UKCRC Registered CTU Network response to consultation National Data Guardian priorities

The UKCRC Registered CTU Network welcomes and supports the work of the National Data Guardian and is broadly supportive of the draft priorities and of the areas of focus presented in the consultation document, which are intended to further the achievement of these priorities.

As a network of clinical trial units, we hoped to see the words ‘research’ and ‘clinical trial’ mentioned in the document and were disappointed that they were not included. We feel there should be a stronger reference to clinical research and more specifically clinical trials in the document.

Priority 1 *Encouraging access and control; Individuals and their health & care data*

The Network welcomes and supports the inclusion of Priority 1 and its underlying areas of focus. However, we note that it may be a challenge to allow patients to see who has viewed their records for research purposes. We would welcome clarity on what this entails in practice and the level of information that patients will be able to see or request regarding that access. Careful consideration must be given to the mechanism and purpose of such an audit trail and the potential impact it may have on research.

Priority 2 *Using patient data in innovation: a dialogue with the public*

The Network welcomes the inclusion of Priority 2. We would urge that ‘innovation’ include clinical and epidemiological research and that consideration is given to how a more joined-up use of data can drive forward innovation in wider clinical research, including clinical trials. It would be helpful to understand how data-controllers use, and/or acknowledge this ‘dialogue’ with the public to support access to data for research and other non-care purposes.

Priority 3 *Getting the basics right: information sharing for individual care*

The Network supports the inclusion of priority 3. We welcome a review of the Caldicott guidelines and any potential initiatives that will drive forward data sharing for research purposes.

Priority 4 *Safeguarding a confidential health and care system*

The Network supports the inclusion of priority 4. However, whilst we support a focus on encouraging individual access (Priority 1) and Safeguarding (Priority 4) we feel there also needs to be a clear priority and drive towards ensuring and encouraging secondary data processing. Many of our member Clinical Trial Units have patients who have consented that they can access their health and care data for secondary data processing but a focus on safeguarding (without the balance of risk assessment) means it is overly difficult for Clinical Trial Units and clinical researchers to access this data. We would urge the NDG to focus on safeguarding but also to encourage access to risk assessed, ethical and consented use of data for secondary data processing from clinical trial researchers.

The Network looks forward to understanding more about the final priorities and areas of focus of the National Data Guardian. We are willing and eager to work with the NDG to share thoughts and considerations particularly from a clinical trials perspective in order to help shape these areas of focus for the future.