EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections and Human Medicines Pharmacovigilance

To whom it may concern

The information that appears on the EU Clinical Trials Register (EU CTR) website is originally provided by the sponsor responsible for the clinical trial. The information is a component of the sponsor application to a National Competent Authority for authorisation to conduct a trial. The information is loaded into the EudraCT database by the national competent authority. The date on which the National Competent Authority loaded the information into EudraCT appears in the EU CTR under the field "date the record was first entered in the EudraCT database". This data is mapped to the WHO ICRTP field "date of registration". The National Competent Authority adds to this information the authorisation of the clinical trial and the opinion from the ethics committee with their respective dates. The trial is then made public in the EU CTR with the start date which corresponds to the authorisation date by the National Competent Authority and ethics committee.

It is possible that the upload of the protocol related information by the National Competent Authority occurs after the sponsor has received the authorisation to conduct the clinical trial.

The sponsor has in all good faith and in compliance with legal requirements submitted their information to the National Competent Authority and Ethics Committee, before the start of the trial, but the information is only later loaded into EudraCT and therefore appears later in the EUCTR. This delay is beyond the control of the sponsor. In such situations the sponsor has registered their trial in advance of the start of the trial as required but the information has not appeared in the EU CTR until later.

This is to clarify that where a clinical trial is published in the WHO register with a date of registration which is after the start date, there is an explanation as explained above. This does not affect the validity, or timeliness, of the study registration by the sponsor.

Sincerely yours,

Fergus Sweeney
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