Site Feasibility Questionnaire

Master response template for clinical research sites

Fill this in once and keep it current. When a sponsor or CRO sends its own feasibility questionnaire, most answers can be copied from here. Use aggregate patient counts only: never include names, dates of birth or any other identifiable patient information.

Site name:	**Last reviewed (date):**
Owner (name and role):	**Study / protocol (if answering for one):**

1. Site and investigator

What the sponsor is checking: Is there a qualified investigator whose paperwork will not hold up start-up?

Question	Your answer
Legal site name and address	
Principal Investigator: name, specialty, medical license number and state	
Date of the PI's current signed CV	
Sub-investigators: names and specialties	
GCP training: provider and completion date for each investigator	
Primary contact for feasibility: name, role, email, phone	

2. Patient population

What the sponsor is checking: Can this site enroll? This is the section sponsors scrutinize hardest.

Question	Your answer
Patients seen with the target condition in the last 12 months (aggregate count)	
Estimated number meeting the key inclusion and exclusion criteria	
How the count was produced (EMR query, diagnosis codes, age range)	
Date the count was last refreshed	
Realistic enrollment estimate for this study, per month and in total	
Main recruitment sources (own patients, referrals, database, outreach)	

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3. Active and pending studies

What the sponsor is checking: Are the eligible patients already committed to another trial?

Question	Your answer
Studies currently enrolling: indication, phase, sponsor	
Studies starting in the next 6 months	
Which of these recruit from the same patient pool as this study	

4. Staff and capacity

What the sponsor is checking: Does a real person have hours for this protocol?

Question	Your answer
Study coordinators: names, years of research experience	
Current number of active studies per coordinator	
Other study staff (nurses, pharmacist, regulatory, data entry)	
Who covers when the lead coordinator is out	

5. Facilities and equipment

What the sponsor is checking: Can the protocol's procedures be done here?

Question	Your answer
Exam and procedure rooms available for study visits	
Private space for monitoring visits, with internet access	
Equipment on site (ECG, vitals, scales, centrifuge, infusion chairs)	
Imaging or other services available by referral, and where	
Secure storage for study records, and how long records are kept	

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6. Laboratory

What the sponsor is checking: Can samples be collected, processed and shipped inside the protocol's windows?

Question	Your answer
Local laboratory used, with CLIA and CAP status where applicable	
Experience with central laboratory kits and shipping	
Sample processing available (centrifuge, refrigerated centrifuge, freezers and temperatures)	
Dry ice availability and courier pickup days	

7. Pharmacy and investigational product

What the sponsor is checking: Is the investigational product safe and accounted for at this site?

Question	Your answer
Storage available: ambient, refrigerated (2 to 8 C), frozen	
Temperature monitoring method and alarm process	
Access control for the storage area	
Who receives, dispenses and reconciles investigational product	

8. Regulatory and data

What the sponsor is checking: How fast can this site start, and will it stand up to an audit?

Question	Your answer
IRB: central or local, and name if local	
Typical time from submission to IRB approval	
Typical time to return a signed CDA and a completed questionnaire	
Typical time to finalize a budget and contract	
Electronic medical record system	
EDC and other study systems the team has used	
How source documents are created and stored	

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9. Track record

What the sponsor is checking: Did past answers match past performance?

Question	Your answer
Number of studies completed in the last 3 years	
For similar studies: enrollment target versus actual	
Sponsor audits or regulatory inspections in the last 5 years, and outcomes	
If the site is new to research: relevant clinical experience of the PI and staff	

10. Standard attachments

What the sponsor is checking: Is the supporting paperwork ready to send today?

Question	Your answer
PI and sub-investigator CVs, signed and dated	
Medical licenses	
GCP training certificates	
Laboratory certifications and normal ranges	
W-9	
Site photos or a one-page site profile	

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