

Title of the project:

Pharmacovigilance in children and adolescents: Multicentre, large simple clinical trial (phase IIIb) on the (off-label-) use of antidepressants and antipsychotics in children and adolescents

Rational pharmacotherapy is a challenging task in child and adolescent psychiatry. Increasing prescription numbers contrast with the uncertainties of safety and efficacy issues. The lack of clinical (authorization) trials often implies a non- age-specific use of drugs. However, young patients show particular metabolic conditions and a higher vulnerability for adverse drug reactions. Thus it seems mandatory to create age-specific pharmacological data about efficacy and safety of psychotropic drug use in minors. Legislation authorities became aware of this situation and introduced European and national scientific pharmacovigilance regulations and programmes accordingly in order to continuously evaluate the benefit-risk-ratio, detect, collect, minimize, and prevent adverse effects of drugs by appropriate measures, e.g. therapeutic drug monitoring. The 'TDM-VIGIL' study, which is funded by the German Federal Institute for Drugs and Medical Devices (BfArM), is designed to collect epidemiological prescription and safety data of psychotropic drugs in children and adolescents using an internet-based data infrastructure (patient registry).

key words: pharmacovigilance, child and adolescent psychiatry, therapeutic drug monitoring, developmental psychopharmacology, quality assurance