


13.3. Annex 4, Form no. PCT-003.03 : Format for contents of non-routine clinical trial Applications

		Pharmacovigilance & Clinical Trial Lead Executive Office		FORM- PCT-003.03	
Title		Format for contents of non-routine clinical trial applications		SOP/PCT_CT001	
S.No Basic Information					
1.	Title of the Study				
2.	Sponsor of the trial				
3.	Principal Investigators				
4.	Site of Clinical Trial				
Indication					
5.	Disease or condition going to be studied				
6.	Existing Therapy/Treatment for the condition if any				
7.	The Condition(s) for non-Routine Procedure				
8.	Detail Explanation on proposed areas to be exempted as non-routine procedure				
Investigational Products					
9.	Name of product				
10.	Proposed Therapeutic Indication				
11.	Detail Justification/analysis of Risk and Benefit in relation to the proposed condition and available treatments if any for non-routine CT authorization procedure				
12.	Detail explanation of on areas of exemption in relation to investigational product				
Other Relevant Administrative Documents					
13.	Sponsor declaration that the trial is candidate for non- routine procedures				
14.	Document proposed for exemption if any for non-routine procedure				
Signature of Sponsor:			Signature of PI:		
Date:			Date:		
For authority use only					
15.	Screened by Name:		Comment/Statement:		
16.	Approved By Name:		Comment/Statement:		