Treating Acute **EX**acerbation of **C**OPD with Chinese Herb**AL** Med**I**cine to aid Anti**B**iotic **U**se **R**eduction

BASELINE WORKSHEET

V2 29-Aug-2021

Participant's Trial ID								

Patient's Initials			

Date of Visit	D	D	M	M	M	Y	Y	Y	Y

Participant Trial ID | | | | | | | | Participant Initials | | | |

Remote participants: **Sections A to D** should be completed with the participant during their initial call. **Section E: Vital Signs** and **Section F: CAT Questionnaire Day 1** should only be completed with the patient once they have received their treatment pack.

Face-to-face participants: **All Sections** should be completed at the participant's initial visit.

Section A: Patient Characteristics

1	What are the participant's month and year of birth?						MMM	YYYY
2	What sex is the participant?	Male		Female		Prefer not to say		

Section B: Relevant Medical History

Is the patient known to suffer from:

1	Chronic Kidney Disease?	Yes		No	
	If Yes, please state stage of Chronic Kidney Disease. *N.B. If Stage 4 or 5, the patient is ineligible for the EXCALIBUR trial*	Stage			
2	Chronic Heart Failure?	Yes		No	
3	Cardiovascular Disease?	Yes		No	
4	Severe Liver Disease?	Yes		No	
	*N.B. **If Yes**, the patient is ineligible for the EXCALIBUR trial*				
5	Hypertension?	Yes		No	
6	Asthma?	Yes		No	
7	Diabetes Mellitus?	Yes		No	
8	Immunosuppression?	Yes		No	

Is the patient currently taking any of the following treatment?

9	Anti-platelet medication?	Yes		No	
10	Anti-diabetic medication?	Yes		No	
11	Diuretics?	Yes		No	

Section C: AECOPD Details

1 For how many days has the patient been experiencing this acute exacerbation of their COPD? *Please round down to the nearest whole number* | | | **Days**

2 Please confirm which of the following AECOPD symptoms that the patient is presenting with. *(Tick all that apply)*

	Increased Sputum Purulence
	Increased Sputum Volume
	Increased Breathlessness

Section D: AECOPD Treatment

Antibiotic Treatment

1 Was the patient prescribed antibiotics during their GP consultation for this AECOPD? **Yes** ☐ **No** ☐

1a *If **Yes**,* please record the antibiotics prescribed to the patient at this visit.

Antibiotic Name	Duration (days)	Are the antibiotics for Immediate Use / Delayed Use / Rescue Medication?

N.B. Rescue medication refers to antibiotics for use in a future exacerbation unrelated to the current episode.

Oral Corticosteroids

2 Is the patient on a maintenance dose of **oral corticosteroids**? **Yes** ☐ **No** ☐

2a ***If Yes to Q2,*** was the patient prescribed an increased dose of oral corticosteroids during their GP consultation to treat this AECOPD? **Yes** ☐ **No** ☐

2b ***If No to Q2,*** was the patient prescribed a dose of oral corticosteroids during their GP consultation to treat this AECOPD? **Yes** ☐ **No** ☐

Remote Participants: Once **Sections A to D** are completed with the patient, please arrange for the patient's treatment pack to be sent out or picked up. Please arrange a follow-up call with the patient to collect **Section E: Vital Signs** and **CAT Questionnaire Day 1**.

Section E: Vital Signs (to be completed before patient's first dose of trial treatment)

On what date were the measurements performed? D D M M M Y Y Y Y

1 Heart Rate ☐☐☐ **Beats/min**

2 Temperature ☐☐.☐ **°C**

3 Oxygen Saturation Levels (Sats) ☐☐☐ **%**

4 Sputum Colour (as per Bronko Test) *(Tick one box only)*

- ☐ **Not Applicable (No Sputum)**
- ☐ **1**
- ☐ **2**
- ☐ **3**
- ☐ **4**
- ☐ **5**

Participant Trial ID | | | | | | | | Participant Initials | | | |

Please complete the following Baseline questionnaire with the patient:

Section F: COPD Assessment Test™ (CAT) - Day 1 (to be completed before patients first dose of trial treatment)

Below are the **8** questions for the COPD Assessment Test (CAT) Questionnaire.

Please confirm the date that this questionnaire was completed with the patient.

D	D	M	M	M	Y	Y	Y	Y

*For each item below, place a mark (**X**) in the box that best describes you currently.*

*Be sure to only select **one** response for each question.*

I never cough	0	1	2	3	4	5	**I cough all the time**
I have no phlegm (mucus) in my chest at all	0	1	2	3	4	5	**My chest is completely full of phlegm (mucus)**
My chest does not feel tight at all	0	1	2	3	4	5	**My chest feels very tight**
When I walk up a hill or one flight of stairs I am not breathless	0	1	2	3	4	5	**When I walk up a hill or one flight of stairs I am very breathless**
I am not limited doing any activities at home	0	1	2	3	4	5	**I am very limited doing activities at home**
I am confident leaving my home despite my lung condition	0	1	2	3	4	5	**I am not at all confident leaving my home because of my lung condition**
I sleep soundly	0	1	2	3	4	5	**I don't sleep soundly because of my lung condition**
I have lots of energy	0	1	2	3	4	5	**I have no energy at all**

Once the Baseline Worksheet has been completed, please talk the participant through the **Participant Diary** to ensure they are comfortable in completing all necessary information.

Please file this **Baseline Worksheet** with this patient's other research notes for monitoring.

Name of Staff Completing Form: _____

Signature of Staff Completing Form: _____

Date form completed: _____