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PRESS RELEASE

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EMA POLICY ON CLINICAL TRIALS AND DATA TRANSPARENCY REQUIRES SUBSTANTIAL CHANGES, ARGUES NEW BRIEFING PAPER

A new study co-authored by 3 leading academics and published by the Pugatch Consilium consultancy finds that the European Medicines Agency's draft policy on *Publication and access to clinical-trial data* is flawed and requires a rethink. While the authors agree that greater transparency could lead to better outcomes in existing and future clinical research, they are concerned the EMA's policy is going one step too far, without fully taking into account the problems generated by "dumping" this information into the public domain.

The authors identify the following specific problems:

• **Possibility for gaps in protection of patient privacy:** The draft policy does not adequately ensure that the measures that would be put in place to protect against disclosure of personal data, including so-called de-identification of data, do not actually lead to a greater ability to re-identify patients. This should include proven and effective safeguards against re-identification technologies.

• **Further 'bureaucratisation' of an already bureaucratic system:** Policymakers should bear in mind the complexities and costs involved in establishing and operating a system for the early release of data. They should consider whether it is possible to actually create an effective system in which patient privacy is protected and where the expected benefits in public welfare outweigh the costs.

• **Conflicting policies on regulatory data protection:** There is a contradiction between the draft policy and the underlying rationale and legal frameworks for the protection of clinical data via regulatory data protection. Greater clarity is required on the scope of protection of clinical trials data based on existing legal frameworks and actual practice, i.e. such that all sensitive clinical information is protected for the duration of exclusivity.

The authors conclude that the release of large amounts of detailed clinical data proposed by the EMA is not a direct or practical solution to the problems the Agency identifies in the current environment for clinical research in Europe. Instead the EMA draft policy should aim for a more pragmatic threshold of transparency with a greater emphasis being placed on coordination of stakeholders and voluntary disclosure of data. This level of transparency should minimise additional red tape associated with the new policy and seek to better avoid breaches of patient privacy.

-ENDS-

NOTES TO EDITORS

- For more information on Pugatch Consilium research: www.pugatch-consilium.com or follow us @PConsilium.
- The report will be launched at a workshop on Monday 16 September in Brussels in association with Maastricht University. For an invitation, please email: helend@pugatch-consilium.com.