Ethical Code for the Conduct of Research and Development

Preamble

- Our Ethical Code for the Conduct of Research and Development is intended to complement Our Credo by providing more specific standards of conduct and behavior for physicians, clinical research scientists and others who are responsible for medical aspects of research and development.
- Our Ethical Code is intended to describe the principles that guide ethical decision-making to help ensure the safe use of our products, as well as the best interests of our patients and their families, doctors, nurses and healthcare providers.
- It is envisioned to be the standard for addressing all ethical dilemmas regarding research and its applications.

Our Ethical Code

- It is our fundamental responsibility to place the well-being of the patient first by appropriately balancing risks and benefits, and to help ensure that the best interests of patients and physicians who use our products receive utmost consideration.1
- It is our responsibility to help ensure access to our products in the communities where we develop them if the need for the product persists.
- It is our responsibility to apply Credo-based values and judgment regarding the design, conduct, analysis and interpretation of clinical studies and results.
- It is our responsibility to adhere to the principles of good clinical practice.
- It is our responsibility to help ensure all Company-based, medically relevant product information is fair and balanced, accurate and comprehensive in order to enable well-informed risk-benefit assessments about our products.
- It is our responsibility to understand differences in values across cultures and to adapt our behaviors in keeping with our ethical principles.
- It is our responsibility to challenge each other regarding medical and ethical concerns and to resolve them appropriately and expeditiously.

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[1] We shall develop plans prior to the initiation of a clinical trial for continued access for clinical trial participants who still need an investigational product identified as beneficial in a Company-sponsored clinical trial, as may be permissible by local laws and regulations. In developing this plan, we will consider circumstances of high unmet need where clinical trial participants may have received medical benefit from an investigational product and do not have reasonable alternative treatment options or could suffer significant medical harm by transitioning off the investigational product to an alternative treatment, and where the investigational product may not otherwise be commercially available. This information shall be disclosed to participants as part of the informed consent process.