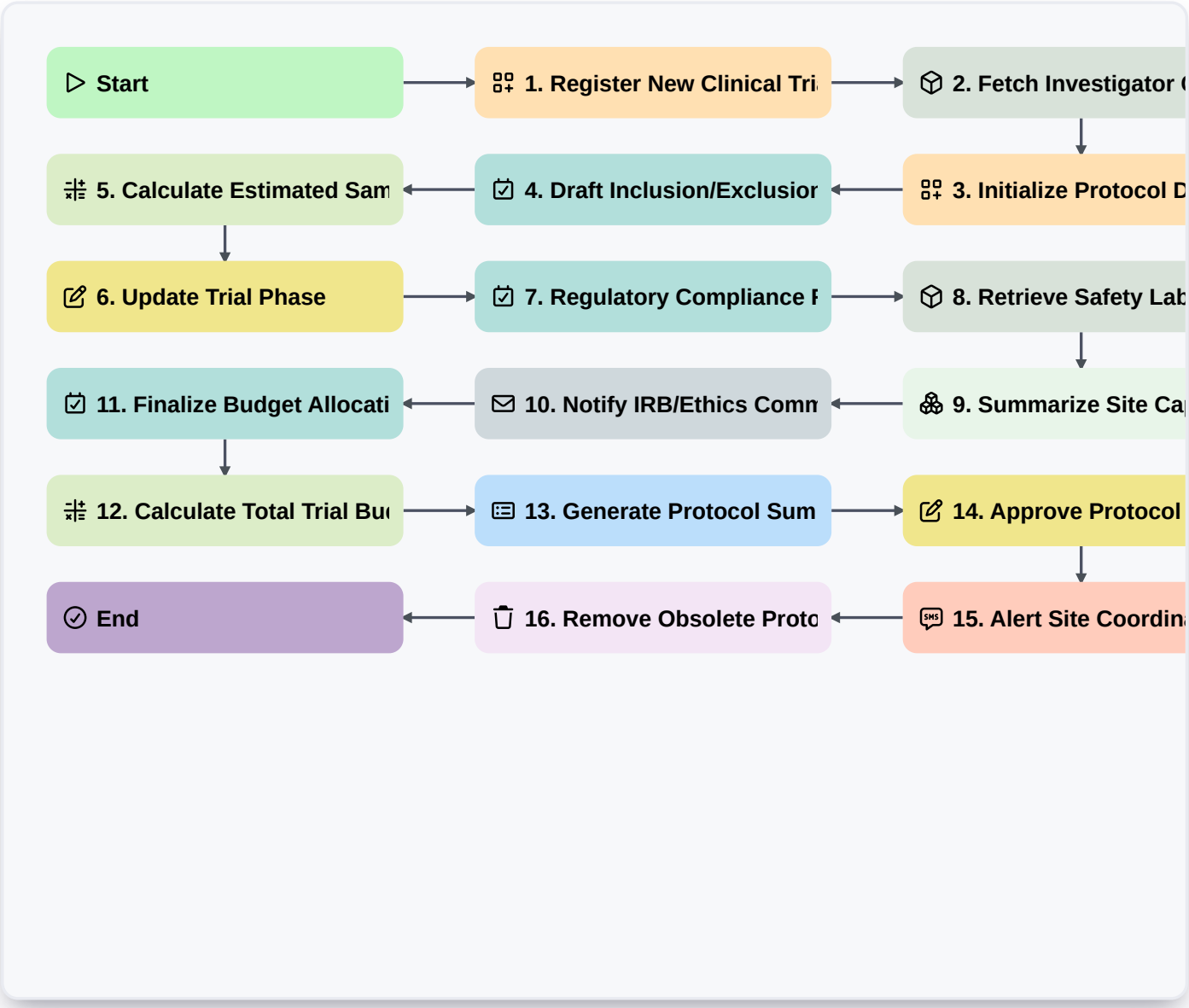
ChecklistGuro

Clinical Trial Protocol Design And Management



Start
Start of the Workflow/Process.

1. Register New Clinical Trial
Create a new entry in the 'Clinical Trial' data model to initiate the protocol design process.

2. Fetch Investigator Credentials
Retrieve investigator details from the 'Medical Staff' data model to assign oversight.

3. Initialize Protocol Document
Create a new entry in the 'Protocol Document' data model linked to the trial.

4. Draft Inclusion/Exclusion Criteria
Assign a task to the Medical Lead to define patient eligibility criteria.

5. Calculate Estimated Sample Size
Execute formula based on power analysis variables and expected dropout rates.

6. Update Trial Phase
Update the 'Clinical Trial' entry status to 'Protocol Drafting'.

7. Regulatory Compliance Review
Assign a task to the Regulatory Affairs specialist to review the draft against local laws.

8. Retrieve Safety Lab Standards
Get laboratory reference ranges from the 'Clinical Standards' data model.

9. Summarize Site Capacity
Aggregate total available beds/equipment from 'Clinical Sites' data model to ensure feasibility.

10. Notify IRB/Ethics Committee
Send an email to the Ethics Committee with the protocol draft attached for review.

11. Finalize Budget Allocation
Assign a task to the Finance Manager to approve trial expenditures.

12. Calculate Total Trial Budget
Sum all estimated costs for site fees, drugs, and monitoring services.

13. Generate Protocol Summary Report
Create a high-level summary report of the protocol design for executive stakeholders.

14. Approve Protocol Version
Update the 'Protocol Document' entry with the 'Approved' status and current version number.

15. Alert Site Coordinator
Send an SMS to the Site Coordinator notifying them that the protocol is ready for site-level implementation.

16. Remove Obsolete Protocol Drafts
Delete outdated versions of the protocol from the 'Protocol Document' data model to maintain a single source of truth.

End
End of the Workflow/Process.