HAI Europe Calls on EFPIA and PhRMA to Truly Commit to Clinical Trial Data Transparency

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HAI Europe calls upon EFPIA and PhRMA to truly commit to clinical trial data transparency

Health Action International (HAI) Europe welcomes any initiative that grants increased access to clinical trial data. However, the commitments made by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and Pharmaceutical Research and Manufacturers of America (PhRMA) in their joint 'Principles for Responsible Clinical Trial Data Sharing' fall woefully short of the data transparency that is needed.

Moreover, the overall commitment to transparency from EFPIA and PhRMA as such can be questioned, for while they claim to support greater access to clinical trial data we know from the recently leaked strategy document that they actually do the opposite. Indeed, the document shows that the pharmaceutical industry opposes many concrete steps towards greater data transparency under the EU Clinical Trials Regulation and the EMA's recent move towards proactive publication of clinical trial data.

Ancel•la Santos, HAI Europe, says: "Ironically industry claims to move towards increased access to clinical trial data, while we now know from this week's leaked EFPIA's internal strategy that at the same time they work to oppose concrete moves towards more transparency in EU regulations".

Mandatory public disclosure of all clinical trial data can minimise the risks of selective reporting of trial results by the pharmaceutical industry. Such reporting practices have led to an overestimation of the benefits of medicines and an underestimation of the risks, posing a significant threat to public health.

The pharmaceutical industry associations propose in their joint statement to make only the synopsis of clinical study reports available, after marketing authorisation has been granted. ''Disclosing only synopses of clinical study reports will not solve the prevailing dangerous practices of reporting bias and mis-use of data by the pharmaceutical industry'' says Ancel·la Santos.

Instead of selective reporting of trial results, the full clinical study report including raw data, needs to be made available in a publicly accessible database. This is crucial to ensure independent reviews of the safety and efficacy of medicines to enable informed decision-making by healthcare professionals and consumers.

EFPIA and PhRMA's proposal for granting access to clinical trial data includes a whole list of restrictive conditions. Given the suggested conditionality, HAI Europe has serious doubts on whether the commitments put forward by them will in practice increase the set of publicly available clinical trial data, as they claim.

For example, if industry has its way, access would only be granted on request and only to whom they consider 'qualified scientific and medical researchers'. This potentially excludes independent review by any other qualified experts including public health organisations.

In addition, the pharmaceutical industry proposes that data considered 'commercially confidential' remains secret. According to Ancel·la Santos Quintano, "the proposed barrier to access to clinical trial data is of immense concern, especially since both the European Ombudsman and the EMA have repeatedly insisted that clinical trial data is not commercially confidential."

If EFPIA and PhRMA take their commitment to increase access to clinical trial data seriously, they should endorse mandatory disclosure of all clinical trial data. Preferably as soon as the trial has been concluded or at a minimum, immediately after marketing authorisation has been granted, rejected or the application withdrawn. HAI Europe calls upon the pharmaceutical industry to make all clinical data available in a publicly accessible database.

Moreover, HAI Europe is highly concerned about the intention that EFPIA and PhRMA expressed in their leaked strategy to mobilise patient organisations to fight their corner to maintain data secrecy. "Clinical trial data belongs first and foremost to the participants enrolling in clinical trials, which are not exempt of safety risks", adds Ancel.la Santos. Making clinical trial data available to the general public contributes to ethical research and responds to the public health needs.

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