On 26 August 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 Kyoto on 15-17 September. 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 and Standards), 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 Pilot to be taking place between October and March, so that full implementation of the Exchange programme can take place as from April 2016. In this context, the EU will stress the importance of broad and active regulators’ participation during the Pilot phase, in order to gain experience and increase the overall effectiveness of the Programme.
- **RPS – Common Data Elements Stream (3rd stream)**: The EU is generally keen to ensure support towards smooth and effective progress of the three streams of this project.
- **SaMD**: As to the proposed Work item Extension on clinical processes, the EU considers that this work should devote specific attention to software having a diagnostic function. Moreover, the nature of the document, as informative document providing guidance, should be clearly stated.
- **Registries**: The EU would like to have the focus and nature of the document better clarified.
- **Adverse event nomenclature**: EU is generally concerned about possible problems related to resources to invest in the development/maintenance of this nomenclature.
- **Standards**: The EU is keen to follow-up the work done so far in this field through exploring ways to promote and incentivise use of standards within jurisdictions as well as improving participation and cooperation among regulators and international standardisation.

**New Work Item Proposals; EU’s contribution to IMDRF Strategic Plan**

- **New Work Item Proposal (NWIP) on Good Regulatory Review**. EU is keen to clarify the **exact** object/scope of the project as well as long-term possible connections with the MDSAP project. Provided that the US initiators clarify adequately these issues and clear benefits arising from this project are identified, EU will not oppose adoption of this NWIP.
In the context of the proposed IMDRF Strategic Plan 2015-2020, EU is keen to ensure that EU’s identified priorities (mainly NCAR, Standards, Clinical Evidence, Risk Benefit Determination) are appropriately reflected in the final document. Moreover a certain degree of flexibility should be foreseen, as to the possible future addition of possible emerging issues identified by the Management Committee and possibility for the Management Committee to consider proposals submitted by Stakeholders in the context of the identified Goals and MTT.

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

- EU will review progress during the Joint Assessment WG meetings and the EU Coordination meeting on IMDRF Activities in March 2016.

- EU will decide on possible future full participation to the Programme during the second half of 2016.