

Supplementary Written Evidence Submitted by TranspáriMED (RRE0092)

ABOUT THE SUBMITTING PARTY

TranspáriMED is a UK-based initiative working to promote clinical trial transparency through a combination of research, advocacy and facilitating peer-to-peer capacity building.

Note: TranspáriMED jointly with Cochrane and the Transparency International Global Health Programme already submitted evidence to this inquiry in September 2021. The present submission is being made by TranspáriMED alone, with the purpose of updating the Committee on recent salient research.

NEW STUDY SHOWS LINK BETWEEN SANCTIONS AND CLINICAL TRIAL REPORTING

The U.S. Food and Drug Administration has recently (re-)started sending out letters to companies and institutions that have failed to make their clinical trial results public as required by law. The letters warn companies and institutions that they could face a fine of \$10,000 per day for each day a clinical trial result is not made public.

These letters have been highly successful at driving legal compliance. A [study published in JAMA](#) on 12 November 2021 found that over 90% of missing trial results flagged in regulatory warning letters had been made public at the time of assessment, highlighting the effectiveness of even the threat of sanctions.

EVIDENCE OF WIDER IMPACT OF SANCTIONS

The U.S. Food and Drug Administration's enforcement efforts are reportedly having impact far beyond the clinical trials singled out for enforcement action:

- Some smaller pharmaceutical and medical device companies, and some non-commercial sponsors (such as universities and hospitals) are now starting to pay more attention to their regulatory compliance. These two groups historically have lower than average clinical trial reporting rates in the US as well as in the EU and UK.
- Companies and institutions receiving a warning letter for one trial often make public the results of all their remaining overdue trials.
- Reporting rates on the US trial registry are accelerating.

At present, the evidence for these wider impacts is only anecdotal. No relevant peer-reviewed studies have yet been published.

(November 2021)