# 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):		
Consecutive Patient no. (1-999) <sup>1</sup>		
<sup>1</sup> This consecutive patient number must be same you will use for the eCRF		

#### eCRF

Please <u>write</u> or <u>circle</u> correct answers below and enter online.

#### Black: Mandatory data

Grey: Optional data

#### Demographics

Date of consent (only if consent is needed)		
Age at admission (must be 70 or above)		years
SARS-CoV-2 (mark answer)	Suspected	🗆 Proven
Gender (mark answer)	🗆 Male	🗆 Female
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 (days)		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>	<ul> <li>yes / □no / □ unknown</li> </ul>
<sup>1</sup> Any type of diabetes mellitus with clinical or <sup>2</sup> Past typical angina, documented pathologic <sup>3</sup> Any grade of chronic renal insufficiency, incr <sup>4</sup> Any grade of chronic arterial hypertension, r <sup>5</sup> Any kind of chronic pulmonary disease of an radiological signs of chronic pulmonary disea <sup>6</sup> Any kind of chronic heart failure of any etiol radiological signs of chronic heart failure	coronary angiography or CAG, medicate eased creatinine values before admission nedicated y etiology (bronchial Asthma, COPD, Pu se	on, medicated, existing dialysis access
Ejection fraction [%] (last assessment)	□% □ unknown	
ACE Inhibitor use? (within ten days before admission)		🗆 yes / 🗆 no / 🗆 unknown
Angiotensin 2 receptor blocker USE (within ten days before admission)		🗆 yes / 🗆 no / 🗆 unknown
Pretreatment with NSAID (nonst drug)? (within ten days before admission)		□ yes / □no / □ unknown
If yes, pretreatment with		<ul> <li>Ibuprofen</li> <li>Diclofenac</li> <li>ASS</li> <li>Piroxicam</li> <li>Naproxen</li> <li>Indametacin</li> <li>Metamizol</li> <li>Other</li> </ul>
Pretreatment with Paracetam admission)?	<b>Ol?</b> (within ten days before	□ yes / □no / □ unknown
(OPTIONAL) Habitat before admission (mark answer)	<ul> <li>Own home (includint</li> <li>Other home with fation</li> <li>Nursing home</li> <li>Hospital ward</li> </ul>	

- o Other
- o Unknown

#### **ICU-Admission**

Bacterial co-infection confirmed	🗆 yes / 🗆 no ,	/ □ unknown	
First Blood gas analysis			
PaO <sub>2</sub>	mmHg	kPa	
FiO <sub>2</sub> <sup>1</sup>	c,	%	
PaO2/FiO2 ratio	automatically calculated in eCRF		
<sup>1</sup> For nasal cannula, please che	ck the table in the appendix to e	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
D-Dimer <sup>1</sup>	μg/mL (DDU)	mg FEU/L
Inflammation (Not mandatory):	403/ 1	100/
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	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: PaO2/FiO2	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: Glasgow coma scale score	0 pts: GCS 15 1 pt: GCS 13-14 2 pts: 10-12 3 pts: 6-9 4 pts: <6	
Cardiovascular system: Mean arterial pressure OR administration of vasopressors required	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	
<sup>Liver:</sup> Bilirubin	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: Platelets (10 <sup>3</sup> /µL or 10 <sup>9</sup> /L)	0 pts: ≥ 150 10^3/µl 1 pt: < 150 10^3/µl 2 pts: < 100 10^3/µl 3 pts: < 50 10^3/µl 4 pts: < 20 10^3/µl	
<sup>Kidneys:</sup> Creatinine (μmol/L)	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)	
SOFA score total (sum of (automatically calculated online)	organ system scores)	

# **Clinical Frailty Scale**

CFS	<ul> <li>Was assessed</li> <li>Was <u>not</u> assessed</li> </ul>
Frailty score (1-9) (see scale at end of document)	<ul> <li>1 = Very fit</li> <li>2 = Well</li> <li>3 = Managing well</li> <li>4 = Vulnerable</li> <li>5 = Mildly frail</li> <li>6 = Moderately frail</li> <li>7 = Severely frail</li> <li>8 = Very severely frail</li> <li>9 = Terminally ill</li> </ul>
Assessors profession (mark answer)	<ul> <li>ICU nurse</li> <li>ICU physician</li> <li>Dedicated research staff</li> <li>Other</li> </ul>
Information obtained from (mark answer)	<ul> <li>Patient</li> <li>Family/caregivers</li> <li>Hospital records</li> <li>Other</li> </ul>

### (OPTIONAL)

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

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. Other Patient 0 Katz scoring was Unknown Family/caregivers 0 obtained by (mark answer) Not performed Hospital records 0 Points Bathing 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. Dressing 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. Toileting 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. Transferring 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. Continence 1 pt: Exercises complete self-control over urination and defecation. 0 pts: Is partially or totally incontinent of bowel or bladder. Feeding 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. Total points (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
If Yes, start of intubation and mechanical ventilation (day number) (Day number. Whole number. The day the treatment was started. The day of admission is number 1)		day	
If Yes, duration of intubation and mechanical ventilation (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
If Yes, start of treatment with prone position: (day number) (Day number. Whole number. The day the treatment was started. The day of admission is number 1)		day	
Tracheostomy performed? (Tracheostomy performed with any technique (surgical, dilatational etc.) during ICU stay)	Yes	No	Unknown
If Yes, day of tracheostomy (day number) (Day number. Whole number. The day the treatment was perfomed. The day of admission is number 1)		day	
Vasoactive drugs used? (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
If Yes, Start of treatment with vasoactive drugs (Day number. Whole number. The day the treatment was started. The day of admission is number 1)		day	
If Yes, Duration of treatment with vasoactive drugs 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	
<pre>!!Please inform ECMO-Ho patient in COVIP fo</pre>	-		
			8

Was ECMO-therapy performed?	Yes	No	Unknown
If yes, type of ECMO (when both types, please select the first type used)	🗆 veno-ver	nous 🗆 veno-art	erial 🗆 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	Yes	No	Unknown
Antiviral drugs	Yes	No	Unknown
Other experimental drugs	Yes	No	Unknown

#### Outcome

Life-sustaining care withhold	Yes	No	Unknown
If Yes, when was the decision made to withhold life-sustaining care (Day number. Whole number. The day of admission is number 1)		day	
Life-sustaining care withdrawn	Yes	No	Unknown
If Yes, when was the decision made to withdraw life-sustaining care (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
ICU length of stay Sum of hours from admission until discharge (or death if patient died in the ICU).			hours
Vital status at 30 days? (from day of ICU admission)	Alive	Dead	Unknown
Vital status at 3 months? (from day of ICU admission) (if your ICU participates in 6 months follow-up)	Alive	Dead	Unknown
If dead, when did the patient die? (Day number. Whole number. The day of admission is number 1)		day	

# (Optional)

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

	0	Patient
EQ-5D-5L Information obtained from	0	Family/caregivers
	0	Hospital records
(mark answer)	0	Other
	0	Not assessed

### EQ-5D-5L

#### Describing the health today

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.

Mobility (walking about)	
There are no problems in walking about	
There are slight problems in walking about	
There are a moderate problems in walking about	
There are a severe problems in walking about	
There is inability to walk about	
Self-care	
There are no problems in washing or dressing	
There are slight problems in washing or dressing	
There are moderate problems in washing or dressing	
There are severe problems in washing or dressing	
There is inability to wash or dress	
Usual activities (for example work, study, housework, family or leisure	
activities))	
There are no problems doing usual activities	
There are slight problems doing usual activities	
There are moderate problems doing usual activities	
There are severe problems doing usual activities	
There is inability to do usual activities	

Pain / discomfort	
There is no pain or discomfort	
There is slight pain or discomfort	
There is moderate pain or discomfort	
There is severe pain or discomfort	
There is has extreme pain or discomfort	
Anxiety / Depression	
There is no anxiety or depression	
There is slight anxiety or depression	
There is moderate anxiety or depression	
There is severe anxiety or depression	
There is extreme anxiety or depression	
We would like to know how good or bad the health is TODAY.	
<ul> <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>	The best health you can imagine 95 90 85 80 75 70 65 60 55 60 45 50 45 45 40 45 45 40 45 40 45 45 40 45 45 40 45 45 40 45 45 40 45 45 40 45 45 40 45 40 45 40 45 40 45 40 45 40 45 40 45 40 45 40 45 40 45 40 45 40 45 45 40 45 45 40 45 45 40 45 45 40 45 45 40 45 40 45 45 40 45 45 40 45 45 40 40 45 40 40 45 40 40 40 45 40 40 45 40 40 45 40 40 45 40 40 45 40 40 45 40 40 45 40 40 45 40 40 40 40 40 40 40 40 40 40 40 40 40

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

<b>APPENDIX:</b>
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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

contact@vipstudy.org