



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 chung7@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 – USA

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?

- _____ M.D.
- _____ Ph.D.
- _____ L.C.S.W.
- _____ R.N.
- _____ 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) 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 use to an institutional IRB? Yes No

If “No”, does your site use a centralized IRB, such as WIRB or Copernicus? Yes No

Is your site typically required to use any additional ethics or review committees? Yes No

If “Yes”, please list the committee(s): _____

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

7. Does your site conduct training for personnel in Good Clinical Practice (GCP), particularly 21 CFR 312, Subpart D, “Responsibilities of Sponsors and Investigators” on at least an annual basis? Yes No

8. Is your site HIPAA-compliant? Yes No

9. Has your site ever been audited by the FDA? Yes No

If “Yes”, please indicate the date of the audit: ____/____/____ (month/day/year)

10. Has your site you ever received a Form 483/Warning Letter from the FDA? Yes No

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

11. Has the FDA or State Medical Board 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 an IRB ever terminated or suspended approval of a trial that your site has conducted? Yes No

IV. Contact Information

Mailing Address

Site Name: _____

Zip/Postal Code: _____

Address 1: _____

Country: _____

Address 2: _____

Site Fax: _____

City: _____

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!