On 11 February the European Coordination meeting on IMDRF activities took place in Brussels in view to prepare the EU’s position for the IMDRF Management Committee meeting scheduled in Brasilia on 8-10 March. Stakeholders were invited to contribute in the morning open session. Following this session, in the afternoon, the Commission and the National Competent Authorities analysed the outcome of the morning discussion and worked on the definition of the final EU’s position. The overview of the decisions taken is briefly presented here as follows.

**IMDRF Existing Work items**

With regard to the decisions to be taken in Tokyo in the context of the existing Work Items (NCAR, MDSAP, SaMD, RPS, Patient Registries, AE nomenclature, Good Review Practices), the EU will be generally supportive towards the work done and the final deliverables proposed by the IMDRF Work Groups.

As to the general progress and future perspectives of these Work items, some specific points were agreed:

- **NCAR:** The EU is particularly keen to ensure a smooth running of the full implementation of the Exchange programme which is planned to start as from April 2016. In this context, the EU recognises the importance of broad and active regulators’ participation, including the MC members currently not participating.
- **RPS – Table of Contents Stream:** The EU is keen to ensure that an effective mechanism for management/change of the ToC in the future is put in place.
- **Registries:** Following receipt of the final proposed document on essential principles, an internal consultation will be organised with Member States and participating stakeholders, in order to gather possible inputs and/or concerns regarding the document as well as future objectives for this Work Group, prior to the meeting in Brasilia.
- **Adverse event nomenclature:** EU is of the opinion that a discussion on the issue of maintenance should take place within the IMDRF Work Group and thereafter at the MC level.

**New Work Item Proposals**

- **New Work Item Proposal (NWIP) on Standards.** The EU will support its NWIP which was the result of cooperation between the EU and DITTA (the global association that represents medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers) and offer the availability of the EU to chair the group.

**Single Audit Pilot Project and EU’s participation as Observer**

- EU will review progress during the Joint Assessment Meetings.
EU to discuss and possibly decide on possible future full participation to the Programme during the IMDRF Coordination meeting of July/August 2016, based on the experience gained in the context of the MDSAP RAC and SME Technical Work Group

EU to raise during the next RAC meeting the importance of better uptake of the Single Audits among manufacturers and auditing organisations