

Overview of Respiratory Network sites – What are our capabilities?

Unit: Lungemedicinsk Afsnit

Hospital: Hospitalsenheden Vest

Date: 23/6 2014

Person providing responses: Pia Holland Gjørup

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	3	
GCP trained nurses	X	3	
Experienced sub-investigators at site	X	2	
GCP-trained investigators	I PRAKSIS, INGEN FORMELLE KURSER	2	
Availability of additional resources in case of e.g. need for unblinded personnel	X		
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
Phase 3 (# past 5 years)			X
Phase 4 (# past 5 years)	X	2	
Experience with infusion in trials (# past 5 years)			

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				
Flowscreen				
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 monitoring of IMP	X	
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	?			

Experience in collaboration with external/central labs	X			
Induced sputum, analysis				X
Centrifuge	X			
Cooling centrifuge	X			

Data Recording			
	YES	NO	Comment
Experience in use of e-CRF	X		
Experience in use of e-diaries e.g	X		
AM3	?		
Log pad	?		
Experience in use of MoveMonitor	?		

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: