



European Medicines Agency

NOTICE OF CALL FOR EXPRESSIONS OF INTEREST FOR URGENT DRUG SAFETY STUDIES

The EMEA has launched a Call for Expressions of Interest with a view to drawing up a list of potential contractors who may be invited to reply to specific invitations to tender in the future.

The ultimate purpose of this call is to enable the EMEA to obtain fast and reliable answers to questions on safety or benefit:risk concerns needing urgent elucidation, mainly by means of observational investigation, and ultimately facilitating regulatory decision-making. The scope of the funding is not restricted to research into the safety of centrally authorised products. The estimated budget per study will be between €50.000 and €130.000.

Studies which may be contracted by EMEA will typically include urgent class reviews or research on off-patent medicines and multiple drug substances, where rapid information on comparative safety is essential. The types of study include:

- Comparative reviews of drug utilisation patterns, including the measurement of effectiveness of risk minimisation activities on appropriate drug use.
- Retrospective observational studies using electronic healthcare databases or other databases where information on drug exposure and medical outcomes can be linked for individual patients.
- Meta-analyses of clinical trials or observational studies, based on aggregated data or individual patients' data available to the applicants.
- Observational research into the safety of vaccines using appropriate study designs.
- Prospective, non-interventional safety or benefit:risk studies, such as surveys, cohort or case-control studies.

For more detailed information on the scope of the studies, application criteria and procedure please see <http://www.emea.europa.eu/htms/general/admin/tenders/list.htm>

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