



Summary of clinical trial results for laypersons – August 2016

Joint response from Cancer Research UK and the British Heart Foundation

The UK has wealth of experience in producing clinical trial summaries for laypersons. Cancer Research UK has had a database of plain-English summaries for clinical trials for 15 years and have published results summaries for 8 years; the database holds details of 2,221 trials and 817 of these include results summaries¹. Cancer Research UK have a team of four information specialists who write the lay summaries, all of whom have a background in cancer nursing, and the database receives around 55,000 visitors each month. While the Cancer Research UK database provides an important resource for cancer patients, we believe that all patients, and the public, should be supported in a similar way. We support the UK Government's NIHR UK Clinical Trials Gateway (UKCTG) which for all trials includes a plain language summary written specifically for a lay audience. We are also appreciative of the role the UK's Health Research Authority has played in setting good practice in this area.

The key principles of layperson summaries are ensuring the information is accessible: not using jargon or medical terms (where these must be used, giving a full explanation), and keeping in mind literacy levels and how use of formatting can help people understand.

The guidance requires that researchers supplying clinical trial results keep to very similar criteria that we ourselves advocate to ensure information is accessible to the majority of readers. We are supportive of this effort to set standards for best practice, and improve patient access to trial results across the EU.

The general comments we have developed in response to this consultation relate to the inclusion of the following additional requirements:

- Include the requirement for an initial abstract-style summary
- Include provision for innovative trial designs that may require more than one summary
- Provide guidance for clinical trials conducted in minors
- Clearly state the timeline for publication of results summaries

Additionally, whilst it should not be mandated, we suggest that the guidance should strongly highlight the importance of public and patient involvement in production of lay summaries.

Include the requirement for an initial abstract-style summary

Throughout the guidance there is an emphasis on keeping the information short and succinct (General principles: line-75, and Health literacy principles and writing styles: line-139) and there is reference to presentation of the 'big picture' before providing detail (line 125). We welcome this approach.

However, in our experience inclusion of all of the '10 elements' in the summary of results (Annex 1, page 13) results in an excessively lengthy read for patients.

¹ <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial>



We recommend that the guidance should require a top-line overview of their study and findings first. Such an overview would allow people viewing the summary to quickly grasp the findings of the study before deciding whether to read additional information and in our experience is beneficial for those with lower literacy levels. This is in line with the principle of the 'inverted pyramid writing style' (line 125).

Research teams are familiar with doing this when writing an abstract for journal publication, and it is an approach we have found particularly helpful.

Include recommendations for innovative trial designs that may require more than one summary

Some arms of modern trials may close, and publish results, long before the overall trial closes. Biomarker/gene research and multi-arm trials which continuously open and close research arms are particularly good examples. It is important that publication is not delayed, and patients get timely access to results. This may lead to successive summaries needing to be published and updated; trial teams need to commit to do this, and be able to link different summaries that are from the same overall piece of research.

Case study: FOCUS4 trial

When the trial opened in 2005 there were five "original comparisons". Survival results of these comparisons have already been presented, but a further five research arms have opened. Recruitment is expected to close in late 2019.

Provide guidance for clinical trials conducted on medicinal products in minors

The guidance entitled 'Ethical Considerations for clinical trials conducted with minors' states that, in the case of a paediatric trial, the summary for laypersons should be understandable by the children that participated in the trial. There does not appear to be provision for children in this guidance. Whilst it should not be mandated, the guidance should recommend that there is public and patient involvement in production of lay summaries for minors, to ensure that the language is accessible to children.

Clearly state the timeline for publication of results summaries

We suggest adding a clear statement regarding the maximum one year timeline, from conclusion of the trial to publication of the results summary, in line with the CTR and paediatric medicines regulation. Timely publication of results is vitally important for transparency, establishing trust with clinical trial participants that the information from their participation is being put to maximum use to further knowledge about their condition.

Additional comments relating to specific lines:

Annex 1, 3.2

This section should be changed to allow researchers to record both recruitment and follow-up phases. This is particularly important for studies where the follow-up period could be very long.

Annex 1, Section 7

4th bullet in section on dealing with multiple endpoints – this should reference the EU database rather than 'website'

For further information, please contact Ed Blandford, Policy Adviser, via Edward.blandford@cancer.org.uk or +44 (0) 203 469 6122.



Cancer Research UK

Cancer Research UK's vision is to bring forward the day when all cancers are cured. Over the last 40 years, cancer survival rates in the UK have doubled. In the 1970s just a quarter of people survived. Today that figure is half. Our ambition is to accelerate progress and see three-quarters of patients surviving the disease within the next 20 years.

Each year more than 25,000 people take part in clinical trials supported by the charity. This year alone 14 new clinical trials received funding from CR-UK, adding to the portfolio of over 250 clinical trials that we support.

Every year more than 25,000 people take part in one or more of over 250 clinical trials supported by the charity. In 2015/16, Cancer Research UK spent £432 million on research across the UK, including our £28 million contribution to the Francis Crick Institute. CRUK directly funds over 200 clinical trials. More than a quarter (28%) of these trials involve at least one other EU country. One in three (33%) of CRUK-supported clinical trials have involvement from countries outside of the UK.

British Heart Foundation

The BHF is the UK's leading heart charity. We are working to achieve our vision of a world in which people do not die prematurely or suffer from cardiovascular disease. Thanks to modern treatments built on our research, huge progress has been made in saving lives. Most babies born today with heart defects survive and seven out of ten people survive a heart attack. However, heart and circulatory disease still kills one in four people and affects 7 million people in the UK, so there is so much more to do.

The BHF is the largest independent funder of cardiovascular research and the third largest charitable funder of medical research in the UK. Each year, thanks to the generosity of our supporters, we are able to fund around £100 million of new research across the UK, in all four nations. Our funding portfolio extends from laboratory science to clinical trials and population studies. We fund people from PhDs to professors as well as investing in large programme and project grants.