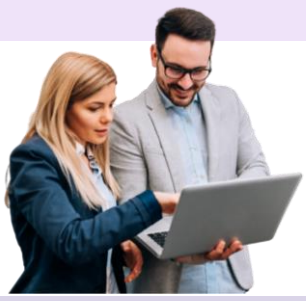
CORTELLIS CMC INTELLIGENCE

Streamline CMC dossier preparation

→ Actionable intelligence to ensure compliance and boost efficiency

Navigating the regulatory CMC approval process is complex – and costly

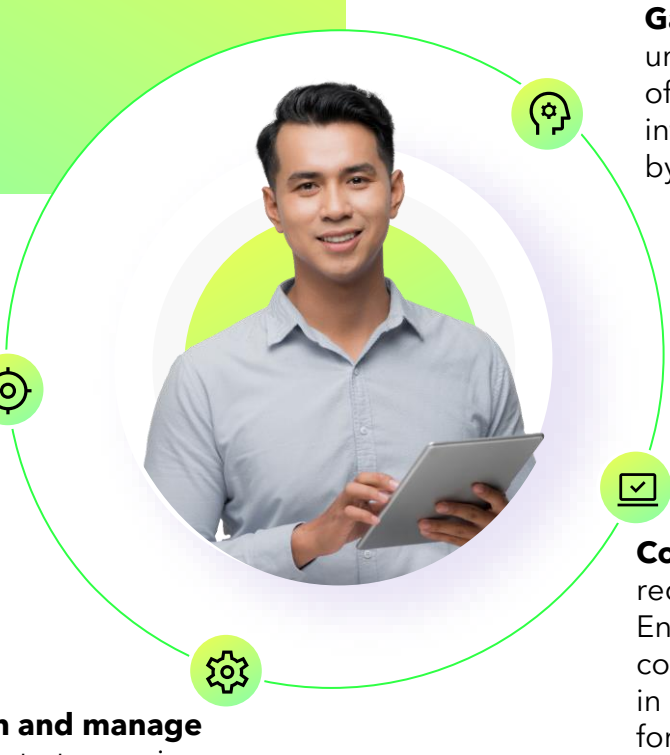
50%
of a company's total non-clinical budget is spent on CMC-related activities.[1]



$500K+
is the cost of a delayed launch, per drug, per day.[2]

18%
of delays following resubmission are due to CMC-related issues.[3]

Insights for effective pre- and post-approval submission preparation:



Find information and stay up-to-date effortlessly using a centralized platform.

Gain a deep understanding of local practice with information provided by Clarivate's experts.

Compare CMC requirements in English across multiple countries, provided in a CTD Module 3 format for easy navigation.

Plan and manage your submission strategy using the end-to-end pathways, with official and estimated timelines.

Approach each stage of the regulatory CMC approval process with confidence

- Risk reduction and increased compliance
- Improved processes and efficiency gains
- More informed strategy and reduced time to market

7K REGULATORY DOCUMENTS

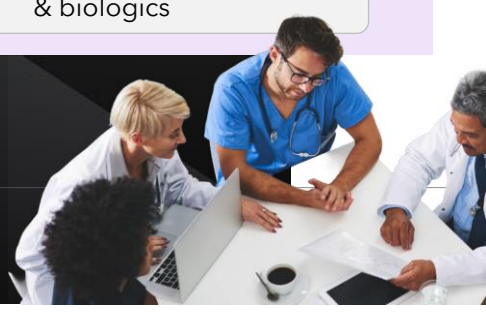
Pre-approval content:

137	Countries for Small molecules
64	Countries for biologics

Post-approval content:

61
Countries for small molecules & biologics

See Cortellis CMC Intelligence in action



Contact us here

FOOTNOTES:

1. https://www.contractpharma.com/issues/2013-06/view_features/characterizing-the-cost-of-non-clinical-development-activity
2. https://doi.org/10.1007/s43441-024-00667-w
3. https://jamanetwork.com/journals/jama/fullarticle/1817795