

Specification of steering group

Overview

This study includes an independent steering committee to provide comprehensive oversight, scientific advice, data monitoring, and guidance throughout the study. Members are selected based on their expertise and absence of commercial, financial, or institutional conflicts of interest, ensuring unbiased contributions. Each member's roles and responsibilities are clearly defined to enhance the study's integrity and success.

Steering Committee Members

1. Cláudia Camila Dias, Stat, PhD - *Statistical Expert*
2. Mariana Lobo, Stat, PhD - *Statistical Expert*
3. Paula Barão, PharmD - *Pharmacovigilance & Pharmacoepidemiology Expert*
4. Ana Margarida Pereira, MD - *Drug Allergy Expert*

Meetings and Evaluation

The steering committee will regularly evaluate the study's progress and the results of the analyses through scheduled meetings. Meetings will be held quarterly, or more frequently if necessary, to review the study's progress, address any emerging issues, and ensure alignment with the study objectives.

Transparency and Public Availability

The composition of the steering committee, including the specific roles and responsibilities of each member, will be made publicly available through appropriate channels, such as the EU PAS Register®, to ensure transparency and accountability.

Inês Ribeiro Vaz, PharmD, PhD

Primary Lead Investigator

Porto Pharmacovigilance Centre / Faculty of Medicine of the University of Porto

Porto, Portugal