

Roche's Position on Responsible Sharing of Scientifically Credible¹ Information

Background and Purpose

In the era of data-driven medicine and diagnostics and given the large volume of available health information, healthcare providers, regulators, payers and, increasingly, patients are looking for easily accessible / digestible scientific information about the effectiveness, safety and value of healthcare solutions. Specifically, these groups expect healthcare companies to share their latest scientific evidence in a timely and transparent manner.

At Roche, we continually collect, use and generate scientific information, data and analyses that benefit patient care and enhance the healthcare system. We share this scientific information in a number of ways, e.g. submissions to regulators and payers, multi-channel approaches with physicians and other healthcare professionals as well as patient-oriented communication in lay language.

The purpose of this position paper is to describe Roche's commitment and principles underlying its responsible sharing of scientifically credible information.

Roche's Position

Commitment and Intent

As one of the world's leading research-based healthcare companies and as a trusted partner, Roche is fully committed to provide a wide range of high quality and up-to-date *transparent* and *science-based* information on our products, solutions and services.

In particular, such information shall be *timely, accurate, unbiased, balanced* and *comprehensive* in terms of content and format to enable (a) physicians and other healthcare professionals to make better-informed medical decisions and achieve the best possible treatment outcomes, and (b) patients to understand scientific evidence and play an active role in decision-making around their care.

Key Principles

To support the optimal use of scientific information for patient care, Roche adheres to the following key principles:

- Evidence-based Information: Roche communicates information that is *factual* and based on *scientifically credible* evidence originated from a verifiable source and generated through applying rigorous science-based principles. These include formulating research questions and

¹ *Scientific Credibility is the extent to which the research, data and information is recognised as accurate and originating from a reliable and verifiable source, and the extent to which the process used to assess and evaluate the accuracy and reliability of information adheres to rigorous scientific principles.*

objectives, performing careful research planning, generating or collecting fit-for-purpose data, conducting the appropriate analyses based on a predefined analysis plan followed by reporting all results.

- Accurate Representation of Data: Roche communicates scientific information ensuring that data are represented accurately. This includes disclosing *limitations* of the data and the statistical and analytical methodologies used.
- Appropriate Context about Data and Outcomes: Roche provides the necessary additional information about the data and research outcomes presented to ensure that accurate conclusions can be made. This may include, for example, epidemiological considerations (e.g. population size, geography, etc.) or the existence of discrepancies with other known evidence.

Approach to Sharing – Tailored and Referenced

At Roche, we endeavour to *tailor* our approach to scientific information sharing to the intended audience to ensure it is *understandable*, *fit-for-purpose* and is *aligned* with its communication preferences. We do it transparently, in context and with appropriate disclaimers to protect patient confidentiality.

Therefore, when communicating evidence, we provide all necessary information allowing the respective audience to evaluate, fully and fairly, the relevance and significance of the shared scientific information in line with relevant international standards^{2,3} and with the patient's best interests at the centre. Such information is dependent on several factors, including:

- The needs and preferences of the target audience
- The complexity of the information presented
- Limitations induced by existing regulations and confidentiality (e.g. Data Protection regulation, Intellectual Property Law, etc.).

In its endeavour to disclose scientific information that is timely, accurate, unbiased, balanced and comprehensive, Roche appropriately *references additional sources* for more comprehensive information, such as:

- Data from clinical trials⁴
- Evidence from real world data activities⁵
- Post hoc analyses of clinical trial results, including sub-population analyses
- Health Economic information
- Prescribing Information for Roche products.

In summary, we believe that our cutting edge and innovative medicines and diagnostics, coupled with the responsible sharing of scientifically credible information as outlined herein, are positively transforming patient care.

² Good Publication Practice for Communicating Company Sponsored Medical Research (GPP3)

³ Principles on Responsible Sharing of Truthful and Non-misleading Information about Medicines with Health Care Professionals and Payers (PhRMA)

⁴ Roche Global Policy on Sharing of Clinical Study Information

(<https://assets.cwp.roche.com/f/126832/x/2c1e1e3ad5/roche-global-policy-on-sharing-of-clinical-study-informationv2-1-april2020-1.pdf>)

⁵ Roche's Position on Access to & Use of Real World Data

(https://assets.cwp.roche.com/f/126832/x/ce0081f641/position_access_use_real_world_data.pdf)

This position paper was proposed by the Sustainability Steering Committee and adopted by the Corporate Executive Committee in May 2022 and entered into force the same day.
