The objective of this review is to assess the feasibility of conducting the study in a country by assessing the resources required.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study Details** | | | | | |
| Study Title: | |  | | | |
| Chief Investigator: | |  | | | |
| Country: | |  | | | |
| Lead Site Name / PI: | |  | | | |
| Planned date of initiation: | |  | | | |
| **Country-level Information** | | | | | |
| Please provide the rational for selecting the country: | | | | | |
|  | | | | | |
| State trial team’s previous experience with the country:  (state ‘none’ is no experience of performing a study in the country) | | | | | |
| Regulatory / approval issues: | |  | | | |
| Insurance cost / issues | |  | | | |
| Trial / site set-up issues: | |  | | | |
| Did the country complete set-up and meet recruitment target: | |  | | | |
| State how the country’s epidemiology data is relevant to the protocol specified participant population, including if applicable and difference in legal definition of the participant population: | | | | | |
|  | | | | | |
| Are there any known competing studies in set-up or ongoing which may affect recruitment in the country: | | | | | |
|  | | | | | |
| Will there be a lead site for the country, how many participating sites will be included in the country: | | | | | |
|  | | | | | |
| State the average timeline for approval and site start-up within the country, and trial specific issues which could potentially impact regulatory / ethical / set-up timelines: | | | | | |
|  | | | | | |
| State IMP status in the country and any known issues in sourcing the IMP for the trial: | | | | | |
|  | | | | | |
| State the insurance / indemnity requirement for the country: | | | | | |
|  | | | | | |
| Are there any costs associated with setting up the country which will not be met by the trial grant and how the cost will be covered: | | | | | |
|  | | | | | |
| Are there any country specific issues which may impact recruitment and compliance to the protocol: | | | | | |
| Existing treatment patterns and guidelines: |  | | | | |
| Standard care: |  | | | | |
| Restriction on movement of biological samples: |  | | | | |
| Issues on data transfer: |  | | | | |
| State any country-level needs and activities that will be outsourced? Has the vendor been audited and or inspected in the past? | | | | | |
|  | | | | | |
| Additional Information:  *(If you have anything else to add which has not been covered by the questionnaire please detail here)* | | | | | |
|  | | | | | |
| **Assessment Completed by:** | | | | | |
| Print Name [Title / Position]: | | |  | | |
| Signature: | | |  | Date: |  |

**Please return a completed and signed copy to** [**resgov@accord.scot**](mailto:resgov@accord.scot)