Draft Agenda

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

1. Welcome
2. Debrief on the IMDRF Management Committee (MC) meetings in Tokyo and MC teleconference held on 01.07.2015
3. Presentation of the Draft Agenda of IMDRF-7 (as proposed by Japan)
4. IMDRF Work Items – Presentation of the state of play and discussion
   a. Review of the NCAR system
   b. Medical Device Single Audit Program
   c. Regulated Products Submission
   d. Software as a Medical Device
   e. Medical Patient Registries
5. EU’s contribution to IMDRF Strategic Plan 2015-2020
6. Update on the Single Audit Pilot Project

II. Authorities only – 14:30 – 17:00

1. IMDRF Work Items – Wrap-up of morning discussion and conclusions on Line to take
   a. Review of the NCAR system
   b. Medical Device Single Audit Program
   c. Regulated Products Submission
   d. Software as a Medical Device