has also some money that we can use to facilitate this. Ian Young and Sverre Sandberg have been talking to the Scientific Division in IFCC represented by Philippe Gillery and Christa Cobbaert in order to develop a collaborative relationship. We would like to advertise and fund applications to establish Working Groups which will carry out harmonization of key measurands. Please see the amended application form in Appendix which describes this project and the application process.

2. Application from Christa Cobbaert for PT/INR standardization
The application has been evaluated by Sverre Sandberg, Ian Young as well as the HOG group. The recommendation was to support the development of a LC-MRM-MS PT - proteoform test – with 11 000 euros

Harmonization Oversight Group (HOG) update:

The HOG is responsible for managing the harmonization activities of the ICHCLR. HOG members are appointed by the Council and represent expertise in a broad range of existing and emerging technologies and disciplines in laboratory medicine as practiced in different areas of the world. The HOG cooperates with other international organizations to promote harmonization activities and maintains the web site to coordinate information about global harmonization activities.

The HOG leadership is:

Ian S.Young MD (Chair)
Professor of Medicine
Queen's University Belfast
UK and Consultant Chemical Pathologist
Belfast Health and Social Care Trust
Belfast, UK

Eun-Hee Lee, MD, PhD (Vice-Chair)
Green Cross Laboratories
Yongin-si, Gyunggi-do
South Korea,

Members:
Members are listed at https://www.harmonization.net/oversight/harmonization-oversight-group/

Stakeholder Members:

Stakeholder Members (e.g. clinical laboratory and medical organizations, IVD manufacturers, metrology institutes, standard-setting organizations, public health organizations, regulatory agencies, and individuals) are committed to supporting harmonization of clinical laboratory results. Stakeholders support the ICHCLR by submitting measurands in need of harmonization, provide feedback on direction and activities of the ICHCLR, and receive all updates and reports on efforts by the ICHCLR to promote harmonization activities internationally.

Members:

Members are listed at https://www.harmonization.net/oversight/stakeholder-members/

In 2021 Chemclin Diagnostics Co., Ltd. Beijing, China joined ICHCLR as a Stakeholder

Joint Committee for Traceability in Laboratory Medicine (JCTLM) membership:

The ICHCLR joined the JCTLM as a Stakeholder member in 2018. This membership enables the ICHCLR to better collaborate with JCTLM on topics of mutual interest to advance harmonization of results on a global basis.

Funding for Start-up Harmonization Projects:

The Council approved using a portion of the ICHCLR fund balance to support start-up costs for new projects to standardize/harmonize results for high priority measurands conducted by other organizations.

As mentioned above, the ICHCLR will now establish WGs to carry out practical harmonization projects (see appendix and www.harmonization.net)

Application for funds will be reviewed by the HOG and approved by the Council.

In 2021 two applications were received:

1. An application from Christa Cobbaert for PT/INR standardization

The application has been evaluated by Ian Young and the HOG grpup. The recommendation was to support the development of a LC-MRM-MS PT - proteoform test - 11 000 euros.

The application is approved by the council.

2. An application from Gary Myers concerning supporting a database development for JCTLM

The JCTLM is launching a project to update the software and functionality of the database in 2021/2022, to ensure its continued availability for the next 10 years, as well as modernizing its operation including the development of a web-based nomination and review process expected to substantially reduce the time for listing resources. In addition, an application programming interface will allow integration of the information in the database directly into user applications.

The JCTLM has secured funding for the first stage of the database update permitting to transfer the database onto a modern software system. Additional funds are required to implement a functionality improvement to permit web-based nomination and review of reference materials, methods and services. The overall requirement for remaining funds is EUR 65.000.

The applicant proposes that ICHCLR contributes $10,000 USD to support the JCTLM database upgrade.

The application is under evaluation by the HOG and the Council

Harmonization.net website:

The HOG maintains the website www.harmonization.net as a global portal for information on harmonization activities.

Measurand Evaluation:

At this time, 142 of the most frequently ordered measurands have been evaluated and recommendations for harmonization have been posted to the “Measurand” section of the web site. Information on harmonization status and priority for harmonization of a measurand is available by clicking on the measurand name. Links to organizations and resources for harmonization of measurands that are actively in progress or in a continuing status are being added to the Measurand table. Information when JCTLM resources are available is also provided. The website functionality was enhanced to allow sorting of the Measurand table and printing the table with any sort applied.

Council/HOG Joint calls:

During this period five Council/HOG joint zoom conference calls were held focused primarily on new measurand prioritization. Due to COVID-19 no HOG/Council face to face meeting was held. The minutes of all calls are available in the Resources section of the web site.

HOG - IFCC Scientific Division cooperative activities:

The HOG has established a close working relationship with the Scientific Division (SD) of IFCC as a result of the secretariat transition to the IFCC. The HOG chair, Ian Young, has participated in two virtual IFCC SD meetings in 2021 and Professor Philippe Gillery SD Chair serves as a member of the HOG. The measurand prioritization work of the ICHCLR continues to support the IFCC SD regarding standardization/harmonization activities to be developed. As mentioned above ICHCLR and IFCC SD have the intention to start a collaboration on practical harmonization work by establishing and funding WGs within the ICHCLR.

ICHCLR/IFCC/JCTLM Workshop 2021: Overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations

The Workshop was held virtually 6-7, December. The workshop will result in the development and publication of recommendations proposing how the laboratory medicine community can address challenges related to reference materials and regulations to more effectively achieve standardized results on a global basis.

ICHCLR/IFCC/JCTLM Workshop 2023: EQA schemes supporting metrological traceability in Laboratory medicine

A Workshop is planned for 2023 and several meetings in the planning group have been held. The workshop is chaired by Tony Badrick (AU)

ICHCLR project to aggregate External Quality Assurance (EQA) data from commutable samples from global EQA providers:

The HOG initiated a pilot project to explore the feasibility of aggregating EQA, or PT, data from commutable samples to provide feedback to in-vitro diagnostics (IVD) manufacturers and the clinical laboratory community regarding the status of harmonization of results for various measurands. Results of the pilot study have been published: Hagen EAE van der, Weykamp C, Sandberg S, Stavelin AV, MacKenzie F, Miller WG. Feasibility for aggregation of commutable external quality assessment results to evaluate metrological traceability and agreement among results. Clin Chem Lab Med. 2021;59(1):117–25.

The ICHCLR and EQALM signed a Memorandum of Understanding in March 2021 to establish a joint taskforce to monitor harmonization of measurands in laboratory medicine through data aggregation (from EQA/PT schemes) (HALMA). The Task Force consist of a steering group, three from EQALM: Gitte Henriksen (chair), Piet Meijer and Wim Couche and three from ICHCLR, Greg Miller, Gary Meyer and Sverre Sandberg. The group had several meetings during the year and established three WGs: WG-commutability, WG for “Description of measurement procedures” and WG for “Specific measurands”.

For more information – see http://www.eqalm.org/site/halma/halma.php

Specific activities planned for 2021

The HOG will continue to identify and prioritize measurands in need of harmonization based on medical importance

Collaborate to produce outputs of joint 2021 workshop with JCTLM - IFCC

HOG chair to attend two IFCC Scientific Division meetings (either virtual or in-person) to coordinate the work of the two organizations.

Continue to work with an international workshop 2023 in conjunction with IFCC Scientific Division and the JCTLM (see above)

Continue the work and collaboration with EQALM in the HALMA Task Force to expand aggregation of EQA data from commutable samples from global EQA providers.

Establish and fund WGs within the ICHCLR in collaboration IFCC SD to do practical harmonization work.

Continue the marketing effort to invite other clinical laboratory professional organizations, clinical practice professional organizations, IVD manufacturers and metrology organizations to join the ICHCLR as Council or Stakeholder members.

Evaluate the organizational structure of ICHCLR and establish additional WGs to accelerate and extent classification of measurands and extend beyond clinical chemistry

Appendix

INTERNATIONAL CONSORTIUM FOR HARMONIZATION OF CLINICAL LABORATORY RESULTS (ICHCLR) PROJECT GRANT APPLICATION FORM

Revised: November 2021

These guidelines for our project grant programme describe our current grant making policy and explain how to apply to us. We have recently established a cooperation with the Scientific Division of the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) and will establish WGs to address the harmonisation of different measurands. Priorities will be given to applications from such WGs. If you need clarification on whether your project fits within our policy, please email the current Harmonization Oversight Group Chair at I.Young@qub.ac.uk.

You can read more about ICHCLR and how it was established on:

https://www.harmonization.net/about/

GENERAL GUIDELINES

Geographical area:
We will consider applications from any region of the world, providing they meet the criteria described below.

Who can apply?
We will consider applications from any individual or group wishing to carry out a project which meets the criteria described below.

Funding limits:
In general, awards will be limited to 30 000 euros per project. At the discretion of the funder, larger grants may be awarded in exceptional circumstances.

The award is intended to cover the costs of essential travel, including laboratory visits, and may include a contribution towards consumables. Salary and equipment costs are generally not eligible and will be considered only in exceptional circumstances.

Expenses will be reimbursed on the submission of appropriate receipts.

Our funding priorities:
The following key priorities should be considered when making an application for funding:

1) Preference will be given to applications which seek to achieve comparability of patient results for measurands where the medical impact of harmonization is high and harmonization

is needed (see table at https://www.harmonization.net/measurands/).

Where an application is being considered for a measurand not listed by ICHCLR, preliminary approval should be sought before making an application. Applications will not be considered in relation to measurands where there is ongoing work being led by another organization.

2) Applicants should aim to establish an ICHCLR Working Group for a specific measurand and complete a programme of work within a maximum of three years. The applicant should propose members of the WG who will be formally appointed by the ICHCLR Harmonization Oversight Group.

3) Applications should specify criteria by which success can be judged, and a mechanism for maintaining comparability of results in practice once achieved.

Successful applicants will be expected to provide regular reports (6 monthly) on progress with their project.

When to apply:
Our project grant programme is a rolling grant programme and applications are considered every two to three months.

How to apply:
Please complete the project grant application form, which can be found at the end of these guidelines, and email the completed application to I.Young@qub.ac.uk

By sending a grant application to us you consent to being contacted in relation to the application and any grant awarded. Please make sure that you have consent from your organisation to pass on its details.

APPLICATION FORM FOR ICHCLR PROJECT GRANT

Please first read our General Guidelines and key priorities outlined above.

Applications should be completed in full. Once completed please ensure that you keep a copy for your own records and send your completed form to I.Young@qub.ac.uk

1.	Lead applicant name:	
	Address:	
	Title and employer details	
	Telephone number:	
	Email address:	
2.	Names and affiliations of proposed individuals who can be part of the working group for the project.	

3.	i) Measurand(s)
	ii) Current ICHCLR classification (https://www.harmonization.net/measurands/)

iii) Please provide us with a description of the project you are requesting funding for, and ensure that your answer includes the following:

- What need your work is addressing and how you know that there is a need for this work
- Details on the project delivery (including any partnership work) and confirmation that is can be realistically achieved in a maximum of three years
- How the outcomes of the project will be implemented in clinical practice to improve comparability of patient results
- How successful implementation will be maintained in the long term

Please include a summary of the clinical use of test results and why standardization/harmonization is needed, along with a summary of the approach to achieve standardization/harmonization. You should, if possible, address coordination with IVD manufacturers and regulatory agencies where relevant.

4.	Project Costs	£
	What is the full cost of the project?	
	What amount are you requesting from ICHCLR?	
	If you are not applying to ICHCLR for the full project costs, how will other costs be met?	

5. Please provide a detailed and accurate full project budget below:		Amount	
Budget Headings	Year 1	Year 2	Year 3
Total:			

6. Project Timetable:	
Start date:	
End date:	

DECLARATION

To the best of my knowledge all the information I have provided in this application form is correct. ICHCLR may request further information as required

Signature:
_____Date:_____

Print Name: _____Job Title:_____

Please send your application by email to:

Prof Ian Young
Chair, Harmonization Oversight Group, ICHCLR

I.Young@qub.ac.uk

APPLICATION PROCESS – WHAT HAPPENS NOW?

All applications received will be acknowledged and we aim to give a decision on your application within 2-3 months.