True clinical trials transparency? Not quite, EFPIA.

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Last week, the European Federation of Pharmaceutical Industries and Associations (EFPIA) posted a videoon You Tube, called Clinical Trials and Transparency. In it, EFPIA claims to be "absolutely willing to be more transparent" with respect to clinical trials data.

For EFPIA to be truly transparent, it should support that clinical study reports, including raw data, are made available on a publicly accessible database and not just trial results "either as a publication somewhere or somewhere else." Disclosing full clinical trial data is essential to minimising the dangerous practice of reporting bias, which can overestimate the benefits of medicines and underestimate their risks. Many adverse health events, including deaths, could have been avoided had the real effects of medicines been known.

EFPIA also refers, in the video, to the need to protect commercial confidentiality. The European Ombudsman declared that neither clinical trial protocols, nor clinical study reports, contain commercially confidential information. The European Medicines Agency and other European regulators have also acknowledged that clinical trial data shall not be considered commercially confidential. The Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament also recognises this in the recital of the Proposal for a Regulation on Clinical Trials.

Furthermore, patient confidentiality will not be jeopardised as a result of disclosing full clinical trial data. European Union legislation requires patient information to be included in non-identifiable form in applications for marketing authorisation submitted to regulatory authorities. De-identification standards need to apply in a way that allow for maintaining the detail and robustness of the data while ensuring patient confidentiality. In clinical trials for smaller populations (e.g. ultra rare diseases), standards can be agreed up front to further protect patient confidentiality.

In the coming months, HAI will continue to work with its stakeholders to advocate for the full disclosure of clinical trial data in an effort to ensure that public health is better protected.