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alzheimer's association®

Jerry Moore
Regulations Officer
Office of Management Assessment
National Institutes of Health
6011 Executive Boulevard, Suite 601
Rockville, MD 20852

March 23, 2015

Re: Clinical Trials Registration and Results Submission

Dear Mr. Moore,

The Alzheimer's Association appreciates the opportunity to comment on the National Institutes of Health's (NIH) proposed changes related to clinical trials registration and results submission. As the largest non-profit funder of Alzheimer's research, the Association is committed to accelerating the progress of new treatments, preventions, and ultimately, a cure. Clinical trials are indispensable to these ends. Increased participation in clinical trials is a priority for the Association, engaging persons with dementia, caregivers, and healthy volunteers through its TrialMatch® program, a matching service that includes more than 225 promising clinical studies being conducted at more than 700 trials sites across the country. Expansion of and increased participation in clinical trials are also explicit objectives within the National Plan to Address Alzheimer's.[1] As a federal member of the Advisory Council on Alzheimer's Research, Care, and Services, NIH, through the National Institute on Aging, is a leader in the fight against this crisis.

The Association supports the proposed changes to rules related to registering clinical trials and submitting trial results to the ClinicalTrials.gov database. Specifically, the Association commends the clarification of the definition of "applicable clinical trial." As NIH notes, certain terms may be used differently in the research and regulatory communities. Making this definition consistent will eliminate confusion about which trials must participate in the ClinicalTrials.gov process. This clarification may lead to increased participation in ClinicalTrials.gov, ultimately resulting in more information about trials being available to the research community and the general public.

The Association also supports the proposed expansion of information to be submitted and the requirement that it be updated regularly. We believe that the availability of more thorough, current information can help to avoid duplication and better inform trial participants and those who are considering becoming participants; these changes will increase the rate of progress in clinical trials for Alzheimer's and other dementias.

Thank you for your leadership in these efforts. The Alzheimer's Association looks forward to our continued partnership with NIH. Please contact Laura Thornhill, Manager of Regulatory Affairs, at 202-638-7042 or lthornhill@alz.org if you have questions or if we can be of assistance.

Sincerely,

Robert Egge
Executive Vice President, Government Affairs

[1] *National Plan to Address Alzheimer's Disease: 2014 Update*, available at http://aspe.hhs.gov/daltcp/napa/NatlPlan2014.pdf.