GHP Guild of Healthcare Pharmacists

30th August 2016

European Commission

Consultation on Clinical Trial Lay Person Summaries

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 the consultation on Clinical Trials Lay Person Summaries. We wish to support these views, as follows:

Support for lay person summaries
We support the spirit and intention of the 2014 clinical trials regulation in respect to introducing requirements for lay summaries. Patients participating in clinical trials have a justifiable expectation that information about the trials they participate in will be available to them, and in a format that they can understand. We therefore support the recommendations being consulted upon as a valuable tool for ensuring the spirit and intention of Article 37 of EU Regulation 536/2014 is delivered upon. WE therefore agree with the statement in the introduction to the document *"Consistency in the way that trial results are presented will help to improve familiarity and comprehension for participants, patients and others."*

We suggest the following amendments:

General principles
Line 75:

- "Keep the document as short as possible, **while covering all aspects stipulated in Regulation 536/2014 and encouraged in accompanying guidance"**

Visuals
Line 250:

- "Well-chosen and clearly designed visual aids can help enhance understanding of text **and their use is therefore encouraged."**

Language
Line 268:

- "Sponsors should consider including an English version if the trial did not include the UK, **the Republic of Ireland, or Malta**, as the use of a common language will allow greater accessibility across the EU **and globally**."

Annex 1 - Templates
At point 8 in the template, we particularly supports the recommendation that the lay summary include information about the ethnic, age and gender profile of participants in the trial. Given the ongoing challenge of overcoming the barriers to participation in trials of under-represented groups, such inclusion can only be helpful. The document might therefore go further in recommending its inclusion in lay summaries.

At point 10 in the template, we suggest amendment:

"Links ~~can~~ **must** be made…

"Links ~~can~~ **must** be provided

Annex 2 – Neutral language guidance
We support the recommendations made in respect to neutral language in Annex 2. However, it appears likely new examples of promotional language will emerge with experience. Therefore the guidance should be kept under review in case new examples should be added.

Additional points of comment
We consider that sponsors should be encouraged to contact trial participants with a link to the layperson summary when published. This does not appear covered in the present document.

The document is correct to promote avoidance of highly technical language in the lay summary. However, on occasion this might be unavoidable. Additionally, given that one of the underlying aspirations of the lay summary requirement is to assist greater familiarity and comprehension of the clinical trials process amongst participants, patients, and others, there may be value in hosting a central repository of agreed definitions of terms used in clinical trials, described for the lay reader, and potentially accompanied with visual aids, including explanatory video. This could be housed on the European Commission website, European Medicines Agency website, or elsewhere.

The ultimate test of the lay summaries, and the guidance and supporting architecture, will be their use and understanding by trial participants and patients. The extent to which lay summaries are achieving this purpose should be kept under continual review therefore, and responsibility assigned for promoting their existence to target groups. As experience develops best practices should be shared.

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

Yours faithfully

Barry Corbett
Professional Secretary
Guild of Healthcare Pharmacists

Colin Rodden
Regional Representative for Scotland
Guild of Healthcare Pharmacists