Submitted on 23 July 2014

The National Cancer Research Institute would like to thank the HRA for the opportunity to respond to their consultation on registration and reporting of clinical trials. NCRI would strongly encourage the HRA to influence register hosts to:

1. **Improve data export functionality of their registers**
2. **Develop export functionalities that are compatible across registers**

What is the National Cancer Research Institute?

The National Cancer Research Institute (NCRI) is a partnership of cancer research funders that work together to promote research for patient and public benefit. The Partnership is supported by a small Secretariat team, who work to address opportunities and challenges that have been identified. More information about the activities of NCRI can be seen at www.ncri.org.uk

How does NCRI use clinical trials registers?

In cancer, NCRI coordinates national trials activity via the Clinical Studies Groups (CSGs) who have a remit to develop a strategic portfolio of trials. Comprehensive overview of national trials activity is key to this, to ensure research gaps are identified and filled so that patients have opportunities to participate in research. Although the UK Clinical Research Network portfolio captures information on trials with NHS support, some early phase trials are not catalogued. Universal trial registration provides an opportunity to improve overview of the portfolio as a whole. The NCRI Secretariat has been using the three HRA-accepted trials registers[1] (clinicaltrials.gov, clinicaltrialsregister.eu and ISRCTN) to feed information on early phase trials into the CSGs.

What difficulties has NCRI encountered when using trials registers?

Although the three HRA-accepted trials registers are a rich source of data, the export functionality of two of the three makes it challenging to use the outputs for strategic overview. Data can be exported from clinicaltrials.gov in an excel file, allowing easy examination of trials of interest. However, it is only possible to export data from clinicaltrialsregister.eu in a plain text file,[2] which does not allow for easy data analysis, and there is no data export function on ISRCTN.

It is also difficult to gain a complete picture of trials, owing to the multiple locations for trial registration. As trials are being captured across the three registers, data from all must be examined to gain a complete overview.

What course of action would NCRI recommend to the HRA?

NCRI would strongly encourage the HRA to influence register hosts to:

1. Improve data export functionality of their registers
2. Develop export functionalities that are compatible across registers

Ideally, data on all UK trials would be captured in a single searchable portal. In the current multiple register situation, improving export functionality may be a more pragmatic alternative to allow easy examination of data from multiple sources.

NCRI would like to take this opportunity to acknowledge the substantial work in trials registration and reporting started by the HRA, which has contributed greatly to strategic overview of trials. We hope that these comments will be of use to the HRA in its next steps.

[1] http://www.hra.nhs.uk/documents/2013/10/clinical-trial-regulation-guidance.pdf, p. 2-3, access date 12.Jun.14
[2] https://www.clinicaltrialsregister.eu/doc/How_to_Search_EU_CTR.pdf, p. 11, access date 12.Jun.14