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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	

3.13. CMVIS

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	

3.14. 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 Identifier	Code	Display Text	Hidden?
codelist-45847	LIP	Lipase	
codelist-45847	PHOS	Phosphate	
codelist-45847	K	Potassium	
codelist-45847	NA	Sodium	
codelist-45847	TP	Total Protein	
codelist-45847	UA	Uric Acid	
codelist-45847	HGB	Hemoglobin	
codelist-45847	HCT	Hematocrit	
codelist-45847	MCH	Mean Corpuscular Hemoglobin (MCH)	
codelist-45847	MCHC	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	pH	
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 Identifier	Code	Display Text	Hidden?
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	B	Black or African American	
codelist-45859	A	Asian	
codelist-45859	I	American Indian or Alaska Native	
codelist-45859	P	Native Hawaiian or Other Pacific Islander	
codelist-45859	M	Mixed Race	
codelist-45859	O	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	M	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	OMT	

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	

3.61. UNIT

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	N	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	1	BLOOD AND LYMPHATIC SYSTEM DISORDERS	
codelist-45884	2	CARDIAC DISORDERS	

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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	Yes No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	Yes No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	Yes No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	Yes No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	Yes No	NY code list

If yes, please complete the early discontinuation form

Informed Consent

(Visit ID = 10, Page ID = 20)

Unique Identifier page-45933-304938-10-20

Consent				
	Date subject signed informed consent	CONSENT.INFCONDT		
	Did subject consent for biological impact sub-study?	CONSENT.BIOSUB	○ Yes ○ No	NY code list
	Did subject consent to share data for additional research?	CONSENT.ADDDATA	○ Yes ○ No	NY code list
	Did subject consent to have specimens stored for additional research?	CONSENT.SPECDATA	○ Yes ○ No	NY code list
	Did subject consent to share biological specimens for research?	CONSENT.BIODATA	○ Yes ○ No	NY code list
Screen Failure				
	Subject deemed screen failure	CONSENT.SCRNFAIL	○ Yes ○ No	NY code list
	If yes, specify reason	CONSENT.SFREASON		
	Date	CONSENT.SFAILDT		

Demographics

(Visit ID = 10, Page ID = 30)

Unique Identifier page-45834-304938-10-30

Demographics				
Date of Birth	DM.BRTHDT			
Sex	DM.SEX	○ Male ○ Female	SEX code list	
Ethnicity				
Of Hispanic or Latino ethnicity	DM.ETHNIC	○ 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.RCOTHER	☐		
Smoking History				
Smoking status	DM.SMOKE	○ Current ○ Former ○ Never	SMOKER code list	
If past smoker, date last smoked	DM.SMOKEDT			
How many total years has subject smoked? (years)	DM.SMOKEYRS			(format 99)
On average during that time, how many packs (or equivalents) per day of cigarettes did the subject smoke? (packs/day)	DM.SMOKPACK			(format 9.9)

Medical History

(Visit ID = 10, Page ID = 40)

Unique Identifier page-45852-304938-10-40

Medical History- Does subject have any history of:			
Coronary artery disease	MH.CAD	○ Yes ○ No	NY code list
Acute MI	MH.ACUTEMI	○ Yes ○ No	NY code list
Valvular heart disease	MH.VALVHD	○ Yes ○ No	NY code list
Heart failure	MH.HF	○ Yes ○ No	NY code list
Atrial fibrillation	MH.AFIB	○ Yes ○ No	NY code list
Diabetes	MH.DIABETES	○ Yes ○ No	NY code list
Pulmonary hypertension	MH.PULMHY	○ Yes ○ No	NY code list
Chronic obstructive pulmonary disease (COPD)	MH.COPD	○ Yes ○ No	NY code list
Asthma	MH.ASTHMA	○ Yes ○ No	NY code list
Pulmonary embolism	MH.PEMBL	○ Yes ○ No	NY code list
Lung cancer	MH.LUNGCANC	○ Yes ○ No	NY code list
Other cancer	MH.OTHCANC	○ Yes ○ No	NY code list
Gastroesophageal reflux (GER)	MH.GERD	○ Yes ○ No	NY code list
Barrett's esophagus	MH.BRTESOPH	○ Yes ○ No	NY code list
Hiatal hernia	MH.HIATAL	○ Yes ○ No	NY code list
Hospitalization for pneumonia / respiratory cause in last 6 months	MH.HOSPPNEU	○ Yes ○ No	NY code list

Vitals

(Visit ID = 10, Page ID = 50)

Unique Identifier page-45962-304938-10-50

Vitals			
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.HRTRATE		(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	RADREVIEW code list
Reason:	EXCLUSON.RVWREAS		
Date of HRCT review	EXCLUSON.HRCTRVW		
Lung Biopsy			
Was lung biopsy reviewed?	EXCLUSON.LUNGBIOP	○ Yes ○ No	NY code list
Date of biopsy	EXCLUSON.BIOPDT		
Local pathology review (Choose one category)	EXCLUSON.PATHRVW	○ UIP pattern ○ Probable UIP pattern ○ Possible UIP pattern ○ Not UIP pattern	PATHREVIEW code list
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.	CM.CMND	☐	

Concomitant Medications

Is subject currently taking or was subject previously taking any of the following medications?

Proton Pump Inhibitors (PPI)	CM.CMPPI	○ Taking daily ○ Taking as needed ○ Previously taking (not current) ○ Never used	cCONMED code list
H2 Blockers (H2 Receptor Antagonists)	CM.CMH2B	○ Taking daily ○ Taking as needed ○ Previously taking (not current) ○ Never used	cCONMED code list
Chronic prednisone (>1month)	CM.CMCP	○ Taking daily ○ Taking as needed ○ Previously taking (not current) ○ Never used	cCONMED code list
If current or previous, chronic/ average dose taken (mg/day):	CM.CMCPDOSE		(format 99.9)
Azathioprine	CM.CMAZT	○ Taking daily ○ Taking as needed ○ Previously taking (not current) ○ Never used	cCONMED code list
N-acetylcystteine (NAC)	CM.CMNAC	○ Taking daily ○ Taking as needed ○ Previously taking (not current) ○ Never used	cCONMED code list
Cotrimoxazole	CM.CMCOT	○ Taking daily ○ Taking as needed ○ Previously taking (not current) ○ Never used	cCONMED code list

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

Please check if ABG was not performed at this visit.	ABG.ABGND	☐	
Arterial Blood Gas			
FiO2 (%)	ABG.ABGFIOX		(format 999)
pH	ABG.ABGPH		(format 9.99)
PaO2 (mm Hg)	ABG.ABGPAOX		(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPACOX		(format 999.9)
SaO2 (%)	ABG.ABGSAOX		(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.	GERD.GERDND	☐	
Frequency Scale for the Symptoms of GERD			
Not Collected	GERD.FQND	☐	
1. Do you get heartburn?	GERD.FQHRTBRN	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
2. Does your stomach get bloated?	GERD.FQBLOAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
3. Does your stomach ever feel heavy after meals?	GERD.FQHEAVY	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQRUB	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
5. Do you feel sick after meals?	GERD.FQSICK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQHRTAFT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQTHROAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
8. Do you feel full while eating meals?	GERD.FQFULL	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
9. Do some things get stuck when you swallow?	GERD.FQSTUCK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQACID	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
11. Do you burp a lot?	GERD.FQBURP	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
12. Do you get heartburn if you bend over?	GERD.FQHRTBND	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

GERD Health Related Quality of Life

Not Collected ☐ GERD.QLND

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 and 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.QLHRTBRN	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
2. Heartburn when lying down?	GERD.QLLYING	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
3. Heartburn when standing up?	GERD.QLSTAND	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
4. Heartburn after meals?	GERD.QLHRTAFT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
5. Does heartburn change your diet?	GERD.QLDIET	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
6. Does heartburn wake you from sleep?	GERD.QLSLEEP	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

7. Do you have difficulty swallowing?	GERD.QLDIFFSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
8. Do you have pain with swallowing?	GERD.QLPAINSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
9. Do you have bloating or gassy feelings?	GERD.QLBLOAT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
10. If you take medication, does this affect your daily life?	GERD.QLMEDS	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

pH Monitoring Results

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	GERD.PHND	☐		
Was probe located 5cm above LES	GERD.PHPROBE	○ Yes ○ No	NY code list	
total time pH <4 (%)	GERD.PHTOTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHUPRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHSUPINE			(format 999.9)
# of reflux episodes	GERD.PHRFLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHRFLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHTMRFL			(format 999.9)

Overall DeMeester Score	GERD.PHSCORE		(format 999.9)
Manometry Results			
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	GERD.MNND	☐	
Lower esophageal sphincter (LES) data			
LES length (cm)	GERD.MNLESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNLESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNLESRDP		(format 999.9)
Upper esophageal sphincter (UES) data			
UES resting pressure (mmHg)	GERD.MNUESRTP		(format 999.9)
UES relaxation (%)	GERD.MNUESRLX		(format 999.9)
Esophageal body motility pattern			
% peristaltic contractions (%)	GERD.MNPERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNHYPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSIMUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNESOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNEBMP	○ Normal motlity ○ 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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation form

Enrollment Information

(Visit ID = 20, Page ID = 20)

Unique Identifier page-45937-304939-20-20

Enrollment Information				
	Does subject meet all study inclusion / exclusion criteria?	ENROLL.INCEXCL	○ Yes ○ No	NY code list
	Enrollment date	ENROLL.ENROLLDT		
	Subject randomization	ENROLL.SUBRAND	○ Surgery ○ OMT	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.SPIROND	☐	
SPIROMETRY			
Indicate at which visit these values were collected	SPIRO.SPRVISIT	○ Screening Visit ○ Enrollment Visit	cSCRENR code list
Pre-Bronchodilator: Primary	SPIRO.PRIMEYES	☐	
FEV1: Actual (liters)	SPIRO.PRMFEV		(format 99.99)
FVC: Actual (liters)	SPIRO.PRMFVC		(format 99.99)
VC: Actual (liters)	SPIRO.PRMVC		(format 99.99)
Pre-Bronchodilator: Replicate 1	SPIRO.REP1YES	☐	
FEV1: Actual (liters)	SPIRO.REP1FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP1FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP1VC		(format 99.99)
Pre-Bronchodilator: Replicate 2	SPIRO.REP2YES	☐	
FEV1: Actual (liters)	SPIRO.REP2FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP2FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP2VC		(format 99.99)
DLCO			
DLCO: actual (mL/min/mmHg)	SPIRO.DLCOACT		(format 99.9)
VA (alveolar volume) (liters)	SPIRO.DLCOVA		(format 9.99)
Hemoglobin: (g/dL)	SPIRO.DLCOHEMO		(format 99.9)
Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLCOADHM		(format 99.9)

6-Minute Walk Test

(Visit ID = 20, Page ID = 40)

Unique Identifier page-80834-304939-20-40

Please check if walk test was not performed at this visit.	WALK.WALKND	☐	
6 Minute Walk Test			
Indicate at which visit these values were collected	WALK.WVISIT	○ Screening Visit ○ Enrollment Visit	cSCRENR code list
Pre-walk modified Borg Dyspnea Scale rating	WALK.PREBORG		cBORG code list
Resting room air SpO2 (%)	WALK.WKSPOX		(format 999)
Was walk performed?	WALK.WKPERF	○ Yes ○ No	NY code list
Reason	WALK.WKREASON		
Was supplemental O2 used during walk?	WALK.WKSUPOX	○ Yes ○ No	NY code list
If yes: Amount of supplemental O2? (liters/min)	WALK.WKAMTOX		(format 99)
If yes: SpO2 on supplemental O2? (%)	WALK.WKSPOSUP		(format 999)
Was a walking aid necessary to perform the 6MWT?	WALK.WKAID	○ Yes ○ No	NY code list
If yes: Specify type of walking aid	WALK.WKSPAID	○ Cane ○ Walker ○ Other	cWALK code list
Other (specify)	WALK.WKAIDOTH		
Did subject complete 6MWT?	WALK.WKCOMPL	○ Yes ○ No	NY code list
If no: What was duration of walk test?			
minutes	WALK.WKMIN		(format 9)
seconds	WALK.WKSEC		(format 99)
If no: Reason for stopping early?	WALK.WKSPRSN	○ Symptoms requiring termination ○ Other	c6MTERM code list
Other (specify)	WALK.WKRSNSP		
Distance walked (meters)	WALK.WKDIST		(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKDSAT	○ Yes ○ No NY code list	
If yes: Walk duration at desaturation			
minutes	WALK.WKDSMIN		(format 9)
seconds	WALK.WKDSSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKDSMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKLOWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POSTBORG		cBORG code list

Blood Collection

(Visit ID = 20, Page ID = 50)

Unique Identifier page-45825-304939-20-50

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.BCPRTM	:		(HH24:MI)
Was DNA collected?	BC.BCDNA	○ Yes ○ No	NY code list	
If yes, Yield (ml)	BC.BCDYLD			(format 99.9)
# of aliquots	BC.BCDALQ			(format 99)
Was plasma collected?	BC.BCPLASMA	○ Yes ○ No	NY code list	
If yes, Yield (ml)	BC.BCPYLD			(format 99.9)
# of aliquots	BC.BCPALQ			(format 99)
Was serum collected?	BC.BCSERUM	○ Yes ○ No	NY code list	
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.HRENR	○ Yes ○ No	NY code list
Was a week 48 HRCT performed on this subject?	HRCT.HRFUP	○ Yes ○ No	NY code list

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.UCSDND	☐

UCSD 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.UCSD1	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level at your own pace	UCSD.UCSD2	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level with others your age	UCSD.UCSD3	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking up a hill	UCSD.UCSD4	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Walking up stairs	UCSD.UCSD5	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
While eating	UCSD.UCSD6	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Standing up from a chair	UCSD.UCSD7	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Brushing teeth	UCSD.UCSD8	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shaving and/or brushing hair	UCSD.UCSD9	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Showering/bathing	UCSD.UCSD10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Dressing	UCSD.UCSD11	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Picking up and straightening	UCSD.UCSD12	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Doing dishes	UCSD.UCSD13	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sweeping/vacuuming	UCSD.UCSD14	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Making bed	UCSD.UCSD15	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shopping	UCSD.UCSD16	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Doing laundry	UCSD.UCSD17	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Washing car	UCSD.UCSD18	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Mowing lawn	UCSD.UCSD19	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Watering lawn	UCSD.UCSD20	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sexual activities	UCSD.UCSD21	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

How much do these limit you in your daily life?

Shortness of breath	UCSD.UCSD22	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Fear of “hurting myself” by overexerting	UCSD.UCSD23	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Fear of shortness of breath	UCSD.UCSD24	○ 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.ICEEQND ☐		
Cough VAS			
Cough VAS	ICEEQ.COUGHVAS ☐		
How would rate the severity of your cough?(0-100)	ICEEQ.COUGHSEV ☐		(format 999)
ICECAP			
Not Collected	ICEEQ.ICEND ☐		
By placing a check in one box in each group below, please indicate which statement best describes your quality of life at the moment.			
Love and Friendship	ICEEQ.ICELOVE	○ I can have all of the love and friendship that I want ○ I can have a lot of the love and friendship that I want ○ I can have a little of the love and friendship that I want ○ I cannot have any of the love and friendship that I want	FRIENDS code list
Thinking about the future	ICEEQ.ICEFUTR	○ I can think about the future without any concern ○ I can think about the future with only a little concern ○ I can only think about the future with some concern ○ I can only think about the future with a lot of concern	THINKING code list

Doing things that make you feel valued	ICEEQ.ICEVALUE	○ I am able to do all of the things that make me feel valued ○ I am able to do many of the things that make me feel valued ○ I am able to do a few of the things that make me feel valued ○ I am unable to do any of the things that make me feel valued	VALUED code list
Enjoyment and pleasure	ICEEQ.ICEENJOY	○ I can have all of the enjoyment and pleasure that I want ○ I can have a lot of the enjoyment and pleasure that I want ○ I can have a little of the enjoyment and pleasure that I want ○ I cannot have any of the enjoyment and pleasure that I want	PLEASURE code list
Independence	ICEEQ.ICEINDEP	○ I am able to be completely independent ○ I am able to be independent in many things ○ I am unable to be independent in a few things ○ I am unable to be at all independent	INDEPEND code list

EQ-5D-3L

Not Collected	ICEEQ.EQND	☐

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

Mobility	ICEEQ.EQMOB	○ 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.EQSC	○ I have no problems with self-care ○ I have some problems washing or dressing myself ○ I am unable to wash or dress myself	Self-Care code list
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQUA	○ 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 list
Pain/Discomfort	ICEEQ.EQPAIN	○ I have no pain or discomfort ○ I have moderate pain or discomfort ○ I have extreme pain or discomfort	PAIN code list
Anxiety/Depression	ICEEQ.EQANX	○ I am not anxious or depressed ○ I am moderately anxious or depressed ○ I am extremely anxious or depressed	ANXIETY code list
Value of EQ-5D VAS (0-100)	ICEEQ.EQVAS		(format 999)

St George's Respiratory Questionnaire

(Visit ID = 20, Page ID = 90)

Unique Identifier page-45914-304939-20-90

Please check if questionnaire was not performed at this visit.	SGRQ.SGRQND	☐

St George's Respiratory Questionnaire

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

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

Before completing the questionnaire:

Please check one box to show how you describe your current health:	SGRQ.CURHLTH	○ Very good ○ Good ○ Fair ○ Poor ○ Very poor	CURHLTH code list

Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check one box for each question

1. Over the past 4 weeks, I have coughed:	SGRQ.STG01	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG02	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG03	○ 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.STG04	○ 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.STG05	○ 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.STG06	○ 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.STG07	○ 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.STG08	○ Yes ○ No	NY code list
Part 2 Section 1			

9. How would you describe your respiratory condition?	SGRQ.STG09	○ 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.STG10	○ 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.STG11A	○ True ○ False	cTRUFLS code list
Washing or dressing yourself	SGRQ.STG11B	○ True ○ False	cTRUFLS code list
Walking around the house	SGRQ.STG11C	○ True ○ False	cTRUFLS code list
Walking outside on a level ground	SGRQ.STG11D	○ True ○ False	cTRUFLS code list
Walking up a flight of stairs	SGRQ.STG11E	○ True ○ False	cTRUFLS code list
Walking up hills	SGRQ.STG11F	○ True ○ False	cTRUFLS code list
Playing sports or other physical activities	SGRQ.STG11G	○ True ○ False	cTRUFLS code list

Section 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.STG12A	○ True ○ False	cTRUFLS code list

Coughing makes me tired	SGRQ.STG12B	○ True ○ False	cTRUFLS code list
I am short of breath when I talk	SGRQ.STG12C	○ True ○ False	cTRUFLS code list
I am short of breath when I bend over	SGRQ.STG12D	○ True ○ False	cTRUFLS code list
My coughing or breathing disturbs my sleep	SGRQ.STG12E	○ True ○ False	cTRUFLS code list
I get exhausted easily	SGRQ.STG12F	○ 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.STG13A	○ True ○ False	cTRUFLS code list
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG13B	○ True ○ False	cTRUFLS code list
I get afraid or panic when I cannot catch my breath	SGRQ.STG13C	○ True ○ False	cTRUFLS code list
I feel that I am not in control of my respiratory problems	SGRQ.STG13D	○ True ○ False	cTRUFLS code list
I do not expect my respiratory problems to get any better	SGRQ.STG13E	○ True ○ False	cTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG13F	○ True ○ False	cTRUFLS code list
Exercise is not safe for me	SGRQ.STG13G	○ True ○ False	cTRUFLS code list
Everything seems too much of an effort	SGRQ.STG13H	○ 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.SGNOTXT	☐

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

My treatment does not help me very much	SGRQ.STG14A	○ True ○ False	cTRUFLS code list
I get embarrassed using my medication in public	SGRQ.STG14B	○ True ○ False	cTRUFLS code list

I have unpleasant side effects from my medication	SGRQ.STG14C	○ True ○ False	cTRUFLS code list
My treatment interferes with my life a lot	SGRQ.STG14D	○ True ○ False	cTRUFLS code list

Section 6

These are questions about how your activities might be affected by your respiratory problems.

15. For each statement, please check the box that applies to you because of your respiratory problems.

I take a long time to get washed or dressed	SGRQ.STG15A	○ True ○ False	cTRUFLS code list
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG15B	○ True ○ False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG15C	○ True ○ False	cTRUFLS code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG15D	○ True ○ False	cTRUFLS code list
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG15E	○ True ○ False	cTRUFLS code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG15F	○ 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.STG15G	○ 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.STF15H	○ 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.STG15I	○ True ○ False	cTRUFLS code list

Section 7

We would like to know how your respiratory problems usually affect your daily life.

16. For each statement, please check the box that applies to you because of your respiratory problems.

I cannot play sports or do other physical activities	SGRQ.STG16A	○ True ○ False	cTRUFLS code list

I cannot go out for entertainment or recreation	SGRQ.STG16B	○ True ○ False	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG16C	○ True ○ False	cTRUFLS code list
I cannot do household chores	SGRQ.STG16D	○ True ○ False	cTRUFLS code list
I cannot move far from my bed or chair	SGRQ.STG16E	○ True ○ 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:	SGRQ.STGLIST	

17. Now please check the box (one only) that you think best describes how your respiratory problems affect you:	SGRQ.STG17	○ It does not stop me from doing anything I would like to do ○ It stops me from doing one or two things I would like to do ○ It stops me from doing most of the things I would like to do ○ It stops me from doing everything I would like to do	cRSPAFT code list

Surgical Intervention

Date of Visit

(Visit ID = 30, Page ID = 10)

Unique Identifier page-304846-304940-30-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list
If yes, please complete the early discontinuation form			

Surgical Intervention

(Visit ID = 30, Page ID = 20)

Unique Identifier page-103007-304940-30-20

Surgery information					
Did subject receive the surgical intervention?	SURGINFO.SURGYN	○ Yes ○ No	NY code list		
Date of surgery	SURGINFO.SURGDT				
Was bronchoscopy performed on subject?	SURGINFO.BRONCHO	○ Yes ○ No	NY code list		
Was bronchial alveolar lavage (BAL) fluid collected?	SURGINFO.BALFLUID	○ Yes ○ No	NY code list		
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	○ Yes ○ No	NY code list		
Number of brushes sent	SURGINFO.AECBRUSH			(format 99)	
Pre-operative details					
Any previous abdominal surgery affecting the operative field?	PREOP.PREVSURG	○ Yes ○ No	NY code list		
Type of surgery	PREOP.TYPESURG				
Pre-operative testing performed					
Endoscopy	PREOP.ENDOSCPY	○ Yes ○ No	NY code list		
Barium swallow	PREOP.BARIUM	○ Yes ○ No	NY code list		
Echocardiogram	PREOP.EKG	○ Yes ○ No	NY code list		
If yes, RVSP (mmHg)	PREOP.RSVPVAL			(format 99)	
Right heart catheterization	PREOP.RGHTHRT	○ Yes ○ No	NY code list		
If yes, mean PA (mmHg)	PREOP.MEANPA			(format 99)	
Gastric emptying study	PREOP.GASTRIC	○ Yes ○ No	NY code list		
Chest x-ray	PREOP.CHSTXRAY	○ Yes ○ No	NY code list		

Intra-operative details			
Operative time (mins)	INTROP.OPTM		(format 999)
Estimated blood loss (cc)	INTROP.BLDLOSS		(format 9999)
Intraoperative complications?	INTROP.INTRCMP	○ Yes ○ No	NY code list
If yes, select complications (Select all that apply)	INTROP.SLCTCOMP	ADD DELETE SELECTED	COMPLICATION code list
Conversion to open procedure?	INTROP.OPNPROC	○ Yes ○ No	NY code list
Was mesh used during procedure?	INTROP.MESH	○ Yes ○ No	NY code list
Size of bougie used in procedure	INTROP.BOUGIE	○ None used ○ 52 ○ 54 ○ 56 ○ 58 ○ 60 ○ Other	BOUGIE code list
Other (Fr.)	INTROP.OTHBOGI		(format 99)
Length of Nissen (cm)	INTROP.NISSEN		(format 99.99)
Length of Nissen - Unknown	INTROP.NSSENUNK	☐	
Hiatus hernia present	INTROP.HIHERNIA	○ Yes ○ No	NY code list
If yes, size of hernia	INTROP.HRNIASZE	○ small (2-3 cm) ○ medium (3-4 cm) ○ large (4+ cm) ○ paraesophageal	HERNIASIZE code list
Identification and preservation of vagus nerges?	INTROP.VGUSNERG	○ Yes ○ No	NY code list
Esophageal lengthening procedure added?	INTROP.LENGTHN	○ Yes ○ No	NY code list
Were there other abnormal intraoperative findings?	INTROP.OTHABNYN	○ Yes ○ No	NY code list
Other abnormal intraoperative findings (Select all that apply)			
Cirrhosis	INTROP.CIRRH	☐	

Hypersplenism	INTROP.HSPN	☐
Hepatomegaly	INTROP.HPTMGLY	☐
Evidence of portal hypertension	INTROP.PHTN	☐
Presence of intra-abdominal adhesions	INTROP.INABDADH	☐
Variant anatomy	INTROP.VARANAT	☐
Other	INTROP.ABNOTHR	☐
If Variant anatomy, Describe	INTROP.VARIANAT	

Month 1 Telephone Contact

Date of Visit

(Visit ID = 40, Page ID = 10)

Unique Identifier page-304846-304941-40-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation 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.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter 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.DAYSSTY			(format 999)
Days spent in ICU	POSTOP.DAYSICU			(format 999)
Was patient readmitted to the hospital within 30 days?	POSTOP.READMIT	○ Yes ○ No	NY code list	
Did patient require re-intubation?	POSTOP.REINTUBE	○ Yes ○ No	NY code list	
Days on ventilator	POSTOP.VENTLTR			(format 999)
Was re-operation for bleeding required?	POSTOP.REOPBLD	○ Yes ○ No	NY code list	
Did patient suffer other post-operative complications (within 30 days of surgery)?	POSTOP.COMPLCTN	○ Yes ○ No	NY code list	
If yes, what complications? (Select all that apply)	POSTOP.CMPSPCFY	ADD DELETE SELECTED		

Month 2 Telephone Contact

Date of Visit

(Visit ID = 50, Page ID = 10)

Unique Identifier page-304846-304942-50-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation form

Monthly Telephone Contact

(Visit ID = 50, Page ID = 20)

Unique Identifier page-304876-304942-50-20

Please check if telephone contact was not performed at this visit.	TELE.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter Form			

Week 12 Visit

Date of Visit

(Visit ID = 60, Page ID = 10)

Unique Identifier page-304846-304943-60-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	Yes No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	Yes No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	Yes No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	Yes No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	Yes No	NY code list
If yes, please complete the early discontinuation form			

Concomitant Medications

(Visit ID = 60, Page ID = 100)

Unique Identifier page-304883-304943-60-100

Medications were not collected at this visit.	CMFP.CMFPND	☐	
Concomitant Medications			
Has the subject taken any of the following medications since the last visit?			
Proton Pump Inhibitors (PPI)	CMFP.CMPPI	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH2B	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Chronic prednisone (>1month)	CMFP.CMCP	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
If current, chronic/ average dose taken (mg/day):	CMFP.CMCPDOSE		(format 99.9)
Azathioprine	CMFP.CMAZT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
N-acetylcystteine (NAC)	CMFP.CMNAC	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Cotrimoxazole	CMFP.CMCOT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMMDI	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Pirfenidone	CMFP.CMPIRF	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Nintedanib	CMFP.CMNINT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list

Documentation of GERD & Esophageal Motility

(Visit ID = 60, Page ID = 20)

Unique Identifier page-188329-304943-60-20

Please check if documentation was not collected at this visit.	GERD.GERDND	☐	
Frequency Scale for the Symptoms of GERD			
Not Collected	GERD.FQND	☐	
1. Do you get heartburn?	GERD.FQHRTBRN	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
2. Does your stomach get bloated?	GERD.FQBLOAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
3. Does your stomach ever feel heavy after meals?	GERD.FQHEAVY	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQRUB	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
5. Do you feel sick after meals?	GERD.FQSICK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQHRTAFT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQTHROAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
8. Do you feel full while eating meals?	GERD.FQFULL	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
9. Do some things get stuck when you swallow?	GERD.FQSTUCK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQACID	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
11. Do you burp a lot?	GERD.FQBURP	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
12. Do you get heartburn if you bend over?	GERD.FQHRTBND	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

GERD Health Related Quality of Life

Not Collected GERD.QLND ☐

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 and 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.QLHRTBRN	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
2. Heartburn when lying down?	GERD.QLLYING	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
3. Heartburn when standing up?	GERD.QLSTAND	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
4. Heartburn after meals?	GERD.QLHRTAFT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
5. Does heartburn change your diet?	GERD.QLDIET	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
6. Does heartburn wake you from sleep?	GERD.QLSLEEP	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

7. Do you have difficulty swallowing?	GERD.QLDIFFSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
8. Do you have pain with swallowing?	GERD.QLPAINSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
9. Do you have bloating or gassy feelings?	GERD.QLBLOAT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
10. If you take medication, does this affect your daily life?	GERD.QLMEDS	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

pH Monitoring Results

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	GERD.PHND	☐	
Was probe located 5cm above LES	GERD.PHPROBE	○ Yes ○ No NY code list	
total time pH <4 (%)	GERD.PHTOTAL		(format 999.9)
upright time pH <4 (%)	GERD.PHUPRHT		(format 999.9)
supine time pH <4 (%)	GERD.PHSUPINE		(format 999.9)
# of reflux episodes	GERD.PHRFLEPS		(format 999.9)
# of reflux episodes >5min	GERD.PHRFLEPL		(format 999.9)
Longest reflux episode (mins)	GERD.PHTMRFL		(format 999.9)

Overall DeMeester Score	GERD.PHSCORE		(format 999.9)
Manometry Results			
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	GERD.MNND	☐	
Lower esophageal sphincter (LES) data			
LES length (cm)	GERD.MNLESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNLESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNLESRDP		(format 999.9)
Upper esophageal sphincter (UES) data			
UES resting pressure (mmHg)	GERD.MNUESRTP		(format 999.9)
UES relaxation (%)	GERD.MNUESRLX		(format 999.9)
Esophageal body motility pattern			
% peristaltic contractions (%)	GERD.MNPERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNHYPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSIMUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNESOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNEBMP	○ Normal motlity ○ 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

Spirometry_DLCO

(Visit ID = 60, Page ID = 30)

Unique Identifier page-80805-304943-60-30

Please check if procedures were not performed	SPIRO.SPIROND	☐	
SPIROMETRY			
Indicate at which visit these values were collected	SPIRO.SPRVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-Bronchodilator: Primary	SPIRO.PRIMEYES	☐	
FEV1: Actual (liters)	SPIRO.PRMFEV		(format 99.99)
FVC: Actual (liters)	SPIRO.PRMFVC		(format 99.99)
VC: Actual (liters)	SPIRO.PRMVC		(format 99.99)
Pre-Bronchodilator: Replicate 1	SPIRO.REP1YES	☐	
FEV1: Actual (liters)	SPIRO.REP1FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP1FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP1VC		(format 99.99)
Pre-Bronchodilator: Replicate 2	SPIRO.REP2YES	☐	
FEV1: Actual (liters)	SPIRO.REP2FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP2FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP2VC		(format 99.99)
DLCO			
DLCO: actual (mL/min/mmHg)	SPIRO.DLCOACT		(format 99.9)
VA (alveolar volume) (liters)	SPIRO.DLCOVA		(format 9.99)
Hemoglobin: (g/dL)	SPIRO.DLCOHEMO		(format 99.9)
Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLCOADHM		(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.ABGND	☐	
Arterial Blood Gas			
FiO2 (%)	ABG.ABGFIOX		(format 999)
pH	ABG.ABGPH		(format 9.99)
PaO2 (mm Hg)	ABG.ABGPAOX		(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPACOX		(format 999.9)
SaO2 (%)	ABG.ABGSAOX		(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.WALKND	☐	
6 Minute Walk Test			
Indicate at which visit these values were collected	WALK.WVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-walk modified Borg Dyspnea Scale rating	WALK.PREBORG		cBORG code list
Resting room air SpO2 (%)	WALK.WKSPOX		(format 999)
Was walk performed?	WALK.WKPERF	○ Yes ○ No	NY code list
Reason	WALK.WKREASON		
Was supplemental O2 used during walk?	WALK.WKSUPOX	○ Yes ○ No	NY code list
If yes: Amount of supplemental O2? (liters/min)	WALK.WKAMTOX		(format 99)
If yes: SpO2 on supplemental O2? (%)	WALK.WKSPOSUP		(format 999)
Was a walking aid necessary to perform the 6MWT?	WALK.WKAID	○ Yes ○ No	NY code list
If yes: Specify type of walking aid	WALK.WKSPAID	○ Cane ○ Walker ○ Other	cWALK code list
Other (specify)	WALK.WKAIDOTH		
Did subject complete 6MWT?	WALK.WKCOMPL	○ Yes ○ No	NY code list
If no: What was duration of walk test?			
minutes	WALK.WKMIN		(format 9)
seconds	WALK.WKSEC		(format 99)
If no: Reason for stopping early?	WALK.WKSPRSN	○ Symptoms requiring termination ○ Other	c6MTERM code list
Other (specify)	WALK.WKRSNSP		
Distance walked (meters)	WALK.WKDIST		(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKDSAT	○ Yes ○ No	NY code list
If yes: Walk duration at desaturation			
minutes	WALK.WKDSMIN		(format 9)
seconds	WALK.WKDSSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKDSMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKLOWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POSTBORG		cBORG code list

Blood Collection

(Visit ID = 60, Page ID = 60)

Unique Identifier page-45825-304943-60-60

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.BCPRTM	:	(HH24:MI)
Was DNA collected?	BC.BCDNA	○ Yes ○ No	NY code list
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLASMA	○ Yes ○ No	NY code list
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERUM	○ Yes ○ No	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 = 60, Page ID = 70)

Unique Identifier page-45995-304943-60-70

Please check if questionnaire was not performed at this visit.	UCSD.UCSDND	☐

UCSD 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.UCSD1	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level at your own pace	UCSD.UCSD2	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level with others your age	UCSD.UCSD3	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking up a hill	UCSD.UCSD4	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Walking up stairs	UCSD.UCSD5	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
While eating	UCSD.UCSD6	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Standing up from a chair	UCSD.UCSD7	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Brushing teeth	UCSD.UCSD8	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shaving and/or brushing hair	UCSD.UCSD9	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Showering/bathing	UCSD.UCSD10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Dressing	UCSD.UCSD11	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Picking up and straightening	UCSD.UCSD12	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Doing dishes	UCSD.UCSD13	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sweeping/vacuuming	UCSD.UCSD14	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Making bed	UCSD.UCSD15	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shopping	UCSD.UCSD16	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Doing laundry	UCSD.UCSD17	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Washing car	UCSD.UCSD18	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Mowing lawn	UCSD.UCSD19	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Watering lawn	UCSD.UCSD20	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sexual activities	UCSD.UCSD21	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

How much do these limit you in your daily life?

Shortness of breath	UCSD.UCSD22	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Fear of “hurting myself” by overexerting	UCSD.UCSD23	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Fear of shortness of breath	UCSD.UCSD24	○ 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.ICEEQND ☐		
Cough VAS			
Cough VAS	ICEEQ.COUGHVAS ☐		
How would rate the severity of your cough?(0-100)	ICEEQ.COUGHSEV ☐		(format 999)
ICECAP			
Not Collected	ICEEQ.ICEND ☐		
By placing a check in one box in each group below, please indicate which statement best describes your quality of life at the moment.			
Love and Friendship	ICEEQ.ICELOVE	○ I can have all of the love and friendship that I want ○ I can have a lot of the love and friendship that I want ○ I can have a little of the love and friendship that I want ○ I cannot have any of the love and friendship that I want	FRIENDS code list
Thinking about the future	ICEEQ.ICEFUTR	○ I can think about the future without any concern ○ I can think about the future with only a little concern ○ I can only think about the future with some concern ○ I can only think about the future with a lot of concern	THINKING code list

Doing things that make you feel valued	ICEEQ.ICEVALUE	○ I am able to do all of the things that make me feel valued ○ I am able to do many of the things that make me feel valued ○ I am able to do a few of the things that make me feel valued ○ I am unable to do any of the things that make me feel valued	VALUED code list
Enjoyment and pleasure	ICEEQ.ICEENJOY	○ I can have all of the enjoyment and pleasure that I want ○ I can have a lot of the enjoyment and pleasure that I want ○ I can have a little of the enjoyment and pleasure that I want ○ I cannot have any of the enjoyment and pleasure that I want	PLEASURE code list
Independence	ICEEQ.ICEINDEP	○ I am able to be completely independent ○ I am able to be independent in many things ○ I am unable to be independent in a few things ○ I am unable to be at all independent	INDEPEND code list

EQ-5D-3L

Not Collected	ICEEQ.EQND	☐

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

Mobility	ICEEQ.EQMOB	○ 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.EQSC	○ I have no problems with self-care ○ I have some problems washing or dressing myself ○ I am unable to wash or dress myself	Self-Care code list
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQUA	○ 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 list
Pain/Discomfort	ICEEQ.EQPAIN	○ I have no pain or discomfort ○ I have moderate pain or discomfort ○ I have extreme pain or discomfort	PAIN code list
Anxiety/Depression	ICEEQ.EQANX	○ I am not anxious or depressed ○ I am moderately anxious or depressed ○ I am extremely anxious or depressed	ANXIETY code list
Value of EQ-5D VAS (0-100)	ICEEQ.EQVAS		(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.SGRQND	☐

St George's Respiratory Questionnaire

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

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

Before completing the questionnaire:

Please check one box to show how you describe your current health:	SGRQ.CURHLTH	○ Very good ○ Good ○ Fair ○ Poor ○ Very poor	CURHLTH code list

Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check one box for each question

1. Over the past 4 weeks, I have coughed:	SGRQ.STG01	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG02	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG03	○ 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.STG04	○ 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.STG05	○ 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.STG06	○ 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.STG07	○ 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.STG08	○ Yes ○ No	NY code list

Part 2
Section 1

9. How would you describe your respiratory condition?	SGRQ.STG09	○ 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.STG10	○ 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.STG11A	○ True ○ False	cTRUFLS code list
Washing or dressing yourself	SGRQ.STG11B	○ True ○ False	cTRUFLS code list
Walking around the house	SGRQ.STG11C	○ True ○ False	cTRUFLS code list
Walking outside on a level ground	SGRQ.STG11D	○ True ○ False	cTRUFLS code list
Walking up a flight of stairs	SGRQ.STG11E	○ True ○ False	cTRUFLS code list
Walking up hills	SGRQ.STG11F	○ True ○ False	cTRUFLS code list
Playing sports or other physical activities	SGRQ.STG11G	○ True ○ False	cTRUFLS code list

Section 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.STG12A	○ True ○ False	cTRUFLS code list

Coughing makes me tired	SGRQ.STG12B	○ True ○ False	cTRUFLS code list
I am short of breath when I talk	SGRQ.STG12C	○ True ○ False	cTRUFLS code list
I am short of breath when I bend over	SGRQ.STG12D	○ True ○ False	cTRUFLS code list
My coughing or breathing disturbs my sleep	SGRQ.STG12E	○ True ○ False	cTRUFLS code list
I get exhausted easily	SGRQ.STG12F	○ 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.STG13A	○ True ○ False	cTRUFLS code list
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG13B	○ True ○ False	cTRUFLS code list
I get afraid or panic when I cannot catch my breath	SGRQ.STG13C	○ True ○ False	cTRUFLS code list
I feel that I am not in control of my respiratory problems	SGRQ.STG13D	○ True ○ False	cTRUFLS code list
I do not expect my respiratory problems to get any better	SGRQ.STG13E	○ True ○ False	cTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG13F	○ True ○ False	cTRUFLS code list
Exercise is not safe for me	SGRQ.STG13G	○ True ○ False	cTRUFLS code list
Everything seems too much of an effort	SGRQ.STG13H	○ 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.SGNOTXT	☐

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

My treatment does not help me very much	SGRQ.STG14A	○ True ○ False	cTRUFLS code list
I get embarrassed using my medication in public	SGRQ.STG14B	○ True ○ False	cTRUFLS code list

I have unpleasant side effects from my medication	SGRQ.STG14C	○ True ○ False	cTRUFLS code list
My treatment interferes with my life a lot	SGRQ.STG14D	○ True ○ False	cTRUFLS code list

Section 6

These are questions about how your activities might be affected by your respiratory problems.

15. For each statement, please check the box that applies to you because of your respiratory problems.

I take a long time to get washed or dressed	SGRQ.STG15A	○ True ○ False	cTRUFLS code list
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG15B	○ True ○ False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG15C	○ True ○ False	cTRUFLS code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG15D	○ True ○ False	cTRUFLS code list
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG15E	○ True ○ False	cTRUFLS code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG15F	○ 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.STG15G	○ 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.STF15H	○ 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.STG15I	○ True ○ False	cTRUFLS code list

Section 7

We would like to know how your respiratory problems usually affect your daily life.

16. For each statement, please check the box that applies to you because of your respiratory problems.

I cannot play sports or do other physical activities	SGRQ.STG16A	○ True ○ False	cTRUFLS code list

I cannot go out for entertainment or recreation	SGRQ.STG16B	○ True ○ False	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG16C	○ True ○ False	cTRUFLS code list
I cannot do household chores	SGRQ.STG16D	○ True ○ False	cTRUFLS code list
I cannot move far from my bed or chair	SGRQ.STG16E	○ True ○ 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:	SGRQ.STGLIST	
17. Now please check the box (one only) that you think best describes how your respiratory problems affect you:	SGRQ.STG17	○ It does not stop me from doing anything I would like to do ○ It stops me from doing one or two things I would like to do ○ It stops me from doing most of the things I would like to do ○ It stops me from doing everything I would like to do

cRSPAFT code list

Month 4 Telephone Contact

Date of Visit

(Visit ID = 70, Page ID = 10)

Unique Identifier page-304846-304944-70-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

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.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter 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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	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.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter Form			

Week 24 Visit

Date of Visit

(Visit ID = 90, Page ID = 10)

Unique Identifier page-304846-304946-90-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation form

Concomitant Medications

(Visit ID = 90, Page ID = 80)

Unique Identifier page-304883-304946-90-80

Medications were not collected at this visit.	CMFP.CMFPND	☐	
Concomitant Medications			
Has the subject taken any of the following medications since the last visit?			
Proton Pump Inhibitors (PPI)	CMFP.CMPPI	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH2B	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Chronic prednisone (>1month)	CMFP.CMCP	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
If current, chronic/ average dose taken (mg/day):	CMFP.CMCPDOSE		(format 99.9)
Azathioprine	CMFP.CMAZT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
N-acetylcystteine (NAC)	CMFP.CMNAC	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Cotrimoxazole	CMFP.CMCOT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMMDI	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Pirfenidone	CMFP.CMPIRF	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Nintedanib	CMFP.CMNINT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list

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.	GERD.GERDND	☐	
Frequency Scale for the Symptoms of GERD			
Not Collected	GERD.FQND	☐	
1. Do you get heartburn?	GERD.FQHRTBRN	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
2. Does your stomach get bloated?	GERD.FQBLOAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
3. Does your stomach ever feel heavy after meals?	GERD.FQHEAVY	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQRUB	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
5. Do you feel sick after meals?	GERD.FQSICK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQHRTAFT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQTHROAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
8. Do you feel full while eating meals?	GERD.FQFULL	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
9. Do some things get stuck when you swallow?	GERD.FQSTUCK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQACID	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
11. Do you burp a lot?	GERD.FQBURP	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
12. Do you get heartburn if you bend over?	GERD.FQHRTBND	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

GERD Health Related Quality of Life

Not Collected GERD.QLND ☐

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 and 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.QLHRTBRN	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
2. Heartburn when lying down?	GERD.QLLYING	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
3. Heartburn when standing up?	GERD.QLSTAND	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
4. Heartburn after meals?	GERD.QLHRTAFT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
5. Does heartburn change your diet?	GERD.QLDIET	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
6. Does heartburn wake you from sleep?	GERD.QLSLEEP	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

7. Do you have difficulty swallowing?	GERD.QLDIFFSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
8. Do you have pain with swallowing?	GERD.QLPAINSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
9. Do you have bloating or gassy feelings?	GERD.QLBLOAT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
10. If you take medication, does this affect your daily life?	GERD.QLMEDS	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

pH Monitoring Results

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	GERD.PHND	☐		
Was probe located 5cm above LES	GERD.PHPROBE	○ Yes ○ No	NY code list	
total time pH <4 (%)	GERD.PHTOTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHUPRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHSUPINE			(format 999.9)
# of reflux episodes	GERD.PHRFLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHRFLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHTMRFL			(format 999.9)

Overall DeMeester Score	GERD.PHSCORE		(format 999.9)
Manometry Results			
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	GERD.MNND	☐	
Lower esophageal sphincter (LES) data			
LES length (cm)	GERD.MNLESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNLESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNLESRDP		(format 999.9)
Upper esophageal sphincter (UES) data			
UES resting pressure (mmHg)	GERD.MNUESRTP		(format 999.9)
UES relaxation (%)	GERD.MNUESRLX		(format 999.9)
Esophageal body motility pattern			
% peristaltic contractions (%)	GERD.MNPERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNHYPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSIMUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNESOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNEBMP	○ Normal motlity ○ 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

Spirometry_DLCO

(Visit ID = 90, Page ID = 20)

Unique Identifier page-80805-304946-90-20

Please check if procedures were not performed	SPIRO.SPIROND	☐	
SPIROMETRY			
Indicate at which visit these values were collected	SPIRO.SPRVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-Bronchodilator: Primary	SPIRO.PRIMEYES	☐	
FEV1: Actual (liters)	SPIRO.PRMFEV		(format 99.99)
FVC: Actual (liters)	SPIRO.PRMFVC		(format 99.99)
VC: Actual (liters)	SPIRO.PRMVC		(format 99.99)
Pre-Bronchodilator: Replicate 1	SPIRO.REP1YES	☐	
FEV1: Actual (liters)	SPIRO.REP1FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP1FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP1VC		(format 99.99)
Pre-Bronchodilator: Replicate 2	SPIRO.REP2YES	☐	
FEV1: Actual (liters)	SPIRO.REP2FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP2FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP2VC		(format 99.99)
DLCO			
DLCO: actual (mL/min/mmHg)	SPIRO.DLCOACT		(format 99.9)
VA (alveolar volume) (liters)	SPIRO.DLCOVA		(format 9.99)
Hemoglobin: (g/dL)	SPIRO.DLCOHEMO		(format 99.9)
Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLCOADHM		(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.ABGND	☐	
Arterial Blood Gas			
FiO2 (%)	ABG.ABGFIOX		(format 999)
pH	ABG.ABGPH		(format 9.99)
PaO2 (mm Hg)	ABG.ABGPAOX		(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPACOX		(format 999.9)
SaO2 (%)	ABG.ABGSAOX		(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.WALKND	☐	
6 Minute Walk Test			
Indicate at which visit these values were collected	WALK.WVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-walk modified Borg Dyspnea Scale rating	WALK.PREBORG		cBORG code list
Resting room air SpO2 (%)	WALK.WKSPOX		(format 999)
Was walk performed?	WALK.WKPERF	○ Yes ○ No	NY code list
Reason	WALK.WKREASON		
Was supplemental O2 used during walk?	WALK.WKSUPOX	○ Yes ○ No	NY code list
If yes: Amount of supplemental O2? (liters/min)	WALK.WKAMTOX		(format 99)
If yes: SpO2 on supplemental O2? (%)	WALK.WKSPOSUP		(format 999)
Was a walking aid necessary to perform the 6MWT?	WALK.WKAID	○ Yes ○ No	NY code list
If yes: Specify type of walking aid	WALK.WKSPAID	○ Cane ○ Walker ○ Other	cWALK code list
Other (specify)	WALK.WKAIDOTH		
Did subject complete 6MWT?	WALK.WKCOMPL	○ Yes ○ No	NY code list
If no: What was duration of walk test?			
minutes	WALK.WKMIN		(format 9)
seconds	WALK.WKSEC		(format 99)
If no: Reason for stopping early?	WALK.WKSPRSN	○ Symptoms requiring termination ○ Other	c6MTERM code list
Other (specify)	WALK.WKRSNSP		
Distance walked (meters)	WALK.WKDIST		(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKDSAT	○ Yes ○ No NY code list	
If yes: Walk duration at desaturation			
minutes	WALK.WKDSMIN		(format 9)
seconds	WALK.WKDSSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKDSMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKLOWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POSTBORG		cBORG code list

Blood Collection

(Visit ID = 90, Page ID = 40)

Unique Identifier page-45825-304946-90-40

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.BCPRTM	:	(HH24:MI)
Was DNA collected?	BC.BCDNA	○ Yes ○ No	NY code list
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLASMA	○ Yes ○ No	NY code list
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERUM	○ Yes ○ No	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.UCSDND	☐

UCSD 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.UCSD1	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level at your own pace	UCSD.UCSD2	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level with others your age	UCSD.UCSD3	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking up a hill	UCSD.UCSD4	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Walking up stairs	UCSD.UCSD5	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
While eating	UCSD.UCSD6	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Standing up from a chair	UCSD.UCSD7	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Brushing teeth	UCSD.UCSD8	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shaving and/or brushing hair	UCSD.UCSD9	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Showering/bathing	UCSD.UCSD10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Dressing	UCSD.UCSD11	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Picking up and straightening	UCSD.UCSD12	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Doing dishes	UCSD.UCSD13	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sweeping/vacuuming	UCSD.UCSD14	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Making bed	UCSD.UCSD15	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shopping	UCSD.UCSD16	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Doing laundry	UCSD.UCSD17	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Washing car	UCSD.UCSD18	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Mowing lawn	UCSD.UCSD19	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Watering lawn	UCSD.UCSD20	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sexual activities	UCSD.UCSD21	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

How much do these limit you in your daily life?

Shortness of breath	UCSD.UCSD22	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Fear of “hurting myself” by overexerting	UCSD.UCSD23	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Fear of shortness of breath	UCSD.UCSD24	○ 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.ICEEQND ☐		
Cough VAS			
Cough VAS	ICEEQ.COUGHVAS ☐		
How would rate the severity of your cough?(0-100)	ICEEQ.COUGHSEV ☐		(format 999)
ICECAP			
Not Collected	ICEEQ.ICEND ☐		
By placing a check in one box in each group below, please indicate which statement best describes your quality of life at the moment.			
Love and Friendship	ICEEQ.ICELOVE	○ I can have all of the love and friendship that I want ○ I can have a lot of the love and friendship that I want ○ I can have a little of the love and friendship that I want ○ I cannot have any of the love and friendship that I want	FRIENDS code list
Thinking about the future	ICEEQ.ICEFUTR	○ I can think about the future without any concern ○ I can think about the future with only a little concern ○ I can only think about the future with some concern ○ I can only think about the future with a lot of concern	THINKING code list

Doing things that make you feel valued	ICEEQ.ICEVALUE	○ I am able to do all of the things that make me feel valued ○ I am able to do many of the things that make me feel valued ○ I am able to do a few of the things that make me feel valued ○ I am unable to do any of the things that make me feel valued	VALUED code list
Enjoyment and pleasure	ICEEQ.ICEENJOY	○ I can have all of the enjoyment and pleasure that I want ○ I can have a lot of the enjoyment and pleasure that I want ○ I can have a little of the enjoyment and pleasure that I want ○ I cannot have any of the enjoyment and pleasure that I want	PLEASURE code list
Independence	ICEEQ.ICEINDEP	○ I am able to be completely independent ○ I am able to be independent in many things ○ I am unable to be independent in a few things ○ I am unable to be at all independent	INDEPEND code list

EQ-5D-3L

Not Collected	ICEEQ.EQND	☐

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

Mobility	ICEEQ.EQMOB	○ 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.EQSC	○ I have no problems with self-care ○ I have some problems washing or dressing myself ○ I am unable to wash or dress myself	Self-Care code list
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQUA	○ 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 list
Pain/Discomfort	ICEEQ.EQPAIN	○ I have no pain or discomfort ○ I have moderate pain or discomfort ○ I have extreme pain or discomfort	PAIN code list
Anxiety/Depression	ICEEQ.EQANX	○ I am not anxious or depressed ○ I am moderately anxious or depressed ○ I am extremely anxious or depressed	ANXIETY code list
Value of EQ-5D VAS (0-100)	ICEEQ.EQVAS		(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.SGRQND** ☐

St George's Respiratory Questionnaire

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

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

Before completing the questionnaire:

Please check one box to show how you describe your current health: **SGRQ.CURHLTH**

- ○ Very good
- ○ Good
- ○ Fair
- ○ Poor
- ○ Very poor

CURHLTH code list

Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check one box for each question

1. Over the past 4 weeks, I have coughed: **SGRQ.STG01**

- ○ Almost Every Day
- ○ Several Days a Week
- ○ A Few Days a Month
- ○ Only with Respiratory Infections
- ○ Not at all

cRSPROB code list

2. Over the past 4 weeks, I have brought up phlegm (sputum): **SGRQ.STG02**

- ○ Almost Every Day
- ○ Several Days a Week
- ○ A Few Days a Month
- ○ Only with Respiratory Infections
- ○ Not at all

cRSPROB code list

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG03	○ 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.STG04	○ 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.STG05	○ 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.STG06	○ 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.STG07	○ 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.STG08	○ Yes ○ No	NY code list

Part 2
Section 1

9. How would you describe your respiratory condition?	SGRQ.STG09	○ 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.STG10	○ 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.STG11A	○ True ○ False	cTRUFLS code list
Washing or dressing yourself	SGRQ.STG11B	○ True ○ False	cTRUFLS code list
Walking around the house	SGRQ.STG11C	○ True ○ False	cTRUFLS code list
Walking outside on a level ground	SGRQ.STG11D	○ True ○ False	cTRUFLS code list
Walking up a flight of stairs	SGRQ.STG11E	○ True ○ False	cTRUFLS code list
Walking up hills	SGRQ.STG11F	○ True ○ False	cTRUFLS code list
Playing sports or other physical activities	SGRQ.STG11G	○ True ○ False	cTRUFLS code list

Section 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.STG12A	○ True ○ False	cTRUFLS code list

Coughing makes me tired	SGRQ.STG12B	○ True ○ False	cTRUFLS code list
I am short of breath when I talk	SGRQ.STG12C	○ True ○ False	cTRUFLS code list
I am short of breath when I bend over	SGRQ.STG12D	○ True ○ False	cTRUFLS code list
My coughing or breathing disturbs my sleep	SGRQ.STG12E	○ True ○ False	cTRUFLS code list
I get exhausted easily	SGRQ.STG12F	○ 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.STG13A	○ True ○ False	cTRUFLS code list
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG13B	○ True ○ False	cTRUFLS code list
I get afraid or panic when I cannot catch my breath	SGRQ.STG13C	○ True ○ False	cTRUFLS code list
I feel that I am not in control of my respiratory problems	SGRQ.STG13D	○ True ○ False	cTRUFLS code list
I do not expect my respiratory problems to get any better	SGRQ.STG13E	○ True ○ False	cTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG13F	○ True ○ False	cTRUFLS code list
Exercise is not safe for me	SGRQ.STG13G	○ True ○ False	cTRUFLS code list
Everything seems too much of an effort	SGRQ.STG13H	○ 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.SGNOTXT	☐

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

My treatment does not help me very much	SGRQ.STG14A	○ True ○ False	cTRUFLS code list
I get embarrassed using my medication in public	SGRQ.STG14B	○ True ○ False	cTRUFLS code list

I have unpleasant side effects from my medication	SGRQ.STG14C	○ True ○ False	cTRUFLS code list
My treatment interferes with my life a lot	SGRQ.STG14D	○ True ○ False	cTRUFLS code list

Section 6

These are questions about how your activities might be affected by your respiratory problems.

15. For each statement, please check the box that applies to you because of your respiratory problems.

I take a long time to get washed or dressed	SGRQ.STG15A	○ True ○ False	cTRUFLS code list
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG15B	○ True ○ False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG15C	○ True ○ False	cTRUFLS code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG15D	○ True ○ False	cTRUFLS code list
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG15E	○ True ○ False	cTRUFLS code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG15F	○ 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.STG15G	○ 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.STF15H	○ 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.STG15I	○ True ○ False	cTRUFLS code list

Section 7

We would like to know how your respiratory problems usually affect your daily life.

16. For each statement, please check the box that applies to you because of your respiratory problems.

I cannot play sports or do other physical activities	SGRQ.STG16A	○ True ○ False	cTRUFLS code list

I cannot go out for entertainment or recreation	SGRQ.STG16B	○ True ○ False	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG16C	○ True ○ False	cTRUFLS code list
I cannot do household chores	SGRQ.STG16D	○ True ○ False	cTRUFLS code list
I cannot move far from my bed or chair	SGRQ.STG16E	○ True ○ 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:	SGRQ.STGLIST		
17. Now please check the box (one only) that you think best describes how your respiratory problems affect you:	SGRQ.STG17	○ It does not stop me from doing anything I would like to do ○ It stops me from doing one or two things I would like to do ○ It stops me from doing most of the things I would like to do ○ It stops me from doing everything I would like to do	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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation form

Monthly Telephone Contact

(Visit ID = 100, Page ID = 20)

Unique Identifier page-304876-304947-100-20

Please check if telephone contact was not performed at this visit.	TELE.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter 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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation 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.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter Form			

Week 36 Visit

Date of Visit

(Visit ID = 120, Page ID = 10)

Unique Identifier page-304846-304949-120-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	Yes No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	Yes No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	Yes No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	Yes No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	Yes No	NY code list
If yes, please complete the early discontinuation form			

Concomitant Medications

(Visit ID = 120, Page ID = 70)

Unique Identifier page-304883-304949-120-70

Medications were not collected at this visit.	CMFP.CMFPND	☐	
Concomitant Medications			
Has the subject taken any of the following medications since the last visit?			
Proton Pump Inhibitors (PPI)	CMFP.CMPPI	○ Taking daily ○ Taking as needed ○ Not Current	
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH2B	○ Taking daily ○ Taking as needed ○ Not Current	
Chronic prednisone (>1month)	CMFP.CMCP	○ Taking daily ○ Taking as needed ○ Not Current	
If current, chronic/ average dose taken (mg/day):	CMFP.CMCPDOSE		(format 99.9)
Azathioprine	CMFP.CMAZT	○ Taking daily ○ Taking as needed ○ Not Current	
N-acetylcystteine (NAC)	CMFP.CMNAC	○ Taking daily ○ Taking as needed ○ Not Current	
Cotrimoxazole	CMFP.CMCOT	○ Taking daily ○ Taking as needed ○ Not Current	
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMMDI	○ Taking daily ○ Taking as needed ○ Not Current	
Pirfenidone	CMFP.CMPIRF	○ Taking daily ○ Taking as needed ○ Not Current	
Nintedanib	CMFP.CMNINT	○ Taking daily ○ Taking as needed ○ Not Current	

Spirometry

(Visit ID = 120, Page ID = 20)

Unique Identifier page-80805-304949-120-20

Please check if procedures were not performed	SPIRO.SPIROND	☐	
SPIROMETRY			
Indicate at which visit these values were collected	SPIRO.SPRVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-Bronchodilator: Primary	SPIRO.PRIMEYES	☐	
FEV1: Actual (liters)	SPIRO.PRMFEV		(format 99.99)
FVC: Actual (liters)	SPIRO.PRMFVC		(format 99.99)
VC: Actual (liters)	SPIRO.PRMVC		(format 99.99)
Pre-Bronchodilator: Replicate 1	SPIRO.REP1YES	☐	
FEV1: Actual (liters)	SPIRO.REP1FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP1FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP1VC		(format 99.99)
Pre-Bronchodilator: Replicate 2	SPIRO.REP2YES	☐	
FEV1: Actual (liters)	SPIRO.REP2FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP2FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP2VC		(format 99.99)
DLCO			
DLCO: actual (mL/min/mmHg)	SPIRO.DLCOACT		(format 99.9)
VA (alveolar volume) (liters)	SPIRO.DLCOVA		(format 9.99)
Hemoglobin: (g/dL)	SPIRO.DLCOHEMO		(format 99.9)
Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLCOADHM		(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.BCPRTM	:	(HH24:MI)
Was DNA collected?	BC.BCDNA	○ Yes ○ No	NY code list
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLASMA	○ Yes ○ No	NY code list
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERUM	○ Yes ○ No	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 = 120, Page ID = 40)

Unique Identifier page-45995-304949-120-40

Please check if questionnaire was not performed at this visit.	UCSD.UCSDND	☐

UCSD 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.UCSD1	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level at your own pace	UCSD.UCSD2	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level with others your age	UCSD.UCSD3	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking up a hill	UCSD.UCSD4	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Walking up stairs	UCSD.UCSD5	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
While eating	UCSD.UCSD6	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Standing up from a chair	UCSD.UCSD7	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Brushing teeth	UCSD.UCSD8	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shaving and/or brushing hair	UCSD.UCSD9	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Showering/bathing	UCSD.UCSD10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Dressing	UCSD.UCSD11	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Picking up and straightening	UCSD.UCSD12	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Doing dishes	UCSD.UCSD13	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sweeping/vacuuming	UCSD.UCSD14	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Making bed	UCSD.UCSD15	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shopping	UCSD.UCSD16	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Doing laundry	UCSD.UCSD17	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Washing car	UCSD.UCSD18	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Mowing lawn	UCSD.UCSD19	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Watering lawn	UCSD.UCSD20	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sexual activities	UCSD.UCSD21	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

How much do these limit you in your daily life?

Shortness of breath	UCSD.UCSD22	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Fear of “hurting myself” by overexerting	UCSD.UCSD23	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Fear of shortness of breath	UCSD.UCSD24	○ 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.ICEEQND ☐		
Cough VAS			
Cough VAS	ICEEQ.COUGHVAS ☐		
How would rate the severity of your cough?(0-100)	ICEEQ.COUGHSEV ☐		(format 999)
ICECAP			
Not Collected	ICEEQ.ICEND ☐		
By placing a check in one box in each group below, please indicate which statement best describes your quality of life at the moment.			
Love and Friendship	ICEEQ.ICELOVE	○ I can have all of the love and friendship that I want ○ I can have a lot of the love and friendship that I want ○ I can have a little of the love and friendship that I want ○ I cannot have any of the love and friendship that I want	FRIENDS code list
Thinking about the future	ICEEQ.ICEFUTR	○ I can think about the future without any concern ○ I can think about the future with only a little concern ○ I can only think about the future with some concern ○ I can only think about the future with a lot of concern	THINKING code list

Doing things that make you feel valued	ICEEQ.ICEVALUE	○ I am able to do all of the things that make me feel valued ○ I am able to do many of the things that make me feel valued ○ I am able to do a few of the things that make me feel valued ○ I am unable to do any of the things that make me feel valued	VALUED code list
Enjoyment and pleasure	ICEEQ.ICEENJOY	○ I can have all of the enjoyment and pleasure that I want ○ I can have a lot of the enjoyment and pleasure that I want ○ I can have a little of the enjoyment and pleasure that I want ○ I cannot have any of the enjoyment and pleasure that I want	PLEASURE code list
Independence	ICEEQ.ICEINDEP	○ I am able to be completely independent ○ I am able to be independent in many things ○ I am unable to be independent in a few things ○ I am unable to be at all independent	INDEPEND code list

EQ-5D-3L

Not Collected	ICEEQ.EQND	☐

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

Mobility	ICEEQ.EQMOB	○ 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.EQSC	○ I have no problems with self-care ○ I have some problems washing or dressing myself ○ I am unable to wash or dress myself	Self-Care code list
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQUA	○ 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 list
Pain/Discomfort	ICEEQ.EQPAIN	○ I have no pain or discomfort ○ I have moderate pain or discomfort ○ I have extreme pain or discomfort	PAIN code list
Anxiety/Depression	ICEEQ.EQANX	○ I am not anxious or depressed ○ I am moderately anxious or depressed ○ I am extremely anxious or depressed	ANXIETY code list
Value of EQ-5D VAS (0-100)	ICEEQ.EQVAS		(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.SGRQND	☐	

St George's Respiratory Questionnaire

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

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

Before completing the questionnaire:

Please check one box to show how you describe your current health:	SGRQ.CURHLTH	○ Very good ○ Good ○ Fair ○ Poor ○ Very poor	CURHLTH code list

Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check one box for each question

1. Over the past 4 weeks, I have coughed:	SGRQ.STG01	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG02	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG03	○ 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.STG04	○ 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.STG05	○ 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.STG06	○ 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.STG07	○ 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.STG08	○ Yes ○ No	NY code list
Part 2 Section 1			

9. How would you describe your respiratory condition?	SGRQ.STG09	○ 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.STG10	○ 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.STG11A	○ True ○ False	cTRUFLS code list
Washing or dressing yourself	SGRQ.STG11B	○ True ○ False	cTRUFLS code list
Walking around the house	SGRQ.STG11C	○ True ○ False	cTRUFLS code list
Walking outside on a level ground	SGRQ.STG11D	○ True ○ False	cTRUFLS code list
Walking up a flight of stairs	SGRQ.STG11E	○ True ○ False	cTRUFLS code list
Walking up hills	SGRQ.STG11F	○ True ○ False	cTRUFLS code list
Playing sports or other physical activities	SGRQ.STG11G	○ True ○ False	cTRUFLS code list

Section 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.STG12A	○ True ○ False	cTRUFLS code list

Coughing makes me tired	SGRQ.STG12B	○ True ○ False	cTRUFLS code list
I am short of breath when I talk	SGRQ.STG12C	○ True ○ False	cTRUFLS code list
I am short of breath when I bend over	SGRQ.STG12D	○ True ○ False	cTRUFLS code list
My coughing or breathing disturbs my sleep	SGRQ.STG12E	○ True ○ False	cTRUFLS code list
I get exhausted easily	SGRQ.STG12F	○ 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.STG13A	○ True ○ False	cTRUFLS code list
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG13B	○ True ○ False	cTRUFLS code list
I get afraid or panic when I cannot catch my breath	SGRQ.STG13C	○ True ○ False	cTRUFLS code list
I feel that I am not in control of my respiratory problems	SGRQ.STG13D	○ True ○ False	cTRUFLS code list
I do not expect my respiratory problems to get any better	SGRQ.STG13E	○ True ○ False	cTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG13F	○ True ○ False	cTRUFLS code list
Exercise is not safe for me	SGRQ.STG13G	○ True ○ False	cTRUFLS code list
Everything seems too much of an effort	SGRQ.STG13H	○ 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.SGNOTXT	☐

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

My treatment does not help me very much	SGRQ.STG14A	○ True ○ False	cTRUFLS code list
I get embarrassed using my medication in public	SGRQ.STG14B	○ True ○ False	cTRUFLS code list

I have unpleasant side effects from my medication	SGRQ.STG14C	○ True ○ False	cTRUFLS code list
My treatment interferes with my life a lot	SGRQ.STG14D	○ True ○ False	cTRUFLS code list

Section 6

These are questions about how your activities might be affected by your respiratory problems.

15. For each statement, please check the box that applies to you because of your respiratory problems.

I take a long time to get washed or dressed	SGRQ.STG15A	○ True ○ False	cTRUFLS code list
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG15B	○ True ○ False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG15C	○ True ○ False	cTRUFLS code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG15D	○ True ○ False	cTRUFLS code list
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG15E	○ True ○ False	cTRUFLS code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG15F	○ 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.STG15G	○ 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.STF15H	○ 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.STG15I	○ True ○ False	cTRUFLS code list

Section 7

We would like to know how your respiratory problems usually affect your daily life.

16. For each statement, please check the box that applies to you because of your respiratory problems.

I cannot play sports or do other physical activities	SGRQ.STG16A	○ True ○ False	cTRUFLS code list

I cannot go out for entertainment or recreation	SGRQ.STG16B	○ True ○ False	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG16C	○ True ○ False	cTRUFLS code list
I cannot do household chores	SGRQ.STG16D	○ True ○ False	cTRUFLS code list
I cannot move far from my bed or chair	SGRQ.STG16E	○ True ○ 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:	SGRQ.STGLIST		
17. Now please check the box (one only) that you think best describes how your respiratory problems affect you:	SGRQ.STG17	○ It does not stop me from doing anything I would like to do ○ It stops me from doing one or two things I would like to do ○ It stops me from doing most of the things I would like to do ○ It stops me from doing everything I would like to do	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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation 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.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter 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.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation form

Monthly Telephone Contact

(Visit ID = 140, Page ID = 20)

Unique Identifier page-304876-304951-140-20

Please check if telephone contact was not performed at this visit.	TELE.TELEND	☐	
Telephone contact			
Date of telephone contact	TELE.TELCONDT		
Was subject determined to have died?	TELE.TELEDETH	○ Yes ○ No	NY code list
If Yes, complete the Death form			
Did subject report any adverse events (serious or non-serious?)	TELE.TELEAE	○ Yes ○ No	NY code list
If Yes, complete the Adverse Events 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.TELEHC	○ Yes ○ No	NY code list
If Yes, complete the Health Care Encounter Form			

Week 48 Visit

Date of Visit

(Visit ID = 150, Page ID = 10)

Unique Identifier page-304846-304952-150-10

Date of visit	DOV.DOVDT		
Did subject complete the visit?	DOV.DOVCOMP	○ Yes ○ No	NY code list
If no, will subject continue in the study?	DOV.DOVCONT	○ Yes ○ No	NY code list
If no, was it due to death of subject?	DOV.DOVDTH	○ Yes ○ No	NY code list
Did subject cross over to surgery?	DOV.DOVSX	○ Yes ○ No	NY code list
If yes, date of surgery?	DOV.DOVSXDT		
Has the subject had a lung transplant?	DOV.DOVLTX	○ Yes ○ No	NY code list

If yes, please complete the early discontinuation form

Concomitant Medications

(Visit ID = 150, Page ID = 120)

Unique Identifier page-304883-304952-150-120

Medications were not collected at this visit.	CMFP.CMFPND	☐	
Concomitant Medications			
Has the subject taken any of the following medications since the last visit?			
Proton Pump Inhibitors (PPI)	CMFP.CMPPI	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH2B	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Chronic prednisone (>1month)	CMFP.CMCP	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
If current, chronic/ average dose taken (mg/day):	CMFP.CMCPDOSE		(format 99.9)
Azathioprine	CMFP.CMAZT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
N-acetylcystteine (NAC)	CMFP.CMNAC	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Cotrimoxazole	CMFP.CMCOT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMMDI	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Pirfenidone	CMFP.CMPIRF	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list
Nintedanib	CMFP.CMNINT	○ Taking daily ○ Taking as needed ○ Not Current	cCMFUP code list

Documentation of GERD & Esophageal Motility

(Visit ID = 150, Page ID = 20)

Unique Identifier page-188329-304952-150-20

Please check if documentation was not collected at this visit.	GERD.GERDND	☐	
Frequency Scale for the Symptoms of GERD			
Not Collected	GERD.FQND	☐	
1. Do you get heartburn?	GERD.FQHRTBRN	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
2. Does your stomach get bloated?	GERD.FQBLOAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
3. Does your stomach ever feel heavy after meals?	GERD.FQHEAVY	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQRUB	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
5. Do you feel sick after meals?	GERD.FQSICK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
6. Do you get heartburn after meals?	GERD.FQHRTAFT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQTHROAT	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
8. Do you feel full while eating meals?	GERD.FQFULL	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
9. Do some things get stuck when you swallow?	GERD.FQSTUCK	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQACID	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
11. Do you burp a lot?	GERD.FQBURP	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list
12. Do you get heartburn if you bend over?	GERD.FQHRTBND	○ Never ○ Occasionally ○ Sometimes ○ Often ○ Always	cGFREQ code list

GERD Health Related Quality of Life

Not Collected GERD.QLND ☐

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 and 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.QLHRTBRN	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
2. Heartburn when lying down?	GERD.QLLYING	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
3. Heartburn when standing up?	GERD.QLSTAND	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
4. Heartburn after meals?	GERD.QLHRTAFT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
5. Does heartburn change your diet?	GERD.QLDIET	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
6. Does heartburn wake you from sleep?	GERD.QLSLEEP	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

7. Do you have difficulty swallowing?	GERD.QLDIFFSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
8. Do you have pain with swallowing?	GERD.QLPAINSW	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
9. Do you have bloating or gassy feelings?	GERD.QLBLOAT	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
10. If you take medication, does this affect your daily life?	GERD.QLMEDS	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

pH Monitoring Results

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	GERD.PHND	☐		
Was probe located 5cm above LES	GERD.PHPROBE	○ Yes ○ No	NY code list	
total time pH <4 (%)	GERD.PHTOTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHUPRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHSUPINE			(format 999.9)
# of reflux episodes	GERD.PHRFLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHRFLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHTMRFL			(format 999.9)

Overall DeMeester Score	GERD.PHSCORE		(format 999.9)
Manometry Results			
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	GERD.MNND	☐	
Lower esophageal sphincter (LES) data			
LES length (cm)	GERD.MNLESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNLESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNLESRDP		(format 999.9)
Upper esophageal sphincter (UES) data			
UES resting pressure (mmHg)	GERD.MNUESRTP		(format 999.9)
UES relaxation (%)	GERD.MNUESRLX		(format 999.9)
Esophageal body motility pattern			
% peristaltic contractions (%)	GERD.MNPERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNHYPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSIMUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNESOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNEBMP	○ Normal motlity ○ 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

Spirometry_DLCO

(Visit ID = 150, Page ID = 30)

Unique Identifier page-80805-304952-150-30

Please check if procedures were not performed	SPIRO.SPIROND	☐	
SPIROMETRY			
Indicate at which visit these values were collected	SPIRO.SPRVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-Bronchodilator: Primary	SPIRO.PRIMEYES	☐	
FEV1: Actual (liters)	SPIRO.PRMFEV		(format 99.99)
FVC: Actual (liters)	SPIRO.PRMFVC		(format 99.99)
VC: Actual (liters)	SPIRO.PRMVC		(format 99.99)
Pre-Bronchodilator: Replicate 1	SPIRO.REP1YES	☐	
FEV1: Actual (liters)	SPIRO.REP1FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP1FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP1VC		(format 99.99)
Pre-Bronchodilator: Replicate 2	SPIRO.REP2YES	☐	
FEV1: Actual (liters)	SPIRO.REP2FEV		(format 99.99)
FVC: Actual (liters)	SPIRO.REP2FVC		(format 99.99)
VC: Actual (liters)	SPIRO.REP2VC		(format 99.99)
DLCO			
DLCO: actual (mL/min/mmHg)	SPIRO.DLCOACT		(format 99.9)
VA (alveolar volume) (liters)	SPIRO.DLCOVA		(format 9.99)
Hemoglobin: (g/dL)	SPIRO.DLCOHEMO		(format 99.9)
Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLCOADHM		(format 99.9)

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.ABGND	☐	
Arterial Blood Gas			
FiO2 (%)	ABG.ABGFIOX		(format 999)
pH	ABG.ABGPH		(format 9.99)
PaO2 (mm Hg)	ABG.ABGPAOX		(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPACOX		(format 999.9)
SaO2 (%)	ABG.ABGSAOX		(format 999.9)

6-Minute Walk Test

(Visit ID = 150, Page ID = 50)

Unique Identifier page-80834-304952-150-50

Please check if walk test was not performed at this visit.	WALK.WALKND	☐	
6 Minute Walk Test			
Indicate at which visit these values were collected	WALK.WVISIT	○ Screening Visit ○ Enrollment Visit	
Pre-walk modified Borg Dyspnea Scale rating	WALK.PREBORG		cBORG code list
Resting room air SpO2 (%)	WALK.WKSPOX		(format 999)
Was walk performed?	WALK.WKPERF	○ Yes ○ No	NY code list
Reason	WALK.WKREASON		
Was supplemental O2 used during walk?	WALK.WKSUPOX	○ Yes ○ No	NY code list
If yes: Amount of supplemental O2? (liters/min)	WALK.WKAMTOX		(format 99)
If yes: SpO2 on supplemental O2? (%)	WALK.WKSPOSUP		(format 999)
Was a walking aid necessary to perform the 6MWT?	WALK.WKAID	○ Yes ○ No	NY code list
If yes: Specify type of walking aid	WALK.WKSPAID	○ Cane ○ Walker ○ Other	cWALK code list
Other (specify)	WALK.WKAIDOTH		
Did subject complete 6MWT?	WALK.WKCOMPL	○ Yes ○ No	NY code list
If no: What was duration of walk test?			
minutes	WALK.WKMIN		(format 9)
seconds	WALK.WKSEC		(format 99)
If no: Reason for stopping early?	WALK.WKSPRSN	○ Symptoms requiring termination ○ Other	c6MTERM code list
Other (specify)	WALK.WKRSNSP		
Distance walked (meters)	WALK.WKDIST		(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKDSAT	○ Yes ○ No	NY code list
If yes: Walk duration at desaturation			
minutes	WALK.WKDSMIN		(format 9)
seconds	WALK.WKDSSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKDSMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKLOWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POSTBORG		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	☐		
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.BCPRTM	:		(HH24:MI)
Was DNA collected?	BC.BCDNA	○ Yes ○ No	NY code list	
If yes, Yield (ml)	BC.BCDYLD			(format 99.9)
# of aliquots	BC.BCDALQ			(format 99)
Was plasma collected?	BC.BCPLASMA	○ Yes ○ No	NY code list	
If yes, Yield (ml)	BC.BCPYLD			(format 99.9)
# of aliquots	BC.BCPALQ			(format 99)
Was serum collected?	BC.BCSERUM	○ Yes ○ No	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.HRENR	○ Yes ○ No	NY code list
Was a week 48 HRCT performed on this subject?	HRCT.HRFUP	○ Yes ○ No	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	☐		
Follow-up bronchoscopy (for surgical subjects only)				
Was bronchoscopy performed on subject?	BRONCHO. BRONYN	○ Yes ○ No	NY code list	
Was bronchial alveolar lavage (BAL) fluid collected?	BRONCHO. BRBAL	○ Yes ○ No	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	○ Yes ○ No	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.UCSDND	☐

UCSD 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.UCSD1	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level at your own pace	UCSD.UCSD2	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking on a level with others your age	UCSD.UCSD3	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
Walking up a hill	UCSD.UCSD4	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Walking up stairs	UCSD.UCSD5	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
While eating	UCSD.UCSD6	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Standing up from a chair	UCSD.UCSD7	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Brushing teeth	UCSD.UCSD8	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shaving and/or brushing hair	UCSD.UCSD9	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Showering/bathing	UCSD.UCSD10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Dressing	UCSD.UCSD11	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Picking up and straightening	UCSD.UCSD12	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Doing dishes	UCSD.UCSD13	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sweeping/vacuuming	UCSD.UCSD14	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Making bed	UCSD.UCSD15	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Shopping	UCSD.UCSD16	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

Doing laundry	UCSD.UCSD17	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Washing car	UCSD.UCSD18	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Mowing lawn	UCSD.UCSD19	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Watering lawn	UCSD.UCSD20	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Sexual activities	UCSD.UCSD21	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	

How much do these limit you in your daily life?

Shortness of breath	UCSD.UCSD22	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Fear of “hurting myself” by overexerting	UCSD.UCSD23	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	
Fear of shortness of breath	UCSD.UCSD24	○ 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.ICEEQND ☐		
Cough VAS			
Cough VAS	ICEEQ.COUGHVAS ☐		
How would rate the severity of your cough?(0-100)	ICEEQ.COUGHSEV ☐		(format 999)
ICECAP			
Not Collected	ICEEQ.ICEND ☐		
By placing a check in one box in each group below, please indicate which statement best describes your quality of life at the moment.			
Love and Friendship	ICEEQ.ICELOVE	○ I can have all of the love and friendship that I want ○ I can have a lot of the love and friendship that I want ○ I can have a little of the love and friendship that I want ○ I cannot have any of the love and friendship that I want	FRIENDS code list
Thinking about the future	ICEEQ.ICEFUTR	○ I can think about the future without any concern ○ I can think about the future with only a little concern ○ I can only think about the future with some concern ○ I can only think about the future with a lot of concern	THINKING code list

Doing things that make you feel valued	ICEEQ.ICEVALUE	○ I am able to do all of the things that make me feel valued ○ I am able to do many of the things that make me feel valued ○ I am able to do a few of the things that make me feel valued ○ I am unable to do any of the things that make me feel valued	VALUED code list
Enjoyment and pleasure	ICEEQ.ICEENJOY	○ I can have all of the enjoyment and pleasure that I want ○ I can have a lot of the enjoyment and pleasure that I want ○ I can have a little of the enjoyment and pleasure that I want ○ I cannot have any of the enjoyment and pleasure that I want	PLEASURE code list
Independence	ICEEQ.ICEINDEP	○ I am able to be completely independent ○ I am able to be independent in many things ○ I am unable to be independent in a few things ○ I am unable to be at all independent	INDEPEND code list

EQ-5D-3L

Not Collected	ICEEQ.EQND	☐

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

Mobility	ICEEQ.EQMOB	○ 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.EQSC	○ I have no problems with self-care ○ I have some problems washing or dressing myself ○ I am unable to wash or dress myself	Self-Care code list
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQUA	○ 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 list
Pain/Discomfort	ICEEQ.EQPAIN	○ I have no pain or discomfort ○ I have moderate pain or discomfort ○ I have extreme pain or discomfort	PAIN code list
Anxiety/Depression	ICEEQ.EQANX	○ I am not anxious or depressed ○ I am moderately anxious or depressed ○ I am extremely anxious or depressed	ANXIETY code list
Value of EQ-5D VAS (0-100)	ICEEQ.EQVAS		(format 999)

St George's Respiratory Questionnaire

(Visit ID = 150, Page ID = 100)

Unique Identifier page-45914-304952-150-100

Please check if questionnaire was not performed at this visit.	SGRQ.SGRQND	☐	

St George's Respiratory Questionnaire

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

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

Before completing the questionnaire:

Please check one box to show how you describe your current health:	SGRQ.CURHLTH	○ Very good ○ Good ○ Fair ○ Poor ○ Very poor	CURHLTH code list

Part 1

Please describe how often your respiratory problems have affected you over the past 4 weeks.

Please check one box for each question

1. Over the past 4 weeks, I have coughed:	SGRQ.STG01	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG02	○ Almost Every Day ○ Several Days a Week ○ A Few Days a Month ○ Only with Respiratory Infections ○ Not at all	cRSPROB code list

3. Over the past 4 weeks, I have had shortness of breath:	SGRQ.STG03	○ 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.STG04	○ 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.STG05	○ 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.STG06	○ 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.STG07	○ 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.STG08	○ Yes ○ No	NY code list

Part 2
Section 1

9. How would you describe your respiratory condition?	SGRQ.STG09	○ 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.STG10	○ 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.STG11A	○ True ○ False	cTRUFLS code list
Washing or dressing yourself	SGRQ.STG11B	○ True ○ False	cTRUFLS code list
Walking around the house	SGRQ.STG11C	○ True ○ False	cTRUFLS code list
Walking outside on a level ground	SGRQ.STG11D	○ True ○ False	cTRUFLS code list
Walking up a flight of stairs	SGRQ.STG11E	○ True ○ False	cTRUFLS code list
Walking up hills	SGRQ.STG11F	○ True ○ False	cTRUFLS code list
Playing sports or other physical activities	SGRQ.STG11G	○ True ○ False	cTRUFLS code list

Section 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.STG12A	○ True ○ False	cTRUFLS code list

Coughing makes me tired	SGRQ.STG12B	○ True ○ False	cTRUFLS code list
I am short of breath when I talk	SGRQ.STG12C	○ True ○ False	cTRUFLS code list
I am short of breath when I bend over	SGRQ.STG12D	○ True ○ False	cTRUFLS code list
My coughing or breathing disturbs my sleep	SGRQ.STG12E	○ True ○ False	cTRUFLS code list
I get exhausted easily	SGRQ.STG12F	○ 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.STG13A	○ True ○ False	cTRUFLS code list
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG13B	○ True ○ False	cTRUFLS code list
I get afraid or panic when I cannot catch my breath	SGRQ.STG13C	○ True ○ False	cTRUFLS code list
I feel that I am not in control of my respiratory problems	SGRQ.STG13D	○ True ○ False	cTRUFLS code list
I do not expect my respiratory problems to get any better	SGRQ.STG13E	○ True ○ False	cTRUFLS code list
I have become frail or an invalid because of my respiratory problems	SGRQ.STG13F	○ True ○ False	cTRUFLS code list
Exercise is not safe for me	SGRQ.STG13G	○ True ○ False	cTRUFLS code list
Everything seems too much of an effort	SGRQ.STG13H	○ 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.SGNOTXT	☐

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

My treatment does not help me very much	SGRQ.STG14A	○ True ○ False	cTRUFLS code list
I get embarrassed using my medication in public	SGRQ.STG14B	○ True ○ False	cTRUFLS code list

I have unpleasant side effects from my medication	SGRQ.STG14C	○ True ○ False	cTRUFLS code list
My treatment interferes with my life a lot	SGRQ.STG14D	○ True ○ False	cTRUFLS code list

Section 6

These are questions about how your activities might be affected by your respiratory problems.

15. For each statement, please check the box that applies to you because of your respiratory problems.

I take a long time to get washed or dressed	SGRQ.STG15A	○ True ○ False	cTRUFLS code list
I cannot take a bath or shower, or I take a long time to do it	SGRQ.STG15B	○ True ○ False	cTRUFLS code list
I walk slower than other people my age, or I stop to rest	SGRQ.STG15C	○ True ○ False	cTRUFLS code list
Jobs such as household chores take a long time, or I have to stop to rest	SGRQ.STG15D	○ True ○ False	cTRUFLS code list
If I walk up one flight of stairs, I have to go slowly or stop	SGRQ.STG15E	○ True ○ False	cTRUFLS code list
If I hurry or walk fast, I have to stop or slow down	SGRQ.STG15F	○ 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.STG15G	○ 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.STF15H	○ 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.STG15I	○ True ○ False	cTRUFLS code list

Section 7

We would like to know how your respiratory problems usually affect your daily life.

16. For each statement, please check the box that applies to you because of your respiratory problems.

I cannot play sports or do other physical activities	SGRQ.STG16A	○ True ○ False	cTRUFLS code list

I cannot go out for entertainment or recreation	SGRQ.STG16B	○ True ○ False	cTRUFLS code list
I cannot go out of the house to do the shopping	SGRQ.STG16C	○ True ○ False	cTRUFLS code list
I cannot do household chores	SGRQ.STG16D	○ True ○ False	cTRUFLS code list
I cannot move far from my bed or chair	SGRQ.STG16E	○ True ○ 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:	SGRQ.STGLIST	

17. Now please check the box (one only) that you think best describes how your respiratory problems affect you:	SGRQ.STG17	○ It does not stop me from doing anything I would like to do ○ It stops me from doing one or two things I would like to do ○ It stops me from doing most of the things I would like to do ○ It stops me from doing everything I would like to do	cRSPAFT code list

CAS

Death

(Visit ID = 160, Page ID = 10)

Unique Identifier page-45934-304953-160-10

Death Form			
Where did subject die?	DEATH.DTHWHERE	○ Inpatient ○ Outpatient	
Date of death	DEATH.DTHDT		
Cause of death	DEATH.DTHCAUSE	○ Pulmonary death ○ Non-pulmonary death ○ Unknown	
Pulmonary death specify	DEATH.DTHPULM	○ Acute exacerbation (definite or suspected) ○ Progression of IPF (other than acute exacerbation) ○ Pulmonary embolism ○ Lung infection ○ Lung cancer ○ Other	
Other specify	DEATH.DTHOTH		
Non-pulmonary death specify	DEATH.DTHSPCFY		

Health Care Encounters

(Visit ID = 160, Page ID = 30)

Unique Identifier page-304895-304953-160-30

Health Care Encounters

Has the subject been admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center since the last contact? (If yes, provide details below)

Admission date	HC.HCSRTDT		
Discharge date	HC.HCENDDT		
Admission type	HC.HCADMIN	○ Hospital ○ ER/urgent care ○ Assisted living / nursing facility ○ Rehabilitation center	HCADMINTYPE code list
Reason for admission	HC.HCREASN		
Check if respiratory-related	HC.HCRESP	☐	
Major procedures performed	HC.HCPROC		
Discharge destination	HC.HCDISCHG	○ Home ○ Assisted living / nursing facility ○ Rehab center ○ Transfer to other hospital ○ Subject died ○ Other	HCDISCHRGE code list

Study Completion/ Early Discontinuation

(Visit ID = 160, Page ID = 40)

Unique Identifier page-304907-304953-160-40

Date of Completion or Discontinuation	DS.DSSTDT	
Did subject complete the study?	DS.CMPLTEYN	○ Yes ○ No NY code list
Reason for Discontinuation	DS.DSTERM	○ Death ○ Lost to Follow-Up ○ Patient Decision ○ Physician Decision ○ Lung Transplant
Please specify	DS.DSTERMSP	
Date	DS.DSLTFDT	
Date of lung transplant	DS.DSLTXDT	

AECODE

(Visit ID = 160, Page ID = 60)

Unique Identifier page-45819-304953-160-60

Visit	AEC.AECVISIT	
Adverse Event	AEC.AETERM	

CMCODE

(Visit ID = 160, Page ID = 70)

Unique Identifier page-45828-304953-160-70

Visit	CMC.CMCVISIT	
Concomitant Medication	CMC.CONMED	

RWCODE

(Visit ID = 160, Page ID = 80)

Unique Identifier page-45948-304953-160-80

Visit	RWC.RWCVISIT	
Respiratory Worsening Term	RWC.RWTERM	

AE

Adverse Events

(Visit ID = 170, Page ID = 10)

Unique Identifier page-304919-304954-170-10

Adverse Events			
AEID	AE.AEID		
Adverse event	AE.AEVENT	○ Respiratory worsening ○ Difficulty swallowing / dysphagia ○ Bloating ○ Flatulence ○ Other	AE EVENT code list
Respiratory worsening specify:	AE.RESPSPEC	○ Community / hospital acquired pneumonia ○ Bronchitis ○ Aspiration pneumonitis ○ Pulmonary embolism ○ Pneumothorax ○ Non-pulmonary cause (e.g. anxiety) ○ Unknown cause	RESPIRATORY code list
Unknown cause specify:	AE.UNKSPCFY	○ Definite acute exacerbation ○ Suspected acute exacerbation ○ Unclassifiable	UNKSPECIFY code list
Other AE specify	AE.AEOTH		
Onset date	AE.AEONSTDT		
End date	AE.AEENDDT		
AE Ongoing	AE.AECONT	☐	
Hospitalized?	AE.HOSP	○ Yes ○ No	NY code list

If Yes, complete the Health Care Encounter Form

Maximum intensity	AE.AEINTNS	○ Mild ○ Moderate ○ Severe	AESEV code list
Was event serious?	AE.AESER	○ Yes ○ No	NY code list
Relationship to intervention	AE.AEREALTE	○ Not a reasonable possibility ○ Reasonable possibility	AERELAT code list
Final outcome	AE.AEOUTCME	○ Subject died ○ Resolved no sequelae ○ Resolved with sequelae ○ Unresolved	FOUTCOME code list

Serious Adverse Events

(Visit ID = 170, Page ID = 20)

Unique Identifier page-45862-304954-170-20

AE Reference ID		(remote value)
This event was marked Serious. Please indicate Serious criteria below (check all that apply).		
Death	SAE.SAESDTH	☐
If Death is selected, was an autopsy performed?	SAE.AUTOPSY	○ Yes ○ No NY code list
Life-threatening	SAE.SAESLIFE	☐
Require inpatient hospitalization or prolongation of existing hospitalization	SAE.SAESHOSP	☐
Persistent or significant disability / incapacity	SAE.SAEDISAB	☐
Congenital anomaly or birth defect	SAE.SAESCONG	☐
Important medical event	SAE.SAESIME	☐
Provide a summary in chronological order of the clinical course of this SAE from onset through resolution. 1. Presenting signs and symptoms 2. Treatments and response to treatments 3. Status of subject at time of report and / or final outcome, as applicable		
Summary	SAE.NARSYMP	
Additional Summary	SAE.NARSYMP1	
Additional Summary	SAE.NARSYMP2	
Additional Summary	SAE.NARSYMP3	
Additional Summary	SAE.NARSYMP4	
Additional Summary	SAE.NARSYMP5	
Additional Summary	SAE.NARSYMP6	
Additional Summary	SAE.NARSYMP7	
Investigator 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	☐