CERTARA

Fact sheet

Safety & Pharmacovigilance Writing

Aggregate Safety Reports | Risk Management Plans | Patient Safety Narratives

Assure patient safety with integrated expertise

Fragmented teams and hand-offs through your product's lifecycle can result in errors that lead to significant risk of non-compliance of regulatory process requirements and patient safety. Certara supports safety-related document authoring throughout the entire safety lifecycle for major global agencies. These capabilities cover the full drug development continuum (First-in-human clinical studies to submission) and the post-marketing setting. We work closely with our regulatory writing, submission support and technology solutions teams, so our solutions can be delivered in concert to provide greater consistency and certainty to your program.

A fully integrated, end-to-end offering tailored to your needs

Clinical Development

- Development Safety Update Report (DSUR)

Pre-marketing Approval

- Summary of Clinical Safety (Module 2.7.4)
- Integrated Summary of Safety (ISS)
- Risk Management Plan (RMP)

Analyses

- Cumulative Safety Analysis
- Support with Benefit Risk Analysis

Additional Support

- Literature Searches

Post-marketing Approval

- Periodic Safety Update Report (PSUR)
- Periodic Benefit-risk Evaluation Report (PBRER)
- Periodic Adverse Drug Experience Report (PADER)
- Safety Assessment Report
- Addendum to Clinical Overview (ACO)
- Health Authority Query Responses
- Signal Evaluations

Narratives

- Technology-enabled Safety Narratives using our AI-empowered CoAuthor™ Tool
- Manual narratives and narrative updates
- Oncology and Non-oncology Templates

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Why Certara?

The value of unmatched scientific expertise and wide-ranging drug development experience

Experience

>90% of all novel drugs approved by the U.S. FDA since 2014 were supported by Certara services or technology

Expertise

60+ years of combined experience writing aggregate safety reports

Tech-enabled

Ability to harness the power of proprietary software platforms like CODEX, SEND, Explorer, Pinnacle 21 for submission compliance and study data automation, and CoAuthor™ to improve productivity when authoring regulatory documents.

Flexible Support

Flexibility to either take the reins (expert writers delivering fully-authored reports), work collaboratively (supporting our clients to author sections of the reports), or act in a purely project management capacity (leading and driving teams to a successful outcome).

Global Expertise

Ability to manage global, multidisciplinary teams and complex projects with short turnaround times, combined with our global footprint, is the perfect combination to make sure that the strict safety and regulatory timelines are easily met.

Tech-enabled Patient Narratives

Gain speed, quality, and consistency across your narrative set thanks to Certara's CoAuthor's narrative builder features, which efficiently manage thousands of narratives to full completion, including review, in a fraction of the time.

Compliant eCTD Templates

Our fully compliant templates for global and regional safety aggregate report submissions will reduce review times, especially with tight deadlines.

Certara Regulatory and Safety Science Practice Leaders

Mary Pilkington PHD

Associate Director, Safety and Pharmacovigilance

Reema Selvaraju

Director, Patient Safety Narratives and Automation

Efficient safety reporting starts with Certara

Read the case study to see how we delivered DSUR excellence for a global biopharma.

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions and regulatory agencies across 70 countries.
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