



eCTD Submission Vendor Selection Checklist

A checklist is a great way to evaluate your options and identify the selection criteria most important to you. At Certara | Synchrogenix, we have worked with a variety of clients to support their needs. This checklist represents the most commonly asked questions and it can help guide your process. For expert guidance, book a free consultation with a submissions specialist: contactus@certara.com

Trait/Weighted vs. Candidate	Impact to Workflow/Process	Vendor A	Vendor B	Vendor C	Certara Synchrogenix
Strong company overview, including solid financials	Company with market leadership and broad expertise; sound financial health.				
Flexibility and scalability	Organization has proven capacity for growth; able to adapt to an industry that is always changing and evolving.				/
Reliability and trust	Includes strong reputation and references. Company able to show solid verification of its quality. Provides case studies, testimonials, and clients you can contact as references.				√
Enterprise features, including "one-stop shop" service offerings	Greatest benefit is your business impact by having only one vendor; other considerations are teamwork, financial accounting, partnering, and cohesiveness.				√
Innovative technology and easy-to-use interface	Company delivers technology that saves time and improves quality/ accuracy with a simple user interface.				✓
Strong user authentication and advanced security	Company can show security is a priority and can demonstrate its validation, and certification.				✓
Clear and comprehensive contract/work order	You are protected by a contract that allows for flexibility, additional considerations, and overall confidence in the project.				/
Efficient/speedy onboarding process	Company can smoothly on-board and ramp-up quickly; this may impact timelines and workflow.				/
Team with deep knowledge and expertise (strong credentials)	The team that will serve you has deep expertise and offers continuity				✓
Availability of user support, training, and on boarding	Company can demonstrate a well-documented training program and highly available first class customer support service.				✓
Support of multiple eCTD jurisdictions	Company's software supports the region(s) where you intend to submit.				/
Companion templates available	Company offers an array of templates, suitable for multiple jurisdictions, while showing expertise with a solid training and support program.				/
Round-the-clock publishing support, including global operations	Company is capable of processing and seamlessly moving your project forward. This may be critical for meeting deadlines.				✓
Specialized consulting and regulatory expertise	The team has experts that are experienced in your therapeutic area; organization can provide real-world advice on strategy.				/
Total Score					