Reviewer's report

Title: Attitudes of Gastroenterologists and Hepatologists Toward Participation in Clinical Research

Version: 1 Date: 26 May 2008

Reviewer: Armin Weinberg

Reviewer's report:

- Major Compulsory Revisions

While I find the information and paper of interest I am concerned about several points that in my opinion require attention prior to publication.

1. The first centers on the purpose of the paper itself. While I can imagine from the survey questions the intent of the study it is oddly difficult to find it clearly stated in either the abstract or the paper itself. Obviously they are trying to ascertain the factors that currently are influencing participation, weighing the impact of various barriers to participation, considering the factors related to patient enrollment, types of clinical research and or phase of trial, physician experience and training, and yes, even general demographics of the physician respondent pool. Indeed they seem to have had an acceptable response rate and should have ample data upon which to draw certain conclusions. Yet the data is really not clearly related to their conclusion which states “Critical gaps in the clinical research infrastructure in the United States limit hepatologists’ and gastroenterologists’ participation in research activities.” Sure the data describes barriers, preferences, experiences, but how are these converted into gaps in the infrastructure of the clinical trial enterprise? Bottom line: Needs work.

2. The second area of concern centers on a lines that may raise a flag about the level of basic understanding of clinical trials enterprise or the inability to distinguish between fact, analysis and opinion. This starts with the first sentence of the introduction that reads, “…and have opportunities to offer their patients cutting-edge therapies.” Or as in the discussion section, “…describes some worrisome trends in terms of an appropriate research infrastructure to address pressing needs for insight into optimal clinical strategies.” Or as in the conclusion, “…this study highlights some of the critical gaps in the clinical research infrastructure in the United States that limit the expansion of evidence-based clinical practice and translational research.” Let me give a few a concrete example, the authors state at "Researchers in gastroenterology and hepatology will not be immune to this trend and may be forced to choose between conducting research that explores scientific questions with limited commercial value and those that serve primarily commercial interests. “ I guess I am just confused by this type of statement. Are they saying that government funded research is less likely to produce findings of commercial value? I hope
not. Preceding this is a line that states “Recent research also indicates that academic-industry relationships…” However, the article referenced here is TWELVE (12) years old. I hardly consider that recent! Lastly, I’ll back up to the statement that, “Funding for biomedical research has traditionally come from government sources and academic institutions.” which just belies my concern that they are well intentioned in the survey and may have useful data but are not really knowledgeable about the realities of clinical research. The latest stats put the government funding levels at probably 20-25%.

3. The third concern does relate to the presentation of the data. For this example I’ll use the following, “One-fourth of the respondents reported that ethical considerations completely prevented them from participating in clinical trials, and nearly half (49.1%) said they were concerned about trial ethics. “ Which one-fourth is it that they are referring to? Hepatologists? Gastroenterologists? Those who did or did not choose to participate in clinical research? Young ones or older ones? This is obviously not a very clear presentation of the results. Perhaps seeing some data in the table would help others but frankly it only made it more disappointing to not know where statements like this actually came from. Or yet another “As might be expected, physicians were most concerned about the inferiority of study medications compared to standards of care.” Excuse me but most concerned compared to what? This apparently comes from survey question #16 where the choice of “Inferior trial medication(s) compared to standard therapy” that is one of ten items that are offered up as items that prevent the respondent from participating in clinical trials. Yet I see nothing in the data, figures, tables, or narrative frankly that warrants this type of statement. Maybe they really didn’t mean “most physicians?”

- Minor Essential Revisions

4. Although we presume the physicians surveyed are well aware of the different phases of clinical research and designs used in the survey questionnaire I would like to know that this was at least confirmed in the pilot test phase or development of the survey instrument. Obviously, without some knowledge of this one can and one should question the validity of results especially related the respondents’ level of interest or experience in types of trials. Again, it would be helpful to know more about the group that was used to develop the survey questions and instrument. In fact, since they described their efforts to increase face and content validity by using different question to elicit the same information I would think sharing more about their instrument development methodology should be relatively easy.

- Discretionary Revisions

5. It might also be of interest to have them discuss the potential impact of enrollment experience vs. self declared participation experience in a set number of trials by the respondents. For example, it is possible to have agreed to participate in a study but fail to accrue. It is also possible to have had more success in fewer with more positive outcomes or feeling about participation in trials in the future. Anyway, this is a potentially important distinction to the
categories used in the current survey.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests' below.

- Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this paper, either now or in the future? Not that I am aware of.

- Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper, either now or in the future? No

- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? No

- Do you have any other financial competing interests? No

- Do you have any non-financial competing interests in relation to this paper? Not that I am aware of.