

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

### Plan and track submission activities

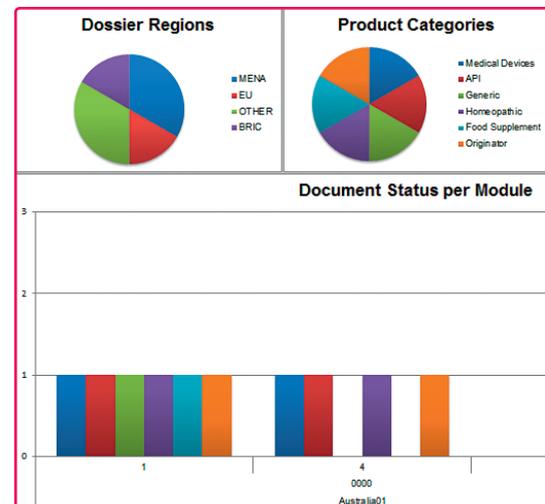
EXTEDO eCTDmanager Dashboard allows CROs, and all Life Sciences organizations that prepare regulatory submissions, to efficiently plan and track the preparation and submission activities associated with one or more dossiers. Through integration with EXTEDO eCTDmanager, submission data is captured and 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.

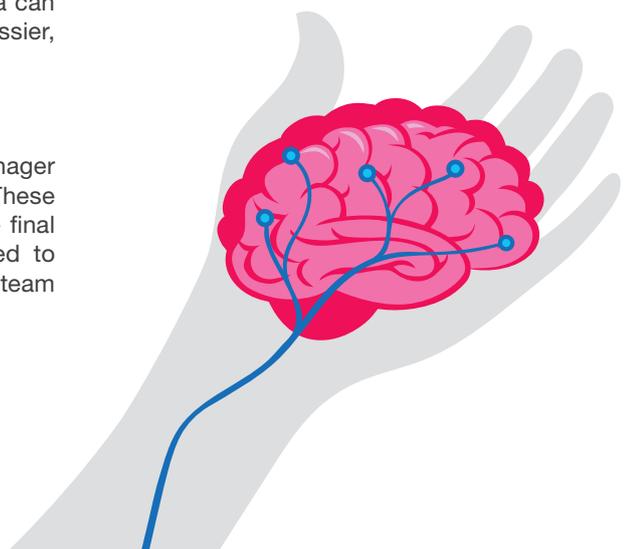
In order to quickly find the exact information required, submission data can also be readily filtered based on facets such as the task performer, dossier, agency or submission status.

### 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



Dashboard Overview – dossier details & status per modules



## Functional Overview

- › Simple project management for submission processes
- › Create Excel-based project dashboards
- › Generate reports for specific or all dossiers
- › Include interim planning data to see the status of interim documents
- › Track task due dates and submission deadlines
- › Create Outlook Tasks, Emails or Appointments at the click of a button

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.

Dossier	Sequence	Module	DOC Nr.	Document Title	Author	Operation	Author Due Date	Publisher	Publish Due Date	Document Status	Outgoing Hyperlinks	Incoming Hyperlinks
Australia01	0000	1	1.0.1	cover-0001	Schmidt, Christine	new	2016-03-05	Lehmann, Oliver	2016-03-10	1_Review	0	0
			1.0.2	tracking-0001	Georgios, Sophia	new	2016-03-05	Huber, Martin	2016-03-10	3_Hyperlinks Released	0	0
			1.0.3	response	Weigl, Stefan	new	2016-03-05	Stein, Michael	2016-03-10	4_Finished	0	0
			1.2.1	appl-form	Scholz, Maren	new	2016-03-05	Neumann, Gerd	2016-03-10	5_Approved	0	0
			1.3.1.2	pi-annotated	Schmidt, Christine	new	2016-03-05	Neumann, Gerd	2016-03-10	0_Pending	0	0
			1.3.1.3	pack-ins	Georgios, Sophia	new	2016-03-05	Neumann, Gerd	2016-03-10	2_Content Released	0	0
			4.2.1.1	primpharm	Scholz, Maren	new	2016-03-09	Neumann, Gerd	2016-03-15	1_Review	0	0
			4.2.1.3	safepharm	Haas, Raphael	new	2016-03-10	Huber, Martin	2016-03-15	2_Content Released	0	0
			4.2.2.2	absorb	Barr, Zubair	new	2016-03-05	Stein, Michael	2016-03-10	3_Hyperlinks Released	0	0
			4.3	litref	Weigl, Stefan	new	2016-03-10	Huber, Martin	2016-03-15	5_Approved	0	0
			2.2	intro	Barr, Zubair	new	2016-04-11	Scholz, Alexanc	2016-04-16	2_Content Released	0	0
			2.3.A	appendices	Haas, Raphael	new	2016-04-11	Huber, Martin	2016-04-16	4_Finished	0	0
			2.3.R	reginfo	Brown, Silke	new	2016-04-11	Neumann, Gerd	2016-04-16	2_Content Released	0	0
				cover	Haas, Raphael	new	2016-02-29	Stein, Michael	2016-03-05	1_Review	0	0
				reg-status	Zhao, Li	new	2016-02-29	Huber, Martin	2016-03-05	0_Pending	0	0
			2.2	Introduction	Georgios, Sophia	new	2016-02-29	Stein, Michael	2016-02-29	2_Content Released	0	0
			1.0.1	cover-0001	Chatti, Hani	new	2016-02-29	Stein, Michael	2016-03-05	3_Hyperlinks Released	0	0
			1.0.2	tracking-0001	Haas, Raphael	new	2016-02-29	Huber, Martin	2016-03-05	1_Review	0	0
			1.0.3	cop	Weigl, Stefan	new	2016-02-29	Huber, Martin	2016-03-05	4_Finished	0	0
			4.3	litref	Haas, Raphael	new	2016-02-29	Huber, Martin	2016-03-05	2_Content Released	0	0
			2.2	Introduction	Brown, Silke	new	2016-02-29	Neumann, Gerd	2016-03-05	3_Hyperlinks Released	0	0
			2.3	quality	Schmidt, Christine	new	2016-02-29	Neumann, Gerd	2016-03-05	0_Pending	0	0
			3.2.A.3	exp	Zhao, Li	new	2016-02-29	Stein, Michael	2016-03-05	5_Approved	0	0
			3.2.R	reginfo	Barr, Zubair	new	2016-02-29	Huber, Martin	2016-03-05	4_Finished	0	0
			1.01	cover-0001	Zhao, Li	new	2016-02-29	Huber, Martin	2016-03-05	5_Approved	0	0
			1.02	classification	Chatti, Hani	new	2016-02-29	Stein, Michael	2016-03-05	1_Review	0	0
			3.2.A.3	exp	Weigl, Stefan	new	2016-02-29	Huber, Martin	2016-03-05	3_Hyperlinks Released	0	0
			3.2.R	reginfo	Haas, Raphael	new	2016-02-29	Huber, Martin	2016-03-05	2_Content Released	0	0
			1.0.1	tracking	Schmidt, Christine	new	2016-02-29	Neumann, Gerd	2016-03-05	5_Approved	0	0
			1.0.2	cover	(Leet)	new	(Leet)	(Leet)	(Leet)	(Leet)	0	0
			1.3.1.1	blatt_4_korrektur	(Leet)	new	(Leet)	(Leet)	(Leet)	(Leet)	0	0

Submission Dashboard – submission details

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### About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.