WRAP-IPF Trial

CRF Annotation

3. Codelists

3.1. ACTIVITY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45971	1	I have no problems with performing my usual activities	
codelist- 45971	2	I have some problems with performing my usual activities	
codelist- 45971	3	I am unable to perform my usual activities	

3.2. AE EVENT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45818	1	Respiratory worsening	
codelist- 45818	2	Difficulty swallowing / dysphagia	
codelist- 45818	3	Bloating	
codelist- 45818	4	Flatulence	
codelist- 45818	5	Other	

3.3. AEINTENSITY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45890	1	Mild	
codelist- 45890	2	Moderate	
codelist- 45890	3	Severe	
codelist- 45890	4	SERIOUS	YES

3.4. AERELAT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45891	1	Not a reasonable possibility	
codelist- 45891	2	Reasonable possibility	

3.5. AESAE_LAB

Unique Identifier	Code	Display Text	Hidden?
codelist- 45892	1	mmol/L	
codelist- 45892	2	mg/dL	
codelist- 45892	3	%	
codelist- 45892	4	g/dL	
codelist- 45892	5	g/L	
codelist- 45892	6	IU/L or U/L or mIU/mL	
codelist- 45892	7	ukat/L	
codelist- 45892	8	umol/L	
codelist- 45892	9	nkat/L	
codelist- 45892	10	mm3	
codelist- 45892	11	mmol/mol	

3.6. AESEV

Unique Identifier	Code	Display Text	Hidden?
codelist- 45820	1	Mild	
codelist- 45820	2	Moderate	
codelist- 45820	3	Severe	

3.7. AEVIS

Unique Identifier	Code	Display Text	Hidden?
codelist- 45973	1	Screen	
codelist- 45973	2	Enroll	
codelist- 45973	3	Surgical Intervention	
codelist- 45973	4	Month 1	
codelist- 45973	5	Month 2	
codelist- 45973	6	Week 12	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45973	7	Month 4	
codelist- 45973	8	Month 5	
codelist- 45973	9	Week 24	
codelist- 45973	10	Month 7	
codelist- 45973	11	Month 8	
codelist- 45973	12	Week 36	
codelist- 45973	13	Month 10	
codelist- 45973	14	Month 11	
codelist- 45973	15	Week 48	

3.8. ANXIETY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45893	1	I am not anxious or depressed	
codelist- 45893	2	I am moderately anxious or depressed	
codelist- 45893	3	I am extremely anxious or depressed	

3.9. ActionDrug

Unique Identifier	Code	Display Text	Hidden?
codelist- 45974	1	None	
codelist- 45974	2	Drug Interrupted	
codelist- 45974	3	Drug Discontinued	
codelist- 45974	99UNK	Unknown	

3.10. BOUGIE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45926	0	None used	
codelist- 45926	1	52	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45926	2	54	
codelist- 45926	3	56	
codelist- 45926	4	58	
codelist- 45926	5	60	
codelist- 45926	98	Other	

3.11. BS

Unique Identifier	Code	Display Text	Hidden?	
codelist- 45827	1	Immunologic		
codelist- 45827	2	HEENT		
codelist- 45827	3	Respiratory		
codelist- 45827	4	Cardiovascular		
codelist- 45827	5	Gastrointestinal		
codelist- 45827	6	Endocrine / Metabolic		
codelist- 45827	7	Neurological		
codelist- 45827	8	Blood / Lymphatic		
codelist- 45827	9	Musculoskeletal		
codelist- 45827	10	Hepatic		
codelist- 45827	11	Allergic		
codelist- 45827	12	Surgical History		
codelist- 45827	13	Dermatological		
codelist- 45827	98	Other		

3.12. CAUSAL

Unique Identifier	Code	Display Text	Hidden?
codelist- 45897	1	Related	
codelist- 45897	2	Not Related	

Unique Identifier	Code	Display Text	Hidden?	
codelist- 45830	1	Screen		
codelist- 45830	2	Enroll	YES	
codelist- 45830	3	Surgical Intervention	YES	
codelist- 45830	4	Month 1	YES	
codelist- 45830	5	Month 2	YES	
codelist- 45830	6	Week 12		
codelist- 45830	7	Month 4	YES	
codelist- 45830	8	Month 5	YES	
codelist- 45830	9	Week 24		
codelist- 45830	10	Month 7	YES	
codelist- 45830	11	Month 8	YES	
codelist- 45830	12	Week 36		
codelist- 45830	13	Month 10	YES	
codelist- 45830	14	Month 11	YES	
codelist- 45830	15	Week 48		

3.13. CMVIS

3.14. COMPLICATION

Unique Identifier	Code	Display Text	Hidden?
codelist- 45929	1	Pneumothorax	
codelist- 45929	2	Enterotomy	
codelist- 45929	3	Aspiration	
codelist- 45929	4	Hemorrhage > 100cc	
codelist- 45929	5	Other	

3.15. COMPSPCFY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45831	1	DVT	
codelist- 45831	2	PE	
codelist- 45831	3	Pneumonia (w/in 30 days)	
codelist- 45831	4	Soft tissue infection	
codelist- 45831	5	Clinically significant dysphagia / PO intolerance	
codelist- 45831	6	Death	

3.16. CURHLTH

Unique Identifier	Code	Display Text	Hidden?
codelist- 45832	1	Very good	
codelist- 45832	2	Good	
codelist- 45832	3	Fair	
codelist- 45832	4	Poor	
codelist- 45832	5	Very poor	

3.17. DEATHCAUSE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45935	1	Pulmonary death	
codelist- 45935	2	Non-pulmonary death	
codelist- 45935	99	Unknown	

3.18. DEATHWHERE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45833	1	Inpatient	
codelist- 45833	2	Outpatient	

3.19. EMPTYSTATE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45836	999999996	NA	
codelist- 45836	999999997	Not Done	
codelist- 45836	999999999	Unknown	

3.20. ETHNIC

Unique Identifier	Code	Display Text	Hidden?
codelist- 45838	1	Hispanic or Latino	
codelist- 45838	2	Not Hispanic or Latino	
codelist- 45838	3	Not Reported	
codelist- 45838	4	Unknown	

3.21. EXCRIT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45840	1	EX01	
codelist- 45840	2	EX02	
codelist- 45840	3	EX03	
codelist- 45840	4	EX04	
codelist- 45840	5	EX05	
codelist- 45840	6	EX06	
codelist- 45840	7	EX07	
codelist- 45840	8	EX08	
codelist- 45840	9	EX09	
codelist- 45840	10	EX10	
codelist- 45840	11	EX11	
codelist- 45840	12	EX12	
codelist- 45840	13	EX13	
codelist- 45840	14	EX14	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45840	15	EX15	
codelist- 45840	16	EX16	
codelist- 45840	17	EX17	
codelist- 45840	18	EX18	
codelist- 45840	19	EX19	
codelist- 45840	20	EX20	
codelist- 45840	21	EX21	
codelist- 45840	22	EX22	
codelist- 45840	23	EX23	
codelist- 45840	24	EX24	
codelist- 45840	25	EX25	
codelist- 45840	26	EX26	
codelist- 45840	27	EX27	
codelist- 45840	28	EX28	
codelist- 45840	29	EX29	
codelist- 45840	30	EX30	
codelist- 45840	31	EX31	
codelist- 45840	32	EX32	
codelist- 45840	33	EX33	

3.22. FINDINGS

Unique Identifier	Code	Display Text	Hidden?
codelist- 45900	1	Cirrhosis	
codelist- 45900	2	Hypersplenism	
codelist- 45900	3	Hepatomegaly	
codelist- 45900	4	Evidence of portal hypertension	
codelist- 45900	5	Presence of intra-abdominal adhesions	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45900	6	Variant anatomy, Describe	
codelist- 45900	98	Other	

3.23. FOUTCOME

Unique Identifier	Code	Display Text	Hidden?
codelist- 45901	1	Subject died	
codelist- 45901	2	Resolved no sequelae	
codelist- 45901	3	Resolved with sequelae	
codelist- 45901	4	Unresolved	

3.24. FRIENDS

Unique Identifier	Code	Display Text	Hidden?
codelist- 45978	1	I can have all of the love and friendship that I want	
codelist- 45978	2	I can have a lot of the love and friendship that I want	
codelist- 45978	3	I can have a little of the love and friendship that I want	
codelist- 45978	4	I cannot have any of the love and friendship that I want	

3.25. HCADMINTYPE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45843	1	Hospital	
codelist- 45843	2	ER/urgent care	
codelist- 45843	3	Assisted living / nursing facility	
codelist- 45843	4	Rehabilitation center	

3.26. HCDISCHRGE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45959	1	Home	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45959	2	Assisted living / nursing facility	
codelist- 45959	3	Rehab center	
codelist- 45959	4	Transfer to other hospital	
codelist- 45959	5	Subject died	
codelist- 45959	6	Other	

3.27. HERNIASIZE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45979	1	small (2-3 cm)	
codelist- 45979	2	medium (3-4 cm)	
codelist- 45979	3	large (4+ cm)	
codelist- 45979	4	paraesophageal	

3.28. INCRIT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45845	1	IN01	
codelist- 45845	2	IN02	
codelist- 45845	3	IN03	
codelist- 45845	4	IN04	
codelist- 45845	5	IN05	
codelist- 45845	6	IN06	
codelist- 45845	7	IN07	
codelist- 45845	8	IN08	
codelist- 45845	9	IN09	

3.29. INDEPEND

Unique Identifier	Code	Display Text	Hidden?
codelist- 45940	1	I am able to be completely independent	
codelist- 45940	2	I am able to be independent in many things	
codelist- 45940	3	I am unable to be independent in a few things	
codelist- 45940	4	I am unable to be at all independent	

3.30. Intensity

Unique Identifier	Code	Display Text	Hidden?
codelist- 45846	1	Mild	
codelist- 45846	2	Moderate	
codelist- 45846	3	Severe	
codelist- 45846	4	Very Severe	

3.31. LBTEST

Unique Identifier	Code	Display Text	Hidden?
codelist- 45847	ALT	Alanine Aminotransferase (ALT)	
codelist- 45847	ALB	Albumin	
codelist- 45847	AP	Alkaline Phosphatase (AP)	
codelist- 45847	AMYLASE	Amylase	
codelist- 45847	AST	Aspartate Aminotransferase (AST)	
codelist- 45847	BILI	Bilirubin (Total)	
codelist- 45847	BILICJ	Bilirubin (Conjugated)	
codelist- 45847	BUN	Blood Urea Nitrogen (BUN)	
codelist- 45847	CA	Calcium	
codelist- 45847	CL	Chloride	
codelist- 45847	CHOL	Cholesterol (total)	
codelist- 45847	CREAT	Creatinine	
codelist- 45847	GLUC	Glucose	

Unique	Code	Display Text	Hidden?
Identifier codelist-	LIP	Lipase	
45847 codelist-	PHOS	Phosphate	
45847 codelist-	к	Potassium	
45847			
codelist- 45847	NA	Sodium	
codelist- 45847	ТР	Total Protein	
codelist- 45847	UA	Uric Acid	
codelist- 45847	HGB	Hemoglobin	
codelist- 45847	НСТ	Hematocrit	
codelist- 45847	МСН	Mean Corpuscular Hemoglobin (MCH)	
codelist- 45847	МСНС	Mean Corpuscular Hemoglobin Concentration (MCHC)	
codelist- 45847	MCV	Mean Corpuscular Volume (MCV)	
codelist- 45847	PLAT	Platelet Count	
codelist- 45847	RBC	Red Blood Cell (RBC) Count	
codelist- 45847	WBC	White Blood Cell (WBC) Count	
codelist- 45847	LYM	Lymphocytes	
codelist- 45847	MONO	Monocytes	
codelist- 45847	BASO	Basophils	
codelist- 45847	EOS	Eosinophils	
codelist- 45847	NEUT	Neutrophils	
codelist- 45847	CAST	Casts	
codelist- 45847	KET	Ketone	
codelist- 45847	NIT	Nitrite	
codelist- 45847	PH	рН	
codelist- 45847	PROT	Protein	
codelist- 45847	CRYS	Crystals	
codelist- 45847	SPG	Specific Gravity	
codelist- 45847	URO	Urobilinogen	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45847	BACT	Bacteria	
codelist- 45847	RBCM	RBC Microscopy	
codelist- 45847	WBCM	WBC Microscopy	
codelist- 45847	EPCEL	Epithelial Cells	
codelist- 45847	OTHER	Other	

3.32. MOBILE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45853	1	I have no problems in walking about	
codelist- 45853	2	I have some problems in walking about	
codelist- 45853	3	I am confined to bed	

3.33. NCOMPLT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45904	1	Adverse Event	
codelist- 45904	2	Complete	YES
codelist- 45904	3	Death	
codelist- 45904	4	Lack of Efficacy	
codelist- 45904	5	Lost to follow-up	
codelist- 45904	6	Non-compliance With Study Drug	
codelist- 45904	8	Physician Decision	
codelist- 45904	9	Pregnancy	
codelist- 45904	10	Progressive Disease	
codelist- 45904	11	Protocol Violation	
codelist- 45904	12	Recovery	
codelist- 45904	13	Trial Screen Failure	
codelist- 45904	14	Study Terminated By Sponsor	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45904	15	Technical Problem	
codelist- 45904	16	Withdrew Consent	
codelist- 45904	17	Study Subject Withdrawal by Parent or Guardian	
codelist- 45904	18	Recurrent Disease	
codelist- 45904	98	Other	

3.34. NY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45983	0	No	
codelist- 45983	1	Yes	

3.35. OTHACN

Unique Identifier	Code	Display Text	Hidden?
codelist- 45942	1	None	
codelist- 45942	2	Medication required	YES
codelist- 45942	3	Hospitalization or prolongation of hospitalization required	YES
codelist- 45942	4	Other	

3.36. OUT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45985	1	Death Related to Adverse Event	
codelist- 45985	2	Not Recovered or Not Resolved	
codelist- 45985	3	Recovered or Resolved	
codelist- 45985	4	Recovered or Resolved with Sequelae	
codelist- 45985	5	Recovering or Resolving	
codelist- 45985	99	Unknown	

3.37. OUTC

Unique Identifier	Code	Display Text	Hidden?
codelist- 45986	1	Recovered/Resolved	
codelist- 45986	2	Recovered/Resolved with Sequelae	
codelist- 45986	3	Not Recovered/Not Resolved	
codelist- 45986	4	Fatal	
codelist- 45986	5	Unknown	

3.38. Ongoing

Unique Identifier	Code	Display Text	Hidden?
codelist- 45854	1	Ongoing	

3.39. Outcome

Unique Identifier	Code	Display Text	Hidden?
codelist- 45855	1	Recovered / Resolved	
codelist- 45855	2	Recovering / Resolving	
codelist- 45855	3	Not recovered / Not resolved	
codelist- 45855	4	Recovered / Resolved with sequelae	
codelist- 45855	5	Fatal	
codelist- 45855	99UNK	Unknown	

3.40. PAIN

Unique Identifier	Code	Display Text	Hidden?
codelist- 45905	1	I have no pain or discomfort	
codelist- 45905	2	I have moderate pain or discomfort	
codelist- 45905	3	I have extreme pain or discomfort	

3.41. PATHREVIEW

Unique Identifier	Code	Display Text	Hidden?
codelist- 45856	1	UIP pattern	
codelist- 45856	2	Probable UIP pattern	
codelist- 45856	3	Possible UIP pattern	
codelist- 45856	4	Not UIP pattern	

3.42. PEB

Unique	Code	Display Text	Hidden?
Identifier			
codelist- 45987	1	General Appearance	
codelist- 45987	2	Hair and Skin	
codelist- 45987	3	Lymphatics	
codelist- 45987	4	HEENT	
codelist- 45987	5	Respiratory	
codelist- 45987	6	Cardiovascular	
codelist- 45987	7	Abdominal	
codelist- 45987	8	Musculoskeletal	
codelist- 45987	9	Mental Status	
codelist- 45987	10	Neurological	
codelist- 45987	11	Endocrine	
codelist- 45987	98	Other	

3.43. PLEASURE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45943	1	I can have all of the enjoyment and pleasure that I want	
codelist- 45943	2	I can have a lot of the enjoyment and pleasure that I want	
codelist- 45943	3	I can have a little of the enjoyment and pleasure that I want	
codelist- 45943	4	I cannot have any of the enjoyment and pleasure that I want	

3.44. POSNEG

Unique Identifier	Code	Display Text	Hidden?
codelist- 45858	1	Positive	
codelist- 45858	2	Negitive	

3.45. RACE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45859	w	White	
codelist- 45859	В	Black or African American	
codelist- 45859	A	Asian	
codelist- 45859	I	American Indian or Alaska Native	
codelist- 45859	Р	Native Hawaiian or Other Pacific Islander	
codelist- 45859	М	Mixed Race	
codelist- 45859	0	Other	

3.46. RACEb

Unique Identifier	Code	Display Text	Hidden?
codelist- 45989	1	White	
codelist- 45989	2	Black or African American	
codelist- 45989	3	Asian	
codelist- 45989	4	American Indian or Alaska Native	
codelist- 45989	5	Native Hawaiian or Other Pacific Islander	
codelist- 45989	6	Mixed Race	
codelist- 45989	7	Other	

3.47. RADREVIEW

Unique Identifier	Code	Display Text	Hidden?
codelist- 45947	1	UIP pattern	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45947	2	Possible UIP pattern	
codelist- 45947	3	Inconsistent with UIP pattern	

3.48. RELATIONSHIP

Unique Identifier	Code	Display Text	Hidden?
codelist- 45906	1	Not related	
codelist- 45906	2	Unlikely related	
codelist- 45906	3	Possibly related	
codelist- 45906	4	Probably related	
codelist- 45906	5	Definitely related	

3.49. RESPIRATORY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45990	1	Community / hospital acquired pneumonia	
codelist- 45990	2	Bronchitis	
codelist- 45990	3	Aspiration pneumonitis	
codelist- 45990	4	Pulmonary embolism	
codelist- 45990	5	Pneumothorax	
codelist- 45990	6	Non-pulmonary cause (e.g. anxiety)	
codelist- 45990	7	Unknown cause	

3.50. ROUTE

Unique Identifier	Code	Display Text	Hidden?
codelist- 45907	1	Oral	
codelist- 45907	2	Sublingual	
codelist- 45907	3	IV	
codelist- 45907	4	IM	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45907	5	Subcutaneous	
codelist- 45907	6	Inhalation	
codelist- 45907	7	Intranasal	
codelist- 45907	8	Topical	
codelist- 45907	9	Transdermal	

3.51. ROUTEa

Unique Identifier	Code	Display Text	Hidden?
codelist- 45860	1	Auricular	
codelist- 45860	2	Intramuscular	
codelist- 45860	3	Inhalation	
codelist- 45860	4	Intradermal	
codelist- 45860	5	Intravenous	
codelist- 45860	6	Intraocular	
codelist- 45860	7	Oral	
codelist- 45860	8	Subcutaneous	
codelist- 45860	9	Sublingual	
codelist- 45860	10	Rectal	
codelist- 45860	11	Topical	
codelist- 45860	12	Transdermal	
codelist- 45860	13	Vaginal	
codelist- 45860	14	Nasal	

3.52. SEVER

Unique Identifier	Code	Display Text	Hidden?
codelist- 45951	1	Mild	
codelist- 45951	2	Moderate	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45951	3	Severe	

3.53. SEX

Unique Identifier	Code	Display Text	Hidden?
codelist- 45913	м	Male	
codelist- 45913	F	Female	

3.54. SMOKER

Unique Identifier	Code	Display Text	Hidden?
codelist- 45864	1	Current	
codelist- 45864	2	Former	
codelist- 45864	3	Never	

3.55. STENRF

Unique Identifier	Code	Display Text	Hidden?
codelist- 45952	1	After	
codelist- 45952	2	Before	
codelist- 45952	3	During	YES
codelist- 45952	4	During/After	YES
codelist- 45952	98	Unknown	
codelist- 45952	5	Coincident	YES
codelist- 45952	6	Ongoing	YES

3.56. SUBJRAND

Unique Identifier	Code	Display Text	Hidden?
codelist- 45991	1	Surgery	
codelist- 45991	2	ОМТ	

3.57. Self-Care

Unique Identifier	Code	Display Text	Hidden?
codelist- 45865	1	I have no problems with self-care	
codelist- 45865	2	I have some problems washing or dressing myself	
codelist- 45865	3	I am unable to wash or dress myself	

3.58. Study Drug Name

Unique Identifier	Code	Display Text	Hidden?
codelist- 45970	1	Drug 1	
codelist- 45970	2	Drug 2	
codelist- 45970	3	Drug 3	

3.59. THINKING

Unique Identifier	Code	Display Text	Hidden?
codelist- 45954	1	I can think about the future without any concern	
codelist- 45954	2	I can think about the future with only a little concern	
codelist- 45954	3	I can only think about the future with some concern	
codelist- 45954	4	I can only think about the future with a lot of concern	

3.60. UCSDBREATH

Unique Identifier	Code	Display Text	Hidden?
codelist- 45996	0	0	
codelist- 45996	1	1	
codelist- 45996	2	2	
codelist- 45996	3	3	
codelist- 45996	4	4	
codelist- 45996	5	5	

3.	6	1		L I	N	I	Т
υ.	U	ι.	- 1	U	IN	I.	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45866	1	appl	
codelist- 45866	2	caps	
codelist- 45866	3	ug/kg	
codelist- 45866	4	gtts	
codelist- 45866	5	gram	
codelist- 45866	6	inj	
codelist- 45866	7	mcg	
codelist- 45866	8	mEq	
codelist- 45866	9	mg	
codelist- 45866	10	mg/kg	
codelist- 45866	11	mL	
codelist- 45866	12	ng	
codelist- 45866	13	puff	
codelist- 45866	14	oz	
codelist- 45866	15	tabs	
codelist- 45866	16	tsp	
codelist- 45866	17	units	
codelist- 45866	18	spray	
codelist- 45866	19	tbsp	

3.62. UNITS

Unique Identifier	Code	Display Text	Hidden?
codelist- 45956	1	mg	
codelist- 45956	2	tabs	
codelist- 45956	3	caps	
codelist- 45956	4	mcg	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45956	5	gram	
codelist- 45956	6	mg/kg	
codelist- 45956	7	ug/kg	
codelist- 45956	8	mL	
codelist- 45956	9	ng	
codelist- 45956	10	tsp	
codelist- 45956	11	tbsp	
codelist- 45956	12	mEq	
codelist- 45956	13	oz	
codelist- 45956	14	puff	
codelist- 45956	15	units	
codelist- 45956	16	spray	
codelist- 45956	17	inj	
codelist- 45956	18	gtts	
codelist- 45956	19	appl	
codelist- 45956	20	units/mL	
codelist- 45956	21	mcg/min	
codelist- 45956	22	units/hr	
codelist- 45956	23	mcg/kg/min	
codelist- 45956	24	mg/min	
codelist- 45956	96NA	Not Applicable	

3.63. UNKSPECIFY

Unique Identifier	Code	Display Text	Hidden?
codelist- 45960	1	Definite acute exacerbation	
codelist- 45960	2	Suspected acute exacerbation	
codelist- 45960	3	Unclassifiable	

3.64. VALUED

Unique Identifier	Code	Display Text	Hidden?
codelist- 45961	1	I am able to do all of the things that make me feel valued	
codelist- 45961	2	I am able to do many of the things that make me feel valued	
codelist- 45961	3	I am able to do a few of the things that make me feel valued	
codelist- 45961	4	I am unable to do any of the things that make me feel valued	

3.65. YESNO

Unique Identifier	Code	Display Text	Hidden?
codelist- 45875	1	Yes	
codelist- 45875	0	No	

3.66. YN

Unique Identifier	Code	Display Text	Hidden?
codelist- 45917	1	Yes	
codelist- 45917	0	No	

3.67. YNNA

Unique Identifier	Code	Display Text	Hidden?
codelist- 45963	1	Yes	
codelist- 45963	2	No	
codelist- 45963	96NA	Not Applicable	

3.68. YesNo_LIB

Unique Identifier	Code	Display Text	Hidden?
codelist- 45920	1	Yes	
codelist- 45920	0	No	

3.69. c6MTERM

Unique Identifier	Code	Display Text	Hidden?
codelist- 45877	1	Symptoms requiring termination	
codelist- 45877	98	Other	

3.70. cBORG

Unique Identifier	Code	Display Text	Hidden?
codelist- 45998	0	0	
codelist- 45998	11	0.5	
codelist- 45998	1	1	
codelist- 45998	2	2	
codelist- 45998	3	3	
codelist- 45998	4	4	
codelist- 45998	5	5	
codelist- 45998	6	6	
codelist- 45998	7	7	
codelist- 45998	8	8	
codelist- 45998	9	9	
codelist- 45998	10	10	
codelist- 45998	97	Not Done	

3.71. cCMFUP

Unique Identifier	Code	Display Text	Hidden?
codelist- 45999	1	Taking daily	
codelist- 45999	2	Taking as needed	
codelist- 45999	3	Not Current	

3.72. cCONMED

Unique Identifier	Code	Display Text	Hidden?
codelist- 46000	1	Taking daily	
codelist- 46000	2	Taking as needed	
codelist- 46000	3	Previously taking (not current)	
codelist- 46000	4	Never used	

3.73. cDAYS

Unique Identifier	Code	Display Text	Hidden?
codelist- 45878	0	No good days	
codelist- 45878	1	1 or 2 good days	
codelist- 45878	2	3 or 4 good days	
codelist- 45878	3	Nearly every days was good	
codelist- 45878	4	Every day was good	

3.74. cEBMP

Unique Identifier	Code	Display Text	Hidden?
codelist- 102968	1	Normal motlity	
codelist- 102968	2	Ineffective (<80% normal contraction)	
codelist- 102968	3	Severely ineffective (<30% normal contraction)	
codelist- 102968	4	Diffuse/distal esophageal spasm (simultaneous contractions in >10% of swallows, with amp > 30mmHg)	
codelist- 102968	5	Aperistalsis (no peristaltic activity observed in esophageal body)	

3.75. cEVAL

Unique Identifier	Code	Display Text	Hidden?
codelist- 45879	1	CAREGIVER	
codelist- 45879	2	CHILD	
codelist- 45879	3	PARENT	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45879	4	CLINICAL RESEARCH COORDINATOR	
codelist- 45879	5	CLINICAL RESEARCH ASSOCIATE	
codelist- 45879	6	CLINICAL STUDY SPONSOR	
codelist- 45879	7	HEALTH CARE PROFESSIONAL	
codelist- 45879	8	INDEPENDENT ASSESSOR	
codelist- 45879	9	INVESTIGATOR	
codelist- 45879	10	FRIEND	
codelist- 45879	11	STUDY SUBJECT	
codelist- 45879	12	SPOUSE	
codelist- 45879	13	DOMESTIC PARTNER	
codelist- 45879	14	ADJUDICATION COMMITTEE	
codelist- 45879	15	GUARDIAN	

3.76. cGFREQ

Unique Identifier	Code	Display Text	Hidden?
codelist- 45965	0	Never	
codelist- 45965	1	Occasionally	
codelist- 45965	2	Sometimes	
codelist- 45965	3	Often	
codelist- 45965	4	Always	

3.77. cGHQOL

Unique Identifier	Code	Display Text	Hidden?
codelist- 46001	0	0	
codelist- 46001	1	1	
codelist- 46001	2	2	
codelist- 46001	3	3	

Unique Identifier	Code	Display Text	Hidden?
codelist- 46001	4	4	
codelist- 46001	5	5	

3.78. cJOB

Unique Identifier	Code	Display Text	Hidden?
codelist- 45966	1	My repriatory problems made me stop working altogether	
codelist- 45966	2	My respiratory problems interfere with my job or made me change my job	
codelist- 45966	3	My respiratory problems do not affect my job	

3.79. cLENGTH

Unique Identifier	Code	Display Text	Hidden?
codelist- 45922	1	A week or more	
codelist- 45922	2	3 or more days	
codelist- 45922	3	1 or 2 days	
codelist- 45922	4	Less than a day	

3.80. cMANO

Unique Identifier	Code	Display Text	Hidden?
codelist- 45923	1	Normal	
codelist- 45923	2	Abnormal	
codelist- 45923	3	Severly ineffective	
codelist- 45923	4	Zero peristalsis	

3.81. cNBRATK

Unique Identifier	Code	Display Text	Hidden?
codelist- 45967	1	More than 3 times	
codelist- 45967	2	3 times	

Unique Identifier	Code	Display Text	Hidden?
codelist- 45967	3	2 times	
codelist- 45967	4	1 time	
codelist- 45967	0	None of the time	

3.82. cNORM

Unique Identifier	Code	Display Text	Hidden?
codelist- 45880	Ν	Normal	
codelist- 45880	A	Abnormal	
codelist- 45880	ND	Not Done	

3.83. cPULMDTH

Unique Identifier	Code	Display Text	Hidden?
codelist- 45881	1	Acute exacerbation (definite or suspected)	
codelist- 45881	2	Progression of IPF (other than acute exacerbation)	
codelist- 45881	3	Pulmonary embolism	
codelist- 45881	4	Lung infection	
codelist- 45881	5	Lung cancer	
codelist- 45881	98	Other	

3.84. cRSCON

Unique Identifier	Code	Display Text	Hidden?
codelist- 45924	1	The most important problem I have	
codelist- 45924	2	Causes me quite a lot of problems	
codelist- 45924	3	Causes me a few problems	
codelist- 45924	4	Causes no problems	

3.85. cRSPAFT

Unique Identifier	Code	Display Text	Hidden?
codelist- 45968	1	It does not stop me from doing anything I would like to do	
codelist- 45968	2	It stops me from doing one or two things I would like to do	
codelist- 45968	3	It stops me from doing most of the things I would like to do	
codelist- 45968	4	It stops me from doing everything I would like to do	

3.86. cRSPROB

Unique Identifier	Code	Display Text	Hidden?
codelist- 45882	1	Almost Every Day	
codelist- 45882	2	Several Days a Week	
codelist- 45882	3	A Few Days a Month	
codelist- 45882	4	Only with Respiratory Infections	
codelist- 45882	0	Not at all	

3.87. cSCRENR

Unique Identifier	Code	Display Text	Hidden?
codelist- 80806	1	Screening Visit	
codelist- 80806	2	Enrollment Visit	

3.88. cSIGNIF

Unique Identifier	Code	Display Text	Hidden?
codelist- 45883	NCS	Not Clinically Significant	
codelist- 45883	CS	Clinically Significant	

3.89. cSOC

Unique Identifier	Code	Display Text	Hidden?
codelist- 45884	-	BLOOD AND LYMPHATIC SYSTEM DISORDERS	
codelist- 45884	2	CARDIAC DISORDERS	

Liniaura	Oada	Display Taxt	
Unique Identifier	Code	Display Text	Hidden?
codelist- 45884	3	CONGENITAL, FAMILIAL AND GENETIC DISORDERS	
codelist- 45884	4	EAR AND LABYRINTH DISORDERS	
codelist- 45884	5	ENDOCRINE DISORDERS	
codelist- 45884	6	EYE DISORDERS	
codelist- 45884	7	GASTROINTESTINAL DISORDERS	
codelist- 45884	8	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	
codelist- 45884	9	HEPATOBILIARY DISORDERS	
codelist- 45884	10	IMMUNE SYSTEM DISORDERS	
codelist- 45884	11	INFECTIONS AND INFESTATIONS	
codelist- 45884	12	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	
codelist- 45884	13	INVESTIGATIONS	
codelist- 45884	14	METABOLISM AND NUTRITION DISORDERS	
codelist- 45884	15	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	
codelist- 45884	16	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	
codelist- 45884	17	NERVOUS SYSTEM DISORDERS	
codelist- 45884	18	PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	
codelist- 45884	19	PSYCHIATRIC DISORDERS	
codelist- 45884	20	RENAL AND URINARY DISORDERS	
codelist- 45884	21	REPRODUCTIVE SYSTEM AND BREAST DISORDERS	
codelist- 45884	22	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	
codelist- 45884	23	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	
codelist- 45884	24	SOCIAL CIRCUMSTANCES	
codelist- 45884	25	SURGICAL AND MEDICAL PROCEDURES	
codelist- 45884	26	VASCULAR DISORDERS	

3.90. cTERM

Unique Identifier	Code	Display Text	Hidden?
codelist- 45885	1	Death	
codelist- 45885	2	Lost to Follow-Up	
codelist- 45885	3	Patient Decision	
codelist- 45885	4	Physician Decision	

3.91. cTERM6m

Unique Identifier	Code	Display Text	Hidden?
codelist- 304908	1	Death	
codelist- 304908	2	Lost to Follow-Up	
codelist- 304908	3	Patient Decision	
codelist- 304908	4	Physician Decision	
codelist- 304908	5	Lung Transplant	

3.92. cTRUFLS

Unique Identifier	Code	Display Text	Hidden?
codelist- 45969	1	True	
codelist- 45969	0	False	

3.93. cWALK

Unique Identifier	Code	Display Text	Hidden?
codelist- 45886	1	Cane	
codelist- 45886	2	Walker	
codelist- 45886	98	Other	

3.94. cWHEEZE

Unique Identifier	Code	Display Text	Hidden?	
codelist- 46002	1	More than 3 times		

Unique Identifier	Code	Display Text	Hidden?	
codelist- 46002	2	3 times		

Screening Visit

Date of Visit (Visit ID = 10, Page ID = 10) Unique Identifier page-304846-304938-10-10

Date of visit	DOV.DOVD T				
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code li	ist	
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code li	ist	
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code li	ist	
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code li	ist	
If yes, date of surgery?	DOV.DOVS XDT				
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code li	st	
If yes, please complete the earl	ly discontinu	ation form			

Informed Consent (Visit ID = 10, Page ID = 20)

Unique Identifier page-45933-304938-10-20

Cons	opt						
S	Date subject signed informed consent	CONSENT.I NFCONDT					
	Did subject consent for biological impact sub-study?	CONSENT.B IOSUB	0	Yes No	NY code list		
	Did subject consent to share data for additional research?	CONSENT.A DDDATA	0	Yes No	NY code list		
	Did subject consent to have specimens stored for additional research?	CONSENT.S PECDATA	0	Yes No	NY code list		
	Did subject consent to share biological specimens for research?	CONSENT.B IODATA	0	Yes No	NY code list		
Scree	en Failure						
	Subject deemed screen failure	CONSENT.S CRNFAIL	0	Yes No	NY code list		
	If yes, specify reason	CONSENT.S FREASON					
	Date	CONSENT.S FAILDT					
Demographics (Visit ID = 10, Page ID = 30)

Unique Identifier page-45834-304938-10-30

D					
Demo	ographics Date of Birth	DM.BRTHD			
	Sex	T DM.SEX	0	Male	
	Sex	DIVI.OLX	0	Female	SEX code list
Ethnie	city				
	Of Hispanic or Latino ethnicity	DM.ETHNIC	0	Yes No	NY code list
Race					
	White	DM.WHITE			
	Black or African American	DM.BLACK			
	Asian	DM.ASIAN			
	American Indian or Alaska Native	DM.NATIVE			
	Native Hawaiian or Pacific Islander	DM.HAWAII			
	Other Race	DM.RCOTH ER			
Smok	ing History				
	Smoking status	DM.SMOKE	000	Current Former Never	SMOKER code list
	lf past smoker, date last smoked	DM.SMOKE DT			
	How many total years has subject smoked? (years)	DM.SMOKE YRS			(format 99)
	On average during that time, how many packs (or equivalents) per day of cigarettes did the subject smoke? (packs/day)	DM.SMOKP ACK			(format 9.9)

Medical History (Visit ID = 10, Page ID = 40) Unique Identifier page-45852-304938-10-40

Coronary artery disease	MH.CAD	0	Yes	
5		0	No	NY code list
Acute MI	MH.ACUTE	0	Yes	NY code list
	MI	0	No	
Valvular heart disease	MH.VALVHD		Yes	NY code list
			No	
Heart failure	MH.HF		Yes	NY code list
	MH.AFIB		No	
Atrial fibrillation			Yes No	NY code list
Diabetes	MH.DIABET		Yes	
	ES		No	NY code list
Pulmonary hypertension	MH.PULMH	-	Yes	NY code list
	Y	0	No	
Chronic obstructive pulmonary	MH.COPD	0	Yes	
disease (COPD)			No	NY code list
Asthma	MH.ASTHM A		Yes	NY code list
			No	
Pulmonary embolism	MH.PEMBL		Yes No	NY code list
Lung cancer	MH.LUNGC		Yes	NY code list
Lung cancer	ANC		No	
Other cancer	MH.OTHCA		Yes	NY code list
	NC		No	
Gastroesophageal reflux	MH.GERD	0	Yes	NY code list
(GER)			No	
Barrett's esophagus	MH.BRTES OPH		Yes	NY code list
			No	
Hiatal hernia	MH.HIATAL		Yes	NY code list
Heapitalization for an even ania	MH.HOSPP	0	No	
Hospitalization for pneumonia / respiratory cause in last 6	NEU	0	Yes No	NY code list

Vitals

(Visit ID = 10, Page ID = 50) Unique Identifier page-45962-304938-10-50

itals		
Date of Collection	VS.VSDT	
Weight (lbs)	VS.WEIGHT	(format 999)
Height (in)	VS.HEIGHT	(format 999)
BP (systolic)(mmHg)	VS.SYSBP	(format 999)
BP (diastolic)(mmHg)	VS.DIABP	(format 999)
Heart rate (bpm)	VS.HRTRAT	(format 999)
SpO2 (%)	VS.SPOX	(format 999)
,		· · · ·

Exclusion_HRCT_Lung Biopsy

(Visit ID = 10, Page ID = 60)

Unique Identifier page-45839-304938-10-60

Exclusion		
FVC %pred (%)	EXCLUSON. FVC	(format 999)
FEV1/FVC ratio (%)	EXCLUSON. FEVFVC	(format 9.99)
Resting room air PaO2 (mmHg)	EXCLUSON. PAOAIR	(format 999)
Distance walked on screening 6MWT (m)	EXCLUSON. WALKED	(format 9999)
HRCT		
Date of HRCT scan	EXCLUSON. HCRTDT	
Local radiology review (Choose one category)	EXCLUSON. RADRVW	 UIP pattern Possible UIP pattern Inconsistent with UIP pattern
Reason:	EXCLUSON. RVWREAS	
Date of HRCT review	EXCLUSON. HRCTRVW	
Lung Biopsy		
Was lung biopsy reviewed?	EXCLUSON. LUNGBIOP	 Yes NY code list No
Date of biopsy	EXCLUSON. BIOPDT	
Local pathology review (Choose one category)	EXCLUSON. PATHRVW	 UIP pattern Probable UIP pattern Possible UIP pattern Possible UIP pattern Not UIP pattern
Reason	EXCLUSON. PATHRSON	
Date of biopsy review	EXCLUSON. BIOPRDT	

Concomitant Medications (Visit ID = 10, Page ID = 70)

Unique Identifier page-304864-304938-10-70

Medications were not collected at this visit.			
comitant Medications			
Is subject currently taking or wa medications?	is subject pr	eviously taking any of th	e following
Proton Pump Inhibitors (PPI)	CM.CMPPI	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code li
H2 Blockers (H2 Receptor Antagonists)	CM.CMH2B	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code I
Chronic prednisone (>1month)	CM.CMCP	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code I
If current or previous, chronic/ average dose taken (mg/day):	CM.CMCPD OSE		(format 99.9)
Azathioprine	CM.CMAZT	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code li
N-acetylcystteine (NAC)	CM.CMNAC	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code li
Cotrimoxazole	CM.CMCOT	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code I

Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CM.CMMDI	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code list
Pirfenidone	CM.CMPIRF	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code list
Nintedanib	CM.CMNINT	 Taking daily Taking as needed Previously taking (not current) Never used 	cCONMED code list

Arterial Blood Gas (Visit ID = 10, Page ID = 80) Unique Identifier page-45888-304938-10-80

	check if ABG was not ed at this visit.	ABG.ABGN D		
Arterial Blood G	Bas			
FiO2 (%)	ABG.ABGFI OX	(format 999)	
рН		ABG.ABGP H	(format 9.99)	
PaO2 (n	nm Hg)	ABG.ABGPA OX	(format 999.9)	
PaCO2	(mm Hg)	ABG.ABGPA COX	(format 999.9)	
SaO2 (%	6)	ABG.ABGSA OX	(format 999.9)	

Documentation of GERD & Esophageal Motility

(Visit ID = 10, Page ID = 90)

Unique Identifier page-188329-304938-10-90

Please check if documentation was not collected at this visit.	DND		
Frequency Scale for the Symptoms of Gl	ERD		
Not Collected	gerd.fqn D		
1. Do you get heartburn?	GERD.FQH RTBRN	 Never Occasionally Sometimes Often Always 	cGFREQ code list
2. Does your stomach get bloated?	GERD.FQBL OAT	 Never Occasionally Sometimes Often Always 	cGFREQ code list
3. Does your stomach ever feel heavy after meals?	GERD.FQH EAVY	 Never Occasionally Sometimes Often Always 	cGFREQ code list
4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQR UB	 Never Occasionally Sometimes Often Always 	cGFREQ code list
5. Do you feel sick after meals?	GERD.FQSI CK	 Never Occasionally Sometimes Often Always 	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQH RTAFT	 Never Occasionally Sometimes Often Always 	cGFREQ code list

7. Do you have an unusual	GERD.FQT	○ Never	
	HROAT	 Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQF ULL	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
	gerd.fqst UCK	 Never Occasionally Sometimes Often Always 	cGFREQ code li
	gerd.fqa Cid	 Never Occasionally Sometimes Often Always 	cGFREQ code li
	GERD.FQB URP	 Never Occasionally Sometimes Often Always 	cGFREQ code li
12. Do you get heartburn if you bend over?	GERD.FQH RTBND	 Never Occasionally Sometimes Often Always 	cGFREQ code li
RD Health Related Quality of Life			

eClinicalOS · WRAP IPE 6016 Design PDE · 10.0

For each question listed below, please rate your level of symptoms on a scale of 0 to 5

0-No symptoms

1-Symptoms noticeable, but not bothersome

2-Symptoms noticeable, but not bothersome, but not every day
3-Symptoms bothersome every day
4-Symptoms affect daily activities

5-Symptoms are incapacitating, unable to do daily activities

1. How bad is your heartburn?	GERD.QLH RTBRN	 0 1 2 3 4
2. Heartburn when lying down?	GERD.QLLY ING	 5 0 1 2 3 4
3. Heartburn when standing up?	GERD.QLST AND	 5 0 1 2 3 4 5
4. Heartburn after meals?	GERD.QLH RTAFT	 0 1 2 3 4 5
5. Does heartburn change your diet?	GERD.QLDI ET	 0 1 2 3 4 5
6. Does heartburn wake you from sleep?	GERD.QLSL EEP	 0 1 2 3 4 5

7. Do you have difficulty swallowing?	GERD.QLDI FFSW	 0 1 2 3 4 5 		
8. Do you have pain with swallowing?	GERD.QLPA INSW	 0 1 2 3 4 5 		
9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	 0 1 2 3 4 5 		
10. If you take medication, does this affect your daily life?	GERD.QLM EDS	 0 1 2 3 4 5 		
pH Monitoring Results		0		
Per Protocol Amendment 3, all Visit Per Protocol Amendment 3, nor Week 24 Visit Not Collected	-	tients shoul		
Was probe located 5cm above LES	D GERD.PHP ROBE	YesNo	NY code lis	t
total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
# of reflux episodes	GERD.PHR FLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHT			(format 999.9)

Created : 18-APR-16 12:12:25 GMT Page 201

Overall DeMeester Score	GERD.PHS CORE		(format 999.9)			
ometry Results						
Per Protocol Amendment 3, all Visit	patients sho	ould check the Not Colle	cted Box at the Week			
Per Protocol Amendment 3, non surgery patients should check the Not Collected Box at the Week 24 Visit						
Not Collected	GERD.MNN D					
Lower esophageal sphincter (LI	ES) data					
LES length (cm)	GERD.MNL ESLNG		(format 99.9)			
LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)			
LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)			
Upper esophageal sphincter (U	ES) data					
UES resting pressure (mmHg)	GERD.MNU ESRTP		(format 999.9)			
UES relaxation (%)	GERD.MNU ESRLX		(format 999.9)			
Esophageal body motility patter	'n					
% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)			
% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)			
% simultaneous contractions (%)	GERD.MNSI MUCN		(format 999.9)			
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)			
Esophageal body motility pattern (select only one)	GERD.MNE BMP	 Normal motility Ineffective (<80% normal contraction) Severely ineffective (<30% normal contraction) Diffuse/distal esophageal spasm (simultaneous contractions in >10% of swallows, with amp > 30mmHg) Aperistalsis (no peristaltic activity observed in esophageal body) 	cEBMP code list			

Enrollment Visit

Date of Visit (Visit ID = 20, Page ID = 10) Unique Identifier page-304846-304939-20-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	○ Yes○ No	NY code list	
If no, will subject continue in the study?	DOV.DOVC ONT	○ Yes○ No	NY code list	
If no, was it due to death of subject?	DOV.DOVD TH	○ Yes○ No	NY code list	
Did subject cross over to surgery?	DOV.DOVS X	○ Yes○ No	NY code list	
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code list	
If yes, please complete the ear	ly discontinu	ation form		
	-			

Enrollment Information

(Visit ID = 20, Page ID = 20)

Unique Identifier page-45937-304939-20-20

Enro	Iment Information				
	Does subject meet all study inclusion / exclusion criteria?	ENROLL.IN CEXCL	○ Yes ○ No	NY code list	
.	Enrollment date	ENROLL.EN ROLLDT			
.	Subject randomization	ENROLL.SU BRAND	SurgeryOMT	SUBJRAND	
	Randomization Date		(remote value)		
	Randomization		(remote value)		

Spirometry_DLCO

(Visit ID = 20, Page ID = 30)

Unique Identifier page-80805-304939-20-30

	Please check if procedures were not performed	SPIRO.SPIR OND			
SPIR	OMETRY				
	Indicate at which visit these values were collected	SPIRO.SPR VISIT		Screening Visit Enrollment Visit	cSCRENR code list
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES			
	FEV1: Actual (liters)	SPIRO.PRM FEV			(format 99.99)
.	FVC: Actual (liters)	SPIRO.PRM FVC			(format 99.99)
	VC: Actual (liters)	SPIRO.PRM VC			(format 99.99)
	Pre-Bronchodilator: Replicate	SPIRO.REP 1YES			
	FEV1: Actual (liters)	SPIRO.REP 1FEV			(format 99.99)
	FVC: Actual (liters)	SPIRO.REP 1FVC			(format 99.99)
	VC: Actual (liters)	SPIRO.REP 1VC			(format 99.99)
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES			
	FEV1: Actual (liters)	SPIRO.REP 2FEV			(format 99.99)
	FVC: Actual (liters)	SPIRO.REP 2FVC			(format 99.99)
	VC: Actual (liters)	SPIRO.REP 2VC			(format 99.99)
DLC	0				
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT			(format 99.9)
	VA (alveolar volume) (liters)	SPIRO.DLC OVA			(format 9.99)
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO	1		(format 99.9)
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM			(format 99.9)

6-Minute Walk Test (Visit ID = 20, Page ID = 40) Unique Identifier page-80834-304939-20-40

Min	Please check if walk test was not performed at this visit. ute Walk Test	WALK.WAL KND	
	Indicate at which visit these values were collected	WALK.WVIS IT	 Screening Visit Enrollment Visit
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	cBORG code list
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	 Yes No NY code list
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	YesNoNY code list
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	Walk.wkai D	 Yes NY code list No
	If yes: Specify type of walking aid	WALK.WKS PAID	 Cane Walker cWALK code list Other
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	 Yes NY code list No
	If no: What was duration of wall	< test?	
	minutes	WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	 Symptoms requiring termination Other C6MTERM code list
	Other (specify)	WALK.WKR SNSP	
	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Created : 18-APR-16 12:12:25 GMT Page 229

Did subject desaturate (SpO2 < 88%)?	WALK.WKD SAT	YesNo	NY code list	
If yes: Walk duration at desatur	ation			
minutes	WALK.WKD SMIN			(format 9)
seconds	WALK.WKD SSEC			(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKD SMTR			(format 9999)
Lowest SpO2 (%)	WALK.WKL OWSP			(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POST BORG		×	cBORG code list
• • •				

Blood Collection

(Visit ID = 20, Page ID = 50)

Unique Identifier page-45825-304939-20-50

Please check if blood sample were not collected at this vis			
Blood Collection Information			
Date blood samples were drawn	BC.BCDT		
Time blood samples were drawn	BC.BCTM		(HH24:MI)
Processing date	BC.BCPRDT	•	
Processing time	BC.BCPRT M		(HH24:MI)
Was DNA collected?	BC.BCDNA	Yes NY code listNo	
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLAS MA	Yes NY code listNo	
lf yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERU M	 Yes NY code list No 	
If yes, Yield (ml)	BC.BCSYLD		(format 99.9)
# of aliquots	BC.BCSALQ		(format 99)
·			

HRCT Collection

(Visit ID = 20, Page ID = 60)

Unique Identifier page-45939-304939-20-60

HRCT Collection			
Was an HRCT performed for this study because a satisfactory HRCT had not been performed within the previous 3 months?	HRCT.HRE NR	 Yes No NY code list 	
Was a week 48 HRCT performed on this subject?	HRCT.HRFU P	Yes NY code listNo	

UCSD Shortness of Breath Questionnaire

(Visit ID = 20, Page ID = 70)

Unique Identifier page-45995-304939-20-70

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND		
UCSD Shortness of Breath Questionnair	e		
When I do, or if I were to do, the 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do beca	-		athlessness as:
At rest	UCSD.UCS		
Allesi	D1		
		0 2	
		03	
		○ 4	
		0 5	
Walking on a level at your own	UCSD.UCS D2	0 0	
pace		0 1	
		° 2	
		03	
		° 4	
		0 5	
Walking on a level with others	UCSD.UCS D3	0	
your age		° 1	
		° 2	
		03	
		○ 4	
		O 5	
Walking up a hill	UCSD.UCS D4	0 0	
	04	° 1	
		° 2	
		03	
		0 4	
		0 5	

Walking up stairs	UCSD.UCS D5	 0 1 2 3 4 5
While eating	UCSD.UCS D6	 0 1 2 3 4 5
Standing up from a chair	UCSD.UCS D7	 0 1 2 3 4 5
Brushing teeth	UCSD.UCS D8	 0 1 2 3 4 5
Shaving and/or brushing hair	UCSD.UCS D9	 0 1 2 3 4 5
Showering/bathing	UCSD.UCS D10	 0 1 2 3 4 5

Dressing	UCSD.UCS D11	 0 1 2 3 4 5
Picking up and straightening	UCSD.UCS D12	 0 1 2 3 4 5
Doing dishes	UCSD.UCS D13	 0 1 2 3 4 5
Sweeping/vacuuming	UCSD.UCS D14	 0 1 2 3 4 5
Making bed	UCSD.UCS D15	 0 1 2 3 4 5
Shopping	UCSD.UCS D16	 0 1 2 3 4 5

Doing laundry UCSD.UCS 0 D17 1 2 3 4 5 Washing car UCSD.UCS 0 D18 0 1 2 3 0 0 1 2 3 4 5 Mowing lawn UCSD.UCS 0 D19 0 1 2 3 4 5 5 5 Mowing lawn UCSD.UCS 0 D19 0 1 2 3 4 5 5 5 Watering lawn UCSD.UCS 0 D20 1 2 3 4 5 Sexual activities UCSD.UCS 0 D21 1 2 3 4 5 How much do these limit you '' your daily life'' 5 How much do these limit you '' your daily life'' 5 UCSD.UCS 1 2 3 4 5			
Washing car UCSD.UCS D18 0 2 3 4 5 Mowing lawn UCSD.UCS D19 0 4 5 Mowing lawn UCSD.UCS D19 0 4 5 Watering lawn UCSD.UCS D20 0 1 2 3 4 5 Sexual activities UCSD.UCS D21 0 2 3 4 5 How much do these limit you in your daily libr 0 1 2 3 4 5 How much do these limit you in your daily libr 0 1 2 3 4 5 How much do these limit you in your daily libr 0 1 2 3 4 5 Shortness of breath UCSD.UCS D22 0 1 2 3 4	Doing laundry	UCSD.UCS	0
Washing car UCSD.UCS D18 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		BH	
Washing car UCSDUCS D18 0 0 Washing car UCSDUCS 0 0 0 Mowing lawn UCSDUCS D19 0 0 Watering lawn UCSDUCS 0 0 0 Vertering lawn UCSDUCS 0 0 0 Sexual activities UCSDUCS 0 0 0 D21 0 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 </td <td></td> <td></td> <td></td>			
Washing car UCSD.UCS D18 0 0 Mowing lawn UCSD.UCS D19 0 0 Mowing lawn UCSD.UCS D19 0 0 Watering lawn UCSD.UCS D20 0 0 Sexual activities UCSD.UCS D21 0 0 Sexual activities UCSD.UCS D21 0 0 Shortness of breath UCSD.UCS D22 0 0 UCSD.UCS 0 0 0 D21 0 0 0 D21 0 0 0 D21 0 0 0 D21 0 0 0 Shortness of breath UCSD.UCS D22 0 0 0 1 2 0 0 2 0 0 0 2 0 0 0 2 0 0 0 2 0 0 0 1 2 0 0 2 0 0 0 2 0 0			
Washing car UCSD.UCS D18 0 0 1 0 2 0 3 0 4 0 5 Mowing lawn UCSD.UCS D19 0 0 1 2 3 0 2 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 4 5 Sexual activities UCSD.UCS D21 0 2 3 4 5 How much do these limit you Ir your dally life: 0 D21 1 2 3 4 5 How much do these limit you Ir your dally life: 0 1 2 <td< td=""><td></td><td></td><td></td></td<>			
Mowing lawn UCSD.UCS D19 0 1 Watering lawn UCSD.UCS D20 0 4 Watering lawn UCSD.UCS D20 0 4 Sexual activities UCSD.UCS D21 0 1 Sexual activities UCSD.UCS D21 0 1 How much do these limit you your daily UFF D22 0 1 Shortness of breath UCSD.UCS D21 0 1 D2 3 4 5 How much do these limit you your daily UFF D22 0 1 Shortness of breath UCSD.UCS D22 0 1 D2 3 4 5			
Mowing lawn UCSD.UCS D19 0 1 Watering lawn UCSD.UCS D20 0 4 Watering lawn UCSD.UCS D20 0 1 VUCSD.UCS D20 0 1 Sexual activities UCSD.UCS D21 0 1 Sexual activities UCSD.UCS D21 0 1 Fhow much do these limit you your daily uiter Shortness of breath UCSD.UCS D21 0 1 Shortness of breath UCSD.UCS D21 0 1 Mow much do these limit you your daily uiter 0 1 Shortness of breath UCSD.UCS D22 1 2 Shortness of breath UCSD.UCS D22 0 1 Shortness of breath UCSD.UCS D22 1 2 Shortness of breath UCSD.UCS D23 0 1 Shortness of breath UCSD.UCS D23 0 1 Shortness of breath UCSD.UCS D23 0 1 Shortness Shortness 0 1 Shortness Shortness 0 1	Washing car	UCSD.UCS	
Mowing lawn UCSD.UCS D19 0 1 Watering lawn UCSD.UCS D20 0 1 Watering lawn UCSD.UCS D20 0 1 Sexual activities UCSD.UCS D21 0 1 Sexual activities UCSD.UCS D21 0 1 How much do these limit you your daily life 0 1 Shortness of breath UCSD.UCS D21 0 1 Shortness of breath UCSD.UCS D21 0 1 Shortness of breath UCSD.UCS D22 0 1 Shortness of breath UCSD.UCS D23 0 1 Shortness of breath UCSD.UCS D23 0 1 Shortness of breath UCSD.UCS D2 0 1 Shortness of breath UCSD.UCS D2 0 1 Shortness of breath UCSD.UCS D2 0 1 Shortness o		Dio	
Mowing lawn UCSD.UCS D19 0 Watering lawn UCSD.UCS D20 0 Watering lawn UCSD.UCS D20 0 Sexual activities UCSD.UCS D21 0 Sexual activities UCSD.UCS D21 0 Mowing lawn UCSD.UCS D21 0 Sexual activities UCSD.UCS D22 0 Sexual activities UCSD.UCS D22 0 Sexual activities UCSD.UCS D22 0 Sexual activities UCSD.UCS D23 0 Sexual activities UCSD.UCS D23 0 Sexual activities UCSD.UCS D23 0 Sexual activities UCSD.UCS D23 0 <t< td=""><td></td><td></td><td></td></t<>			
Mowing lawn UCSD.UCS D19 0 0 1 0 2 0 3 0 1 0 2 0 1 0 1 0 1 0 1 0 2 0 1 0 2 0 3 0 1 0 1 0 2 0 2 0 1 0 2 0 3 0 1 0 2 0 3 0 3 0 2 0 3 0 1 0 2 0 1 0 2 0 1 0 1 0 2 0 3 0 1 0 3 0 <td< td=""><td></td><td></td><td></td></td<>			
Mowing lawn UCSD.UCS D19 0 9 1 2 3 4 5 Watering lawn UCSD.UCS D20 0 2 3 4 5 Sexual activities UCSD.UCS D21 0 21 3 22 3 23 4 5 5 How much do these limit you : your daily life 0 D21 1 2 3 4 5 How much do these limit you : your daily life 1 D22 1 22 3 4 5 How much do these limit you : your daily life 1 D21 1 2 3 4 5 How much do these limit you : Just and the set in			
D19 1 D19 1 Q 3 Q 3 Q 3 Q 4 Q 5 Watering lawn UCSD.UCS D20 0 Q 1 Q 3 Q 3 Q 3 Q 3 Q 4 Q 3 Q 1 Q 3 Q 1 Q 3 Q 1 Q 3 Q 3 Q 3 Q 3 Q 4 Shortness of breath UCSD.UCS D22 0 Q 1 2 Q 1 2 Q 3 4 Q 3 4			
Vatering lawn UCSD.UCS D20 0 0 1 VCSD.UCS D20 0 1 Sexual activities UCSD.UCS D21 0 4 Sexual activities UCSD.UCS D21 0 1 How much do these limit your jour daily life? 1 Shortness of breath UCSD.UCS D21 0 1 How much do these limit your jour daily life? 0 Shortness of breath UCSD.UCS D22 0 1 Galartic intervention 0 Shortness of breath UCSD.UCS D22 0 1 Galartic intervention 0 Galartinterventinter 0	Mowing lawn	UCSD.UCS D19	
Watering lawn UCSD.UCS 0 D20 0 1 2 3 4 5 4 5 Sexual activities UCSD.UCS D21 0 D21 1 2 3 4 5 How much do these limit you in your daily liffe? 1 Shortness of breath UCSD.UCS D22 0 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 4 5 1 2 3 4 5 1 2 3 4 5 4 5 1 2 3 4 5 1 2 3 4 5 4 5 1 2 3 1 3 4 5 4 5 1 5 2 3 6 <td< td=""><td></td><td></td><td></td></td<>			
○ 4 ○ 5 Watering lawn UCSD.UCS D20 0 ○ 1 ○ 3 ○ 4 ○ 5 Sexual activities UCSD.UCS D21 0 ○ 1 ○ 1 ○ 3 ○ 3 ○ 3 ○ 4 ○ 5			_
Watering lawn UCSD.UCS D20 0 0 1 2 3 4 5 Sexual activities UCSD.UCS D21 0 5 1 2 3 4 5 Sexual activities UCSD.UCS D21 0 5 1 4 5 5 1 5 2 6 3 6 4 5 5 How much do these limit you trout daily life: 0 D22 1 2 3 6 1 6 1 7 1 8 1 9 1 1 2 3 1 2 3 3 1 2 3 3 1 2 3 3 1 3 1 3 3 4 5 <td></td> <td></td> <td></td>			
Watering lawn UCSD.UCS D20 0 0 1 2 3 0 4 0 5 Sexual activities UCSD.UCS D21 0 0 1 2 3 4 5 How much do these limit you in your daily life? 1 Shortness of breath UCSD.UCS D22 0 0 1 2 3 4 5 How much do these limit you in your daily life? 1 D2 1 2 3 6 1 2 3 4 5			
Sexual activities UCSD.UCS D21 UCSD.UCS D21 0 3 4 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS 0 1 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS 0 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 1 5 1 5 1 1 5 1 1 5 1 1 1 1 1 1 1 1 1 1 1 1 1			
 Sexual activities UCSD.UCS D21 0 1 2 3 4 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS D22 1 2 3 4 5 	Watering lawn	UCSD.UCS D20	
Sexual activities UCSD.UCS D21 UCSD.UCS C C C C C C C C C C C C C C C C C C			
Sexual activities UCSD.UCS DI21 UCSD.UCS DI21			
Sexual activities UCSD.UCS D21 0 0 D21 0 1 2 3 4 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS D22 0 1 2 3 4 5 1 2 3 4 5 1 2 5 1 2 6 7 1 2 6 7 7 7 7 7 7 7 7 7 7 7 7 7			
Sexual activities UCSD.UCS 0 0 D21 0 1 2 3 4 5 How much do these limit you in your daily life Shortness of breath UCSD.UCS 0 0 D22 0 1 2 3 0 4			
D21 0 1 2 3 4 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS 0 D22 0 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 4 5 1 2 4 5 1 2 4 5 1 2 4 5 1 2 4 5 1 2 4 5 1 2 4 5 1 2 4 5 1 2 2 1 2 2 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2	Converte attraction		
 2 3 4 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS D22 0 1 2 3 4 	Sexual activities	D21	-
How much do these limit you in your daily life? Shortness of breath UCSD.UCS 0 D22 0 1 2 3 4			
 4 5 How much do these limit you in your daily life? Shortness of breath UCSD.UCS D22 0 1 2 3 4 			-
 How much do these limit you in your daily life? Shortness of breath UCSD.UCS D22 0 1 2 3 4 			
How much do these limit you in your daily life? Shortness of breath UCSD.UCS D22 0 0 0 1 2 3 3 4 4			
Shortness of breath UCSD.UCS 0 0 D22 0 1 2 3 4	How much do these limit you in	n vour deilv li	
0 1 0 2 0 3 0 4			
0 2 0 3 0 4	Chortness of breath	D22	°
○ 3 ○ 4			
° 4			
			0 5

Fear of "hurting myself" by overexerting	UCSD.UCS D23	 0 1 2 3 4 5
Fear of shortness of breath	UCSD.UCS D24	 0 1 2 3 4 5

Patient Reported Outcome Battery

(Visit ID = 20, Page ID = 80)

Unique Identifier page-45844-304939-20-80

Please check if outcome battery was not performed at this visit.	ICEEQ.ICEE QND			
h VAS				
Cough VAS	ICEEQ.COU GHVAS			
How would rate the severity of your cough?(0-100)	ICEEQ.COU GHSEV			(format 999)
AP				
Not Collected	ICEEQ.ICEN D			
By placing a check in one box in describes your quality of life at t	the moment.		-	which statement best
Love and Friendship	ICEEQ.ICEL OVE	0	I can have all of the love and friendship that I want	FRIENDS code list
		0	I can have a lot of the love and friendship that I want	
		0	I can have a little of the love and friendship that I want	
		0	I cannot have any of the love and friendship that I want	
Thinking about the future	ICEEQ.ICEF UTR	0	I can think about the future without any concern	
		0	I can think about the future with only a little concern	
		0	I can only think about the future with some concern	THINKING code lis
		0	I can only think about the future	

		 many things I am unable to be independent in a 	
		 I am able to be independent in 	INDEPEND code
Independence	ICEEQ.ICEI NDEP	 I am able to be completely independent 	
		 I cannot have any of the enjoyment and pleasure that I want 	
		 I can have a little of the enjoyment and pleasure that I want 	
		 I can have a lot of the enjoyment and pleasure that I want 	PLEASURE cod
Enjoyment and pleasure	ICEEQ.ICEE NJOY	 I can have all of the enjoyment and pleasure that I want 	
		 I am unable to do any 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 able to do many of the things that make me feel valued	VALUED code list
Doing things that make you feel valued	ICEEQ.ICEV ALUE	 I am able to do all of the things that make me feel valued 	

By placing a check in one box in each group below, please indicate which statement best describes your own health state today.

Mobility	ICEEQ.EQM OB	 problems in walking about I have some problems in 	MOBILE code list
		 walking about I am confined to bed 	
Self-Care	ICEEQ.EQS C	 I have no problems with self care 	-
		 I have some problems washing or dressing mysel 	
		 I am unable to wash or dress myself 	
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQU A	 I have no problems with performing my usual activities 	
		 I have some problems with performing my usual activities 	ACTIVITY code I
		 I am unable to perform my usual activities 	
Pain/Discomfort	ICEEQ.EQP AIN	 I have no pain or discomfort 	
		 I have moderate pain or discomfort 	PAIN code lis
		 I have extreme pain or discomfort 	
Anxiety/Depression	ICEEQ.EQA NX	 I am not anxious or depressed 	
		 I am moderately anxious or depressed 	ANXIETY co
		 I am extremely anxious or depressed 	
	ICEEQ.EQV		

St George's Respiratory Questionnaire (Visit ID = 20, Page ID = 90)

Unique Identifier page-45914-304939-20-90

Please check if questionnaire	SGRQ.SGR QND		
was not performed at this visit.	QIID		
eorge's Respiratory Questionnaire	(
This questionnaire is designed troubling you and how it affects illness cause you the most prot problems are.	your life. W	e are using it to find or	ut which aspects of your
Please read the instructions ca spend too long deciding about			tand anything. Do not
Before completing the question	naire:		
Please check one box to show	SGRQ.CUR	Very good	
how you describe your current	HLTH	Good	CURHLTH code list
health:		• Fair	
		Poor	
		Very poor	
weeks. Please check one box for each	question		d you over the past 4
weeks.		 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory 	
weeks. Please check one box for each 1. Over the past 4 weeks, I	question	 Almost Every Day Several Days a Week A Few Days a Month Only with 	
weeks. Please check one box for each 1. Over the past 4 weeks, I	question SGRQ.STG0 1 SGRQ.STG0	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections 	cRSPROB code li
weeks. Please check one box for each 1. Over the past 4 weeks, I have coughed:	question SGRQ.STG0 1	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code li
 weeks. Please check one box for each 1. Over the past 4 weeks, I have coughed: 2. Over the past 4 weeks, I have brought up phlegm 	question SGRQ.STG0 1 SGRQ.STG0	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a Month 	cRSPROB code li
 weeks. Please check one box for each 1. Over the past 4 weeks, I have coughed: 2. Over the past 4 weeks, I have brought up phlegm 	question SGRQ.STG0 1 SGRQ.STG0	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a 	cRSPROB code li

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG0	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code lis
4. Over the past 4 weeks, I have had wheezing attacks:	SGRQ.STG0 4	 Not at all Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code list
5. How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks?	SGRQ.STG0 5	 More than 3 times 3 times 2 times 1 time None of the time 	cNBRATK code list
6. How long did your worst respiratory attack last? (Go to question 7 if you did not have a severe attack)	SGRQ.STG0 6	 A week or more 3 or more days 1 or 2 days Less than a day 	cLENGTH code I
7. Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had?	SGRQ.STG0 7		cDAYS code list
8. If you wheeze, is it worse when you get up in the morning?	SGRQ.STG0 8	YesNoNoNY code list	
rt 2 ction 1			

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0	The most important problem I have	
		0	Causes me quite a lot of problems	cRSCON code
		0	Causes me a few problems	
		0	Causes no problems	
10. If you have ever held a job:	SGRQ.STG1 0	0	My repriatory problems made me stop working altogether	
		0	My respiratory problems interfere with my job or made me change my job	cJOB code list
		0	My respiratory problems do not affect my job	

Section 2

These are questions about what activities usually make you feel short of breath these days.

11. For each statement, please check the box that applies to you these days.

	Sitting or lying still	1A	0	True False	cTRUFLS code list
	Washing or dressing yourself	SGRQ.STG1 1B	0	True False	cTRUFLS code list
	Walking around the house	SGRQ.STG1 1C	0	True False	cTRUFLS code list
	Walking outside on a level ground	SGRQ.STG1 1D	0	True False	cTRUFLS code list
	Walking up a flight of stairs	SGRQ.STG1 1E	0	True False	cTRUFLS code list
	Walking up hills	SGRQ.STG1 1F	0	True False	cTRUFLS code list
	Playing sports or other physical activities	SGRQ.STG1 1G	0	True False	cTRUFLS code list
Sectio	on 3				

These are more questions about your cough and shortness of breath these days.

12. For each statement, please check the box that applies to you these days.

Coughing hurts

SGRQ.STG1 O True

False cTRUFLS code list

	SGRQ.STG1 2B	○ Tr ○ Fa	rue alse	TRUFLS	code list
I am short of breath when I talk	SGRQ.STG1 2C	○ Tr ○ Fa		TRUFLS	code list
	SGRQ.STG1 2D	O Tr O Fa		TRUFLS	code list
	SGRQ.STG1 2E	 Tr Fa 	ue	TRUFLS	code list
	SGRQ.STG1 2F	O Tr O Fa	Č C	TRUFLS	code list
tion 4					
These are questions about other effects that your respiratory problems may have on you these days.					
13. For each statement, please of	SGRQ.STG1	0		s to you the	ese uays.
	3A		rue c alse c	TRUFLS	code list
	SGRQ.STG1 3B		rue c alse	TRUFLS	code list

or neighbors	50	0	False		
I get afraid or panic when I cannot catch my breath	SGRQ.STG1 3C	0	True False	cTRUFLS	code list
I feel that I am not in control of my respiratory problems	SGRQ.STG1 3D	000	True False	cTRUFLS	code list
I do not expect my respiratory problems to get any better	SGRQ.STG1 3E	0	True False	cTRUFLS	code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG1 3F	0	True False	cTRUFLS	code list
Exercise is not safe for me	SGRQ.STG1 3G	0	True False	cTRUFLS	code list
Everything seems too much of an effort	SGRQ.STG1 3H	0	True False	cTRUFLS	code list

Section 5

These are questions about your respiratory treatment. If you are not receiving treatment, go to section 6.

Not Receiving Respiratory Treatment	SGRQ.SGN OTXT			
14. For each statement, please	check the b	ox that appli	ies to you these days.	
My treatment does not help me very much	SGRQ.STG1 4A	 True False 	cTRUFLS code list	
I get embarrassed using my medication in public	SGRQ.STG1 4B	 True False 	cTRUFLS code list	

Created : 18-APR-16 12:12:25 GMT Page 261

	SGRQ.STG1 4C	0	True False	cTRUFLS code list
	SGRQ.STG1 4D	000	True False	cTRUFLS code list
ion 6				
These are questions about how problems.	your activiti	es i	night be	affected by your respiratory
15. For each statement, please or respiratory problems.	check the b	ox t	hat applie	es to you because of your
	SGRQ.STG1 5A	0	True False	cTRUFLS code list
	SGRQ.STG1 5B	000	True False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG1 5C	0	True False	cTRUFLS code list
	SGRQ.STG1 5D	0	True False	cTRUFLS code list
	SGRQ.STG1 5E	0	True False	cTRUFLS code list
	SGRQ.STG1 5F	000	True False	cTRUFLS code list
	SGRQ.STG1 5G	0	True False	cTRUFLS code list
	SGRQ.STF1 5H	00	True False	cTRUFLS code list
My breathing makes it difficult	SGRQ.STG1 51	0	True False	cTRUFLS code list
ion 7				
We would like to know how your	respiratory	pro	blems us	sually affect your daily life.

I cannot play sports or do other	SGRQ.STG1	True	
physical activities	6A	False	cTRUFLS code list

	l cannot go out for entertainment or recreation	SGRQ.STG1 6B	TrueFalse	cTRUFLS c	ode list	
	l cannot go out of the house to do the shopping	SGRQ.STG1 6C	TrueFalse	cTRUFLS c	ode list	
I	l cannot do household chores	SGRQ.STG1 6D	TrueFalse	cTRUFLS c	ode list	
l	l cannot move far from my bed or chair	SGRQ.STG1 6E	TrueFalse	cTRUFLS c	ode list	
 	 Sexual intercourse Going to a place of worship, or Going out in bad weather or in Visiting family or friends or play 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: 	to smoky roo	 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 doing in things to do It stops 	s me from most of the I would like	CRSPAFT COO	

Surgical Intervention

Date of Visit

(Visit ID = 30, Page ID = 10)

Unique Identifier page-304846-304940-30-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code li	st
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code li	st
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code li	st
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code li	st
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code li	st
If yes, please complete the ear	ly discontinu	ation form		

Surgical Intervention (Visit ID = 30, Page ID = 20) Unique Identifier page-103007-304940-30-20

Surge	ery information					
.	Did subject receive the surgical intervention?	SURGINFO. SURGYN	0	Yes No	NY code list	t
8	Date of surgery	SURGINFO. SURGDT			3	
	Was bronchoscopy performed on subject?	SURGINFO. BRONCHO	0 0	Yes No	NY code list	t
	Was bronchial alveolar lavage (BAL) fluid collected?	SURGINFO. BALFLUID	0	Yes No	NY code list	t
	Volume of BAL instilled (ml)	SURGINFO. BALNSTLD				(format 999)
	Volume of BAL collected (ml)	SURGINFO. BALCOLL				(format 999)
	Were airway epithelial cells (AEC) collected?	SURGINFO. AECYN	0 0	Yes No	NY code list	t
	Number of brushes sent	SURGINFO. AECBRUSH				(format 99)
Pre-o	perative details					
	Any previous abdominal surgery affecting the operative field?	PREOP.PRE VSURG	0	Yes No	NY code list	t
	Type of surgery	PREOP.TYP ESURG				
	Pre-operative testing performed	1				
	Endoscopy	PREOP.EN DOSCPY		Yes No	NY code lis	
	Barium swallow	PREOP.BAR IUM		Yes No	NY code lis	t
	Echocardiogram	PREOP.EK G	0	Yes No	NY code list	t
	If yes, RVSP (mmHg)	PREOP.RSV PVAL				(format 99)
	Right heart catheterization	PREOP.RG HTHRT		Yes No	NY code list	t
	If yes, mean PA (mmHg)	PREOP.ME ANPA				(format 99)
	Gastric emptying study	PREOP.GA STRIC		Yes No	NY code lis	t
	Chest x-ray	PREOP.CH STXRAY	1.000	Yes No	NY code lis	t

Created : 18-APR-16 12:12:25 GMT Page 277

Operative time (mins)	INTROP.OP TM		(fe	ormat 999)
Estimated blood loss (cc)	INTROP.BL DLOSS		(fe	ormat 9999)
Intraoperative complications?	INTROP.INT RCMP	○ Yes NY ○ No	✓ code list	
If yes, select complications (Select all that apply)	INTROP.SL CTCOMP	DELETE SELECTED		ION code list
Conversion to open procedure?	INTROP.OP NPROC	○ Yes ○ No	NY cod	e list
Was mesh used during procedure?	INTROP.ME SH	YesNo	NY cod	e list
Size of bougie used in procedure	INTROP.BO UGIE	 None use 52 54 56 58 60 Other 	-	GIE code list
Other (Fr.)	INTROP.OT HBOGI		(fe	ormat 99)
Length of Nissen (cm)	INTROP.NIS SEN		(fe	ormat 99.99)
Length of Nissen - Unknown	INTROP.NS SENUNK			
Hiatus hernia present	INTROP.HIH ERNIA	YesNo	NY code	list
If yes, size of hernia	INTROP.HR NIASZE	 small (2-3 medium (large (4+ paraesop 	3-4 cm) cm)	HERNIASIZE code
Identification and preservation of vagus nerges?	INTROP.VG USNERG	YesNo	NY code	list
Esophageal lengthening procedure added?	INTROP.LE NGTHN	YesNo	NY code	list
Were there other abnormal intraoperative findings?	INTROP.OT HABNYN	YesNo	NY code	list
Other abnormal intraoperative f (Select all that apply) Cirrhosis	indings INTROP.CIR RH			
Hypersplenism	INTROP.HS PN			
---------------------------------------	---------------------	--		
Hepatomegaly	INTROP.HP TMGLY			
Evidence of portal hypertension	INTROP.PH TN			
Presence of intra-abdominal adhesions	INTROP.INA BDADH			
Variant anatomy	INTROP.VA RANAT			
Other	INTROP.AB			
If Variant anatomy, Describe	INTROP.VA RIANAT			

Month 1 Telephone Contact

Date of Visit

(Visit ID = 40, Page ID = 10)

U	Inique	Identifier	page-304846-304941-40-10
---	--------	------------	--------------------------

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code	list
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code	list
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code	list
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code	list
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code	list
If yes, please complete the ear	ly discontinu	ation form		

Monthly Telephone Contact (Visit ID = 40, Page ID = 20)

Unique Identifier page-304876-304941-40-20

	Please check if telephone contact was not performed at this visit.	TELE.TELE ND			
Telep	hone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	○ Yes○ No	NY code list	
	If Yes, complete the Death form	n			
	Did subject report any adverse events (serious or non- serious?)	TELE.TELE AE	YesNo	NY code list	
	If Yes, complete the Adverse E	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	TELE.TELE HC	○ Yes ○ No	NY code list	
	If Yes, complete the Health Car	e Encounte	r Form		

Post-Operative Details (Visit ID = 40, Page ID = 30) Unique Identifier page-45945-304941-40-30

Post-operative details				
Length of stay post- operatively. (days)	POSTOP.DA YSSTY			(format 999)
Days spent in ICU	POSTOP.DA YSICU			(format 999)
Was patient readmitted to the hospital within 30 days?	POSTOP.RE C ADMIT	Yes No	NY code list	
Did patient require re- intubation?	INTUBE	> Yes > No	NY code list	
Days on ventilator	POSTOP.VE			(format 999)
Was re-operation for bleeding required?	POSTOP.RE OPBLD	> Yes > No	NY code list	
Did patient suffer other post- operative complications (within 30 days of surgery)?	POSTOP.C C OMPLCTN C	103	NY code list	
If yes, what complications? (Select all that apply)	POSTOP.C MPSPCFY	DELETE SELEC	V 🗣 ADD	

Month 2 Telephone Contact

Date of Visit (Visit ID = 50, Page ID = 10)

Unique Identifier page-304846-304942-50-10

Date of visit	DOV.DOVD T					
Did subject complete the visit?	DOV.DOVC OMP	○ Ye		NY code lis	t	
If no, will subject continue in the study?	DOV.DOVC ONT	○ Ye	-	NY code lis	t	
If no, was it due to death of subject?	DOV.DOVD TH	○ Ye		NY code lis	t	
Did subject cross over to surgery?	DOV.DOVS X	YeNo		NY code lis	t	
If yes, date of surgery?	DOV.DOVS XDT					
Has the subject had a lung transplant?	DOV.DOVLT X	○ Ye○ No		NY code lis	t	
If ves, please complete the earl	lv discontinu	ation fo	orm			

Monthly Telephone Contact (Visit ID = 50, Page ID = 20)

Unique Identifier page-304876-304942-50-20

	k if telephone not performed at	TELE.TELE ND					
Telephone contact							
Date of telep	hone contact	TELE.TELC ONDT					
Was subject have died?	determined to	TELE.TELE DETH	0	Yes No	NY code list		
	lete the Death form eport any adverse ous or non-		0	Yes No	NY code list		
If Yes, comp	lete the Adverse E	vents form					
with the heal (admitted to emergency r	eport any contacts th care system the hospital, oom/urgent care, ty, or rehabilitation	TELE.TELE HC		Yes No	NY code list		
If Yes, comp	lete the Health Car	e Encounte	r Fori	m			

Week 12 Visit

Date of Visit (Visit ID = 60, Page ID = 10) Unique Identifier page-304846-304943-60-10

Date of visit	DOV.DOVD T		
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code list
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code list
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code list
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code list
If yes, date of surgery?	DOV.DOVS XDT		
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code list
If yes, please complete the ear	ly discontinu	ation form	

Concomitant Medications (Visit ID = 60, Page ID = 100) Unique Identifier page-304883-304943-60-100

CMFP.CMF Medications were not collected PND at this visit. **Concomitant Medications** Has the subject taken any of the following medications since the last visit? CMFP.CMP Proton Pump Inhibitors (PPI) \bigcirc Taking daily PI 0 cCMFUP code list Taking as needed \bigcirc Not Current CMFP.CMH H2 Blockers (H2 Receptor O Taking daily **2B** cCMFUP code list Antagonists) O Taking as needed O Not Current Chronic prednisone (>1month) CMFP.CMC \bigcirc Taking daily cCMFUP code list Taking as needed \bigcirc Not Current CMFP.CMC If current, chronic/ average (format 99.9) PDOSE dose taken (mg/day): CMFP.CMA Azathioprine \bigcirc Taking daily ZΤ cCMFUP code list Taking as needed Not Current CMFP.CMN N-acetylcystteine (NAC) O Taking daily cCMFUP code list AC O Taking as needed O Not Current CMFP.CMC Cotrimoxazole Taking daily OT cCMFUP code list Taking as needed Not Current CMFP.CMM Albuterol/ atrovent/ other O Taking daily cCMFUP code list DI metered-dose inhaler (MDI) O Taking as needed O Not Current Taking daily Pirfenidone CMFP.CMPI RF Taking as needed cCMFUP code list Not Current CMFP.CMNI Nintedanib O Taking daily NT cCMFUP code list O Taking as needed Not Current

Documentation of GERD & Esophageal Motility

(Visit ID = 60, Page ID = 20)

Unique Identifier page-188329-304943-60-20

and the second secon			
was not collected at this visit.	GERD.GER DND		
Frequency Scale for the Symptoms of GE	RD		
	gerd.fqn D		
	GERD.FQH RTBRN	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQBL OAT	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQH EAVY	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQR UB	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQSI CK	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQH RTAFT	 Never Occasionally Sometimes Often Always 	cGFREQ code list

7. Do yo (e.g. bur throat?	u have an unusual ning) sensation in your	GERD.FQT HROAT	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
8. Do yo meals?	u feel full while eating	GERD.FQF ULL	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
9. Do so when yo	me things get stuck u swallow?	GERD.FQST UCK	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
	ou get bitter liquid ming up into your	GERD.FQA CID	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
11. Do y	ou burp a lot?	GERD.FQB URP	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
bend ove	-	GERD.FQH RTBND	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
D Health R Not Colle	elated Quality of Life	GERD.QLN		

0-No symptoms

1-Symptoms noticeable, but not bothersome

2-Symptoms noticeable, but not bothersome, but not every day
3-Symptoms bothersome every day
4-Symptoms affect daily activities

5-Symptoms are incapacitating, unable to do daily activities

1. How bad is your heartburn? G	GERD.QLH RTBRN	 0 1 2 3 4 5
2. Heartburn when lying down? G	GERD.QLLY NG	 0 1 2 3 4 5
3. Heartburn when standing G up?	GERD.QLST AND	
4. Heartburn after meals? G	GERD.QLH RTAFT	 0 1 2 3 4 5
5. Does heartburn change your G diet?	GERD.QLDI	 0 1 2 3 4 5
6. Does heartburn wake you G from sleep?	GERD.QLSL EEP	 0 1 2 3 4 5

7. Do you have difficulty swallowing?	gerd.qldi FFSW	 0 1 2 3 4 5 				
8. Do you have pain with swallowing?	GERD.QLPA INSW	 0 1 2 3 4 5 				
9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	 0 1 2 3 4 5 				
10. If you take medication, does this affect your daily life?	GERD.QLM EDS	 0 1 2 3 4 5 				
H Monitoring Results		Ū				
Per Protocol Amendment 3, all patients should check the Not Collected Box at the Week 12 Visit Per Protocol Amendment 3, non surgery patients should check the Not Collected Box at the Week 24 Visit Not Collected <u>GERD.PHN</u>						
Was probe located 5cm above LES	D GERD.PHP ROBE	YesNo	NY code list			
total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)		
upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)		
supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)		
# of reflux episodes	GERD.PHR FLEPS			(format 999.9)		
# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)		
Longest reflux episode (mins)						

Created : 18-APR-16 12:12:25 GMT Page 317

Overall DeMeester Score	GERD.PHS		(format 999.9)
ometry Results	CORE		
Per Protocol Amendment 3, all Visit	patients sho	ould check the Not Collect	cted Box at the Week 12
Per Protocol Amendment 3, nor Week 24 Visit	n <mark>surgery</mark> pa	tients should check the	Not Collected Box at the
Not Collected	GERD.MNN D		
Lower esophageal sphincter (Ll	ES) data		
LES length (cm)	GERD.MNL ESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)
Upper esophageal sphincter (U	,		
UES resting pressure (mmHg)	GERD.MNU ESRTP		(format 999.9)
UES relaxation (%)	GERD.MNU ESRLX		(format 999.9)
Esophageal body motility patter	'n		
% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSI MUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNE BMP	 Normal motity Ineffective (<80% normal contraction) Severely ineffective (<30% normal contraction) Diffuse/distal esophageal spasm (simultaneous contractions in >10% of swallows, with amp > 30mmHg) Aperistalsis (no peristaltic activity observed in 	cEBMP code
		esophageal body)	

Spirometry_DLCO

(Visit ID = 60, Page ID = 30)

Unique Identifier page-80805-304943-60-30

	Please check if procedures were not performed	SPIRO.SPIR OND			
SPIR	OMETRY				
	Indicate at which visit these values were collected	SPIRO.SPR VISIT	 Screening Enrollmer 		
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES			
	FEV1: Actual (liters)	SPIRO.PRM FEV		(format 99.99)	
6	FVC: Actual (liters)	SPIRO.PRM FVC		(format 99.99)	
	VC: Actual (liters)	SPIRO.PRM VC		(format 99.99)	
	Pre-Bronchodilator: Replicate 1	SPIRO.REP 1YES			
	FEV1: Actual (liters)	SPIRO.REP 1FEV		(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 1FVC		(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 1VC		(format 99.99)	
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES			
	FEV1: Actual (liters)	SPIRO.REP 2FEV		(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 2FVC		(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 2VC		(format 99.99)	
DLC	C				
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT		(format 99.9)	
	VA (alveolar volume) (liters)	SPIRO.DLC OVA		(format 9.99)	
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO		(format 99.9)	
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM		(format 99.9)	

Arterial Blood Gas (Visit ID = 60, Page ID = 40) Unique Identifier page-45888-304943-60-40

Please check if ABG was not performed at this visit.	ABG.ABGN 🗆 D	
Arterial Blood Gas		
FiO2 (%)	ABG.ABGFI OX	(format 999)
рН	ABG.ABGP	(format 9.99)
PaO2 (mm Hg)	ABG.ABGPA OX	(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPA COX	(format 999.9)
SaO2 (%)	ABG.ABGSA OX	(format 999.9)

6-Minute Walk Test (Visit ID = 60, Page ID = 50) Unique Identifier page-80834-304943-60-50

	Please check if walk test was not performed at this visit.	WALK.WAL KND	
3 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	 Screening Visit Enrollment Visit
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	CBORG code list
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	Yes NY code listNo
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	YesNY code listNo
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	Walk.Wks Posup	(format 999)
	Was a walking aid necessary to perform the 6MWT?	Walk.wkai D	 Yes NY code list No
	If yes: Specify type of walking aid	WALK.WKS PAID	 Cane Walker CWALK code list Other
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	YesNy code list
	If no: What was duration of walk	ctest?	
	minutes	WALK.WKMI	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	 Symptoms requiring termination Other C6MTERM code list
	Other (specify)	WALK.WKR SNSP	
	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Did subject desaturate (SpO2	WALK.WKD	○ Yes	NY code list
< 88%)?	SAT	○ No	
If yes: Walk duration at desatur	ration		
minutes	WALK.WKD		(format 9)
mindtoo	SMIN		(Iormat o)
seconds	WALK.WKD		(format 99)
	SSEC		х , , , , , , , , , , , , , , , , , , ,
If yes: walk distance at	WALK.WKD		(format 9999)
desaturation (meters)	SMTR		
Lowest SpO2 (%)	WALK.WKL		(format 999)
1 ()	OWSP		· · · · · · · · · · · · · · · · · · ·
Post-walk modified Borg	WALK.POST	* A	cBORG code list
Dyspnea Scale rating	BORG		

Blood Collection

(Visit ID = 60, Page ID = 60)

Unique Identifier page-45825-304943-60-60

	lease check if blood samples ere not collected at this visit.	BC.BCND			
Blood Co	ollection Information				
	ate blood samples were rawn	BC.BCDT			
	ime blood samples were rawn	BC.BCTM			(HH24:MI)
P	rocessing date	BC.BCPRDT			
P	rocessing time	BC.BCPRT M			(HH24:MI)
V	/as DNA collected?	BC.BCDNA	○ Yes○ No	NY code lis	st
lf	yes, Yield (ml)	BC.BCDYLD			(format 99.9)
#	of aliquots	BC.BCDALQ			(format 99)
	/as plasma collected?	BC.BCPLAS MA	YesNo	NY code lis	
lf	yes, Yield (ml)	BC.BCPYLD			(format 99.9)
#	of aliquots	BC.BCPALQ			(format 99)
W	/as serum collected?	BC.BCSERU M	YesNo	NY code lis	st
lf	yes, Yield (ml)	BC.BCSYLD			(format 99.9)
	of aliquots	BC.BCSALQ			(format 99)

UCSD Shortness of Breath Questionnaire

(Visit ID = 60, Page ID = 70)

Unique Identifier page-45995-304943-60-70

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND				
SD Shortness of Breath Questionnaire	Э				
When I do, or if I were to do, the following tasks, I would rate my breathlessness as: 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do because of breathlessness					
At rest	UCSD.UCS D1	 0 1 2 3 4 5 			
Walking on a level at your own pace	UCSD.UCS D2	 0 1 2 3 4 5 			
Walking on a level with others your age	UCSD.UCS D3	 0 1 2 3 4 5 			
Walking up a hill	UCSD.UCS D4	 0 1 2 3 4 5 			

Walking up stairs	UCSD.UCS D5	 0 1 2 3 4 5
While eating	UCSD.UCS D6	 0 1 2 3 4 5
Standing up from a chair	UCSD.UCS D7	 0 1 2 3 4 5
Brushing teeth	UCSD.UCS D8	 0 1 2 3 4 5
Shaving and/or brushing hair	UCSD.UCS D9	 0 1 2 3 4 5
Showering/bathing	UCSD.UCS D10	 0 1 2 3 4 5

Dressing	UCSD.UCS D11	 0 1 2 3 4 5
Picking up and straightening	UCSD.UCS D12	 0 1 2 3 4 5
Doing dishes	UCSD.UCS D13	 0 1 2 3 4 5
Sweeping/vacuuming	UCSD.UCS D14	 0 1 2 3 4 5
Making bed	UCSD.UCS D15	 0 1 2 3 4 5
Shopping	UCSD.UCS D16	 0 1 2 3 4 5

Doing laundry	UCSD.UCS D17	 0 1 2 3 4 5
Washing car	UCSD.UCS D18	 5 0 1 2 3 4 5
Mowing lawn	UCSD.UCS D19	 0 1 2 3 4 5
Watering lawn	UCSD.UCS D20	 0 1 2 3 4 5
Sexual activities	UCSD.UCS D21	 0 1 2 3 4 5
How much do these limit you in Shortness of breath	your daily li UCSD.UCS D22	

Fear of "hurting myself" by overexerting	UCSD.UCS D23	 0 1 2 3 4 5
Fear of shortness of breath	UCSD.UCS D24	 0 1 2 3 4 5

Patient Reported Outcome Battery

(Visit ID = 60, Page ID = 80)

Unique Identifier page-45844-304943-60-80

Please check if outcome battery was not performed at this visit.	ICEEQ.ICEE QND			
h VAS				
Cough VAS	ICEEQ.COU GHVAS			
How would rate the severity of your cough?(0-100)	ICEEQ.COU GHSEV			(format 999)
AP				
Not Collected	ICEEQ.ICEN D			
By placing a check in one box i describes your quality of life at			elow, please indicate	which statement best
Love and Friendship	ICEEQ.ICEL OVE	0	I can have all of the love and friendship that I want	FRIENDS code list
		0	I can have a lot of the love and friendship that I want	
		0	I can have a little of the love and friendship that I want	
		0	I cannot have any of the love and friendship that I want	
Thinking about the future	ICEEQ.ICEF UTR	0	I can think about the future without any concern	
		0	I can think about the future with only a little concern	THINKING code
		0	I can only think about the future with some concern	
		0	I can only think about the future	

5D-3L			at all independent	
		0	independent in a few things	
		0	l am able to be independent in many things	INDEPEND code
Independence	ICEEQ.ICEI NDEP	0	l am able to be completely independent	
		0	I cannot have any of the enjoyment and pleasure that I want	
		0	I can have a little of the enjoyment and pleasure that I want	
			I can have a lot of the enjoyment and pleasure that I want	PLEASURE code
Enjoyment and pleasure	ICEEQ.ICEE NJOY	0	I can have all of the enjoyment and pleasure that I want	
		0	l am unable to do any of the things that make me feel valued	
		0	l am able to do a few of the things that make me feel valued	
		0	many of the things that make me feel valued	VALUED code list
Doing things that make you feel valued	ICEEQ.ICEV ALUE		I am able to do all of the things that make me feel valued	

By placing a check in one box in each group below, please indicate which statement best describes your own health state today.

Mobility	ICEEQ.EQM	I have no	
Moonly	OB	problems in	4
		 walking abou I have some 	MOBILE code list
		problems in walking abou	t
		 I am confined bed 	
Self-Care	ICEEQ.EQS C	 I have no problems with care 	n self-
		 I have some problems was or dressing m 	
		 I am unable t wash or dres myself 	0
Usual activities (e.g. work,	ICEEQ.EQU A	I have no	_
study, housework, family or leisure activities)	~	problems with performing m usual activitie	y .
		 I have some problems with performing m usual activitie 	y .
		I am unable t perform my u activities	
Pain/Discomfort	ICEEQ.EQP AIN	 I have no pai discomfort 	n or
		 I have moder pain or discord 	
		 I have extrem pain or discord 	
Anxiety/Depression	ICEEQ.EQA NX	 I am not anxi or depressed 	
		 I am moderate anxious or depressed 	ANXIETY code list
		 I am extreme anxious or depressed 	ly
Value of EQ-5D VAS (0-100)	ICEEQ.EQV	·	(format 999)

St George's Respiratory Questionnaire

(Visit ID = 60, Page ID = 90)

Unique Identifier page-45914-304943-60-90

Please check if questionnaire was not performed at this visit.	SGRQ.SGR QND			
eorge's Respiratory Questionnaire				
This questionnaire is designed troubling you and how it affects illness cause you the most prob problems are.	your life. W	e are using i	it to find out which	ch aspects of your
Please read the instructions car spend too long deciding about y	refully and as our answers	sk if you do r 3.	not understand a	anything. Do not
Before completing the question	naire:			
Please check one box to show how you describe your current health:	SGRQ.CUR HLTH	 Very god Good Fair Poor 		ILTH code list
		Very port	or	
1				
weeks. Please check one box for each 1. Over the past 4 weeks, I have coughed:	question SGRQ.STG0 1	 Almost B Several Week A Few D Month Only wit Respirat Infection Not at a 	Days a h tory is	cRSPROB code
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG0 2	 Almost I Several Week 		

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG0	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code I
4. Over the past 4 weeks, I have had wheezing attacks:	SGRQ.STG0 4	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code I
5. How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks?	SGRQ.STG0 5	 More than 3 times 3 times 2 times 1 time None of the time 	cNBRATK code
6. How long did your worst respiratory attack last? (Go to question 7 if you did not have a severe attack)	SGRQ.STG0 6	 A week or more 3 or more days 1 or 2 days Less than a day 	cLENGTH code I
7. Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had?	SGRQ.STG0 7	 No good days 1 or 2 good days 3 or 4 good days Nearly every days was good Every day was good 	cDAYS code list
8. If you wheeze, is it worse when you get up in the	SGRQ.STG0 8	YesNoNY code list	

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0	The most important problem I have	
		0	Causes me quite a lot of problems	cRSCON code lis
		0	Causes me a few problems	
		0	Causes no problems	
10. If you have ever held a job:	SGRQ.STG1 0	0	My repriatory problems made me stop working altogether	
		0	My respiratory problems interfere with my job or made me change my job	cJOB code list
		0	My respiratory problems do not affect my job	

Section 2

These are questions about what activities usually make you feel short of breath these days.

11. For each statement, please check the box that applies to you these days.

	Sitting or lying still	SGRQ.STG1 1A	0	True False	cTRUFLS	code list
	Washing or dressing yourself	SGRQ.STG1 1B	000	True False	cTRUFLS	code list
	Walking around the house	SGRQ.STG1 1C	0	True False	cTRUFLS	code list
	Walking outside on a level ground	SGRQ.STG1 1D	000	True False	cTRUFLS	code list
	Walking up a flight of stairs	SGRQ.STG1 1E	0	True False	cTRUFLS	code list
	Walking up hills	SGRQ.STG1 1F	0	True False	cTRUFLS	code list
	Playing sports or other physical activities	SGRQ.STG1 1G	0	True False	cTRUFLS	code list
Sectio	on 3					

These are more questions about your cough and shortness of breath these days.

12. For each statement, please check the box that applies to you these days.

Coughing hurts

- SGRQ.STG1 O True
 - False cTRUFLS code list

	_		
	SGRQ.STG1 2B	TrueFalse	cTRUFLS code list
I am short of breath when I talk	SGRQ.STG1 2C	TrueFalse	cTRUFLS code list
	SGRQ.STG1 2D	TrueFalse	cTRUFLS code list
	SGRQ.STG1 2E	TrueFalse	cTRUFLS code list
	SGRQ.STG1 2F	TrueFalse	cTRUFLS code list
ction 4			
these days.			ratory problems may have on you
13. For each statement, please of		-	ies to you these days.
	SGRQ.STG1 3A	 True False 	cTRUFLS code list
	SGRQ.STG1 3B	TrueFalse	cTRUFLS code list

nuisance to my family, friends, or neighbors	30	• False	;	
I get afraid or panic when I cannot catch my breath	SGRQ.STG1 3C	TrueFalse	cTRUFLS c	ode list
I feel that I am not in control of my respiratory problems	SGRQ.STG1 3D	TrueFalse	cTRUFLS c	ode list
l do not expect my respiratory problems to get any better	SGRQ.STG1 3E	TrueFalse	cTRUFLS c	ode list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG1 3F	TrueFalse	cTRUFLS c	ode list
Exercise is not safe for me	SGRQ.STG1 3G	TrueFalse	cTRUFLS c	ode list
Everything seems too much of an effort	SGRQ.STG1 3H	TrueFalse	cTRUFLS c	ode list

Section 5

These are questions about your respiratory treatment. If you are not receiving treatment, go to section 6.

Not Receiving Respiratory Treatment	SGRQ.SGN OTXT					
14. For each statement, please	check the b	ox t	hat appli	ies to you th	ese days.	
My treatment does not help me	SGRQ.STG1	0	True			
very much	4A	0	False	cTRUFLS c	ode list	
l get embarrassed using my		0	True			
medication in public	48	0	False	cTRUFLS c	ode list	
	Treatment 14. For each statement, please My treatment does not help me very much	Treatment OTXT 14. For each statement, please check the b My treatment does not help me SGRQ.STG1 very much 4A get embarrassed using my SGRQ.STG1	Treatment OTXT 14. For each statement, please check the box t My treatment does not help me very much I get embarrassed using my SGRQ.STG1 Graduation I get embarrassed using my	Treatment OTXT 14. For each statement, please check the box that applied by treatment does not help me sort and the sort and the sort applied by treatment does not help me sort applied by treatment does	Treatment OTXT 14. For each statement, please check the box that applies to you th My treatment does not help me very much SGRQ.STG1 True I get embarrassed using my SGRQ.STG1 True	Treatment OTXT 14. For each statement, please check the box that applies to you these days. My treatment does not help me very much SGRQ.STG1 True I get embarrassed using my SGRQ.STG1 True SGRQ.STG1 True True I get embarrassed using my SGRQ.STG1 True

Created : 18-APR-16 12:12:25 GMT Page 372

I have unpleasant side effects	SGRQ.STG1 4C	0	True	cTRUFLS code list
from my medication		0	False	
My treatment interferes with my life a lot	SGRQ.STG1 4D	0	True False	cTRUFLS code list
on 6				
These are questions about how problems.	your activiti	es i	night b	e affected by your respiratory
15. For each statement, please respiratory problems.	check the b	ox t	hat app	blies to you because of your
I take a long time to get washed or dressed	SGRQ.STG1 5A	0	True False	cTRUFLS code list
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG1 5B	000	True False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG1 5C	0	True False	cTRUFLS code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG1 5D	000	True False	cTRUFLS code list
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG1 5E	0	True False	cTRUFLS code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG1 5F	0	True False	cTRUFLS code list
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl or play golf	SGRQ.STG1 5G	0	True False	cTRUFLS code list
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	SGRQ.STF1 5H	00	True False	cTRUFLS code list
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SGRQ.STG1 51	0	True False	cTRUFLS code list
on 7				
We would like to know how you	r respiratory	pro	blems	usually affect your daily life.

I cannot play sports or do other	SGRQ.STG1	0	True	
physical activities	bА	0	False	cTRUFLS code list

I cannot go out for entertainment or re		SGRQ.STG1 6B		True False	cTRUFLS	code list	t
I cannot go out of t do the shopping	the house to	SGRQ.STG1 6C		True False	cTRUFLS	code list	t
I cannot do housel	hold chores	SGRQ.STG1 6D		True False	cTRUFLS	code list	t
l cannot move far t or chair	from my bed	SGRQ.STG1 6E		True False	cTRUFLS	code list	t
Here is a list of oth (You do have to ch	ner activities t	hat your res	pirato	ory pro	blems may	prevent	you from doing
 Going to a place of 	of warahin ar						
•Going out in bad y •Visiting family or f Please write in any important activities respiratory problem you from doing:	weather or in riends or play y other s that your ns may stop	to smoky roo ying with chi SGRQ.STGL IST	oms Idren				
•Going out in bad v •Visiting family or f Please write in any important activities respiratory problem	weather or in riends or play y other s that your ms may stop eck the box u think best ur respiratory	to smoky roc ying with chi SGRQ.STGL	oms Idren	It does me fror anythin ike to c It stops	not stop m doing ng I would do s me from		
 Going out in bad y Visiting family or f Please write in any important activities respiratory probler you from doing: 17. Now please ch (one only) that you describes how you 	weather or in riends or play y other s that your ms may stop eck the box u think best ur respiratory	to smoky roo ying with chi SGRQ.STGL IST	oms Idren	It does me fror anythin ike to c It stops doing c	not stop m doing ng I would do		cRSPAFT cod
 Going out in bad y Visiting family or f Please write in any important activities respiratory probler you from doing: 17. Now please ch (one only) that you describes how you 	weather or in riends or play y other s that your ms may stop eck the box u think best ur respiratory	to smoky roo ying with chi SGRQ.STGL IST	oms Idren	t does me fror anythin ike to d t stops doing d things l to do t stops doing n	not stop m doing ng I would do s me from one or two		cRSPAFT cod

Month 4 Telephone Contact

Date of Visit (Visit ID = 70, Page ID = 10) Unique Identifier page-304846-304944-70-10

	Date of visit	DOV.DOVD T	
	Did subject complete the visit?	DOV.DOVC OMP	Yes NY code listNo
	If no, will subject continue in the study?	DOV.DOVC ONT	 Yes NY code list No
	If no, was it due to death of subject?	DOV.DOVD TH	 Yes NY code list No
	Did subject cross over to surgery?	DOV.DOVS X	 Yes No NY code list
	If yes, date of surgery?	DOV.DOVS XDT	
	Has the subject had a lung	DOV.DOVLT X	Yes NY code list

transplant? No If yes, please complete the early discontinuation form

Monthly Telephone Contact (Visit ID = 70, Page ID = 20)

Unique Identifier page-304876-304944-70-20

	Please check if telephone contact was not performed at this visit.	TELE.TELE ND			
Tele	phone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	YesNo	NY code list	
	If Yes, complete the Death form	ı			
	Did subject report any adverse events (serious or non- serious?)	TELE.TELE AE	YesNo	NY code list	
	If Yes, complete the Adverse E	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?		YesNo	NY code list	
	If Yes, complete the Health Car	e Encounte	r Form		

Month 5 Telephone Contact

Date of Visit (Visit ID = 80, Page ID = 10)

Unique Identifier page-304846-304945-80-10

Date of visit	DOV.DOVD T		8		
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code list		
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code list		
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code list		
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code list		
If yes, date of surgery?	DOV.DOVS XDT				
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code list		
If yes, please complete the early discontinuation form					
Monthly Telephone Contact

(Visit ID = 80, Page ID = 20)

Unique Identifier page-304876-304945-80-20

	Please check if telephone contact was not performed at this visit.	TELE.TELE ND			
Telep	phone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	YesNo	NY code list	
	If Yes, complete the Death form	า			
	Did subject report any adverse events (serious or non- serious?)	TELE.TELE AE	YesNo	NY code list	
	If Yes, complete the Adverse E	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	HC	○ Yes ○ No	NY code list	
	If Yes, complete the Health Car	e Encounte	r Form		

Week 24 Visit

Date of Visit (Visit ID = 90, Page ID = 10) Unique Identifier page-304846-304946-90-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code list	
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code list	
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code list	
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code list	
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code list	
If ves, please complete the earl	lv discontinu	ation form		

Concomitant Medications (Visit ID = 90, Page ID = 80)

Unique Identifier page-304883-304946-90-80

Medications were not collected	CMFP.CMF		
at this visit.	PND		
comitant Medications			
Has the subject taken any of the	-		st visit?
Proton Pump Inhibitors (PPI)	CMFP.CMP PI	 Taking daily Taking as needed Not Current 	cCMFUP code li
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH 2B	 Taking daily Taking as needed Not Current 	cCMFUP code li
Chronic prednisone (>1month)	CMFP.CMC P	 Taking daily Taking as needed Not Current 	cCMFUP code li
If current, chronic/ average dose taken (mg/day):	CMFP.CMC PDOSE		(format 99.9)
Azathioprine	CMFP.CMA ZT	 Taking daily Taking as needed Not Current 	cCMFUP code li
N-acetylcystteine (NAC)	CMFP.CMN AC	 Taking daily Taking as needed Not Current 	cCMFUP code li
Cotrimoxazole	CMFP.CMC OT	 Taking daily Taking as needed Not Current 	cCMFUP code li
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMM DI	 Taking daily Taking as needed Not Current 	cCMFUP code li
Pirfenidone	CMFP.CMPI RF	 Taking daily Taking as needed Not Current 	cCMFUP code li
Nintedanib	CMFP.CMNI NT	 Taking daily Taking as needed Not Current 	cCMFUP code li

Documentation of GERD & Esophageal Motility

(Visit ID = 90, Page ID = 100)

Unique Identifier page-188329-304946-90-100

Please check if documentation was not collected at this visit.	DND		
Frequency Scale for the Symptoms of Gl	ERD		
Not Collected	gerd.fqn D		
1. Do you get heartburn?	GERD.FQH RTBRN	 Never Occasionally Sometimes Often Always 	cGFREQ code list
2. Does your stomach get bloated?	GERD.FQBL OAT	 Never Occasionally Sometimes Often Always 	cGFREQ code list
3. Does your stomach ever feel heavy after meals?	GERD.FQH EAVY	 Never Occasionally Sometimes Often Always 	cGFREQ code list
4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQR UB	 Never Occasionally Sometimes Often Always 	cGFREQ code list
5. Do you feel sick after meals?	GERD.FQSI CK	 Never Occasionally Sometimes Often Always 	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQH RTAFT	 Never Occasionally Sometimes Often Always 	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	gerd.fqt Hroat	NeverOccasionally	
		SometimesOftenAlways	cGFREQ code lis
	GERD.FQF ULL	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQST UCK	 Always Never Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQA CID	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQB URP	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
12. Do you get heartburn if you bend over?	GERD.FQH RTBND	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
RD Health Related Quality of Life			

For each question listed below, please rate your level of symptoms on a scale of 0 to 5

0-No symptoms

1-Symptoms noticeable, but not bothersome

2-Symptoms noticeable, but not bothersome, but not every day
3-Symptoms bothersome every day
4-Symptoms affect daily activities

5-Symptoms are incapacitating, unable to do daily activities

1. How bad is your heartburn? G	GERD.QLH RTBRN	 0 1 2 3 4 5
2. Heartburn when lying down? G	GERD.QLLY NG	 0 1 2 3 4 5
3. Heartburn when standing G up?	GERD.QLST AND	
4. Heartburn after meals? G	GERD.QLH RTAFT	 0 1 2 3 4 5
5. Does heartburn change your G diet?	GERD.QLDI	 0 1 2 3 4 5
6. Does heartburn wake you G from sleep?	GERD.QLSL EEP	 0 1 2 3 4 5

7. Do you have difficulty swallowing?	GERD.QLDI FFSW	 0 1 2 3 4 5 		
8. Do you have pain with swallowing?	GERD.QLPA INSW	 0 1 2 3 4 5 		
9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	 0 1 2 3 4 5 		
10. If you take medication, does this affect your daily life?	GERD.QLM EDS	 0 1 2 3 4 5 		
oH Monitoring Results				
Per Protocol Amendment 3, all Visit Per Protocol Amendment 3, nor Week 24 Visit Not Collected	surgery pa	tients sho		
Was probe located 5cm above LES	d Gerd.Php Robe	YesNo	NY code list	
total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
# of reflux episodes	GERD.PHR FLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHT			(format 999.9)

Created : 18-APR-16 12:12:25 GMT Page 409

Overall DeMeester Score	GERD.PHS CORE		(format 999.9)
ometry Results			
Per Protocol Amendment 3, all Visit	patients sho	ould check the Not Colle	cted Box at the Week
Per Protocol Amendment 3, nor Week 24 Visit	n surgery pa	atients should check the	Not Collected Box at t
Not Collected	GERD.MNN D		
Lower esophageal sphincter (LI	ES) data		
LES length (cm)	GERD.MNL ESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)
Upper esophageal sphincter (U	ES) data		
UES resting pressure (mmHg)	GERD.MNU ESRTP		(format 999.9)
UES relaxation (%)	GERD.MNU ESRLX		(format 999.9)
Esophageal body motility patter	'n		
% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSI MUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNE BMP	 Normal motility Ineffective (<80% normal contraction) Severely ineffective (<30% normal contraction) Diffuse/distal esophageal spasm (simultaneous contractions in >10% of swallows, with amp > 30mmHg) Aperistalsis (no peristaltic activity observed in 	cEBMP code

Spirometry_DLCO

(Visit ID = 90, Page ID = 20)

Unique Identifier page-80805-304946-90-20

	Please check if procedures were not performed	SPIRO.SPIR OND			
SPIR	OMETRY				
	Indicate at which visit these values were collected	SPIRO.SPR VISIT	 Screening Enrollmer 		
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES			
	FEV1: Actual (liters)	SPIRO.PRM FEV		(format 99.99)	
6	FVC: Actual (liters)	SPIRO.PRM FVC		(format 99.99)	
	VC: Actual (liters)	SPIRO.PRM VC		(format 99.99)	
	Pre-Bronchodilator: Replicate 1	SPIRO.REP 1YES			
	FEV1: Actual (liters)	SPIRO.REP 1FEV		(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 1FVC		(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 1VC		(format 99.99)	
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES			
	FEV1: Actual (liters)	SPIRO.REP 2FEV		(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 2FVC		(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 2VC		(format 99.99)	
DLC	C				
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT		(format 99.9)	
	VA (alveolar volume) (liters)	SPIRO.DLC OVA		(format 9.99)	
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO		(format 99.9)	
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM		(format 99.9)	

Arterial Blood Gas (Visit ID = 90, Page ID = 90) Unique Identifier page-45888-304946-90-90

Please check if ABG was not performed at this visit.	ABG.ABGN D	
Arterial Blood Gas		
FiO2 (%)	ABG.ABGFI OX	(format 999)
рН	ABG.ABGP H	(format 9.99)
PaO2 (mm Hg)	ABG.ABGPA	(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPA COX	(format 999.9)
SaO2 (%)	ABG.ABGSA OX	(format 999.9)

6-Minute Walk Test (Visit ID = 90, Page ID = 30) Unique Identifier page-80834-304946-90-30

	Please check if walk test was not performed at this visit.	WALK.WAL KND	
6 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	 Screening Visit Enrollment Visit
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	CBORG code list
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	Yes NY code listNo
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	YesNoNY code list
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	Walk.wkai D	 Yes No NY code list
	If yes: Specify type of walking aid	WALK.WKS PAID	 Cane Walker cWALK code list Other
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	Yes NY code listNo
	If no: What was duration of wall	<pre>< test?</pre>	
	minutes	WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	 Symptoms requiring termination Other C6MTERM code list
	Other (specify)	WALK.WKR SNSP	
8	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKD SAT	YesNo	NY code list
If yes: Walk duration at desatur	ration		
minutes	WALK.WKD SMIN		(format 9)
seconds	WALK.WKD SSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKD SMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKL OWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POST BORG		CBORG code list

Blood Collection

(Visit ID = 90, Page ID = 40)

Unique Identifier page-45825-304946-90-40

Please check if blood sar were not collected at this				
Blood Collection Information				
Date blood samples were drawn	BC.BCDT			
Time blood samples were drawn	BC.BCTM		(HH24:MI)
Processing date	BC.BCPRDT			
Processing time	BC.BCPRT M		(HH24:MI)
Was DNA collected?	BC.BCDNA	YesNo	NY code list	
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLAS MA	YesNo	NY code list	
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERU M	YesNo	NY code list	
If yes, Yield (ml)	BC.BCSYLD		(format 99.9)
# of aliquots	BC.BCSALQ			format 99)
			,	

UCSD Shortness of Breath Questionnaire

(Visit ID = 90, Page ID = 50)

Unique Identifier page-45995-304946-90-50

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND						
D Shortness of Breath Questionnaire	Э						
When I do, or if I were to do, the following tasks, I would rate my breathlessness as: 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do because of breathlessness							
At rest	UCSD.UCS D1	 0 1 2 3 4 5 					
Walking on a level at your own pace	UCSD.UCS D2	 0 1 2 3 4 5 					
Walking on a level with others your age	UCSD.UCS D3	 0 1 2 3 4 5 					
Walking up a hill	UCSD.UCS D4	 0 1 2 3 4 5 					

Walking up stairs	UCSD.UCS D5	 0 1 2 3 4 5
While eating	UCSD.UCS D6	 0 1 2 3 4 5
Standing up from a chair	UCSD.UCS D7	 0 1 2 3 4 5
Brushing teeth	UCSD.UCS D8	 0 1 2 3 4 5
Shaving and/or brushing hair	UCSD.UCS D9	 0 1 2 3 4 5
Showering/bathing	UCSD.UCS D10	 0 1 2 3 4 5

Dressing	UCSD.UCS D11	 0 1 2 3 4 5
Picking up and straightening	UCSD.UCS D12	 0 1 2 3 4 5
Doing dishes	UCSD.UCS D13	 0 1 2 3 4 5
Sweeping/vacuuming	UCSD.UCS D14	 0 1 2 3 4 5
Making bed	UCSD.UCS D15	 0 1 2 3 4 5
Shopping	UCSD.UCS D16	 0 1 2 3 4 5

Doing laundry	UCSD.UCS D17	 0 1 2 3 4 5
Washing car	UCSD.UCS D18	 5 0 1 2 3 4 5
Mowing lawn	UCSD.UCS D19	 0 1 2 3 4 5
Watering lawn	UCSD.UCS D20	 0 1 2 3 4 5
Sexual activities	UCSD.UCS D21	 0 1 2 3 4 5
How much do these limit you in Shortness of breath	your daily li UCSD.UCS D22	

Fear of "hurting myself" by overexerting	UCSD.UCS D23	 0 1 2 3 4 5
Fear of shortness of breath	UCSD.UCS D24	 0 1 2 3 4 5

Patient Reported Outcome Battery

(Visit ID = 90, Page ID = 60)

Unique Identifier page-45844-304946-90-60

Please check if outcome battery was not performed at this visit.	ICEEQ.ICEE QND			
h VAS				
Cough VAS	ICEEQ.COU GHVAS			
How would rate the severity of your cough?(0-100)	ICEEQ.COU GHSEV			(format 999)
AP				
Not Collected	ICEEQ.ICEN D			
By placing a check in one box i describes your quality of life at	the moment.			which statement best
Love and Friendship	ICEEQ.ICEL OVE	0	I can have all of the love and friendship that I want	
		0	I can have a lot of the love and friendship that I want	FRIENDS code list
		0	I can have a little of the love and friendship that I want	
		0	I cannot have any of the love and friendship that I want	
Thinking about the future	ICEEQ.ICEF UTR	0	I can think about the future without any concern	
		0	I can think about the future with only a little concern	THINKING code l
		0	I can only think about the future with some concern	
			I can only think	

Deine things that make way	ICEEQ.ICEV	0					
Doing things that make you feel valued	ALUE	0	I am able to do all of the things that make me feel valued				
		0	I am able to do many of the things that make me feel valued	VALUED code list			
		0	I am able to do a few of the things that make me feel valued				
		0	I am unable to do any of the things that make me feel valued				
Enjoyment and pleasure	ICEEQ.ICEE NJOY	0	I can have all of the enjoyment and pleasure that I want				
		0	I can have a lot of the enjoyment and pleasure that I want	PLEASURE code			
					0	I can have a little of the enjoyment and pleasure that I want	
		0	I cannot have any of the enjoyment and pleasure that I want				
Independence	ICEEQ.ICEI NDEP	0	l am able to be completely independent				
		0	I am able to be independent in many things	INDEPEND code			
		0	l am unable to be independent in a few things				
		0	I am unable to be at all independent				
5D-3L							
Not Collected	ICEEQ.EQN						

By placing a check in one box in each group below, please indicate which statement best describes your own health state today.

		0	
Mobility	ICEEQ.EQM OB	 I have no problems in walking about I have some problems in walking about I am confined to bed 	MOBILE code list
Self-Care	ICEEQ.EQS C	 I have no problems with se care I have some problems washin or dressing myse I am unable to wash or dress myself 	Self-Care code I
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQU A	 I have no problems with performing my usual activities I have some problems with performing my usual activities I am unable to perform my usual activities 	ACTIVITY code
Pain/Discomfort	ICEEQ.EQP AIN	 I have no pain or discomfort I have moderate pain or discomfor I have extreme pain or discomfor 	t PAIN code list
Anxiety/Depression	ICEEQ.EQA NX	 I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed 	ANXIETY code
	ICEEQ.EQV		(format 999)

St George's Respiratory Questionnaire (Visit ID = 90, Page ID = 70)

Unique Identifier page-45914-304946-90-70

Please check if questionnaire was not performed at this visit.	SGRQ.SGR QND			
George's Respiratory Questionnaire				
This questionnaire is designed t troubling you and how it affects illness cause you the most prob problems are.	your life. W	'e a	re using it to find ou	t which aspects of your
Please read the instructions car spend too long deciding about y			f you do not underst	and anything. Do not
Before completing the questionr				
Please check one box to show	SGRQ.CUR HLTH	0	Very good	
how you describe your current health:		0		CURHLTH code list
		0	Fair	
		0	Poor	
rt 1		0	Very poor	
Please describe how often your weeks. Please check one box for each o	question	prol	blems have affected	l you over the past 4
weeks.		0	Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory	d you over the past 4
weeks. Please check one box for each of 1. Over the past 4 weeks, I	question	000	Almost Every Day Several Days a Week A Few Days a Month Only with	
weeks. Please check one box for each of 1. Over the past 4 weeks, I have coughed:	question		Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a	
 weeks. Please check one box for each of 1. Over the past 4 weeks, I have coughed: 2. Over the past 4 weeks, I have brought up phlegm 	question SGRQ.STG0 1		Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week	cRSPROB code lis

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG0	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code list
4. Over the past 4 weeks, I have had wheezing attacks:	SGRQ.STG0 4	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code list
5. How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks?	SGRQ.STG0 5	 More than 3 times 3 times 2 times 1 time None of the time 	cNBRATK code list
6. How long did your worst respiratory attack last? (Go to question 7 if you did not have a severe attack)	SGRQ.STG0 6	 A week or more 3 or more days 1 or 2 days Less than a day 	cLENGTH code list
7. Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had?	SGRQ.STG0 7	 No good days 1 or 2 good days 3 or 4 good days Nearly every days was good Every day was good 	cDAYS code list
8. If you wheeze, is it worse when you get up in the morning?	SGRQ.STG0 8	YesNoNy code list	
Part 2 Section 1			

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0000	The most important problem I have Causes me quite a lot of problems Causes me a few problems Causes no problems	cRSCON code list
10. If you have ever held a job:	SGRQ.STG1	0	My repriatory 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	cJOB code list

Section 2

These are questions about what activities usually make you feel short of breath these days.

11. For each statement, please check the box that applies to you these days.

	Sitting or lying still	SGRQ.STG1 1A		True False	cTRUFLS code list
	Washing or dressing yourself	SGRQ.STG1 1B	-	True False	cTRUFLS code list
	Walking around the house	SGRQ.STG1 1C	0	True False	cTRUFLS code list
	Walking outside on a level ground	SGRQ.STG1 1D	1.1.1.1	True False	cTRUFLS code list
	Walking up a flight of stairs	SGRQ.STG1 1E		True False	cTRUFLS code list
	Walking up hills	SGRQ.STG1 1F	0 0	True False	cTRUFLS code list
	Playing sports or other physical activities	SGRQ.STG1 1G	0	True False	cTRUFLS code list
Sectio	on 3				

These are more questions about your cough and shortness of breath these days.

12. For each statement, please check the box that applies to you these days.

Coughing hurts

SGRQ.STG1 O True cTRUFLS code list 2A O False

	0000 0704	○
Coughing makes me tired	SGRQ.STG1 2B	 True False CTRUFLS code list
I am short of breath when I talk	SGRQ.STG1 2C	 True cTRUFLS code list False
l am short of breath when l bend over	SGRQ.STG1 2D	 True cTRUFLS code list False
My coughing or breathing disturbs my sleep	SGRQ.STG1 2E	 True cTRUFLS code list False
I get exhausted easily	SGRQ.STG1 2F	 True False CTRUFLS code list
tion 4		
	er effects tha	t your respiratory problems may have on you
these days.		· · · · · · · · · · · · · · · · · · ·
13. For each statement, please	check the b	ox that applies to you these days.
My cough or breathing is embarrassing in public	SGRQ.STG1 3A	 True cTRUFLS code list False
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG1 3B	 True False CTRUFLS code list
I get afraid or panic when I cannot catch my breath	SGRQ.STG1 3C	 True cTRUFLS code list False
I feel that I am not in control of my respiratory problems	SGRQ.STG1 3D	 True False CTRUFLS code list
I do not expect my respiratory problems to get any better	SGRQ.STG1 3E	 True CTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG1 3F	 True cTRUFLS code list False
Exercise is not safe for me	SGRQ.STG1 3G	 True cTRUFLS code list False
Everything seems too much of an effort	SGRQ.STG1 3H	 True cTRUFLS code list False
tion 5		
	r respiratory	treatment. If you are not receiving treatment,
Not Receiving Respiratory Treatment	SGRQ.SGN OTXT	
14. For each statement, please	check the b	ox that applies to you these days.
My treatment does not help me very much		 True False CTRUFLS code list
I get embarrassed using my medication in public	SGRQ.STG1 4B	 True cTRUFLS code list False

Created : 18-APR-16 12:12:25 GMT Page 464

I have unpleasant side effects	SGRQ.STG1	0	True		ande list
from my medication	4C	0	False	cTRUFLS	code list
My treatment interferes with my life a lot	SGRQ.STG1 4D	000	True False	cTRUFLS	code list
on 6					
These are questions about how problems.	v your activiti	ies I	might be	affected by	your respiratory
15. For each statement, please respiratory problems.	check the b	ox t	hat appli	es to you be	ecause of your
I take a long time to get washed or dressed	SGRQ.STG1 5A	0	True False	cTRUFLS	code list
I cannot take a bath or shower or I take a long time to do it	SGRQ.STG1 5B	0	True False	cTRUFLS	code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG1 5C	0	True False	cTRUFLS	code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG1 5D	000	True False	cTRUFLS	code list
If I walk up one flight of stairs, have to go slowly or stop	SGRQ.STG1 5E	0	True False	cTRUFLS	code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG1 5F	0	True False	cTRUFLS	code list
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl or play golf	SGRQ.STG1 5G	0	True False	cTRUFLS	code list
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	SGRQ.STF1 5H	0 0	True False	cTRUFLS	code list
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SGRQ.STG1 5I	0	True False	cTRUFLS	code list
on 7	• 4			11 60 -	1 11 114
We would like to know how you	ur respiratory	' pro	oblems u	sually affect	your daily life.

I cannot play sports or do other	SGRQ.STG1	0	True	cTRUFLS code list
physical activities	UA	0	False	

Here is a list of other activities the	hat your res	piratory prob	lems may prevent you from doin u of ways your shortness of brea
I cannot move far from my bed or chair	SGRQ.STG1 6E	 True False 	cTRUFLS code list
I cannot do household chores	SGRQ.STG1 6D	TrueFalse	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG1 6C	 True False 	cTRUFLS code list
l cannot go out for entertainment or recreation	SGRQ.STG1 6B	 True False 	cTRUFLS code list

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

SGRQ.STGL Please write in any other IST important activities that your respiratory problems may stop you from doing: SGRQ.STG1 O It does not stop

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

problems affect you:

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

like to do

me from doing

anything I would

 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

cRSPAFT code list

Month 7 Telephone Contact

Date of Visit

(Visit ID = 100, Page ID = 10)

Unique Identifier page-304846-304947-100-10

Date of visit	DOV.DOVD T		
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code list
If no, will subject continue in the study?	DOV.DOVC ONT	○ Yes○ No	NY code list
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code list
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code list
If yes, date of surgery?	DOV.DOVS XDT		
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code list
If yes, please complete the ear	ly discontinu	ation form	

Monthly Telephone Contact

(Visit ID = 100, Page ID = 20)

Unique Identifier page-304876-304947-100-20

C	Please check if telephone contact was not performed at his visit.	TELE.TELE ND			
Telepho	one contact				
D	Date of telephone contact	TELE.TELC ONDT			
	Vas subject determined to ave died?	TELE.TELE DETH	YesNo	NY code list	
lf	f Yes, complete the Death form	1			
е	Did subject report any adverse events (serious or non- serious?)	TELE.TELE AE	YesNo	NY code list	
lf	f Yes, complete the Adverse Ev	vents form			
w (a e n	Did subject report any contacts with the health care system admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	TELE.TELE HC	○ Yes ○ No	NY code list	
lf	f Yes, complete the Health Car	e Encounte	r Form		

Month 8 Telephone Contact

Date of Visit

(Visit ID = 110, Page ID = 10)

Unique Identifier page-304846-304948-110-10

Date of visit	DOV.DOVD T		
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code list
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code list
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code list
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code list
If yes, date of surgery?	DOV.DOVS XDT		
Has the subject had a lung transplant?	DOV.DOVLT X	○ Yes ○ No	NY code list
If yes, please complete the ear	ly discontinu	ation form	

Monthly Telephone Contact

(Visit ID = 110, Page ID = 20)

Unique Identifier page-304876-304948-110-20

	Please check if telephone contact was not performed at this visit.	TELE.TELE ND			
Telep	phone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	YesNo	NY code list	
	If Yes, complete the Death form Did subject report any adverse events (serious or non-		○ Yes ○ No	NY code list	
	serious?) If Yes, complete the Adverse Ev	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	TELE.TELE HC	YesNo	NY code list	
	If Yes, complete the Health Car	e Encounte	r Form		

Week 36 Visit

Date of Visit (Visit ID = 120, Page ID = 10) Unique Identifier page-304846-304949-120-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code lis	st
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code lis	st
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code lis	st
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code lis	st
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code lis	st
If yes, please complete the ear	ly discontinu	ation form		

Concomitant Medications (Visit ID = 120, Page ID = 70)

Unique Identifier page-304883-304949-120-70

Medications were not collected at this visit.	CMFP.CMF PND		
Concomitant Medications			
Has the subject taken any of the Proton Pump Inhibitors (PPI)	e following r CMFP.CMP PI	 medications since the las Taking daily Taking as needed Not Current 	st visit?
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH 2B	 Taking daily Taking as needed Not Current	
Chronic prednisone (>1month)	CMFP.CMC P	 Taking daily Taking as needed Not Current 	
If current, chronic/ average dose taken (mg/day):	CMFP.CMC PDOSE		(format 99.9)
Azathioprine	CMFP.CMA ZT	 Taking daily Taking as needed Not Current 	
N-acetylcystteine (NAC)	CMFP.CMN AC	 Taking daily Taking as needed Not Current 	
Cotrimoxazole	CMFP.CMC OT	 Taking daily Taking as needed Not Current 	
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMM DI	 Taking daily Taking as needed Not Current 	
Pirfenidone	CMFP.CMPI RF	 Taking daily Taking as needed Not Current 	
Nintedanib	CMFP.CMNI NT	Taking dailyTaking as neededNot Current	

Spirometry (Visit ID = 120, Page ID = 20) Unique Identifier page-80805-304949-120-20

	Please check if procedures were not performed	SPIRO.SPIR OND				
SPIR	OMETRY					
	Indicate at which visit these values were collected	SPIRO.SPR VISIT	0	Screening Visit Enrollment Visit		
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES				
	FEV1: Actual (liters)	SPIRO.PRM FEV			(format 99.99)	
6	FVC: Actual (liters)	SPIRO.PRM FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.PRM VC			(format 99.99)	
	Pre-Bronchodilator: Replicate 1	SPIRO.REP 1YES				
	FEV1: Actual (liters)	SPIRO.REP 1FEV			(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 1FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 1VC			(format 99.99)	
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES				
	FEV1: Actual (liters)	SPIRO.REP 2FEV			(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 2FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 2VC			(format 99.99)	
DLC	C					
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT			(format 99.9)	
	VA (alveolar volume) (liters)	SPIRO.DLC OVA			(format 9.99)	
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO			(format 99.9)	
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM			(format 99.9)	

Blood Collection

(Visit ID = 120, Page ID = 30)

Unique Identifier page-45825-304949-120-30

	Please check if blood samples were not collected at this visit.	BC.BCND			
Blood	Collection Information				
	Date blood samples were drawn	BC.BCDT			
	Time blood samples were drawn	BC.BCTM			(HH24:MI)
	Processing date	BC.BCPRDT			
	Processing time	BC.BCPRT M			(HH24:MI)
	Was DNA collected?	BC.BCDNA	○ Yes	NY code lis	t
			O No		
	If yes, Yield (ml)	BC.BCDYLD			(format 99.9)
	# of aliquots	BC.BCDALQ			(format 99)
	Was plasma collected?	BC.BCPLAS MA	YesNo	NY code li	st
	lf yes, Yield (ml)	BC.BCPYLD			(format 99.9)
	# of aliquots	BC.BCPALQ			(format 99)
	Was serum collected?	BC.BCSERU M	YesNo	NY code lis	
	If yes, Yield (ml)	BC.BCSYLD			(format 99.9)
	# of aliquots	BC.BCSALQ			(format 99)

UCSD Shortness of Breath Questionnaire

(Visit ID = 120, Page ID = 40)

Unique Identifier page-45995-304949-120-40

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND						
CSD Shortness of Breath Questionnaire							
When I do, or if I were to do, the following tasks, I would rate my breathlessness as: 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do because of breathlessness							
At rest	UCSD.UCS D1	 0 1 2 3 4 5 					
Walking on a level at your own pace	UCSD.UCS D2	 0 1 2 3 4 5 					
Walking on a level with others your age	UCSD.UCS D3	 0 1 2 3 4 5 					
Walking up a hill	UCSD.UCS D4	 0 1 2 3 4 5 					
Walking up stairs	UCSD.UCS D5	 0 1 2 3 4 5 					
------------------------------	-----------------	--					
While eating	UCSD.UCS D6	 0 1 2 3 4 5 					
Standing up from a chair	UCSD.UCS D7	 0 1 2 3 4 5 					
Brushing teeth	UCSD.UCS D8	 0 1 2 3 4 5 					
Shaving and/or brushing hair	UCSD.UCS D9	 0 1 2 3 4 5 					
Showering/bathing	UCSD.UCS D10	 0 1 2 3 4 5 					

Dressing	UCSD.UCS D11	 0 1 2 3 4 5
Picking up and straightening	UCSD.UCS D12	 0 1 2 3 4 5
Doing dishes	UCSD.UCS D13	 0 1 2 3 4 5
Sweeping/vacuuming	UCSD.UCS D14	 0 1 2 3 4 5
Making bed	UCSD.UCS D15	 0 1 2 3 4 5
Shopping	UCSD.UCS D16	 0 1 2 3 4 5

Doing laundry	UCSD.UCS D17	 0 1 2 3 4 5
Washing car	UCSD.UCS D18	 5 0 1 2 3 4 5
Mowing lawn	UCSD.UCS D19	 0 1 2 3 4 5
Watering lawn	UCSD.UCS D20	 0 1 2 3 4 5
Sexual activities	UCSD.UCS D21	 0 1 2 3 4 5
How much do these limit you in Shortness of breath	your daily li UCSD.UCS D22	

Fear of "hurting myself" by overexerting	UCSD.UCS D23	 0 1 2 3 4 5
Fear of shortness of breath	UCSD.UCS D24	 0 1 2 3 4 5

Patient Reported Outcome Battery

(Visit ID = 120, Page ID = 50)

Unique Identifier page-45844-304949-120-50

Please check if outcome battery was not performed at this visit.	ICEEQ.ICEE QND			
h VAS				
Cough VAS	ICEEQ.COU GHVAS			
How would rate the severity o your cough?(0-100)	of ICEEQ.COU GHSEV			(format 999)
P				
Not Collected	ICEEQ.ICEN D			
By placing a check in one box describes your quality of life a	at the moment			which statement best
_ove and Friendship	ICEEQ.ICEL OVE		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	FRIENDS code list
			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	ICEEQ.ICEF UTR	0	I can think about the future without any concern	
		0	I can think about the future with only a little concern	THINKING code lis
		0	I can only think about the future with some concern	
		0	I can only think about the future with a lot of concern	

Doing things that make you feel valued	ICEEQ.ICEV ALUE	0	I am able to do all of the things that make me feel valued	
		0	I am able to do many of the things that make me feel valued	VALUED code list
		0	I am able to do a few of the things that make me feel valued	
		0	l am unable to do any of the things that make me feel valued	
Enjoyment and pleasure	ICEEQ.ICEE NJOY	0	I can have all of the enjoyment and pleasure that I want	
		0	I can have a lot of the enjoyment and pleasure that I want	PLEASURE code list
		0	I can have a little of the enjoyment and pleasure that I want	
		0	I cannot have any of the enjoyment and pleasure that I want	
Independence	ICEEQ.ICEI NDEP	0	l am able to be completely independent	
		0	I am able to be independent in many things	INDEPEND code I
		0	I am unable to be independent in a few things	
		0	I am unable to be at all independent	
5D-3L Not Collected	ICEEQ.EQN			

By placing a check in one box in each group below, please indicate which statement best describes your own health state today.

A. A. 1997		0	
Mobility	ICEEQ.EQM OB	 I have no problems in walking about I have some problems in walking about I am confined to bed 	MOBILE code lis
Self-Care	ICEEQ.EQS C	 I have no problems with selecare I have some problems washing or dressing myse I am unable to wash or dress myself 	g Self-Care code
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQU A	 I have no problems with performing my usual activities I have some problems with performing my usual activities I am unable to perform my usual activities 	ACTIVITY code
Pain/Discomfort	ICEEQ.EQP AIN	 I have no pain or discomfort I have moderate pain or discomfor I have extreme pain or discomfor 	
Anxiety/Depression	ICEEQ.EQA NX	 I am not anxious or depressed I am moderately anxious or depressed I am extremely anxious or depressed 	ANXIETY code
Value of EQ-5D VAS (0-100)	ICEEQ.EQV		(format 999)

St George's Respiratory Questionnaire

(Visit ID = 120, Page ID = 60)

Unique Identifier page-45914-304949-120-60

Please check if questionnaire was not performed at this visit.	SGRQ.SGR QND		
eorge's Respiratory Questionnaire			
This questionnaire is designed troubling you and how it affects illness cause you the most prob problems are.	your life. W	e are using it to find ou	t which aspects of your
Please read the instructions can spend too long deciding about y			and anything. Do not
Before completing the question			
Please check one box to show	SGRQ.CUR HLTH	Very good	
how you describe your current health:		Good	CURHLTH code list
nealth.		Fair	
		Poor	
		Very poor	
weeks. Please check one box for each	•		
Please check one box for each 1. Over the past 4 weeks, I	question SGRQ.STG0 1	 Almost Every Day 	
Please check one box for each	•	 Almost Every Day Several Days a Week 	cRSPROB code I
Please check one box for each 1. Over the past 4 weeks, I	•	Several Days a	cRSPROB code I
Please check one box for each 1. Over the past 4 weeks, I	•	 Several Days a Week A Few Days a 	cRSPROB code I
Please check one box for each 1. Over the past 4 weeks, I	•	 Several Days a Week A Few Days a Month Only with Respiratory 	cRSPROB code I
Please check one box for each 1. Over the past 4 weeks, I	SGRQ.STG0	 Several Days a Week A Few Days a Month Only with Respiratory Infections 	cRSPROB code I
Please check one box for each 1. Over the past 4 weeks, I have coughed:	SGRQ.STG0	 Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	
Please check one box for each 1. Over the past 4 weeks, I have coughed: 2. Over the past 4 weeks, I have brought up phlegm	SGRQ.STG0	 Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a 	
Please check one box for each 1. Over the past 4 weeks, I have coughed: 2. Over the past 4 weeks, I have brought up phlegm	SGRQ.STG0	 Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a 	cRSPROB code I

3. Over the past 4 weeks, I	SGRQ.STG0	Almost Every Day	
have had shortness of breath:	3	 Several Days a Week 	
		 A Few Days a Month 	cRSPROB code lis
		 Only with Respiratory Infections 	
		 Not at all 	
4. Over the past 4 weeks, I	SGRQ.STG0	 Almost Every Day 	
have had wheezing attacks:	4	 Several Days a Week 	
		 A Few Days a Month 	cRSPROB code
		 Only with Respiratory Infections 	
		 Not at all 	
5. How many times during the	SGRQ.STG0	O More than 3 times	
past 4 weeks have you suffered from severe or very	5	O 3 times	cNBRATK code
unpleasant respiratory		2 times	CINDRATE COULD
attacks?		1 time	
		None of the time	
6. How long did your worst respiratory attack last?	SGRQ.STG0 6	• A week or more	
(Go to question 7 if you did not		 3 or more days 	cLENGTH code
have a severe attack)		○ 1 or 2 days	
	0000 0700	 Less than a day 	
7. Over the past 4 weeks, in a typical week, how many good	SGRQ.STG0 7	No good days	
days (with few respiratory		• 1 or 2 good days	
problems) have you had?		• 3 or 4 good days	cDAYS code list
		 Nearly every days was good 	
		 Every day was 	
		good	
8. If you wheeze, is it worse when you get up in the morning?	SGRQ.STG0 8	YesNY codeNolist	

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0000	The most important problem I have Causes me quite a lot of problems Causes me a few problems Causes no	cRSCON code list
10. If you have ever held a job:	SGRQ.STG1	0	problems My repriatory problems made me stop working altogether My respiratory problems interfere with my job or made me change my job My respiratory problems do not	cJOB code list

Section 2

These are questions about what activities usually make you feel short of breath these days.

11. For each statement, please check the box that applies to you these days.

	Sitting or lying still	1A		True False	cTRUFLS o	code list	
	Washing or dressing yourself	SGRQ.STG1 1B		True False	cTRUFLS o	code list	
	Walking around the house	SGRQ.STG1 1C		True False	cTRUFLS of	code list	
	Walking outside on a level ground	SGRQ.STG1 1D		True False	cTRUFLS o	code list	
	Walking up a flight of stairs	SGRQ.STG1 1E		True False	cTRUFLS o	code list	
	Walking up hills	SGRQ.STG1 1F	1.1.1.1	True False	cTRUFLS o	code list	
	Playing sports or other physical activities	SGRQ.STG1 1G	0	True False	cTRUFLS o	code list	
Sectio	on 3						

These are more questions about your cough and shortness of breath these days.

12. For each statement, please check the box that applies to you these days.

Coughing hurts

SGRQ.STG1 O True

• False cTRUFLS code list

Coughing makes me tired	SGRQ.STG1 2B	 True cTRUFLS code list False
I am short of breath when I talk	SGRQ.STG1 2C	 True cTRUFLS code list False
I am short of breath when I bend over	SGRQ.STG1 2D	 True cTRUFLS code list False
My coughing or breathing disturbs my sleep	SGRQ.STG1 2E	 True cTRUFLS code list False
I get exhausted easily	SGRQ.STG1 2F	 True cTRUFLS code list False
tion 4		
	er effects that	t your respiratory problems may have on you
these days.		
•		ox that applies to you these days.
My cough or breathing is embarrassing in public	SGRQ.STG1 3A	 True False CTRUFLS code list
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG1 3B	 True cTRUFLS code list False
I get afraid or panic when I cannot catch my breath	SGRQ.STG1 3C	TrueFalseCTRUFLS code list
I feel that I am not in control of my respiratory problems	SGRQ.STG1 3D	 True cTRUFLS code list False
I do not expect my respiratory problems to get any better	SGRQ.STG1 3E	 True False cTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG1 3F	 True False CTRUFLS code list
Exercise is not safe for me	SGRQ.STG1 3G	 True cTRUFLS code list False
Everything seems too much of an effort	SGRQ.STG1 3H	 True False CTRUFLS code list
ction 5		
These are questions about your go to section 6.	r respiratory	treatment. If you are not receiving treatment
Not Receiving Respiratory Treatment	SGRQ.SGN OTXT	
14. For each statement, please	check the b	ox that applies to you these days.
My treatment does not help me very much	SGRQ.STG1 4A	 True CTRUFLS code list

very much	40	0	False	CTRUFLS code list
l get embarrassed using my medication in public	SGRQ.STG1 4B	1.000	True False	cTRUFLS code list

Created : 18-APR-16 12:12:25 GMT Page 527

•	cTRUFLS code list cTRUFLS code list e affected by your respiratory lies to you because of your cTRUFLS code list cTRUFLS code list
False might be that appl True False True False True False	e affected by your respiratory lies to you because of your cTRUFLS code list cTRUFLS code list cTRUFLS code list
that appl True False True False True False	lies to you because of your cTRUFLS code list cTRUFLS code list cTRUFLS code list
that appl True False True False True False	lies to you because of your cTRUFLS code list cTRUFLS code list cTRUFLS code list
True False True False True False	cTRUFLS code list cTRUFLS code list cTRUFLS code list
False True False True False	cTRUFLS code list cTRUFLS code list
False True False	cTRUFLS code list
False	
True	
False	cTRUFLS code list
True False	cTRUFLS code list
True False	cTRUFLS code list
	usually affect your daily life.
	False

l cannot play sports or do other physical activities	SGRQ.STG1 6A	0	True False	cTRUFLS code list

I cannot go out for	SGRQ.STG1	0	True		
entertainment or recreation	6B		False	cTRUFLS	code list
i dannet ge dat er tre nedet te	SGRQ.STG1 6C	0	True	cTRUFLS	code list
do the shopping	00	0	False		
I cannot do household chores	SGRQ.STG1	0	True	cTRUFLS	code list
	6D	0	False		
I cannot move far from my bed	SGRQ.STG1	0	True		
or chair	6E	0	False	cTRUFLS	code list

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do 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 SGRQ.STG1 O It does not stop

(one only) that you think best describes how your respiratory

problems affect you:

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

me from doing

 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 cRSPAFT code list

Month 10 Telephone Contact

Date of Visit

(Visit ID = 130, Page ID = 10)

Unique Identifier page-304846-304950-130-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code	list
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code	list
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code	list
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code	list
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code	list
If yes, please complete the ear	ly discontinu	ation form		

Monthly Telephone Contact

(Visit ID = 130, Page ID = 20)

Unique Identifier page-304876-304950-130-20

	Please check if telephone contact was not performed at this visit.	TELE.TELE ND			
Tele	phone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	YesNo	NY code list	
	If Yes, complete the Death form	า			
	Did subject report any adverse events (serious or non- serious?)	TELE.TELE AE	YesNo	NY code list	
	If Yes, complete the Adverse E	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	HC	○ Yes ○ No	NY code list	
	If Yes, complete the Health Car	e Encounte	r Form		

Month 11 Telephone Contact

Date of Visit

(Visit ID = 140, Page ID = 10)

Unique Identifier page-304846-304951-140-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code	list
If no, will subject continue in the study?	DOV.DOVC ONT	○ Yes○ No	NY code	list
If no, was it due to death of subject?	DOV.DOVD TH	○ Yes ○ No	NY code	list
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code	list
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code	list
If yes, please complete the ear	ly discontinu	ation form		

Monthly Telephone Contact

(Visit ID = 140, Page ID = 20)

Unique Identifier page-304876-304951-140-20

C	Please check if telephone contact was not performed at his visit.	TELE.TELE ND					
Telepho	one contact						
Ε	Date of telephone contact	TELE.TELC ONDT					
	Nas subject determined to nave died?	TELE.TELE DETH	0 Y 0 N		NY code lis	t	
ŀ	f Yes, complete the Death form	Ì					
e	Did subject report any adverse events (serious or non- serious?)	TELE.TELE AE	~	∕es No	NY code lis	t	
ŀ	f Yes, complete the Adverse Ev	vents form					
(e r	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	TELE.TELE HC	~	∕es No	NY code lis	t	
ł	f Yes, complete the Health Car	e Encounte	r Forn	n			

Week 48 Visit

Date of Visit (Visit ID = 150, Page ID = 10) Unique Identifier page-304846-304952-150-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	YesNo	NY code list	
If no, will subject continue in the study?	DOV.DOVC ONT	YesNo	NY code list	
If no, was it due to death of subject?	DOV.DOVD TH	YesNo	NY code list	
Did subject cross over to surgery?	DOV.DOVS X	YesNo	NY code list	
If yes, date of surgery?	DOV.DOVS XDT		1	
Has the subject had a lung transplant?	DOV.DOVLT X	YesNo	NY code list	
If yes, please complete the ear	ly discontinu	ation form		

Concomitant Medications (Visit ID = 150, Page ID = 120)

Unique Identifier page-304883-304952-150-120

Medications were not collected at this visit.	CMFP.CMF PND		
omitant Medications			
Has the subject taken any of the	•	nedications since the la	st visit?
	CMFP.CMP PI	 Taking daily Taking as needed Not Current 	cCMFUP code lis
	CMFP.CMH 2B	 Taking daily Taking as needed Not Current 	cCMFUP code lis
Chronic prednisone (>1month)	CMFP.CMC P	 Taking daily Taking as needed Not Current 	cCMFUP code lis
	CMFP.CMC PDOSE		(format 99.9)
	CMFP.CMA ZT	 Taking daily Taking as needed Not Current 	cCMFUP code lis
	CMFP.CMN AC	 Taking daily Taking as needed Not Current 	cCMFUP code lis
00000000	CMFP.CMC OT	 Taking daily Taking as needed Not Current 	cCMFUP code lis
	CMFP.CMM DI	 Taking daily Taking as needed Not Current 	cCMFUP code lis
	CMFP.CMPI RF	 Taking daily Taking as needed Not Current 	cCMFUP code lis
	CMFP.CMNI NT	 Taking daily Taking as needed Not Current 	cCMFUP code lis

Documentation of GERD & Esophageal Motility

(Visit ID = 150, Page ID = 20)

Unique Identifier page-188329-304952-150-20

was not collected at this visit.	GERD.GER DND		
Frequency Scale for the Symptoms of GE	RD		
	gerd.fqn D		
	gerd.fqh Rtbrn	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQBL OAT	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	gerd.fqh Eavy	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQR UB	 Never Occasionally Sometimes Often Always 	cGFREQ code list
	GERD.FQSI CK	 Never Occasionally Sometimes Often Always 	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQH RTAFT	 Never Occasionally Sometimes Often Always 	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	gerd.fqt Hroat	NeverOccasionally	
		SometimesOftenAlways	cGFREQ code lis
	GERD.FQF ULL	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQST UCK	 Always Never Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQA CID	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
	GERD.FQB URP	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
12. Do you get heartburn if you bend over?	GERD.FQH RTBND	 Never Occasionally Sometimes Often Always 	cGFREQ code lis
RD Health Related Quality of Life			

For each question listed below, please rate your level of symptoms on a scale of 0 to 5

0-No symptoms

1-Symptoms noticeable, but not bothersome

2-Symptoms noticeable, but not bothersome, but not every day
3-Symptoms bothersome every day
4-Symptoms affect daily activities

5-Symptoms are incapacitating, unable to do daily activities

1. How bad is your heartburn?	GERD.QLH RTBRN	 0 1 2 3 4
2. Heartburn when lying down?	GERD.QLLY ING	 5 0 1 2 3 4
3. Heartburn when standing up?	GERD.QLST AND	 5 0 1 2 3 4 5
4. Heartburn after meals?	GERD.QLH RTAFT	 0 1 2 3 4 5
5. Does heartburn change your diet?	GERD.QLDI ET	 0 1 2 3 4 5
6. Does heartburn wake you from sleep?	GERD.QLSL EEP	 0 1 2 3 4 5

7. Do you have difficulty swallowing?	GERD.QLDI FFSW	 0 1 2 3 4 5 		
8. Do you have pain with swallowing?	GERD.QLPA INSW	 0 1 2 3 4 5 		
9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	 0 1 2 3 4 5 		
10. If you take medication, does this affect your daily life?	GERD.QLM EDS	 0 1 2 3 4 5 		
H Monitoring Results		U		
Per Protocol Amendment 3, all Visit Per Protocol Amendment 3, nor Week 24 Visit Not Collected		tients sho		
Was probe located 5cm above LES	GERD.PHP ROBE	YesNo	NY code list	
total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
# of reflux episodes	GERD.PHR FLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHT MRFL			(format 999.9)

Created : 18-APR-16 12:12:25 GMT Page 564

Overall DeMeester Score	GERD.PHS CORE		(format 999.9)
ometry Results			
Per Protocol Amendment 3, all Visit	patients sho	ould check the Not Colle	cted Box at the Week
Per Protocol Amendment 3, nor Week 24 Visit	n surgery pa	atients should check the	Not Collected Box at
Not Collected	GERD.MNN D		
Lower esophageal sphincter (L	ES) data		
LES length (cm)	GERD.MNL ESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)
Upper esophageal sphincter (U	ES) data		
UES resting pressure (mmHg)	GERD.MNU ESRTP		(format 999.9)
UES relaxation (%)	GERD.MNU ESRLX		(format 999.9)
Esophageal body motility patter	'n		
% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSI MUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNE BMP	 Normal motility Ineffective (<80% normal contraction) Severely ineffective (<30% normal contraction) Diffuse/distal esophageal spasm (simultaneous contractions in >10% of swallows, with amp > 30mmHg) Aperistalsis (no peristaltic activity observed in esophageal body) 	cEBMP code I

Spirometry_DLCO

(Visit ID = 150, Page ID = 30)

Unique Identifier page-80805-304952-150-30

Arterial Blood Gas (Visit ID = 150, Page ID = 40) Unique Identifier page-45888-304952-150-40

Please check if ABG was not performed at this visit.	ABG.ABGN 🗆 D	
Arterial Blood Gas		
FiO2 (%)	ABG.ABGFI OX	(format 999)
рН	ABG.ABGP	(format 9.99)
PaO2 (mm Hg)	ABG.ABGPA	(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPA	(format 999.9)
SaO2 (%)	ABG.ABGSA	(format 999.9)

6-Minute Walk Test (Visit ID = 150, Page ID = 50) Unique Identifier page-80834-304952-150-50

0 M.	Please check if walk test was not performed at this visit.	WALK.WAL KND	
6 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	 Screening Visit Enrollment Visit
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	cBORG code list
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	 Yes NY code list
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	YesNY code list
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	WALK.WKAI D	 Yes NY code list No
	If yes: Specify type of walking aid	WALK.WKS PAID	 Cane Walker cWALK code list Other
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	Yes NY code listNo
	If no: What was duration of wall	<pre>< test?</pre>	
	minutes	WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	 Symptoms requiring termination Other C6MTERM code list
	Other (specify)	WALK.WKR SNSP	
÷	Distance walked (meters)	WALK.WKDI ST	(format 9999)

		_	
Did subject desaturate (SpO < 88%)?	2 WALK.WKD SAT	YesNo	NY code list
If yes: Walk duration at desa	turation		
minutes	WALK.WKD SMIN		(format 9)
seconds	WALK.WKD SSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKD SMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKL OWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POST BORG		CBORG code list
•			

Blood Collection

(Visit ID = 150, Page ID = 60)

Unique Identifier page-45825-304952-150-60

	Please check if blood samples were not collected at this visit.	BC.BCND				
Bloo	d Collection Information					
	Date blood samples were drawn	BC.BCDT				
	Time blood samples were drawn	BC.BCTM			(HH24:MI)	
	Processing date	BC.BCPRDT				
	Processing time	BC.BCPRT M			(HH24:MI)	
	Was DNA collected?	BC.BCDNA	YesNo	NY code list		
	lf yes, Yield (ml)	BC.BCDYLD			(format 99.9)	
	# of aliquots	BC.BCDALQ			(format 99)	
	Was plasma collected?	BC.BCPLAS MA	YesNo	NY code list		
	If yes, Yield (ml)	BC.BCPYLD			(format 99.9)	
	# of aliquots	BC.BCPALQ			(format 99)	
	Was serum collected?	BC.BCSERU M	YesNo	NY code list	· · · ·	
	If yes, Yield (ml)	BC.BCSYLD			(format 99.9)	
	# of aliquots	BC.BCSALQ			(format 99)	
	·					

HRCT Collection

(Visit ID = 150, Page ID = 70)

Unique Identifier page-45939-304952-150-70

HRCT Collection				
Was an HRCT performed for this study because a satisfactory HRCT had not been performed within the previous 3 months?	HRCT.HRE NR	○ Yes ○ No	NY code list	
Was a week 48 HRCT performed on this subject?	HRCT.HRFU P	YesNo	NY code list	

Bronchoscopy (Visit ID = 150, Page ID = 110) Unique Identifier page-45826-304952-150-110

	Check this box if the subject is randomized into OMT.	BRONCHO. BROOMT				
F	llow-up bronchoscopy (for surgical su	bjects only)				
	Was bronchoscopy performed on subject?	BRONCHO. BRONYN	YesNo	NY code list		
	Was bronchial alveolar lavage (BAL) fluid collected?	BRONCHO. BRBAL	YesNo	NY code list		
	If yes: Volume of BAL instilled (ml)	BRONCHO. BRBALINS			(format 999.99)	
	Volume of BAL collected (ml)	BRONCHO. BRBALCOL			(format 999.99)	
	Were airway epithelial cells (AEC) collected?	BRONCHO. BRAEC	YesNo	NY code list		
	If yes: Number of brushes sent	BRONCHO. BRAECBR			(format 999)	

UCSD Shortness of Breath Questionnaire

(Visit ID = 150, Page ID = 80)

Unique Identifier page-45995-304952-150-80

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND	
SD Shortness of Breath Questionnaire	<u>j</u>	
	e following t	asks, I would rate my breathlessness as: thlessness
At rest	UCSD.UCS D1	 0 1 2 3 4 5
Walking on a level at your own pace	UCSD.UCS D2	 0 1 2 3 4 5
Walking on a level with others your age	UCSD.UCS D3	 0 1 2 3 4 5
Walking up a hill	UCSD.UCS D4	 0 1 2 3 4 5

Walking up stairs	UCSD.UCS D5	 0 1 2 3 4 5
While eating	UCSD.UCS D6	 0 1 2 3 4 5
Standing up from a chair	UCSD.UCS D7	 0 1 2 3 4 5
Brushing teeth	UCSD.UCS D8	 0 1 2 3 4 5
Shaving and/or brushing hair	UCSD.UCS D9	 0 1 2 3 4 5
Showering/bathing	UCSD.UCS D10	 0 1 2 3 4 5

Dressing	UCSD.UCS D11	 0 1 2 3 4 5
Picking up and straightening	UCSD.UCS D12	 0 1 2 3 4 5
Doing dishes	UCSD.UCS D13	 0 1 2 3 4 5
Sweeping/vacuuming	UCSD.UCS D14	 0 1 2 3 4 5
Making bed	UCSD.UCS D15	 0 1 2 3 4 5
Shopping	UCSD.UCS D16	 0 1 2 3 4 5

Doing laundry	UCSD.UCS D17	 0 1 2 3 4 5
Washing car	UCSD.UCS D18	 0 1 2 3 4 5
Mowing lawn	UCSD.UCS D19	 0 1 2 3 4 5
Watering lawn	UCSD.UCS D20	 0 1 2 3 4 5
Sexual activities	UCSD.UCS D21	 0 1 2 3 4 5
How much do these limit you in Shortness of breath	your daily li UCSD.UCS D22	

Fear of "hurting myself" by overexerting	UCSD.UCS D23	 0 1 2 3 4 5
Fear of shortness of breath	UCSD.UCS D24	 0 1 2 3 4 5
Patient Reported Outcome Battery

(Visit ID = 150, Page ID = 90)

Unique Identifier page-45844-304952-150-90

Please check if outcome battery was not performed at this visit.	ICEEQ.ICEE QND			
h VAS				
Cough VAS	ICEEQ.COU GHVAS			
How would rate the severity of your cough?(0-100)	ICEEQ.COU GHSEV			(format 999)
AP				
Not Collected	ICEEQ.ICEN D			
By placing a check in one box i describes your quality of life at	n each grou the moment	p be	elow, please indicate	which statement best
Love and Friendship	ICEEQ.ICEL OVE	0	I can have all of the love and friendship that I want	FRIENDS code lis
		0	I can have a lot of the love and friendship that I want	FRIENDS COde is
		0	I can have a little of the love and friendship that I want	
		0	I cannot have any of the love and friendship that I want	
Thinking about the future	ICEEQ.ICEF UTR	0	I can think about the future without any concern	
		0	I can think about the future with only a little concern	THINKING code
		0	Loop only think	
		0	I can only think about the future with some concern	

Doing things that make you	ICEEQ.ICEV	I am able to do all	
Doing things that make you feel valued	ALUE	of the things that make me feel valued	
		 I am able to do many of the things VALUED that make me feel valued) code li
		 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	ICEEQ.ICEE NJOY	 I can have all of the enjoyment and pleasure that I want 	
		 I can have a lot of the enjoyment and pleasure that I PLEASU 	JRE cod
		 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	ICEEQ.ICEI NDEP	 I am able to be completely independent 	
		 I am able to be independent in many things INDEPEI 	ND code
		 I am unable to be independent in a few things 	
		 I am unable to be at all independent 	
5D-3L			
Not Collected	ICEEQ.EQN		

By placing a check in one box in each group below, please indicate which statement best describes your own health state today.

Mability	ICEEQ.EQM	0	L boyo no	-
Mobility	OB	0	I have no problems in walking about I have some problems in walking about I am confined to	MOBILE code list
			bed	
Self-Care	ICEEQ.EQS C	0	I have no problems with self- care	
		0	I have some problems washing or dressing myself	Self-Care cod
		0	I am unable to wash or dress myself	
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQU A	0	I have no problems with performing my usual activities	
		0	I have some problems with performing my usual activities	ACTIVITY code li
		0	l am unable to perform my usual activities	
Pain/Discomfort	ICEEQ.EQP AIN	0	l have no pain or discomfort	
		0	I have moderate pain or discomfort	PAIN code list
		0	I have extreme pain or discomfort	
Anxiety/Depression	ICEEQ.EQA NX	0	I am not anxious or depressed	
		0	I am moderately anxious or depressed	ANXIETY code
		0	I am extremely anxious or depressed	
Value of EQ-5D VAS (0-100)	ICEEQ.EQV AS			(format 999)

St George's Respiratory Questionnaire

(Visit ID = 150, Page ID = 100)

Unique Identifier page-45914-304952-150-100

SGRQ.SGR Please check if questionnaire QND was not performed at this visit. St George's Respiratory Questionnaire This guestionnaire 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 SGRQ.CUR Very good HLTH CURHLTH code list how you describe your current 0 Good health: Fair Poor Very poor Part 1 Please describe how often your respiratory problems have affected you over the past 4 weeks. Please check one box for each question SGRQ.STG0 O 1. Over the past 4 weeks, I Almost Every Day have coughed: 0 Several Days a Week cRSPROB code list A Few Days a Month Only with Respiratory Infections Not at all SGRQ.STG0 O Almost Every Day 2. Over the past 4 weeks, I have brought up phlegm O Several Days a (sputum): Week cRSPROB code list O A Few Days a Month Only with Respiratory Infections O Not at all

	SGRQ.STG0 3	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code list
	SGRQ.STG0 4	 Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all 	cRSPROB code lis
	SGRQ.STG0 5	 More than 3 times 3 times 2 times 1 time None of the time 	cNBRATK code list
	SGRQ.STG0 6	 A week or more 3 or more days 1 or 2 days Less than a day 	cLENGTH code list
7. Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had?	SGRQ.STG0 7	 No good days 1 or 2 good days 3 or 4 good days Nearly every days was good Every day was good 	cDAYS code list
8. If you wheeze, is it worse when you get up in the morning?	SGRQ.STG0 8	YesNoNY code list	

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0	The most important problem I have	
		0	Causes me quite a lot of problems	cRSCON code lis
		0	Causes me a few problems	
		0	Causes no problems	
10. If you have ever held a job:	SGRQ.STG1 0	0	My repriatory problems made me stop working altogether	
		0	My respiratory problems interfere with my job or made me change my job	cJOB code list
		0	My respiratory problems do not affect my job	

Section 2

These are questions about what activities usually make you feel short of breath these days.

11. For each statement, please check the box that applies to you these days.

	Sitting or lying still	SGRQ.STG1 1A		True False	cTRUFLS	code list	
	Washing or dressing yourself	SGRQ.STG1 1B	0	True False	cTRUFLS	code list	
	Walking around the house	SGRQ.STG1 1C	0	True False	cTRUFLS	code list	
	Walking outside on a level ground	SGRQ.STG1 1D	0	True False	cTRUFLS	code list	
	Walking up a flight of stairs	SGRQ.STG1 1E	0	True False	cTRUFLS	code list	
	Walking up hills	SGRQ.STG1 1F	0	True False	cTRUFLS	code list	
	Playing sports or other physical activities	SGRQ.STG1 1G	0	True False	cTRUFLS	code list	
Sectio	on 3						

These are more questions about your cough and shortness of breath these days.

12. For each statement, please check the box that applies to you these days.

Coughing hurts

SGRQ.STG1 O True CTRUFLS code list O False

SGRQ.STG1 2B	TrueFalse	cTRUFLS code list
SGRQ.STG1 2C	TrueFalse	cTRUFLS code list
SGRQ.STG1 2D	TrueFalse	cTRUFLS code list
SGRQ.STG1 2E	TrueFalse	cTRUFLS code list
SGRQ.STG1 2F	 True False 	cTRUFLS code list

Section 4

These are questions about other effects that your respiratory problems may have on you these days.

13. For each statement, please check the box that applies to you these days.

	My cough or breathing is embarrassing in public	SGRQ.STG1 3A	0	True False	cTRUFLS code list
	My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG1 3B	0	True False	cTRUFLS code list
	I get afraid or panic when I cannot catch my breath	SGRQ.STG1 3C	0	True False	cTRUFLS code list
	I feel that I am not in control of my respiratory problems	SGRQ.STG1 3D	000	True False	cTRUFLS code list
	l do not expect my respiratory problems to get any better	SGRQ.STG1 3E	0	True False	cTRUFLS code list
	I have become frail or an invalid because of my respiratory problems	SGRQ.STG1 3F	0	True False	cTRUFLS code list
	Exercise is not safe for me	SGRQ.STG1 3G	0	True False	cTRUFLS code list
	Everything seems too much of an effort	SGRQ.STG1 3H	0	True False	cTRUFLS code list
Sectio	on 5				
	These are questions about you go to section 6.	r respiratory	trea	atment. If y	ou are not receiving treatment,
	Not Receiving Respiratory Treatment	SGRQ.SGN OTXT			
	14. For each statement, please		ox t	hat applies	to you these days.
	My treatment does not help me very much	SGRQ.STG1 4A	0	True False	cTRUFLS code list

I get embarrassed using my SGRQ.STG1 O True CTRUFLS code list medication in public O False

Created : 18-APR-16 12:12:25 GMT Page 625

I have unpleasant side effects from my medication	SGRQ.STG1 4C	 True cTRUFLS code list False
My treatment interferes with my life a lot	SGRQ.STG1 4D	 True cTRUFLS code list False
ction 6		
These are questions about how problems.	your activiti	ies might be affected by your respiratory
15. For each statement, please respiratory problems.	check the b	ox that applies to you because of your
I take a long time to get washed or dressed	SGRQ.STG1 5A	 True cTRUFLS code list False
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG1 5B	TrueFalseCTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG1 5C	 True cTRUFLS code list False
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG1 5D	True cTRUFLS code listFalse
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG1 5E	 True cTRUFLS code list False
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG1 5F	 True cTRUFLS code list False
My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl or play golf	SGRQ.STG1 5G	 True False CTRUFLS code list
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden	SGRQ.STF1 5H	True cTRUFLS code listFalse
or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim		
My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	SGRQ.STG1 51	 True cTRUFLS code list False
ction 7		
We would like to know how you	r respiratory	problems usually affect your daily life.
16. For each statement, please respiratory problems.	check the b	ox that applies to you because of your

I cannot play sports or do other physical activities	SGRQ.STG1 6A	 True False 	cTRUFLS code list
1			

I cannot go out for entertainment or recreation	SGRQ.STG1 6B	TrueFalse	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG1 6C	TrueFalse	cTRUFLS code list
I cannot do household chores	SGRQ.STG1 6D	TrueFalse	cTRUFLS code list
I cannot move far from my bed or chair	SGRQ.STG1 6E	TrueFalse	cTRUFLS code list

Here is a list of other activities that your respiratory problems may prevent you from doing. (You do 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 SGRQ.STG1 O It does not stop

(one only) that you think best describes how your respiratory

problems affect you:

me from doing anything I would like to doIt 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 cRSPAFT code list

CAS

Death

(Visit ID = 160, Page ID = 10)

Unique Identifier page-45934-304953-160-10

Death	n Form			
8	Where did subject die?	DEATH.DTH WHERE	 Inpatient Outpatient 	
8	Date of death	DEATH.DTH DT		
	Cause of death	DEATH.DTH CAUSE	 Pulmonary death Non-pulmonary death Unknown 	
	Pulmonary death specify	DEATH.DTH PULM	 Acute exacerbation (definite or suspected) Progression of IPF (other than acute exacerbation) Pulmonary embolism Lung infection Lung cancer Other 	
<u>86</u>	Other specify	DEATH.DTH OTH		
8 8	Non-pulmonary death specify	DEATH.DTH SPCFY		

Health Care Encounters (Visit ID = 160, Page ID = 30)

Unique Identifier page-304895-304953-160-30

Health Care Encounters	
facility, or rehabilitation center since	he hospital, emergency room/urgent care, nursing e the last contact? (If yes, provide details below) HCSRT
Discharge date HC.	
Admission type HC. N	HCADMI Hospital ER/urgent care HCADMINTYPE code list Assisted living / nursing facility Rehabilitation center
Reason for admission HC.	HCREA
Check if respiratory-related HC.	HCRES
Major procedures performed HC.	HCPRO
Discharge destination HC. HG	HCDISC Home Assisted living / nursing facility Rehab center Transfer to other hospital Subject died Other

Study Completion/ Early Discontinuation

(Visit ID = 160, Page ID = 40)

Unique Identifier page-304907-304953-160-40

	of Completion or ntinuation	DS.DSSTDT			
Did su study	ubject complete the ?	DS.CMPLTE YN	YesNo	NY code list	
Reaso	on for Discontinuation	DS.DSTER M	 Death Lost to Follo Patient Dec Physician D Lung Trans 	ision Decision	
Pleas	e specify	DS.DSTER MSP			
Date		DS.DSLTFD T			
Date	of lung transplant	DS.DSLTXD T			

AECODE

(Visit ID = 160, Page ID = 60) Unique Identifier page-45819-304953-160-60

Visit	AEC.AECVI SIT
Adverse Event	AEC.AETER

CMCODE (Visit ID = 160, Page ID = 70)

Unique Identifier page-45828-304953-160-70

Visit	CMC.CMCVI
Concomitant Medication	CMC.CONM ED

RWCODE (Visit ID = 160, Page ID = 80)

Unique Identifier page-45948-304953-160-80

Visit	RWC.RWCV	
Respiratory Worsening Term	RWC.RWTE	

AE

Adverse Events (Visit ID = 170, Page ID = 10) Unique Identifier page-304919-304954-170-10

AEID	AE.AEID			
Adverse event	AE.AEVENT	0 0 0	Respiratory worsening Difficulty swallowing / dysphagia Bloating Flatulence Other	AE EVENT code list
Respiratory worsening specify:	AE.RESPSP EC	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Community / hospital acquired pneumonia Bronchitis Aspiration pneumonitis Pulmonary embolism Pneumothorax Non-pulmonary cause (e.g. anxiety) Unknown cause	RESPIRATORY code lis
Unknown cause specify:	AE.UNKSPC FY	0	Definite acute exacerbation Suspected acute exacerbation Unclassifiable	UNKSPECIFY code list
Other AE specify	AE.AEOTH			
	AE.AEONST			
	AE.AEENDD			
AE Ongoing	AE.AECONT			
	AE.HOSP		Yes No NY code list	

If Yes, complete the Health Care Encounter Form

Maximum intensity	AE.AEINTN S	MildModerateSevere	AESEV code list
Was event serious?	AE.AESER	○ Yes○ No	NY code list
Relationship to intervention	AE.AEREAL TE	 Not a reasonable possibility Reasonable possibility 	AERELAT code list
Final outcome	AE.AEOUTC ME	 Subject died Resolved no sequelae Resolved with sequelae Unresolved 	FOUTCOME code

Serious Adverse Events (Visit ID = 170, Page ID = 20) Unique Identifier page-45862-304954-170-20

	AE Reference ID		(re	mote	value)
This e	event was marked Serious. Please i	ndicate Serio			· · · · · · · · · · · · · · · · · · ·
6 5	Death	SAE.SAESD TH			
.	If Death is selected, was an autopsy performed?	SAE.AUTOP SY	0	Yes No	NY code list
8 8	Life-threatening	SAE.SAESLI FE			
	Require inpatient hospitalization or prolongation of existing hospitalization	SAE.SAESH OSP			
.	Persistent or significant disability / incapacity	SAE.SAEDI SAB			
.	Congenital anomaly or birth defect	SAE.SAESC ONG			
8	Important medical event	SAE.SAESI ME			
Provi	de a summary in chronological orde	er of the clinic	al co	ourse o	of this SAE from onset through resolution.
2. Tre	esenting signs and symptoms eatments and response to treatment atus of subject at time of report and		ome	. as ar	pplicable
8	Summary	SAE.NARSY MP]
8	Additional Summary	SAE.NARSY MP1]
.	Additional Summary	SAE.NARSY MP2]
8 8	Additional Summary	SAE.NARSY MP3]
.	Additional Summary	SAE.NARSY MP4]
8	Additional Summary	SAE.NARSY MP5]
8 8	Additional Summary	SAE.NARSY MP6]
8	Additional Summary	SAE.NARSY MP7]
Inves	tigator Verification				
	I verify that the data on this SAE form accurately displays the results of the examination, tests, evaluations and treatments noted within.	SAE.SAEPI			

Created : 18-APR-16 12:12:25 GMT Page 656