Roche Data Ethics Principles

13 principles to guide ethical data use

Table of Contents

Roche Data Ethics Principles

Roche recognizes there is a person behind every data point and will treat data with the highest level of integrity and care. Roche aims to be a highly trusted data partner and a good data citizen (adhering to our data responsibilities) across the globe within the healthcare ecosystem and with regulatory bodies, Health Authorities, and most importantly, patients and research participants. A key part of achieving our aim is raising awareness of ethical behavior throughout the data lifecycle, from collection, use, overall management and storage across the development and commercialization of our products and technologies.

An essential starting point is Roche's peer-reviewed journal article, [The Evolution of Data Ethics in Clinical Research and Drug Development.](#) Following this, Roche has adopted 13 data ethics principles to guide our behaviour, incorporating principles from the [International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)](#). Our statement of principles excludes concepts relating to artificial intelligence (AI), deeming this complex topic worthy of a separate, future guidance document. Our data ethics principles align with our [corporate values](#) of integrity, passion, and courage.

1. Beneficence

Our use of data maximises social good.

The promise of expanding data use in clinical research and healthcare can only be fully realized if patients and research participants trust that their data will be used for good.

Roche aims for meaningful innovation when defining the purpose of our research and the use of the data we collect, as well as the data generated for patients by diagnostics instruments and other medical devices. Overall, the principle of beneficence supports the use of data in ways that promote health and well-being, preserve human dignity, and reflect stewardship of our planet. As an example, Roche was the first company to deliver clinical trial results to the International COVID-19 Alliance and Workbench, a coordinated platform to help researchers access data and speed up the development of COVID-19 treatments.

2. Autonomy

Respect individuals' consent, privacy, and protect their rights.

Data should be collected and used in ways that are consistent with the intentions and understanding of individuals and their choices about who has access to their personal data and how it may be used.

At Roche, we respect the voluntary nature of the research process and allow potential research participants to make informed decisions through a robust informed consent process. At Roche, we also respect the provision to withdraw consent for data use without prejudice to its legal obligation to ensure the safety and reliability of products in the interest of public health. We also make sure that the data generated by medical instruments are not shared or used without proper authorization.

3. Transparency

Individuals are informed to facilitate their understanding of how their personal data are used.

Promoting trust-building, individuals should be informed in a manner that is appropriate and understandable to the relevant audience. Legally permissible limitations on such rights should be clearly explained. Data governance standards and practices should be made available for public review, when appropriate.

At Roche, we work with industry and patient partners, academia, and governments to advance data literacy to empower patients and their caregivers with information to make informed decisions. Internally, Roche promotes a data culture & data literacy professional development. In order to facilitate understanding, details regarding the data processing are disclosed, including the following:

- the type and extent of data collected about them,
- how the data 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.

At Roche we use informed consent forms for research that include information about data collection, sharing, and management and these forms are written in lay language and approved by appropriate review bodies (e.g., regional research ethics committees). Data collection, management, and quality assurance are described in Roche clinical trial protocols posted for public viewing on ClinicalTrials.gov.

4. Data Quality

Fit for purpose, high quality data are used to make decisions.

Data use includes 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, processes for mitigating these risks should be pursued and documented.

At Roche, we employ Data Quality Leads to identify, design and execute fit-for-purpose data sources and management solutions, adhering to F.A.I.R. (Findable, Accessible, Interoperable, Reusable) principles as well as data quality principles within the ICH Guideline for Good Clinical Practice and the European Medicines Agency Data Quality Framework for EU Medicines Regulation [currently a draft under public review].

5. Data Integrity

We optimize our insights by promoting data integrity

Reliable data builds trust in our research. Data integrity is the overall accuracy, completeness, and consistency of data.

Roches aims to ensure the integrity of its clinical development data, including when there are changes to the computerized systems, such as software upgrades or migration of data. Roche is guided by the ALCOA+ principles and we use robust research and analysis methods that produce meaningful, trustable data. Everyone at Roche has a duty of care to perform their work with integrity (one of our core values). Best practices are used in the collection, use, and overall management of data from our patients and research participants. Our Code of Conduct sets the standards for our way of working and training and resources are provided to facilitate best practice. At Roche, appointed staff are responsible for programs governing compliance to all applicable regulations and guidance, both external and internal procedures.

6. Fairness, Non-Discrimination, & Justice

Data should be equitable, inclusive, and seek to support the mission of responding to the needs of all patients.

> In an effort to build trust and eliminate harmful biases, technologies should leverage data and include data-driven processes for quantifying the potential for bias in the populations in which they are being deployed.

Through its Roche Advancing Inclusive Research® (AIR) Position Statement, Roche aims for a world where all individuals have access to the best healthcare and in a future where science strives to be diverse, inclusive, and equitable. One example is the African Genomics Program, Roche and its partners are working to correct the dramatic imbalance in global genomic data and catalyze the creation of an open databank of meaningful genomic data for all Africans. Another project focuses on women's health for faster diagnoses. By revolutionizing how data is collected and shared at scale, disease burdens in historically overlooked populations can be addressed. Roche is also committed to a fair distribution of digital resources, aiming for the ability to use data and digital technologies with global presence and access. We work with our affiliates and partners to reach patients worldwide with the benefits that are derived from health data.

7. Ethics by Design

Controls to prevent harm and risks to individuals are built into the design of data architecture and data processing.
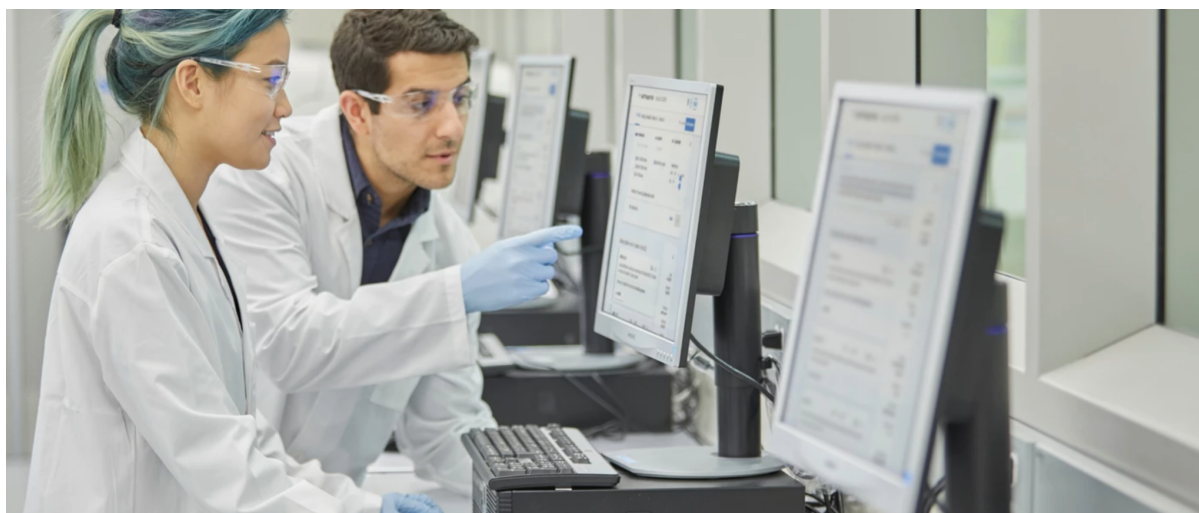
> This is a form of proactive ethics that should include having processes in place to identify, assess, and mitigate risks of harm during the collection, use, and management of data.

At Roche, we take proactive steps to understand potential risks involved in data collection, use and overall management, and employ risk mitigation strategies based on best practices. We have various departments including Bioethics, Compliance, Privacy, and Legal who work to prevent and respond to risks and harms associated with collecting, using, and managing sensitive data.

8. Responsible Data Sharing

Data sharing is based on processes that actively and consistently consider, prioritize and protect individual rights.

> Data should be obtained by lawful and legitimate means and there should be designated individuals accountable for safeguarding the data and ensuring confidentiality.

Third parties working with Roche are informed about and expected to adhere to these principles including through legally binding agreements. In addition, data interoperability initiatives prioritize, include, and support ethical and responsible data-sharing practices. Roche is a member of the non-profit Vivli, a global clinical research data-sharing platform that helps researchers responsibly share and access patient-level data from clinical trials to advance science. Also, Roche provides clinical trial data to the European Medicines Agency (EMA) for open-access data sharing.

9. Accountability

Monitoring, governance and disciplinary actions are operationalized.

> Accountability should be reflective, reasonable, and systematic in order to optimally protect personal data, reducing risks for the individual and mitigating social and ethical implications.

Roche views data ethics as a corporate strength and senior management supports the data ethics principles. Through robust compliance programs Roche monitors, learns lessons, and incorporates meaningful corrective action as appropriate. Roche encourages individuals to speak up if they have any ethical concerns, and follows up with appropriate investigations and remedies.

10. Proportionality

Data is collected with due consideration for risks and benefits, and the data is used in a purposeful manner.

> Proportionality should be applied such that only that personal data which is adequate and relevant for the purposes of the processing is collected and processed.

With respect to personal information, Roche works in ways aiming for only [necessary data collection](#) and fit-for-purpose contexts. Also, Roche understands that there can be limits to the meaningfulness of data and thus makes careful analyses and conclusions with the data we are entrusted with. A proportionate approach is taken across all data activities, including data ambitions, data uses, data partnerships, and data outputs. Key considerations assess whether data is necessary, desirable, suitable, adequate or appropriate to the circumstances and aim for the potential benefits to outweigh the potential impacts that data practices may have on individuals, populations, communities or society. As an example, Roche employs statisticians to help design research studies with appropriate methodologies and sample sizes, reflecting on risk benefits, and helping researchers analyze and interpret data for clinical significance.

11. Privacy

We respect the privacy of all individuals and act in accordance with relevant laws and regulations

> Privacy protection measures should appropriately prepare the data for use (e.g. through use of anonymization and pseudonymization techniques where relevant and appropriate), restricting re-identification of individuals from anonymized and pseudonymized data without permission including by the Roche Code of Conduct.

Roche has teams of local and global privacy experts to guide the creation and implementation of internal policy, as well as provide advisory and corrective action services. Roche uses Data Protection Impact Assessment (DPIA) as a process to help identify and minimize the data protection risks of a project.

12. Security

Data systems are designed to be secure

Reflecting on the harms of data breaches, data security should include reasonable steps to safeguard data from unauthorized or accidental access, processing, erasure, loss, or use.

Roche applies strong cybersecurity standards, including having processes in place to identify, assess, and mitigate risks of breaches in security, and notifying individuals when their data is breached. Roche has teams of local and global data security experts to guide the creation and implementation of internal policy, as well as provide advisory and corrective action services.

13. Sustainability

Data is processed efficiently across the life cycle to ensure a small carbon footprint.

Digital services should be designed with efficiency and operational such that they can have a positive long-term effect on users.

Roche aims to eliminate waste, optimise networks and data transmission, and drive efficiency in workload management (including eliminating unnecessary duplication of development efforts). At Roche, a group exists to support an ecosystem of platforms and tools that include providing carbon footprint updates to users.

This position statement was created by Roche's Data Ethics Workstream on 2 December 2022.
It was reviewed and adopted on 15 March 2023.