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Press release

Proposals to revise guidance on first-in-human clinical trials

Comments invited on a concept paper on changes intended to support best practices

The European Medicines Agency (EMA), in cooperation with the European Commission and the Member States of the European Union (EU), is proposing changes to current guidance on first-in-human clinical trials to further improve strategies to identify and mitigate risks to trial participants. These changes are outlined in a new concept paper which has been released for public consultation. Comments on the proposals should be sent to FIH-rev@ema.europa.eu until 30 September 2016 using the form provided.

Clinical trials are essential for the development of medicines and without them patients cannot gain access to new potentially life-saving medicines. EU and international guidelines are in place to ensure that first-in-human 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.

The release of the concept paper is part of a review of the EMA guideline published in 2007 that provides advice on first-in-human clinical trials, in particular on the data needed to enable their appropriate design and allow the initiation of treatment in trial participants. This review identified those parts of the current guideline which need to be amended to take into account the evolution of practices in the conduct of these studies since the guideline was first published. The review also takes into account the lessons learnt from the tragic incident which took place during a Phase I first-in-human clinical trial in Rennes, France, in January 2016.

In recent years, the practice for conducting first-in-human clinical trials has evolved towards a more integrated approach, with sponsors conducting several steps of clinical development within a single clinical trial protocol (e.g. to assess single and multiple ascending doses, food interactions, or different age groups). This responds to the need for a structured approach to the conduct of these trials, with incremental decisions on next steps based on the data collected at each previous step. This enables an approach designed for the specificities of each medicine, its mechanism of action, and intended therapeutic use.

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The concept paper, setting out the proposed changes to the guideline, was prepared by an EU-wide expert group that includes experts from the national competent authorities who authorise clinical trials in the EU and it was adopted by the Committee for Medicinal Products for Human Use (CHMP). It addresses the increased complexity of the protocols of first-in-human clinical trials.

This concept paper and the comments received from stakeholders will form the basis for an update of the guideline. A draft revised guideline is expected to be published before the end of 2016 for consultation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The current 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products' is available here.
3. In a single ascending dose trial, a single dose of the investigational medicine is given to each volunteer in a small group of clinical trial participants to assess the safety, if this is positive each participant in the next group receives a single dose at the next higher dose of the investigational medicine.
4. In multiple ascending dose trials, each subject is treated on multiple occasions (e.g. once a day for a week) at a given dose level. The treatment is then increased progressively to higher doses in successive groups of volunteers, provided the safety and tolerability at the previous dose is acceptable.
5. In the EU, the approval and conduct of clinical trials is within the remit of the relevant authorities of the European Member States.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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