
FDA and EMA reach landmark decisions on C-Path's Simulation Tool for Alzheimer's disease

July 2013: In a big step forward for Alzheimer's disease (AD) therapy development, both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have independently reached favorable decisions on the value of Critical Path Institute's new disease simulation tool for improving trial design in mild and moderate Alzheimer's disease. The first such instrument to ever receive this recognition, the tool represents an enabling advancement to improve the design of future clinical trials in AD. The new tool applies computerized models to simulate "what-if" scenarios for clinical trials. The goal of this virtual tool is to serve as a public resource for sponsors designing trials of new therapies for AD.