

	Laboratorios Farmacéuticos Rovi S.A. y sociedades dependientes	Version 2.0
	DATA TRANSPARENCY POLICY	Approval Date: 01.08.2024

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1.- INTRODUCTION

ROVI GROUP has a clear commitment to regulatory compliance, ethical behavior and transparency, a commitment that is reflected in all its policies and decisions.

2.- PURPOSE

The object of this document is to describe the Data Transparency Policy of Rovi Group as a basis of our commitment to the transparency of the data obtain from the clinical trials performed by the company.


3.- CONTENT

In a clinical trial the rights, safety, dignity and well-being of subjects should be protected, and the data generated should be reliable and robust. The interest of the subjects should always take priority over all other interest.

With this premise, ROVI is committed to the transparency of the data demonstrating the safety and efficacy of our products, complying always with the ethical principles for medical investigations in human-beings defined in the Declaration of Helsinki. Likewise, throughout our long history of developing new drugs, clinical trials have been complied international and national regulations. Our current lines of development are focused on glycomics platforms and ISM®, our proprietary drug delivery system, which aims to improve patient compliance with treatment and therefore to improve the quality of their life.

Before starting any clinical trial, Rovi Group register the studies in the corresponding databases, such as Clinicaltrials.gov, CTIS, REec and the ChiCTR. Depending on the databases, the information will consist of the publication of information related to the clinical trial, such as the design and conduct, making this information publicly available.

Once the trial is completed, the main results corresponding to the main and secondary variables are published. ROVI Group is committed with the specific timeframes defined for results

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disclosure. Results of clinical trials conducted in line with the respective regulatory requirements and/or company commitments, generally within 12month of trial completion.

Additionally, the clinical development department publishes the results of clinical trials in scientific journals, as well as articles, regardless of whether they are positive or negative. In these results we maintain the anonymity of the published data, which prior to publication are reviewed by the Compliance and Intellectual Property Department, which is governed by international and national regulations.

Once the trial is completed, the main results corresponding to the main and secondary variables are published.

In line with this commitment, Rovi has developed internal procedures describing these activities approved by the Research and Development Director and Study Directors.

4. DOCUMENT VERSIONS

Version	Approval Date
1.0	29.07.2024
2.0	01.08.2024