POST AUTHORISATION SAFETY STUDIES (PASS)

1. I have to conduct a NON interventional Post Authorisation Safety Study (PASS), which documentation should I submit and how (e.g. start/conclusion notifications, protocol, protocol amendment, interim/final/progress reports)?

Since 31 January 2023 the AIFA's Register of Observational Studies (RSO) has represented the management tool in force for non interventional PASS. Additional information can be found at the following link: https://www.aifa.gov.it/-/registro-degli-studi-osservazionali-rso-attivazione-a-partire-dal-31-gennaio-2023

Unless specific requests from the authority, the submission of a copy of the documentation to the AIFA's Pharmacovigilance Office is not required.

2. I have to conduct an interventional PASS, which documentation should I submit and how (e.g. start/conclusion notifications, protocol, protocol amendment, interim/final/progress reports)?

The documentation should be submitted to the AIFA's Clinical Trial Office (Ufficio Sperimentazione Clinica) through CTIS, in accordance to the Regulation (UE) n. 536/2014, while the updates of the ongoing trials, approved in accordance to the Dir. 2001/20/CE and not yet migrated to CTIS, should be submitted through the National Observatory on Clinical Trials (OsSC) by the 30 January 2025.

January 31, 2025