

# COVIP study patient data form

Use this form to record patient data offline for each patient. Upon completion, follow the data entry links you've received per email and enter patient data. You may also enter data directly online if preferred.

For use only at investigators site (NOT part of eCRF):	
Patient name	
Patient ID (internal hospital records)	
Admitted to ICU date:	
Date of death (if dead):	

## eCRF

Please write or circle correct answers below and enter online.

**Black:** Mandatory data      **Grey:** Optional data

## Demographics

Consecutive Patient no. (1-999) This consecutive patient number must be same you will use for the eCRF	
Date of consent/inclusion	
Age at admission (must be 70 or above) years	
SARS-CoV-2 (must be proven)	<input type="checkbox"/> Proven
Gender (mark answer)	<input type="checkbox"/> Male <input type="checkbox"/> Female
Weight	kg
Height	cm
Days in the hospital prior to ICU admission (if patient is admitted to hospital and ICU same day, it's day 1) days	
Days with symptom onset prior to hospital admission (if patient is admitted to hospital the day symptoms begin, it's day 1) days	

Past medical history	Diabetes <sup>1</sup> Ischemic heart disease <sup>2</sup> Renal insufficiency <sup>3</sup> Arterial hypertension <sup>4</sup> Pulmonary comorbidity <sup>5</sup> Chronic heart failure <sup>6</sup>	<input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown <input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown <input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown <input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown <input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown <input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown
<sup>1</sup> Any type of diabetes mellitus documented in patient charts or documents or according to anamnesis (patient or relatives), anti-diabetic drugs or insulin in current medication <sup>2</sup> Documented pathologic coronary angiography, Known coronary artery disease according to patient charts, previous percutaneous coronary intervention (PCI) or coronary bypass surgery <sup>3</sup> Documented chronic renal insufficiency Grade 3 or higher, creatinine clearance <60ml/min documented in the past, chronic dialysis <sup>4</sup> Any grade of chronic arterial hypertension, medicated <sup>5</sup> Any kind of chronic pulmonary disease of any etiology (bronchial asthma, COPD, Pulmonary fibrosis), medicated, clinical or radiological signs of chronic pulmonary disease <sup>6</sup> Any kind of chronic heart failure of any etiology, medicated, clinical, echocardiographic or radiological signs of chronic heart failure, or as documented in patient charts.		
Ejection fraction [%] (last assessment)	<input type="checkbox"/> _____ % <input type="checkbox"/> unknown	
ACE Inhibitor use? (within ten days before admission)	<input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown	
Angiotensin 2 receptor blocker use (within ten days before admission)	<input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown	
NSAID (nonsteroidal anti-inflammatory drug) use?	<input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown	
If yes, treatment with	<input type="checkbox"/> Ibuprofen <input type="checkbox"/> Diclofenac <input type="checkbox"/> ASS <input type="checkbox"/> Piroxicam <input type="checkbox"/> Naproxen <input type="checkbox"/> Indametacin <input type="checkbox"/> Metamizol <input type="checkbox"/> Other	
Paracetamol use? (within ten days before admission)?	<input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown	

(OPTIONAL) Habitat before admission (mark answer)	<input type="radio"/> Own home (including if with spouse) <input type="radio"/> Other home with family or caregivers <input type="radio"/> Nursing home <input type="radio"/> Hospital ward <input type="radio"/> Other <input type="radio"/> Unknown
---	--

### ICU-Admission

Bacterial co-infection confirmed	<input type="checkbox"/> yes / <input type="checkbox"/> no / <input type="checkbox"/> unknown	
First Blood gas analysis		
PaO <sub>2</sub>	mmHg	kPa
FiO <sub>2</sub> <sup>1</sup>	%	
PaO <sub>2</sub> /FiO <sub>2</sub> ratio	automatically calculated in eCRF	
<sup>1</sup> For nasal cannula, please check the table in the appendix to estimate FiO <sub>2</sub>		

### Laboratory values on **day 1**

	Common units	SI-Units
Lowest thrombocyte count <sup>1</sup>	10 <sup>3</sup> /μL	10 <sup>9</sup> /L
Highest creatinine <sup>1</sup>	mg/dL	mmol/L
Highest total bilirubin <sup>1</sup>	mg/dL	mmol/L
Highest D-Dimer <sup>1</sup>	μg/mL (DDU)	mg FEU/L
<i>Inflammation (Not mandatory):</i>		
Highest Leucocyte <sup>1</sup>	10 <sup>3</sup> /μL	10 <sup>9</sup> /L
Lowest Lymphocyte count <sup>1</sup>	10 <sup>3</sup> /μL	10 <sup>9</sup> /L
Highest Procalcitonin <sup>1</sup>	ng/dL	μg/L
Highest CRP <sup>1</sup>	mg/L	nmol/L
<sup>1</sup> on day 1		
Highest lactate <b>day 1</b>	mg/dL	mmol/L
Highest lactate <b>day 2</b>	mg/dL	mmol/L

## SOFA score (at or close to time of admission)

Organ system	Grading	Score (0-4)
Respiratory system: <b>PaO<sub>2</sub>/FiO<sub>2</sub></b>	0 pts: >400 mmHg (>= 53 kPa) 1 pt: <400 mmHg (< 53 kPa) 2 pts: <300 mmHg (< 40 kPa) 3 pts: < 200 mmHg (< 27 kPa) AND mechanically ventilated 4 pts: < 100 mmHg (< 13 kPa) AND mechanically ventilated	
Nervous system: <b>Glasgow coma scale score</b>	0 pts: GCS 15 1 pt: GCS 13-14 2 pts: 10-12 3 pts: 6-9 4 pts: <6	
Cardiovascular system: <b>Mean arterial pressure OR administration of vasopressors required</b>	0 pts: MAP ≥ 70 mmHg 1 pt: MAP < 70 mmHg 2 pts: Dopamine ≤ 5 µg/kg/min or dobutamine (any dose) 3 pts: Dopamine > 5 µg/kg/min OR epinephrine ≤ 0.1 µg/kg/min OR norepinephrine ≤ 0.1 µg/kg/min 4 pts: Dopamine > 15 µg/kg/min OR epinephrine > 0.1 µg/kg/min OR norepinephrine > 0.1 µg/kg/min	
Liver: <b>Bilirubin</b>	0 pts: < 20 µmol/L (< 1.2 mg/dL) 1 pt: 20-32 µmol/L (1.2-1.9 mg/dL) 2 pts: 33-101 µmol/L (2.0-5.9 mg/dL) 3 pts: 102-204 µmol/L (6.0-11.9 mg/dL) 4 pts: > 204 µmol/L (>12.0 mg/dL)	
Coagulation: <b>Platelets</b> (10 <sup>3</sup> /µL or 10 <sup>9</sup> /L)	0 pts: ≥ 150 10 <sup>3</sup> /µl 1 pt: < 150 10 <sup>3</sup> /µl 2 pts: < 100 10 <sup>3</sup> /µl 3 pts: < 50 10 <sup>3</sup> /µl 4 pts: < 20 10 <sup>3</sup> /µl	
Kidneys: <b>Creatinine (µmol/L)</b>	0 pts: < 110 (< 1.2 mg/dL) 1 pt: 110-170 (1.2-1.9 mg/dL) 2 pts: 171-299 (2.0-3.4 mg/dL) 3 pts: 300-440 (3.5-4.9 mg/dL) (or < 500 ml/day) 4 pts: > 440 (> 5.0 mg/dL) (or < 200 ml/day)	
<b>SOFA score total (sum of organ system scores)</b> (automatically calculated online)		

## Clinical Frailty Scale

CFS	<ul style="list-style-type: none"> <li><input type="radio"/> Was assessed</li> <li><input type="radio"/> Was <u>not</u> assessed</li> </ul>
Frailty score (1-9) (see scale at end of document)	<ul style="list-style-type: none"> <li><input type="radio"/> 1 = Very fit</li> <li><input type="radio"/> 2 = Well</li> <li><input type="radio"/> 3 = Managing well</li> <li><input type="radio"/> 4 = Vulnerable</li> <li><input type="radio"/> 5 = Mildly frail</li> <li><input type="radio"/> 6 = Moderately frail</li> <li><input type="radio"/> 7 = Severely frail</li> <li><input type="radio"/> 8 = Very severely frail</li> <li><input type="radio"/> 9 = Terminally ill</li> </ul>
Assessors profession (mark answer)	<ul style="list-style-type: none"> <li><input type="radio"/> ICU nurse</li> <li><input type="radio"/> ICU physician</li> <li><input type="radio"/> Dedicated research staff</li> <li><input type="radio"/> Other</li> </ul>
Information obtained from (mark answer)	<ul style="list-style-type: none"> <li><input type="radio"/> Patient</li> <li><input type="radio"/> Family/caregivers</li> <li><input type="radio"/> Hospital records</li> <li><input type="radio"/> Other</li> </ul>

## (OPTIONAL)

### KATZ - Katz Index of Independence in Activities of Daily Living

<p>This simple questionnaire assesses six usual activities: Bathing, dressing, toileting, transferring, continence and feeding. A short explanation is given to each score where 1 represents Independence and 0 Dependence. The higher the score (max 6) the better the function of ADL are. This information should be obtained during the initial conversation with the patient/next-of kin. Independence = 1 point, Dependence = 0 points.</p>		
Katz scoring was obtained by (mark answer)	<ul style="list-style-type: none"><li><input type="radio"/> Patient</li><li><input type="radio"/> Family/caregivers</li><li><input type="radio"/> Hospital records</li></ul>	<ul style="list-style-type: none"><li><input type="radio"/> Other</li><li><input type="radio"/> Unknown</li><li><input type="radio"/> Not performed</li></ul>
		Points
<b>Bathing</b> 1 pt: Bathes self completely or needs help in bathing only a single part of the body such as back, genital area or disabled extremity. 0 pts: Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.		
<b>Dressing</b> 1 pt: Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes. 0 pts: Needs help with dressing self or needs to be completely dressed.		
<b>Toileting</b> 1 pt: Goes to toilet, gets on and off, arranges clothes, cleans genital area without help. 0 pts: Needs help transferring to the toilet, cleaning self or uses bedpan or commode.		
<b>Transferring</b> 1 pt: Moves in and out of bed or chair unassisted. Mechanical transfer aids are acceptable. 0 pts: Needs help in moving from bed to chair or requires a complete transfer.		
<b>Continence</b> 1 pt: Exercises complete self-control over urination and defecation. 0 pts: Is partially or totally incontinent of bowel or bladder.		
<b>Feeding</b> 1 pt: Gets food from the plate into mouth without any help. Preparation of food may be done by another person. 0 pts: Needs partial or total help with feeding or requires parental feeding.		
<b>Total points</b> (6 = high i.e. patient is independent, 0 = Low i.e. patient is dependent) (automatically calculated in eCRF).		

## ICU interventions

Intubation and mechanical ventilation?	Yes	No	Unknown
<b>If Yes, start of intubation and mechanical ventilation (day number)</b> (Day number. Whole number. The day the treatment was started. The day of admission is number 1)	day		
<b>If Yes, duration of intubation and mechanical ventilation</b> (Sum of hours, cumulated for ICU stay (whole number). If extubated and re-intubed, please supply the total (added) amount of hours intubated and on mechanical ventilation)	hours		
Treatment with prone position:	Yes	No	Unknown
<b>If Yes, start of treatment with prone position: (day number)</b> (Day number. Whole number. The day the treatment was started. The day of admission is number 1)	day		
<b>Tracheostomy performed?</b> (Tracheostomy performed with any technique (surgical, dilatational etc.) during ICU stay)	Yes	No	Unknown
<b>If Yes, day of tracheostomy (day number)</b> (Day number. Whole number. The day the treatment was performed. The day of admission is number 1)	day		
<b>Vasoactive drugs used?</b> (Vasopressors, inopressors or inodilators (at any point during the ICU stay). Only if adrenergic agents were used. Pure vasodilators should be disregarded).	Yes	No	Unknown
<b>If Yes, Start of treatment with vasoactive drugs</b> (Day number. Whole number. The day the treatment was started. The day of admission is number 1)	day		
<b>If Yes, Duration of treatment with vasoactive drugs</b> Sum hours (whole number, cumulated hours during ICU stay).	hours		

Renal Replacement Therapy used?	Yes	No	Unknown
If Yes, Start of Renal Replacement Therapy (RRT) (Day number. Whole number. The day the treatment was started. The day of admission is number 1)	day		
If Yes, Duration of Renal Replacement Therapy (RRT) Sum hours (whole number, cumulated hours during ICU stay).	hours		
Cytokine filter system	Yes	No	Unknown
Non-invasive ventilation (NIV) used?	Yes	No	Unknown
If Yes, Start of Non-invasive ventilation (NIV) (Day number. Whole number. The day the treatment was started. The day of admission is number 1)	day		
If Yes, Duration of Non-invasive ventilation (NIV) Sum hours (whole number, cumulated hours during ICU stay).	hours		
Transfer to another hospital for ECMO?	Yes	No	Unknown
If Yes, Day of transfer (Because your hospital does not offer ECMO / has no more ECMO capacities. Day number. Whole number. The day of admission is number 1)	day		
<p align="center"><b>!!Please inform ECMO-Hospital, to not include the patient in COVIP for a second time!!</b></p>			



Was ECMO-therapy performed?		Yes	No	Unknown
If yes, type of ECMO (when both types, please select the first type used)		<input type="checkbox"/> veno-venous <input type="checkbox"/> veno-arterial <input type="checkbox"/> unknown		
If Yes, Start of ECMO (Day number. Whole number. The day the treatment was started. The day of admission is number 1)		day		
If Yes, Duration of ECMO Sum hours (whole number, cumulated hours during ICU stay).		hours		
Use of drugs:				
Antibiotics		Yes	No	Unknown
Corticosteroids	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Corticosteroids or placebo given as part of trial <input type="checkbox"/> Unknown			
Antiviral drugs	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Antiviral drugs or placebo given as part of trial <input type="checkbox"/> Unknown			
Other experimental drugs		Yes	No	Unknown
Other experimental trial (non-drug)		Yes	No	Unknown

## Outcome

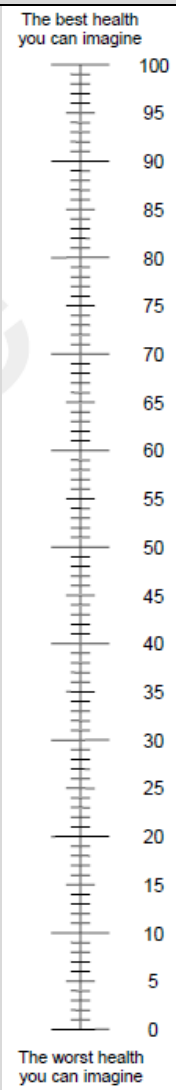
Life-sustaining care withhold	Yes	No	Unknown
<b>If Yes, when was the decision made to withhold life-sustaining care</b> (Day number. Whole number. The day of admission is number 1)	day		
Life-sustaining care withdrawn	Yes	No	Unknown
<b>If Yes, when was the decision made to withdraw life-sustaining care</b> (Day number. Whole number. The day of admission is number 1)	day		
Was treatment withdrawn or withhold performed in triage condition without consulting the caregiver?	Yes	No	Unknown
Survived to ICU discharge	Yes	No	Unknown
<b>ICU length of stay</b> Sum of hours from admission until discharge (or death if patient died in the ICU).	hours		
<b>Vital status at 30 days?</b> (from day of ICU admission)	Alive	Dead	Unknown
<b>Vital status at 3 months?</b> (from day of ICU admission) (if your ICU participates in 6 months follow-up)	Alive	Dead	Unknown
<b>If dead, when did the patient die?</b> (Day number. Whole number. The day of admission is number 1)	day		

# (Optional)

## EQ-5D-5L after 3 month

EQ-5D-5L Information obtained from (mark answer)	<ul style="list-style-type: none"> <li><input type="radio"/> Patient</li> <li><input type="radio"/> Family/caregivers</li> <li><input type="radio"/> Hospital records</li> <li><input type="radio"/> Other</li> <li><input type="radio"/> Not assessed</li> </ul>
---	---

<b><u>EQ-5D-5L</u></b>	
<b>Describing the health today</b>	
<i>Please answer on behalf of the patient or by yourself, respectively. Under each heading, mark ONE box that you think the patient would make to describe his/her own health TODAY if he/she were able to do.</i>	
<b>Mobility (walking about)</b>	
There are no problems in walking about	<input type="checkbox"/>
There are slight problems in walking about	<input type="checkbox"/>
There are a moderate problems in walking about	<input type="checkbox"/>
There are a severe problems in walking about	<input type="checkbox"/>
There is inability to walk about	<input type="checkbox"/>
<b>Self-care</b>	
There are no problems in washing or dressing	<input type="checkbox"/>
There are slight problems in washing or dressing	<input type="checkbox"/>
There are moderate problems in washing or dressing	<input type="checkbox"/>
There are severe problems in washing or dressing	<input type="checkbox"/>
There is inability to wash or dress	<input type="checkbox"/>
<b>Usual activities (for example work, study, housework, family or leisure activities))</b>	
There are no problems doing usual activities	<input type="checkbox"/>
There are slight problems doing usual activities	<input type="checkbox"/>
There are moderate problems doing usual activities	<input type="checkbox"/>
There are severe problems doing usual activities	<input type="checkbox"/>
There is inability to do usual activities	<input type="checkbox"/>

<b>Pain / discomfort</b>	
There is no pain or discomfort	<input type="checkbox"/>
There is slight pain or discomfort	<input type="checkbox"/>
There is moderate pain or discomfort	<input type="checkbox"/>
There is severe pain or discomfort	<input type="checkbox"/>
There is has extreme pain or discomfort	<input type="checkbox"/>
<b>Anxiety / Depression</b>	
There is no anxiety or depression	<input type="checkbox"/>
There is slight anxiety or depression	<input type="checkbox"/>
There is moderate anxiety or depression	<input type="checkbox"/>
There is severe anxiety or depression	<input type="checkbox"/>
There is extreme anxiety or depression	<input type="checkbox"/>
<b>We would like to know how good or bad the health is TODAY.</b>	
<ul style="list-style-type: none"> <li>• This scale is numbered from 0 to 100.</li> <li>• 100 means the best health imaginable</li> <li>• 0 means the worst health imaginable</li> <li>• Mark an X on the scale to indicate how the health is TODAY.</li> <li>• Now, please write the number you marked on the scale in the box below</li> </ul>	

## Clinical Frailty Scale



**1 Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



**2 Well** – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.



**3 Managing Well** – People whose medical problems are well controlled, but are not regularly active beyond routine walking.



**4 Vulnerable** – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day.



**5 Mildly Frail** – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



**6 Moderately Frail** – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.



**7 Severely Frail** – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



**8 Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



**9 Terminally Ill** – Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.

### Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

## Katz Index of Independence in Activities of Daily Living

Activities Points (1 or 0)	Independence (1 Point)	Dependence (0 Points)
	<b>NO</b> supervision, direction or personal assistance.	<b>WITH</b> supervision, direction, personal assistance or total care.
<b>BATHING</b> Points: _____	<b>(1 POINT)</b> Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	<b>(0 POINTS)</b> Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing
<b>DRESSING</b> Points: _____	<b>(1 POINT)</b> Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	<b>(0 POINTS)</b> Needs help with dressing self or needs to be completely dressed.
<b>TOILETING</b> Points: _____	<b>(1 POINT)</b> Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	<b>(0 POINTS)</b> Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
<b>TRANSFERRING</b> Points: _____	<b>(1 POINT)</b> Moves in and out of bed or chair unassisted. Mechanical transfer aids are acceptable	<b>(0 POINTS)</b> Needs help in moving from bed to chair or requires a complete transfer.
<b>CONTINENCE</b> Points: _____	<b>(1 POINT)</b> Exercises complete self control over urination and defecation.	<b>(0 POINTS)</b> Is partially or totally incontinent of bowel or bladder
<b>FEEDING</b> Points: _____	<b>(1 POINT)</b> Gets food from plate into mouth without help. Preparation of food may be done by another person.	<b>(0 POINTS)</b> Needs partial or total help with feeding or requires parenteral feeding.
<b>TOTAL POINTS:</b> _____ <b>SCORING:</b> 6 = High ( <i>patient independent</i> )   0 = Low ( <i>patient very dependent</i> )		

## APPENDIX:

Low-Flow System	Oxygen Flow Rates (L/min)	FiO <sub>2</sub>
Nasal cannula	1	0.24
	2	0.28
	3	0.32
	4	0.36
	5	0.40
	6	0.44
Simple face mask	5-6	0.40
	6-7	0.50
	7-8	0.60
Partial-rebreathing mask	6	0.60
	7	0.70
	8	0.80
	9	0.80
	10	0.80
Non-rebreathing mask	10	0.80
	15	0.90
Adapted from Critical Care Medicine: Perioperative Management by Michael James Murray, Lippincott Williams & Wilkins, 2002		

When entering data in the online form, the **ICU ID** and the **email address of the ICU primary contact** is needed.

Sincerely, the COVIP steering committee

[www.vipstudy.org](http://www.vipstudy.org)

[contact@vipstudy.org](mailto:contact@vipstudy.org)