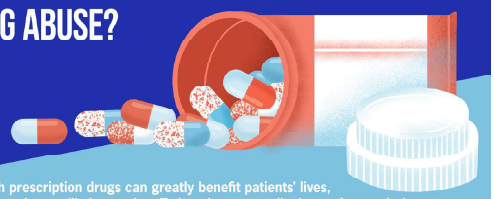
HOW CAN BIOPHARMA COMPANIES BEST PREVENT PRESCRIPTION DRUG ABUSE?



Although prescription drugs can greatly benefit patients' lives, their abuse is steadily increasing. Today, the non-medical use of prescription drugs, and especially those that influence the Central Nervous System, is affecting millions of people worldwide, resulting in significant health consequences and a rising number of deaths.

1 IN 5
people in the U.S. have abused prescription drugs for non-medical purposes

46
people die every day from prescription opioid overdose in the U.S.

740+
New Psychoactive Substances (NPS) registered worldwide since 2017

HOW CAN ABUSE LIABILITY ASSESSMENT PREVENT DRUG MISUSE?

"Abuse liability refers to a drug that is used for nonmedical purposes for the positive psychoactive effects it produces. Hence, new drug applications for drugs that may affect the Central Nervous System have to come with an assessment to evaluate 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 and of government agencies for the approval and, if necessary, placement of the new medication into one of five schedules for controlled substances."

- Maria Pilla, Head of Global Preclinical Development at Aptuit, an Evotec company

What is included in the abuse liability assessment?

- **Compound characterisation & pharmacology tests**
- **Preclinical behavioural studies**
- **Human abuse liability studies**

Key considerations for drug developers

- Investigate the drug's blood-brain barrier permeability & distribution in the brain
- Identify interactions with targets of relevance for drug dependence
- Plan for potential abuse liability at the candidate selection stage
- Design your studies well to provide enough abuse liability evidence

Outcomes

- Preliminary understanding for the need of abuse liability assessment
- Identification of optimal development strategies early in the process, thus minimising time & financial implications
- Mitigation of impacts on the commercial viability of drug development projects
- Reduction of project delays while scheduling is being discussed with authorities

Remember: Testing for abuse liability requires an expert, integrated and multidisciplinary approach

EVOTEC'S SOLUTION? AN INTEGRATED DEVELOPMENT PROGRAM

25+
years of experience in abuse liability testing

13
locations worldwide

9
abuse liability programs since 2015

Evotec uses a two-tiered, integrated approach for its abuse liability assessment programs.

First, the compound undergoes pharmacological and pharmacokinetic characterisation.

Second, Evotec can then determine and perform the most suitable behavioural studies to unveil a compound's abuse potential from different perspectives, including...

- **Drug discrimination**, determining the compound's similarity with known abused drugs
- **Self-administration**, understanding the compound's reinforcing properties
- **Physical dependence**, analysing the compound's potential to cause withdrawal symptoms

Advantages of an integrated development program

- Potential issues can be anticipated & addressed timely
- Development times can be minimised
- Likelihood of success can be maximised
- Effective team interaction & communication
- Program driven by experts through all its phases

Are you struggling to find the right partner for your abuse liability assessment or do you just need some expert support? Get in touch with the abuse liability experts at Evotec or visit their website for more information!

Sources

Aptuit, an Evotec company
Centers for Disease Control and Prevention
National Institute on Drug Abuse
Talbott Recovery
United Nations Office on Drugs & Crime
- World Drug Report 2017
- World Drug Report 2018

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