Regulatory Science

48842

Sponsor types of US interventional COVID-19 studies listed in ClinicalTrials.gov

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ABSTRACT IMPACT: Increase understanding of the types of sponsors responding to the COVID-19 pandemic. OBJECTIVES/GOALS: The COVID-19 pandemic has impacted millions of lives globally. To learn more about this disease and find potential diagnostic, treatment, and preventative products, the healthcare community has initiated a staggering number of clinical trials. Clinicaltrials.gov was reviewed to determine the types of sponsors who are conducting COVID-19 studies. METHODS/STUDY POPULATION: Clinicaltrials.gov was searched using terms 'COVID-19' and 'SARS-Cov-2'. Search results were further defined to include only 'Interventional' studies. Of these, only studies with sites located in the United States were selected and for which the 'Condition' included at least one of the following terms: 'COVID', 'COVID-19', 'Coronavirus', 'SARS-Cov-2', 'SARS', or '2019-nCoV'. Study sponsors were then categorized as: (1) commercial, (2) academic, or (3) other, based on 'Sponsor' information within each study listing. A Google search was conducted for any sponsor that was not easily categorized to obtain additional information to support the proper assessment of sponsor type. The types of sponsors were analyzed over time using the 'First Posted' date of each study listing. RESULTS/ANTICIPATED RESULTS: A total of 3662 studies were retrieved, of which 2075 were 'Interventional' studies. The studies were further reduced to 681 studies by including only United States sites and the desired 'Condition'. The percentage of studies from this refined dataset, by sponsor type, were found to be 63% academic, 34% commercial, and 3% other. The relationship between time and sponsor type demonstrated that academic sponsors had the highest percentage of study postings in the first month (March) of the COVID-19 pandemic compared to commercial and other sponsors. Following this first month, academic study postings gradually declined, while commercial sponsors had an increase in postings per month into July, followed by a gradual decline. Few other sponsor type postings were made and occurred primarily in August. DISCUSSION/SIGNIFICANCE OF FINDINGS: The number and timing of listings may be a reflection of study intention and regulatory pathway requirements. Additional variables, such as inconsistent terminology, collaborators, funding, and study start date may influence results. Further analysis may reveal how modification of listing information may result in expedited pandemic response.

Team Science

39607

Mapping the Draining Lymph Nodes in Central Nervous System Malignancies

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ABSTRACT IMPACT: We seek to determine which lymph nodes drain the human brain. OBJECTIVES/GOALS: Lymphatic vessels train lymphatic fluid from the central nervous system (CNS), but the specific lymph nodes that these vessels drain to remains unknown in humans. We intend on using technetium tilmanocept (TcTM)to map the draining lymph nodes of the CNSin humans. METHODS/STUDY POPULATION: Patients having a tumor resected are eligible for the trial. All patients will have TcTM injected intracranially after tumor resection. Six patients will be enrolled in Cohort 1 to define the time course of drainage to the lymph nodes. Patients in Cohort 1 will be imaged with planar LS within 7 hours of injection and the following day. Either 12 or 24 patients will be enrolled into Cohort 2 to localize the draining lymph nodes with SPECT-CT. The optimal imaging timepoint from Cohort 1 will be used for Cohort 2. Patients in Cohort 2 will be stratified depending on if their tumor is in the frontal, parietal, occipital, or temporal lobe. RESULTS/ANTICIPATED RESULTS: We anticipate that we will detect TcTMin the deep cervical lymph nodes after injection into the brain. It is unclear exactly which lymph nodes the tracer will go to. We hypothesize that the results among patients will be similar, but interindividual variation is a possibility. Furthermore, patients with disease in different lobes of the brain may have different lymph drainage patterns. DISCUSSION/SIGNIFICANCE OF FINDINGS: We seek to answer a fundamental question of human anatomy: what lymph nodes drain the human brain? Additionally, knowing which nodes drain the human brain could shape future research of immunotherapy in patients with brain cancer or autoimmune disease such as multiple sclerosis.

Translational Science, Policy, & Health Outcomes Science

54770

A Comprehensive Online Platform for Plain Language Clinical Trial Result Summary Development

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ABSTRACT IMPACT: This work will impact participants of clinical trials by better informing them of their trial's results and their important role within the clinical research process. OBJECTIVES/GOALS: This project aims to equip researchers with an online tool for the development, dissemination, and collection of participant feedback for plain language clinical trial (CT) result summaries (PLCTRS). PLCTRS ensure that participants fully understand their trial's results and their role in the CT process. METHODS/STUDY POPULATION: This online development platform is a web application made with CSS, HTML, and JavaScript. First, general trial identification information including study aims and eligibility will be input by researchers. Then, they will be prompted with tips and suggestions for composing in plain language and to ensure inclusion of all essential trial information. Next, the platform will disseminate this writing electronically to participants. Participants then provide meaningful feedback on the platform about their comprehension for the researcher, which the platform will aggregate and summarize for revisions. This process of drafting and feedback is repeated until a satisfactory PLCTRS is finalized. RESULTS/ANTICIPATED RESULTS: The anticipated results of this project are overall improved comprehension of clinical trial results by participants. This comprehension will be measured by participants ability to answer certain questions not only regarding trial outcomes, but also about the trial in general. For instance, before and after interacting with the

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