

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, 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.

| Essential traits | Impact to workflow and process | Vendor A | Vendor B | Certara |
|--|--|----------|----------|---------|
| 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 onboard 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 onboarding | Company can demonstrate a well-documented training program and highly available first class customer support service. | | | ✓ |
| Support for multiple eCTD applications | 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. | | | ✓ |
| Global publishing support | 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 | | | | |

Get expert guidance with a submissions specialist

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