

August 30, 2012

Dr. Charles Jaffe  
Chief Executive Officer  
Health Level Seven International  
3300 Washtenaw Avenue, Suite 227  
Ann Arbor, MI 48104  
USA

Dear Dr. Jaffe,

Pursuant to discussions prior to and during our telephone conversation of 4 June 2012, the ICH (International Conference on Harmonisation) Secretariat submits this letter and has registered on-line for a HL7 organizational membership on behalf of the ICH Steering Committee.

It should be noted that as ICH is not itself a legal entity it has appointed IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) to act as its trustee. IFPMA also provides the Secretariat to ICH. In that capacity, it is IFPMA which is formally requesting HL7 Organizational Membership as ICH's proxy for purposes of this agreement. Heretofore, the name ICH will be used to represent the ICH consortium as represented by IFPMA.

ICH brings together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Further information on the ICH process can be found on the ICH website [www.ich.org](http://www.ich.org).

Much of the focus of ICH is on the development of guidance in the areas of safety, quality and efficacy associated with the development and registration of human pharmaceutical products. Such guidance is published by ICH via the ICH website and by individual regulatory authorities both from the ICH regions and beyond. In some instances, these guidances include an electronic message implementation for communication between industry and regulators. Until recently, ICH developed its own technical specifications for the transfer of information between parties, however in 2006 the ICH Steering Committee took a key decision that technical specifications should no longer be developed solely within ICH, but should be created in collaboration with Standards Development Organisations (SDOs) to enable wider inter-operability across the regulatory and healthcare communities. In this regard, ICH has engaged with the Joint Initiative on SDO Global Health Informatics Standardization and its members. In line with this engagement, ICH has acquired Liaison D status with ISO and now seeks to formalise its relationship with HL7. Our understanding of the rights and responsibilities of ICH under this organizational membership, and as discussed via email and teleconferences, is as follows:

- ICH will maintain an organizational membership with HL7 as an entity under the "government agencies, professional associations and universities category". Under this membership and as agreed in discussion with HL7, ICH may:

- Reproduce and distribute all HL7 copyrighted materials on an internal basis solely for use within their organization (in this case, to ICH participants working specifically on ICH-sponsored projects to develop and/or identify data exchange standards for ICH adoption)
- Reproduce and distribute excerpts of HL7 Protocol Specifications in its Implementation Guides, which in this case will be published by ICH on its public website
- Users of ICH Implementation Guides may re-publish ICH's guides without themselves needing to be HL7 organizational members and without infringing HL7 copyright
- ICH recognizes that this membership does not confer or imply any rights, obligations or any other relationship on behalf of or with the member or other participating organizations to ICH
- HL7 shall be clearly identified as publisher of the Protocol Specifications and holder of the copyright, and any additions, omissions, or other modifications to the HL7 Protocol Specifications shall be clearly identified to end-users:
  - In each ICH Implementation Guide the HL7 copyright statement, as provided by HL7, will appear on a separate page, immediately following the Table of Contents, and before the body of the document; the copyright statement is as follows: "Sections of this document referencing the HL7 Standard [name and version of HL7 standard to be specified] are used with the publisher's permission. The HL7 Standard [name and version of HL7 standard to be specified] is copyrighted by Health Level Seven International ® ALL RIGHTS RESERVED"
- ICH will provide its Implementation Guides to HL7 for publication and free access on HL7's [www.HITStandardsLibrary.org](http://www.HITStandardsLibrary.org) website:
  - HL7 administrators will publish ICH-provided documents with no changes. On ICH's request, HL7 administrators will remove and/or replace documents with new ones provided by ICH
  - ICH will have sole authority for the content maintenance for these documents
  - Regions creating regional addenda to ICH Implementation Guides may also publish to this website with the same process and authority, provided that HL7 membership and copyright statement are maintained if excerpts from HL7 Protocol Specifications are included; if no copyrighted material is included, membership and copyright statement are unnecessary
- Prior to publication, ICH will provide HL7 with its Implementation Guides and, if relevant, accompanying material (e.g. HL7-generated XML schemas) to review for any concerns with infringement of intellectual property rights; HL7 will provide its approval and any comments in that regard within 4 weeks of receipt, upon which ICH will address comments
- HL7 recognizes that neither ICH nor IFPMA can be held responsible for enforcing the inclusion of the HL7 copyright statement anywhere except in the ICH Implementation Guides published by ICH

In reviewing the HL7 Bylaws, it is further understood that, generally, regulatory authorities and other organizations wishing to access HL7 Protocol Specifications for internal development, implementation and distribution, or to include excerpts of HL7 copyrighted material in their regional Implementation Guides, will need to maintain an HL7 membership as specified in HL7's Bylaws. Where an extenuating circumstance exists that makes this difficult, the organization or agency will work directly with HL7 to address the issue. Organizations do not require membership to purchase HL7 Standards or 3<sup>rd</sup>-party –developed tools using the standards to create messages.

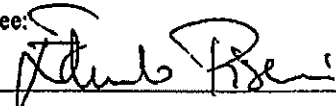
This agreement requires that ICH maintains organizational membership with HL7. Either party may terminate this agreement without cause upon ninety (90) days written notice. In the event of termination, HL7 agrees that ICH can still have the right (in line with the terms agreed in this agreement) to continue to publish any Implementation Guides already approved for publication by HL7 at the time of termination. It is also agreed that following termination ICH can publish updated versions of these Implementation Guides to include editorial changes for readability and clarity as long as no updates involving HL7 Intellectual Property are made.

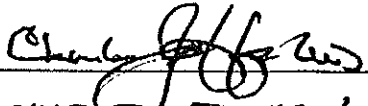
In order to fully execute on this agreement, please review our understanding and confirm that it is yours as well through your signature below.

Kind regards,



Dr. Odette Morin  
Director  
The ICH Secretariat

ICH Trustee:  
Signature   
Printed Name EDUARDO PISANI  
Title DIRECTOR GENERAL  
Date 30 August, 2012

HL7 Trustee:  
Signature   
Printed Name CHARLES JAFFE, MD  
Title CEO  
Date 8-31-12