**Optimise II Trial: Feasibility questionnaire for potential sites**

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| --- | --- | --- | --- |
| Date completed: |  | Completed by (name/role): |  |
| Site name: |  | | |
| Suggested principal investigator (PI): |  | | |
| Main contact (name/role): |  | | |
| Phone (inc international code): |  | | |
| e-mail: |  | | |

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Comments** | **Check** |
| **Clinical Aspects** | | |
| Does the Principal Investigator have any comments to make about the trial? For example with regards safety, ethical acceptability, scientific soundness? |  | Yes  No |
| Are the procedures documented in the protocol consistent with your hospital standards of care? |  | Yes  No |
| **Investigators/Site Experience** | | |
| Does the Principal Investigator have previous experience with:   1. Clinical research? 2. Study population? 3. Trial intervention? |  | Yes  No  Yes  No  Yes  No |
| How many studies/trials is this hospital currently recruiting from this patient population? |  | Total open & enrolling: \_\_  Total in follow-up: \_\_ |
| How many working hours per week do the research team estimate they have available for the OPTIMISE II trial? |  | \_\_\_\_ hours / week |
| Have the site staff received relevant regulatory training (eg Good Clinical Practice / Research Governance)? |  | Yes  No |
| Does the site anticipate that training staff in GCP and other regulatory requirements will be a problem? What resources are in place to do this? |  | Yes  No |
| **Trial Population and Recruitment** | | |
| What is your anticipated likely recruitment rate, having reviewed inclusion & exclusion criteria? |  | \_\_\_\_ patients / week |
| Are there any circumstances that may be expected to affect recruitment? |  | Yes  No |
| **Facilities and Equipment** | | |
| Would the site be able to use Edwards Lifesciences cardiac output monitoring equipment (which will be provided) if relevant training was provided? |  | Yes  No |
| Does the site have adequate, secure storage for study records (e.g. paper CRFs and Consent Forms)? |  | Yes  No |
| Are archiving facilities available to the site? |  | Yes  No |
| **Electronic Data** | | |
| Do site staff have experience with online case report forms? |  | Yes  No |
| Are there local policies in place for the storage, transfer and security of data? |  | Yes  No |
| Does the site have support for data entry? |  | Yes  No |
| **Monitoring/Audit** | | |
| Are study staff willing to allow the OPTIMISE II management team access to the medical records and source documents to ensure compliance with good clinical practice and adherence to the protocol? |  | Yes  No |