PLATFORM 4: National Pharmacovigilance Platform – 5-year work plan

The implementation of the National Psychopharmacovigilance Platform will comprise 4 work packages that aim to increase and implement knowledge on the prevention, safety and effectiveness related to both off-label and licensed pharmacological interventions in children and adolescents by optimizing treatment regimes informed both by evidence-based interventions as well as medicine-based evidence applying state-of-the-art modeling and AI analyses. Innovative responsive digital platforms will provide an avenue for instant dissemination and patient participation. The work packages are: (P1) Definition and implementation of national transdisciplinary pharmacology network, (P2) consolidation and extension of the scope of the national registry on psychopharmacology and pharmacovigilance, (P3) establishment of a national developmental data-exploitation platform, IV) implementation of optimized treatment and pharmacovigilance measures in real world. These work packages will facilitate the establishment of a large interdisiciplinary infrastructure on pharmacological interventions in children and youth spanning both mental as well as somatic health impairments thus synergistically bridging existing structural gaps in the German health care system.

Work package P1 Interdisciplinary network establishment and governance will comprise i) the structured integration of existing partners with leading pharmacolgical expertise within the DZKJ and relevant partners beyond into a trans-discipline framework spanning pediatrics, psychiatry, pharmacology, pharmaceutics, chemistry, biology as well as epidemiology, ii) will define shared and dedicated research responsibilities, iii) implement governance, patient participation and communication structures. Work package P2 will i) consolidate the existing national registry on psychopharmacological off-label use and contributing networks, ii) expand the scope of the platform for broader applicability spanning real world use to complex RCTs, accompanied by an expansion of integrated deep phenotpying modules (e.g. pharmacogenetics, brain imaging, social determinants, mobile data asessments). Work package P3 will be pursued in close collaboration with the CHILDhealth Platform 1 (cohorts) and i) provide an IT infrastructure to integrate, analyse and systematically exploit pharmacological data and cohorts, ii) harmonize phenotyping procedures on molecular, systemic and clinical levels, iii) apply novel AI based modeling procedures on pharmacokinetics, pharmacodynamis and pharmacogenetics, and investigate specific risk groups (e.g. intellectual development disorder). Work package P4 addresses the implementation of pharmacovigilance and pharmacotherapy knowledge into real world by providing i) clinical recommendations, national consensus statements, proposing age adapted therapeutic serum ranges, and ultimately define evidence-based guidelines for pharmacovigilance guided drug treatment, ii) dissemination of evidence and reccomendations via established networks, iii) Implementation of an evidence-based TDM-sevice, and a national hotline for state-of-the-art, evidence-based, age-adapted advice to clinicians/patients and by provision of digital education tools and informed consent materials, iv) support of regulatory institutions in post-marketing drug safety surveillance.

	GANTT Chart	Year 1	Year 2	Year 3	Year 4	Year 5
P1	**National trans-disciplinary pharmacology network**					
MS1.1	Definition of partner sites and institutions					
MS1.2	Definition of dedicated and shared research priorities and responsibilities					
MS1.3	Establishment of governance infrastructure, patient particiaption, communication					
P2	**National registry platform**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
MS2.1	update and consolidate national registry on off-label use					
MS2.2	expand applicability of registry to patients by mobile integration and smart design					
MS2.3	extend registry by deep phenotyping modules and RCT-designs					
P3	**National data integration and exploitation pipeline**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
MS3.1	Build IT infrastructure (with Platform 1 - cohorts) for data integration					
MS3.2	harmonize phenotyping procedures on molecular, systemic and clinical levels					
MS3.3	apply novel AI based modeling procedures					
P4	**Implementation into real world**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
MS4.1	define evidence-based guidelines for pharmacovigilance guided drug treatment					
MS4.2	dissemination of evidence and reccomendations via established networks					
MS4.3	provide national hotline, TDM service, digital education and information tools					
MS4.4	support of regulatory institutions in post-marketing drug safety surveillance.					