

LAUNCH AND LANGUAGE EXCELLENCE

	PRODUCT STAGES	PRODUCT EVOLUTION	LANGUAGE AND AI
PRE-MARKET	<p>DESIRED PRODUCT TARGET PRODUCT PROFILE (TPP)</p>	<p>The TPP describes the desired commercial profile of the drug. It is the foundation for performance and safety claims for the product and its positioning.</p>	<p>Early language/narratives on the desired product positioning are founded.</p> <p>Language assets can be established to support product communication and messaging.</p> <p>AI driven language services offer limited benefits at this early stage.</p>
	<p>INVESTIGATIONAL DRUG CLINICAL DEVELOPMENT PLAN (CDP)</p>	<p>The CDP contains the research strategy and the planned clinical program that will generate scientific data to support the desired product.</p>	<p>Vast amounts of data, documentation and language assets are generated through clinical trials and R&D production.</p> <p>Language assets for clinical, safety and quality performance of the drug accumulate in multiple languages during clinical development.</p> <p>AI offers significant efficiencies, cost-savings and language consistency which can later be carried over to regulatory filing and launch phase.</p>
	<p>FINAL DRUG CANDIDATE GLOBAL REGULATORY STRATEGY (GRS)</p>	<p>The GRS lays out the regulatory strategy for the final drug candidate including its regulatory pathways, objectives, and territories where regulatory filings are planned and executed.</p>	<p>Vast amounts of documentation and language assets from R&D/clinical stage can be transferred to regulatory filing stage where all pre-clinical, clinical, and quality documentation is compiled, summarized, and critically assessed.</p> <p>AI is a great opportunity for efficiencies, cost-savings, and language consistency for the initial filing of the new drug application to post-market filings.</p>
LAUNCH	<p>APPROVED COMMERCIAL PRODUCT GLOBAL LAUNCH STRATEGY (GLS)</p>	<p>A launch strategy can be global or fall in waves across different territories as defined in the GRS.</p> <p>Launch communication activities commence long ahead of commercial entry into the market to prepare all internal and external stakeholders for product adoption.</p>	<p>The vast repository of content and language assets from pre-market stage can help ensure product success, differentiation, and manage launch expectations.</p> <p>AI can be applied to communication and language services with particular benefit for large scale roll out in multiple countries where content is multilingual.</p>