Is clinical trial transparency under threat?

Last month, HAI and TranspariMED hosted an event in the European Parliament on the issue of clinical trial transparency. The conversation was fruitful – with representatives of the European Commission, the European Medicines Agency, civil society and the parliament agreeing on the importance of transparency and the need to make concrete progress on implementation of the Clinical Trial Regulation.

However, the real ‘elephant in the room’ was the recent opinion by the Court of Justice of the European Union’s Advocate General.

Transparency and Clinical Trials event in the EU Parliament

A couple of weeks before the event, the Advocate General expressed an opinion on clinical trial transparency which has concerned the organisations working on access to medicines across the European Union.

The Advocate General, Gerard Hogan, was giving his recommendations on a long-

running legal case surrounding the disclosure of clinical trial data by the European Medicines Agency (EMA). He argued that because clinical trials are very time consuming, information about them is by nature commercially sensitive, and so such data are 'presumptively confidential'. This recommendation was in agreement with the position of the pharmaceutical company making the appeal to the Court of Justice of the European Union (CJEU), PTC Therapeutics International Limited, which argued that its clinical study report on ultra-orphan drug Translarna should be presumptively confidential.

Whilst the recommendations and opinions of the Advocate General are non-binding, his position will colour the CJEU's assessment of the appeal. And, if this opinion was to be taken up by the CJEU more broadly, it would undo the paradigm shift the Clinical Trials Regulation heralded, and drastically impact even the EMA's ability to scrutinise clinical trial data. As Senior Policy Advisor Jaume Vidal commented, *"it is the shared responsibility of all involved to ensure that commercial interests do not jeopardise patient safety—curtailing access to clinical trial data would do just that."*

During the event, parliamentary sponsor Michèle Rivasi MEP (Greens) also called for renewed action to protect transparency in clinical trials:

"Public health requires transparency, the most complete transparency possible. We, politicians, citizens and patients, cannot accept that clinical studies remain confidential, unreported or subject to trade secrets. We all know that opacity or lack of information do not favour the general interest, particularly in the health domain or when commercial interests are at stake."

“Public health requires transparency, the most complete transparency possible.”
Michèle Rivasi MEP

A representative from the European Ombudsman’s office provided his perspective, recognising the enormous progress of the EMA on transparency, and the – prior to this opinion – CJEU’s supportive stance on public interest. He expressed hope that the court ‘would be wise’, and that, if it were not, the European Parliament would be willing to change the law to better protect transparency and public interest.

Transparency is one of the key tenets of access to affordable, effective medicines, and HAI will be closely watching the developments at the CJEU. If it appears that transparency is under threat, we will work with civil society partners across the EU and allies in the European Parliament to protect the public interest and the right to health.