**HMA Management Group**
Heads of Medicines Agencies Permanent Secretariat
c/o Paul-Ehrlich-Institute
Paul-Ehrlich-Straße 51-59
63225 Langen
Germany

Copy to:

- Emer Cooke, Executive Director, European Medicines Agency
- Stella Kyriakides, European Commissioner for Health and Food Safety

Thursday, 06 May 2021

**Improving clinical trial sponsors' compliance with CTIMP results reporting requirements**

Dear Professor Dr. Broich,

**We ask the Heads of Medicines Agencies (HMA) Management Group to initiate a process to ensure that National Competent Authorities adopt and implement common minimum standards for promoting sponsors' compliance with clinical trial results reporting requirements on EudraCT and, in future, on CTIS.**

HMA itself has long promoted trial reporting, including by co-signing the June 2019 public letter to trial sponsors. However, despite significant improvements in sponsor compliance in recent years, **thousands of due clinical trials are still missing results on EudraCT**; the results of many of those trials have not been made public in other formats either. This creates gaps in the medical evidence base that have significant potential to harm European patients, taxpayers and public health.

HMA's mission is to "foster an effective and efficient European medicines regulatory system". The persistent failure of many sponsors to meet their obligations indicates that the European medicines regulatory system is currently neither effective nor efficient with regard to ensuring the timely reporting of clinical trial results by sponsors.

Registry data show significant differences in average compliance rates by sponsors across different Member States, illustrating that some National Competent Authorities (NCAs) have been successful in promoting voluntary compliance. In addition, registry data indicate that some NCAs have updated the completion status of many trials for which they are responsible, while other NCAs have still not done so.

Civil society engagement with multiple trial sponsors across several countries clearly shows that many sponsors – including both commercial and non-commercial sponsors – continue to be unaware of their obligation to make trial results public on EudraCT. While this lack of awareness is especially widespread among smaller sponsors, a civil society group recently encountered one such sponsor with a portfolio of 45 CTIMPs. On many occasions, following notification by a civil society group, sponsors have immediately agreed to improve their compliance record on a voluntary basis. (The academic literature also shows that simple reminders can substantially increase reporting rates.)

**Registry data, civil society interactions with sponsors and the literature strongly suggest that a small amount of proactive engagement by NCAs could rapidly and significantly improve sponsors' compliance rates**, including for already overdue legacy trials. From a regulatory perspective, these are extremely low hanging fruit.

Considering the above, we ask the HMA Management Group to set out the following common minimum standards, to be adopted and implemented by all NCAs:

1. **Contact all sponsors of completed trials for which results are overdue**[1]

2. **Review sponsors' results disclosure compliance during pharmacovigilance inspections**

3. **Systematically update the completion status of all clinical trials**[2]

Each of the measures above has already been, or is currently being, implemented by at least one NCA, demonstrating their feasibility.

In addition, we ask HMA in collaboration with NCAs to compile and publish a document providing an

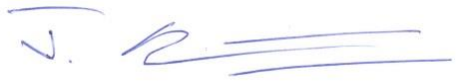
4. **overview of national legal and regulatory frameworks**

governing CTIMP results reporting in the context of the forthcoming EU Clinical Trial Regulation. For each Member State, the document should list relevant laws, regulations and/or administrative rules, briefly outline mechanisms for monitoring compliance, and provide details on sanctions and sanction mechanisms.[3] Making such an overview available to industry, non-commercial trial sponsors, civil society and citizens across Europe would further HMA's mission to foster an effective and efficient European medicines regulatory system.

The adoption and implementation of common minimum standards as outlined above would require only minimal resources, but would generate substantial benefits for European patients, taxpayers and public health.

Please let us know what action the HMA Management Group intends to take with respect to the four recommendations outlined above.

Thank you for your time, best wishes,



Till Bruckner

[1] This outreach could be based on EudraCT DWH reports compiled by EMA. Note that it would probably be more efficient for EMA to simultaneously compile DWH reports for all NCAs, rather than compiling individual reports case-by-case upon request by individual NCAs. NCAs' outreach to sponsors should include a clear and comprehensible explanation of sponsor obligations, and provide links to guidance material on how to upload trial results, possibly based on a template developed by HMA.

[2] The systematic update should include the insertion of correct trial completion dates into trial protocols. See this case study for more details.

[3] An important data point in this regard is whether a given NCA will be able to directly impose sanctions on sponsors following an administrative process, or whether the NCA will have to go through the courts to impose sanctions.

Signed on behalf of 18 European civil society groups:

- Access to Medicines Ireland
- AllTrials
- BUKO Pharma-Kampagne
- Cochrane
- Cochrane Austria
- Cochrane Germany
- Cochrane Sweden
- France Assos Santé
- France Lymphome Espoir
- Health Action International
- International Society of Drug Bulletins
- Melanoma Patient Network Europe
- NoGracias
- Prescrire
- Salud por Derecho
- Transparency International France
- Transparency International Global Health
- TranspariMED

*Contact address for HMA's response:*
*Till Bruckner*
*TranspariMED*
*tillbruckner@gmail.com*