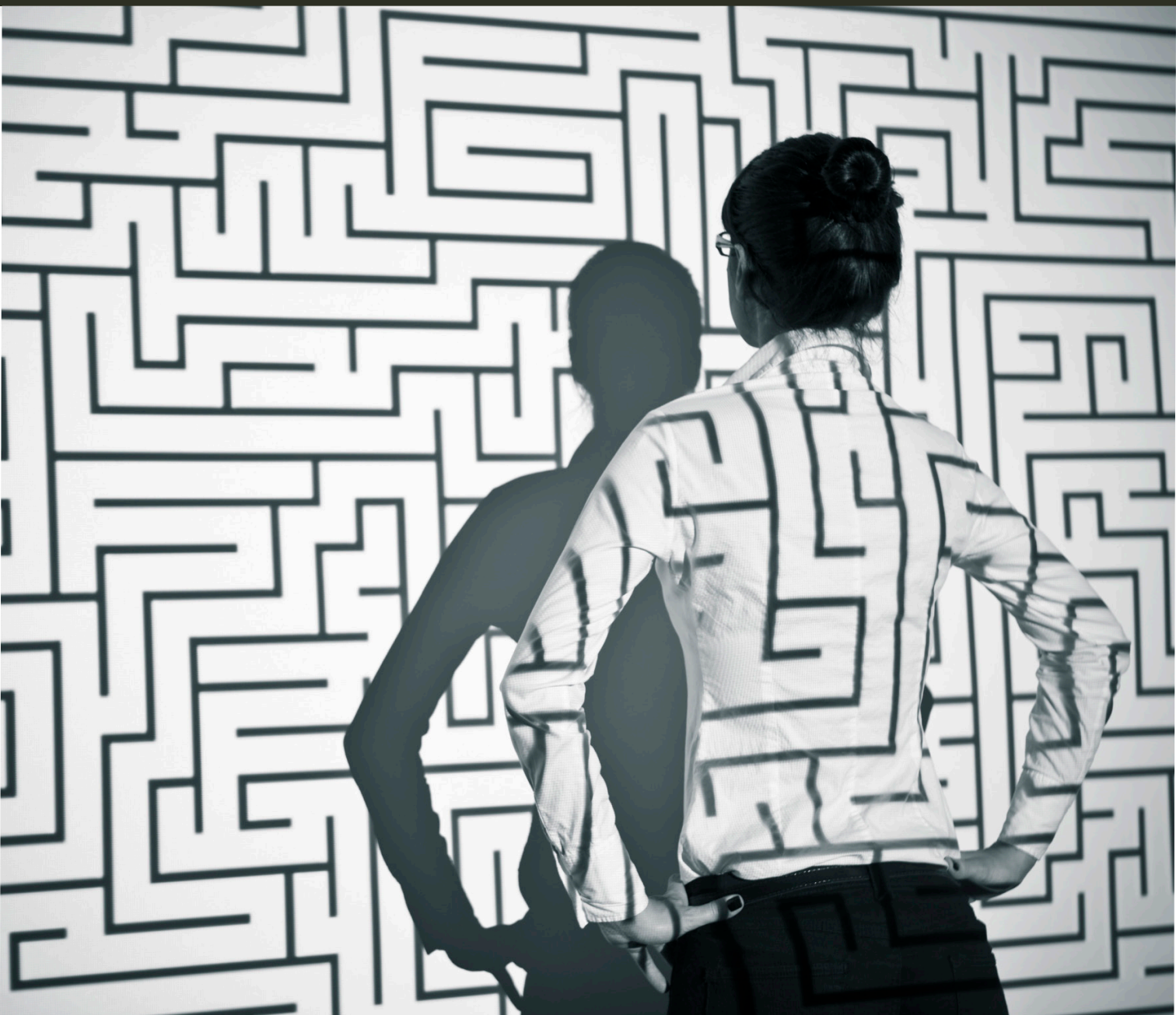


SCIFORMIX

Right Decisions, Right Time

www.sciformix.com



Right Decisions, Right Time

Today's "flat" and increasingly complex world presents unprecedented challenges and opportunities for pharmaceutical companies to manage the combination of evolving regulatory requirements, rising drug development costs and shrinking product pipelines.

Early engagement with strategic support partners can significantly help you in managing the challenges.

We at Sciformix partner with our clients through the product lifecycle to help them make the right decisions at the right time.

Our expertise in key areas and our flexible global delivery model allows us to provide solutions tailored to the unique requirements of each client and to enhance efficiency, quality and compliance, while containing costs.

Our expert and dedicated client teams, combined with our robust processes, ensure consistent quality and full regulatory compliance at competitive costs, providing long term value to our clients.

Shared Success

Sciformix personnel have a deep understanding of the regulations governing the global pharmaceutical industry. Our client-specific solutions use efficient and mature processes, robust metrics, best practices, state-of-the-art technology and broad therapeutic area expertise to deliver cost-effective, consistent and high-quality results.

We sharply reduce startup cost and time to market by fostering alignment with the client and ensuring adherence to the project schedule through trusted project and alliance management tools. Sciformix provides long term value to the clients by employing best practices like milestone based payments, co-investment in assets and shared risks and incentives.

Sciformix will partner with your organization to support outsourcing of end-to-end or specific services.

Biometrics

Sciformix offers superior statistical expertise, efficient data management and optimal programming effort to deliver high quality data and analysis in a timely and cost-effective manner. Our expertise spans from Model Based Drug Design to final statistical analysis.

Data Management	Programming	Statistics
<ul style="list-style-type: none"> • Data Management Plan • CRF and database design • Validation procedures • Data Capture, Vendor data load • Discrepancy management • Coding and safety reconciliation • Database lock 	<ul style="list-style-type: none"> • Programming specifications • Development of SDTM and ADaM datasets • Creation of derived datasets • Programming and validation for TLGs • eSubmission support • Mapping legacy data to CDISC standards • Monitoring study quality 	<ul style="list-style-type: none"> • Study Design (including adaptive & Bayesian designs) • Clinical Trial Simulation • Sample size calculation • Statistical Analysis Plan • Interim Analysis • Blinded Tables Review • Statistical report, Clinical Study report • Exploratory and ad-hoc analysis

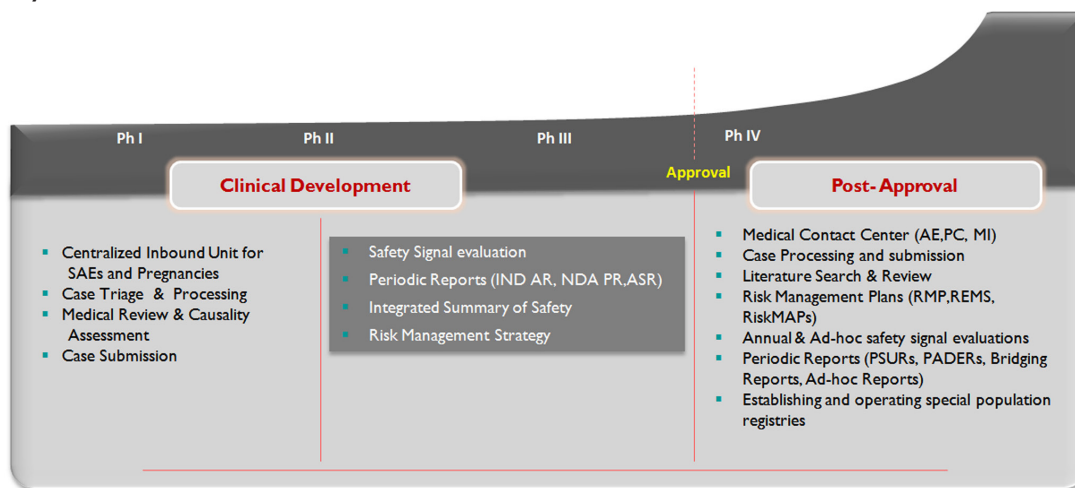
Scientific Writing

Our scientific writing team authors every type of regulatory report required, including reports for analysis of clinical trials, safety of marketed products, and manufacturing or formulation changes.

Safety Writing	Clinical Writing	Regulatory Writing
<ul style="list-style-type: none"> • Post-marketing periodic safety reports - PSURs, NDA PRs/PADERS, Summary Bridging Reports & Ad-hoc Reports • Pre-marketing safety reports - IND ARs, EU ASRs • Safety case narratives • Patient Medication Guides • Risk Management Plans 	<ul style="list-style-type: none"> • Clinical trial protocols • Investigator's Brochure (IB) • Clinical Study Reports (CSR) & web synopses • Informed Consent Documents • Abstracts & Manuscripts • Standard responses to medical queries • Product-specific Web content 	<ul style="list-style-type: none"> • Company Core Data Sheets (CCDS) • Summary of Product Characteristics (SmPC), Patient Information Leaflets • Nonclinical & Clinical Overviews (Modules 2.4 & 2.5 of CTD) • Application for Bio-waivers.

Safety and Risk Management

Our global pharmacovigilance team delivers the full gamut of safety and risk management services throughout the product lifecycle using our own validated safety database and appropriate literature database subscriptions. Alternatively, we can also use the client's database via client's network.



Regulatory Affairs

The Sciformix regulatory team provides support for developing a registration strategy and for submissions management (authoring, compiling, and publishing dossiers). We provide post-approval support throughout the product lifecycle, including authoring amendments, type II variations, annual reports and responses to regulatory audits.

Clinical Development (Phase I, II & III)		Post Approval
<ul style="list-style-type: none"> Animal Pharmacology and Toxicology Protocols Animal Pharmacology and Toxicology Study Reports Investigational New Drug Application (IND) 	<ul style="list-style-type: none"> Biologic License Application (BLA) Market Authorization Application (MAA) Device Application <ul style="list-style-type: none"> Investigational Device Exemption (IDE) 510 (K) Pre-market Approval (PMA) Dossier for Lesser Regulated Markets Drug Master File CEP / COS Plasma Master File (PMF) Vaccine Antigen Master File (VAMF) 	<ul style="list-style-type: none"> Amendments <ul style="list-style-type: none"> Post-Approval Studies (PAS) Changes Being Effectuated (CBE), CBE30 Variation Labeling Summary of Product Characteristics

Talk to us to explore the ways in which we can help you.

Sciformix Corporation

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