

Study Protocol V. 2.4 – NAPKON-HAP
1.5 Table 1: Study Flow-Chart

Visit	V1/Enrollment	V2	V3	V4	V5	V6	V7	V8-V13 (ICU/ IMC) ¹	V8-V11; V14-V17 (ICU/IMC) ¹	V- discharge ⁵	FU M3	FU M6	FU M12	FU M24	FU M36	UVx
Time of Visits¹	Monday / Wednesday / Friday from day of enrolment								1x/ week	Day of discharge	3 months after symptom onset "deep phenotyping"	6 months after symptom onset ⁴	12 months after symptom onset "deep phenotyping"	24 months after symptom onset	36 months after symptom onset	unscheduled
Visit Windows⁴	-	-	-	-	-	-	-	-	-	-	+/- 3 weeks	+/- 3 weeks	+/- 3 weeks	Examination in case of abnormal result at month 12 +/- 4 weeks	Examination in case of abnormal result at month 24 +/- 4 weeks	Optional for in- and outpatients ⁶
Informed Consent/Authorization	X															
DOCUMENTATION OF CLINICAL ASSESSMENT																
Epidemiological and demographical data	X															
Medical History / update of medical history	X										X	X	X	X	X	X
Vital signs	X	X	X	X	X	X	X	X	X	X						
Clinical symptoms	X	X	X	X	X	X	X	X	X	X						
Clinical blood sample results (chemistry, hematology) / Routine blood testing	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
SARS-CoV-2 PCR testing	X	X	X	X	X	X	X	X	X	X						
Concomitant medication	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Clinical records from patient charts, e.g. parameters of mechanical ventilation, hemodynamics etc.	X	X	X	X	X	X	X	X	X	X						

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Erstellt von Christina Pley, Charlotte Thibeault, Fridolin Steinbeis	Datum 25.11.2020	Geändert von Christian Wildberg und Beate Balzuweit	Datum 27.10.2022
Überprüft von Florian Kurth und Thomas Zoller	Datum 27.10.2022	Aktualisierung geplant für	Datum
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Additional clinical data, e.g. chest X-ray, CT, echocardiography	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Any additional medical events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Hospitalizations or ER visits after discharge																X
CLINICAL ASSESSMENT																
Vital signs											X	X	X	X	X	X
Clinical symptoms											X	X	X	X	X	X
Physical examination											X	X	X	X	X	X
Bio banking of serial blood samples ¹	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Bio banking of saliva and urine ²	X			X			X	X		X						
Upload of image data and biosignals (clinical routine or study specific)	X									X	X	X	X	X	X	X
Clinical severity scores (GCS, SOFA, etc.)	X	X	X	X	X	X	X	X	X	X						
CRB-65 score	X															
WHO Clinical Ordinal Scale		daily documentation during hospital stay									X	X	X	X	X	X
Outcome											X	X	X	X	X	X
SCORES																
NYHA, PCFS, elements of rose NIHSS, Frailty score, Barthel index, Katz index											X	X	X	X	X	X
PATIENT REPORTED OUTCOMES (PROM'S) / QUALITY OF LIFE																
PROMIS-57 Profile, PROMIS Kognitive Funktionen, PROMIS Dyspnoe Functional Limitations	X (only PROMIS-29 Profile v2.1 - acute)										X	X	X	X	X	X
Eq5D5L, neuropathy detect questionnaire, pain detect questionnaire, NEI VFQ, SGRQ																
CFS screening, CFS criteria												X	X	X	X	X
CARDIOLOGY FOLLOW-UP																
ECG, echocardiography											X	X	X	X	X	X

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24h ECG, cardiac MRI, sphygmocor										X	(X)	X	X	X	X
RESPIRATORY FOLLOW-UP															
Body plethysmography, respiratory muscle function test, blood gas analysis										X	X	X	X	X	X
Chest-HR-CT Scan ³												X	X	X	X
Cardiopulmonary exercise testing										X	(X)	X	X	X	X
NEUROLOGY / PSYCHIATRY / OPHTHALMOLOGY FOLLOW-UP															
Physical activity testing, somatosensory testing, smell / taste test										X	(X)	X	X	X	X
Cognitive tests: MoCa, CANTAB										X	(X)	x			
Brain MRI, EEG										X	(X)	X	X	X	X
Optical coherence tomography, funduscopy / -photography										X	(X)	X	X	X	X
ENDOCRINOLOGY FOLLOW-UP															
Age reader, body composition (BIA), glucose monitoring (7 days)										X	(X)	X	X	X	X

1 - For patients without intensive care unit (ICU)/intermediate care unit (IMC) stay, clinical visits including eCRF documentation and biosampling will be performed 3x/week for 2 weeks (7 visits) and followed by eCRF documentation and biosampling on a weekly basis (1x/week) for additional 4 weeks (4 visits) and at time of discharge. **(V1-V11 + V discharge)**.

For patients with ICU/IMC stay at any time since admission, clinical visits including eCRF documentation and biosampling will be performed 3x/week for 4 weeks (13 visits) and followed by eCRF documentation and biosampling on a weekly basis (1x/week) for additional 4 weeks (4 visits) and at time of discharge. **(V1-V17 + V discharge)**.

Selected parameters such as medical events and WHO-Scale will be recorded on a daily basis independent from study visits.

2 - Sampling of urine, saliva and oropharyngeal swabs will be performed once per week for all patients for 2 weeks + V discharge and for 4 weeks + V discharge for patients on ICU or IMC.

3 - Examinations only in case of prior abnormal findings in CT scan and age of patient >50 years. In case of abnormal findings still at month 12, examinations are conducted at month 24 and 36.

4 - For patients who are unable to attend or complete examinations at follow-up visit FU M3 (month 3), examinations missed can be rescheduled to FU M6 (month 6)

5 - Documentation of all medical events and WHO-Scale till time of discharge/death

6 - Optional for extension of hospital stay > 11/17 visits or unplanned outpatient visit as well as patients who are admitted to the hospital again after discharge.

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