Every year around 300,000 people are diagnosed with cancer in the UK. Every year more than 150,000 people die from cancer. Cancer Research UK is the world’s leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, Cancer Research UK’s vision is to bring forward the day when all cancers are cured. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2011/12 we spent £332 million on research. The charity’s pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.

Clinical studies are a vital in advancing our knowledge of cancer. We currently fund over 240 clinical studies in the UK; we are one of the largest funders of clinical research in Europe. In 2011/12 over 37,000 patients were recruited to clinical studies supported by CR-UK.

Cancer Research UK welcomes the opportunity to feed into the proposals for the new Declaration of Helsinki. We are committed to conducting robust and ethical research and recognise the importance the Declaration has for setting the standards. Given that most clauses of the Declaration have either not been amended or have seen only very minor changes we have focused our comments on the most relevant sections.

34. Post trial access

In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the study. This information should also be disclosed to participants during the informed consent process. All study participants should be informed about the outcome of the study.

We believe that the new text concerning post trial access does not take into account the way in which clinical trials are run and the ability of the health system to provide treatments following the closure of a clinical trial if it is deemed beneficial.

Practical implications of providing post-trial access

Typically Cancer Research UK’s trials involving innovative new medicines allow patients who react positively to treatment to receive around 6-12 more cycles of the treatment, generally this amounts to four weeks worth of treatment following the end of a study. We do this for our phase I – II studies because at this early stage of development we do not know what the long-term side effects of the medicine are, it may in fact be unethical to continue treatment where there is limited knowledge about the long-term effects of the treatment.

Additionally interventions in cancer trials are unlikely to be found to be ‘beneficial’ for some years after people have taken part. At that point, it may not still be suitable for the patient and/or the amount of time that has passed may mean it would no longer be beneficial. Given that arranging post trial access to
a treatment would be difficult because of the potential costs and administration involved we do not believe that it should be a requirement in ethics approvals.

The findings of a single study are not necessarily enough information to determine clinical benefit of a treatment in a certain population. Instead it is the wealth of evidence about a treatment that should dictate how treatments are used. That is why we believe that this amendment is not reflective of how knowledge on a medicine is developed. In the UK it is the role of NICE to assess the evidence of a treatment to determine if it is enough benefit to be cost effective for the NHS to prescribe. We believe that this is a robust system that should not be bypassed to the proposals in clause 34.

**Investment in clinical research**

Since 2008, over 30 Pharmaceutical companies have provided over £136 million of financial support and free drugs to academic trials supported by Cancer Research UK. This support allows our trials to take place in order to improve knowledge of cancer treatments. Should the principle of post trials access be embedded into research ethics committee consideration or law then it could jeopardise the involvement of pharmaceutical companies in trials because of the extra costs involved. This would undermine our ability to understand more about cancer treatments.

Due to these concerns we believe the text of the 2008 Declaration should be retained which references or to other appropriate care or benefits. We believe that this supports the ethical consideration that patients involved in research should continue to receive care following a study without impacting the science of clinical research or Sponsors ability to run studies.

**Reporting to research participants**

We are supportive of the fact that the new Declaration is not specific about the way in which research participants are informed about the outcome of the study. Cancer Research UK currently uses our CancerHelp UK website as a means to inform patients of the outcome of trials.

The website provides information for the public about cancer trials and studies that recruit people in the UK. It receives around 400,000 views a month. The summaries and the summaries of the outcomes of the study are written in plain English by our team of specialist nurses and all the information is reviewed and approved by the team or organisation running the trial before it is added to CancerHelp UK.

We aim to list all cancer trials and studies recruiting in the UK - not only those supported by Cancer Research UK. We currently have more than 1,500 studies listed on the site, including more than 500 trials that are open to recruitment, over 500 studies that are closed to recruitment but ongoing, and more than 400 trials with results.

Requiring Sponsors or researchers to contact each patient individually would be logistically difficult and we believe there are more effective ways of achieving this. There may be additional ethical issues in the cases of serious illness concerning contacting the families of patients who have died during or following the end of a trial.

Cancer Research UK is supportive of the intention of the clauses within the Declaration to ensure research participants continue to receive healthcare and understand outcomes of trials. However we
think that the wording for this clause in particular needs to be changed to reflect how evidence for clinical research is developed and how treatments are delivered.

For any further information on any of the issues raised above please contact Daniel Bridge, daniel.bridge@cancer.org.uk, 0203 469 8153.