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Pharmacogenomics and individualized therapy - the regulator's science

The challenge of modern drug regulation is the correct risk benefit estimations in different patient groups over the complete life cycle of a drug. While the complete market recall of a drug is a regulator’s disaster, regulators need to weigh their decisions on best current knowledge on patient risk factors leading to rational stratification of patient populations according to their estimated benefit-risk ratio. Research gaps and the accelerated turnaround of knowledge in modern medicine brings up the necessity for regulatory motivated research on molecular and clinical patient risk factors for drug safety and efficacy to support stratified risk-benefit assessments. At the BfArM, a regulatory research division was founded in 2012 to address these specific topics. We are performing studies on patient-specific risk factors for drug toxicity and efficacy. It is crucial for regulatory decisions to gain knowledge on longterm disease courses in dependence of molecular profiles and on pharmacogenetic risk factors for drug safety. Therefore, we are active in establishing longterm disease/or side effect follow-up cohorts in patients with extensive pharmacogenetic diagnostics. Such clinical longterm follow-up studies support regulatory work in three main areas: first, it provides independent data on the prognostic value of molecular subtypes important for regulatory advices in drug development. Second, it enables the recognition of safety signals important for pharmacovigilance, and, third, it supports validation of biomarkers and companion diagnostics chaperoning drug therapy.