HELSINKI DECLARATION

2000.	2008.	2013.
Article 30. At the conclusion of the study, every participant entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods inedited by the study.	Article 33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example access to interventions identified as beneficial in the study or other appropriate care or benefits.	Article 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

FUTURE CONSIDERATIONS

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FUTURE CONSIDERATIONS

- 1.2.Towards collective agents

1.2.1Obligations of access to care after research

-part of the protocol and explained in the informed consent

- REC should evaluate it and decide if there are provisos whether to continue or not

- responsible for assurance of post trial access- sponsors, researchers, governments

- a) Obligations of access to an intervention identified as beneficial in a study

-beneficial- by sound clinical evaluation, evidence of safety and efficacy

- b) Obligation of access to other appropriate care

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REFLECTION PAPER ON ETHICAL AND GCP ASPECTS OF CLINICAL TRIALS OF MEDICINAL PRODUCTS FOR HUMAN USE CONDUCTED OUTSIDE OF THE EU/EEA AND SUBMITTED IN MARKETING AUTHORIZATION APPLICATIONS TO THE EU REGULATORY AUTHORITIES, EMA

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- Information and possible action by regulators of countries outside EU/EE
- Request for additional information or action by the sponsor
- Inspection or re-inspection
- Rejection of data/exclusion of trial/negative opinion
- Education and Facilitation
- Warning
- Transparency regarding clinical trial conduct and compliance including non-compliant Marketing

Authorizations

- Suspension of the Marketing Authorization/Urgent Safety restriction /Revocation of the Marketing Authorization
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