GLOBAL CORPORATE POLICY

CLINICAL TRIALS

DATA SHARING AND PUBLIC INFORMATION DISCLOSURE POLICY

Effective date	July 2024
Approved use	

Content

1. Purpose

Almirall is committed to disclosing clinical trial information to be compliant with the format and timelines requirements of the Health Agencies and International Committee of Medical Journal Editors (ICMJE).

Clinical trials will be registered before starting the study by means of public registry databases such as ClinicalTrials.gov and CTIS/EudraCT or any other National registries as required and published in leading biomedical journals.

Summary of results, including Plain Language Summaries will be reported on registries such as ClinicalTrials.gov, European Clinical Trials Database (EudraCT), and/or the EU CTIS. Procedures will be followed to ensure results are reported in compliance with applicable laws and regulations.

Almirall is also committed to disclosing clinical trial information and sharing clinical trial data with independent researchers, patients and healthcare professionals to conform with internationally accepted scientific and ethical standards.

Almirall has implemented the policies recommended in the EFPIA/PhRMA Joint Position Papers on the Disclosure of Clinical Trial Information via Clinical Trials Registries and Databases and the Principles for Responsible Clinical Trial Data Sharing.

Additional details about the procedures to be followed when disclosing clinical trials information will be described in the applicable SOP (PRC 0001249).

2. Scope

The policy applies to all personnel involved in the management of clinical study information from Almirall SA-sponsored studies conducted by Global Clinical Development or Global Medical Affairs and Market Companies-sponsored clinical studies.

Global Medical Affairs will oversee the policy compliance for clinical studies conducted by the Market Companies.

3. Policy elements

Almirall will disclose clinical trials in a manner consistent with applicable national laws and rules governing personal data privacy and protection of intellectual property rights. Clinical trials activity will be registered, and results disclosed by means of recognized public databases such as Clinicaltrials.gov in the US, and CTIS /EudraCT in EU.

Almirall will attend to any individual level data requests from qualified scientific and medical researchers from medicines and indications approved in the United States (US) and the European Union on or after January in 2014. Following the approval process of the request, all data to be provided will be anonymized and any supplementary documentation will be redacted to protect both data privacy and confidential commercial information.

Almirall is committed to EFPIA / PhRMA's Joint Position on the Publication of Clinical Trial Results in the Scientific Literature publication. Therefore, at a minimum, all Phase III clinical trials will be published irrespective of whether the results are positive or negative. Clinical trials other than Phase III are required to be publicly registered in accredited public database before study initiation whenever the intention is to publish the results in a peer-reviewed journal.

Before submitting any public information that may have implications for Almirall's product intellectual property rights, the main/principal Almirall author, has an obligation to ensure that contents have been reviewed and approved by Intellectual Property Team.

Almirall's R&D website will inform the public about this policy and will provide basic information about Almirall clinical trials activity with reference to the public websites where Almirall is registering clinical trials and reporting study results. Any specific clinical trials information request regarding individual patient data or documentation will be also attended into Almirall web. (Contact Us | Almirall).

4. Governance

This policy requires a governance process to maintain compliance. A core team with representants from Intellectual Property, Regulatory Affairs, Global Clinical Development and Global Medical Affairs departments will assess and communicate to the Sponsor and Owner of this policy the impact of any new regulatory demands or practices. Core Team members will review this policy every 4 years.

The involved departments will allocate the necessary resources and processes to ensure alignment, consistency, and adherent application of this policy.

Corporate Policy Sponsor: [title/position]: CHIEF SCIENTIFIC OFFICER·EXECUTIVE DIRECTION R&D		
Corporate Policy Owner: [title/position]: VP, GLOBAL CLINICAL DEVELOPMENT·GLOBAL CLINICAL DEVELOPMENT		
Overview of changes	Version	Effective Date
New Sponsor title/position		
New Owner title/position		
Policy reviewed and updated according to the new Policy Template		
Governance structure has been simplified and 4 years for policy review has been specified		

All employees are required to report any suspected violation of the Corporate Policies in accordance with Almirall Code of Ethics and other internal guidelines. Suspected violations can be reported to your direct manager, People & Culture, your local Compliance or Legal representative or through the SpeakUp! channel.

5. Appendices

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