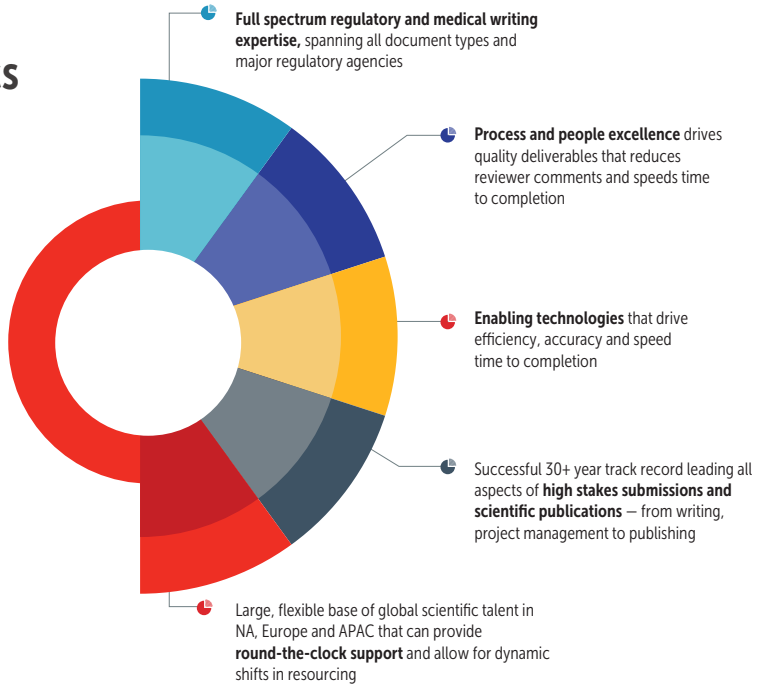
CERTARA | SYNCHROGENIX

Scientific and Medical Communications

Our People. Our Proven Approach. Your Success.

Inform and accelerate your therapeutics to patients with a writing partnership leveraged by technology and flexible, highly qualified professionals.

Our clients include pharmaceutical, biotech, and startup companies; patient advocacy groups; healthcare professionals; researchers; payers, and the public. By engaging our writers for scientific and medical communications, companies benefit from Synchrogenix's suite of services.



Our Medical Writers

Increase exposure of your key findings and accelerate your therapeutics to healthcare providers and the scientific community with the knowledgeable professionals your scientific investment deserves.

Our scientific medical writers

- Increase the impact factor of your key findings by providing outstanding writing support and process guidance to maximize acceptance decisions
- Mitigate your risk of potential misrepresentations by working effectively across geographies and cultures to gain alignment across authoring teams
- Alleviate your internal burden by owning and driving project timelines

Medical Communications & Publications

- Manuscripts
- Abstracts
- Posters
- Oral Presentations
- Medical Slide Sets

Our Regulatory Writers

Accelerate your time to submission with seasoned regulatory writers who coordinate across submission documents to maximize successful creation and delivery for your product.

Our highly qualified writers offer support across all functions (Quality/CMC, Nonclinical, Clinical, and Regulatory) and

- Have highly skilled, dedicated QC groups and strategic consulting professionals at their disposal to mitigate your risk of a refuse to file a response and any issues that may postpone your submission and product approval
- Meet your targets because they are mission-critical professionals who deliver on time, every time
- Alleviate your internal burden by operating as a team to own and drive project timelines and document development strategies

Regulatory Documents

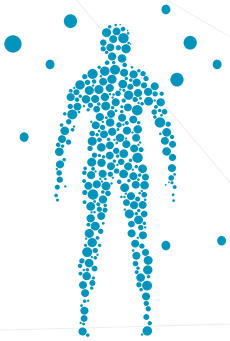
- Clinical Study Protocols
- Clinical Study Reports
- Briefing Documents
- All ICH Module 2, 3, 4, 5 Summaries
- Pediatric Investigational Plans
- Investigator Brochures
- PBRERs and DSURs

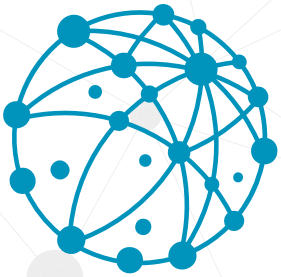
certara.com/regulatory-science/scientific-and-medical-communications-and-publications/

Flexible and Scalable Resource Pools

Synchrogenix's full-time, wholly owned offshore and domestic contractor resource pools provide 24-hour support and the flexibility and scalability required for rapid response to your most urgent needs.

We handle the administrative burden and onboarding so that you can engage highly skilled medical and regulatory writers with the least amount of friction.





100+
indications in 15 therapeutic areas

250+
full-time employees in 17 global locations

100%
approval on submissions we've supported

Over the past year

we have supported client manuscripts across a variety of therapeutic areas including immunology, neuroscience, oncology, and rare disease that were published in journals including *Journal of Drugs in Dermatology, Clinical Rheumatology, Current Medical Research and Opinion*, and *Journal of Pharmacology and Experimental Therapeutics.*

Delivering Commitments to Patients & Stakeholders

A small biotech company came to us in need of support for their first-ever NDA, which had a submission deadline in nine months. In addition to having a large clinical study program, they were relying on historical data on the active ingredient for much of their nonclinical requirements and needed to integrate a large, parallel clinical program conducted by their licensee in Japan. After an initial kickoff meeting, we developed a detailed daily timeline through to submission. We led weekly submission team meetings and authored nearly every document. Through careful planning and expert delivery, we delivered the NDA on schedule, with FDA approval in the standard ten months.