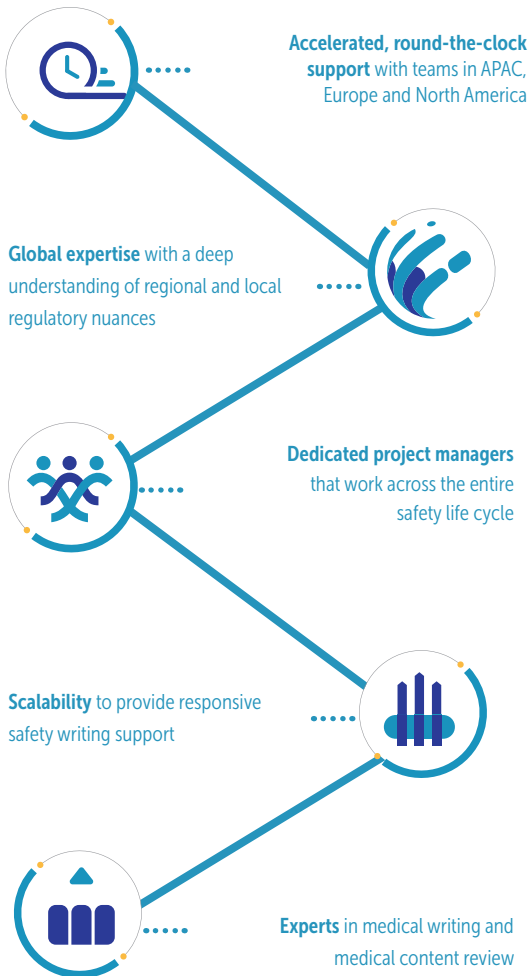# Safety and Pharmacovigilance

Assure Patient Safety with One Team for all Your Safety/PV Documents

Achieve safety-related document compliance with one team that delivers project management, data analysis, medical writing, and medical review capabilities round-the-clock.

Synchrogenix supports safety-related document authoring for all major global agencies.

Accelerated, round-the-clock support with teams in APAC, Europe and North America

Global expertise with a deep understanding of regional and local regulatory nuances

Dedicated project managers that work across the entire safety life cycle

Scalability to provide responsive safety writing support

Experts in medical writing and medical content review

Anticipating Challenges Helps Assure Patient Safety & Report Compliance

- Proactive management of project timelines
- Deep regulatory knowledge enables streamlined, yet thorough compliance to regulations and guidelines
- Flexibility to meet changing requirements and tight timelines

Authoring all safety-related documents required throughout the drug development lifecycle, including safety narratives, eCTD documents (2.7.4, ISS), aggregate reports, risk management plans, cumulative safety analysis, literature searches, global value dossiers, and signal evaluations.

- DSUR/IND Annual Report
- RMP
- PSUR/PBRER/PADER
- Addendum to Clinical Overview

- Signal assessment report
- Safety analysis document/report
- CCDS
- Benefit-Risk Analysis

142 de novo RMP/RMP updates authored

105 PSUR/PBRERs authored

155 literature searches/reviews completed

223 Annual Safety Report/DSURs authored

Over the past 5 years

80K Patient Narratives authored