National Institute for Health Research

Public consultation on the revision of "Summary of Clinical Trial Results for Laypersons"

Response on behalf of the NIHR Clinical Research Network

NIHR Clinical Research Network
Date 31 August 2016

Delivering research to
make patients, and the NHS, better

1. Stakeholder details

This response is submitted on behalf of the National Institute for Health Research (NIHR) Clinical Research Network.

Our national network makes people and the NHS better by enabling and embedding high quality clinical research as an integral part of healthcare. As part of the NIHR, we improve the health and wealth of the nation through health research.

The NIHR Clinical Research Network aims to:

- Increase the opportunities for ALL people across England to participate in and contribute to research
- Provide researchers with the practical support they need to make clinical research studies happen in the NHS
- Work as a single network to improve the efficient and effective delivery of high quality clinical research
- Increase national and international clinical research investment to support the country's growth
- Provide a coordinated and innovative approach to national research priorities.

2. General comments

The NIHR CRN welcomes the opportunity to comment on the proposed guidance for the summary of trial results for lay persons. We believe the current draft is a useful and thorough baseline tool for researchers in a much needed area of work. We believe the document will support those developing and delivering clinical trials to communicate better with patients and public.

We have the following specific comments on the proposed text.

Line number(s)	Comment and proposed changes
45-63	It is noted in the Introduction and Scope section, that the guidance was developed to meet the requirements of the EU Portal and Database reporting on the results of research, and only applies to lay summaries included in the EU database. We would note however, that the proposed guidance is a helpful resource and could just as well be applicable to lay summaries used at earlier stages of the research life cycle, such as when applying for funding (where in the UK there are often lay people on funding panels) and at the recruitment stage, for Patient Information Sheets, as well as reporting to participants at the end of studies. In our view, whilst the purpose of the guidance is in relation to summaries included in the EU database, the Introduction and Scope sections of the document should make clear its applicability to lay summaries at all stages' of the research cycle.

Line number(s)	Comment and proposed changes
72	Add ‘or medical terminology’
81-85	We would suggest changing the tone of this paragraph from a suggestion (‘consider’) to an expectation. Whilst we agree that there will be some studies where this isn’t feasible, it would help to set the expectation that involvement and feedback from patients and their families is the expectation rather than the exception.
164	Under section 6, Readability and use of plain language - English, there should be a reference to the Plain English Campaign's guidance training and Crystal Mark accreditation see http://www.plainenglish.co.uk/.
264	In the section on language, it may help to highlight the need to take international differences in terminology into account e.g. the translated words having a specific meaning culturally which does not apply in another language.