

IPFnet

Annotated Design For Trial: panther_ipf

Protocol: Panther IPF

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October 7, 2010 2:41PM

Time and Events Schedule For Study: panther_ipf

	Assessment	CRF	Screening and History (SCNHX) [S]	Enrollment (ENRL) [S]	Week 4 (WK04) [S]	Week 15 (WK15) [S]	Week 30 (WK30) [S]	Week 45 (WK45) [S]	Week 60/Early Termination (WK60/ET) [S]	Final Visit (FINAL) [S]	Cross Active Study (CAS) [S]	Adverse Events (AE) [S]	Unscheduled Visit (UNSCH) [U/R]	Investigator Signature (INVSIG) [S]	Conflict (Conflict) [U/R/D]
1	Subject Demographics	SUBJINFO	1												
2	Eligibility	ELIG	2												
3	Informed Consent	CONSENT	3												
4	Past Medical History/Physical Findings	MEDHX	4												
5	High-Resolution Computed Tomography (HRCT)/Diagnosis of IPF	HRCT	5												
6	Surgical Lung Biopsy/Diagnosis of IPF	SLB	6												
7	Arterial Blood Gas	ABG	7						3-DF						
8	Screening Spirometry	SSPIRO	8												
9	Lung Volume	LVOL	9						6-DF						
10	Visit Status	VISTAT		1	1	1	1	1	1	1					
11	Vital Signs	VTL		2-DF	2-DF	2-DF	2-DF	2-DF	2-DF				2		
12	Spirometry	SPIRO		3-DF		3-DF	3-DF	3-DF	4-DF				3		
13	Diffusing Capacity of the Lung for Carbon Monoxide	DLCO		4-DF					5-DF						
14	6-Minute Walk Test	6MWT1		5-DF			5-DF		7-DF						
15	6-Minute Walk Test	6MWT2		6-DF			6-DF		8-DF						
16	Hospital Anxiety and Depression Scale	HADS		7-DF	3-DF	4-DF	7-DF	4-DF	9-DF						
17	Log Review	REVIEWS		8-DF											
18	Initial Study Drug Dosing	INITSDRG		9-DF											
19	Gender Substudy Questionnaire	GENDERS		10-DF											
20	EUROQOL Questionnaire Part1	EUROQOL1		11-DF			12-DF		14-DF						
21	EUROQOL Questionnaire Part2	EUROQOL2		12-DF			13-DF		15-DF						
22	ICECAP Questionnaire	ICECAP		13-DF			14-DF		16-DF						
23	UCSDSOB Shortness of Breath Questionnaire Part1	UCSDSOB1		14-DF			15-DF		17-DF						
24	UCSDSOB Shortness of Breath Questionnaire Part2	UCSDSOB2		15-DF			16-DF		18-DF						
25	St. Georges Part 1	STGRG1		16-DF			17-DF		19-DF						
26	St. Georges Part 2	STGRG2		17-DF			18-DF		20-DF						
27	St. Georges Part 3	STGRG3		18-DF			19-DF		21-DF						
28	St. Georges Part 4	STGRG4		19-DF			20-DF		22-DF						
29	St. Georges Part 5	STGRG5		20-DF			21-DF		23-DF						
30	St. Georges Part 6	STGRG6		21-DF			22-DF		24-DF						
31	SF36 Assessment Part 1	SF36_1		22-DF			23-DF		25-DF						
32	SF36 Assessment Part 2	SF36_2		23-DF			24-DF		26-DF						
33	Log Review	REVIEWX			4-DF	5-DF		5-DF					4		
34	Outpatient Visits	OUTPT			5-DF	6-DF	10-DF	6-DF	12-DF						
35	FVC Confirmation	FVC				7-DF	11-DF	7-DF	13-DF				5-DF		
36	Log Review	REVIEW					8-DF		10-DF						
37	Study Drug Compliance	SDRGCOMP					9-DF		11-DF						
38	Study Completion/Termination	TERM									1				
39	Death	DEATH									2				
40	Study Drug Dosing	SDRGCHG									3-RF				
41	Urgent or Inpatient Admissions	INPT									4-RF				
42	Concomitant Medications	MED									5-RF				
43	GERD Changes	GERD									6-RF				
44	Sleep Apnea Changes	SLPCHG									7-RF				
45	Study Drug Log	KIT									8-RF				
46	Telephone Contact Log	PHONE									9-RF				
47	Adverse Events	AE										1-RF			
48	Adjudication Docs Tracking	ADJTRK										2-RF			
49	Adjudication Report	ADJRPT										3-RF			
50	Unscheduled Visit Status	UNSCVIST											1		
51	Signature Completion	SIGN												1	

Key: [S] = Scheduled Visit [O] = Optional Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

panther_ipf : Screening (SCR)

1.*	IVRS generated subject initials	A3	(panther_ipfcdd:SCR.IVRSPT / Subject Initials)
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* Item is not required

CDD: panther_ipfcdd Table: SCR Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
IVRSPT	STRING(3) - A3	

panther_ipf : Enrollment (ENR)**Subject Number**

1.	Subject Number	A10	(Altering this value will change it throughout the trial) (panther_ipfcdd: ENR.SUBJNO / Subject Number)
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CDD: panther_ipfcdd Table: ENR Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SUBJNO	STRING(10) - A10	

panther_ipf : Subject Demographics (SUBJINFO)		
Subject Information		
1.	Subject Number	A10 (Altering this value will change it throughout the trial) (panther_ipfcdd:SUBJINFO.SUBJNO / Subject Number)
2.	IVRS generated subject initials	A3 (Altering this value will change it throughout the trial) (panther_ipfcdd:SUBJINFO.IVRSINIT / Subject Initials)
3.	Randomization Date	Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:SUBJINFO.RANDT / Randomization Date)
Demographics		
4.	Date of Birth	Req [v] / Req [v] / Req [v] (1910-2009) (panther_ipfcdd:SUBJINFO.DOBBDT / Date of birth)
5.	Sex	(panther_ipfcdd:SUBJINFO.SEX / Gender) <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="radio"/> (panther_ipfcdd:SUBJINFO.CBPOT / Childbearing potential) Female Female of childbearing potential? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> (panther_ipfcdd:SUBJINFO.NOCBPO / No Child Potential) No If No, reason <input type="radio"/> Hysterectomy <input type="radio"/> Tubal ligation <input type="radio"/> Post-menopausal (natural [= > 2 years] or surgical) <input checked="" type="radio"/> Other (specify) (panther_ipfcdd:SUBJINFO.NOCBSP / No Child, Specify) A50
6.	Ethnicity	(panther_ipfcdd:SUBJINFO.ETHNIC / Ethnicity) <input type="radio"/> Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino
7.	Race (check all that apply)	(panther_ipfcdd:SUBJINFO.RACE / Race) <input type="radio"/> Select all the races that apply in the list (panther_ipfcdd:SUBJINFO.WHITE / Race: WHITE) <input type="checkbox"/> White (panther_ipfcdd:SUBJINFO.BLACK / Race: BLACK) <input type="checkbox"/> Black or African American (panther_ipfcdd:SUBJINFO.ASIAN / Race: ASIAN) <input type="checkbox"/> Asian (panther_ipfcdd:SUBJINFO.AMERIND / Race: NATIVE) <input type="checkbox"/> American Indian or Alaska Native (panther_ipfcdd:SUBJINFO.NATHWN / Race: HAWAIIAN) <input type="checkbox"/> Native Hawaiian or Other Pacific Islander (panther_ipfcdd:SUBJINFO.OTHRACE / Race: OTHER) <input type="checkbox"/> Other Race (specify): (panther_ipfcdd:SUBJINFO.RACESP / Other Race, Specify) A50
Smoking History		
8.	Does the subject have any history of smoking?	(panther_ipfcdd:SUBJINFO.SMOKING / Smoking History) <input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> (panther_ipfcdd:SUBJINFO.PASTCURR / Smoker) Yes Current Status <input type="radio"/> Current Smoker <input checked="" type="radio"/> Past Smoker: Date last smoked: Req/Unk [v] / Req/Unk [v] / Req [v] (1940-2016) (panther_ipfcdd:SUBJINFO.SMOKEDT / Date Last Smoked) How many total years has the subject smoked? (years) xxx (n >= 0) (panther_ipfcdd:SUBJINFO.SMKYEARS / Total Smoking Years) On average during that time, how many packs (or equivalents) per day of cigarettes did the subject smoke? (packs/day) xxxxxxxx. (n >= 0.0) (panther_ipfcdd:SUBJINFO.SMKPK / Packs Smoked Per Day)
Thiopurine Methyltransferase (TPMT)		
9.	Specify enzyme activity level	(panther_ipfcdd:SUBJINFO.TPMTEZYM / TPMT Enzyme) <input type="radio"/> Negligible TPMT <input type="radio"/> Low TPMT <input checked="" type="radio"/> Normal TPMT
Disease History		
10.	Did subject have a CT consistent with diagnosis of IPF prior to consent?	(panther_ipfcdd:SUBJINFO.IPFCT / CT Diagnosis) <input type="radio"/> No <input checked="" type="radio"/> Yes If Yes: date of earliest: Req/Unk [v] / Req/Unk [v] / Req [v] (1990-2016) (panther_ipfcdd:SUBJINFO.DCTDT / CT Date)
11.	Did subject have a surgical lung biopsy consistent with diagnosis of IPF prior to consent?	(panther_ipfcdd:SUBJINFO.IPFBOP / Lung Biopsy Diagnosis) <input type="radio"/> No <input checked="" type="radio"/> Yes If Yes: date of earliest: Req/Unk [v] / Req/Unk [v] / Req [v] (1990-2016) (panther_ipfcdd:SUBJINFO.DBIOPDT / Lung Biopsy Date)
12.*	Source Document Verification Completion	(panther_ipfcdd:SUBJINFO.SDVSTAT / SDV Complete) <input type="radio"/> Complete <input type="radio"/> Partially Complete <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcdd Table: SUBJINFO Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DCTDT	DATE - DDMONYYYY	
DOBDT	DATE - DDMONYYYY	
DBIOPDT	DATE - DDMONYYYY	
ASIAN	NUMERIC	
SMOKING	NUMERIC	
WHITE	NUMERIC	
OTHRACE	NUMERIC	
TPMTEZYM	NUMERIC	
NATHWN	NUMERIC	
IPFCT	NUMERIC	
PASTCURR	NUMERIC	
IPFBOP	NUMERIC	
AMERIND	NUMERIC	
BLACK	NUMERIC	
NOCBPO	NUMERIC	
ETHNIC	NUMERIC	
SUBJNO	STRING(10) - A10	
SMKPK	FLOAT - F9.0	
IVRSINIT	STRING(3) - A3	
NOCBSP	STRING(50) - A50	
CBPOT	NUMERIC	
RACE	NUMERIC	
SEX	NUMERIC	
SMKEYEARS	NUMERIC - N3	
SMOKEDT	DATE - DDMONYYYY	
RANDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	
RACESP	STRING(50) - A50	

panther_ipf : Eligibility (ELIG)		
Eligibility		
1.	Did the subject meet all eligibility criteria?	(panther_ipfcdd:ELIG1.ELIGCRIT / Eligibility Criteria Met) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
2.*	Source Document Verification Completion	(panther_ipfcdd:ELIG1.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
Which eligibility criteria did the subject not meet?		
3.		
Eligibility Criteria Entry		
3.a	Which eligibility criteria did the subject not meet?	Pulldown List 1 <input type="button" value="v"/> (panther_ipfcdd:ELIG2.INCEXC / Criteria Not Met) (panther_ipfcdd:ELIG2.WAIVER / Waiver Given) Was a waiver given? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieINCEXC01	Exclusion Criteria 1	1	
ieINCEXC02	Exclusion Criteria 2	2	
ieINCEXC03	Exclusion Criteria 3	3	
ieINCEXC04	Exclusion Criteria 4	4	
ieINCEXC05	Exclusion Criteria 5	5	
ieINCEXC06	Exclusion Criteria 6	6	
ieINCEXC07	Exclusion Criteria 7	7	
ieINCEXC08	Exclusion Criteria 8	8	
ieINCEXC09	Exclusion Criteria 9	9	
ieINCEXC10	Exclusion Criteria 10	10	
ieINCEXC11	Exclusion Criteria 11	11	
ieINCEXC12	Exclusion Criteria 12	12	
ieINCEXC13	Exclusion Criteria 13	13	
ieINCEXC14	Exclusion Criteria 14	14	
ieINCEXC15	Exclusion Criteria 15	15	
ieINCEXC16	Exclusion Criteria 16	16	
ieINCEXC17	Exclusion Criteria 17	17	
ieINCEXC18	Exclusion Criteria 18	18	
ieINCEXC19	Exclusion Criteria 19	19	
ieINCEXC20	Exclusion Criteria 20	20	
ieINCEXC21	Exclusion Criteria 21	21	
ieINCEXC22	Exclusion Criteria 22	22	
ieINCEXC23	Exclusion Criteria 23	23	
ieINCEXC24	Exclusion Criteria 24	24	
ieINCEXC25	Exclusion Criteria 25	25	
ieINCEXC26	Exclusion Criteria 26	26	
ieINCEXC27	Exclusion Criteria 27	27	
ieINCEXC28	Exclusion Criteria 28	28	
ieINCEXC45	Inclusion Criteria 1 not met	31	
ieINCEXC46	Inclusion Criteria 2 not met	32	
ieINCEXC47	Inclusion Criteria 3 not met	33	
ieINCEXC48	Inclusion Criteria 4 not met	34	
ieINCEXC49	Inclusion Criteria 5 not met	35	
ieINCEXC42	Study is too time consuming	42	
ieINCEXC43	Study is too experimental	43	
ieINCEXC44	Other	44	

CDD: panther_ipfcdd Table: ELIG1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ELIGCRIT	NUMERIC	
SDVSTAT	NUMERIC	

CDD: panther_ipfcdd Table: ELIG2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
INCEXC	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 31, 32, 33, 34, 35, 42, 43, 44	
WAIVER	NUMERIC	

panther_ipf : Informed Consent (CONSENT)	
Eligibility	
1. Date informed consent signed:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:CONSENT.CONSNLDT / Consent Date)
2. Did subject grant permission for the CT study?	(panther_ipfcdd:CONSENT.CTCSNT / CT Consent) [0] <input type="radio"/> No [1] <input type="radio"/> (panther_ipfcdd:CONSENT.CTDATEUSE / CT Data Use) Yes If yes, who can use the CT data? [1] <input type="radio"/> Investigators involved with study only [2] <input type="radio"/> Non-commercial use only [3] <input type="radio"/> Commercial and non-commercial use
3. Did subject grant permission for monitoring for survival after completion of the study?	(panther_ipfcdd:CONSENT.ALIVECST / Survival Consent) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4. Did subject grant permission to participate in a fibrocytes ancillary study?	(panther_ipfcdd:CONSENT.FIBROCST / Fibrocytes Consent) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5. Did subject grant permission to have his/her biological samples stored in the biospecimen repository	(panther_ipfcdd:CONSENT.BLDSAMPL / Biological Sample Consent) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, Date research sample consent signed Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:CONSENT.BLDSAMDT / Biological Consent Date)
6. Did subject grant permission to participate in the oxidant stress sub-study?	(panther_ipfcdd:CONSENT.OXCNSNT / Oxidant Consent) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7.* Source Document Verification Completion	(panther_ipfcdd:CONSENT.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

Column Name	Column Data Type	Design Note
CTCSNT	NUMERIC	
CONSNLDT	DATE - DDMONYYYY	
BLDSAMDT	DATE - DDMONYYYY	
ALIVECST	NUMERIC	
CTDATEUSE	NUMERIC	
BLDSAMPL	NUMERIC	
FIBROCST	NUMERIC	
SDVSTAT	NUMERIC	
OXCNSNT	NUMERIC	

panther_ipf : Past Medical History/Physical Findings (MEDHX)	
Past Medical History/Physical Findings	
Does subject have a current or past history of:	
1. Coronary artery disease	(panther_ipfcdd:MEDHX.CADHIST / Coronary Artery Disease) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
2. Acute MI	(panther_ipfcdd:MEDHX.ACUTEMI / Acute MI) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
3. Valvular heart disease	(panther_ipfcdd:MEDHX.VALVULAR / Valvular Heart Disease) [0] <input type="radio"/> No [1] <input type="radio"/> Yes, Specify: (panther_ipfcdd:MEDHX.VALVULSP / Valvular, Specify) A50 [99] <input type="radio"/> Unknown
4. Heart failure	(panther_ipfcdd:MEDHX.HFAILURE / Heart Failure) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
5. Atrial fibrillation	(panther_ipfcdd:MEDHX.ATRIALFB / Atrial Fibrillation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
6. Intermittent claudication	(panther_ipfcdd:MEDHX.CLAUDICA / Claudication) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
7. Cirrhosis or other serious, chronic liver disease	(panther_ipfcdd:MEDHX.LIVERDIS / Cirrhosis) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
8. Diabetes	(panther_ipfcdd:MEDHX.DIABETES / Diabetes) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
9. Lung cancer	(panther_ipfcdd:MEDHX.LGCANCER / Lung Cancer) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
10. Other cancer (excluding basal cell carcinoma)	(panther_ipfcdd:MEDHX.OTHCAN / Other Cancer) [0] <input type="radio"/> No [1] <input type="radio"/> Yes, Specify: (panther_ipfcdd:MEDHX.OTHCANSP / Cancer, Specify) A50 [99] <input type="radio"/> Unknown
11. Gastroesophageal reflux disorders (GERD): Barretts esophagus	(panther_ipfcdd:MEDHX.BARRETS / Baretts) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
12. Gastroesophageal reflux disorders (GERD): Hiatal hernia	(panther_ipfcdd:MEDHX.HIATALHN / Hiatal Hernia) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
13. Gastroesophageal reflux disorders (GERD): Fundoplication surgery	(panther_ipfcdd:MEDHX.FUNDSURG / Fundoplication) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
14. Gastroesophageal reflux disorders (GERD): Gastroesophageal reflux	(panther_ipfcdd:MEDHX.REFLUX / Reflux) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes How was gastroesophageal reflux diagnosed (panther_ipfcdd:MEDHX.PHMONITR / pH Monitoring) [1] <input type="checkbox"/> 24 hr pH monitoring (panther_ipfcdd:MEDHX.ENDOSCOPY / Endoscopy) [1] <input type="checkbox"/> Endoscopy (panther_ipfcdd:MEDHX.UPBARIUM / Swallow Test) [1] <input type="checkbox"/> Upper GI/barium swallow test (panther_ipfcdd:MEDHX.HTBURN / Heartburn) [1] <input type="checkbox"/> Symptoms of heartburn (panther_ipfcdd:MEDHX.GDIAUNK / Diagnosis Unknown) [1] <input type="checkbox"/> Unknown/Other Non-pharmaceutical interventions for gastroesophageal reflux (panther_ipfcdd:MEDHX.ELEV / Elevated Bed) [1] <input type="checkbox"/> Sleeping with the head end of the bed elevated with 6 to 8 inch blocks on the floor (panther_ipfcdd:MEDHX.RECLIN / Recliner) [1] <input type="checkbox"/> Sleeping in a recliner (panther_ipfcdd:MEDHX.FOOD / Limiting Food Beverage) [1] <input type="checkbox"/> Limiting foods and beverages that cause symptoms (panther_ipfcdd:MEDHX.NOFLAT / Avoiding Laying Flat) [1] <input type="checkbox"/> Avoiding lying down flat for 3 hours after a meal (panther_ipfcdd:MEDHX.BEDSNK / Avoiding Bedtime Snacks) [1] <input type="checkbox"/> Avoiding bedtime snacks (panther_ipfcdd:MEDHX.SMLMEAL / Small Meals) [1] <input type="checkbox"/> Eating small meals (panther_ipfcdd:MEDHX.NOGERDIN / No Intervention) [1] <input type="checkbox"/> None
15. Sleep apnea (central or obstructive)	(panther_ipfcdd:MEDHX.SLPAPNEA / Sleep Apnea) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> (panther_ipfcdd:MEDHX.CPAP / CPAP Treatment) Yes If Yes: CPAP treatment [0] <input type="radio"/> None [1] <input type="radio"/> Daily [2] <input type="radio"/> Intermittent
16. Asthma	(panther_ipfcdd:MEDHX.ASTHMA / Asthma) No Yes Unknown

		[0] <input type="radio"/> [1] <input type="radio"/> [99] <input type="radio"/>
17.	Evidence of pulmonary hypertension	(panther_ipfcdd:MEDHX.HYPERTEN / Hypertension) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (panther_ipfcdd:MEDHX.HYPRECHO / Diagnosis Echo) If Yes: Identify the method of diagnosing pulmonary hypertension [1] <input type="checkbox"/> Echo (panther_ipfcdd:MEDHX.HYPRCATH / Diagnosis Cath) [1] <input type="checkbox"/> Cath
18.	Emphysema or chronic bronchitis	(panther_ipfcdd:MEDHX.EMPHYS / Emphysema or Bronchitis) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
19.	Connective tissue features (thought clinically insignificant)	(panther_ipfcdd:MEDHX.CNTISSUE / Connective Tissue) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (panther_ipfcdd:MEDHX.RAYNAUDS / Raynauds) [1] <input type="checkbox"/> Raynaud's (panther_ipfcdd:MEDHX.POSANA / Positive ANA) [1] <input type="checkbox"/> Positive ANA - Titer: 1 : xxxxxxxx. (panther_ipfcdd:MEDHX.POSANA1 / Positive ANA Titer) (panther_ipfcdd:MEDHX.POSRF / Positive RF) [1] <input type="checkbox"/> Positive RF - Level: (IU/mL) xxxxxxxx. (panther_ipfcdd:MEDHX.POSRF1 / Positive RF Level) (panther_ipfcdd:MEDHX.MYALGIA / Arthralgia Myalgia) [1] <input type="checkbox"/> Significant arthralgia/myalgia (panther_ipfcdd:MEDHX.SICCA / Sicca) [1] <input type="checkbox"/> Sicca symptoms (panther_ipfcdd:MEDHX.DYSFHAGA / Dysphagia) [1] <input type="checkbox"/> Dysphagia (panther_ipfcdd:MEDHX.OTHITIS / Other tissue features) [1] <input type="checkbox"/> Other (specify): (panther_ipfcdd:MEDHX.OTHTISSP / Tissue Features, Specify) A50
20.	Exposure to organic or inorganic antigens known to cause interstitial lung disease (thought clinically insignificant)	(panther_ipfcdd:MEDHX.ANTIGENS / Antigen Exposure) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
21.	Clubbing	(panther_ipfcdd:MEDHX.CLUBBING / Clubbing) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
22.	Bibasilar, inspiratory crackles	(panther_ipfcdd:MEDHX.CRACKLES / Crackles) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
23.	Jugular venous distension	(panther_ipfcdd:MEDHX.JVD / JVD) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
24.	Increased P2	(panther_ipfcdd:MEDHX.INCSEPPT / Increased P2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
25.	Peripheral edema	(panther_ipfcdd:MEDHX.PEREDEMA / Peripheral Edema) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
26.	Other significant condition/finding	(panther_ipfcdd:MEDHX.OTH1 / Other Finding) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (panther_ipfcdd:MEDHX.OTH1SP / Other Finding, Specify) Other (specify): A200
27.*	Source Document Verification Completion	(panther_ipfcdd:MEDHX.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcdd Table: MEDHX Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
HYPERTEN	NUMERIC	
ASTHMA	NUMERIC	
HYPRCATH	NUMERIC	
OTH1SP	STRING(200) - A200	
DYSFHAGA	NUMERIC	
POSANA1	FLOAT - F9.0	
HFAILURE	NUMERIC	
UPBARIUM	NUMERIC	
JVD	NUMERIC	
OTHTISSP	STRING(50) - A50	
PHMONITR	NUMERIC	
ENDOSCOP	NUMERIC	

POSRF1	FLOAT - F9,0	
ELEV	NUMERIC	
MYALGIA	NUMERIC	
VALVULAR	NUMERIC	
OTHCANSP	STRING(50) - A50	
GDIANK	NUMERIC	
CLUBBING	NUMERIC	
HIATALHN	NUMERIC	
SICCA	NUMERIC	
HTBURN	NUMERIC	
CNTISSUE	NUMERIC	
ATRIALFB	NUMERIC	
ANTIGENS	NUMERIC	
REFLUX	NUMERIC	
LIVERDIS	NUMERIC	
VALVULSP	STRING(50) - A50	
INCSEPPT	NUMERIC	
HYPRECHO	NUMERIC	
EMPHYS	NUMERIC	
CADHIST	NUMERIC	
NOGERDIN	NUMERIC	
CLAUDICA	NUMERIC	
FUNDSURG	NUMERIC	
SDVSTAT	NUMERIC	
RAYNAUDS	NUMERIC	
FOOD	NUMERIC	
LGCANCER	NUMERIC	
OTHCAN	NUMERIC	
BARRETS	NUMERIC	
RECLIN	NUMERIC	
PEREDEMA	NUMERIC	
POSRF	NUMERIC	
POSANA	NUMERIC	
SMLMEAL	NUMERIC	
CRACKLES	NUMERIC	
NOFLAT	NUMERIC	
DIABETES	NUMERIC	
OTHITIS	NUMERIC	
ACUTEMI	NUMERIC	
BEDSNK	NUMERIC	
CPAP	NUMERIC	
OTHC1	NUMERIC	
SLPAPNEA	NUMERIC	

panther_ipf : High-Resolution Computed Tomography (HRCT)/Diagnosis of IPF (HRCT)**High-Resolution Computed Tomography (HRCT)/Diagnosis of IPF (HRCT)**

1.	Date of HRCT:	<input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2007-2016) (panther_ipfcdd:HRCT.HRCTDT / HRCT Date)
2.	Adequate Inspiration?	(panther_ipfcdd:HRCT.ADQINSPR / Adequate Inspiration) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
3.	Prone Images?	(panther_ipfcdd:HRCT.PRONE / Prone Images) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
4.	Expiratory Images?	(panther_ipfcdd:HRCT.EXPIMAGE / Expiratory Images) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
5.	Motion Artifact:	(panther_ipfcdd:HRCT.MOVEMENT / Motion Artifact) [1] <input type="radio"/> None [2] <input type="radio"/> Mild [3] <input type="radio"/> Moderate [4] <input type="radio"/> Severe [5] <input type="radio"/> Non-diagnostic [99] <input type="radio"/> Unknown
6.	Pulmonary artery diameter (cm):	(panther_ipfcdd:HRCT.PULAUNK / Pulmonary Art Diameter Unk) [1] <input type="radio"/> xxxxxxxx. (panther_ipfcdd:HRCT.PULATDIA / Pulmonary Artery Diameter) [99] <input type="radio"/> Unknown
7.	Aorta diameter (cm):	(panther_ipfcdd:HRCT.AORTUNK / Aorta Diameter Unknown) [1] <input type="radio"/> xxxxxxxx. (panther_ipfcdd:HRCT.AORTADIA / Aorta Diameter) [99] <input type="radio"/> Unknown
8.	Predominant craniocaudal distribution of abnormality	(panther_ipfcdd:HRCT.LUNGDIST / Craniocaudal Abnormality) [1] <input type="radio"/> Lower lung [2] <input type="radio"/> Mid-lung [3] <input type="radio"/> Upper lung [4] <input type="radio"/> Diffuse [99] <input type="radio"/> Unknown
9.	Predominant axial distribution	(panther_ipfcdd:HRCT.AXDIST / Axial Distribution) [1] <input type="radio"/> Peripheral [2] <input type="radio"/> Central/peribronchovascular [3] <input type="radio"/> Diffuse [99] <input type="radio"/> Unknown
10.	Reticular abnormality:	(panther_ipfcdd:HRCT.RETICULR / Reticular Abnormality) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
11.	Honeycombing:	(panther_ipfcdd:HRCT.HONECOMB / Honeycombing) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
12.	Extensive ground glass abnormality: extent > reticular abnormality	(panther_ipfcdd:HRCT.GRDGLASS / Ground Glass Abnormality) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
13.	Profuse micronodules: bilateral	(panther_ipfcdd:HRCT.MICRONDL / Profuse Micronodules) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
14.	Discrete cysts: multiple, in both lungs, not in areas of honeycombing	(panther_ipfcdd:HRCT.CYSTS / Discrete Cysts) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
15.	Mosaic attenuation/lobular air trapping: bilateral, in 3 or more lobes	(panther_ipfcdd:HRCT.MOSAIC / Mosaic Attenuation) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
16.	Consolidation:	(panther_ipfcdd:HRCT.CONOLID / Consolidation) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
17.	Presence of emphysema:	(panther_ipfcdd:HRCT.EMPHYSEM / Emphysema) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present (panther_ipfcdd:HRCT.EMPHYYPN / Extent of Emphysema) If Present: extent of emphysema > the extent of fibrotic change (honeycombing, reticular changes)

		[0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
18.	Entry Criteria	(panther_ipfcdd:HRCT.UIPPATRN / Entry Criteria) [1] <input type="radio"/> Definite UIP pattern [2] <input type="radio"/> Consistent with UIP pattern [3] <input type="radio"/> Inconsistent with UIP pattern [99] <input type="radio"/> Unknown
19.*	Source Document Verification Completion	(panther_ipfcdd:HRCT.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcdd Table: HRCT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PRONE	NUMERIC	
SDVSTAT	NUMERIC	
PULAUNK	NUMERIC	
CYSTS	NUMERIC	
AXDIST	NUMERIC	
EMPHYSEM	NUMERIC	
LUNGDIST	NUMERIC	
CONSOLID	NUMERIC	
RETICULR	NUMERIC	
AORTUNK	NUMERIC	
MOSAIC	NUMERIC	
PULATDIA	FLOAT - F9.0	
MOVEMENT	NUMERIC	
MICRONDL	NUMERIC	
ADQINSR	NUMERIC	
HONECOMB	NUMERIC	
HRCTDT	DATE - DDMONYYYY	
EXPIMAGE	NUMERIC	
EMPHYYPN	NUMERIC	
AORTADIA	FLOAT - F9.0	
GRDGLASS	NUMERIC	
UIPPATRN	NUMERIC	

panther_ipf : Surgical Lung Biopsy/Diagnosis of IPF (SLB)	
Surgical Lung Biopsy/Diagnosis of IPF (SLB)	
1. Date of biopsy:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1910-2015) (panther_ipfcdd:SLB.SLBDT / Lung Biopsy Date)
Clinical Center	
2. Did the Clinical Center evaluate the surgical lung biopsy?	<p>(panther_ipfcdd:SLB.CCDONE / Clinical Evaluation)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>(panther_ipfcdd:SLB.CCSCARR / Clinical UIP Criteria)</p> <p>Criteria for diagnosis of UIP: check all that apply</p> <p>[1] <input type="checkbox"/> Clear evidence of scarring, architectural distortion with or without honeycombing</p> <p>(panther_ipfcdd:SLB.CCFIBRO / Clinical Fibroblast Foci)</p> <p>[1] <input type="checkbox"/> (panther_ipfcdd:SLB.CCPRES / Clinical Foci Present)</p> <p>Fibroblast foci</p> <p>If Fibroblast foci present, check quantity</p> <p>[1] <input type="radio"/> 1+</p> <p>[2] <input type="radio"/> 2+</p> <p>[3] <input type="radio"/> 3+</p> <p>[4] <input type="radio"/> 4+</p> <p>[99] <input type="radio"/> Unknown</p> <p>(panther_ipfcdd:SLB.CCPAREN / Clinical Pathcy Involvement)</p> <p>[1] <input type="checkbox"/> Patchy involvement of lung parenchyma</p> <p>(panther_ipfcdd:SLB.CCUIPDX / Clinical Absence Features)</p> <p>[1] <input type="checkbox"/> Absence of features against a diagnosis of UIP</p> <p>(panther_ipfcdd:SLB.CCDIAG / Clinical Con of Diagnosis)</p> <p>Confidence of diagnosis of UIP (check only one):</p> <p>[1] <input type="radio"/> Definite</p> <p>[2] <input type="radio"/> Probable</p> <p>[3] <input type="radio"/> Possible</p> <p>[4] <input type="radio"/> Not UIP</p>
Central	
3. Did a Central reader evaluate the surgical lung biopsy?	<p>(panther_ipfcdd:SLB.CDONE / Central Evaluation)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>(panther_ipfcdd:SLB.CSCARR / Central UIP Criteria)</p> <p>Criteria for diagnosis of UIP: check all that apply</p> <p>[1] <input type="checkbox"/> Clear evidence of scarring, architectural distortion with or without honeycombing</p> <p>(panther_ipfcdd:SLB.CFIBRO / Central Fibroblast Foci)</p> <p>[1] <input type="checkbox"/> (panther_ipfcdd:SLB.CPRES / Central Foci Present)</p> <p>Fibroblast foci</p> <p>If Fibroblast foci present, check quantity</p> <p>[1] <input type="radio"/> 1+</p> <p>[2] <input type="radio"/> 2+</p> <p>[3] <input type="radio"/> 3+</p> <p>[4] <input type="radio"/> 4+</p> <p>[99] <input type="radio"/> Unknown</p> <p>(panther_ipfcdd:SLB.CPAREN / Central Pathcy Involvement)</p> <p>[1] <input type="checkbox"/> Patchy involvement of lung parenchyma</p> <p>(panther_ipfcdd:SLB.CUIPDX / Central Absence of Features)</p> <p>[1] <input type="checkbox"/> Absence of features against a diagnosis of UIP</p> <p>(panther_ipfcdd:SLB.CDIAG / Central Con of Diagnosis)</p> <p>Confidence of diagnosis of UIP (check only one):</p> <p>[1] <input type="radio"/> Definite</p> <p>[2] <input type="radio"/> Probable</p> <p>[3] <input type="radio"/> Possible</p> <p>[4] <input type="radio"/> Not UIP</p>
Tie Breaker	
4. Did a Tie Breaker evaluate the surgical lung biopsy?	<p>(panther_ipfcdd:SLB.TBDONE / Tie Breaker Evaluation)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>(panther_ipfcdd:SLB.TBSCARR / Tie Breaker UIP Criteria)</p> <p>Criteria for diagnosis of UIP: check all that apply</p> <p>[1] <input type="checkbox"/> Clear evidence of scarring, architectural distortion with or without honeycombing</p> <p>(panther_ipfcdd:SLB.TBFIBRO / Tie Breaker Fibroblast Foci)</p> <p>[1] <input type="checkbox"/> (panther_ipfcdd:SLB.TBPRES / Tie-Breaker Foci Present)</p> <p>Fibroblast foci</p> <p>If Fibroblast foci present, check quantity</p> <p>[1] <input type="radio"/> 1+</p> <p>[2] <input type="radio"/> 2+</p> <p>[3] <input type="radio"/> 3+</p> <p>[4] <input type="radio"/> 4+</p> <p>[99] <input type="radio"/> Unknown</p> <p>(panther_ipfcdd:SLB.TBPAREN / Tie Breaker Pathcy Involve)</p> <p>[1] <input type="checkbox"/> Patchy involvement of lung parenchyma</p> <p>(panther_ipfcdd:SLB.TBUIPDX / Tie Break Absence Features)</p> <p>[1] <input type="checkbox"/> Absence of features against a diagnosis of UIP</p> <p>(panther_ipfcdd:SLB.TBDIAG / Tie Break Con of Diagnosis)</p> <p>Confidence of diagnosis of UIP (check only one):</p> <p>[1] <input type="radio"/> Definite</p>

	<p>[2] <input type="radio"/> Probable [3] <input type="radio"/> Possible [4] <input type="radio"/> Not UIP</p>
<p>Adjudication</p> <p>5. Did an adjudicator evaluate the surgical lung biopsy?</p>	<p>(panther_ipfcdd:SLB.AJJDONE / Adjudication Evaluation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd:SLB.AJSCARR / Adjudication UIP Criteria) Criteria for diagnosis of UIP: check all that apply [1] <input type="checkbox"/> Clear evidence of scarring, architectural distortion with or without honeycombing (panther_ipfcdd:SLB.AJFIBRO / Adjud Fibroblast Foci) [1] <input type="checkbox"/> (panther_ipfcdd:SLB.AJPRES / Adjudication Foci Present) Fibroblast foci If Fibroblast foci present, check quantity: [1] <input type="radio"/> 1+ [2] <input type="radio"/> 2+ [3] <input type="radio"/> 3+ [4] <input type="radio"/> 4+ [99] <input type="radio"/> Unknown (panther_ipfcdd:SLB.AJPAREN / Adj Patchy Involvement) [1] <input type="checkbox"/> Patchy involvement of lung parenchyma (panther_ipfcdd:SLB.AJUIPDX / Adj Absence of Features) [1] <input type="checkbox"/> Absence of features against a diagnosis of UIP (panther_ipfcdd:SLB.AJCHOIC / Adj Confidence of Diagnosis) Confidence of diagnosis of UIP (check only one): [1] <input type="radio"/> Definite [2] <input type="radio"/> Probable [3] <input type="radio"/> Possible [4] <input type="radio"/> Not UIP</p>
<p>6.* Source Document Verification Completion</p>	<p>(panther_ipfcdd:SLB.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable</p>
<p>* Item is not required</p>	

CDD: panther_ipfcdd Table: SLB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
CCPRES	NUMERIC	
CCDONE	NUMERIC	
CDIAG	NUMERIC	
AJPRES	NUMERIC	
AJFIBRO	NUMERIC	
CPAREN	NUMERIC	
AJUIPDX	NUMERIC	
CPRES	NUMERIC	
TBPAREN	NUMERIC	
CCDIAG	NUMERIC	
CCUIPDX	NUMERIC	
SDVSTAT	NUMERIC	
AJCHOIC	NUMERIC	
TBSCARR	NUMERIC	
TBFIBRO	NUMERIC	
AJSCARR	NUMERIC	
AJJDONE	NUMERIC	
TBDIAG	NUMERIC	
CCPAREN	NUMERIC	
SLBDT	DATE - DDMONYYYY	
CCFIBRO	NUMERIC	
CFIBRO	NUMERIC	
TBUIPDX	NUMERIC	
CDONE	NUMERIC	
TBDONE	NUMERIC	
CSCARR	NUMERIC	
CCSCARR	NUMERIC	
TBPRES	NUMERIC	
CUIPDX	NUMERIC	
AJPAREN	NUMERIC	

panther_ipf : Arterial Blood Gas (ABG)		
Arterial Blood Gas		
1.	Date of Assessment	Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2009-2016) (panther_ipfcdd: ABG.ABGASDT / ABG Date)
2.	Barometric pressure	(panther_ipfcdd: ABG.BARPRUNK / Barometric Press, Not Done) [1] <input type="radio"/> xxx mmHg (panther_ipfcdd: ABG.BARPRESS / Barometric Pressure) [97] <input type="radio"/> Not Done
3.	Clinic altitude	(panther_ipfcdd: ABG.ALTITUDE / Clinic Altitude) [1] <input type="radio"/> < 4000 ft [2] <input type="radio"/> >= 4000 ft [97] <input type="radio"/> Not Done
4.	FIO2	(panther_ipfcdd: ABG.FIO2UNK / FIO2 Unknown) [1] <input type="radio"/> xxxxxxxx. % (panther_ipfcdd: ABG.FIO2 / FIO2) [97] <input type="radio"/> Not Done
5.	pH	(panther_ipfcdd: ABG.PHUNK / pH Unknown) [1] <input type="radio"/> xxxxxxxx. (panther_ipfcdd: ABG.PH / pH) [97] <input type="radio"/> Not Done
6.	PaO2	(panther_ipfcdd: ABG.PAO2UNK / PaO2 Unknown) [1] <input type="radio"/> xxxxxxxx. mmHg (panther_ipfcdd: ABG.PAO2 / PaO2) [97] <input type="radio"/> Not Done
7.	PaCO2	(panther_ipfcdd: ABG.PACO2UNK / PaCO2 Unknown) [1] <input type="radio"/> xxxxxxxx. mmHg (panther_ipfcdd: ABG.PACO2 / PaCO2) [97] <input type="radio"/> Not Done
8.	SaO2	(panther_ipfcdd: ABG.SAO2UNK / SaO2 Unknown) [1] <input type="radio"/> xxxxxxxx. % (panther_ipfcdd: ABG.SAO2 / SaO2) [97] <input type="radio"/> Not Done
9.*	Source Document Verification Completion	(panther_ipfcdd: ABG.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
PHUNK	NUMERIC	
PAO2UNK	NUMERIC	
BARPRESS	NUMERIC - N3	
FIO2	FLOAT - F9.0	
ALTITUDE	NUMERIC	
PH	FLOAT - F9.0	
FIO2UNK	NUMERIC	
ABGASDT	DATE - DDMYYYY	
SAO2UNK	NUMERIC	
BARPRUNK	NUMERIC	
PACO2UNK	NUMERIC	
SDVSTAT	NUMERIC	
PACO2	FLOAT - F9.0	
PAO2	FLOAT - F9.0	
SAO2	FLOAT - F9.0	

panther_ipf : Screening Spirometry (SSPIRO)	
Assessment Date	
1.	Date of Screening Spirometry assessment: <input type="text"/> Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:SSPIRO.SSPIRODT / Spirometry Date)
Pre Bronchodilator - Primary	
2.	FEV1: Actual (panther_ipfcdd:SSPIRO.FEV1UNK / FEV1 Pre Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV1PRP / FEV1 Pre Primary) [97] <input type="radio"/> Not Done
3.	FEV6: Actual (panther_ipfcdd:SSPIRO.FEV6UNK / FEV6 Pre Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV6PRP / FEV6 Pre Primary) [97] <input type="radio"/> Not Done
4.	FVC: Actual (panther_ipfcdd:SSPIRO.FVCUNK / FVC Pre Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FVCPRP / FVC Pre Primary) [97] <input type="radio"/> Not Done
Pre Bronchodilator - Replicate 1	
5.	FEV1: Actual (panther_ipfcdd:SSPIRO.FEV1UNK1 / FEV1 Pre Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV1PRR1 / FEV1 Pre Rep 1) [97] <input type="radio"/> Not Done
6.	FEV6: Actual (panther_ipfcdd:SSPIRO.FEV6UNK1 / FEV6 Pre Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV6PRR1 / FEV6 Pre Rep 1) [97] <input type="radio"/> Not Done
7.	FVC: Actual (panther_ipfcdd:SSPIRO.FVCUNK1 / FVC Pre Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FVCPRR1 / FVC Pre Rep 1) [97] <input type="radio"/> Not Done
Pre Bronchodilator - Replicate 2	
8.	FEV1: Actual (panther_ipfcdd:SSPIRO.FEV1UNK2 / FEV1 Pre Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV1PRR2 / FEV1 Pre Rep 2) [97] <input type="radio"/> Not Done
9.	FEV6: Actual (panther_ipfcdd:SSPIRO.FEV6UNK2 / FEV6 Pre Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV6PRR2 / FEV6 Pre Rep 2) [97] <input type="radio"/> Not Done
10.	FVC: Actual (panther_ipfcdd:SSPIRO.FVCUNK2 / FVC Pre Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FVCPRR2 / FVC Pre Rep 2) [97] <input type="radio"/> Not Done
Post Bronchodilator - Primary	
11.	FEV1: Actual (panther_ipfcdd:SSPIRO.FEV1UNK3 / FEV1 Post Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV1PSP / FEV1 Post Primary) [97] <input type="radio"/> Not Done
12.	FEV6: Actual (panther_ipfcdd:SSPIRO.FEV6UNK3 / FEV6 Post Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV6PSP / FEV6 Post Primary) [97] <input type="radio"/> Not Done
13.	FVC: Actual (panther_ipfcdd:SSPIRO.FVCUNK3 / FVC Post Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FVCPSP / FVC Post Primary) [97] <input type="radio"/> Not Done
Post Bronchodilator - Replicate 1	
14.	FEV1: Actual (panther_ipfcdd:SSPIRO.FEV1UNK4 / FEV1 Post Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV1PSR1 / FEV1 Post Rep 1) [97] <input type="radio"/> Not Done
15.	FEV6: Actual (panther_ipfcdd:SSPIRO.FEV6UNK4 / FEV6 Post Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV6PSR1 / FEV6 Post Rep 1) [97] <input type="radio"/> Not Done
16.	FVC: Actual (panther_ipfcdd:SSPIRO.FVCUNK4 / FVC Post Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FVCPSR1 / FVC Post Rep 1) [97] <input type="radio"/> Not Done
Post Bronchodilator - Replicate 2	
17.	FEV1: Actual (panther_ipfcdd:SSPIRO.FEV1UNK5 / FEV1 Post Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV1PSR2 / FEV1 Post Rep 2) [97] <input type="radio"/> Not Done
18.	FEV6: Actual (panther_ipfcdd:SSPIRO.FEV6UNK5 / FEV6 Post Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FEV6PSR2 / FEV6 Post Rep 2) [97] <input type="radio"/> Not Done
19.	FVC: Actual (panther_ipfcdd:SSPIRO.FVCUNK5 / FVC Post Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd:SSPIRO.FVCPSR2 / FVC Post Rep 2) [97] <input type="radio"/> Not Done
20.*	Source Document Verification Completion (panther_ipfcdd:SSPIRO.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete

[3] Not Applicable

* Item is not required

CDD: panther_ipfcdd	Table: SSIRO	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
FEV6UNK	NUMERIC	
FVCPRR2	FLOAT - F9.0	
FVCUNK	NUMERIC	
FEV6PRR1	FLOAT - F9.0	
FVCP SR1	FLOAT - F9.0	
FEV1PRR2	FLOAT - F9.0	
FVCUNK2	NUMERIC	
FEV6UNK1	NUMERIC	
SDVSTAT	NUMERIC	
SSPIRODT	DATE - DDMONYYYY	
FVCUNK1	NUMERIC	
FEV6UNK4	NUMERIC	
FVCPRR1	FLOAT - F9.0	
FEV6PSR2	FLOAT - F9.0	
FVCPRP	FLOAT - F9.0	
FEV1PSR1	FLOAT - F9.0	
FEV6UNK3	NUMERIC	
FVCPSP	FLOAT - F9.0	
FEV1UNK	NUMERIC	
FEV1UNK5	NUMERIC	
FEV6PSR1	FLOAT - F9.0	
FEV1UNK4	NUMERIC	
FEV6PRR2	FLOAT - F9.0	
FEV1PSP	FLOAT - F9.0	
FEV1UNK1	NUMERIC	
FEV1PRP	FLOAT - F9.0	
FEV1PSR2	FLOAT - F9.0	
FEV1UNK2	NUMERIC	
FVCP SR2	FLOAT - F9.0	
FEV1PRR1	FLOAT - F9.0	
FVCUNK4	NUMERIC	
FEV6UNK5	NUMERIC	
FEV6UNK2	NUMERIC	
FVCUNK3	NUMERIC	
FVCUNK5	NUMERIC	
FEV1UNK3	NUMERIC	
FEV6PSP	FLOAT - F9.0	
FEV6PRP	FLOAT - F9.0	

panther_ipf : Lung Volume (LVOL)		
Lung Volume		
1.	Date of Lung Volume assessment:	Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2009-2016) (panther_ipfccd:LVOL.LUNGVLDT / Lung Volume Date)
2.	Total lung capacity (TLC)	(panther_ipfccd:LVOL.TLCUNK / TLC Not Done) [1] <input type="radio"/> xxxxxxxx liters (panther_ipfccd:LVOL.TLC / TLC) [97] <input type="radio"/> Not Done
3.	Functional residual capacity (FRC)	(panther_ipfccd:LVOL.FRCUNK / FRC Not Done) [1] <input type="radio"/> xxxxxxxx liters (panther_ipfccd:LVOL.FRC / FRC) [97] <input type="radio"/> Not Done
4.	Slow vital capacity (SVC)	(panther_ipfccd:LVOL.SVCUNK / SVC Not Done) [1] <input type="radio"/> xxxxxxxx liters (panther_ipfccd:LVOL.SVC / SVC) [97] <input type="radio"/> Not Done
5.*	Source Document Verification Completion	(panther_ipfccd:LVOL.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
SVCUNK	NUMERIC	
TLC	FLOAT - F9.0	
TLCUNK	NUMERIC	
LUNGVLDT	DATE - DDMYYYYY	
SDVSTAT	NUMERIC	
SVC	FLOAT - F9.0	
FRC	FLOAT - F9.0	
FRCUNK	NUMERIC	

panther_ipf : Visit Status (VISTAT)**Visit Status**

1.	Did the visit occur?	<p>(panther_ipfcdd:VISTAT.VISOCCUR / Visit Occurred)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>Date of Visit:</p> <p>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfcdd:VISTAT.VISITDT / Visit Date)</p>
2.*	Source Document Verification Completion	<p>(panther_ipfcdd:VISTAT.SDVSTAT / SDV Complete)</p> <p>[1] <input type="radio"/> Complete</p> <p>[2] <input type="radio"/> Partially Complete</p> <p>[3] <input type="radio"/> Not Applicable</p>
* Item is not required		

CDD: panther_ipfcdd Table: VISTAT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
VISITDT	DATE - DDMONYYYY	
VISOCCUR	NUMERIC	
SDVSTAT	NUMERIC	

panther_ipf : Vital Signs (VTL)		
Vital Signs		
1.	Weight	(panther_ipfcdd:VTL.WTDONE / Weight Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxxxxxxx. <input type="radio"/> lbs <input type="radio"/> kg (panther_ipfcdd:VTL.WEIGHT / Weight)
2.	Height	(panther_ipfcdd:VTL.HTDONE / Height Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxxxxxxx. <input type="radio"/> in <input type="radio"/> cm (panther_ipfcdd:VTL.HEIGHT / Height)
3.	Blood Pressure (systolic)	(panther_ipfcdd:VTL.SYSDONE / Systolic BP Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxx mmHg (panther_ipfcdd:VTL.BPSYS / Systolic BP)
4.	Blood Pressure (diastolic)	(panther_ipfcdd:VTL.DIADONE / Diastolic BP Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxx mmHg (panther_ipfcdd:VTL.BPDIA / Diastolic BP)
5.	Heart Rate	(panther_ipfcdd:VTL.HR8DONE / Heart Rate Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxx Beats/Min (panther_ipfcdd:VTL.HRATE / Heart Rate)
6.	SpO2	(panther_ipfcdd:VTL.SPO2DONE / SpO2 Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxxxxxxx. % (panther_ipfcdd:VTL.SPO2 / SpO2)
7.*	Source Document Verification Completion	(panther_ipfcdd:VTL.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
HRATE	NUMERIC - N3	
WEIGHT	FLOAT - F9.0	
BPDIA	NUMERIC - N3	
SPO2	FLOAT - F9.0	
WTDONE	NUMERIC	
SDVSTAT	NUMERIC	
SYSDONE	NUMERIC	
BPSYS	NUMERIC - N3	
SPO2DONE	NUMERIC	
HR8DONE	NUMERIC	
DIADONE	NUMERIC	
HTDONE	NUMERIC	
HEIGHT	FLOAT - F9.0	

panther_ipf : Spirometry (SPIRO)		
Assessment Date		
1.	Date of Spirometry assessment:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd: SPIRO.SPIRODT / Spirometry Date)
Primary		
2.	FEV1: Actual	(panther_ipfcdd: SPIRO.FEV1UNK6 / FEV1 Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FEV1P / FEV1 Primary) [97] <input type="radio"/> Not Done
3.	FEV6: Actual	(panther_ipfcdd: SPIRO.FEV6UNK6 / FEV6 Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FEV6P / FEV6 Primary) [97] <input type="radio"/> Not Done
4.	FVC: Actual	(panther_ipfcdd: SPIRO.FVCUNK6 / FVC Primary Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FVCP / FVC Primary) [97] <input type="radio"/> Not Done
5.	FVC difference from baseline	xxxxxxxx. % (panther_ipfcdd: SPIRO.FVCCAL / FVC Difference)
6.*	Has the site confirmed the FVC change?	(panther_ipfcdd: SPIRO.FVCCRA / Confirmed FVC Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
Replicate 1		
7.	FEV1: Actual	(panther_ipfcdd: SPIRO.FEV1UNK7 / FEV1 Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FEV1R1 / FEV1 Rep 1) [97] <input type="radio"/> Not Done
8.	FEV6: Actual	(panther_ipfcdd: SPIRO.FEV6UNK7 / FEV6 Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FEV6R1 / FEV6 Rep 1) [97] <input type="radio"/> Not Done
9.	FVC: Actual	(panther_ipfcdd: SPIRO.FVCUNK7 / FVC Rep 1 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FVCPR1 / FVC Rep 1) [97] <input type="radio"/> Not Done
Replicate 2		
10.	FEV1: Actual	(panther_ipfcdd: SPIRO.FEV1UNK8 / FEV1 Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FEV1R2 / FEV1 Rep 2) [97] <input type="radio"/> Not Done
11.	FEV6: Actual	(panther_ipfcdd: SPIRO.FEV6UNK8 / FEV6 Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FEV6R2 / FEV6 Rep 2) [97] <input type="radio"/> Not Done
12.	FVC: Actual	(panther_ipfcdd: SPIRO.FVCUNK8 / FVC Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx. liters (panther_ipfcdd: SPIRO.FVCPR2 / FVC Rep 2) [97] <input type="radio"/> Not Done
13.*	Source Document Verification Completion	(panther_ipfcdd: SPIRO.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcdd Table: SPIRO Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
FEV1UNK7	NUMERIC	
SDVSTAT	NUMERIC	
FEV6R2	FLOAT - F9.0	
FEV6UNK8	NUMERIC	
FEV1P	FLOAT - F9.0	
FEV1UNK8	NUMERIC	
FEV6P	FLOAT - F9.0	
FEV6R1	FLOAT - F9.0	
FVCCRA	NUMERIC	
FVCCAL	FLOAT - F9.0	
FVCUNK7	NUMERIC	
FVCP	FLOAT - F9.0	
SPIRODT	DATE - DDMONYYYY	
FEV1UNK6	NUMERIC	
FEV6UNK7	NUMERIC	
FEV6UNK6	NUMERIC	
FVCPR2	FLOAT - F9.0	
FEV1R1	FLOAT - F9.0	
FEV1R2	FLOAT - F9.0	

FVCPR1	FLOAT - F9.0	
FVCUNK8	NUMERIC	
FVCUNK6	NUMERIC	

panther_ipf : Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)**Diffusing Capacity of the Lung for Carbon Monoxide**

1.	Date of Assessment	Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2009-2016) (panther_ipfcdd:DLCO.DLCODT / DLCO Date)
2.	DLCO: Actual	(panther_ipfcdd:DLCO.DLCOUNK / DLCO Not Done) [1] <input type="radio"/> xxxxxxxx mL/min/mmHg (panther_ipfcdd:DLCO.DLCO / DLCO) [97] <input type="radio"/> Not Done
3.*	Altitude-corrected DLCO (National Jewish and University of Utah only):	xxxxxxx mL/min/mmHg (panther_ipfcdd:DLCO.ALTDLCO / Altitude Corrected DLCO)
4.	VI (inspired volume):	(panther_ipfcdd:DLCO.VIUNK / VI Not Done) [1] <input type="radio"/> xxxxxxxx liters (panther_ipfcdd:DLCO.VI / VI) [97] <input type="radio"/> Not Done
5.	VA (alveolar volume):	(panther_ipfcdd:DLCO.VAUNK / VA Not Done) [1] <input type="radio"/> xxxxxxxx liters (panther_ipfcdd:DLCO.VA / VA) [97] <input type="radio"/> Not Done
6.*	Source Document Verification Completion	(panther_ipfcdd:DLCO.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable

* Item is not required

CDD: panther_ipfcdd Table: DLCO Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DLCOUNK	NUMERIC	
DLCO	FLOAT - F9.0	
VAUNK	NUMERIC	
VA	FLOAT - F9.0	
VI	FLOAT - F9.0	
DLCODT	DATE - DDMYYYY	
VIUNK	NUMERIC	
SDVSTAT	NUMERIC	
ALTDLCO	FLOAT - F9.0	

panther_ipf : 6-Minute Walk Test (6MWT1)		
6-Minute Walk Test		
1.	Pre-walk modified Borg Dyspnea Scale rating	Pulldown List 1 <input type="button" value="v"/> (panther_ipfcdd: SIXMWT1.PREBORG / PreWalk Borg Dyspnea Rating)
2.	Resting room air SpO2	xxxxxxx.% (panther_ipfcdd: SIXMWT1.RESTSPO2 / Resting SpO2)
3.	Was walk performed?	(panther_ipfcdd: SIXMWT1.WLKND / Walk Performed) [1] <input type="radio"/> Yes [0] <input type="radio"/> No (panther_ipfcdd: SIXMWT1.WLKNDS / Walk Not Performed, Specify) Reason walk test not performed? A50
4.*	Source Document Verification Completion	(panther_ipfcdd: SIXMWT1.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieBORG0	0	0	
ieBORG1	0.5	11	
ieBORG2	1	1	
ieBORG3	2	2	
ieBORG4	3	3	
ieBORG5	4	4	
ieBORG6	5	5	
ieBORG7	6	6	
ieBORG8	7	7	
ieBORG9	8	8	
ieBORG10	9	9	
ieBORG11	10	10	
ieBORG12	Not Done	97	

CDD: panther_ipfcdd Table: SIXMWT1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PREBORG	NUMERIC - 0, 11, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 97	
RESTSPO2	FLOAT - F9.0	
WLKNDS	STRING(50) - A50	
WLKND	NUMERIC	
SDVSTAT	NUMERIC	

panther_ipf : 6-Minute Walk Test (6MWT2)		
1.	Was supplemental O2 used during walk?	(panther_ipfccd: SIXMWT2.SUPPLOXY / Supplemental O2 Used) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Specify amount of supplemental O2 (liters/min) (panther_ipfccd: SIXMWT2.SUPO2 / Supplemental O2 Amount) xxxxxxxx. If Yes: SpO2 on Supplemental O2 (%) (panther_ipfccd: SIXMWT2.SUPSO2 / SpO2 on Supplemental O2) xxxxxxxx.
2.	Was a walking aid necessary to perform the 6MWT?	(panther_ipfccd: SIXMWT2.WALKAID / Walking Aid Used) [0] <input type="radio"/> No [1] <input type="radio"/> (panther_ipfccd: SIXMWT2.TYPEAID / Type of Walking Aid) Yes If Yes: Specify type of walking aid [1] <input type="radio"/> Cane [2] <input type="radio"/> Walker [98] <input type="radio"/> Other (specify) (panther_ipfccd: SIXMWT2.AIDSP / Walking Aid, Specify) A50
3.	Did Subject Complete 6-Minute Walk?	(panther_ipfccd: SIXMWT2.COMPLWLK / Completed Walk) [1] <input type="radio"/> Yes [0] <input type="radio"/> No If No: What was the duration of the walk test (min:sec)? (panther_ipfccd: SIXMWT2.WLKTMIN / Walk Time Unknown) [0] <input type="radio"/> xx : (panther_ipfccd: SIXMWT2.WLKMIN / Walk Duration Minutes) A2 (panther_ipfccd: SIXMWT2.WLKSEC / Walk Duration Seconds) [99] <input type="radio"/> Unknown (panther_ipfccd: SIXMWT2.STOPREA) Reason for stopping early [1] <input type="radio"/> SpO2 < 80% [2] <input type="radio"/> Developed signs and symptoms requiring termination of test [98] <input type="radio"/> Other (specify) (panther_ipfccd: SIXMWT2.STPOTHSP) A50
4.	Did subject desaturate (SpO2 <= 88%)?	(panther_ipfccd: SIXMWT2.DESATURA / Desaturate) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Walk duration at desaturation (min:sec): xx : (panther_ipfccd: SIXMWT2.DESATMIN / Desaturation Minutes) xx (panther_ipfccd: SIXMWT2.DESATSEC / Desaturation Seconds) If Yes: Walk distance at desaturation (meters) (panther_ipfccd: SIXMWT2.DESATDIS / Walk Distance at Desat) xxxxxxxx.
5.	Lowest SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.LOWSPO2 / Lowest SpO2)
6.	Distance Walked	xxxxxxxx. meters (panther_ipfccd: SIXMWT2.DISTANCE / Distance Walked)
7.	Post-walk modified Borg Dyspnea Scale rating	Pulldown List 1 <input type="button" value="v"/> (panther_ipfccd: SIXMWT2.POSTBORG / Post-Walk Borg Dysp Rating)
Walk details		
8.	Pre-walk Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHRPW / Pre-Walk Heart Rate)
9.*	1 minute Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR1 / 1 Minute Heart Rate)
10.*	1 minute SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSP021 / 1 Minute SpO2)
11.*	2 minute Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR2 / 2 Minute Heart Rate)
12.*	2 minute SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSP022 / 2 Minute SpO2)
13.*	3 minute Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR3 / 3 Minute Heart Rate)
14.*	3 minute SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSP023 / 3 Minute SpO2)
15.*	4 minute Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR4 / 4 Minute Heart Rate)
16.*	4 minute SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSP024 / 4 Minute SpO2)
17.*	5 minute Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR5 / 5 Minute Heart Rate)
18.*	5 minute SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSP025 / 5 Minute SpO2)
19.*	6 minute Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR6 / 6 Minute Heart Rate)
20.*	6 minute SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSP026 / 6 Minute SpO2)
Post Walk recovery details		
21.*	1 minute recovery Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR1P / 1 Minute Post Heart Rate)
22.*	1 minute recovery SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSO1P / 1 Minute Post SpO2)
23.*	2 minute recovery Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR2P / 2 Minute Post Heart Rate)
24.*	2 minute recovery SpO2	xxxxxxxx. % (panther_ipfccd: SIXMWT2.WLKSO2P / 2 Minute Post SpO2)

25.*	3 minute recovery Heart Rate	xxx bpm (panther_ipfccd: SIXMWT2.WLKHR3P / 3 Minute Post Heart Rate)
26.*	3 minute recovery SpO2	xxxxxxx. % (panther_ipfccd: SIXMWT2.WLKS03P / 3 Minute Post SpO2)
27.*	Source Document Verification Completion	(panther_ipfccd: SIXMWT2.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieBORG0	0	0	
ieBORG1	0.5	11	
ieBORG2	1	1	
ieBORG3	2	2	
ieBORG4	3	3	
ieBORG5	4	4	
ieBORG6	5	5	
ieBORG7	6	6	
ieBORG8	7	7	
ieBORG9	8	8	
ieBORG10	9	9	
ieBORG11	10	10	
ieBORG12	Not Done	97	

CDD: panther_ipfccd Table: SIXMWT2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SUPSP02	FLOAT - F9.0	
TYPEAID	NUMERIC	
WALKAID	NUMERIC	
DESATSEC	NUMERIC - N2	
SUPPLOXY	NUMERIC	
COMPLWLK	NUMERIC	
AIDSP	STRING(50) - A50	
POSTBORG	NUMERIC - 0, 11, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 97	
WLKSEC	STRING(2) - A2	
WLKHR4	NUMERIC - N3	
WLKMIN	NUMERIC - N2	
LOWSP02	FLOAT - F9.0	
DESATMIN	NUMERIC - N2	
WLKHRPW	NUMERIC - N3	
WLKSP026	FLOAT - F9.0	
WLKSP021	FLOAT - F9.0	
STPOTHSP	STRING(50) - A50	
DISTANCE	FLOAT - F9.0	
SUP02	FLOAT - F9.0	
WLKHR1	NUMERIC - N3	
WLKSP023	FLOAT - F9.0	
WLKHR6	NUMERIC - N3	
STOPREA	NUMERIC	
WLKSP022	FLOAT - F9.0	
WLKSP025	FLOAT - F9.0	
WLKS03P	FLOAT - F9.0	
WLKHR3	NUMERIC - N3	
DESATURA	NUMERIC	
WLKSP024	FLOAT - F9.0	
DESATDIS	FLOAT - F9.0	
WLKHR2	NUMERIC - N3	
WLKHR2P	NUMERIC - N3	
WLKS02P	FLOAT - F9.0	
WLKTMUNK	NUMERIC	
SDVSTAT	NUMERIC	
WLKHR3P	NUMERIC - N3	

WLKHR5	NUMERIC - N3	
WLKSO1P	FLOAT - F9.0	
WLKHR1P	NUMERIC - N3	

panther_ipf : Hospital Anxiety and Depression Scale (HADS)		
Hospital Anxiety and Depression Scale		
1.	Depression score	(panther_ipfcdd: HADS.SADEVAL / Depression Score) [1] <input type="radio"/> xxx (panther_ipfcdd: HADS.SADSCOR / Depression Not Evaluable) [2] <input type="radio"/> Not Evaluable
2.	Anxiety score	(panther_ipfcdd: HADS.ANXIEVAL / Anxiety Score) [1] <input type="radio"/> xxx (panther_ipfcdd: HADS.ANXITSCR / Anxiety Not Evaluable) [2] <input type="radio"/> Not Evaluable
3.*	Source Document Verification Completion	(panther_ipfcdd: HADS.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
ANXIEVAL	NUMERIC	
ANXITSCR	NUMERIC - N3	
SADEVAL	NUMERIC	
SDVSTAT	NUMERIC	
SADSCOR	NUMERIC - N3	

panther_ipf : Log Review (REVIEWS)		
Clinical Review		
1.	Has the subject taken any medications in the past 30 days?	(panther_ipfcdd:REVIEW.RVWCM1 / Medications) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Comcomitant Medication Form (MED)
2.	Did the subject complete the EuroQol?	(panther_ipfcdd:REVIEW.RVWEURO1 / EuroQol CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
3.	Did the subject complete the ICECAP?	(panther_ipfcdd:REVIEW.RVWICE1 / ICECAP CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
4.	Did the subject complete the UCSD_SOBQ?	(panther_ipfcdd:REVIEW.RVWUCSD1 / UCSD SOBQ CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
5.	Did the subject complete the SGRO?	(panther_ipfcdd:REVIEW.RVWSGRQ1 / SRGQ CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
6.	Did the subject complete the SF-36?	(panther_ipfcdd:REVIEW.RVWSF36A / SF-36 CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
7.	Did the subject complete the Gender substudy questionnaire?	(panther_ipfcdd:REVIEW.RVWGNDR / CRF Gender Substudy) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
8.*	Source Document Verification Completion	(panther_ipfcdd:REVIEW.SDVSTAT1 / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
RVWCM	NUMERIC	
RVWINPT	NUMERIC	
RVWGERD	NUMERIC	
RVWSDRG	NUMERIC	
SDVSTAT1	NUMERIC	
RVWSGRQ	NUMERIC	
RVWUCSD1	NUMERIC	
RVWICE1	NUMERIC	
SDVSTAT	NUMERIC	
RVXSDRG	NUMERIC	
RVWEURO	NUMERIC	
RVWSF36A	NUMERIC	
RVXAE	NUMERIC	
RVWSLP	NUMERIC	
RVWAE	NUMERIC	
RVWGNDR	NUMERIC	
RVWUCSD	NUMERIC	
RVXGERD	NUMERIC	
RVWSF36	NUMERIC	
RVWEURO1	NUMERIC	
RVWSGRQ1	NUMERIC	
SDVSTAT2	NUMERIC	
RVWCM1	NUMERIC	
RVXINPT	NUMERIC	
RVXSLP	NUMERIC	
RVWICE	NUMERIC	
RVXCM	NUMERIC	

panther_ipf : Intial Study Drug Dosing (INITSDRG)		
Azathioprine Initial Study Drug Dosing		
1.	Did the subject start Azathioprine/placebo?	(panther_ipfccdd: INITSDRG.INTAZA / Azathioprine Started) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Azathioprine/placebo Start Date Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfccdd: INITSDRG.INTAZADT / Azathioprine Start Date) Azathioprine/placebo dose (mg) per administration (panther_ipfccdd: INITSDRG.INTAZADD / Azathioprine Dose) xxxxxxxx. (panther_ipfccdd: INITSDRG.AZAFREQ / Azathioprine Freq) Azathioprine/placebo frequency [1] <input type="radio"/> Three times per day [2] <input type="radio"/> Twice per day [3] <input type="radio"/> Once per day [4] <input type="radio"/> Every other day [5] <input type="radio"/> Twice per week [98] <input type="radio"/> Other (specify) (panther_ipfccdd: INITSDRG.AZAFRQOT / Azathioprine Freq. Specify) A50
Prednisone Initial Study Drug Dosing		
2.	Did the subject start Prednisone/placebo?	(panther_ipfccdd: INITSDRG.INTPRD / Prednisone Started) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Prednisone/placebo Start Date Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfccdd: INITSDRG.INTPRDDT / Azathioprine Start Date) Prednisone/placebo dose (mg) per administration (panther_ipfccdd: INITSDRG.INTPRDDD / Prednisone Dose) xxxxxxxx. (panther_ipfccdd: INITSDRG.PRDFREQ / Prednisone Freq) Prednisone/placebo frequency [1] <input type="radio"/> Three times per day [2] <input type="radio"/> Twice per day [3] <input type="radio"/> Once per day [4] <input type="radio"/> Every other day [5] <input type="radio"/> Twice per week [98] <input type="radio"/> Other (specify) (panther_ipfccdd: INITSDRG.PRDFRQOT / Prednisone Freq. Specify) A50
NAC Initial Study Drug Dosing		
3.	Did the subject start NAC/placebo?	(panther_ipfccdd: INITSDRG.INTNAC / NAC Started) [0] <input type="radio"/> No [1] <input type="radio"/> Yes NAC/placebo Start Date Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfccdd: INITSDRG.INTNACDT / NAC Start Date) NAC/placebo dose (mg) per administration (panther_ipfccdd: INITSDRG.INTNACDD / NAC Dose) xxxxxxxx. (panther_ipfccdd: INITSDRG.NACFREQ / NAC Freq) NAC/placebo frequency [1] <input type="radio"/> Three times per day [2] <input type="radio"/> Twice per day [3] <input type="radio"/> Once per day [4] <input type="radio"/> Every other day [5] <input type="radio"/> Twice per week [98] <input type="radio"/> Other (specify) (panther_ipfccdd: INITSDRG.NACFRQOT / NAC Freq. Specify) A50
4.*	Source Document Verification Completion	(panther_ipfccdd: INITSDRG.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfccdd	Table: INITSDRG	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
NACFRQOT	STRING(50) - A50	
SDVSTAT	NUMERIC	
PRDFRQOT	STRING(50) - A50	
INTAZA	NUMERIC	
NACFREQ	NUMERIC	
INTNACDD	FLOAT - F9.0	
INTNACDT	DATE - DDMONYYYY	
INTAZADD	FLOAT - F9.0	
INTAZADT	DATE - DDMONYYYY	

INTPRD	NUMERIC	
AZAFROOT	STRING(50) - A50	
INTPRDDD	FLOAT - F9.0	
INTNAC	NUMERIC	
PRDFREQ	NUMERIC	
INTPRDDT	DATE - DDMONYYYY	
AZAFREQ	NUMERIC	

panther_ipf : Gender Substudy Questionnaire (GENDERSS)	
To be completed by female participants only	
1.* At what age did you begin monthly menstruation (monthly period)?	xxxx. years old (panther_ipfcdd: GENDERSS.PERIOD / Menstruation Age)
2.* Have you reached menopause?	(panther_ipfcdd: GENDERSS.MENOPAUS / Menopause) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: GENDERSS.MENOAGE / Menopause Age) If yes, at what age did that occur? xxxx.
3.* Did you ever use oral contraceptive medications?	(panther_ipfcdd: GENDERSS.NOPREG / Oral Contraceptives) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: GENDERSS.NOPREGYS / Contraceptive Years) If yes, for how many years? xxxx.
4.* Did you ever use hormone replacement therapy?	(panther_ipfcdd: GENDERSS.HRT / HRT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: GENDERSS.HRTYRS / HRT Years) If yes, for how many years? xxxx.
5.* Have you ever been pregnant (include miscarriages, abortions)?	(panther_ipfcdd: GENDERSS.PREGNANT / Pregnant) [0] <input type="radio"/> No [1] <input type="radio"/> Yes How old were you at the time of your first pregnancy? (panther_ipfcdd: GENDERSS.PRGNAGE / Age First Pregnancy) xxxx. How many times have you been pregnant? (panther_ipfcdd: GENDERSS.PREGNUMB / Number of Pregnancies) xxx (panther_ipfcdd: GENDERSS.BABYGEND / Sex of Children) What were the sexes of your children born and unborn? [1] <input type="radio"/> All male [2] <input type="radio"/> All female [3] <input type="radio"/> Male and female [99] <input type="radio"/> Unknown (panther_ipfcdd: GENDERSS.BRESFEED / Breastfeed) Did you ever breastfeed? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: GENDERSS.BRFEEDNO / Breastfeed) If yes, for approximately how many total months did you breastfeed (total for all children)? xxx
6.* Have you ever had an ovary removed?	(panther_ipfcdd: GENDERSS.OVREM / Ovary Removed) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: GENDERSS.OVNUM / Number Ovaries Removed) Was one removed or both? [1] <input type="radio"/> One [2] <input type="radio"/> Both At what age was your ovary or ovaries removed? (panther_ipfcdd: GENDERSS.OVAGE / Age Ovary Removed) xxxx.
7.* Source Document Verification Completion	(panther_ipfcdd: GENDERSS.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

CDD: panther_ipfcdd	Table: GENDERSS	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
BABYGEND	NUMERIC	
PERIOD	FLOAT - F5.0	
OVREM	NUMERIC	
HRTYRS	FLOAT - F5.0	
PREGNUMB	NUMERIC - N3	
NOPREGYS	FLOAT - F5.0	
MENOAGE	FLOAT - F5.0	
OVNUM	NUMERIC	
OVAGE	FLOAT - F5.0	
SDVSTAT	NUMERIC	
BRESFEED	NUMERIC	
PREGNANT	NUMERIC	
MENOPAUS	NUMERIC	
NOPREG	NUMERIC	
HRT	NUMERIC	

BRFEEDNO	NUMERIC - N3	
PRGNAGE	FLOAT - F5.0	

panther_ipf : EUROQOL Questionnaire Part1 (EUROQOL1)		
By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.		
1.*	Mobility	(panther_ipfcdd: EUROQOL EQMOB / Mobility) [1] <input type="radio"/> I have no problems in walking about [2] <input type="radio"/> I have some problems in walking about [3] <input type="radio"/> I am confined to bed
2.*	Self-care	(panther_ipfcdd: EUROQOL EQSC / Self-Care) [1] <input type="radio"/> I have no problems with self-care [2] <input type="radio"/> I have some problems washing or dressing myself [3] <input type="radio"/> I am unable to wash or dress myself
3.*	Usual activities (e.g., work, study, housework, family, or leisure activities):	(panther_ipfcdd: EUROQOL EQUA / Usual Activities) [1] <input type="radio"/> I have no problems with performing my usual activities [2] <input type="radio"/> I have some problems with performing my usual activities [3] <input type="radio"/> I am unable to perform my usual activities
4.*	Pain/discomfort	(panther_ipfcdd: EUROQOL EQPAIN / Pain/Discomfort) [1] <input type="radio"/> I have no pain or discomfort [2] <input type="radio"/> I have moderate pain or discomfort [3] <input type="radio"/> I have extreme pain or discomfort
5.*	Anxiety/depression	(panther_ipfcdd: EUROQOL EQANX / Anxiety/Depression) [1] <input type="radio"/> I am not anxious or depressed [2] <input type="radio"/> I am moderately anxious or depressed [3] <input type="radio"/> I am extremely anxious or depressed
EuroQol Thermometer Response (Study staff use only)		
6.*	Response to the EuroQol thermometer (0-100):	xxxxxxxxxxxx (panther_ipfcdd: EUROQOL EURTHERM / EuroQol Thermometer)
7.*	Source Document Verification Completion	(panther_ipfcdd: EUROQOL SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcdd	Table: EUROQOL	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
EQEDU	NUMERIC	
EQSMK	NUMERIC	
EQWKHL	NUMERIC	
EQWKHLSP	STRING(100)	
EQILLOTH	NUMERIC	
EQGENDR	NUMERIC	
EQAGE	FLOAT	
SDVSTAT	NUMERIC	
EQACTSP	STRING(100)	
EQACT	NUMERIC	
EQZIP	NUMERIC	
EQILLYOU	NUMERIC	
EQILLFAM	NUMERIC	
EQPAIN	NUMERIC	
SDVSTAT1	NUMERIC	
EQUA	NUMERIC	
EQANX	NUMERIC	
EQMOB	NUMERIC	
EQSC	NUMERIC	
EURTHERM	NUMERIC - N11	

panther_ipf : EUROQOL Questionnaire Part2 (EUROQOL2)	
EUROQOL2	
1.* Have you experienced serious illness	(panther_ipfcdd: EUROQOL.EQILLYOU) in you yourself? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: EUROQOL.EQILLFAM / Illness in Family) in your family? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd: EUROQOL.EQILLOTH / Illness Others) in caring for others? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.* What is your age in years?	xxxxxxxxxxxxxx. (panther_ipfcdd: EUROQOL.EQAGE / Age)
3.* Are you	(panther_ipfcdd: EUROQOL.EQGENDR / Gender) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
4.* Are you	(panther_ipfcdd: EUROQOL.EQSMK / Smoker) [1] <input type="radio"/> A current smoker [2] <input type="radio"/> An ex-smoker [3] <input type="radio"/> A never smoker
5.* Do you now, or did you ever, work in health or social services?	(panther_ipfcdd: EUROQOL.EQWKHL / Healthcare Work) [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes - If Yes: In what capacity? A100 (panther_ipfcdd: EUROQOL.EQWKHLSP / Healthcare Work, Specify)
6.* Which of the following best describes your main activity?	(panther_ipfcdd: EUROQOL.EQACT / Main Activity) [1] <input type="radio"/> Employed (including self employment) [2] <input type="radio"/> Retired [3] <input type="radio"/> Keeping house [4] <input type="radio"/> Student [5] <input type="radio"/> Seeking work [98] <input type="radio"/> Other (please specify): A100 (panther_ipfcdd: EUROQOL.EQACTSP / Main Activity, Specify)
7.* What is the highest level of education you have completed?	(panther_ipfcdd: EUROQOL.EQEDU / Education) [1] <input type="radio"/> Some high school or less [2] <input type="radio"/> High school graduate or GED [3] <input type="radio"/> Vocational college or some college [4] <input type="radio"/> College degree [5] <input type="radio"/> Professional or graduate degree
8.* If you know your zip code, please write it here:	xxxxxxxxxxx (panther_ipfcdd: EUROQOL.EQZIP / Zip Code)
9.* Source Document Verification Completion	(panther_ipfcdd: EUROQOL.SDVSTAT1 / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

CDD: panther_ipfcdd	Table: EUROQOL	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
EQEDU	NUMERIC	
EQSMK	NUMERIC	
EQWKHL	NUMERIC	
EQWKHLSP	STRING(100) - A100	
EQILLOTH	NUMERIC	
EQGENDR	NUMERIC	
EQAGE	FLOAT - F16.0	
SDVSTAT	NUMERIC	
EQACTSP	STRING(100) - A100	
EQACT	NUMERIC	
EQZIP	NUMERIC - N11	
EQILLYOU	NUMERIC	
EQILLFAM	NUMERIC	
EQPAIN	NUMERIC	
SDVSTAT1	NUMERIC	
EQUA	NUMERIC	
EQANX	NUMERIC	
EQMOB	NUMERIC	
EQSC	NUMERIC	
EURTHERM	NUMERIC - N11	

panther_ipf : ICECAP Questionnaire (ICECAP)

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

1.*	Love and Friendship	(panther_ipfcd: ICECAP.ICELOVE / Love and Friendship) [1] <input type="radio"/> I can have all of the love and friendship that I want [2] <input type="radio"/> I can have a lot of the love and friendship that I want [3] <input type="radio"/> I can have a little of the love and friendship that I want [4] <input type="radio"/> I cannot have any of the love and friendship that I want
2.*	Thinking about the future	(panther_ipfcd: ICECAP.ICEFUTR / Thinking About Future) [1] <input type="radio"/> I can think about the future without any concern [2] <input type="radio"/> I can think about the future with only a little concern [3] <input type="radio"/> I can only think about the future with some concern [4] <input type="radio"/> I can only think about the future with a lot of concern
3.*	Doing things that make you feel valued	(panther_ipfcd: ICECAP.ICEVALUE / Value) [1] <input type="radio"/> I am able to do all of the things that make me feel valued [2] <input type="radio"/> I am able to do many of the things that make me feel valued [3] <input type="radio"/> I am able to do a few of the things that make me feel valued [4] <input type="radio"/> I am unable to do any of the things that make me feel valued
4.*	Enjoyment and pleasure	(panther_ipfcd: ICECAP.ICEENJOY / Enjoyment) [1] <input type="radio"/> I can have all of the enjoyment and pleasure that I want [2] <input type="radio"/> I can have a lot of the enjoyment and pleasure that I want [3] <input type="radio"/> I can have a little of the enjoyment and pleasure that I want [4] <input type="radio"/> I cannot have any of the enjoyment and pleasure that I want
5.*	Independence	(panther_ipfcd: ICECAP.ICEINDEP / Independence) [1] <input type="radio"/> I am able to be completely independent [2] <input type="radio"/> I am able to be independent in many things [3] <input type="radio"/> I am able to be independent in a few things [4] <input type="radio"/> I am unable to be at all independent
6.*	Source Document Verification Completion	(panther_ipfcd: ICECAP.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcd Table: ICECAP Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
ICEVALUE	NUMERIC	
SDVSTAT	NUMERIC	
ICEENJOY	NUMERIC	
ICEFUTR	NUMERIC	
ICEINDEP	NUMERIC	
ICELOVE	NUMERIC	

panther_ipf : UCSDSOB Shortness of Breath Questionnaire Part1 (UCSDSOB1)		
When I do, or if I were to do, the following tasks, I would rate my breathlessness as:		
1.*	At rest	Pulldown List 1 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD1 / At Rest)
2.*	Walking on a level at your own pace	Pulldown List 2 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD2 / Walking Level at Own Pace)
3.*	Walking on a level with others your age	Pulldown List 3 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD3 / Walk Level Others Your Age)
4.*	Walking up a hill	Pulldown List 4 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD4 / Walking Up a Hill)
5.*	Walking up stairs	Pulldown List 5 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD5 / Walking Up Stairs)
6.*	While eating	Pulldown List 6 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD6 / While Eating)
7.*	Standing up from a chair	Pulldown List 7 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD7 / Standing Up from a Chair)
8.*	Brushing teeth	Pulldown List 8 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD8 / Brushing Teeth)
9.*	Shaving and/or brushing hair	Pulldown List 9 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD9 / Shaving and/or Brush Hair)
10.*	Showering/bathing	Pulldown List 10 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD10 / Showering/Bathing)
11.*	Dressing	Pulldown List 11 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD11 / Dressing)
12.*	Picking up and straightening	Pulldown List 12 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD12 / Pick up and Straightening)
13.*	Source Document Verification Completion	(panther_ipfcdd:UCSDSOB.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 5:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	

ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 6:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 7:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 8:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 9:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 10:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 11:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 12:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	

ieIPFUCS3	3	3
ieIPFUCS4	4 - Severe	4
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5

CDD: panther_ipfcdd Table: UCSDSOB Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
UCSD21	NUMERIC	
UCSD3	NUMERIC - 0, 1, 2, 3, 4, 5	
SDVSTAT	NUMERIC	
UCSD6	NUMERIC - 0, 1, 2, 3, 4, 5	
SDVSTAT1	NUMERIC	
UCSD24	NUMERIC	
UCSD20	NUMERIC	
UCSD12	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD7	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD9	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD16	NUMERIC	
UCSD17	NUMERIC	
UCSD22	NUMERIC	
UCSD15	NUMERIC	
UCSD18	NUMERIC	
UCSD2	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD5	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD19	NUMERIC	
UCSD8	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD11	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD1	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD23	NUMERIC	
UCSD10	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD14	NUMERIC	
UCSD13	NUMERIC	
UCSD4	NUMERIC - 0, 1, 2, 3, 4, 5	

panther_ipf : UCSDSOB Shortness of Breath Questionnaire Part2 (UCSDSOB2)

When I do, or if I were to do, the following tasks, I would rate my breathlessness as:

1.*	Doing dishes	Pulldown List 1 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD13 / Doing Dishes)
2.*	Sweeping/vacuuming	Pulldown List 2 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD14 / Sweeping/Vacuuming)
3.*	Making bed	Pulldown List 3 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD15 / Making Bed)
4.*	Shopping	Pulldown List 4 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD16 / Shopping)
5.*	Doing laundry	Pulldown List 5 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD17 / Doing Laundry)
6.*	Washing car	Pulldown List 6 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD18 / Washing Car)
7.*	Mowing lawn	Pulldown List 7 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD19 / Mowing Lawn)
8.*	Watering lawn	Pulldown List 8 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD20 / Watering Lawn)
9.*	Sexual activities	Pulldown List 9 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD21 / Sexual Activities)
How much do these limit you in your daily life?		
10.*	Shortness of breath	Pulldown List 10 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD22 / Shortness of Breath)
11.*	Fear of hurting myself	Pulldown List 11 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD23 / Fear of Hurting Myself)
12.*	Fear of shortness of breath	Pulldown List 12 <input type="button" value="v"/> (panther_ipfcdd:UCSDSOB.UCSD24 / Fear of Shortness of Breath)
13.*	Source Document Verification Completion	(panther_ipfcdd:UCSDSOB.SDVSTAT1 / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable

* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 5:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	

ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 6:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 7:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 8:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 9:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 10:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 11:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	
ieIPFUCS2	2	2	
ieIPFUCS3	3	3	
ieIPFUCS4	4 - Severe	4	
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5	

Pulldown List 12:			
RefName	Display Text	Value	Design Note
ieIPFUCS0	0 - None At All	0	
ieIPFUCS1	1	1	

ieIPFUCS2	2	2
ieIPFUCS3	3	3
ieIPFUCS4	4 - Severe	4
ieIPFUCS5	5 - Maximal / Unable To Do Because of Breathlessness	5

CDD: panther_ipfcdd Table: UCSDSOB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
UCSD21	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD3	NUMERIC - 0, 1, 2, 3, 4, 5	
SDVSTAT	NUMERIC	
UCSD6	NUMERIC - 0, 1, 2, 3, 4, 5	
SDVSTAT1	NUMERIC	
UCSD24	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD20	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD12	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD7	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD9	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD16	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD17	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD22	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD15	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD18	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD2	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD5	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD19	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD8	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD11	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD1	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD23	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD10	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD14	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD13	NUMERIC - 0, 1, 2, 3, 4, 5	
UCSD4	NUMERIC - 0, 1, 2, 3, 4, 5	

panther_ipf : St. Georges Part 1 (STGRG1)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you the most problems, rather than what the doctors and nurses think your problems are. Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

1.*	Before completing the questionnaire: Please check one box to show how you describe your current health:	<p>(panther_ipfcdd: STGRG1.CURHLTH / Current Health)</p> <p>[1] <input type="radio"/> Very good</p> <p>[2] <input type="radio"/> Good</p> <p>[3] <input type="radio"/> Fair</p> <p>[4] <input type="radio"/> Poor</p> <p>[5] <input type="radio"/> Very poor</p>
2.*	Source Document Verification Completion	<p>(panther_ipfcdd: STGRG1.SDVSTAT / SDV Complete)</p> <p>[1] <input type="radio"/> Complete</p> <p>[2] <input type="radio"/> Partially Complete</p> <p>[3] <input type="radio"/> Not Applicable</p>
* Item is not required		

CDD: panther_ipfcdd Table: STGRG1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
STG8	NUMERIC	
STG03D	NUMERIC	
STG03E	NUMERIC	
STG02E	NUMERIC	
STG04B	NUMERIC	
STG04C	NUMERIC	
STG6A	NUMERIC	
CURHLTH	NUMERIC	
STG01B	NUMERIC	
STG5A	NUMERIC	
STG5C	NUMERIC	
STG7D	NUMERIC	
STG03A	NUMERIC	
STG04D	NUMERIC	
STG02B	NUMERIC	
STG5D	NUMERIC	
STG7C	NUMERIC	
STG7E	NUMERIC	
STG04E	NUMERIC	
STG04A	NUMERIC	
STG02A	NUMERIC	
STG7A	NUMERIC	
STG6C	NUMERIC	
SDVSTAT1	NUMERIC	
STG01C	NUMERIC	
STG01E	NUMERIC	
STG7B	NUMERIC	
STG5B	NUMERIC	
STG5E	NUMERIC	
STG03C	NUMERIC	
STG6D	NUMERIC	
STG02C	NUMERIC	
STG03B	NUMERIC	
STG01A	NUMERIC	
STG6B	NUMERIC	
STG02D	NUMERIC	
SDVSTAT	NUMERIC	
STG01D	NUMERIC	

panther_ipf : St. Georges Part 2 (STGRG2)	
Please describe how often your respiratory problems have affected you over the past 4 weeks.	
1.* Over the past 4 weeks, I have coughed:	(panther_ipfcdd: STGRG1.STG01A / Coughed Every Day) [1] <input type="checkbox"/> Almost Every Day (panther_ipfcdd: STGRG1.STG01B / Coughed Several Days) [2] <input type="checkbox"/> Several Days a Week (panther_ipfcdd: STGRG1.STG01C / Coughed a Few Days) [3] <input type="checkbox"/> A Few Days a Month (panther_ipfcdd: STGRG1.STG01D / Coughed with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (panther_ipfcdd: STGRG1.STG01E / Did Not Cough) [5] <input type="checkbox"/> Not At All
2.* Over the past 4 weeks, I have brought up phlegm (sputum):	(panther_ipfcdd: STGRG1.STG02A / Phlegm Every Day) [1] <input type="checkbox"/> Almost Every Day (panther_ipfcdd: STGRG1.STG02B / Phlegm Several Days) [2] <input type="checkbox"/> Several Days a Week (panther_ipfcdd: STGRG1.STG02C / Phlegm a Few Days) [3] <input type="checkbox"/> A Few Days a Month (panther_ipfcdd: STGRG1.STG02D / Phlegm with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (panther_ipfcdd: STGRG1.STG02E / Did Not Have Phlegm) [5] <input type="checkbox"/> Not At All
3.* Over the past 4 weeks, I have had shortness of breath:	(panther_ipfcdd: STGRG1.STG03A / SOB Every Day) [1] <input type="checkbox"/> Almost Every Day (panther_ipfcdd: STGRG1.STG03B / SOB Several Days) [2] <input type="checkbox"/> Several Days a Week (panther_ipfcdd: STGRG1.STG03C / SOB a Few Days) [3] <input type="checkbox"/> A Few Days a Month (panther_ipfcdd: STGRG1.STG03D / SOB with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (panther_ipfcdd: STGRG1.STG03E / Did Not Have SOB) [5] <input type="checkbox"/> Not At All
4.* Over the past 4 weeks, I have had wheezing attacks:	(panther_ipfcdd: STGRG1.STG04A / Wheezing Every Day) [1] <input type="checkbox"/> Almost Every Day (panther_ipfcdd: STGRG1.STG04B / Wheezing Several Days) [2] <input type="checkbox"/> Several Days a Week (panther_ipfcdd: STGRG1.STG04C / Wheezing a Few Days) [3] <input type="checkbox"/> A Few Days a Month (panther_ipfcdd: STGRG1.STG04D / Wheeze with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (panther_ipfcdd: STGRG1.STG04E / Did Not Have SOB) [5] <input type="checkbox"/> Not At All
5.* How many times during the past 4 weeks have you suffered from severe or very unpleasant respiratory attacks?	(panther_ipfcdd: STGRG1.STG5A / Respiratory Attack 3+) [1] <input type="checkbox"/> More than 3 times (panther_ipfcdd: STGRG1.STG5B / Respiratory Attack 3 Times) [1] <input type="checkbox"/> 3 times (panther_ipfcdd: STGRG1.STG5C / Respiratory Attack 2 Times) [1] <input type="checkbox"/> 2 times (panther_ipfcdd: STGRG1.STG5D / Respiratory Attack 1 Times) [1] <input type="checkbox"/> 1 time (panther_ipfcdd: STGRG1.STG5E / No Respiratory Attacks) [1] <input type="checkbox"/> None of the time
6.* How long did the worst respiratory attack last?	(panther_ipfcdd: STGRG1.STG6A / Respiratory Attack 1 Week) [1] <input type="checkbox"/> A week or more (panther_ipfcdd: STGRG1.STG6B / Respiratory Attack 3+ Days) [1] <input type="checkbox"/> 3 or more days (panther_ipfcdd: STGRG1.STG6C / Respiratory Attack 1-2 Days) [1] <input type="checkbox"/> 1 or 2 days (panther_ipfcdd: STGRG1.STG6D / Resp Attack Less than Day) [1] <input type="checkbox"/> Less than a day
7.* Over the past 4 weeks, in a typical week, how many good days (with few respiratory problems) have you had?	(panther_ipfcdd: STGRG1.STG7A / No Good Days) [1] <input type="checkbox"/> No good days (panther_ipfcdd: STGRG1.STG7B / One to Two Good Days) [1] <input type="checkbox"/> 1 or 2 good days (panther_ipfcdd: STGRG1.STG7C / Three to Four Good Days) [1] <input type="checkbox"/> 3 or 4 good days (panther_ipfcdd: STGRG1.STG7D / Nearly Every Day Good) [1] <input type="checkbox"/> Nearly everyday was good (panther_ipfcdd: STGRG1.STG7E / Every Day Good) [1] <input type="checkbox"/> Every day was good
8.* If you wheeze, is it worse when you get up in the morning?	(panther_ipfcdd: STGRG1.STG8 / Wheeze in Morning) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
9.* Source Document Verification Completion	(panther_ipfcdd: STGRG1.SDVSTAT1 / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

CDD: panther_ipfcdd Table: STGRG1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
STG8	NUMERIC	
STG03D	NUMERIC	
STG03E	NUMERIC	
STG02E	NUMERIC	
STG04B	NUMERIC	
STG04C	NUMERIC	
STG6A	NUMERIC	
CURHLTH	NUMERIC	
STG01B	NUMERIC	
STG5A	NUMERIC	
STG5C	NUMERIC	
STG7D	NUMERIC	
STG03A	NUMERIC	
STG04D	NUMERIC	
STG02B	NUMERIC	
STG5D	NUMERIC	
STG7C	NUMERIC	
STG7E	NUMERIC	
STG04E	NUMERIC	
STG04A	NUMERIC	
STG02A	NUMERIC	
STG7A	NUMERIC	
STG6C	NUMERIC	
SDVSTAT1	NUMERIC	
STG01C	NUMERIC	
STG01E	NUMERIC	
STG7B	NUMERIC	
STG5B	NUMERIC	
STG5E	NUMERIC	
STG03C	NUMERIC	
STG6D	NUMERIC	
STG02C	NUMERIC	
STG03B	NUMERIC	
STG01A	NUMERIC	
STG6B	NUMERIC	
STG02D	NUMERIC	
SDVSTAT	NUMERIC	
STG01D	NUMERIC	

panther_ipf : St. Georges Part 3 (STGRG3)		
Section 1		
1.*	How would you describe your respiratory condition?	(panther_ipfcdd: STGRG2.STG9A / Most Important Problem) [1] <input type="checkbox"/> The most important problem I have (panther_ipfcdd: STGRG2.STG9B / Quite a lot of Problems) [1] <input type="checkbox"/> Causes me quite a lot of problems (panther_ipfcdd: STGRG2.STG9C / Few Problems) [1] <input type="checkbox"/> Causes me a few problems (panther_ipfcdd: STGRG2.STG9D / No Problems) [1] <input type="checkbox"/> Causes me no problems
2.*	If you have ever held a job	(panther_ipfcdd: STGRG2.STG10A / Stop Working) [1] <input type="checkbox"/> My respiratory problems made me stop working altogether (panther_ipfcdd: STGRG2.STG10B / Interfere or Change Job) [1] <input type="checkbox"/> My respiratory problems interfere with my job or made me change my job (panther_ipfcdd: STGRG2.STG10C / Do not Affect Job) [1] <input type="checkbox"/> My respiratory problems do not affect my job
Section 2		
These are questions about what activities usually make you feel short of breath these days.		
3.*	Sitting or lying still	(panther_ipfcdd: STGRG2.STG11A / Sitting Still) [1] <input type="radio"/> True [0] <input type="radio"/> False
4.*	Washing or dressing yourself	(panther_ipfcdd: STGRG2.STG11B / Walking or Dressing) [1] <input type="radio"/> True [0] <input type="radio"/> False
5.*	Walking around the house	(panther_ipfcdd: STGRG2.STG11C / Walking around House) [1] <input type="radio"/> True [0] <input type="radio"/> False
6.*	Walking outside on a level ground	(panther_ipfcdd: STGRG2.STG11D / Walking Level Ground) [1] <input type="radio"/> True [0] <input type="radio"/> False
7.*	Walking up a flight of stairs	(panther_ipfcdd: STGRG2.STG11E / Walking Flight Stairs) [1] <input type="radio"/> True [0] <input type="radio"/> False
8.*	Walking up hills	(panther_ipfcdd: STGRG2.STG11F / Walking Up Hills) [1] <input type="radio"/> True [0] <input type="radio"/> False
9.*	Playing sports or other physical activities	(panther_ipfcdd: STGRG2.STG11G / Playing Sports) [1] <input type="radio"/> True [0] <input type="radio"/> False
Section 3		
These are more questions about your cough and shortness of breath these days.		
10.*	Coughing hurts	(panther_ipfcdd: STGRG2.STG12A / Coughing Hurts) [1] <input type="radio"/> True [0] <input type="radio"/> False
11.*	Coughing makes me tired	(panther_ipfcdd: STGRG2.STG12B / Coughing Tired) [1] <input type="radio"/> True [0] <input type="radio"/> False
12.*	I am short of breath when I talk	(panther_ipfcdd: STGRG2.STG12C / SOB when Talking) [1] <input type="radio"/> True [0] <input type="radio"/> False
13.*	I am short of breath when I bend over	(panther_ipfcdd: STGRG2.STG12D / SOB Bending Over) [1] <input type="radio"/> True [0] <input type="radio"/> False
14.*	My coughing or breathing disturbs my sleep	(panther_ipfcdd: STGRG2.STG12E / Disturbs my Sleep) [1] <input type="radio"/> True [0] <input type="radio"/> False
15.*	I get exhausted easily	(panther_ipfcdd: STGRG2.STG12F / Exhausted Easily) [1] <input type="radio"/> True [0] <input type="radio"/> False
16.*	Source Document Verification Completion	(panther_ipfcdd: STGRG2.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
STG13D	NUMERIC	
STG11B	NUMERIC	
STG12B	NUMERIC	
STG11G	NUMERIC	
STG11E	NUMERIC	
STG13E	NUMERIC	
STG13B	NUMERIC	
STG14A	NUMERIC	
STG13A	NUMERIC	
STG12E	NUMERIC	
STG14C	NUMERIC	
STG11F	NUMERIC	
STG12F	NUMERIC	
STG12A	NUMERIC	
SDVSTAT1	NUMERIC	

STG9C	NUMERIC	
STG9B	NUMERIC	
STG13G	NUMERIC	
STG11C	NUMERIC	
STG12D	NUMERIC	
STG13H	NUMERIC	
SDVSTAT	NUMERIC	
STG9A	NUMERIC	
STG14B	NUMERIC	
STG13F	NUMERIC	
STG14D	NUMERIC	
STG10C	NUMERIC	
STG13C	NUMERIC	
STG9D	NUMERIC	
STG10B	NUMERIC	
STG12C	NUMERIC	
STG10A	NUMERIC	
STG11D	NUMERIC	
STG11A	NUMERIC	

panther_ipf : St. Georges Part 4 (STGRG4)		
Section 4		
These are questions about other effects that your respiratory problems may have on you these days.		
1.*	My cough or breathing is embarrassing in public	(panther_ipfcdd:STGRG2.STG13A / Embarrassing) [1] <input type="radio"/> True [2] <input type="radio"/> False
2.*	My respiratory problems are a nuisance to my family, friends or neighbors	(panther_ipfcdd:STGRG2.STG13B / Nuisance) [1] <input type="radio"/> True [2] <input type="radio"/> False
3.*	I get afraid or panic when I cannot catch my breath	(panther_ipfcdd:STGRG2.STG13C / Afraid or Panic) [1] <input type="radio"/> True [2] <input type="radio"/> False
4.*	I feel that I am not in control of my respiratory problems	(panther_ipfcdd:STGRG2.STG13D / Not in Control) [1] <input type="radio"/> True [2] <input type="radio"/> False
5.*	I do not expect my respiratory problems to get any better	(panther_ipfcdd:STGRG2.STG13E / Will not get Better) [1] <input type="radio"/> True [2] <input type="radio"/> False
6.*	I have become frail or an invalid because of my respiratory problems	(panther_ipfcdd:STGRG2.STG13F / Frail) [1] <input type="radio"/> True [2] <input type="radio"/> False
7.*	Exercise is not safe for me	(panther_ipfcdd:STGRG2.STG13G / Exercise not Safe) [1] <input type="radio"/> True [2] <input type="radio"/> False
8.*	Everything seems too much of an effort	(panther_ipfcdd:STGRG2.STG13H / Too Much Effort) [1] <input type="radio"/> True [2] <input type="radio"/> False
Section 5		
These are questions about your respiratory treatment. If your are not receiving treatment, +go to Section 6.		
9.*	My treatment does not help me very much	(panther_ipfcdd:STGRG2.STG14A / Treatment Does Not Help) [1] <input type="radio"/> True [2] <input type="radio"/> False
10.*	I get embarrassed using my medication in public	(panther_ipfcdd:STGRG2.STG14B / Embarrassed Using Meds) [1] <input type="radio"/> True [2] <input type="radio"/> False
11.*	I have unpleasant side effects from my medication	(panther_ipfcdd:STGRG2.STG14C / Unpleasant Side Effects) [1] <input type="radio"/> True [2] <input type="radio"/> False
12.*	My treatment interferes with my life a lot	(panther_ipfcdd:STGRG2.STG14D / Treatment Interferes) [1] <input type="radio"/> True [2] <input type="radio"/> False
13.*	Source Document Verification Completion	(panther_ipfcdd:STGRG2.SDVSTAT1 / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
STG13D	NUMERIC	
STG11B	NUMERIC	
STG12B	NUMERIC	
STG11G	NUMERIC	
STG11E	NUMERIC	
STG13E	NUMERIC	
STG13B	NUMERIC	
STG14A	NUMERIC	
STG13A	NUMERIC	
STG12E	NUMERIC	
STG14C	NUMERIC	
STG11F	NUMERIC	
STG12F	NUMERIC	
STG12A	NUMERIC	
SDVSTAT1	NUMERIC	
STG9C	NUMERIC	
STG9B	NUMERIC	
STG13G	NUMERIC	
STG11C	NUMERIC	
STG12D	NUMERIC	
STG13H	NUMERIC	
SDVSTAT	NUMERIC	
STG9A	NUMERIC	
STG14B	NUMERIC	
STG13F	NUMERIC	
STG14D	NUMERIC	
STG10C	NUMERIC	
STG13C	NUMERIC	

STG9D	NUMERIC	
STG10B	NUMERIC	
STG12C	NUMERIC	
STG10A	NUMERIC	
STG11D	NUMERIC	
STG11A	NUMERIC	

panther_ipf : St. Georges Part 5 (STGRG5)**Section 6**

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

1.*	I take a long time to get washed or dressed	(panther_ipfcdd:STGRG3.STG15A / Time to Wash or Dress) [1] <input type="radio"/> True [0] <input type="radio"/> False
2.*	I cannot take a bath or shower, or I take a long time to do it	(panther_ipfcdd:STGRG3.STG15B / Time to Bathe) [1] <input type="radio"/> True [0] <input type="radio"/> False
3.*	I walk slower than other people my age, or I stop to rest	(panther_ipfcdd:STGRG3.STG15C / Walk Slower) [1] <input type="radio"/> True [0] <input type="radio"/> False
4.*	Jobs such as household chores take a long time, or I have to stop to rest	(panther_ipfcdd:STGRG3.STG15D / Household Chores) [1] <input type="radio"/> True [0] <input type="radio"/> False
5.*	If I walk up one flight of stairs, I have to go slowly or stop	(panther_ipfcdd:STGRG3.STG15E / Walk Stairs Slowly) [1] <input type="radio"/> True [0] <input type="radio"/> False
6.*	If I hurry or walk fast, I have to stop or slow down	(panther_ipfcdd:STGRG3.STG15F / Slow Down Walking) [1] <input type="radio"/> True [0] <input type="radio"/> False
7.*	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	(panther_ipfcdd:STGRG3.STG15G / Walk Up Hills) [1] <input type="radio"/> True [0] <input type="radio"/> False
8.*	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	(panther_ipfcdd:STGRG3.STG15H / Carry Heavy Loads) [1] <input type="radio"/> True [0] <input type="radio"/> False
9.*	My breathing makes it difficult to do things such as very heavy manual work, ride a bike, run, swim fast, or play competitive sports	(panther_ipfcdd:STGRG3.STG15I / Heavy Manual Work) [1] <input type="radio"/> True [0] <input type="radio"/> False

Section 7

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

10.*	I cannot play sports or do other physical activities	(panther_ipfcdd:STGRG3.STG16A / Cannot Play Sports) [1] <input type="radio"/> True [0] <input type="radio"/> False
11.*	I cannot go out for entertainment or recreation	(panther_ipfcdd:STGRG3.STG16B / Cannot go Out) [1] <input type="radio"/> True [0] <input type="radio"/> False
12.*	I cannot go out of the house to do the shopping	(panther_ipfcdd:STGRG3.STG16C / Cannot go Shopping) [1] <input type="radio"/> True [0] <input type="radio"/> False
13.*	I cannot do household chores	(panther_ipfcdd:STGRG3.STG16D / Cannot do Chores) [1] <input type="radio"/> True [0] <input type="radio"/> False
14.*	I cannot move far from my bed or chair	(panther_ipfcdd:STGRG3.STG16E / Cannot Move) [1] <input type="radio"/> True [0] <input type="radio"/> False
15.*	Source Document Verification Completion	(panther_ipfcdd:STGRG3.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable

* Item is not required

CDD: panther_ipfcdd Table: STGRG3 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
STGLIST	STRING(255)	
STG16A	NUMERIC	
STG17B	NUMERIC	
STG16C	NUMERIC	
SDVSTAT	NUMERIC	
STG17C	NUMERIC	
STG15C	NUMERIC	
STG15E	NUMERIC	
STG15I	NUMERIC	
STG15F	NUMERIC	
STG16E	NUMERIC	
STG15A	NUMERIC	
STG16D	NUMERIC	
SDVSTAT1	NUMERIC	
STG15D	NUMERIC	
STG17A	NUMERIC	
STG15H	NUMERIC	
STG17D	NUMERIC	
STG16B	NUMERIC	
STG15G	NUMERIC	
STG15B	NUMERIC	

panther_ipf : St. Georges Part 6 (STGRG6)	
<p>Here is a list of other activities that your respiratory problems may prevent you from doing.</p> <ul style="list-style-type: none"> _ Going for walks or walking the dog _ Doing activities or chores at home or in the garden _ Sexual intercourse _ Going to a place of worship, or a place of entertainment _ Going out in bad weather or into smoky rooms _ Visiting family or friends or playing with children 	
1.* Please write in any other important activities that your respiratory problems may stop you from doing:	A255 (panther_ipfcdd: STGRG3.STGLIST / Important Activities, Spec)
2.* Now please check the one that you think best describes how your respiratory problems affect you:	<p>(panther_ipfcdd: STGRG3.STG17A / Problems do not Stop Me)</p> <p>[1] <input type="checkbox"/> It does not stop me from doing anything I would like to do</p> <p>(panther_ipfcdd: STGRG3.STG17B / Problems Affect 1-2 Things)</p> <p>[2] <input type="checkbox"/> It stops me from doing one or two things I would like to do</p> <p>(panther_ipfcdd: STGRG3.STG17C / Problems Affect Most Things)</p> <p>[3] <input type="checkbox"/> It stops me from doing most of the things I would like to do</p> <p>(panther_ipfcdd: STGRG3.STG17D / Problems Affect Everything)</p> <p>[4] <input type="checkbox"/> It stops me from doing everything I would like to do</p>
3.* Source Document Verification Completion	<p>(panther_ipfcdd: STGRG3.SDVSTAT1 / SDV Complete)</p> <p>[1] <input type="radio"/> Complete</p> <p>[2] <input type="radio"/> Partially Complete</p> <p>[3] <input type="radio"/> Not Applicable</p>
* Item is not required	

Column Name	Column Data Type	Design Note
STGLIST	STRING(255) - A255	
STG16A	NUMERIC	
STG17B	NUMERIC	
STG16C	NUMERIC	
SDVSTAT	NUMERIC	
STG17C	NUMERIC	
STG15C	NUMERIC	
STG15E	NUMERIC	
STG15I	NUMERIC	
STG15F	NUMERIC	
STG16E	NUMERIC	
STG15A	NUMERIC	
STG16D	NUMERIC	
SDVSTAT1	NUMERIC	
STG15D	NUMERIC	
STG17A	NUMERIC	
STG15H	NUMERIC	
STG17D	NUMERIC	
STG16B	NUMERIC	
STG15G	NUMERIC	
STG15B	NUMERIC	

panther_ipf : SF36 Assessment Part 1 (SF36_1)		
Assessment		
1.*	In general, would you say your health is:	Pulldown List 1 (panther_ipfcd:SF36.SF1 / General Health)
2.*	Compared to one year ago, how would you rate your health in general now?	Pulldown List 2 (panther_ipfcd:SF36.SF2 / Health Comp to One Year Ago)
The following items are about activities you might do during a typical day. Does your health now limit you? If so, how much?		
3.*	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	(panther_ipfcd:SF36.SF3A / Vigorous Activities) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
4.*	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	(panther_ipfcd:SF36.SF31 / Moderate Activities) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
5.*	Lifting or carrying groceries	(panther_ipfcd:SF36.SF32 / Groceries) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
6.*	Climbing several flights of stairs	(panther_ipfcd:SF36.SF33 / Several Flights of Stairs) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
7.*	Climbing one flight of stairs	(panther_ipfcd:SF36.SF34 / One Flight of Stairs) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
8.*	Bending, kneeling or stooping	(panther_ipfcd:SF36.SF35 / Bending Kneeling) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
9.*	Walking more than a mile	(panther_ipfcd:SF36.SF36 / Walking More than 1 Mile) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
10.*	Walking several blocks	(panther_ipfcd:SF36.SF37 / Walking Several Blocks) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
11.*	Walking one block	(panther_ipfcd:SF36.SF38 / Walking One Block) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
12.*	Bathing or dressing yourself	(panther_ipfcd:SF36.SF39 / Bathing or Dressing) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?		
13.*	Cut down on the amount of time you spend on work or other activities	Pulldown List 3 (panther_ipfcd:SF36.SF4A / Physical - Amount of Time)
14.*	Accomplished less than you would like	Pulldown List 4 (panther_ipfcd:SF36.SF4B / Physical - Accomplish Less)
15.*	Were limited in the kind of work or other activities	Pulldown List 5 (panther_ipfcd:SF36.SF4C / Physical - Limited Work)
16.*	Had difficulty performing the work or other activities (for example, it took extra effort)	Pulldown List 6 (panther_ipfcd:SF36.SF4D / Physical - Diff Working)
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?		
17.*	Cut down on the amount of time you spend on work or other activities	Pulldown List 7 (panther_ipfcd:SF36.SF5A / Emotional - Amount of Time)
18.*	Accomplished less than you would like	Pulldown List 8 (panther_ipfcd:SF36.SF5B / Emotional - Accomplish Less)
19.*	Did work or other activities less carefully than usual	Pulldown List 9 (panther_ipfcd:SF36.SF5C / Emotional - Limited Work)
20.*	Source Document Verification Completion	(panther_ipfcd:SF36.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieXCOND1	Excellent	1	
ieXCOND2	Very Good	2	
ieXCOND3	Good	3	
ieXCOND4	Fair	4	
ieXCOND5	Poor	5	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieIPFHLT1	Much better than one year ago	1	
ieIPFHLT2	Somewhat better than one year ago	2	
ieIPFHLT3	About the same as one year ago	3	
ieIPFHLT4	Somewhat worse than one year ago	4	
ieIPFHLT5	Much worse now than one year ago	5	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieIPTIM1	All of the Time	1	
ieIPTIM2	Most of the Time	2	
ieIPTIM3	Some of the Time	3	
ieIPTIM4	A Little of the Time	4	

ieIPFTIM5	None of the Time	5	
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Pulldown List 4:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 5:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 6:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 7:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 8:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 9:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

CDD: panther_ipfcdd Table: SF36 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SF11C	NUMERIC	
SF33	NUMERIC	
SF11D	NUMERIC	
SF39	NUMERIC	
SF9G	NUMERIC	
SF36	NUMERIC	
SF9F	NUMERIC	
SF6	NUMERIC	
SF9I	NUMERIC	
SF8	NUMERIC	
SF5B	NUMERIC - 1, 2, 3, 4, 5	

SF9D	NUMERIC	
SF9A	NUMERIC	
SF9B	NUMERIC	
SF3A	NUMERIC	
SF9C	NUMERIC	
SF9E	NUMERIC	
SDVSTAT1	NUMERIC	
SF9H	NUMERIC	
SF11B	NUMERIC	
SF31	NUMERIC	
SF7	NUMERIC	
SF10	NUMERIC	
SF37	NUMERIC	
SF11A	NUMERIC	
SF35	NUMERIC	
SF38	NUMERIC	
SF32	NUMERIC	
SDVSTAT	NUMERIC	
SF4A	NUMERIC - 1, 2, 3, 4, 5	
SF2	NUMERIC - 1, 2, 3, 4, 5	
SF34	NUMERIC	
SF4B	NUMERIC - 1, 2, 3, 4, 5	
SF5A	NUMERIC - 1, 2, 3, 4, 5	
SF4C	NUMERIC - 1, 2, 3, 4, 5	
SF1	NUMERIC - 1, 2, 3, 4, 5	
SF4D	NUMERIC - 1, 2, 3, 4, 5	
SF5C	NUMERIC - 1, 2, 3, 4, 5	

panther_ipf : SF36 Assessment Part 2 (SF36_2)		
SF36_2		
1.*	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	Pulldown List 1 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF6 / Social Activities)
2.*	How much bodily pain have you had during the past 4 weeks?	Pulldown List 2 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF7 / Bodily Pain)
3.*	During the past 4 weeks, how much did pain interfere with your normal work (including both outside the home and housework)?	Pulldown List 3 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF8 / Pain Interference)
These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.		
4.*	Did you feel full of life?	Pulldown List 4 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9A / Full of Life)
5.*	Have you been very nervous?	Pulldown List 5 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9B / Nervous)
6.*	Have you felt so down in the dumps that nothing could cheer you up?	Pulldown List 6 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9C / Feeling Down)
7.*	Have you felt calm and peaceful?	Pulldown List 7 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9D / Calm)
8.*	Did you have a lot of energy?	Pulldown List 8 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9E / Energized)
9.*	Have you felt downhearted and depressed?	Pulldown List 9 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9F / Depressed)
10.*	Did you feel worn out?	Pulldown List 10 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9G / Worn Out)
11.*	Have you been happy?	Pulldown List 11 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9H / Happy)
12.*	Did you feel tired?	Pulldown List 12 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF9I / Tired)
13.*	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?	Pulldown List 13 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF10 / Social Activity Time)
How True or False is each of the following statements for you?		
14.*	I seem to get sick a little easier than other people	Pulldown List 14 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF11A / Get Sick Easier)
15.*	I am as healthy as anybody I know	Pulldown List 15 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF11B / Healthy)
16.*	I expect my health to get worse	Pulldown List 16 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF11C / Health Get Worse)
17.*	My health is excellent	Pulldown List 17 <input type="button" value="v"/> (panther_ipfcdd:SF36.SF11D / Health Excellent)
18.*	Source Document Verification Completion	(panther_ipfcdd:SF36.SDVSTAT1 / SDV Complete) <input type="radio"/> [1] Complete <input type="radio"/> [2] Partially Complete <input type="radio"/> [3] Not Applicable
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieIPFXTN1	Not at all	1	
ieIPFXTN2	Slightly	2	
ieIPFXTN3	Moderately	3	
ieIPFXTN4	Quite a bit	4	
ieIPFXTN5	Extremely	5	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieIPFBPN1	None	1	
ieIPFBPN2	Very mild	2	
ieIPFBPN3	Mild	3	
ieIPFBPN4	Moderate	4	
ieIPFBPN5	Severe	5	
ieIPFBPN6	Very severe	6	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieIPFXTN1	Not at all	1	
ieIPFXTN2	Slightly	2	
ieIPFXTN3	Moderately	3	
ieIPFXTN4	Quite a bit	4	
ieIPFXTN5	Extremely	5	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 5:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 6:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 7:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 8:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 9:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 10:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 11:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 12:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 13:			
RefName	Display Text	Value	Design Note
ieIPFTIM1	All of the Time	1	
ieIPFTIM2	Most of the Time	2	
ieIPFTIM3	Some of the Time	3	
ieIPFTIM4	A Little of the Time	4	
ieIPFTIM5	None of the Time	5	

Pulldown List 14:			
RefName	Display Text	Value	Design Note
ieIPFTRU1	Definitely True	1	
ieIPFTRU2	Mostly True	2	
ieIPFTRU3	Don't Know	3	
ieIPFTRU4	Mostly False	4	
ieIPFTRU5	Definitely False	5	

Pulldown List 15:			
RefName	Display Text	Value	Design Note
ieIPFTRU1	Definitely True	1	
ieIPFTRU2	Mostly True	2	
ieIPFTRU3	Don't Know	3	
ieIPFTRU4	Mostly False	4	
ieIPFTRU5	Definitely False	5	

Pulldown List 16:			
RefName	Display Text	Value	Design Note
ieIPFTRU1	Definitely True	1	
ieIPFTRU2	Mostly True	2	
ieIPFTRU3	Don't Know	3	
ieIPFTRU4	Mostly False	4	
ieIPFTRU5	Definitely False	5	

Pulldown List 17:			
RefName	Display Text	Value	Design Note
ieIPFTRU1	Definitely True	1	
ieIPFTRU2	Mostly True	2	
ieIPFTRU3	Don't Know	3	
ieIPFTRU4	Mostly False	4	
ieIPFTRU5	Definitely False	5	

CDD: panther_ipfcdd Table: SF36 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SF11C	NUMERIC - 1, 2, 3, 4, 5	
SF33	NUMERIC	
SF11D	NUMERIC - 1, 2, 3, 4, 5	
SF39	NUMERIC	
SF9G	NUMERIC - 1, 2, 3, 4, 5	
SF36	NUMERIC	
SF9F	NUMERIC - 1, 2, 3, 4, 5	
SF6	NUMERIC - 1, 2, 3, 4, 5	
SF9I	NUMERIC - 1, 2, 3, 4, 5	
SF8	NUMERIC - 1, 2, 3, 4, 5	
SF5B	NUMERIC - 1, 2, 3, 4, 5	
SF9D	NUMERIC - 1, 2, 3, 4, 5	
SF9A	NUMERIC - 1, 2, 3, 4, 5	
SF9B	NUMERIC - 1, 2, 3, 4, 5	
SF3A	NUMERIC	
SF9C	NUMERIC - 1, 2, 3, 4, 5	
SF9E	NUMERIC - 1, 2, 3, 4, 5	
SDVSTAT1	NUMERIC	
SF9H	NUMERIC - 1, 2, 3, 4, 5	
SF11B	NUMERIC - 1, 2, 3, 4, 5	
SF31	NUMERIC	

SF7	NUMERIC - 1, 2, 3, 4, 5, 6	
SF10	NUMERIC - 1, 2, 3, 4, 5	
SF37	NUMERIC	
SF11A	NUMERIC - 1, 2, 3, 4, 5	
SF35	NUMERIC	
SF38	NUMERIC	
SF32	NUMERIC	
SDVSTAT	NUMERIC	
SF4A	NUMERIC - 1, 2, 3, 4, 5	
SF2	NUMERIC - 1, 2, 3, 4, 5	
SF34	NUMERIC	
SF4B	NUMERIC - 1, 2, 3, 4, 5	
SF5A	NUMERIC - 1, 2, 3, 4, 5	
SF4C	NUMERIC - 1, 2, 3, 4, 5	
SF1	NUMERIC - 1, 2, 3, 4, 5	
SF4D	NUMERIC - 1, 2, 3, 4, 5	
SF5C	NUMERIC - 1, 2, 3, 4, 5	

panther_ipf : Log Review (REVIEWX)	
Clinical Review	
Record all phone contacts on Telephone (PHONE) form	
1. Did the subject have an adverse event since the last visit?	(panther_ipfcdd:REVIEW.RVXAE / Adverse Event) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Adverse Event Form (AE)
2. Did the subject have a change in medications since the last visit?	(panther_ipfcdd:REVIEW.RVXCM / Change in Medications) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Comcomitant Medication Form (MED)
3. Was the subject admitted to the hospital, emergency room, observational unit, assisted living/nursing facility, or rehabilitation center since the last visit?	(panther_ipfcdd:REVIEW.RVXINPT / Urgent Admission) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on the Urgent or Inpatient Admission Form (INPT)
4. Did the subject have a change in GERD status since the last visit?	(panther_ipfcdd:REVIEW.RVXGERD / GERD Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Gerd Change Form (GERD)
5. Did the subject have a change in sleep apnea since the last visit?	(panther_ipfcdd:REVIEW.RVXSLP / Sleep Apnea Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Sleep Apnea Change Form (SLPCHG)
6. Did the subject have a change in study drug dosing since the last visit?	(panther_ipfcdd:REVIEW.RVXSDRG / Dosing Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Study Drug Change Form (SDRGCHG)
7.* Source Document Verification Completion	(panther_ipfcdd:REVIEW.SDVSTAT2 / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

CDD: panther_ipfcdd Table: REVIEW Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RVWCM	NUMERIC	
RVWINPT	NUMERIC	
RVWGERD	NUMERIC	
RVWSDRG	NUMERIC	
SDVSTAT1	NUMERIC	
RVWSGRQ	NUMERIC	
RVWUCSD1	NUMERIC	
RVWICE1	NUMERIC	
SDVSTAT	NUMERIC	
RVXSDRG	NUMERIC	
RVWEURO	NUMERIC	
RVWSF36A	NUMERIC	
RVXAE	NUMERIC	
RVWSLP	NUMERIC	
RVWAE	NUMERIC	
RVWGNDR	NUMERIC	
RVWUCSD	NUMERIC	
RVXGERD	NUMERIC	
RVWSF36	NUMERIC	
RVWEURO1	NUMERIC	
RVWSGRQ1	NUMERIC	
SDVSTAT2	NUMERIC	
RVWCM1	NUMERIC	
RVXINPT	NUMERIC	
RVXSLP	NUMERIC	
RVWICE	NUMERIC	
RVXCM	NUMERIC	

panther_ipf : Outpatient Visits (OUTPT)

Outpatient Visits	
<p>1. Has the subject required any non-urgent outpatient visits since the last study visit (do not include protocol-specific study visits)?</p>	<p>(panther_ipfcdd:OUTPT.OUTVISIT / Outpatient Visits) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(panther_ipfcdd:OUTPT.PULVISIT / Pulmonologist) [1] <input type="checkbox"/> Pulmonologist Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.PULRSP / Pulmonary Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.PULNORSP / Pulmonary Non-Resp Related)</p> <p>(panther_ipfcdd:OUTPT.CARVISIT / Cardiologist) [1] <input type="checkbox"/> Cardiologist Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.CARRSP / Cardiology Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.CARNORSP / Cardiology Non-Resp Related)</p> <p>(panther_ipfcdd:OUTPT.OSPVISIT / Other Specialist) [1] <input type="checkbox"/> Other Specialist Other Specialist: (specify): (panther_ipfcdd:OUTPT.OSPSPEC / Other Specialist, Specify) A50 Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.OSPRSP / Other Spec Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.OSPNORSP / Oth Special NonResp Related)</p> <p>(panther_ipfcdd:OUTPT.PRMVISIT / PCP) [1] <input type="checkbox"/> Primary care physician (or NP/PA) Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.PRMRSP / PCP Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.PRMNORSP / PCP Non-Resp Related)</p> <p>(panther_ipfcdd:OUTPT.OPTVISIT / PT) [1] <input type="checkbox"/> Occupational or physical therapy Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.OPTRSP / PT Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.OPTNORSP / PT Non-Resp Related)</p> <p>(panther_ipfcdd:OUTPT.MENVISIT / Mental Health) [1] <input type="checkbox"/> Mental Health provider Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.MENRSP / Mental Health Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.MENNORSP / Mental Health NonResp Relat)</p> <p>(panther_ipfcdd:OUTPT.OTHVISIT / Other Outpatient Visit) [1] <input type="checkbox"/> Other (specify) Other (specify): (panther_ipfcdd:OUTPT.OTHSPEC / Other Outpatient, Specify) A50 Number of Respiratory related visits: xxx (panther_ipfcdd:OUTPT.OTHRSP / Other Resp Related) Number of Non-Respiratory related visits: xxx (panther_ipfcdd:OUTPT.OTHNORSP / Other Non Resp Related)</p>
<p>2.* Source Document Verification Completion</p>	<p>(panther_ipfcdd:OUTPT.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable</p>
<p>* Item is not required</p>	

CDD: panther_ipfcdd Table: OUTPT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
CARVISIT	NUMERIC	
OUTVISIT	NUMERIC	
OSPSPEC	STRING(50) - A50	
PRMVISIT	NUMERIC	
MENVISIT	NUMERIC	
PULNORSP	NUMERIC - N3	
PRMNORSP	NUMERIC - N3	
OPTVISIT	NUMERIC	
PRMRSP	NUMERIC - N3	
OTHVISIT	NUMERIC	
PULVISIT	NUMERIC	
OTHRSP	NUMERIC - N3	
OSPNORSP	NUMERIC - N3	
OSPVISIT	NUMERIC	
PULRSP	NUMERIC - N3	
OTHNORSP	NUMERIC - N3	
CARNORSP	NUMERIC - N3	
MENNORSP	NUMERIC - N3	
OPTNORSP	NUMERIC - N3	
MENRSP	NUMERIC - N3	
OTHSPEC	STRING(50) - A50	

OPTRSP	NUMERIC - N3	
OSPRSP	NUMERIC - N3	
CARRSP	NUMERIC - N3	
SDVSTAT	NUMERIC	

panther_ipf : FVC Confirmation (FVC)		
*		
1.	Was a FVC confirmation visit performed?	(panther_ipfcdd:FVC.DISFVCRD / Confirmation Performed) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date of visit to confirm FVC: Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:FVC.DISFVCDT / Date of FVC Confirmation) FVC in liters: xxxxxxxx. (panther_ipfcdd:FVC.DISFVC / FVC in Liters) (panther_ipfcdd:FVC.DISFVCYN / 10% Drop Confirmed) Is a 10% FVC drop confirmed? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd:FVC.DISFVCY / Cause of FVC Reduction) Cause of reduction in FVC from baseline? [1] <input type="radio"/> Due to disease progression [2] <input type="radio"/> Due to other complications
2.	FVC Difference from baseline:	xxxxxxxx. % (panther_ipfcdd:FVC.DISCAL / FVC Diff from Baseline)
3.*	Source Document Verification Completion	(panther_ipfcdd:FVC.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfcdd Table: FVC Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SDVSTAT	NUMERIC	
DISCAL	FLOAT - F9.0	
DISFVCYN	NUMERIC	
DISFVCRD	NUMERIC	
DISFVC	FLOAT - F9.0	
DISFVCY	NUMERIC	
DISFVCDT	DATE - DDMONYYYY	

panther_ipf : Log Review (REVIEW)		
Clinical Review		
Record all phone contacts on Telephone (PHONE) form		
1.	Did the subject have an adverse event since the last visit?	(panther_ipfccdd:REVIEW.RVWAE / Adverse Events) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Adverse Event Form (AE)
2.	Has the subject taken any medications in the past 30 days?	(panther_ipfccdd:REVIEW.RVWCM / Change in Medications) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Comcomitant Medication Form (MED)
3.	Was the subject admitted to the hospital, emergency room, observational unit, assisted living/nursing facility, or rehabilitation center since the last visit?	(panther_ipfccdd:REVIEW.RVWINPT / Urgent Admission) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on the Urgent or Inpatient Admission Form (INPT)
4.	Did the subject have a change in GERD status since the last visit?	(panther_ipfccdd:REVIEW.RVWGERD / GERD Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Gerd Change Form (GERD)
5.	Did the subject have a change in sleep apnea since the last visit?	(panther_ipfccdd:REVIEW.RVWSLP / Sleep Apnea Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Sleep Apnea Change Form (SLPCHG)
6.	Did the subject have a change in study drug dosing since the last visit?	(panther_ipfccdd:REVIEW.RVWSDRG / Dosing Change) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Study Drug Change Form (SDRGCHG)
7.	Did the subject complete the EuroQoL?	(panther_ipfccdd:REVIEW.RVWEURO / EuroQoL CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
8.	Did the subject complete the ICECAP?	(panther_ipfccdd:REVIEW.RVWICE / ICECAP CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
9.	Did the subject complete the UCSD_SOBQ?	(panther_ipfccdd:REVIEW.RVWUCSD / UCSD SOBQ CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
10.	Did the subject complete the SGRQ?	(panther_ipfccdd:REVIEW.RVWSGRQ / SGRQ CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
11.	Did the subject complete the SF-36?	(panther_ipfccdd:REVIEW.RVWSF36 / SF-36 CRF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, fax to the DCRI at 919-668-7100
12.*	Source Document Verification Completion	(panther_ipfccdd:REVIEW.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

CDD: panther_ipfccdd Table: REVIEW Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RVWCM	NUMERIC	
RVWINPT	NUMERIC	
RVWGERD	NUMERIC	
RVWSDRG	NUMERIC	
SDVSTAT1	NUMERIC	
RVWSGRQ	NUMERIC	
RVWUCSD1	NUMERIC	
RVWICE1	NUMERIC	
SDVSTAT	NUMERIC	
RVXSDRG	NUMERIC	
RVWEURO	NUMERIC	
RVWSF36A	NUMERIC	
RVXAE	NUMERIC	

RVWSLP	NUMERIC	
RVWAE	NUMERIC	
RVWGDR	NUMERIC	
RVWUCSD	NUMERIC	
RVXGERD	NUMERIC	
RVWSF36	NUMERIC	
RVWEURO1	NUMERIC	
RVWSGRQ1	NUMERIC	
SDVSTAT2	NUMERIC	
RVWCM1	NUMERIC	
RVXINPT	NUMERIC	
RVXSLP	NUMERIC	
RVWICE	NUMERIC	
RVXCM	NUMERIC	

panther_ipf : Study Drug Compliance (SDRGCOMP)		
Study Drug Compliance		
1.	Date of Assessment	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:SDRGCOMP.DRGCMPDT / Compliance Date)
2.	Of the last 7 days, how many days did the subject take their study Azathioprine/Placebo?	xxx (panther_ipfcdd:SDRGCOMP.AZACOMP / Azathioprine Compliance)
3.	Of the last 7 days, how many days did the subject take their study Prednisone/Placebo?	xxx (panther_ipfcdd:SDRGCOMP.PREDCOMP / Prednisone Compliance)
4.	Of the last 7 days, how many days did the subject take their study NAC/Placebo?	xxx (panther_ipfcdd:SDRGCOMP.NACCOMP / NAC Compliance)
5.*	Source Document Verification Completion	(panther_ipfcdd:SDRGCOMP.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
PREDCOMP	NUMERIC - N3	
AZACOMP	NUMERIC - N3	
NACCOMP	NUMERIC - N3	
DRGCMPDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	

panther_ipf : Study Completion/Termination (TERM)		
Study Completion/Termination		
1.	Did the subject terminate the study prior to week 60?	<p>(panther_ipfcdd: TERM.TERMCOMP / Terminate Early)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>If Yes: Date of study termination: Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd: TERM.TERMDT / Termination Date)</p> <p>(panther_ipfcdd: TERM.TERMREA / Termination Reason)</p> <p>If Yes: Reason for early study termination:</p> <p>[1] <input type="radio"/> Death</p> <p>[2] <input type="radio"/> Lung transplant</p> <p>[3] <input type="radio"/> Adverse event</p> <p>[4] <input type="radio"/> Subject withdrew consent</p> <p>[5] <input type="radio"/> MD decision</p> <p>[6] <input type="radio"/> Lost to follow-up</p> <p>[98] <input type="radio"/> Other (specify): _____ (panther_ipfcdd: TERM.TERMSP / Termination Reason, Specify)</p> <p>A100</p>
2.	Was Azathioprine unblinded?	<p>(panther_ipfcdd: TERM.UNBLINDA / AZA Unblinded)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>If yes: Date of unblinding: Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd: TERM.UNBLNADT / AZA Unblind Date)</p> <p>(panther_ipfcdd: TERM.UNBLAAE / AZA Unblind Reason)</p> <p>If yes, Reason for unblinding</p> <p>[1] <input type="radio"/> Suspected drug toxicity</p> <p>[2] <input type="radio"/> Adverse Event</p> <p>[98] <input type="radio"/> Other reason for unblinding: _____ (panther_ipfcdd: TERM.UNBLNDAR / AZA Unblind, Specify)</p> <p>A100</p>
3.	Was Prednisone unblinded?	<p>(panther_ipfcdd: TERM.UNBLINDP / Prednisone Unblinded)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>If yes: Date of unblinding: Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd: TERM.UNBLNPDT / Prednisone Unblind Date)</p> <p>(panther_ipfcdd: TERM.UNBLPAE / Prednisone Unblind Reason)</p> <p>If yes, Reason for unblinding</p> <p>[1] <input type="radio"/> Suspected drug toxicity</p> <p>[2] <input type="radio"/> Adverse Event</p> <p>[98] <input type="radio"/> Other reason for unblinding: _____ (panther_ipfcdd: TERM.UNBLNDPR / Prednisone Unblind, Specify)</p> <p>A100</p>
4.	Was NAC unblinded?	<p>(panther_ipfcdd: TERM.UNBLINDN / NAC Unblinded)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>If yes: Date of unblinding: Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd: TERM.UNBLNNDT / NAC Unblind Date)</p> <p>(panther_ipfcdd: TERM.UNBLNAE / NAC Unblind Reason)</p> <p>If yes, Reason for unblinding</p> <p>[1] <input type="radio"/> Suspected drug toxicity</p> <p>[2] <input type="radio"/> Adverse Event</p> <p>[98] <input type="radio"/> Other reason for unblinding: _____ (panther_ipfcdd: TERM.UNBLNDNR / NAC Unblind, Specify)</p> <p>A100</p>
5.*	Source Document Verification Completion	<p>(panther_ipfcdd: TERM.SDVSTAT / SDV Complete)</p> <p>[1] <input type="radio"/> Complete</p> <p>[2] <input type="radio"/> Partially Complete</p> <p>[3] <input type="radio"/> Not Applicable</p>
* Item is not required		

Column Name	Column Data Type	Design Note
CDD: panther_ipfcdd	Table: TERM	Key Type: PATIENTVISIT
UNBLINDP	NUMERIC	
UNBLNNDT	DATE - DDMONYYYY	
UNBLINDN	NUMERIC	
UNBLNDNR	STRING(100) - A100	
TERMCOMP	NUMERIC	
UNBLNADT	DATE - DDMONYYYY	
UNBLAAE	NUMERIC	
SDVSTAT	NUMERIC	
TERMDT	DATE - DDMONYYYY	
UNBLPAE	NUMERIC	

UNBLNDPR	STRING(100) - A100	
TERMREA	NUMERIC	
UNBLNDAR	STRING(100) - A100	
TERMSP	STRING(100) - A100	
UNBLNPD	DATE - DDMYYYY	
UNBLNAE	NUMERIC	
UNBLINDA	NUMERIC	

panther_ipf : Death (DEATH)	
Death	
1. Where did the subject die?	(panther_ipfcdd: DEATH.DEATHLOC / Death Location) [1] <input type="radio"/> Inpatient [2] <input type="radio"/> Outpatient
2. Date of death:	Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd: DEATH.DEADDT / Death Date)
3. Cause of death is best attributed to:	(panther_ipfcdd: DEATH.DEADCAUS / Cause of Death) [1] <input type="radio"/> (panther_ipfcdd: DEATH.CARDEATH / Death Type Cardiovascular) Cardiovascular [1] <input type="radio"/> Congestive heart failure [2] <input type="radio"/> Myocardial infarction [3] <input type="radio"/> Stroke [4] <input type="radio"/> Sudden Cardiovascular Death [2] <input type="radio"/> (panther_ipfcdd: DEATH.RESPDEAD / Death Type Respiratory) Respiratory [1] <input type="radio"/> IPF [2] <input type="radio"/> Pneumonia [3] <input type="radio"/> Lung Cancer [98] <input type="radio"/> Other (specify): A50 (panther_ipfcdd: DEATH.OTRESEDD / Death Type Resp, Specify) [3] <input type="radio"/> (panther_ipfcdd: DEATH.CNCRDEAD / Death Type Cancer) Cancer [1] <input type="radio"/> Breast Cancer [2] <input type="radio"/> Colon Cancer [3] <input type="radio"/> Prostate Cancer [98] <input type="radio"/> Other (specify): A50 (panther_ipfcdd: DEATH.OTCNREDD / Death Type Cancer, Specify) [98] <input type="radio"/> Other (specify): A50 (panther_ipfcdd: DEATH.OTHRDEAD / Death Type Other) [99] <input type="radio"/> Unknown
4. Was death related to IPF?	(panther_ipfcdd: DEATH.IPFDEATH / Death Related to IPF) [1] <input type="radio"/> Definitely related [2] <input type="radio"/> Probably related [3] <input type="radio"/> Unlikely related [4] <input type="radio"/> Not at all related
5. * Source Document Verification Completion	(panther_ipfcdd: DEATH.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

Column Name	Column Data Type	Design Note
DEADCAUS	NUMERIC	
OTHRDEAD	STRING(50) - A50	
SDVSTAT	NUMERIC	
OTCNREDD	STRING(50) - A50	
RESPDEAD	NUMERIC	
DEADDT	DATE - DDMONYYYY	
OTRESEDD	STRING(50) - A50	
CNCRDEAD	NUMERIC	
DEATHLOC	NUMERIC	
IPFDEATH	NUMERIC	
CARDEATH	NUMERIC	

panther_ipf : Study Drug Dosing (SDRGCHG) - Repeating Form						
#	Drug	Date of Change	New Dosage	Adjustment reason(s)	Source Document Verification Completion	
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Study Drug Dosing Change						
1.	Drug	(panther_ipfcdd:SDRGCHG.DRUGCHG / Drug Change) [1] <input type="radio"/> Azathioprine/placebo [2] <input type="radio"/> Prednisone/placebo [3] <input type="radio"/> NAC/placebo				
2.	Date of Dosage Change or Discontinuation	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfcdd:SDRGCHG.DOSECHDT / Drug Change Date)				
3.	New Dosage per administration	(panther_ipfcdd:SDRGCHG.DOSECHG / Type of Changed) [1] <input type="radio"/> xxxxxxxx mg (panther_ipfcdd:SDRGCHG.NEWDOSE / New Dose) (panther_ipfcdd:SDRGCHG.NEWUNIT / New Unit) [1] <input type="radio"/> Three times per day [2] <input type="radio"/> Twice per day [3] <input type="radio"/> Once per day [4] <input type="radio"/> Every other day [5] <input type="radio"/> Twice per week [98] <input type="radio"/> Other (specify) (panther_ipfcdd:SDRGCHG.OTHNEWUN / Other Unit, Specify) A25 [2] <input type="radio"/> Temporary Discontinuation [3] <input type="radio"/> Permanent Discontinuation				
4.	Dosage adjustment reason(s)	(panther_ipfcdd:SDRGCHG.DOSEALG / Adjustment Reason) [1] <input type="radio"/> (panther_ipfcdd:SDRGCHG.ALGALTL / ALT Low) [1] <input type="checkbox"/> (panther_ipfcdd:SDRGCHG.ALGALTH / ALT High) ALT/AST [1] <input type="radio"/> 2 - 3 x ULN [2] <input type="radio"/> > 3 x ULN (panther_ipfcdd:SDRGCHG.ALGWBC / WBC Low) [1] <input type="checkbox"/> (panther_ipfcdd:SDRGCHG.ALGWBC / WBC High) WBC [1] <input type="radio"/> 3 - 3.4 and/or PLT 80,000-99,999 [2] <input type="radio"/> < = 3.0 and/or PLT < 80,000 (panther_ipfcdd:SDRGCHG.ALGGI / GI Symptoms) [1] <input type="checkbox"/> GI symptoms (panther_ipfcdd:SDRGCHG.ALGDERM / Dermatologic) [1] <input type="checkbox"/> Dermatologic reactions (panther_ipfcdd:SDRGCHG.ALGFVR / Fever Chills) [1] <input type="checkbox"/> Unexplained fever/chills (panther_ipfcdd:SDRGCHG.ALGCOF / Cough Dyspnea) [1] <input type="checkbox"/> Increased cough/dyspnea (panther_ipfcdd:SDRGCHG.PROTREAS / Per Protocol) [1] <input type="checkbox"/> Per protocol increase or taper (panther_ipfcdd:SDRGCHG.RESLVREA / Resolution) [1] <input type="checkbox"/> Resolution of problem (panther_ipfcdd:SDRGCHG.HOSREAS / Hospitalization) [1] <input type="checkbox"/> Hospitalization (panther_ipfcdd:SDRGCHG.MDREAS / MD Decision) [1] <input type="checkbox"/> Other MD decision (panther_ipfcdd:SDRGCHG.SUBJREAS / Subject Decision) [1] <input type="checkbox"/> Subject decision or withdrew consent (panther_ipfcdd:SDRGCHG.TERMREAS / Early Termination) [1] <input type="checkbox"/> Early termination/death (panther_ipfcdd:SDRGCHG.COMPREAS / Completed Trial) [1] <input type="checkbox"/> Completed trial				
5.*	Source Document Verification Completion	(panther_ipfcdd:SDRGCHG.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable				
* Item is not required						

CDD: panther_ipfcdd Table: SDRGCHG Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DOSECHG	NUMERIC	
NEWUNIT	NUMERIC	
COMPREAS	NUMERIC	
SUBJREAS	NUMERIC	
ALGALTL	NUMERIC	
NEWDOSE	FLOAT - F9.0	
ALGCOF	NUMERIC	
ALGWBC	NUMERIC	
HOSREAS	NUMERIC	
TERMREAS	NUMERIC	

ALGDERM	NUMERIC	
DRUGCHG	NUMERIC	
PROTREAS	NUMERIC	
MDREAS	NUMERIC	
ALGGI	NUMERIC	
DOSECHDT	DATE - DDMONYYYY	
OTHNEWUN	STRING(25) - A25	
SDVSTAT	NUMERIC	
ALGWBCH	NUMERIC	
DOSEALG	NUMERIC	
ALGALTH	NUMERIC	
RESLVREA	NUMERIC	
ALGFVR	NUMERIC	

panther_ipf : Urgent or Inpatient Admissions (INPT) - Repeating Form							
#	Admission Date	Admission Type	Reason for Admission	Was reason for Admission respiratory-related.	Major Procedures Performed	Was subject discharged?	Source Document Verification Completion
1							
Urgent or inpatient admissions							
1.	Admission Date	Req/Unk / Req/Unk / Req (2009-2016) (panther_ipfcdd: INPT.ADMITDT / Admission Date)					
2.	Admission Type	(panther_ipfcdd: INPT.ADMITYPE / Admission Type) [1] <input type="radio"/> Hospital [2] <input type="radio"/> ER/urgent care [3] <input type="radio"/> Assisted living/nursing facility [4] <input type="radio"/> Rehabilitation center					
3.	Reason for Admission	A100 (panther_ipfcdd: INPT.HOSPREAS / Reason for Admission)					
4.	Was reason for Admission respiratory-related.	(panther_ipfcdd: INPT.RESPREL / Resp Related Admission) [0] <input type="radio"/> No [1] <input type="radio"/> Yes					
5.	Major Procedures Performed	A100 (panther_ipfcdd: INPT.MAJPROC / Major Procedures)					
6.	Was subject discharged?	(panther_ipfcdd: INPT.DISCHRG / Discharged) [1] <input type="radio"/> Yes Discharged: date: Req / Req / Req (2009-2016) (panther_ipfcdd: INPT.DISCHDT / Discharge Date) (panther_ipfcdd: INPT.DISCHDES / Discharge Destination) Discharge destination: [1] <input type="radio"/> Home [2] <input type="radio"/> Assisted living/nursing facility [3] <input type="radio"/> Rehab center [4] <input type="radio"/> Transfer to other hospital [98] <input type="radio"/> Other (specify) (panther_ipfcdd: INPT.DISCGSP / Discharge, Specify) A100 [0] <input type="radio"/> (panther_ipfcdd: INPT.NOTDISCH / Reason Not Discharged) No [1] <input type="radio"/> Died [2] <input type="radio"/> Remains inpatient					
7.*	Source Document Verification Completion	(panther_ipfcdd: INPT.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable					
* Item is not required							

Column Name	Column Data Type	Design Note
ADMITDT	DATE - DDMONYYYY	
NOTDISCH	NUMERIC	
MAJPROC	STRING(100) - A100	
ADMITYPE	NUMERIC	
SDVSTAT	NUMERIC	
DISCHDES	NUMERIC	
DISCHRG	NUMERIC	
HOSPREAS	STRING(100) - A100	
RESPREL	NUMERIC	
DISCGSP	STRING(100) - A100	
DISCHDT	DATE - DDMONYYYY	

panther_ipf : Concomitant Medications (MED) - Repeating Form							
#	Medication Name	When did the subject start the medication?	Start Date	Stop Date	Indication	Source Document Verification Completion	
1							
Concomitant Medications							
1.	Medication Name	A100 (panther_ipfcdd: MED.MEDICATN / Medication Name)					
2.	When did the subject start the medication?	(panther_ipfcdd: MED.MEDSTRT / Medication Started) [1] <input type="radio"/> Pre-randomization [2] <input type="radio"/> Post-randomization					
3.	Start Date	Req/Unk / Req/Unk / Req/Unk (1930-2016) (panther_ipfcdd: MED.MEDSTRDT / Start Date)					
4.	Stop Date	(panther_ipfcdd: MED.MEDCONTU / Continuing) [0] <input type="radio"/> Req/Unk / Req/Unk / Req (2007-2016) (panther_ipfcdd: MED.MEDSTPDT / Stop Date) [1] <input type="radio"/> Continuing					
5.	Indication	(panther_ipfcdd: MED.INDICATE / Indication) [1] <input type="radio"/> Non-Gastroesophageal disorder, specify: (panther_ipfcdd: MED.THERAPY / Nongastro Indicat, Specify) A50 [2] <input type="radio"/> Gastroesophageal disorder (panther_ipfcdd: MED.GRDBARET / Indicat Barretts Esophagus) Gastroesophageal disorder, specific indication(s) [1] <input type="checkbox"/> Barretts esophagus (panther_ipfcdd: MED.GRDCCOF / Indciation Cough) [1] <input type="checkbox"/> Cough (panther_ipfcdd: MED.GRDHTBRN / Indciation Heartburn) [1] <input type="checkbox"/> Heartburn symptoms (panther_ipfcdd: MED.GRDHH / Indication Hiatal Hernia) [1] <input type="checkbox"/> Hiatal hernia (panther_ipfcdd: MED.GRDIPF / Indication IPF) [1] <input type="checkbox"/> IPF (panther_ipfcdd: MED.GRDOTH / Indication Other) [1] <input type="checkbox"/> Other (specify): (panther_ipfcdd: MED.GRDOTSP / Indication Other, Specify) A50 Dose per administration: xxxxxxxx (panther_ipfcdd: MED.GERDOSE / Gastro Dose) (panther_ipfcdd: MED.GDOSEUNT / Gastro Unit) Unit: [1] <input type="radio"/> mg [2] <input type="radio"/> tab [3] <input type="radio"/> tsp [98] <input type="radio"/> Other (specify): (panther_ipfcdd: MED.GDSUNTSP / Gastro Unit, Specify) A50 (panther_ipfcdd: MED.GERDFREQ / Gastro Frequency) Frequency: [1] <input type="radio"/> Three times per day [2] <input type="radio"/> Twice per day [3] <input type="radio"/> Once per day [4] <input type="radio"/> Every other day [7] <input type="radio"/> Twice per week [5] <input type="radio"/> PRN (>= 1/wk) [6] <input type="radio"/> PRN (< 1/wk)					
6.*	Source Document Verification Completion	(panther_ipfcdd: MED.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable					
* Item is not required							

CDD: panther_ipfcdd Table: MED Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
GDSUNTSP	STRING(50) - A50	
GERDFREQ	NUMERIC	
GDOSEUNT	NUMERIC	
MEDSTPDT	DATE - DDMONYYYY	
GERDOSE	FLOAT - F9.0	
GRDHTBRN	NUMERIC	
GRDIPF	NUMERIC	
GRDOTSP	STRING(50) - A50	
GRDBARET	NUMERIC	
MEDSTRDT	DATE - DDMONYYYY	
MEDSTRT	NUMERIC	
GRDHH	NUMERIC	
THERAPY	STRING(50) - A50	

MEDCONTU	NUMERIC	
SDVSTAT	NUMERIC	
MEDICATN	STRING(100) - A100	
GRDCOF	NUMERIC	
INDICATE	NUMERIC	
GRDOTH	NUMERIC	

panther_ipf : GERD Changes (GERD) - Repeating Form										
#	Status change date	Change type	Elevated bed	Sleep in recliner	Limiting foods	Avoids lying after meal	Avoids bedtime snacks	Eats small meals	Source Document Verification Completion	
1										
GERD Status Review										
1.	Date of change in GERD status					Req/Unk / Req/Unk / Req (2009-2016) (panther_ipfcdd:GERD.GRDCHGDT / GERD Status Change)				
2.	Type of change					(panther_ipfcdd:GERD.GERDSTAT / Type of GERD Change) [1] <input type="radio"/> Newly diagnosed [2] <input type="radio"/> Changes in non-pharmaceutical interventions [99] <input type="radio"/> Other (including medications only)				
3.	Is the subject sleeping with the head end of the bed elevated with 6 to 8 inch blocks on the floor?					(panther_ipfcdd:GERD.GELEV / Bed Elevated) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown				
4.	Is the subject sleeping in a recliner?					(panther_ipfcdd:GERD.GRECLIN / Recliner) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown				
5.	Is the subject limiting foods and beverages that cause symptoms?					(panther_ipfcdd:GERD.GFOOD / Limiting Foods) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown				
6.	Is the subject avoiding lying down flat for 3 hours after a meal?					(panther_ipfcdd:GERD.GNOFLAT / Laying Flat) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown				
7.	Is the subject avoiding bedtime snacks?					(panther_ipfcdd:GERD.GBEDSNK / Avoiding Bedtime Snacks) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown				
8.	Is the subject eating small meals?					(panther_ipfcdd:GERD.GSMLMEAL / Eating Small Meals) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown				
9.*	Source Document Verification Completion					(panther_ipfcdd:GERD.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable				
* Item is not required										

Column Name	Column Data Type	Design Note
GRECLIN	NUMERIC	
GELEV	NUMERIC	
GSMLMEAL	NUMERIC	
GNOFLAT	NUMERIC	
GFOOD	NUMERIC	
GRDCHGDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	
GBEDSNK	NUMERIC	
GERDSTAT	NUMERIC	

panther_ipf : Sleep Apnea Changes (SLPCHG) - Repeating Form					
#		Date of change	Change type	Current CPAP treatment	Source Document Verification Completion
1					
Sleep Apnea Changes					
1.	Date of change in Sleep Apnea	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (panther_ipfcdd:SLPCHG.APNEADT / Sleep Apnea Change Date)			
2.	Type of change	(panther_ipfcdd:SLPCHG.APNEACHG / Type of Change) [1] <input type="radio"/> Newly diagnosed [2] <input type="radio"/> Changes in CPAP treatment [98] <input type="radio"/> Other (including medications only)			
3.	Current CPAP treatment	(panther_ipfcdd:SLPCHG.NEWCPAP / CPAP Treatment) [0] <input type="radio"/> None [1] <input type="radio"/> Daily [2] <input type="radio"/> Intermittent			
4.*	Source Document Verification Completion	(panther_ipfcdd:SLPCHG.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable			
* Item is not required					

Column Name	Column Data Type	Design Note
NEWCPAP	NUMERIC	
APNEADT	DATE - DDMYYYYY	
SDVSTAT	NUMERIC	
APNEACHG	NUMERIC	

panther_ipf : Study Drug Log (KIT) - Repeating Form			
#	Date of Kit Dispensed	List all the study drug kits given to the subject on this date	Source Document Verification Completion
1			
-			
1.	Date of Kit Dispensed	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (panther_ipfcdd:KIT1.PILSTADT / Kit Dispense Date)	
	Study Drug	Study Drug Kit Number	
2.			
List all the study drug kits given to the subject on this date Entry			
2.a	Study Drug	(panther_ipfcdd:KIT2.KITTYPE / Study Drug Dispensed) [1] <input type="radio"/> Azathioprine [2] <input type="radio"/> Prednisone [3] <input type="radio"/> NAC	
2.b	Study Drug Kit Number	A25 (panther_ipfcdd:KIT2.AKITNO / Study Drug Kit Number)	
-			
3.*	Source Document Verification Completion	(panther_ipfcdd:KIT1.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable	
* Item is not required			

CDD: panther_ipfcdd Table: KIT1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PILSTADT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	

CDD: panther_ipfcdd Table: KIT2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
AKITNO	STRING(25) - A25	
KITTYPE	NUMERIC	

panther_ipf : Telephone Contact Log (PHONE) - Repeating Form			
#		Date of telephone contact:	Source Document Verification Completion
1	<input type="text"/>		

Telephone Contact:

Record all study related telephone contacts with subject. Record all reported AEs and medication changes on appropriate log.

1.	Date of telephone contact:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:PHONE.PHONEDT / Date of Phone Contact)
2.*	Source Document Verification Completion	(panther_ipfcdd:PHONE.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable

* Item is not required

Column Name	Column Data Type	Design Note
PHONEDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	

panther_ipf : Adverse Events (AE) - Repeating Form																		
#	Select event from list or provide description in Other	Is this a suspected acute exacerbation?	Onset Date and Time	End Date	Final Outcome	Maximum Intensity	Relationship to Azathioprine/Placebo	Relationship to Prednisone/Placebo	Relationship to NAC/placebo	Action Taken with Azathioprine/Placebo	Action Taken with Prednisone/Placebo	Action Taken with NAC/placebo	Was This Event Serious?	Serious Criteria (check all that apply)	Initial (presenting) signs and symptoms:	What interventions/action/diagnostic procedures/tests were used to identify and treat the event?	Subject's response to treatment.	What clinical information or evidence identified the resolution/stabilization of this event?
1																		

Adverse Event

1. Select event from list or provide description in Other
 Pulldown List 1 (panther_ipfcdd:AE1.TERMLIST / Adverse Event)
 Other (specify): A100 (panther_ipfcdd:AE1.AETERM / Adverse Event, Specify)

2. Is this a suspected acute exacerbation?
 (panther_ipfcdd:AE1.SUSACUTE / AE Acute Exacerbation)
 [0] No
 [1] Yes

3. Onset Date and Time
 Req / Req/Unk / Req (2009-2016) (panther_ipfcdd:AE1.AESTDTM / AE Onset Date)
 Req/Unk : Req/Unk 24-hour clock

4. End Date
 (panther_ipfcdd:AE1.AEONGO / AE Ongoing)
 [0] Req / Req/Unk / Req (2009-2016) (panther_ipfcdd:AE1.AEENDT / AE End Date)
 [1] Continuing

5. Final Outcome
 (panther_ipfcdd:AE1.AEOUT / AE Outcome)
 [1] Death
 [2] Resolved no sequelae
 [3] Resolved with sequelae
 [4] Unresolved

6. Maximum Intensity
 (panther_ipfcdd:AE1.AESEV / AE Severity)
 [1] Mild
 [2] Moderate
 [3] Severe

7. Relationship to Azathioprine/Placebo
 (panther_ipfcdd:AE1.AERELATA / AE AZA Relationship)
 [0] Not a reasonable possibility
 [1] Reasonable possibility
 If reasonable possibility, provide rationale (panther_ipfcdd:AE1.AZARATN / AE AZA Rationale)
 A250

8. Relationship to Prednisone/Placebo
 (panther_ipfcdd:AE1.AERELATP / AE Pred Relationship)
 [0] Not a reasonable possibility
 [1] Reasonable possibility
 If reasonable possibility, provide rationale (panther_ipfcdd:AE1.PRDRATN / AE PRD Rationale)
 A250

9. Relationship to NAC/placebo
 (panther_ipfcdd:AE1.AERELATN / AE NAC Relationship)
 [0] Not a reasonable possibility
 [1] Reasonable possibility
 If reasonable possibility, provide rationale (panther_ipfcdd:AE1.NACRATN / AE NAC Rationale)
 A250

10. Action Taken with Azathioprine/Placebo
 (panther_ipfcdd:AE1.AEACTNA / AZA Action Taken)
 [1] None
 [2] Interrupted
 (panther_ipfcdd:AE1.INRABTA / AZA Interruption Lessen)
 Did the event lessen or abate when drug stopped?
 [0] No
 [1] Yes
 (panther_ipfcdd:AE1.INRRCRA / AZA Interruption Reoccur)
 Did the event reoccur once the drug restarted?
 [0] No
 [1] Yes
 [3] (panther_ipfcdd:AE1.DISABTA / AZA Discontinued Lessen)
 Permanently discontinued
 Did the event lessen or abate when drug stopped?
 [0] No
 [1] Yes
 [4] Dosage change

11. Action Taken with Prednisone/Placebo
 (panther_ipfcdd:AE1.AEACTNP / Prednisone Action Taken)
 [1] None
 [2] Interrupted
 (panther_ipfcdd:AE1.INRABTP / Pred Interruption Lessen)

		<p>Did the event lessen or abate when drug stopped?</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(panther_ipfcdd:AE1.INRRCRP / Pred Interruption Reoccur) Did the event reoccur once the drug restarted?</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>[3] <input type="radio"/> (panther_ipfcdd:AE1.DISABTP / Pred Discontinued Lessen) Permanently discontinued Did the event lessen or abate when drug stopped?</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>[4] <input type="radio"/> Dosage change</p>
12.	Action Taken with NAC/placebo	<p>(panther_ipfcdd:AE1.AEACTNN / NAC Action Taken) [1] <input type="radio"/> None</p> <p>[2] <input type="radio"/> Interrupted (panther_ipfcdd:AE1.INRABTN / NAC Interruption Lessen) Did the event lessen or abate when drug stopped?</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(panther_ipfcdd:AE1.INRRCRN / NAC Interruption Reoccur) Did the event reoccur once the drug restarted?</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>[3] <input type="radio"/> (panther_ipfcdd:AE1.DISABTN / NAC Discontinued Lessen) Permanently discontinued Did the event lessen or abate when drug stopped?</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>[4] <input type="radio"/> Dosage change</p>
13.	Was This Event Serious?	<p>(panther_ipfcdd:AE1.AESER / Serious) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p>
ONLY COMPLETE THE FOLLOWING QUESTIONS IF THIS EVENT IS SERIOUS		
14.*	Serious Criteria (check all that apply)	<p>(panther_ipfcdd:AE1.AESHOSP / Hospitalization) [1] <input type="checkbox"/> Hospitalization or Prolonging of Existing Hospitalization (panther_ipfcdd:AE1.AESDISAB / Significant Disability) [1] <input type="checkbox"/> Persistent or Significant Disability (panther_ipfcdd:AE1.AESLIFE / Life Threatening) [1] <input type="checkbox"/> Life threatening (panther_ipfcdd:AE1.AESCONG / Congenital Anomaly) [1] <input type="checkbox"/> Congenital anomaly (panther_ipfcdd:AE1.AESDTH / Death) [1] <input type="checkbox"/> Death (panther_ipfcdd:AE1.AESMIE / Important Medical Event) [1] <input type="checkbox"/> Important medical event</p>
15.*	Initial (presenting) signs and symptoms:	<p>A1000 (panther_ipfcdd:AE1.SAESS / Initial Signs and Symptoms)</p>
16.*	What interventions/action/diagnostic procedures/tests were used to identify and treat the event?	<p>A1000 (panther_ipfcdd:AE1.SAEINTV / Diagnostic Procedures)</p>
17.*	Subject's response to treatment.	<p>A1000 (panther_ipfcdd:AE1.SAERESP / Response to Treatment)</p>
18.*	What clinical information or evidence identified the resolution/stabilization of this event?	<p>A1000 (panther_ipfcdd:AE1.SAECLIN / Resolution Stab of Event)</p>
19.*	PI's opinion of other possible causes of the event (pre-existing conditions; concomitant medications; etc)	<p>A1000 (panther_ipfcdd:AE1.SAEPICAU / Other causes of the event)</p>
20.*	Are there any relevant tests or labs for this SAE	<p>(panther_ipfcdd:AE1.SAELAB / Relevant Tests or Labs) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p>
	Relevant lab/diagnostic test name	Date of test
21.		
21.a*	Name of relevant lab/diagnostic test (one per entry)	A100 (panther_ipfcdd:AE2.LABDONE / Lab Test Performed)
21.b*	Date of test	Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:AE2.SAELABDT / Date of Test)
21.c*	Result	A25 (panther_ipfcdd:AE2.SAERSLT / Test Result)

21.d*	Unit (If applicable)	<input type="text" value="A100"/>	(panther_ipfcdd:AE2.SAELUNIT / Lab Unit)
21.e*	Normal Range (If applicable)	<input type="text" value="A100"/>	(panther_ipfcdd:AE2.SAELRNG / Normal Lab Range)
Serious Adverse Event Investigator Verification			
22.*	Investigator Verification	(panther_ipfcdd:AE1.INVAESIG / Investigator AE Signature) [1] <input type="checkbox"/> Yes	
	Date of Investigator Signature	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (panther_ipfcdd:AE1.INVAEDT / Investigator AE Sig DATE)	
23.*	Is this AE associated with an adjudication case?	(panther_ipfcdd:AE1.AECASE / Adjudication Case) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (panther_ipfcdd:AE1.CASENUM / Adjudication Case Id) If yes, Adjudication case identifier: <input type="text" value="A25"/>	
24.*	Source Document Verification Completion	(panther_ipfcdd:AE1.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable	

* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieTERMLI01	Abdominal pain	1	
ieTERMLI02	Acid Reflux (Esophageal)	2	
ieTERMLI03	Anorexia	3	
ieTERMLI04	Bronchitis	4	
ieTERMLI05	Chills	5	
ieTERMLI06	Cough	6	
ieTERMLI07	Diarrhea	7	
ieTERMLI08	Dizziness	8	
ieTERMLI09	Drowsiness	9	
ieTERMLI10	Dyspnea	10	
ieTERMLI11	Fatigue	11	
ieTERMLI12	Fever	12	
ieTERMLI13	Headache	13	
ieTERMLI19	Heartburn	19	
ieTERMLI14	Lower respiratory tract infection	14	
ieTERMLI15	Nausea	15	
ieTERMLI16	Pneumonia	16	
ieTERMLI17	Stomach discomfort	17	
ieTERMLI18	Upper Respiratory infection	18	
ieTERMLI20	Exacerbation of Idiopathic Pulmonary Fibrosis	20	
ieTERMLI98	Other	98	

CDD: panther_ipfcdd Table: AE1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
AERELATA	NUMERIC	
AEOUT	NUMERIC	
INRABTP	NUMERIC	
INVAESIG	NUMERIC	
AEACTNN	NUMERIC	
AESDISAB	NUMERIC	
DISABTP	NUMERIC	
AESDTH	NUMERIC	
SUSACUTE	NUMERIC	
AEENDT	DATE - DDMONYYYY	
INRABTA	NUMERIC	
DISABTA	NUMERIC	
AEACTNP	NUMERIC	
INRABTN	NUMERIC	
SAEPICAU	STRING(255) - A1000	
AERELATP	NUMERIC	
AESHOSP	NUMERIC	
AEONGO	NUMERIC	
INRRCRN	NUMERIC	

AECASE	NUMERIC	
AESLIFE	NUMERIC	
AESCONG	NUMERIC	
AESTDTM	DATE - DDMONYYYY HHMM	
CASENUM	STRING(25) - A25	
SAERESP	STRING(255) - A1000	
INRRRCRA	NUMERIC	
INVAEDT	DATE - DDMONYYYY	
AERELATN	NUMERIC	
SAELAB	NUMERIC	
AESEV	NUMERIC	
TERMLIST	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 19, 14, 15, 16, 17, 18, 20, 98	
INRRRCRP	NUMERIC	
AESER	NUMERIC	
AECTNA	NUMERIC	
SDVSTAT	NUMERIC	
AETERM	STRING(100) - A100	
DISABTN	NUMERIC	
AESMIE	NUMERIC	
SAECLIN	STRING(255) - A1000	
NACRATN	STRING(250) - A250	
AZARATN	STRING(250) - A250	
SAEINTV	STRING(255) - A1000	
PRDRATN	STRING(250) - A250	
SAESS	STRING(255) - A1000	

CDD: panther_ipfcdd Table: AE2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SAELUNIT	STRING(100) - A100	
LABDONE	STRING(100) - A100	
SAELRNG	STRING(100) - A100	
SAERSLT	STRING(25) - A25	
SAELABDT	DATE - DDMONYYYY	

panther_ipf : Adjudication Docs Tracking (ADJTRK) - Repeating Form

#	Case ID	Earliest Date:	Latest Date:	Medical monitor's assessment of events to adjudicate in this case	Site investigator: Select the suspected events involved in this case	Investigator opinion of the case	Was research blood obtained during the date range of interest	Was research BAL obtained during the date range of interest	Identify all the known types of treatment facilities during the date range of interest	Admission/Discharge Summary available?	Lab report(s) available?	Transfusion report(s) available?	X-ray report(s) available?	Respiratory culture report(s) available?	Pulmonary function test report(s) available?	Blood culture report(s) available?	Bronchoscopy report(s) available?	Pulse oximetry report(s) available?	CT scan available (important)?	Surgical lung biopsy slide available?	Arterial Blood Gas report(s) available?	Echocardiogram available?	Clinic / hospital records available?
1																							

Adjudication Case Document Request

The DCC initiates this form. Study coordinator will be notified when to complete site portion.

1.	Case ID	A20	(panther_ipfcdd:ADJTRK1.CASEID / Case ID)
2.	Earliest Date:	Req [v] / Req [v] / Req [v]	(2009-2016) (panther_ipfcdd:ADJTRK1.MMERLDT / Earliest Date)
3.	Latest Date:	Req [v] / Req [v] / Req [v]	(2009-2016) (panther_ipfcdd:ADJTRK1.MMLTEDT / Latest Date)
4.	Medical monitor's assessment of events to adjudicate in this case	(panther_ipfcdd:ADJTRK1.MMADJAE / Medical Monitor AE Event) [1] <input type="checkbox"/> Acute Exacerbation (panther_ipfcdd:ADJTRK1.MMADJDT / Medical Monitor Death Event) [1] <input type="checkbox"/> Death (panther_ipfcdd:ADJTRK1.MMADJHS / Medical Monitor Hosp Event) [1] <input type="checkbox"/> Non-elective hospitalizations	

Investigator Assessment of Case

5.	Site investigator: Select the suspected events involved in this case	(panther_ipfcdd:ADJTRK1.PIADJAE / Investigator AE Event) [1] <input type="checkbox"/> Acute Exacerbation (panther_ipfcdd:ADJTRK1.PIADJDT / Investigator Death Event) [1] <input type="checkbox"/> Death (panther_ipfcdd:ADJTRK1.PIADJHS / Investigator Hospital Event) [1] <input type="checkbox"/> Non-elective hospitalizations	
6.	Investigator opinion of the case	A2000	(panther_ipfcdd:ADJTRK1.PIADJNR / Investigator Opinion)

Acute Exacerbation Research Biological Samples

7.	Was research blood obtained during the date range of interest	(panther_ipfcdd:ADJTRK1.BLDOBTAN / Blood Obtained) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date blood obtained Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:ADJTRK1.BLDOBDT / Blood Date)	
8.	Was research BAL obtained during the date range of interest	(panther_ipfcdd:ADJTRK1.BALOBTAN / BAL Obtained) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date BAL obtained Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:ADJTRK1.BALOBDT / BAL Date)	

Adjudication Docs Submission

9.	Identify all the known types of treatment facilities during the date range of interest	(panther_ipfcdd:ADJTRK1.TRTFAC01 / Facility Local doctor) [1] <input type="checkbox"/> Local physician/clinic (panther_ipfcdd:ADJTRK1.TRTFAC02 / Facility IPF Clinic) [1] <input type="checkbox"/> IPF clinic (panther_ipfcdd:ADJTRK1.TRTFAC03 / Facility Local ER) [1] <input type="checkbox"/> Local ER (panther_ipfcdd:ADJTRK1.TRTFAC04 / Facility IPF ER) [1] <input type="checkbox"/> IPF ER (panther_ipfcdd:ADJTRK1.TRTFAC05 / Facility Local Hospital) [1] <input type="checkbox"/> Local hospital (panther_ipfcdd:ADJTRK1.TRTFAC06 / Facility IPF Hospital) [1] <input type="checkbox"/> IPF hospital	
10.	Admission/Discharge Summary available?	(panther_ipfcdd:ADJTRK1.DISSUM / Discharge Summary) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date sent for adjudication Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:ADJTRK1.DISSUMDT / Date Summary Report(s) Sent)	
11.	Lab report(s) available?	(panther_ipfcdd:ADJTRK1.LABRPT / Lab Reports) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date sent for adjudication Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:ADJTRK1.LABRPTDT / Date Lab Report(s) Sent)	
12.	Transfusion report(s) available?	(panther_ipfcdd:ADJTRK1.TRNFUS / Transfusion) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date sent for adjudication Req [v] / Req [v] / Req [v] (2009-2016) (panther_ipfcdd:ADJTRK1.TRNFUSDT / Date Transfusion Reprt Sent)	
13.	X-ray report(s) available?	(panther_ipfcdd:ADJTRK1.XRAYRPT / X-Ray) No	

		<input type="radio"/> [0] <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.XRARPTDT / Date X-Ray Report(s) Sent)
14.	Respiratory culture report(s) available?	(panther_ipfccd:ADJTRK1.RSPCLRTP / Respiratory Culture) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.RSPCLTDT / Date Resp Cult Report Sent)
15.	Pulmonary function test report(s) available?	(panther_ipfccd:ADJTRK1.PULMRPT / Pulmonary Function Test) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.PLMRPTDT / Date PFT Report(s) Sent)
16.	Blood culture report(s) available?	(panther_ipfccd:ADJTRK1.BLDRPT / Blood Culture) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.BLDRPTDT / Date Blood Cult Report Sent)
17.	Bronchoscopy report(s) available?	(panther_ipfccd:ADJTRK1.BRONRPT / Bronchoscopy) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.BRNRPTDT / Date Broncho Report(s) Sent)
18.	Pulse oximetry report(s) available?	(panther_ipfccd:ADJTRK1.PULOXRPT / Pulse Oxymetry) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.PULOXTDT / Pulse Oxymetry Report Sent)
19.	CT scan available (important)?	(panther_ipfccd:ADJTRK1.HRCTSCAN / CT Scan) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.HRCTSNDT / Date CT Scan Sent)
20.	Surgical lung biopsy slide available?	(panther_ipfccd:ADJTRK1.SLBSLIDE / Lung Biopsy Slide) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.SLBSLDDT / Date Lung Biopsy Slide Sent)
21.	Arterial Blood Gas report(s) available?	(panther_ipfccd:ADJTRK1.ABGRPT / ABG) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.ABGRPTDT / Date ABG Report(s) Sent)
22.	Echocardiogram available?	(panther_ipfccd:ADJTRK1.ECHOGRM / Echo) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.ECHOGMDT / Date Echo Sent)
23.	Clinic / hospital records available?	(panther_ipfccd:ADJTRK1.HOSPREC / Hospital Records) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.HOSRECDT / Date Hospital Records Sent)
24.	Physician and nurse progress notes available?	(panther_ipfccd:ADJTRK1.MDNOTES / Progress Notes Available) <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.MDNOTEDT / Date Progress Notes Sent)
25.	Autopsy report(s) available?	(panther_ipfccd:ADJTRK1.AUTOPSRT / Autopsy) <input type="radio"/> [97] NA <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date report sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.AUTOPSDT / Date Autopsy Report(s) Sent)
26.	Death certificate available?	(panther_ipfccd:ADJTRK1.DTHCERT / Death Certificate) <input type="radio"/> [97] NA <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date report sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.CERTDATE / Date Death Certificate Sent)
27.	Death narrative available?	(panther_ipfccd:ADJTRK1.DTHNRT / Death Narrative) <input type="radio"/> [97] NA <input type="radio"/> [0] No <input type="radio"/> [1] Yes Date report sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (panther_ipfccd:ADJTRK1.DTHNRDT / Date Death Narrative Sent)

Adjudication Docs Tracking

28.	Source Document Verification Completion	(panther_ipfcdd:ADJTRK1.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
29.	Adjudication Status:	(panther_ipfcdd:ADJTRK1.ADJSTAT / Adjudication Status) [1] <input type="radio"/> new [2] <input type="radio"/> waiting source docs [3] <input type="radio"/> waiting adjudication [4] <input type="radio"/> adjudicated [5] <input type="radio"/> not a true trigger
	Reviewer	Date sent to reviewer
30.		
30.a	Reviewer	A30 (panther_ipfcdd:ADJTRK2.ADJRVR / Reviewer)
30.b	Date sent to reviewer	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:ADJTRK2.ADJRVSDT / Date Sent to Reviewer)
30.c	Date returned from reviewer	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:ADJTRK2.ADJRVSDT / Date Returned from Reviewer)
* Item is not required		

CDD: panther_ipfcdd Table: ADJTRK1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
TRNFUS	NUMERIC	
AUTOPSDT	DATE - DDMONYYYY	
BALOBAN	NUMERIC	
BLDRPT	NUMERIC	
MDNOTES	NUMERIC	
PIADJAE	NUMERIC	
BALOBDT	DATE - DDMONYYYY	
AUTOPSDT	NUMERIC	
TRTFAC06	NUMERIC	
BLDOBAN	NUMERIC	
TRTFAC05	NUMERIC	
ABGRPT	NUMERIC	
MMERLDT	DATE - DDMONYYYY	
DTHNRDT	DATE - DDMONYYYY	
RSPCLTDT	DATE - DDMONYYYY	
CASEID	STRING(20) - A20	
MMADJAE	NUMERIC	
PIADJNR	STRING(255) - A2000	
TRTFAC02	NUMERIC	
LABRPTDT	DATE - DDMONYYYY	
HRCTSNDT	DATE - DDMONYYYY	
PULOXRPT	NUMERIC	
ABGRPTDT	DATE - DDMONYYYY	
DISSUM	NUMERIC	
MMADJHS	NUMERIC	
SDVSTAT	NUMERIC	
ECHOGMDT	DATE - DDMONYYYY	
RSPCLTRP	NUMERIC	
BLDOBDT	DATE - DDMONYYYY	
PULOXDT	DATE - DDMONYYYY	
XRARPTDT	DATE - DDMONYYYY	
MMLTDT	DATE - DDMONYYYY	
TRTFAC03	NUMERIC	
DTHCERT	NUMERIC	
ECHOGRM	NUMERIC	
PIADJDT	NUMERIC	
TRNFUSDT	DATE - DDMONYYYY	
DISSUMDT	DATE - DDMONYYYY	
TRTFAC04	NUMERIC	
DTHNRT	NUMERIC	
PLMRPTDT	DATE - DDMONYYYY	

XRAYRPT	NUMERIC	
CERTDATE	DATE - DDMONYYYY	
PIADJHS	NUMERIC	
BRONRPT	NUMERIC	
LABRPT	NUMERIC	
SLBSLDDT	DATE - DDMONYYYY	
ADJSTAT	NUMERIC	
MMADJDT	NUMERIC	
MDNOTEDT	DATE - DDMONYYYY	
HRCTSCAN	NUMERIC	
BLDRPTDT	DATE - DDMONYYYY	
TRTFAC01	NUMERIC	
SLBSLIDE	NUMERIC	
PULMRPT	NUMERIC	
HOSPREC	NUMERIC	
BRNRPTDT	DATE - DDMONYYYY	
HOSRECDT	DATE - DDMONYYYY	

CDD: panther_ipfcdd Table: ADJTRK2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
ADJRVSDT	DATE - DDMONYYYY	
ADJRVR	STRING(30) - A30	
ADJRVRDT	DATE - DDMONYYYY	

panther_ipf : Adjudication Report (ADJRPT) - Repeating Form

#	Case ID	Was a suspected acute exacerbation adjudicated?	Did subject have a non-elective hospitalization during the timeframe of this case?	Did subject die during the timeframe of this case?
1				

1. Case ID	A20	(panther_ipfcdd:ADJRPT.CASEID2 / Case ID)
------------	-----	-------------------------------------------

Acute Exacerbation Adjudication

2. Was a suspected acute exacerbation adjudicated?

(panther_ipfcdd:ADJRPT.ADJACEX / Exacerbation Adjudicated)

[0] No

[1] Yes

Date of onset | Req [v] / | Req [v] / | Req [v] (2009-2016) (panther_ipfcdd:ADJRPT.ADJAEDT / Exacerbation onset date)

(panther_ipfcdd:ADJRPT.ADJAEOUT / Adjudication Outcome)

Outcome [1] Treated as outpatient

[2] Hospitalized, not mechanically ventilated

[3] Hospitalized and mechanically ventilated

(panther_ipfcdd:ADJRPT.ACEXCOFF / Productive Cough)

Productive cough? [0] No

[1] Yes

[99] Unknown

(panther_ipfcdd:ADJRPT.ACEXFVR / Fever)

Fever? [0] No

[1] Yes

[99] Unknown

(panther_ipfcdd:ADJRPT.ACEXHEAD / Headache)

Headache? [0] No

[1] Yes

[99] Unknown

(panther_ipfcdd:ADJRPT.ACEXCONG / Congestion)

Congestion? [0] No

[1] Yes

[99] Unknown

(panther_ipfcdd:ADJRPT.ACEXACHE / Achiness)

Achiness? [0] No

[1] Yes

[99] Unknown

(panther_ipfcdd:ADJRPT.ACEXST / Sore Throat)

Sore throat? [0] No

[1] Yes

[99] Unknown

(panther_ipfcdd:ADJRPT.ADJDYSPN / Clinical A Met)

Clinical: A Unexplained worsening of dyspnea or cough within 30 days, triggering unscheduled medical care (e.g., clinic, study visit, hospitalization):

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJDVT / Clinical B Met)

Clinical: B No clinical suspicious or overt evidence of cardiac event, pulmonary embolism, or deep venous thrombosis to explain acute worsening of dyspnea:

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJPNEU / Clinical C Met)

Clinical: C No pneumothorax:

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJXRA / Radiologic A Met)

Radiologic/Physiologic: A Bilateral radiographic change including new ground glass opacity or consolidation on chest X-ray or CT scan:

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJPAO2 / Radiologic B Met)

Radiologic/Physiologic: B Decline of \geq 8 mm Hg in resting room air PaO2 from last recorded level:

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJINFCT / Microbiologic A Met)

Microbiologic: A No clinical evidence for infection (i.e., absence of grossly purulent sputum, fever $>$ 39°C orally):

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJLRT / Microbiologic B Met)

Microbiologic: B Lack of positive microbiological results from lower respiratory tract

[1] Met

[2] Not Met

[3] Data Insufficient to Judge

(panther_ipfcdd:ADJRPT.ADJBLD / Microbiologic C Met)

Microbiologic: C Lack of positive pathogen in blood cultures:

Met

- [1]
 [2] Not Met
 [3] Data Insufficient to Judge
 (panther_ipfccd:ADJRPT.ADJFINAL / Final Diagnosis)
 Final diagnosis:
 [1] Definite acute exacerbation (all criteria met; no alternative etiology)
 [2] Unclassifiable acute worsening (Insufficient data to evaluate all criteria; no alternative etiology)
 [3] Not acute exacerbation (alternative etiology identified that explains acute worsening)
 [4] Not acute exacerbation (specify)
 [98] Other (panther_ipfccd:ADJRPT.ADJFNLOT / Final Diagnosis, Specify)
 Other (specify):

Hospitalization Adjudication

3. Did subject have a non-elective hospitalization during the timeframe of this case?

- (panther_ipfccd:ADJRPT.ADJHOSP / Hosp During Adjudication)
 [0] No
 [1] Yes
 Date of admission | Req / | Req / | Req (2009-2016) (panther_ipfccd:ADJRPT.ADJHOSDT / Hospital admission date)
 (panther_ipfccd:ADJRPT.ADJHOSRS / Hospitalization Cause)
 Was hospitalization primarily attributed to:
 [2] Acute exacerbation
 [3] Other respiratory-related
 [98] Other (panther_ipfccd:ADJRPT.ADJHSRSP / Hospital Cause, Specify)
 Other (specify):

Death Adjudication

4. Did subject die during the timeframe of this case?

- (panther_ipfccd:ADJRPT.ADJDIE / Death During Adjudication)
 [0] No
 [1] (panther_ipfccd:ADJRPT.ADJDICSE / Primary Cause of Death)
 Yes
 If Yes: Was death primarily attributed to:
 [1] Cardiovascular event
 [2] Acute exacerbation
 [98] Other (panther_ipfccd:ADJRPT.ADJDICSP / Cause of Death, Specify)
 Other (specify):

CDD: panther_ipfccd Table: ADJRPT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
ACEXCONG	NUMERIC	
ADJLRT	NUMERIC	
ADJPNEU	NUMERIC	
ADJAEDT	DATE - DDMONYYYY	
ADJXRA	NUMERIC	
ADJINFCT	NUMERIC	
ADJDIE	NUMERIC	
ADJACEX	NUMERIC	
ACEXHEAD	NUMERIC	
ACEXACHE	NUMERIC	
ADJDYSPN	NUMERIC	
ADJHSRSP	STRING(100) - A100	
ADJHOSP	NUMERIC	
ACEXST	NUMERIC	
ADJHOSRS	NUMERIC	
ADJAEOUT	NUMERIC	
ADJFNLOT	STRING(100) - A100	
ACEXCOFF	NUMERIC	
ADJHOSDT	DATE - DDMONYYYY	
ADJDICSP	STRING(100) - A100	
ADJDVT	NUMERIC	
CASEID2	STRING(20) - A20	
ADJFINAL	NUMERIC	
ACEXFVR	NUMERIC	
ADJBLD	NUMERIC	
ADJPAO2	NUMERIC	
ADJDICSE	NUMERIC	

panther_ipf : Unscheduled Visit Status (UNSCVIST)	
Unscheduled visit	
1. Contact Date	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (panther_ipfcdd:UNSCVIST.CONTDT / Unscheduled Visit Date)
2. Type of Contact	(panther_ipfcdd:UNSCVIST.UNSCRSN / Unscheduled Visit Reason) [1] <input type="radio"/> Acute Exacerbation [2] <input type="radio"/> Other (panther_ipfcdd:UNSCVIST.UNSCOTHR / Unsch Visit Reason, Other) Specify Other A50
3. * Source Document Verification Completion	(panther_ipfcdd:UNSCVIST.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required	

Column Name	Column Data Type	Design Note
UNSCOTHR	STRING(50) - A50	
SDVSTAT	NUMERIC	
CONTDT	DATE - DDMONYYYY	
UNSCRSN	NUMERIC	

panther_ipf : Signature Completion (SIGN)

Signature		
1.	Casebook Ready for Signature	(panther_ipfcdd: SIGN.PISIGN / PI Signature Present) [1] <input type="checkbox"/> Yes
2.*	Source Document Verification Completion	(panther_ipfcdd: SIGN.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
PISIGN	NUMERIC	
SDVSTAT	NUMERIC	

CRB Electronic Signature Affidavit

By my dated signature below, I, **[First Name] [Last Name]**, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

CRF Electronic Signature Affidavit

By my dated signature below, I, **[First Name] [Last Name]**, verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

CDISC Laboratory Data Interchange Standard
Transmission Data Fields

Base Model

FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Good Transmission Practice (GTP) Level								
Model Version	Yes	VERSION	##-#-##	7	Text	The version of the CDISC Laboratory Data Interchange Standard model indicating by definition which fields are contained within it.	(none)	01.0.2
File Creation Date and Time	Yes	FILCRDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The local date and time the data file was created by the sender. This includes a Universal Time Offset plus/minus hours and minutes.	(none)	
Transmission Source ID	Yes	TRMSRNUM	(none)	20	Text	The ID of the organization that is the source of the data transmission.	(none)	blank
Transmission Source Name	No	TRMSRNAM	(none)	40	Text	The Name of the organization that is the source of the data transmission.	(none)	'LABCORP'
Study Level								
Study ID or Number	Yes	STUDYID	(none)	20	Text	The ID of the study.	(none)	PANTHER-IPF
Study Name	No	STUDNAM	(none)	200	Text	The name of the study.	(none)	blank
Transmission Type	Yes	TRMTYP	(none)	1	Code	This indicates what type of transmission the data transmission is. There are two transmission types: C - Cumulative I - Incremental	(none)	'C'
Site Level								
Site ID or Number	Yes	SITEID	(none)	20	Text	The ID of the site.	(none)	
Investigator Level								
Investigator ID or Number	No	INVID	(none)	20	Text	The ID of the investigator.	(none)	blank
Investigator Name	No	INVNAM	(none)	80	Text	The name of the investigator.	(none)	Inv Last Name
Subject Level								
Screen ID or Number	Cond.	SCRNNUM	(none)	20	Text	The ID of the subject <i>before</i> randomization.	(none)	Esoterix Patient ID
Subject ID or Number	Cond.	SUBJID	(none)	20	Text	The ID of the subject <i>after</i> randomization.	(none)	Esoterix Randomization #; not populated for Screen visits

CDISC Laboratory Data Interchange Standard
Transmission Data Fields

Base Model

FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Spare subject level ID or Number	No	SUBJSID	(none)	20	Text	Spare subject level identifier. (For use with original screen IDs in cases where re-screening with new numbers is allowed, for example).	(none)	blank
Subject Initials	No	SUBJINIT	(none)	4	Text	The initials of the subject.	(none)	
Subject Sex	No	SEX	(none)	1	Text or Coded	The sex of the subject.	HL7 Gender Vocabulary Domain	'M' or 'F'
Subject Sex Code List ID	No	SEXCD	(none)	40	Text	If utilized, the code list identifier and version number for the Subject Sex code.		blank
Subject Date Of Birth	No	BRTHDTM	YYYY-MM-DD	10	Text	The date of birth of the subject.	(none)	
Subject Race	No	RACE	(none)	20	Text or Coded	The biological race of the subject.	HL7 Race Vocabulary Domain	blank
Subject Race Code List ID	No	RACECD	(none)	40	Text	If utilized, the code list identifier and version number for the Subject Race code.		blank
Visit Level								
Visit ID or Number	Yes	VISITNUM	(none)	20	Text	The ID or Number of the visit.	(none)	
Visit Name	No	VISIT	(none)	40	Text	The name of the visit.	(none)	
Visit Type	Yes	VISITYP	(none)	1	Code	This indicates what type of visit the subject visit is. There are two visit types: S - Scheduled U - Unscheduled	(none)	
Visit Type Modifier	No	VISITMOD	(none)	1	Code	This indicates what subtype of visit the subject visit is. There are three visit subtypes: T - Early Termination R - Retest O - Physician Ordered The differentiation of multiple Retest and Early Termination visits can be determined by collection date and time	(none)	blank
Accession Level								
Central Laboratory ID	Yes	LBNUM	(none)	20	Text	The ID of the central laboratory delivering the data.	(none)	blank

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FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Central Laboratory Name	No	LBNAM	(none)	40	Text	The name of the central laboratory delivering the data.	(none)	'Labcorp'
Accession ID or Number	No	ACCSNUM	(none)	20	Text	The ID of the kit used at a subject visit.	(none)	Esoterix 9-digit Requisition #
Last Active Date and Time	No	LACTDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The local date and time of the last modification made to the accession record at the central laboratory. This includes a Universal Time Offset plus/minus hours and minutes.	(none)	blank
Record Type Level							This level required for certain implementations,e.g. SAS & ASCII.	
Record Extension Type	Yes	RECEXTYP	(none)	10	Text	This allows specification of extensions (TBD) from the Base Lab Model definition. For a lab record, this would contain 'BASE'. For a Microbiology data, this would contain 'MICROBIO'.		'Base'
Base Specimen Level								
Specimen ID or Number	No	SPECNUM	(none)	10	Text	The ID of an individual kit item used at a subject visit.	(none)	blank
Actual Collection Date and Time	Yes	LBDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The local date and time of actual specimen collection at the site.	(none)	
Planned Collection Time Elapsed	No	PTMEL	DDD-hh-mm (Days, Hours, Minutes.)	9	Text	The time elapsed since a reference point, e.g., 000-03-00 for 3 hours.	(none)	blank
Planned Collection Time Elapsed Description	No	PTMELTX	(none)	40	Text	The time elapsed, e.g., "3 Hours Post Dose" or "Post Dose" per preference.	(none)	blank
Collection End Date and Time	No	COLENDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The collection end local date and time of a timed specimen collection.	(none)	blank

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FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Received Date and Time	No	RCVDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The local date and time of specimen receipt at the central laboratory. This includes a Universal Time Offset plus/minus hours and minutes.	(none)	
Specimen Condition	No	SPECCND	(none)	2048	Text	Free or standardized text describing the condition of the specimen e.g. Hemolyzed, Icteric, Lipemic etc.	See example list in Appendix A of the document.	blank
Lab - Specimen Comments	No	SPECCOM	(none)	2048	Text	Comments in addition to the specimen condition from the central or performing laboratory describing the specimen.		blank
Investigator - Specimen Comments	No	SPECICOM	(none)	2048	Text	Comments in addition to the specimen condition from the investigator describing the specimen.		blank
Specimen Material ID	No	SPECMNUM	(none)	20	Text or Coded	The ID of the specimen material.	HL7 V 2.4 Specimen Source Code Table 0070	blank
Specimen Material Code List ID	No	SPECMCD	(none)	40	Text	If utilized, the code list identifier and version number for the Specimen Material ID code.		blank
Specimen Material Name	No	LBSPEC	(none)	40	Text	The name of the specimen material (e.g. "Blood", "Urine" etc.).	HL7 V 2.4 Specimen Source Code Table 0070	blank
Subject Age at Collection	No	AGEATCOL	(none)	3	Numeric	The age of the subject at the collection visit. This is the age that will be used to determine which age-stratified reference ranges (if any) should be applied to the subject's test results.	(none)	

FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Subject Age Units	Cond.	AGEU	(none)	1	Code	The units in which the age of the subject is measured. There are three subject age units: Y - Years M - Months D - Days	(none)	'Y'
Fasting Status	Cond.	FASTSTAT	(none)	1	Code	The fasting status of the subject for the specimen collected. There are four fasting statuses: Y - Yes N - No U - Unknown and blank if not relevant.	(none)	
Base Battery Level								
Battery ID	Yes	BATTRID	(none)	20	Text	The ID of the battery or panel to which the test belongs. If a Battery ID does not exist, use the Test ID from the next level.	(none)	blank
Battery Name	No	BATTRNAM	(none)	40	Text	The name of battery or panel to which the test belongs.	(none)	
Base Test Level								
Performing Laboratory ID	Yes	PLBNUM	(none)	20	Text	The ID of the laboratory that performed the test.	(none)	blank
Performing Laboratory Name	No	PLBNAM	(none)	40	Text	The name of the laboratory that performed the test.	(none)	'LABCORP'
Lab Test ID	Yes	LBTESTCD	(none)	20	Text	The ID of the test performed as defined by the data provider.	(none)	Esoterix 5-digit interal test code
Lab Test Name	No	LBTEST	(none)	100	Text	The name of the test performed as defined by the data provider.	(none)	Esoterix Short Test Name
Test ID	Cond.	TSTCD	(none)	20	Text	The ID of the test performed as defined by the data recipient.	(none)	blank
Test Name ID	No	TSTNAM	(none)	100	Text	The name of the test performed as defined by the data recipient.	(none)	blank
LOINC Code	No	LBLOINC	(none)	10	Code	The LOINC code ID for the test performed.	LOINC	blank
LOINC Code List ID	No	LOINCCD	(none)	40	Text	If utilized, the code list identifier and version number for the LOINC code.		blank

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FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Additional Test Description	No	TSTDESC	(none)	100	Text	Additional Test Description to characterize additional aspects associated with the test. This information may be important for interpretation for the study. For example: instrument model number, lot numbers, etc...	(none)	blank
Test Status	Yes	TSTSTAT	(none)	1	Code	This indicates what the status of the test is. There are three test statuses: D - Done N - Not Performed X - Cancelled	(none)	
Test Level Comments	No	TSTCOM	(none)	2048	Text	Free or standardized texts of all laboratory-generated comments relating to the specific test.	(none)	
Testing Date and Time	No	TSTDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The local date and time of testing. This includes a Universal Time Offset plus/minus hours and minutes.	(none)	
Test Type	No	TSTTYP	(none)	1	Code	This indicates what the type of the test performed is. There are three test types: S - Study Test N - Non-Study Test U - Unscheduled Study Test	(none)	'S'
Base Result Level								
Reported Text Result	Cond.	RPTRESC	(none)	2048	Text or Coded	Reported text result by laboratory.	(none)	blank
Reported Text Result Code List ID	No	RPTRESCD	(none)	40	Text	If utilized, the code list identifier and version number for the Reported Text Result code.		blank
Reported Numeric Result	Cond.	RPTRESN	(none)	20	Numeric	Reported numeric result by laboratory.	(none)	blank
Reported Numeric Result Precision	Cond.	RPTRESNP	(none)	5	Text	Reported numeric result precision at laboratory. Example: 5,3 - representing the total size of 5 with 3 positions to right of the decimal. (1.345)	(none)	blank

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FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Reported Reference Range Low	No	RPTNRLO	(none)	40	Text	Reported lower limit of reference range.	(none)	blank
Reported Reference Range High	No	RPTNRHI	(none)	40	Text	Reported upper limit of reference range.	(none)	blank
Reported Units	No	RPTU	(none)	20	Text or Coded	Reported result units by laboratory.	HL7 Common ISO derived units and ISO+ extensions	blank
Reported Units Code List ID	No	RPTUCD	(none)	40	Text	If utilized, the code list identifier and version number for the Reported Units code.		blank
Conventional Text Result	No	CNVRESC	(none)	2048	Text or Coded	Conventional text result at laboratory.	(none)	
Conventional Text Result Code List ID	No	CNVRESCD	(none)	40	Text	If utilized, the code list identifier and version number for the Conventional Text Result code.		blank
Conventional Numeric Result	Cond.	CNVRESN	(none)	20	Numeric	Conventional numeric result at laboratory.	(none)	
Conventional Numeric Result Precision	Cond.	CNVRESNP	(none)	5	Text	Conventional numeric result precision at laboratory. Example: 5,3 - representing the total size of 5 with 3 positions to right of the decimal. (1.345)	(none)	blank
Conventional Reference Range Low	No	CNVNRLO	(none)	40	Text	Conventional lower limit of reference range.	(none)	
Conventional Reference Range High	No	CNVNRHI	(none)	40	Text		(none)	
Conventional Units	No	CNVU	(none)	20	Text or Coded	Conventional result units at laboratory.	HL7 Common ISO derived units and ISO+ extensions	
Conventional Units Code List ID	No	CNVUCD	(none)	40	Text	If utilized, the code list identifier and version number for the Conventional Units code.		blank
SI Text Result	No	SIRESC	(none)	2048	Text or Coded	SI text result at laboratory.	(none)	
SI Text Result Code List ID	No	SIRESCD	(none)	40	Text	If utilized, the code list identifier and version number for the SI Text Result code.		blank

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FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
SI Numeric Result	Cond.	SIRESN	(none)	20	Numeric	SI numeric result at laboratory.	(none)	
SI Numeric Result Precision	Cond.	SIRESNP	(none)	5	Text	SI numeric result precision at laboratory. Example: 5,3 - representing the total size of 5 with 3 positions to right of the decimal. (1.345)	(none)	blank
SI Reference Range Low	No	SINRLO	(none)	40	Text	SI lower limit of reference range.	(none)	
SI Reference Range High	No	SINRHI	(none)	40	Text	SI upper limit of reference range.	(none)	
SI Units	No	SIU	(none)	20	Text or Coded	SI result units at laboratory.	HL7 Common ISO derived units and ISO+ extensions	
SI Units Code List ID	No	SIUCD	(none)	40	Text	If utilized, the code list identifier and version number for the SI Units code.		Not populated
Reported Result Type	Cond.	RPTRTYP	(none)	1	Code	This indicates what the type of the reported result is if the test was done. There are 6 reported result types: C - Coded N - Numeric T - Text G - Greater Than (quantifiable limit) L - Less Than (quantifiable limit) R - Range If a test is cancelled, the Reported Result Type should be left blank.	(none)	'N' or 'T'
Reported Result Status	No	RPTRSTAT	(none)	1	Code	This indicates what the status of the reported result is and is provided for Quality Control purposes. There are two reported result statuses: P - Preliminary F - Final	(none)	'F'

FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRESENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST	LABCORP COMMENTS
Alert Flag	No	ALRTFL	(none)	2	Code	The alert flag generated by the reference ranges applied and tied to the reported result. There are 9 alert flag values: H = High, L=Low, I=Indeterminate	(none)	
Delta Flag	No	DELTFI	(none)	2	Text	The delta flag generated by the reference ranges applied and tied to the reported result. There are three delta flags: D+ for an increase in value D- for a decrease in value and blank for no flag.	(none)	blank
Toxicity Grade	No	TOXGR	(none)	1	Code	The toxicity grade generated by the toxicity ranges applied and tied to the reported result.	NCI Common Toxicity Criteria	blank
Toxicity Grade Code List ID	No	TOXGRCD	(none)	40	Text	If utilized, the code list identifier and version number for the Toxicity Grade code.		blank
Exclusion Flag	No	EXCLFL	(none)	2	Code	The exclusion flag generated by the reference ranges applied and tied to the reported result. There are four exclusion flag values: LX - Low Exclusion HX - High Exclusion EX - Excluded (for exclusions not falling under high or low) and blank for no flag.	(none)	blank
Blinding Flag	No	BLNDFL	(none)	1	Code	This indicates the blinding status. There are five blinding flag values: S - Blinded to Sponsor I - Blinded to Investigator B - Blinded to Sponsor and Investigator C - Custom Blinding or blank	(none)	blank

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Reported Date and Time	No	RPTDTM	YYYY-MM-DDThh:mm:ss±hh:mm (24 hour clock with Coordinated Universal Time (UTC))	25	Text	The local date and time at which the result was reported to the investigator site. This includes a Universal Time Offset plus/minus hours and minutes.	(none)	blank
Transaction Type	Yes	TRNSTYP	(none)	1	Code	This indicates what type of record the data record is and consequently how it should be processed when it is imported into the study database. There are 4 transaction types: M - Remove (existing record) I - Insert (new record) R - Retransmit (existing record without changes) U - Update (or revise existing record at result record)	(none)	blank