Appendix I

Steps and activities list in a model clinical trial

1. Signing MSA
2. Draft protocol preparation
3. Protocol review
4. Protocol finalization & Approval
5. IB Development
6. IB review
7. IB finalization & Approval
8. CRF designing
9. CRF review
10. Draft CRF completion guidelines
11. CRF & completion guidelines approval
12. Vendor selection (Central lab) Identification
13. Central lab_Quotation
14. Central lab_meeting/review
15. Central lab_finalization
16. Central lab_contract signing
17. Vendor selection (courier ) identification
18. Courier_Quotation
19. Courier_meeting/review
20. Courier_finalization
21. Courier_Contract signing
22. Study ICF preparation (English only)
23. ICF review and approval
24. Protocol training to CRAs (ppt preparation)
25. Request for IP formulation & final preparation
26. Drug labeling design
27. Drug labeling review/approval
28. Drug label printing
29. Site identification & screening
30. Telephonic feasibility
31. Site selection screening
32. Site selection visit planning / site confirmation
33. Site selection visits
34. Collection of site Essential documents
35. Finalization of SSV reports
36. Finalization of sites
37. Budget negotiation
38. CTA customization / review
39. CTA review by legal department
40. "ICF translations, review, approval, translation certificate"
41. Study Insurance certificate
42. DCGI submission
43. CTA signing by all parties
44. CTRI registration
45. CRA site allocation
46. preparation of EC submission packets
47. Study monitoring plan preparation & approval
48. Study travel plan preparation & Approval
49. EC approval
50. Quotation for required infrastructure at site
51. Approval of site infrastructure quotation
52. "Procurement of site requirements (thermohygrometer, data logger etc)"
53. Infrastructure installed at site
54. Investigator meeting planning
55. IM presentation finalization
56. IM binder printing
57. DCGI approval
58. SIV preparation
59. Dispatch of IP and other site requirements
60. SIV
61. FSFV
62. Enrollment timelines
63. SMV & medical monitoring (depends on treatment period & FU)
64. CRF retrieval
65. DM database designing
66. DM database approval
67. Data validation plan approval
68. Data entry
69. Data validation
70. DCF generation & tracking
71. LSLV
72. DCF resolution
73. Data cleaning
74. Database lock
75. SCOV
76. Statistical analysis
77. CSR writing
78. Final CSR
Appendix II

Major Steps and activities list in a model clinical trial

1. Draft protocol preparation, review, finalization & approval
2. IB Development, review, finalization & approval
3. CRF & ICF (English only) designing, review, draft CRF completion guidelines and approval
4. Vendor selection and identification (Central lab & Courier)- Quotation, meeting/review finalization & contract signing
5. Protocol training to the trial monitors/CRAs
6. Request for IP formulation & final preparation
7. Drug labeling design, review/approval & printing
8. Site identification & screening
9. Telephonic feasibility & Site selection screening
10. Site selection visit planning / site confirmation
11. Site selection visits & Collection of site Essential documents
12. Finalization of SSV reports & Finalization of sites
13. Budget negotiation, CTA customization / review & CTA review by legal department
14. "ICF translations, review, approval, translation certificate"
15. Study Insurance certificate, DCGI submission, CTAs/Monitors signing by all parties
16. CTRI registration, Preparation of EC submission packets & allocation of sites to the CRA
17. Study monitoring plan preparation & approval and Study travel plan preparation & Approval
18. EC approval
19. Quotation for required infrastructure at site & Approval of site infrastructure quotation
20. Procurement of site requirements (e.g. thermohygrometer, data logger etc)
21. Infrastructure installed at site
22. Investigator meeting planning, IM presentation finalization, IM binder printing
23. DCGI approval
24. SIV preparation, Dispatch of IP and other site requirements
25. SIV
26. FSFV, Enrollment timelines
27. SMV & medical monitoring (depends on treatment period & FU)
28. CRF retrieval
29. DM database designing, DM database approval, Data validation plan approval
30. Data entry & Data validation
31. DCF generation & tracking
32. LSLV
33. DCF resolution, Data cleaning & Database lock
34. SCOV
35. Statistical analysis, CSR writing & Final CSR
Appendix III

Following are modified list of activities in the clinical trial included in this management plan

2. Development of CRF & ICF (designing, review, draft completion guidelines & approval).
3. Develop outsourcing plan (business proposal, receive & evaluate, audit vendors, choose vendors, contract negotiation).
5. Set up database (validate DB, develop data quality, develop SAP, write analysis program).
6. Selection of potential sites (site identification & screening, telephonic feasibility & site selection screening, site selection visits planning/site visit confirmation, site selection visit & collection of site essential documents, finalization of SSV reports & finalization of qualified sites).
7. Budget negotiation, CTA customization/review & CTA review by legal dpt. and final negotiate contract.
8. ICF translations, review, approval, translation certificate, study insurance certificate.
9. DCGI submission and approval, CTAs signing by all the parties.
10. CTRI registration, preparation of EC submission packets & allocation of sites to the CRA.
11. EC approval.
12. Study monitoring plan preparation and approval and study travel plan preparation and approval.
13. Quotation for required infrastructure at site & approval, procurement and infrastructure installation at sites.
14. Investigator meeting planning, IM presentation finalization, IM binder printing.
15. SIV preparation, dispatch of IP and other site requirements, SIV.
16. FSFV, enrolment timelines, enrolment of patients.

17. Conduct monitoring (SMV, Medical monitoring), corrective action plan-review meeting.

18. CRF retrieval.

19. DM database designing, approval & Data validation plan approval.

20. Data Entry, Data Validation, DCF generation & tracking.

21. LSLV.

22. DCF resolution, Data cleaning & Database lock.

23. SCOV, Destroy unused drug records, close contracts.

24. Statistical analysis, CSR writing & final CSR.

25. Reconcile final records and close study.
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<tr>
<th>ID</th>
<th>Task Name</th>
<th>Duration</th>
<th>Start</th>
<th>Finish</th>
<th>Predecessors</th>
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