

Overview of Respiratory Network sites – What are our capabilities?

Unit: Vaerloese Laegehus; General Practice, Medical Center with doctors and staff

Hospital: NA

Date: March 4.th 2015

Person providing responses: Torben Soerensen, M.D.

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	x	1	
GCP trained nurses	x	1	
Experienced sub-investigators at site			x
GCP-trained investigators			
Availability of additional resources in case of e.g. need for unblinded personnel	x	2	
Personnel trained and experienced in quit-smoking counseling	x		

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)	x	1	
Phase 3 (# past 5 years)	x	8	
Phase 4 (# past 5 years)			x
Experience with infusion in trials (# past 5 years)			x

Experience with Assessments/Procedures (tick all that apply)				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Spirometry testing (meeting ATS/ERS requirements) e.g.	x			
Masterscope		x		
Flowscreen		x		
Threadmill exercise test VO _{2max}		x		
Bike exercise test VO _{2max}		x		
6MWT	x			
Incremental and Endurance shuttle walk test	x			
X-ray		x		
HRCT scanning		x		
Body box/ plethysmography		x		
Diffusion capacity test - DLCO		x		
ECG	x			
FENO		x		
Alveolar NO		x		
Nasal NO		x		
Skin prick test	x			
Methacholine test/histamine test		x		
Mannitol test		x		
Exercise-asthma test	x			
Bronchoscopy		x		
FOT (Forced Oscillation Test)		x		
Eucapnic hyperventilation test		x		
CO measurement		x		
Induced sputum, Easyneb		x		
Nasal lavage/ nasal irrigation		x		

Facility		
	YES	NO
Separate and locked room for IMP	x	
Possibility for temperature	x	

monitoring of IMP		
Room for Monitor	x	

Other Procedures		
	YES	NO
Availability of written SOP procedure for study procedures (e.g. informed consent)	x	
Possibility of 24 h visits		x
Possibility of 24h PK sampling		x
Establishment of databases	x	
Establishment of biobanks		x
Satellite sites		x
Possibility of archiving of study material for 15 years	x	

Laboratory				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Refrigerator	x			
with temp monitoring	x			
Freezer – 20 degrees	x			
with temp monitoring	x			
Freezer – 80 degrees		x		
with temp monitoring		x		
Local lab for blood sample analysis	x			
Local lab certification	x			
IATA certification for handling dry ice shipment	x			
Experience in collaboration with external/central labs	x			
Induced sputum, analysis		x		
Centrifuge	x			

Cooling centrifuge		x		
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Data Recording			
	YES	NO	Comment
Experience in use of e-CRF	x		
Experience in use of e-diaries e.g	x		
AM3		x	
Log pad	x		
Experience in use of MoveMonitor		x	

IT			
	YES	NO	Comment
Availability of back up plan in case of crash	x		
Own computers, high speed internet	x		
Internal firewalls	x		
Wireless internet connection	x		
Electronic medical record system	x		
Electronic medical record system – certified (need of passwords, CRA only access to certain patients etc)	x		

Other Comments: