

ICH E14/S7B IWG/DG Work Plan

26 August 2016

Topic Adopted: December 2015

Last Face-to-Face Meeting: Jacksonville, FL, USA - December 2015

1. Anticipated Milestones

Completion Date	Deliverable
December 2017	Preliminary recommendation to ICH Assembly regarding whether to re-open ICH E14 and S7B for complete revision

2. Timelines

Date	Task / Activity	Details
Quarterly Teleconferences (next meeting 23 August 2016)	Track Progress of CiPA Initiative	<ul style="list-style-type: none">➤ Discuss progress of CiPA initiative, review data as it emerges, and provide guidance on developing a path towards using these assays for regulatory decision making.➤ When CiPA initiative is ready for widespread implementation, the discussion group will assess the scope of the effort required to re-open ICH E14 and S7B for complete revision and make a recommendation.