

Request for Information

Date:

Name of Study Sponsor:

Name of Study PI:

Name of Research Protocol Specialist:

Phone:

Email:

Name of Contact (if questions arise about drug):

When do you require this quote be returned?

Study Information:

1. What is the title of the study?
2. What is study protocol #?
3. What is the anticipated start date for this study?
4. How many patients are expected to participate in the study?
5. What is the accrual rate?
6. What is the total trial length?
7. Is the trial randomized?
 - a. If so, what is the randomization schema?
8. Do you require McKesson to create a randomization code for the trial?
9. How many sites will be participating in the trial?
10. Do you require distribution to Canada?

Drug Information

11. Please list the drugs you require McKesson to distribute.

Manufacturer	Drug Name	Strength	NDC	Packaging (#, size, type)	Storage/Shipping Requirements	Temperature Monitors?

12. Will the study drug be provided on consignment by the manufacturer?
13. Do you require McKesson to procure the study drug?
14. Do the study drugs being used require compliance to any FDA-required REMS (risk evaluation mitigation strategy) or other patient education programs?
15. Will the study drug be provided with investigational labeling?
 - a. If not, will the study drug be provided with commercial labeling?
16. Is the study blinded?
17. Who will be providing the placebo (if needed)?
 - a. Do you need McKesson to facilitate these services?
18. At study close, do you want McKesson to receive back and reconcile unused drug?

Treatment Schedule and Shipping Requirements

19. What is the treatment schedule? If possible, please provide a copy of the concept or protocol.
20. How long do you expect each patient to remain on the study? (# of cycles, months, etc.)
21. How much drug should be included with each shipment (examples: 2 cycles, 1 carton, 20 bottles)
22. Are bulk- or patient-specific shipments required?
23. Are controlled shippers and temperature monitors required for shipment?
 - a. If so, are there specific shippers and temperature monitors you would like to use?

Please return completed form to RFIClinicalResearchServices@McKesson.com.