

New Molecular Entity [NME]

New Molecular Entities (NMEs) are compounds that emerge from the process of medicine discovery, that are not a version or derivative of an existing, previously investigated/approved substance. They have promising activity against a particular target thought to be important in a disease, however, little is known about the efficacy, safety, toxicity, pharmacokinetics and metabolism in humans. A full development programme of non-clinical and clinical trials must be performed to evaluate the potential of an NCE to become a medicinal product.