

Dear Ottawa group members,

This is the invitation to the Ottawa group dialogue on Sunday, 3 May, in Atlanta, Georgia, during the Annual Meeting of the Society for Clinical Trials, SCT. Please note the information about the room and the change of time: The meeting will be in two parts: from 15:00-17:00 (3-5 PM) in the Cottonwood room B and from 17:15-19:00 (5:15 to 7PM) in the Cottonwood room A.

The goal of this meeting is to further our principles of public disclosure of trial results. At the same time, we might decide to provide recommendations for finalizing the FDAAA, due by 22<sup>nd</sup> June 2009. For those of you that cannot attend it, we shall post the proposed comments to the FDAAA for your input. Following the meeting we shall post the outcomes.

Let me remind you that already in our Ottawa Statement part 1 (OS1) we identified that both prospective registration of trial elements and timely reporting of its results are integral parts of trial registration. We outlined the operationalization of prospective registration of trial elements in OS2 (in 2005) and of result reporting in OS3 (2006). Few international initiatives on results disclosure have been taking place in the meantime, including the PROCTOR meeting, call for reproducibility, as well as regulatory efforts at country levels, such as in the USA (FDAAA) and in the European Union.

PROCTOR (<http://www.cmj.hr/2008/49/2/18461682.htm>), identified a need to develop international standards public disclosure of trial results and thus complement and complete the trial registration.

Having that in mind, and worried about isolated and non-coordinated efforts that seem to be taking place, I felt an urgent need to continue our discussion on a development of international standards for registration of trial results, and organized a session at the SCT meeting on Tuesday 5<sup>th</sup> May (<http://www.sctweb.org/meeting2.cfm>). to inform and engage SCT members.

I believe however, that we need to meet as the Ottawa Group, and further our principles of public disclosure of trial results and at the same time provide recommendations on the FDAAA. These comments, due by 22<sup>nd</sup> June 2009, will be used to finalize the US regulations on expansion of clinical trials registry and results databank.

Many of Ottawa group members will be at the SCT meeting and we hope that some of you might decide to come just for this meeting.

Please reserve this time: Sunday 5 May from 3 to 7PM, Atlanta Georgia, @ the SCT Annual Meeting.

Kind regards

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