MASSACHUSETTS GENERAL HOSPITAL
CLINICAL TRIALS NETWORK AND INSTITUTE

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On behalf of CTNI, we appreciate your time and effort in completing this questionnaire. The information you provide will be entered into our database, which is continuously updated and used during the site selection process for our studies. Please return this document, **along with the CV of your Medical Director**, to Sara Chung, Senior Clinical Research Coordinator, at schung7@partners.org. If you have any questions, please feel free to contact Martina Flynn, Director of Clinical Trial Operations, at (617) 643-6028. Thank you!

# CTNI SITE EXPERIENCE SURVEY – Global

## I. Experience

**1. How many clinical research trials has your site conducted? _____**

Please list the *number of trials* in each of the following:

_____ Phase I
_____ Phase II A/B
_____ Phase III
_____ Phase IV

**2. How many clinical research trials has your site conducted in each of the following therapeutic areas?**

_____ Major depressive disorder
_____ Bipolar disorder
_____ Generalized anxiety disorder
_____ Panic disorder
_____ Obsessive–compulsive disorder
_____ Post–traumatic stress disorder
_____ Social anxiety disorder
_____ Schizophrenia
_____ Alzheimer's disease
_____ Attention deficit–hyperactivity disorder - adult
_____ Attention deficit–hyperactivity disorder - pediatric
_____ Pain

**3. How many clinical research trials is your site *currently* conducting? _____**

Is there a maximum allowed of trials in any area(s)? ☐ **Yes** ☐ **No**

If "**Yes**", what area(s)?_____

**4. What was the completion date of the last trial your site conducted? _____ /_____** (month/year)

What was the therapeutic area of the trial? _____

How many patients were *screened*? _____

How many patients were *screen–failed*? _____

How many patients were *enrolled*? _____

How many patients were *completed*? _____

What percent of the enrollment target was met?

☐ <25% ☐ 25% ☐ 50% ☐ 75% ☐ met target ☐ exceed target

What was the placebo response rate (if available)?

☐ >50% ☐ >40% ☐ >30% ☐ >20% ☐ 10-20% ☐ <10%

**5. How many of the following personnel do you have at your site?**

_____ MBBS or MD (Doctor of Medicine)
_____ Psychiatrist (Specialist)
_____ PhD (Doctorate or equivalent)
_____ RN (Registered Nurse)
_____ Research Coordinator
_____ Other: _____

Please list the *number of years* that your coordinator(s) have been employed:

_____ Research Coordinator #1
_____ Research Coordinator #2
_____ Research Coordinator #3

Who typically performs patient *diagnostic* assessments at your site? _____
Who typically performs patient *efficacy* assessments at your site? _____
Who typically performs patient *safety* assessments at your site? _____

**6. Does your site have *direct* access to any of the following?**

☐ Laboratory (central or local)
☐ Infusion facility
☐ Pharmacy
☐ Secure storage facility (e.g., biospecimen/blood samples)

## II. Patient Population and Recruitment

**1. Does your site have a database to identify potential patients for trials? ☐ Yes ☐ No**

If "**Yes**", how many patients are currently listed in the database? _____

**2. How many patients does your site treat *per month* with:**

_____ Major depressive disorder
_____ Bipolar disorder
_____ Generalized anxiety disorder
_____ Panic disorder
_____ Obsessive–compulsive disorder
_____ Post–traumatic stress disorder
_____ Social anxiety disorder
_____ Schizophrenia
_____ Alzheimer's disease
_____ Attention deficit–hyperactivity disorder - adult
_____ Attention deficit–hyperactivity disorder - pediatric
_____ Pain

**3. What are the primary language(s)/dialect(s) of the patients treated at your site?**

_____: _____ % of population
_____: _____ % of population
_____: _____ % of population

**4. What type(s) of patient *recruitment* strategies does your site utilize?**

- ☐ Patient database
- ☐ Print advertising (e.g., newspaper, mailers, flyers)
- ☐ Radio or television advertising
- ☐ Internet postings
- ☐ Local area clinics/events
- ☐ Other sources

Does your site have satellite sites? ☐ **Yes** ☐ **No**

If "**Yes**", how many satellite sites does your site have? _____

If "**Yes**", how many days *per week* are they staffed? _____/week

If "**Yes**", how far are they from the primary site? _____

**5. What type(s) of patient *retention* strategies does your site utilize?**

_____

_____

_____

## III. Regulatory

**1. What is the average turnaround time for regulatory documents at your site?**

☐ >45 days ☐ >30 days ☐ >14 days ☐ 14 days ☐ 7-14 days ☐ <7 days

**2. What is the average turnaround time for contract negotiation at your site?**

☐ >3 months ☐ >60 days ☐ >30 days ☐ 30 days ☐ 7-30 days ☐ <7 days

**3. What is the average turnaround time for query resolution at your site?**

☐ >30 days ☐ >14 days ☐ >7 days ☐ 7 days ☐ 1-7 days ☐ 1 day

**4. What is the average number of protocol deviations received by your site for any given study?**

☐ >5 deviations ☐ 5 deviations ☐ 4 deviations ☐ 3 deviations ☐ 2 deviations ☐ 0-1 deviations

**5. Is your site required to submit to any of the following?**

a) central investigational review board/national ethics review committee ☐ **Yes** ☐ **No**

**b) local ethics review committee** ☐ **Yes** ☐ **No**

c) independent ethics review committee(s), separate from your institution's ☐ **Yes** ☐ **No**

**How often does your institution's ethics review committee meet?** _____

**What is the average turnaround time for approval?** _____

**Is your site required to submit proposals to a scientific review committee (SRC)?** ☐ **Yes** ☐ **No**

**How often does your SRC meet?** _____

**What is the average turnaround time for review by the SRC?** _____

**6. Does your site have clinical research Standard Operating Procedures (SOPs) in place?** ☐ **Yes** ☐ **No**

**7. Does your site comply with the ICH E6 Guideline for Good Clinical Practice (GCP)?** ☐ **Yes** ☐ **No**

If "**Yes**", does your site conduct training for personnel, particularly *21 CFR 312, Subpart D, "Responsibilities of Sponsors and Investigators"* on at least an annual basis? ☐ **Yes** ☐ **No**

**8. Has your site ever been audited or inspected by a governmental regulatory agency, such as the EMA?**

☐ **Yes** ☐ **No**

If "**Yes**", please indicate the date of the audit: _____/_____ /_____ (month/day/year)

If "**Yes**", please indicate the name of the agency: _____

**9. Has your site ever received a Warning Letter from the FDA or an Inspection Report from the EMA?**

☐ **Yes** ☐ **No**

If "**Yes**", please provide a copy of the report(s) with this questionnaire.

**10.** Has a governmental regulatory agency ever terminated or disapproved a trial that your site has conducted, or sanctioned a Principal/Co-/Sub- Investigator from your site, *or* has a Principal/Co-/Sub- Investigator ever had privileges at any hospital suspended, revoked, or restricted, *or* has a review board ever terminated or suspended approval of a trial that your site has conducted? ☐ **Yes** ☐ **No**

## IV. Contact Information

**Mailing Address**

Site Name: _____ Postal Code: _____

Address 1: _____ Country: _____

Address 2: _____ Site Fax: _____

City/Municipality: _____ Site Phone: _____

State/Province: _____

**Person to Contact Regarding Potential Studies**

Name: _____ Phone: _____

Title/Degree: _____ Email: _____

**Medical Director**

Name: _____ Phone: _____

Title/Degree: _____ Email: _____

**Additional Investigator #1**

Name: _____ Phone: _____

Title/Degree: _____ Email: _____

**Additional Investigator #2**

Name: _____ Phone: _____

Title/Degree: _____ Email: _____

**Additional Investigator #3**

Name: _____ Phone: _____

Title/Degree: _____ Email: _____

**Research Coordinator/Nurse** *(optional)*

Name: _____ Phone: _____

Email: _____

**Name of Person Completing Questionnaire:** _____ **Date:** _____

Again, we thank you for your time, effort, and collaboration with CTNI and look forward to hearing back from you soon!

Submit