CRITICAL PATH INSTITUTE

European Medicines Agency Deems Imaging Biomarker a Qualified Measure to Select Patients with Early Stages of Cognitive Impairment for Alzheimer's Disease Clinical Trials

Based on a request for regulatory review by Critical Path Institute's (C-Path) Coalition Against Major Diseases (CAMD), the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use has issued a positive opinion on the use of magnetic resonance imaging (MRI) to measure hippocampal volume as a tool to enrich recruitment into regulated clinical trials in the pre-dementia stage of Alzheimer's disease (AD). This is the first imaging-based biomarker for AD to be granted a positive opinion by a regulatory agency.