

Unité de recherche UMR1027
Epidémiologie et analyses en santé publique
Risques, maladies chroniques et handicaps

Directeur : Sandrine Andrieu

ENCePP Secretariat
European Medicines Agency
7 Westferry Circus
Canary Wharf
London, E14 4HB
UK

04 April 2013

Application for Encepp study seal

Dear Sir or Madam,

I, the lead investigator, hereby confirm on behalf of the INSERM 1027 Pharmacoepidemiology research team that no steering group is foreseen for the study "Association between anxiolytic or hypnotic drugs and total mortality", as stated in the completed check-list of the ENCePP Code of Conduct for ENCePP Studies.

The protocol and further results were and will be discussed all along the study with our study sponsor, the European Medicine Agency.

An informal steering group has discussed study design and implementation, and will examine study results. It was composed of:

Julie Dupouy, MD (general practitioner, Toulouse University)
Virginie Gardette, MD, PhD (epidemiologist, Toulouse University INSERM 1027)
Joelle Micallef, MD, PhD (pharmacoepidemiologist, University of Aix-Marseille)
Maryse Lapeyre-Mestre (pharmacoepidemiologist, Toulouse University INSERM 1027)

At the centre level, internal seminars were already implemented within INSERM 1027 research Unit, in order to discuss methodological issues.

Yours faithfully,

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