

Overview of Respiratory Network sites – What are our capabilities?

Unit: Klinik for Allergi

Hospital: Gentofte

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Person providing responses: Claus R. Johnsen

Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	X	8	
GCP trained nurses	X	7	
Experienced sub-investigators at site	x	8	
GCP-trained investigators	x	8	
Availability of additional resources in case of e.g. need for unblinded personnel	x	3	
Personnel trained and experienced in quit-smoking counseling	x	2	

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)	x	1	
Phase 2 (# past 5 years)	x	4	
Phase 3 (# past 5 years)	x	4	
Phase 4 (# past 5 years)	x	0	
Experience with infusion in trials (# past 5 years)	x	0	

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			
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 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		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			
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: