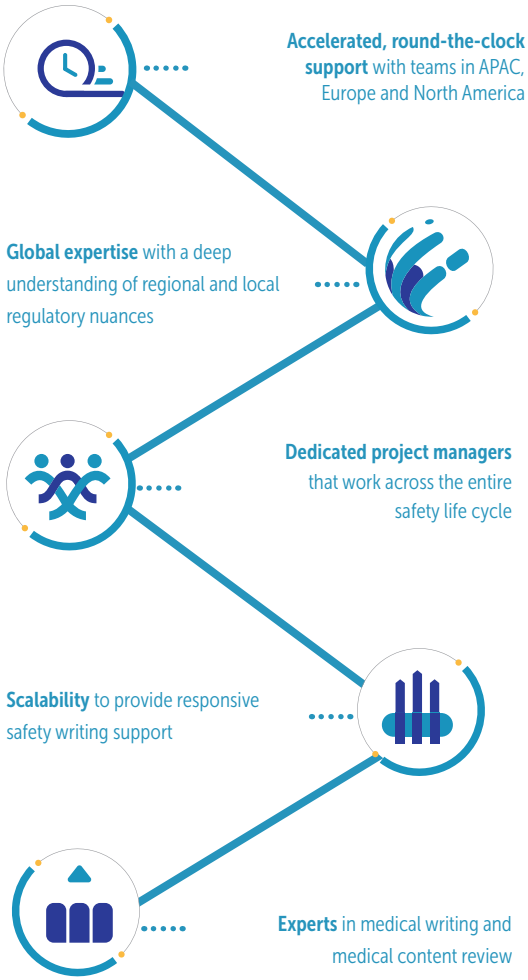
CERTARA | SYNCHROGENIX

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.

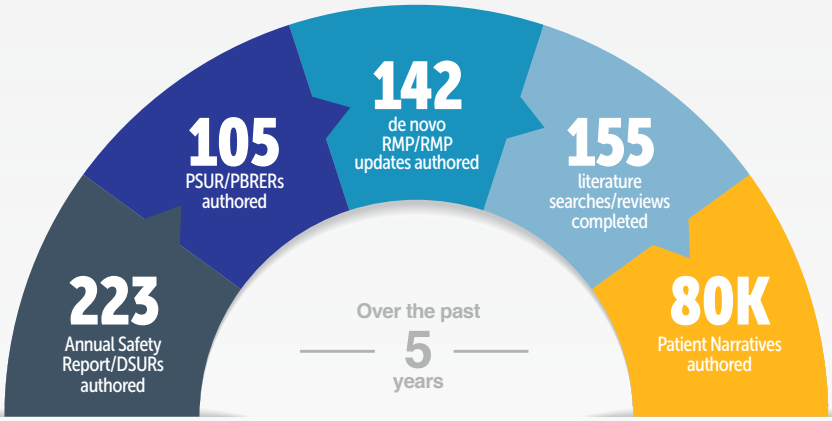


Anticipating Challenges Helps Assure Patient Safety & Report Compliance

- 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



For more information, please contact us at +1 302-892-4800 or contactus@synchrogenix.com