IFPMA | Ethoscope

Data ethics principles

MAY 2021

Preamble

These Data Ethics Principles are intended to help the pharmaceutical industry **use data responsibly and sustainably**, in alignment with the IFPMA Ethos of **care, fairness, respect, and honesty.**

- Ethical data use is critical to innovation, advancing scientific and medical understanding, ensuring patient safety, and improving healthcare for the benefit of individual patients and broader society.
- Ethical data use helps build a culture of trust with our stakeholders. Conversely, unethical data use can harm individuals and society, and damage that trust. As stated in the IFPMA Code of Practice, "Patient trust is the lifeblood of our industry: we must take every opportunity to earn, sustain, and grow that trust." This includes how we handle and use data.

Data in scope

These principles cover all types of data collected, analysed, stored, shared, and otherwise processed by pharmaceutical companies.

Generally, these data relate to, or are derived from, data gathered from individuals, whether the data are directly identifiable, pseudonymized, anonymized, or aggregated. This includes, for example:

- Patient data stemming from clinical research projects, various types of patient support programs, as well as real world data from healthcare settings, apps and social media, and safety reporting
- Healthcare professional data stemming from scientific education, and marketing and sales activities
- Employee and business partner data.

These principles should also be read to apply to data that did not originally relate to an individual (e.g., data on sales, production speed, etc.) to the extent processing of such data can potentially harm or benefit individuals and society.

Approach to data ethics in the pharmaceutical context

As a starting point, ethical data use requires consideration of the impact of data use on

individuals and how such use aligns with human values, risks, and benefits. Therefore, the IFPMA Data Ethics Principles provide the foundation for ethical decision-making with the interest and benefit of the individual as the primary focus, and with acknowledgement of the significant benefits to both individuals and society from data use.

- → Extensive regulations and international guidance for the pharmaceutical industry provide a strong foundation to secure individual rights, especially in ensuring that data is collected from patients in a lawful and ethical way and that patients' rights with respect to their data are protected.
- → Fast-moving technological developments may result in ethical dilemmas requiring assessment and decision-making in the absence of formal legal requirements. Ethical principles can serve as a guide that goes beyond compliance with law or existing codes of practice, especially in the contexts of developing or adapting business practices to address innovative technologies.
- → Data ethics programs should be implemented globally by members, with equal application across jurisdictions to ensure that diverging standards in national laws do not create situations where individuals' basic rights are compromised due to a lack of specific, locally applicable legal protection.

The IFPMA Data Ethics Principles draw on established concepts in consumer protection, privacy, bio- and healthcare ethics, human rights, and business ethics to propose a way of working with data that maximizes benefits and minimizes harm for individuals and society.

Principles of ethical data use

1. **Autonomy: Respect individuals' privacy, protect their rights, and honor confidentiality.** Data should be collected and used in ways that are consistent with the intentions and understanding of the individual. Best efforts should be made to make individuals aware of how their data will be used and, where appropriate and possible, offer them choices about who has access to their data and how it may be used.

2. **Transparency: Individuals should be able to understand how their personal data are used.** Individuals should be informed, in a manner that is appropriate and understandable to the relevant audience, regarding the type and extent of data collected about them, how it will be used (including, to the extent possible, secondary uses of data), how technologies are used to aid data-based decisions that impact them, how their rights (including the right to privacy) are protected, and what actions they may take to exercise their rights. Legally permissible limitations on such rights should be clearly explained. Data governance standards and practices should be made available for public review, when appropriate.

3. **Data quality: The best quality data available should be used to make decisions.** Data use should include processes to identify, prevent, and off-set poor quality, incomplete, or inaccurate data. When data quality, completeness, or accuracy presents risks of bias or harm to the individual, processes for the mitigating these risks should be pursued and documented.

4. **Fairness and non-discrimination: Data acquisition should be inclusive, equitable, and seek to support the industry's mission of responding to the needs of all patients.** Engaging a diverse set of stakeholders in decision-making around data use and development of technologies to leverage data can build trust and support efforts to eliminate harmful biases. Technologies leveraging data should also include data-driven processes for quantifying the potential for bias in the populations in which they are being deployed.

5. **Ethics by design: Controls to prevent harm and risks to individuals should be built into the design of data architecture and data processing.** This includes having processes in place to identify, assess, and mitigate risks of intentional and unintentional discrimination and bias, breaches in privacy and security, physical harm, and other adverse impacts on individuals. Protecting privacy also includes applying strong cybersecurity standards (as well as notifying individuals when their data is breached, where the risk to the individual is deemed high) and appropriately preparing the data for use (e.g., anonymization and pseudonymization techniques where relevant) and restricting re-identification of anonymized data without permission.

6. **Responsible data sharing: Data sharing should be based on processes that actively and consistently consider, prioritize, and protect individual rights.** Data should always be obtained by legitimate means, and there should be designated individuals accountable for protection and confidentiality of data. Third parties working with IFPMA members should be informed about and expected to adhere to these principles. In addition, data interoperability initiatives should prioritize, include, and support ethical and responsible data sharing practices.

7. **Responsibility and accountability: Data ethics principles should be operationalized through effective governance, clear standards, training, monitoring activities, and disciplinary sanctions.** Senior management should be aware, and ensure the application, of ethics principles in decisions around the use of data in strategic activities.

What happens next?

These principles are a starting point for each IFPMA member to consider how their internal processes, controls, operations, and policies should be adapted to incorporate data ethics and ethical decision-making around data.

However, exercising data ethics is an ongoing journey and will require sustained effort and commitment from IFPMA members, individuals, and the biopharmaceutical industry generally. Therefore, data ethics programs need to be routinely revisited to consider evolving technologies, specific applications, e.g., big data and AI, the regulatory environment, stakeholder expectations, and current understanding of the risks and benefits to individuals of data use.

As members incorporate Data Ethics into their activities now and in the future, they should use the framework provided by the IFPMA Ethos to build a culture of trust through demonstrating care, fairness, respect, and honesty.