



Aggregate Reports

Elevate Your Aggregate Reporting:

Harness extensive medical writing expertise to seamlessly prepare, review, and submit Development Safety Update Reports (DSURs) and annual/semi-annual aggregate reports. Our skilled team ensures compliance, examines safety data, and collaborates seamlessly to deliver comprehensive, timely, and regulatory-compliant reports.

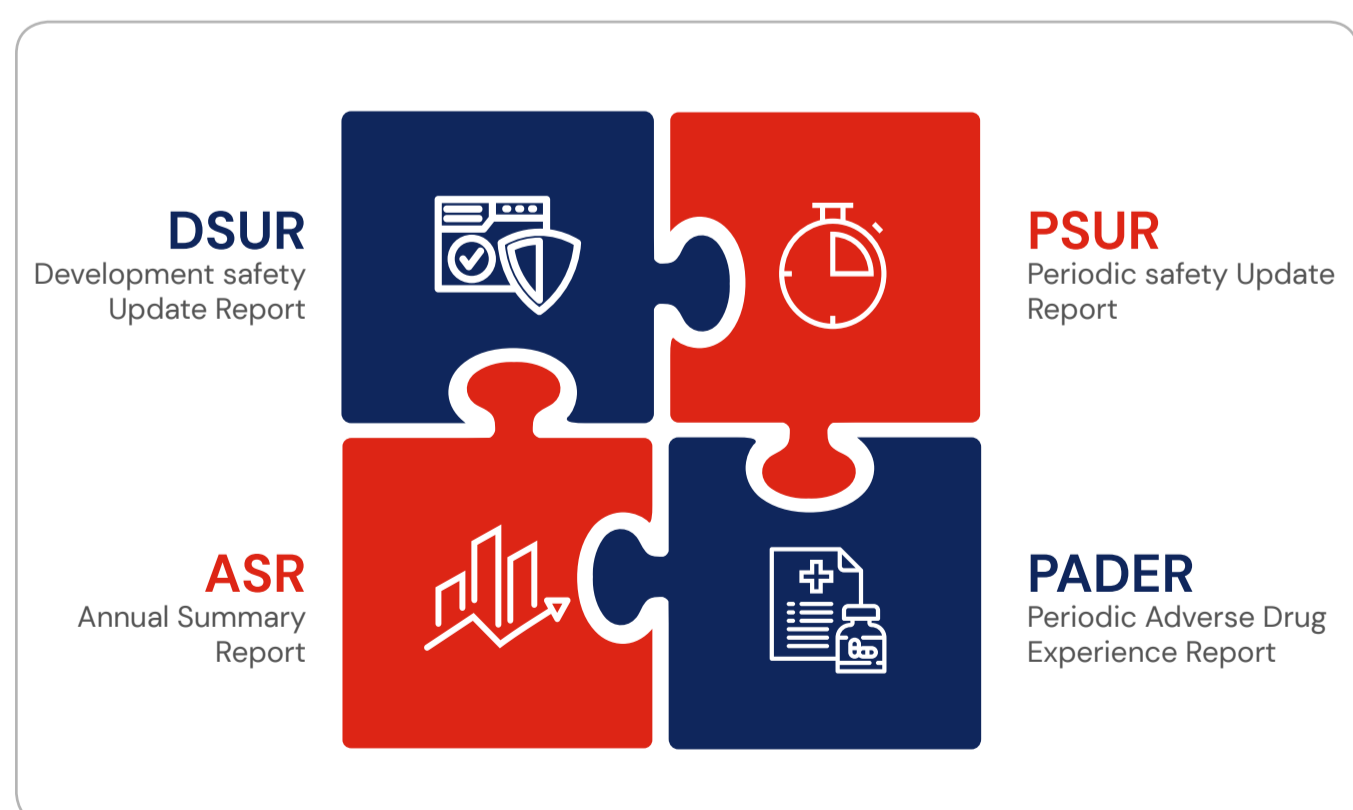
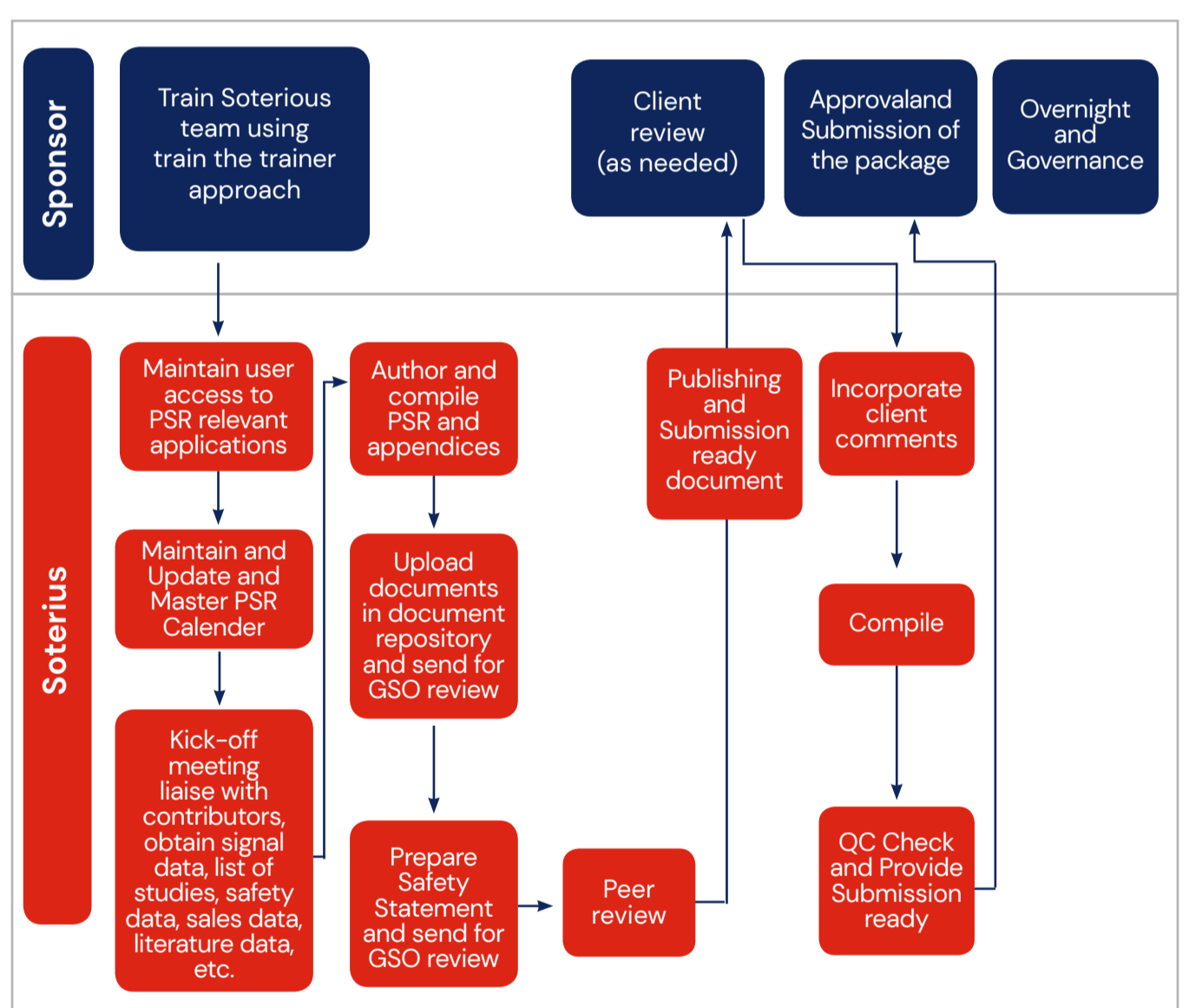
Unlocking a legacy of proficiency: Our adept team boasts substantial experience in crafting comprehensive aggregate reports. Delve into our journey through the snapshots below:

Soterius has an experienced team that can support sponsor in the following activities relevant to annual/semi-annual aggregate reports:

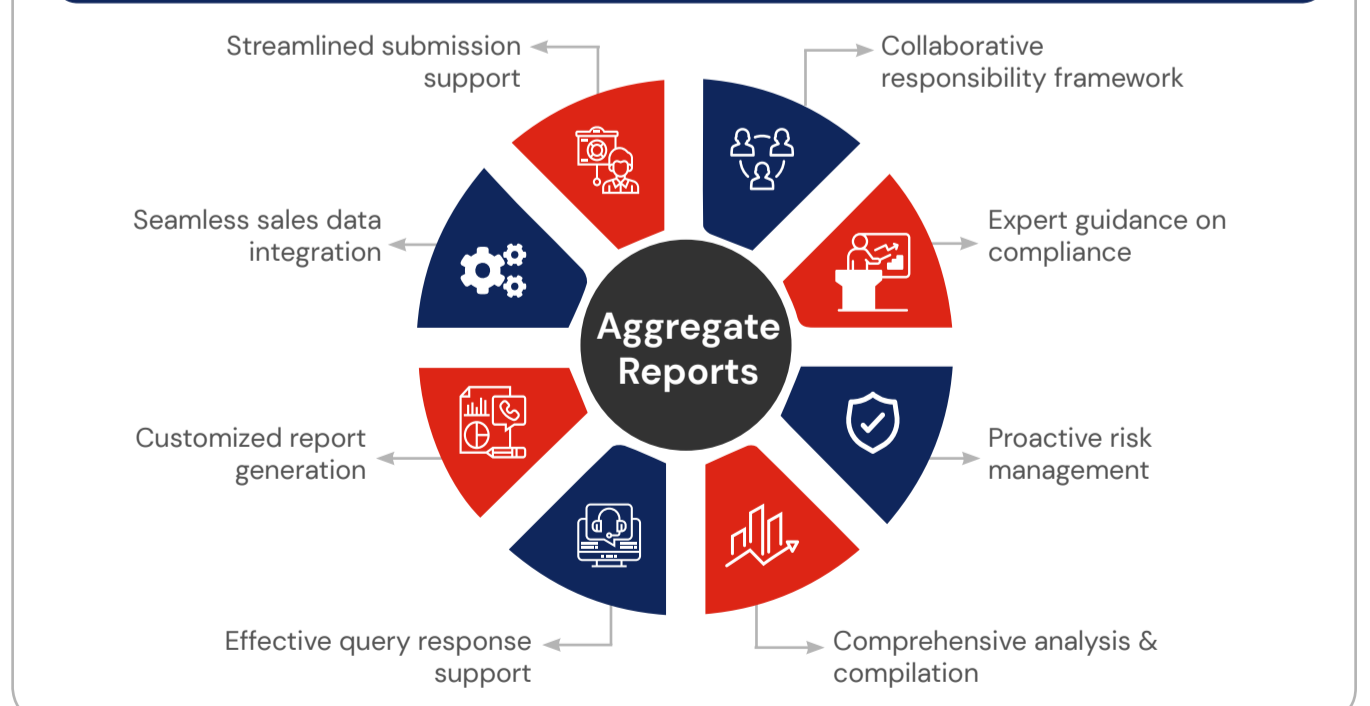
- ✿ Preparation, compilation, authoring, publishing and distribution of reports to ensure timely submission of the PBRERs as per applicable regulatory requirements.
- ✿ Cumulative review of ICSRs/SAEs to be included in the periodic reports.
- ✿ Line listing generation and review of report-related outputs from the safety database.
- ✿ Inputs for generation of customized reports and line listings from the safety database.
- ✿ Sales data generation and publishing in aggregate reports, where required.

- ✿ Quality control and compliance tracking for report outputs, draft and final reports and submission data.
- ✿ Reviewing and taking action on the assessment report conclusions received from the regulatory agencies, as required.
- ✿ Provide support in responding to any post submission regulatory authority requests.

Collaborative Roles: Sponsor & Soterius



Facing Challenges? Get Solutions



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