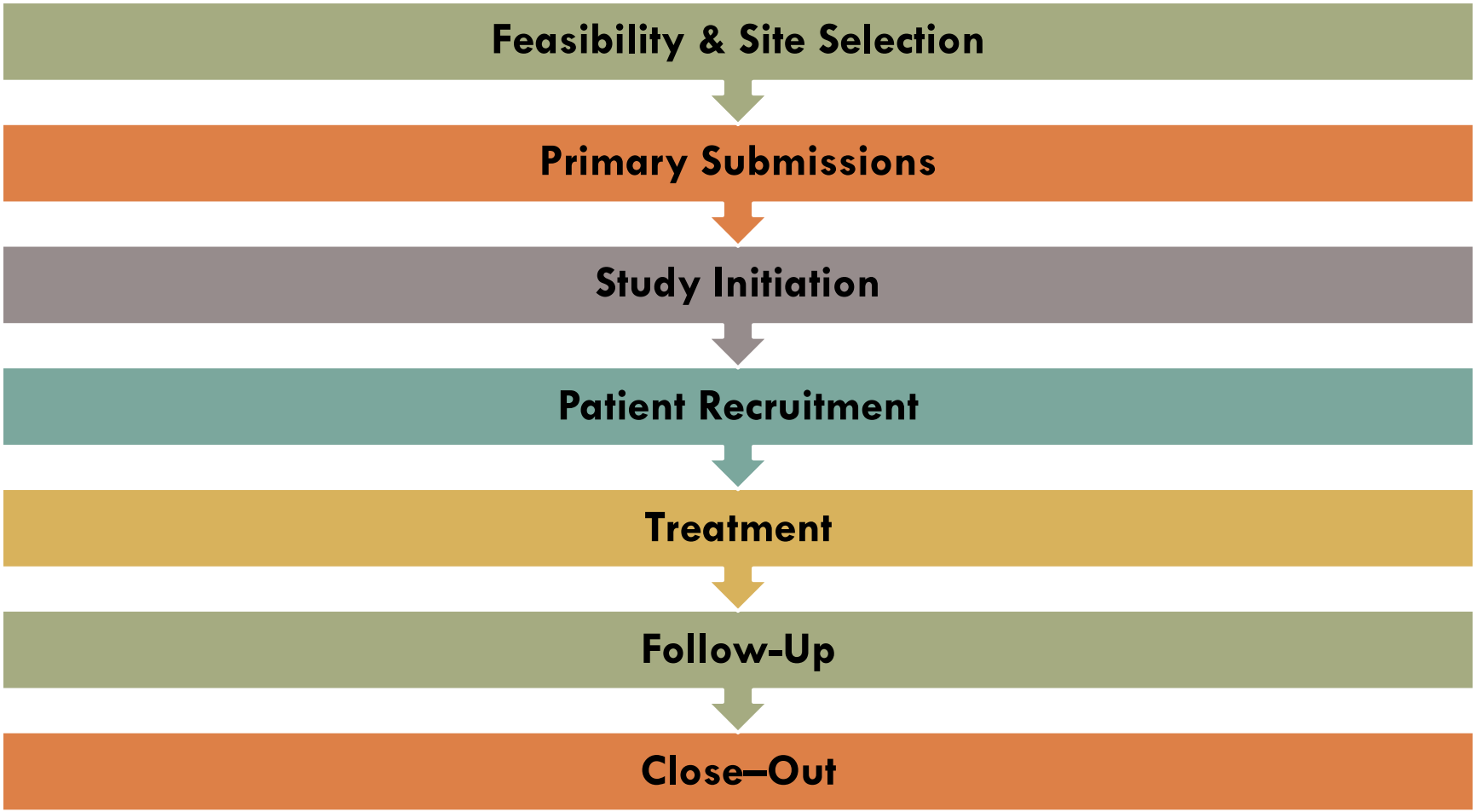
Q-TRIALS
TRIAL SIMULATION

Trial Simulation



Feasibility & Site Selection

- Using our connections with leading investigators
- Estimating recruitment and treatment potential

Primary Submissions

- Preparing submission packages
- Correspondence with MoH and local committees until approvals are granted
- Translations
- Import of investigational product and lab kits

Study Initiation

- Initiating all sites
- Investigational product and lab kits distribution

Patient Recruitment

- Monitoring recruitment and consent process
- Coordinating collections of biological samples for a central laboratory
- Ensuring achievement of recruitment goals

Treatment

- Monitoring
- Coordinating collections of biological samples for a central laboratory
- Monitoring pharmacy, patient randomization, prescriptions
- Ensuring site compliance or reporting deviations
- Ensuring achievement of treatment goals
- Interim submissions and reports
- Import and distribution of investigational product and lab kits, return to depot and destruction
- Translations

Follow-Up until Close–Out

- Follow-Up
- Monitoring – patient FU process and site adhering to timelines
- Ensuring closure of all queries and pending issues
- Closing pharmacy and investigational product return to depot
- Closing site and collecting all data
- Close-out submissions