

# Mitigating Nonadherence in Clinical Trials: Future Directions

Autumn 2016 Workshop – 26 September

## **A. Reviewed comments from the Feb 2016 Session on Mitigating Nonadherence in Clinical Trials and made the following suggestions for getting the Nonadherence WG recommendations in front of stakeholders:**

- 1. Send out e-mail to all attendees asking for more ideas.
- 2. All attendees promote the JClin Pharmacol Nonadherence paper. (Post findings on Twitter/elsewhere?)
- 3. Enlist Pharma to Share NA data and utilize [clinicalstudydatarequest.com](http://clinicalstudydatarequest.com); Draft clear request statement to Pharma/NIH.
- 4. Develop a Best Practices statement to aid in adding NA recommendations to protocols. Enlist the help of CROs.
- 5. Make the NA Working Group available to consult on adding NA measures to protocols
- 6. Promote WG recommendations at other meetings and to FDA
- 7. Continue the WG for at least another ISCTM; Poster on these/other ideas for getting NA recommendations out there at Feb ISCTM.

## **B. Should a new WG on Size vs. Success in Clinical Trials be Recommended to the ISCTM Scientific Committee?**

- Not yet. More discussion is needed. Could not get a clear picture of whether the focus should be on size alone (vs size being one of the reasons why Ph 3 studies are not as successful as Ph 2), whether there was enough commitment from representatives of Pharma to provide data on size vs. success and whether these issues are best tackled as a separate WG or as an offshoot/subgroup of the Nonadherence WG.