ICHCLR Council/Harmonization Oversight Group (HOG) Meeting

DATE: February 10 and 11, 2014 **LOCATION:** AACC, Washington, DC

HOG Members:
Dr. Greg Miller (Chair)
Dr. Eun-Hee Lee
Dr. Stephen Master
Mr. Joseph Passarelli, MS
Dr. William Rosner
Dr. Thomas Scholl
Dr. Ian Young
Dr. Linda Thienpont
Dr. Katleen Van Eytfanghe (Guest)

ICHCLR Council
Dr. Gary Myers (Chair)
Dr. Anthony Killeen
Dr. Gye-Cheol Kwon
Dr. Wenxiang Chen
Dr. Naotaka Hamasaki

AACC Staff:
Ms. Janet Kriezman (CEO, AACC)
Dr. Cheryl Kassed (Director, Science and Research)
Ms. Ashlie Doran (Scientific and Practice Affairs Coordinator)

Minutes:

I. Welcome and Introductions

Dr. Myers welcomed everyone to AACC's office. Each participant introduced themselves.

II. Historical review and development of ICHCLR (see Roadmap paper @ www.harmonization.net under Resources)

Dr. Myers provided a brief overview of the history and development of the ICHCLR. AACC was very involved in standards development and standardization in the 1970s through the early 1990s. AACC terminated its active involvement in standards development in the 90s and closed the AACC Standards Committee. In 2008, Dr. Steve Gutman of the FDA attended an AACC Board Meeting and suggested that AACC get more involved in harmonization to stimulate progress in this area that was needed for patient safety and effective medicine. The Board recognized that it would not be productive to duplicate the efforts of other organizations and decided to organize a conference of stakeholders in standardization and harmonization to critically assess the current state of the art and to recommend a course of action to address the unmet needs for harmonization in laboratory medicine.

In October 2010, AACC convened an international leadership forum to facilitate discussion on harmonization. There were 94 participants representing 62 organizations with 12 different countries represented. The conference recommendations were published in Clinical Chemistry as the "Roadmap for harmonization of clinical laboratory measurement procedures" which led to a new organization

that has now been launched as the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR).

Following the conference, a steering committee was formed to implement the recommendations with Dr. Miller and Dr. Myers serving as the chairs. Three task forces were developed. One task force worked on the infrastructure for the ICHCLR. Another worked on checklists for submitting and evaluating measurands. A third worked on a tool box of technical approaches as a starting place for harmonization activities. In 2012, AACC brought the task forces and the steering committee together for a status update in Washington, DC. At the conclusion, the decision to form the ICHCLR was made. A charter was developed and AACC agreed to serve as the secretariat. Several organizations, including AACC, the College of American Pathologists, the Chinese Association for Clinical Laboratory Management, the Korean Society of Clinical Chemistry, and the Japanese Committee for Clinical Laboratory Standards joined the Council to provide governance oversight and support administrative costs of the ICHCLR by contributing $50,000 in annual dues. Next, the Harmonization Oversight Group (HOG) and the Strategic Partners Group were formed. The infrastructure for the ICHCLR is now in place.

The goals for this first joint meeting of the Council and HOG are to review and finalize the operating procedures for the ICHCLR and plan how to facilitate the work of the Consortium, in particular to develop a list of high value measurands for which harmonization is needed. Later, Special Working Groups (SWGs), then Harmonization Implementation Groups (HIGs) will be developed to address specific measurands. Dr. Myers concluded that AACC is committed to supporting this initiative and is very happy that several other organizations have joined the Council to make the ICHCLR possible. The program has received great interest from other organizations and from the IVD industry.

III. Review of key activities to date

1. Lectures presented (Attachment 3.1)

Drs. Miller and Myers shared a list of presentations they have made in the past year to promote the ICHCLR and harmonization topics. The group agreed that key presentations by other Council or HOG members to promote the program should be captured. Dr. Miller requested the group share any resources they think might be appropriate to be posted to the web site in addition to what is currently posted. Drs. Miller and Myers will prepare an updated presentation to replace the lecture on the web site from the 2012 AACC annual meeting titled, "Tackling the Problem: The Global Harmonization Initiative." The slides would be available to anyone who wanted to present material on the ICHCLR.

2. FDA-IVD meeting (Attachment 3.2)

In June 2013, the FDA and IVD industry members, including AdvaMedDx, convened to discuss regulatory considerations when recalibration was needed to conform to harmonization recommendations. The FDA was open to working with AACC and IVD companies and would like

to be informed as early as possible when harmonization efforts for a particular measurand are started. One recommendation was for IVD companies to meet as a group to develop data submission requirements for a particular measurand harmonization activity. Dr. Thienpont said she has a pre-submission meeting scheduled with the FDA and several IVD companies regarding TSH harmonization on March 6.

Mr. Passarelli suggested that it would be helpful if there were a contact person or a consistent group at the FDA that IVD companies associated with ICHCLR could work with throughout the harmonization process. Dr. Myers indicted that he would discuss this suggestion with the FDA and request a contact person or group be assigned to work with the ICHCLR on Harmonization.

Dr. Miller acknowledged that the meeting with FDA was US-centric. Dr. Myers suggested that perhaps if they find appropriate contacts at international FDAs, they could be informed of harmonization activities. Mr. Passarelli stated that the details of country requirements are updated frequently. It would be desirable to have such information available on the web site resources tab.

3. **ISO revision of 17511**

   Dr. Miller informed the group of ongoing revision of 17511. Key points agreed to for the revision include: traceability is to be established from the patient results; commutability requirements for calibrators will be clarified; and processes for harmonization when there are no reference materials will be addressed.

4. **ISO preliminary work item (Attachment 3.4)**

   The HOG, through the USA ISO representative ANSI, proposed a preliminary work item that was approved by TC212 at its November 2013 meeting. The proposed title is "Requirements for traceability of measurand values using harmonization measurement procedures not supported by SI-traceable references." JCTLM requires that harmonization components conform to ISO standards. Consequently, this new standard will be important to enable JCTLM to list harmonization processes.

5. **JCTLM members and stakeholders meeting (Attachment 3.5)**

   The meeting took place in December 2013. Dr. Thienpont stated that the JCTLM Quality Manual now requires commutability information for reference materials. She said this was a big step forward. Dr. Miller stated that one session addressed commutability challenges and that an IFCC Working Group was formed in 2013 to advance the science related to commutability, understanding its importance, and informing reference material providers and measurement procedure manufacturers of implementation options.

6. **WHO Commutability Consultation (Attachment 3.6)**

Meetings at WHO were held in April and October 2013. The April meeting was organized by the WHO Blood Safety/Infectious Disease Group. The October meeting was the Expert Committee on Biological Standardization at which the report from the April meeting was presented, although the report is not yet available publicly. WHO embraces the value and importance of commutability and recognizes that it is challenging to do the validation. Progress is limited by the technical difficulty to produce RMs for complex bio measurands and the resources required to validate commutability. WHO's commitment to the importance of commutability is an important advance in laboratory medicine. Unfortunately, WHO is not able to join the consortium but would like to be informed of its work. IFCC does have a formal liaison relationship with WHO.

7. **IFCC Working Group on Commutability**

   The WG is large – about 25 people reflecting the interest in this area. Dr. Miller chairs the WG and reported that initial work is focusing on formal procedures for assessment of commutability that address the influence of non-specificity and imprecision on acceptance criteria. Four task forces are working on these challenges: TF for statistical approaches to evaluate commutability, TF for acceptance criteria, TF for types of patient samples to include; TF for qualification of measurement procedures to include.

8. **AACC position statement on harmonization (www.harmonization.net under Resources)**

   As part of its strategic plan, AACC is working to increase its visibility as a leader in laboratory medicine through increasing its advocacy efforts. Dr. Myers indicted a desire on the part of the AACC Board to develop position statements on key topics that would be of interest to the laboratory community. The first position statement was on harmonization. It can be viewed on the Harmonization.net website,

   A press release was prepared and the position statement released to the media. The Journal of Comparative Effectiveness Research requested an editorial from AACC on why harmonization is important. Dr. Christenson and Dr. Kassed drafted the editorial that will be published in the May issue of the journal. Dr. Kassed said that the editorial elaborates on the abbreviated press release and includes real world examples as the audience is not limited to lab professionals.

   Dr. Rosner suggested that perhaps AACC should get the message into other journals, even outside clinical chemistry. He suggested JAMA, for example. Dr. Young agreed.

   Dr. Miller added that it is important to share the message internationally. Dr. Kassed stated that the Harmonization editorial would be published in a UK-based journal. Dr. Miller welcomed input from the group on how to achieve spreading the message about the need for harmonization internationally.

9. **Clinical Chemistry Q&A on Harmonization (Attachment 3.8)**

Dr. Rosner, Dr. Young, Mr. Passarelli and Dr. Eckfeldt contributed expert opinions on the topic in Clinical Chemistry's Q&A on Harmonization. It is now published online at: http://www.clinchem.org/content/early/2013/10/07/clinchem.2012.201186.full.pdf+html

IV. Reports from Council and HOG members (harmonization activities from around the world)

Each Council and HOG member updated the group on harmonization activities they are involved in or are aware of.

Dr. Rosner highlighted a paper that was published in March on the importance of estrogen standardization. He said he'd send it to the group. He noted that the Endocrine Society was sponsoring the PATH program (Partnership for the Accurate Testing of Hormones) with active projects for testosterone and estradiol standardization.

Dr. Killeen stated a number of accuracy based PT/EQA surveys that use commutable materials have/will be done by CAP to assess harmonization for a number of tests. Dr. Myers asked if the CAP website lists the reference measurement procedure used for traceability in the various accuracy based PT surveys CAP offers. . Dr. Killeen responded that it didn't, but he could gather the information. Dr. Rosner asked if the CAP surveys were peer-based review or accuracy based. Dr. Killeen stated that they still offer both, but high quality labs tend to choose accuracy based surveys.

Mr. Passarelli stated that Roche is involved in harmonization/standardization activities. He said that harmonization activities are generally market and regulatory driven. He mentioned several tests Roche is working/has worked on, including: Vitamin D; bone markers; pregnancy tests; troponin; HbA1c.

Dr. Master mentioned the successful harmonization of Cystatin C. Longitudinal studies show the harmonized measurement procedures perform very well.

Dr. Thienpont said she was involved in many harmonization programs. She particularly mentioned a study on thyroid function tests. She said she uses a panel of individual human samples for a statistical approach based on an all procedures trimmed mean as a value assignment process which has been recently published in CCLM.

Dr. Hamasaki said that the Japanese society started harmonization activities in 1989. In 2000, they tried to make a conventional reference material. Dr. Myers asked if harmonization of measurement procedures was performed by individual laboratories or by the IVD industry. He replied that the laboratories did the recalibrations and they discussed their findings with IVD manufacturers. He indicated that standardization of laboratory measurements for 30 analytes had been accomplished for primary care diagnosis throughout Japan.

Dr. Young said the IFCC activity has been substantial and sustained over many years. As many IFCC activities had been previously discussed, he did not repeat them. He commented on a meeting on

harmonization to be held the following day in the UK. He said that there is integrated health care in the UK. All labs are accredited/inspected by a central body. There is a movement for all labs to share one electronic medical record system. However, there is variation in reference intervals among labs. This creates the possibility for confusion when combined in the patient's record. Dr. Young commented there was strong government momentum behind the EMR project. Dr. Graham Beastall, IFCC President, was attending the harmonization meeting in the UK and was given ten minutes within a full day program to inform the group on harmonization considerations.

Dr. Kwon stated that the Korea Research Institute of Standards and Science (KRISS) National Reference Laboratory Standard is the equivalent to USA's CDC. He mentioned the standardization of cholesterol, for example, in all labs. Dr. Myers asked if there was an advocacy group for the IVD industry in Korea similar to AdvaMedDx in the US and EDMA in Europe. Dr. Kwon replied that there was and that it was included in the society for laboratory medicine.

Dr. Chen said that in China they have a special network within the Centers for Clinical Lab Medicine that started working on harmonization in the 1980s. He said it is affiliated with the government as well as some private organizations. Dr. Chen indicated 8-10 common measurands had been standardized. Dr. Myers asked if the focus was on the individual laboratories or on the IVD companies. Dr. Chen indicated that China was following the international concept of harmonization and were checking commutability or reference materials in the programs.

V. Status of Strategic Partners Group (Attachment 5.0)

Dr. Myers reviewed the status of the ICHCLR Strategic Partners Group. The Strategic Partners Group permits companies, organizations and societies interested in harmonization to become more involved in harmonization activities of the ICHCLR. By joining the Strategic Partners Group, members can nominate individuals for consideration to the membership on the Harmonization Oversight Group, recommend measurands, and review and comment on work activity completed. Efforts to solicit members to the Strategic Partners Group began in October 2013. The current list of members to the Strategic Partners Group was provided as an attachment to the meeting agenda. Dr. Myers indicated AACC staff will begin another call for groups to join the Strategic Partners Group. Companies and organizations can join the Strategic Partners Group through the harmonization website.

Mr. Passarelli and Dr. Scholl as the industry representatives to the HOG expressed concern with the word "Partner " in Strategic Partners Group. The term "Partner" may be a barrier to IVD companies and government groups joining the Strategic Partners Group because the term may create a perceived relationship that is problematic for these type of groups. There was discussion among the members and several suggestions were offered to change the name, but none of the suggested changes were considered more appropriate than "Partner".

Dr. Myers suggested that he would see what the AACC attorney suggests about the Strategic Partners Group name.

VI. Governance and administrative procedures

1. Council

Dr. Myers reviewed the primary responsibility of the ICHCLR Council. He indicated the Council is responsible to set the tone and policies needed to operate the Consortium. The Council provides the administration and governance oversight for the Consortium. When harmonization projects are begun under HOG management, the HOG will update the Council on progress of approved projects. Concerns and issues brought up by members of the Strategic Partners Group would be reviewed by the Council and remedial action recommended, if necessary.

While the budget reflects two in-person meetings of the Council, Dr. Myers recommended that until a number of harmonization projects are underway the business of the Council could be conducted via e-mail and conference calls.

2. Financial report

Dr. Myers reviewed the current financial report for the Consortium. His report was presented in two parts. He first presented a historical review of the financial resources expended by AACC during the development phase of the harmonization initiative starting with the International Leadership Forum in 2010. The second part of his financial report covered the revenue and expenses since the formation of the ICHCLR in 2013.

Dr. Miller noted that invoices for Council dues will be sent at the end of 2014 for membership renewal for 2015. He said there was a conscious decision to stagger the invoices to ensure the funds were put towards the appropriate year.

There was further discussion around the expected cost for a harmonization project and how projects would be funded. Dr. Myers indicated that funds would need to be raised for each approved harmonization project. Several members that have been involved in previous harmonization projects indicated a single project could cost several hundred thousand dollars.

On review of the ICHCLR Financial Report, it was asked if the surplus from FY2013 carries forward into FY2014. Dr. Myers said he would follow up on this question. Subsequent to the meeting, it was confirmed that unspent money would carry forward to the next year.

Dr. Thienpont noted that a particularly expensive aspect of harmonization is the cost of obtaining appropriate clinical samples. Dr. Young suggested that a core infrastructure could be established designed to provide samples for all harmonization groups. Dr. Miller acknowledged that sample acquisition was a very serious challenge that would benefit form a central resource.

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Dr. Miller stated that this program brings prioritization to harmonization based on clinical need, global agreement, and direct benefit to patient care. Dr. Thienpont added that the advantage in this project is that manufacturers can share the cost which is a considerable advantage. Dr. Scholl said it would be harder to work as an outside IVD group. Harmonization is expensive, but it is less expensive to participate in an organized process.

3. Harmonization management procedures for HOG

Dr. Miller said that it was envisioned that measurands would be submitted by the Strategic Partners Group and other stakeholders. Once submitted, a SWG would be formed to advise on prioritization and technical feasibility for harmonization. The SWG would complete the Harmonization Checklist to make its recommendation to the HOG using a structured format that would become the documentation for the process. The HOG would establish a measurand's priority considering the SWG recommendation. For a high priority measurand, the HOG would coordinate with any external organizations that would be interested to take the lead for harmonization or standardization when possible. For harmonization projects to be organized by the Consortium, a HIG would then create an initial work plan to be used to secure funding. Once funding was committed, the HIG would be responsible to conduct the harmonization work.

One of the main limitations in current activities by various groups is the lack of prioritization and lack of coordination of work among different groups. These limitations are what prompted formation of the Consortium. The main challenge facing the HOG at this time is developing an initial list of high priority measurands for which harmonization can be pursued.

Dr. Lee was nominated and unanimously approved by the Council members as the Vice-Chair of the HOG.

4. Process to form SWG or HIG

Mr. Passarelli stated that there are a limited number of individuals involved in harmonization, who could be a part of a SWG or HIG. Dr. Killeen suggested that it always comes down to funding. Dr. Young suggested that there may be a limit to the amount of time that people working in harmonization have to focus on any additional projects. He suggested that perhaps younger professionals be involved. Dr. Miller agreed and suggested a mentorship arm to the Consortium. Dr. Young suggested that when a HIG is developed that there deliberately be one to two younger, and probably less experienced, professionals included to make the process sustainable. Dr. Myers also suggested an educational aspect to teach younger professionals about harmonization and its importance.

Mr. Passarelli asked where individuals for the HIG would come from. Dr. Miller stated that the same pool of experts for the SWG could be used for a HIG. A SWG would only exist for about three

months and it was likely some of the same experts would become part of a HIG for a given measurand.

Mr. Passarelli suggested maybe four to five projects could be handled simultaneously with suitable champions identified. Dr. Young agreed indicating that for IFCC the working group needs to raise their own funding per project. He indicated that frequently there is more of a time issue than a money issue. Dr. Killeen suggested that money, time and changing biomarkers are all issues. Dr. Myers said that we need to address barriers, to identify ways to handle these limitations, and make harmonization more appealing to a new group of experts. If a lot of up front work is done, perhaps that will help. Dr. Young suggested that working on funding and obtaining the needed patient samples will remove two substantial barriers.

5. Approval of ICHCLR operating procedures (www.harmonization.net under Resources)

The draft ICHCLR operating procedures were reviewed and updated. Dr. Killeen moved to accept the updated ICHCLR operating procedures. Dr. Chen seconded the motion. All council members approved the motion. The updated operating procedures will be placed on the website.

The charter of the International Consortium for Harmonization of Clinical Laboratory Results was reviewed by all attendees. Dr. Myers recommended the document be changed to revise Strategic Partners responsibilities to be review and comment on harmonization activities of HIGs. Dr. Killeen made a motion to accept the revision of the charter. Dr. Kwon seconded. All council members agreed to the change

VII. Advancing the Consortium's role in harmonization

1. Nominate measurands for prioritization

At this point, the ICHCLR has the infrastructure to succeed. The program has received no nominations of measurands, in spite of several rounds of emails to stakeholders. The HOG and Council members broke out into three small groups and brainstormed to develop an initial list of candidate measurands for consideration shown in the attached Addendum I – Brainstormed Measurands. Measurands known to have active standardization or harmonization activity were identified with strikethrough text.

Dr. Young stated in regards to PSA that there is a WHO reference material that is held by NIBSC. NIBSC approached IFCC because they are running out of material. He said there is a working group established and a chair to determine a new reference material. He also said viral load markers were being worked on in the EU. Dr. Young also said that ionized calcium was worked on by the IFCC in the 1980s and the work was published. He said two years ago that IFCC was approached by Swiss investigators regarding a reference measurement procedure for ionized calcium, but the initiative was declined.

Dr. Miller suggested that it might be beneficial to contact EQA providers that are using commutable materials to learn which measurands are of interest and may need harmonization.

Dr. Myers asked if IFCC has any historical record of measurands that have been worked on previously. Dr. Young replied that the IFCC does have a record of all measurands considered for harmonization. He said he would attempt to obtain that information from the IFCC office. He also mentioned that not all work that was initiated led to a completed project with a harmonized measurand.

Next steps. Dr. Miller suggested that the list of measurands be divided up amongst the group and a preliminary literature search be completed as well as gathering any current activity information on each measurand. This information can be shared electronically and discussed over a series of conference calls. On the conference calls, the HOG can categorize and prioritize the measurands. Then, they can determine which measurands need to be sent to a special working group.

Dr. Hamasaki asked about the strategy and goal. Dr. Miller replied that the goal is to create a prioritized list of measurands in need of harmonization. This list can then be put on the www.harmonization.net website. The next step then would include looking for champions to take on the work. He continued that the HOG can appoint a HIG to determine the best approach for successful harmonization, and funding solicited to support the work.

Dr. Kassed asked if the harmonization process included the IVD industry implementing harmonization. Dr. Miller used Cystatin C as an example. IFCC worked to create a reference material for this measurand which was shown to be commutable for a number of routine measurement procedures. Manufacturers then needed to recalibrate to be traceable to the new reference material. However, manufacturers are reluctant to do the recalibration until a new reference material is listed by JCTLM which ensures its acceptance as an international higher order reference material. Dr. Thienpont stated that JCTLM listing is very important for implementation. In addition, there are regulatory requirements in various countries that need to be complied with to recalibrate. Consequently, the process takes a number of years. Dr. Myers added that it was important to communicate that the harmonization process is ready to implement. Mr. Passarelli added that harmonization should be implemented if it improves patient care.

2. Review of harmonization website (www.harmonization.net)

Dr. Myers led a review of the harmonization.net website. He pointed out each of the various sections on the website and the intended information that would be available on the Consortium. The revised operating procedures would be added. Dr. Myers stated that the intent was to create an area on the website where documents could be shared among a HIG and the HOG. This feature is under-development by AACC's IT department. He indicated that people will be able to sign up to receive updates on harmonization. Updates and progress reports will be able to be distributed in the near future. He reviewed the Resources section and suggested that members of the HOG and

Council could recommend relevant documents for inclusion in this section. Dr. Miller suggested that his piece titled, "Tackling the Problem: The Global Harmonization Initiative," could be removed because it is no longer timely. The soon-to-be published harmonization Q&A will be included on the Resource page. Dr. Myers stated that copyright and citation as well as permission would be obtained for all pieces on the Resources page. It was suggested that all links be checked. The Council page will be updated with the inclusion of the Japanese Committee for Clinical Laboratory Standards. The process to nominate a measurand via the website was reviewed. To access the submission process, individuals are asked to register with AACC but are not required to be a member to complete the measurand submission process.

3. How to advance the measurand table; what to include; how to obtain information

There was considerable discussion about the measurand table. The purpose of the table is to catalogue activity by organizations around the world that are working on measurand harmonization. Dr. Myers requested the members of the Council and HOG provide the names of organizations with contacts that are known to be working to develop reference measurement procedures and reference materials. AACC staff will then contact each organization to gather appropriate information to populate the table. It is important to get the table up-to-date and keep it up-to-date. There was discussion on the table headers and content structure.

The suggested title of the table is, "Summary of Active Measurand Processes." The status column should indicate "active" or "available." It was suggested that there be a column for clinical importance with a link to the SWG full report and the column titled technical feasibility be deleted. The table will include a link to the JCTLM website listings so this information would not need to be duplicated in this table .The priority column would remain, be renamed "medical importance", and a link to a statement describing criteria for the classification would be added. Harmonization work listed from groups outside the Consortium would be identified with the following disclaimer: "Priority established by the sponsoring organization." There will be a link to respective references. Dr. Kassed suggested that there be pop-up boxes with definitions.

Dr. Myers will convey the group's suggestions to AACC's IT staff for implementation. The website will evolve as needed.

4. Checklists review – development needed? (see Attachment 7.4)

The checklist developed by one of the initial AACC Harmonization task forces for the report from a SWG to the HOG was reviewed and edits suggested. Dr. Miller will integrate all suggested changes and circulate the updated checklist for further review and approval via email.

VIII. ICHCLR promotion/marketing plans

Dr. Myers gave a brief overview of some plans for promoting the ICHCLR. The website, position statements, press releases, annual reports, and an information flyer will all be used to promote and market the ICHCLR.

Dr. Myers also suggested that AACC could provide appropriate materials and information to Council and HOG members to assist with their respective outreach to other organizations and other IVD companies. He mentioned that AACC has communicated with AdvaMedDx concerning the plans for the harmonization initiative and AACC would be scheduling another staff-to-staff meeting with AdvaMedDX to further promote this activity. Dr. Miller and Dr. Myers will continue to give presentations on harmonization whenever possible. Dr. Myers said he plans to work with AACC's marketing department to further promote the ICHCLR. Once materials are developed, each ICHCLR member could help spread the word. He said AACC would also be promoting advocacy efforts on harmonization to members of Congress with the intent to get language in the appropriation bills on the importance of harmonization and the need for government support.

Dr. Myers said that he was open to ideas on materials to help them share their involvement and purpose in ICHCLR. It was suggested that each participating organization in ICHCLR could add a link on their website to www.harmonization.net. Dr. Rosner suggested a medical writer be enlisted. He also suggested gathering suggestions/requests from clinicians. In addition, he suggested the use of multiple languages on promotional materials.

Dr. Scholl suggested that harmonization project sponsors be targeted now. Dr. Myers stated that the current effort has been put towards identifying and reaching out to potential organizations as Council and Strategic Partners Group members. With the submission of measurands to be harmonized, the next need will be to identify supporters of Harmonization Implementation Groups. Additional IVD companies' involvement is also a future need. Mr. Passarelli stated that requests for funding from IVD companies need to be made 12 to 18 months in advance in order to get into their budget cycle. Dr. Scholl agreed. He added that it was harder to accept a request at the end of the year. Dr. Miller suggested that perhaps they could market within their own companies and suggested they include information about harmonization in their internal newletters. Dr. Myers added that AACC has hired a new staff person to head AACC's corporate outreach activities.

IX. Additional Business

Dr. Hamasaki presented a summary of a program developed by the Japanese Committee for Clinical Laboratory Standards (JCCLS) titled, "Multianalyte Conventional Reference Material: A Useful Tool for Nationwide Standardization of Laboratory Measurements for Primary Care Diagnosis (A Model Study in Japan)." He said the investigators planned to submit the work to *Clinical Chemistry*. He said the data indicated that consistent results could be achieved between manufacturers using the reference material. He indicated that the group would pursue JCTLM listing for the candidate reference material.

X. Communication Schedule (conference calls and meetings)

Conference calls were agreed to be approximately monthly at 7 a.m. eastern time USA. Dates of each conference call would be determined via Doodle poll. The next conference call will be April 1. A meeting of the HOG and Council members will be scheduled at the 2014 AACC Annual Meeting in

Chicago for those members that plan to attend the AACC meeting. More details of the meeting will follow.

XI. **End of Meeting**

Dr. Myers thanked everyone for their time, for volunteering, and for traveling to be a part of the ICHCLR. From an AACC perspective, this is an outstanding group of experts. He looks forward to what their work will mean to laboratory medicine. On behalf of the AACC staff and Board, he thanked all participants for their important contributions.

Addendum I

AFP
α2-micro globulin
ALP (implementation phase)
Anti-streptolysin O antibody (ASO)
APO(b)
Autoimmune markers
Bilirubin
BNP and pro-BNP
β2-micro globulin
CA125
CAlD
Cardioplasmin
CEA
Coagulation markers
CRP
Cystatin C (implementation phase)
Cytokines
Estrogen R alpha
FGF 23
Free light chains (low priority)
Fructosamine
FSH
Growth Hormone (high priority)
Herceptin
Homocysteine
Immunosuppressant drugs (Tacrolimus, Sirolimus, Cyclosporine)
Immunoglobulin E (IgE)
Ionized Calcium
KIM-1
LDL particles
LH
MDx analytes
Neurological markers
NGAL
Placental growth factor
Preeclampsia Markers
Prolactin
PSA (NIBSC renewing WHO)
PTH (IFCC WG)

Rheumatoid factor (RF)
Serology markers
SHBG (high priority)
Soluble endoglin
Thyroglobulin
Total Protein (low priority)
Troponin I (IFCC WG)
Troponin T
Urine Chloride (low priority)
Urine-free cortisol
Viral load markers
Viruses