Ref: MC2016/10

April 7, 2016

To:

Prof. Tim Sprosen

Nuttfield Dept. of Population Health

University of Oxford

United Kingdom

Dear Prof. Sprosen,

I am writing to you on behalf of the ICH Management Committee in response to your letter dated January 31, 2016 regarding the Integrated Addendum to the ICH E6(R1) Guideline on Good Clinical Practice. The Management Committee extends its appreciation for the enclosed comments on the *Step 2b* document which will be transmitted to the ICH E6(R2) Expert Working Group (EWG). In line with ICH processes, the EWG will consider these comments alongside other comments received from the public consultation conducted in ICH Member countries and regions.

The aim of public consultations in the ICH countries and regions is indeed to allow as many stakeholders as possible to provide input and is why your comments are appreciated. The current work on the E6 Integrated Addendum is itself in response to an identified need to modernize the approach to Good Clinical Practice to facilitate innovative approaches to better ensure data quality and protection of clinical trial subjects. In an effort to increase transparency, which was part of the objectives of the reform of ICH, the ICH Association provides a wide range of information on the work of ICH and the technical working groups on its website. The provision of topic-specific concept papers, business plans, work plans and presentations, along with the agendas and minutes of Assembly meetings, serve to keep stakeholders informed, and enable them to provide valuable input. In addition, the work of ICH is regularly being presented in various events, such as public meetings that are organized in several ICH Member countries and regions.

The Management Committee will also deliberate further on the important points raised in your letter, but would like to address here one issue raised in your letter regarding the purpose of ICH. The focus of ICH activities is defined in ICH's Articles of Association, available on the ICH website following the establishment of ICH as an international non-profit organization. The mission of ICH continues to be the promotion of public health through the international harmonization of technical requirements that contributes to the regulatory decision-making in the field of medicines for human use. The Articles of Association also reflect recent ICH organizational changes following the ICH reform, aiming at better-equipping ICH to face the challenges of global pharmaceutical development and regulation. In addition to reinforcing the regulatory driven nature of ICH's work, the changes open-up participation in ICH to a wider audience. While more regulators and industry sectors now

have an opportunity to engage in ICH activities, other international organizations with an interest in pharmaceuticals can also engage by becoming ICH observers (see Article 17(1)(d) of the Articles of Association).

Thank you for the interest you have shown in ICH and its activities and I would like to reiterate that ICH values all stakeholder input recognizing its benefit to current ICH activities and in informing future directions.

Yours sincerely,

Dawn Ronan
Director
ICH Secretariat