

Overview of Respiratory Network sites – What are our capabilities?

Unit: Klinik for Allergi

Hospital: Gentofte

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| 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: