



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on access to clinical trial data

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Scope of today's workshop

We are committed to proactive publication of clinical trial data, once a marketing authorisation decision has been taken.

We will deliver this project in dialogue with our stakeholders.

We acknowledge that there are practical and other considerations that need to be addressed and resolved.

Today's workshop is the first step in the process to deliver this vision.

We are not here to decide if we publish clinical trial data, but how, focusing on the future.



Open clinical trial data for all – Why?

- Build trust and confidence in the system
- Ethical responsibility to the patients enrolled in clinical trials
- Public health benefit: independent (re)analysis of data broadens knowledge base
- Scientific progress: sharing of complex data can open new horizons



Scope: What are we NOT talking about today

- New clinical trials legislation
 - All studies
 - No specific cases



Now the floor is yours.
We are here to listen.