# Proposal Template

# 1 Title and front cover and introduction

This proposal is submitted by *CRO Name* in response to the Request for Proposal tendered by *Pharma Name*.



The picture on the front of CRO offices of other relevant landmark gives a good first impression.

This proposal was submitted on *Date* and assumptions and prices are valid for 60 days.

Reference Number: 123

Address and contact.

Please address any question or other communications to:

*Contact Name*

*Title*

*Address*

*e-mail :*

*Telephone :*

**Introduction**

This proposal is submitted to *Pharma name* in Response to a request for proposal to provide full service support for their Phase II clinical study in the treatment of mild to moderate asthma with *Product name or reference number.*

**2** **Executive Summary**

A brief and focused description of the overall proposal highlighting what is expected of the CRO and how the CRO will conduct and complete the project. It should also include the timeline and the overall cost. The Executive Summary should be no longer than one side of A4. If you have the space you could also add the potential benefits of using your CRO, i.e. unique selling points USP, but avoid turning this into a general sales pitch. Brief details of the risks, both threats and opportunities that you have recognised.

**3 The main structure of the Proposal**

The rest of the proposal can be split into four major sections:

1. The Technical Proposal
2. The Management Proposal
3. The Commercial Proposal
4. Appendices

You do not have to use these as titles, (although I see no reason why not) but they are there to give the proposal a logical structure and to make sure that you do not miss out any key items.

**3.1 The Technical Proposal**

* **Goals –** This is where you confirm that you have understood what is required of you by the sponsor. The goal may be as simple as the sponsor requires clean data on 400 patients by the 30th June 2016, or it may include extra information about unique services that have been requested of you. Specific details of what the CRO will perform are covered in the scope of work section.
* **Approach –** In this section you need to demonstrate how you will execute the study to meet the above goals. **It is important that you address all of the questions that may have been raised in the Request for Proposal (RFP).** For example you may need to explain how you are going to recruit the patients, what are the advantages of using your electronic data capture system, what project management tools, (project plans, risk analysis, earned value, stakeholder engagement, MS Project etc) you will use, how you will ensure that serious adverse events will be dealt with, how risk based monitoring will work etc. This is a good place to emphasise your unique selling points (USPs), e.g. how you could achieve rapid start-up, and to highlight the risk and opportunities that have presented themselves. If you have been asked to provide feasibility to back up your design then this is a good place to report your findings and give some assessment of how reliable your think they are. I have not got a lot of faith in quality of feasibility conducted in 2 week by questionnaires, but if this all you have been able to do then you should make it clear how much faith you have in the results.
* **Scope of Work -** This where the roles and responsibilities are defined. In many cases this can be reduced to a simple tick box. This is also the place to define the timeline.A Gantt chart is a good idea, but avoid too much detail, just the major milestones e.g. signing the contract, site initiation, patient recruitment, database lock, final study report. The scope of work should also list the project deliverables, e.g. Protocol, e-crf, sites initiated, data cleaned, final report etc. The sponsor should be more interested in the deliverables than the work breakdown structure so a list of what you are delivering should indicate that you understand what is important to them.
* **Dependencies –** Defining the role of 3rd Party suppliers, e.g. Investigators central labs, couriers, equipment suppliers, drug manufactures etc. You should make it clear who is responsible for managing these suppliers i.e. you or the sponsor.

**3.2 Management Proposal**

* **The Project Team -** Who is the project manager and the main point of contact. An organisational chart showing the structure of the project team would be a good idea. It might be useful to show the matrix structure i.e. how the individuals in the project team are line managed and trained.
* **Work Breakdown Structure (WBS)–** The work breakdown structure is a technique for defining and organising to total scope of work. It identifies all of the tasks that are required to deliver the deliverables. A number of sponsors may ask you to complete a bid grid which includes all of the tasks they have identified. This is often a detailed budget by task which also identifying the staff types who are undertaking this activity. You may no choice but to complete the sponsors bid grid but you should always develop your own WBS and point out any major discrepancies.
* **Quality –** a brief description of what you think the sponsor requires in respect to the quality of the deliverables, and how you propose to ensure that this level of quality will be delivered and maintained. Example – how data quality is maintained, e.g. site audits, query generation and resolution, co-monitoring etc.
* **Safety Management-** Details of you will handle SAEs an SUSARs

**3.3 Commercial Proposal**

* **Price –** Details of the price from the pricing model.
* **Key assumptions –** Details of the assumptions that are driving the price, e.g. Numbers of patients, sites, counties, monitoring visits, team and client meeting etc.
* **Pricing Criteria –** Fixed priced with variable pass-thorough cost, fee for service, fixed unit priced, or a hybrid of some or all of the above. If the project is fixed price then the financial risk is with the CRO and under those circumstances the CRO may wish it charge a high enough margin to cover the risk. If the project is fee for service then with a guaranteed margin you may wish reduce your profit margin in line with the low level of risk. The level of financial risk that a CRO undertakes is also linked to the how detailed the scope of work is.
* **Payment schedule-** e.g. milestones, monthly , linked to Earned Value etc.
* **Terms and Conditions –** The legal part of the contract, normally considered as a separate document i.e. services agreement or master services agreement.

**4 Appendices**

* CV’s of key project members
* Details on how functional departments work e.g. Project management, Data management etc. The detail might be what software they use, how they are trained and managed etc. Look to highlight USPs.