DRAFT AGENDA

I. Plenary – 10:00 to 13:00 (Authorities and stakeholders)

1. Welcome
2. Debrief on the IMDRF Management Committee (MC) meetings in Brasilia and MC teleconference held on 29.06.2016
3. Presentation of the Draft Agenda of IMDRF-10
4. IMDRF Work Items – Presentation of the state of play and discussion
   a. Review of the NCAR system
   b. Regulated Products Submission
   c. Software as a Medical Device
   d. Medical Patient Registries
   e. Medical Device Adverse Event Terminology
   f. Good Regulatory Review Practice – Competence and Training Requirements for Pre-market Reviewers and Product Specialists
   g. Improving the quality of international medical device standards for regulatory use
5. New Work Item Proposals
6. Update and discussion on the Single Audit Programme (MDSAP) Pilot Project