

Overview of Respiratory Network sites – What are our capabilities?

Unit:

Allergi- og Lungeklinikken Helsingør, Sct. Olai Gade 39,1, 3000 Helsingør,
ved praktiserende speciallæger
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Date: 8-11-2015

Person providing responses: Kirsten Sidenius, praktiserende speciallæge, PhD
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Staff and Training			
	YES	#(number)	NO
Experienced study nurses at site	+	2	
GCP trained nurses	+	2	
Experienced sub-investigators at site	+	3	
GCP-trained investigators	+	3	
Availability of additional resources in case of e.g. need for unblinded personnel	+		
Personnel trained and experienced in quit-smoking counseling	+	1	

Clinical Trial Experience			
	YES	#(number)	NO
Phase 1 (# past 5 years)			x
Phase 2 (# past 5 years)			x
Phase 3 (# past 5 years)	x	5	
Phase 4 (# past 5 years)	x	2	
Experience with infusion in trials (# past 5 years)			X (no, but from more than 5 years ago)

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.	+		Medical Electronic Construction (MEC) Belgium	
Masterscope		+		
Flowscreen		+		
Threadmill exercise test VO _{2max}				+
Bike exercise test VO _{2max}				+
6MWT	+			
Incremental and Endurance shuttle walk test				
X-ray		+	Can refer	+
HRCT scanning		+	Can refer	+
Body box/ plethysmography	+		MEC	
Diffusion capacity test - DLCO	+		MEC	
ECG	+			
FENO	+		Aerocrine NIOX MINO og NIOX VERO	
Alveolar NO	+			
Nasal NO	+			
Skin prick test	+			
Methacholine test/histamine test	+			
Mannitol test	+			
Exercise-asthma test	+			
Bronchoscopy		+		+
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	+	
Possibility for temperature monitoring of IMP	+	
Room for Monitor	+	

Other Procedures		
	YES	NO
Availability of written SOP procedure for study procedures (e.g. informed consent)	+	
Possibility of 24 h visits	+	
Possibility of 24h PK sampling	+	
Establishment of databases	+	
Establishment of biobanks		+
Satellite sites		+
Possibility of archiving of study material for 15 years		+

Laboratory				
	YES	NO	Site has equipment at site	Site can insource other department/ local lab to perform
Refrigerator	+			
with temp monitoring	+			
Freezer – 20 degrees		+		
with temp monitoring				
Freezer – 80 degrees		+		
with temp monitoring				
Local lab for blood sample analysis	+			
Local lab certification	+			
IATA certification for handling dry ice shipment		+		
Experience in collaboration with external/central labs	+			
Induced sputum, analysis		+		+
Centrifuge	+			
Cooling centrifuge		+		

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

IT			
	YES	NO	Comment
Availability of back up plan in case of crash	+		
Own computers, high speed internet	+		
Internal firewalls			
Wireless internet connection	+		
Electronic medical record system	+		
Electronic medical record system – certified (need of passwords, CRA only access to certain patients etc)	+		

Other Comments:

Our main interest in the clinic and where we have many patients are:
Allergic as well as non-allergic asthma (including difficult to treat asthma), allergic rhinitis,
diagnostic of dyspnea and cough, allergic sting reactions and urticaria.
Studies concerning these diseases/problems are properly those, where we could be
interested in participating.

We also do see diagnosed KOL-patients as well as other lung patients, and as we do not
have a static clinic, studies with these patients might be interesting in the future.

More information of the clinic can be found at www.allergia.dk

We are active in DALFUMAT (Danske referenceværdier for lungefunktion) so our
Bobybox/diffusion/spirometry equipment and our performance of doing these tests are
thereby certified. One of our doctors has taken ERSs European Spirometry Driving
License (ESDL) and another doctor and a nurse have taken the similar English education.

The Clinic has a long tradition of doing clinical as well as other kind of research.

As we are a clinic “Site can insource other department/ local lab to perform” means that we
will outsource to another site.