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

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| --- |
| **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**