# CLINICAL TRIALS POLICY

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**Approved by: Chief Compliance Officer and the Compliance Management Committee**

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# Clinical Trials Policy

## 1. Purpose

This policy sets forth the policies governing the sponsorship of, or participation in, clinical studies by Bausch Health Companies Inc. (BHC), including all its subsidiaries and divisions ("Bausch" or "Bausch Health"). The purpose of this policy (the "Policy") is to ensure that Bausch Health-sponsored clinical studies comply with all applicable federal healthcare program requirements, FDA and other relevant local regulatory requirements, including Good Clinical Practice ("GCP"), and other Bausch Health Policies.

## 2. Scope

Bausch Health may retain Healthcare Professionals and academic organizations to perform Bausch Health-sponsored clinical studies. Sponsored studies are designed and conducted, or supervised, by Bausch Health.

This Policy is applicable to all clinical studies (Phase I – Phase IV) that are sponsored by Bausch Health, whether conducted in the United States or abroad, which are undertaken to support drug or device approval by the FDA. This Policy also applies to all Phase IV studies conducted post approval to support company goals and objectives specific to the drug or device. It does not apply to studies conducted in foreign countries that are intended to support marketing authorization only in countries other than the United States.

This Policy applies to all Bausch Health employees and agents and all parties with whom Bausch Health contracts (e.g., contract research organizations ("CROs"), vendors, or consultants), who are involved in Bausch Health-sponsored clinical studies. The Company's Chief Medical Officer is responsible for oversight and implementation of this policy, and for ensuring clinical trials adhere to the Company's ethical standards.

Bausch Health also provides financial support for independent third-party studies or Investigator-Initiated Studies (IISs). Although Bausch Health may provide funding for these supported studies, it either does not actively participate in them (in terms of designing, conducting, supervising, or monitoring the studies) or its participation is limited. This Policy does not apply to such studies. For information regarding Bausch Health-funded but not sponsored studies, see the U.S. Policy on Grants and Investigator-Initiated Studies.

## 4. Definitions

### Contract Research Organization (CRO)

A person or an organization (commercial, academic, or other) contracted by Bausch Health to perform one or more of a trial-related duties and functions. Bausch Health may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with Bausch Health.

**Healthcare Professional (HCP):**

For the purpose of this Policy, Healthcare Professional ("HCP") includes licensed medical practitioners, medical staff members involved in providing patient care, including, but not limited to, physicians, nurses, nurse practitioners, physician assistants, medical assistants, office technicians, dentists, dental assistants, dental hygienists, medical residents, pharmacists, and other individuals in the position to arrange for or recommend Bausch Health products.

**Fair Market Value (FMV):**

The price to be paid for a legitimate service under normal market conditions. For certain services, the Ethics & Compliance Department maintains Fair Market Value ("FMV") rate cards reflecting the approved value that employees may pay to HCPs who perform work on our behalf.

## 5. Commitment to Research Integrity

Bausch Health is committed to designing and conducting clinical studies in accordance with the highest scientific and ethical standards and in compliance with all applicable regulatory requirements.

## 6. Scientific Purpose of Research Activities

Bausch Health activities relating to the sponsorship of, or participation in, clinical studies ("research activities") must be directed by the Research and Development Department. Sales, marketing, and other commercial employees may provide input on general research areas that might be of commercial interest to Bausch Health and may be appraised of new research findings and the status of studies, but they may not otherwise be involved in the conduct of studies. All requests from HCPs for information about Bausch Health's research activities should be handled in accordance with Bausch Health's U.S. Medical Information Requests Policy.

### a. Business Needs Assessment

A "Business Needs Assessment" is required for Bausch Health sponsored Research related activities (including Phase IV clinical trials and Post Marketing Surveillance/ Registry studies). The Business Needs Assessment may or may not be a part of the annual budget plan and review. This requirement is part of Bausch Health's commitment to ensure compliance in all aspects of our business.

### b. Process to Develop Business Needs Assessment

As part of the Business Needs Assessment Process, the relevant Clinical Product Teams (CPTs) should establish Clinical Strategies, Objectives, Goals and Plans for assigned brands and prioritize lists of Research activities for approved strategies. The US CPT should identify the business or scientific need and the estimated number of the various Research engagements to occur during the year as well as the budgeted amounts to be spent on those activities. In addition, prior to the retention of a Researcher, Bausch Health shall ensure that a needs assessment has been completed to justify the retention of the Researcher.

Predefined templates (for Research activities) should be created and completed by each CPT, for each product, to document tactical plans including budgets and business need(s) for each activity. The template should include, at minimum:

- Study description or Objective
- Business impact (example: new indication, confirmatory study, regulatory request, safety, etc.)
- Anticipated risks and mitigation activities of the study
- Planned study budget
- Number of Investigators (planned)
- Study Duration

### c. Business Needs Assessment Plan Review and Approval

The Clinical Unit Head, or designee, should review and approve the Business Needs Assessment Plan. During the normal course of business, throughout the year, changes or revisions in tactical details or budgets may occur. Deviations or changes from the annual approved plan for Research activities shall be documented and subject to re-approval.

All data used to justify or validate the Needs assessment in the tactical plan should be appropriately archived and retrievable in the event of an audit. Approvals and approved plans by product will also be archived.

### d. Requests for Research Funding

All requests for clinical research support must be referred to R&D for evaluation. Sales, marketing, or other commercial employees are not permitted to:

- Attempt to influence medical or regulatory affairs to hire particular clinical investigators based on the potential impact on Bausch Health's sales;
- Commit to, or provide funding for, clinical research;
- Supply drugs or devices (including starters/samples) directly to HCPs including clinical investigators for use in clinical studies; or
- Assist clinical investigators in recruiting patients for Bausch Health-sponsored clinical studies.

For information pertaining to Bausch Health-funded Investigator-Initiated Studies, see the U.S. Grants and Investigation-Initiated Studies Policy.

### e. Selection of Clinical Investigators

Conducting a Bausch Health-sponsored clinical study can potentially be a valuable opportunity for HCPs. The selection of a particular HCP to serve as a clinical investigator for Bausch Health could therefore pose risks under healthcare laws if done for the wrong reasons. Thus, such selection and subsequent interactions with the HCP must be in compliance with all applicable federal laws and regulations.

As is the case with all financial interactions between Bausch Health and HCPs, it is illegal to attempt to influence an HCP's prescribing or purchasing practices by providing financial incentives. Bausch Health therefore cannot take an HCP's prescribing or purchasing behavior into account when deciding whether or not to engage him or her as an investigator unless it is deemed necessary to the research activity as part of the consideration of whether an HCP has expertise in a particular clinical area.

Bausch Health can never engage an HCP as a clinical investigator in order to:

- Establish or improve Bausch Health's relationship with an HCP;
- Gain or improve access to a particular HCP;
- Reward past prescribing or purchasing behaviors; or
- Induce future prescribing or purchasing behaviors.

Bausch Health must ensure that the financial arrangements, design and methodology, and source of control of the study design and publishing do not call into question the bona fide scientific purposes of the research activity.

## 7. Research Activity-Related Compensation

Bausch Health should ensure that the following guidelines are implemented in establishing appropriate financial arrangements between Bausch Health and clinical investigators:

- **Payment for Services:** Any payments for research services should not exceed the fair market value of the services rendered. To the extent possible, the payment should be specified in the aggregate. "Milestone" payment structures should be used for larger projects, when possible, to ensure that the services outlined in the contract are actually performed. Payments should also be structured so as to avoid any incentive (real or apparent) to enroll inappropriate study subjects. Informed consent forms should disclose to study subjects that the investigator, his/her institution, and staff may be receiving payment from Bausch Health for services related to the study. All financial arrangements pertaining to a clinical study should be in writing using Bausch Health's clinical study agreement template.

- **Service Specificity:** The research arrangement should specify the services to be performed by the researcher and the "deliverables." Services should be substantive in nature and involve more than minimal recordkeeping and should not involve activities that the service provider is already required to perform.

- **Supply of Study Product:** It is Bausch Health's policy to provide free drug or device for use by subjects participating in its clinical studies. In exceptional circumstances, such as where a study is observational or where a study involves a drug or device that is the established standard of care for the use at issue, Bausch Health might be permitted to use commercial product, but only with the approval of the Legal Department and Regulatory Affairs Department.

- **Selection of Researchers:** Researchers will be selected based on their expertise, not on their ability to influence sales (e.g., by virtue of membership on a formulary committee). To the extent possible, expertise should be expressed in terms of training and years of therapeutic experience, as opposed to number of patients treated with alternative treatments.

- **Study Size:** Research studies should be no larger than necessary to obtain the desired information. Study size should be determined on a justifiable and rational basis.

- **Study Substance:** In all cases, research and other services should be bona fide, conducted pursuant to an appropriate protocol, and designed to elicit useful information. Where clinical issues are being evaluated, medical and scientific employees should provide input on protocols and related documents. Sales, marketing, and other commercial employees may provide input on general research areas that might be of commercial interest to Bausch Health but will not otherwise be involved in the design and conduct of clinical studies.

### a. Fair Market Value Process for Research-Related Activities

Bausch Health uses a Fair Market Value calculation to determine fees paid for various Research Activities. Protocols and amendments should make use of benchmarking cost data from Bausch Health's historical research data as well as industry benchmarks in developing the budget template. The 50th percentile (median) cost data should be used as the target and should be used to calculate a cost per patient. Negotiations may begin at the 50th percentile or lower and Bausch Health should implement an approval matrix process for budgets and exceptions above the 50th percentile. Documentation of this approval must be archived within the trial master file.

## 8. Conducting Clinical Trials

As previously stated, Bausch Health will ensure that all research activities comply with applicable federal healthcare program and FDA requirements and other applicable local regulatory requirements, including GCP. All protocols are reviewed and approved by designees within the Research and Development Department. In addition, the status of ongoing clinical studies is reviewed at the research and development review meetings. This policy also incorporates the guidelines set forth in PhRMA's Principles on the Conduct of Clinical Trials and Communication of Clinical Trial Results, which were last revised in 2020. Summarized below are Bausch Health's policies with respect to key requirements applicable to the conduct of clinical studies.

### a. Investigational New Drug Application and Investigational Device Exemptions

Prior to initiating a clinical study, Bausch Health must submit the requisite investigational new drug ("IND") application to the FDA or applicable local regulatory application in the country where the trial will be conducted, describing the pharmaceutical product that Bausch Health proposes to study, as well as the study design, protocols, and other relevant details, unless the study is exempt from requiring

an IND or other regulatory filing. For U.S. studies, a non-exempt Bausch Health-sponsored study may not begin until thirty (30) days after the IND has been received, unless earlier written authorization has been received from FDA. A study may not proceed if FDA has imposed a clinical hold on the study (unless and until the hold has been lifted by FDA).

**b. Compassionate Use of Unapproved Drugs and Devices**

Bausch Health may consider requests for "compassionate use" of an unapproved product in cases where the potential risks and benefits to a patient can be evaluated on the basis of meaningful human clinical data. In addition, the compassionate use may not jeopardize enrollment in ongoing Bausch Health-sponsored studies, or otherwise disrupt an ongoing Bausch Health drug or device development program, and there must be available supply of the investigational drug or device. Bausch Health will consider for compassionate use only patients who:

- Suffer from a serious or life-threatening disease condition;
- Have exhausted all standard treatment options without success (or who have a disease for which no standard treatment exists); and
- Do not qualify for any ongoing clinical studies.

The patient's HCP must agree to:

- Direct the administration of the investigational drug or device under Bausch Health approved protocol or guidelines that includes Bausch Health data collection procedures, or under an investigator-sponsored protocol or approved standard of care with specified data sharing to Bausch Health (including safety information);
- Conduct the study in accordance with all applicable laws and regulations; and
- Conduct the compassionate use under appropriate ethical standards (including institutional review board review) and informed consent.

The role of evaluating compassionate use requests rests with the Chief Medical Officer or designee.

**c. Registry and Post-Marketing Surveillance Studies**

**Registry:** A prospective observational study of patients with certain shared characteristics (e.g., particular disease, exposure, or risk factor), that collects ongoing and supporting data over time on well-defined outcomes of interest for analysis and reporting. Properly designed and executed, registries can provide a real-world view of clinical practice, patient outcomes, safety, and comparative effectiveness.

**Post Marketing Surveillance**: Not all Phase IV studies are Post Marketing Surveillance (PMS) studies, but every PMS study is a phase IV study. Through PMS, the real-world effectiveness of a drug, as evaluated in an observational, non-interventional trial in a naturalistic setting, supports the efficacy data that is generated from a pre-marketing randomized controlled trial. Often, the safety profile of a drug is characterized only by continuing safety surveillance through a spontaneous adverse

event monitoring system and a post-marketing surveillance/non-interventional study. Further evaluation of a new indication may necessitate regulatory action (change in labeling, risk management/minimization action plan, etc.).

Additionally, these types of studies require a Needs Assessment and FMV determination. Refer to Sections 6 and 7 of this document.

### d. Institutional Review Board Requirement

A qualified institutional review board ("IRB") or local ethics committee ("EC") must review and approve all Bausch Health-sponsored studies prior to initiation. IRBs or ECs enlisted to review Bausch Health protocols must be independent from Bausch Health, and their membership must comply with applicable health authority requirements. No subjects may be enrolled in a Bausch Health-sponsored clinical study until the IRB or EC provides written authorization for the study to begin. The IRB/EC has the right to approve changes to an in-process study. The IRB/EC cannot provide approval or determinations for research that has already been concluded.

### e. Protocol Inclusion and Exclusion

Clinical study protocols must define medically sound eligibility criteria for subjects entering the study and must ensure that the study population is medically appropriate for the study objective. All subjects should satisfy all eligibility criteria, and all study specific procedures and assessments should be performed as described in the protocols and in accordance with the study's scientific goals.

Bausch Health is committed to conducting inclusive and diverse clinical trials and reducing barriers to clinical trial access.

### f. Informed Consent (IC)

All informed consents (IC) should comply with the applicable regulatory requirement(s) and should adhere to GCPs. Prior to obtaining a subject's consent, the informed consent should have the IRB/EC's written approval of the informed consent and any other written information to be provided to subjects.

Subjects may be enrolled in a clinical study only after providing their free, prior, and informed consent. Disclosure of the material risks associated with participation in the study must be given, and potential subjects must be offered the opportunity to discuss those risks and the availability of other treatments with the investigator and/or qualified study staff.

For subjects incapable of giving informed consent (e.g., pediatric subjects), the assent of the subject (when possible) and the informed consent of a legally authorized representative is required, and the representative should receive a copy of the signed consent paperwork.

All research participants have the right to withdraw from clinical study participation at any time without penalty or loss of benefits to which they are otherwise entitled.

### g. Privacy and Confidentiality

Bausch Health must respect the privacy rights of its research participants and safeguard the confidentiality of their medical information in accordance with all applicable laws and regulations. Any access by Bausch Health, regulatory authorities, or other researchers to patient information must be granted by a patient authorization form compliant with the laws of the country in which the patient resides. For the United States, patient authorization forms must be compliant with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA-compliant patient authorization forms will be necessary to authorize disclosure of coded study information and to grant access to un-coded information in appropriate circumstances (e.g., to follow up on serious adverse events).

### h. Compensation of Study Subjects

Bausch Health may provide financial compensation for study subjects to participate in a clinical study, provided that the compensation is non-coercive. Any proposed study subject payment must be reviewed and approved by an independent IRB or EC. The size of payments and the payment structure should be reviewed to ensure they are reasonable, and not coercive. Compensation cannot be made wholly contingent upon the subject's reaching a milestone, such as completing the study, because that could be coercive. However, a reasonable payment may be made to subjects who reach specified milestones.

A reasonable stipend may be paid to study subject to cover costs associated with meals, travel, and the like. The stipend may be paid in advance or in arrears in periodic increments, as appropriate.

Bausch Health may also provide token thank you gifts—with a monetary value of $25 or less—to study participants, but there may not be any contingencies associated with the gift, and any gift given to a study participant must be approved by the IRB or EC.

Subjects should be permitted to withdraw from the study without forfeiting any of the payments that were due to them up to that point. The subject's right to sue in case of injury cannot be waived in exchange for additional compensation.

### i. Standard of Care and Use of Placebo Controls

Whenever a Bausch Health-sponsored clinical study involves a control group, whenever possible, the control must be either an established effective treatment that is medically and ethically appropriate for the study or, where appropriate, a placebo.

In all cases, the IRB or EC must review the appropriateness of the proposed treatment for the control group.

### j. Contract Research Organizations

In circumstances where Bausch Health delegates certain responsibilities to a CRO, the ultimate responsibility for the quality and integrity of the trial data always resides with Bausch Health. The CRO should implement quality assurance and quality control. Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing. Bausch Health should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and

functions that are subcontracted by the CROs. Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by Bausch Health.

### k. Policy on Emerging Technologies

As of the date of this Policy, Bausch Health does not conduct research utilizing stem cell, nanotechnology, or genetic engineering. Bausch Health acknowledges the ethical issues posed by research involving these and similar emerging technologies. Should we begin conducting research utilizing such technologies in the future, we are firmly committed to maintaining the highest ethical standards for such activity.

### l. Animal Testing Policy

Bausch Health is committed to limiting the use of animals in research whenever possible. We prioritize non-animal research, including computer simulations and in vitro testing when feasible. When animal testing is required in order to develop safe and effective Company products, we are committed to utilizing the absolute minimum number of animals necessary in order to obtain our research objectives.

### m. Responsibilities of the Study Team at the Investigative Site

It is Bausch Health's duty to design, conduct, and monitor all Bausch Health-sponsored clinical research to ensure that the rights and safety of study subjects are protected. Investigators and study staff must be trained on the clinical study protocols, the product(s), and procedural issues associated with the conduct of the study. Any suspected material violations from Bausch Health's clinical study protocols must be promptly investigated and appropriate remedial action taken. All research participants must also be informed of the mechanisms for raising any grievances pertaining to the conduct of a clinical trial.

While Bausch Health may transfer specific sponsor obligations or study functions to a CRO, the ultimate responsibility for the quality and integrity of study conduct and data resides with Bausch Health. Refer to the Research and Development Standard Operating Procedure on Vendor Oversight.

### n. Quality Assurance

Procedures are followed to ensure that trials are conducted in accordance with good clinical practices and that data are generated, documented, and reported accurately and in compliance with all applicable requirements.

### o. Monitoring and Recordkeeping

The requirements of this Policy apply to all trials conducted by or on behalf of Bausch Health. Bausch Health regularly monitors its trials for compliance with this Policy, regardless of whether the trial is being conducted by the company or by CRO partners.

Appropriately trained and qualified individuals must monitor Bausch Health clinical studies and verify compliance with good clinical practices, adherence to protocols, enrollment of appropriate study subjects, and the accuracy and complete reporting of clinical study data. If Bausch Health learns of deficiencies on the part of a clinical

investigator, it must work with the investigator to remediate, or it may discontinue the investigator's involvement in the study and report the issue to the relevant authorities.

All Bausch Health investigational products must be tracked and controlled from the time they leave Bausch Health through to their use, appropriate disposal, or return to Bausch Health. Records documenting the control of investigational product must be established for all Bausch Health-sponsored clinical studies. Records must be kept and archived in accordance with applicable regulatory requirements and Bausch Health record retention policies.

Payments or transfers of value of any kind (such as meals, expenses and honoraria) made to Primary Investigators directly or through a third party, such as a CRO, must be tracked and provided to the Compliance Department to enable Bausch Health to meet its payment reporting obligations.

### p. Data Safety Monitoring Board

Bausch Health may use a data safety monitoring board ("DSMB") to monitor randomized clinical studies with mortality or major morbidity as primary or secondary endpoints, studies where participants may face an elevated safety risk, and other studies where an independent review of study data is warranted. Establishment and conduct of the DSMB will follow federal and local requirements.

### q. Post-Study Care

Prior to initiating a clinical study, Bausch Health must determine the appropriateness, relevance, and feasibility of continuing to supply the investigational product and/or alternative therapies (e.g. as in an open-label extension protocol), or necessary follow-up care to study subjects after the conclusion of the study.

### r. Clinical Study Registration, Reporting, and Publication

Bausch Health is committed to the timely disclosure of data from clinical studies, other than Phase I studies, of Bausch Health's investigational or marketed products. Bausch Health will report study results in an objective, accurate, balanced, and complete manner. Any report of a Bausch Health-sponsored clinical study will discuss the study's limitations and will disclose Bausch Health's financial support.

Bausch Health will register and report clinical study results in accordance with applicable national and local state law requirements, including posting all required clinical study data at www.clinicaltrials.gov or other applicable clinical trial registries for studies conducted outside of the U.S.

Investigators who participated in a Bausch Health-sponsored clinical study may want to review relevant statistical tables, figures, and reports for the entire study. Provision of this information may be subject to reasonable limitations on use, which will be communicated to the investigators at the time the information is provided.

Bausch Health is committed to the publication of clinically meaningful clinical study results in credible databases or peer reviewed journals. Details of Bausch Health's

authorship and publication policies may be found in the Bausch Health's U.S. Publications Policy.

## 9. Training

Employees who participate in clinical trial activities shall receive training on this policy on at least an annual basis.

## 10. Review of Policy

The Chief Compliance Officer or his or her designee will periodically review this policy and update as necessary. Failure to comply with this policy may result in disciplinary procedures up to, and including, termination in accordance with Bausch Health's U.S. Compliance Investigations, Employee Discipline, and Corrective and Preventive Actions Policy, as well as immediate termination of the arrangement.

## 11. Related Policies and Procedures

Please see the following Bausch Health Companies Policies for more information:

- U.S. Grants and Investigator-Initiated Study Review Process Policy (BHC-USCMP-011)
- U.S. Publications Policy (BHC-US-CMP-014)
- U.S. Medical Information Requests Policy (BHC-US-CMP-009)
- U.S. Healthcare Compliance Policy (BHC-US-CMP-001)
- U.S. HIPAA Policy (BHC-US-CMP-019)
- U.S. Privacy Policy (BHC-US-CMP-021)
- U.S. Compliance Investigations, Employee Discipline, and Corrective and Preventive Actions Policy (BHC-US-CMP-006)
- SOP on Investigator-Initiated Study Review Process (BHC-US-CMP-SOP-107)

## 12. Questions

Questions about this Policy should be directed to the Chief Medical Officer or the Ethics & Compliance Department.