

June 12, 2015

FIFARMA welcomes the World Health Organization's Statement on Public Disclosure of Clinical Trial Results (refer to link 1 below) and is supportive of its intention of making the registration of interventional trials a scientific, ethical and moral responsibility. FIFARMA member companies reaffirm their commitment to publish clinical trial results regardless of the outcome of the trials. At a minimum, results from all phase 3 clinical trials and clinical trial results of significant medical importance should be submitted for publication. (see also "Joint EFPIA/PhRMA Principles for Responsible Clinical Trial Data Sharing, to clinical trial registration and data transparency" on link 2 below). From a FIFARMA perspective it is imperative that this initiative strikes a balance between responsible reporting for public health benefit and safeguarding patient confidentiality, respecting the integrity of the regulatory systems worldwide, and maintaining incentives for investments in biomedical research.

- 1. <u>http://www.who.int/mediacentre/news/notes/2015/medical-research-transparency/en/</u>
- 2. <u>http://www.efpia.eu/mediaroom/254/44/EFPIA-Welcomes-WHO-Statement-on-</u> <u>Clinical-Trials-Data-Disclosure</u>