eCTD dashboard

EXTEDO
eRegulatory Affairs

Product Information

eCTDmanager™ Dashboard

The effortless way to monitor the progress of your electronic submissions

During the creation of electronic submissions it is common for Regulatory Affairs teams to need to track their status and progress. Within many organizations project tracking involves reviewing data, documentation and task statuses captured within multiple discreet applications. With information separated into individual silos this task can be time intensive and is readily prone to errors.

Benefits
› Easily track the status and progress of electronic submissions
› Reduce time and effort searching for submission data
› Identify and optimize bottlenecks in submission process
› No need for an additional tool
› Drill-down reports showing:
    › regional dossiers
    › product category dossiers
    › dossier status
    › open tasks

Dashboard Overview – dossier details & status per modules
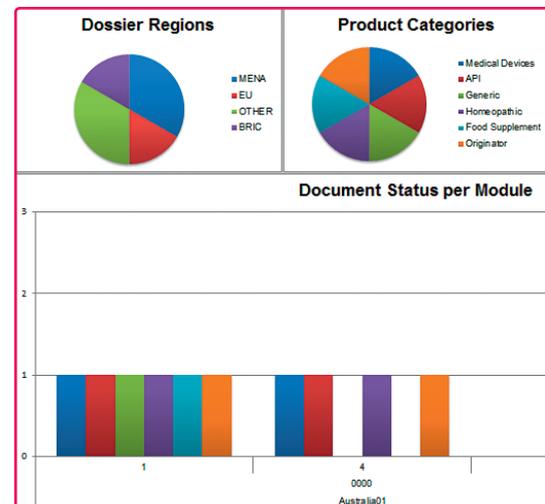
Plan and track submission activities

EXTEDO eCTDmanager Dashboard allows CROs, and all Life Sciences organizations that prepare regulatory submissions, to efficiently plan and track the preparation and submission activities associated with one or more dossiers. Through integration with EXTEDO eCTDmanager, submission data is captured and presented through an Excel Dashboard providing easy access to all the information required to monitor any submission.

During the production phase, eCTDmanager Dashboard enables submission related activities to be assigned to individuals and Outlook reminder emails, tasks and appointments can be easily sent directly from the task overview report. The dashboard also provides direct access to the contents of each submission, this includes metadata such as the submission status (new, replace, delete), as well as any attached documents.
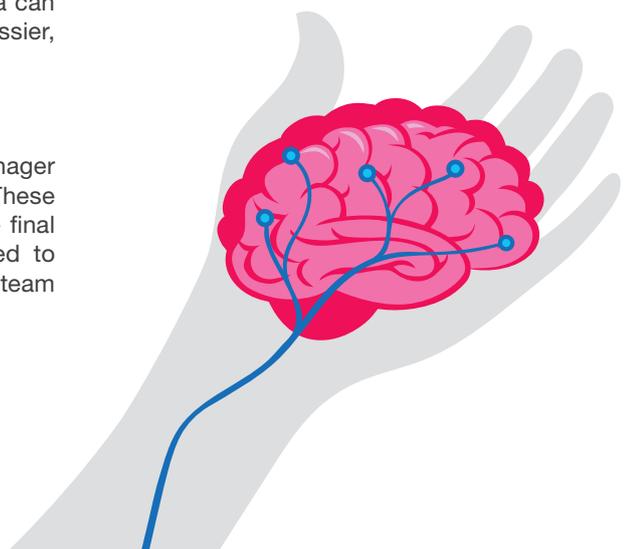
In order to quickly find the exact information required, submission data can also be readily filtered based on facets such as the task performer, dossier, agency or submission status.

Optimize your submission processes

To support the preparation and planning of submissions, eCTDmanager Dashboard provides the ability to create interim document overviews. These enable users to create an entire submission without the need to have final documentation in place. Instead, placeholder documents are created to which responsibilities and due dates can be assigned. This way your full team

knows exactly which documents are required and by when any interim documents need to be replaced by final versions.

By providing a single overview of all key activities and dates eCTDmanager Dashboard enables you to easily monitor the progress and deadlines associated with each submission; which tasks have been completed, what tasks come next, when was it released, and how long the authorities took to approve it. With this information to hand, internal process can be optimized and the quality and production time of future submissions can be significantly improved.

If your organization creates regulatory submissions using eCTDmanager, eCTDmanager Dashboard is the essential add-on for monitoring the progress of your electronic submissions.

Submission Dashboard – submission details

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