

Institute of Clinical Pharmacology and Toxicology (PVZ FAKOS), Charite Universitaetsmedizin Berlin

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Institution

Educational Institution

Institution identification

PURI

<https://redirect.ema.europa.eu/resource/2587>

Institution ID

2587

Institution countries

Germany

Type of institution

Educational Institution

ENCePP partner

Yes

Institution description

The center of pharmacovigilance PVZ-FAKOS conducts the Berlin Case-Control Surveillance (FAKOS). Aim is to detect rare adverse drug reactions (ADR) in the postmarketing period, to quantify their relative risks and to investigate pharmacogenetic for these ADR. PVZ-FAKOS is being funded by the German Drug Authority BfArM. FAKOS ascertains patients with rare haematological diseases (2000-2010), acute hepatitis and pancreatitis since 2002, longQT syndrome since 2008 and acute renal failure requiring dialysis since 2010. Cases and controls are recruited in all Berlin hospitals and interviewed with a standardized questionnaire about prior drug use, concomitant diseases, and Other risk factors. All cases undergo scrutiny whether their disease might be caused by drug intake to permit early generation of ADR

signals. The data are used to evaluate the possibility of an ADR. Blood samples analysed for polymorphisms of drug-metabolizing enzymes, transporters and Other genetic variants.

Institution details

Experience with collecting data directly from individual patients or respondents:

Yes

Interest in carrying out research that is funded by pharmaceutical companies:

Yes

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