

# ABUSE LIABILITY ASSESSMENT

- ▶ 25+ years' experience in preclinical models of drug dependence and abuse liability in a pharmaceutical neuroscience center of excellence environment
- ▶ GLP compliant in accordance with the most recent guidelines for neuroscience drug development
- ▶ Can be integrated within a multidisciplinary full-scope clinical-enabling program with chemistry, pharmacology, DMPK, safety assessment, regulatory and clinical support, all driven by our drug development experts



## AREAS OF EXPERTISE

COMPOUND  
CHARACTERISATION

PHARMACOLOGICAL  
ASSESSMENT

PRECLINICAL  
BEHAVIOURAL STUDIES

Abuse liability assessment refers to the testing of a neuroactive substance for its potential to become a drug of abuse. Since 2017, ICH guidelines recommend that all New Drug Applications (NDAs) for drugs that may affect the Central Nervous System include an assessment of the drug's potential for addiction. This assessment is essential to guide the decisions of pharmaceutical companies for the development and commercialisation of their new drugs. Equally important, this assessment guides government agency consideration for approval and, if appropriate, placement of the new medication into one of five schedules for controlled substances.

Increasingly, abuse liability is incorporated early in development to allow for proper risk mitigation. Thus, planning for potential abuse liability should begin at the candidate selection stage to avoid unexpected surprises during early clinical trials.

### EVOTEC EXPERTISE

- ▶ Fully-integrated packages, including all aspects of drug development on a single site (INDiGO)
- ▶ GLP Safety and Behavioural Assessment (inclusive of Abuse Liability assessment)
- ▶ Consulting on abuse liability strategy including 8-factor analysis
- ▶ Evaluation of chemical similarity to drugs of abuse
- ▶ Broad range of behavioural studies including: drug discrimination; self-administration; withdrawal; locomotor activity
- ▶ Integration of behavioural assessment with DMPK assessment to establish PK/PD relationship



*Evotec – the right partner for your abuse liability assessment.  
Contact us for an expert evaluation.*