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Press office

Press release

Improving safety of first-in-human clinical trials

EMA starts EU-wide reflection on necessary changes to best practices

The European Medicines Agency (EMA) has started a review of the guidelines that describe first-in-human clinical trials and the data needed to enable their appropriate design and allow initiation. This is being done in cooperation with the European Commission and the Member States of the European Union (EU).

The review will identify which areas may need to be revised in the light of the tragic incident which took place during a Phase I first-in-human clincial trial in Rennes, France, in January 2016. The trial led to the death of one participant and hospitalisation of five others.

EMA's review will take into account the findings from two in-depth investigations into what went wrong during this trial, one carried out by the Temporary Specialist Scientific Committee (TSSC) set up by the French medicines agency ANSM and the other by the Inspection générale des affaires sociales (IGAS), the inspectorate for social affairs in France.

Both reports include a series of recommendations regarding the requirements for authorisation and conduct of first-in-human clinical trials for further examination by the international regulatory and public health community.

EMA's work will focus on best practices and guidance. The aim is to agree a concept paper by July identifying areas for change and proposals to further minimise the risk of similar accidents. The concept paper will form the basis for an EU-wide review of the guidelines. This process will include targeted discussions with stakeholders and a public consultation on proposed changes later in 2016.

The EMA review has started with two groups of experts who are carrying out preparatory work. One group is looking at pre-clinical aspects and the data needed from laboratory tests or animal studies to safely initiate first tests in humans. The other group is looking at clinical aspects of the design of first-in-human trials and how these could be improved to better ensure the safety of human volunteers taking part in these trials. This will lead into one EU-wide expert group discussion on revision of guidelines.

Clinical trials are essential for the development of medicines and without them patients cannot gain access to new potentially life-saving medicines. In the EU, the approval and conduct of clinical trials is within the remit of the relevant authorities of the European Member States.

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EU guidelines are in place to ensure that these clinical trials are conducted as safely as possible. These guidelines include the requirement for extensive studies, including in animals, to gather information about a medicine before it is given to humans.

Severe adverse reactions in healthy volunteers such as those observed in the trial in Rennes are extremely rare during clinical trials. Since 2005, approximately 14,700 phase I clinical trials (with participation of 305,000 subjects) have been conducted in the EU, including 3,100 first-in-human studies. Only one other severe incident has been previously reported in that time in the EU.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Report of the Temporary Specialist Scientific Committee (TSSC)
3. Report of the Inspection générales des affaires sociales (IGAS)
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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