Clinical Trial Regulation in Europe

Joint Report* | September 2022 | Download PDF

Clinical trial transparency benefits patients and taxpayers. The report 'Clinical Trial Regulation in Europe' provides an overview of national clinical trial reporting rules and their implementation across seven European countries.

Key findings – drug trials

• National medicines regulators in seven major European Union countries now have legal powers to impose fines of up to EUR 250,000 on clinical trial sponsors that fail to make the results of drug trials public as required by law. These powers only apply to drug trials launched after January 2022.

• Regulators expect that monitoring data from the new European CTIS trial registry will enable them to detect and follow up on future violations. However, in practice, the process of imposing fines is likely to consume considerable regulatory resources.

• Regulators in six countries – Austria, Belgium, Denmark, Finland, Germany, and the Netherlands – are actively prompting trial sponsors to make the results of their past drug trials public. Their efforts have been remarkably successful.

• Regulators in four countries – France, Italy, Spain and Sweden – appear to be taking little or no action on missing drug trial results. This threatens to undermine European efforts to secure the 3,055 drug trial results that are still missing.

Key findings – other trials

• Medical device trials. It is still unclear whether and how monitoring data from the new EUDAMED database will support national regulators' efforts to ensure that medical device trial results are rapidly reported as required by law.

• Other trials. There are currently no legal requirements to make the results of other clinical trials public. This regulatory vacuum is perpetuating costly medical research waste.

Policy recommendations

• Pre-2022 drug trials. National medicines regulators in France, Italy, Spain and Sweden should emulate successful approaches pioneered elsewhere and directly contact trial sponsors to ensure that missing trial results are made public on EudraCT before they are lost forever.

• Post-2022 drug trials. National medicines regulators in all EU Member States should aim to build a culture of compliance with CTR legal reporting requirements from the very

beginning. Specifically, they should develop action plans for how they will respond if and when the first drug trial result within their jurisdiction becomes overdue.

• Medical device trials. The European Commission and national regulators should jointly define what EUDAMED monitoring data is required to enable national regulators to rapidly detect and respond to instances in which MDR legal reporting requirements are violated.

• Other trials. National medicines regulators and civil society groups should engage with policy makers at the national level to develop safeguards that ensure that all interventional clinical trials rapidly make their results public. See Annex 1 for a useful model.

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**Joint report with TranspariMED, Cochrane Austria, Transparency International, Salud por Derecho, Concillium Scientific, Melanoma Patient Network Europe, Buko Pharma-Kampagne and Universities Allied for Essential Medicines.*