Guide to CTIS Workspace Organisation

To enable submissions under the new regulation, a new online platform was put in place. This allows one central application to cover 30 European countries using one single portal — the Clinical Trials Information System, CTIS. The CTIS is organised by workspaces, which include sponsor and authority workspaces enclosed within a limited access database, along with a public portal.

Sponsor Workspace

Users submit a clinical trial application (CTA) to the sponsor workspace. This area is searchable by users and can be used to send reminders that trials or recruitment are beginning, red-flag any violations, provide notifications about the conclusion of a trial, and publish outcomes summaries.

Authority Workspace

The authority workspace provides further details on the tasks related to CTAs. Users can validate applications, inquire for more information, make decisions, and monitor the progress of studies with communication tools to streamline contact between participating Member States and representatives.

Public Portal

The public portal is an open-source platform available to the public. It provides searchable, detailed information on clinical trials in the EU and EEA and registered in the CTIS. It is available in all official EU languages.

Management Approaches in CTIS

The Sponsor can choose between two different management approaches in CTIS; the organisation-centric approach or the trial-centric approach. With former, Sponsors will attend access management in CTIS on an organisational level and can have an easy overview of all clinical trial applications within their organisation. It does, however, require some initial set-up and on-going work with handling accesses for the different trials. The alternative option would be to choose the trial-centric approach that facilitates a quick and easy way to get started on the first application.

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