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To: gcprenovation@ich.org

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Response from MoreTrials Collaboration to ICH's Plans for GCP Renovation

MoreTrials welcomes ICH's recent reflection paper on plans to modernise ICH-Good Clinical Practice (GCP) guidelines.

It follows the engagement of ICH and regulatory bodies with MoreTrials following our feedback on the proposed update to ICH-GCP (E6). The result of those discussions was the adoption at the end of last year of the proposals suggested by MoreTrials to improve the update to ICH-GCP

The current proposals to renovate ICH-GCP show a clear recognition from ICH of the need for fundamental change to ICH-GCP through more open dialogue with all stakeholders (i.e. not just the pharmaceutical industry and regulators but also academic researchers, other non-commercial researchers, patient groups and the public). Indeed, ICH's press release acknowledges this need:

> *"ICH's decision to invite stakeholder comment on the proposed renovations at this early stage, ahead of guideline development efforts, recognises the considerable stake and relevant expertise in the research community beyond ICH."*

That said, the ICH's current proposals fall short in two important respects:

1. New guideline development should start by developing a guideline on the key principles to do a randomised trial well:

   While we support the proposal to start this work by revising E8 and welcome the focus on concepts, such as Quality-by-Design, the scope of this first revised guideline should be randomised trials and this first guideline should be written as a single document which is applicable to all types of randomised trials.

   This new guideline should cover those key principles – rather than procedural detail – that are most important for doing a randomised trial well. By "well" we mean a randomised trial that addresses an important question, that is designed to address this question reliably, and which is conducted to protect the safety and well-being of participants. This single guideline should be developed to be applicable to all types of randomised trial (industry/academic, registration/not, licensed treatment/not), including trials which use novel sources of data (EHR, registries, smartphones, etc).

   Further, as advocated by our sister campaign. AllTrials, new guidelines should require prospective registration of all trials and a summary of the results should be made publicly available at the end of the study.

2. <u>The development of new and revised guidelines should involve all stakeholders and should be fully transparent</u>:

   We support the general approach outlined of initially revising guideline E8 *General Considerations for Clinical Trials* followed by further revision of ICH-GCP (E6). However, no single stakeholder should initiate and decide on the guideline development to be undertaken (as currently proposed, where ICH would write "concept papers" on the scope, remit and formation of an expert working group, and then invite comment during a 30-day public consultation). Instead, all stakeholders should be fully involved in these early scoping discussions and at every subsequent point in the process of development (whereas the current proposal is only that meetings are held with so-called "outside" stakeholders at key guideline development milestones decided by ICH). There is also a lack of any clarity on who decides the membership of the various Expert Working Groups who will take forward this work.

   At the moment, the proposals appear to suggest that academic researchers would only be involved in developing a single new annex to the revised E6 concerned with non-randomised trials. This may well be a misunderstanding on our part, but, if it is the case, then it is unacceptable.

   Another important aspect of this work is that it should be open to all stakeholders and entirely transparent. This would include making the membership and reports of any expert working group meetings publicly available. In addition, all responses to consultations during guideline development should be published.

To reiterate, we welcome these proposals. However, as outlined above, we now need to move beyond ICH merely asking for "stakeholder comment" and instead put in place an effective partnership of all key stakeholders to take this work forward in order to do more trials better.

We look forward to receiving your response.

Sent on behalf of the supporters of the MoreTrials Collaboration

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