

## WATCH

Wessex Asthma Lifetime Cohort Ethics REC No.: 14/WM/1226



## Year 1 Follow-up CRF

Study Site: AAAA	Subject No. W00999/XXX	Visit Date $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$
1. Re-consent		Last consent: 21 Mar 2017 (Enrolment CRF)
1.1 Re-consent		(Emonnone oral)
Ongoing verbal consent obtained?	Yes O No O	Enrolment written
Re-consent taken by		consent: 21 Mar 2017
2. Asthma History		Responses from 21 Mar 2017 (Enrolment CRF)
2.1 Do you self-manage exacerbations?	Yes O No O	Yes
2.2 Since your last WATCH study visit, how asthma-related Intensive Care Unit (ICL		0 visits
2.3 Since your last WATCH study visit, have	e you been intubated? Yes O	No
	No O	
	Not known	
2.4 Since your last WATCH study visit, how	many asthma-related (If zero, enter zero)	
a) visits to GP	or Not known	2 GP visits
b) visits to Emergency Dept. (ED)	or Not known	0 ED visits
c) hospitalisations	or Not known	0 hospitalisations
d) courses of oral corticosteroids (OC	S) or Not known	6 OCS courses
(If on maintenance, record the number of times needed to double-dose)	— > If > 0: Dose	Missing
	Duration days	Missing
e) days lost from work/education	∣ ∣ or Not known	0 days lost
-,,	or Not applic. (i.e. not in work nor educa	•
f) courses of antibiotics	or Not known	6 courses amoxillin,
	→ If > 0, which antibiotics?	doxycycline
2.5 Are you on long-term antibiotics?	Yes O No O	No
	→ Which antibiotic(s)?	

## 3. Medications

3.1 Please document any changes to the following medications which were 'Ongoing' at the last visit.

(Either tick the 'Still Ongoing?'	check boxes or, if ended, record when.)
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					<u>Sta</u>	rte	<u>d</u>	<u>Still</u>	<u> E n</u>	<u>ded</u>	
<u>Drug</u>	Quantity	<u>Units</u>	<u>Frequency</u>	Route	<u>Month</u>	<u>Year</u>	<u>NK</u>	Onging?	<u>Month</u>	<u>Year</u>	<u>NK</u>
Fostair	100/6	mcg	2 puffs BD	Inhaler	1	2015					
Ciclesonide	80	mcg	2 puffs OD	Inhaler	1	2015					
Spiriva	2.5	mcg	2 puffs OD	Inhaler	1	2015					
Ventolin	100	mg	PRN	Inhaler	1	2015					
Montelukast	10	mg	nocte	РО	1	2015					
Sertraline	50	mg	OD	РО	5	2016					
Alendronic Acid	70	mg	once a week	РО	11	2016					
Lansoprazole	30	mg	OD	РО							

3.2 New asthma	a and non-astl	hma medic <u>D o</u>	d any changes i	n doses to exi	_	diation, s	ast visit.	En	d e d	
Drug		Quantity	Frequency	Route	Month		Onging?	Month		<u>NK</u>
1										
2										
3										
4			 							
5										
6										
7.										
8										
9.										
10.										

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Version 3.3, 19 Sep 2017

4. Asthma Treatment Details	Responses from 21Mar 2017
Since the last WATCH Visit have you been treated with	(Enrolment CRF)
4.1 Omalizumab (Xolair)? Yes   No   Please enter details into Section 3 'Medications' above  → Please enter details into Section 3 'Medications' above	No
4.2 Mepolizumab? Yes No ○  → Please enter details into Section 3 'Medications' above	No
4.3 Reslizumab?  Yes  No  Please enter details into Section 3 'Medications' above	Not on CRF
4.4 Bronchial Thermoplasty? Yes $O \longrightarrow D D / M M / Y Y$ Yes $O \longrightarrow D D / M M / Y Y$ Yes $O \longrightarrow D D / M M / Y Y$	No, never
4.5 Thermal laminar Airflow Device?  e.g. from LASER study  Yes O D D / M M / Y Y  No O Q4.6	No
4.6 Inhaler technique:  Date technique assessed  DD / MM / YY  Technique: Good O  No changes needed  No changes needed  Minor changes needed  Minor changes or change of inhaler needed	Not done
4.7 Action plan:  Adequate plan pre-existing? Yes O No O  Action plan given?  Yes O No O  Date performed DD/MM/YY	Missing Missing
Comments	

5. Smoking Histo	ry	Respnses from 21Mar2017 (Enrolment CRF)
5.1 Smoking status	Never smoked ○ → Q5.3	Ex-smoker
	Current smoker	Started aged 20
	Ex-smoker O -> Age started	Finished aged 22
5.2 Pack-year history		
a) Cigarettes	Number smoked per day cigarettes	
	Number of years smoked years	
b) Pipes / Cigars	Number smoked per day pipes / cigars Pipes	
	Number of years smokedyears Cigars	
	Other	
c) Cigarillos	Number smoked per day cigarillos	
	Number of years smoked years	
	Pack-years Calculation	
d) Tobacco	Grams smoked per day = Cigarettes per day x yrs smoked / 20 or	
	Ounces smoked per day	
	Number of years smokedyears 12.5g or 0.5oz tobacco = 20 cigarettes	
	Total pack years	
5.3 Passive exposure		In the past
	In the past O Parents? Tick all that apply  Spouse?	
	Never 0	
	Others?	
	Number of yearsyears	50 yrs
E-cigarettes		
5.4 Uses e-cigarettes r	regularly? Yes ○ No ○ → Next Section	No
	> 5.4.1 Used for how long?yearsmonths	
	5.4.2 Nicotine dose mgs (Common values are	
	<b>5.4.3 How long does it</b> 0, 3, 6, 12, 18 and 20)	
	take to use 10ml of e- liquid?	
	weeks adays	
	5.4.4 Which flavour(s)?	
Commonts		
Comments		

6. Nasal Disease						Responses from 21 Mar 2017
Since the last WATCH Study Visit have	you					(Enrolment CRF)
6.1 had rhinitis? Yes	No O	Not	known O			Yes
6.2 had nasal polyps? Yes	No O	Not	known O			Yes
6.3 had nasal surgery? Yes O	No O	Not	known O			Yes
Comments						
6.4 had any Perennial Allergy? γ	es O	No O	Not known	0		No
6.5 had any Seasonal Allergy? γ	es O	No O	Not known	0		No
Comments						
6.6 had CT Sinuses performed? (Clinical indication only)	Yes O	No O	N/K O			Yes; Date: 01/07/2016
	->	Date perforn	ned DD/	M M / Y Y		
		Findings: [	Normal			
		[	Polyps			
		-	Mucosal th	nickening		
			— □ Sinus opad	cification / abnormalit	ty	
			Abnormal :	nasal turbinates		
			ᆜ □ Other <del>→</del>			
		L			I	
7. Reflux History Since your last WATCH Study Visit have	e vou					Responses from 21 Mar 2017 (Enrolment CRF)
7.1 been diagnosed with GORD?	Yes O	No O				
(Patient self-report or clinician diagnosis in letter / notes)						Yes
7.2 had any symptoms of GORD?	Yes, and o	ongoing desp	ite on treatmen	it O		Yes, and ongoing
	Yes, but n	ot on treatme	ent at present	0		despite treatment
	No, on trea	atment and s	ymptoms contr	olled O		
	No			0		
7.3 had any oesophageal testing p	performed or	planned				
(Only if clinically indicated)				Requested, but		
	<u>′es,</u> lone		Requested, not yet done	not done for some reason e.g. DNA		
a) Barium swallow?	0	0	0	0		No/Never
	→ Date _	DD/MM	/ <u>Y</u> <u>Y</u>			
b) OGD?	0	0	0	0		No/Never
	→ Date	DD/MM	/ Y Y			
c) Oesophageal manometry	0	0	0	0		No/Never
PH / impedance?	→ Date	D D / M M		0		110,710101
d) Other?	O Date	0	0	0		No/Never
> Specify	/ Date	D D / M M	/ <u>I</u> <u>I</u>			

Page completed by Date completed DD D / MM / YY

8. Psychological History	/					Responses from 21 Mar 2017
Since your last WATCH Study Vi	sit have you					(Enrolment CRF)
8.1 had any Diagnosis* of	: - Depre	ssion?	Yes	O No O		No
	- Anxie	ty?	Yes	O No O		No
		psychological / iatric comorbidity?	Yes	O No O		No
* Patient self-report or clii	nician diagnosi	s in letter / notes.		>Specify		
8.2been seen by mental h	ealth profes	sionals?				
	<u>Yes</u>		<u>No</u>	Requested. not yet done	Requested, but not done for some reason e.g. DNA	
a) Psychiatrist?	0		0	0	0	No/Never
., .,	→ Date	DD/MM/YY				
	,	Completed O				
		Ongoing O				
I) Beach de visto		Oligonia C		_	_	A I = /A I =
b) Psychologist?	O Data		0	0	0	No/Never
	→ Date	DD/MM/YY				
		Completed O				
		Ongoing O				
c) Specialist asthma	Ο		0	0	0	No/Never
psychologist?	→ Date	$\underline{D}\;\underline{D}\;I\;\underline{M}\;\underline{M}\;I\;\underline{Y}\;\underline{Y}$				
		Completed O				
		Ongoing O				
d) Other?	φ		0	0	0	No/Never
	> Date	DD/MM/YY				
		Completed O				
		Ongoing O				
⇒ Specify ∟						

9. Breathing Pattern	Disorders				Responses from
Since your last WATCH Stud					21 Mar 2017 (Enrolment CRF)
9.1 had any diagnosis of:	a) Vocal cord dysfunction?	<u>No</u> O			No
(Patient self-report or clinician diagnosis in letter / notes)	b) Dysfunctional breathing?	0			Yes
9.2 had any investigation	s for VCD?			Democrated but	
	Yes. done	<u>No</u>	Requested, not yet done	Requested, but not done for some reason e.g. DNA	
a) Nasendoscopy?	0	0	0	0	Yes; Date: 01/06/2015
	→ Date DD/MM/YY				
	Completed O Ongoing	0			
b) Other?	Date DD/MM/YY	0	0	0	Missing
	Completed O Ongoing	0			
⇒ Specify					
9.3 been seen by a BPD /	VCD specialist?				
	Yes. done	<u>No</u>	Requested,	Requested, but not done for some reason e.g. DNA	
a) Physiotherapist?	Q	0	0	0	No/Never
	→ Date DD/MM/YY				
	Completed O Ongoing	0			
b) Specialist asthma physiotherapist?	9	0	0	0	No/Never
	Date DD/MM/YY				
c) Speech therapist?	Completed O Ongoing				No/Never
c) Speech therapist?	Date DD/MM/YY	0	0	0	NO/Never
	Date DD / MM / YY  Completed O Ongoing	0			
d) Other?	Q	0	0	0	No/Never
	→ Date DD/MM/YY				
	Completed O Ongoing	0			
<b>→</b> Specify					

	orbidities and Proced	ures			_	_		Last asked/upo 21 Mar 201
10.1 Co	omorbidities	Previ	ously	had? *	<u>C </u>	urrentl <u>have?</u>	<u>у</u>	
		Yes	<u>No</u>	<u>N/K</u>	<u>Yes</u>	No	<u>N/K</u>	
a)	COPD	0	Ø	0	0	0	0	
	Allergic Bronchopulmonary Aspergillosis or SAFS	0	Ø	0	0	0	0	
c)	Non-CF Bronchiectasis	0	Ø	0	0	0	0	
d)	Cystic Fibrosis	0	Ø	0	0	0	0	
<b>e</b> )	Bronchiolitis	0	Ø	0	0	0	0	
f)	Churg Strauss Syndrome	0	Ø	0	0	0	0	
g	Chronic urticaria / angioedem	a ()	Ø	0	0	0	0	
h)	Sulphite sensitivity	Ø	0	0	0	0	0	
i)	Salicylate (aspirin) sensitivity	Ø	0	0	0	0	0	
j)	Eczema	0	Ø	0	0	0	0	
k)	Latex allergy	0	Ø	0	0	0	0	
I)	Sleep apnoea	0	Ø	0	0	0	0	
	,			s at earlier visi	ts.			
		Please ı	update as r	necessary.				
Exist	ing Other Comorbidities							
	RHINITIS	V			0	0	0	
	GORD	V			0	0	0	
	DYSFUNCTIONAL BREATHING	V			0	0	0	
	OSTEOPOROSIS	Ø			0	0	0	
	IRRITABLE BOWEL	€			0	0	0	
	SYNDROME							
<u>New</u> 1.	comorbidities since last visit	(write in)						
2.		0			0	0	0	
3.		_ 0			0	0	0	
4. 5.		0			0	0	0	
		_ 0			0	0	0	
6.		0			0	0	0	
10.2 Pr	ocedures	Ever	Recei	v e d ?				
		<u>Yes</u>	<u>No</u>	<u>N/K</u>	If 'Yes', Date	of Proced	<u>dure</u>	
a)	Bariatric surgery	0	0	0	<u>D</u> <u>D</u> /	<u>M M / Y</u>	Y	
b	Hiatus hernia repair	0	0	0		<u>M M / Y</u>		
c)	Hysterectomy	0	0	0		<u>M M / Y</u>		
	ous Other Procedures						_	
Nam	Dunna duman niman lant vinit	(uurita in)						
	Procedures since last visit	(write in)						
						<u>M</u> <u>M</u> / <u>Y</u>		
					<u>D</u> <u>D</u> /	<u>M M / Y</u>	Y	
3.		0			<u>D</u> <u>D</u> /	$\underline{M} \underline{M} / \underline{Y}$	Y	
4.		0			<u>D</u> <u>D</u> /	<u>M</u> <u>M</u> / <u>Y</u>	Y	
		1.0			DD/	M M / Y	Υ	
5.								

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11. Anthrop	ometry						
11.1 Height		metres	How obtained?	Measured O	Asked patient	0	Height: 1.58m on 21 Mar 2017 (Enrolment
11.2 Weight	=	kg	How obtained?	Measured O	Asked patient	0	Weight: 69.70kg on 21 Mar 2017 (Enrolment
12. Imaging	- HRCT						Scan last performed
12.1 HRCT per	formed? Yes	Q N	lo O				21 Mar 2017 (Enrolment CRF)
		>12.2	Date performed	D D / M M / Y Y	7		
		12.3	HRCT evidence of:		Yes	<u>No</u>	
		С	entral bronchiectas	sis	0	0	
		o	ther bronchiectasis	<b>s</b>	0	0	
		В	ronchial dilation wi	thout bronchiectas	sis O	0	
		В	ronchial wall thicke	ening	0	0	
		G	Fround glass shadov	wing	0	0	
		M	lucus plugging		0	0	
		Α	ir trapping		0	0	
		s	can reported as nor	rmal by radiologist	0	0	
		E	mphysema - Centril	lobular	0	0	
		E	mphysema - Panaci	inar	0	0	
		o	other category / other	er findings	Q	0	
					>S <sub>k</sub>	pecify in 'Comments' below	
13. Imaging	- DEXA						No record of any
13.1 DEXA sca	n performed?	Yes O	No O				previous scan.
		>	13.2 Date performed	d DD/MM/)	<u> </u>		
			13.3 Spinal bone de	ensity (L1-4) T score	9		
			13.4 Femoral neck b	oone density (L1-4)	T score: a) Lef	t	
					b) Rigi	nt	
Comments							
Comments							
14. Concord	lance						No record of any previous results.
14.1 % Concor	rdance prevent	er	%				·
14.2 Number o	of refills for the	reliever	per ho	w many weeks?	wks		
14.3 Subjective	e clinical impre	ssion of co	oncordance Good	d O			
			Sub-	optimal			
			Poor				
			Unab	ole to comment O			
Comments							

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At this point ask the patient to complete the Questionnaires (esp. ACQ 6/7 and EuroQoL-5D)

## **Questionnaires Previously Completed**

<u>CRF</u>	ACQ	6/7	EuroQol EQ-5D-5I				Epworth Sleepiness		HADS	
	<u>Date</u>	<u>Score</u>	<u>Date</u>	<u>Score</u>	<u>Date</u>	<u>Score</u>	<u>Date</u>	<u>Score</u>	<u>Date</u>	<u>Score</u>
Enrolment	13/03/2017	4.2	13/03/2017	313	13/03/2017	99	13/03/2017	18	13/03/2017	99

15. Dietary Assessment			No previous record.
15.1 Body composition assessed?	Yes O	No ○ → Q15.2 <u>Test Result</u> FFM	
		FFMi         kg/m2           SMM         kg           PhA         degrees	
15.2 Seen by asthma specialist diet	ician?		
Not required	0		
Ongoing	0	Tick ONE	
To be seen	0	only	
Discharged, treated	0		
Discharged, DNA	0		
16. Research Samples			
16.1 Date research bloods taken	DD/M		Collected 21Mar 2017
16.2 Date urine taken		M/YY	Collected 21 Mar 2017
16.3 Date sputum taken	DD/M	M/YY	Not yet collected
16b. Research Samples fo	r Patient	s Enrolled in "WATCH NIH" Study	
16b.1 Date PBMC #1 DD / M	<u>M / Y Y</u>		Not yet collected
16b.2 Date PBMC #2 D D / M	<u>M / Y Y</u>		Not yet collected
16b.3 Date PBMC #3 D D / M	<u>M / Y Y</u>		Not yet collected
16b.4 Date Sputum DD / M	<u>M / Y Y</u>		Not yet collected
16b.5 Date Bronch DD / M	<u>M / Y Y</u>		Not yet collected

17.	FeNO (Ex	haled Nitric Ox	ide)						Test last performed 21		
17.1 Was FeNO(50) done?							Mar 2017 (Enrolment CRF)				
Yes ○ No ○ → 17.2											
		→ 17.1.1 Date performed	d <u>DD/MM</u>	/ <u>Y</u> <u>Y</u>							
		17.1.2 Where done?	UHS PFT O	UHS Resea	arch Lab.	0	IOW OPD Clinic	0			
				UHS Resp.	Centre	0	Portsmouth OPD Clin	nic O			
		17.1.3 Did the patien drinking for at FeNO measure	t least 2 hours pri		Yes O		No O Unkno				
		17.1.4 Bedfont (50ml/s	sec) 1		2		3				
	17.2 Was Multi	ple Flow NO done?	(University Hospital	Southampton o	nly)				No record of any		
	Yes O	No O → Next S	ection						previous test.		
		→ 17.2.1 Date performe	d DD/MM	/ <u>Y Y</u>							
		17.2.2 Test results	Attach the results Please ensure the			clearly	on the printout.				
	Comments										
	Comments										
18.	. Spirometr	ту							No record of any previous test.		
	<b>18.1 Was Spirometry done?</b> Yes ○ → 18.2 No ○ → Next Section										
	Use historical REVERSIBILITY data if available within last 12 months										
	18.2 Date of tes	st DD/MM/Y)	<u> </u>								
	18.3 Where done? UHS PFT O		UHS Res	search Lab.	0	101	W OPD Clinic	0			
		UHS Res	sp. Centre	0	Ро	rtsmouth OPD Clinic	0				
	-	otable spirometry obtain parameters of good quality)		No	0						
	<b>18.5 Was a was</b> (SABA 4 hou	shout period observed ars and LABA 12 hours)	? Yes O	No	$0 \longrightarrow F$	Record r	esults as POST-BD				
		f short-acting β-agonis		e <u>D</u> <u>D</u> / <u>M</u>	M/Y	<u>′</u> T	ime <u>H H : M M</u>				
	(Salbutamol,	Ventolin, Terbutaline, Brical	or NA	or NA (e.g. if using maintenance inhaler as reliever)							
18.7 Last use of long-acting β-agonist (Formoterol, Fumarate, Salmeterol, Bambuterol)				D/MM/	ΥΥ	Time	НН:М <u>М</u>				
	18.8 Test result	Test results Attach the results printout to this CRF.  Please ensure the Subject No. is written clearly on the printout.									
	Comments										

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19.1 Date of test DD / M M	1 <u>Y Y</u>			No record of any previous test.			
19.2 Where done? UHS I	PFT O UHS Research L		Clinic O				
40.0 Mathadasa d							
		Other O					
Nitrogen	Nitrogen washout ○ Specify						
19.4 Test results Attach the r Please ensi							
Comments	Comments						
20. Single Breath Diffus	ion / Transfer Facto			No record of any previous test.			
20.1 Was test done?				previous test.			
Yes ○ No O →	Next Section						
→ 20.2 Date of t	est DD/MM/YY						
20.3 Where d	one? UHS PFT O UHS Re	search Lab. O IOW C	OPD Clinic O				
		Portsi	mouth OPD Clinic O				
20.4 Test res	20.4 Test results Attach the results printout to this CRF.  Please ensure the Subject No. is written clearly on the printout.						
Comments							
21. Impulse Oscillometr	y (IOS)			No record of any			
21.1 Was test done? Yes O	No O → Next Section			previous test.			
<ul><li>If Yes:</li><li>21.2 Date of tests □ □ / N</li></ul>	<u>M/YY</u>						
21.3 Where done? UHS PF	T O UHS Research		Clinic O h OPD Clinic O				
21.4 Was a washout period ol (SABA 4 hours and LABA 12 h		No ○ —> Record results	as POST-BD				
21.5 Last use of short-acting		/ <u>M</u> <u>M</u> / <u>Y</u> <u>Y</u> Time	HH:MM				
(Salbutamol, Ventolin, Terbuta	or NA (e.g. ii	f using maintenance inhaler as rei	liever)				
21.6 Last use of long-acting β (Formoterol, Fumarate, Salmete							
21.7 Test results Attach the Please er							
Comments							

22. Multiple	Breath Nitrogen Washout (MBNW) (University Hospital Southampton only)	No record of any
22.1 Was tes	t done? Yes O No O → Next Section	previous test.
	≥ 22.2 Date of test □□□/MM/YY	
	22.3 Time of test HH: MM	
	22.4 Test Results Attach the results printout to this CRF.	
	Please ensure the Subject No. is written clearly on the printout.	
Comments		•••
23. Allergy T	esting	Last tested
	test form attached?	21Mar 2017 (Enrolment CRF)
Yes O	No O	
<u></u>	23.2 Date performed DD / MM M/YY	
	23.3 Number of days H1 or H2 anti-histamines omitted?  (If greater than 3 days just enter '3')  n/a or days	
	23.4 Number of days Tricyclic Antidepressants (TCAs) omitted?  (If greater than 7 days just enter '7')  n/a or days	
Comments		
24. Alleray R	AST Testing	••••
24.1 Previous	_	
04014		
24.2 New test Aller	s carried out since last WATCH Study visit gen <u>Test Date</u> <u>Result Grade</u> <u>Notes</u>	
1.	DD/MM/YY	
2.		
۷.		1
3.		1
4		_
5.		

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25.	Sputum		No record of any previous sputums.			
	25.1 Sputum e 25.2 Sputum n					
26.	26. Bronchoscopy 26.1 Bronchoscopy performed? (Only if clinically indicated) Yes O No O					
	<b>*</b>	26.2 Date performed				
		a) Biopsies b) Brushings  Mumber Time Site of Samples  H H : M M L  H H : M M L				
	Comments	26.5 Bronchial lavage  In Out In MI				
27.		earch Study Participations	Set in			
	a) WATCH BI		Code			
	b) WATCH NIF					
	d) Panos					
	e) WSAC					
	f) UBIOPRED					
	g) SoMOSA					
	h) RASP UK					
	i) RASP Bron	ch				
	j) MEPO					
	k) MIDAS					
	Others (specify)					
	i					
	ii					
	iii					
	iv					

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