



EXCALIBUR

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

ELIGIBILITY / RANDOMISATION FORM
V2 15-Jul-2021

GP Practice	
--------------------	--

Patient's Initials				
---------------------------	--	--	--	--

Patient's Month and Year of birth	M	M	M	Y	Y	Y	Y
--	---	---	---	---	---	---	---

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

If the Patient is randomised onto the EXCALIBUR trial, please record:

Participant's Trial ID							
-------------------------------	--	--	--	--	--	--	--



Participant Trial ID

Participant Initials

Section A: Consent

Is the patient willing to sign consent for the EXCALIBUR Trial?

Yes

No

If NO, please send the patient the PIS for the qualitative sub-study along with the Qualitative Researcher's contact email, or give the patient a Qualitative Study invitation letter.

PLEASE ENTER PATIENT DETAILS ONTO SCREENING LOG AND STORE THIS ELIGIBILITY/RANDOMISATION FORM IN SECTION 2.3 OF THE ISF.

If YES, please complete the information below and overleaf.

1	Please confirm the version of the PIS given to / access by the patient			
2	Please confirm the version of the ICF signed by the patient			
3	Date Informed Consent was signed	DD	MMM	YYYY
4	Did the patient consent to their contact details being shared with the researcher for the Qualitative interview?	YES		NO
5	How was patient identification verified prior to consent? (confirmation of DOB and address; photo ID presented; etc)			

Name of member of staff taking consent: _____

Signature of member of staff taking consent: _____



Participant Trial ID

Participant Initials

Section B: Eligibility

Is the patient willing to be screened for eligibility to participate in the EXCALIBUR trial and for data to be stored anonymously if they are not eligible?	Yes	No

Inclusion Criteria

<i>If the answer to any of the following is NO then the patient is NOT eligible for the Trial</i>		Yes	No
1.	Is the patient presenting with a current acute exacerbation of COPD with at least one of the following: <ul style="list-style-type: none"> Increased sputum purulence Increased sputum volume Increased breathlessness 		
2.	Has the current acute exacerbation of COPD lasted for at least 24 hours and no longer than 21 days?		
3.	Is the responsible clinician considering use of antibiotics for the acute exacerbation?		
4.	Does the patient have a diagnosis of COPD in their clinical record?		
5.	Is the patient aged 40 years or older?		
6.	Is the patient able to provide written informed consent?		
7.	Is the patient able to provide the primary outcome data for 2 and 4 weeks within the expected windows?		

Exclusion Criteria

<i>If the answer to any of the following is YES then the patient is NOT eligible for the Trial</i>		Yes	No
1.	Does the responsible clinician feel urgent referral to hospital is necessary?		
2.	Is the patient presenting with or currently has a severe illness (e.g. suspected pneumonia, pulmonary embolism or lung cancer; necessity for emergency admission to hospital)?		
3.	Does the patient have a primary diagnosis of bronchiectasis, lung cancer or other active chronic respiratory disease?		
4.	Is the patient currently on or previously had antibiotics or corticosteroids for this AECOPD?		
5.	Is the patient on a maintenance dose of antibiotics for treatment of their COPD?		
6.	Is the patient known to be, or suspected to be pregnant?		
7.	Is the patient a woman of childbearing potential who is at risk of pregnancy and not using an effective form of contraception?		
8.	Is the patient currently breast-feeding?		
9.	Does the patient suffer from Stage 4 or 5 Chronic Kidney Disease?		
10.	Does the patient suffer from Severe Liver Disease?		
11.	Is the patient unable to read and understand the study materials?		
12.	Has the patient previously been recruited into the "EXCALIBUR" trial?		
13.	Has the patient previously been recruited into another drug trial within the last 6 weeks?		



Participant Trial ID

--	--	--	--	--	--	--

Participant Initials

--	--	--

Eligibility (cont.)

Did the patient meet all eligibility criteria?

Yes

No

Name of GP or Nurse Prescriber determining eligibility: _____

Signature of GP or Nurse Prescriber determining eligibility: _____

Date eligibility was confirmed: _____ DD/MMM/YYYY

If the patient did NOT meet all eligibility criteria, the patient is not eligible for the EXCALIBUR Trial.

PLEASE ENTER PATIENT DETAILS ONTO SCREENING LOG AND STORE THIS ELIGIBILITY/RANDOMISATION FORM IN SECTION 2.3 OF THE ISF.

If the patient meets all the eligibility criteria, please move onto Section C: Randomisation.

Section C: Randomisation

Is the patient willing to be randomised onto the EXCALIBUR Trial?

Yes

No

If NO, please send the patient the PIS for the qualitative sub-study along with the Qualitative Researcher's contact email, or give the patient a Qualitative Study invitation letter.

PLEASE ENTER PATIENT DETAILS ONTO SCREENING LOG AND STORE THIS ELIGIBILITY / RANDOMISATION FORM IN THE APPROPRIATE SECTION OF THE ISF.

If YES, randomise your patient by selecting the next available sequentially-numbered patient pack.

Patient Identifier (enter your site ID in the first four boxes followed by the three digit Patient Pack number)

--	--	--	--	--	--	--

PLEASE ATTACH **HERE THE TEAR OFF LABEL FROM THE PATIENT MEDICATION PACK ONCE THE PATIENT HAS BEEN RANDOMISED TO THE TRIAL.**



Participant Trial ID

Participant Initials

Section D: Form Sign-Off

Name of Staff Completing Form: _____

Signature of Staff Completing Form: _____

Date Form Completed: _____ DD/MMM/YYYY

Now move onto the Baseline Worksheet to collect the Baseline information for the participant.

Please email a scanned copy of the completed form to EXCALIBUR@soton.ac.uk **within 24 hours of randomisation.**

Please file the original Eligibility/Randomisation Form in Section 2.3 of your Investigator Site File.

FOR SCTU USE ONLY

<i>Patient ID checked</i>	Signature	DD/MMM/YYYY
<i>Patient's Initials checked</i>	Signature	DD/MMM/YYYY
<i>Correct Eligibility / Randomisation form checked</i>	Signature	DD/MMM/YYYY
<i>Protocol Version at time of Randomisation</i>	Version:	