Sponsor Feasibility Questionaire for PT&R /v1.5

1a	Protocol:	
1b	Sponsor:	
1c	CRO (i.a.):	

2a	What is the overal target for this trial?	
2b	What is the national target for this trial?	
2c	What is the site's target for this trial?	
2d	Is the recruitment competative?	

3a	How many sites will be participating in The Netherlands	
	Are any sites already active	
	Are we a back up site?	
3b	In which regions are they situated.	

4	Is the protocol final (version and date?)	

5	What are the overall estimated timelines for this protocol	
	FPFV	
	LPFV	
	LPLV	

6a	When do you expect the approval in The Netherlands	
6b	When will the SIVs be planned?	

7	Will there be an investigators meeting	
	if so, when and where	
	how many people can attend	

8	Will this trial be using paper CRF or eDC?	
	if eDC which one	
	is there a mandatory eDC training; nethod of delivery and duration of training?	
	will you provide worksheets (if not, please provide print out of CRF/eDC to us prior to initition)	

9	Will this trial be using additional vendors	
	is so which one(s)	
	is there a mandatory training for these and the duration	
	will they provide the patient specific results automatically or do we have to collect them through a portal?	

10	Will this trial be using an IVRS/IWRS	
	if so which one(s)	
	is there a mandatory training for these and the duration	
	are the confirmations automatically faxed/emailed to the site or do we need to use a portal?	

11	Will this trial use diaries?	
	paper or ediaries?	
	if ediaries which one	
	will there be a helpdesk for the participants ?	
	will the helpdesk be in a local language?	

	will there be a helpdesk for the sites	
	is there a mandatory training for this, if so method of delivery and duration	
	will they provide the patient specific results (i.e. compliance) automatically or do we have to collect them through a portal?	

12	Will this trial use portals	
	if so which one(s)	
	is there a mandatory training for these, if so method of delivery and duration	
	will they provide the patient specific results automatically or do we have to collect them through a portal?	

13	What are all the mandatory trainings for this trial and their delivery methode (meeting, web, CD) and their duration.	
	for PI	
	for Research assistents	
	for other staff members	

14a	Which Lab will be used	

14b	Which courier will be used	
14c	Are dry ice shipment necessary?	
14 d	Do they provide the results automatically via email or fax, or do we have to collect them ourselves through a portal?	

15a	What recruitment tools are available	
15b	What is the site specific recruitment budget	
15c	Is there a national recruitment budget? If yes, how much	

16a	Is the IP shipped under temperature registration	
17b	How heavy is the shipment material	
17c	Does shipment material need to be distroyed by the site or by CRO/sponsor or will it be reused?	

17a	Who will do the budget negotiations	
17b	Who will be the CRA	
17c	Are there other members of your company we will be working with? (please provide all contact details)	

18	Is there an ICF available for us to review?	

19	Are there any protocol specific equipement / requirements?	

20	What is the monitoring schedule?	

PM: This information is used to set up the trial budget. If the information provided is incorrect this may lead to additional costs that will be invoiced based on our hourly rate

Answers provided by	
date:	