WHO Supports Trials Transparency

The Honorable Linda McAvan and Transparency in Clinical Trials writes,

Many thanks for writing to me about the important issue of transparency in clinical trial results. My colleague Glenis Willmott, Labour MEPs spokesperson on health, is the European Parliament’s Rapporteur on the Clinical Trials Regulation.

On 29 May MEPs will vote on the Clinical Trials Regulation, and Glenis’ proposals to improve transparency in trial results. Glenis is calling for a detailed summary of every trial to be published on a publicly accessible EU database one year after it has been completed. This applies to all trials, whether they were successful or not. It is especially important that we know the results of research that has not worked, or has gone wrong, to avoid it happening again.

On top of the summary it is vital that we can access much fuller results where possible. That is why Glenis has been pushing for the publication of full Clinical Study Reports.
Although this idea has been met with some resistance, she is currently negotiating with the other political groups and is hopeful that we will have the necessary support to ensure the publication of Clinical Study Reports for commercial trials, once the medicine has been authorised.

Glenis is also fighting for financial penalties to be imposed where these transparency requirements are not met. We know from experience in the United States that without proper enforcement, trial results remain largely unreported.

If the committee supports these proposals on 29 May Glenis will enter into negotiations with EU governments to agree the final legislation. It is therefore important that you also raise your concerns with the British government.

This legislation is being made at EU level to enable cross-border trials, which are vital for many studies, especially into rare diseases. It also means we are much better able to regulate trans-national pharmaceutical companies. This law is a real opportunity to lead the way in transparency globally, and Labour MEPs are determined that we will take it.

Many thanks for your support in this important matter. I hope that, once agreed, the Clinical Trials Regulation will improve transparency in the interest of patient safety and good science.

Best wishes
Linda McAvan MEP

For WHO Position please see http://www.gfmer.ch/Medical_education_En/PGC_SRH_2009/Why_register_clinical_trials_Ghersi_2009.htm