INNOVA TRIALS LLC REPORT

SITE DETAILS

Site Name: Santiago

Location: Montevideo, Uruguay

Status: TokenSent

Score: 0%

Registered: 9/2/2026

Evaluated: Pending

Evaluated By: N/A

EVALUATION SUMMARY

1. [Infrastructure] Does the site have access to local laboratories?

Answer: Not Answered

2. [Infrastructure] Do you have a functioning generator?

Answer: Not Answered

3. [Infrastructure] Do you have strict control over medical equipment calibrations (thermometers, scales, blood pressure monitors, others)?

Answer: Not Answered

4. [Infrastructure] Do you have documented management for the disposal of pathogenic waste (waste from procedures, laboratory, among others)?

Answer: Not Answered

5. [Infrastructure] Does the site have a pharmacy dedicated exclusively to clinical research for the preparation and dispensing of the Investigational Product (IP)? Will the IP storage be carried out in the pharmacy?

Answer: Not Answered

6. [Infrastructure] What equipment do you have for IP refrigeration? (e.g., Freezer -20°C to -30°C, -70°C to -80°C, -135°C)

Answer: Not Answered

7. [Infrastructure] Describe what resources, equipment, and/or facilities the site has available for use in the study.

Answer: Not Answered

8. [Infrastructure] Does the site have the capacity to send digital images for centralized review? Does the site have sufficient high-speed internet connectivity to operate electronic data capture (EDC) systems?

Answer: Not Answered

9. [Infrastructure] Does the site have 24-hour observation and/or overnight stay capacity available for clinical research?

Answer: Not Answered

10. [Infrastructure] Can the site offer afternoon, weekend, and/or holiday service hours for study visits, if required? Does the site have the capacity to administer medication during weekends for continuous dosing schedules?

Answer: Not Answered

11. [Infrastructure] Does the site have an automated and documented temperature monitoring system for the storage of biological samples?

Answer: Not Answered

12. [Infrastructure] How are source documents corresponding to clinical research archived and protected?

Answer: Not Answered

13. [Infrastructure] Do you have a documented circuit for temperature control of each thermometer at the site? What type of thermometers do you use for recording?

Answer: Not Answered

14. [Infrastructure] Do you have a laboratory for sample processing? In the case of being a provider, do you have an evaluation system?

Answer: Not Answered

15. [Infrastructure] Do you have a circuit designed for double-blind studies?

Answer: Not Answered

16. [Staff] Does the site have enough properly trained staff to guarantee eCRF loading within 5 business days after the patient's visit?

Answer: Not Answered

17. [Staff] Do you have specific staff for the following roles: PI, SI, SC, research nursing, data manager, contract manager, recruiters, others?

Answer: Not Answered

18. [Staff] Is there any member of your team designated as responsible for the processing and shipment of biological samples?

Answer: Not Answered

19. [Staff] Do you have a system for updating staff documentation? (CV, GCP, training)?

Answer: Not Answered

20. [Staff] Do you have documented traceable initial and continuous training processes in clinical research?

Answer: Not Answered

21. [Staff] Is there a clearly defined person responsible for on-site and remote monitoring?

Answer: Not Answered

22. [Quality Management] Are there written, current, versioned, and accessible SOPs for staff?

Answer: Not Answered

23. [Quality Management] Does it have formal internal audit systems or a quality management system? Is there a documented and in-use CAPA system?

Answer: Not Answered

24. [Quality Management] Does the center have ISO or other certifications?

Answer: Not Answered

25. [Quality Management] Is there a formal record of errors in taking informed consent from the patient?

Answer: Not Answered

26. [Quality Management] Does the center have ISO or other certifications?

Answer: Not Answered

27. [Quality Management] Are screen failures and dropouts systematically recorded? And SF rate?

Answer: Not Answered

28. [Quality Management] Do you have documentation of the major deviation rate of the center in the last year?

Answer: Not Answered

29. [Technology] Do you have an electronic medical record (EMR)?

Answer: Not Answered

30. [Technology] In which technological systems do you have experience? (e.g., eConsent, eCOA, eISF, Medidata Rave, Oracle RDC, Veeva Vault)

Answer: Not Answered

31. [Data Management] Do you measure the average query resolution time (Queries Average TAT)?

Answer: Not Answered

32. [Data Management] Is there a data transmission tracking/control system to the CRF?

Answer: Not Answered

33. [Data Management] Is there documented follow-up of actions derived from monitoring (Follow up letter)?

Answer: Not Answered

34. [Patient Safety] Is there an international safety system for medication-related SAEs?

Answer: Not Answered

35. [Patient Safety] Does the site have a fully equipped and available emergency service (ER)?

Answer: Not Answered

36. [Patient Safety] Do you have a system that ensures AEs and SAEs are reported in a timely manner?

Answer: Not Answered

37. [Scientific Reputation] Do you have a history of external audits/inspections without critical findings in any of them?

Answer: Not Answered

38. [Scientific Reputation] In which therapeutic specialties do you have experience with clinical trials?

Answer: Not Answered

39. [Scientific Reputation] Does the center have verifiable experience in Phase I studies?

Answer: Not Answered

40. [Scientific Reputation] Does the center have verifiable experience in Phase II–IV studies?

Answer: Not Answered

41. [IMP Management] Does the site have a complete and traceable circuit for IMP handling?

Answer: Not Answered

42. [Sponsor Relationship] Does the site allow remote monitoring visits?

Answer: Not Answered

43. [Sponsor Relationship] Does the site allow on-site monitoring visits?

Answer: Not Answered

44. [Sponsor Relationship] Does the site grant study monitors direct and controlled access to the electronic medical record (EMR) for source data verification?

Answer: Not Answered

45. [Patient Experience] Does the center have systems for measuring customer satisfaction? (patient, sponsor)

Answer: Not Answered

46. [Patient Experience] Is there a formal transfer management system that guarantees that the patient does not incur any economic expense?

Answer: Not Answered

47. [Start Up] What is the average total time from the first submission of documentation to final approval by the IEC/IRB? Do you use a local, central, or both IEC? Does your IEC have any extra requirements for the submission/approval of documents?

Answer: Not Answered

48. [Start Up] Does the site have the capacity to submit documentation to its Ethics Committee (IEC/IRB) prior to the signature/execution of the contract?

Answer: Not Answered

49. [Start Up] Does the composition of the IEC/IRB members comply with ICH-GCP requirements?

Answer: Not Answered

50. [Start Up] Is there a clearly defined person responsible for start-up management?

Answer: Not Answered

51. [Start Up] How is the comprehensive review of the protocol performed before the start (operational feasibility, vendors, required resources)?

Answer: Not Answered

52. [Recruitment] What methods has the site used for recruiting patients for clinical research? Is the site willing to carry out active dissemination and promotion actions of the study towards other local sites and/or referral networks?

Answer: Not Answered

53. [Post Study] Is the management of physical and digital archives post-study closure clearly defined? Is there a follow-up of SAEs once the study is concluded?

Answer: Not Answered