

Appendix. Survey of Involvement and Participation in Clinical Trials

Physicians are frequently asked to participate in clinical research and are increasingly presented with a wide variety of research projects from which to choose. This questionnaire aims to define the factors which influence hepatologists to participate in clinical research.

I. DEMOGRAPHIC AND PRACTICE INFORMATION

1. Gender Male <input type="checkbox"/> Female <input type="checkbox"/>		2. Race/ Ethnicity (Optional)				
3. Age 25-30 years <input type="checkbox"/> 31-40 years <input type="checkbox"/> 41- 55 years <input type="checkbox"/> 56-70 years <input type="checkbox"/> >70 years <input type="checkbox"/>		African American <input type="checkbox"/> Asian <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Other (please specify) _____ <input type="checkbox"/>				
4. Specialty Gastroenterologist <input type="checkbox"/> Hepatologist <input type="checkbox"/> Infectious Diseases specialist <input type="checkbox"/> Internal Medicine specialist <input type="checkbox"/> Other (please specify) _____ <input type="checkbox"/>		5. Practice setting Primary Care Center <input type="checkbox"/> Tertiary Care/ Academic Facility <input type="checkbox"/> Community Hospital <input type="checkbox"/> Private Practice <input type="checkbox"/> Other (please specify) _____ <input type="checkbox"/>				
6. Current degree MD or equivalent <input type="checkbox"/> PhD <input type="checkbox"/> MD/PhD <input type="checkbox"/> Other (please specify) _____ <input type="checkbox"/>		7. Years in practice < 5 years <input type="checkbox"/> 6 – 10 years <input type="checkbox"/> 11 – 20 years <input type="checkbox"/> > 20 years <input type="checkbox"/>				
8. Please indicate the percentage of time you spend on each of the following professional activities:						
	0%	1 – 25%	26 – 50%	51 – 75%	> 75%	
Research-Basic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Research-Clinical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Research-Academic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Clinical- academic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Clinical-Private-Practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Industry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other (please specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

II. EXPERIENCE WITH CLINICAL THERAPEUTIC TRIALS

9. How many clinical trials have you participated in as an investigator during the last <u>12 months</u>?	none <input type="checkbox"/>	1 – 4 trials <input type="checkbox"/>	5 – 10 trials <input type="checkbox"/>	>10 trials <input type="checkbox"/>
10. How many clinical trials have you participated in as an investigator during the last <u>5 years</u>?	none <input type="checkbox"/> (skip to Q16)	1 – 4 trials <input type="checkbox"/>	5 – 10 trials <input type="checkbox"/>	>10 trials <input type="checkbox"/>

11. Please indicate the type(s) of clinical trials you have participated in as an investigator:

- Drug trials (Human studies)
- Basic Science Research
- Non-drug trials (eg. Procedural)
- Non-drug epidemiological research
- Other (please specify) _____

12. Please indicate the funding source for clinical trials you have participated in as an investigator:

- Pharmaceutical company
- Government institutions
- Non government/ charitable/ philanthropic agencies
- University/ Hospital funding
- Other (please specify) _____

13. Please indicate in order from 1 to 5 your preference for source of funding for trials (1 = most preferred, 5 = least preferred or N/A):

- Pharmaceutical company _____
- Government institutions _____
- Non government/ charitable/ philanthropic agencies _____
- University/ Hospital funding _____
- Other (please specify) _____

14. Regardless of whether you currently participate in clinical trials or not, please indicate the importance of the factors below in influencing your decision to enroll patients in clinical trials.

	Extremely important	Very Important	Somewhat important	Not at all important	Not sure
Patient's level of education	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient's race/ethnicity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient's socioeconomic status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient's ability to comprehend trial protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pressure from patient / patient's family members	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concern about losing patient to follow up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anticipated logistical problems (eg travel)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severity of disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cost incurred by you or your department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cost incurred by the patient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient's inability to comply or adhere to trial protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. How important are the factors below in influencing your participation in clinical trials?

	Extremely important	Very Important	Somewhat important	Not at all important	Not sure
Easy access to clinical trials/therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Level of funding/ equitable compensation for time and effort associated with the trial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relationship or previous experience with the institution conducting the trial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Offer from sponsors to fund additional projects/ establish a research fund etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendation from peers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Industry marketing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intellectual pursuit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. Which factors prevent you from participating in clinical trials:

	Completely prevents me	Is a concern, but doesn't prevent me from participating	Not a concern	Not sure
Increasing complexity of trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Excessive trial costs not covered by the trial sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Complexity of Institutional Review Board requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inferior trial medication(s) compared to standard therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lack of specialized support staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concern about sponsor control of trial decision-making, data, publication, etc	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Too busy with clinical practice commitments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethical considerations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty in accessing the appropriate patient population	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not interested in participating in sponsored clinical research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17. What is the likelihood of you enrolling the following patients in clinical therapeutic trials?

	Very likely	Somewhat likely	Not at all likely	Not sure
Non English speaking patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients > 65 yrs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unemployed patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients with reduced numeracy and literacy skills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patients with advanced disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uninsured patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. Please indicate your level of interest for participating as an investigator in the following trials:

	Very interested	Somewhat interested	Not at all interested	Not sure
Phase I trials (Initial introduction of an investigational new drug or pilot study to establish a safe dose range)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phase II trials (Controlled clinical studies conducted to evaluate the effectiveness of a drug for a particular condition)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phase III trials (pre-marketing controlled studies to determine safety, efficacy and appropriate dosage for a particular condition)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phase IV trials (Post marketing or open label studies to delineate additional information about drug risks, benefits and optimal use)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials with a study duration = 2 yrs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials with a study duration > 2 yrs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials with a placebo/ non treatment arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials involving invasive procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Trials with multiple arms and crossover protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials funded by pharmaceutical companies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials funded by government agencies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trials funded by non government agencies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. Consider a 45 year old male with Hepatitis C cirrhosis (genotype 1) who is unresponsive to pegylated interferon and ribavirin therapy and requests further treatment. How likely are you to enroll this patient in each of these trials:

A. A multi-center trial involving long term combination therapy for 5 years with the aim of reversing fibrosis. The trial includes multiple arms with varying doses. The trial is sponsored by a government institution which only funds the cost of the trial drug without reimbursement for additional costs.

Very likely	Somewhat likely	Not at all likely	Not sure
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B. A 6-month trial involving an oral agent with antiviral effects recommended for non-responders to standard therapy in phase II of clinical trial investigation. The trial includes multiple arms with varying doses. No significant side-effects were reported in phase I of drug evaluation. The trial is sponsored by a pharmaceutical company which funds all trial costs.

Very likely	Somewhat likely	Not at all likely	Not sure
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. A 12-month trial of an intravenous agent with anti-fibrotic effects in phase III of development. Minimal side-effects were reported in phase I and II of drug evaluation. The trial includes multiple arms with varying doses and a non-treatment arm. The trial is sponsored by a biotechnology company which funds all trial costs and also provides additional funds for support staff.

Very likely	Somewhat likely	Not at all likely	Not sure
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thank you for your participation.