Last update: 22 Mar 2016

Question & Answer Log for the RPD SIG

Nr.	Date	Question	Answer	Responder
1	07-Mar-2016	For trials with sites in the US and the EU, do we have to post results in both the US and EU, or would posting in one region suffice?	No. If you have sites in both regions, you must meet the requirements for both regions.	CM
2	07-Mar-2016	For trials with sites in the US and the EU, do we have to post results in both the US and EU at the same time, i.e. at the time of posting in the EU after 12 months?	No. Only as per regional timelines. You are free to post results in the ClinicalTrials.gov early, i.e. at the time of posting in the EU clinical trial registry.	CM
3	07-Mar-2016	Do results from all interventional clinical trials in patients have to be disclosed irrespective of the MAA outcome?	Correct.	CM
4	07-Mar-2016	Do results from all interventional clinical trials in patients have to be disclosed irrespective of the NDA outcome?	No. The US FDAAA 801 requires posting of results from “applicable trials” contained in the NDA/BLA within 30 days of NDA/BLA approval.	CM
5	07-Mar-2016	Is disclosure of results from standard Phase I trials mandatory in the US?	No. This is optional. However, an increasing number of companies are posting Phase I trials in ClinicalTrials.gov.	CM
6	07-Mar-2016	Do results from all interventional clinical trials in adult patients have to be disclosed within 12 months of LSO in the EU?	Correct.	CM
7	07-Mar-2016	Registration of clinical trials before First Subject In (FSI) is a regulatory requirement in the US?	No.	CM
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