Ennov Successfully Completes eCTD 4.0 Submission with EMA—Giving Customers a Head Start

Successfully completing an EMA eCTD 4.0 test submission, Ennov gives customers early readiness, lower risk, and smoother compliance.

Ennov eCTD4.0

PARIS, FRANCE, May 26, 2025 /EINPresswire.com/ -- Ennov, a global provider of unified regulatory platform for life sciences, has successfully completed an eCTD 4.0 test submission to the European Medicines Agency (EMA). One of only four vendors to reach this milestone, Ennov's submission was accepted, loaded into the EMA's system, and reviewed without issue: proving full compatibility.

A big win for all customers for eCTD 4.0 readiness

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> *Diarmuid Waide, senior RIM consultant at Ennov*

This successful test shows Ennov is ready for eCTD 4.0—well ahead of upcoming regulatory deadlines. As the EMA continues its phased rollout, Ennov customers benefit from:

- Early readiness for eCTD 4.0 submissions
- Lower implementation risk with validated, regulator-tested software
- Smoother transitions with no need to change systems or rebuild processes

"While MAHs can't submit eCTD 4.0 just yet, this gives our customers a clear advantage," said Diarmuid Waide, senior

RIM consultant at Ennov. “When the next pilot phase begins, they’ll be ready. With no last-minute surprises. And they know they can trust Ennov to support them for all the upcoming versions.” The EMA will expand testing to include MAHs in the coming months. Ennov is continuing active collaboration in the pilot and preparing to support more detailed submission scenarios as they evolve.

About Ennov
Ennov provides unified, cloud-based software for Regulatory, Quality, Clinical, and Pharmacovigilance in the life sciences. More than 450 organizations worldwide rely on Ennov’s single platform to simplify compliance and streamline operations.

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