

Electronic Submissions Partner Evaluation Check List

The following questions will assist sponsors in the evaluation and selection of an appropriate electronic submission partner.

| Questions | Partner | | |
|---|---------|---|---|
| | A | B | C |
| 1. Does the partner provide Regulatory Affairs, Regulatory Operations and Project Management expertise? | | | |
| a. Number of RA Professionals | | | |
| b. Number of RO Professionals | | | |
| 2. Does the partner have expertise in all submission formats | | | |
| a. eCTD | | | |
| b. Hybrid (CTD content in NDA folder structure) | | | |
| c. Paper | | | |
| 3. Does the partner provide guidance or conversion capabilities for creation of CDISC SDTM compliant datasets? | | | |
| 4. Does the partner have SPL/PIM capabilities? | | | |
| 5. Does the partner provide resources to support regulatory agency meetings? | | | |
| 6. Does the partner provide staff augmentation for long and short-term projects? | | | |
| 7. Does the partner provide a complete outsourcing model for submission capabilities? | | | |
| a. Can the partner create all electronic Case Report Tabulation output (i.e., Data Definition Tables) | | | |
| b. Does the partner's outsourcing model include daily maintenance submissions (IND amendments, NDA supplements, etc.) | | | |
| 8. Can the partner provide guidance and assistance in developing a sponsor's internal electronic submission capabilities? | | | |
| 9. Does the partner offer knowledge transfer programs? | | | |
| 10. Has the partner ever prepared a submission for a sponsor that resulted in an RTF? | | | |
| 11. Does the partner have documented, quality processes and methodologies for creating electronic submissions? | | | |
| a. Will the partner agree to host a sponsor audit of partner facilities and processes? | | | |
| 12. Will the partner provide client references for project work that is similar in scope to sponsor's current project? | | | |