CONTENT AND DOCUMENT OWNERSHIP

CONTENT TYPE	CONTENT OWNER	CONTENT INTERDEPENDENCE
COMPOUND LEVEL DOCUMENTS		
Target Product Profile (TPP)	Product Core Team	Living document adjusted as clinical results are obtained with impact on commercial profile. Impacts CDP and GRS.
Clinical Development Plan (CDP)	Product Core Team	Living document adjusted as clinical results and regulatory scientific advice are obtained. Impacts TPP and GRS.
Global Regulatory Strategy (GRS)	Product Core Team	Living document adjusted as regulatory scientific advice is obtained. Impacts CDP and TPP.
Investigator's Brochure (IB)	Product Core Team	Living document to be continuously updated as pre-clinical and clinical data are obtained. Impacts/impacted by all trials.
Investigational Medicinal Product Dossier (IMPD)	Product Core Team	Living document updated as more information is obtained on the drug candidate.
TRIAL LEVEL DOCUMENTS		
Pre-Clinical Trial no 1, 2, etc.	Pre-Clinical Research Team	Trial reports to inform go/no/go decision on clinical development. Impacts CDP/clinical trials.
CLINICAL TRIAL NO 1 • Clinical Trial Protocol • Informed Consent Form • Patient Information Sheet • Case Report Form • Clinical Trial Report • Layperson Summary • Investigator's Brochure • Investigational Medicinal Product • Dossier • SAE reporting • Etc.	Clinical Trial Project Team 1	Initial clinical trial documents are created based on compound level documents, in particular the CDP. Repetitive content and translations are limited at this point and include primarily information carried-over from compound level documents to the trial documents.
CLINICAL TRIAL NO 2, 3, 4, ETC. • Clinical Trial Protocol • Informed Consent Form • Patient Information Sheet • Case Report Form • Clinical Trial Report • Layperson Summary • Investigator's Brochure • Investigational Medicinal Product • Dossier • SAE reporting • Etc.	Clinical Trial Project Team 2, 3, 4, etc.	Clinical trial documents created with partial repetition/carry-over from clinical trial no 1 and with updated compound level documents. Trial content and language repetitions include general, administrative and background information, e.g., on the drug, pre-clinical studies, risks and benefits, dosage, GCP compliance, population, and literature references. Repetition volumes increase as more clinical studies are executed and language assets are built.
COMPOUND AND TRIAL LEVEL DOCUMENTS		

MARKETING AUTHORIZATION APPLICATION/ NEW DRUG APPLICATION
• Module 1:
  • Regional Information
  • SmPC/Prescribing Information
• Module 2:
  • Overall Quality Summary
  • Non-clinical Overview
  • Non-clinical Summary
  • Clinical Overview
  • Clinical Summary
• Module 3:
  • Quality
• Module 4:
  • Non-clinical Study Reports
• Module 5:
  • Clinical Study Reports
	Regulatory Affairs/Operations
	Product Core Team
		New drug application/marketing authorization application is compiled based on pre-clinical and clinical study documentation and quality information on the drug.
		
		Substantial repetitions/carry-over from documentation accumulated through drug development and to the submission dossier.
		
		Substantial repetitions if new drug application is submitted in more regulatory territories.