Autoenro between 2	STEP-IPF PROTOCOL =STEPIPF STUDYBOOK=DATA_FORMS NODATA <xyes> FORM=SCREENING Screening/History INTIALS Subject ID: 02 - INVSITE 2nd and 3rd char and between 5th and 6th where KIT_NUMBER='3' Subject ID: 02 - INVSITE Note: INITIALS is not Subject Initials:</xyes>
	Informed Consent first page, and then populate through all
	1 Date informed consent signed: day /
	 Date informed consent signed:
	in the biospecimen repository?
	If Yes: Date research sample consent signed:/
	If Yes: Answer all questions below (If not included in Consent mark NA):
	Blood and biologic specimens for future use by the approved investigators in studies SPEC2I <ipfyna></ipfyna>
	of pulmonary fibrosis?
	of pulmonary fibrosis?
	Demographics
	Date of birth:/
	Date of birth: ///
	3 Ethnicity (check only one): 1 Hispanic of Latino
	4 Race (check all that apply): American Indian or Alaska Native Native Hawaiian or other racific Islander
	AMERIND <xyes> AND White NATHWN<xyes> WHITE<xyes> Black or African American Other (specify): OTHPACE</xyes></xyes></xyes>
	ASIAN <xyes> BLACK<xyes> BLACK<xyes> BLACK<xyes> BLACK<xyes> BLACK<xyes> BLACK<xyes> BLACK<xyes> BLACK</xyes></xyes></xyes></xyes></xyes></xyes></xyes></xyes>
	Childbearing Potential (Complete for female subjects only)
ſ	Female of childbearing potential?
	No → If No: Provide reason (check only one):HysterectomyRest_menopausal (natural [CHU_DRQTI) (TYPE 1)
	No → If No: Provide reason (check only one): NOCBPOT <ippnch> Postmenopausal (natural [CHutzDR:QCT]) (TYPE 1) D2 Tubal ligation 98 Other (specify): NOCBSP<v:50></v:50></ippnch>
	Yes CBPOT <xyesno></xyesno>
	Smoking History
[
	Does the subject have any history of smoking?
	2 Is the AUSTEC VIRE CHREGANK>, Past smoker → Date subject last smoked:
	2 Is the AUSTEC URR < HP.F.SMIK>, Past smoker → Date subject last smoked: SMOKEM <zm@nth> your SMOKEY<i:4></i:4></zm@nth>
	3 How many total years has the subject smoked? _ <u>SMK</u> YEARS <f:9:3></f:9:3>
	4 On average during that time, how many packs (or equivalents) per day of cigarettes did the subject smoke?
	packs per day
L	SMOKPK <f:9.3></f:9.3>

CRF, page 1

Site Personnel's Initials: ____

Note on CRF page 1:

- Version 2 of the CRF changes the response set for Informed Consent, question 2. The original response set must be maintained. Screen should allow both sets of responses:
- For CRF version 2.0 16NOV2007: (Question 2 i, ii as on annotation page 1)
- For CRF version 1.0 24JUL2007 (Question 2 a,b,c,d,e as below)
- a. Blood and biologic specimens for future use in pulmonary fibrosis studies SPEC2A<IPFYNA>
- b. Blood and biologic specimens to be examined for inherited IPF factors SPEC2B<IPFYNA>
- c. Blood and biologic specimens for use in developing improved IPF treatments SPEC2C<IPFYNA>
- d. Blood and biologic specimens for use in research about other health problems SPEC2D<IPFYNA>
- e. Permission to use these biologic samples in research, even after subject's death SPEC2E<IPFYNA>



		/	-
Screen	ina	/Hie	story
9410011			

Subject ID: 02 - _______ - ______ - _________

Subject Initials: ____ ___

Disease History	
IPFCT <xyesno> 1 Did subject have a CT consistent with diagnosis of IPF prior to consent? □0 No DCTDT □1 Yes → If Yes: Date (If multiple, provide earliest): /</xyesno>	DISHIST (TYPE 1)
Screening Spirometry Date of assessment:/SPIRDT /	SPIROMET (TYPE 4)
Pre bronchodilator: FEV1 <f:9:3> Post bronchodilator: 1 FEV1: Actual: liters 4 FEV1: Actual: PSTFEV1 2 FEV6: Actual: liters 5 FEV6: Actual: 3 FVC: Actual: liters 6 FVC: Actual: PSTFV</f:9:3>	F:9:3> liters
Screening Echo 1 Date of assessment:	ECHO (TYPE 1)
 3 Right ventricular systolic pressure:,mm Hg 4 Right ventricular enlargement?	~
Lung Volume Date of assessment:	LGVOLUME (TYPE 1)



NODATA<XYES>

Screening/History

Subject ID: 02 - _______ - _____

ubiect #	Subject Initials:	

I Pre-walk modified borg Dyspace Scale rating: PREBORG PREBORG PREBORG I Pre-walk modified borg Dyspace Scale rating: PREBORG PREBORG PREBORG I Pre-walk modified borg Dyspace Scale rating: PREBORG PREBORG PREBORG I Pre-walk modified borg Dyspace Scale rating: Pre-walk modified borg Dyspace Scale rating: Pre-walk Image: State Scale rating: Pre-walk ratio State Scale Rating: State Scale Rating: State Scale Rating: Image: Scale Rating: State Scale Rating: State Scale Rating: State Scale Rating: State Scale Rating: Image: Scale Rating: State Scale Rating: State Scale Rating: State Scale Rating: State Scale Rating: Image: Scale Rating: State Scale Rating: Image: Scale Rating: State Rating:	W-					erovalu v
Image: Instrument and the second s	Screening 6-M	Ainute Walk	CTest (6MWT)			
0 0.0cds 1 2.2 3.3 3.4 5.5 6.6 7.7 8.8 9.9 10 10 97, Not done 2 Resting room or sp0;				(See page 10)		WALK (TYPE 4)
3 Was supplemental O ₂ used during walk? SUPPLO_YXYESNO2 SpO ₂ on Supplemental O ₂ :% 4 Was walk performed? No WLKND Yes SUPSPO2 5 Was walk performed? Yes WLKNDS WLKNDS 6 Was walk performed? Yes WLKNDS WLKNDS 7 Yes Yes Yes Was walk performed? Yes 9 Was walk performed? Yes Yes WLKNDS Yes 9 Was walk performed? Yes Yes Yes Yes Yes 9 Was walk performed? Yes Yes Yes Yes Yes Yes 9 Was walk performed? Yes Yes Yes Yes Yes Yes 9 Was walk performed? Yes Y	0 0 0 , 6 5	1 1 2 2 3	3 4 4 5 5	EBORG <ipfbrg> 6 6 7 7 8 8</ipfbrg>	<v:3> 9 9 10 10</v:3>	97, Not done
□, Yes 5 Was a wolking oid necessary to perform the 6MWT? □, No WALKAID <xyesno> □, Yes If Yes: Specify (deck only one): □, Cane □, Yes If Yes: Specify (deck only one): □, Cane □, Yes AIDSP<v:100> □, Yes Heart Rate Sp0, WALKTIME (TYPE 4)PS Pre-wolk □ Iminute 1 minute WLKHRpf:3> % WLKSPO2<f:9:3> 2 minutes □ bpm % 3 minutes □ bpm % 4 minutes □ bpm % 5 minutes □ bpm % 6 minutes of recovery after completion or step of 6-Minute Walk Test minute 1 Minute Post bpm % 2 minutes 2 Minutes Post □ bpm % DESATSEC<:</f:9:3></v:100></xyesno>	3 Was supplementa	I O ₂ used during v	walk?NOPPLC	SnO on	Supplemental O	
VAL\$#in#fe>IPFTMT> <i:3> Heart Rate Sp02 WALKTIME (TYPE 4)PS Pre-walk bpm bpm 1 minute bpm % 2 minutes bpm % 3 minutes bpm % 4 minutes bpm % 5 minutes bpm % 6 minutes bpm % 1 minutes bpm % 1 minutes bpm % 2 minutes of recovery after completion or step of 6-Minute Walk Test % 1 minute 1 Minute Post bpm % 2 minutes 2 Minutes Post bpm % 3 minutes/Winutes Post bpm % 6 Did subject desoturate (Sp02 ≤ 88%)? DESATSEC<!--:--> Walk duration at desaturation: meters DESATDIS Valk distance at desaturation: </i:3>	5 Was a walking air	d necessary to per	rform the 6MWT? ne): Cane Walker TY	PEAID <ipfaid><i: AIDSP<v:100< td=""><td>3></td><td></td></v:100<></i: </ipfaid>	3>	
Pre-walk bpm 1 minute bpm 2 minutes bpm 3 minutes bpm 4 minutes bpm 5 minutes bpm 6 minutes bpm 7 Hree minutes of recovery after completion or stop of 6-Minute Walk Test 1 minute 1 Minute Post 2 minutes bpm 2 minutes bpm 2 minutes bpm 1 minute 1 Minute Post 2 minutes bpm 2 minutes bpm 3 minutes bpm 2 minutes bpm 2 minutes bpm 3 minutes bpm 2 minutes bpm 2 minutes bpm 2 minutes bpm 3 minutes bpm 2 minutes bpm 3 minutes <td< td=""><td>WALS MINUTES</td><td></td><td></td><td></td><td>po₂WALKT</td><td>IME (TYPE 4)PS</td></td<>	WALS MINUTES				po ₂ WALKT	IME (TYPE 4)PS
2 minutes bpm % 3 minutes bpm % 4 minutes bpm % 5 minutes bpm % 6 minutes bpm % 7 Three minutes of recovery after completion or step of 6-Minute Walk Test % 1 minute 1 Minute Post % 2 minutes 2 Minutes Post % 3 minutes3Minutes Post % 6 Did subject desaturate (SpO2 ≤ 88%)? PSATURA <xyesno> Wes → If Yes: Walk duration ot desaturation:min /sec sec Wolk distance at desaturation:min /sec min /sec min /sec PO2<ff:9:3> Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) PO2<ff:9:3> meters Did Subject Complete 6-Minute Walk? If Stopped Signs and symptoms requiring termination of te CO_IMBLWLK<xyesno< td=""> min sec </xyesno<></ff:9:3></ff:9:3></xyesno>		<u>vii><i.>></i.></u>	bpm			
3 minutes bpm % 4 minutes bpm % 5 minutes bpm % 6 minutes bpm % 7 Three minutes of recovery after completion or stop of 6-Minute Walk Test % 1 minute 1 Minute Post bpm % 2 minutes 2 Minutes Post bpm % 3 minutes ³ Minutes Post bpm % 3 minutes ³ Minutes Post bpm % 6 Did subject desaturate (SpO ₂ ≤ 88%)? Distance walked Distance Valked Did Subject Complete If Stopped Early: Specify Reason (Check only one) PO2< <f:9:3> meters Did Subject Complete If Stopped Early: Specify Reason (Check only one) SPO2<<f:9:3> meters meters meters meters Duration: </f:9:3></f:9:3>	1 minute				% WLł	(SPO2 <f:9:3></f:9:3>
4 minutes bpm % 5 minutes bpm % 6 minutes bpm % 7 Three minutes of recovery after completion or stop of 6-Minute Walk Test % 1 minute 1 Minute Post % 2 minutes 2 Minutes Post % 3 minutes ³ Minutes Post % % 3 minutes ³ Minutes Post % % 6 Did subject desoturate (SpO ₂ ≤ 88%)? DPSATURA <xyesno> DESATMIN<!--:3--> DESATSEC<!--:</td--> Wolk distance of desoturation: meters DESATSEC<!--:</td--> weters weters Volk distance of desoturation: meters DESATDIS </xyesno>	2 minutes	·	bpm			
5 minutes bpm % 6 minutes bpm % Three minutes of recevery after completion or step of 6-Minute Walk Test % 1 minute 1 Minute Post bpm % 2 minutes 2 Minutes Post bpm % 3 minutes ³ Minutes Post bpm % 6 Did subject desaturate (SpO ₂ ≤ 88%)? DESATURA <xyesno> DESATMIN<1:3> DESATSEC<i:< td=""> Walk distance at desaturation: meters DESATSEC<i:< td=""> meters sec Valk distance at desaturation: meters DESATDIS sec sec PO2<f:9:3> DISTANCE<f:9:3> </f:9:3></f:9:3></i:<></i:<></xyesno>	3 minutes		bpm		%	
ó minutes bpm % Three minutes of recovery after completion or stop of 6-Minute Walk Test 1 minute 1 Minute Post bpm % 2 minutes 2 Minutes Post bpm % 3 minutes3Minutes Post bpm % 3 minutes3Minutes Post bpm % 6 Did subject desaturate (SpO2 ≤ 88%)? PSATURA <xyesno> DESATMIN<</xyesno>	4 minutes		bpm		%	
Three minutes of recovery after completion or stop of 6-Minute Walk Test 1 minute 1 Minute Post	5 minutes		bpm		%	
1 minute 1 Minute Post bpm % 2 minutes 2 Minutes Post bpm % 3 minutes Post bpm % 6 Did subject desaturate (SpO2 ≤ 88%)? Desatter (SpO2 ≤ 88%)? Desatter (SpO2 ≤ 88%)? Desatter (SpO2 ≤ 88%)? Valk distance at desaturation: meters DESATDIS Valk distance at desaturation: meters DESATDIS PO2 <f:9:3> Distance Walked Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) PO2<f:9:3> DISTANCE<f:9:3> minsec Developed signs and symptoms requiring termination of te CO_MESLWLK<xyesno< td=""> ge Other (specify): </xyesno<></f:9:3></f:9:3></f:9:3>	6 minutes		bpm		%	
2 minutes 2 Minutes Post bpm % 3 minutes ³ Minutes Post bpm % 6 Did subject desaturate (SpO2 ≤ 88%)? DESATURA <xyesno> DESATMIN<i:3> DESATSEC<i:< td=""> Walk distance at desaturation: min /sec walk distance at desaturation: meters DESATDIS Lowest SpO2 Distance Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) PO2<f:9:3> DISTANCE<f:9:3> meters meters min /sec Duration: meters min /sec stopped signs and symptoms requiring termination of termination of termination of termination of termination 7 Post-walk modified Borg Dyspnea Scale rating:POSTBORG<ipfbrg><v:3></v:3></ipfbrg></f:9:3></f:9:3></i:<></i:3></xyesno>			npletion or stop o	f 6-Minute Walk Test		
3 minutes3Minutes Post bpm % 6 Did subject desaturate (SpO₂ ≤ 88%)? DESATURA <xyesno> DESATMIN<i:3> DESATSEC<i:< td=""> Walk distance at desaturation: min /sec min /sec meters DESATDIS Lowest SpO₂ Distance Walked Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) PO2<f:9:3> DISTANCE<f:9:3> min </f:9:3></f:9:3></i:<></i:3></xyesno>	1 minute 1 Minute Po	ost	bpm		%	
 6 Did subject desaturate (SpO₂ ≤ 88%)? DESATURA<xyesno> DESATMIN<i:3> DESATSEC<i: Walk distance at desaturation:min /sec Walk distance at desaturation:meters DESATDIS< </i: </i:3></xyesno> Lowest SpO₂ Distance Walked Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) DISTANCE<f:9:3>meters DISTANCE<f:9:3>meters Duration:</f:9:3></f:9:3> Duration:sec Duration: Duration: Desatore Complete Duration:			bpm		%	
Walk distance at desaturation: meters DESATDIS< Lowest Sp02 Distance Walked Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) PO2 <f:9:3> DISTANCE<f:9:3> WLKMIN<i:3> WLKSEC<i:3> STOPREA<ipfrea><i:3> Duration: min sec Duration: meters STOPREA<ipfrea><i:3> Duration: min sec Duration is and symptoms requiring termination of terminatin terminatin terminatin termination of termination of terminatin</i:3></ipfrea></i:3></ipfrea></i:3></i:3></f:9:3></f:9:3>					%	
Lowest SpO2 Distance Walked Did Subject Complete 6-Minute Walk? If Stopped Early: Specify Reason (Check only one) PO2 <f:9:3> DISTANCE<f:9:3> WLKMIN<i:3> WLKSEC<i:3> STOPREA<ipfrea><i:3> Duration: /</i:3></ipfrea></i:3></i:3></f:9:3></f:9:3>	6 Did subject desatu	ırate (SpO₂ ≤ 88%,)? DESATURA< Yes → If Yes:	XYESNO> Walk duration at desc Walk distance at desa	DESATMIN< turation: turation:	:3> DESATSEC <i: min / sec ^{meters} DESATDIS<i< td=""></i<></i:
7 Post-walk modified Borg Dyspnea Scale rating:POSTBORG <ipfbrg><v:3></v:3></ipfbrg>		TORONO TORONO TORONO TORONO	6-Minute Wa	nplete If Ik?	Stopped Early (Check	: Specify Reason only one)
7 Post-walk modified Borg Dyspnea Scale rating: POSTBORG IPFBRG> <v:3> 0 0 5.5 1 1 2 2 3 4 4 5 5 6 7 7 8 8 9 1010 97, Not done</v:3>	BPO2 <f:9:3></f:9:3>	TANCE <f:9:3< td=""><td>Duration: CO₁M₂SLWLK<x< td=""><td>3> WLKSEC<i:3> SpO₂ < 4 Develope YESNO> 98 Other (s</i:3></td><td>30% STOPRI ad signs and symp pecify):S</td><td>EA<ipfrea><i:3> toms requiring termination of te TPOTHSP<v:100></v:100></i:3></ipfrea></td></x<></td></f:9:3<>	Duration: CO ₁ M ₂ SLWLK <x< td=""><td>3> WLKSEC<i:3> SpO₂ < 4 Develope YESNO> 98 Other (s</i:3></td><td>30% STOPRI ad signs and symp pecify):S</td><td>EA<ipfrea><i:3> toms requiring termination of te TPOTHSP<v:100></v:100></i:3></ipfrea></td></x<>	3> WLKSEC <i:3> SpO₂ < 4 Develope YESNO> 98 Other (s</i:3>	30% STOPRI ad signs and symp pecify):S	EA <ipfrea><i:3> toms requiring termination of te TPOTHSP<v:100></v:100></i:3></ipfrea>
		d Borg Dyspnea S	cale rating: POSTE 3 4 4 5 5	3ORG<ipfbrg><</ipfbrg> 6 6 7 7 8 8	/:3> 9.9 1010	97, Not done



Screening/History

Subject ID: 02 - ______ - _____ Subject # Subject Initials: ______

High-Resolution Computed Tomography (HRCT	/Diagnosis of IPF HRCT (TYPE 1)
Date of HRCT:///	
3. Inconsistent with IPF (Previous choice)	Clinical Center HRCTINT <ipfhrc><i:3></i:3></ipfhrc>
4. Suggests alternative diagnosis (addition to the code list) Interpretation of HRCT (check only one):	Definite IPF Consistent with IPF Suggests alternative diagnosis PULATDIA <f:9:3></f:9:3>
2 Pulmonary artery diameter:	cm AORTADIA <f:9:3></f:9:3>
3 Aorta diameter:	LUNGDIST <ipflng><i:3></i:3></ipflng>
4 Predominant craniocaudal distribution of abnormality (check only one):	□1 Lower lung □2 Mid-lung □3 Upper lung □4 Diffuse
5 Predominant axial distribution (check only one):	□ ₁ Peripheral □ ₂ Central/peribronchovascular □ ₃ Diffuse RETICULR <ipfabp></ipfabp>
6 Reticular abnormality:	Absent Present Present
7 Honeycombing:	□ ₀ Absent □1 Pr @R'DGLASS <ipfabp></ipfabp>
8 Extensive ground glass abnormality (extent > reticular abnormality):	□ ₀ Absent □ ₁ Pr MHCRONDL <ipfabp></ipfabp>
9 Profuse micronodules (present in upper, mid, and lower lung zones):	□ ₀ Absent □ ₁ Present CYSTS <ipfabp></ipfabp>
10 Discrete cysts (not in areas of honeycombing):	MOSAIC <ipfabp></ipfabp>
11 Mosaic attenuation:	□ ₀ Absent □ ₁ PresentAIRTRAP <ipfabp></ipfabp>
12 Air trapping:	CONSOLID <ipfabp></ipfabp>
13 Consolidation:	🔲 o Absent 🔄 1 Present

Screening/History

Subject Initials:



ADJPRES <IPFOUACI:35 Presence of parciny involvement ADUCHOIC <IPFIST><I:3> ADJPAREN <XYES> Absence of features against a architectural distortion, \pm honeycombing ADJFIBRO <XYES> ADJDIAG <IPFDIA><I:3> Presence of fibroblast foci → If REN <XYES> 3 3+ Chronic HP ADJCHSP <V:50> ADJSCARR <XYES> Present: Check quantity: ADJUIPDX <XYES> Clear evidence of scarring, ADJNOTDN <XYES> Adjudication **SLBIOP (TYPE 1)** of lung parenchyma 2 2 + diagnosis of UIP Other (specify): □2 Probable -+ □₃ Possible □₁ Definite □2 NSIP combing TBFIBRO <XYES TBCHOIC <IPFIST> of lung parenchyma TBPAREN <XYES> FBPRES <IPFQUA><I:3> Presence of parchy involvement □3 Chronic HP TBCHSP <V:50> Absence of features against a architectural distortion, \pm honey-Presence of fibroblast foci → If **2** 2 + **3** 3 + VOTDN <XYES> Tie-breaker TB01AG <IPFDIA><I:3> **TBSCARR<XYES**: Present: Check quantity: Clear evidence of scarring, TBUIPDX <XYES> _₀7 Not done diagnosis of UIP Other (specify): **7** Probable -+ □₁ Definite 3 Possible Subsection North m UIP □. Chronic HP CECHSP <V:50> GE PRES </Presence of paticity involvement REN <XYES Absence of features against a combing CEFIBRO <XYES> Presence of fibroblast foci → If architectural distortion, \pm honey-CEDIAG <IPFDIA><I:3> CESCARR <XYES> **2** + **3** 3 + Present: Check quantity: □ Clear evidence of scarring, CEUIPDX <XYES> of lung parenchyma Central diagnosis of UIP 4 Other (specify) □ ₉₇ Not done SLBNODN <XYES> □2 Probable **-**□1 Definite 3 Possible **_**2 NSIP of lung parenchyma CCPAREN <XYES> combing CCFIBRO <XYES> Presence of patchy involvement CCSCARR <XYES> Absence of features against a architectural distortion, \pm honey-Presence of fibroblast foci → If CCHOIC <IPFIST><I:3> Chronic HP CCCHSP <V:50> **1** 1 + **2** 2 + **3** 3 + CCUIPDX <XYES> CCDIAG <IPFDIA><I:3> Surgical Lung Biopsy/Diagnosis of IPF Present: Check quantity: Clear evidence of scarring, **Clinical Center** _4 Other (specify): diagnosis of UIP _____2 Probable □_3 Possible Definite SLBDT <DATE> **],** NSIP CCPRES <IPFQUA><I:3 Criteria for diagnosis of Confidence of diagnosis UIP (check those present): of UIP (check only one): First choice diagnosis day (check only one): Date of biopsy: 2 (7)

WHITE and YELLOW–Duke Clinical Research Institute SEP 2008 2008 DCRI – Confidential

 IPFnet Step-IPF CRF V4.0_17 SEP 2008
 2008 DCR

 STEP_IPF VERSION 7.0_17SEP2009

Site Personnel's Initials: _ PINK—retain at site



Screening/History

Subject ID: 02 - _______ - ______ - _______

Subject Initials: ____ ___

Past Medical History/Physical Fin	dings	
Does the subject have a known current or past	history of:	MEDHIST1 (TYPE 1)
1 Coronary artery disease CADHIST <xyesn< th=""><th>No 1 Yes</th><th></th></xyesn<>	No 1 Yes	
2 Acute MI ACUTEMI <xyesno></xyesno>	□ ₀ No □ ₁ Yes	
3 Valvular heart disease VALVULAR <xyesno< th=""><th>□₀ No □₁ Yes →</th><th>If Yes: Specify: VALVUSP<v:100></v:100></th></xyesno<>	□ ₀ No □ ₁ Yes →	If Yes: Specify: VALVUSP <v:100></v:100>
4 Heart failure (congestive heart failure or congestive heart disease) HFAILURE <xyesno></xyesno>	□ ₀ No □ ₁ Yes	
5 Atrial fibrillation ATRIALFB <xyesno></xyesno>	□ _o No □ ₁ Yes	
6 Intermittent claudication CLAUDICA <xyesno< th=""><th>No 1 Yes</th><th></th></xyesno<>	No 1 Yes	
7 Cirrhosis or other serious, chronic liver disease	🛛 🗤 No 🔄 🖓 Yes	
B Diabetes DIABETES <xyesno></xyesno>	□ ₀ No □ ₁ Yes	
9 Lung cancer LGCANCER <xyesno></xyesno>	□ ₀ No □ ₁ Yes	
10 Other cancer (excluding basal cell carcinoma)	\Box_0 No \Box_1 Yes \rightarrow	OTHCANSP <v:100> If Yes: Specify:</v:100>
OTHCAN <xyesno> 11 Gastroesophageal reflux disorders (GERD) GERD<xyesno></xyesno></xyesno>	D ₀ No D ₁ Yes → PHMONITR <xyes ENDOSCOP<xye< th=""><th></th></xye<></xyes 	
	UPBARIUM <xye HTBURN<xyes< th=""><th>S> Upper GI/barium swallow test</th></xyes<></xye 	S> Upper GI/barium swallow test
	ELEV <xyes> RECLIN<xyes> FOOD<xyes> NOFLAT<xyes> BEDSNK<xyes> SMLMEAL<xyes></xyes></xyes></xyes></xyes></xyes></xyes>	OR Unknown GDIAUNK <xyes> Non-pharmaceutical interventions (check all that apply): Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor Sleeping in a recliner Limiting foods and beverages that cause symptoms Avoiding lying down flat for 3 hours after a meal Avoiding bedtime snacks Eating small meals Fundoplication surgery FUNDSURG<xyes></xyes></xyes>
12 Sleep apnea (central or obstructive)	$\square_0 \text{ No } \square_1 \text{ Yes} \rightarrow$	If Yes: CPAP treatment (check only one):
SLPAPNEA <xyesno></xyesno>		□ ₁ Dail ÇPAP<ipfcpa></ipfcpa> □ ₂ Intermittent

Site Personnel's Initials: _____



Screening/History

Subject ID: 02 - _______ - ____

______ Subject Initials: _____

Past Medical History/Physical Finding	S (continued)	
Does the subject have a known current or past history	of:	MEDHIST2 (TYPE 1)
13 Asthma	O No 1 Yes	ASTHMA <xyesno></xyesno>
14 Evidence of pulmonary hypertension HYPERTEN <xyesno></xyesno>	□ _o No □ ₁ Yes → HYPRECHO <xy< th=""><th>If Yes: Source (check all heproverthe CYES)</th></xy<>	If Yes: Source (check all heproverthe CYES)
15 Emphysema or chronic bronchitis	🔲 o No 🔄 🗋 Yes	EMPHYSEM <xyesno></xyesno>
	RAYNAUDS <xyes POSANA< POSRF<xyes> MYALGIA<) SICCA<xyes> DYSPHAGA OTHTIS<xyes></xyes></xyes></xyes></xyes 	Positive ANA → Titer: <u>1</u> : Positive RF → Level: Significant arthralgia/myalgia Sicca symptoms
17 Exposure to organic or inorganic antigens known to cause interstitial lung disease (thought clinically insignificant)	□ ₀ No □ ₁ Yes	ANTIGENS <xyesno></xyesno>
18 Clubbing	□ ₀ No □ ₁ Yes	CLUBBING <xyesno></xyesno>
19 Bibasilar, inspiratory crackles	□ ₀ No □ ₁ Yes	CRACKLES <xyesno></xyesno>
20 Jugular venous distension	o No 1 Yes	JVD <xyesno></xyesno>
21 Increased P2	□ ₀ No □ ₁ Yes	INCSEPPT <xyesno></xyesno>
22 Peripheral edema	□ ₀ No □ ₁ Yes	PEREDEMA <xyesno></xyesno>
23 Other significant condition/finding	□ ₁ Yes → OTHC1 <xyes></xyes>	If Yes: Specify: OTHC1SP <v:100></v:100>
24 Other significant condition/finding OTH	□ ₁ Yes → 2 <xyes></xyes>	If Yes: Specify: OTH2CSP <v:100></v:100>

Site Personnel's Initials: ____ _



Screening/History

THIS IS A REPEATING PAGE Subject ID: 02 - ______

site # _____ subject #

OR _____ Continuing

OR , Continuing

_ Subject Initials: ___ ___

Prior Medications Record any non-study medications taken within 30 days of randomization, including over-the-counter and prescription drugs, and herbal remedies, with the exception of medications taken to treat gastroesophageal disorders, including GERD and Barrett's esophagus (record on GERD Prior Medication page). MEDLOG(TYPE 4)R **Stop Date OR** Indication **Medication Name Start Date** ✓ if Continuing MEDROWNO<I:3> MEDSTPDT MEDSTRDT MEDICATN<V:100> ____/____/____/_____year THERAPY<V:100> 1 MEDCONTUR XYES> 2 ____/____/____/_____ ____/____/___/___ WHODRUG B2 WHONAME<V:80> OR _____, Continuing WHOCODE<V:32> CODETM<DATETIME> 3 CODER<V:20> OR ____ Continuing WORKFLOW<V:5> CONFLVL<V:2> MATCHES<V:4> 4 ____/______/____/___ OR _____ Continuing WHODRUG ATC B2 ATC TERM<V:110> 5 ATC CODE<V:40> ____/____/____/_____ CODETIM2<DATETIME> OR , Continuing CODER2<V:20> WORKFLO2<V:5> 6 CONFLVL2<V:2> MATCHES2<V:4> OR , Continuing THERAP2<V:100> 7 _____/____/_____/_____veor OR , Continuing 8 OR _____ Continuing 9

10

Site Personnel's Initials: ____

CRF, page 8.____

PFnet STEP-IPF

THIS IS A REPEATING PAGE

Screening/History Subject Initials: subject # site # Subject ID: 02

NODATA<XYES>

GERD Prior Medications

Record any medications taken to treat gastroesophageal disorders, including GERD and Barrett's esophagus (e.g., proton pump inhibitors, antacids, H, receptor antagonists, metoclopramidel, taken within 30 days of randomization, including over-the-counter and prescription drugs and herbal remedieGERDLOG (TYPE 4)R GRDHTBRN<XYES> Barnett's esophagus GRDHH<XYES> GRDOSP<V:100>
 Heartburn symptoms Heartburn symptoms (Check all that apply) Indication Hiatal hernia Hiatal hernia Hiatal hernia **GRDOTH<XYES>** Barrett's esophagus Barrett's esophagus Other (specify): Other (specify): Stop Date OR Check if Continuing Cough Cough MEDSTPDT GRDCOF ЪF ЧЧ G MEDCONTU<XYES> year Continuing OR 1, Continuing year year month month month g day day day year year year MEDSTRDT Start Date <IPFREQ> month nonth nonth day (Check only one) 5 PRN (2 1/wk) PRN (5, 1/wk) 5 PRN (2 1/wk) 6 PRN (< 1/wk) 6 PRN (< 1/wk) 1 PRN (2 1/wk) Frequency A QID A QID A QID BID , BID]₃ TID QD]₃ TID 3 TID 1 QD NI<IP _<mark>98</mark> Other 98 Other 98 Other Dose GERDOSE<1:3 2 tab Ja Isp 2 tab 3 lsp J1 mg 2 tab 3 lsp J1 mg 6 mg **ODO** CORFTM+SQATEJIME> MEDICATN<V:100> WORKFLOW<V:5> GERDRWN0<1:3> WHONAME<V:80> WHOCODE<V:32> Check if self-prescribed SELFMEDS<XYES> Check if self-prescribed MATCHES<V:4> CONFLVL<V:2> WHODRUG B2 CODER<V:20> (1)

> Site Personnel's Initials: **PINK**—retain at site

CODER2<V:20>d Creck It self-prescribed WORKFL02<V:5>

Heartburn symptoms

Hiatal hernia

Cough

IPF

Barrett's esophagus

Other (specify):

OR 1, Continuing

rear

day

year

 $_{5}$ PRN ($\geq 1/wk$) BRN (< 1/wk)

_<mark>98</mark> Other

QID

2 tab 3 lsp

CODETIM2<DATETIME>

ATC_CODE<V:40>

1 mg

BID 3 TID

J, QD

WHODRUG ATC B2 ATC_TERM<V:110>

4

Heartburn symptoms

Hiatal hernia

Cough

IPF

Barrett's esophagus

Other (specify):

OR 1 Continuing

year

day

year

20

GERD'

GERDIPF<V:100> HARD CODE AS

MATCHES2<V:4>

CONFLVL2<V:2>

-0

2 BID

1 QD

BRN (< 1/wk)

_]98 Other

3 lsp

5 PRN (2 1/wk)

IPFnet Step-IPF CRF V4.0_17 SEP 2008 STEP_IPF VERSION 7.0 2008 DCRI — Confidential 17SEP2009

WHITE and YELLOW–Duke Clinical Research Institute

, Check if self-prescribed



FORM=PRERAND

NODATA<XYES> Pre-Randomization Walk 1

SEE ANNOTATION PAGE 3 Subject ID: 02 -

		\$	Subject ID: 02	site #		Subject Initials:
6-Minute W	alk Test (6MW)	-)				
	ssessment:/_		00 to 23.59	WA	LKTM	WALK (TYPE4)
1 Pre-walk modi □ 0 □ 0.5	fied Borg Dyspnea S		7 8	9	10 D ₉₇	Not done
2 Resting room o	air SpO ₂ :	%				
3 Was suppleme	ntal O ₂ used during	walk? \Box_0 No \Box_1 Yes \rightarrow If	Yes: Specify:	li	ters/min	
4 Was walk perf	formed? $\square_0 \text{ No} \rightarrow \square_1 \text{ Yes}$	Provide reason:			nental O ₂ :	%
□ ₀ No	aid necessary to pe es: Specify (check only o					
		98 Other (specify):				
6 Minutes	H	leart Rate	1	5 pO 2	WALKTI	ME(TYPE4)PS
Pre-walk		bpm				
1 minute		bpm			%	
2 minutes		bpm			%	
3 minutes		bpm			%	
4 minutes		bpm			%	
5 minutes		bpm			%	
6 minutes		bpm		9	%	
Three minutes of	recovery after co	mpletion or stop of 6-Min	ute Walk Tes	t		
1 minute		bpm			%	
2 minutes		bpm			%	
3 minutes		bpm			%	
6 Did subject des	saturate (SpO $_2 \le 88\%$	-				
		☐1 Yes → If Yes: Walk de Walk di			n: min / _ n: r	
Lowest SpO ₂	Distance Walked	Did Subject Complete 6-Minute Walk?	ŀ	f Stopp	ed Early: Spe (Check only on	
%		□ ₀ No → If No: Duration:/		ed signs	and symptoms re	quiring termination of test
		LIOW Duke Clinical Process			Site Pe	ersonnel's Initials:

WHITE and YELLOW—Duke Clinical Research Institute • PINK—ret<mark>BiAGstar</mark>EP = 1

IPFnet Step-IPF CRE V4.0 17 SEP 2008 STEP_IPF VERSION 7.0 _17SEP 2009

	rep-ipf PFnet	SEE ANNOTATIO	k	NODATA <xy Pre-Randomizatio Walk</xy
	alk Test (6MW)	,		WALK (TYP
	fied Borg Dyspnea S		00 to 23:59	WALK (TTF
0 0.5		3 4 5 6	7 8 9	10 D ₉₇ Not done
	air SpO ₂ :			
 4 Was walk perf 5 Was a walking 		walk? $\square_0 \text{ No}$ $\square_1 \text{ Yes} \rightarrow \text{ If}$ Provide reason:	SpO ₂ on Supplem	ental O ₂ :%
$\Box_0 \operatorname{No} \\ \Box_1 \operatorname{Yes} \to \operatorname{If} Ye$	e s: Specify (check only o	2 Walker		
6 Minutes		98 Other (specify):	SpO ₂	WALKTIME(TYPE4)P
Pre-walk		bpm		
1 minute		bpm	%	
2 minutes		bpm	%	
3 minutes		bpm	%	
4 minutes		bpm	%	
5 minutes		bpm	%	
6 minutes		bpm	%	
Three minutes of	recovery after co	mpletion or stop of 6-Minu	vte Walk Test	
1 minute		bpm	%	
2 minutes		bpm	%	
		bpm	%	
3 minutes				
	⊥ saturate (SpO ₂ ≤ 889	$\Box_1 \text{ Yes} \rightarrow If Yes: Walk due to the set of the s$	uration at desaturation stance at desaturation:	
	saturate (SpO₂ ≤ 889 Distance Walked	$\Box_1 \text{ Yes} \rightarrow If Yes: Walk due to the set of the s$	stance at desaturation:	
6 Did subject des		□, Yes → If Yes: Walk du Walk di Did Subject Complete	stance at desaturation: If Stoppe In SpO ₂ < 80% D Developed signs of	meters d Early: Specify Reason

 IPFnet Step-IPF CRF V4.0_17 SEP 2008
 2008 DCRI - Confidential

 STEP_IPF VERSION 7.0_17SEP2009

CRF, page 10.2



Enrollment/Week 0

Subject ID: 02 - ________ - ___________

_____ Subject Initials: ____ ___

Visit date://VISITDT	VISTDATE (TYPE 4) PAGE
Eligibility	
Did the subject meet all eligibility criteria? INCL1 <i:3> INCL2<i:3></i:3></i:3>	INCL3 <i:3></i:3>
$\Box_0 \text{ No} \rightarrow \text{ If No: Inclusion criteria not met: } \#_ \#_ \#_\$	ELIGIBLE (TYPE 1)
Exclusion criteria present: # <u>EXCL</u> 1# <u>LI:3></u> , # <u>EXCL2<i:3></i:3></u> 	EXCL3 <i:3></i:3>
Randomization	
Date of randomization:/	RANDOM (TYPE 1)
NYHA Functional Class	
1= 2= 3= 4= Current NYHA heart failure classification (check only one): 1 11 111 1V	NYHA (TYPE 4)
NYHACLAS <x< td=""><td>KCLAS></td></x<>	KCLAS>
Vital Signs	
1 Weight: 1b kg WEIGHT <f:9:3> WTUNITS<xwgt< td=""><td>^{'U>} VITALS (TYPE 4)</td></xwgt<></f:9:3>	^{'U>} VITALS (TYPE 4)
⊁⊞⊛ਆः <e:9:3></e:9:3> □₁ in □₂ cm HTUNITS <xhgtu> (Height only on p</xhgtu>	age 11)
BPSYS <i:3> BPDIA<i:3></i:3></i:3>	
3 Blood pressure: / mm Hg	
4 Heart rate: HRATE <i:3< td=""><td></td></i:3<>	
SPO2 <f9:3> ONLY ON PAGE 112</f9:3>	

FORM=ENROLLMENT

**VISTDATE PANEL (FOR PAGE 47 and 86 ONLY) EARLYTER <XYES> (FOR PAGE 112 ONLY) UNSCHREA<IPFUNS> AND UNSCHSP<V:100>

Site Personnel's Initials: _____



Enrol	Iment,	/W	eek	0
			0014	-

Subject ID: 02 - _______ - _____ - _______

Subject Initials: ____

Spirometry*	
Date of assessment:/	SPIROMET(TYPE 4)
1 FEV1: Actual: liters FEV1 <f:9:3></f:9:3>	SEE ANNOTATION P.2 NOTE: DO NOT ADD QUESTIONS
2 FEV ₆ : Actual: liters FEV6 <f:9:3></f:9:3>	4,5,6
3 FVC: Actual: liters FVC <f:9:3></f:9:3>	
Diffusing Capacity of the Lung for Carbon Mo	noxide (dlco)*
Date of assessment:/	DLCO(TYPE 4)
1 DLCO: Actual:	.co (National Jewish only): ALTIDLCO <f:9:3> mL/min/mm Hg</f:9:3>
2 VI (inspired volume): VI <f:9:3>liters</f:9:3>	
3 VA (alveolar volume): liters	
Arterial Blood Gas (ABG)*	
Date of assessment:/	ABG(TYPE 4)
Barometric pressure: mm Hg BARPRESS><1:3>	
2 Clinic altitude (check only one): $\Box_1 < 4000 \text{ ft}$ $\Box_2 \ge 4000 \text{ ft}$ ALTITU	JDE <ipfalt><i:3></i:3></ipfalt>
3 FiO ₂ :% FIO2 <i:3></i:3>	
4 pH: PH <f:9:3> PAO2<i:3></i:3></f:9:3>	
5 PaO ₂ : mm Hg	
6 PαCO ₂ : mm Hg PACO2 <i:3></i:3>	
7 SaO ₂ :% SAO2 <i:3></i:3>	

*Screening visit may be used if within 14 days of enrollment.



NODATA<XYES>

Enrollment/Week 0

	Sub	ject ID: 02	#	Subject Initials:
S	elf-administered Questionnaires	-44 <u>65</u> 5	na siya karan	
Do	ate administered:/		SEL	FREPT(TYPE 4)
1	EuroQol EURORPT <ipfsef><i:3></i:3></ipfsef>	. 🔄 1 Attached	97 Not done	
2	SF-36 SF36RPT <ipfsef><i:3></i:3></ipfsef>	. 🔲 1 Attached	97 Not done	
3	UCSD Shortness-of-Breath	. 🔲 1 Attached	□ ₉₇ Not done	
4	St. George's Respiratory STGRGRPT <ipfsef><1:3></ipfsef>	. 🔲 1 Attached	97 Not done	
5	ICERPT <ipfsef><i:3></i:3></ipfsef>	. 🗌 1 Attached	97 Not done	
6	GENDRPT <ipfsef><i:3> Gender Substudy Questionnaire</i:3></ipfsef>	. 🔲 Attached	97 D ₉₇ Not done	96 96 NA (male)





Enrollment/Week 0

Subject ID: 02 - _______ - ______ subject #

Subject Initials: ____

describe your own health state today.	EUROQOL1 (TYPE
 Mobility: □₁ I have no problems in walking about □₂ I have some problems in walking about □₃ I am confined to bed 	IOB <ipfemo><i:3></i:3></ipfemo>
2 Self-care: Et □₁ I have no problems with self-care □₂ I have some problems washing or dressing m □₃ I am unable to wash or dress myself	QSC <ipfesc><i:3> iyself</i:3></ipfesc>
3 Usual activities (e.g., work, study, housewor □, I have no problems with performing my usua □, I have some problems with performing my us □, I am unable to perform my usual activities	activities
 4 Pain/discomfort: □₁ I have no pain or discomfort □₂ I have moderate pain or discomfort □₃ I have extreme pain or discomfort 	QPAIN <ipfepn><i:3></i:3></ipfepn>
 5 Anxiety/depression: □₁ I am not anxious or depressed □₂ I am moderately anxious or depressed □₃ I am extremely anxious or depressed 	QANX <ipfean><i:3></i:3></ipfean>
you are ready for the Eu	STOP. Idy coordinator know that IroQol Thermometer worksheet.
EuroQol Thermometer Response (Stud	v staff use only)



Enrollment/Week 0

Eu	uroQol Questionnaire EQ-5D (continued)
	ecause all replies are anonymous, it will help us to understand your answers better if we ave a little background data from everyone, as covered in the following questions. EUROQOL2 (TYPE
	Have you experienced serious illness: in you yourself? in your family? in caring for others? No No Yes EQILLYOU <xyesno> EQILLFAM<xyesno> EQILLFAM<xyesno> EQILLOTH<xyesno></xyesno></xyesno></xyesno></xyesno>
2	What is your age in years?
	Are you (please check appropriate box): , Male <u>EQGENDR<xgendr></xgendr></u>
4	Are you (please check only one): An ex-smoker A never smoker
5	Do you now, or did you ever, work in health or social services? □No EQWKHL <xyesno> □Yes → If Yes: In what capacity? EQWKHLSP <v:100></v:100></xyesno>
6	Which of the following best describes your main activity (please check only one)? 1 Employed (including self employment) 2 Retired EQACT <ipfeac><i:3> _3 Keeping house 4 Student 5 Seeking work 98 Other (please specify):</i:3></ipfeac>
7	What is the highest level of education you have completed (please check only one)? Some high school or less High school graduate or GED Vocational college or some college College degree Professional or graduate degree EQEDU <ipfedu><i:3></i:3></ipfedu>
8	If you know your zip code, please write it here:EQZIP <i:5></i:5>



Enrol	lment/	Week	0
Enrol	lment/	Week	0

Subject ID: 02 - _______ - ______ - ______

Subject Initials: ___ ___

S	F-36 Assessment				
1	In general, would you say your health is: SF1 <xcond><i:3> ₁ Excellent □₂ Very good □₃ Good □₄ Fair □₅ Poor</i:3></xcond>	SF3	6_1(T	YPE 4	•)
2	<u>Compared to one year ago</u> , how would you rate your health in general				
	\square_1 Much better than one year ago \square_3 About the same as one year ago \square_2 Somewhat better than one year ago \square_4 Somewhat worse than one year ago			orse nov e year a	
3	The following items are about activities you might do during a typical do		Yes,	Yes,	No, Not
	Does <u>your health now limit you</u> in these activities? If so, how much?		Limited A Lot	Limited A Little	Limited At All
	a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports SF3A <ipfact><i:3></i:3></ipfact>		\Box_1		□₃
	b. Moderate activities, such as moving a table, pushing a vacuum cleaner.			_ 2	
	bowling, or playing golf SF3B <ipfact><i:3> c. Lifting or carrying groceries SF3C<ipfact><i:3></i:3></ipfact></i:3></ipfact>			2	
	d. Climbing several flights of stairs			 2	□₃ □₃
	e. Climbing one flight of stairs SF3E <ipfact><i:3></i:3></ipfact>			2 	□_3 □_3
	f. Bending, kneeling or stooping				3 □_3
	g. Walking more than a mile SF3G <ipfact><i:3></i:3></ipfact>			2	\square_3
	h. Walking several blocks SF3H <ipfact><i:3></i:3></ipfact>		\Box	\square_2	□ ₃
	i. Walking one block SF3I <ipfact><i:3></i:3></ipfact>				
	j. Bathing or dressing yourselfSF3J <ipfact><i:3></i:3></ipfact>				\square_3
4	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of your physical health</u> ?	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Cut down on the amount of time you spend on work or other activities		3		5
	b. Accomplished less than you would like		\square_3		□ ₅
	c. Were limited in the kind of work or other activities $SF4C < IPFTIM > < \frac{1:3}{1}$	_ 2			5
	d. Had difficulty performing the work or other activities (for example, it took extra effort)	_ 2	3	_ 4	_ 5
5	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of any emotional problems</u> (such as feeling depressed or anxious)?	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Cut down on the amount of time you spend on work or other activities <u>SF5A<ipftim><1:3></ipftim></u>		3	4	_ 5
	b. Accomplished less than you would like SF5B <ipftim><1:3></ipftim>		3		5
	c. Did work or other activities less carefully than usual	 2	3		5

WHITE and YELLOW-Duke Clinical Research Institute
 PINK-retain at site



Enrol	Iment/Week	0
		-

Subject ID: 02 - _______ - ______ - _______

Subject Initials: _____

S	-36 Assessment (continued)					
6	During the <u>past 4 weeks</u> , to what extent has your physical interfered with your normal social activities with family, frie 1 Not at all 2 Slightly 3 Moderately 4 Quite a bit SF6 <ipfxtn><i:3></i:3></ipfxtn>	ends, ne	ighbors	, or gro		4)
١,	How much <u>bodily</u> pain have you had during the <u>past 4 we</u>			01 30_	2(111 E	-,
ľ	\square_1 None \square_2 Very mild \square_3 Mild \square_4 Moderate \square_5 Sever		Very seve	er <mark>\$</mark> F7 <ip< th=""><th>FBPN><</th><th>:3></th></ip<>	FBPN><	:3>
8	During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with outside the home and housework)? \Box_1 Not at all \Box_2 Slightly \Box_3 Moderately \Box_4 Quite a bit	-	:		uding botl XTN <i:3></i:3>	
9	These questions are about how you feel and how things have been feeling.					
	How much of the time during the <u>past 4 week</u> s	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Did you feel full of life? SF9A <ipftim><i:3></i:3></ipftim>			\square_3		□ ₅
	b. Have you been very nervous? SF9B <ipftim><i:3></i:3></ipftim>					□ ₅
	c. Have you felt so down in the dumps that nothing could cheer you up?			□ ₃		5
	d. Have you felt calm and peaceful? <u>SF9D<ipftim><1:3></ipftim></u>		2			5
	e. Did you have a lot of energy? SF9E <ipftim><i:3></i:3></ipftim>			_ 3		5
	f. Have you felt downhearted and depressed?SE9E <ipetim< th=""><th>>∢I:β></th><th>2</th><th>_3</th><th>4</th><th>5</th></ipetim<>	> ∢I: β>	2	_ 3	4	5
	g. Did you feel worn out?SF9G <ipftim><i:3></i:3></ipftim>		 2			_ 5
	h. Have you been happy? SF9H <ipftim><i:3></i:3></ipftim>		2	□_ ₃		5
	i. Did you feel tired?SF9I <ipftim><i:3></i:3></ipftim>		 2	□_ ₃		_ 5
10	During the <u>past 4 weeks</u> , how much of the time has your <u>p</u> problems interfered with your social activities (like visiting fri				onal	
	\square_1 All of the time \square_2 Most of the time \square_3 Some of the time SF10 <ipftim><i:3></i:3></ipftim>				I₅ None of	the time
11		Definitely		Don't Know	Mostly False	Definitely False
	a. I seem to get sick a little easier than other people	\Box_1	_ 2	3	_ 4	_ 5
	b. I am as healthy as anybody I know SF11B <ipftru:< th=""><th>><<mark> :3</mark>></th><th>2</th><th>□_3</th><th></th><th>5</th></ipftru:<>	>< <mark> :3</mark> >	2	□_3		5
	c. I expect my health to get worseSF11C <ipftru:< th=""><th>><[:3]></th><th></th><th>□_3</th><th></th><th>□₅</th></ipftru:<>	><[:3]>		□_3		□ ₅
	d. My health is excellentSF11D <ipftru:< th=""><th>>< :3></th><th>2</th><th>□_3</th><th></th><th>_5</th></ipftru:<>	>< :3 >	 2	□_3		_ 5

WHITE and YELLOW-Duke Clinical Research Institute
• PINK-retain at site



Enrollment/Week 0

		Subject ID:	02 - <u></u> site		Sub	ject Initials:
				# S00	<u>JCSDSC</u>)B1(TYPE 4)
UCSD Shortness-of-Breath Questie	onnaire	UCSD SO	BQ			
When I do, or if I were to do, the following tasks, I would rate my breathlessness as <mark>a</mark> ll <i:1> <ipfucs></ipfucs></i:1>	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest UCSD1	0= 0	1= 1	<mark>2=</mark> 2	3= 3	4= 4	<mark>5=</mark> 5
2 Walking on a level at your own pace UCSD2	0	1	2	3	4	5
 Walking on a level with others your age UCSD3 	0	1	2	3	4	5
4 Walking up a hill UCSD4	0	1	2	3	4	5
5 Walking up stairs UCSD5	0	1	2	3	4	5
6 While eating UCSD6	0	1	2	3	4	5
7 Standing up from a c <mark>h@5D7</mark>	0	1	2	3	4	5
8 Brushing teeth UCSD8	0	1	2	3	4	5
UCSD9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing UCSD10	0	1	2	3	4	5
11 Dressing UCSD11	0	1	2	3	4	5
UCSD12 12 Picking up and straightening	0	1	2	3	4	5

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Enrollment/Week 0

		Subject I	D: 02	te # =	Sul	oject Initials:
UCSD Shortness-of-Breath Quest	ionnair				UCSDSO	DB2(TYPE 4)
When I do, or if I were to do, the following tasks, I would rate my breathlessness as: All <1:1> <1PFUCS	None At All	1=		3=	Severe	Maximal/ Unable To Do Because of Breathlessness 5=
13 Doing dishes UCSD13	0	1	<mark>2=</mark> 2	3	4= 4	5
14 Sweeping/vacuuming UCSD14	0	1	2	3	4	5
15 Making bed UCSD15	0	1	2	3	4	5
16 Shopping UCSD16	0	1	2	3	4	5
17 Doing laundryUCSD17	0	1	2	3	4	5
18 Washing car UCSD18	0	1	2	3	4	5
19 Mowing lawn UCSD19	0	1	2	3	4	5
20 Watering lawn UCSD20	0	1	2	3	4	5
21 Sexual activities UCSD21	0	1	2	3	4	5
How much do these limit you in your dai	ly life?					
22 Shortness of breat CSD22	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
UCSD24 24 Fear of shortness of breath	0	1	2	3	4	5



Enrollment/Week 0

Subject ID: 02 - ______ - _______ subject #

Subject Initials: ____

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)
STGRG1 (TYPE 4)
This questionnaire is designed to help us learn much more about how your breathing
is troubling you and how it affects your life. We are using it to find out which aspects of
your illness cause you the most problems, rather than what the doctors and nurses
think your problems are.
Please read the instructions carefully and ask if you do not understand anything.
Do not spend too long deciding about your answers.
bo hor spend loo long deciding about your driswers.
Before completing the questionnaire:
Please check one box to show how you describe your current health: 🚺 Very good
2 Good
CURHLTH <ipfchl><i:3> 3 Fair</i:3></ipfchl>
⁴ Poor
5
very poor

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Enrollment/Week 0

Subject ID: 02 - _______ - ________

Subject Initials: ____ __

St. George's Respiratory Questionnaire Part 1 Please describe how often your respiratory problems have affected you over the past 4 weeks. **A Few** Only with Several Almost Not Please check 🗹 one box for each question. Days a Days a Respiratory **Every Day** At All Week Month Infections All are <XYES> STG1A STG1B STG1D STG1E STG1C 1 Over the past 4 weeks, I have coughed: 2 Over the past 4 weeks, I have brought up STG2A STG2B STG2D STG2E STG2C phlegm (sputum): STG3A STG3B STG3C STG3D STG3E 3 Over the past 4 weeks, I have had shortness of breath: STG4C STG4D STG4E 4 Over the past 4 weeks, I have had wheezing STG4A STG4B attacks: 5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check ✓ one: More than 3 times STG5A<XYES> STG5B<XYES> 3 times STG5C<XYES> 2 times STG5D<XYES> 1 time STG5E<XYES> None of the time 6 How long did the worst respiratory attack last? Please check ∠ one: (Go to question 7 if you did not have a severe attack) A week or more STG6A<XYES> □ 3 or more days STG6B<XYES> 1 or 2 days STG6C<XYES> Less than a day STG6D<XYES> 7 Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had? Please check 🗸 one: □ No good days STG7A<XYES> 1 or 2 good days STG7B<XYES> 3 or 4 good days STG7C<XYES> Nearly every day was good STG7D<XYES> Every day was good STG7E<XYES> 8 If you wheeze, is it worse when you get up in the morning? Please check 🗹 one: No. STG8<XYESNO> , Yes



Enrollment/Week 0

Subject ID: 02 - ________ - _______ Subject Initials: ______

St. George's Respiratory Questionnaire Part 2	
Section 1	STGRG3 (TYPE 4)
9 How would you describe your respiratory condition? Please check ✓ on ☐ The most important problem I have STG9A <xyes> ☐ Causes me quite a lot of problems STG9B<xyes> ☐ Causes me a few problems STG9C<xyes> ☐ Causes me no problems STG9D<xyes></xyes></xyes></xyes></xyes>	
 10 If you have ever held a job (please check one): My respiratory problems made me stop working altogether My respiratory problems interfere with my job or made me change my job My respiratory problems do not affect my job 	STG10A <xyes> STG10B<xyes> STG10C<xyes></xyes></xyes></xyes>
Section 2	
These are questions about what activities usually make you feel short of br	eath <u>these</u> <u>day</u> s.
For each statement, please check 🗹 the box that applies to you these da	iys.
11 Sitting or lying stillSTG11A <ipftof><i:3></i:3></ipftof>	
Washing or dressing yourself	1 Trueo False
Walking around the house STG11C <ipftof><i:3></i:3></ipftof>	
Walking outside on a level ground <u>STG11D<ipftof><i:3></i:3></ipftof></u>	1 Trueo False
Walking up a flight of stairs	🔲 1 True 📃 o False
Walking up hillsSTG11F <ipftof><i:3></i:3></ipftof>	🗋 True 🔲 Galse
Playing sports or other physical activities STG11G<ipftof><i:3></i:3></ipftof>	🗋 , True 📃 o False
Section 3 12 These are more questions about your cough and shortness of breath <u>the</u>	<u>əse</u> days.
For each statement, please check 🗹 the box that applies to you these	
Coughing hurts	<mark>l:3></mark> … □, True □₀ False
Coughing makes me tired	
I am short of breath when I talk	a (n)
I am short of breath when I bend over	
My coughing or breathing disturbs my sleep	
I get exhausted easily	🗋 , True 🗖 Galse

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Enrollment/Week 0

Subject ID: 02 - ______ - _____ - ______

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St. George's Respiratory Questionnaire Part 2 (continued) STGRG4 (TYPE 4)								
 Section 4 13 These are questions about other effects that your respiratory problems may have on you <u>these</u> <u>days</u>. 								
For each statement, please check 🗹 the box that applies to you these days.								
My cough or breathing is embarrassing in publicSTG13A <ipftof><i:3>, True, False</i:3></ipftof>								
My respiratory problems are a nuisance to my family, friends or neighbors								
I get afraid or panic when I cannot catch my breathSTG13C <ipftof><i 37="" false<="" th="" true=""></i></ipftof>								
STG13D <ipftof><i:3> I feel that I am not in control of my respiratory problems, True</i:3></ipftof>								
I do not expect my respiratory problems to get any better								
I have become frail or an invalid because of my respiratory problems, True, False								
Exercise is not safe for meFalse								
Everything seems too much of an effortSTG13H <ipftof><i< td=""></i<></ipftof>								
 Section 5 14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6. 								
For each statement, please check 🗹 the box that applies to you these days.								
STG14A <ipftof><i:3> My treatment does not help me very much</i:3></ipftof>								
I get embarrassed using my medication in public								
STG14C <ipftof><i:3> I have unpleasant side effects from my medication</i:3></ipftof>								
My treatment interferes with my life a lotSTG14D <ipftof><i37 false<="" th="" true=""></i37></ipftof>								



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Subject ID:	02	 	-

_____ Subject Initials: ___ ___

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St. George's Respiration Questionnaire Part 2 (continued)	
Section 6	STGRG5 (TYPE 4)
15 These are questions about how your activities might be affected by your r	espiratory problems.
For each statement, please check 🗹 the box that applies to you because of your r e	espiratory problems.
I take a long time to get washed or dressed <u>STG15A<ipftof><i< u=""></i<></ipftof></u>	:3≥ ₁ True □ ₀ False
I cannot take a bath or shower, or I take a long time to doi 1615B <ipftof< td=""><td>רסואים רמוצים <mark>אייייייייייייייייייייייייייייייייייי</mark></td></ipftof<>	רסואים רמוצים <mark>אייייייייייייייייייייייייייייייייייי</mark>
I walk slower than other people my age, or I stop to rest <mark>STG15C<ipftof< mark=""></ipftof<></mark>	
STG15D <ipftof Jobs such as household chores take a long time, or I have to stop to rest</ipftof 	>< <mark> :3></mark> □ ₁ True □ ₀ False
If I walk up one flight of stairs, I have to go slowly or stop	TOF> <i:3> </i:3>
If I hurry or walk fast, I have to stop or slow downSTG15F <ipf< td=""><td>TOF ><!--:3--> False</td></ipf<>	TOF > :3 False
My breathing makes it difficult to do things such as walk up hills, carry	
Alert on screen: Following question such as weeding, dance, bowl, or play s not on pre-version 3 CRFs	STG15G<ipftof><i:3></i:3></ipftof> □ ₁ True □ ₀ False
My breathing makes it difficult to do things such as carry heavy loads,	STG15H <ipftof><i:3></i:3></ipftof>
dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	□ ₁ True □ ₀ False
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	STG15I <ipftof><i:3></i:3></ipftof>
Section 7 16 We would like to know how your respiratory problems <u>usually</u> affect you	r daily life.
For each statement, please check 🗹 the box that applies to you because of your r e	espiratory problems.
I cannot play sports or do other physical activities STG16A <ipftof< td=""><td>F><1:3></td></ipftof<>	F><1:3>
I cannot go out for entertainment or recreation STG16B <ipftor< td=""><td>F>ch:3></td></ipftor<>	F>ch:3>
I cannot go out of the house to do the shopping	F><1:3>
I cannot do household choresSTG16D <ipftof< td=""><td>^E><i;3≫< b="">ue □_o False</i;3≫<></td></ipftof<>	^E > <i;3≫< b="">ue □_o False</i;3≫<>
I cannot move far from my bed or chairSTG16E <ipftof< td=""><td>F><1:3> 1 True False</td></ipftof<>	F><1:3> 1 True False





Enrollment/Week 0

Subject ID: 02 - _______ - _____

_ Subject Initials: _

______subject #_____subject init

St. George's Respiratory Questionnaire (continued)

STGRG6 (TYPE 4)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

- · Going for walks or walking the dog
- · Doing activities or chores at home or in the garden
- Sexual intercourse
- · Going to a place of worship, or a place of entertainment
- · Going out in bad weather or into smoky rooms
- · Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

STGLIST<V:200>

17 Now please check the box (one only) that you think best describes how your respiratory problems affect you:

t does	not	stop	me	rom	do	ing	any	/thing	1	would	like	to	do
										اداد مدر			

It stops me from doing one or two things I would like to do

☐ It stops me from doing most of the things I would like to do

It stops me from doing everything I would like to do

STG17A<XYES> STG17B<XYES> STG17C<XYES> STG17D<XYES>

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.



Enrollment/Week 0

Subject ID: 02 - _______ - ___________

Subject Initials: ____

ICECAP Questionnaire

By placing a check ∠ in one box in each group below, please indicate which statement best describes your quality of life at the moment. ICECAP (TYPE 4)

Love and Friendship ICELOVE <ipfluv><i:3></i:3></ipfluv>	\Box_1 I can have all of the love and friendship that I want \Box_2 I can have a lot of the love and friendship that I want \Box_3 I can have a little of the love and friendship that I want \Box_4 I cannot have any of the love and friendship that I want
Thinking about the future ICEFUTR <ipffut><i:3></i:3></ipffut>	□ ₁ I can think about the future without any concern □ ₂ I can think about the future with only a little concern □ ₃ I can only think about the future with some concern □ ₄ I can only think about the future with a lot of concern
Doing things that make you feel valued ICEVALUE <ipfval><i:3></i:3></ipfval>	\Box_1 I am able to do all of the things that make me feel valued \Box_2 I am able to do many of the things that make me feel valued \Box_3 I am able to do a few of the things that make me feel valued \Box_4 I am unable to do any of the things that make me feel valued
Enjoyment and pleasure ICEENJOY <ipfjoy><i:3></i:3></ipfjoy>	\Box_1 I can have all of the enjoyment and pleasure that I want \Box_2 I can have a lot of of the enjoyment and pleasure that I want \Box_3 I can have a little of the enjoyment and pleasure that I want \Box_4 I cannot have any of the enjoyment and pleasure that I want
Independence ICEINDEP <ipfind><i:3></i:3></ipfind>	 I am able to be completely independent I am able to be independent in many things I am able to be independent in a few things I am unable to be at all independent

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Enrollment/Week 0

Subject ID: 02 - _______ -

Subject Initials: ____

subject #

Gender Substudy Questionnaire

To be completed by female participants only

We want to thank you in advance for answering several additional questions. Because the cause of IPF is not well understood, 1 we are trying to learn more about who gets the disease. We know that in general, women are less likely to develop pulmonary fibrosis. This may be related to estrogen, a hormone more common in women. Therefore we are asking that all female study participants answer several questions related to estrogen exposure which may help us better understand the disease.

1	At what age did you begin monthly menstruation (monthly period)?	PERIOD <i:3> years old</i:3>
2	Have you reached menopause?	$\Box_{0} \text{ No} \rightarrow \text{ If No, skip to question 4}$ $\Box_{1} \text{ Yes} \qquad \text{MENOPAUS}{<}XYESNO$
3	If you have reached menopause, at what age did that occur?	years old MENOAGE <f:9:3></f:9:3>
4	Did you ever use oral contraceptive medications?	$\Box_{0} \text{ No} \rightarrow \text{If No, skip to question 6}$ $\Box_{1} \text{ Yes} \text{ NOPREG}$
5	If you did use oral contraceptives, for how many years?	years NOPREGYS <f:9:3></f:9:3>
6	Did you ever use hormone replacement therapy?	$\Box_{0} \text{ No} \rightarrow \text{If No, skip to question 8}$ $\Box_{1} \text{ Yes} \qquad \qquad$
7	If you did use hormone replacement therapy, for how many years?	HRTYRS <f:9:3></f:9:3>
8	Have you ever been pregnant (include miscarriages, abortions)?	$\Box_{0} \text{ No} \rightarrow \text{ If No, skip to question 14}$ $\Box_{1} \text{ Yes } \text{ PREGNANT < XYESNO>}$
9	If you have been pregnant, how old were you at the time of your first pregnancy?	years old PREGNAGE <f:9:3></f:9:3>
10	How many times have you been pregnant?	PREGNUMB <i:3></i:3>
11	What were the sex of your children, born and unborn?(Check only one)BABYGEND <ipfbab><i:3:< td=""></i:3:<></ipfbab>	□, All male 99 = UNKNOWN □₂ All female □₃ Male and female
12	Did you ever breastfeed?	\square_0 No → If No, skip to question 14 \square_1 Yes BRESFEED<xyesno></xyesno>
13	If you did breastfeed, for approximately how many total months did you breastfeed (total for all pregnancies)?	months BRFEEDNO <f:9:3></f:9:3>
14	Have you ever had an ovary removed?	$\Box_{0} \text{ No} \rightarrow \text{If No, end of questions}$ $\Box_{1} \text{ Yes} \text{OVREM-XYESNO>}$
15	If you had an ovary removed, was one removed or both?	OVNUM <ipfovr><1:3></ipfovr>
16	At what age was your ovary or ovaries removed?	OVAGE <f:9:3></f:9:3>



	Subject ID: 02 Subject Initials:	
Vis	it date:/// SEE ANNOTATION P.11 VISTDATE (TYPE 4)	
Vi	ital Signs	
1	Weight:	
2	Blood pressure:/ MH HE ANNOTATION P.11 systolic diastolic MH HE EXCEPT NO HEIGHT or SPO2	
G	ERD Substudy Review	
	Record all GERD related medications in the GERD Concomitant Medications log	
1	Have there been any changes in the subject's GERD status since last visit? $\Box_0 \text{ No} \rightarrow \text{Skip to question 3}$ GERDCHGS <xyesno> GERDSUB(TYPE 4) $\Box_1 \text{ Yes} \rightarrow \text{ If Yes: Check only one:}$</xyesno>	
GE	Image: Strict only one. Image: Strict one.	
2	If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below: Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor Sleeping in a recliner	> 10> 0>
3	Have there been any changes in the subject's obstructive sleep apnea status since last visit? □ No → Skip to Safety Review APNEACHG <xyesno> □ Yes → If Yes: Check only one: □ Newly diagnosed → Record on Adverse Event Log □ Changes in CPAP treatment □ Changes in CPAP treatment □ Skip to Safety Review If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment: □ None □ Daily □ Intermittent NEWCPAP<ipfcpa><i:3></i:3></ipfcpa></xyesno>	
	afety Review s the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care	
(e.	g., clinic, study visit, hospitalization)?	
	No □ ₁ Yes → If Yes: Please send support materials for acute exacerbation review. SAFETY (TYPE 4) WORSDYSP <xyesno></xyesno>	
	Record any new Adverse Events on the Adverse Event Log page. Record any new or changed medications on the Concomitant Medications Log page.	

Site Personnel's Initials: _____

NODATA<XYES>

Week 1



NODAT	ΓA <xyes></xyes>
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Week 6

Subject ID: 02 - _______ - _ _______ - __________

Subject Initials: ___ ___

SEE ANNOTATION P.11	VISTDATE (TYPE 4)
ANNOTATION P.11 E: EXCEPT NO HEIGHT or SPO2	VITALS (TYPE 4)
'y one): 🗌 I 🗌 II 🗌 III 🗌 IV	NYHA (TYPE 4)
E ANNOTATION P.11	
– SEE ANNOTA NOTE: DO NO 4,5,6	SPIROMET(TYPE 4) ATION P.2 OT ADD QUESTIONS
or Carbon Monoxide (DLCO)
→ Altitude-corrected DLCO (National Jewish o SEE ANNOTATION P.12	DLCO (TYPE 4) nly): · mL/min/mm Hg
	SEE ANNOTATION P.11 ANNOTATION P.11 E: EXCEPT NO HEIGHT or SPO2 y one): □ 1 □ 11 □ 111 □ 1V E ANNOTATION P.11 - SEE ANNOTATION P.11 - SEE ANNOTATION P.11 - SEE ANNOTATION P.11 - SEE ANNOTATION P.11 - SEE ANNOTATION P.11 - Altitude corrected DLCO (National Jewish of the second se



SEE ANNOTATION P.3

NODATA<XYES>

Week 6

		Su	ubject ID: 02	subjec	Subject Initials:			
6-Minute W	alk Test (6MW)	т)						
	t:/				WALK (TYPE 4)			
Pre-walk modi	fied Borg Dyspnea S	Scale rating:] 3	7 8 9	10	□ ₉₇ Not done			
2 Resting room o	iir SpO ₂ :	%			pa.			
3 Was suppleme	3 Was supplemental O ₂ used during walk? □ ₀ No □ ₁ Yes → If Yes: Specify: liters/min SpO ₂ on Supplemental O ₂ : %							
4 Was walk perf	formed? □ ₀ No →	Provide reason:			· /•			
□ ₀ No	aid necessary to pe es: Specify (check only o							
		ge Other (specify):		WA	LKTIME (TYPE 4)			
6 Minutes	F	leart Rate	SpO ₂		· · · · · ·			
Pre-walk		bpm						
1 minute		bpm	%					
2 minutes		bpm	%					
3 minutes		bpm	%					
4 minutes		bpm	%					
5 minutes		bpm	%					
6 minutes		bpm	%					
Three minutes of 1 minute	recovery after co	mpletion or stop of 6-Minu	te Walk Test %					
2 minutes		bpm bpm	^					
3 minutes		bpm	%					
	aturate (SpO₂ ≤ 88%		%					
a	, , , , , , , , , , , , , , , , , , , ,	\Box_1 Yes \rightarrow If Yes: Walk du						
			stance at desaturation:					
Lowest SpO ₂	Distance Walked	Did Subject Complete 6-Minute Walk?		Check o	: Specify Reason nly one)			
·_%	meters	$\Box_{0} \text{ No} \rightarrow \text{ If No:}$ $Duration: \underline{/}_{min} / _{sec}$ $\Box_{1} \text{ Yes}$			oms requiring termination of test			
7 Post-walk mod □ 0 □ 0.5	ified Borg Dyspneo	Scale rating:] 3	7 8 9	10	□ ₉₇ Not done			

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Site Personnel's Initials: ____ _

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Week 6

Subject ID: 02			
	site #	subject #	

Subject Initials: ____ ___

	Outpatient Visits Has the subject required any non-urgent outpatient visits since the last stud $\Box_0 \text{ No } \Box_1 \text{ Yes} \rightarrow \text{ If Yes: Provide details below.}$	ly visit (do not include protoco OUTPATNT (T	
	NONURGNT <xyesno> Provider Type PROVTYPE<ipfpro><i:3> OUTPTSP<v:100></v:100></i:3></ipfpro></xyesno>	No. of Respiratory- related Visits	No. of Non-respiratory- related Visits
1=	1 Pulmonologist	RESVITNO <i:3></i:3>	NONRESNO <i:3></i:3>
2=	2 Cardiologist		
3=	3 Other specialist:		
4=	4 Primary care physician (or NP or PA)		
5=	5 OT or PT		
6=	6 Mental health provider		
7=	7 Other (specify):		



5

NODATA<XYES>

Week	6
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Subject ID: 02 - ________ - _______ subject # Subject Initials: _____ Self-administered Questionnaires Date administered: ____/_____/_SEE_ANNOTATION P. 13 **SELFREPT (TYPE 4)** 1 EuroQol , Attached Not done 2 SF-36 Not done , Attached 97 Not done UCSD Shortness-of-Breath , Attached St. George's Respiratory Not done ____ Attached ICECAP , Attached Not done **GERD Substudy Review** Record all GERD related medications in the GERD Concomitant Medications log Have there been any changes in the subject's GERD status since last visit? **SEE ANNOTATION P. 28 GERDSUB (TYPE 4)** $\Box_0 \text{ No} \rightarrow \text{Skip to question 3}$ \square_1 Yes \rightarrow If Yes: Check only one: Newly diagnosed → Record on Adverse Event Log How diagnosed (check all that apply): 24 hr pH monitoring Endoscopy Upper GI/barium swallow test OR Unknown Symptoms of heartburn 2 Changes in non-pharmaceutical interventions \square_{os} Other (including medications only) \rightarrow Skip to question 3 2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below: Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor O, No O, Yes Limiting foods and beverages that cause symptoms Avoiding lying down flat for 3 hours after a meal 3 Have there been any changes in the subject's obstructive sleep apnea status since last visit? $\square_0 \text{ No} \rightarrow \text{Skip to Safety Review}$, Yes → If Yes: Check only one: \square_1 Newly diagnosed \rightarrow Record on Adverse Event Log Changes in CPAP treatment □₀₈ Other (including medications only) → Skip to Safety Review 4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment: One 1 Daily 2 Intermittent **Safety Review** Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care (e.g., clinic, study visit, hospitalization)? **SEE ANNOTATION P. 28 SAFETY (TYPE 4)** \square_0 No \square_1 Yes \rightarrow If Yes: Please send support materials for acute exacerbation review.

Record any new Adverse Events on the Adverse Event Log page.

Record any new or changed medications on the Concomitant Medications Log page.



Week 6

SEE ANNOTATION P. 14 Subject ID: 02 -

site # _____subject #

Subject Initials: _____

EuroQol Questionnaire EQ-5D English version for the U.S. By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today. 1 Mobility: EUROQOL1(TYPE 4) , I have no problems in walking about , I have some problems in walking about \Box_3 I am confined to bed 2 Self-care: , I have no problems with self-care 2 I have some problems washing or dressing myself □_a I am unable to wash or dress myself 3 Usual activities (e.g., work, study, housework, family, or leisure activities): , I have no problems with performing my usual activities , I have some problems with performing my usual activities \Box_3 I am unable to perform my usual activities 4 Pain/discomfort: , I have no pain or discomfort , I have moderate pain or discomfort , I have extreme pain or discomfort 5 Anxiety/depression: , I am not anxious or depressed , I am moderately anxious or depressed \Box_3 I am extremely anxious or depressed STOP. Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet. EuroQol Thermometer Response (Study staff use only)

Response to the EuroQol thermometer (0–100): ____

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Subject Initials: ____

subject #

site #

Week 6

SEE	NOT	ΑΤΙΟ	N F	2.15
		C	hin at	ID. 02

EuroQol Questionnaire EQ-5D (continued) Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions. **EUROQOL2 (TYPE 4)** 1 Have you experienced serious illness: in you yourself? O No , Yes 🗋 No 🔄, Yes in your family? in caring for others? __ No __ Yes 2 What is your age in years? **3** Are you (please check appropriate box): , Male , Female 4 Are you (please check only one): __, A current smoker , An ex-smoker A never smoker 5 Do you now, or did you ever, work in health or social services? No. ____ Yes → If Yes: In what capacity? _____ 6 Which of the following best describes your main activity (please check only one)? , Employed (including self employment) , Retired , Keeping house □₄ Student Seeking work Other (please specify): 7 What is the highest level of education you have completed (please check only one)? , Some high school or less □₂ High school graduate or GED □₃ Vocational college or some college College degree s Professional or graduate degree 8 If you know your zip code, please write it here: ______



Week 6

2	SF-36 Assessment							
1	1 In general, would you say your health is:							
2	Compared to one year ago, how would you rate your health in g	genera	l now?					
	\square_1 Much better than one year ago \square_3 About the same as one year				orse nov			
	\square_2 Somewhat better than one year ago \square_4 Somewhat worse than one y	ear ago) i		e year a	~		
3	The following items are about activities you might do during a ty Does <u>your health now limit you</u> in these activities? If so, how mu	pical d ch?	ay.	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All		
	a. Vigorous activities, such as running, lifting heavy objects, participating strenuous sports			2	□₃			
	b. Moderate activities, such as moving a table, pushing a vacuum cle bowling, or playing golf		\Box_1	2	□ ₃			
	c. Lifting or carrying groceries			\Box_1	_ 2	□ ₃		
	d. Climbing several flights of stairs			\Box_1	2	□_ 3		
	e. Climbing one flight of stairs			\Box_1		□_3		
	f. Bending, kneeling or stooping			\Box_1		3		
	g. Walking more than a mile			\Box_1	 2	3		
	h. Walking several blocks							
	i. Walking one block			\Box_1		□ ₃		
	j. Bathing or dressing yourself							
4	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of your physical health</u> ?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time		
	a. Cut down on the amount of time you spend on work or other activities		_ 2		4	5		
	b. Accomplished less than you would like	\Box_1	_ 2	_ 3		5		
	c. Were limited in the kind of work or other activities	\Box_1	_ 2	□₃		_ 5		
	d. Had difficulty performing the work or other activities (for example, it took extra effort)	\Box_{1}		\square_3		5		
5	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of any emotional problems</u> (such as feeling depressed or anxious)?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time		
	a. Cut down on the amount of time you spend on work or other activities	\Box_1		□_3		_ 5		
	b. Accomplished less than you would like			□ ₃		5		
	c. Did work or other activities less carefully than usual	\Box_1	_ 2	□₃		5		



Week 6

	SEE ANNOTATION P. 17 Subject ID: 02					eek 6	
SF-36	SAssessment (continued)						
 During the past <u>4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? □1 Not at all □2 Slightly □3 Moderately □4 Quite a bit □5 Extremely SF36_2 (TYPE 4) 							
	w much <u>bodily</u> pain have you had during the <u>past</u> 4 we None \square_2 Very mild \square_3 Mild \square_4 Moderate \square_5 Seve		Very seve	ere			
out	ring the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with side the home and housework)? Not at all2 Slightly3 Moderately4 Quite a bit	-		vork (incl	luding both	n work	
we	ese questions are about how you feel and how things h <u>eks</u> . For each question, please give the one answer tha en feeling.						
I	w much of the time during the <u>past</u> <u>4 week</u> s	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time	
a.	Did you feel full of life?		_ 2	3		5	
ь. І	Have you been very nervous?		2	_ 3		5	
	Have you felt so down in the dumps that nothing could cheer you up?	\Box_1	2	_ 3		_ 5	
d.	Have you felt calm and peaceful?		 2			5	
e.	Did you have a lot of energy?	\Box_1	 2	\square_3	 4	5	
f. -	lave you felt downhearted and depressed?	\Box_1	 2	_ 3		5	
g.	Did you feel worn out?		 2	\square_3		5	
h.	Have you been happy?	\Box ,	 2	□_3		5	
i. D	Did you feel tired?		 2	₃		5	
pro	10 During the <u>past 4 weeks</u> , how much of the time has your <u>physical health or emotional</u> <u>problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?						
	All of the time \square_2 Most of the time \square_3 Some of the time	∐₄ A lit	tle of the	time]₅ None of	the time	
11 Но уоч	w True or False is <u>each</u> of the following statements for ?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False	
α.	seem to get sick a little easier than other people	\Box_1	 2	3		5	
b.	am as healthy as anybody I know	\Box ,	2	3		5	
c.	expect my health to get worse	\Box_1		_ 3		5	
d. /	My health is excellent	\Box_1	2	□,3		5	



	Subject	initials: _	 _
#			
ÔOF		A /T\	

SEE ANNOTATION P. 18 Subject ID: 02					Week 6		
		Subject ID:	02	#	Sub	oject Initials:	
					JCSDSC	DB1 (TYPE 4)	
UCSD Shortness-of-Breath Ques When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All	UCSD SO	BQ		Severe	Maximal/ Unable To Do Because of Breathlessness	
1 At rest	0	1	2	3	4	5	
2 Walking on a level at your own pace	e O	1	2	3	4	5	
3 Walking on a level with others your age	0	1	2	3	4	5	
4 Walking up a hill	0	1	2	3	4	5	
5 Walking up stairs	0	1	2	3	4	5	
6 While eating	0	1	2	3	4	5	
7 Standing up from a chair	0	1	2	3	4	5	
8 Brushing teeth	0	1	2	3	4	5	
9 Shaving and/or brushing hair	0	1	2	3	4	5	
10 Showering/bathing	0	1	2	3	4	5	
11 Dressing	0	1	2	3	4	5	
12 Picking up and straightening	0	1	2	3	4	5	



Week 6

SEE ANNOTATION P. 19 Subject ID: 02 - _____

	UČSDSOB2 (TYPE 4)						
UCSD Shortness-of-Breath Ques	tionnair	e ucsd s	OBQ (conti	nued)			
When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness	
13 Doing dishes	0	1	2	3	4	5	
14 Sweeping/vacuuming	0	1	2	3	4	5	
15 Making bed	0	1	2	3	4	5	
16 Shopping	0	1	2	3	4	5	
17 Doing laundry	0	1	2	3	4	5	
18 Washing car	0	1	2	3	4	5	
19 Mowing lawn	0	1	2	3	4	5	
20 Watering lawn	0	1	2	3	4	5	
21 Sexual activities	0	1	2	3	4	5	
How much do these limit you in your daily life?							
22 Shortness of breath	0	1	2	3	4	5	
23 Fear of "hurting myself"	0	1	2	3	4	5	
24 Fear of shortness of breath	0	1	2	3	4	5	



Week 6

SEE ANNOTATION P. 20 Subject ID: 02 -

site # _____subject #

Subject Initials: _____

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

STGRG1 (TYPE 4) This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:	
Please check one box to show how you describe your current health:	Very good
	Good
	🗌 Fair
	Poor
	🗌 Very poor



Week 6

	SEE ANNOT	ATION P. 2	1			leek 6			
		Subject ID: (02	=	_ Subject Initia	ls:			
	St. George's Respiratory Questionnaire Part 1								
P	Please describe how often your respiratory problems have affected you over the past 4 weeks. STGSG2(TYPE 4)								
	Please check 🗹 one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with	Not At All			
ï	Over the past 4 weeks, I have coughed:								
2	Over the past 4 weeks, I have brought up phlegm (sputum):								
3	Over the past 4 weeks, I have had shortness of breath:								
4	Over the past 4 weeks, I have had wheezing attacks:								
	 5 How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks? Please check intervention of the severe of the s								
7	 ☐ 1 or 2 days ☐ Less than a day Over the past 4 weeks, in a typical week, how problems) have you had? Please check ✓ one: ☐ No good days ☐ 1 or 2 good days ☐ 3 or 4 good days ☐ Nearly every day was good ☐ Every day was good If you wheeze, is it worse when you get up in th ☐ No ☐ Yes 				-				



Weel	k 6
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SEE ANNOTATION P. 22		Week 6				
SEE ANNOTATION P. 22 Subject ID: 02	bject # S	ubject Initials:				
St. George's Respiratory Questionnaire Part 2						
Section 1 STGRG3 (TYPE 4) 9 How would you describe your respiratory condition? Please check ✓ one: ☐ The most important problem I have ☐ Causes me quite a lot of problems ☐ Causes me a few problems ☐ Causes me no problems						
 10 If you have ever held a job (please check one): My respiratory problems made me stop working altogether My respiratory problems interfere with my job or made me change my job My respiratory problems do not affect my job 						
Section 2						
These are questions about what activities usually make you feel short of bree		<u>day</u> s.				
For each statement, please check 🗹 the box that applies to you these day	5.					
11 Sitting or lying still	🗌, True	□ _o False				
Washing or dressing yourself	🗌 ₁ True	□ _o False				
Walking around the house	🗌, True	□ _o False				
Walking outside on a level ground	🔄, True	□ _o False				
Walking up a flight of stairs	🗌, True	□ _o False				
Walking up hills	🗌, True	□ _o False				
Playing sports or other physical activities	🗌, True	□ _o False				
 Section 3 12 These are more questions about your cough and shortness of breath <u>thes</u> 	<u>e day</u> s.					
For each statement, please check 🗹 the box that applies to you these d	ays.					
Coughing hurts	, True	□ _o False				
Coughing makes me tired	🗌, True	□ _o False				
I am short of breath when I talk	🗌, True	□ _o False				
I am short of breath when I bend over	🗌, True	□ _o False				
My coughing or breathing disturbs my sleep	🗌, True	□ _o False				
I get exhausted easily	□, True	□ _o False				

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 PINK-retain at site



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Week 6

Subj	ect	Initials:	 _	_

Subject ID: 02	Sub	ect Initials:
St. George's Respiratory Questionnaire Part 2 (continued)		
 Section 4 STG 13 These are questions about other effects that your respiratory problems may <u>days</u>. 	RG4 (TY y have on	PE 4) you <u>these</u>
For each statement, please check 🗹 the box that applies to you these days.		
My cough or breathing is embarrassing in public	□, True	□ _o False
My respiratory problems are a nuisance to my family, friends or neighbors	□, True	🔲 o False
I get afraid or panic when I cannot catch my breath	□ ₁ True	□ _o False
I feel that I am not in control of my respiratory problems	□, True	□ _o False
I do not expect my respiratory problems to get any better	□, True	□ _o False
I have become frail or an invalid because of my respiratory problems	□, True	□ _o False
Exercise is not safe for me	, True	□ _o False
Everything seems too much of an effort	□, True	□ _o False
 Section 5 14 These are questions about your respiratory treatment. If you are not received Section 6. 	ng treatm	ient, +go to
For each statement, please check 🗹 the box that applies to you these days.		
My treatment does not help me very much	□, True	□ _o False
I get embarrassed using my medication in public	□, True	□ _o False
I have unpleasant side effects from my medication	□, True	□ _o False
My treatment interferes with my life a lot	□, True	□ _o False



Week 6

CEE	ANNOTA	TION D 24	
SEE		TION P. 24	
		A 1 1 4 10 00	

Subject ID: 02 - ______ - ______ subject #

St. George's Respiration Questionnaire Part 2 (continued)				
Section 6 15 These are questions about how your activities might be affected by your re	GRG5 (TYPE 4) espiratory problems.			
For each statement, please check 🗹 the box that applies to you because of your re	espiratory problems.			
I take a long time to get washed or dressed	□ ₁ True □ ₀ False			
I cannot take a bath or shower, or I take a long time to do it	□_ ₁ True □_ ₀ False			
I walk slower than other people my age, or I stop to rest	□] ₁ True □] ₀ False			
Jobs such as household chores take a long time, or I have to stop to rest	□_ ₁ True □_ ₀ False			
If I walk up one flight of stairs, I have to go slowly or stop	□ ₁ True □ ₀ False			
If I hurry or walk fast, I have to stop or slow down	□_ ₁ True □_ ₀ False			
My breathing makes it difficult to do things such as walk up hills, carry light gardening such as weeding, dance, bowl, or play SEE PAGE 24	□ ₁ True □ ₀ False			
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	SEE PAGE 24			
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SEE PAGE 24			
Section 7 16 We would like to know how your respiratory problems <u>usually</u> affect your daily life.				
For each statement, please check 🗹 the box that applies to you because of your re	espiratory problems.			
I cannot play sports or do other physical activities	, True o False			
I cannot go out for entertainment or recreation	□ ₁ True □ ₀ False			
I cannot go out of the house to do the shopping	□_1 True □_0 False			
I cannot do household chores	□_1 True □_0 False			
I cannot move far from my bed or chair	□ ₁ True □ ₀ False			



Week 6

SEE ANNOTATION P. 25 Subject ID: 02 -

site # _____subject #

Subject Initials: ____ _

St. George's Respiratory Questionnaire (continued)

STGRG6 (TYPE 4) Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

- · Going for walks or walking the dog
- Doing activities or chores at home or in the garden
- Sexual intercourse
- · Going to a place of worship, or a place of entertainment
- · Going out in bad weather or into smoky rooms
- · Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

17 Now please check the box (one only) that you think best describes how your respirate	ory
problems affect you:	

- □ It does not stop me from doing anything I would like to do
- It stops me from doing one or two things I would like to do
- It stops me from doing most of the things I would like to do
- □ It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.



Week 6

Subject Initials: ____

ICECAP Questionnaire

By placing a check 🗹 in one box in each group below, please indicate which statement best describes your quality of life at the moment. **ICECAP (TYPE 4)**

Love and Friendship	\Box_1 I can have all of the love and friendship that I want \Box_2 I can have a lot of the love and friendship that I want \Box_3 I can have a little of the love and friendship that I want \Box_4 I cannot have any of the love and friendship that I want
Thinking about the future	□ ₁ I can think about the future without any concern □ ₂ I can think about the future with only a little concern □ ₃ I can only think about the future with some concern □ ₄ I can only think about the future with a lot of concern
Doing things that make you feel valued	\Box_1 I am able to do all of the things that make me feel valued \Box_2 I am able to do many of the things that make me feel valued \Box_3 I am able to do a few of the things that make me feel valued \Box_4 I am unable to do any of the things that make me feel valued
Enjoyment and pleasure	\Box_1 I can have all of the enjoyment and pleasure that I want \Box_2 I can have a lot of of the enjoyment and pleasure that I want \Box_3 I can have a little of the enjoyment and pleasure that I want \Box_4 I cannot have any of the enjoyment and pleasure that I want
Independence	 I am able to be completely independent I am able to be independent in many things I am able to be independent in a few things I am unable to be at all independent



Week 12

		Subject ID: 02	=	Subject Initials:
Vi	sit date:///Check if Early Te daySEE ANNOTATIO		ER <xyes> Die-blind phase: VISTDATI</xyes>	E (TYPE 4)
V	ital Signs			
1	Weight: 1b		VITALS (1	TYPE 4)
2	Blood pressure:/ mSEE ANNOTATIO	N P.11		
3	Heart rate: bpm		02	
N	YHA Functional Class			
Cu	rrent NYHA heart failure classification (check only one): 1 SEE ANNOTA		ΝΥΗΑ (ΤΥ	′PE 4)
S	pirometry			
Do	ate of assessment:/	P.2		
1	FEV ₁ : Actual: liters NOTE: DO NOT AD	D QUESTIONS		
	FEV ₆ : Actual: liters 4,5,6		CDIDOME	
3	FVC: Actual: liters		SPIROWE	T (TYPE 4)
-				
D	iffusing Capacity of the Lung for Carbo	n Monoxide (D	LCO)	
				(PE 4)
	iffusing Capacity of the Lung for Carbon nte of assessment:/	FION P.12	DLCO (TY	
Do 1 2	ote of assessment://SEE ANNOTA DLCO: Actual: mL/min/mm Hg → Altitude-corre VI (inspired volume): liters	FION P.12	DLCO (TY	
Do 1 2	nte of assessment:/	FION P.12	DLCO (TY	
Do 1 2 3	ote of assessment://SEE ANNOTA DLCO: Actual: mL/min/mm Hg → Altitude-corre VI (inspired volume): liters	FION P.12	DLCO (TY	
Dc 1 2 3 A	nte of assessment://SEE ANNOTA DLCO: Actual: mL/min/mm Hg → Altitude.com VI (inspired volume): liters VA (alveolar volume): liters rterial Blood Gas (ABG)	FION P.12	DLCO (TY	mL/min/mm Hg
Do 1 2 3 A Do	nte of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Dc 1 2 3 A Dc 1	the of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Do 1 2 3 A Do 1 2	the of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Do 1 2 3 A Do 1 2	the of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Dc 1 2 3 A Dc 1 2 3 4	the of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Dc 1 2 3 A Dc 1 2 3 4	the of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Dec 1 2 3 A Dec 1 2 3 4 5 6	nte of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg
Dec 1 2 3 A Dec 1 2 3 4 5 6	the of assessment:/	FION P.12	DLCO (TY	mL/min/mm Hg

CRF, page 47

STEP-IPF
IPFnet

NODATA<XYES>

W	ee	k	12

SEE ANNOTATION PAGE 3

		s	iubject ID: 02	Subject # S	ubject Initials:
6-Minute W	alk Test (6MW1	1			
Date of assessmen	nt:/	/		V	VALK (TYPE4)
1 Pre-walk modi	fied Borg Dyspnea S	cale rating:] 3 4 5 6	7 8 9	10	ot done
2 Resting room	air SpO ₂ :	%			
3 Was supplemental O₂ used during walk? □₀ No □₁ Yes → If Yes: Specify: liters/min					
SpO ₂ on Supplemental O ₂ :%					
4 Was walk per		Provide reason:	· · · · ·		
J Yes 5 Was a walking aid necessary to perform the 6MWT? □0 No □1 Yes → If Yes: Specify (check only one): □1 Cane □2 Walker					
6 Minutes	H		SpO ₂	WALKTIM	E(TYPE4)PS
Pre-walk		bpm			
1 minute		bpm	%		
2 minutes		bpm	%		
3 minutes		bpm	%		
4 minutes		bpm	%		
5 minutes		bpm	%		
6 minutes		bpm	%		
Three minutes o	f recovery after co	mpletion or stop of 6-Minu	te Walk Test		
1 minute		bpm	%		
2 minutes		bpm	%		
3 minutes		bpm	%		
 6 Did subject desaturate (SpO₂ ≤ 88%)? □₀ No □₁ Yes → If Yes: Walk duration at desaturation: min / sec Walk distance at desaturation: meters 					
Lowest SpO ₂	Distance Walked	Did Subject Complete 6-Minute Walk?		d Early: Specify (Check only one)	Reason
%	meters	$\Box_{0} \text{ No} \rightarrow \text{ If No:}$ $Duration: \underline{/}_{min} / _{sec}$ $\Box_{1} \text{ Yes}$	$\Box_1 \text{ SpO}_2 < 80\%$ $\Box_2 \text{ Developed signs a}$ $\Box_{98} \text{ Other (specify): } _$		
7 Post-walk mod	lified Borg Dyspnea	Scale rating:			

Site Personnel's Initials: ____ PINK—retain at site

0 0.5 1 2 3 4 5 6 7 8 9 10 gr Not done

Q STEP-IPF

SEE ANNOTATION P. 31

- subject # site # Subject ID: 02 - ___

Week 12

Subject Initials:

NODATA<XYES>

Has the subject been admitted to the hospital, emergency room,/urgent care, assisted living/nursing facility, or rehabilitation center since the last study visit (do not include	room,/urgent care, assisted living/nursing	g facility, or rehabilitation center since th	ie last study visit (do not include
protocol-specific study visits)? □_0 No □_1 Yes → If Yes: Prc	Provide details below.		INPATNT (TYPE 4)R
	Reason for Admission	Major Procedures Performed	Discharge Destination (check only one)
1 Admission date:			 Home Assisted living/nursing facility Assisted living/nursing facility Rehab center Transfer to other hospital Subject died Other (specify):
Assisted living/nursing facility 4 Rehabilitation center	1 Check if respiratory-related.		
 2 Admission date:			 Home Assisted living/nursing facility Rehab center Transfer to other hospital Subject died
 1 rospitation 2 ER/urgent care 3 Assisted living/nursing facility 4 Rehabilitation center 	1 Check if respiratory-related.		Other (specify):
 3 Admission date:day /			 Home Assisted living/nursing facility Rehab center Transfer to other hospital Subject died
□2 ER/urgent care □3 Assisted living/nursing facility □4 Rehabilitation center	, Check if respiratory-related.		98 Other (specify):

Site Personnel's Initials: ____ PINK-retain at site

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 STEP_IPF VERSION 7.0_17SEP2009

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Week 12

Subject Initials: ____

Outpatient Visits

Has the subject required any non-urgent outpatient visits since the last study visit (do not include protocol-specific study visits)? \square_0 No \square_1 Yes \rightarrow If Yes: Provide details below. OUTPATNT (TYPE 4)PS \square_0 No \square_1 Yes \rightarrow If Yes: Provide details below.

	Provider Type	No. of Respiratory- related Visits	No. of Non-respiratory- related Visits
1	Pulmonologist		
2	Cardiologist		
3	Other specialist:		
4	Primary care physician (or NP or PA)		
5	OT or PT		
6	Mental health provider		
7	Other (specify):		

Site Personnel's Initials: _ PINK-retain at site



NODATA<XYES>

2

	IPFnet	Wee	k 1
	Subject ID: 02	Subject Initials:	
		te #subject #	
S	Self-administered Questionnaires		
Da	Date administered:/	SELFREPT (TYPE 4)
1			
2	No GENDRPT	1 Attached ₉₇ Not done 1 Attached ₉₇ Not done	
3			
4	4 St. George's Respiratory		
5			
G	GERD Substudy Review		
	Record all GERD related medications in the GERD Concomit	tant Medications log	
1	Have there been any changes in the subject's GERD status since last visit?		
	$\Box_0 \text{ No} \rightarrow \text{Skip to question 3}$	GERDSUB (TYPE	4)
	\square_1 Yes → If Yes: Check only one: SEE ANNOTATION P. 28		-
	, Newly diagnosed → Record on Adverse Event Log		
	How diagnosed (check all that apply):		
	🗌 24 hr pH monitoring 📃 Endoscopy	Upper GI/barium swallow test	
	Symptoms of heartburn OR	Unknown	
	2 Changes in non-pharmaceutical interventions		
	□ ₉₈ Other (including medications only) → Skip to question 3		
2	2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer	all questions below:	
	Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor		
	Sleeping in a recliner		
	Limiting foods and beverages that cause symptoms		
	Avoiding lying down flat for 3 hours after a meal		
	Avoiding bedtime snacks	-	
	Eating small meals		
2			
3	→ nove more been any changes in the subject's obstructive sleep apneal status since \Box_0 No → Skip to Safety Review		
	$\square_{0} \text{ Yes} \rightarrow \text{ If Yes: Check only one:}$		
	Newly diagnosed → Record on Adverse Event Log Changes in CPAP treatment		
	□2 Changes in CrAr irediment □2 Changes in CrAr irediment □3 Other (including medications only) → Skip to Safety Review		
A	 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPA 	A D transferrante	
7		Ar fredment.	
	□ ₀ None □ ₁ Daily □ ₂ Intermittent		
S	Safety Review		
	SEE ANNOTATION P. 28		
Ho	Has the subject experienced unexplained worsened dyspnea or cough since last visit, t	triggering unscheduled medical care	(e.g.,
clin	clinic, study visit, hospitalization)?	SAFETY (TYPE 4)	
	$\square_0 \text{ No}$ $\square_1 \text{ Yes} \rightarrow$ If Yes: Please send support materials for acute exacerbation r	review.	
	Record any new Adverse Events on the Adverse Eve	ent Log page.	
	Record any new or changed medications on the Concomitant I	Medications Log page.	



Week 12

SEE ANNOTATION P. 14 Subject ID: 02 - _________ - ___________

EuroQol Questionnaire EQ-5D English version for the U.S.	
By placing a checkmark in one box in each group below, ple describe your own health state today.	ase indicate which statements best
 Mobility: ¹ I have no problems in walking about ² I have some problems in walking about ³ I am confined to bed 	EUROQOL1(TYPE 4)
 Self-care: 1 have no problems with self-care 2 l have some problems washing or dressing myself 1 am unable to wash or dress myself 	
3 Usual activities (e.g., work, study, housework, family, or le	isure activities):
 4 Pain/discomfort: 1 have no pain or discomfort 1 have moderate pain or discomfort 1 have extreme pain or discomfort 	
 Anxiety/depression: I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed 	
STOP. Please let your study coordinato you are ready for the EuroQol Thermo	
EuroQol Thermometer Response (Study staff use or	nly)
Response to the EuroQol thermometer (0–100):	

~	SEE ANNOTATION P.15 Subject ID: 02 subject #	NODATA <xyes> Week 12 Subject Initials:</xyes>
Eu	uroQol Questionnaire EQ-5D (continued)	
lit		ter if we have a L2(TYPE 4)
	Have you experienced serious illness: in you yourself? No Yes in your family? No Yes in caring for others? No Yes	
2	What is your age in years?	
3	Are you (please check appropriate box): □, Male □₂ Female	
4	Are you (please check only one): _1 A current smoker _2 An ex-smoker _3 A never smoker	
5	Do you now, or did you ever, work in health or social services? □₀ No □₁ Yes → If Yes: In what capacity?	
6	Which of the following best describes your main activity (please check only one)? 	
7	What is the highest level of education you have completed (please check only one)? Some high school or less High school graduate or GED Vocational college or some college College degree Professional or graduate degree	2
8	If you know your zip code, please write it here:	



Week 12

SEE ANNOTATION P. 16 Subject ID: 02 - ________ - _________

Subject Init

Subject Initials: ____ ___

S	F-36 Assessment							
1	In general, would you say your health is: \Box_1 Excellent \Box_2 Very good \Box_3 Good \Box_4 Fair \Box_5 Poor		F36_1	(TYP	E 4)			
2	<u>Compared to one year ago</u> , how would you rate your health in g	-						
	□₁ Much better than one year ago □₃ About the same as one year ago □₅ Much worse now □₂ Somewhat better than one year ago □₄ Somewhat worse than one year ago than one year ago							
	W. W., M. Mat							
	The following items are about activities you might do during a ty Does <u>your health now limit you</u> in these activities? If so, how mu	ch?	ay.	Limited A Lot	Limited A Little	Limited At All		
	 Vigorous activities, such as running, lifting heavy objects, participating strenuous sports 			\Box_1		□₃		
	 Moderate activities, such as moving a table, pushing a vacuum cle bowling, or playing golf			\Box_1		□_3		
	c. Lifting or carrying groceries			\Box_1	2	□ ₃		
	d. Climbing several flights of stairs			\Box_1	2	□ ₃		
	e. Climbing one flight of stairs					□_3		
	f. Bending, kneeling or stooping			\Box_1	2	_ 3		
	g. Walking more than a mile			\Box_1	2	□ ₃		
	h. Walking several blocks					□ ₃		
	i. Walking one block				_ 2	3		
	j. Bathing or dressing yourself				 2	□_ ₃		
4	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of your physical health</u> ?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time		
	a. Cut down on the amount of time you spend on work or other activities	\Box_1	 2	□_ 3	4	_ 5		
	b. Accomplished less than you would like	\Box_1	_ 2	3		5		
	c. Were limited in the kind of work or other activities	\Box_1	_ 2	□_3		5		
	d. Had difficulty performing the work or other activities (for example, <i>it took extra effort</i>)			□₃	4	_ 5		
5	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of any emotional problems</u> (such as feeling depressed or anxious)?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time		
	a. Cut down on the amount of time you spend on work or other activities	\Box_{ι}				_ 5		
	b. Accomplished less than you would like	\Box_1	_ 2	3		5		
	c. Did work or other activities less carefully than usual	\Box_1	_ 2	\square_3		5		

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Week 12

	SEE ANNOTATION P. 1 Subject ID: (02	# =	bject #	Subject Initial	s:
S	-36 Assessment (continued)					
6	During the past 4 weeks, to what extent has your physical interfered with your normal social activities with family, friendly Not at all \square_2 Slightly \square_3 Moderately \square_4 Quite a bit	ends, ne	ighbors			
7	How much <u>bodily</u> pain have you had during the <u>past 4 we</u> \Box_1 None \Box_2 Very mild \Box_3 Mild \Box_4 Moderate \Box_5 Sever				YPE 4)	
8	During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with outside the home and housework)? \Box_1 Not at all \Box_2 Slightly \Box_3 Moderately \Box_4 Quite a bit	-		vork (incl	uding both	h work
9	These questions are about how you feel and how things he weeks. For each question, please give the one answer that been feeling.					
	How much of the time during the <u>past 4 week</u> s	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Did you feel full of life?		2	_ 3	_ 4	5
	b. Have you been very nervous?		2	_ 3		5
	c. Have you felt so down in the dumps that nothing could cheer you up?		_ 2	□₃		_ 5
	d. Have you felt calm and peaceful?		2	3		5
	e. Did you have a lot of energy?	\Box_1	2	_ 3	4	5
	f. Have you felt downhearted and depressed?	\Box_1	2	_ 3	4	5
	g. Did you feel worn out?	\Box_1	2	_ 3		5
	h. Have you been happy?	\Box ,	2	□ ₃	_ 4	5
	i. Did you feel tired?	\Box_1	 2	_ 3		5
10	During the <u>past 4 weeks</u> , how much of the time has your <u>p</u> <u>problems</u> interfered with your social activities (like visiting fri				onal	
	\square_1 All of the time \square_2 Most of the time \square_3 Some of the time	□₄ A litt	le of the	time 🗌]₅ None of	the time
11	How True or False is <u>each</u> of the following statements for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
	a. I seem to get sick a little easier than other people	\Box_1		\square_3	_ 4	5
	b. I am as healthy as anybody I know	\Box ,	2	□_ ₃	 4	5
	c. I expect my health to get worse	\Box_1		_ 3		5
	d. My health is excellent	\Box_1		□_3		_ 5

SEE ANNOTATION P. 17

WHITE and YELLOW–Duke Clinical Research Institute
 PINK–retain at site



Week 12

			10			Week 12
SEE	ANNOTAT	Subject ID:	02	#	Sub	oject Initials:
	•				JCSDSC	DB1 (TYPE 4)
UCSD Shortness-of-Breath Questi When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All	UCSD SOI	BQ		Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest	0	1	2	3	4	5
2 Walking on a level at your own pace	0	1	2	3	4	5
3 Walking on a level with others your age	0	1	2	3	4	5
4 Walking up a hill	o	1	2	3	4	5
5 Walking up stairs	0	1	2	3	4	5
6 While eating	0	1	2	3	4	5
7 Standing up from a chair	0	1	2	3	4	5
8 Brushing teeth	0	1	2	3	4	5
9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing	0	1	2	3	4	5
11 Dressing	0	1	2	3	4	5
12 Picking up and straightening	0	1	2	3	4	5



Week 12

SEE ANNOTATION P. 19 Subject ID: 02 - ____ - ___ - ___ - ____

					32 [#] (TYP	bject Inifials: E 4)
UCSD Shortness-of-Breath Que When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All	' e ucsd s	OBQ (conti	nued)	Severe	Maximal/ Unable To Do Because of Breathlessness
13 Doing dishes	0	1	2	3	4	5
14 sweeping/vacuuming	0	1	2	3	4	5
15 Making bed	0	1	2	3	4	5
16 Shopping	0	1	2	3	4	5
17 Doing laundry	0	1	2	3	4	5
18 Washing car	0	Ĩ	2	3	4	5
19 Mowing lawn	0	1	2	3	4	5
20 Watering lawn	0	1	2	3	4	5
21 Sexual activities	0	1	2	3	4	5
How much do these limit you in your d	laily life?					
22 Shortness of breath	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
24 Fear of shortness of breath	0	1	2	3	4	5



Week 12

SEE ANNOTATION P. 20 Subject ID: 02 -

_____ = ______

site #

Subject Initials: _____

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

STGRG1(TYPE 4)

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:	
Please check one box to show how you describe your current health:	Very good
	Good
	🗌 Fair
	Poor
	🗌 Very poor



Week 12

S	St. George's Respiratory Questionnaire Part 1							
PI	Please describe how often your respiratory problems have affected you over the past 4 weeks.							
	STGRG2(TYPE 4)							
	Please check 🗹 one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All		
ĩ	Over the past 4 weeks, I have coughed:							
2	Over the past 4 weeks, I have brought up phlegm (sputum):							
3	Over the past 4 weeks, I have had shortness of breath:							
4	Over the past 4 weeks, I have had wheezing attacks:							
5	How many times during the past 4 weeks have respiratory attacks? Please check ∠ one: More than 3 times 3 times 2 times 1 time None of the time	you suffere	ed from so	evere or ve	ry unpleasa	nt		
6	 6 How long did the worst respiratory attack last? Please check ∠ one: (Go to question 7 if you did not have a severe attack) A week or more 3 or more days 1 or 2 days Less than a day 							
7	Over the past 4 weeks, in a typical week, how problems} have you had? Please check ✓ one: ○ No good days ○ 1 or 2 good days ○ 3 or 4 good days ○ Nearly every day was good ○ Every day was good	many good	l days (w	ith few resp	oiratory			
8	If you wheeze, is it worse when you get up in t No Yes	he morning	? Please d	:heck ☑ on	e:			



W	ee	k	12

SEE ANNOTATION P. 22		Week 12
SEE ANNOTATION P. 22 Subject ID: 02	subject #	Subject Initials:
St. George's Respiratory Questionnaire Part 2		
Section 1		
 9 How would you describe your respiratory condition? Please check ☐ The most important problem I have ☐ Causes me quite a lot of problems ☐ Causes me a few problems ☐ Causes me no problems 	one: STGRG3(T	YPE 4)
 10 If you have ever held a job (please check ∠ one): My respiratory problems made me stop working altogether My respiratory problems interfere with my job or made me change my jo My respiratory problems do not affect my job 	b	
Section 2		
These are questions about what activities usually make you feel short of	breath <u>these</u>	<u>day</u> s.
For each statement, please check 🗹 the box that applies to you these	days.	
11 Sitting or lying still	🗌, True	□ _o False
Washing or dressing yourself	🗌 ₁ True	□ _o False
Walking around the house	🗌, True	□ _o False
Walking outside on a level ground	🗌, True	□ _o False
Walking up a flight of stairs	🗌 , True	□ _o False
Walking up hills	🗌 , True	□ _o False
Playing sports or other physical activities	🗌, True	□ _o False
Section 312 These are more questions about your cough and shortness of breath	<u>these</u> days.	
For each statement, please check 🗹 the box that applies to you the	se days.	
Coughing hurts	🗌, True	□ _o False
Coughing makes me tired	🗌 , True	□ _o False
I am short of breath when I talk	🗌 , True	□ _o False
I am short of breath when I bend over	🔲 , True	□ _o False
My coughing or breathing disturbs my sleep	🗌 ₁ True	□ _o False
I get exhausted easily	🗌 ₁ True	□ _o False

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SEE	ANN	OTA	TION	P. 23

Week 12

SEE ANNOTATION P. 23 Subject ID: 02	Sub	ject Initials:					
St. George's Respiratory Questionnaire Part 2 (continued)							
 Section 4 STGRG4(TYPE 4) 13 These are questions about other effects that your respiratory problems may have on you <u>these</u> <u>days</u>. 							
For each statement, please check 🗹 the box that applies to you these days.							
My cough or breathing is embarrassing in public	🗆, True	□ _o False					
My respiratory problems are a nuisance to my family, friends or neighbors	□ ₁ True	□ _o False					
I get afraid or panic when I cannot catch my breath	□, True	□ _o False					
I feel that I am not in control of my respiratory problems	□ ₁ True	□ _o False					
I do not expect my respiratory problems to get any better	□ ₁ True	□ _o False					
I have become frail or an invalid because of my respiratory problems	□ ₁ True	□ _o False					
Exercise is not safe for me	□, True	□ _o False					
Everything seems too much of an effort	□, True	□ _o False					
 Section 5 14 These are questions about your respiratory treatment. If you are not received Section 6. 	ng treatm	ient, +go to					
For each statement, please check 🗹 the box that applies to you these days.							
My treatment does not help me very much	□, True	□ _o False					
I get embarrassed using my medication in public	□, True	□ _o False					
I have unpleasant side effects from my medication	□ ₁ True	□ _o False					
My treatment interferes with my life a lot	□, True	□ _o False					



	ATATION D 94
JEE ANN	OTATION P. 24
	A 1 1 1 10 00

Subject ID: 02 - ______ - _____ Subject # Subject #

Subject Initials: ___ ___

Week 12

St. George's Respiration Questionnaire Part 2 (continued)	
Section 6 15 These are questions about how your activities might be affected by your re	RG5(TYPE 4) espiratory problems.
For each statement, please check 🗹 the box that applies to you because of your re	spiratory problems.
I take a long time to get washed or dressed	□ ₁ True □ ₀ False
I cannot take a bath or shower, or I take a long time to do it	□ ₁ True □ ₀ False
I walk slower than other people my age, or I stop to rest	1 Trueo False
Jobs such as household chores take a long time, or I have to stop to rest	1 Trueo False
If I walk up one flight of stairs, I have to go slowly or stop	□ ₁ True □ ₀ False
If I hurry or walk fast, I have to stop or slow down	□ ₁ True □ ₀ False
My breathing makes it difficult to do things such as walk up hills, carry light gardening such as weeding, dance, bowl, or play SEE PAGE 24	□ ₁ True □ ₀ False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	SEE PAGE 24
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SEEPAGE 240
Section 7 16 We would like to know how your respiratory problems <u>usually</u> affect your	daily life.
For each statement, please check 🗹 the box that applies to you because of your re	spiratory problems.
I cannot play sports or do other physical activities	□ ₁ True □ ₀ False
I cannot go out for entertainment or recreation	□ ₁ True □ ₀ False
I cannot go out of the house to do the shopping	□ ₁ True □ ₀ False
I cannot do household chores	□ ₁ True □ ₀ False
ı cannot move far from my bed or chair	□ ₁ True □ ₀ False



Week 12

SEE ANNOTATION P. 25 Subject ID: 02 - _

subject #

Subject Initials: _

site # St. George's Respiratory Questionnaire (continued) Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.) STGRG6(TYPE 4) Going for walks or walking the dog Doing activities or chores at home or in the garden Sexual intercourse Going to a place of worship, or a place of entertainment Going out in bad weather or into smoky rooms Visiting family or friends or playing with children Please write in any other important activities that your respiratory problems may stop you from doing: 17 Now please check the box (one only) that you think best describes how your respiratory problems affect you: It does not stop me from doing anything I would like to do It stops me from doing one or two things I would like to do It stops me from doing most of the things I would like to do It stops me from doing everything I would like to do Before you finish, would you please make sure that you have answered all the questions. Thank you for completing this questionnaire.



Week 12

Subject Initials: ____ ___

ICECAP Questionnaire

By placing a check 🗹 in one box in each group below, please indicate which statement best describes your quality of life at the moment.

ICECAP(TYPE 4)

Love and Friendship	\Box_1 I can have all of the love and friendship that I want \Box_2 I can have a lot of the love and friendship that I want \Box_3 I can have a little of the love and friendship that I want \Box_4 I cannot have any of the love and friendship that I want
Thinking about the future	□ ₁ I can think about the future without any concern □ ₂ I can think about the future with only a little concern □ ₃ I can only think about the future with some concern □ ₄ I can only think about the future with a lot of concern
Doing things that make you feel valued	\Box_1 I am able to do all of the things that make me feel valued \Box_2 I am able to do many of the things that make me feel valued \Box_3 I am able to do a few of the things that make me feel valued \Box_4 I am unable to do any of the things that make me feel valued
Enjoyment and pleasure	\Box_1 I can have all of the enjoyment and pleasure that I want \Box_2 I can have a lot of of the enjoyment and pleasure that I want \Box_3 I can have a little of the enjoyment and pleasure that I want \Box_4 I cannot have any of the enjoyment and pleasure that I want
Independence	 I am able to be completely independent I am able to be independent in many things I am able to be independent in a few things I am unable to be at all independent

Structy Drug Log Structy Drug Log Structy Drug Log Record of Structy Drug andmants Double-Blind Phase Struct Phase Struct Phase Record of Structy Drug andmants Double-Blind Phase Structure Ja Structure Ja Mrtr RowModessine Double-Blind Phase Structure Ja Number of Plus Number of Plus ArriNo-Vision Double-Blind Phase Dispensed Date Number of Plus Number of Plus Number of Plus ArriNo-Vision Double-Blind Phase Dispensed Date Dispensed Date Number of Plus Number of Plus ArriNo-Vision Dispensed Date Dispensed Date Number of Plus Number of Plus Number of Plus ArriNo-Vision Dispensed Dispensed Date Number of Plus Number of Plus Plus ArriNo-Vision Dispensed Dispensed Dispensed Dispensed Dispensed 2 Dispensed Dispensed Dispensed Dispensed Dispensed Dispensed 3 Dispensed Dispensed Dispensed Dispensed Dispensed Dispensed 3 Dimeter Dimeter Dispensed							NODAT	NODATA <xyes></xyes>
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Y Drug Enclimento Work 12 Number Number of PIII. Botte Number Dispensed Date Number of PIII. (drexk only one) Dispensed Date Dispensed Date Number of PIII. BOTTLENO <ipfboit><i:3.> PILSTADT Dispensed Date Number of PIII. BOTTLENO<ipfboit><i:3.> PILSTADT PILSTADT Returned BOTTLENO<ipfboit><i:3.> PILSTADT PILSTADT Returned BOTTLENO<ipfboit> PILSTADT PILSTADT PILSTADT BOTTLENO PILSTADT PILSTADT PILSTADT PILSTADT PILSTADT PILST</ipfboit></ipfboit></ipfboit></ipfboit></ipfboit></i:3.></ipfboit></i:3.></ipfboit></i:3.></ipfboit>							STYDRUG	et Initials: TYPE 4)R
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	PFnet		ole-Blind	mpletion/Termi Phase (Weeks	5 0-1
Study Comp	letion/Terminat	ion—Double-Blind I	Phase		
				TERM (TYPE 4	.)
	terminate early from this				·
$\square_0 \text{ No} \rightarrow \text{If No}$	b: Is subject participating i	in the open-label phase? 🔲 🛛	No \rightarrow If No: R v _o $OPENLA$	BL <xyesno></xyesno>	00>
\Box , Yes \rightarrow If Ye	s: Date of study terminat	ion:	142		
RMREA <ipfter< td=""><td>2<1.32</td><td></td><td>or .</td><td></td><td></td></ipfter<>	2<1.32		or .		
	Reason (check primary re		ant Farm		
	\square_1 Lung transplant	Death Form and Expedited Ev	en rorm.		
		را):	>	→ Complete Adverse Eve	ents Form
	□_4 Subject withdrew con				
	□ ₅ MD decision				
	□ ₆ Lost to follow-up	TERMSP <v:1< td=""><td>100> (one</td><td>e specify)</td><td></td></v:1<>	1 00> (one	e specify)	
	98 Other (specify):				
	CONTU <xyesno></xyesno>	study drug prior to Week 12 v			
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	□ ₃ MD decision □ ₉₈ Other				
3 Was study drug □ ₀ No U □ ₁ Yes → If Ye	g unblinded? NBLIND <xyesno> s: Date unblinded:</xyesno>	UNBLNDT			
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Investigator	's Signature				
		CDF and all of the other			TYPE
	the data recorded on these	CRF pages and certify that they a	ire accurate and	complete to the best of my kho	medge.
I have reviewed all of	INCIC	<xyes></xyes>			



Sector IPFnet	FORM= WEEK13	Week 13
	Subject ID: 02	Subject Initials:
Visit date://///	SEE ANNOTATION P. 11	VISTDATE (TYPE 4)
Vital Signs		
Weight:	3 Heart rate: mm Hg EE ANNOTATION P. 11	- bpm VITALS(TYPE 4)
GERD Substudy Review		
Record all GERD rela	ated medications in the GERD Concomi	tant Medications log
 Have there been any changes in the sub □₀ No → Skip to question 3 □₁ Yes → If Yes: Check only one: □, Newly diagnosed 	iject's GERD status since last visit? SEE ANNOTATION P. 28 → Record on Adverse Event Log	GERDSUB (TYPE 4)
2 Changes in non-ph	How diagnosed (check all that apply): 24 hr pH monitoring Endoscopy Symptoms of heartburn OF armaceutical interventions	Upper GI/barium swallow test
	nedications only) → Skip to question 3	
Sleeping with the head end of the bed Sleeping in a recliner Limiting foods and beverages that caus Avoiding lying down flat for 3 hours at Avoiding bedtime snacks	n non-pharmaceutical interventions, answe elevated with 6" to 8" blocks on the floor se symptoms fter a meal	□ No □ 1 Yes □ 0 No □ 1 Yes
$\Box_0 \text{ No} \rightarrow \text{Skip to Safety Review}$ $\Box_1 \text{ Yes} \rightarrow \text{ If Yes: Check only one:}$	→ Record on Adverse Event Log	last visit?
	nedications only) → Skip to Safety Review	AP treatment:
Safety Review		
Has the subject experienced unexplained v clinic, study visit, hospitalization)? $\Box_0 \operatorname{No} \ \Box_1 \operatorname{Yes} \rightarrow \operatorname{If} \operatorname{Yes}$: Please send sup		w.
	ew Adverse Events on the Adverse Events on the Adverse Events on the Concomitant	

Site Personnel's Initials: ____ ___

NODATA<XYES>



Week 18

Subject ID: 02 - _______ - ______ - _______

Visit date://	SEE ANNOTATION P.11	VISTDATE (TYPE 4)
Vital Signs 1 Weight:	SEE ANNOTATION P.11 ¹⁹ NOTE: EXCEPT NO HEIGHT of	VITALS (TYPE 4) r SPO2
NYHA Functional Class Current NYHA heart failure classification (check Spirometry	SEE ANNOTATION P.11	NYHA (TYPE 4)
Date of assessment://	r	SPIROMET (TYPE 4)
1 FEV1: Actual: liters 2 FEV6: Actual: liters 3 FVC: Actual: liters	SEE ANNOTATION P.2 NOTE: DO NOT ADD QU 4,5,6	ESTIONS
Diffusing Capacity of the Lung	g for Carbon Monoxide (DLG	20)
Date of assessment:		DLCO (TYPE 4) h only): · mL/min/mm Hg

	STEP-IPF
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W	ee	k	18

SEE ANNOTATION PAGE 3

		1	Subject ID: 02		Subject Initials:
6-Minute W	alk Test (6MW	τ)			
Date of assessmen	It:/	/year			WALK (TYPE4
Pre-walk modi	fied Borg Dyspnea S	icale rating:] 3	7 8 9	10 D ₉₇	Not done
2 Resting room o	air SpO ₂ :	%			
3 Was suppleme	ental O ₂ used during	walk? $\square_0 \text{ No } \square_1 \text{ Yes} \rightarrow$			
			SpO ₂ on Supplem	nental O ₂ :	%
4 Was walk perf	formed? $\square_0 \text{ No} \rightarrow \square_1 \text{ Yes}$	Provide reason:			· · · · · · · · · · · · · · · · · · ·
O No	g aid necessary to po es: Specify (check only	_			
6 Minutes	P	leart Rate	SpO ₂	WALKTI	ME(TYPE4)PS
Pre-walk	_	bpm			
1 minute	_	bpm	%		
2 minutes		bpm	%		
3 minutes	_	bpm	%		
4 minutes		bpm	%		
5 minutes		bpm	%		
6 minutes		bpm	%		
Three minutes of	f recovery after co	mpletion or stop of 6-Min	ute Walk Test		
1 minute		bpm	%		
2 minutes		bpm	%		
3 minutes		bpm	%		
5 Did subject des	saturate (SpO₂ ≤ 889	$\square_1 $ Yes \rightarrow If Yes: Walk d	uration at desaturation: istance at desaturation:		
Lowest SpO ₂	Distance Walked	Did Subject Complete 6-Minute Walk?	If Stoppe	d Early: Spec (Check only on	
%	meters	$\Box_{0} \text{ No} \rightarrow \text{ If No:}$ Duration: $$	□ ₁ SpO ₂ < 80% □ ₂ Developed signs a □ ₉₈ Other (specify): _		quiring termination of test
7 Post-walk mod	lified Borg Dyspnea	Scale rating:			

0 0.5 1 2 3 4 5 6 7 8 9 10

97 Not done

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SEE ANNOTATION P. 31

= ______subject # site # Subject ID: 02 - ___

Subject Initials:

NODATA<XYES> Week 18

Hes ubject leer admitted to the loopidu, orregency room/urgent care, assisted king/runsing facility, or evaluatitation canter since the last study visit (do not include proceeder stody visit)? INDATNT (TYPE 4)R Receive the include proceeder study visit)? Include proceedire study visit)? Number of the loopidu proceeder study visit)? Include proceedures study visit)? Include proceedu	5	Urgent or Inpatient Admissions			
Reason for Admission Marior Procedures Performed Admission date:	Ha	as the subject been admitted to the hospital, emergenc) :ol-specific study visits)? □_0 No □_1 Yes → If Yes: Prov	r room/urgent care, assisted living/nursin ide details below.	ng facility, or rehabilitation center since th	ne last study visit (do not include pro- INPATNT (TYPE 4)R
Admission date:	λ		Reason for Admission		Discharge Destination (check only one)
Admission date:	-	day //// day /honth. / check only one): te (nursing facility center	□1 Check if respiratory-related.		1 Home 2 Assisted living/nursing facility 3 Rehab center 4 Transfer to other hospital 5 Subject died 9 Other (specify):
Admission date:	7	Admission date:	□1 Check if respiratory-related.		1 Home 2 Assisted living/nursing facility 3 Rehab center 4 Transfer to other hospital 5 Subject died 9 Other (specify):
	n	day_/// day	□1 Check if respiratory-related.		 Home Assisted living/nursing facility Assisted living/nursing facility Rehab center Transfer to other hospital Subject died Other (specify):

Site Personnel's Initials: _ PINK-retain at site

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Week 18

Subject Initials: ____ ___

Outpatient Visits

Subject ID: 02 - _______ - ___________



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	Week 18
	Subject ID: 02 - Subject Initials:
	site #
Se	elf-administered Questionnaires
Da	te administered:
1 2	EuroQol
3	UCSD Shortness-of-Breath
4	St. George's Respiratory
5	ICECAP
G	ERD Substudy Review
	Record all GERD related medications in the GERD Concomitant Medications log
1	Have there been any changes in the subject's GERD status since last visit?
	$\Box_0 \text{ No} \rightarrow \text{Skip to question 3} \qquad $
	\square_1 Yes → If Yes: Check only one: SEE ANNOTATION P. 28
	\square_1 Newly diagnosed \rightarrow Record on Adverse Event Log
	How diagnosed (check all that apply):
	24 hr pH monitoring Endoscopy Upper GI/barium swallow test
	Symptoms of heartburn OR Unknown
	Changes in non-pharmaceutical interventions
	□ ₉₈ Other (including medications only) → Skip to question 3
2	If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below:
	Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor $\Box_0 \text{ No} \Box_1$ Yes
	Sleeping in a recliner
	Limiting foods and beverages that cause symptoms
	Avoiding lying down flat for 3 hours after a meal
	Avoiding bedtime snacks
	Eating small meals No Yes
-	
3	Have there been any changes in the subject's obstructive sleep apnea status since last visit?
	$\Box_0 \text{ No} \rightarrow \text{Skip to Safety Review}$
	$\Box_1 \text{ Yes} \rightarrow \text{ If Yes: Check only one:}$
	Newly diagnosed → Record on Adverse Event Log Changes in CPAP treatment
	_ ₉₈ Other (including medications only) → Skip to Safety Review
*	If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment:
	□ ₀ None □ ₁ Daily □ ₂ Intermittent
S	afety Review
	SEE ANNOTATION P. 28
Ha	s the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care
(e.	g., clinic, study visit, hospitalization)?
	\square_0 No \square_1 Yes \rightarrow If Yes: Please send support materials for acute exacerbation review. SAFETY (TYPE 4)
	Record any new Adverse Events on the Adverse Event Log page.
	Record any new or changed medications on the Concomitant Medications Log page.



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SEE ANNOTATION P. 14

NODATA<XYES>

Week 18

Subject ID: 02 - _______ - - ________

Subject Initials: ____ ___

EUROQOL1 (TYPE 4) By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.
 Mobility: 1 have no problems in walking about 2 I have some problems in walking about 3 I am confined to bed
2 Self-care:
 Usual activities (e.g., work, study, housework, family, or leisure activities): 1 have no problems with performing my usual activities 2 have some problems with performing my usual activities 3 a m unable to perform my usual activities
4 Pain/discomfort: □₁ I have no pain or discomfort □₂ I have moderate pain or discomfort □₃ I have extreme pain or discomfort
5 Anxiety/depression:
STOP. Please let your study coordinator know that you are ready for the EuroQol Thermometer worksheet.
EuroQol Thermometer Response (Study staff use only)
Response to the EuroQol thermometer (0–100):

CRF, page 73



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	SEE /	ANNOT	IOITA	NP. 15
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	Subject ID: 02 Subject # Subject Initials:
Eu	roQol Questionnaire EQ-5D (continued)
Be lit	EUROQOL2 (TYPE 4) cause all replies are anonymous, it will help us to understand your answers better if we have a the background data from everyone, as covered in the following questions.
1	Have you experienced serious illness: in you yourself? No Yes in your family? No Yes in caring for others? No Yes
2	What is your age in years?
3	Are you (please check appropriate box): _1 Male _2 Female
4	Are you (please check only one): An ex-smoker An ever smoker
5	Do you now, or did you ever, work in health or social services? □_ No □_ Yes → If Yes: In what capacity?
6	Which of the following best describes your main activity (please check only one)?
7	What is the highest level of education you have completed (please check only one)?
8	If you know your zip code, please write it here:



Week 18

SEE ANNOTATION P. 16

Subject ID: 02 - _______ - ______ - _______

Subject Initials: ___ ___

S	F-36 Assessment									
	In general, would you say your health is:	S	F36_1	(TYP	E 4)					
-	, Excellent □₂ Very good □₃ Good □₄ Fair □₅ Poor <u>Compared to one year ago</u> , how would you rate your health in g	anara								
2	\Box_1 Much better than one year ago \Box_3 About the same as one year			Auch w	orse nov	,				
	\Box_2 Somewhat better than one year ago \Box_4 Somewhat worse than one year ago than one year ago									
3	The following items are about activities you might do during a ty Does <u>your health now limit you</u> in these activities? If so, how mu	pical de ch?	ay.	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All				
	a. Vigorous activities, such as running, lifting heavy objects, participating strenuous sports			\Box_1	 2	□₃				
	b. Moderate activities, such as moving a table, pushing a vacuum cle bowling, or playing golf	eaner,			_ 2	□ ₃				
	c. Lifting or carrying groceries			\Box_1	2	□₃				
	d. Climbing several flights of stairs			\Box	2	□,				
	e. Climbing one flight of stairs			\Box_1	2	\square_3				
	f. Bending, kneeling or stooping		\Box_1	2	□_ 3					
	g. Walking more than a mile		\Box_1	2	□ ₃					
	h. Walking several blocks			\Box_1	2	□ ₃				
	i. Walking one block			\Box_1	 2	□ ₃				
	j. Bathing or dressing yourself			\Box_1	2	□₃				
4	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of your physical health</u> ?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time				
	a. Cut down on the amount of time you spend on work or other activities	\Box_1	2	\square_3	_ 4	5				
	b. Accomplished less than you would like	\Box_{1}	2		4	5				
	$\ensuremath{c.}$. Were limited in the \ensuremath{kind} of work or other activities	\Box_1		□_3		5				
	d. Had difficulty performing the work or other activities (for example, it took extra effort)			\square_3	_ 4	□ ₅				
5	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of any emotional problems</u> (such as feeling depressed or anxious)?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time				
	a. Cut down on the amount of time you spend on work or other activities	\Box_1		3	4	□ ₅				
	b. Accomplished less than you would like	\Box_1	_ 2	\square_3	4	5				
	c. Did work or other activities less carefully than usual	\Box_1		\square_{3}		5				



Week 18

SEE ANNOTATION P. 17

Subject ID: 02 - _______ - ______ - _________

Subject Initials: ____ ___

S	F-36 Assessment (continued)							
6	6 During the past <u>4 weeks</u> , to what extent has your physical health or emotional problems ⁴) interfered with your normal social activities with family, friends, neighbors, or groups? □, Not at all □ ₂ Slightly □ ₃ Moderately □ ₄ Quite a bit □ ₅ Extremely							
7	7 How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u> ? 1 None 2 Very mild 3 Mild 4 Moderate 5 Severe 6 Very severe							
8	During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with outside the home and housework)? \Box_1 Not at all \Box_2 Slightly \Box_3 Moderately \Box_4 Quite a bit	-		vork (incl	uding bot	n work		
9	These questions are about how you feel and how things he weeks. For each question, please give the one answer that been feeling.	ave bee t comes	n with y closest t	you <u>durir</u> to the w	ng <u>the par</u> ay you ha	<u>st 4</u> ive		
	How much of the time during the <u>past 4 week</u> s	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time		
	a. Did you feel full of life?		 2	3		5		
	b. Have you been very nervous?	\Box_1		3		5		
	c. Have you felt so down in the dumps that nothing could cheer you up?		2	_ 3		5		
	d. Have you felt calm and peaceful?		 2	 3		5		
	e. Did you have a lot of energy?	\Box_1	2			5		
	f. Have you felt downhearted and depressed?	\Box ,	2	_ 3	4	5		
	g. Did you feel worn out?		2	_ 3	4	5		
	h. Have you been happy?	\Box ,	2	\square_3		5		
	i. Did you feel tired?	\Box_1	 2	\square_{3}		5		
10	During the <u>past 4 weeks</u> , how much of the time has your <u>p</u> <u>problems</u> interfered with your social activities (like visiting fr				onal			
	\Box_1 All of the time \Box_2 Most of the time \Box_3 Some of the time	□₄ A lit	tle of the	time 🗌]₅ None of	the time		
11	How True or False is <u>each</u> of the following statements for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False		
	a. I seem to get sick a little easier than other people	\Box_1	 2	3	_ 4	5		
	ь. I am as healthy as anybody I know	\Box ,	 2	3	_ 4	5		
	c. I expect my health to get worse	\Box_1		\square_3		5		
	d. My health is excellent	□,	2	3		5		

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SEE ANNOTATION P. 18

Week 18

Subject ID: 02 - _____ - ____

Subject Initials: ____

		Subject ID:	02	#	Sub	oject Initials:	
UCSD Shortness-of-Breath Questionnaire UCSD SOBQ							
When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness	
1 At rest	0	1	2	3	4	5	
2 Walking on a level at your own pace	0	1	2	3	4	5	
 Walking on a level with others your age 	0	1	2	3	4	5	
4 Walking up a hill	0	1	2	3	4	5	
5 Walking up stairs	0	1	2	3	4	5	
6 While eating	0	٦	2	3	4	5	
7 Standing up from a chair	0	1	2	3	4	5	
8 Brushing teeth	0	1	2	3	4	5	
9 Shaving and/or brushing hair	0	1	2	3	4	5	
10 Showering/bathing	0	1	2	3	4	5	
11 Dressing	0	1	2	3	4	5	
12 Picking up and straightening	0	1	2	3	4	5	



SEE ANNOTATION P. 19

Week 18

	SEE ANNO						
		Subject	ID: 02			bject Initials:	
					2 (TYPE	4)	
UCSD Shortness-of-Breath Que When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All	e ucsd s	OBQ (conti	nued)	Severe	Maximal/ Unable To Do Because of Breathlessness	
13 Doing dishes	0	1	2	3	4	5	
14 Sweeping/vacuuming	0	1	2	3	4	5	
15 Making bed	0	1	2	3	4	5	
16 Shopping	0	1	2	3	4	5	
17 Doing laundry	0	1	2	3	4	5	
18 Washing car	0	1	2	3	4	5	
19 Mowing lawn	0	1	2	3	4	5	
20 Watering lawn	0	1	2	3	4	5	
21 Sexual activities	0	Ĩ	2	3	4	5	
How much do these limit you in your daily life?							
22 Shortness of breath	0	1	2	3	4	5	
23 Fear of "hurting myself"	0	ĩ	2	3	4	5	
24 Fear of shortness of breath	0	1	2	3	4	5	



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SEE ANNOTATION P. 20

Subject ID: 02 - _______ - ______ - __________

Subject Initials: _____

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

STGRG1(TYPE 4) This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:	
Please check one box to show how you describe your current healt	h: 🗌 Very good
	Good
	🗌 Fair
	Poor
	🗌 Very poor



Week 18

SEE ANNOTATION P. 21

Subject ID: 02 - ______ - _____ - _____ subject #

Subject Initials: ___ ___

St. George's Respiratory Questionnaire Part 1

Please describe how often your respiratory problems have affected yos Jorr the past 4 weeks.						
	Please check 🗹 one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All
1	Over the past 4 weeks, I have coughed:					
2	Over the past 4 weeks, I have brought up phlegm (sputum):					
3	Over the past 4 weeks, I have had shortness of breath:					
4	Over the past 4 weeks, I have had wheezing attacks:					
5	How many times during the past 4 weeks have respiratory attacks? Please check ∠ one: More than 3 times 3 times 2 times 1 time None of the time	you suffere	ed from se	evere or ver	y unpleasa	nt
6	How long did the worst respiratory attack last? (Go to question 7 if you did not have a severe attack A week or more 3 or more days 1 or 2 days Less than a day		eck ⊠ one	9:		
7	Over the past 4 weeks, in a typical week, how problems} have you had? Please check ✓ one: □ No good days □ 1 or 2 good days □ 3 or 4 good days □ Nearly every day was good □ Every day was good	many good	days (wi	th few resp	iratory	

8 If you wheeze, is it worse when you get up in the morning? Please check ∠ one:

- □₀ No
- □, Yes



NA.	1 10	6
Wee	K Ið	5

SEE ANNOTATION P. 22

Subject ID: 02 - _______ - ______ - _________

Subject Initials: ____ ___

St. George's Respiratory Questionnaire Part 2						
Section 1 STGRG3 (TYPE 4)						
 9 How would you describe your respiratory condition? Please check one: ☐ The most important problem I have ☐ Causes me quite a lot of problems ☐ Causes me a few problems ☐ Causes me no problems 10 If you have ever held a job (please check one): ☐ My respiratory problems made me stop working altogether 						
 My respiratory problems interfere with my job or made me change my job My respiratory problems do not affect my job 						
Section 2						
These are questions about what activities usually make you feel short of brea	oth <u>these</u>	<u>day</u> s.				
For each statement, please check 🗹 the box that applies to you these day	s.					
11 Sitting or lying still	🗌, True	□ _o False				
Washing or dressing yourself	□, True	□ _o False				
Walking around the house	🗌, True	□ _o False				
Walking outside on a level ground	🗌, True	□ _o False				
Walking up a flight of stairs	🗌, True	□ _o False				
Walking up hills	🗌, True	□ _o False				
Playing sports or other physical activities						
 Section 3 12 These are more questions about your cough and shortness of breath <u>these day</u>s. 						
For each statement, please check 🗹 the box that applies to you these days.						
Coughing hurts	🗌, True	□ _o False				
Coughing makes me tired	🗌, True	□ _o False				
I am short of breath when I talk	🗌, True	□ _o False				
I am short of breath when I bend over	🗌, True	□ _o False				
My coughing or breathing disturbs my sleep	□, True	□ _o False				
I get exhausted easily						

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Week 18

	SEE ANNOTATION P. 23		Week 18
	Subject ID: 02	oct # Subj	ect Initials:
St. George's Respiratory G	uestionnaire Part 2 (continued)		
Section 4 13 These are questions about othe <u>days</u> .	STG er effects that your respiratory problems ma	RG4 (TY y have on	
For each statement, please check 🛛	I the box that applies to you these days.		
My cough or breathing is embo	arrassing in public	□, True	□ _o False
My respiratory problems are a or neighbors	ı nuisance to my family, friends	□, True	□ _o False
l get afraid or panic when I car	nnot catch my breath	□, True	□ _o False
I feel that I am not in control of	my respiratory problems	□, True	□ _o False
I do not expect my respiratory	problems to get any better	□, True	□ _o False
I have become frail or an inval	id because of my respiratory problems	□, True	□ _o False
Exercise is not safe for me		□, True	□ _o False
Everything seems too much of	an effort	□, True	□ _o False
Section 5 14 These are questions about your Section 6.	r respiratory treatment. If you are not receiv	ing treatm	ent, +go to
For each statement, please check 🛛	✓ the box that applies to you these days.		
My treatment does not help me	e very much	□, True	□ _o False
l get embarrassed using my me	edication in public	□, True	□ _o False
I have unpleasant side effects f	rom my medication	□ ₁ True	□ _o False
My treatment interferes with m	y life a lot	, True	□₀ False



SEE ANNOTATION P. 24 Subject ID: 02	ject # Su	Week 18
ste # subj St. George's Respiration Questionnaire Part 2 (continued)	907 #	
STG 15 These are questions about how your activities might be affected by your re	RG5 (T spiratory	· · · · · ·
For each statement, please check 🗹 the box that applies to you because of your re	spiratory	problems.
I take a long time to get washed or dressed	🗌 ₁ True	o False
I cannot take a bath or shower, or I take a long time to do it	🔲 1 True	o False
I walk slower than other people my age, or I stop to rest	🗌 ₁ True	🗌 ₀ False
Jobs such as household chores take a long time, or I have to stop to rest	🔄 ₁ True	🗌 ₀ False
If I walk up one flight of stairs, I have to go slowly or stop	🔄 ı True	o False
If I hurry or walk fast, I have to stop or slow down	□ ₁ True	🗌 _o False
My breathing makes it difficult to do things such as walk up hills, carry light gardening such as weeding, dance, bowl, or play SEE PAGE 24	□ ₁ True	🔲 o False
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	SEE PA	GE 24
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SEE PA	AGE 24
Section 7 16 We would like to know how your respiratory problems <u>usually</u> affect your	daily life).
For each statement, please check 🗹 the box that applies to you because of your re	spiratory	problems.
I cannot play sports or do other physical activities	🗌 ₁ True	o False
I cannot go out for entertainment or recreation	🗌 ₁ True	o False
I cannot go out of the house to do the shopping	🗌 ₁ True	□_ ₀ False
I cannot do household chores	🗌 1 True	🔲 o False
I cannot move far from my bed or chair	1 True	o False



SEE ANNOTATION P. 25

Subject ID: 02 - _______ - ______ subject #

Subject Initials: ___ ___

NODATA<XYES>

Week 18

St. George's Respiratory Questionnaire (continued)

STGRG6 (TYPE 4)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

- · Going for walks or walking the dog
- · Doing activities or chores at home or in the garden
- Sexual intercourse
- · Going to a place of worship, or a place of entertainment
- · Going out in bad weather or into smoky rooms
- · Visiting family or friends or playing with children

Please write in any other important activities that your respiratory problems may stop you from doing:

17 Now please check the box (one only) that you think best describes how your respire	tory
problems affect you:	

- □ It does not stop me from doing anything I would like to do
- It stops me from doing one or two things I would like to do
- It stops me from doing most of the things I would like to do
- □ It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.

PINK-retain at site



Week 18

SEE ANNOTATION P. 26

Subject ID: 02 - _ site # subject # Subject Initials: ____

ICECAP Questionnaire

By placing a check 🗹 in one box in each group below, please indicate which statement best) describes your quality of life at the moment. Love and Friendship \Box_1 I can have **all** of the love and friendship that I want , I can have a lot of the love and friendship that I want , I can have a little of the love and friendship that I want I cannot have **any** of the love and friendship that I want Thinking about the future , I can think about the future without any concern , I can think about the future with only a little concern , I can only think about the future with **some** concern $\Box_{\mathbf{A}}$ I can only think about the future with **a lot** of concern Doing things that make you feel , I am able to do **all** of the things that make me feel valued valued , I am able to do **many** of the things that make me feel valued , I am able to do **a few** of the things that make me feel valued , I am unable to do **any** of the things that make me feel valued **Enjoyment and pleasure** , I can have **all** of the enjoyment and pleasure that I want , I can have **a lot** of of the enjoyment and pleasure that I want , I can have a little of the enjoyment and pleasure that I want □ I cannot have **any** of the enjoyment and pleasure that I want Independence , I am able to be **completely** independent , I am able to be independent in many things \Box_{a} I am able to be independent in a few things I am **unable** to be at all independent



Week 24

Subject ID: 02 - _______ - ______ - _________

Subject Initials: ___ ___

Visit date:// Check if Ear SEE ANNO	EARLYTER <xyes> ly Termination visit for double-blind phase: DTATION P.11 VISTDATE (TYPE 4)</xyes>
Vital Signs	
1 Weight: 1 lb2 kg	VITALS (TYPE 4)
2 Blood pressure:/ mm Hg SEE AI systolic diastolic mm Hg	EXCEPT NO HEIGHT or SPO2
3 Heart rate: bpm	
NYHA Functional Class	
Current NYHA heart failure classification (check only one): SEE ANNC	TATION P.11 NYHA (TYPE 4)
Spirometry	
Date of assessment:	SPIROMET (TYPE 4)
FEV ACTUAL:	DTATION P.2
3 FVC: Actual: liters 4,5,6	NOT ADD QUESTIONS
Diffusing Capacity of the Lung for Car	bon Monoxide (dlco)
Date of assessment://	DLCO (TYPE 4)
DLCO: Actual:, mL/min/mm Hg → Altitude VI (inspired volume): liters SEE ANNO	corrected DLCO (National Jewish only): mL/min/mm Hg
3 VA (alveolar volume): liters	DIATION P.12
Arterial Blood Gas (ABG)	
Date of assessment://	DTATION P.12 ABG (TYPE 4)
Barometric pressure: mm Hg	
2 Clinic altitude (check only one): $\Box_1 < 4000$ ft $\Box_2 \ge 4000$	ft
3 FiO ₂ :%	
. 4 pH:	
5 PaO ₂ : mm Hg	
6 PaCO ₂ : mm Hg	
7 SaO ₂ :%	

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SEE ANNOTATION PAGE 3

	S	Subject ID: 02			
6-Minute Walk Test (6MWT)					
Date of assessmen	t://yeor	WALK (TYPE4)			
Pre-walk modil 0 0.5	ied Borg Dyspnea Scale rating: 1 2 3 4 5 6	7 8 9 10 9 ₉₇ Not done			
2 Resting room air SpO ₂ :%					
3 Was suppleme	ntal O ₂ used during walk? $\Box_0 \operatorname{No} \Box_1 \operatorname{Yes} \to \operatorname{If}$				
4 Was walk part	ormed? □_o No → Provide reason:	SpO ₂ on Supplemental O ₂ :%			
+ was waik peri					
□ ₀ No	aid necessary to perform the 6MWT?				
	98 Other (specify):				
6 Minutes	Heart Rate	Spo ₂ WALKTIME(TYPE4)PS			
Pre-walk	bpm				
1 minute	bpm	%			
2 minutes	bpm	%			
3 minutes	bpm	%			
4 minutes	bpm	%			
5 minutes	bpm	%			
6 minutes	bpm	%			
Three minutes of	recovery after completion or stop of 6-Minu	Jte Walk Test			
1 minute	bpm	%			
2 minutes	bpm	%			
3 minutes	bpm	%			
6 Did subject des	saturate (SpO ₂ \leq 88%)? \Box_0 No				
		uration at desaturation: min / sec istance at desaturation: meters			
Lowest SpO ₂	Distance Walked Did Subject Complete 6-Minute Walk?	If Stopped Early: Specify Reason (Check only one)			
%	$ ____ meters \qquad \square_0 \text{ No} \rightarrow \text{ If No:} \\ Duration: __/\{min} /\{sec} \\ \square_1 \text{ Yes} $	□ ₁ SpO ₂ < 80% □ ₂ Developed signs and symptoms requiring termination of test □ ₉₈ Other (specify):			
Post-walk modified Borg Dyspnea Scale rating: 0 0.5 1 2 3 4 5 6 7 8 9 10 97 Not done					

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Site Personnel's Initials: ____ ___

				NODATA <xyes></xyes>
	STEP-IPF			Week 24
59 5885799	IPFnet	SEE ANNOTATION P. 31	1 Subject ID: 02 ====	
91020901 XXXX - 9	Urgent or Inpatient Admissions			
WF	Has the subject been admitted to the hospital, emergency room/urgent care, assisted living/nursing facility, or rehabilitation center since the last study visit (do not include protocol-specific study visits)? $\square_0 \operatorname{No} = \square_1 \operatorname{Yes} \rightarrow \operatorname{If} \operatorname{Yes}$; Provide details below.	y room/urgent care, assisted living/nursing f Yes → If Yes: Provide details below.	facility, or rehabilitation center since the II	the last study visit INPATNT (TYPE 4)R
lITE an		Reason for Admission	Major Procedures Performed	Discharge Destination (check only one)
d YELLOW—Duke Clir	Admission date:			1 Home 2 Assisted living/nursing facility 3 Rehab center 4 Transfer to other hospital 5 Subject died 9 Other (specify):
ical Rese	ursing facility enter	1. Check if respiratory-related.		
arch Institute • F	 2 Admission date:			1 Home 2 Assisted living/nursing facility 3 Rehab center 4 Transfer to other hospital 5 Subject died ∞ Other (specify):
PINK—reto	 Let, urgen care Assisted living/nursing facility Rehabilitation center 	1, Check if respiratory-related.		
Site Personn ain at site	 3 Admission date:			1 Home 2 Assisted living/nursing facility 3 Rehab center 4 Transfer to other hospital
el's Initials:	1 Hospital 2 ER/urgent care 3 Assisted living/nursing facility 4 Rehabilitation center	□, Check if respiratory-related.		_s Subject died _g Other (specify):



Week 24

SEE ANNOTATION P. 32 Subject ID: 02 - _______

_____subject #

Subject Initials: ____ _

Outpatient Visits

Has the subject required any non-urgent outpatient visits since the last study visit (do not include protocol-specific study visits)? \Box_0 No \Box_1 Yes \rightarrow If Yes: Provide details below. OUTPATNT (TYPE 4)R

	Provider Type	No. of Respiratory- related Visits	No. of Non-respiratory- related Visits
1	Pulmonologist		
2	Cardiologist		
3	Other specialist:		
4	Primary care physician (or NP or PA)		
5	OT or PT		
6	Mental health provider		
7	Other (specify):		



Wee	k 24
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Subject ID: 02 - ________ - _______ subject # Subject Initials: _____ Self-administered Questionnaires SEE ANNOTATION P. 13 SELFREPT (TYPE 4) **No GENDRPT** 1 EuroQol Attached Not done 2 SF-36 Not done , Attached 97 Not done UCSD Shortness-of-Breath , Attached St. George's Respiratory Attached . Not done 97 Not done ICECAP , Attached **GERD Substudy Review** Record all GERD related medications in the GERD Concomitant Medications log Have there been any changes in the subject's GERD status since last visit? **GERDSUB (TYPE 4)** $\Box_0 \text{ No} \rightarrow \text{Skip to question 3}$ **SEE ANNOTATION P. 28** \square_1 Yes \rightarrow If Yes: Check only one: ____, Newly diagnosed → Record on Adverse Event Log How diagnosed (check all that apply): 24 hr pH monitoring Endoscopy Upper GI/barium swallow test OR Unknown Symptoms of heartburn 2 Changes in non-pharmaceutical interventions \square_{os} Other (including medications only) \rightarrow Skip to question 3 2 If newly diagnosed GERD or changes in non-pharmaceutical interventions, answer all questions below: Sleeping with the head end of the bed elevated with 6" to 8" blocks on the floor O, No O, Yes Limiting foods and beverages that cause symptoms Avoiding lying down flat for 3 hours after a meal 3 Have there been any changes in the subject's obstructive sleep apnea status since last visit? $\square_0 \text{ No} \rightarrow \text{Skip to Safety Review}$, Yes → If Yes: Check only one: \square_1 Newly diagnosed \rightarrow Record on Adverse Event Log Changes in CPAP treatment □₀₈ Other (including medications only) → Skip to Safety Review 4 If newly diagnosed sleep apnea or changes in CPAP treatment, specify current CPAP treatment: One 1 Daily 2 Intermittent **Safety Review SEE ANNOTATION P. 28** Has the subject experienced unexplained worsened dyspnea or cough since last visit, triggering unscheduled medical care (e.g., clinic, study visit, hospitalization)? **SAFETY (TYPE 4)** \square_0 No \square_1 Yes \rightarrow If Yes: Please send support materials for acute exacerbation review. Record any new Adverse Events on the Adverse Event Log page. Record any new or changed medications on the Concomitant Medications Log page.



Week 24

Subject Initials: ___ ___

EuroQol Questionnaire EQ-5D English version for the U.S.	
By placing a checkmark in one box in each group below, p describe your own health state today.	lease indicate which statements best
Mobility: I have no problems in walking about I have some problems in walking about I am confined to bed 	EUROQOL1 (TYPE 4)
 Self-care: 1 have no problems with self-care 2 I have some problems washing or dressing myself 3 I am unable to wash or dress myself 	
3 Usual activities (e.g., work, study, housework, family, or □₁ have no problems with performing my usual activities □₂ have some problems with performing my usual activities □₃ am unable to perform my usual activities	leisure activities):
 4 Pain/discomfort: 1 have no pain or discomfort 2 have moderate pain or discomfort 3 have extreme pain or discomfort 	
 5 Anxiety/depression: I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed 	
STOP. Please let your study coordina you are ready for the EuroQol Thern	
EuroQol Thermometer Response (Study staff use	only)
Response to the EuroQol thermometer (0-100):	



Week 24

SEE	ΔΝΝΟΤΔ'	TION P. 15
022	/	Subject ID: 02

Subject ID: 02 - ________ - _______ site #

Subject Initials: ___ ___

EU	roQol Questionnaire EQ-5D (continued)
	EUROQOL2 (TYPE 4) cause all replies are anonymous, it will help us to understand your answers better if we have a le background data from everyone, as covered in the following questions.
1	Have you experienced serious illness: in you yourself? No, Yes in your family? No, Yes in caring for others? No, Yes
2	What is your age in years?
3	Are you (please check appropriate box):
4	Are you (please check only one): A current smoker An ex-smoker
	Do you now, or did you ever, work in health or social services? □_o No □_1 Yes → If Yes: In what capacity?
	Which of the following best describes your main activity (please check only one)? 1 Employed (including self employment) 2 Retired 3 Keeping house 4 Student 5 Seeking work 98 Other (please specify):
	What is the highest level of education you have completed (please check only one)?
8	If you know your zip code, please write it here:

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Week 24

Subject Initials: ___ ___

	F-36 Assessment					
	In general, would you say your health is:					
	Excellent \square_2 Very good \square_3 Good \square_4 Fair \square_5 Poor		F36_1	(TYPE	Ξ4)	
2	<u>Compared to one year ago</u> , how would you rate your health in g					6.01
	\square_1 Much better than one year ago \square_3 About the same as one year \square_2 Somewhat better than one year ago \square_4 Somewhat worse than one y				orse nov e year a	
				Yes,	Yes,	No, Not
3	The following items are about activities you might do during a ty Does <u>your health now limit you</u> in these activities? If so, how muc	ch?	ay.	Limited A Lot		Limited At All
	a. Vigorous activities, such as running, lifting heavy objects, participating strenuous sports			\Box_1	2	□₃
	b. Moderate activities, such as moving a table, pushing a vacuum cle bowling, or playing golf			\Box_1	 2	□₃
	c. Lifting or carrying groceries			\Box_1	2	□ ₃
	d. Climbing several flights of stairs				2	_ 3
	e. Climbing one flight of stairs			\Box_1	2	\square_3
	f. Bending, kneeling or stooping				2	_ 3
	g. Walking more than a mile		\Box_1	2	_ 3	
	h. Walking several blocks		\Box_1		3	
	i. Walking one block			\Box_1	 2	□ ₃
	j. Bathing or dressing yourself				 2	□_ ₃
4	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of your physical health</u> ?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Cut down on the amount of time you spend on work or other activities		_ 2	3	4	5
	b. Accomplished less than you would like		_ 2	_ 3		5
	c. Were limited in the ${\bf kind}$ of work or other activities		_ 2	□ ₃		5
	d. Had difficulty performing the work or other activities (for example, <i>it took extra effort</i>)	\Box_1		□ ₃	4	5
5	During the <u>past 4 weeks</u> , have you had any of the following problems with your work or other regular daily activities <u>as a</u> <u>result of any emotional problems</u> (such as feeling depressed or anxious)?	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Cut down on the amount of time you spend on work or other activities	\Box_{1}		$\square_{\mathfrak{z}}$		5
	b. Accomplished less than you would like			□ ₃		5
	c. Did work or other activities less carefully than usual		_ 2	□ ₃		5



Week 24

SEE	ΙΟΙ	ΆТ	ION	A F	P. 1	7
			C.L.	-	ID.	00

Subject ID: 02 - _______ - ______ subject # Subject Initials: ___ ___

S	-36 Assessment (continued)					
6	 During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? 1 Not at all2 Slightly3 Moderately4 Quite a bit5 Extremely 					
7	How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u> ? SF36_2(TYPE 4)					
8	 During the past <u>4 weeks</u>, how much did pain interfere with your normal work (including both work outside the home and housework)? Not at all Slightly Moderately Quite a bit Extremely 					
9	These questions are about how you feel and how things have been feeling.					
	How much of the time during the <u>past</u> <u>4</u> <u>week</u> s	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	a. Did you feel full of life?		2	_ 3		5
	b. Have you been very nervous?		 2	_ 3		_ 5
	c. Have you felt so down in the dumps that nothing could cheer you up?					□_ ₅
	d. Have you felt calm and peaceful?		2	_ 3		5
	e. Did you have a lot of energy?		2	_ 3		_ 5
	f. Have you felt downhearted and depressed?	\Box_1	2	_ 3		□ ₅
	g. Did you feel worn out?		2	_ 3		□ ₅
	h. Have you been happy?	\Box_1	2	□_3	4	
	i. Did you feel tired?		2	□_ 3		□ ₅
10	10 During the <u>past 4 weeks</u> , how much of the time has your <u>physical health or emotional</u> <u>problems interfered with your social activities</u> (like visiting friends, relatives, etc.)? □ ₁ All of the time □ ₂ Most of the time □ ₃ Some of the time □ ₄ A little of the time □ ₅ None of the time					
11	How True or False is <u>each</u> of the following statements for you?	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
	a. I seem to get sick a little easier than other people	\Box_1		_ 3		□ ₅
	b. I am as healthy as anybody I know	\Box_1	2	□ ₃	_ 4	□ ₅
	c. I expect my health to get worse			□₃		□ ₅
	d. My health is excellent		 2	□_ 3		□ ₅

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Week 24

			10			Week 24
SEE	ANNOTAT	Subject ID:	02	#	Sub	oject Initials:
UCSD Shortness-of-Breath Question	onnaire		20		JCSDS	OB1 (TYPE 4
When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
1 At rest	0	1	2	3	4	5
2 Walking on a level at your own pace	0	1	2	3	4	5
3 Walking on a level with others your age	0	1	2	3	4	5
4 Walking up a hill	0	1	2	3	4	5
5 Walking up stairs	0	1	2	3	4	5
6 While eating	0	1	2	3	4	5
7 Standing up from a chair	0	1	2	3	4	5
8 Brushing teeth	0	1	2	3	4	5
9 Shaving and/or brushing hair	0	1	2	3	4	5
10 Showering/bathing	0	1	2	3	4	5
11 Dressing	0	1	2	3	4	5
12 Picking up and straightening	0	1	2	3	4	5



Week 24

SEE ANNOTATION P. 19 Subject ID: 02 - ____ - ___ - ___ - ____

Subject Initials: ___ ___

					TYPE 4	4)
UCSD Shortness-of-Breath Que	estionnair	e ucsd s	iOBQ (conti	nued)		
When I do, or if I were to do, the following tasks, I would rate my breathlessness as:	None At All				Severe	Maximal/ Unable To Do Because of Breathlessness
13 Doing dishes	0	1	2	3	4	5
14 Sweeping/vacuuming	0	1	2	3	4	5
15 Making bed	0	1	2	3	4	5
16 Shopping	0	1	2	3	4	5
17 Doing laundry	0	1	2	3	4	5
18 Washing car	0	1	2	3	4	5
19 Mowing lawn	0	1	2	3	4	5
20 Watering lawn	0	1	2	3	4	5
21 Sexual activities	0	1	2	3	4	5
How much do these limit you in your daily life?						
22 Shortness of breath	0	1	2	3	4	5
23 Fear of "hurting myself"	0	1	2	3	4	5
24 Fear of shortness of breath	0	1	2	3	4	5



Week 24

SEE ANNOTATION P. 20 Subject ID: 02 -

site #

Subject Initials: ____ __

St. George's Respiratory Questionnaire (SGRQ) (English for the United States)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are.

STGRG1(TYPE 4)

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the questionnaire:	
Please check one box to show how you describe your current health:	Very good
	Good
	Fair
	Poor
	Very poor
	very poor



Week 24

Subject Initials: ____ ___

S	St. George's Respiratory Questionnaire Part 1							
PI	ease describe how often your respiratory probl	lems have a	iffected y		e past <mark>4 we</mark> e 2(TYPE 4)			
	Please check 🗹 one box for each question.	Almost Every Day	Several Days a Week	A Few Days a Month	Only with Respiratory Infections	Not At All		
ĩ	Over the past 4 weeks, I have coughed:							
2	Over the past 4 weeks, I have brought up phlegm (sputum):							
3	Over the past 4 weeks, I have had shortness of breath:							
4	Over the past 4 weeks, I have had wheezing attacks:							
5	How many times during the past 4 weeks have respiratory attacks? Please check ✓ one:	you suffere	ed from so	evere or ve	ry unpleasa	nt		
6	How long did the worst respiratory attack last? (Go to question 7 if you did not have a severe attac A week or more 3 or more days 1 or 2 days Less than a day		eck I on∢	e:				
7	Over the past 4 weeks, in a typical week, how problems) have you had? Please check ✓ one: □ No good days □ 1 or 2 good days □ 3 or 4 good days □ Nearly every day was good □ Every day was good		l days (wi	ith few resp	iratory			
8	If you wheeze, is it worse when you get up in t No Yes	he morning	? Please d	:heck ☑ on	e:			



Wee	k 24
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Subject Initials: _____

5t. George's Respiratory Questionnaire Part 2				
Section 1				
 How would you describe your respiratory condition? Please check one: The most important problem I have Causes me quite a lot of problems Causes me a few problems Causes me no problems If you have ever held a job (please check one): My respiratory problems made me stop working altogether 				
 My respiratory problems interfere with my job or made me change my job My respiratory problems do not affect my job 				
Section 2				
hese are questions about what activities usually make you feel short of breath <u>these day</u> s.				
or each statement, please check 🗹 the box that applies to you these days.				
1 Sitting or lying still				
Washing or dressing yourself				
Walking around the house D ₁ True D ₀ False				
Walking outside on a level ground				
Walking up a flight of stairs False				
Walking up hills				
Playing sports or other physical activities				
Section 3 12 These are more questions about your cough and shortness of breath <u>these</u> <u>day</u> s.				
For each statement, please check 🗹 the box that applies to you these days.				
Coughing hurts D ₁ True D ₀ False				
Coughing makes me tired D ₁ True D ₀ False				
I am short of breath when I talk 🗋 True 📄 False				
I am short of breath when I bend over				
My coughing or breathing disturbs my sleep				
I get exhausted easily D ₁ True D ₀ False				

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Week 24

Subje	ct Ir	nitial	s:	_	_

Subject ID: 02	Sub	ect Initials:			
St. George's Respiratory Questionnaire Part 2 (continued)					
 Section 4 STGRG4(TYPE 4) 13 These are questions about other effects that your respiratory problems may have on you <u>these</u> <u>days</u>. 					
For each statement, please check 🗹 the box that applies to you these days.					
My cough or breathing is embarrassing in public	□, True	□ _o False			
My respiratory problems are a nuisance to my family, friends or neighbors	□ ₁ True	🔲 o False			
I get afraid or panic when I cannot catch my breath	□ ₁ True	□ _o False			
I feel that I am not in control of my respiratory problems	□, True	□ _o False			
I do not expect my respiratory problems to get any better	□, True	□ _o False			
I have become frail or an invalid because of my respiratory problems	□, True	□ _o False			
Exercise is not safe for me	, True	□ _o False			
Everything seems too much of an effort	□, True	□ _o False			
 Section 5 14 These are questions about your respiratory treatment. If you are not receiving treatment, +go to Section 6. 					
For each statement, please check 🗹 the box that applies to you these days.					
My treatment does not help me very much	□, True	□ _o False			
I get embarrassed using my medication in public	□, True	□ _o False			
I have unpleasant side effects from my medication	□, True	□ _o False			
My treatment interferes with my life a lot	□, True	□ _o False			



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SEE	ANNOTA	TUN	P. 24

Subject Initials: ___ ___

Week 24

SEE ANNOTATION F. 24 Subject ID: 02	ect # Su	ıbject Initials:		
St. George's Respiration Questionnaire Part 2 (continued)				
Section 6 STG 15 These are questions about how your activities might be affected by your re	RG5(T) spiratory	(PE 4) problems.		
For each statement, please check 🗹 the box that applies to you because of your re	spiratory	problems.		
I take a long time to get washed or dressed	□ ₁ True	o False		
I cannot take a bath or shower, or I take a long time to do it	🔲 ₁ True	□_ ₀ False		
I walk slower than other people my age, or I stop to rest	1 True	o False		
Jobs such as household chores take a long time, or I have to stop to rest	🔄 ı True	o False		
If I walk up one flight of stairs, I have to go slowly or stop	True 1	o False		
If I hurry or walk fast, I have to stop or slow down	□ ₁ True	🔲 o False		
My breathing makes it difficult to do things such as walk up hills, carry light gardening such as weeding, dance, bowl, or play SEE PAGE 24	1 True	🔲 o False		
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	SEE PA	GE 24		
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SEE PA			
Section 7 16 We would like to know how your respiratory problems <u>usually</u> affect your daily life.				
For each statement, please check 🗹 the box that applies to you because of your re	spiratory	problems.		
I cannot play sports or do other physical activities	1 True	🗌 o False		
I cannot go out for entertainment or recreation	, True	o False		
I cannot go out of the house to do the shopping	1 True	o False		
I cannot do household chores	🔄 ₁ True	□_ ₀ False		
I cannot move far from my bed or chair	□ ₁ True	o False		



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Week 24

NODATA<XYES>

SEE ANNOTATION P. 25 Subject ID: 02 -

 Subject Initials: ___ __

St. George's Respiratory Questionnaire (continued)

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do not have to check these; they are just to remind you of ways your shortness of breath may affect you.)

• Going for walks or walking the dog

STGRG6(TYPE 4)

- Doing activities or chores at home or in the garden
- Sexual intercourse
- · Going to a place of worship, or a place of entertainment
- · Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other	important activities th	at your respiratory	problems may	stop you from
doing:				

17 Now please check the box (one only) that you think best describes how your respiratory problems affect you:

- It does not stop me from doing anything I would like to do
- It stops me from doing one or two things I would like to do
- It stops me from doing most of the things I would like to do
- It stops me from doing everything I would like to do

Before you finish, would you please make sure that you have answered all the questions.

Thank you for completing this questionnaire.



Week 24

Subject Initials: ____ ___

ICECAP Questionnaire

By placing a check 🗹 in one box in each group below, please indicate which statement best describes your quality of life at the moment.

ICECCAP(TYPE 4)

Love and Friendship	\Box_1 I can have all of the love and friendship that I want \Box_2 I can have a lot of the love and friendship that I want \Box_3 I can have a little of the love and friendship that I want \Box_4 I cannot have any of the love and friendship that I want
Thinking about the future	□ ₁ I can think about the future without any concern □ ₂ I can think about the future with only a little concern □ ₃ I can only think about the future with some concern □ ₄ I can only think about the future with a lot of concern
Doing things that make you feel valued	\Box_1 I am able to do all of the things that make me feel valued \Box_2 I am able to do many of the things that make me feel valued \Box_3 I am able to do a few of the things that make me feel valued \Box_4 I am unable to do any of the things that make me feel valued
Enjoyment and pleasure	\Box_1 I can have all of the enjoyment and pleasure that I want \Box_2 I can have a lot of of the enjoyment and pleasure that I want \Box_3 I can have a little of the enjoyment and pleasure that I want \Box_4 I cannot have any of the enjoyment and pleasure that I want
Independence	 I am able to be completely independent I am able to be independent in many things I am able to be independent in a few things I am unable to be at all independent

Contraction FORM=CL TERM Connect Dispense Select Dispense Select Dispense Select Dispense Select Dispense Select Dispense Record of Study Drug Wanker Effect Number Munther Effect Number Select Dispense Select Dispense 1 Image: Study Drug Number Dispense Number Number of Plils Nu		STEP-IP	ų,		SEE	SEE ANNOTATION P. 65	NODATA <xyes> Study Dru</xyes>	ODATA <xyes> Study Drug Log</xyes>
Subject I: 0.0			let		FORN	A=OL TERM	Open-Lak	oel Phase
Could of Study Drug Wakit 10 Market Number Number of Pils Numer of Pils Number of Pils						l	Subject # Subject	t Initials:
With the bill with the bill bill bill bill bill bill bill bil	~	ecord of Study Dr	r ug Week 12 to V	Veek 24				
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$		Kit Number	Bottle Number (check only one)		Number of Pills Dispensed	Stop Date	Number of Pills Returned	Number of Pills Lost*
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	-		#1		150			
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	7		#1	month	150			
	r,		#1	month	150	/		
	4		#1		150			

IPFnet Step-IPF CRF V4.0_17 SEP 2008 2008 DCRI – Confidential STEP_IPF VERSION 7.0_17SEP2009

> Site Personnel's Initials: ____ ___ WHITE and YELLOW-Duke Clinical Research Institute • PINK-retain at site

Study Completic	on/Termination
Open-Label Phase	(Weeks 12-24)

STEP-IPF

Subject Initials: ___ ___

Study Completion/Termination—	Open-Label Phase	
Did the subject terminate early from this phase? No		TERM (TYPE 4)
$\Box_1 \text{ Yes} \rightarrow \text{ If Yes: Date of study termination: } \{data}$	_//	
aa Reason (check primary reason):	y moon year	
\Box_1 Death \rightarrow Complete Death I	Form and Expedited Event Form.	
2 Lung transplant	SEE ANNOTATION P. 66	
□ ₃ Adverse event (specify):	EXCEPT EXCLUDE:	→ Complete Adverse Events Form
4 Subject withdrew consent	OPENLABL	
□ ₅ MD decision	NOCOUNTIN	
6 Lost to follow-up	UNBLIND	
	UNBLINDT	
	UNBLINDR	
2 Did the subject permanently discontinue study d □ ₀ No □ ₁ Yes → If Yes: Date discontinued:day	/year	
Reason for discontinuation (che		
1 Subject withdrew consent for		
		— → Complete Adverse Events Form
98 Other (specify):		
Investigator's Signature		
I have reviewed all of the data recorded on these CRF pag	ges and certify that they are accurate and	signature (TYPE 4)
Investigator:		Date:///
Signature	of investigator	day month year



STEP			NODATA <xyes></xyes>
	net FORM=DE	EATHPAGE	Death Form
		Subject ID: 02	_ Subject Initials:
Death Form			
press presidents of the subscription of the	Inpatient 2 Outpatient DEATH	DE LOC <ipfloc><i:3></i:3></ipfloc>	ATH (TYPE 1)
3 Cause of death (chec	k only one):		
Pulmonary death	→ Check only one:1 Progression of II	PF	
DEATHCAU <ipf< th=""><th>CAU<i:3></i:3></th><th>PULDEATH<ipfpul><i:3></i:3></ipfpul></th><th></th></ipf<>	CAU <i:3></i:3>	PULDEATH <ipfpul><i:3></i:3></ipfpul>	
	\square_{98} Other (specify):	DEATHSP <v:100></v:100>	
□₂ Non pulmonary d □ ₉₉ Unknown			
Investigator's S	bignature		
		SIGNA y that they are accurate and complete to the	TUR (TYPE 4) e best of my knowledge.
Investigator:	SAME AS P.64	Date:	//yeor
	Signature of investigator	day	month year



FORM=CONMEDS

NODATA<XYES>

Concomitant Medications Log

SEE ANNOTATION P.8

Subject ID: 02 - ________ - ______ subject #

Subject Initials: ____

Concomitant Medications

Record any new non-study medications taken during the course of the study, including over-the-counter and prescription drugs, and herbal remedies, with the exception of medications taken to treat gastrointestinal disorders, including GERD and Barrett's esophagus (record on GERD Concomitant Medications Log). MEDLOG (TYPE 4)R

Medication Name	Start Date	Stop Date OR ✓ if Continuing	Indication
1	doy///wor	doy //yeor OR □_1 Continuing	
2	///year	//	
3	//year	/	
4	//year	/ _{month} / _{yeor} OR □_ ₁ Continuing	
5	/nonthyear	/	
6	///ywar	//	
7	day month year	//	
8	///yeor	//	
9	///	/	
10	///yeor	//	

GERDLOG GERDLOG GERDLOG GERDLOG GERDLOG Record any new or changed medications taken to treat gastrossophageal disorders, including Over-the-counter and prescription drugs and herbal remedies. Record any new or changed medications taken to treat gastrossophageal disorders, including Over-the-counter and prescription drugs and herbal remedies. Frequency Medication Name Dose (Creck only one) Start Date Stop Date OR Indication herbal remedies. I	Jications ions taken to b, taken with a spectral a spec	treat gastroesopl tin 30 days of ran Frequency (Check only one) (Check onl	ageal disorders, including G domization, including overti start Date	SEE ANNOTATION P.9 Subject ID: 02 - orders, including GERD and Barrett's esophagus n, including over-the-counter and prescription di art Date Check if Continuing check if Continuing OR	GER DIOTATION P.9 Subject ID: 02
Check if self-prescribed	2 2 2 2 2 2 2 2 2 2 2 2 2 2	PRN (< 1/wk) PRN (day / year	day	s esop

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PINK—retain at site
IPFnet Step-IPF CRF V4.0_17 SEP 2008
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CRF, page 109.____

Adverse Event Log NODATA<XYES>

FORM=ADVERSE EVENT

THIS IS A REPEATING PAGE

Fnet

STEP-IPF

subject # site # Subject ID: 02 -

Subject Initials:

		<u>n</u>							
	Did the subject have a	Did the subject have any adverse event(s) after first do	se of study medicat	YAE <xyes< th=""><th>\ \ \ \ \ \ \</th><th>ion? □, № □, Yes → If Yes, provide details below: ANYAE<xyesno></xyesno></th><th></th><th>ADVERSE (TYPE 4)</th><th>E 4)</th></xyes<>	\ \ \ \ \ \ \	ion? □, № □, Yes → If Yes, provide details below: ANYAE <xyesno></xyesno>		ADVERSE (TYPE 4)	E 4)
WHITE an	AENUMBER<1:3> # Adverse Event	Onset Date	End Date OR Check if Continuing	Hospitalized?	Maximum Intensity	Relationship to Study Drug	Actions Taken with Study Drug <u>AE</u> C	ms Taken Was This h Study Final Outcome Event Drug AEQUTCM <ipfout><<mark>\$\$</mark>tjous?</ipfout>	Was This Event Ssrjous?
d YELLOW-Du	AETERM <v:100></v:100>	AEONSTDT	AEENDDT AEI day /	AEHOSP <xyesno> </xyesno>	ld oderc vere	AERE Not 1 CIPEREL Role 3> reasonable 2 Interrupter possibility 2 Discontinu keasonable 2 Discontinu possibility 2 Discontinu	 ₹EI_Assie:3> □2 Interrupted □3 Discontinued □4 Dosage change 	4	 Sevential Sevential Seventia Sevential Sevential Sevential Sevential Sevential S
ke Clinical Rese			AECONTU <xyes></xyes>	AEIN 0 No 1 Yes	NTENS <xii 1 Mild 2 Moderate 3 Severe</xii 	NTNS341:32 reasonable possibility possibility possibility	□, None □, None □, Interrupted □, Discontinued	□, Subject died □, Resolved <i>no</i> sequelae □, Resolved <i>with</i> sequelae	0 No 1 Yes*
arch Institute	MEDRTEXT <v:100> WORKFLOW<v<u>:5> CODETM<datetime></datetime></v<u></v:100>	100> :5> /	$\frac{-\frac{1}{doy}-\frac{1}{month}-\frac{1}{month}-\frac{1}{month}-\frac{1}{month}-\frac{1}{month}}{OR \Box_{1} Ongoing}$	□ ₀ No	□, Mild □2 Moderate □3 Severe	□o Not a reasonable possibility □, Reasonable possibility	 □1 None □2 Interrupted □3 Discontinued □4 Dosage change 	□1 Subject died □2 Resolved no sequelae □3 Resolved with sequelae □4 Unesolved	0 No 1 Yes*
PINK	MATCHES <v:4> CONFLVL<v:2></v:2></v:4>	day	$\frac{1}{\frac{day}{day}} - \frac{1}{\frac{1}{nonth}} - \frac{1}$	□ 0 No 1 Yes	□, Mild □_2 Moderate □_3 Severe	 Not a reasonable possibility Reasonable possibility possibility 	 □1 None □2 Interrupted □3 Discontinued □4 Dosage change 	 □1, Subject died □2, Resolved no sequelae □3, Resolved with sequelae □4, Unresolved 	□o No □1 Yes*
Site Pers retain at site	-	day /	day //	□ 0 No 1 Yes	□, Mild □_2 Moderate □_3 Severe	□o Not a reasonable possibility possibility possibility	□1 None □2 Interrupted □3 Discontinued □4 Dosage change	 Subject died Resolved no sequelae Resolved with sequelae Unresolved 	0 No 1 Yes*
onnel's Initials: _	Investigator's Signature I have reviewed all of the data recorde Investigator:	Investigator's Signature I have reviewed all of the data recorded on these CRF Investigator:	CRF pages and certify that they are accurate and complete to the best of my knowledge. Date: dot month year	hey are accura	te and comp SEE ANNC ite:	bates and complete to the best of SEE ANNOTATION P.64 day month year		SIGNATUR (TYPE 4)	9E 4)

"If serious and relationship to study drug is a reasonable possibility or death occurred, please submit Expedited Event (EE) Form. "If serious, submit Pfizer Investigator Initiated Research SAE Form.

STEP-IPF		NODATA <xyes></xyes>
IPFnet	FORM=MISSED VISIT	Missed Visit Form
		Subject Initials:
Missed Visit		
Instructions: Complete this form only if	the subject missed an entire study visit but is con	tinuing in the trial.
Complete one form per mi	ssed visit.	
Do not send the CRF page	s for this missed visit.	MVISITFM (TYPE 4)
Missed visit (check only one): Week	1	
□_₂ Week		
□ ₃ Week	MISVIS <ipfmis><i:3></i:3></ipfmis>	
□_₄ Week	13	
5 Week	18	
□ ₆ Week	24	
Study Coordinator: Submit the origina	I of each form to the DCRI with the next batch of	f CRF pages.
Maintain a copy ir	n the subject's CRF binder in place of the schedul	ed visit pages.

	FORM=UNSCHEDULED PEATING PAGE Subject ID: 02	NODATA <xyes> Unscheduled Visit</xyes>
Unscheduled Visit Visit date:// Reason for unscheduled visit (check all that UNSCHREA <ipfuns></ipfuns>		VISTDATE (TYPE 4)
4 SpO ₂ :%	^{mm Hg} EE ANNOTATION P.11 XCEPT NO HEIGHT	VITALS (TYPE 4)
Spirometry Date of assessment: //	SEE ANNOTATION P.2 NOTE: DO NOT ADD QUESTIONS 4,5,6	SPIROMET (TYPE 4)
Investigator's Signature I have reviewed all of the data recorded on the Investigator:	se CRF pages and certify that they are accurate and FATION P.64 Signature of investigator	SIGNATUR(TYPE 4) complete to the best of my knowledge. Date:/

STEP-IPF NODATA<XYES> **FORM=EXACERBATION PFnet Acute Exacerbation Identification Report** Subject Initials: Subject ID: 02 - _ THIS IS A REPEATING PAGE sito # subject # ACEXID (TYPE 4) Acute Exacerbation Identification Complete one form for each episode of acute worsening 1 Event description: EXACRBTN<V:100> 2 Location of medical care (check only one): \Box_1 Local physician/clinic \Box_2 Local ER \rightarrow If local, specify facility: 3 IPFnet ER $\begin{array}{c} \textbf{BLOODOBT} < \textbf{XYESNO} > \\ \textbf{Research blood obtained?} \bigcirc \textbf{No} & \bigcirc_1 \text{ Yes} \rightarrow \textbf{If Yes: Date:} & \underbrace{\textbf{BLOODDI}}_{day} & \underbrace{\textbf{Month}}_{day} & \underbrace{\textbf{Month}}_{day}$ BLAOBT<XYESNO> Research BAL obtained? $\square_0 \text{ No} \square_1 \text{ Yes} \rightarrow \text{ If If Yes: Date: } _____$ 5 6 Outcome (check only one): _______, Treated as outpatient ______, Hospitalized, not mechanically ventilated DUTCOME<IPFWHF><I:3> □₃ Hospitalized and mechanically ventilated During this episode of acute worsening, did the subject have (answer all questions): all have <XYNUNK>

 JGH
 Productive cough?
 0
 No
 1
 Yes
 99
 Unknown
 CONGESTN
 Congestion?
 0
 No
 1
 Yes
 99
 Unknown

 /ER
 Fever?
 0
 No
 1
 Yes
 99
 Unknown
 ACHINESS
 0
 No
 1
 Yes
 99
 Unknown

 CO /ER _{Fever?} FE CHEHeadache? No No 1 Yes ____ Unknown SORE Tree Throat? ___ No HA Performed **Performed But** 8 Reports collected: REPORTS<IPFTSX><I:3> **Date Performed** Not Performed and Report Unavailable Attached TESTDT 1 = CT scan(s): month year 2= Chest x-ray*: Prior to event □, month year Chreat xoray Peri-event . 3= month year □. . $\square_2 \rightarrow$ 4= Echocardiogram month year 5= Pulmonary function tests □. \Box $\square_2 \rightarrow$ \Box 6= Pulse oximetry and vital signs __,→ veor \Box □. 7= Arterial blood gases $\square_2 \rightarrow$ Vecr 8= Respiratory cultures: Sputum \Box month year 9=Respiratory cultures Endotracheal aspirate □. year 10=Respiratory cultures Lavage □. 11=Bronchoscopy: Report \Box year 12= Bronchoscopy Cell count month yeor 13 =Bronchoscopy Differential nonth □. 4= Blood cultures . $\square_2 \rightarrow$ nonth de 15=Clinic/hospital records related to the event $\square_2 \rightarrow$ day month year /SENTDT Date this form and supporting materials sent to DCC for adjudication: da vear

WHITE and YELLOW—Duke Clinical Research Institute IPFnet Step-IPF CRF V4.0_17 SEP 2008 2008 DCRI — Confidential STEP IPF VERSION 7.0 17SEP2009

Acute Exacerbation Identification Report, page 113.

Site Personnel's Initials: _____ PINK—retain at site



FORM=LOCAL LAB

NODATA<XYES>

Local Lab

THIS IS A REPEATING PAGE

subject ID: 02 - ______ - - _____OCEUAR I(#PE 4)PS

LABVS	Complete this form only if the Central Lab was not used for this visit.							
	Check visit: 1 Screening 2 2 Enrollment/Week 0 3 Week 1 4 Week 6 5 5 Week 12 6 6 Week 13 7 Week 18 8 Week 24							
	Date of assessment:		/ LABD1	0				
	Labs	month	year LADD					
	Assessment	Not Done	Value	Units	LLN	ULN		
LABAS	SES <ipflab><i:3></i:3></ipflab>		LABVAL <f:9:3></f:9:3>		LABLLN <f:9:3></f:9:3>	LABULN <f:9:3></f:9:3>		
1=	ALT/SGPT:	97						
	LAE	BND <xyes< th=""><th>\$></th><th>LABUNT <ipfl< th=""><th>UT></th><th></th></ipfl<></th></xyes<>	\$>	LABUNT <ipfl< th=""><th>UT></th><th></th></ipfl<>	UT>			
2=	2 AST/SGOT:	97		□_ ₁ U/L □_ ₂ IU/L				
3=	3 Total bilirubin:	97		□₃ mg/dL □₄μmol/L				
4=	4 Creatinine	97		□ ₃ mg/dL □ ₄ μmol/L				
5=	5 Hemoglobin (Hgb):	97		□ ₅ g/dL □ ₆ g/L □ ₇ mmol/L				
6=	6 WBC:	97		□ ₈ 10°/L OR 10 ³ /mm ³ □ ₉ /mm ³				
7=	7 BNP:	97		□ ₁₀ pg/mL □ ₁₁ ng/L				

Site Personnel's Initials: ____

CRF, page 114._

STEP-IPF

NODATA<XYES> FORM=EXACERBATION ADJ **Acute Exacerbation Adjudication Report**

THIS IS A REPEATING PAGE

Subject ID: 02 - _______ Subject Initials: _______ Subject Initials: _______

Complete one form for each episode of acute worsening.			
Event description: EXACRBAJ <v:100></v:100>			
2 Date of event:/// EXADJDT			
The following three criteria will define acute exacerbation (AEx) in subjects with acute worsening of their respiratory condition:	Met	Not Met	In te
3 Clinical (all of the following must be met): CLINA <ipfxaj><1:3></ipfxaj>			
 A Unexplained worsening of dyspnea or cough within 30 days, triggering unscheduled medical care (e.g., clinic, study visit, hospitalization): CLINB <			
venous thrombosis to explain acute worsening of dyspnea:		2	
C No pneumothorax: CLINC <ipfxaj><i:3></i:3></ipfxaj>		2	
 4 Radiologic/Physiologic (only one of the following must be met): A Radiographic change including new ground glass opacity or consolidation on chest X-ray or CT scan: RADLGA<ipfxaj><i:3></i:3></ipfxaj> 		2	
B Decline of ≥ 5% in resting room air SpO₂ from last recorded level OR decline of ≥ 8 mm Hg in resting room air PaO₂ from last recorded level:RADLGB <ipfxaj><i:< p=""></i:<></ipfxaj>	3> □1	2	
 5 Microbiologic (all of the following must be met): MICROA<ipfxaj><i:3> A No clinical evidence for infection (i.e., absence of grossly purulent sputum, fever > 39°C orally): B Lack of positive microbiological results from lower respiratory tract defined as </i:3></ipfxaj> 			
 (1) clinically significant bacterial growth on sputum or endotracheal aspirate cultures; (2) quantitative culture by protected brush specimen ≥10³ cfu/mL or BAL > 10⁴ cfu/mL; (3) the presence of specific pathogens on stains of any of the above: C Lack of positive pathogen in blood cultures: 		□_2 □_2	
 Final diagnosis (check only one): 1 Definite acute exacerbation (all criteria met; no alternative etiological data to evaluate all of 2 Unclassifiable acute worsening (Insufficient data to evaluate all of 3 Not acute exacerbation (alternative etiology identified that explose (specify):	riteria; no c		etiol
7 Date of final adjudication:/ / FNLADJDT			
Signature			
Adjudication Committee Members involved in review (check all who apply): All <i:1><xyes> COLLARD SCHWARZ Robert Kaner Hal Collard Marvin Schwarz COLBY David Lynch Joao de ADJMBRSP<v:100> LYNCH ANDRA</v:100></xyes></i:1>	Andrade DE	ANSTR Kevin	O Anst
R <xyes></xyes>	67 - A	t of my kn	owl
Adjudication Committee member: Date: Date:	/	ĘXC	

	5	STEP-IPF	BIOLOGICAL SAMPLES Biological Sample Collection
		THIS IS A REPEATING PAGE	
	Bio	ogical Sample Collections	
	Comp	lete this form for each visit biological sample collection	is expected or an Acute Exacerbation, and submit it with the next
		of CRFs. Keep copy in subject file.	
		reck visit:1 Enrollment2 Week 03 Week 12 (ere any biological samples collected during this visit?	\square_4 Week 18 \square_5 Week 24 \square_6 Acute Exacerbation \square_7 Other
		$\begin{bmatrix} 0 & N \circ \mathbf{B} \\ \mathbf{O} & O & O \\ \mathbf{O} & O & O \\ \end{bmatrix}_{1} \text{ Yes} \rightarrow \text{ If Yes: Date of collection: } \underbrace{ \frac{B & O & O \\ \frac{d & o & O \\ \frac{d & o & o \\ m & o & o \\ o & o & o \\ \end{bmatrix}}_{\text{month}} B & O & O \\ \frac{d & O & O \\ d & d & d \\ d \\ d & d \\ d \\ d & d \\ \mathsf$	(ESNO>
		A	yeor 3EL <v:15></v:15>
	Samp	le	Was sample drawn and appropriately labeled and stored?
1=	001	(0.5 ml Serum) BIOSAMP <ipfbsm></ipfbsm>	□ ₀ No □ ₁ Yes BIOSMDON <xyesno></xyesno>
2=	002	(0.5 ml Serum)	0 No 1 Yes
3=	003	(0.5 ml Serum)	□ ₀ No □ ₁ Yes
4=	004	(0.5 ml Serum)	□ _o No □ ₁ Yes
5=	005	(4.0 ml Serum)	O No 1, Yes
6=	006	(2.0 ml Serum)	□ ₀ No □ ₁ Yes
7=	007	(0.5 ml Plasma)	□ ₀ No □ ₁ Yes
8=	008	(0.5 ml Plasma)	□ _o No □, Yes
9=	009	(0.5 ml Plasma)	□ _o No □ ₁ Yes
10=	010	(0.5 ml Plasma)	□ _o No □ ₁ Yes
11=	011	(4.0 ml Plasma)	□ _o No □ ₁ Yes
12=	012	(2.0 ml Plasma)	□ ₀ No □ ₁ Yes
13=	013	013 (8.5 ml DNA) (8.5 ml DNA Enrollment/Acute Exacerbation only)	□ _o No □ ₁ Yes
14=	014	014 (8.5 ml DNA) (8.5 ml DNA Enrollment/Acute Exacerbation only)	□ ₀ No □ ₁ Yes
15=	015	(5.0 ml Urine)	□ _o No □ ₁ Yes
16=	016	(5.0 ml Urine)	□ ₀ No □ ₁ Yes
17=	017	(5.0 ml Urine)	□ _o No □ ₁ Yes
18=	018	(5.0 ml Urine)	□ ₀ No □ ₁ Yes

DCRI Forms Management: Make copy for CDI; put original in subject folder IPFnet Step-IPF CRF V4.0_17 SEP 2008 2008 DCRI – Confidential

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