

Overview of Respiratory Network sites – What are our capabilities?

Unit: Lungemedicinsk Afdeling

Hospital: Gentofte

Date: 15 June 2014

Person providing responses: Seersholm

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	x	2	
GCP trained nurses	x	2	
Experienced sub-investigators at site	x	3	
GCP-trained investigators	x	3	
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	2	
Phase 2 (# past 5 years)	x	3	
Phase 3 (# past 5 years)	x	12	
Phase 4 (# past 5 years)	x	1	
Experience with infusion in trials (# past 5 years)	x	2	

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		x	
Masterscope	x		x	
Flowscreen	x		x	
Threadmill exercise test VO _{2max}		x		x
Bike exercise test VO _{2max}		x		x
6MWT	x		x	
Incremental and Endurance shuttle walk test	x		x	
X-ray	x		x	
HRCT scanning	x		x	
Body box/ plethysmography	x		x	
Diffusion capacity test - DLCO	x		x	
ECG	x		x	
FENO	x		x	
Alveolar NO	x		x	
Nasal NO	x		x	
Skin prick test	x		x	
Methacholine test/histamine test	x		x	
Mannitol test	x		x	
Exercise-asthma test		x		x
Bronchoscopy	x		x	
FOT (Forced Oscillation Test)		x		
Eucapnic hyperventilation test		x		
CO measurement	x		x	
Induced sputum, Easyneb	x		x	
Nasal lavage/ nasal irrigation	x		x	

Facility		
	YES	NO
Separate and locked room for IMP	x	
Possibility for temperature monitoring of IMPx	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		x	
with temp monitoring	x		x	
Freezer – 20 degrees	x		x	
with temp monitoring	x		x	
Freezer – 80 degrees	x		x	
with temp monitoring	x		x	
Local lab for blood sample analysis	x		x	
Local lab certification	x		x	
IATA certification for handling dry ice shipment	x		x	

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

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: