# 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

I Indiana	0.4.	Disales Took	1111111111
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	99999997	Not Done	
codelist- 45836	99999999	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	ТР	Total Protein	
codelist- 45847	UA	Uric Acid	
codelist- 45847	HGB	Hemoglobin	
codelist- 45847	НСТ	Hematocrit	
codelist- 45847	МСН	Mean Corpuscular Hemoglobin (MCH)	
codelist- 45847	мснс	Mean Corpuscular Hemoglobin Concentration (MCHC)	
codelist- 45847	MCV	Mean Corpuscular Volume (MCV)	
codelist- 45847	PLAT	Platelet Count	
codelist- 45847	RBC	Red Blood Cell (RBC) Count	
codelist- 45847	WBC	White Blood Cell (WBC) Count	
codelist- 45847	LYM	Lymphocytes	
codelist- 45847	MONO	Monocytes	
codelist- 45847	BASO	Basophils	
codelist- 45847	EOS	Eosinophils	
codelist- 45847	NEUT	Neutrophils	
codelist- 45847	CAST	Casts	
codelist- 45847	KET	Ketone	
codelist- 45847	NIT	Nitrite	
codelist- 45847	PH	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	В	Black or African American	
codelist- 45859	A	Asian	
codelist- 45859	I	American Indian or Alaska Native	
codelist- 45859	Р	Native Hawaiian or Other Pacific Islander	
codelist- 45859	М	Mixed Race	
codelist- 45859	0	Other	

#### 3.46. RACEb

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

## 3.47. RADREVIEW

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

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

#### 3.48. RELATIONSHIP

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

#### 3.49. RESPIRATORY

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

## 3.50. ROUTE

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

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

## 3.51. ROUTEa

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

## 3.52. SEVER

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

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

#### 3.53. SEX

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

## 3.54. SMOKER

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

#### 3.55. STENRF

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

## 3.56. SUBJRAND

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

#### 3.57. Self-Care

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

## 3.58. Study Drug Name

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

#### 3.59. THINKING

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

## 3.60. UCSDBREATH

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

#### 3.61. 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		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		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.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code list	
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?  If yes, please complete the ear	DOV.DOVLT X	O No	NY code list	
yez, p.eaes complete and car	.,			

#### **Informed Consent**

(Visit ID = 10, Page ID = 20)

Unique Identifier page-45933-304938-10-20

Cons	ent						
<b>5</b>	Date subject signed informed consent	CONSENT.I NFCONDT					
	Did subject consent for biological impact sub-study?	CONSENT.B IOSUB	0	Yes No	NY code list		
	Did subject consent to share data for additional research?	CONSENT.A DDDATA	0	Yes No	NY code list		
	Did subject consent to have specimens stored for additional research?	CONSENT.S PECDATA	_	Yes No	NY code list		
	Did subject consent to share biological specimens for research?	CONSENT.B IODATA	0	Yes No	NY code list		
Scree	Screen Failure						
	Subject deemed screen failure	CONSENT.S CRNFAIL	0	Yes No	NY code list		
	If yes, specify reason	CONSENT.S FREASON					
	Date	CONSENT.S FAILDT		•			

# Demographics

(Visit ID = 10, Page ID = 30)

Unique Identifier page-45834-304938-10-30

Dome	ographics				
a Demo	Date of Birth	DM.BRTHD T	10		
	Sex	DM.SEX	<ul><li>Male</li><li>Female</li></ul>	SEX code list	
Ethni	city				
	Of Hispanic or Latino ethnicity	DM.ETHNIC	<ul><li>Yes</li><li>No</li></ul>	NY code list	
Race					
	White	DM.WHITE			
	Black or African American	DM.BLACK			
	Asian	DM.ASIAN			
	American Indian or Alaska Native	DM.NATIVE			
	Native Hawaiian or Pacific Islander	DM.HAWAII			
	Other Race	DM.RCOTH ER			
Smok	king History				
	Smoking status	DM.SMOKE	<ul><li>Current</li><li>Former</li><li>Never</li></ul>	SMOKER code list	
	If past smoker, date last smoked	DM.SMOKE DT			
	How many total years has subject smoked? (years)	DM.SMOKE YRS		(format 99)	
	On average during that time, how many packs (or equivalents) per day of cigarettes did the subject smoke? (packs/day)	DM.SMOKP ACK		(format 9.9)	

## Medical History

(Visit ID = 10, Page ID = 40)

Unique Identifier page-45852-304938-10-40

cal History- Does subject have any	history <u>of:</u>		
Coronary artery disease	MH.CAD	<ul><li>Yes</li><li>No</li></ul>	NY code list
Acute MI	MH.ACUTE MI	<ul><li>Yes</li><li>No</li></ul>	NY code list
Valvular heart disease	MH.VALVHD	<ul><li>Yes</li><li>No</li></ul>	NY code list
Heart failure	MH.HF	<ul><li>Yes</li><li>No</li></ul>	NY code list
Atrial fibrillation	MH.AFIB	<ul><li>Yes</li><li>No</li></ul>	NY code list
Diabetes	MH.DIABET ES	<ul><li>Yes</li><li>No</li></ul>	NY code list
Pulmonary hypertension	MH.PULMH Y	<ul><li>Yes</li><li>No</li></ul>	NY code list
Chronic obstructive pulmonary disease (COPD)	MH.COPD	<ul><li>Yes</li><li>No</li></ul>	NY code list
Asthma	MH.ASTHM A	<ul><li>Yes</li><li>No</li></ul>	NY code list
Pulmonary embolism	MH.PEMBL	<ul><li>Yes</li><li>No</li></ul>	NY code list
Lung cancer	MH.LUNGC ANC	<ul><li>Yes</li><li>No</li></ul>	NY code list
Other cancer	MH.OTHCA NC	<ul><li>Yes</li><li>No</li></ul>	NY code list
Gastroesophageal reflux (GER)	MH.GERD	<ul><li>Yes</li><li>No</li></ul>	NY code list
Barrett's esophagus	MH.BRTES OPH	<ul><li>Yes</li><li>No</li></ul>	NY code list
Hiatal hernia	MH.HIATAL	<ul><li>Yes</li><li>No</li></ul>	NY code list
Hospitalization for pneumonia / respiratory cause in last 6 months	MH.HOSPP NEU	<ul><li>Yes</li><li>No</li></ul>	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.HRTRAT E	(format 999)
SpO2 (%)	VS.SPOX	(format 999)

### Exclusion\_HRCT\_Lung Biopsy

(Visit ID = 10, Page ID = 60)

Unique Identifier page-45839-304938-10-60

Exclu	sion			
855	FVC %pred (%)	EXCLUSON. FVC	(fc	ormat 999)
	FEV1/FVC ratio (%)	EXCLUSON. FEVFVC	(fc	ormat 9.99)
	Resting room air PaO2 (mmHg)	EXCLUSON. PAOAIR	(fc	ormat 999)
	Distance walked on screening 6MWT (m)	EXCLUSON. WALKED	(fc	ormat 9999)
HRCT	Г			
	Date of HRCT scan	EXCLUSON. HCRTDT		
	Local radiology review (Choose one category)	EXCLUSON. RADRVW	<ul> <li>UIP pattern</li> <li>Possible UIP pattern</li> <li>Inconsistent with UIP pattern</li> </ul>	DREVIEW code list
	Reason:	EXCLUSON. RVWREAS		
	Date of HRCT review	EXCLUSON. HRCTRVW		
Lung	Biopsy			
	Was lung biopsy reviewed?	EXCLUSON. LUNGBIOP	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>	
	Date of biopsy	EXCLUSON. BIOPDT		
	Local pathology review (Choose one category)	EXCLUSON. PATHRVW	<ul> <li>UIP pattern</li> <li>Probable UIP pattern</li> <li>Possible UIP pattern</li> <li>Not UIP pattern</li> </ul>	HREVIEW 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 wa medications?	Is subject currently taking or was subject previously taking any of the following medications?						
Proton Pump Inhibitors (PPI)	CM.CMPPI	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list				
H2 Blockers (H2 Receptor Antagonists)	CM.CMH2B	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list				
Chronic prednisone (>1month)	CM.CMCP	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list				
If current or previous, chronic/ average dose taken (mg/day):	CM.CMCPD OSE		(format 99.9)				
Azathioprine	CM.CMAZT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list				
N-acetylcystteine (NAC)	CM.CMNAC	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list				
Cotrimoxazole	CM.CMCOT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list				

Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CM.CMMDI	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list
Pirfenidone	CM.CMPIRF	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	cCONMED code list
Nintedanib	CM.CMNINT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Previously taking (not current)</li><li>Never used</li></ul>	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.ABGN □ D	
Arterial Blood Gas		
FiO2 (%)	ABG.ABGFI OX	(format 999)
рН	ABG.ABGP H	(format 9.99)
PaO2 (mm Hg)	ABG.ABGPA OX	(format 999.9)
PaCO2 (mm Hg)	ABG.ABGPA COX	(format 999.9)
SaO2 (%)	ABG.ABGSA OX	(format 999.9)

### 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.GER DND					
Frequency Scale for the Symptoms of GERD							
	Not Collected	GERD.FQN D					
	1. Do you get heartburn?	GERD.FQH RTBRN	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list			
	2. Does your stomach get bloated?	GERD.FQBL OAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list			
	3. Does your stomach ever feel heavy after meals?	GERD.FQH EAVY	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list			
	4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQR UB	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list			
	5. Do you feel sick after meals?	GERD.FQSI CK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list			
	6. Do you get heartburn after meals?	GERD.FQH RTAFT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list			

7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQT HROAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
8. Do you feel full while eating meals?	GERD.FQF ULL	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
9. Do some things get stuck when you swallow?	GERD.FQST UCK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQA CID	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
11. Do you burp a lot?	GERD.FQB URP	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
12. Do you get heartburn if you bend over?	GERD.FQH RTBND	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
GERD Health Related Quality of Life			
Not Collected	GERD.QLN		

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

0-No symptoms

1-Symptoms noticeable, but not bothersome

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

- 5-Symptoms are incapacitating, unable to do daily activities

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

7. Do you have difficulty swallowing?	GERD.QLDI FFSW	0 0 1 0 2 0 3 0 4 0 5		
8. Do you have pain with swallowing?	GERD.QLPA INSW	0 0 1 0 2 0 3 0 4 0 5		
9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	0 0 1 0 2 0 3 0 4 0 5		
10. If you take medication, does this affect your daily life?	GERD.QLM EDS	0 0 1 0 2 0 3 0 4 0 5		
pH Monitoring Results		3		
Per Protocol Amendment 3, all Visit	patients sho	uld check th	ne Not Collec	ted Box at the Week 12
Per Protocol Amendment 3, no Week 24 Visit	n surgery pa	tients should	d check the N	Not Collected Box at the
Not Collected	GERD.PHN D			
Was probe located 5cm above LES	GERD.PHP ROBE	<ul><li>Yes</li><li>No</li></ul>	NY code lis	t
total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
# of reflux episodes	GERD.PHR FLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHT MRFL			(format 999.9)

C	Overall DeMeester Score	GERD.PHS CORE		(format 999.9)
Manom	etry Results			
	Per Protocol Amendment 3, all   /isit	patients sho	ould check the Not Collec	ted Box at the Week 12
	Per Protocol Amendment 3, nor Week 24 Visit	n surgery pa	atients should check the l	Not Collected Box at the
	Not Collected	GERD.MNN D		
	ower esophageal sphincter (LE	,		
L	LES length (cm)	GERD.MNL ESLNG		(format 99.9)
L	LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)
L	LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)
	Jpper esophageal sphincter (UI JES resting pressure (mmHg)	ES) data GERD.MNU ESRTP		(format 999.9)
L	JES relaxation (%)	GERD.MNU ESRLX		(format 999.9)
Е	Esophageal body motility patter	n		
	% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)
	% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)
	% simultaneous contractions %)	GERD.MNSI MUCN		(format 999.9)
N e	Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)
	Esophageal body motility pattern (select only one)	GERD.MNE BMP	<ul> <li>Normal motity</li> <li>Ineffective (&lt;80% normal contraction)</li> <li>Severely ineffective (&lt;30% normal contraction)</li> <li>Diffuse/distal esophageal spasm (simultaneous contractions in &gt;10% of swallows, with amp &gt; 30mmHg)</li> <li>Aperistalsis (no peristaltic activity observed in esophageal body)</li> </ul>	cEBMP code list
			ocopiiagoai body)	

# **Enrollment Visit**

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

Date of visit	DOV.DOVD T	<b>II</b>	
Did Subject comblete the visit:	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code list
II IIO. WIII SUDICCI COITIIIIUC III	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code list
	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code list
	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code list
	DOV.DOVS XDT		
Has the subject had a lung transplant?	DOV.DOVLT X	<ul><li>Yes</li><li>No</li></ul>	NY code list
If yes, please complete the early	/ discontinu	ation form	

### **Enrollment Information**

(Visit ID = 20, Page ID = 20)

Unique Identifier page-45937-304939-20-20

Enrol	Iment Information				
	Does subject meet all study inclusion / exclusion criteria?	ENROLL.IN CEXCL	<ul><li>Yes</li><li>No</li></ul>	NY code list	
<b>55</b>	Enrollment date	ENROLL.EN ROLLDT			
88	Subject randomization	ENROLL.SU BRAND	<ul><li>Surgery</li><li>OMT</li></ul>	SUBJRAND	
	Randomization Date		(remote value)		
	Randomization		(remote value)		

### Spirometry\_DLCO

(Visit ID = 20, Page ID = 30)

Unique Identifier page-80805-304939-20-30

	Please check if procedures were not performed	SPIRO.SPIR OND			
SPIR	OMETRY				
	Indicate at which visit these values were collected	SPIRO.SPR VISIT	0	Screening Visit Enrollment Visit	cSCRENR code list
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES			
	FEV1: Actual (liters)	SPIRO.PRM FEV			(format 99.99)
<b>55</b>	FVC: Actual (liters)	SPIRO.PRM FVC			(format 99.99)
	VC: Actual (liters)	SPIRO.PRM VC			(format 99.99)
	Pre-Bronchodilator: Replicate 1	SPIRO.REP 1YES			
	FEV1: Actual (liters)	SPIRO.REP 1FEV			(format 99.99)
	FVC: Actual (liters)	SPIRO.REP 1FVC			(format 99.99)
	VC: Actual (liters)	SPIRO.REP 1VC			(format 99.99)
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES			
	FEV1: Actual (liters)	SPIRO.REP 2FEV			(format 99.99)
	FVC: Actual (liters)	SPIRO.REP 2FVC			(format 99.99)
	VC: Actual (liters)	SPIRO.REP 2VC			(format 99.99)
DLCC					
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT			(format 99.9)
	VA (alveolar volume) (liters)	SPIRO.DLC OVA			(format 9.99)
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO			(format 99.9)
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM			(format 99.9)

### 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.WAL KND	
6 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	<ul><li>Screening Visit</li><li>Enrollment Visit</li></ul>
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	WALK.WKAI D	<ul><li>Yes</li><li>NY code list</li><li>No</li></ul>
	If yes: Specify type of walking aid	WALK.WKS PAID	<ul><li>Cane</li><li>Walker cWALK code list</li><li>Other</li></ul>
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	<ul><li>Yes</li><li>NY code list</li><li>No</li></ul>
	If no: What was duration of wall	c test?	
	minutes	WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	<ul><li>Symptoms requiring termination</li><li>Other</li><li>c6MTERM code list</li></ul>
	Other (specify)	WALK.WKR SNSP	
<b>5</b> 5	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKD SAT	<ul><li>Yes</li><li>No</li></ul>	NY code list		
If yes: Walk duration at desatu	ration				
minutes	WALK.WKD SMIN			(format 9)	
seconds	WALK.WKD SSEC			(format 99)	
If yes: walk distance at desaturation (meters)	WALK.WKD SMTR			(format 9999)	
Lowest SpO2 (%)	WALK.WKL OWSP			(format 999)	
Post-walk modified Borg Dyspnea Scale rating	WALK.POST BORG		<u> </u>	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.BCPRT M		(HH24:MI)
Was DNA collected?	BC.BCDNA	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>	
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLAS MA	<ul><li>Yes NY code list</li><li>No</li></ul>	
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERU M	<ul><li>Yes</li><li>Ny code list</li><li>No</li></ul>	
If yes, Yield (ml)	BC.BCSYLD		(format 99.9)
# of aliquots	BC.BCSALQ		(format 99)

### **HRCT Collection**

(Visit ID = 20, Page ID = 60)

Unique Identifier page-45939-304939-20-60

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

### UCSD Shortness of Breath Questionnaire

(Visit ID = 20, Page ID = 70)

Unique Identifier page-45995-304939-20-70

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

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

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

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

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

### Patient Reported Outcome Battery

(Visit ID = 20, Page ID = 80)

Unique Identifier page-45844-304939-20-80

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

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

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

### St George's Respiratory Questionnaire

(Visit ID = 20, Page ID = 90)

Unique Identifier page-45914-304939-20-90

	Please check if questionnaire was not performed at this visit.	SGRQ.SGR QND		
St Geo	orge's Respiratory Questionnaire			
t i	This questionnaire is designed t troubling you and how it affects illness cause you the most prob problems are.	your life. W	e are using it to find ou	it which aspects of your
	Please read the instructions car spend too long deciding about y			tand anything. Do not
F	Before completing the questions Please check one box to show how you describe your current health:		<ul><li>Very good</li><li>Good</li><li>Fair</li><li>Poor</li><li>Very poor</li></ul>	CURHLTH code list
Part 1			very poor	
\ 	Please describe how often your weeks. Please check one box for each of the past 4 weeks, I have coughed:		<ul> <li>Almost Every Day</li> <li>Several Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> <li>Not at all</li> </ul>	cRSPROB code lis
ŀ	2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG0 2		cRSPROB code lis

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

9. How would you describe your respiratory condition?	SGRQ.STG0 9	<ul><li>The most important I have</li></ul>		
		<ul><li>Causes m lot of prob</li></ul>		cRSCON code
		<ul><li>Causes m problems</li></ul>		
		<ul><li>Causes n problems</li></ul>		
10. If you have ever held a job	SGRQ.STG1	O My repriati problems me stop v altogether	måde vorking	
		<ul> <li>My respiration problems with my journal made me my job</li> </ul>	interfere b or	cJOB code lis
		<ul> <li>My respiration</li> <li>problems</li> <li>affect my</li> </ul>	do not	
Sitting or lying still	SGRQ.STG1 1A	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Washing or dressing yourself	SGRQ.STG1 1B	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Walking around the house	SGRQ.STG1 1C	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Walking outside on a level ground	SGRQ.STG1 1D	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Walking up a flight of stairs	SGRQ.STG1 1E	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Walking up hills	SGRQ.STG1 1F	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Playing sports or other physical activities	SGRQ.STG1 1G	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
tion 3				
These are more questions about	4	h and chartnes	ee of breath	Albana dava
12. For each statement, please				•
Coughing hurts		ox that applies		_

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

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

entertainment or recreation  I cannot go out of the house to do the shopping  I cannot do household chores  I cannot move far from my bed or chair  Here is a list of other activities the (You do have to check these; the may affect you.)  •Going for walks or walking the depoing activities or chores at hone •Sexual intercourse  •Going to a place of worship, or a efficient or playing please write in any other important activities that your respiratory problems may stop you from doing:	y are just to og ne or in the a place of e smoky roe	<ul> <li>False</li> <li>True</li> <li>False</li> <li>True</li> <li>True</li> <li>False</li> <li>True</li> <li>True</li> <li>False</li> <li>True</li> <li>True</li> <li>True cTRUFLS code list</li> <li>False</li> <li>False</li> <li>piratory problems may prevent you from doing. to remind you of ways your shortness of breath</li> </ul>
I cannot do household chores I cannot move far from my bed or chair  Here is a list of other activities the (You do have to check these; the may affect you.) •Going for walks or walking the depoing activities or chores at home sexual intercourse •Going to a place of worship, or a egoing out in bad weather or into evisiting family or friends or playing Please write in any other important activities that your respiratory problems may stop you from doing:  17. Now please check the box (one only) that you think best describes how your respiratory	GGRQ.STG1 GGRQ.STG1 GE  at your reserver are just to og the or in the or in the or smoky rook	<ul> <li>False</li> <li>True cTRUFLS code list</li> <li>False</li> <li>True cTRUFLS code list</li> <li>False</li> </ul> piratory problems may prevent you from doing, to remind you of ways your shortness of breath
I cannot move far from my bed or chair  Here is a list of other activities the (You do have to check these; the may affect you.)  Going for walks or walking the depoing activities or chores at home sexual intercourse  Going to a place of worship, or a egoing out in bad weather or into evisiting family or friends or playing Please write in any other important activities that your respiratory problems may stop you from doing:  17. Now please check the box (one only) that you think best describes how your respiratory	at your res y are just to og ne or in the smoky roe	False True cTRUFLS code list False piratory problems may prevent you from doing. to remind you of ways your shortness of breath
Here is a list of other activities the (You do have to check these; the may affect you.)  •Going for walks or walking the d •Doing activities or chores at hon •Sexual intercourse •Going to a place of worship, or a •Going out in bad weather or into •Visiting family or friends or playing please write in any other important activities that your respiratory problems may stop you from doing:  17. Now please check the box (one only) that you think best describes how your respiratory	at your res y are just to og ne or in the a place of e smoky roe	Piratory problems may prevent you from doing. to remind you of ways your shortness of breath
(You do have to check these; the may affect you.)  •Going for walks or walking the d •Doing activities or chores at hon •Sexual intercourse •Going to a place of worship, or a •Going out in bad weather or into •Visiting family or friends or playing Please write in any other important activities that your respiratory problems may stop you from doing:  17. Now please check the box (one only) that you think best describes how your respiratory	y are just to og ne or in the a place of e smoky roe	to remind you of ways your shortness of breath
(You do have to check these; the may affect you.)  •Going for walks or walking the d •Doing activities or chores at hon •Sexual intercourse •Going to a place of worship, or a •Going out in bad weather or into •Visiting family or friends or playing Please write in any other important activities that your respiratory problems may stop you from doing:  17. Now please check the box (one only) that you think best describes how your respiratory	y are just to og ne or in the a place of e smoky roe	to remind you of ways your shortness of breath
(one only) that you think best describes how your respiratory	GGRQ.STGL ST	
	GRQ.STG1	<ul> <li>It does not stop         me from doing         anything I would         like to do</li> <li>It stops me from         doing one or two         things I would like         to do</li> <li>It stops me from</li> </ul>

# **Surgical Intervention**

Date of Visit (Visit ID = 30, Page ID = 10) Unique Identifier page-304846-304940-30-10

Date of visit	DOV.DOVD T				
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code lis	et	
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code lis	et	
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code lis	et .	
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code lis	t	
If yes, date of surgery?	DOV.DOVS XDT				
Has the subject had a lung transplant?  If yes, please complete the ear	DOV.DOVLT X	<ul><li>Yes</li><li>No</li></ul>	NY code lis	st .	
yee, pieaes complete and call	.,				

### **Surgical Intervention**

(Visit ID = 30, Page ID = 20)

Unique Identifier page-103007-304940-30-20

	ery information					
655	Did subject receive the surgical intervention?	SURGINFO. SURGYN	0	Yes No	NY code list	
<b>5</b>	Date of surgery	SURGINFO. SURGDT				
	Was bronchoscopy performed on subject?	SURGINFO. BRONCHO	0	Yes No	NY code list	
	Was bronchial alveolar lavage (BAL) fluid collected?	SURGINFO. BALFLUID	0	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	0	Yes No	NY code list	
	Number of brushes sent	SURGINFO. AECBRUSH				(format 99)
Pre-o	perative details					
	Any previous abdominal surgery affecting the operative field?	PREOP.PRE VSURG	0	Yes No	NY code list	
	Type of surgery	PREOP.TYP ESURG				
	Pre-operative testing performed	ı				
	Endoscopy	PREOP.EN DOSCPY		Yes No	NY code list	
	Barium swallow	PREOP.BAR IUM	0	Yes No	NY code list	
	Echocardiogram	PREOP.EK G	0	Yes No	NY code list	
	If yes, RVSP (mmHg)	PREOP.RSV PVAL				(format 99)
	Right heart catheterization	PREOP.RG HTHRT	0	Yes No	NY code list	
	If yes, mean PA (mmHg)	PREOP.ME ANPA				(format 99)
	Gastric emptying study	PREOP.GA STRIC		Yes No	NY code list	
	Chest x-ray	PREOP.CH STXRAY		Yes No	NY code list	

tra-operative details Operative time (mins)	INTROP.OP			(format 999)
Estimated blood loss (cc)	TM INTROP.BL			(format 9999)
Intraoperative complications?	DLOSS INTROP.INT RCMP	O Yes	NY code list	(.o.mat cooc)
If yes, select complications (Select all that apply)	INTROP.SL CTCOMP	DELETE SELECT		ATION code list
Conversion to open procedure?	INTROP.OP NPROC	O Yes	NY co	ode list
Was mesh used during procedure?	INTROP.ME SH	<ul><li>Yes</li><li>No</li></ul>	NY co	ode list
Size of bougie used in procedure	INTROP.BO UGIE	<ul> <li>None</li> <li>52</li> <li>54</li> <li>56</li> <li>58</li> <li>60</li> <li>Other</li> </ul>		JGIE code list
Other (Fr.)	INTROP.OT HBOGI			(format 99)
Length of Nissen (cm)	INTROP.NIS SEN			(format 99.99)
Length of Nissen - Unknown	INTROP.NS SENUNK			
Hiatus hernia present	INTROP.HIH ERNIA	<ul><li>Yes</li><li>No</li></ul>	NY co	de list
If yes, size of hernia	INTROP.HR NIASZE	o mediu	(2-3 cm) m (3-4 cm) 4+ cm) sophageal	HERNIASIZE code
Identification and preservation of vagus nerges?	INTROP.VG USNERG	<ul><li>Yes</li><li>No</li></ul>	NY cod	le list
Esophageal lengthening procedure added?	INTROP.LE NGTHN	<ul><li>Yes</li><li>No</li></ul>	NY coo	le list
Were there other abnormal intraoperative findings?	INTROP.OT HABNYN	<ul><li>Yes</li><li>No</li></ul>	NY coo	le list
Other abnormal intraoperative (Select all that apply) Cirrhosis	indings INTROP.CIR RH			

Hypersplenism	INTROP.HS PN	
Hepatomegaly	INTROP.HP TMGLY	
Evidence of portal hypertension	INTROP.PH TN	
Presence of intra-abdominal adhesions	INTROP.INA BDADH	
Variant anatomy	INTROP.VA RANAT	
Other	INTROP.AB NOTHR	
If Variant anatomy, Describe	INTROP.VA RIANAT	

# **Month 1 Telephone Contact**

Date of Visit (Visit ID = 40, Page ID = 10) Unique Identifier page-304846-304941-40-10

Date of visit	DOV.DOVD T			
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code list	
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If yes, date of surgery?	DOV.DOVS XDT			
Has the subject had a lung transplant?  If yes, please complete the earl	DOV.DOVLT X	<ul><li>Yes</li><li>No</li></ul>	NY code list	
yee, prease complete the can	,			

# Monthly Telephone Contact

(Visit ID = 40, Page ID = 20)

Unique Identifier page-304876-304941-40-20

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

## Post-Operative Details

(Visit ID = 40, Page ID = 30)

Unique Identifier page-45945-304941-40-30

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

# **Month 2 Telephone Contact**

Date of Visit (Visit ID = 50, Page ID = 10) Unique Identifier page-304846-304942-50-10

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

# 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.TELE ND			
Telephone contact				
Date of telephone contact	TELE.TELC ONDT			
Was subject determined to have died?	TELE.TELE DETH	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If Yes, complete the Death form Did subject report any adverse events (serious or non- serious?)		<ul><li>Yes</li><li>No</li></ul>	NY code list	
If Yes, complete the Adverse E	vents form			
Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	HC	<ul><li>Yes</li><li>No</li></ul>	NY code list	
If Yes, complete the Health Ca	re Encounte	r Form		

# Week 12 Visit

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

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

### **Concomitant Medications**

(Visit ID = 60, Page ID = 100)

Unique Identifier page-304883-304943-60-100

Medications were not collected at this visit.	CMFP.CMF PND		
Concomitant Medications			
Has the subject taken any of the Proton Pump Inhibitors (PPI)	e following r CMFP.CMP	medications since the las  Taking daily	t visit?
	PI	<ul><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH 2B	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Chronic prednisone (>1month)	CMFP.CMC P	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
If current, chronic/ average dose taken (mg/day):	CMFP.CMC PDOSE		(format 99.9)
Azathioprine	CMFP.CMA ZT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
N-acetylcystteine (NAC)	CMFP.CMN AC	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Cotrimoxazole	CMFP.CMC OT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMM DI	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Pirfenidone	CMFP.CMPI RF	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Nintedanib	CMFP.CMNI NT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	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.GER DND		
Frequ	uency Scale for the Symptoms of Gl	ERD		
	Not Collected	GERD.FQN D		
	1. Do you get heartburn?	GERD.FQH RTBRN	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	2. Does your stomach get bloated?	GERD.FQBL OAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	3. Does your stomach ever feel heavy after meals?	GERD.FQH EAVY	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQR UB	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	5. Do you feel sick after meals?	GERD.FQSI CK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	6. Do you get heartburn after meals?	GERD.FQH RTAFT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list

	7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQT HROAT	000	Never Occasionally Sometimes Often Always	cGFREQ code list
	8. Do you feel full while eating meals?	GERD.FQF ULL	0 0 0 0	Never Occasionally Sometimes Often Always	cGFREQ code list
	9. Do some things get stuck when you swallow?	GERD.FQST UCK	000	Never Occasionally Sometimes Often Always	cGFREQ code list
	10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQA CID	0 0 0 0	Never Occasionally Sometimes Often Always	cGFREQ code list
	11. Do you burp a lot?	GERD.FQB URP	000	Never Occasionally Sometimes Often Always	cGFREQ code list
	12. Do you get heartburn if you bend over?	GERD.FQH RTBND	0 0 0 0	Never Occasionally Sometimes Often Always	cGFREQ code list
GERI	D Health Related Quality of Life				
	Not Collected	GERD.QLN			

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

- 0-No symptoms
- 1-Symptoms noticeable, but not bothersome
- 2-Symptoms noticeable, but not bothlersome, 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? GERT	SERD.QLH 0 0 RTBRN 0 1 0 2 0 3 0 4 0 5
2. Heartburn when lying down? GE	
3. Heartburn when standing GE AN	GERD.QLST 0 0 0 1 0 2 0 3 0 4 0 5
4. Heartburn after meals? GERT	SERD.QLH
5. Does heartburn change your GE diet?	SERD.QLDI
6. Does heartburn wake you GE from sleep?	GERD.QLSL

	7. Do you have difficulty swallowing?	GERD.QLDI FFSW	0 0 1 0 2 0 3 0 4 0 5		
	8. Do you have pain with swallowing?	GERD.QLPA INSW	0 0 1 0 2 0 3 0 4 0 5		
	9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	0 0 1 0 2 0 3 0 4 0 5		
	10. If you take medication, does this affect your daily life?	GERD.QLM EDS	0 0 1 0 2 0 3 0 4 0 5		
nH M	lonitoring Results		3		
pi i iv	Per Protocol Amendment 3, all Visit	patients sho	uld check	the Not Collec	ted Box at the Week 12
	Per Protocol Amendment 3, no Week 24 Visit	n surgery pa	tients sho	ould check the l	Not Collected Box at the
	Not Collected	GERD.PHN D			
	Was probe located 5cm above LES	GERD.PHP ROBE	<ul><li>Yes</li><li>No</li></ul>	NY code list	
	total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
	upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
	supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
	# of reflux episodes	GERD.PHR FLEPS			(format 999.9)
	# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
	Longest reflux episode (mins)	GERD.PHT MRFL			(format 999.9)

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

# Spirometry\_DLCO

(Visit ID = 60, Page ID = 30)

Unique Identifier page-80805-304943-60-30

	Please check if procedures were not performed	SPIRO.SPIR OND				
SPIR	OMETRY					
	Indicate at which visit these values were collected	SPIRO.SPR VISIT	0	Screening Visit Enrollment Visit		
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES				
	FEV1: Actual (liters)	SPIRO.PRM FEV			(format 99.99)	
<b>66</b>	FVC: Actual (liters)	SPIRO.PRM FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.PRM VC			(format 99.99)	
	Pre-Bronchodilator: Replicate 1	SPIRO.REP 1YES				
	FEV1: Actual (liters)	SPIRO.REP 1FEV			(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 1FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 1VC			(format 99.99)	
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES				
	FEV1: Actual (liters)	SPIRO.REP 2FEV			(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 2FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 2VC			(format 99.99)	
DLCC						
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT			(format 99.9)	
	VA (alveolar volume) (liters)	SPIRO.DLC OVA			(format 9.99)	
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO			(format 99.9)	
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM			(format 99.9)	

#### Arterial Blood Gas

(Visit ID = 60, Page ID = 40)

Unique Identifier page-45888-304943-60-40

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

### 6-Minute Walk Test

(Visit ID = 60, Page ID = 50)

Unique Identifier page-80834-304943-60-50

	Please check if walk test was not performed at this visit.	WALK.WAL KND	
6 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	<ul><li>Screening Visit</li><li>Enrollment Visit</li></ul>
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	<ul><li>Yes</li><li>Ny code list</li><li>No</li></ul>
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	<ul><li>Yes</li><li>Ny code list</li></ul>
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	WALK.WKAI D	<ul><li>Yes</li><li>Ny code list</li><li>No</li></ul>
	If yes: Specify type of walking aid	WALK.WKS PAID	<ul><li>Cane</li><li>Walker cWALK code list</li><li>Other</li></ul>
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	If no: What was duration of wall	c test?	
	minutes	WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	<ul><li>Symptoms requiring termination</li><li>Other</li><li>C6MTERM code list code li</li></ul>
	Other (specify)	WALK.WKR SNSP	
<b>5</b>	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKD SAT	O Yes	NY code list
~ 00 /0):		O No	
If yes: Walk duration at desatu	ration		
minutes	WALK.WKD SMIN		(format 9)
seconds	WALK.WKD SSEC		(format 99)
If yes: walk distance at desaturation (meters)	WALK.WKD SMTR		(format 9999)
Lowest SpO2 (%)	WALK.WKL OWSP		(format 999)
Post-walk modified Borg Dyspnea Scale rating	WALK.POST BORG		cBORG code list
•			

### **Blood Collection**

(Visit ID = 60, Page ID = 60)

Unique Identifier page-45825-304943-60-60

Please check if blood sample were not collected at this visit					
Blood Collection Information					
Date blood samples were drawn	BC.BCDT				
Time blood samples were drawn	BC.BCTM			(HH24:MI)	
Processing date	BC.BCPRDT	•			
Processing time	BC.BCPRT M			(HH24:MI)	
Was DNA collected?	BC.BCDNA	<ul><li>Yes</li><li>No</li></ul>	NY code lis	st	
If yes, Yield (ml)	BC.BCDYLD			(format 99.9)	
# of aliquots	BC.BCDALQ			(format 99)	
Was plasma collected?	BC.BCPLAS MA	<ul><li>Yes</li><li>No</li></ul>	NY code lis	t	
If yes, Yield (ml)	BC.BCPYLD			(format 99.9)	
# of aliquots	BC.BCPALQ			(format 99)	
Was serum collected?	BC.BCSERU M	<ul><li>Yes</li><li>No</li></ul>	NY code lis	st	
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.UCS DND		
UCSD Shortness of Breath Questionnaire	e		
When I do, or if I were to do, the 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do beca	-		eathlessness as:
At rest	UCSD.UCS D1	0 0 1 0 2 0 3 0 4 0 5	
Walking on a level at your own pace	UCSD.UCS D2	0 0 1 0 2 0 3 0 4 0 5	
Walking on a level with others your age	UCSD.UCS D3	0 0 1 0 2 0 3 0 4 0 5	
Walking up a hill	UCSD.UCS D4	0 0 1 0 2 0 3 0 4 0 5	

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

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

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

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

## Patient Reported Outcome Battery

(Visit ID = 60, Page ID = 80)

Unique Identifier page-45844-304943-60-80

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

Independence	ICEEQ.ICEI NDEP	<ul><li>and pleasure that I want</li><li>I am able to be completely independent</li></ul>	
		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	PLEASURE code lis
Enjoyment and pleasure	ICEEQ.ICEE NJOY	valued	
		<ul> <li>I am able to do a few of the things that make me feel valued</li> <li>I am unable to do any of the things that make me feel</li> </ul>	
		I am able to do many of the things that make me feel valued	VALUED code list
Doing things that make you feel valued	ICEEQ.ICEV ALUE	I am able to do all of the things that make me feel valued	

describes your own health state today.

Page 364 Created: 18-APR-16 12:12:25 GMT

Mobility	ICEEQ.EQM OB	<ul> <li>I have no problems in walking about</li> <li>I have some problems in</li> </ul>	MOBILE code list
		walking about  I am confined to bed	
Self-Care	ICEEQ.EQS C	<ul> <li>I have no problems with self care</li> </ul>	4
		<ul> <li>I have some problems washing or dressing mysel</li> </ul>	
		I am unable to wash or dress myself	
Usual activities (e.g. work, study, housework, family or leisure activities)	ICEEQ.EQU A	I have no problems with performing my usual activities	
		<ul> <li>I have some problems with performing my usual activities</li> </ul>	ACTIVITY code li
		I am unable to perform my usual activities	
Pain/Discomfort	ICEEQ.EQP AIN	<ul> <li>I have no pain or discomfort</li> </ul>	
		<ul> <li>I have moderate pain or discomfort</li> </ul>	PAIN code list
		<ul> <li>I have extreme pain or discomfort</li> </ul>	
Anxiety/Depression	ICEEQ.EQA NX	<ul> <li>I am not anxious or depressed</li> </ul>	
		<ul> <li>I am moderately anxious or depressed</li> </ul>	ANXIETY code list
		<ul> <li>I am extremely anxious or depressed</li> </ul>	
Value of EQ-5D VAS (0-100)	ICEEQ.EQV		(format 999)

## St George's Respiratory Questionnaire

(Visit ID = 60, Page ID = 90)

Unique Identifier page-45914-304943-60-90

Please check if questionnaire was not performed at this visit.	SGRQ.SGR QND		
George's Respiratory Questionnaire			
This questionnaire is designed troubling you and how it affects illness cause you the most prob problems are.	your life. W	e are using it to find	out which aspects of your
Please read the instructions can spend too long deciding about y	refully and as your answers	sk if you do not unde 3.	erstand anything. Do not
Before completing the question Please check one box to show how you describe your current health:		<ul><li>Very good</li><li>Good</li><li>Fair</li><li>Poor</li><li>Very poor</li></ul>	CURHLTH code list
t 1		rely poe.	
weeks.  Please check one box for each  1. Over the past 4 weeks, I have coughed:	SGRQ.STG0	<ul> <li>Almost Every Da</li> <li>Several Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> <li>Not at all</li> </ul>	cRSPROB code I
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG0 2	<ul> <li>Almost Every Da</li> <li>Several Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> </ul>	cRSPROB code lis

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

9. How would you describe						
your respiratory condition?	SGRQ.STG0 9	0	The mos importar I have	st nt problem		
		0	Causes lot of pro	me quite a oblems	cF	RSCON code lis
		0	Causes problem	me a few s		
		0	Causes problem			
10. If you have ever held a job	SGRQ.STG1	0	My repri problem me stop altogethe	s måde working		
		0	problem with my	s interfere		cJOB code list
		0	My respi problem affect m	s do not		
ection 2						
These are questions about wh	at activities u	sua	lly make	you feel sho	ort of brea	th these days.
11. For each statement, please	check the b	ox t	hat applie	es to you the	ese days.	
Sitting or lying still	SGRQ.STG1 1A	0	True			
		$\circ$	False	CIRUFLS	code list	
Washing or dressing yourself	SGRQ.STG1 1B	000	False True False	cTRUFLS		
Washing or dressing yourself Walking around the house			True		code list	
	1B SGRQ.STG1	0 0	True False True	cTRUFLS	code list	
Walking around the house  Walking outside on a level	SGRQ.STG1	00000	True False True False True False True False True	cTRUFLS	code list	
Walking around the house  Walking outside on a level ground	SGRQ.STG1 1C SGRQ.STG1 1D SGRQ.STG1	0000000	True False True False True False True False True False True	cTRUFLS cTRUFLS	code list code list code list code list	
Walking around the house  Walking outside on a level ground  Walking up a flight of stairs	SGRQ.STG1 1C SGRQ.STG1 1D SGRQ.STG1 1E SGRQ.STG1	0000000	True False True False True False True False True False True False True	cTRUFLS cTRUFLS cTRUFLS	code list code list code list code list code list	
Walking around the house  Walking outside on a level ground  Walking up a flight of stairs  Walking up hills  Playing sports or other	SGRQ.STG1 1C SGRQ.STG1 1D SGRQ.STG1 1E SGRQ.STG1 1F SGRQ.STG1	000000000000	True False True False True False True False True False True False	cTRUFLS cTRUFLS cTRUFLS cTRUFLS	code list code list code list code list code list	
Walking around the house  Walking outside on a level ground  Walking up a flight of stairs  Walking up hills  Playing sports or other physical activities	SGRQ.STG1 1C SGRQ.STG1 1D SGRQ.STG1 1E SGRQ.STG1 1F SGRQ.STG1 1G	00000000000	True False	cTRUFLS cTRUFLS cTRUFLS cTRUFLS cTRUFLS	code list code list code list code list code list code list	ays.
Walking around the house  Walking outside on a level ground  Walking up a flight of stairs  Walking up hills  Playing sports or other physical activities	SGRQ.STG1	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	True False	cTRUFLS cTRUFLS cTRUFLS cTRUFLS cTRUFLS	code list code list code list code list code list code list	ays.

Coughing makes me tired	SGRQ.STG1 2B	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
I am short of breath when I talk	SGRQ.STG1 2C	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
I am short of breath when I bend over	SGRQ.STG1 2D	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
My coughing or breathing disturbs my sleep	SGRQ.STG1 2E	<ul><li>True</li><li>False</li><li>True cTRUFLS code list</li></ul>
I get exhausted easily	SGRQ.STG1 2F	
Section 4		1 4,00
	er effects tha	at your respiratory problems may have on you
<ol><li>For each statement, please</li></ol>		oox that applies to you these days.
My cough or breathing is embarrassing in public	SGRQ.STG1 3A	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
My respiratory problems are a nuisance to my family, friends, or neighbors	SGRQ.STG1 3B	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
I get afraid or panic when I cannot catch my breath	SGRQ.STG1 3C	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
I feel that I am not in control of my respiratory problems	SGRQ.STG1 3D	<ul><li>True cTRUFLS code list</li><li>False</li></ul>
I do not expect my respiratory problems to get any better	SGRQ.STG1 3E	<ul><li>True</li><li>False cTRUFLS code list</li></ul>
I have become frail or an invalid because of my respiratory problems	SGRQ.STG1 3F	<ul><li>True</li><li>False</li><li>True cTRUFLS code list</li></ul>
Exercise is not safe for me	SGRQ.STG1 3G	<ul><li>True</li><li>False</li><li>True cTRUFLS code list</li></ul>
Everything seems too much of an effort	SGRQ.STG1 3H	<ul><li>True</li><li>False</li><li>True cTRUFLS code list</li></ul>
Section 5		
These are questions about you go to section 6.	r respiratory	treatment. If you are not receiving treatment,
Not Receiving Respiratory Treatment	SGRQ.SGN OTXT	
•		oox that applies to you these days.
My treatment does not help me very much	SGRQ.STG1 4A	<ul><li>True</li><li>False cTRUFLS code list</li></ul>
I get embarrassed using my medication in public	SGRQ.STG1 4B	

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

I cannot go out for entertainment or recreation	SGRQ.STG1 6B	<ul><li>True</li><li>False</li></ul>	cTRUFLS co	ode list	
I cannot go out of the house to do the shopping	SGRQ.STG1 6C	<ul><li>True</li><li>False</li></ul>	cTRUFLS co	ode list	
I cannot do household chores	SGRQ.STG1 6D	<ul><li>True</li><li>False</li></ul>	cTRUFLS co	ode list	
I cannot move far from my bed or chair	SGRQ.STG1 6E	<ul><li>True</li><li>False</li></ul>	cTRUFLS co	ode list	
	ome or in the	•			
<ul> <li>Sexual intercourse</li> <li>Going to a place of worship, or</li> <li>Going out in bad weather or in</li> <li>Visiting family or friends or play</li> <li>Please write in any other important activities that your respiratory problems may stop you from doing:</li> <li>17. Now please check the box (one only) that you think best describes how your respiratory</li> </ul>	r a place of e	oms Idren  It does me from	not stop n doing		

# **Month 4 Telephone Contact**

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

Date of visit	DOV.DOVD T		
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes NY code list</li><li>No</li></ul>	
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes NY code list</li><li>No</li></ul>	
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes NY code list</li><li>No</li></ul>	
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>	
If yes, date of surgery?	DOV.DOVS XDT		
Has the subject had a lung transplant?	DOV.DOVLT X	No NY code list	
If yes, please complete the ear	iy discontine	uation form	

# Monthly Telephone Contact

(Visit ID = 70, Page ID = 20)

Unique Identifier page-304876-304944-70-20

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

# **Month 5 Telephone Contact**

Date of Visit (Visit ID = 80, Page ID = 10) Unique Identifier page-304846-304945-80-10

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

## Monthly Telephone Contact

(Visit ID = 80, Page ID = 20)

Unique Identifier page-304876-304945-80-20

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

## Week 24 Visit

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

Date of visit	DOV.DOVD T	
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li><li>No</li><li>NY code list</li></ul>
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes NY code list</li><li>No</li></ul>
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes NY code list</li><li>No</li></ul>
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
If yes, date of surgery?	DOV.DOVS XDT	
Has the subject had a lung transplant?  If yes, please complete the ear	DOV.DOVLT X	O No NY code list
n yee, please complete the car	iy aloooniina	Lation form

### **Concomitant Medications**

(Visit ID = 90, Page ID = 80)

Unique Identifier page-304883-304946-90-80

Medications were not collected at this visit.	CMFP.CMF PND		
Concomitant Medications			
Has the subject taken any of the	ne following i	medications since the las	t visit?
Proton Pump Inhibitors (PPI)	CMFP.CMP PI	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
H2 Blockers (H2 Receptor Antagonists)	CMFP.CMH 2B	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Chronic prednisone (>1month)	CMFP.CMC P	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
If current, chronic/ average dose taken (mg/day):	CMFP.CMC PDOSE		(format 99.9)
Azathioprine	CMFP.CMA ZT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
N-acetylcystteine (NAC)	CMFP.CMN AC	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Cotrimoxazole	CMFP.CMC OT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Albuterol/ atrovent/ other metered-dose inhaler (MDI)	CMFP.CMM DI	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Pirfenidone	CMFP.CMPI RF	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	cCMFUP code list
Nintedanib	CMFP.CMNI NT	<ul><li>Taking daily</li><li>Taking as needed</li><li>Not Current</li></ul>	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.GER DND		
Frequ	uency Scale for the Symptoms of Gl	ERD		
	Not Collected	GERD.FQN D		
	1. Do you get heartburn?	GERD.FQH RTBRN	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	2. Does your stomach get bloated?	GERD.FQBL OAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	3. Does your stomach ever feel heavy after meals?	GERD.FQH EAVY	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQR UB	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	5. Do you feel sick after meals?	GERD.FQSI CK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	6. Do you get heartburn after meals?	GERD.FQH RTAFT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list

7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQT HROAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
8. Do you feel full while eating meals?	GERD.FQF ULL	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
9. Do some things get stuck when you swallow?	GERD.FQST UCK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQA CID	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
11. Do you burp a lot?	GERD.FQB URP	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
12. Do you get heartburn if you bend over?	GERD.FQH RTBND	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
SERD Health Related Quality of Life			
Not Collected	GERD OLN		

Not Collected

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? GR	GERD.QLH RTBRN	<ul><li>0</li><li>1</li><li>2</li><li>3</li><li>4</li><li>5</li></ul>	
2. Heartburn when lying down? G	GERD.QLLY NG	0 0 1 0 2 0 3 0 4 0 5	
3. Heartburn when standing Gup?	GERD.QLST	0 0 1 0 2 0 3 0 4	
4. Heartburn after meals? GR	GERD.QLH RTAFT	0 0 1 0 2 0 3 0 4 0 5	
5. Does heartburn change your G diet?	GERD.QLDI	0 0 1 0 2 0 3 0 4 0 5	
6. Does heartburn wake you from sleep?	GERD.QLSL EEP	0 0 1 0 2 0 3 0 4 0 5	

	Do you have difficulty vallowing?	GERD.QLDI FFSW	0 0 1 0 2 0 3 0 4 0 5		
8. sw	Do you have pain with vallowing?	GERD.QLPA INSW	0 0 1 0 2 0 3 0 4 0 5		
	Do you have bloating or assy feelings?	GERD.QLBL OAT	0 0 1 0 2 0 3 0 4 0 5		
	). If you take medication, bes this affect your daily life?	GERD.QLM EDS	0 0 1 0 2 0 3 0 4 0 5		
nH Manit	toring Results		<u> </u>		
	er Protocol Amendment 3, all	patients sho	uld check	the Not Collec	cted Box at the Week 12
	er Protocol Amendment 3, nor eek 24 Visit	n surgery pa	tients sho	ould check the	Not Collected Box at the
No	ot Collected	GERD.PHN D			
W: LE	as probe located 5cm above ES	GERD.PHP ROBE	<ul><li>Yes</li><li>No</li></ul>	NY code list	
tot	tal time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
up	oright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
su	pine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
# 0	of reflux episodes	GERD.PHR FLEPS			(format 999.9)
# 0	of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
Lo	ongest reflux episode (mins)	GERD.PHT MRFL			(format 999.9)

Overall DeMeester Score	GERD.PHS CORE		(format 999.9)
Manometry Results			
Per Protocol Amendment 3, all Visit	patients sho	ould check the Not Collec	cted Box at the Week 12
Per Protocol Amendment 3, not Week 24 Visit	n surgery pa	atients should check the	Not Collected Box at the
Not Collected	GERD.MNN D		
Lower esophageal sphincter (L	•		
LES length (cm)	GERD.MNL ESLNG		(format 99.9)
LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)
LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)
Upper esophageal sphincter (U UES resting pressure (mmHg)	ES) data GERD.MNU ESRTP		(format 999.9)
UES relaxation (%)	GERD.MNU ESRLX		(format 999.9)
Esophageal body motility patter			
% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)
% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)
% simultaneous contractions (%)	GERD.MNSI MUCN		(format 999.9)
Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)
Esophageal body motility pattern (select only one)	GERD.MNE BMP	<ul> <li>Normal motity</li> <li>Ineffective (&lt;80% normal contraction)</li> <li>Severely ineffective (&lt;30% normal contraction)</li> <li>Diffuse/distal esophageal spasm (simultaneous contractions in &gt;10% of swallows, with amp &gt; 30mmHg)</li> <li>Aperistalsis (no peristaltic activity observed in</li> </ul>	cEBMP code list
		esophageal body)	

## Spirometry\_DLCO

(Visit ID = 90, Page ID = 20)

Unique Identifier page-80805-304946-90-20

	Please check if procedures were not performed	SPIRO.SPIR OND				
SPIR	OMETRY					
	Indicate at which visit these values were collected	SPIRO.SPR VISIT	0	Screening Visit Enrollment Visit		
	Pre-Bronchodilator: Primary	SPIRO.PRI MEYES				
	FEV1: Actual (liters)	SPIRO.PRM FEV			(format 99.99)	
<b>66</b>	FVC: Actual (liters)	SPIRO.PRM FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.PRM VC			(format 99.99)	
	Pre-Bronchodilator: Replicate 1	SPIRO.REP 1YES				
	FEV1: Actual (liters)	SPIRO.REP 1FEV			(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 1FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 1VC			(format 99.99)	
	Pre-Bronchodilator: Replicate 2	SPIRO.REP 2YES				
	FEV1: Actual (liters)	SPIRO.REP 2FEV			(format 99.99)	
	FVC: Actual (liters)	SPIRO.REP 2FVC			(format 99.99)	
	VC: Actual (liters)	SPIRO.REP 2VC			(format 99.99)	
DLCC						
	DLCO: actual (mL/min/mmHg)	SPIRO.DLC OACT			(format 99.9)	
	VA (alveolar volume) (liters)	SPIRO.DLC OVA			(format 9.99)	
	Hemoglobin: (g/dL)	SPIRO.DLC OHEMO			(format 99.9)	
	Hemoglobin adjusted DLCO: (mL/min/mmHg)	SPIRO.DLC OADHM			(format 99.9)	

#### Arterial Blood Gas

(Visit ID = 90, Page ID = 90)

Unique Identifier page-45888-304946-90-90

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

### 6-Minute Walk Test

(Visit ID = 90, Page ID = 30)

Unique Identifier page-80834-304946-90-30

	Please check if walk test was not performed at this visit.	WALK.WAL KND	
6 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	<ul><li>Screening Visit</li><li>Enrollment Visit</li></ul>
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	<ul><li>Yes NY code list</li><li>No</li></ul>
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	WALK.WKAI D	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	If yes: Specify type of walking aid	WALK.WKS PAID	<ul><li>Cane</li><li>Walker cWALK code list</li><li>Other</li></ul>
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	<ul><li>Yes</li><li>Ny code list</li><li>No</li></ul>
	If no: What was duration of wall	k test?	
	minutes	WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	<ul><li>Symptoms requiring termination</li><li>Other</li><li>C6MTERM code list</li></ul>
	Other (specify)	WALK.WKR SNSP	
<b>5</b>	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Did subject desaturate (SpO2 < 88%)?	WALK.WKD SAT	<ul><li>Yes</li><li>No</li></ul>	NY code list		
If yes: Walk duration at desatu	ration				
minutes	WALK.WKD SMIN			(format 9)	
seconds	WALK.WKD SSEC			(format 99)	
If yes: walk distance at desaturation (meters)	WALK.WKD SMTR			(format 9999)	
Lowest SpO2 (%)	WALK.WKL OWSP			(format 999)	
Post-walk modified Borg Dyspnea Scale rating	WALK.POST [ BORG		~	cBORG code list	
•					

### **Blood Collection**

(Visit ID = 90, Page ID = 40)

Unique Identifier page-45825-304946-90-40

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

### UCSD Shortness of Breath Questionnaire

(Visit ID = 90, Page ID = 50)

Unique Identifier page-45995-304946-90-50

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND						
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.UCS D1	0 0 1 0 2 0 3 0 4 0 5					
Walking on a level at your own pace	UCSD.UCS D2	0 0 1 0 2 0 3 0 4 0 5					
Walking on a level with others your age	UCSD.UCS D3	0 0 1 0 2 0 3 0 4 0 5					
Walking up a hill	UCSD.UCS D4	0 0 1 0 2 0 3 0 4 0 5					

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

Dressing	UCSD.UCS D11	0 0	
	ווט	0 1	
		0 2	
		0 3	
		0 4	
		0 5	
Picking up and straightening	UCSD.UCS D12	0 0	
	D12	0 1	
		O 2	
		0 3	
		0 4	
		0 5	
Doing dishes	UCSD.UCS	0 0	
-	D13	° 1	
		0 2	
		0 3	
		0 4	
		0 5	
Sweeping/vacuuming	UCSD.UCS	0 0	
	D14	0 1	
		O 2	
		0 3	
		0 4	
		0 5	
Making bed	UCSD.UCS	0 0	
<b>G</b>	D15	0 1	
		0 2	
		0 3	
		0 4	
		0 5	
Shopping	UCSD.UCS	0 0	
	D16	0 1	
		O 2	
		0 3	
		0 4	
		0 5	

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

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

### Patient Reported Outcome Battery

(Visit ID = 90, Page ID = 60)

Unique Identifier page-45844-304946-90-60

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

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

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

## St George's Respiratory Questionnaire

(Visit ID = 90, Page ID = 70)

Unique Identifier page-45914-304946-90-70

Please check if questionnaire was not performed at this visit.	SGRQ.SGR QND		
eorge's Respiratory Questionnaire			
This questionnaire is designed to troubling you and how it affects illness cause you the most problems are.	your life. W	e are using it to find	out which aspects of your
Please read the instructions car spend too long deciding about y			erstand anything. Do not
Before completing the question		0	
Please check one box to show how you describe your current health:	SGRQ.CUR HLTH	<ul><li>Very good</li><li>Good</li><li>Fair</li></ul>	CURHLTH code list
		Poor	
1		<ul><li>Very poor</li></ul>	
weeks.  Please check one box for each  1. Over the past 4 weeks, I have coughed:	question SGRQ.STG0 1 SGRQ.STG0	<ul> <li>Almost Every Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> <li>Not at all</li> <li>Almost Every Days</li> </ul>	cRSPROB code lis
2. Over the past 4 weeks, I have brought up phlegm (sputum):	2 2	<ul> <li>Almost Every Days</li> <li>Several Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> </ul>	cRSPROB code lis

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

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0	The moimportal	ost ant problem	-D000N d- l'-4
		0	Cause lot of p	s me quite a roblems	cRSCON code list
		0	Cause: proble	s me a few ms	
			Cause: proble		
10. If you have ever held a job:	SGRQ.STG1	0		ms made p working	
		0	problem with m	piratory ms interfere y job or me change	cJOB code list
		0		piratory ms do not my job	
Section 2					
These are questions about wha	nt activities u	sua	lly make	e you feel sh	ort of breath these days.
11. For each statement, please		-		lies to you th	ese days.
Sitting or lying still	SGRQ.STG1 1A	0	True False	cTRUFLS c	ode list
Washing or dressing yourself	SGRQ.STG1 1B	0	True False	cTRUFLS o	ode list
Walking around the house	SGRQ.STG1 1C	0	True False	cTRUFLS o	ode list
Walking outside on a level ground	SGRQ.STG1 1D	0	True False	cTRUFLS o	ode list
Walking up a flight of stairs	SGRQ.STG1	0	True	cTRUFLS c	edo list
Walking up a flight of stairs	1E	0	False		oue list
Walking up hills	SGRQ.STG1	000	True False	cTRUFLS o	
	SGRQ.STG1	00000	True False True	cTRUFLS c	ode list
Walking up hills  Playing sports or other	SGRQ.STG1 1F SGRQ.STG1	0	True False		ode list
Walking up hills  Playing sports or other physical activities	SGRQ.STG1 1F SGRQ.STG1 1G	0 0 0	True False True False	cTRUFLS c	ode list ode list
Walking up hills  Playing sports or other physical activities  Section 3	SGRQ.STG1 1F SGRQ.STG1 1G ut your cougl	h ar	True False True False ad short hat app	cTRUFLS o	ode list ode list th these days.

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

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

I cannot go out for entertainment or recreation	SGRQ.STG1 6B	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
I cannot go out of the house to do the shopping	SGRQ.STG1 6C	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
I cannot do household chores	SGRQ.STG1 6D	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
I cannot move far from my bed or chair	SGRQ.STG1 6E	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
Sexual intercourse     Going to a place of worship, or     Going out in bad weather or in			nt	
<ul> <li>Going to a place of worship, or</li> </ul>			nt	
	to smoky roc ying with chil SGRQ.STGL IST SGRQ.STG1 7	It does me from anything like to do	not stop n doing g I would	cRSPAFT code

# **Month 7 Telephone Contact**

Date of Visit (Visit ID = 100, Page ID = 10) Unique Identifier page-304846-304947-100-10

Date of visit	DOV.DOVD T				
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code li	ist	
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code li	ist	
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code li	ist	
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code li	ist	
If yes, date of surgery?	DOV.DOVS XDT				
Has the subject had a lung transplant?  If yes, please complete the ear	DOV.DOVLT X <i>ly discontinu</i>	<ul><li>Yes</li><li>No</li><li>Nation form</li></ul>	NY code li	ist	
•					

## 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.TELE ND			
Tele	phone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	<ul><li>Yes</li><li>No</li></ul>	NY code list	
	If Yes, complete the Death form Did subject report any adverse events (serious or non- serious?)		<ul><li>Yes</li><li>No</li></ul>	NY code list	
	If Yes, complete the Adverse E	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?		<ul><li>Yes</li><li>No</li></ul>	NY code list	
	If Yes, complete the Health Car	e Encounte	r Form		

# **Month 8 Telephone Contact**

Date of Visit (Visit ID = 110, Page ID = 10) Unique Identifier page-304846-304948-110-10

Date of visit	DOV.DOVD T		
	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code list
	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code list
	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code list
	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code list
ii vos. dato di salaciv:	DOV.DOVS XDT		
Has the subject had a lung transplant?  If yes, please complete the early	DOV.DOVLT X	<ul><li>Yes</li><li>No</li></ul>	NY code list
ii yes, piease complete the early	, diacontinu	auon ionn	

## Monthly Telephone Contact

(Visit ID = 110, Page ID = 20)

Unique Identifier page-304876-304948-110-20

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

## Week 36 Visit

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

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

### **Concomitant Medications**

(Visit ID = 120, Page ID = 70)

Unique Identifier page-304883-304949-120-70

Medications were not collected at this visit.	CMFP.CMF PND		
ncomitant Medications			
Has the subject taken any of the	e following r	medications since the last visit?	
Proton Pump Inhibitors (PPI)	CMFP.CMP	<ul><li>Taking daily</li></ul>	
	PI	<ul><li>Taking as needed</li></ul>	
		Not Current	
H2 Blockers (H2 Receptor	CMFP.CMH	<ul> <li>Taking daily</li> </ul>	
Antagonists)	2B	O Taking as needed	
		O Not Current	
Chronic prednisone (>1month)	CMFP.CMC	<ul><li>Taking daily</li></ul>	
	Р	Taking as needed	
		Not Current	
f current, chronic/ average	CMFP.CMC PDOSE	(format 99.9)	
dose taken (mg/day):			
Azathioprine	CMFP.CMA ZT	<ul><li>Taking daily</li></ul>	
		Taking as needed	
		Not Current	
N-acetylcystteine (NAC)	CMFP.CMN AC	Taking daily	
		O Taking as needed	
		Not Current	
Cotrimoxazole	CMFP.CMC OT	<ul><li>Taking daily</li></ul>	
		Taking as needed	
		Not Current	
Albuterol/ atrovent/ other	CMFP.CMM DI	raining daily	
netered-dose inhaler (MDI)	<b>-</b> .	<ul> <li>Taking as needed</li> </ul>	
		<ul> <li>Not Current</li> </ul>	
Pirfenidone	CMFP.CMPI RF	<ul><li>Taking daily</li></ul>	
	T C	<ul><li>Taking as needed</li></ul>	
		<ul> <li>Not Current</li> </ul>	
Nintedanib	CMFP.CMNI	<ul> <li>Taking daily</li> </ul>	
		<ul> <li>Taking as needed</li> </ul>	
		Not Current	

## Spirometry

(Visit ID = 120, Page ID = 20)

Unique Identifier page-80805-304949-120-20

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

### **Blood Collection**

(Visit ID = 120, Page ID = 30)

Unique Identifier page-45825-304949-120-30

Please check if blood samples were not collected at this visit.	BC.BCND			
Blood Collection Information				
Date blood samples were drawn	BC.BCDT			
Time blood samples were drawn	BC.BCTM		(HH24:MI)	
Processing date	BC.BCPRDT			
Processing time	BC.BCPRT M		(HH24:MI)	
Was DNA collected?	BC.BCDNA	O Yes N'	Y code list	
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)	
# of aliquots	BC.BCDALQ		(format 99)	
Was plasma collected?	BC.BCPLAS MA	O Yes O No	NY code list	
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)	
# of aliquots	BC.BCPALQ		(format 99)	
Was serum collected?	BC.BCSERU M	O Yes N'	Y 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.UCS DND		
UCSD Shortness of Breath Questionnair	e		
When I do, or if I were to do, the 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do beca	ause of brea		hlessness as:
At rest	UCSD.UCS D1	0 0	
	Di	<sup>0</sup> 1	
		0 2	
		0 3	
		0 4	
		0 5	
Walking on a level at your own pace	D2	0 0	
pace		0 1	
		O 2 O 3	
		0 4	
		0 5	
Walking on a level with others	UCSD.UCS	0 0	
your age	D3	0 1	
		0 2	
		O 3	
		O 4	
		○ 5	
Walking up a hill	UCSD.UCS D4	0 0	
	<b>D</b> 4	0 1	
		0 2	
		0 3	
		0 4	
		O 5	

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

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

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

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

### Patient Reported Outcome Battery

(Visit ID = 120, Page ID = 50)

Unique Identifier page-45844-304949-120-50

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

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

Mobility ICEEQ OB	ICEEQ.EQM OB	<ul> <li>I have no problems in walking about</li> </ul>	MOBILE code lis
		<ul> <li>I have some problems in walking about</li> </ul>	
		<ul> <li>I am confined to bed</li> </ul>	
Self-Care	ICEEQ.EQS C	<ul> <li>I have no problems with s care</li> </ul>	elf-
		<ul> <li>I have some problems washi or dressing mys</li> </ul>	
		I am unable to wash or dress myself	
Coddi dolivilioo (o.g. work,	ICEEQ.EQU A	I have no problems with performing my usual activities	
		<ul> <li>I have some problems with performing my</li> </ul>	ACTIVITY code
		usual activities  I am unable to perform my usu activities	al
Pain/Discomfort	ICEEQ.EQP AIN	I have no pain of discomfort	r
		I have moderate pain or discomform	
		I have extreme pain or discomfo	
Anxiety/Depression	ICEEQ.EQA NX	I am not anxious or depressed	
		I am moderately anxious or depressed	ANXIETY code
		I am extremely anxious or depressed	
	ICEEQ.EQV		

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### St George's Respiratory Questionnaire

(Visit ID = 120, Page ID = 60)

Unique Identifier page-45914-304949-120-60

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

Over the past 4 weeks, I e had shortness of breath:  Over the past 4 weeks, I e had wheezing attacks:	SGRQ.STG0 3 SGRQ.STG0 4	0 0 0 0 0 0	Almost Every Day Several Days a Week A Few Days a Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a Month Only with	cRSPROB cod	
	SGRQ.STG0 4	0 000 0	Month Only with Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a Month		
	SGRQ.STG0	0 0 0 0	Respiratory Infections Not at all Almost Every Day Several Days a Week A Few Days a Month	cRSPROB co	ode
	SGRQ.STG0	0 0 0	Almost Every Day Several Days a Week A Few Days a Month	cRSPROB co	ode
	SGRQ.STG0	0 0	Several Days a Week A Few Days a Month	cRSPROB co	od€
			A Few Days a Month	cRSPROB co	ode
		0	Only with		
			Respiratory Infections		
		0			
5. How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory	SGRQ.STG0 5	0	More than 3 times		
			3 times 2 times	cNBRATK co	de
cks?		0	1 time None of the time		
low long did your worst	SGRQ.STG0	1.00	A week or more		
piratory attack last? to question 7 if you did not e a severe attack)		0	3 or more days 1 or 2 days	cLENGTH co	ode
over the past 4 weeks, in a	SGRQ.STG0	-	Less than a day		
cal week, how many good	7	0	1 or 2 good days		
			3 or 4 good days Nearly every days	cDAYS code I	ist
		0	Every day was good		
	SGRQ.STG0 8	0 0	Yes NY code No list		
	Over the past 4 weeks, in a cal week, how many good s (with few respiratory plems) have you had?  Tyou wheeze, is it worse en you get up in the rning?	cal week, how many good 7 s (with few respiratory plems) have you had?  Tyou wheeze, is it worse en you get up in the	Over the past 4 weeks, in a cal week, how many good s (with few respiratory olems) have you had?  Signal Si	Over the past 4 weeks, in a cal week, how many good s (with few respiratory olems) have you had?  SGRQ.STG0  1 or 2 good days 3 or 4 good days Nearly every days was good Every day was good  You wheeze, is it worse en you get up in the  SGRQ.STG0  No good days 1 or 2 good days SGRQ.STG0  Yes NY code	Over the past 4 weeks, in a cal week, how many good s (with few respiratory olems) have you had?  SGRQ.STG0  1 or 2 good days 3 or 4 good days Nearly every days was good Every day was good  Syou wheeze, is it worse en you get up in the  SGRQ.STG0  No good days 1 or 2 good days Servery days was good  Every day was good

The most important problem I have
<ul> <li>Causes me quite a lot of problems</li> </ul>
<ul> <li>Causes me a few problems</li> </ul>
Causes no problems
<ul> <li>My repriatory problems made me stop working altogether</li> </ul>
<ul> <li>My respiratory problems interfere with my job or made me change my job</li> <li>CJOB code list</li> </ul>
<ul> <li>My respiratory problems do not affect my job</li> </ul>
usually make you feel short of breath these days.
box that applies to you these days.
True
True cTRUFLS code list
cTRUFLS code list
<ul> <li>False</li> <li>True cTRUFLS code list</li> </ul>
<ul> <li>False</li> <li>True cTRUFLS code list</li> <li>False</li> <li>True</li> <li>True</li> </ul>
<ul> <li>False</li> <li>True</li> <li>False</li> <li>True</li> <li>False</li> <li>True</li> <li>False</li> <li>True</li> <li>Tru</li></ul>
CTRUFLS code list  False  True False  True False  CTRUFLS code list
False  CTRUFLS code list  True False  CTRUFLS code list  True False  CTRUFLS code list
False  CTRUFLS code list  True False  CTRUFLS code list  True False  CTRUFLS code list
False  CTRUFLS code list  True False  CTRUFLS code list  True False  CTRUFLS code list
False  CTRUFLS code list  True False  CTRUFLS code list  True False  CTRUFLS code list

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

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

I cannot go out for entertainment or recreation	SGRQ.STG1 6B	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
I cannot go out of the house to do the shopping	SGRQ.STG1 6C	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
I cannot do household chores	SGRQ.STG1 6D	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
I cannot move far from my bed or chair	SGRQ.STG1 6E	<ul><li>True</li><li>False</li></ul>	cTRUFLS	code list
<ul><li>Sexual intercourse</li><li>Going to a place of worship, o</li><li>Going out in bad weather or in</li></ul>	to smoky rod	oms	t	
•Going to a place of worship, o			t	
•Going to a place of worship, o	to smoky roo ying with chi SGRQ.STGL IST SGRQ.STG1 7	It does reme from anything like to doing or	not stop n doing g I would o	cRSPAFT cod

# **Month 10 Telephone Contact**

Date of Visit (Visit ID = 130, Page ID = 10) Unique Identifier page-304846-304950-130-10

Date of visit	DOV.DOVD T	10	
Did subject complete the visit?	DOV.DOVC OMP	<ul><li>Yes</li><li>No</li></ul>	NY code list
If no, will subject continue in the study?	DOV.DOVC ONT	<ul><li>Yes</li><li>No</li></ul>	NY code list
If no, was it due to death of subject?	DOV.DOVD TH	<ul><li>Yes</li><li>No</li></ul>	NY code list
Did subject cross over to surgery?	DOV.DOVS X	<ul><li>Yes</li><li>No</li></ul>	NY code list
If yes, date of surgery?	DOV.DOVS XDT		
Has the subject had a lung transplant?  If yes, please complete the ear	DOV.DOVLT X <i>ly discontinu</i>	○ Yes ○ No lation form	NY code list

### Monthly Telephone Contact

(Visit ID = 130, Page ID = 20)

Unique Identifier page-304876-304950-130-20

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

# **Month 11 Telephone Contact**

Date of Visit (Visit ID = 140, Page ID = 10) Unique Identifier page-304846-304951-140-10

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

### 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.TELE ND			
Tele	ohone contact				
	Date of telephone contact	TELE.TELC ONDT			
	Was subject determined to have died?	TELE.TELE DETH	<ul><li>Yes</li><li>No</li></ul>	NY code list	
	If Yes, complete the Death form Did subject report any adverse events (serious or non- serious?)		<ul><li>Yes</li><li>No</li></ul>	NY code list	
	If Yes, complete the Adverse E	vents form			
	Did subject report any contacts with the health care system (admitted to the hospital, emergency room/urgent care, nursing facility, or rehabilitation center)?	TELE.TELE HC	O Yes O No	NY code list	
	If Yes, complete the Health Car	e Encounter	r Form		

## Week 48 Visit

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

Date of visit	DOV.DOVD T		
Did subject complete the visit?	DOV.DOVC OMP	O Yes NY coo	de list
If no, will subject continue in the study?	DOV.DOVC ONT	O Yes NY coo	de list
If no, was it due to death of subject?	DOV.DOVD TH	O Yes O No NY coo	de list
Did subject cross over to surgery?	DOV.DOVS X	O Yes NY coo	de list
If yes, date of surgery?	DOV.DOVS XDT		
Has the subject had a lung transplant?  If yes, please complete the ear	DOV.DOVLT X	O Yes O No NY coo	de list
ii yoo, picase complete the ear	iy disoonund	auon ionni	

#### **Concomitant Medications**

(Visit ID = 150, Page ID = 120)

Unique Identifier page-304883-304952-150-120

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

### 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.GER DND		
Frequ	uency Scale for the Symptoms of Gl	ERD		
	Not Collected	GERD.FQN D		
	1. Do you get heartburn?	GERD.FQH RTBRN	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	2. Does your stomach get bloated?	GERD.FQBL OAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	3. Does your stomach ever feel heavy after meals?	GERD.FQH EAVY	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	4. Do you sometimes subconsciously rub your chest with your hand?	GERD.FQR UB	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	5. Do you feel sick after meals?	GERD.FQSI CK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	6. Do you get heartburn after meals?	GERD.FQH RTAFT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list

	7. Do you have an unusual (e.g. burning) sensation in your throat?	GERD.FQT HROAT	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	8. Do you feel full while eating meals?	GERD.FQF ULL	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	9. Do some things get stuck when you swallow?	GERD.FQST UCK	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	10. Do you get bitter liquid (acid) coming up into your throat?	GERD.FQA CID	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	11. Do you burp a lot?	GERD.FQB URP	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
	12. Do you get heartburn if you bend over?	GERD.FQH RTBND	<ul><li>Never</li><li>Occasionally</li><li>Sometimes</li><li>Often</li><li>Always</li></ul>	cGFREQ code list
GERI	Health Related Quality of Life			
	Not Collected	GERD.QLN		

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

- 0-No symptoms
- 1-Symptoms noticeable, but not bothersome
- 2-Symptoms noticeable, but not bothlersome, but not every day 3-Symptoms bothersome every day 4-Symptoms affect daily activities

- 5-Symptoms are incapacitating, unable to do daily activities

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

7. Do you have difficulty swallowing?	GERD.QLDI FFSW	0 0 1 0 2 0 3 0 4 0 5		
8. Do you have pain with swallowing?	GERD.QLPA INSW	0 0 1 0 2 0 3 0 4 0 5		
9. Do you have bloating or gassy feelings?	GERD.QLBL OAT	0 0 1 0 2 0 3 0 4 0 5		
10. If you take medication, does this affect your daily life?	GERD.QLM EDS	0 0 1 0 2 0 3 0 4 0 5		
oH Monitoring Results		0		
Per Protocol Amendment 3, all Visit	patients sho	uld check	the Not Collec	cted Box at the Week 12
Per Protocol Amendment 3, no Week 24 Visit	n surgery pa	itients sho	ould check the I	Not Collected Box at the
Not Collected	GERD.PHN D			
Was probe located 5cm above LES	GERD.PHP ROBE	<ul><li>Yes</li><li>No</li></ul>	NY code list	
total time pH <4 (%)	GERD.PHT OTAL			(format 999.9)
upright time pH <4 (%)	GERD.PHU PRHT			(format 999.9)
supine time pH <4 (%)	GERD.PHS UPINE			(format 999.9)
# of reflux episodes	GERD.PHR FLEPS			(format 999.9)
# of reflux episodes >5min	GERD.PHR FLEPL			(format 999.9)
Longest reflux episode (mins)	GERD.PHT			(format 999.9)

	Overall DeMeester Score	GERD.PHS CORE		(format 999.9)
Manor	metry Results			
	Per Protocol Amendment 3, all Visit	patients sho	ould check the Not Collec	cted Box at the Week 12
	Per Protocol Amendment 3, nor Week 24 Visit	n surgery pa	atients should check the	Not Collected Box at the
	Not Collected	GERD.MNN D		
	Lower esophageal sphincter (LI	•		
	LES length (cm)	GERD.MNL ESLNG		(format 99.9)
	LES resting pressure (mmHg)	GERD.MNL ESRTP		(format 999.9)
	LES residual pressure (mmHg)	GERD.MNL ESRDP		(format 999.9)
	Upper esophageal sphincter (U UES resting pressure (mmHg)	ES) data GERD.MNU ESRTP		(format 999.9)
	UES relaxation (%)	GERD.MNU ESRLX		(format 999.9)
	Esophageal body motility patter	'n		
	% peristaltic contractions (%)	GERD.MNP ERICN		(format 999.9)
	% hypotensive or dropped contractions (%)	GERD.MNH YPOCN		(format 999.9)
	% simultaneous contractions (%)	GERD.MNSI MUCN		(format 999.9)
	Mean amplitude: distal esophageal amplitude (mmHg)	GERD.MNE SOAMP		(format 999.9)
	Esophageal body motility pattern (select only one)	GERD.MNE BMP	<ul> <li>Normal motity</li> <li>Ineffective (&lt;80% normal contraction)</li> <li>Severely ineffective (&lt;30% normal contraction)</li> <li>Diffuse/distal esophageal spasm (simultaneous contractions in &gt;10% of swallows, with amp &gt; 30mmHg)</li> <li>Aperistalsis (no peristaltic activity observed in appreciable activity</li> </ul>	cEBMP code list
			esophageal body)	
				6

### Spirometry\_DLCO

(Visit ID = 150, Page ID = 30)

Unique Identifier page-80805-304952-150-30

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

#### Arterial Blood Gas

(Visit ID = 150, Page ID = 40)

Unique Identifier page-45888-304952-150-40

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

#### 6-Minute Walk Test

(Visit ID = 150, Page ID = 50)

Unique Identifier page-80834-304952-150-50

	Please check if walk test was not performed at this visit.	WALK.WAL KND	
6 Min	ute Walk Test		
	Indicate at which visit these values were collected	WALK.WVIS IT	<ul><li>Screening Visit</li><li>Enrollment Visit</li></ul>
	Pre-walk modified Borg Dyspnea Scale rating	WALK.PREB ORG	cBORG code list
	Resting room air SpO2 (%)	WALK.WKS POX	(format 999)
	Was walk performed?	WALK.WKP ERF	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	Reason	WALK.WKR EASON	
	Was supplemental O2 used during walk?	WALK.WKS UPOX	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>
	If yes: Amount of supplemental O2? (liters/min)	WALK.WKA MTOX	(format 99)
	If yes: SpO2 on supplemental O2? (%)	WALK.WKS POSUP	(format 999)
	Was a walking aid necessary to perform the 6MWT?	WALK.WKAI D	<ul><li>Yes</li><li>Ny code list</li><li>No</li></ul>
	If yes: Specify type of walking aid	WALK.WKS PAID	<ul><li>Cane</li><li>Walker cWALK code list</li><li>Other</li></ul>
	Other (specify)	WALK.WKAI DOTH	
	Did subject complete 6MWT?	WALK.WKC OMPL	<ul><li>Yes NY code list</li><li>No</li></ul>
	If no: What was duration of walk minutes	test? WALK.WKMI N	(format 9)
	seconds	WALK.WKS EC	(format 99)
	If no: Reason for stopping early?	WALK.WKS PRSN	<ul><li>Symptoms requiring c6MTERM code list termination</li><li>Other</li></ul>
	Other (specify)	WALK.WKR SNSP	
-	Distance walked (meters)	WALK.WKDI ST	(format 9999)

Did subject desaturate (SpO2	WALK.WKD	O Yes	NY code list
< 88%)?	SAT	O No	NY Code list
		140	
If yes: Walk duration at desatu	ration		
minutes	WALK.WKD		(format 9)
	SMIN		,
seconds	WALK.WKD		(format 99)
	SSEC		,
If yes: walk distance at	WALK.WKD		(format 9999)
desaturation (meters)	SMTR		,
Lowest SpO2 (%)	WALK.WKL		(format 999)
Lowest SpO2 (70)	OWSP		(Ioiiilat 999)
Post-walk modified Borg	WALK.POST		✓ cBORG code list
Dyspnea Scale rating	BORG		CDONO code list
Dysprica coale rating			

#### **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	<u> </u>	
Time blood samples were drawn	BC.BCTM		(HH24:MI)
Processing date	BC.BCPRDT		
Processing time	BC.BCPRT M		(HH24:MI)
Was DNA collected?	BC.BCDNA	O Yes O No NY code list	
If yes, Yield (ml)	BC.BCDYLD		(format 99.9)
# of aliquots	BC.BCDALQ		(format 99)
Was plasma collected?	BC.BCPLAS MA	<ul><li>Yes NY code list</li><li>No</li></ul>	
If yes, Yield (ml)	BC.BCPYLD		(format 99.9)
# of aliquots	BC.BCPALQ		(format 99)
Was serum collected?	BC.BCSERU M	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>	
If yes, Yield (ml)	BC.BCSYLD		(format 99.9)
# of aliquots	BC.BCSALQ		(format 99)
			H

#### **HRCT Collection**

(Visit ID = 150, Page ID = 70)

Unique Identifier page-45939-304952-150-70

HRCT Collection				
Was an HRCT performed for this study because a satisfactory HRCT had not been performed within the previous 3 months?	HRCT.HRE NR	O Yes O No	NY code list	
Was a week 48 HRCT performed on this subject?	HRCT.HRFU P	<ul><li>Yes</li><li>No</li></ul>	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 su	bjects only)				
Was bronchoscopy performed on subject?	BRONCHO. BRONYN	<ul><li>Yes</li><li>No</li></ul>	NY code list		
Was bronchial alveolar lavage (BAL) fluid collected?	BRONCHO. BRBAL	<ul><li>Yes</li><li>No</li></ul>	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	<ul><li>Yes</li><li>No</li></ul>	NY code list		
If yes: Number of brushes sent	BRONCHO. BRAECBR			(format 999)	

#### UCSD Shortness of Breath Questionnaire

(Visit ID = 150, Page ID = 80)

Unique Identifier page-45995-304952-150-80

Please check if questionnaire was not performed at this visit.	UCSD.UCS DND		
UCSD Shortness of Breath Questionnair	e		
When I do, or if I were to do, the 0 None at all 1 2 3 4 Severe 5 Maximal or unable to do beca	ause of brea		hlessness as:
At rest	UCSD.UCS D1	0 0	
	ы	<sup>0</sup> 1	
		0 2	
		0 3	
		0 4	
		0 5	
Walking on a level at your own pace	D2	0 0	
pace		0 1	
		O 2 O 3	
		0 4	
		0 5	
Walking on a level with others	UCSD.UCS	0 0	
your age	D3	0 1	
		0 2	
		O 3	
		O 4	
		○ 5	
Walking up a hill	UCSD.UCS D4	0 0	
	<b>D</b> 4	0 1	
		0 2	
		0 3	
		0 4	
		O 5	

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

Dressing	UCSD.UCS D11	0 0	
	ווט	0 1	
		0 2	
		0 3	
		0 4	
		0 5	
Picking up and straightening	UCSD.UCS D12	0 0	
	D12	0 1	
		O 2	
		0 3	
		0 4	
		0 5	
Doing dishes	UCSD.UCS	0 0	
-	D13	° 1	
		0 2	
		0 3	
		0 4	
		0 5	
Sweeping/vacuuming	UCSD.UCS	0 0	
	D14	0 1	
		O 2	
		0 3	
		0 4	
		0 5	
Making bed	UCSD.UCS	0 0	
<b>G</b>	D15	0 1	
		0 2	
		0 3	
		0 4	
		0 5	
Shopping	UCSD.UCS	0 0	
	D16	0 1	
		O 2	
		0 3	
		0 4	
		0 5	

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

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

# Patient Reported Outcome Battery

(Visit ID = 150, Page ID = 90)

Unique Identifier page-45844-304952-150-90

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

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

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

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

# 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.SGR QND		
eorge's Respiratory Questionnaire			
This questionnaire is designed to troubling you and how it affects illness cause you the most problems are.	your life. W	e are using it to find ou	ut which aspects of your
Please read the instructions car spend too long deciding about y	efully and as our answers	sk if you do not unders s.	tand anything. Do not
Before completing the question	naire:		
Please check one box to show how you describe your current health:	SGRQ.CUR HLTH	<ul><li>Very good</li><li>Good</li><li>Fair</li><li>Poor</li><li>Very poor</li></ul>	CURHLTH code list
1		i di ji padi	
weeks. Please check one box for each 1. Over the past 4 weeks, I have coughed:	SGRQ.STG0	<ul> <li>Almost Every Day</li> <li>Several Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> <li>Not at all</li> </ul>	cRSPROB code lis
2. Over the past 4 weeks, I have brought up phlegm (sputum):	SGRQ.STG0	<ul> <li>Almost Every Day</li> <li>Several Days a Week</li> <li>A Few Days a Month</li> <li>Only with Respiratory Infections</li> </ul>	cRSPROB code

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

9. How would you describe your respiratory condition?	SGRQ.STG0 9	0	The moimportal	ost ant problem		
		0		s me quite a roblems	C	RSCON code li
		0	Cause: proble	s me a few ms		
		0	Cause: proble			
10. If you have ever held a job	SGRQ.STG1 0	0		ms made p working		
		0	problem with m	piratory ms interfere y job or me change		cJOB code list
		0	My res	piratory ns do not		
tion 2						
These are questions about who			-	-		
11. For each statement, please	check the b SGRQ.STG1	ox t		•	•	<b>).</b>
Sitting or lying still	1A	0	True False	cTRUFLS	code list	
Washing or dressing yourself	SGRQ.STG1 1B	0	True False	cTRUFLS	code list	
Walking around the house	SGRQ.STG1 1C	0	True False	cTRUFLS	code list	
Walking outside on a level ground	SGRQ.STG1 1D	0	True False	cTRUFLS	code list	
Walking up a flight of stairs	SGRQ.STG1 1E	0	True False	cTRUFLS	code list	
Walking up hills	SGRQ.STG1 1F	0	True False	cTRUFLS	code list	
Walking up hills  Playing sports or other physical activities		0000	False True	cTRUFLS		
Playing sports or other	1F SGRQ.STG1		False			
Playing sports or other physical activities	1F SGRQ.STG1 1G	0	False True False	cTRUFLS	code list	days.
Playing sports or other physical activities	1F SGRQ.STG1 1G ut your cougl	h ar	False True False ad short hat app	cTRUFLS ness of brea	code list	-

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

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

I cannot go out for entertainment or recreation	SGRQ.STG1 6B	<ul><li>True</li><li>False</li></ul>	cTRUFLS	S code list
I cannot go out of the house to do the shopping	SGRQ.STG1 6C	<ul><li>True</li><li>False</li></ul>	cTRUFLS	S code list
I cannot do household chores	SGRQ.STG1 6D	<ul><li>True</li><li>False</li></ul>	cTRUFLS	S code list
I cannot move far from my bed or chair	SGRQ.STG1 6E	<ul><li>True</li><li>False</li></ul>	cTRUFLS	S code list
<ul> <li>Going for walks or walking the Doing activities or chores at horese.</li> <li>Sexual intercourse.</li> <li>Going to a place of worship, or Going out in bad weather or intevisiting family or friends or play.</li> <li>Please write in any other important activities that your respiratory problems may stop you from doing:</li> </ul>	me or in the a place of e to smoky roo	entertainment oms		
17. Now please check the box (one only) that you think best describes how your respiratory problems affect you:	SGRQ.STG1 7	<ul> <li>It does not me from d anything I like to do</li> <li>It stops me</li> </ul>	oing would	

# CAS

### Death

(Visit ID = 160, Page ID = 10)

Unique Identifier page-45934-304953-160-10

Death	n Form			
<b>66</b>	Where did subject die?	DEATH.DTH WHERE	I O Inpatient O Outpatient	
<b>66</b>	Date of death	DEATH.DTH DT	-	
<b>3</b>	Cause of death	DEATH.DTH CAUSE	<ul><li>Pulmonary death</li><li>Non-pulmonary death</li><li>Unknown</li></ul>	
	Pulmonary death specify	DEATH.DTH PULM	Acute exacerbation (definite or suspected)  Progression of IPF (other than acute exacerbation)  Pulmonary embolism  Lung infection  Lung cancer  Other	
	Other specify	DEATH.DTH OTH	1	
	Non-pulmonary death specify	DEATH.DTH SPCFY	1	

## **Health Care Encounters**

(Visit ID = 160, Page ID = 30)

Unique Identifier page-304895-304953-160-30

Health	Care Encounters					
	Has the subject been admitted facility, or rehabilitation center s Admission date					
	Discharge date	HC.HCEND DT				
	Admission type	HC.HCADMI N	0 /	Hospital ER/urgent care Assisted living / nursing facility Rehabilitation center	HCADMINTYPE code	list
	Reason for admission	HC.HCREA SN				
	Check if respiratory-related	HC.HCRES P				
	Major procedures performed	HC.HCPRO C				
	Discharge destination	HC.HCDISC HG	0 / 0   0 -	Home Assisted living / nursing facility Rehab center Transfer to other hospital Subject died Other	HCDISCHRGE code I	ist

# 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.CMPLTE YN	<ul><li>Yes</li><li>Ny code list</li><li>No</li></ul>
Reason for Discontinuation	DS.DSTER M	<ul> <li>Death</li> <li>Lost to Follow-Up</li> <li>Patient Decision</li> <li>Physician Decision</li> <li>Lung Transplant</li> </ul>
Please specify	DS.DSTER MSP	
Date	DS.DSLTFD T	
Date of lung transplant	DS.DSLTXD T	

## **AECODE**

(Visit ID = 160, Page ID = 60)

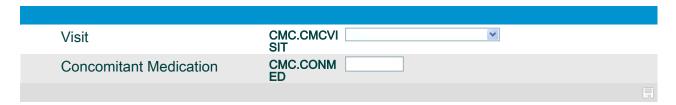
Unique Identifier page-45819-304953-160-60

Visit	AEC.AECVI SIT	
Adverse Event	AEC.AETER M	

### **CMCODE**

(Visit ID = 160, Page ID = 70)

Unique Identifier page-45828-304953-160-70



## **RWCODE**

(Visit ID = 160, Page ID = 80)

Unique Identifier page-45948-304953-160-80

Visit	RWC.RWCV SISIT	
Respiratory Worsening Term	RWC.RWTE RM	

# AE

#### **Adverse Events**

(Visit ID = 170, Page ID = 10)

Unique Identifier page-304919-304954-170-10

dverse Events			
AEID	AE.AEID		
Adverse event	AE.AEVENT	<ul> <li>Respiratory worsening</li> <li>Difficulty swallowing / dysphagia</li> <li>Bloating</li> <li>Flatulence</li> <li>Other</li> </ul>	AE EVENT code list
Respiratory worsening specify:	AE.RESPSP EC	<ul> <li>Community / hospital acquired pneumonia</li> <li>Bronchitis</li> <li>Aspiration pneumonitis</li> <li>Pulmonary embolism</li> <li>Pneumothorax</li> <li>Non-pulmonary cause (e.g. anxiety)</li> <li>Unknown cause</li> </ul>	RESPIRATORY code
Unknown cause specify:	AE.UNKSPC FY	<ul><li>Definite acute exacerbation</li><li>Suspected acute exacerbation</li><li>Unclassifiable</li></ul>	UNKSPECIFY code lis
Other AE specify	AE.AEOTH		
Onset date	AE.AEONST DT		
End date	AE.AEENDD T	<b>I</b>	
AE Ongoing	AE.AECONT		
Hospitalized?	AE.HOSP	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>	
If Yes, complete the Health Car	e Encounter	Form	

Maximum intensity	AE.AEINTN S	<ul><li>Mild</li><li>Moderate</li><li>Severe</li></ul>	AESEV code list
Was event serious?	AE.AESER	<ul><li>Yes</li><li>No</li></ul>	NY code list
Relationship to intervention	AE.AEREAL TE	<ul><li>Not a reasonable possibility</li><li>Reasonable possibility</li></ul>	AERELAT code lis
Final outcome	AE.AEOUTC ME	<ul><li>Subject died</li><li>Resolved no sequelae</li><li>Resolved with sequelae</li><li>Unresolved</li></ul>	FOUTCOME code

### Serious Adverse Events

(Visit ID = 170, Page ID = 20)

Unique Identifier page-45862-304954-170-20

	AE Reference ID		(remote value)	
This e	event was marked Serious. Please i	indicate Serio	ous criteria below (check all that apply).	
866	Death	SAE.SAESD TH		
66	If Death is selected, was an autopsy performed?	SAE.AUTOP SY	<ul><li>Yes</li><li>No</li><li>NY code list</li></ul>	
655	Life-threatening	SAE.SAESLI FE		
	Require inpatient hospitalization or prolongation of existing hospitalization	SAE.SAESH OSP		
	Persistent or significant disability / incapacity	SAE.SAEDI SAB		
<b>56</b>	Congenital anomaly or birth defect	SAE.SAESC ONG		
800	Important medical event	SAE.SAESI ME		
Provi	de a summary in chronological orde	er of the clinic	al course of this SAE from onset through resolution	n.
2. Tre	esenting signs and symptoms eatments and response to treatment atus of subject at time of report and	ts / or final outc	ome, as applicable	
	Summary	SAE.NARSY MP		
	Additional Summary	SAE.NARSY MP1		
	Additional Summary	SAE.NARSY MP2		
	Additional Summary	SAE.NARSY MP3		
	Additional Summary	SAE.NARSY MP4		
	Additional Summary	SAE.NARSY MP5		
	Additional Summary	SAE.NARSY MP6		
	Additional Summary	SAE.NARSY MP7		
Inves	tigator Verification			
<b>5</b> 5	I verify that the data on this SAE form accurately displays the results of the examination, tests, evaluations and treatments noted within.	SAE.SAEPI		