

TRANSVAC – ECRIN : JOB DESCRIPTION FORM
Marie Curie Industry-Academic Partnership

Job title : Consultant Clinical Development

Location : Dando and Colucci LLC & ECRIN coordination (www.ecrin.org), INSERM Headquarters, Paris, France

Duration : 22 months

(at the end of this period, the researcher is committed to return to his/her home organisation for 12 months).

Start : January 2007

General description :

*** Focus on translational research and on interaction with biotechnology SMEs:**

- participate in the activity of ECRIN working groups in charge of defining tools, guidelines and procedures to support clinical studies in the EU, with special reference to the comparison of national regulatory systems in the EU.
- participate in the development of services supporting phase 1-2 trials on biotechnology-derived products
- develop training documents on clinical trial issues in the biotechnology field
- assist in the development of a strategy for centre selection and fostering patient recruitment.
- assist in the development of model contracts for EU clinical studies between ECRIN and biotechnology SMEs
- assist in the design of a procedure for cost evaluation in EU clinical studies

*** Implementation of Transvac research projects:**

- reverse engineering of research projects
- preparation of EU mono- or multicentre clinical research projects from the Transvac portfolio: centre selection, cost evaluation, contracts, insurance, patient enrolment, ethical and regulatory requirements, adverse event reporting, data management, monitoring, drug dispensing, management of blood/tissue samples.

Competence and skills :

- Knowledge of EU legislation and regulatory requirements in clinical research
- Project management skills
- Effective oral and written communication skills
- Effective organisational skills
- Ability to work in a multicultural environment

Education requirements :

- MD, Pharmacist, and/or PhD
- Fluent in English

Other requirements :

- Not resident in France for 18 months preceding January 2007
- Non-french

Contact :

Jacques Demotes, ECRIN Coordination
demotes@bordeaux.inserm.fr