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The EU Portal: A Gate to Simplified Clinical Research?

The new Clinical Trial Regulation opens up a new era for the conduct of clinical trials in the EU and is an opportunity for the EU to foster clinical research.

The Regulation mandates the European Medicines Agency (EMA) to develop the IT platforms - EU Portal and Database - to support sponsors and Member States in carrying out their roles and responsibilities.

The EU Portal and Database is therefore a pillar of the new CT Regulation. It enables a single EU entry point for the submission of data and documents to cover clinical trial application, modification, registration and results reporting. It also allows for streamlined and coordinated assessment and provides publicly available information from the EU Database, increasing transparency of clinical trials and their results.

This presentation will provide an update on the current status of development of the EU Portal and DB, including of the relevant functionalities for sponsors, and on timelines for implementation.