GHP Guild of Healthcare Pharmacists

31st August 2016

European Commission

Consultation on risk proportionate approaches to clinical trial regulation

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,500 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

The European Association of Hospital Pharmacists (EAHP) has made the Guild aware of its views on this consultation. We wish to support these views, as follows:

Support for the intent within the consultation document

We support of the endeavours of the European Commission to facilitate more risk proportionate approaches to clinical trial regulation. The consultation document is correct to assert that many clinical trials pose only a minimal additional risk to subject safety compared to normal clinical practice. It follows therefore that approaches to clinical trial regulation should ideally be adapted to the risk to the subject of the research carried out.

Support for the reflections on risk assessment within the consultation document

Rationales and reflections provided within the consultation document in respect to interpreting risk (e.g. lines 99-108) are supported. For example, the IMP perspective alone does not determine whether a trial is low intervention; other factors such as trial design and patient population must be factored in. Equally, if a trial is not low intervention, this does not mean that risk proportionate procedures cannot or should not be applied.

Interpreting "published scientific evidence"

As the consultation document sets out, the 2014 Clinical Trials Regulation stipulates that "published scientific evidence" is a factor in determining whether a proposed trial is "low intervention". The consultation document then expands on what can constitute "published scientific evidence.

Lines 124-127: *"The published scientific evidence supporting the safety and efficacy of an IMP which is not used in accordance with the terms of the marketing authorisation could include evidence based treatment guidelines and health technology assessment reports, and clinical trial data published in scientific peer-reviewed journals or other appropriate evidence."*

We suggest that marketing authorization granted in another country (e.g. USA) also be accepted as evidence.

We also suggest amendment to the following lines in the following sections:

Risk identification and evaluation

- Line 189, "The risk evaluation ~~should~~ **must** commence prior to the finalization of the protocol."
- Line 193, "The risk assessment and mitigation ~~should~~ **must** be described and implemented."
- Line 194, "The documentation ~~should~~ **must** include the rationale and responsible functions of any specific actions required (e.g. monitor, investigator etc.)
- Line 200, "Careful consideration ~~should~~ **must** also be given to the adequacy of the measures to protect the privacy of trial subjects"

Risk review

- Line 227, "An ongoing reassessment of the risks ~~should~~ **must** be performed..

Risk communication

- Line 235, "There ~~should~~ **must** be a process to ensure that the risk assessment and mitigation plan and any subsequent updates, as well as any changes that may impact on trial conduct e.g protocol amendments, serious breaches, safety reporting, protocol deviations etc. are shared with the relevant personnel, **including all healthcare professionals involved with the trial**.

Risk reporting

- Line 241, "The sponsor ~~should~~ **must** describe the implemented risk adaptions in the clinical study report"

Safety reporting

- Line 246, "Any such adaptions ~~should~~ **must** be clearly stated and justified in the protocol"
- Line 251, "As a general rule, any adverse event considered by the investigator as being potentially related to the IMP, and therefore representing an adverse reaction, ~~should~~ **must** be reported to the sponsor"
- Line 262, "Risk adaptions to adverse event recording, collection and reporting ~~should~~ **must** be detailed in the risk assessment and mitigation plan"
- Line 288, "The risk assessment ~~should~~ **must** consider whether the clinical trial under evaluation includes a new population…"

Traceability and accountability

- Line 366, "Other risk factors, like the stability of the active ingredient that impact the management of IMP ~~should~~ **must** also be considered in the risk assessment and for example, temperature monitoring or light protection if applicable, ~~should~~ **must** be adapted depending on the outcome of that risk assessment."
  New line after line 366: If stability or reconstitution could be a problem, pharmacists must be involved in handling the IMP.

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

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