

Alliance Management Systems Bioethics Policy

AMS POL 01
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1. ABOUT THIS POLICY

Alliance is committed to upholding the highest ethical standards in all aspects of its operations, including its research, development, manufacturing, marketing and distribution of healthcare products. As a global consumer healthcare company, Alliance recognises its responsibility to respect the dignity and autonomy of patients and consumers and to promote their well-being through the provision of safe and effective products.

This policy outlines the ethical principles and guidelines that Alliance applies globally to work performed by Alliance and at the direction of Alliance in its business operations and interactions with stakeholders including external contract research organisations, consultants or third-party vendors.

2. ETHICAL PRINCIPLES

- **Respect for Autonomy:** Alliance recognises the right of patients and consumers to make their own decisions about their health and wellbeing. In all our interactions with patients and consumers, we will respect their autonomy and promote their right to informed consent, confidentiality and privacy.
- **Beneficence:** Alliance is committed to promoting the well-being of patients and consumers through the development and provision of safe and effective healthcare products. We will ensure that our products are based on sound scientific principles and are designed to meet the needs of patients and consumers.
- **Non-maleficence:** Alliance recognises our obligation to do no harm to patients and consumers. We will ensure that our products are safe and effective and that our marketing practices do not misrepresent or exaggerate the benefits of our products. We will ensure that research on humans or animals is designed in accordance with accepted ethical and professional standards, compliant with all applicable legislation, regulation, standards and guidelines. To the extent possible, we will minimise the use of animals to where no other legal or valid scientific alternative exists, ensure that they are treated humanely and with the highest standards of care.
- **Justice:** Alliance recognises our responsibility to ensure that our products are accessible and affordable to all, regardless of their socio-economic status. We will seek to promote equity and fairness in the distribution of our products and in our interactions with stakeholders. We recognise that protecting the environment is of vital importance to human life, believe in the sustainable use of global resources and the importance of maintaining global biodiversity.

3. GUIDELINES

Innovation and Development: Alliance maintains a portfolio of projects designed to deliver new healthcare products which are safe, effective and of good quality, to meet the needs of our patients and consumers. In order to establish the safety and efficacy of our products and in accordance with regulatory requirements, we conduct safety assessments and clinical investigations when required. Alliance is committed to compliance with the recognised quality and safety standards in every country in which we operate, commission studies or intend to market our products. Alliance is committed to working only with institutions, researchers, partners and contractors who embrace standards of ethical behaviour which are consistent with our own.

Established Products: Alliance places the highest priority on the safety of our products and we keep our

established products under constant review. We conduct new pre-clinical or clinical studies when necessary, to ensure the continued supply of safe and therapeutic products with a favourable benefit / risk ratio. We update the safety or performance information of established products where needed, for example, before making changes to ingredients, sources of ingredients, indicated uses or approving novel claims.

Human Clinical Evaluations: Alliance is committed to protecting the life, health, privacy and dignity of those participating in clinical evaluations and to protecting the integrity of the data obtained from these studies. We ensure that the appropriate informed consent procedures are followed when conducting clinical investigations and that appropriate procedures relating to the protection of personal data are applied when we collect or access any health information. Study participants are free to withdraw from any study, at any time, without detriment to their medical care. We conduct studies with human participants in accordance with all applicable ethical and regulatory requirements and operate within the recognised international quality and safety standards in the countries and territories in which we operate.

Clinical Research and Patient Safety: Alliance is committed to detecting, assessing and reporting adverse reactions to our development and established products as early as possible and to providing updated information to investigators, prescribers, consumers and research participants, as appropriate. We maintain risk management plans for all products. These documents are updated when more safety data become available, so that we can minimise risk and optimise benefits for patients. We follow defined processes aimed at ensuring all relevant safety information is incorporated in product labelling and investigator's brochures.

Clinical Trial Transparency: Alliance is committed to global clinical trial transparency and we believe there are important public health benefits associated with making clinical study information available in a timely, accurate, meaningful and objective way. We comply with all global laws and regulations for study registration and reporting of results.

Privacy of Information and Data Protection: Alliance protects the privacy of research participants by ensuring all patient data is anonymised to conceal a participant's identity. All participant information is handled in a secure way. We interact with patients only with their prior consent or in response to requests for potential clinical trial participation. We are sensitive to the privacy rights of individuals who are defined to be members of small populations, such as those with rare diseases. In such situations, the 'risk of identification by association with a small population' will be assessed and managed in an appropriate manner.

Animal Welfare: The responsible use of animals is a vital part of biomedical research to protect the safety of patients and consumers and to meet the requirements of international regulators. No animals are used directly by Alliance companies and to the extent possible, we minimise their use according to the principles of the 3R's (Replacement, Reduction and Refinement). Where possible, we rely on pre-existing literature reviews and we carefully consider and justify all investigations involving animals and animal tissues, restricting them to be used only where no other legal or valid scientific alternative exists. When animals are used, we adopt a humane approach in their care and treatment, with the greatest consideration given to their health and welfare, consistent with meeting the necessary scientific objectives. Alliance does not commission work using wild-caught non-human primates or great ape species. Alliance does not conduct animal testing in the development of cosmetic products or dietary (food) supplements for any global territory. We believe our cosmetic and food products can be validated as safe and effective without compromising animal welfare. A few countries still require animal testing data to meet their local regulatory requirements and historic (literature) data may be referenced in these cases.

Sustainability: Alliance recognises that protecting the environment is of vital importance to human life, believes in the sustainable use of global resources and the importance of maintaining global biodiversity.

Manufacturing & Distribution: Alliance's manufacturing and distribution processes adhere to the highest standards of safety and quality and are compliant with all applicable regulations and guidelines.

Marketing and Promotion: Alliance ensures that our marketing and promotional activities are truthful,

accurate, and not misleading. Alliance's products are marketed in a manner that promotes safety, accessibility and affordability for patients and consumers.

We do not make false or exaggerated claims about the benefits of our products and do not engage in practices that promote inappropriate or excessive use of our products. Instead, we seek to promote equity and fairness in the provision of our products and work to address any barriers to access.

4. CONCLUSION

Alliance is committed to upholding the highest ethical standards in all aspects of our operations. This policy outlines the ethical principles and guidelines that we will adhere to in our business operations and interactions with stakeholders. We recognise our responsibility to promote the well-being of patients and consumers and to ensure that our products are safe, effective and affordable. Alliance will work to promote equity, fairness and justice in its interactions with stakeholders and will strive to earn and maintain the trust of patients, consumers and society at large.

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