

Impact of external factors on the future of CNS therapy development

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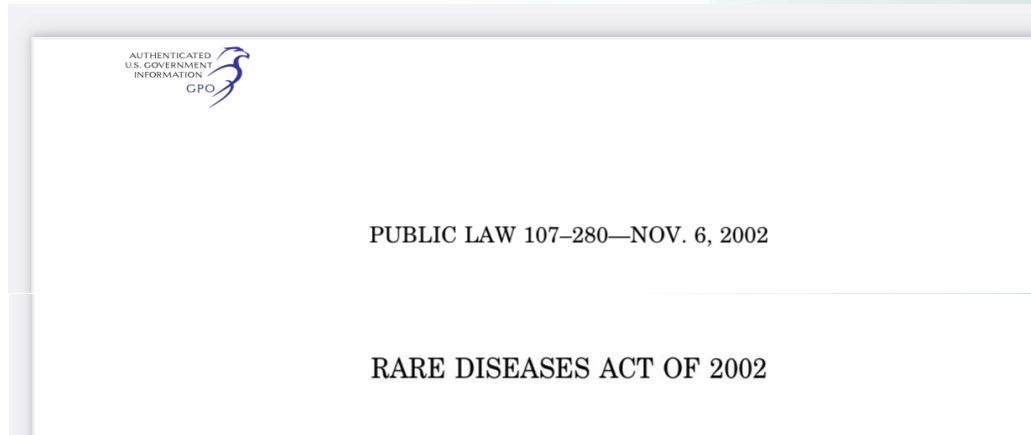
Disclosures: Employed by Noema Pharma AG

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Neurosciences

Adapting CNS R&D strategy to a rapidly evolving environment

Rapidly evolving external factors significantly impact R&D strategy

- Scientific realities
- Evolving regulations –
- Patient empowerment – e.g., role of DTC
- Clinical execution – e.g., site consolidation in the USA, academic research realities
- Regional influences – e.g., geopolitical events
- Pricing and reimbursement
- Increased role of artificial intelligence
- Impact of changing policy



The screenshot displays the 'CONGRESS.GOV' website interface. At the top, there is a navigation bar with a hamburger menu, the site name, and a 'Sign In' link. Below this is a search bar with 'Advanced Searches' and 'Browse' options, and a search input field containing 'Examples: hr5, sres9, "health care"'. A 'MORE OPTIONS' dropdown is visible below the search bar. Further down, there are links for 'Citation', 'Subscribe', 'Share/Save', and 'Site Feedback'. The main content area features the title 'H.R.5376 - Inflation Reduction Act of 2022' and '117th Congress (2021-2022)'. A 'LAW' tab is active, and a 'Hide Overview' button is present. The details section includes: 'Sponsor: Rep. Yarmuth, John A. [D-KY-3] (Introduced 09/27/2021)', 'Committees: House - Budget', 'Committee Meetings: 08/04/22 10:00AM 04/27/22 2:30PM', 'Committee Reports: H. Rept. 117-130, Book 1; H. Rept. 117-130, Book 3; H. Rept. 117-130, Book 2', 'Committee Prints: H.Prt. 117-17, H.Prt. 117-18, H.Prt. 117-19', 'Latest Action: 08/16/2022 Became Public Law No: 117-169. (All Actions)', and 'Roll Call Votes: There have been 43 roll call votes'.

Business | Wonder drugs

Big pharma is warming to the potential of AI

But some worry the Terminator is coming



IMAGE: BRYAN ANSELM/REDUX/EYEVINE

FDA's IStand Pilot Program accepts submission of first artificial intelligence-based and digital health technology for neuroscience

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[1/23/2024] FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) recently accepted a new submission into the [Innovative Science and Technology Approaches for New Drugs \(ISTAND\) Pilot Program](#). This submission is the first artificial intelligence-based and digital health technology-based project and the first project in neuroscience to be accepted into IStand.

“This marks a pioneering step for the IStand program as the first artificial intelligence-based, digital health technology project in neuroscience to be accepted into the pilot program,” said Peter Stein, M.D., director of CDER’s Office of New Drugs. “Our acceptance aligns with FDA’s vision of optimizing drug development and evaluation, potentially expediting the availability of safe and effective treatments.”