



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2016
EMA/CHMP/302887/2016

CHMP List of questions

To be addressed by Semler Research Center (SRC) Private Limited located at SRC Private Limited, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India (also known as JP Nagar site) and Semler Research Center (SRC) Private Limited PA Arcade, No 21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India (also known as Sakar Nagar Clinical site)

Procedure number: EMEA/H/A-31/1443



The Semler Research Center (SRC) Private Limited, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India (also known as JP Nagar site) and Semler Research Center (SRC) Private Limited PA Arcade, No 21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India (also known as Sakar Nagar Clinical site) were subject to recent GCP inspections carried out by the WHO and the US FDA where critical findings were identified on the inspected studies, as well as serious deficiencies in the quality management system in place at the sites (covering clinical and bioanalytical activities), which affect the trustworthiness of the data generated by the sites and cast doubt on the reliability of the corresponding bioequivalence studies conducted to support a marketing authorisation.

The Semler Research Center (SRC) is invited to provide the following information:

1. Any relevant and substantiated information to be considered by the Committee for Medicinal Products for Human Use (CHMP) when determining the impact of the inspection findings on the benefit-risk balance of medicinal products authorised, as well as for pending marketing authorisation applications, on the basis of trials performed since the set-up of the sites.
2. A list of marketing authorisations/ marketing authorisation applications in the European Union for which Semler Research Center (SRC) has been involved in the clinical and/or bioanalytical activities in the context of bioequivalence studies.