

Overview of Respiratory Network sites – What are our capabilities?

Unit: Medicinsk afd.

Hospital:Kolding Sygehus

Date: 15.09.2015

Person providing responses: Axel Møller/Bodil Felthaus

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	x	4	
GCP trained nurses	x	4	
Experienced sub-investigators at site	x	2	
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	1	

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)	-		
Phase 2 (# past 5 years)	x	3	
Phase 3 (# past 5 years)	x	10	
Phase 4 (# past 5 years)	x	6	
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		x	
Masterscope	x			
Flowscreen		x		
Threadmill exercise test VO _{2max}		x		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		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		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			
Local lab certification	x			
IATA certification for handling dry ice shipment	x			
Experience in collaboration with external/central labs	x			
Induced sputum, analysis		x		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	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: