

Overview of Respiratory Network sites – What are our capabilities?

Unit: Lungeambulatorium Sønderborg

Hospital: Sygehus Sønderjylland, Sønderborg

Date: 26.09.2015

Person providing responses: Zofia Grzywacz, overlæge

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	2	
GCP trained nurses	X	2	
Experienced sub-investigators at site	X	2	
GCP-trained investigators	X	1	
Availability of additional resources in case of e.g. need for unblinded personnel	X	5	
Personnel trained and experienced in quit-smoking counseling	X	5	

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

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

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	Print of electronical record is possible

Other Comments:

