UNIVERSAL Trial Case Report Form
IRAS ID: 309464

Participant Trial Number									**Patient Initials**			

Data collection once enrolled

REGISTRATION

Participant Registration Number	_ _ _ _ _ _

Date Enrolled (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Inclusion Criteria	**Yes**	**No***
Is the patient aged 18 years or older?		
Does the patient have symptoms of an acute respiratory illness** (ARI)?		
Is patient a medical inpatient, who was admitted in the past 36 hours?		
** Patient is not eligible for the trial*		
***An episode of acute respiratory illness is defined as an acute upper or lower respiratory illness (including rhinitis, rhinosinusitis, pharyngitis, pneumonia, bronchitis and influenza-like illness) or an acute exacerbation of a chronic respiratory illness (including exacerbation of COPD, asthma or bronchiectasis). For the study, acute respiratory illness as a provisional, working, differential or confirmed diagnosis must be made by a treating clinician.*		

Exclusion Criteria	**Yes***	**No**
A combined nasal and throat swab cannot be performed		
Has the patient or the patient's consultee declined consent?		
Has the patient previously been enrolled into Stage 2 of the UNIVERSAL study?		
** Patient is not eligible for the trial*		

Eligibility	**Yes**	**No**
Is the patient eligible to take part in Stage 1 of the study?		

Participant Trial Number								

Consent & Admission Details

Who has provided consent?

Patient ☐ Personal Consultee ☐ Nominated Consultee ☐

Date Consented (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time patient consented (24 hour clock):	:

Date seen in ED or admitted to AMU if admitted directly (DD/MMM/YYYY)*:	_ _ / _ _ _ / _ _ _ _
Time presented to ED or admitted to AMU/ward if admitted directly (24 hour clock):	:

**This is the date and time as recorded in top right-hand corner on page 1 of ED notes, or time admitted to ward on Doctors Worklist system in AMU.*

Route into hospital (tick one box only)	
Via ED	
Directly admitted to AMU bypassing ED	
Directly to ward bypassing AMU AND ED	

Participation in interventional study	**Yes**	**No**
Is the patient enrolled into an interventional study of an antiviral therapy for viral respiratory infection?		
If yes, please record Trial name here		

Participant Trial Number | | | | | | | | |

Patient Characteristics

Biological Sex: Male ☐ Female ☐ Prefer not to say ☐

Date of birth: ☐☐☐☐☐☐☐☐ mmmyyyy

Age on the day of consent: ☐☐☐ Years

Height (Metres) OR	☐.☐☐
Height (Feet and Inches)	☐ ☐☐
Weight (Kilograms)	☐☐☐.☐☐
BMI	☐☐.☐

Postcode: ☐☐☐☐ ☐☐☐

Number of people in household: Adults ☐ Children ☐☐

Smoking History: Never ☐ Past ☐ Current ☐

If Past or Current smoker:

Average number of cigarettes per day ☐☐ *Number of years smoking* ☐☐

History of Vaping: Never ☐ Past ☐ Current ☐

Number of years if past or current: ☐☐

Ethnicity	*(tick one box only)*
White	
Mixed or multiple ethnic	
Asian or Asian British	
Black, African, Caribbean, or Black British	
Other ethnic group (Please specify below)	

Participant Trial Number								

Vaccination History	***Yes***	***No***
Received influenza vaccine this influenza season (self-reported)		
Received pneumonia vaccine in the past (self-reported)		
Received COVID vaccine dose 1 (self-reported)		
Received COVID vaccine dose 2 (self-reported)		
Received COVID vaccine dose 3 (self-reported)		
Received COVID vaccine dose 4 (self-reported)		
Received COVID vaccine dose 5 (self-reported)		

Participant Trial Number								

Symptoms in the last 21 days

Symptoms	Yes	No	Duration (days)
Runny or dripping nose			
Congested or stuffy nose			
Sinus pressure			
Scratchy or itchy throat			
Sore or painful throat			
Difficulty swallowing			
Teary or watery eyes			
Sore or painful eyes			
Eyes sensitive to light			
Trouble breathing			
Chest congestion			
Chest tightness			
Dry or hacking cough			
Wet or loose cough			
Coughing			
Coughed up mucus or phlegm			
Felt nauseous (feeling like you wanted to throw-up)			
Stomach-ache			
Vomited			
Diarrhoea			
Felt dizzy			
Head congestion			
Headache			
Lack of appetite			
Sleeping more than usual			
Body aches or pains			
Weak or tired			
Chills or shivering			
Felt cold			
Felt hot			
Sweating			
Altered Mental Status			

Participant Trial Number								

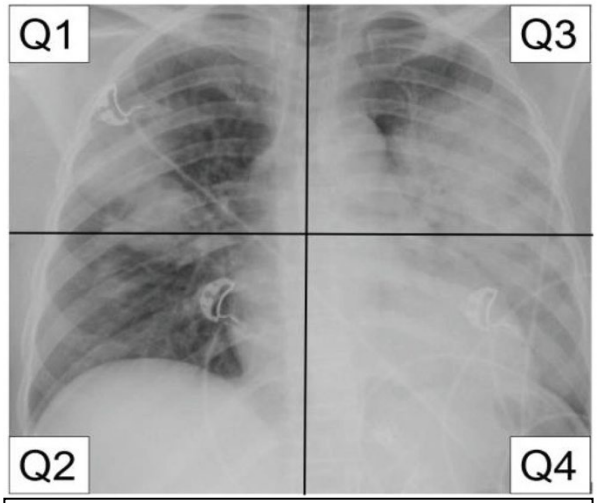
Observations	**First observations recorded on Admission to hospital (e.g. from ED)**
Pulse (Beats per minute)	
Blood pressure (mmHg)	
Respiratory Rate (Breaths per minute)	
Oxygen Saturation (%)	
Inspired oxygen (air/litres/FiO2)	
Oxygen delivery method if on supplemental oxygen (nasal cannulae/venturi/NRB/optiflow)	
If on supplemental oxygen, what is the oxygen concentration? (litres/FiO2)	
Temperature (°C)	

Blood results on presentation to hospital* *Write 'ND' if not done. Record first available instance (unless invalid) – *must be within 24 hours of presentation*			
Hb (g/l)		Glucose (ABG, VBG or lab glucose) mmol/L	
Haematocrit (%)		Sodium (mmol/L)	
WBC (10^9/L)		Potassium (mmol/L)	
Platelets (10^9/L)		Urea (mmol/L)	
Neutrophils (10^9/L)		Creatinine (umol/L)	
Eosinophils (10^9/L)		Total Protein (g/L)	
Lymph (10^9/L)		Albumin (g/L)	
D-dimer (ug/L)		Bilirubin (umol/L)	
Ferritin (ug/L)		ALT (U/L	
CRP (mg/L)		ALP (U/L)	
LDH (U/L)		Troponin (ng/L)	
Procalcitonin (ng/mL)		pH (VBG or ABG if done)	

Participant Trial Number								

Radiology

XR/CT	*Date:*
For XR: RALE score*	



**Please record score using the adjacent table.*

Consolidation is scored per each quadrant. Density is scored for each quadrant that has a consolidation score ≥1. If Quadrant consolidation score is a negative value, then Quadrant score is 0.

Consolidation	
Consolidation Score	**Extent of alveolar opacities**
0	**None**
1	**<25%**
2	**25-50%**
3	**50-75%**
4	**>75%**
Density	
Density Score	**Density of alveolar opacities**
1	**Hazy**
2	**Moderate**
3	**Dense**
Final RALE Score	
Right Lung	**Left Lung**
Upper Quadrant **Cons x Den = Q1 Score** ……	**Upper Quadrant** **Cons x Den = Q3 Score** ……
Lower Quadrant **Cons x Den = Q2 Score** …..	**Lower Quadrant** **Cons x Den = Q4 Score** …..
Total RALE = Q1 + Q2 +Q3 + Q4	

Radiologist Report	*Please print/download chest x-ray report. When done, attach*

Working / Differential Diagnoses (list all, number) (from admitting consultant AMU post take ward round notes)
1.

Participant Trial Number								

Medication:.
Please record antibiotics, antiviral medications e.g. neuraminidase inhibitors, remdesivir, nebulised therapies, inhaled therapies, systemic corticosteroids, immunosuppressing medication or biological therapies prescribed by admitting team. **Please record patients regular medications on presentation (from prior to admission) with regards to anti-tussive therapies, inhaled therapies e.g. SABA, LABA, LAMA, ICS, long term antibiotics e.g. long term macrolides, or any immunosuppressing medications or biological therapies in the UNIVERSAL Medicine log. Other medications do not need to be recorded.**

Participant Trial Number								

Co-Morbidities	Yes	No
Chronic obstructive pulmonary disease		
Asthma		
Interstitial lung disease		
Bronchiectasis		
Hypertension		
History of myocardial infarction		
Congestive Heart Failure		
Peripheral Vascular Disease		
Atrial Fibrillation		
Previous Stroke		
Chronic kidney disease or Chronic Renal Failure		
Chronic Liver disease		
Peptic Ulcer Disease		
Chronic neurological disorder		
Active Metastatic solid tumour		
Active Malignant neoplasm (including leukaemia & lymphoma)		
Diabetes Mellitus		
Obesity (Body mass index >30)		
Acquired immune deficiency syndrome/Human immunodeficiency virus		
Rheumatological disorder or Connective Tissue Disease		
Dementia		
Congenital Immune Deficiency Syndrome		

	Yes	**No**
Pregnant		
Care/Nursing Home Resident		
Healthcare Worker		

Charlson Co-morbidity Score

Condition Name	ICD-10 codes	Score	Yes
Pulmonary disease	J40-J47, J60-J67	4	
History of Acute myocardial infarction	I21, I22, I23, I252, I258	5	
Cerebral vascular accident	G450, G451, G452, G454, G458, G459, G46, I60-I69	11	
Congestive heart failure	I50	13	
Peripheral vascular disease	I71, I739, I790, R02, Z958, Z959	6	
Renal disease	I12, I13, N01, N03, N052-N056, N072-N074, N18, N19, N25	10	
Liver disease	K702, K703, K717, K73, K74	8	
Severe liver disease	K721, K729, K766, K767	18	
Peptic ulcer	K25, K26, K27, K28	9	
Diabetes	E101, E105, E106, E108, E109, E111, E115, E116, E118, E119, E131, E136, E138, E139, E141, E145, E146, E148, E149	3	
Diabetes complications	E102, E103, E104, E107, E112, E113, E114, E117, E132, E133, E134, E137, E142, E143, E144, E147	-1	
Connective tissue disorder	M05, M060, M063, M069, M32, M332, M34, M353	4	
Dementia	F00, F01, F02, F03, F051	14	
Cancer	C00-C76, C81-C97	8	
Metastatic cancer	C77, C78, C79, C80	14	
Paraplegia	G041, G81, G820, G821, G822	1	
HIV	B20, B21, B22, B23, B24, O987	2	
	TOTAL SCORE		

Ordinal Scale for Clinical Improvement on Admission (*please circle one score*)		
Patient State	**Descriptor**	**Score**
Uninfected	Uninfected; no viral RNA detected	0
Ambulatory mild disease	Asymptomatic; viral RNA detected	1
	Symptomatic; independent	2
	Symptomatic; assistance needed	3
Hospitalised: moderate disease	Hospitalised; no oxygen therapy*	4
	Hospitalised; oxygen by mask or nasal prongs	5
Hospitalised: severe disease	Hospitalised; oxygen by NIV or high flow	6
	Intubation and mechanical ventilation, pO2/FiO2 ≥150 or SpO2/FiO2 ≥200	7
	Mechanical ventilation pO2/FIO2 <150 (SpO2/FiO2 <200) or vasopressors	8
	Mechanical ventilation pO2/FiO2 <150 and vasopressors, dialysis, or ECMO	9
Dead	Death	10

ECMO=extracorporeal membrane oxygenation. FiO2=fraction of inspired oxygen. NIV=non-invasive ventilation.

*pO2=partial pressure of oxygen. SpO2=oxygen saturation. *If hospitalised for isolation only, record status as for ambulatory patient.*

Participant Trial Number								

Point of Care Testing	**Yes**	**No**
Did the patient undergo testing via rapid multiplex PCR?		
If **yes,** please specify result below		
Panel Result (*For example* GeneXpert, LIAT (cobast), QIAstat-Dx, ePLEX systems)		

Result	**(Tick if positive)**
Sars-CoV-2	
Influenza A	
Influenza A H1	
Influenza A H3	
Influenza H1-2009	
Influenza B	
Adenovirus	
Bordetella Pertussis	
Coronavirus 229E	
Coronavirus HKU1	
Coronavirus NL63	
Coronavirus OC43	
Rhinovirus/Enterovirus	
Human Metapneumovirus	
Mycoplasma pneumoniae	
Parainfluenza 1	
Parainfluenza 2	
Parainfluenza 3	
Parainfluenza 4	
Respiratory Syncytial Virus	

Participant Trial Number								

Biofire FilmArray RESPIRATORY PANEL TEST

BioFire FilmArray 2.1 plus Respiratory Panel	**Yes**	**No**
Did the patient undergo testing via BioFire FilmArray?		
Date Nose & Throat Swab taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _	
Time Nose & Throat Swab taken (24 hour clock)	_ _ : _ _	
Date of test (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _	
Time of test (24 hour clock)*	_ _ : _ _	
**The time of test should be taken from the BioFire Results Report*		

BioFire FilmArray 2.1 plus Respiratory panel test Result			
Result	**(Tick)**	**Result**	**(Tick)**
Negative		**PLEASE NOTE: IF THE PATIENT TESTS NEGATIVE FOR VIRAL INFECTION THEIR PARTICIPATION IN THE TRIAL ENDS HERE. PLEASE COMPLETE THE END OF STUDY FORM.**	
Invalid or equivocal result			
Patient did not undergo testing via BioFire FilmArray system		Influenza A/H3	
Adenovirus		Influenza B	
Coronavirus HKU1		Parainfluenza 1	
Coronavirus NL63		Parainfluenza 2	
Coronavirus 229E		Parainfluenza 3	
Coronavirus OC43		Parainfluenza 4	
Human Metapneumovirus		Bordetella pertussis*	
Human Rhinovirus/ Enterovirus		Bordetella parapertussis*	
Respiratory Syncytial Virus		Mycoplasma pneumonia*	
Influenza A		Chlamydophila pneumoniae*	
-Influenza A / H1		MERS-CoV	
-Influenza A/H1-2009		SARS-CoV-2	

**as these are bacterial (rather than viral) pathogens, positivity for any of these tests without an additional positive viral test, do not determine eligibility for the trial*

Eligibility	**Yes**	**No**
Did the patient test positive for a respiratory ***viral*** infection?		
Is the patient eligible for Stage 2 of the study?		

Enrolment Segment CRF (Visit 1) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Participant Trial Number								

Participant Trial Number								

The Following Sections are only to be completed for those participants who are eligible for Stage 2.

DAY1 STAGE 2: SAMPLE COLLECTION CRF (VISIT 1)

Participant Identification Number	_ _ _ _ - _ _ _ _

DATA COLLECTION: FLU-PRO+ and EQ-5D-5L questionnaire to be completed.

Participant Trial Number								

SAMPLING	
Nasopharyngeal/oropharyngeal Sampling *nasopharyngeal preferred. Oropharyngeal can be offered if patient unable to tolerate	
Nasal Swab in Amies Media	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Combined nose and throat swab (viral medium)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Swab type taken (Nasopharyngeal or Oropharyngeal or Nose and throat swab)	
Nasosorption (wick)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Blood Sampling	
Whole blood for SERUM (Plain tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Whole blood for PLASMA (EDTA tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Whole blood for DNA (DNA PAXgene tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Whole blood for RNA (RNA PAXgene tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Additional optional samples	
Blood Sampling	
Whole blood for Biomarker and Cellular analysis (LiHep tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _

Sample collection Segment (Visit 1) CRF Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Participant Trial Number								

DAY 3 CRF (VISIT 2)

Date of visit (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

DATA COLLECTION: FLU-PRO+ and EQ-5D-5L questionnaire to be completed)

Section 2 – Sample Collection Day 3

SAMPLING	
Nasopharyngeal/oropharyngeal Sampling *nasopharyngeal preferred. Oropharyngeal can be offered if patient unable to tolerate	
Combined nose and throat swab (viral medium)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Swab type taken (Nasopharyngeal or Oropharyngeal or Nose and throat swab)	
Blood Sampling	
Whole blood for SERUM (Plain tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Whole blood for PLASMA (EDTA tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Whole blood for DNA (DNA PAXgene tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Whole blood for RNA (RNA PAXgene tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Additional optional samples	
Nasal Sampling	
Nasosorption (wick)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _
Blood Sampling	
Whole blood for Biomarker and Cellular analysis	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _

Participant Trial Number								

Day 3 CRF (Visit 2) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

DAY 7 SAMPLE COLLECTION CRF (VISIT 3)

Date of visit (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

DATA COLLECTION: FLU-PRO+ and EQ-5D-5L questionnaire to be completed

SAMPLING	
Blood Sampling	
Whole blood for SERUM (Plain tube)	
Date taken (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _
Time taken (24 hour clock)	_ _ : _ _

Day 7 CRF (Visit 3) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

DISCHARGE CRF (VISIT 4)

Participant Trial Number								

Date filled out	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)

DATA COLLECTION: EQ-5D-5L questionnaire to be completed and Post-viral infection PROs (GAD-7, PHQ-9, FACIT Fatigue Scale) Can be via phone call if patient already discharged.

Participant Trial Number								

Once patients have been discharged the following clinical data is to be collected retrospectively from electronic and physical case notes, discharge summary and HRG coding. Patients will continue completing FluPro and EQ-5D-5L questionnaires weekly until week 4 then fortnightly until 12 weeks post enrolment into the study. EQ-5D-5L will continue monthly until 26 weeks-post enrolment

Date and Time of Discharge	
Date discharged: (DD/MMM/YYYY)	__/___/____
Time discharged (24 hour clock)	__:__

Date (DD/MMM/YYYY)	**OSCI score**	**Date** (DD/MMM/YYYY)	**OSCI score**	**Date** (DD/MMM/YYYY)	**OSCI score**
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	
__/___/____		__/___/____		__/___/____	

Medication:
Please record medication given in hospital and/or for taking home including only antibiotics, antivirals, inhaled therapies, oral corticosteroids, oxygen (presence or absence of supplemental oxygen), nebulised therapies, biologic or immunomodulatory agents, covid treatments and anti-tussive (anti coughing treatments) **(on the UNIVERSAL Medication Log other medications do not need to be recorded)**
Each line should represent one treatment course. If the same medication is subsequently prescribed for another, discrete, course, then put this as a separate line. Please list as per ED notes and AMU notes and e-prescribing information without duplication (course can start in ED notes and continue on JAC e-prescribing, for example).

Participation in interventional study	**Yes**	**No**
Is the patient enrolled into an interventional study of an antiviral therapy for viral respiratory infection? *If yes, please record details below*		
Trial name		

Participant Trial Number								

Treatment received

Participant Trial Number								

Tests for Infection		
Within admission, patient tested for	**Yes**	**No**
Laboratory Respiratory Virus PCR (not FilmArray)		
Sputum sample		
Mycoplasma serology		
Legionella urinary antigen		
Pneumococcal urinary antigen		
Blood Cultures		
HIV		
If yes, please record details in the table below: ** All details via e-Quest*		

Test	**Date** (DD/MMM/YYYY) **& time** (24hr clock) **of result***	**Result* Positive?**	**Comments**
Laboratory Resp. Virus PCR (1st)	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
Laboratory Resp. Virus PCR (2st)	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
Sputum sample	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
Mycoplasma serology	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
Legionella urinary antigen	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
Pneumococcal urinary antigen	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
Blood cultures	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		
HIV	_ _ / _ _ _ / _ _ _ _ _ _ : _ _		

Last Blood results prior to discharge from hospital*			
Date (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _		
Hb (g/l)		Sodium (mmol/L)	
WBC (10^9/L)		Potassium (mmol/L)	
Platelets (10^9/L)		Urea (mmol/L)	
Neutrophils (10^9/L)		Creatinine (umol/L)	
Eosinophils (10^9/L)		Total Protein (g/L)	
Lymph (10^9/L)		Albumin (g/L)	
D-dimer (ug/L)		Bilirubin (umol/L)	
Ferritin (ug/L)		Troponin (ug/L)	
CRP (mg/L)		ALT (U/L)	
LDH (U/L)		ALP (U/L)	
Procalcitonin (ng/mL)			
** Record from e-Quest. Write 'ND' if not done. Record last available instance prior to discharge (unless invalid)*			

Participant Trial Number								

Safety / Mortality / Severity data / SAE monitoring:	**Yes**	**No**
Admitted to ICU or Respiratory High Dependency (except as ICU stepdown) this admission		
If Yes: Specify duration of total level 2 and 3 care in days	_ _ days	
Died within 30 days of enrolment		
Died within 60 days of enrolment		
Represented to hospital within 30 days of discharge		
Readmitted to hospital within 30 days of discharge*		
if patient is readmitted for this ARI, please complete readmission CRF (p31)		

Admission to General Intensive Care Unit (GICU) or Respiratory High Dependency Unit (RHDU) this admission				
Transferred to GICU or RHDU this admission? *(Circle one option)* **:** *If yes, complete details below*			**Yes**	**No**
Unit	**Date of entry** (DD/MMM/YYYY)	**Time of entry** (24 hour clock)	**Date of exit** (DD/MMM/YYYY)	**Time of exit** (24 hour clock)
GICU	_ _ / _ _ _ / _ _ _	_ _ : _ _	_ _ / _ _ _ / _ _ _	_ _ : _ _
RHDU	_ _ / _ _ _ / _ _ _	_ _ : _ _	_ _ / _ _ _ / _ _ _	_ _ : _ _

If admitted to HDU/ICU Please choose Number of Organs Supported Please circle 1 to choose corresponding ACC HRG code

Number of Organs Supported	ACC HRG Code
1	XC06Z
2	XC05Z
3	XC04Z
4	XC03Z
5	XC02Z
6	XC01Z

Participant Trial Number								

First Chest x-ray Report done *(Please circle one option)*	**Yes**	**No**
If yes, please complete details below.		
First chest radiography radiologist report mentions:	**Yes**	**No**
Consolidation / Infiltrates / Pneumonia		
Pulmonary Oedema		
Tumour / Malignancy / Neoplasm		
Pleural effusion		
Nil acute or normal		
Other diagnosis – please specify:		

Was a CT chest done? *(Please circle one option)*	**Yes**	**No**
If yes, please upload report		

Hospital discharge summary

Length of Admission: (Days) ☐

Primary Diagnosis	**ICD-10 Code**

Secondary Diagnoses and Comorbidities	**ICD-10 Code**

Participant Trial Number								

During Admission did the participant receive (as documented on discharge summary)? (tick all that apply):

Nebuliser Therapy (OPCS Code E893):Yes ☐ **No** ☐

Long Term Oxygen assessment (OPCS Code E872): Yes ☐ **No** ☐

Ambulatory Oxygen assessment(OPCS code E873) Yes ☐ **No** ☐

Other Oxygen therapy support (OPCS code E879) Yes ☐ **No** ☐

Blood Gas Analysis (OPCS Code E924) Yes ☐ **No** ☐

Smoking Cessation/Nicotine Replacement Therapy (OPCS Codes E981-E989):

None ☐ **Nicotine Patches** ☐ **Nicotine Gum** ☐ **Nicotine Inhalator** ☐

Nicotine Lozenges ☐ **Other specified smoking cessation therapy** ☐

Other unspecified smoking cessation therapy ☐

Respiratory Education(OPCS E971-E979): None documented ☐

Education for inhaled therapy ☐

Education for peak flow technique ☐

Education for self management of respiratory health ☐

Other specified respiratory education ☐

Other unspecified respiratory education ☐

Did the participant receive invasive ventilation (OPCS E851): Yes ☐ **No** ☐

Did the participant receive CPAP (OPCS code E856): Yes ☐ **No** ☐

Did the participant receive Non-Invasive Ventilation(E852): Yes ☐ **No** ☐

LOCAL HOSPITAL APC HRG CODE (HRG FROM CODING TEAM AT LOCAL HOSPITAL)	

Participant Trial Number								

CENTRAL CODING TEAM APC HRG CODE (CLINICAL TRIALS UNIT WILL ARRANGE CODING TEAM SEPEARATE FROM HOSPITAL TO GENERATE CODE)	

Online questionnaire/follow-up details confirmed for	**Yes**	**Date due** (DD/MMM/YYYY)
Online symptom questionnaires (FluPro+, EQ-5D-5L) at weeks 1, 2, 4, 8 and 12 (*enter date when next questionnaire is due*)		_ _ / _ _ _ / _ _ _ _
6 week (Visit 5) Telephone call		_ _ / _ _ _ / _ _ _ _

Discharge CRF (Visit 4) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY**)**	_ _ / _ _ _ / _ _ _ _

Any section for which there was not enough space can be continued here and on further pages if needed. Please put the section heading clearly before continuing.

Participant Trial Number								

Participant Trial Number								

READMISSION CRF

Date of visit	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)

Ordinal Scale for Clinical Improvement on Admission (*please circle one score*)		
Patient State	**Descriptor**	**Score**
Uninfected	Uninfected; no viral RNA detected	0
Ambulatory mild disease	Asymptomatic; viral RNA detected	1
	Symptomatic; independent	2
	Symptomatic; assistance needed	3
Hospitalised: moderate disease	Hospitalised; no oxygen therapy*	4
	Hospitalised; oxygen by mask or nasal prongs	5
Hospitalised: severe disease	Hospitalised; oxygen by NIV or high flow	6
	Intubation and mechanical ventilation, pO2/FiO2 ≥150 or SpO2/FiO2 ≥200	7
	Mechanical ventilation pO2/FIO2 <150 (SpO2/FiO2 <200) or vasopressors	8
	Mechanical ventilation pO2/FiO2 <150 and vasopressors, dialysis, or ECMO	9
Dead	Death	10
ECMO=extracorporeal membrane oxygenation. FiO2=fraction of inspired oxygen. NIV=non-invasive ventilation.		
*pO2=partial pressure of oxygen. SpO2=oxygen saturation. *If hospitalised for isolation only, record status as for ambulatory patient.*		

Observations	**First observations recorded on re-admission to hospital (e.g. from ED)**
Pulse (Beats per minute)	
Blood pressure (mmHg)	
Respiratory Rate (Breaths per minute)	
Oxygen Saturation (%)	
Inspired oxygen (air/litres/FiO2)	
Oxygen delivery method (nasal cannulae/venturi/NRB/optiflow)	
Temperature (°C)	

(Only to be completed if readmission is related to index illness that caused the original hospital admission)

Participant Trial Number								

Symptoms	**Yes**	**No**
Runny or dripping nose		
Congested or stuffy nose		
Sinus pressure		
Scratchy or itchy throat		
Sore or painful throat		
Difficulty swallowing		
Teary or watery eyes		
Sore or painful eyes		
Eyes sensitive to light		
Trouble breathing		
Chest congestion		
Chest tightness		
Dry or hacking cough		
Wet or loose cough		
Coughing		
Coughed up mucus or phlegm		
Felt nauseous (feeling like you wanted to throw-up)		
Stomach-ache		
Vomited		
Diarrhoea		
Felt dizzy		
Head congestion		
Headache		
Lack of appetite		
Sleeping more than usual		
Body aches or pains		
Weak or tired		
Chills or shivering		
Felt cold		
Felt hot		
Sweating		
Altered Mental State		

Participant Trial Number								

Working / Differential Diagnoses (list all, number) (from admitting consultant AMU post take ward round notes)
1.

Readmission CRF Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY**)**	_ _ / _ _ _ / _ _ _ _

Participant Trial Number								

POST-DISCHARGE 6 WEEKS FOLLOW UP (VISIT 5)

Date of visit (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Ordinal Scale for Clinical Improvement on Admission (*please circle one score*)		
Patient State	**Descriptor**	**Score**
Uninfected	Uninfected; no viral RNA detected	0
Ambulatory mild disease	Asymptomatic; viral RNA detected	1
	Symptomatic; independent	2
	Symptomatic; assistance needed	3
Hospitalised: moderate disease	Hospitalised; no oxygen therapy*	4
	Hospitalised; oxygen by mask or nasal prongs	5
Hospitalised: severe disease	Hospitalised; oxygen by NIV or high flow	6
	Intubation and mechanical ventilation, pO2/FiO2 ≥150 or SpO2/FiO2 ≥200	7
	Mechanical ventilation pO2/FIO2 <150 (SpO2/FiO2 <200) or vasopressors	8
	Mechanical ventilation pO2/FiO2 <150 and vasopressors, dialysis, or ECMO	9
Dead	Death	10

ECMO=extracorporeal membrane oxygenation. FiO2=fraction of inspired oxygen. NIV=non-invasive ventilation.

*pO2=partial pressure of oxygen. SpO2=oxygen saturation. *If hospitalised for isolation only, record status as for ambulatory patient.*

Is the patient fully recovered from the index illness for which they were originally enrolled into the study?	**Yes**	**No**
In the past 24 hours, did the patient experience any signs or symptoms of their acute respiratory infection?	**Yes**	**No**
In the past 24 hours, did the patient feel that their usual activities (e.g. work, study, housework, family or leisure activities) have returned to the level from before your acute respiratory infection and did not require additional assistance/support*?	**Yes**	**No**

*Assistance/support is defined as additional help of other people and/or requirement for supplemental oxygen (or a higher level of supplemental oxygen), compared to the pre-viral respiratory infection state.

**The result of the OSCI assessment must be based upon the patient's responses to the two questions specified above and must not be adjusted based on the results from other

outcome assessments (e.g. EQ 5D-5L), even if these data provide conflicting clinical information.

Participant Trial Number								

Healthcare Utilisation or Contact since last visit/ for <u>original illness</u>			
Admission to hospital for the original illness (*please circle*)		**Yes**	**No**
	Date of Admission	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
	Date of Discharge	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
Any visits or contacts to healthcare services for the original illness (*please circle*)		**Yes**	**No**
If yes, please record number of visits and reason for visit.		Number of visits or contacts	
• GP in usual working hours			
• Practice nurse in usual working hours			
• Hospital Emergency Department			
• Out of hours GP service			
• Pharmacist without a prescription from your GP			
• Walk in centre			
• Specialist			
• Other			

New investigations since last visit for original illness *(Please circle one option)*	**Yes**	**No**
If Yes, please record below:		

Investigation	**Date (DD/MM/YYYY)**	**Result**

Participant Trial Number								

Participant Trial Number								

Medication:.
Please record any changes to the patient's medication (new or stopped), since the last visit, on the UNIVERSAL Medication Log including antibiotics, antivirals, inhaled therapies, oral corticosteroids, oxygen, nebulised therapies, biologic or immunomodulatory agents, covid treatments and anti-tussive (anti-coughing treatments)other medications do not need to be recorded

Any absence from work or college for this illness *(please circle one option)*	**Yes**	**No**	**N/A***
If yes, number of days			
**if patient does not work or attend college*			

DATA COLLECTION: FLU-PRO+ and EQ-5D-5L questionnaires to be completed at this timepoint and Post-viral infection PROs (GAD-7, PHQ-9,FACIT Fatigue Scale) Data collected electronically at this timepoint does not need to be duplicated in the phonecall.

Online questionnaire/follow-up details confirmed for	**Yes**	**Date due** (DD/MMM/YYYY)
Online symptom questionnaires (FluPro+ and EQ-5D-5L) at weeks 1, 2, 4, 8 and 12 (*enter date when next questionnaire is due*)		_ _ / _ _ _ / _ _ _ _
12 week (Visit 6) Telephone call		_ _ / _ _ _ / _ _ _ _

Post-Discharge 6 Weeks Follow Up (VISIT 5) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Participant Trial Number								

POST-DISCHARGE 12 WEEKS FOLLOW UP (VISIT 6)

Date of visit (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Ordinal Scale for Clinical Improvement on Admission (*please circle one score***)**		
Patient State	**Descriptor**	**Score**
Uninfected	Uninfected; no viral RNA detected	0
Ambulatory mild disease	Asymptomatic; viral RNA detected	1
	Symptomatic; independent	2
	Symptomatic; assistance needed	3
Hospitalised: moderate disease	Hospitalised; no oxygen therapy*	4
	Hospitalised; oxygen by mask or nasal prongs	5
Hospitalised: severe disease	Hospitalised; oxygen by NIV or high flow	6
	Intubation and mechanical ventilation, pO2/FiO2 ≥150 or SpO2/FiO2 ≥200	7
	Mechanical ventilation pO2/FIO2 <150 (SpO2/FiO2 <200) or vasopressors	8
	Mechanical ventilation pO2/FiO2 <150 and vasopressors, dialysis, or ECMO	9
Dead	Death	10

ECMO=extracorporeal membrane oxygenation. FiO2=fraction of inspired oxygen. NIV=non-invasive ventilation.

*pO2=partial pressure of oxygen. SpO2=oxygen saturation. *If hospitalised for isolation only, record status as for ambulatory patient.*

Is the patient fully recovered from the index illness for which they were originally enrolled into the study	**Yes**	**No**
In the past 24 hours, did the patient experience any signs or symptoms of their acute respiratory infection?	**Yes**	**No**
In the past 24 hours, did the patient feel that their usual activities (e.g. work, study, housework, family or leisure activities) have returned to the level from before your acute respiratory infection and did not require additional assistance/support*?	**Yes**	**No**

Participant Trial Number								

Healthcare Utilisation or Contact since last visit/ for <u>original illness</u>			
Admission to hospital for the original illness (*please circle*)		**Yes**	**No**
	Date of Admission	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
	Date of Discharge	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
Any visits or contacts to healthcare services for the original illness (*please circle*)		**Yes**	**No**
If yes, please record number of visits and reason for visit.		Number of visits or contacts	
• GP in usual working hours			
• Practice nurse in usual working hours			
• Hospital Emergency Department			
• Out of hours GP service			
• Pharmacist without a prescription from your GP			
• Walk in centre			
• Specialist			
• Other			

New investigations since last visit for original illness *(Please circle one option)*	**Yes**	**No**
If Yes, please record below:		

Participant Trial Number								

Investigation	Date (DD/MM/YYYY)	Result

Medication:.
Please record any changes to the patient's medication (new or stopped), since the last visit, on the UNIVERSAL Medication Log including antibiotics, antivirals, inhaled therapies, oral corticosteroids, oxygen, nebulised therapies, biologic or immunomodulatory agents, covid treatments and anti-tussives (anti-coughing treatments). Other medications do not need to be recorded.

Any absence from work or college for this illness since last visit *(please circle one option)*	**Yes**	**No**	**N/A***
If yes, number of days			
**if patient does not work or attend college*			

DATA COLLECTION: FLU-PRO+ and EQ-5D-5L questionnaires to be completed at this timepoint and Post-viral infection PROs (GAD-7, PHQ-9,FACIT Fatigue Scale) Data collected electronically at this timepoint does not need to be duplicated in the phonecall.

Participant Trial Number								

Patients will now be asked to complete a final EQ-5D-5L questionnaires at Week 26.

Online questionnaire/follow-up details confirmed for	**Yes**	**Date due** (DD/MMM/YYYY)
EQ-5D-5L online questionnaires at weeks 1, 2, 4, 8, 12 and 26 if not fully recovered (*enter date commencing*)		_ _ / _ _ _ / _ _ _ _
26 week (Visit 7) Telephone call		_ _ / _ _ _ / _ _ _ _

Post-Discharge 12 Weeks Follow Up (VISIT 6) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Participant Trial Number								

POST-DISCHARGE 26 WEEKS FOLLOW UP (VISIT 7)

Date of visit (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _

Ordinal Scale for Clinical Improvement on Admission (*please circle one score***)**		
Patient State	**Descriptor**	**Score**
Uninfected	Uninfected; no viral RNA detected	0
Ambulatory mild disease	Asymptomatic; viral RNA detected	1
	Symptomatic; independent	2
	Symptomatic; assistance needed	3
Hospitalised: moderate disease	Hospitalised; no oxygen therapy*	4
	Hospitalised; oxygen by mask or nasal prongs	5
Hospitalised: severe disease	Hospitalised; oxygen by NIV or high flow	6
	Intubation and mechanical ventilation, pO2/FiO2 ≥150 or SpO2/FiO2 ≥200	7
	Mechanical ventilation pO2/FIO2 <150 (SpO2/FiO2 <200) or vasopressors	8
	Mechanical ventilation pO2/FiO2 <150 and vasopressors, dialysis, or ECMO	9
Dead	Death	10

ECMO=extracorporeal membrane oxygenation. FiO2=fraction of inspired oxygen. NIV=non-invasive ventilation.

*pO2=partial pressure of oxygen. SpO2=oxygen saturation. *If hospitalised for isolation only, record status as for ambulatory patient.*

Is the patient fully recovered from the index illness for which they were originally enrolled into the study	**Yes**	**No**
In the past 24 hours, did the patient experience any signs or symptoms of their acute respiratory infection?	**Yes**	**No**
In the past 24 hours, did the patient feel that their usual activities (e.g. work, study, housework, family or leisure activities) have returned to the level from before your acute respiratory infection and did not require additional assistance/support*?	**Yes**	**No**

Participant Trial Number								

Healthcare Utilisation or Contact since last visit/ for <u>original illness</u>			
Admission to hospital for the original illness (*please circle*)		**Yes**	**No**
	Date of Admission	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
	Date of Discharge	_ _ / _ _ _ / _ _ _ _ (DD/MMM/YYYY)	
Any visits or contacts to healthcare services for the original illness (*please circle*)		**Yes**	**No**
If yes, please record number of visits and reason for visit.		Number of visits or contacts	
• GP in usual working hours			
• Practice nurse in usual working hours			
• Hospital Emergency Department			
• Out of hours GP service			
• Pharmacist without a prescription from your GP			
• Walk in centre			
• Specialist			
• Other			

New investigations since last visit for original illness *(Please circle one option)*			**Yes**	**No**
If Yes, please record below:				
Investigation	**Date (DD/MM/YYYY)**	**Result**		

Participant Trial Number								

Investigation	Date (DD/MM/YYYY)	Result

New investigations since last visit for original illness *(Please circle one option)*	Yes	No
If Yes, please record below:		

Participant Trial Number								

Medication:.
Please record any changes to the patient's medication (new or stopped), since the last visit, on the UNIVERSAL Medication Log including antibiotics, antivirals, inhaled therapies, oral corticosteroids, oxygen, nebulised therapies, biologic or immunomodulatory agents, covid treatments and anti-tussives (anti-coughing treatments). Other medications do not need to be recorded.

Any absence from work or college for this illness since last visit *(please circle one option)*	**Yes**	**No**	**N/A***
If yes, number of days			
**if patient does not work or attend college*			

DATA COLLECTION: EQ-5D-5L questionnaire to be completed at this timepoint and Post-viral infection PROs (GAD-7, PHQ-9,FACIT Fatigue Scale) Data collected electronically at this timepoint does not need to be duplicated in the phonecall.

Post-Discharge 26 Weeks Follow Up (VISIT 7) Completed by			
Name		**Signature**	
Role	**Doctor / Nurse** (Please circle)	**Date** (DD/MMM/YYYY)	_ _ / _ _ _ / _ _ _ _