COPD Biologics audit

Draft Dataset

Version 1.0: June 2026

Introduction

This document outlines the National Respiratory Audit Programme COPD Biologics Dataset.

The National Respiratory Audit Programme (NRAP), in collaboration with NHS England (NHSE) and the Respiratory Transformation Partnership (RTP), is developing the first national dataset to monitor the use of biologic therapies for Chronic Obstructive Pulmonary Disease (COPD). Biologics have emerged as an important new treatment option for selected patients with eosinophilic COPD and there is a need for a national mechanism to track quality, access and outcomes for patients receiving these new medicines.

This document outlines key data points within an NRAP COPD Biologics Dataset, systematic collection of which will generate high-quality, real-world data to support clinical care, service improvement, commissioning, and policy. The structure is based on stakeholder feedback, NICE technology appraisal [Project documents | Dupilumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils [ID6235] | Guidance | NICE] Project information | Mepolizumab for maintenance treatment of uncontrolled chronic obstructive pulmonary disease with raised blood eosinophils [ID1237] | Guidance | NICE, NHSE COPD Biologics commissioning support documents [NHS England » Chronic obstructive pulmonary disease: commissioning strategies and resources. The dataset is grounded in NHSE principles of value, equity, and access, ensuring that biologic therapies are used responsibly, consistently, and to maximal benefit for patients and the NHS. By mapping provision, measuring adherence to NICE guidance, and identifying variation, this work will highlight opportunities to improve referral pathways, service configuration, and patient outcomes across the country.

In addition to creating a national dataset to monitor the uptake and use of COPD biologics, this resource is specifically designed to support frontline clinical teams in running services efficiently and in line with national guidance. Developed with extensive clinician input, it will provide a template for multidisciplinary teams to support with initiation, monitoring, governance, and reporting requirements, reducing administrative burden while strengthening clinical oversight. As part of the NHS Respiratory Data Strategy, NRAP will work towards automated data capture and linkage, ensuring that the dataset evolves into a streamlined, minimally burdensome digital workflow that directly supports clinicians delivering COPD biologic therapy.

The dataset has been developed in conjunction with a wide range of multiprofessional clinicians across primary, secondary and tertiary care, as well as researchers, service providers, patient organisations and stakeholder organisations. Please see appendix 1 for details.

Population covered

Adults with a confirmed diagnosis of Chronic Obstructive Pulmonary Disease (COPD) who will be prescribed a NICE approved biologic medication, referred to as 'patients' in this dataset.

Eligibility:

Adult patients with uncontrolled* COPD, and raised blood eosinophils** who are on appropriate inhaled therapy.

*Uncontrolled COPD is defined as 1 or more severe exacerbations or 2 or more moderate exacerbations of COPD in the previous 12 months.

**Raised blood eosinophils is defined as a blood eosinophil count of 0.3 x 10^9 cells per litre or more (300 cells per microlitre or more).

Exclusions:

Patients with a primary diagnosis of Asthma are excluded from this patient population.

Section 1: Patient information

Item No.	Question	Text under question	Pop-up help note	Validation
Patient information				
1.1	NHS number	The field will accept valid NHS numbers which are ten digits long. Optionally, you can enter spaces or dashes or 3-3-4 format.	The NHS number is essential to create a Patient Record. It should only consist of digits. • It may be formatted as 000 000 0000 (spaces) or 000-000-0000 (dashes) • It should contain exactly 10 digits. • NHS Numbers start with a 4, 6 or 7 • A warning will be given if the number appears invalid.	**Look of answer option:** ___ ___ ____ Must be a 10-digit number.
1.2	Date of birth	dd/mm/yyyy	Date of birth may be entered numerically e.g. 01/03/1957 can be inputted as 1 3 57.	**Look of answer option:** __/__/____

Section 1: Patient information				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				The web-tool does not accept any patients: • below 18 years of age • or above 115 years of age at time of arrival (116 and older). ***Cannot be a date in the future.***
1.3	Home postcode	Please enter the full postcode.		Allows '[NFA]' for patients with no fixed abode.
1.4	Ethnicity	Please enter the patient's ethnicity as it appears in the notes.	It is not expected that services ask patients about their ethnicity. Please answer this question based on the information recorded in the patient notes.	**Drop down list 18 options:** • White British • White Irish • Any other White background • White and Black Caribbean • White and Black African • White and Asian • Any other mixed background • Indian • Pakistani • Bangladeshi • Any other Asian background • Caribbean • African

Section 1: Patient information				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				• Any other Black background • Chinese • Any other ethnic group • Not known • Not recorded ***Select <u>one</u> option only***
1.5	Gender	Please enter the patient's gender as it appears in the notes/referral information.		**Radio buttons <u>5</u> options:** • Male (including trans man) • Female (including trans woman) • Non-binary • Not known (not recorded/asked) • Not stated (person asked but declined to provide a response) ***Select <u>one</u> option only.***
1.5a	Is the patient's gender identity the same as birth indicator?	Please enter the patient's gender as it appears in the notes/referral information.		**Radio buttons <u>4</u> options:** • Yes – the person's identity is the same as their gender assigned at birth • No – the person's identity is not the same as their gender assigned at birth • Not known (not recorded/asked)

Section 1: Patient information				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				• Not stated (person asked but declined to provide a response) ***Select <u>one</u> option only.***

Section 2: MDT				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
2.1	Date the patient was referred for consideration for biologic therapy	Please record the date as noted in format dd/mm/yyyy		**Look of answer option:** __/__/____ ***Cannot be a date in the future***
2.2	Date of COPD Biologic Multi-Disciplinary Team (MDT) review	Please record the date as noted in format dd/mm/yyyy	This is the baseline for the 4 week target to initiation	**Look of answer option:** __/__/____ ***Cannot be a date in the future***
2.3	Please indicate COPD Biologic MDT members present at meeting			**Radio buttons 7 options:** • Respiratory Consultant • Respiratory specialist nurse • Respiratory specialist physiotherapist • Respiratory specialist pharmacist • Primary care representative • MDT administrator • Other [free text option] ***More than 1 option can be selected.*** ***To note, respiratory consultant is a mandatory field.***

Section 2: MDT				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
2.4	Confirm the host organisation for COPD Biologic MDT			**Radio buttons 4 options:** • Acute hospital trust (on behalf of ICB wide pathway) • Acute hospital trust (on behalf of local population) • Community trust (on behalf of ICB wide pathway) • Community trust (on behalf of local population) **Select 1 option only**
2.5	Has the patient had a face-to-face respiratory consultant review to confirm suitability for biologics?	Patients must have a face-to-face respiratory consultant review prior to starting a biologic as per the RTP/NHSE model pathway.		**Radio buttons 4 options:** • Yes • No • Planned
2.6	Date of the patient's face to face respiratory consultant review			**Look of answer option:** __/__/____

Section 3: Diagnosis, eligibility & optimisation of COPD Please note, where "in last 12 months" is in reference to within 12 months of MDT clinic date".				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
3.1a	***Forced exhaled volume in one second (FEV1)*** What was the patient's most recent FEV1 value?		*Baseline value*	Numerical free text with range validation: ***---Litres***
3.1b	*What was the date of the patient's most recent FEV1 value?*			Warning flag if date is over 24 months old asking user to review if this is the most recent value. **Look of answer option:** __/__/____ ***Cannot be a date in the future***
3.1c	**FEV1 % *predicted*** What was the patient's most recent FEV1 % predicted value?	Must use the same set of spirometry results as reported in Q3.1a.	*Baseline value*	Numerical free text with range validation: ***---% predicted***
3.1d	What was the date of the patient's most recent FEV1 % predicted value?			Warning flag if date is over 24 months old asking user to review if this is the most recent value. **Look of answer option:** __/__/____ ***Cannot be a date in the future***

3.1e	***Forced exhaled volume (FEV1) / Forced vital capacity (FVC) ratio*** What was the patient's most recent FEV1/FVC ratio value?	Must use the same set of spirometry results as reported in Q3.1a.	*Baseline value*	Numerical free text with range validation: ***---Ratio %***
3.1f	What was the date of the patient's most recent FEV1/FVC ratio value?			Warning flag if date is over 24 months old asking user to review if this is the most recent value. **Look of answer option:** __/__/____ ***Cannot be a date in the future***
3.1g	***Obstructive spirometry*** *If spirometry is not obstructive, please confirm basis for COPD diagnosis*			**Question should be greyed out unless answer to Q3.1e is >70%** **Radio buttons 3 options:** • Radiological emphysema • Mixed obstructive/restrictive spirometry • Other (provide free text) ***Can select 1 option only***
3.2a	***Blood eosinophil count*** *What is the patient's most recent blood eosinophil count?*			Numerical free text with range validation, to two decimal places: *--- cells/microlitre*
3.2b	***Date of most recent blood eosinophil count*** *Date of most recent*	Please record the date as noted in format dd/mm/yyyy		**Look of answer option:** __/__/____

	blood eosinophil count			***Cannot be a date in the future***
3.2c	***Highest blood eosinophil count*** *What is the patient's highest blood eosinophil count?*	*This should be a blood eosinophil count of >0.3 (NICE guidance link)*		Numerical free text with range validation, to two decimal places: *--- cells/microlitre*
3.2d	***Highest blood eosinophil count date*** Date of the patient's highest blood eosinophil count			**Look of answer option:** __/__/____ ***Cannot be a date in the future***
3.3	***Does the patient have a reported a history of chronic bronchitis for 3 months in the preceding 12 months in the absence of other known causes of chronic cough?***			**Radio button 2 options:** • **Yes** • **No** **Select one option only**
3.4a	***Is the patient currently receiving inhaled triple therapy?***	*Triple therapy includes inhaled therapy involving an inhaled corticosteroid, a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA).*		**Radio buttons 3 options:** • Yes, single device triple therapy • Yes, multiple device triple therapy • No ***Select one option only***

3.4b	***If not on triple therapy, which inhaled treatments is the patient receiving?***			**Question greyed out unless answer to 3.4a is "no".** • LAMA/LABA • LABA/ICS **Select one option only**
3.4c	***Please confirm length of time patient has been on current inhaled therapy***			**Drop down box with 12 options:** • Less than 3 months • 3-12 months • Greater than 12 months **Select <u>one</u> option only**
3.4d	***Has the patient's adherence to COPD medication been checked?***	*Adherence refers to medicines possession ratio over previous 12 months*		**Radio buttons <u>2</u> options*:*** • Yes • No ***Select <u>one</u> option only***
3.4e	***Has the patient's inhaler technique been checked?***			**Radio buttons <u>2</u> options*:*** • Yes • No ***Select <u>one</u> option only***
3.5	***COPD treatment*** *Is the patient being prescribed any of the following therapies?*			**Radio buttons, tick all that apply:** • Prophylactic antibiotics (oral or nebulised)

				• Mucolytics (oral or nebulised) • Roflumilast • Maintenance prednisolone
3.6a	***Frequency of COPD moderate exacerbations*** Number of moderate COPD exacerbations in the last 12 months		*A moderate COPD exacerbation is defined as sustained worsening of respiratory status that requires treatment with systemic corticosteroids and/or antibiotics. This aligns with NICE guideline NG115.*	**Drop down box with 10 options**: • 1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 • 9 • 10 • 11 • 12 • >12 ***Select only one option***
3.6b	***Frequency of COPD severe exacerbations*** Number of severe COPD exacerbations in the last 12 months		*A severe COPD exacerbation is defined as a rapid deterioration in respiratory status that requires hospitalisation. This aligns with NICE guideline NG115.*	**Drop down box with 10 options**: • 1 • 2 • 3 • 4 • 5 • 6 • 7

				• 8 • 9 • 10 • 11 • 12 • >12 ***Select only one option***
3.7	***Vaccination*** Has the patient received the following vaccinations line with national guidance?			**Radio buttons 4 options. Please tick all that apply*:*** • Annual influenza • Pneumococcal • RSV • COVID-19 ***Allow all options to be selected***
3.8a	***Smoking status*** What is the patient's smoking status?	A current smoker is someone who has smoked in the last 28 days.	*This question aligns to:* • *NICE 2022 (Tobacco - treating dependence) QS207. https://www.nice.org.uk/guidance/qs207* • *NICE 2019 (Chronic obstructive pulmonary disease in over 16s: diagnosis and management) NG115 1.2*	**Radio buttons 3 options*:*** • Current • Ex-smoker • Never smoker ***Select one option only***
3.8b	***Tobacco dependence support and treatment*** If a current smoker, has the patient been offered tobacco dependence treatment	Tobacco dependence treatment and support includes referral for smoking cessation behavioural support and appropriate pharmacotherapy and/or a nicotine vape.		**Grey out unless answer to 3.8a is "Current".** **Radio buttons 3 options*:*** • Yes, patient accepted • Yes, patient declined • No

	and support in the last 12 months?			***Select <u>one</u> option only***
3.9a	***Pulmonary rehabilitation*** Has the patient been assessed for suitability for referral to pulmonary rehabilitation in the last 12 months?			**Radio buttons <u>4</u> options*:*** • Patient assessed and referred • Patient assessed and declined • Patient assessed and not suitable • No ***Select <u>one</u> option only***
3.9b	***Pulmonary Rehabilitation completion*** Has the patient completed pulmonary rehabilitation in the last 12 months?			**Grey out unless answer to 3.9a is "patient assessed and referred".** **Radio buttons 2 options*:*** • Yes • No ***Select <u>one</u> option only***
3.10	***Self-management plan*** Does the patient have a current personalised COPD self-management plan?			**Radio buttons <u>3</u> options*:*** • Yes • No ***Select <u>one</u> option only***
3.11a	***MRC score*** What is the patient's most recent MRC score?			**Radio buttons <u>5</u> options*:*** • 0 • 1 • 2 • 3

				• 4 ***Select <u>one</u> option only***
3.11b	***MRC score date*** Date of the patient's most recent MRC score			**Look of answer option:** __/__/____ ***Cannot be a date in the future.***
3.12a	***CAT score*** What is the patient's most recent CAT score?			Drop down box with numbers from 1-40 available ***Select one option only***
3.12b	***CAT score date*** Date of the patient's most recent CAT score			**Look of answer option:** __/__/____ ***Cannot be a date in the future.***
3.13	***Comorbidity management*** Has other co-morbidity been considered/management addressed and where appropriate discussed at an MDT?		**Consider co-morbidities relevant to COPD and exacerbation risk such as the following:** Chronic airway infection/colonisation Other respiratory conditions e.g. bronchiectasis, ILD, sleep disordered breathing Respiratory failure requiring oxygen/NIV Cor pulmonale Cardiovascular disease including ischaemic heart disease, heart failure, arrhythmias Gastroesophageal reflux Diabetes Obesity Malnutrition Osteoporosis	**Radio buttons <u>2</u> options*:*** • Yes • No ***Select <u>one</u> option only***

			Anxiety Depression Substance misuse/addiction	

Eligibility confirmation – sections will be automatically populated from Section1-3 on webtool			
Section 4: Confirmation of eligibility for biologic			
Item No.	**Confirmation / sign off**	**Pop-up help note**	**Validation**
4.1	*I confirm that the following criteria apply:*		**Check boxes 3 options:** ☐ *Blood eosinophil count ≥300 cells/microlitre* ☐ *Treated with triple therapy (ICS + LABA + LAMA) or dual therapy (if intolerant of triple)* ☐ *Experienced at least 1 severe or 2 moderate exacerbations in the past 12 months* ***All options should be selected***
4.2	*I confirm the patient has uncontrolled COPD and an MDT decision to commence a trial of biologic therapy has been made*		**Check box option:** ☐ *MDT decision made* ***Select to confirm***
4.3	*I confirm the patient will receive the licensed dose and frequency of biologic medication for uncontrolled COPD*		**Check box option:** ☐ *Patient will receive the licensed dose and frequency of Dupilumab for uncontrolled COPD (300mg subcutaneously every two weeks)* ☐ *Patient will receive the licensed dose and frequency of Mepolizumab for uncontrolled COPD (100mg subcutaneously every four weeks)* ***Select to confirm***
4.4	*I confirm the patient will be counselled regarding side effects including receiving a written patient information leaflet. The patient will be advised to report any new onset or worsening of*		**Check box option:**

Eligibility confirmation – sections will be automatically populated from Section1-3 on webtool			
Section 4: Confirmation of eligibility for biologic			
Item No.	**Confirmation / sign off**	**Pop-up help note**	**Validation**
	eye symptoms (such as watering, itching, redness, swelling, dryness, a feeling of gritty eye or sensation of foreign body in the eyes) and not to self-manage.		☐ *Patient will be counselled regarding side effects including written patient information leaflet (specifically eye symptoms).* ***Select to confirm***
4.5	*I confirm the patient will be reviewed at no later than 1 year after initiation. The patient understands that their prescription for biologic therapy will stop if, compared with the twelve months before starting it, their number of severe exacerbations is higher, or this number is the same and their number of moderate exacerbations is higher.*		**Check box option:** ☐ *Patient will be systematically reviewed no later than 1 year after initiation. The patient understands that the biologic therapy will stop if, compared with the twelve months before starting it, their number of severe exacerbations is higher, or this number is the same and their number of moderate exacerbations is higher.* ***Select to confirm***

Section 5: Biologic prescription				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
5.1	Date of biologic prescription	Please record the date as noted in format dd/mm/yyyy		**Look of answer option:** __/__/____ ***Cannot be a date in the future***

Section 6: First dose of Biologic therapy received				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
6.1a	Date first dose of biologic received			**Look of answer option:** __/__/____ ***Cannot be a date in the future***
6.1b	Where was first dose of biologic administered?			**Radio buttons 3 options:** • Acute hospital trust • Community setting • Home ***Select one option only***
6.2a	Date second dose of biologic received			**Look of answer option:** __/__/____ ***Cannot be a date in the future***
6.2b	Where was the second dose of biologic administered?			**Radio buttons 3 options:** • Acute hospital trust • Community setting • Home ***Select one option only***
6.3	Is the patient receiving their ongoing biologic treatment via a homecare service?			**Radio buttons 4 options:** • Yes • No, Homecare not available • No, Homecare not appropriate • No, patient declined • Other

Section 6: First dose of Biologic therapy received				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				If other, please provide free text box ***Select <u>one</u> option only***

Ad hoc review – in response to request by patient or clinical team				
Section 7: Ad hoc review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
Patient information				
7.1	***Date of patient review***			**Look of answer option:** __/__/____
7.2	***Reason for ad hoc review:***			**Drop down box:** • COPD exacerbation • Biologic side effect • Other If other, please provide free text box ***Select <u>one</u> option only***
7.3	***Moderate COPD exacerbations*** Number of moderate COPD exacerbations within the last 12 months		*A moderate COPD exacerbation is defined as sustained worsening of respiratory status that requires treatment with systemic corticosteroids and/or antibiotics. This aligns with NICE guideline NG115.*	Numerical free text with range validation: ---
7.4	***Severe COPD exacerbations*** Number of severe COPD		*A severe COPD exacerbation is defined as a rapid deterioration in respiratory status that requires hospitalisation. This aligns with NICE guideline NG115*	Numerical free text with range validation: ---

Ad hoc review – in response to request by patient or clinical team				
Section 7: Ad hoc review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
	exacerbations within the last 12 months			
7.5	***MRC score*** What is the patient's MRC score at this review?			**Radio buttons 5 options:** • 0 • 1 • 2 • 3 • 4 ***Select one option only***
7.6	***CAT score*** What is the patient's CAT score at this review?			Drop down box with numbers from 1-40 available ***Select one option only***
7.7	***Outcome*** Will the patient be continuing biologic therapy until the 12-month review?			**Radio buttons 7 options:** • Yes • No, due to lack of response • No, due to side-effects • No, due to patient wishes • No, switch to another COPD biologic • No, lost to follow-up

Ad hoc review – in response to request by patient or clinical team				
Section 7: Ad hoc review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				• No, due to death ***Select one option only***
7.8	***Side effects*** If discontinued due to side effects (Q7.7), please confirm which side effects were experienced:			**Grey out unless answer to Q7.7 is side effects.** **4 Radio buttons** • Eye • Skin • Joint • Eosinophilia • Other – add free text option

First annual review				
Section 8: 12-month review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
Patient information				
8.1	Date of review			**Look of answer option:** __/__/____
8.2a	Is the patient receiving their biologic via a homecare service?			**Radio buttons 4 options:** • Yes • No, Homecare not available • No, Homecare not appropriate • No, patient declined • Other ***Select one option only***
8.2b	If answer to 8.2a is no, where was the patient being administered biologics?			**Question to be greyed out if answer to Q8.2a is yes** **Radio buttons 3 options:** • Acute hospital trust • Community setting • Other If other, please provide free text box ***Select one option only***

First annual review				
Section 8: 12-month review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
8.3a	*Has the patient had further spirometry since initiation of biologic?*			**Radio buttons 2 options:** • Yes • No ***Select one option only***
8.3b	***Forced exhaled volume (FEV1)*** What was the patient's most recent FEV1 value?		*Baseline value*	***Grey out if answer to 8.3a is no*** Numerical free text with range validation: ***---Litres***
8.3c	**FEV1 % *predicted*** What was the patient's most recent FEV1 % predicted?	Must use the same set of spirometry results as reported in Q8.3.	*Baseline value*	***Grey out if answer to 8.3a is no*** Numerical free text with range validation: ***---% predicted***
8.3d	***Forced exhaled volume (FEV1) / Forced vital capacity (FVC) ratio*** What was the patient's most recent FEV1/FVC ratio value?	Must use the same set of spirometry results as reported in Q8.3.	*Baseline value*	***Grey out if answer to 8.3a is no*** Numerical free text with range validation: ***---Ratio %***

First annual review				
Section 8: 12-month review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
8.4	***Moderate COPD exacerbations*** Number of moderate COPD exacerbations, within the last 12 months		*A moderate COPD exacerbation is defined as sustained worsening of respiratory status that requires treatment with systemic corticosteroids and/or antibiotics. This aligns with NICE guideline NG115.*	Numerical free text with range validation: ---
8.5	***Severe COPD exacerbations*** Number of severe COPD exacerbations within last 12 months		*A severe COPD exacerbation is defined as a rapid deterioration in respiratory status that requires hospitalisation. This aligns with NICE guideline NG115.*	Numerical free text with range validation: ---
8.6	***MRC score*** What is the patient's MRC score at this review?			**Radio buttons 5 options*:*** • 0 • 1 • 2 • 3 • 4 ***Select one option only***
8.7	***CAT score*** What is the patient's CAT score at this review?			Drop down box with numbers from 1-40 available ***Select one option only***
8.8	***Eligibility to continue treatment***		As per NICE guidance. Assess response at 12 months.	**Check box 2 options:**

First annual review				
Section 8: 12-month review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
	Does the patient meet the eligibility criteria to continue biologic therapy?		Stop biologic if, compared with the 12 months before starting it, the number of severe exacerbations: • is higher, or • is the same, and the number of moderate exacerbations is higher.	☐ Yes ☐ No ***Select to confirm***
8.9	***Confirmation to continue*** Confirmation that the MDT decision to continue biologic for a further 12 months has been made following consultant review.			**Check box 2 options:** ☐ Yes, patient will continue biologic ☐ No, patient will discontinue biologic ***Select to confirm***
8.10	***Continue treatment*** *If 'no' selected in question 8.9, what is the reason for discontinuing biologic?*			**Question to greyed out if response to Q8.9 is yes** **Check boxes 6 options:** • Lack of response • Side effects • Patient wishes • Patient to move to different biologic treatment • Lost to follow up • Patient died

First annual review				
Section 8: 12-month review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				Select 1 option only
8.11	***If discontinued due to side effects, please confirm which side effects were experienced***			**Grey out question unless answer to 8.10 is side effects.** **4 Radio buttons:** • Eye • Skin • Joint • Eosinophilia • Other (free text box) **Can select more than one option**

Subsequent annual review				
Section 9: Annual review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
Patient information				
9.1a	Is the patient receiving their biologic via a homecare service?			**Radio buttons 4 options:** • Yes • No, Homecare not available • No, Homecare not appropriate • No, patient declined • Other ***Select one option only***
9.1b	If answer to 9.1a is no, where is the patient being administered the biologic?			**Question to be greyed out if answer to Q9.1a is yes** **Radio buttons 3 options:** • Acute hospital trust • Community setting • Other If other, please provide free text box ***Select one option only***
9.2a	*Has the patient had further spirometry since initiation of biologic?*			**Radio buttons 2 options:** • Yes • No ***Select one option only***

Subsequent annual review				
Section 9: Annual review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
9.2b	***Forced exhaled volume (FEV1)*** What was the patient's most recent FEV1 value?		*Baseline value*	**Grey out if answer to 9.2a is no.** Numerical free text with range validation: ***---Litres***
9.2c	**FEV1 % *predicted*** What was the patient's most recent FEV1 % predicted?	Must use the same set of spirometry results as reported in Q9.2b	*Baseline value*	**Grey out if answer to 9.2a is no.** Numerical free text with range validation: ***---% predicted***
9.2d	***Forced exhaled volume (FEV1) / Forced vital capacity (FVC) ratio*** What was the patient's most recent FEV1/FVC ratio?	Must use the same set of spirometry results as reported in Q9.2b	*Baseline value*	***Grey out if answer to 9.2a is no*** Numerical free text with range validation: ***---Ratio %***
9.3	***Moderate COPD exacerbations*** Number of moderate COPD exacerbations		*A moderate COPD exacerbation is defined as sustained worsening of respiratory status that requires treatment with systemic corticosteroids*	Numerical free text with range validation: ---

Subsequent annual review				
Section 9: Annual review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
	in last 12 months?		*and/or antibiotics. This aligns with NICE guideline NG115.*	
9.4	***Severe COPD exacerbations*** Number of severe COPD exacerbations in last 12 months?		*A severe COPD exacerbation is defined as a rapid deterioration in respiratory status that requires hospitalisation. This aligns with NICE guideline NG115.*	Numerical free text with range validation: ---
9.5a	***MRC score*** What is the patient's MRC score at this review?			**Radio buttons 5 options:** • 0 • 1 • 2 • 3 • 4 ***Select one option only***
9.6a	***CAT score*** What is the patient's CAT score at this review?			Drop down box with numbers from 1-40 available ***Select one option only***
9.7	***Eligibility to continue treatment*** Does the patient	Eligibility to continue is that the patient has fewer severe exacerbations or the same number of severe exacerbations and fewer moderate exacerbations.	As per NICE guidelines. Assess response to biologic at 12 months. Stop biologic if, compared with the 12 months before starting it, the number of severe	**Check box 2 options:** • Yes • No

Subsequent annual review				
Section 9: Annual review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
	meet the eligibility criteria to continue biologic?		exacerbations: • is higher, or • is the same, and the number of moderate exacerbations is higher.	***Select to confirm***
9.8	***Confirmation to continue*** Confirmation that the MDT decision to continue biologic for a further 12 months has been made following consultant review			**Check box 2 options:** • Yes, patient will continue • No, patient will discontinue ***Select to confirm***
9.9	***Continue treatment*** If 'no' selected in question 9.8, what is the reason for discontinuing the prescribing of biologic?			**Question to be greyed out if answer to Q9.8 is yes** **Check boxes 6 options:** • Lack of response • Side effects • Patient wishes • Patient to move to different biologic treatment • Lost to follow up • Patient died

Subsequent annual review				
Section 9: Annual review				
Item No.	**Question**	**Text under question**	**Pop-up help note**	**Validation**
				Select 1 option only
9.10	***If discontinued due to side effects, please confirm which side effects were experienced***			**Only open question when answer to Q9.9 is side effects.** **Radio buttons 4 options:** • Eye • Skin • Joint pain • Eosinophilia • Other (free text box) ***Select one option only***

Appendix 1:

Name	Organisation
Dr Hannah Burke	University Hospital Southampton, National Respiratory Audit Programme (NRAP) COPD Clinical Fellow
Prof James Dodd	University of Bristol, North Bristol NHS Trust, National Respiratory Audit Programme (NRAP) Adult Asthma Clinical Lead
Dr Katherine Hickman	National Respiratory Audit Programme (NRAP) Primary Care Clinical Lead
Dr Irem Patel	Kings College London, Kings College Hospital NHS Trust, National Respiratory Audit Programme (NRAP) COPD Clinical Lead
Prof Jenni Quint	Imperial College London, National Respiratory Audit Programme (NRAP) Data Analysis Lead
Prof Tom Wilkinson	University Hospital Southampton, National Respiratory Audit Programme (NRAP) Senior Clinical Lead
Harriet Shannon	Association of Chartered Physiotherapists in Respiratory Care
Sarah Sleet	Asthma and Lung UK
Prof Mona Bafadhel	Chair, British Thoracic Society Clinical Statement on COPD Biologics Working Group
Prof Neil Greening	Chair, British Thoracic Society COPD Specialist Advisory Group
Prof Richard Russell	Chair, British Thoracic Society
Sally Welham	Chief Executive, British Thoracic Society Chief Executive
Prof Mick Steiner	Chief Medical Officer for Leicester, Leicestershire and Rutland Integrated Care Board
Grainne D'Ancona	Consultant Pharmacist, Guy's and St Thomas's Hospital NHS Trust
Charlotte Evans	Health Innovation Network (Health Innovation Oxford & Thames Valley)
James Rose	Health Innovation Network (Health Innovation Oxford & Thames Valley)
Dr Jonathan Fuld	National Clinical Director for Respiratory, NHS England
Dr Sarah Elkin	Respiratory Transformation Partnership COPD Neighbourhood Pathway Lead