Science and Technology Committee
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From Rt Hon Norman Lamb MP, Chair

Fergus Sweeney
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Dear Fergus Sweeney,

Clinical Trials Transparency

Thank you for your letter of 22 October 2019, in which you indicated that you would be happy to meet with the Committee to discuss issues with the reporting of clinical trials results.

On 29 October the Committee heard from UK universities, English NHS Trusts and the Sense about Science campaign about several issues that researchers and clinical staff had encountered with the EudraCT system and the European Medicines Agency (EMA) service desk. We also discussed these issues with a representative of the Medicines and Healthcare products Regulatory Agency (MHRA).

Unfortunately, in preparation for the December UK general election, this Parliament will soon be dissolved and the Committee will be unable to meet with you to discuss these issues. In lieu of a public evidence session, I would ask that you write to the Committee to address the following:

- Whether you agree that an urgent priority should be to ensure that the registration of all clinical trials, the reporting of all data on research outcomes, and the correction of errors etc should be made as ‘user-friendly’ as possible in order to maximise compliance;
- What concerns the MHRA and sponsors of clinical trials have raised with the EMA regarding technical issues with the EudraCT system, and what actions the EMA have undertaken to solve them;
- If the EMA will change the current EudraCT system to give sponsors increased powers to edit information themselves (particularly for historical clinical trials) and if not, why;
- What guidance and support the EMA provides to sponsors of clinical trials on the issues that can be addressed by the EMA service desk and those that fall under the remit of national competent authorities;
- What actions, if any, the EMA is taking to bolster the capacity of the EMA service desk and the capability of its personnel;

- What guidance and support the EMA has given to national competent authorities (and relevant sponsors) in relation to the duplication of efforts in the reporting of results of multi-national clinical trials;
- Whether you agree that the objective should be for all registers to share all trial data in order to maximise transparency of research outcomes;
- The expected completion date for the new EU trials portal, what delays have been encountered during its development and why they occurred; and
- What consultation the EMA has had with potential users of the new EU trials portal and if the new system will address the issues with the current EudraCT system.

I will be placing this letter on my Committee's website in due course. I would be grateful if you could send your response ahead of the beginning of the new UK Parliament.

Yours,

Rt Hon Norman Lamb MP
Chair