

# Regulatory Dossier Submissions

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Dossier Conversion and Documentation  
Support for Asia-Based Pharmaceutical  
Company

# Dossier Conversion and Documentation Support

## Asia-based Pharmaceutical Company

### *Business Need*

- The client had conducted multicenter studies for a resuscitative fluid in patients with post-CABG, traumatic brain injury, and stroke .  
Because the studies were conducted in the pre-CTD era, all the reports and documents had to be converted into CTD format for health authority submission.

### *Our Solution*

- Clinical and technical writing teams were deployed to convert all legacy documents into CTD format
- A publishing team was deployed to ensure submission readiness of the documentation packages

### *Outcome*

Successfully completed the conversion of reports/documents in CTD format within 3 months. A multi-year contract is in place to provide publishing and submission readiness support.



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