

(NCT) numbers identified from internal research administration systems. Business intelligence software (Microsoft PowerBI) was applied to the corresponding dataset to enable end user exploration and analysis of the trials within ClinicalTrials.gov. RESULTS/ANTICIPATED RESULTS: A total of 3,271 studies associated with UM were identified, of which, 3,054 (93.3%) had at least one condition MeSH term linked. A total of 7,711 MeSH terms were associated with the trials overall, representing 1,112 unique MeSH terms; the most common terms were carcinoma (164), lymphoma (155), HIV Infections (139), neoplasms (136), and leukemia (122). Utilizing MeSH hierarchy, trials were characterized were categorized into 36 different trees. The most common top tree nodes were neoplasms (1,181), followed by pathological conditions/signs and symptoms (913), immune system diseases (574), nervous system diseases (513), and digestive system diseases (483). Within trees, a total of 184, 681, and 1057 different MeSH terms were specified at the second, third, and fourth nodes in the hierarchy respectively. DISCUSSION/SIGNIFICANCE: Utilizing existing metadata from trials posted on ClinicalTrials.gov and MeSH tree structures can enable organizations to readily explore the foci of clinical trials research. High rates of MeSH term association to research study conditions are necessary to ensure adequate representation of research foci.

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An umbrella protocol that establishes an enterprise-wide framework for the operation of a Clinical Data Warehouse

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OBJECTIVES/GOALS: To streamline the standards and procedures for operating a research-specific, clinical data warehouse, achieved by defining roles, introducing a common language, and categorizing dataset types to provide transparency regarding data security risks inherent in the use of patient data. METHODS/STUDY POPULATION: We established a Bioethics committee responsible for ensuring clinical data is securely procured, maintained, and extracted in a manner that adheres to all federal, state, and local laws. We created an operational framework in the form of an umbrella IRB protocol and shared it with the bioethics committee for feedback and approval. The protocol was approved first by the bioethics committee and subsequently by the IRB. It was then disseminated across the institution and published online for continuous reference and use by committee members, researchers, and the data warehouse service team. RESULTS/ANTICIPATED RESULTS: The resulting framework defined the roles of researchers, data warehouse service team members, and honest brokers; explains the procedures for accessing and securely delivering data; and lists six categories of datasets according to type and implicit risks: datasets that are preparatory for research/aggregate counts, anonymized datasets, coded datasets, limited datasets, identified datasets for recruitment purposes, and defined identified cohort datasets. The protocol is approved and in use enterprise-wide, has reduced the number of questions from stakeholders, and has given researchers, IRB members, and informatics staff confidence in the use of the clinical research data warehouse. DISCUSSION/SIGNIFICANCE: We offer our framework to CTAs interested in streamlining their data warehouse operations. We believe the adoption of this framework will establish strong procedures for ensuring compliance with IRB requirements, data privacy, and data security while reducing barriers to clinical research.

Other

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Tyrosine kinase inhibition reduces pathological markers of Alzheimer's Disease*

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OBJECTIVES/GOALS: Alzheimer's Disease (AD) displays numerous pathological features, including amyloid-beta deposition, extensive neuroinflammation, and vascular fibrosis. However, putative therapeutic options for alleviating these features remain limited, emphasizing the need to develop comprehensive treatments for patients with AD. METHODS/STUDY POPULATION: CSF from human AD patients treated with nilotinib (n=12), a tyrosine kinase inhibitor, or placebo (n=11) was collected and sequenced, and significantly altered miRNAs were identified and analyzed for alterations to disease-associated genes via gene ontology analysis. TgAPP mice were injected intraperitoneally with one of two novel tyrosine kinase inhibitors, BK40143 or BK40197, or DMSO (n=12 per group) daily for six weeks, during which memory deficits between groups were measured, before brains were harvested for analysis of amyloid-beta load via ELISA, microglial activation via Sholl analysis, and vascular collagen levels via immunohistochemistry. RESULTS/ANTICIPATED RESULTS: CSF obtained from AD subjects treated with nilotinib revealed significantly increased (p<0.05) levels of miRNAs regulating autophagy, neuroinflammation, and collagen production compared to placebo. These results were validated in vivo in TgAPP mice, who displayed improved recall on the novel object recognition test and Morris water maze following treatment with our drugs, correlating with decreased levels of brain amyloid-beta (30% decrease, p=0.002), decreased microglial reactivity and activation (40% decrease, p=0.01), and decreased vascular fibrosis (50% decrease, p=0.005) along small brain blood vessels compared to controls. DISCUSSION/SIGNIFICANCE: These data identify tyrosine kinase inhibition as a valid therapeutic strategy for alleviating various pathological features associated with AD and warrant further investigation as a treatment option for human patients as a means of slowing cognitive decline.

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Maternal hypertension results in a decreased number of glial cells in offspring during early development

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OBJECTIVES/GOALS: Preeclampsia, a hypertensive disorder in pregnancy, disrupts immune cell profiles at birth in both mice and humans. In mice, it affects offspring's memory and behavior. This study aimed to investigate whether preeclampsia induces lasting immune cell changes after birth and its impact on astrocyte and microglia cell counts in offspring. METHODS/STUDY POPULATION: Preeclampsia was induced in C57BL/6 females by infusion of vasopressin (24 ng/hr) or saline throughout gestation via osmotic minipump. Parturition was allowed to occur naturally. Offspring were euthanized at various timepoints post-delivery for experimental measures. Total urine protein was determined via bicinchoninic acid assay. Single cell suspensions were prepared from thymus spleen, and brain tissue and separated via density gradient.