

CLINICAL TRIALS IMPLEMENTATION MONITOR SUMMARY

Updated Jan 2016	Austria	Belgium	Denmark	Finland	France	Germany	Ireland	Italy	Lithuania	Norway	Poland	Slovenia	Spain	Sweden	The Netherlands	UK	Croatia	Hungary	Portugal	Greece	Czech Republic	
Activities ONGOING implemented by national trade association to engage with national stakeholders in the implementation phase of the Clinical Trials Regulation	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Activities PLANNED by trade association to engage with national stakeholders in the implementation phase of the Clinical Trials Regulation	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Red	Green	Green	Green	Green	Green	Green	Green	Red	Green	Green
Has your Member State (e.g. competent authority, Ethics Committee, Ministry) initiated any activities to prepare for the implementation of the Clinical Trials Regulation?	Green	Green	Green	Green	Green	Green	Red	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Red	Green	Green
Are your Competent Authority and Ethics Committees collaborating in order to plan the assessment procedure?	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Red	Green	Green	Green	Green	Green	Green	Green	Yellow	Yellow	Green
Are the assessment responsibilities between the Competent Authority and Ethics Committees defined?	Green	Green	Green	Yellow	Red	Green	Green	Red	Green	Green	Red	Red	Green	Red	Green	Green	Green	Green	Green	Green	Yellow	Green
Are there discussions on how national databases will fit with the EU Portal/Database?	Green	Green	Green	Green	Red	Green	Green	Red	Green	Yellow	Yellow	Yellow	Green	Yellow	Green	Green	Green	Green	Green	Red	Yellow	Red
Are there local activities aiming to assess PPD and CCI information and disclosure of documents in CT portal and database?	Green	Green	Green	Green	Red	Green	Green	Red	Yellow	Yellow	Yellow	Yellow	Red	Yellow	Yellow	Red	Red	Red	Green	Red	Yellow	Yellow

YES NO I don't know

*Information missing from following countries: Bulgaria, Cyprus, Iceland, Latvia, Luxembourg, Malta, Romania, Slovakia