Anti-Counterfeiting

Patient safety is paramount at Neurocrine Biosciences. This includes the integrity of our supply chain of authentic medicines. To achieve this, we have implemented a robust anti-counterfeiting strategy to prevent the introduction of counterfeit, tampered, or diverted medicines into our supply chain. This multi-pronged approach leverages serialization, covert and overt product authentication measures, and stringent diversion mitigation procedures.

Mandated by the U.S. FDA and EMA, serialization entails assigning a unique code to each saleable and aggregated unit (from individual packages to pallets) for electronic tracking throughout the supply chain. This system allows verification of a prescription drug's authenticity and its journey, empowering patients, physicians, and all stakeholders to confirm the legitimacy of the medication. Beyond serialization, we incorporate covert and overt measures directly embedded into our products. These confidential safeguards, regularly updated, enable field-level identification of authenticity, independent of serialization data.

Neurocrine Biosciences is committed to combating diversion. Upon suspicion of diversionary activity, we conduct thorough investigations in collaboration with local, state, and federal law enforcement. We also proactively inform supply chain partners to ensure collective vigilance against potential threats.

CLINICAL TRIALS PROGRAM

We are committed to implementing and maintaining strong ethics into our clinical trials program. The foundation of our clinical trials standard and program is governed by the International Council for Harmonisation (ICH) and GCP guidelines, as well as FDA and any applicable international regulations. Our Chief Medical Officer and Chief Regulatory Officer provide managerial oversight to our clinical trials program.

Our clinical trial standards apply to all trials conducted, including any offshore and outsourced trials. We regularly monitor our trials and conduct audit programs to ensure compliance. We conduct risk and impact assessments before beginning any trial, and the Institutional Review Board has authority to approve, modify and stop trials. We have standard operating procedures in place to obtain trial participants' informed consent, and these procedures help ensure this consent is free of conflicts or illegal activities. To ensure clinical trial integrity, employees involved in trials are provided training and awareness programs. All ongoing trials are monitored regularly, and we have grievance mechanisms in place for participants in the case of an incident.

Clinical trial diversity

At Neurocrine, we consider diversity internally as well as with our vendors in clinical trials when we initiate any programs. We have in place a DE&I Evidence Generation Committee with the goal to enhance representation of diverse study populations in different stages of drug development programs of targeted disease epidemiology.

Functions represented within the DE&I Evidence Generation Committee include:

- Health Economics and Outcomes Research (HEOR)
- Clinical Operations
- Clinical & Medical Development
- Biometrics
- Field Medical
- Patient Advocacy
- Regulatory Affairs
- Public Policy
- Human Resources

We established this committee seeking to contribute to present and future research portfolios of the noncommercial assets and commercial business, and to advance the health and welfare of underrepresented populations. The Committee uses a customized framework and workstream across all research portfolios focusing on neurological, neuroendocrine, and neuropsychiatric disorders, using FDA guidance and Multi-Regional Clinical Trials Center (MRCT) recommendations. This involves evaluating both current pre-approval gaps and post-approval unmet needs. We began providing employee awareness trainings in 2023.