

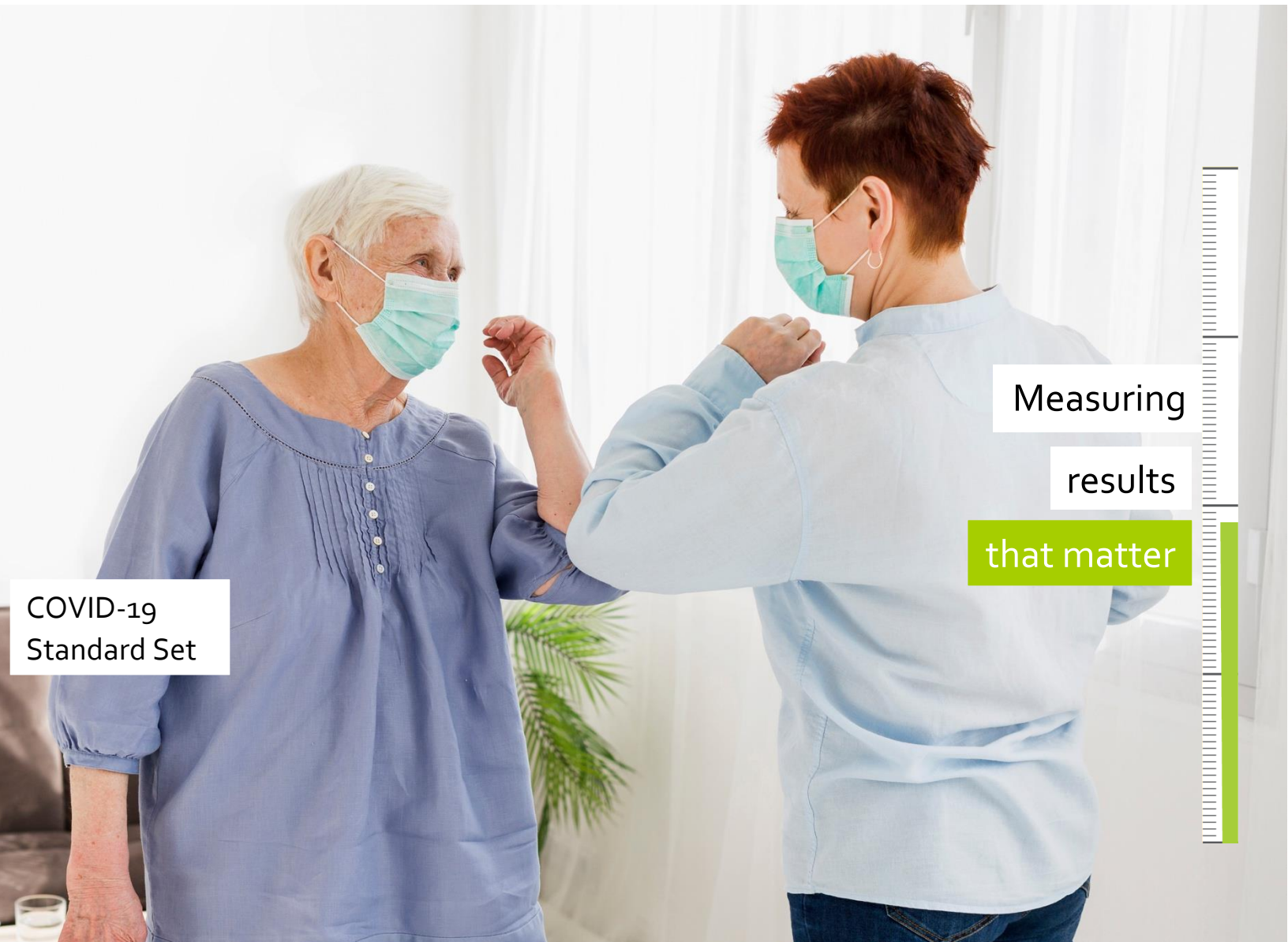


**ICHOM**

International Consortium for  
Health Outcomes Measurement

COVID-19 Standard Set  
**DATA COLLECTION  
REFERENCE GUIDE**

Version 1.0.0  
Revised: October 7<sup>th</sup>, 2020



COVID-19  
Standard Set

Measuring

results

that matter





# ICHOM

## COVID-19 Standard Set

We are thrilled that you are interested in measuring outcomes for the COVID-19 Infection according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

© 2020 ICHOM. All rights reserved. When using this set of outcomes, or quoting therefrom, in any way, we solely require that you always make a reference to ICHOM as the source so that this organisation can continue its work to define more standard outcome sets. Please cite as follows: ICHOM COVID-19 Working Group, COVID-19, October 2020, (available at: <https://www.ichom.org/portfolio/covid-19/>)

# Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardised outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes, is included in the appendix.

Our aim is to make Standard Sets freely accessible to healthcare institutions worldwide to begin measuring, and ultimately benchmark the outcomes they achieve. In order to have a guide from which we can benchmark outcomes, we require feedback from initial implementation efforts. As such, this Reference Guide may undergo revisions on a regular basis. If you have any suggestions or would like to provide feedback, please contact [info@ichom.org](mailto:info@ichom.org)

## Working Group Members for the COVID-19 Standard Set

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for COVID-19 in partnership with ICHOM, under the leadership of Kees Brinkman, ICHOM Standard Set Chair. The work was supported by William Seligman, ICHOM Research Fellow, Luz Fialho, ICHOM Director of Outcomes Research, Nick Sillett, ICHOM Project Manager, and Christina Nielsen, ICHOM Research Associate.

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<b>Brazil</b> Maiara Anschau Floriani Gisele Alsina Nader Bastos Ingvar Ludwig Marcelo Pio de Almeida Fleck	<b>Pakistan</b> Farhala A. Baloch Ayesha Kamran Kamal Nasreen Muhammad Saleem	<b>United Kingdom</b> Philip Collis* Lucinda Gabriel Anju Devianee Keetharuth Christine Owen Anne-Marie Russell	
<b>Canada</b> Evan H. Kwong Douglas Woodhouse	<b>Portugal</b> Ana Londral		
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\*Patient representative

# Scope of the COVID-19 Standard Set

For the COVID-19 Standard Set, the following conditions and treatment approaches (or interventions) are covered by our Standard Set.

<b>Conditions</b>	All adults with confirmed or highly suspected SARS-CoV-2 infection
<b>Populations</b>	Adults aged 18 years and above
<b>Stages</b>	Set designed to measure outcomes on patients for up to 3 months after initial infection. This can then be extended for a further 3 months depending on clinical course and recovery.
<b>Treatment approaches</b>	Primary, Secondary or Tertiary Care Settings
<b>Excluded populations</b>	Children and young people under the age of 18

# ICHOM Standard Set for COVID-19

## Case-Mix Variables

Variable	Measure	Supporting Information	Timing	Data Source
<b>Demographic Factors</b>				
Age	Year of birth.		Baseline	Administrative
Sex	The patient's sex at birth.		Baseline	Administrative
Race	The biological race of the patient.	This measure should be recorded based on local standards in the particular geographic region and should be self-reported by the patient. All patients may choose not to answer this question.	Baseline	Patient/ Administrative
Ethnicity	The cultural ethnicity of the patient that they most closely identify with.	This measure should be recorded based on local standards in the particular geographic region and should be self-reported by the patient. All patients may choose not to answer this question.	Baseline	Patient/ Administrative
Level of Education	Highest level of education completed based on local standard definitions of education levels.	This measure may vary based on local standards for education levels so please consult the International Standard Classification to select the level that most closely relates to your education experience. Please follow this link here: <a href="http://uis.unesco.org/sites/default/files/documents/international-standard-classification-of-education-isced-2011-en.pdf">http://uis.unesco.org/sites/default/files/documents/international-standard-classification-of-education-isced-2011-en.pdf</a>	Baseline	Patient
<b>Clinical Factors</b>				
Comorbidities	Prior and current diagnosis of disease or no presence of diagnosis.	Measured using ICHOM's Self-Administered Comorbidities Questionnaire (SACQ)	Baseline	Patient/Clinician
Body Mass Index	Height and weight are used to calculate BMI.	BMI calculated as kg/m <sup>2</sup>	Baseline	Clinician/ Healthcare provider
<b>Treatment-Related Factors</b>				
Need for ventilation	Did the patient require any ventilation during their hospital admission?		Baseline/ Updated monthly	Clinician/ Healthcare provider
Type of ventilation	What type of ventilation was administered?	Mechanical or non-mechanical	Baseline/ Updated monthly	Clinician/ Healthcare provider
Duration of ventilation	How long did the patient require ventilation?	In days	Baseline/ Updated monthly	Clinician/ Healthcare provider
Duration of critical care admission	How long was the patient's initial stay in critical care?	In days	Baseline/ Updated monthly	Clinician/ Healthcare provider

## Outcomes

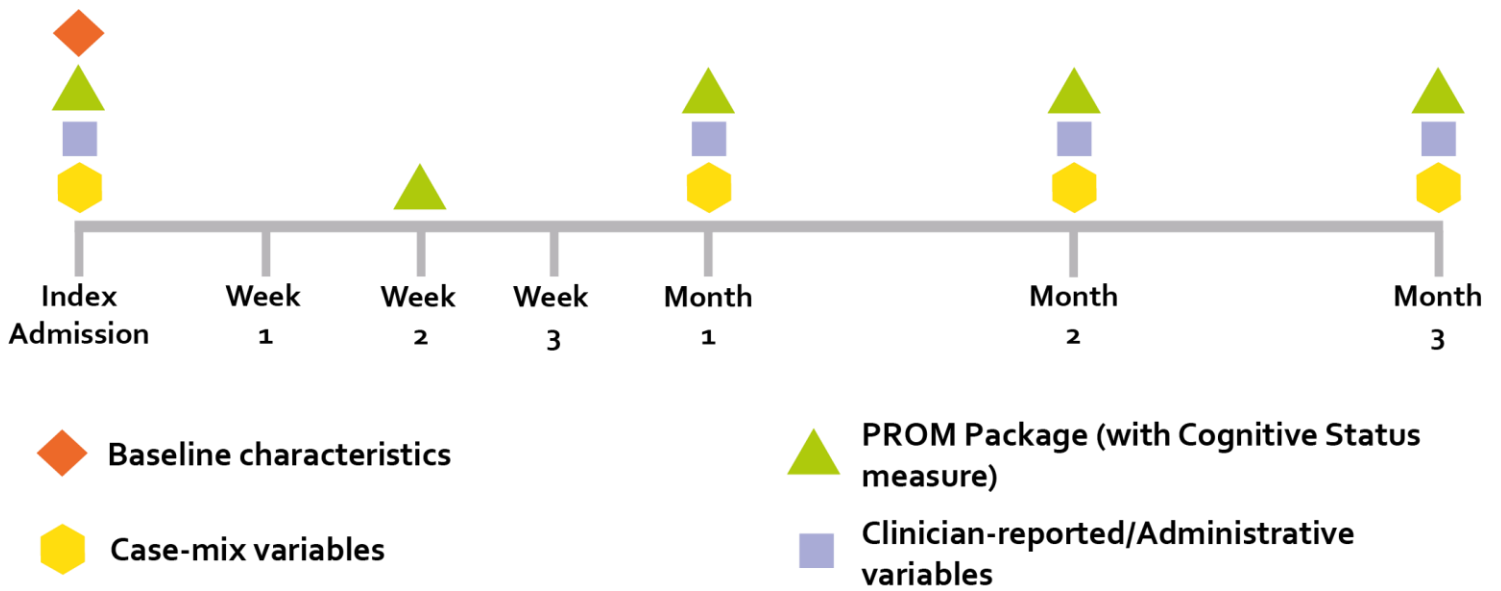
Outcome	Timing	Measure	Supporting Definition/Information	Data Source
<b>Functional Status and Quality of Life</b>				
Health-related quality of life	Baseline/ every two weeks for first month, then monthly	PROMIS Global Health 1.2	The perceived quality of an individual's daily life, assessing their health and wellbeing or lack thereof. A multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning.	Patient
General physical functioning	Baseline/ every two weeks for first month, then monthly	PROMIS Global Health 1.2	An individual's ability to perform and/or participate in usual daily activities required to meet essential needs, fulfil usual roles, meet usual responsibilities, and maintain health and well-being.	Patient
Vitality/energy	Baseline/ every two weeks for first month, then monthly	FLU-PRO	Capacity for work and leisure activities, and efficiency of accomplishment related to a feeling of weariness or tiredness.	Patient
<b>Mental Functioning</b>				
Mental health symptoms and emotional wellbeing	Baseline/ every two weeks for first month, then monthly	PROMIS Global Health 1.2	An individual's emotional, psychological, and social wellbeing, including negative feelings and fears, as well as moderate to high levels of anxiety or psychological distress.	Patient
Cognitive status	Baseline/ every two weeks for first month, then monthly	Clinician Measure – this will assess whether a patient is able to self-report their outcomes. If unable, only clinician / administrative measures are to be used.	An individual's mental process of knowing, including awareness, perception, reasoning, and judgment.	Clinician/ Healthcare provider
<b>Social Functioning</b>				
Feelings of loneliness and isolation	Baseline/ every two weeks for first month, then monthly	PROMIS Social Isolation 4a	An individual's negative feelings related to the perception of being alone, disconnected or isolated.	Patient
Productivity	Baseline/ every two weeks for first month, then monthly	PROMIS Global Health 1.2	An individual's ability to carry out tasks, actions or participate in life situations.	Patient
<b>Clinical Outcomes</b>				
Survival	Baseline/ Updated monthly	Clinician Measure	Any cause of death in a patient with COVID-19.	Clinician/ Administrative

Meeting criteria for critical care admission	Baseline/ every two weeks for first month, then monthly	FLU-PRO	Patients whose medical needs cannot be met through standard ward-based care in an acute hospital, who would meet criteria for a high dependency or critical care unit. Patients who meet criteria for critical care admission may not in fact be admitted to critical care facilities for other reasons e.g. resource constraints, however should be included under this definition.	Patient
Disease course severity	Baseline/ Updated monthly	FLU-PRO; Clinician Measure	Mild: no need for hospitalization. Moderate: hospitalisation without need for non-invasive or mechanical ventilation. Severe: received non-invasive and/or mechanical ventilation, or died; admission to HDU/ICU.	Patient
Persisting Organ Damage	Baseline/ Updated monthly	Clinician Measure	End-organ damage, including the central or peripheral nervous system, as a result of the COVID-19 infection that results in impaired function in the individual.	Clinician/ Healthcare provider
Duration of hospitalisation	Baseline/ Updated monthly	Clinician Measure	Number of nights spent in hospital being treated for symptoms related to COVID-19 (irrespective of whether COVID-19 was the reason for admission or if the patient developed COVID-19 while in hospital for another reason). This includes nights spent in hospital on subsequent hospital admissions during the follow-up period if the individual being readmitted was being treated for symptoms related to COVID-19 on that admission.	Clinician/ Healthcare provider
<b>Symptoms</b>				
Symptoms	Baseline/ every two weeks for first month, then monthly	FLU-PRO	A subjective perception suggesting bodily impairment or malfunction, affecting the individual in a negative manner.	Patient

# Follow-Up Timeline

The following timeline illustrates when Standard Set variables should be collected from patients and clinicians. This Standard Set is designed to track patient outcomes over a 3-month period following the diagnosis of the patient with confirmed or highly suspected SARS-CoV-2 infection. The outcome collection period can be extended for a further 3 months if the patient has not yet recovered. This is at the discretion of the physician and we recommend collecting outcomes on a monthly basis during the extension period.

When PROMs are collected, the cognitive status measure will also be used to assess if the patient, with or without assistance, is able to self-report and complete the measures. For the duration that the patient is unable to report their own outcomes, then only the clinician-reported and administrative measures are to be used when scheduled.





# Collecting Patient-Reported Outcome Measures

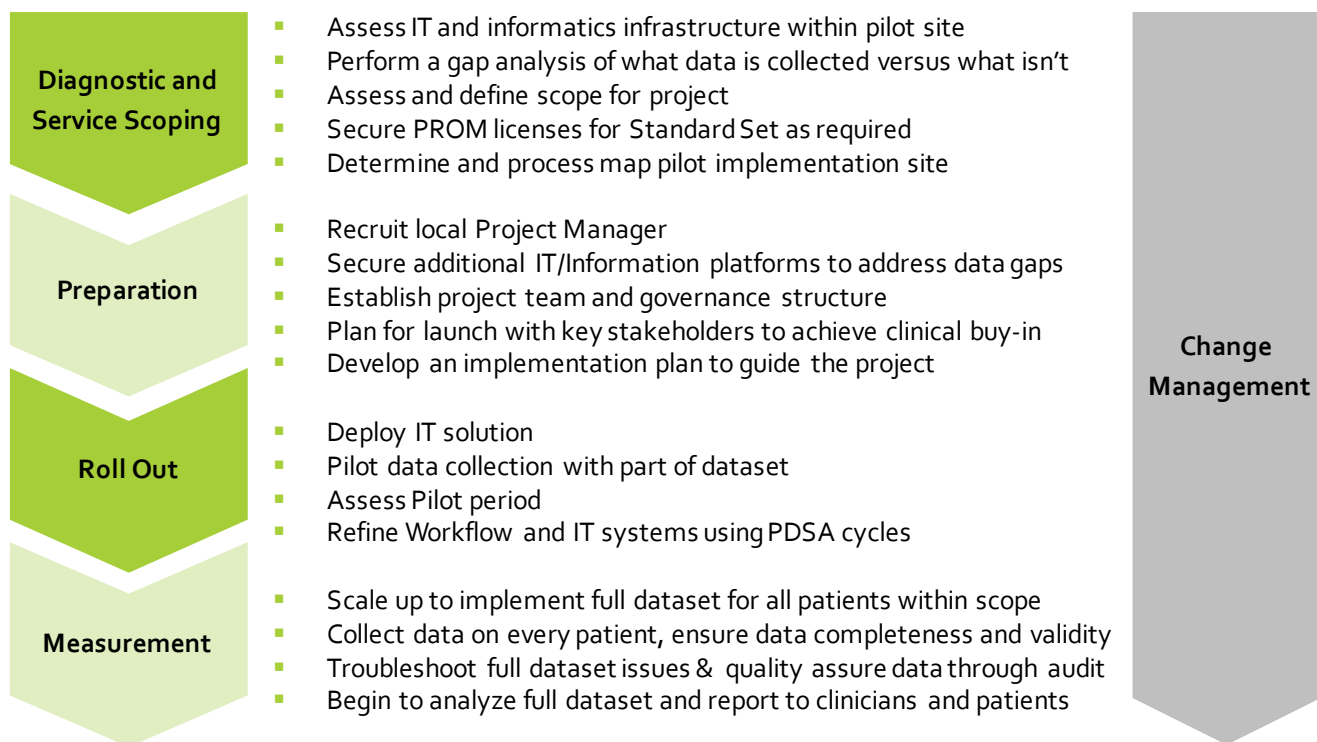
Patient-Reported Outcome Measure	Licensing Information	Scoring Information
PROMIS Global Health 1.2	<p>Respondent-ready PDF of the instrument for all measurement systems are available at <a href="http://www.HealthMeasures.net">www.HealthMeasures.net</a> in "Search &amp; View Measures." These measures may be used in paper or electronic form for single use (i.e., solely for the user's own individual clinical trial, academic research study, healthcare or clinical application, community-based or educational program, or other discrete application with a defined timeline, area of focused health measurement, and deliverables or research products) without permission or fees as long as the text is not changed.</p>	<p>The easiest way to use this instrument is with the HealthMeasures Scoring Service (<a href="https://www.assessmentcenter.net/ac_scoring-service">https://www.assessmentcenter.net/ac_scoring-service</a>). However, these can be manually scored by calculating the raw score by summing the values of each item response. These total raw scores can then be converted to a T-score by using the conversion tables located in the Global Health 1.2 Scoring Manual from the HealthMeasures website.</p>
PROMIS Short Form v2.0 - Social Isolation 4a	<p>Respondent-ready PDF of the instrument for all measurement systems are available at <a href="http://www.HealthMeasures.net">www.HealthMeasures.net</a> in "Search &amp; View Measures." These measures may be used in paper or electronic form for single use (i.e., solely for the user's own individual clinical trial, academic research study, healthcare or clinical application, community-based or educational program, or other discrete application with a defined timeline, area of focused health measurement, and deliverables or research products) without permission or fees as long as the text is not changed.</p>	<p>The easiest way to use this instrument is with the HealthMeasures Scoring Service (<a href="https://www.assessmentcenter.net/ac_scoring-service">https://www.assessmentcenter.net/ac_scoring-service</a>). However, these can be manually scored by calculating the raw score by summing the values of each item response. These total raw scores can then be converted to a T-score by using the conversion tables located in the Social Isolation 4a Scoring Manual from the HealthMeasures website.</p>
FLU-PRO	<p>The FLU-PRO is available in 9 languages and free to use for non-profit organisations. Leidos Biomedical Research holds the copyright to the instrument and manages all licensing and user agreements. Evidera scientists can assist and advise on the use of the FLU-PRO in clinical research. More information on licensing can be found <a href="#">here</a>.</p>	<p>FLU-PRO scoring includes total and subscale scores for symptom severity by body system. The instrument also provides data on the presence/absence of symptoms, symptom profiles, and change over time. More information on scoring can be found <a href="#">here</a>.</p>

## The Growing ICHOM Community

There is a growing community of healthcare providers implementing the ICHOM Standard Sets. To support your organisation in implementing the set and the measurement of outcomes data, we have outlined a framework to guide the implementation and reporting of patient-centered outcomes.

### Implementation framework:

The framework below, outlines the structured process to guide the implementation of an ICHOM Standard Set at your organisation. Typically, an implementation project takes 9 months to complete.



### ICHOM is also able to support organisations with a variety of support models:

1. Capacity building – direct advisory support
2. Community models – supporting a community of providers in outcomes adoption and innovation
3. Education – workshops and short courses regarding Value Based Healthcare and implementation skills

### Translating the Set Tools:

PROMs within the ICHOM Sets are available in a number of languages. To check the availability of translations, we advise contacting the Tool authors directly to obtain and translate the PROM surveys into your desired language. To independently translate PROM surveys, if permitted by its license, we recommend following the 10 steps outlined below:<sup>\*1</sup>

<b>Step 1</b>	Preparation	Initial work carried out before the translation work begins
<b>Step 2</b>	Forward Translation	Translation of the original language, also called source, version of the instrument into another language, often called the target language
<b>Step 3</b>	Reconciliation	Comparing and merging more than one forward translation into a single forward translation
<b>Step 4</b>	Back Translation	Translation of the new language version back into the original language
<b>Step 5</b>	Back Translation Review	Comparison of the back-translated versions of the instrument with the original to highlight and investigate discrepancies between the original and the reconciled translation, which is then revised in the process of resolving the issues
<b>Step 6</b>	Harmonisation	Comparison of back translations of multiple language versions with each other and the original instrument to highlight discrepancies between the original and its derivative translations, as well as to achieve a consistent approach to translation problems
<b>Step 7</b>	Cognitive Debriefing	Testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation
<b>Step 8</b>	Review of Cognitive Debriefing Results and Finalisation	Comparison of the patients' or lay persons' interpretation of the translation with the original version to highlight and amend discrepancies
<b>Step 9</b>	Proofreading	Final review of the translation to highlight and correct any typographic, grammatical or other errors
<b>Step 10</b>	Final Report	Report written at the end of the process documenting the development of each translation

\*These ten steps follow the ISPOR Principles of Good Practice: The Cross-Cultural Adaptation Process for Patient-Reported Outcomes Measures<sup>1</sup> Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., et al. (2005). Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. *Value in Health*, 8(2), 94–104. doi:10.1111/j.1524-4733.2005.04054.x.

# Appendix

# Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM COVID-19 Standard Set as consistently as possible to the Working group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID\_TIMESTAMP form for future analyses. For example, VARIABLEID\_BASE (baseline); VARIABLEID\_2WEEK (2 week follow-up); VARIABLEID\_2MO (2<sup>nd</sup> month follow-up), etc.

## Case-Mix Variables

### Demographic Factors

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**Variable ID:** N/A

**Variable:** Patient ID

**Definition:** Indicate the patient's medical record number

**Supporting Definition:** This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution

**Displayed Value:**

**Inclusion Criteria:** All patients

**Timing:** On all forms

**Data Source:** Administrative or clinical

**Type:** Numerical

**Value Domain:**

**Response Options:** According to institution

---

**Variable ID:** YearOfBirth

**Variable:** Year of Birth

**Definition:** Year of birth

**Supporting Definition:** None

**Displayed Value:** In what year were you born?

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Data Source:** Administrative

**Type:** Single answer

**Value Domain:** Date

**Response Options:** YYYY

---

**Variable ID:** Sex

**Variable:** Sex

**Definition:** The patient's sex at birth

**Supporting Definition:** For statistical purposes, the following category codes, labels and definitions are preferred: CODE 1 Male: Persons who have male or predominantly masculine biological characteristics, or male sex assigned at birth. CODE 2 Female: Persons who have female or predominantly feminine biological characteristics, or female sex assigned at birth. CODE 3 Other: Persons who have mixed or non-binary biological characteristics (if known), or a nonbinary sex assigned at birth. The

value meaning of 'Other' has been assigned to Code 3 for this value domain, which replaces 'Intersex or indeterminate' for the superseded value domain Sex code N. Terms such as 'indeterminate', 'intersex', 'non-binary', and 'unspecified' are variously used to describe the 'Other' category of sex. The label 'Other' is used because a more descriptive term has not been widely agreed within the general community. Sex refers to the chromosomal, gonadal and anatomical characteristics associated with biological sex. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.

**Displayed Value:** Please indicate your sex at birth  
**Inclusion Criteria:** All patients  
**Timing:** Baseline  
**Data Source:** Administrative  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= Male  
 2= Female  
 3= Other  
 999= Undisclosed

**Variable ID:** Race  
**Variable:** Race  
**Definition:** The biological race of the person  
**Supporting Definition:** This measure should be recorded based on local standards in the particular geographic region and should be self-reported by the patient. This is an optional question but ICHOM encourages that this information is collected and is as racially and ethnically inclusive as possible. This data will help to support combating health disparities based on race but all patient data regarding race and ethnicity will be kept confidential. The patient's response will then be coded based on LOINC's standards. All patients may choose not to answer as well.  
**Displayed Value:** Please indicate the biological race that you identify with.  
**Inclusion Criteria:** All patients  
**Timing:** Baseline  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** Please report your race based on your geographic region's local standards.

**Variable ID:** Ethnicity  
**Variable:** Ethnicity  
**Definition:** The cultural ethnicity of the person that they most closely identify with  
**Supporting Definition:** This measure should be recorded based on local standards in the particular geographic region and should be self-reported by the patient. This is an optional question but ICHOM encourages that this information is collected and is as racially and ethnically inclusive as possible. This data will help to support combating health disparities based on ethnicity but all patient data regarding race and ethnicity will be kept confidential. The patient's response will then be coded based on LOINC's standards. All patients may choose not to answer as well.  
**Displayed Value:** Please indicate the ethnicity that you identify with  
**Inclusion Criteria:** All patients  
**Timing:** Baseline  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** Please report your ethnicity based on your geographic region's local standards.

**Variable ID:** EducationLevel

**Variable:** Level of Education

**Definition:** Highest level of education completed based on local standard definitions of education levels

**Supporting Definition:** This measure may vary based on local standards for education levels so please consult the International Standard Classification to select what level most closely relates to your education experience. Please follow this link here:  
<http://uis.unesco.org/sites/default/files/documents/international-standard-classification-of-education-isced-2011-en.pdf>

**Displayed Value:** Please indicate your highest level of schooling.

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0= None (includes early/primary education)  
1= Primary (includes lower/upper secondary education)  
2= Secondary (includes post-secondary non-tertiary and short-cycle tertiary education)  
3= Tertiary (includes Bachelor's/Master's/Doctoral level education or equivalent)

---

## Clinical Factors

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**Variable ID:** ComorbiditiesSACQ

**Variable:** SACQ comorbidities

**Definition:** Indicate whether the patient has a documented history of any of the following comorbidities

**Supporting Definition:** Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003). Phrased as a patient-reported measure, but information can be abstracted by other means if patient is unable to answer.

**Displayed Value:** Have you been told by a doctor that you have any of the following?

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Data Source:** Patient/Clinician

**Type:** Single answer

**Value Domain:** Multiple answer  
Separate multiple entries with ","

**Response Options:** 0 = I have no other diseases  
1 = Heart disease (For example, angina, heart attack, or heart failure)  
2 = High blood pressure  
3 = Leg pain when walking due to poor circulation  
4 = Lung disease (For example, asthma, chronic bronchitis, or emphysema)  
5 = Diabetes  
6 = Kidney disease  
7 = Liver disease  
8 = Problems caused by stroke  
9 = Disease of the nervous system (For example, multiple sclerosis)  
10 = Other cancer (within the last 5 years)  
11 = Depression  
12 = Arthritis

---

**Variable ID:** WeightValue

**Variable:** Body weight

**Definition:** The weight (body mass) of a person, measuring in the indicated units

**Supporting Definition:** The collection of anthropometric measurements, particularly in those who are overweight or obese or who are concerned about their weight, should be

performed with great sensitivity and without drawing attention to an individual's weight.

**Displayed Value:** Please indicate your body weight.

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Data Source:** Clinician

**Type:** Single answer

**Value Domain:** Quantity

**Response Options:** None

---

**Variable ID:** WeightUnit

**Variable:** Body weight units

**Definition:** Units of body mass (weight)

**Supporting Definition:** None

**Displayed Value:** Please indicate what units of measurement (kilograms or pounds) that your weight is in.

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Data Source:** Clinician

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 1= kilograms  
2= lbs

---

**Variable ID:** BMIValue

**Variable:** Body mass index

**Definition:** Body mass index

**Supporting Definition:** Height and weight are used to calculate BMI. BMI calculate as  $\text{kg}/\text{m}^2$

**Displayed Value:** None

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Data Source:** Clinician

**Type:** Single answer

**Value Domain:** Quantity

**Response Options:** None

---

## Treatment-Related Factors

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**Variable ID:** VentilationRequirement

**Variable:** Need for Ventilation

**Definition:** Did the patient require any ventilation during their hospital admission?

**Supporting Definition:** None

**Displayed Value:** Did the patient require any ventilation during their hospital admission?

**Inclusion Criteria:** All patients

**Timing:** Baseline/Updated monthly

**Data Source:** Clinician

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0= No  
1= Yes

---

**Variable ID:** VentilationType

**Variable:** Type of Ventilation

**Definition:** What type of ventilation was administered?

**Supporting Definition:** None

**Displayed Value:** What type of ventilation was required?



**Inclusion Criteria:** If responded "Yes" to "Did the patient require any ventilation during their hospital admission?"  
**Timing:** Baseline/Updated monthly  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= Mechanical  
2= Non-mechanical

---

**Variable ID:** VentilationLength  
**Variable:** Length of Ventilation  
**Definition:** How long did the patient require ventilation (in days)?  
**Supporting Definition:** None  
**Displayed Value:** How long did the patient require ventilation (in days)?  
**Inclusion Criteria:** If responded "Yes" to "Did the patient require any ventilation during their hospital admission?"  
**Timing:** Baseline/Updated monthly  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Quantity  
**Response Options:** None

---

**Variable ID:** CriticalCareDuration  
**Variable:** Duration of critical care admission  
**Definition:** How long was the patient's initial stay in critical care (in days)?  
**Supporting Definition:** None  
**Displayed Value:** How long was the patient's initial stay in critical care (in days)?  
**Inclusion Criteria:** All patients  
**Timing:** Baseline/Updated monthly  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Quantity  
**Response Options:** None

---

## Outcomes

### Clinical Outcomes

---

**Variable ID:** VitalStatus  
**Variable:** Vital Status  
**Definition:** Indicate if the person has deceased, regardless of cause  
**Supporting Definition:** None  
**Displayed Value:** None  
**Inclusion Criteria:** All patients  
**Timing:** All Timepoints  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domains:** Code  
**Response Options:** 0= No  
1= Yes  
999= Unknown

---

**Variable ID:** COVIDDeath  
**Variable:** COVID-19 Related Death  
**Definition:** Was the death of the patient directly due to the SARS-CoV-2 infection?  
**Supporting Definition:** None  
**Displayed Value:** None

**Inclusion Criteria:** If responded "Yes" to "Indicate if the person has deceased, regardless of cause"  
**Timing:** All Timepoints  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= No  
1= Yes  
999= Unknown

---

**Variable ID:** DeathLocation  
**Variable:** Location of Death  
**Definition:** The location of death for a deceased person  
**Supporting Definition:** None  
**Displayed Value:** None  
**Inclusion Criteria:** If responded "Yes" to "Indicate if the person has deceased, regardless of cause"  
**Timing:** All Timepoints  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= At home  
2= Hospital  
3= Nursing home/ Non-hospice long term care facility  
4= Hospice  
888= Other  
999= Unknown

---

**Variable ID:** OrganDamage  
**Variable:** Persisting Organ Damage  
**Definition:** As a result of the SARS-CoV-2 infection, has there been any diagnosed long-term organ damage? This includes damage to the peripheral or central nervous system.  
**Supporting Definition:** None  
**Displayed Value:** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline/Updated monthly  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= No  
1= Yes  
999= Unknown

---

**Variable ID:** OrganDamageType  
**Variable:** Persisting Organ Damage Type  
**Definition:** Please detail the type of long-term organ damage.  
**Supporting Definition:** None  
**Displayed Value:** None  
**Inclusion Criteria:** If responded "Yes" to "As a result of the SARS-CoV-2 infection, has there been diagnosed organ damage? This includes damage to the peripheral or central nervous system."  
**Timing:** Baseline/Updated monthly  
**Data Source:** Clinician  
**Type:** Single answer  
**Value Domain:** Multiple answer  
Separate multiple entries with ";"  
**Response Options:** 1= Long-term respiratory issues  
2= Long-term cardiovascular issues  
3= Long-term renal issues

---

4= Long-term neurological issues  
999= Other

---

**Variable ID:** UnplannedReadmissions  
**Variable:** Number of unplanned readmissions  
**Definition:** How many unplanned readmissions to hospital, or critical care / high dependency unit due to SARS-CoV-2 infection have there been since index admission?  
**Supporting Definition:** This is a cumulative measure to be updated each month over the course of the set.  
**Displayed Value:** None  
**Inclusion Criteria:** All patients  
**Timing:** All Timepoints  
**Data Source:** Administrative  
**Type:** Single answer  
**Value Domain:** Quantity  
**Response Options:** None

---

**Variable ID:** HospitalisationsDuration  
**Variable:** Duration of hospitalisations  
**Definition:** The total length (in days) of all COVID-19 related admissions to hospital or acute care facility since index admission  
**Supporting Definition:** This is a cumulative measure to be updated each month over the course of the set.  
**Displayed Value:** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline/Updated monthly  
**Data Source:** Administrative  
**Type:** Single answer  
**Value Domain:** Quantity  
**Response Options:** None

---

**Variable ID:** DiseaseSeverity  
**Variable:** Disease course severity  
**Definition:** How severe is the patient's SARS-CoV-2 infection?  
**Supporting Definition:** Mild: no need for hospitalization.  
Moderate: hospitalisation without need for non-invasive or mechanical ventilation.  
Severe: received non-invasive and/or mechanical ventilation, or died; admission to HDU/ICU.  
**Displayed Value:** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline/Updated monthly  
**Data Source:** Clinician  
**Type:** Single Answer  
**Value Domain:** Code  
**Response Options:** 1= Mild  
2= Moderate  
3= Severe

---

## Mental Functioning

---

**Variable ID:** CognitiveStatus  
**Variable:** Cognitive status  
**Definition:** Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
**Supporting Definition:** If the patient is unable to self-report, only clinician and administrative outcomes will be collected.  
**Displayed Value:** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Clinician

**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= No  
1= Yes

---

## Functional Status and Quality of Life

---

**Variable ID:** PROMIS-10\_Q01

**Variable:** Global01

**Definition:** Please respond to each question or statement by marking one box per row: In general, would you say your health is:

**Supporting Definition:** None

**Displayed Value:** In general, would you say your health is:

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 5= Excellent  
4= Very good  
3= Good  
2= Fair  
1= Poor

---

**Variable ID:** PROMIS-10\_Q02

**Variable:** Global02

**Definition:** In general, would you say your quality of life is:

**Supporting Definition:** None

**Displayed Value:** In general, would you say your quality of life is:

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 5= Excellent  
4= Very good  
3= Good  
2= Fair  
1= Poor

---

**Variable ID:** PROMIS-10\_Q03

**Variable:** Global03

**Definition:** In general, how would you rate your physical health?

**Supporting Definition:** None

**Displayed Value:** In general, how would you rate your physical health?

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 5= Excellent  
4= Very good  
3= Good

---

2= Fair  
1= Poor

---

**Variable ID:** PROMIS-10\_Q04  
**Variable:** Globalo4  
**Definition:** In general, how would you rate your mental health, including your mood and your ability to think?  
**Supporting Definition:** None  
**Displayed Value:** In general, how would you rate your mental health, including your mood and your ability to think?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 5= Excellent  
4= Very good  
3= Good  
2= Fair  
1= Poor

---

**Variable ID:** PROMIS-10\_Q05  
**Variable:** Globalo5  
**Definition:** In general, how would you rate your satisfaction with your social activities and relationships?  
**Supporting Definition:** None  
**Displayed Value:** In general, how would you rate your satisfaction with your social activities and relationships?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 5= Excellent  
4= Very good  
3= Good  
2= Fair  
1= Poor

---

**Variable ID:** PROMIS-10\_Q09r  
**Variable:** Globalogr  
**Definition:** In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)  
**Supporting Definition:** None  
**Displayed Value:** In general, please rate how well you carry out your usual social activities and roles. {This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient

**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 5= Excellent  
4= Very good  
3= Good  
2= Fair  
1= Poor

---

**Variable ID:** PROMIS-10\_Q06  
**Variable:** Globalo6  
**Definition:** To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?  
**Supporting Definition:** None  
**Displayed Value:** To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 5= Completely  
4= Mostly  
3= Moderately  
2= A little  
1= Not at all

---

**Variable ID:** PROMIS-10\_Q10r  
**Variable:** Global10r  
**Definition:** In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?  
**Supporting Definition:** None  
**Displayed Value:** In the past 7 days: How often have you been bothered by emotional problems such as feeling anxious, depressed, or irritable?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 5= Never  
4= Rarely  
3= Sometimes  
2= Often  
1= Always

---

**Variable ID:** PROMIS-10\_o8r  
**Variable:** Globalo8r  
**Definition:** In the past 7 days, how would you rate your fatigue on average?  
**Supporting Definition:** None  
**Displayed Value:** How would you rate your fatigue on average?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 5= Never  
4= Rarely  
3= Sometimes  
2= Often  
1= Always

---

**Variable ID:** PROMIS-10\_07r  
**Variable:** Global07r  
**Definition:** In the past 7 days, how would you rate your pain on average?  
**Supporting Definition:** Indicate pain level on a scale of 0-10, where 0 = No pain, and 10 = Worst imaginable pain  
**Displayed Value:** How would you rate your pain on average?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** Numerical value between 0 and 10

---

## Social Functioning

---

**Variable ID:** PROMIS-ISOLATION\_Q01  
**Variable:** Question 1 of PROMIS Short Form v2.0- Social Isolation 4a  
**Definition:** Please respond to each item by marking one box per row: I feel left out...  
**Supporting Definition:** None  
**Displayed Value:** I feel left out...  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= Never  
2= Rarely  
3= Sometimes  
4= Usually  
5= Always

---

**Variable ID:** PROMIS-ISOLATION\_Q02  
**Variable:** Question 2 of PROMIS Short Form v2.0- Social Isolation 4a  
**Definition:** I feel that people barely know me...  
**Supporting Definition:** None  
**Displayed Value:** I feel that people barely know me...  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?"  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= Never

---

2= Rarely  
3= Sometimes  
4= Usually  
5= Always

---

**Variable ID:** PROMIS-ISOLATION\_Q03  
**Variable:** Question 3 of PROMIS Short Form v2.0- Social Isolation 4a  
**Definition:** I feel isolate from others...  
**Supporting Definition:** None  
**Displayed Value:** I feel isolated from others...  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= Never  
2= Rarely  
3= Sometimes  
4= Usually  
5= Always

---

**Variable ID:** PROMIS-ISOLATION\_Q04  
**Variable:** Question 4 of PROMIS Short Form v2.0- Social Isolation 4a  
**Definition:** I feel that people are around me but not with me...  
**Supporting Definition:** None  
**Displayed Value:** I feel that people are around me but not with me...  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 1= Never  
2= Rarely  
3= Sometimes  
4= Usually  
5= Always

---

## Symptoms

---

**Variable ID:** FLUPRO\_Q01  
**Variable:** Question 1 of FLUPRO  
**Definition:** Please rate the extent to which you had each symptom during the past 24 hours:  
Runny or dripping nose  
**Supporting Definition:** None  
**Displayed Value:** Please rate the extent to which you had each symptom during the past 24 hours:  
Runny or dripping nose.  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
"  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all

---



1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q02  
**Variable:** Question 2 of FLUPRO  
**Definition:** Congested or stuffy nose  
**Supporting Definition:** None  
**Displayed Value:** Congested or stuffy nose  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q03  
**Variable:** Question 3 of FLUPRO  
**Definition:** Sinus pressure  
**Supporting Definition:** None  
**Displayed Value:** Sinus pressure  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q04  
**Variable:** Question 4 of FLUPRO  
**Definition:** Scratchy or itchy throat  
**Supporting Definition:** None  
**Displayed Value:** Scratchy or itchy throat  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q05

**Variable:** Question 5 of FLUPRO  
**Definition:** Sore or painful throat  
**Supporting Definition:** None  
**Displayed Value:** Sore or painful throat  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Qo6  
**Variable:** Question 6 of FLUPRO  
**Definition:** Difficulty swallowing  
**Supporting Definition:** None  
**Displayed Value:** Difficulty swallowing  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Qo7  
**Variable:** Question 7 of FLUPRO  
**Definition:** Teary or watery eyes  
**Supporting Definition:** None  
**Displayed Value:** Teary or watery eyes  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Qo8  
**Variable:** Question 8 of FLUPRO  
**Definition:** Sore or painful eyes  
**Supporting Definition:** None  
**Displayed Value:** Sore or painful eyes  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q09  
**Variable:** Question 9 of FLUPRO  
**Definition:** Eyes sensitive to light  
**Supporting Definition:** None  
**Displayed Value:** Eyes sensitive to light  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q10  
**Variable:** Question 10 of FLUPRO  
**Definition:** Trouble breathing  
**Supporting Definition:** None  
**Displayed Value:** Trouble breathing  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q11  
**Variable:** Question 11 of FLUPRO  
**Definition:** Chest congestion  
**Supporting Definition:** None  
**Displayed Value:** Chest congestion  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit

---

2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q12  
**Variable:** Question 12 of FLUPRO  
**Definition:** Chest tightness  
**Supporting Definition:** None  
**Displayed Value:** Chest tightness  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q13  
**Variable:** Question 13 of FLUPRO  
**Definition:** Wet or loose cough  
**Supporting Definition:** None  
**Displayed Value:** Wet or loose cough  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q14  
**Variable:** Question 14 of FLUPRO  
**Definition:** Dry or hacking cough  
**Supporting Definition:** None  
**Displayed Value:** Dry or hacking cough  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q15  
**Variable:** Question 15 of FLUPRO  
**Definition:** Felt nauseous (feeling like you wanted to throw-up)

**Supporting Definition:** None  
**Displayed Value:** Felt nauseous (feeling like you wanted to throw-up)  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q16  
**Variable:** Question 16 of FLUPRO  
**Definition:** Stomachache  
**Supporting Definition:** None  
**Displayed Value:** Stomachache  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q17  
**Variable:** Question 17 of FLUPRO  
**Definition:** Felt dizzy  
**Supporting Definition:** None  
**Displayed Value:** Felt dizzy  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q18  
**Variable:** Question 18 of FLUPRO  
**Definition:** Head congestion  
**Supporting Definition:** None  
**Displayed Value:** Head congestion  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient

**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q19  
**Variable:** Question 19 of FLUPRO  
**Definition:** Headache  
**Supporting Definition:** None  
**Displayed Value:** Headache  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q20  
**Variable:** Question 20 of FLUPRO  
**Definition:** Lack of appetite  
**Supporting Definition:** None  
**Displayed Value:** Lack of appetite  
**Inclusion Criteria:** All patients  
**Timing:**  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q21  
**Variable:** Question 21 of FLUPRO  
**Definition:** Sleeping more than usual  
**Supporting Definition:** None  
**Displayed Value:** Sleeping more than usual  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

---

**Variable ID:** FLUPRO\_Q22  
**Variable:** Question 22 of FLUPRO  
**Definition:** Body aches or pains  
**Supporting Definition:** None  
**Displayed Value:** Body aches or pains  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q23  
**Variable:** Question 23 of FLUPRO  
**Definition:** Weak or tired  
**Supporting Definition:** None  
**Displayed Value:** Weak or tired  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q24  
**Variable:** Question 24 of FLUPRO  
**Definition:** Chills or shivering  
**Supporting Definition:** None  
**Displayed Value:** Chills or shivering  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q25  
**Variable:** Question 25 of FLUPRO  
**Definition:** Felt cold  
**Supporting Definition:** None  
**Displayed Value:** Felt cold

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q26

**Variable:** Question 26 of FLUPRO

**Definition:** Sneezing

**Supporting Definition:** None

**Displayed Value:** Sneezing

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0= Never  
1= Rarely  
2= Sometimes  
3= Often  
4= Always

---

**Variable ID:** FLUPRO\_Q27

**Variable:** Question 27 of FLUPRO

**Definition:** Coughing

**Supporting Definition:** None

**Displayed Value:** Coughing

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0= Never  
1= Rarely  
2= Sometimes  
3= Often  
4= Always

---

**Variable ID:** FLUPRO\_Q28

**Variable:** Question 28 of FLUPRO

**Definition:** Coughed up mucus or phlegm

**Supporting Definition:** None

**Displayed Value:** Coughed up mucus or phlegm

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code



**Response Options:** 0= Never  
1= Rarely  
2= Sometimes  
3= Often  
4= Always

---

**Variable ID:** FLUPRO\_Q29  
**Variable:** Question 29 of FLUPRO  
**Definition:** How many times did you vomit?  
**Supporting Definition:** None  
**Displayed Value:** How many times did you vomit?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= 0 times  
1= 1 time  
2= 2 times  
3= 3 times  
4= 4 or more times

---

**Variable ID:** FLUPRO\_Q30  
**Variable:** Question 30 of FLUPRO  
**Definition:** How many times did you have diarrhea?  
**Supporting Definition:** None  
**Displayed Value:** How many times did you have diarrhea?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= 0 times  
1= 1 time  
2= 2 times  
3= 3 times  
4= 4 or more times

---

**Variable ID:** FLUPRO\_Q31  
**Variable:** Question 31 of FLUPRO  
**Definition:** Loss of taste  
**Supporting Definition:** None  
**Displayed Value:** Loss of taste  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= No  
1= Yes

---

**Variable ID:** FLUPRO\_Q32  
**Variable:** Question 32 of FLUPRO  
**Definition:** Loss of smell  
**Supporting Definition:** None

**Displayed Value:** Loss of smell  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= No  
1= Yes

---

**Variable ID:** FLUPRO\_Q33  
**Variable:** Question 33 of FLUPRO  
**Definition:** 1. Overall, how severe were your symptoms today?  
**Supporting Definition:** None  
**Displayed Value:** 1. Overall, how severe were your symptoms today?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= No symptoms  
1= Mild  
2= Moderate  
3= Severe  
4= Very severe

---

**Variable ID:** FLUPRO\_Q34  
**Variable:** Question 34 of FLUPRO  
**Definition:** 2. Overall, how were your symptoms today compared to yesterday?  
**Supporting Definition:** None  
**Displayed Value:** 2. Overall, how were your symptoms today compared to yesterday?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code  
**Response Options:** 0= Much better  
1= Somewhat better  
2= A little better  
3= About the same  
4= A little worse  
5= Somewhat worse  
6= Much worse

---

**Variable ID:** FLUPRO\_Q35  
**Variable:** Question 35 of FLUPRO  
**Definition:** 3. How much did your symptoms interfere with your usual activities today?  
**Supporting Definition:** None  
**Displayed Value:** 3. How much did your symptoms interfere with your usual activities today?  
**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "  
**Timing:** Baseline, Week 2, Week 4 and monthly thereafter  
**Data Source:** Patient  
**Type:** Single answer  
**Value Domain:** Code

---

**Response Options:** 0= Not at all  
1= A little bit  
2= Somewhat  
3= Quite a bit  
4= Very much

---

**Variable ID:** FLUPRO\_Q36

**Variable:** Question 36 of FLUPRO

**Definition:** 4. Have you returned to your usual activities today?

**Supporting Definition:** None

**Displayed Value:** 4. Have you returned to your usual activities today?

**Inclusion Criteria:** If responded "Yes" to "Is the patient in a cognitive state to be able to understand and, with or without assistance, answer the patient-reported outcome measures?" "

**Timing:** Baseline, Week 2, Week 4 and monthly thereafter

**Data Source:** Patient

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0= No  
1= Yes

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# Working Group Member Conflicts of Interests

At the beginning of the Working group process, we ask all Working Group members to declare any conflicts of interests they have. We then circulate these within the Group to ensure transparency.

Name	Affiliation	Declarations
Farhala A. Baloch	The Aga Khan University, Karachi, Pakistan	None declared
Maiara Anschau Floriani	Hospital Moinhos de Vento, Brazil	None declared
Gisele Alsina Nader Bastos	Hospital Moinhos de Vento, Brazil	None declared
Kees Brinkman	OLVG Hospital (Santeon), Netherlands	On advisory boards for MSD, Gilead (also received research grant) and ViiV (also received research grant).
Philip Collis	NIHR, NHS England, UK	None declared
Caroline Daly	Winchester Hospital, USA	None declared
Juan Dapuetto	Universidad de la República, Uruguay	None declared
Ingel Demedts	AZ Delta Hospital Roeselare, Belgium	None declared
Luz Fialho	ICHOM, UK	None declared
Anna Flynn	Australian Centre for Value-Based Health Care, Australia	None declared
Lucinda Gabriel	Kings Health Partners, UK	None declared
Joel J. Gagnier	Department of Orthopaedic Surgery and Epidemiology, University of Michigan, USA	None declared
Rocío García García	Department of Pneumology, Hospital Universitario 12 de Octubre, Spain	On advisory boards of Novartis, GlaxoSmithKline and Mundipharma. Speaker fees from Boehringer, GlaxoSmithKline and Novartis. Sub-investigator on clinical trials of Gilead and Roche.
Ayeesha Kamran Kamal	The Aga Khan University, Karachi, Pakistan	None declared
Anju Devianee Keetharuth	University of Sheffield, UK	None declared
Evan H. Kwong	Division of Physical Medicine and Rehabilitation, Providence Health Care, Vancouver, Canada	None declared
Ana Londral	Value for Health CoLAB, Portugal	None declared
Ingvar Ludwig	Hospital do Coração, Brazil	None declared
Carlos Lumbreras	Hospital Universitario 12 de Octubre, Spain	None declared
Alejandro Moscoso	Clinical del Country, Colombia	None declared
Nasreen Muhammad Saleem	The Aga Khan University, Karachi, Pakistan	None declared
Christina Nielsen	ICHOM, USA	None declared
Mohammed Omer Nasser	Abu Dhabi Health Services Company (SEHA), UAE	None declared
Christine Owen	NHS Wales, United Kingdom	None declared
Marcelo Pio de Almeida Fleck	Universidade Federal do Rio Grande do Sul	None declared
John H Powers III	George Washington University School of Medicine, USA	Provided clinical trial design consulting for Arrebus, Gilead, Romark, Eicos, GlaxoSmithKline, Johnson and Johnson, Otsuka, Eli Lilly, Evofem, Mustang, OPKO and Vir
Anne-Marie Russell	University of Exeter, College of Medicine and Health, Exeter, UK	Previous speaker fees, unrestricted grants and travel grants from Hoffman La Roche and Boehringer Ingelheim.
William Seligman	Imperial College Healthcare NHS Trust, UK	None declared
Nick Sillett	ICHOM, UK	None declared
Michaela Kim Smith	Mediclinic, South Africa	None declared
Tracy Y. Wang	Duke University, USA	Has received research grants from Abbott, Astra Zeneca (and personal fees), Boston Scientific, Cryolife (and personal fees), Chiesi, Portola, Bristol Myers Squibb and Regeneron.
Douglas Woodhouse	University of Calgary, Canada	None declared
Eyal Zimlichman	Sheba Medical Center, Israel	Advisory board member and holds equity in Earlysense LTD, Valera Health, Profility and Hello Heart.

# ICHOM Contact Information

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# Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
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[www.ichom.org](http://www.ichom.org)