- **EMC**. Erasmus University Medical Center (Netherlands). Contractor

  As the Tenderer, Erasmus University Medical Center (EMC) will be responsible of overall scientific leadership of the service in order to ensure that results are provided according to the overall strategy set up in the technical description. In this regard, the results of analyses will be circulated per e-mail between the subcontractors and the tenderer and discussed upon. The same procedure will apply for internal discussion of reports drafts.

  EMC will be the service reference point in front of the EMA and the final responsible of providing all reports and protocols, as well as the final manuscript, to the Agency according to the content and timeline described in the Tender technical specifications.

  EMC will provide strategic guidance, devise changes in scoping and focus of the different tasks and methodologies, and co-ordinate all inputs from subcontractors. To that end, bi-weekly interactions with the subcontractors will be set up so as to discuss the progress of the project. When appropriate, results of analyses and reports' drafts will be discussed.

  EMC will be in charge of setting-up high quality standards applicable throughout the work plan, directing the efforts towards assessment and validation of the service provision, and supervising overall ethical principles so as to ensure a suitable design and set-up of the drug utilisation study.

- **PHARMO.** PHARMO Coöperation UA (Netherlands). Subcontractor

  PHARMO Institute will support EMC in the scientific co-ordination and management of the proposed project. PHARMO will contribute to the set of criteria to assess and advise the project team on how best to achieve its objectives and research directions. PHARMO has a wide experience in observational studies using linked databases where diverse patient-centric exposure and outcomes information can be studied. PHARMO will perform data extraction from its database and run Jerboa to produce aggregated data in collaboration with the sub-contractors and tenderer.

  PHARMO will liaise with all subcontractors and the tenderer in order to achieve the scientific objectives, especially in the design of the study protocol and the harmonization of the algorithms for case definition. PHARMO will take an important role in dissemination of results of the proposed project.

- **UNIMIB.** Università di Milano-Bicocca (Italy). Subcontractor

  The Unit will perform the extraction from the administrative database of the Lombardy Region (Italy) of all prescriptions information relevant to the study aim both for oral contraceptive and co-medicaments, including Anatomical Therapeutic and Chemical classification (ATC) code, dispensation date and defined daily dose (DOD). This information will be used to evaluate drug utilization patterns. Demographic characteristics (i.e. age, gender) will be extracted from the patients database.

  Information on comorbidities will be evaluated both in the prescription and hospital discharge databases (ICD-9 CM of diagnosis, discharge date) of the Lombardy Region. The Unit will also assist the other investigators in the planning, execution and interpretation of the required statistical analyses.

- **ARS.** Agenzia regionale di sanità della Toscana (Italy). Subcontractor

  ARS will liaise with PHARMO and EMC during the design of the study protocol and the harmonization of the algorithms for case definition. ARS will participate to teleconference and meetings

  ARS will perform data extraction from its database and run Jerboa to produce aggregated data that can be sent EMC and PHARMO.

- **SYNAPSE.** Synapse Research Management Partners S.L. (Spain). Subcontractor

  SYNAPSE will follow-up activities and monitor compliance with the work plan, planned resources and time schedule. It will also provide close support to the Tenderer, including appropriate liaison with the European Medicines Agency. SYNAPSE will also support the other subcontractors taking part in the service, promoting synergy and efficiency throughout. It will facilitate communication among all actors involved, ensuring timely delivery of the project deliverables according to the EMA requirements and tracking milestone achievements.

  SYNAPSE will also drive risk management (identification, assessment of threats and opportunities, mitigation and contingency plans), and will manage quality control procedures on deliverables and reports in closely cooperation with the Tenderer. SYNAPSE will be responsible of overall financial management (cost control, budget management, payments control), supporting the Tenderer in budget re-arrangements. Finally, it will support meetings organisation.