1. Laboratories
2. Database suppliers
3. Any supplier conducting randomisation
4. IMP suppliers/distributers
5. Sponsor/CRO/CTU
6. Other

1. Laboratories

To be used for Sponsored CTIMPS studies. Please note that GCP applies to all Laboratory work but the adherence to the EMA guidance can be proportionate for work other than primary endpoints.

a. For this project, what work is your lab agreeing to do, and is this towards the primary end point of the study?
b. Does your lab have any accreditations? (e.g. CPA, GLP ETC) Does the planned work fall under this accreditations?
c. Has your lab conducted this sort of work previously (please provide details)?
d. Is your lab compliant with GCP and the EMA document (28 February 2012 EMA/INS/GCP/532137/2010 Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples)
e. Please describe the Quality Management System in place in your lab and provide an SOP index.
f. Please provide proof or GCP training for relevant staff within you laboratory.

2. Database suppliers

a. Has your company been previously undertaken to provide a database for a Clinical trial?
b. Has any such Clinical Trial been inspected by the MHRA? If yes, was there a favourable outcome.
c. Will the work undertaken by your company be in compliance with GCP and the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031), and all subsequent amendments?
d. Please describe the Quality Management System in place in your company and provide an SOP index.
e. Please provide a short summary of how databases are designed, and validated.
f. Please provide proof or GCP training for relevant staff.

3. Any supplier conducting randomisation

a. Has your company been previously undertaken to provide a randomisation service for a Clinical Trial?
b. Has any such Clinical Trial been inspected by the MHRA? If yes, was there a favourable outcome.
c. Will the work undertaken by your company be in compliance with GCP and the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031), and all subsequent amendments?
d. Please describe the Quality Management System in place in your company and provide an SOP index.
e. Please provide a short summary of how databases are designed, and validated.
f. Please provide proof or GCP training for relevant staff.

4. IMP suppliers/distributers

a. Please describe the Quality Management System in place in your company and provide an SOP index.
b. Will the work undertaken by your company be in compliance with GCP and the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031), and all subsequent amendments?
c. Please provide proof or GCP training for relevant staff.

5. Sponsor/CRO/CTU

a. Has your company previously acted as Sponsor/CRO/CTU for a Clinical Trial conducted within the UK?
b. Has any such Clinical Trial been inspected by the MHRA? If yes, are you able to provide a summary?
c. How many previous Phase I, II, and III (as appropriate) has your company sponsored/coordinated?
d. Please summarise the monitoring arrangements for these studies.
e. Please describe the Quality Management System in place in your company and provide an SOP index.

6. Other: for questions about these vendors please refer to the GCP Managers.

a. Statistician
b. Data managers
c. Consultant
d. Freelancer/Contractor