REQUEST FOR INFORMATION (RFI): NOVEL INTERVENTIONS TO BE TESTED IN PROOF-OF-CONCEPT CLINICAL TRIALS FOR BIPOLAR DISORDER AND SCHIZOPHRENIA

KEY DATES:

Release Date: December 5, 2014
Closing Date for winter review: January 30, 2015

ISSUED BY:

Massachusetts General Hospital Clinical Trials Network and Institute

PURPOSE:

The Stanley Center for Psychiatric Research at the Broad Institute and the MGH Clinical Trials Network and Institute (CTNI) were recently awarded a contract from the Stanley Medical Research Institute, aimed at testing compounds with putative therapeutic effects in bipolar disorder and schizophrenia. In order to prioritize proof-of-concept (POC) trials for compounds on the basis of their therapeutic promise and on the basis of empirical evidence of target engagement and known neurobiological mechanisms, the Stanley Center for Psychiatric Research at the Broad Institute and the MGH CTNI are issuing this Request for Information (RFI) for pharmaceutical and biotechnology companies, inviting them to submit for consideration novel compounds and treatments with existing human safety data which are ready for phase II clinical trials in bipolar disorder and schizophrenia.

The POC trials of these promising novel compounds would be carried out under the joint leadership of the Stanley Center for Psychiatric Research at the Broad Institute and the MGH CTNI. All these POC trials will be conducted with the explicit goal of yielding a clear answer as to the potential utility of the drug/treatment being tested – that is, to provide sufficient data to inform a decision to pursue further, larger-scale studies. Therefore, through the use of novel designs and methodologies, each POC trial will be adequately powered to exclude a clinically significant effect.

Every effort will be made to standardize assessments and designs across studies, to facilitate cross-study comparisons (for example, in terms of effect size and placebo response). Being able to conduct cross-study comparisons of the efficacy of these novel compounds will enable us to draw conclusions on the relative efficacy of the manipulations of specific CNS targets.

A review process, conducted by a joint scientific advisory board (SAB), scheduled to convene in February 2015, will determine which compound(s)/treatment(s), if any, will be selected for POC trials supported by the Stanley Medical Research Institute (SMRI).

When the compound/treatment selected for testing belongs to a given biotech or pharmaceutical company and the trial does not simply focus on the repurposing of a generic compound, cost sharing (e.g., 50% of the site payments) on the part of such company will be required. Cost sharing requirements will be negotiated with the sponsor company on a case-by-case basis. All data generated through these POC trials will belong to the Stanley Center for Psychiatric Research at the Broad Institute and the MGH CTNI and will be published without regard for possible commercial interests. Data will be shared with the entity providing the study intervention and/or supporting shared costs.

INFORMATION SOUGHT:

Pharmaceutical or biotechnology companies with compounds/treatments they would like to submit for consideration should send a Letter of Intent, which includes non-confidential information sufficient to describe the compound, its target/mechanism of action including evidence of target engagement, expected human safety profile,, and any published clinical trial results. If a compound is selected for review by the SAB, a confidentiality agreement will be negotiated in order to share additional information.

HOW TO SUBMIT A RESPONSE:

Information should be submitted by email to:

Martina Flynn
Director of Operations
Massachusetts Hospital CTNI
One Bowdoin Square, 9th Floor
Boston, MA 02114
(617)-643-6028

Email: mflynn2@partners.org

You will receive an electronic acknowledgement of receipt of your response.