

Teva's
Policy on
Clinical Trial
Transparency
& Disclosure

Teva Pharmaceutical Industries Ltd, including all its directors, executives, employees and subsidiary and affiliated companies (hereinafter “Teva”), is committed to offering innovative healthcare solutions to improve patient health and treatment outcomes. Clinical trials (studies) are essential to this innovation, as they support the development of new medicines and the progress of evidence-based medicines. Teva ensures that the critical data from our clinical trials are handled with the utmost care and protection to promote patient safety, data quality, and integrity.

Our clinical trials comply with all global regulations regarding clinical trial registrations and results disclosures. We prepare redacted clinical reports and supporting documents in order to be compliant with Health Canada’s Public Release of Clinical Information, EMA Policy 0070 and EMA Policy 0043, respectively. We also comply with international guidelines and regulations fundamental to clinical research and drug development around the world, including the Declaration of Helsinki and the ICH guidelines on Good Clinical Practice (GCP). This focus on compliance ensures our clinical trials are well-designed and carefully conducted to support participants enrolled in them.

We also have a comprehensive set of processes and policies defining the way we conduct, monitor, collect and review data and oversee our studies, assuring studies (trials) are conducted according to guidelines and relevant local regulations. This is fundamental to our approach to leading a responsible business and consistent with our mission, values and Code of Conduct.

We educate, inform and engage in dialogue with employees to ensure all those covered by this policy are aware of our expectations and their responsibilities.

Our Clinical Trials Transparency Aspiration, Approach and Commitments

Registration: Phase I-IV clinical trials are registered on [ClinicalTrials.gov](https://clinicaltrials.gov), [ClinicalTrialsRegister.eu](https://clinicaltrialsregister.eu), [EUClinicalTrials.eu](https://euclinicaltrials.eu) or a national register, as applicable per regulatory requirements. Teva registers expanded access studies on ClinicalTrials.gov, as available by product. Non-interventional post-authorisation studies are registered on the EU PAS register, hosted on ENCePP.eu, if applicable. We also register additional clinical trials using Teva Specialty Branded products in accordance with the [IFPMA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases](#).

Participant protection: The informed consent process is required for all clinical trials conducted in human participants. The process ensures the participant understands the study purpose, potential benefits and risks and alternative treatment options. It also helps them decide whether they want to participate in the study. Participants have an opportunity to ask questions about the study before deciding whether to participate. In addition, all clinical trial participants are monitored by the study doctor for safety information and health changes. An ethics committee or Institutional Review Board (IRB) reviews study information and study conduct to ensure appropriate procedures are followed. We also endeavor to best ensure that participant privacy, including protected personal data, is respected and protected during transparency and disclosure activities.

Trial results: Summary results of phase I-IV clinical trials are disclosed on public web sites such as [ClinicalTrials.gov](https://www.clinicaltrials.gov), [ClinicalTrialsRegister.eu](https://www.clinicaltrialsregister.eu), [EUClinicalTrials.eu](https://eucclinicaltrials.eu) or a national register as required per regulations. We also aim to prepare summary results for additional clinical trials using Teva Specialty Branded products in accordance with the [IFPMA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases](#).

Plain language summaries: In addition to the trial results posted as per the above, Teva shares simple summaries of the clinical trial results. These summaries are posted on our clinical trial web site and on [EUClinicalTrials.eu](https://eucclinicaltrials.eu), when required, for applicable clinical trials conducted using Teva Specialty Branded products.

Data sharing: Teva is committed to sharing clinical trial data with qualified researchers for approved Teva Specialty Branded products. We will also consider requests for clinical trial documents (e.g., redacted protocol) if needed to accompany data requests. Before deciding whether to share participant-level or study-level clinical trial data, Teva considers the scientific merit of the proposed research, protection of clinical trial participant information, results publication plan and protection of commercially-confidential information, and other relevant factors. Teva also shares synopses of clinical study reports for clinical trials using Teva Specialty Branded products in accordance with our commitments under the [IFPMA](#) and [EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing](#).

Publications: Teva is committed to submitting all phase III clinical trials and clinical trial results of significant medical importance for publication regardless of whether the results are positive or negative under the [IFPMA Joint Position on the Publication of Clinical Trial Results in the Scientific Literature](#). When possible, these results will be submitted to peer-reviewed journals no later than 18 months after the completion of the clinical trial for already marketed products or regulatory approval or discontinuation for investigational products.

Contract Research Organizations (CROs) expectation: At Teva, we work with CROs to conduct most of our clinical trials; these organizations are referred to as Third Party Representatives (TPRs). Each TPR must adhere to Teva's ethical business standards, which are included in their contracts, and to Teva's TPR policy (which refers to Teva's Code of Conduct). In certain cases, we train the CROs on Teva's ethical guidelines and request certification.

Management: Teva utilizes a full outsourcing model to manage our clinical trials worldwide. Teva Clinical Program Managers are responsible for managing and overseeing the outsourced activities.

Application of this Policy

This policy is supported by internal procedures that ensure our commitments are upheld, including periodic audits. We communicate this position to our employees and on our website, and we share our progress in our annual Social Impact Report.