The ‘ENCePP Study’ Seal

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Goal 2009

The main goal for 2009 is to have in place an **operational network system** that would allow the conduct of **'ENCePP studies'**

(in line with the EMEA Work Programme 2009)

This is reflected in the
ENCePP Work Plan 2009

(available at http://www.encepp.eu/documents/publications/ENCePP_WorkPlan_2009.pdf)

‘ENCePP study’

In principle, **all Pharmacoepidemiological and Pharmacovigilance studies**

- that fulfill the **CORe requirements,** and
- whose **Lead Investigator** belongs to an entity that is included in the ENCePP Inventory of centres

CORe requirements

- **Code of Conduct:** Compliance with the rules of the ENCePP Code of Conduct (Checklist & Declaration)
- **Operational Research Standards (ORS):** Application of ORS (Checklist)

The signed Declaration and Checklists and the study protocol shall be provided to the ENCePP Secretariat before the study commences.

- **Register of Post-Authorisation Studies:** Registration in the Register before study start

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