ACT EU MSP Kick-off Session 2: How can EFPIA contribute to the successful implementation of the CTR, and what does success look like?

EFPIA representing the research-based pharma industry in the EU has been contributing by analysing, commenting and collaboratively advocating since the first draft of the CTR was published, and will continue in doing so. In this intense phase of the CTR implementation and the transition from the CTD to the CTR, EFPIA has identified and communicated challenges that need to be addressed in order to make the implementation and transition a success from our perspective. A non-exhaustive selection is the following:

CT Transition from CTD to CTR: process and period

MS (+ EC) alignment and harmonisation

Streamlining and efficiencies

CTIS Functionality/Maturity

EFPIA will continue to support regulators in a cooperative manner to find solutions for the challenges identified and to keep the EU an attractive area for the conduct of Clinical Trials.