

# Expert Conference on the Revision of the Declaration of Helsinki



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**PhARMA**  
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# Outline

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- **General Position Statements on the Revision of the Declaration of Helsinki**
- **Position Statements on Post-study Access**
  - Comments on Sponsor's Role and Responsibilities in Post-Study Access

# Introduction

- **Biopharmaceutical companies are committed to high-quality clinical research that is both scientifically and ethically rigorous**
- **Biopharmaceutical companies are committed to sponsoring clinical trials that fully comply with all legal and regulatory requirements**
- **PhRMA highly values the fundamental principles of the Declaration of Helsinki and has incorporated them into its own voluntary principles**
  - Principles on Conduct of Clinical Trials and Communication of Clinical Trials Results (*PhRMA, 2009*)

*“In sponsoring and conducting clinical research, PhRMA members place great importance on respecting and protecting the safety of research participants. Principles for the conduct of clinical research are set forth in internationally recognized documents, such as the Declaration of Helsinki and the Guideline for Good Clinical Practice of the International Conference on Harmonization.”*

# General Position Statements on the Revision of the Declaration of Helsinki

- PhRMA recognizes the importance of preserving the original intent of the Declaration of Helsinki as a concise set of guiding principles addressing ethical responsibilities of physicians and physician-investigators
- Biopharmaceutical companies remain supportive of the basic principles of the Declaration of Helsinki and other global ethical guidance documents, in alignment with their obligation to comply with the legal and regulatory requirements of clinical trials
- PhRMA welcomes the opportunity to contribute expert input and support the WMA with any future revision of the Declaration of Helsinki

# Position Statements on Post-study Access

- **PhRMA recognizes the value of providing additional clarity on post-study access in the Declaration of Helsinki, without altering its original intent of a set of guiding principles:**
  - Clearly define what constitutes post-study access
  - Make explicit reference to roles and responsibilities in providing post-study access, including :
    - Primary responsibility of host-country governments to provide access to medical care (including approved medicines) through their healthcare systems
    - Role and responsibility of local National Regulatory Authorities (NRAs) and Ethic Review Committees (ERCs) in determining whether a proposed research study is suitable for the host-country
  - Strengthen the concept that post-study benefits to study participants and host communities can take many forms, and are not limited to the potential identification of a beneficial intervention in the study

# Comments on Sponsor's Role and Responsibilities in Post-Study Access

- **Comments are specific for post-study access to study medications by patients who participated in a clinical trial**
- **The sponsor may offer post-study access to study medications in specific circumstances (*for example, life-threatening diseases, severe debilitating medical conditions, or clinical emergencies for which no appropriate alternative therapies are locally available*):**
  - Subject to local legal and regulatory requirements
  - Guided by the best available evidence for a favorable benefit/risk profile
- **Plans for post-study access (including discontinuation) should be guided by the documented pre-trial agreement and any potential modifications**
- **In cases where the sponsor plans to provide post-study access to the study medication, supply may be discontinued if:**
  - In the sponsor's opinion, new information becomes available that affects negatively the previous benefit/risk assessment of the medication
  - The reviewing agency rejects the request for marketing authorization based upon an assessment of benefit/risk and there are no further plans to seek authorization
- **In all circumstances, the sponsor will work with relevant local healthcare authorities and services in the best interest of the study participants**