Providing trial therapy to participants at the end of trials

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Context

The WMA Declaration of Helsinki currently states in clause 34:

In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

The Faculty of Pharmaceutical Medicine recognises that it may not always be possible to supply investigational medicinal products post cessation of a clinical trial e.g. for technical/manufacturing process considerations; it is likely that supply will be more difficult after conclusion of early phase trials. Also, what constitutes ‘beneficial’ is not well defined, and it is unclear if this should be taken as an overall favourable benefit:risk profile for the population under study or an individual patient appearing to benefit would be sufficient.

The Faculty strongly urges its members and their companies to make trial therapies available at the conclusion of a trial where:

1) a positive benefit:risk assessment can be made, either based on positive overall trial results or clear objective benefits in individual patients can be demonstrated

2) it is legally permissible to do so and appropriate ethical and regulatory approval has been granted

As a minimum, pharmaceutical physicians should ensure that there is clarity in trial protocols and patient information about whether the trial therapy will be supplied, and if so, provide a clear description of the procedures for supply, and the duration of supply after conclusion of a clinical trial.