

IPFnet

Annotated Design For Trial: ace_ipf

Protocol: ACE IPF

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February 17, 2010 2:46PM

Time and Events Schedule For Study: ace_ipf

	Assessment	CRF	Screening and History (SCNHX) [S]	Enrollment (ENRL) [S]	Wk 01 (WKO1) [S]	Wk 16 (Wk 16) [S]	Wk 32 (Wk 32) [S]	Wk 48 (Wk 48) [S]	Wk 64 (Wk 64) [S]	Wk 80 (Wk 80) [S]	Wk 96 (Wk 96) [S]	Wk 112 (Wk 112) [S]	Wk 128 (Wk 128) [S]	Wk 144 (Wk 144) [S]	Cross Active Study (CAS) [S]	AE (AE) [S]	EQUIP (EQUIP) [S]	LTF (LTF) [S]	UNSCH (UNSCH) [U/R]	Investigator Signature (INVSIG) [S]	Conflict (Conflict) [U/R/D]
1	Subject Demographics	SUBJINFO	1																		
2	Informed Consent	CONSENT	2																		
3	Eligibility	ELIG	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			3-DF			3-DF								
8	Screening Spirometry	SSPIRO	8																		
9	Lung Volume	LVOL	9				6-DF			6-DF			6-DF								
10	Visit Status	VISTAT		1	1	1	1	1	1	1	1	1	1	1							
11	Vital Signs	VTL		2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF	2-DF					2		
12	Spirometry	SPIRO		3-DF		3-DF	3-DF	4-DF	3-DF	3-DF	4-DF	3-DF	3-DF	4-DF					3		
13	Diffusing Capacity of the Lung for Carbon Monoxide	DLCO		4-DF				5-DF			5-DF			5-DF							
14	6-Minute Walk Test	6MWT1		5-DF				7-DF			7-DF			7-DF							
15	6-Minute Walk Test	6MWT2		6-DF				8-DF			8-DF			8-DF							
16	Log Review	REVIEWS		7-DF																	
17	Initial Study Drug Dosing	INITSDRG		8-DF																	
18	Gender Substudy Questionnaire	GENDERS		9-DF																	
19	EUROQOL Questionnaire Part1	EUROQOL1		10-DF		7-DF	8-DF	12-DF	7-DF	7-DF	12-DF	7-DF	7-DF	12-DF							
20	EUROQOL Questionnaire Part2	EUROQOL2		11-DF		8-DF	9-DF	13-DF	8-DF	8-DF	13-DF	8-DF	8-DF	13-DF							
21	ICECAP Questionnaire	ICECAP		12-DF		9-DF	10-DF	14-DF	9-DF	9-DF	14-DF	9-DF	9-DF	14-DF							
22	UCSDSOB Shortness of Breath Questionnaire Part1	UCSDSOB1		13-DF		10-DF	18-DF	15-DF	10-DF	10-DF	15-DF	10-DF	10-DF	15-DF							
23	UCSDSOB Shortness of Breath Questionnaire Part2	UCSDSOB2		14-DF		11-DF	19-DF	16-DF	11-DF	11-DF	16-DF	11-DF	11-DF	16-DF							
24	St. Georges Part 1	STGRG1		15-DF		12-DF	12-DF	17-DF	12-DF	12-DF	17-DF	12-DF	12-DF	17-DF							
25	St. Georges Part 2	STGRG2		16-DF		13-DF	13-DF	18-DF	13-DF	13-DF	18-DF	13-DF	13-DF	18-DF							
26	St. Georges Part 3	STGRG3		17-DF		14-DF	14-DF	19-DF	14-DF	14-DF	19-DF	14-DF	14-DF	19-DF							
27	St. Georges Part 4	STGRG4		18-DF		15-DF	15-DF	20-DF	15-DF	15-DF	20-DF	15-DF	15-DF	20-DF							
28	St. Georges Part 5	STGRG5		19-DF		16-DF	16-DF	21-DF	16-DF	16-DF	21-DF	16-DF	16-DF	21-DF							
29	St. Georges Part 6	STGRG6		20-DF		17-DF	17-DF	22-DF	17-DF	17-DF	22-DF	17-DF	17-DF	22-DF							
30	SF36 Assessment Part 1	SF36_1		21-DF		18-DF	7-DF	23-DF	18-DF	18-DF	23-DF	18-DF	18-DF	23-DF							
31	SF36 Assessment Part 2	SF36_2		22-DF		19-DF	11-DF	24-DF	19-DF	19-DF	24-DF	19-DF	19-DF	24-DF							
32	Log Review	REVIEWX			3-DF														4		
33	Outpatient Visits	OUTPT		4-DF	5-DF	5-DF	10-DF	5-DF	5-DF	10-DF	5-DF	5-DF	10-DF								
34	FVC Confirmation	FVC		5-DF	6-DF	6-DF	11-DF	6-DF	6-DF	11-DF	6-DF	6-DF	11-DF					5-DF			
35	Log Review	REVIEW			4-DF	4-DF	9-DF	4-DF	4-DF	9-DF	4-DF	4-DF	9-DF								
36	Study Completion/Termination	TERM													1						
37	Death	DEATH													2						
38	Urgent or Inpatient Admissions	INPT													3-RF						
39	Concomitant Medications	MED													4-RF						
40	GERD Changes	GERD													5-RF						
41	Sleep Apnea Changes	SLPCHG													6-RF						
42	Study Drug Log	KIT													7-RF						
43	Telephone Contact Log	PHONE													8-RF						
44	Adverse Events	AE														1-RF					
45	Adjudication Docs Tracking	ADJTRK														2-RF					
46	Adjudication Report	ADJRPT														3-RF					
47	Computer Tracker	COMPTRKR															1				
48	INR Monitors Tracker	INRTRKR															2				
49	Survival Status Form	LTF																1			
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

ace_ipf : Screening (SCR)

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

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

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

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

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

ace_ipf : Subject Demographics (SUBJINFO)		
Subject Information		
1.	Subject Number	A10 (Altering this value will change it throughout the trial) (ace_ipfccd:SUBJINFO.SUBJNO / Subject Number)
2.	IVRS generated subject initials	A3 (Altering this value will change it throughout the trial) (ace_ipfccd:SUBJINFO.IVRSINIT / Subject Initials)
3.	Randomization Date	Req [v] / Req [v] / Req [v] (2009-2016) (ace_ipfccd:SUBJINFO.RANDT / Randomization Date)
Demographics		
4.	Date of Birth	Req [v] / Req [v] / Req [v] (1910-1990) (ace_ipfccd:SUBJINFO.DOBDT / Date of birth)
5.	Sex	(ace_ipfccd:SUBJINFO.SEX / Gender) [1] <input type="radio"/> Male [2] <input type="radio"/> (ace_ipfccd:SUBJINFO.CBPOT / Childbearing potential) Female Female of childbearing potential? [1] <input type="radio"/> Yes [0] <input type="radio"/> (ace_ipfccd:SUBJINFO.NOCBPO / No Child Potential) No If No, reason [1] <input type="radio"/> Hysterectomy [2] <input type="radio"/> Tubal ligation [3] <input type="radio"/> Post-menopausal (natural [= > 2 years] or surgical) [98] <input type="radio"/> Other (specify) (ace_ipfccd:SUBJINFO.NOCBSP / No Child, Specify) A50
6.	Ethnicity	(ace_ipfccd:SUBJINFO.ETHNIC / Ethnicity) [1] <input type="radio"/> Hispanic or Latino [2] <input type="radio"/> Not Hispanic or Latino
7.	Race (check all that apply)	(ace_ipfccd:SUBJINFO.RACE / Race) [1] <input type="radio"/> Select all the races that apply in the list (ace_ipfccd:SUBJINFO.WHITE / Race: WHITE) [1] <input type="checkbox"/> White (ace_ipfccd:SUBJINFO.BLACK / Race: BLACK) [1] <input type="checkbox"/> Black or African American (ace_ipfccd:SUBJINFO.ASIAN / Race: ASIAN) [1] <input type="checkbox"/> Asian (ace_ipfccd:SUBJINFO.AMERIND / Race: NATIVE) [1] <input type="checkbox"/> American Indian or Alaska Native (ace_ipfccd:SUBJINFO.NATHWN / Race: HAWAIIAN) [1] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander (ace_ipfccd:SUBJINFO.OTHRACE / Race: OTHER) [1] <input type="checkbox"/> Other Race (specify): (ace_ipfccd:SUBJINFO.RACESP / Other Race, Specify) A50
Smoking History		
8.	Does the subject have any history of smoking?	(ace_ipfccd:SUBJINFO.SMOKING / Smoking History) [0] <input type="radio"/> No [1] <input type="radio"/> (ace_ipfccd:SUBJINFO.PASTCARR / Smoker) Yes Current Status [2] <input type="radio"/> Current Smoker [1] <input type="radio"/> Past Smoker: Date last smoked: Req/Unk [v] / Req/Unk [v] / Req [v] (1940-2016) (ace_ipfccd:SUBJINFO.SMOKEDT / Date Last Smoked) How many total years has the subject smoked? (years) xxx (n >= 0) (ace_ipfccd: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) (ace_ipfccd:SUBJINFO.SMKPK / Packs Smoked Per Day)
Disease History		
9.	Did subject have a CT consistent with diagnosis of IPF prior to consent?	(ace_ipfccd:SUBJINFO.IPFCT / CT Diagnosis) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: date of earliest: Req/Unk [v] / Req/Unk [v] / Req [v] (1990-2016) (ace_ipfccd:SUBJINFO.DCTDT / CT Date)
10.	Did subject have a surgical lung biopsy consistent with diagnosis of IPF prior to consent?	(ace_ipfccd:SUBJINFO.IPFBIOP / Lung Biopsy Diagnosis) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: date of earliest: Req/Unk [v] / Req/Unk [v] / Req [v] (1990-2016) (ace_ipfccd:SUBJINFO.DBIOPDT / Lung Biopsy Date)
Subgroups		
11.	DLCO	(ace_ipfccd:SUBJINFO.DLCO / DLCO) [1] <input type="radio"/> DLCO < 35%

		[2] <input type="radio"/> DLCO >= 35%
12.	Is subject taking prednisone at enrollment?	(ace_ipfcdd:SUBJINFO.PRED / Prednisone) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Concomitant Medications Log
13.	Is subject on concomitant FDA -approved treatment for IPF at enrollment?	(ace_ipfcdd:SUBJINFO.FDAACON / FDA Tx) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:SUBJINFO.FDAACONSP / FDA TX, Specify) If yes: specify (and also record on Concomitant Medications): A50
14.*	Source Document Verification Completion	(ace_ipfcdd:SUBJINFO.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
ASIAN	NUMERIC	
AMERIND	NUMERIC	
NATHWN	NUMERIC	
OTHRACE	NUMERIC	
RACESP	STRING(50) - A50	
SMOKING	NUMERIC	
PASTCURR	NUMERIC	
SMOKEDT	DATE - DDMONYYYY	
SMKYEARS	NUMERIC - N3	
SMKPK	FLOAT - F9.0	
IPFCT	NUMERIC	
DCTDT	DATE - DDMONYYYY	
IPFBIOP	NUMERIC	
DBIOPDT	DATE - DDMONYYYY	
DLCO	NUMERIC	
PRED	NUMERIC	
FDAACON	NUMERIC	
FDAACONSP	STRING(50) - A50	
SDVSTAT	NUMERIC	
SUBJNO	STRING(10) - A10	
IVRSINIT	STRING(3) - A3	
RANDT	DATE - DDMONYYYY	
DOBDT	DATE - DDMONYYYY	
SEX	NUMERIC	
CBPOT	NUMERIC	
NOCBPO	NUMERIC	
NOCBSP	STRING(50) - A50	
ETHNIC	NUMERIC	
RACE	NUMERIC	
WHITE	NUMERIC	
BLACK	NUMERIC	

ace_ipf : Informed Consent (CONSENT)	
Consent	
1.	Date informed consent signed: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd: CONSENT.CONSNSTD / Consent Date)
2.	Did subject grant permission for monitoring for survival after completion of the study? (ace_ipfcdd: CONSENT.ALIVECST / Survival Consent) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3.	Did subject grant permission to have his/her biological samples stored in the biospecimen repository (ace_ipfcdd: CONSENT.BLDSAMPL / Biological Sample Consent) [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes If yes, Date research sample consent signed Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd: CONSENT.BLDSAMDT / Biological Consent Date)
4.	Did subject consent to Acute Exacerbation blood draws? (ace_ipfcdd: CONSENT.ACEXCST / Acute Exacerbation Consent) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5.*	Source Document Verification Completion (ace_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	

CDD: ace_ipfcdd	Table: CONSENT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
CONSNSTD	DATE - DDMONYYYY	
ALIVECST	NUMERIC	
BLDSAMPL	NUMERIC	
BLDSAMDT	DATE - DDMONYYYY	
ACEXCST	NUMERIC	
SDVSTAT	NUMERIC	

ace_ipf : Eligibility (ELIG)		
Eligibility		
1.	Did the subject meet all eligibility criteria? Which eligibility criteria did the subject not meet?	(ace_ipfcdd:ELIG1.ELIGCRIT / Eligibility Criteria Met) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
2.		
Eligibility Criteria Entry		
2.a	Which eligibility criteria did the subject not meet? Pulldown List 1 <input type="button" value="v"/> (ace_ipfcdd:ELIG2.INCEXC / Criteria Not Met) (ace_ipfcdd:ELIG2.WAIVER / Waiver Given) Was a waiver given? [0] <input type="radio"/> No [1] <input type="radio"/> Yes	
3.*	Source Document Verification Completion	(ace_ipfcdd:ELIG1.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
ieCRITRA01	Subject does not have a diagnosis of IPF	99	
ieCRITRA02	Subject is not between 35 to 80 years of age	98	
ieCRITRA03	Subject is not capable of understanding and signing consent	97	
ieCRITRA04	Subject did not progress despite conventional therapy	96	
ieCRITRA05	Current enrollment in another investigative protocol	89	
ieCRITRA06	Current treatment with another investigational drug	88	
ieCRITRA07	Subject is actively listed for lung transplantation at time of enrollment	87	
ieCRITRA08	Subject who will not be able to perform/complete the study	86	
ieCRITRA09	Estimated life expectancy < 12 months due to non-pulmonary cause	85	
ieCRITRA10	Subject has another respiratory disease that is predominant as judged by PI in addition to IPF	84	
ieCRITRA11	Anticoagulation-related exclusions	83	
ieCRITRA12	Withdrew consent	82	
ieCRITRA13	Study is too time consuming	81	
ieCRITRA14	Study is too experimental	80	
ieCRITRA15	Other	79	

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

CDD: ace_ipfcdd Table: ELIG2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
WAIVER	NUMERIC	
INCEXC	NUMERIC - 99, 98, 97, 96, 89, 88, 87, 86, 85, 84, 83, 82, 81, 80, 79	

ace_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	(ace_ipfcdd: MEDHX.CADHIST / Coronary Artery Disease) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
2. Acute MI	(ace_ipfcdd: MEDHX.ACUTEMI / Acute MI) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
3. Valvular heart disease	(ace_ipfcdd: MEDHX.VALVULAR / Valvular Heart Disease) [0] <input type="radio"/> No [1] <input type="radio"/> Yes, Specify: (ace_ipfcdd: MEDHX.VALVULSP / Valvular, Specify) A50 [99] <input type="radio"/> Unknown
4. Heart failure	(ace_ipfcdd: MEDHX.HFAILURE / Heart Failure) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
5. Atrial fibrillation	(ace_ipfcdd: MEDHX.ATRIALFB / Atrial Fibrillation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
6. Pulmonary embolism	(ace_ipfcdd: MEDHX.PULEMB / Embolism) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
7. Deep vein thrombosis	(ace_ipfcdd: MEDHX.DVT / DVT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
8. Cerebral vascular accident	(ace_ipfcdd: MEDHX.CVA / CVA) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
9. Intermittent claudication	(ace_ipfcdd: MEDHX.CLAUDICA / Claudication) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
10. Cirrhosis or other serious, chronic liver disease	(ace_ipfcdd: MEDHX.LIVERDIS / Cirrhosis) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
11. Diabetes	(ace_ipfcdd: MEDHX.DIABETES / Diabetes) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
12. Lung cancer	(ace_ipfcdd: MEDHX.LGCANCER / Lung Cancer) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
13. Other cancer (excluding basal cell carcinoma)	(ace_ipfcdd: MEDHX.OTHCAN / Other Cancer) [0] <input type="radio"/> No [1] <input type="radio"/> Yes, Specify: (ace_ipfcdd: MEDHX.OTHCANSP / Cancer, Specify) A50 [99] <input type="radio"/> Unknown
14. Gastroesophageal reflux disorders (GERD): Barretts esophagus	(ace_ipfcdd: MEDHX.BARRETS / Barretts) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
15. Gastroesophageal reflux disorders (GERD): Hiatal hernia	(ace_ipfcdd: MEDHX.HIATALHN / Hiatal Hernia) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
16. Gastroesophageal reflux disorders (GERD): Fundoplication surgery	(ace_ipfcdd: MEDHX.FUNDSURG / Fundoplication) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
17. Gastroesophageal reflux disorders (GERD): Gastroesophageal reflux	(ace_ipfcdd: MEDHX.REFLUX / Reflux) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes How was gastroesophageal reflux diagnosed (ace_ipfcdd: MEDHX.PHMONITR / pH Monitoring) [1] <input type="checkbox"/> 24 hr pH monitoring (ace_ipfcdd: MEDHX.ENDOSCOPI / Endoscopy) [1] <input type="checkbox"/> Endoscopy (ace_ipfcdd: MEDHX.UPBARIUM / Swallow Test) [1] <input type="checkbox"/> Upper GI/barium swallow test (ace_ipfcdd: MEDHX.HTBURN / Heartburn) [1] <input type="checkbox"/> Symptoms of heartburn (ace_ipfcdd: MEDHX.GDIAUNK / Diagnosis Unknown) [1] <input type="checkbox"/> Unknown/Other Non-pharmaceutical interventions for gastroesophageal reflux (ace_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 (ace_ipfcdd: MEDHX.RECLIN / Recliner) [1] <input type="checkbox"/> Sleeping in a recliner (ace_ipfcdd: MEDHX.FOOD / Limiting Food Beverage) [1] <input type="checkbox"/> Limiting foods and beverages that cause symptoms (ace_ipfcdd: MEDHX.NOFLAT / Avoiding Laying Flat) [1] <input type="checkbox"/> Avoiding lying down flat for 3 hours after a meal (ace_ipfcdd: MEDHX.BEDSNK / Avoiding Bedtime Snacks) [1] <input type="checkbox"/> Avoiding bedtime snacks

		<p>(ace_ipfcdd: MEDHX.SMLMEAL / Small Meals) [1] <input type="checkbox"/> Eating small meals (ace_ipfcdd: MEDHX.NOGERDIN / No Intervention) [1] <input type="checkbox"/> None</p>
18.	Sleep apnea (central or obstructive)	<p>(ace_ipfcdd: MEDHX.SLPAPNEA / Sleep Apnea) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> (ace_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</p>
19.	Asthma	<p>(ace_ipfcdd: MEDHX.ASTHMA / Asthma) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
20.	Evidence of pulmonary hypertension	<p>(ace_ipfcdd: MEDHX.HYPERTEN / Hypertension) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (ace_ipfcdd: MEDHX.HYPRECHO / Diagnosis Echo) If Yes: Identify the method of diagnosing pulmonary hypertension [1] <input type="checkbox"/> Echo (ace_ipfcdd: MEDHX.HYPRCATH / Diagnosis Cath) [1] <input type="checkbox"/> Cath</p>
21.	Emphysema or chronic bronchitis	<p>(ace_ipfcdd: MEDHX.EMPHYS / Emphysema or Bronchitis) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
22.	Connective tissue features (thought clinically insignificant)	<p>(ace_ipfcdd: MEDHX.CNTISSUE / Connective Tissue) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (ace_ipfcdd: MEDHX.RAYNAUDS / Raynauds) [1] <input type="checkbox"/> Raynaud's (ace_ipfcdd: MEDHX.POSANA / Positive ANA) [1] <input type="checkbox"/> Positive ANA - Titer: 1 : xxxxxxxx. (ace_ipfcdd: MEDHX.POSANA1 / Positive ANA Titer) (ace_ipfcdd: MEDHX.POSRF / Positive RF) [1] <input type="checkbox"/> Positive RF - Level: (IU/mL) xxxxxxxx. (ace_ipfcdd: MEDHX.POSRF1 / Positive RF Level) (ace_ipfcdd: MEDHX.MYALGIA / Arthralgia Myalgia) [1] <input type="checkbox"/> Significant arthralgia/myalgia (ace_ipfcdd: MEDHX.SICCA / Sicca) [1] <input type="checkbox"/> Sicca symptoms (ace_ipfcdd: MEDHX.DYSPHAGA / Dysphagia) [1] <input type="checkbox"/> Dysphagia (ace_ipfcdd: MEDHX.OTHITIS / Other tissue features) [1] <input type="checkbox"/> Other (specify): _____ (ace_ipfcdd: MEDHX.OTHITISSP / Tissue Features, Specify) A50 </p>
23.	Exposure to organic or inorganic antigens known to cause interstitial lung disease (thought clinically insignificant)	<p>(ace_ipfcdd: MEDHX.ANTIGENS / Antigen Exposure) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
24.	Clubbing	<p>(ace_ipfcdd: MEDHX.CLUBBING / Clubbing) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
25.	Bibasilar, inspiratory crackles	<p>(ace_ipfcdd: MEDHX.CRACKLES / Crackles) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
26.	Jugular venous distension	<p>(ace_ipfcdd: MEDHX.JVD / JVD) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
27.	Increased P2	<p>(ace_ipfcdd: MEDHX.INCSEPPT / Increased P2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
28.	Peripheral edema	<p>(ace_ipfcdd: MEDHX.PEREDEMA / Peripheral Edema) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p>
29.	Other significant condition/finding	<p>(ace_ipfcdd: MEDHX.OTHC1 / Other Finding) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes _____ (ace_ipfcdd: MEDHX.OTHC1SP / Other Finding, Specify) Other (specify): A200</p>
30.*	Source Document Verification Completion	<p>(ace_ipfcdd: MEDHX.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete Partially Complete</p>

[2]
 [3] Not Applicable

* Item is not required

Column Name	Column Data Type	Design Note
CADHIST	NUMERIC	
ACUTEMI	NUMERIC	
VALVULAR	NUMERIC	
VALVULSP	STRING(50) - A50	
HFAILURE	NUMERIC	
ATRIALFB	NUMERIC	
PULEMB	NUMERIC	
DVT	NUMERIC	
CVA	NUMERIC	
CLAUDICA	NUMERIC	
LIVERDIS	NUMERIC	
DIABETES	NUMERIC	
LGCANCER	NUMERIC	
OTHCAN	NUMERIC	
OTHCANSP	STRING(50) - A50	
BARRETS	NUMERIC	
HIATALHN	NUMERIC	
FUNDSURG	NUMERIC	
REFLUX	NUMERIC	
PHMONITR	NUMERIC	
ENDOSCOPI	NUMERIC	
UPBARIUM	NUMERIC	
HTBURN	NUMERIC	
GDIANK	NUMERIC	
ELEV	NUMERIC	
RECLIN	NUMERIC	
FOOD	NUMERIC	
NOFLAT	NUMERIC	
BEDSNK	NUMERIC	
SMLMEAL	NUMERIC	
NOGERDIN	NUMERIC	
SLPAPNEA	NUMERIC	
CPAP	NUMERIC	
ASTHMA	NUMERIC	
HYPERTEN	NUMERIC	
HYPRECHO	NUMERIC	
HYPRCATH	NUMERIC	
EMPHYS	NUMERIC	
CNTISSUE	NUMERIC	
RAYNAUDS	NUMERIC	
POSANA	NUMERIC	
POSANA1	FLOAT - F9.0	
POSRF	NUMERIC	
POSRF1	FLOAT - F9.0	
MYALGIA	NUMERIC	
SICCA	NUMERIC	
DYSPHAGA	NUMERIC	
OTHTIS	NUMERIC	
OTHTISSP	STRING(50) - A50	
ANTIGENS	NUMERIC	

CLUBBING	NUMERIC	
CRACKLES	NUMERIC	
JVD	NUMERIC	
INCSEPPT	NUMERIC	
PEREDEMA	NUMERIC	
OTH1	NUMERIC	
OTH1SP	STRING(200) - A200	
SDVSTAT	NUMERIC	

ace_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"/> Req <input type="checkbox"/> / <input type="checkbox"/> Req <input type="checkbox"/> / <input type="checkbox"/> Req <input type="checkbox"/> (2007-2016) (ace_ipfccdd:HRCT.HRCTDT / HRCT Date)
2.	Adequate Inspiration? (ace_ipfccdd:HRCT.ADCINSPR / Adequate Inspiration) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
3.	Prone Images? (ace_ipfccdd:HRCT.PRONE / Prone Images) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
4.	Expiratory Images? (ace_ipfccdd:HRCT.EXPIIMAGE / Expiratory Images) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
5.	Motion Artifact: (ace_ipfccdd: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): (ace_ipfccdd:HRCT.PULAUNK / Pulmonary Art Diameter Unk) [1] <input type="text"/> xxxxxxxx. (ace_ipfccdd:HRCT.PULATDIA / Pulmonary Artery Diameter) [99] <input type="radio"/> Unknown
7.	Aorta diameter (cm): (ace_ipfccdd:HRCT.AORTUNK / Aorta Diameter Unknown) [1] <input type="text"/> xxxxxxxx. (ace_ipfccdd:HRCT.AORTADIA / Aorta Diameter) [99] <input type="radio"/> Unknown
8.	Predominant craniocaudal distribution of abnormality (ace_ipfccdd: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 (ace_ipfccdd: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: (ace_ipfccdd:HRCT.RETICULR / Reticular Abnormality) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
11.	Honeycombing: (ace_ipfccdd: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 (ace_ipfccdd:HRCT.GRDGLASS / Ground Glass Abnormality) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
13.	Profuse micronodules: bilateral (ace_ipfccdd: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 (ace_ipfccdd: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 (ace_ipfccdd:HRCT.MOSAIC / Mosaic Attenuation) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
16.	Consolidation: (ace_ipfccdd:HRCT.CONOLID / Consolidation) [0] <input type="radio"/> Absent

		<input type="radio"/> [1] <input type="radio"/> Present [99] <input type="radio"/> Unknown
17.	Emphysema:	(ace_ipfcdd:HRCT.EMPHYSEM / Emphysema) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present (ace_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	(ace_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	(ace_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		

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

ace_ipf : Surgical Lung Biopsy/Diagnosis of IPF (SLB)	
1.	Date of biopsy: <input type="text"/> / <input type="text"/> / <input type="text"/> (2007-2015) (ace_ipfcdd:SLB.SLBDT / Lung Biopsy Date)
Clinical Center	
2.	<p>Did the Clinical Center evaluate the surgical lung biopsy?</p> <p>(ace_ipfcdd:SLB.CCDONE / Clinical Evaluation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(ace_ipfcdd:SLB.CCSCARR / Clinical 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</p> <p>(ace_ipfcdd:SLB.CCFIBRO / Clinical Fibroblast Foci) [1] <input type="checkbox"/> (ace_ipfcdd:SLB.CCPRES / Clinical 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+</p> <p>(ace_ipfcdd:SLB.CCPAREN / Clinical Pathcy Involvement) [1] <input type="checkbox"/> Patchy involvement of lung parenchyma</p> <p>(ace_ipfcdd:SLB.CCUIPDX / Clinical Absence Features) [1] <input type="checkbox"/> Absence of features against a diagnosis of UIP</p> <p>(ace_ipfcdd:SLB.CCDIAG / Clinical Con 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>
Central	
3.	<p>Did a Central reader evaluate the surgical lung biopsy?</p> <p>(ace_ipfcdd:SLB.CDONE / Central Evaluation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(ace_ipfcdd:SLB.CSCARR / Central 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</p> <p>(ace_ipfcdd:SLB.CFIBRO / Central Fibroblast Foci) [1] <input type="checkbox"/> (ace_ipfcdd:SLB.CPRES / Central 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+</p> <p>(ace_ipfcdd:SLB.CPAREN / Central Pathcy Involvement) [1] <input type="checkbox"/> Patchy involvement of lung parenchyma</p> <p>(ace_ipfcdd:SLB.CUIPDX / Central Absence of Features) [1] <input type="checkbox"/> Absence of features against a diagnosis of UIP</p> <p>(ace_ipfcdd:SLB.CDIAG / Central Con 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>
Tie Breaker	
4.	<p>Did a Tie Breaker evaluate the surgical lung biopsy?</p> <p>(ace_ipfcdd:SLB.TBDONE / Tie Breaker Evaluation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(ace_ipfcdd:SLB.TBSCARR / Tie Breaker 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</p> <p>(ace_ipfcdd:SLB.TBFIBRO / Tie Breaker Fibroblast Foci) [1] <input type="checkbox"/> (ace_ipfcdd:SLB.TBPRES / Tie-Breaker 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+</p> <p>(ace_ipfcdd:SLB.TBPAREN / Tie Breaker Pathcy Involve) [1] <input type="checkbox"/> Patchy involvement of lung parenchyma</p> <p>(ace_ipfcdd:SLB.TBUIPDX / Tie Break Absence Features)</p>

	<p>[1] <input type="checkbox"/> Absence of features against a diagnosis of UIP (ace_ipfccdd:SLB.TBDIAG / Tie Break Con of Diagnosis) Confidence of diagnosis of UIP (check only one):</p> <p>[1] <input type="radio"/> Definite [2] <input type="radio"/> Probable [3] <input type="radio"/> Possible [4] <input type="radio"/> Not UIP</p>
Adjudication	
<p>5. Did an adjudicator evaluate the surgical lung biopsy?</p>	<p>(ace_ipfccdd:SLB.AJJDONE / Adjudication Evaluation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfccdd: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 (ace_ipfccdd:SLB.AJFIBRO / Adjud Fibroblast Foci) [1] <input type="checkbox"/> (ace_ipfccdd: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+ (ace_ipfccdd:SLB.AJPAREN / Adj Patchy Involvement) [1] <input type="checkbox"/> Patchy involvement of lung parenchyma (ace_ipfccdd:SLB.AJUIPDX / Adj Absence of Features) [1] <input type="checkbox"/> Absence of features against a diagnosis of UIP (ace_ipfccdd: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>(ace_ipfccdd: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>	

Column Name	Column Data Type	Design Note
CCDIAG	NUMERIC	
CDONE	NUMERIC	
CSCARR	NUMERIC	
CFIBRO	NUMERIC	
CPRES	NUMERIC	
CPAREN	NUMERIC	
CUIPDX	NUMERIC	
CDIAG	NUMERIC	
TBDONE	NUMERIC	
TBSCARR	NUMERIC	
TBFIBRO	NUMERIC	
TBPRES	NUMERIC	
TBPAREN	NUMERIC	
TBUIPDX	NUMERIC	
TBDIAG	NUMERIC	
ADJDONE	NUMERIC	
AJSCARR	NUMERIC	
AJFIBRO	NUMERIC	
AJPRES	NUMERIC	
AJPAREN	NUMERIC	
AJUIPDX	NUMERIC	
AJCHOIC	NUMERIC	
SDVSTAT	NUMERIC	

SLBDT	DATE - DDMYYYY	
CCDONE	NUMERIC	
CCSCARR	NUMERIC	
CCFIBRO	NUMERIC	
CCPRES	NUMERIC	
CCPAREN	NUMERIC	
CCUIPDX	NUMERIC	

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

CDD: ace_ipfcdd Table: ABG Key Type: PATIENTVISIT

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

CDD: panther_ipfcdd Table: ABG Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note

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

ace_ipf : Screening Spirometry (SSPIRO)		
Assessment Date		
1.	Date of Screening Spirometry assessment:	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:SSPIRO.SSPIRODT / Spirometry Date)
Pre Bronchodilator - Primary		
2.	FEV1: Actual	(ace_ipfcdd:SSPIRO.FEV1UNK / FEV1 Pre Primary Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV1PRP / FEV1 Pre Primary) <input type="checkbox"/> [97] Not Done
3.	FEV6: Actual	(ace_ipfcdd:SSPIRO.FEV6UNK / FEV6 Pre Primary Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV6PRP / FEV6 Pre Primary) <input type="checkbox"/> [97] Not Done
4.	FVC: Actual	(ace_ipfcdd:SSPIRO.FVCUNK / FVC Pre Primary Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FVCPRP / FVC Pre Primary) <input type="checkbox"/> [97] Not Done
Pre Bronchodilator - Replicate 1		
5.	FEV1: Actual	(ace_ipfcdd:SSPIRO.FEV1UNK1 / FEV1 Pre Rep 1 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV1PRR1 / FEV1 Pre Rep 1) <input type="checkbox"/> [97] Not Done
6.	FEV6: Actual	(ace_ipfcdd:SSPIRO.FEV6UNK1 / FEV6 Pre Rep 1 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV6PRR1 / FEV6 Pre Rep 1) <input type="checkbox"/> [97] Not Done
7.	FVC: Actual	(ace_ipfcdd:SSPIRO.FVCUNK1 / FVC Pre Rep 1 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FVCPRR1 / FVC Pre Rep 1) <input type="checkbox"/> [97] Not Done
Pre Bronchodilator - Replicate 2		
8.	FEV1: Actual	(ace_ipfcdd:SSPIRO.FEV1UNK2 / FEV1 Pre Rep 2 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV1PRR2 / FEV1 Pre Rep 2) <input type="checkbox"/> [97] Not Done
9.	FEV6: Actual	(ace_ipfcdd:SSPIRO.FEV6UNK2 / FEV6 Pre Rep 2 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV6PRR2 / FEV6 Pre Rep 2) <input type="checkbox"/> [97] Not Done
10.	FVC: Actual	(ace_ipfcdd:SSPIRO.FVCUNK2 / FVC Pre Rep 2 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FVCPRR2 / FVC Pre Rep 2) <input type="checkbox"/> [97] Not Done
Post Bronchodilator - Primary		
11.	FEV1: Actual	(ace_ipfcdd:SSPIRO.FEV1UNK3 / FEV1 Post Primary Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV1PSP / FEV1 Post Primary) <input type="checkbox"/> [97] Not Done
12.	FEV6: Actual	(ace_ipfcdd:SSPIRO.FEV6UNK3 / FEV6 Post Primary Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV6PSP / FEV6 Post Primary) <input type="checkbox"/> [97] Not Done
13.	FVC: Actual	(ace_ipfcdd:SSPIRO.FVCUNK3 / FVC Post Primary Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FVCPSR / FVC Post Primary) <input type="checkbox"/> [97] Not Done
Post Bronchodilator - Replicate 1		
14.	FEV1: Actual	(ace_ipfcdd:SSPIRO.FEV1UNK4 / FEV1 Post Rep 1 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV1PSR1 / FEV1 Post Rep 1) <input type="checkbox"/> [97] Not Done
15.	FEV6: Actual	(ace_ipfcdd:SSPIRO.FEV6UNK4 / FEV6 Post Rep 1 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV6PSR1 / FEV6 Post Rep 1) <input type="checkbox"/> [97] Not Done
16.	FVC: Actual	(ace_ipfcdd:SSPIRO.FVCUNK4 / FVC Post Rep 1 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FVCPSR1 / FVC Post Rep 1) <input type="checkbox"/> [97] Not Done
Post Bronchodilator - Replicate 2		
17.	FEV1: Actual	(ace_ipfcdd:SSPIRO.FEV1UNK5 / FEV1 Post Rep 2 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV1PSR2 / FEV1 Post Rep 2) <input type="checkbox"/> [97] Not Done
18.	FEV6: Actual	(ace_ipfcdd:SSPIRO.FEV6UNK5 / FEV6 Post Rep 2 Not Done) <input type="checkbox"/> [1] xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FEV6PSR2 / FEV6 Post Rep 2)

19. FVC: Actual	[97] <input type="radio"/> Not Done (ace_ipfcdd:SSPIRO.FVCUNK5 / FVC Post Rep 2 Not Done) [1] <input type="radio"/> xxxxxxxx.liters (ace_ipfcdd:SSPIRO.FVCPSR2 / FVC Post Rep 2) [97] <input type="radio"/> Not Done
20.* Source Document Verification Completion	(ace_ipfcdd:SSPIRO.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: ace_ipfcdd Table: SSPIRO Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
FVCUNK	NUMERIC	
FVCPRP	FLOAT - F9.0	
FEV1UNK1	NUMERIC	
FVCUNK5	NUMERIC	
FVCPSR2	FLOAT - F9.0	
SDVSTAT	NUMERIC	
FEV1PRR1	FLOAT - F9.0	
FEV6UNK1	NUMERIC	
FEV6PRR1	FLOAT - F9.0	
FVCUNK1	NUMERIC	
FVCPRR1	FLOAT - F9.0	
FEV1UNK2	NUMERIC	
FEV1PRR2	FLOAT - F9.0	
FEV6UNK2	NUMERIC	
FEV6PRR2	FLOAT - F9.0	
FVCUNK2	NUMERIC	
FVCPRR2	FLOAT - F9.0	
FEV1UNK3	NUMERIC	
FEV6PSP	FLOAT - F9.0	
FVCUNK3	NUMERIC	
FVCPSP	FLOAT - F9.0	
FEV1UNK4	NUMERIC	
FEV1PSR1	FLOAT - F9.0	
FEV6UNK4	NUMERIC	
FEV6PSR1	FLOAT - F9.0	
FVCUNK4	NUMERIC	
FVCPSR1	FLOAT - F9.0	
FEV1UNK5	NUMERIC	
FEV1PSR2	FLOAT - F9.0	
FEV6UNK5	NUMERIC	
FEV6PSR2	FLOAT - F9.0	
SSPIRODT	DATE - DDMONYYYY	
FEV1UNK	NUMERIC	
FEV1PRP	FLOAT - F9.0	
FEV6UNK	NUMERIC	
FEV6PRP	FLOAT - F9.0	
FEV1PSP	FLOAT - F9.0	
FEV6UNK3	NUMERIC	

ace_ipf : Lung Volume (LVOL)		
Lung Volume		
1.	Date of Lung Volume assessment:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcd:LVOL.LUNGLD / Lung Volume Date)
2.	Total lung capacity (TLC)	(ace_ipfcd:LVOL.TLCUNK / TLC Not Done) [1] <input type="radio"/> xxxxxxxx liters (ace_ipfcd:LVOL.TLC / TLC) [97] <input type="radio"/> Not Done
3.	Functional residual capacity (FRC)	(ace_ipfcd:LVOL.FRCUNK / FRC Not Done) [1] <input type="radio"/> xxxxxxxx liters (ace_ipfcd:LVOL.FRC / FRC) [97] <input type="radio"/> Not Done
4.	Slow vital capacity (SVC)	(ace_ipfcd:LVOL.SVCUNK / SVC Not Done) [1] <input type="radio"/> xxxxxxxx liters (ace_ipfcd:LVOL.SVC / SVC) [97] <input type="radio"/> Not Done
5.*	Source Document Verification Completion	(ace_ipfcd: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		

CDD: ace_ipfcd	Table: LVOL	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
LUNGLD	DATE - DDMYYYY	
TLCUNK	NUMERIC	
TLC	FLOAT - F9.0	
FRCUNK	NUMERIC	
FRC	FLOAT - F9.0	
SVCUNK	NUMERIC	
SVC	FLOAT - F9.0	
SDVSTAT	NUMERIC	

ace_ipf : Visit Status (VISTAT)		
Visit Status		
1.	Did the visit occur?	(ace_ipfcdd:VISTAT.VISOCCUR / Visit Occurred) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date of Visit: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:VISTAT.VISITDT / Visit Date)
2.*	Source Document Verification Completion	(ace_ipfcdd:VISTAT.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
VISOCCUR	NUMERIC	
VISITDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	

ace_ipf : Vital Signs (VTL)		
Vital Signs		
1.	Weight	(ace_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 (ace_ipfcdd:VTL.WEIGHT / Weight)
2.	Height	(ace_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 (ace_ipfcdd:VTL.HEIGHT / Height)
3.	Blood Pressure (systolic)	(ace_ipfcdd:VTL.SYSDONE / Systolic BP Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxx mmHg (ace_ipfcdd:VTL.BPSYS / Systolic BP)
4.	Blood Pressure (diastolic)	(ace_ipfcdd:VTL.DIADONE / Diastolic BP Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxx mmHg (ace_ipfcdd:VTL.BPDIA / Diastolic BP)
5.	Heart Rate	(ace_ipfcdd:VTL.HRSDONE / Heart Rate Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxx mmHg (ace_ipfcdd:VTL.HRATE / Heart Rate)
6.	SpO2	(ace_ipfcdd:VTL.SPO2DONE / SpO2 Not Done) [97] <input type="radio"/> Not done [1] <input type="radio"/> xxxxxxxx. % (ace_ipfcdd:VTL.SPO2 / SpO2)
7.*	Source Document Verification Completion	(ace_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
WTDONE	NUMERIC	
WEIGHT	FLOAT - F9.0	
HTDONE	NUMERIC	
HEIGHT	FLOAT - F9.0	
SYSDONE	NUMERIC	
BPSYS	NUMERIC - N3	
DIADONE	NUMERIC	
BPDIA	NUMERIC - N3	
HRSDONE	NUMERIC	
HRATE	NUMERIC - N3	
SPO2DONE	NUMERIC	
SPO2	FLOAT - F9.0	
SDVSTAT	NUMERIC	

ace_ipfd : Spirometry (SPIRO)		
Assessment Date		
1.	Date of Spirometry assessment:	Req [v] / Req [v] / Req [v] (2009-2016) (ace_ipfdcd: SPIRO.SPIRODT / Spirometry Date)
Primary		
2.	FEV1: Actual	(ace_ipfdcd: SPIRO.FEV1UNK6 / FEV1 Primary Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FEV1P / FEV1 Primary) [97] [o] Not Done
3.	FEV6: Actual	(ace_ipfdcd: SPIRO.FEV6UNK6 / FEV6 Primary Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FEV6P / FEV6 Primary) [97] [o] Not Done
4.	FVC: Actual	(ace_ipfdcd: SPIRO.FVCUNK6 / FVC Primary Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FVCP / FVC Primary) [97] [o] Not Done
5.	FVC difference from baseline	xxxxxxxx. % (ace_ipfdcd: SPIRO.FVCCAL / FVC Difference)
6.*	Has the site confirmed the FVC change?	(ace_ipfdcd: SPIRO.FVCCRA / Confirmed FVC Change) [0] [o] No [1] [o] Yes
Replicate 1		
7.	FEV1: Actual	(ace_ipfdcd: SPIRO.FEV1UNK7 / FEV1 Rep 1 Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FEV1R1 / FEV1 Rep 1) [97] [o] Not Done
8.	FEV6: Actual	(ace_ipfdcd: SPIRO.FEV6UNK7 / FEV6 Rep 1 Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FEV6R1 / FEV6 Rep 1) [97] [o] Not Done
9.	FVC: Actual	(ace_ipfdcd: SPIRO.FVCUNK7 / FVC Rep 1 Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FVCP1 / FVC Rep 1) [97] [o] Not Done
Replicate 2		
10.	FEV1: Actual	(ace_ipfdcd: SPIRO.FEV1UNK8 / FEV1 Rep 2 Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FEV1R2 / FEV1 Rep 2) [97] [o] Not Done
11.	FEV6: Actual	(ace_ipfdcd: SPIRO.FEV6UNK8 / FEV6 Rep 2 Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FEV6R2 / FEV6 Rep 2) [97] [o] Not Done
12.	FVC: Actual	(ace_ipfdcd: SPIRO.FVCUNK8 / FVC Rep 2 Not Done) [1] [o] xxxxxxxx. liters (ace_ipfdcd: SPIRO.FVCP2 / FVC Rep 2) [97] [o] Not Done
13.*	Source Document Verification Completion	(ace_ipfdcd: SPIRO.SDVSTAT / SDV Complete) [1] [o] Complete [2] [o] Partially Complete [3] [o] Not Applicable
* Item is not required		

Column Name	Column Data Type	Design Note
SPIRODT	DATE - DDMYYYYY	
FEV1UNK6	NUMERIC	
FEV1P	FLOAT - F9.0	
FEV6UNK6	NUMERIC	
FEV6P	FLOAT - F9.0	
FVCUNK6	NUMERIC	
FVCP	FLOAT - F9.0	
FVCCAL	FLOAT - F9.0	
FVCCRA	NUMERIC	
FEV1UNK7	NUMERIC	
FEV1R1	FLOAT - F9.0	
FEV6UNK7	NUMERIC	
FEV6R1	FLOAT - F9.0	

FVCUNK7	NUMERIC	
FVCPR1	FLOAT - F9.0	
FEV1UNK8	NUMERIC	
FEV1R2	FLOAT - F9.0	
FEV6UNK8	NUMERIC	
FEV6R2	FLOAT - F9.0	
FVCUNK8	NUMERIC	
FVCPR2	FLOAT - F9.0	
SDVSTAT	NUMERIC	

ace_ipf : Diffusing Capacity of the Lung for Carbon Monoxide (DLCO)		
Diffusing Capacity of the Lung for Carbon Monoxide		
1.	Date of Assessment	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd:DLCO.DLCODT / DLCO Date)
2.	DLCO: Actual	(ace_ipfcdd:DLCO.DLCOUNK / DLCO Not Done) [1] <input type="radio"/> xxxxxxxx mL/min/mmHg (ace_ipfcdd:DLCO.DLCOACTL / DLCO) [97] <input type="radio"/> Not Done
3.*	Altitude-corrected DLCO (National Jewish and University of Utah only):	xxxxxxx mL/min/mmHg (ace_ipfcdd:DLCO.ALTIDLCO / Altitude Corrected DLCO)
4.	VI (inspired volume):	(ace_ipfcdd:DLCO.VIUNK / VI Not Done) [1] <input type="radio"/> xxxxxxxx liters (ace_ipfcdd:DLCO.VI / VI) [97] <input type="radio"/> Not Done
5.	VA (alveolar volume):	(ace_ipfcdd:DLCO.VAUNK / VA Not Done) [1] <input type="radio"/> xxxxxxxx liters (ace_ipfcdd:DLCO.VA / VA) [97] <input type="radio"/> Not Done
6.*	Source Document Verification Completion	(ace_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: ace_ipfcdd	Table: DLCO	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
DLCODT	DATE - DDMYYYYY	
DLCOUNK	NUMERIC	
DLCOACTL	FLOAT - F9.0	
ALTIDLCO	FLOAT - F9.0	
VIUNK	NUMERIC	
VI	FLOAT - F9.0	
VAUNK	NUMERIC	
VA	FLOAT - F9.0	
SDVSTAT	NUMERIC	

ace_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"/> (ace_ipfcdd: SIXMWT1.PREBORG / PreWalk Borg Dyspnea Rating) (panther_ipfcdd: SIXMWT1.PREBORG / PreWalk Borg Dyspnea Rating)
2.	Resting room air SpO2	xxxxxxx. % (ace_ipfcdd: SIXMWT1.RESTSPO2 / Resting SpO2) (panther_ipfcdd: SIXMWT1.RESTSPO2 / Resting SpO2)
3.	Was walk performed?	(ace_ipfcdd: SIXMWT1.WLKND / Walk Performed) (panther_ipfcdd: SIXMWT1.WLKND / Walk Performed) [1] <input type="radio"/> Yes [0] <input type="radio"/> No (ace_ipfcdd: SIXMWT1.WLKNDSP / Walk Not Performed, Specify) Reason walk test not performed? (panther_ipfcdd: SIXMWT1.WLKNDSP / Walk Not Performed, Specify) A50
4.*	Source Document Verification Completion	(ace_ipfcdd: SIXMWT1.SDVSTAT / SDV Complete) (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: ace_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	
WLKND	NUMERIC	
WLKNDSP	STRING(50) - A50	
SDVSTAT	NUMERIC	

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	
WLKND	NUMERIC	
WLKNDSP	STRING(50) - A50	
SDVSTAT	NUMERIC	

ace_ipf : 6-Minute Walk Test (6MWT2)		
1.	Was supplemental O2 used during walk?	(ace_ipfcdd: SIXMWT2.SUPPLOXY / Supplemental O2 Used) (panther_ipfcdd: SIXMWT2.SUPPLOXY / Supplemental O2 Used) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Specify amount of supplemental O2 (liters/min) (ace_ipfcdd: SIXMWT2.SUPO2 / Supplemental O2 Amount) xxxxxxxx. (panther_ipfcdd: SIXMWT2.SUPO2 / Supplemental O2 Amount) If Yes: SpO2 on Supplemental O2 (%) (ace_ipfcdd: SIXMWT2.SUPSP02 / SpO2 on Supplemental O2) xxxxxxxx. (panther_ipfcdd: SIXMWT2.SUPSP02 / SpO2 on Supplemental O2)
2.	Was a walking aid necessary to perform the 6MWT?	(ace_ipfcdd: SIXMWT2.WALKAID / Walking Aid Used) (panther_ipfcdd: SIXMWT2.WALKAID / Walking Aid Used) [0] <input type="radio"/> No [1] <input type="radio"/> (ace_ipfcdd: SIXMWT2.TYPEAID / Type of Walking Aid) (panther_ipfcdd: 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) (ace_ipfcdd: SIXMWT2.AIDSP / Walking Aid, Specify) A50 (panther_ipfcdd: SIXMWT2.AIDSP / Walking Aid, Specify)
3.	Did Subject Complete 6-Minute Walk?	(ace_ipfcdd: SIXMWT2.COMPLWLK / Completed Walk) (panther_ipfcdd: 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)? xx : (ace_ipfcdd: SIXMWT2.WLKMIN / Walk Duration Minutes) A2 (ace_ipfcdd: SIXMWT2.WLKSEC / Walk Duration Seconds) (panther_ipfcdd: SIXMWT2.WLKMIN / Walk Duration Minutes) (panther_ipfcdd: SIXMWT2.WLKSEC / Walk Duration Seconds) (ace_ipfcdd: SIXMWT2.STOPREA / Reason Stopped Early) (panther_ipfcdd: SIXMWT2.STOPREA / Reason Stopped Early) 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) (ace_ipfcdd: SIXMWT2.STPOTHSP / Stopped Reason, Specify) A50 (panther_ipfcdd: SIXMWT2.STPOTHSP / Stopped Reason, Specify)
4.	Did subject desaturate (SpO2 <= 88%)?	(ace_ipfcdd: SIXMWT2.DESATURA / Desaturate) (panther_ipfcdd: SIXMWT2.DESATURA / Desaturate) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Walk duration at desaturation (min:sec): xx : (ace_ipfcdd: SIXMWT2.DESATMIN / Desaturation Minutes) xx (ace_ipfcdd: SIXMWT2.DESATSEC / Desaturation Seconds) (panther_ipfcdd: SIXMWT2.DESATMIN / Desaturation Minutes) (panther_ipfcdd: SIXMWT2.DESATSEC / Desaturation Seconds) If Yes: Walk distance at desaturation (meters) (ace_ipfcdd: SIXMWT2.DESATDIS / Walk Distance at Desat) xxxxxxxx. (panther_ipfcdd: SIXMWT2.DESATDIS / Walk Distance at Desat)
5.	Lowest SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.LOWSPO2 / Lowest SpO2) (panther_ipfcdd: SIXMWT2.LOWSPO2 / Lowest SpO2)
6.	Distance Walked	xxxxxxxx. meters (ace_ipfcdd: SIXMWT2.DISTANCE / Distance Walked) (panther_ipfcdd: SIXMWT2.DISTANCE / Distance Walked)
7.	Post-walk modified Borg Dyspnea Scale rating	Pulldown List 1 <input type="button" value="v"/> (ace_ipfcdd: SIXMWT2.POSTBORG / Post-Walk Borg Dysp Rating) (panther_ipfcdd: SIXMWT2.POSTBORG / Post-Walk Borg Dysp Rating)
Walk details		
8.	Pre-walk Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHRPW / Pre-Walk Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHRPW / Pre-Walk Heart Rate)
9.*	1 minute Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR1 / 1 Minute Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR1 / 1 Minute Heart Rate)
10.*	1 minute SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSP021 / 1 Minute SpO2) (panther_ipfcdd: SIXMWT2.WLKSP021 / 1 Minute SpO2)
11.*	2 minute Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR2 / 2 Minute Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR2 / 2 Minute Heart Rate)
12.*	2 minute SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSP022 / 2 Minute SpO2) (panther_ipfcdd: SIXMWT2.WLKSP022 / 2 Minute SpO2)
13.*	3 minute Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR3 / 3 Minute Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR3 / 3 Minute Heart Rate)
14.*	3 minute SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSP023 / 3 Minute SpO2) (panther_ipfcdd: SIXMWT2.WLKSP023 / 3 Minute SpO2)
15.*	4 minute Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR4 / 4 Minute Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR4 / 4 Minute Heart Rate)
16.*	4 minute SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSP024 / 4 Minute SpO2)

		(panther_ipfcdd: SIXMWT2.WLKSP024 / 4 Minute SpO2)
17.*	5 minute Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR5 / 5 Minute Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR5 / 5 Minute Heart Rate)
18.*	5 minute SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSP025 / 5 Minute SpO2) (panther_ipfcdd: SIXMWT2.WLKSP025 / 5 Minute SpO2)
19.*	6 minute Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR6 / 6 Minute Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR6 / 6 Minute Heart Rate)
20.*	6 minute SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSP026 / 6 Minute SpO2) (panther_ipfcdd: SIXMWT2.WLKSP026 / 6 Minute SpO2)
Post Walk recovery details		
21.*	1 minute recovery Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR1P / 1 Minute Post Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR1P / 1 Minute Post Heart Rate)
22.*	1 minute recovery SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSO1P / 1 Minute Post SpO2) (panther_ipfcdd: SIXMWT2.WLKSO1P / 1 Minute Post SpO2)
23.*	2 minute recovery Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR2P / 2 Minute Post Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR2P / 2 Minute Post Heart Rate)
24.*	2 minute recovery SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSO2P / 2 Minute Post SpO2) (panther_ipfcdd: SIXMWT2.WLKSO2P / 2 Minute Post SpO2)
25.*	3 minute recovery Heart Rate	xxx bpm (ace_ipfcdd: SIXMWT2.WLKHR3P / 3 Minute Post Heart Rate) (panther_ipfcdd: SIXMWT2.WLKHR3P / 3 Minute Post Heart Rate)
26.*	3 minute recovery SpO2	xxxxxxxx. % (ace_ipfcdd: SIXMWT2.WLKSO3P / 3 Minute Post SpO2) (panther_ipfcdd: SIXMWT2.WLKSO3P / 3 Minute Post SpO2)
27.*	Source Document Verification Completion	(ace_ipfcdd: SIXMWT2.SDVSTAT / SDV Complete) (panther_ipfcdd: 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		

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	

Column Name	Column Data Type	Design Note
SUPPLOXY	NUMERIC	
SUPO2	FLOAT - F9.0	
SUPSP02	FLOAT - F9.0	
WALKAID	NUMERIC	
TYPEAID	NUMERIC	
AIDSP	STRING(50) - A50	
COMPLWLK	NUMERIC	
WLKMIN	NUMERIC - N2	
WLKSEC	STRING(2) - A2	
STOPREA	NUMERIC	
STPOTHSP	STRING(50) - A50	
DESATURA	NUMERIC	

DESATMIN	NUMERIC - N2	
DESATSEC	NUMERIC - N2	
DESATDIS	FLOAT - F9.0	
LOWSP02	FLOAT - F9.0	
DISTANCE	FLOAT - F9.0	
POSTBORG	NUMERIC - 0, 11, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 97	
WLKHRPW	NUMERIC - N3	
WLKHR1	NUMERIC - N3	
WLKSPO21	FLOAT - F9.0	
WLKHR2	NUMERIC - N3	
WLKSPO22	FLOAT - F9.0	
WLKHR3	NUMERIC - N3	
WLKSPO23	FLOAT - F9.0	
WLKHR4	NUMERIC - N3	
WLKSPO24	FLOAT - F9.0	
WLKHR5	NUMERIC - N3	
WLKSPO25	FLOAT - F9.0	
WLKHR6	NUMERIC - N3	
WLKSPO26	FLOAT - F9.0	
WLKHR1P	NUMERIC - N3	
WLKS01P	FLOAT - F9.0	
WLKHR2P	NUMERIC - N3	
WLKS02P	FLOAT - F9.0	
WLKHR3P	NUMERIC - N3	
WLKS03P	FLOAT - F9.0	
SDVSTAT	NUMERIC	

CDD: panther_ipfcdd Table: SIXMWT2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SUPPLOXY	NUMERIC	
SUPO2	FLOAT - F9.0	
SUPSP02	FLOAT - F9.0	
WALKAID	NUMERIC	
TYPEAID	NUMERIC	
STPOTHSP	STRING(50) - A50	
AIDSP	STRING(50) - A50	
COMPLWLK	NUMERIC	
DESATSEC	NUMERIC - N2	
DISTANCE	FLOAT - F9.0	
WLKMIN	NUMERIC - N2	
DESATURA	NUMERIC	
WLKSEC	STRING(2) - A2	
POSTBORG	NUMERIC - 0, 11, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 97	
STOPREA	NUMERIC	
WLKSPO21	FLOAT - F9.0	
WLKSPO23	FLOAT - F9.0	
WLKHRPW	NUMERIC - N3	
DESATMIN	NUMERIC - N2	
WLKHR4	NUMERIC - N3	
WLKSPO24	FLOAT - F9.0	
DESATDIS	FLOAT - F9.0	
WLKSPO25	FLOAT - F9.0	
WLKHR2	NUMERIC - N3	
WLKSPO22	FLOAT - F9.0	
WLKSPO26	FLOAT - F9.0	
LOWSP02	FLOAT - F9.0	

WLKHR6	NUMERIC - N3	
WLKHR3P	NUMERIC - N3	
WLKSO3P	FLOAT - F9.0	
WLKHR1	NUMERIC - N3	
SDVSTAT	NUMERIC	
WLKHR3	NUMERIC - N3	
WLKHR1P	NUMERIC - N3	
WLKHR5	NUMERIC - N3	
WLKSO1P	FLOAT - F9.0	
WLKHR2P	NUMERIC - N3	
WLKSO2P	FLOAT - F9.0	

ace_ipf : Log Review (REVIEWS)		
Clinical Review		
1.	Has the subject taken any medications in the past 30 days?	(ace_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?	(ace_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?	(ace_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?	(ace_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 SGRQ?	(ace_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?	(ace_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?	(ace_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	(ace_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	
RVWAE	NUMERIC	
RVWSLP	NUMERIC	
RVWEURO	NUMERIC	
RVWICE	NUMERIC	
RVWUCSD	NUMERIC	
RVWSGRQ	NUMERIC	
RVWSF36	NUMERIC	
SDVSTAT	NUMERIC	
RVWCM1	NUMERIC	
RVWEURO1	NUMERIC	
RVWICE1	NUMERIC	
RVWUCSD1	NUMERIC	
RVWSGRQ1	NUMERIC	
RVWSF36A	NUMERIC	
RVWGNDR	NUMERIC	
SDVSTAT1	NUMERIC	
RVXAE	NUMERIC	
RVXCM	NUMERIC	
RVXGERD	NUMERIC	

RVXINPT	NUMERIC	
RVXSLP	NUMERIC	
SDVSTAT2	NUMERIC	

ace_ipf : Intial Study Drug Dosing (INITSDRG)	
Warfarin Initial Study Drug Dosing	
1.	<p>Did the subject start Warfarin/placebo?</p> <p>(ace_ipfcdd: INITSDRG.INIWAR / Warfarin Started) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>Warfarin/placebo Start Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: INITSDRG.INTWARDT / Warfarin Start Date) Warfarin/placebo daily dose (mg) (ace_ipfcdd: INITSDRG.INTWARDS / Warfarin Dose) xxxxxxxx.</p>
2.*	<p>Source Document Verification Completion</p> <p>(ace_ipfcdd: INITSDRG.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable</p>
* Item is not required	

CDD: ace_ipfcdd	Table: INITSDRG	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
INIWAR	NUMERIC	
INTWARDT	DATE - DDMONYYYY	
INTWARDS	FLOAT - F9.0	
SDVSTAT	NUMERIC	

ace_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 (ace_ipfcdd:GENDERSS.PERIOD / Menstruation Age)
2.* Have you reached menopause?	(ace_ipfcdd:GENDERSS.MENOPAUS / Menopause) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:GENDERSS.MENOAGE / Menopause Age) If yes, at what age did that occur? xxxx.
3.* Did you ever use oral contraceptive medications?	(ace_ipfcdd:GENDERSS.NOPREG / Oral Contraceptives) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:GENDERSS.NOPREGYS / Contraceptive Years) If yes, for how many years? xxxx.
4.* Did you ever use hormone replacement therapy?	(ace_ipfcdd:GENDERSS.HRT / HRT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:GENDERSS.HRTYRS / HRT Years) If yes, for how many years? xxxx.
5.* Have you ever been pregnant (include miscarriages, abortions)?	(ace_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? (ace_ipfcdd:GENDERSS.PRGNAGE / Age First Pregnancy) xxxx. How many times have you been pregnant? (ace_ipfcdd:GENDERSS.PREGNUMB / Number of Pregnancies) xxx (ace_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 (ace_ipfcdd:GENDERSS.BRESFEED / Breastfeed) Did you ever breastfeed? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:GENDERSS.BRFEEDNO / Breastfeed Months) If yes, for approximately how many total months did you breastfeed (total for all children)? xxx
6.* Have you ever had an ovary removed?	(ace_ipfcdd:GENDERSS.OVREM / Ovary Removed) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_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? (ace_ipfcdd:GENDERSS.OVAGE / Age Ovary Removed) xxxx.
7.* Source Document Verification Completion	(ace_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: ace_ipfcdd Table: GENDERSS Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PERIOD	FLOAT - F5.0	
MENOPAUS	NUMERIC	
MENOAGE	FLOAT - F5.0	
NOPREG	NUMERIC	
NOPREGYS	FLOAT - F5.0	
HRT	NUMERIC	
HRTYRS	FLOAT - F5.0	
PREGNANT	NUMERIC	
PRGNAGE	FLOAT - F5.0	

PREGNUMB	NUMERIC - N3	
BABYGEND	NUMERIC	
BRESFEED	NUMERIC	
BRFEEDNO	NUMERIC - N3	
OVREM	NUMERIC	
OVNUM	NUMERIC	
OVAGE	FLOAT - F5.0	
SDVSTAT	NUMERIC	

ace_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	(ace_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	(ace_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):	(ace_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	(ace_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	(ace_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 (ace_ipfcdd:EUROQOL.EURTHERM / EuroQol Thermometer)
7.*	Source Document Verification Completion	(ace_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		

Column Name	Column Data Type	Design Note
EQMOB	NUMERIC	
EQSC	NUMERIC	
EQUA	NUMERIC	
EQPAIN	NUMERIC	
EQANX	NUMERIC	
EURTHERM	NUMERIC - N11	
SDVSTAT	NUMERIC	
EQILLYOU	NUMERIC	
EQILLFAM	NUMERIC	
EQILLOTH	NUMERIC	
EQAGE	FLOAT	
EQGENDR	NUMERIC	
EQSMK	NUMERIC	
EQWKHL	NUMERIC	
EQWKHLS	STRING(100)	
EQACT	NUMERIC	
EQACTSP	STRING(100)	
EQEDU	NUMERIC	
EQZIP	NUMERIC	
SDVSTAT1	NUMERIC	

ace_ipf : EUROQOL Questionnaire Part2 (EUROQOL2)		
EUROQOL2		
1.*	Have you experienced serious illness	(ace_ipfcdd:EUROQOL.EQILLYOU / Illness in yourself) in you yourself? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:EUROQOL.EQILLFAM / Illness in Family) in your family? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_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. (ace_ipfcdd:EUROQOL.EQAGE / Age)
3.*	Are you	(ace_ipfcdd:EUROQOL.EQGENDR / Gender) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
4.*	Are you	(ace_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?	(ace_ipfcdd:EUROQOL.EQWKHL / Healthcare Work) [0] <input type="radio"/> No [1] <input type="radio"/> Yes - If Yes: In what capacity? <input type="text" value="A100"/> (ace_ipfcdd:EUROQOL.EQWKHLSP / Healthcare Work, Specify)
6.*	Which of the following best describes your main activity?	(ace_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): <input type="text" value="A100"/> (ace_ipfcdd:EUROQOL.EQACTSP / Main Activity, Specify)
7.*	What is the highest level of education you have completed?	(ace_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:	xxxxxxxxxxxx (ace_ipfcdd:EUROQOL.EQZIP / Zip Code)
9.*	Source Document Verification Completion	(ace_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: ace_ipfcdd	Table: EUROQOL	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
EQMOB	NUMERIC	
EQSC	NUMERIC	
EQUA	NUMERIC	
EQPAIN	NUMERIC	
EQANX	NUMERIC	
EURTHERM	NUMERIC - N11	
SDVSTAT	NUMERIC	
EQILLYOU	NUMERIC	
EQILLFAM	NUMERIC	
EQILLOTH	NUMERIC	
EQAGE	FLOAT - F16.0	
EQGENDR	NUMERIC	
EQSMK	NUMERIC	
EQWKHL	NUMERIC	
EQWKHLSP	STRING(100) - A100	
EQACT	NUMERIC	
EQACTSP	STRING(100) - A100	
EQEDU	NUMERIC	
EQZIP	NUMERIC - N11	
SDVSTAT1	NUMERIC	

ace_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	(ace_ipfcdd: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	(ace_ipfcdd: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	(ace_ipfcdd: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	(ace_ipfcdd: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	(ace_ipfcdd: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	(ace_ipfcdd: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: ace_ipfcdd	Table: ICECAP	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ICELOVE	NUMERIC	
ICEFUTR	NUMERIC	
ICEVALUE	NUMERIC	
ICEENJOY	NUMERIC	
ICEINDEP	NUMERIC	
SDVSTAT	NUMERIC	

ace_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"/> (ace_ipfcdd:UCSDSOB.UCSD1 / At Rest)
2.*	Walking on a level at your own pace	Pulldown List 2 <input type="button" value="v"/> (ace_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"/> (ace_ipfcdd:UCSDSOB.UCSD3 / Walk Level Others Your Age)
4.*	Walking up a hill	Pulldown List 4 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD4 / Walking Up a Hill)
5.*	Walking up stairs	Pulldown List 5 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD5 / Walking Up Stairs)
6.*	While eating	Pulldown List 6 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD6 / While Eating)
7.*	Standing up from a chair	Pulldown List 7 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD7 / Standing Up from a Chair)
8.*	Brushing teeth	Pulldown List 8 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD8 / Brushing Teeth)
9.*	Shaving and/or brushing hair	Pulldown List 9 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD9 / Shaving and/or Brush Hair)
10.*	Showering/bathing	Pulldown List 10 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD10 / Showering/Bathing)
11.*	Dressing	Pulldown List 11 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD11 / Dressing)
12.*	Picking up and straightening	Pulldown List 12 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD12 / Pick up and Straightening)
* 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	

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

ace_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"/> (ace_ipfcdd:UCSDSOB.UCSD13 / Doing Dishes)
2.*	Sweeping/vacuuming	Pulldown List 2 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD14 / Sweeping/Vacuuming)
3.*	Making bed	Pulldown List 3 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD15 / Making Bed)
4.*	Shopping	Pulldown List 4 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD16 / Shopping)
5.*	Doing laundry	Pulldown List 5 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD17 / Doing Laundry)
6.*	Washing car	Pulldown List 6 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD18 / Washing Car)
7.*	Mowing lawn	Pulldown List 7 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD19 / Mowing Lawn)
8.*	Watering lawn	Pulldown List 8 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD20 / Watering Lawn)
9.*	Sexual activities	Pulldown List 9 <input type="button" value="v"/> (ace_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"/> (ace_ipfcdd:UCSDSOB.UCSD22 / Shortness of Breath)
11.*	Fear of hurting myself	Pulldown List 11 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD23 / Fear of Hurting Myself)
12.*	Fear of shortness of breath	Pulldown List 12 <input type="button" value="v"/> (ace_ipfcdd:UCSDSOB.UCSD24 / Fear of Shortness of Breath)
13.*	Source Document Verification Completion	(ace_ipfcdd:UCSDSOB.SDVSTAT / SDV Complete) <input type="radio"/> Complete <input type="radio"/> Partially Complete <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	

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

ace_ipf : St. Georges Part 1 (STGRG1)	
<p>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.</p>	
1.*	<p>Before completing the questionnaire: Please check one box to show how you describe your current health:</p> <p>(ace_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.*	<p>Source Document Verification Completion</p> <p>(ace_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	

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

ace_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:	(ace_ipfcdd:STGRG1.STG01A / Coughed Every Day) [1] <input type="checkbox"/> Almost Every Day (ace_ipfcdd:STGRG1.STG01B / Coughed Several Days) [2] <input type="checkbox"/> Several Days a Week (ace_ipfcdd:STGRG1.STG01C / Coughed a Few Days) [3] <input type="checkbox"/> A Few Days a Month (ace_ipfcdd:STGRG1.STG01D / Coughed with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (ace_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):	(ace_ipfcdd:STGRG1.STG02A / Phlegm Every Day) [1] <input type="checkbox"/> Almost Every Day (ace_ipfcdd:STGRG1.STG02B / Phlegm Several Days) [2] <input type="checkbox"/> Several Days a Week (ace_ipfcdd:STGRG1.STG02C / Phlegm a Few Days) [3] <input type="checkbox"/> A Few Days a Month (ace_ipfcdd:STGRG1.STG02D / Phlegm with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (ace_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:	(ace_ipfcdd:STGRG1.STG03A / SOB Every Day) [1] <input type="checkbox"/> Almost Every Day (ace_ipfcdd:STGRG1.STG03B / SOB Several Days) [2] <input type="checkbox"/> Several Days a Week (ace_ipfcdd:STGRG1.STG03C / SOB a Few Days) [3] <input type="checkbox"/> A Few Days a Month (ace_ipfcdd:STGRG1.STG03D / SOB with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (ace_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:	(ace_ipfcdd:STGRG1.STG04A / Wheezing Every Day) [1] <input type="checkbox"/> Almost Every Day (ace_ipfcdd:STGRG1.STG04B / Wheezing Several Days) [2] <input type="checkbox"/> Several Days a Week (ace_ipfcdd:STGRG1.STG04C / Wheezing a Few Days) [3] <input type="checkbox"/> A Few Days a Month (ace_ipfcdd:STGRG1.STG04D / Wheeze with Resp Infection) [4] <input type="checkbox"/> Only with Respiratory Infections (ace_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?	(ace_ipfcdd:STGRG1.STG5A / Respiratory Attack 3+) [1] <input type="checkbox"/> More than 3 times (ace_ipfcdd:STGRG1.STG5B / Respiratory Attack 3 Times) [1] <input type="checkbox"/> 3 times (ace_ipfcdd:STGRG1.STG5C / Respiratory Attack 2 Times) [1] <input type="checkbox"/> 2 times (ace_ipfcdd:STGRG1.STG5D / Respiratory Attack 1 Times) [1] <input type="checkbox"/> 1 time (ace_ipfcdd:STGRG1.STG5E / No Respiratory Attacks) [1] <input type="checkbox"/> None of the time
6.* How long did the worst respiratory attack last?	(ace_ipfcdd:STGRG1.STG6A / Respiratory Attack 1 Week) [1] <input type="checkbox"/> A week or more (ace_ipfcdd:STGRG1.STG6B / Respiratory Attack 3+ Days) [1] <input type="checkbox"/> 3 or more days (ace_ipfcdd:STGRG1.STG6C / Respiratory Attack 1-2 Days) [1] <input type="checkbox"/> 1 or 2 days (ace_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?	(ace_ipfcdd:STGRG1.STG7A / No Good Days) [1] <input type="checkbox"/> No good days (ace_ipfcdd:STGRG1.STG7B / One to Two Good Days) [1] <input type="checkbox"/> 1 or 2 good days (ace_ipfcdd:STGRG1.STG7C / Three to Four Good Days) [1] <input type="checkbox"/> 3 or 4 good days (ace_ipfcdd:STGRG1.STG7D / Nearly Every Day Good) [1] <input type="checkbox"/> Nearly everyday was good (ace_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?	(ace_ipfcdd:STGRG1.STG8 / Wheeze in Morning) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

9.* Source Document Verification Completion

(ace_ipfcdd: STGRG1.SDVSTAT1 / SDV Complete)

[1] Complete[2] Partially Complete[3] Not Applicable

* Item is not required

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

ace_ipf : St. Georges Part 3 (STGRG3)		
Section 1		
1.*	How would you describe your respiratory condition?	(ace_ipfcdd:STGRG2.STG9A / Most Important Problem) [1] <input type="checkbox"/> The most important problem I have (ace_ipfcdd:STGRG2.STG9B / Quite a lot of Problems) [1] <input type="checkbox"/> Causes me quite a lot of problems (ace_ipfcdd:STGRG2.STG9C / Few Problems) [1] <input type="checkbox"/> Causes me a few problems (ace_ipfcdd:STGRG2.STG9D / No Problems) [1] <input type="checkbox"/> Causes me no problems
2.*	If you have ever held a job	(ace_ipfcdd:STGRG2.STG10A / Stop Working) [1] <input type="checkbox"/> My respiratory problems made me stop working altogether (ace_ipfcdd:STGRG2.STG10B / Interfere or Change Job) [1] <input type="checkbox"/> My respiratory problems interfere with my job or made me change my job (ace_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	(ace_ipfcdd:STGRG2.STG11A / Sitting Still) [1] <input type="radio"/> True [0] <input type="radio"/> False
4.*	Washing or dressing yourself	(ace_ipfcdd:STGRG2.STG11B / Walking or Dressing) [1] <input type="radio"/> True [0] <input type="radio"/> False
5.*	Walking around the house	(ace_ipfcdd:STGRG2.STG11C / Walking around House) [1] <input type="radio"/> True [0] <input type="radio"/> False
6.*	Walking outside on a level ground	(ace_ipfcdd:STGRG2.STG11D / Walking Level Ground) [1] <input type="radio"/> True [0] <input type="radio"/> False
7.*	Walking up a flight of stairs	(ace_ipfcdd:STGRG2.STG11E / Walking Flight Stairs) [1] <input type="radio"/> True [0] <input type="radio"/> False
8.*	Walking up hills	(ace_ipfcdd:STGRG2.STG11F / Walking Up Hills) [1] <input type="radio"/> True [0] <input type="radio"/> False
9.*	Playing sports or other physical activities	(ace_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	(ace_ipfcdd:STGRG2.STG12A / Coughing Hurts) [1] <input type="radio"/> True [0] <input type="radio"/> False
11.*	Coughing makes me tired	(ace_ipfcdd:STGRG2.STG12B / Coughing Tired) [1] <input type="radio"/> True [0] <input type="radio"/> False
12.*	I am short of breath when I talk	(ace_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	(ace_ipfcdd:STGRG2.STG12D / SOB Bending Over) [1] <input type="radio"/> True [0] <input type="radio"/> False
14.*	My coughing or breathing disturbs my sleep	(ace_ipfcdd:STGRG2.STG12E / Disturbs my Sleep) [1] <input type="radio"/> True [0] <input type="radio"/> False
15.*	I get exhausted easily	(ace_ipfcdd:STGRG2.STG12F / Exhausted Easily) [1] <input type="radio"/> True [0] <input type="radio"/> False
16.*	Source Document Verification Completion	(ace_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		

CDD: ace_ipfcdd	Table: STGRG2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
STG11G	NUMERIC	
STG12A	NUMERIC	
STG12B	NUMERIC	
STG12C	NUMERIC	
STG12D	NUMERIC	
STG12E	NUMERIC	
STG12F	NUMERIC	
SDVSTAT	NUMERIC	

STG13A	NUMERIC	
STG13B	NUMERIC	
STG13C	NUMERIC	
STG13D	NUMERIC	
STG13E	NUMERIC	
STG13F	NUMERIC	
STG13G	NUMERIC	
STG13H	NUMERIC	
STG14A	NUMERIC	
STG14B	NUMERIC	
STG14C	NUMERIC	
STG14D	NUMERIC	
SDVSTAT1	NUMERIC	
STG9A	NUMERIC	
STG9B	NUMERIC	
STG9C	NUMERIC	
STG9D	NUMERIC	
STG10A	NUMERIC	
STG10B	NUMERIC	
STG10C	NUMERIC	
STG11A	NUMERIC	
STG11B	NUMERIC	
STG11C	NUMERIC	
STG11D	NUMERIC	
STG11E	NUMERIC	
STG11F	NUMERIC	

ace_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	(ace_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	(ace_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	(ace_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	(ace_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	(ace_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	(ace_ipfcdd:STGRG2.STG13F / Frail) [1] <input type="radio"/> True [2] <input type="radio"/> False
7.*	Exercise is not safe for me	(ace_ipfcdd:STGRG2.STG13G / Exercise not Safe) [1] <input type="radio"/> True [2] <input type="radio"/> False
8.*	Everything seems too much of an effort	(ace_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	(ace_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	(ace_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	(ace_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	(ace_ipfcdd:STGRG2.STG14D / Treatment Interferes) [1] <input type="radio"/> True [2] <input type="radio"/> False
13.*	Source Document Verification Completion	(ace_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		

CDD: ace_ipfcdd	Table: STGRG2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
STG11G	NUMERIC	
STG12A	NUMERIC	
STG12B	NUMERIC	
STG12C	NUMERIC	
STG12D	NUMERIC	
STG12E	NUMERIC	
STG12F	NUMERIC	
SDVSTAT	NUMERIC	
STG13A	NUMERIC	
STG13B	NUMERIC	
STG13C	NUMERIC	
STG13D	NUMERIC	
STG13E	NUMERIC	
STG13F	NUMERIC	
STG13G	NUMERIC	
STG13H	NUMERIC	
STG14A	NUMERIC	
STG14B	NUMERIC	
STG14C	NUMERIC	
STG14D	NUMERIC	
SDVSTAT1	NUMERIC	
STG9A	NUMERIC	

STG9B	NUMERIC	
STG9C	NUMERIC	
STG9D	NUMERIC	
STG10A	NUMERIC	
STG10B	NUMERIC	
STG10C	NUMERIC	
STG11A	NUMERIC	
STG11B	NUMERIC	
STG11C	NUMERIC	
STG11D	NUMERIC	
STG11E	NUMERIC	
STG11F	NUMERIC	

ace_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	(ace_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	(ace_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	(ace_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	(ace_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	(ace_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	(ace_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	(ace_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	(ace_ipfcdd:STGRG3.STG15H / Cary 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	(ace_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	(ace_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	(ace_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	(ace_ipfcdd:STGRG3.STG16C / Cannot go Shopping) [1] <input type="radio"/> True [0] <input type="radio"/> False
13.*	I cannot do household chores	(ace_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	(ace_ipfcdd:STGRG3.STG16E / Cannot Move) [1] <input type="radio"/> True [0] <input type="radio"/> False
15.*	Source Document Verification Completion	(ace_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		

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

STG15D	NUMERIC	
STG15E	NUMERIC	
STG15F	NUMERIC	

ace_ipf : St. Georges Part 6 (STGRG6)		
<p>Here is a list of other activities that your respiratory problems may prevent you from doing.</p> <p><u>Going for walks or walking the dog</u></p> <p><u>Doing activities or chores at home or in the garden</u></p> <p><u>Sexual intercourse</u></p> <p><u>Going to a place of worship, or a place of entertainment</u></p> <p><u>Going out in bad weather or into smoky rooms</u></p> <p><u>Visiting family or friends or playing with children</u></p>		
1.*	Please write in any other important activities that your respiratory problems may stop you from doing:	A255 (ace_ipfcdd:STGRG3.STGLIST / Important Activities, Spec)
2.*	Now please check the one that you think best describes how your respiratory problems affect you:	(ace_ipfcdd:STGRG3.STG17A / Problems do not Stop Me) [1] <input type="checkbox"/> It does not stop me from doing anything I would like to do (ace_ipfcdd:STGRG3.STG17B / Problems Affect 1-2 Things) [2] <input type="checkbox"/> It stops me from doing one or two things I would like to do (ace_ipfcdd:STGRG3.STG17C / Problems Affect Most Things) [3] <input type="checkbox"/> It stops me from doing most of the things I would like to do (ace_ipfcdd:STGRG3.STG17D / Problems Affect Everything) [4] <input type="checkbox"/> It stops me from doing everything I would like to do
3.*	Source Document Verification Completion	(ace_ipfcdd:STGRG3.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: ace_ipfcdd	Table: STGRG3	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
STG15A	NUMERIC	
STG15G	NUMERIC	
STG15H	NUMERIC	
STG15I	NUMERIC	
STG16A	NUMERIC	
STG16B	NUMERIC	
STG16C	NUMERIC	
STG16D	NUMERIC	
STG16E	NUMERIC	
SDVSTAT	NUMERIC	
STGLIST	STRING(255) - A255	
STG17A	NUMERIC	
STG17B	NUMERIC	
STG17C	NUMERIC	
STG17D	NUMERIC	
SDVSTAT1	NUMERIC	
STG15B	NUMERIC	
STG15C	NUMERIC	
STG15D	NUMERIC	
STG15E	NUMERIC	
STG15F	NUMERIC	

ace_ipf : SF36 Assessment Part 1 (SF36_1)	
Assessment	
1.*	In general, would you say your health is: Pulldown List 1 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF1 / General Health)
2.*	Compared to one year ago, how would you rate your health in general now? Pulldown List 2 <input type="button" value="v"/> (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 (ace_ipfcdd: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 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF4A / Physical - Amount of Time)
14.*	Accomplished less than you would like Pulldown List 4 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF4B / Physical - Accomplish Less)
15.*	Were limited in the kind of work or other activities Pulldown List 5 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF4C / Physical - Limited Work)
16.*	Had difficulty performing the work or other activities (for example, it took extra effort) Pulldown List 6 <input type="button" value="v"/> (ace_ipfcdd: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 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF5A / Emotional - Amount of Time)
18.*	Accomplished less than you would like Pulldown List 8 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF5B / Emotional - Accomplish Less)
19.*	Did work or other activities less carefully than usual Pulldown List 9 <input type="button" value="v"/> (ace_ipfcdd:SF36.SF5C / Emotional - Limited Work)
20.*	Source Document Verification Completion (ace_ipfcdd: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
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 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: ace_ipfcdd	Table: SF36	Key Type: PATIENTVISIT
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Column Name	Column Data Type	Design Note
SF7	NUMERIC	
SF8	NUMERIC	
SF9A	NUMERIC	
SF9B	NUMERIC	
SF9C	NUMERIC	
SF9D	NUMERIC	
SF9E	NUMERIC	
SF9F	NUMERIC	
SF9G	NUMERIC	
SF9H	NUMERIC	
SF9I	NUMERIC	
SF10	NUMERIC	
SF11A	NUMERIC	
SF11B	NUMERIC	
SF11C	NUMERIC	
SF11D	NUMERIC	
SF6	NUMERIC	
SDVSTAT	NUMERIC	
SDVSTAT1	NUMERIC	
SF38	NUMERIC	
SF39	NUMERIC	
SF4A	NUMERIC - 1, 2, 3, 4, 5	
SF4B	NUMERIC - 1, 2, 3, 4, 5	
SF4C	NUMERIC - 1, 2, 3, 4, 5	
SF4D	NUMERIC - 1, 2, 3, 4, 5	
SF5A	NUMERIC - 1, 2, 3, 4, 5	
SF5B	NUMERIC - 1, 2, 3, 4, 5	
SF5C	NUMERIC - 1, 2, 3, 4, 5	
SF33	NUMERIC	
SF34	NUMERIC	
SF35	NUMERIC	
SF36	NUMERIC	
SF37	NUMERIC	
SF1	NUMERIC - 1, 2, 3, 4, 5	
SF2	NUMERIC - 1, 2, 3, 4, 5	
SF3A	NUMERIC	
SF31	NUMERIC	
SF32	NUMERIC	

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: ace_ipfcdd Table: SF36 Key Type: PATIENTVISIT			
Column Name	Column Data Type		Design Note
SF7	NUMERIC - 1, 2, 3, 4, 5, 6		

SF8	NUMERIC - 1, 2, 3, 4, 5	
SF9A	NUMERIC - 1, 2, 3, 4, 5	
SF9B	NUMERIC - 1, 2, 3, 4, 5	
SF9C	NUMERIC - 1, 2, 3, 4, 5	
SF9D	NUMERIC - 1, 2, 3, 4, 5	
SF9E	NUMERIC - 1, 2, 3, 4, 5	
SF9F	NUMERIC - 1, 2, 3, 4, 5	
SF9G	NUMERIC - 1, 2, 3, 4, 5	
SF9H	NUMERIC - 1, 2, 3, 4, 5	
SF9I	NUMERIC - 1, 2, 3, 4, 5	
SF10	NUMERIC - 1, 2, 3, 4, 5	
SF11A	NUMERIC - 1, 2, 3, 4, 5	
SF11B	NUMERIC - 1, 2, 3, 4, 5	
SF11C	NUMERIC - 1, 2, 3, 4, 5	
SF11D	NUMERIC - 1, 2, 3, 4, 5	
SF6	NUMERIC - 1, 2, 3, 4, 5	
SDVSTAT	NUMERIC	
SDVSTAT1	NUMERIC	
SF38	NUMERIC	
SF39	NUMERIC	
SF4A	NUMERIC - 1, 2, 3, 4, 5	
SF4B	NUMERIC - 1, 2, 3, 4, 5	
SF4C	NUMERIC - 1, 2, 3, 4, 5	
SF4D	NUMERIC - 1, 2, 3, 4, 5	
SF5A	NUMERIC - 1, 2, 3, 4, 5	
SF5B	NUMERIC - 1, 2, 3, 4, 5	
SF5C	NUMERIC - 1, 2, 3, 4, 5	
SF33	NUMERIC	
SF34	NUMERIC	
SF35	NUMERIC	
SF36	NUMERIC	
SF37	NUMERIC	
SF1	NUMERIC - 1, 2, 3, 4, 5	
SF2	NUMERIC - 1, 2, 3, 4, 5	
SF3A	NUMERIC	
SF31	NUMERIC	
SF32	NUMERIC	

ace_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?	(ace_ipfcdd:REVIEW.RVXAE) [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?	(ace_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?	(ace_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?	(ace_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?	(ace_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.* Source Document Verification Completion	(ace_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: ace_ipfcdd Table: REVIEW Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RVWCM	NUMERIC	
RVWINPT	NUMERIC	
RVWGERD	NUMERIC	
RVWAE	NUMERIC	
RVWSLP	NUMERIC	
RVWEURO	NUMERIC	
RVWICE	NUMERIC	
RVWUCSD	NUMERIC	
RVWSGRO	NUMERIC	
RVWSF36	NUMERIC	
SDVSTAT	NUMERIC	
RVWCM1	NUMERIC	
RVWEURO1	NUMERIC	
RVWICE1	NUMERIC	
RVWUCSD1	NUMERIC	
RVWSGRO1	NUMERIC	
RVWSF36A	NUMERIC	
RVWGNDR	NUMERIC	
SDVSTAT1	NUMERIC	
RVXAE	NUMERIC	
RVXCM	NUMERIC	
RVXGERD	NUMERIC	
RVXINPT	NUMERIC	
RVXSLP	NUMERIC	
SDVSTAT2	NUMERIC	

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

CDD: ace_ipfcdd	Table: OUTPT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
OUTVISIT	NUMERIC	
PULVISIT	NUMERIC	
PULRSP	NUMERIC - N3	
PULNORSP	NUMERIC - N3	
CARVISIT	NUMERIC	
CARRSP	NUMERIC - N3	
CARNORSP	NUMERIC - N3	
OSPVISIT	NUMERIC	
OSPSPEC	STRING(50) - A50	
OSPRSP	NUMERIC - N3	
OSPNORSP	NUMERIC - N3	
PRMVISIT	NUMERIC	
PRMRSP	NUMERIC - N3	
PRMNORSP	NUMERIC - N3	
OPTVISIT	NUMERIC	

OPTRSP	NUMERIC - N3	
OPTNORSP	NUMERIC - N3	
MENVISIT	NUMERIC	
MENRSP	NUMERIC - N3	
MENNORSP	NUMERIC - N3	
OTHVISIT	NUMERIC	
OTHSPEC	STRING(50) - A50	
OTHRSP	NUMERIC - N3	
OTHNORSP	NUMERIC - N3	
SDVSTAT	NUMERIC	

ace_ipf : FVC Confirmation (FVC)		
.		
1.	Was a FVC confirmation visit performed?	(ace_ipfccdd:FVC.DISFVCRD / Confirmation Performed) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date of visit to confirm FVC: Req / Req / Req (2009-2016) (ace_ipfccdd:FVC.DISFVCDT / Date of FVC Confirmation) FVC in liters: xxxxxxx. (ace_ipfccdd:FVC.DISFVC / FVC in Liters) (ace_ipfccdd:FVC.DISFVCYN / 10% Drop Confirmed) Is a 10% FVC drop confirmed? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfccdd: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:	xxxxxxx. % (ace_ipfccdd:FVC.DISCAL / FVC Diff from Baseline)
3.*	Source Document Verification Completion	(ace_ipfccdd: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		

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

ace_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?	(ace_ipfcdd:REVIEW.RVWAE / Adverse Events) [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?	(ace_ipfcdd:REVIEW.RVWCM / Change in Medications) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, record on Concomitant 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?	(ace_ipfcdd: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?	(ace_ipfcdd: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?	(ace_ipfcdd: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 complete the EuroQoL?	(ace_ipfcdd:REVIEW.RVWEURO / EuroQoL 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 ICECAP?	(ace_ipfcdd:REVIEW.RVWICE / ICECAP 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 UCSD_SOBQ?	(ace_ipfcdd: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
9.	Did the subject complete the SGRQ?	(ace_ipfcdd:REVIEW.RVWSGRQ / SRGQ 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 SF-36?	(ace_ipfcdd: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
11.*	Source Document Verification Completion	(ace_ipfcdd: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: ace_ipfcdd Table: REVIEW Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RVWCM	NUMERIC	
RVWINPT	NUMERIC	
RVWGERD	NUMERIC	
RVWAE	NUMERIC	
RVWSLP	NUMERIC	
RVWEURO	NUMERIC	
RVWICE	NUMERIC	
RVWUCSD	NUMERIC	
RVWSGRQ	NUMERIC	
RVWSF36	NUMERIC	

SDVSTAT	NUMERIC	
RVWCM1	NUMERIC	
RVWEURO1	NUMERIC	
RVWICE1	NUMERIC	
RVWUCSD1	NUMERIC	
RVWSGRO1	NUMERIC	
RVWSF36A	NUMERIC	
RVWGNDR	NUMERIC	
SDVSTAT1	NUMERIC	
RVXAE	NUMERIC	
RVXCM	NUMERIC	
RVXGERD	NUMERIC	
RVXINPT	NUMERIC	
RVXSLP	NUMERIC	
SDVSTAT2	NUMERIC	

ace_ipf : Study Completion/Termination (TERM)	
Study Completion/Termination	
1. Did the subject terminate the study prior to week 144 or the common study end date?	(ace_ipfcdd: TERM.TERMCOMP / Terminate Early) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Date of study termination: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd: TERM.TERMDT / Termination Date) (ace_ipfcdd: TERM.TERMREA / Termination Reason) If Yes: Reason for early study termination: [1] <input type="radio"/> Death [2] <input type="radio"/> Lung transplant [3] <input type="radio"/> Adverse event [4] <input type="radio"/> Subject withdrew consent [5] <input type="radio"/> MD decision [6] <input type="radio"/> Lost to follow-up [98] <input type="radio"/> Other (specify): _____ (ace_ipfcdd: TERM.TERMSP / Term Reason, Specify) A100
2. Was Warfarin/Placebo discontinued prior to study termination?	(ace_ipfcdd: TERM.STDRDC / Warfarin Discontinued) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes: Date of discontinuation: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd: TERM.STDRDCDT / Warfarin Discontinue Date) (ace_ipfcdd: TERM.DISREAS) If yes: Check reason for discontinuation: [1] <input type="radio"/> MD decision [2] <input type="radio"/> Adverse event [3] <input type="radio"/> Subject withdrew consent [98] <input type="radio"/> Other (specify): _____ (ace_ipfcdd: TERM.DISSP / Discon Reason, Specify) A100
3. Was Warfarin/Placebo unblinded?	(ace_ipfcdd: TERM.UNBLIND / Warfarin Unblinded) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes: Date of unblinding: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd: TERM.UNBLNDT / Warfarin Unblind Date) (ace_ipfcdd: TERM.UNBLREA / Unblind Reason) If yes, Reason for unblinding [1] <input type="radio"/> Suspected drug toxicity [2] <input type="radio"/> Adverse Event [98] <input type="radio"/> Other reason for unblinding: _____ (ace_ipfcdd: TERM.UNBLNDR / Unblind Reason, Other) A100
4.* Source Document Verification Completion	(ace_ipfcdd: TERM.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: ace_ipfcdd	Table: TERM	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
STDRDCDT	DATE - DDMONYYYY	
DISREAS	NUMERIC	
DISSP	STRING(100) - A100	
UNBLIND	NUMERIC	
UNBLNDT	DATE - DDMONYYYY	
UNBLREA	NUMERIC	
UNBLNDR	STRING(100) - A100	
SDVSTAT	NUMERIC	
TERMCOMP	NUMERIC	
TERMDT	DATE - DDMONYYYY	
TERMREA	NUMERIC	
TERMSP	STRING(100) - A100	
STDRDC	NUMERIC	

ace_ipf : Death (DEATH)			
Death			
1.	Where did the subject die?	(ace_ipfccdd:DEATH1.DEATHLOC / Death Location) [1] <input type="radio"/> Inpatient [2] <input type="radio"/> Outpatient	
2.	Date of death:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfccdd:DEATH1.DEADDT / Death Date)	
3.	Cause of death is best attributed to:	(ace_ipfccdd:DEATH1.DEADCAUS / Cause of Death) [1] <input type="radio"/> (ace_ipfccdd:DEATH1.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"/> (ace_ipfccdd:DEATH1.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 (ace_ipfccdd:DEATH1.OTRESDED / Death Type Resp, Specify) [3] <input type="radio"/> (ace_ipfccdd:DEATH1.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 (ace_ipfccdd:DEATH1.OTCNRDED / Death Type Cancer, Specify) [98] <input type="radio"/> Other (specify): A50 (ace_ipfccdd:DEATH1.OTHRDEAD / Death Type Other, Specify) [99] <input type="radio"/> Unknown	
4.	Was death related to IPF?	(ace_ipfccdd:DEATH1.IPFDEATH / IPF Death) [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	(ace_ipfccdd:DEATH1.SDVSTAT / SDV Complete) [1] <input type="radio"/> Complete [2] <input type="radio"/> Partially Complete [3] <input type="radio"/> Not Applicable	
6.*	Death adjudication Status:	(ace_ipfccdd:DEATH1.DEDSTAT / Death 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"/> no adjudication needed	
	Reviewer	Date sent to reviewer	Date returned from reviewer
7.			
. Entry			
7.a	Reviewer	Pulldown List 1 <input type="checkbox"/> (ace_ipfccdd:DEATH2.DEDRVR / Death Reviewer)	
7.b	Date sent to reviewer	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfccdd:DEATH2.DEDSNTDT / Date Death Sent)	
7.c	Date returned from reviewer	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfccdd:DEATH2.DEDRTNDT / Date Death Returned)	
* Item is not required			

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	

ieCECRE08	8	8
ieCECRE09	9	9
ieCECRE10	10	10
ieCECRE11	11	11
ieCECRE12	12	12
ieCECRE13	13	13
ieCECRE14	14	14
ieCECRE15	15	15
ieCECRE16	16	16
ieCECRE17	17	17
ieCECRE18	18	18
ieCECRE19	19	19
ieCECRE20	20	20
ieCECRE21	21	21
ieCECRE22	22	22
ieCECRE23	23	23
ieCECRE24	24	24
ieCECRE25	25	25
ieCECRE26	26	26
ieCECRE27	27	27
ieCECRE28	28	28
ieCECRE29	29	29
ieCECRE30	30	30
ieCECRE31	31	31
ieCECRE32	32	32
ieCECRE33	33	33
ieCECRE34	34	34
ieCECRE35	35	35
ieCECRE36	36	36
ieCECRE37	37	37
ieCECRE38	38	38
ieCECRE39	39	39
ieCECRE40	40	40
ieCECRE41	41	41
ieCECRE42	42	42
ieCECRE43	43	43
ieCECRE44	44	44
ieCECRE45	45	45
ieCECRE46	46	46
ieCECRE47	47	47
ieCECRE48	48	48
ieCECRE49	49	49
ieCECRE50	50	50

CDD: ace_ipfcdd Table: DEATH1 Key Type: PATIENTVISIT

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

SDVSTAT	NUMERIC	
DEDSTAT	NUMERIC	

CDD: ace_ipfcdd Table: DEATH2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DEDRVR	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, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50	
DEDSNTDT	DATE - DDMONYYYY	
DEDRTNDT	DATE - DDMONYYYY	

ace_ipf : Urgent or Inpatient Admissions (INPT)		
Urgent or inpatient admissions		
1.	Admission Date	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd:INPT.ADMITDT / Admission Date)
2.	Admission Type	(ace_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	<input type="text" value="A100"/> (ace_ipfcdd:INPT.HOSPREADS / Reason for Admission)
4.	Was reason for Admission respiratory-related.	(ace_ipfcdd:INPT.RESPREL / Resp Related Admission) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5.	Major Procedures Performed	<input type="text" value="A100"/> (ace_ipfcdd:INPT.MAJPROC / Major Procedures)
6.	Was subject discharged?	(ace_ipfcdd:INPT.DISCHRG / Discharged) [1] <input type="radio"/> Yes Discharged: date: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd:INPT.DISCHDT / Discharge Date) (ace_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) <input type="text" value="A100"/> (ace_ipfcdd:INPT.DISCOSP / Discharge, Specify) [0] <input type="radio"/> (ace_ipfcdd:INPT.NOTDISCH / Reason Not Discharged) No [1] <input type="radio"/> Died [2] <input type="radio"/> Remains inpatient
7.*	Source Document Verification Completion	(ace_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		

CDD: ace_ipfcdd	Table: INPT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ADMITDT	DATE - DDMYYYYY	
ADMITYPE	NUMERIC	
HOSPREADS	STRING(100) - A100	
RESPREL	NUMERIC	
MAJPROC	STRING(100) - A100	
DISCHRG	NUMERIC	
DISCHDT	DATE - DDMYYYYY	
DISCHDES	NUMERIC	
DISCOSP	STRING(100) - A100	
NOTDISCH	NUMERIC	
SDVSTAT	NUMERIC	

ace_ipf : Concomitant Medications (MED)		
Concomitant Medications		
1.	Medication Name	A100 (ace_ipfccd:MED.MEDICATN / Medication Name)
2.	When did the subject start the medication?	(ace_ipfccd: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) (ace_ipfccd:MED.MEDSTRDT / Start Date)
4.	Stop Date	(ace_ipfccd:MED.MEDCONTU / Continuing) [0] <input type="radio"/> Req/Unk / Req/Unk / Req (2007-2016) (ace_ipfccd:MED.MEDSTPDT / Stop Date) [1] <input type="radio"/> Continuing
5.	Indication	(ace_ipfccd:MED.INDICATE / Indication) [1] <input type="radio"/> Non-Gastroesophageal disorder, specify: (ace_ipfccd:MED.THERAPY / Nongastro Indicat, Specify) A50 [2] <input type="radio"/> Gastroesophageal disorder (ace_ipfccd:MED.GRDBARET / Indicat Barretts Esophagus) Gastroesophageal disorder, specific indication(s) [1] <input type="checkbox"/> Barretts esophagus (ace_ipfccd:MED.GRDCOF / Indciation Cough) [1] <input type="checkbox"/> Cough (ace_ipfccd:MED.GRDHTBRN / Indciation Heartburn) [1] <input type="checkbox"/> Heartburn symptoms (ace_ipfccd:MED.GRDHH / Indication Hiatal Hernia) [1] <input type="checkbox"/> Hiatal hernia (ace_ipfccd:MED.GRDIPF / Indication IPF) [1] <input type="checkbox"/> IPF (ace_ipfccd:MED.GRDOTH / Indication Other) [1] <input type="checkbox"/> Other (specify): (ace_ipfccd:MED.GRDOTSP / Indication Other, Specify) A50 Dose per administration: xxxxxxxx (ace_ipfccd:MED.GERDOSE / Gastro Dose) (ace_ipfccd: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): (ace_ipfccd:MED.GDSUNTSP / Gastro Unit, Specify) A50 (ace_ipfccd: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	(ace_ipfccd: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		

Column Name	Column Data Type	Design Note
MEDICATN	STRING(100) - A100	
MEDSTRT	NUMERIC	
MEDSTRDT	DATE - DDMONYYYY	
MEDCONTU	NUMERIC	
MEDSTPDT	DATE - DDMONYYYY	
INDICATE	NUMERIC	
THERAPY	STRING(50) - A50	
GRDBARET	NUMERIC	
GRDCOF	NUMERIC	
GRDHTBRN	NUMERIC	

GRDHH	NUMERIC	
GRDIPF	NUMERIC	
GRDOTH	NUMERIC	
GRDOTSP	STRING(50) - A50	
GERDOSE	FLOAT - F9.0	
GDOSEUNT	NUMERIC	
GDSUNTSP	STRING(50) - A50	
GERDFREQ	NUMERIC	
SDVSTAT	NUMERIC	

ace_ipf : GERD Changes (GERD)		
GERD Status Review		
1.	Date of change in GERD status	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:GERD.GRDCHGDT / GERD Status Change)
2.	Type of change	(ace_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?	(ace_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?	(ace_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?	(ace_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?	(ace_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?	(ace_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?	(ace_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	(ace_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		

CDD: ace_ipfcdd	Table: GERD	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
GRDCHGDT	DATE - DDMONYYYY	
GERDSTAT	NUMERIC	
GELEV	NUMERIC	
GRECLIN	NUMERIC	
GFOOD	NUMERIC	
GNOFLAT	NUMERIC	
GBEDSNK	NUMERIC	
GSMLMEAL	NUMERIC	
SDVSTAT	NUMERIC	

ace_ipf : Sleep Apnea Changes (SLPCHG)		
Sleep Apnea Changes		
1.	Date of change in Sleep Apnea	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd:SLPCHG.APNEADT / Sleep Apnea Change Date)
2.	Type of change	(ace_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	(ace_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	(ace_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		

CDD: ace_ipfcdd Table: SLPCHG Key Type: PATIENTVISIT

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

ace_ipf : Study Drug Log (KIT)		
Study Drug Log		
1.	Date of Kit Dispensed	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd:KIT.PILSTDT / Kit Dispensed Date)
2.	Study Drug Kit Number	A25 (ace_ipfcdd:KIT.KITNO / Kit Number)
3.*	Source Document Verification Completion	(ace_ipfcdd:KIT.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
PILSTDT	DATE - DDMYYYYY	
KITNO	STRING(25) - A25	
SDVSTAT	NUMERIC	

ace_ipf : Telephone Contact Log (PHONE)	
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="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:PHONE.PHONEDT / Date of Phone Contact)
2.*	Source Document Verification Completion (ace_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	

ace_ipf : Adverse Events (AE)		
Adverse Event		
1.	Select event from list or provide description in Other	Pulldown List 1 <input type="button" value="v"/> (ace_ipfcdd:AE1.TERMLIST / Adverse Event) Other (specify): <input type="text" value="A100"/> (ace_ipfcdd:AE1.AETERM / Adverse Event, Specify)
2.	Is this a suspected acute exacerbation?	(ace_ipfcdd:AE1.SUSACUTE / AE Acute Exacerbation) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3.	Is this a suspected bleeding event that required medical attention?	(ace_ipfcdd:AE1.SUSBLD / Bleeding Event) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4.	Onset Date and Time	Req <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:AE1.AESTDTM / AE Onset Date) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
5.	End Date	(ace_ipfcdd:AE1.AEONGO / AE Ongoing) (panther_ipfcdd:AE1.AEONGO / AE Ongoing) [0] <input type="radio"/> Req <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:AE1.AEENDT / AE End Date) (panther_ipfcdd:AE1.AEENDT / AE End Date) [1] <input type="radio"/> Continuing
6.	Maximum Intensity	(ace_ipfcdd:AE1.AESEV / AE Outcome) [1] <input type="radio"/> Mild [2] <input type="radio"/> Moderate [3] <input type="radio"/> Severe
7.	Relationship to Warfarin/Placebo	(ace_ipfcdd:AE1.AERELAT / Relationship to Warfarin) [0] <input type="radio"/> Not a reasonable possibility [1] <input type="radio"/> Reasonable possibility
8.	Actions Taken with Warfarin/Placebo	(ace_ipfcdd:AE1.AEACTN / Action Taken with Warfarin) [1] <input type="radio"/> None [2] <input type="radio"/> Interrupted (ace_ipfcdd:AE1.INRABT / Warfarin Interrupt Lessen) Did the event lessen or abate when drug stopped? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:AE1.INRRCR / Warfarin Interrupt Reoccur) Did the event reoccur once the drug restarted? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [3] <input type="radio"/> (ace_ipfcdd:AE1.DISABT / Warfarin Discontinue Lessen) Permanently discontinued Did the event lessen or abate when drug stopped? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [4] <input type="radio"/> Dosage change
9.	Final Outcome	(ace_ipfcdd:AE1.AEOUT / Final Outcome) (panther_ipfcdd:AE1.AEOUT / AE Outcome) [1] <input type="radio"/> Death [2] <input type="radio"/> Resolved no sequelae [3] <input type="radio"/> Resolved with sequelae [4] <input type="radio"/> Unresolved
10.	Was This Event Serious?	(ace_ipfcdd:AE1.AESER / Serious) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
ONLY COMPLETE THE FOLLOWING QUESTIONS IF THIS EVENT IS SERIOUS		
11.*	Serious Criteria (check all that apply)	(ace_ipfcdd:AE1.AESHOSP / Hospitalization) [1] <input type="checkbox"/> Hospitalization or Prolonging of Existing Hospitalization (ace_ipfcdd:AE1.AESDISAB / Significant Disability) [1] <input type="checkbox"/> Persistent or Significant Disability (ace_ipfcdd:AE1.AESLIFE / Life Threatening) [1] <input type="checkbox"/> Life threatening (ace_ipfcdd:AE1.AESCONG / Congenital Anomaly) [1] <input type="checkbox"/> Congenital anomaly (ace_ipfcdd:AE1.AESDTH / Death) [1] <input type="checkbox"/> Death (ace_ipfcdd:AE1.AESMIE / Important Medical Event) [1] <input type="checkbox"/> Important medical event
12.*	Initial (presenting) signs and symptoms:	<input type="text" value="A250"/> (ace_ipfcdd:AE1.SAESS / Initial Signs and Symptoms)

13.*	What interventions/action/diagnostic procedures/tests were used to identify and treat the event?	A250	(ace_ipfcdd:AE1.SAEINTV / Diagnostic Procedures)			
14.*	Subject's response to treatment.	A250	(ace_ipfcdd:AE1.SAERESP / Response to Treatment)			
15.*	What clinical information or evidence identified the resolution/stabilization of this event?	A250	(ace_ipfcdd:AE1.SAECLIN / Resolution Stabilization)			
16.*	PI's opinion of other possible causes of the event (pre-existing conditions; concomitant medications; etc)	A250	(ace_ipfcdd:AE1.SAEPICAU / Other causes of the event)			
17.*	Are there any relevant tests or labs for this SAE	(ace_ipfcdd:AE1.SAELAB / Relevant Tests or Labs) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				
	Relevant lab/diagnostic test name	Date of test		Result	Unit	Normal Range
18.						
18.a*	Name of relevant lab/diagnostic test (one per entry)	A100	(ace_ipfcdd:AE2.LABDONE / Lab Test Performed)			
18.b*	Date of test	Req / Req / Req (2009-2016)	(ace_ipfcdd:AE2.SAELABDT / Date of Test)			
18.c*	Result	A25	(ace_ipfcdd:AE2.SAERSLT / Test Result)			
18.d*	Unit (if applicable)	A100	(ace_ipfcdd:AE2.SAELUNIT / Lab Unit)			
18.e*	Normal Range (if applicable)	A100	(ace_ipfcdd:AE2.SAELRNG / Normal Lab Range)			
Serious Adverse Event Investigator Signature						
19.*	Investigator Signature	(ace_ipfcdd:AE1.INVAESIG / Investigator AE Signature) [0] <input type="radio"/> No, data changed since last verification [1] <input type="radio"/> Yes				
20.*	Date of AE verification	Req / Req / Req (2008-2015)	(ace_ipfcdd:AE1.INVAEDT / Investigator Signature DATE)			
Serious adverse event tracking page:						
21.*	SAFETY: Was SAE sent to sponsor?	(ace_ipfcdd:AE1.SAESPON / Sent to Sponsor) [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes Date Req / Req / Req (2009-2016)	(ace_ipfcdd:AE1.SAESPNDT / Sponsor Date)			
22.*	SAFETY: Is this SAE linked to another SAE?	(ace_ipfcdd:AE1.SAELINK / SAE Linked) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				
23.*	SAFETY: Was the site instructed to complete and submit a MedWatch form?	(ace_ipfcdd:AE1.SITEWTCH / MedWatch Requested) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				
24.*	SAFETY: What was subject's warfarin/placebo daily dose at event onset?	xxxxxxxx mg	(ace_ipfcdd:AE1.SAEDOSE / Study drug dose SAE onset)			
25.*	SAFETY: What was subject's most recent INR prior to event onset?	xxxxxxxx	(ace_ipfcdd:AE1.SAEINR / Most recent INR)			
26.*	SAFETY: Date of most recent dose change	Req / Req / Req (2009-2016)	(ace_ipfcdd:AE1.SAEINRDT / Most Recent Dose Change Date)			
27.*	SAFETY: Is this event expected per the Product Insert?	(ace_ipfcdd:AE1.SAEKNOWN / Event Anticipated) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				
28.*	SAFETY: Preferred Term:	A200	(ace_ipfcdd:AE1.PREFSAE / Preferred Term)			
29.*	SAFETY: Was Medical Review obtained?	(ace_ipfcdd:AE1.SAEREVU / Medical Review) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				
30.*	Safety MEDICAL MONITOR: Do you agree with expectedness?	(ace_ipfcdd:AE1.MMEXPAGR / MM agree with expectedness) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				

31.*	Safety MEDICAL MONITOR: Do you agree with Preferred Term?	<input type="radio"/> (ace_ipfcdd:AE1.MMPTAGR / MM agree with Preferred Term) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
32.*	Safety MEDICAL MONITOR: Comments	A200 (ace_ipfcdd:AE1.MMCOMM / Medical Monitor comments)
33.*	Safety MEDICAL MONITOR: Date of latest review	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:AE1.MMREVDT / MM latest review date)
34.*	Is this AE associated with an adjudication case?	(ace_ipfcdd:AE1.AECASE / Adjudication Case) [0] <input type="radio"/> No [1] <input type="radio"/> If yes, Adjudication case identifier: (ace_ipfcdd:AE1.CASENUM / Adjudication Case Id) A25
35.*	Source Document Verification Completion	(ace_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	
ieTERMLI21	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: ace_ipfcdd Table: AE1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
TERMLIST	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 19, 14, 15, 16, 17, 18, 20, 98	
AETERM	STRING(100) - A100	
SUSACUTE	NUMERIC	
SUSBLD	NUMERIC	
AESTDTM	DATE - DDMONYYYY HHMM	
AEONGO	NUMERIC	
AEENDT	DATE - DDMONYYYY	
AESEV	NUMERIC	
AERELAT	NUMERIC	
AEACTN	NUMERIC	
INRABT	NUMERIC	
INRRCR	NUMERIC	
DISABT	NUMERIC	

AEOUT	NUMERIC	
AESE	NUMERIC	
AESHOSP	NUMERIC	
AESDISAB	NUMERIC	
AESLIFE	NUMERIC	
AESCONG	NUMERIC	
AESDTH	NUMERIC	
AESMIE	NUMERIC	
SAESS	STRING(250) - A250	
SAEINTV	STRING(250) - A250	
SAERESP	STRING(250) - A250	
SAECLIN	STRING(250) - A250	
SAEPICAU	STRING(250) - A250	
SAELAB	NUMERIC	
INVAESIG	NUMERIC	
INVAEDT	DATE - DDMONYYYY	
SAESPON	NUMERIC	
SAESPNDT	DATE - DDMONYYYY	
SAELINK	NUMERIC	
SITWTCH	NUMERIC	
SAEDOSE	FLOAT - F9.0	
SAEINR	FLOAT - F9.0	
SAEINRDT	DATE - DDMONYYYY	
SAEKNOWN	NUMERIC	
PREFSAE	STRING(200) - A200	
SAEREVU	NUMERIC	
MMEXPAGR	NUMERIC	
MMPTAGR	NUMERIC	
MMCOMM	STRING(200) - A200	
MMREVDT	DATE - DDMONYYYY	
AECASE	NUMERIC	
CASENUM	STRING(25) - A25	
SDVSTAT	NUMERIC	

CDD: ace_ipfcdd Table: AE2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
LABDONE	STRING(100) - A100	
SAELABDT	DATE - DDMONYYYY	
SAERSLT	STRING(25) - A25	
SAELUNIT	STRING(100) - A100	
SAELRNG	STRING(100) - A100	

CDD: panther_ipfcdd Table: AE1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
AEENDT	DATE - DDMONYYYY	
AEONGO	NUMERIC	
AEACTNN	NUMERIC	
AESHOSP	NUMERIC	
AESDTH	NUMERIC	
AEOUT	NUMERIC	

ace_ipf : Adjudication Docs Tracking (ADJTRK)	
Adjudication Case Document Request	
The DCC initiates this form. Study coordinator will be notified when to complete site portion.	
1. Case ID	A20 (ace_ipfcdd:ADJTRK1.CASEID / Case ID) (panther_ipfcdd:ADJTRK1.CASEID / Case ID)
2. Earliest Date:	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.MMERLDT / Earliest Date) (panther_ipfcdd:ADJTRK1.MMERLDT / Earliest Date)
3. Latest Date:	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.MMLTEDT / Latest Date) (panther_ipfcdd:ADJTRK1.MMLTEDT / Latest Date)
4. Medical monitor's assessment of events to adjudicate in this case	(ace_ipfcdd:ADJTRK1.MMADJAE / Medical Monitor AE Event) (panther_ipfcdd:ADJTRK1.MMADJAE / Medical Monitor AE Event) [1] <input type="checkbox"/> Acute Exacerbation (ace_ipfcdd:ADJTRK1.MMADJDT / Medical Monitor Death Event) [1] <input type="checkbox"/> Death (ace_ipfcdd:ADJTRK1.MMADJHS / Medical Monitor HospI Event) (panther_ipfcdd:ADJTRK1.MMADJHS / Medical Monitor Hosp Event) [1] <input type="checkbox"/> Non-elective hospitalizations (ace_ipfcdd:ADJTRK1.MMADJBL / Medical Monitor Bleed Event) [1] <input type="checkbox"/> Bleeding event
Investigator Assessment of Case	
5. Site investigator: Select the suspected events involved in this case	(ace_ipfcdd:ADJTRK1.PIADJAE / Investigator AE Event) (panther_ipfcdd:ADJTRK1.PIADJAE / Investigator AE Event) [1] <input type="checkbox"/> Acute Exacerbation (ace_ipfcdd:ADJTRK1.PIADJDT / Investigator Death Event) [1] <input type="checkbox"/> Death (ace_ipfcdd:ADJTRK1.PIADJHS / Investigator Hospital Event) (panther_ipfcdd:ADJTRK1.PIADJHS / Investigator Hospital Event) [1] <input type="checkbox"/> Non-elective hospitalizations (ace_ipfcdd:ADJTRK1.PIADJBL / Investigator Bleeding Event) [1] <input type="checkbox"/> Bleeding event
6. Investigator opinion of the case	A2000 (ace_ipfcdd:ADJTRK1.PIADJNR / Investigator Opinion)
Acute Exacerbation Research Biological Samples	
7. Was research blood obtained during the date range of interest	(ace_ipfcdd:ADJTRK1.BLDOBTAN / Blood Obtained) (panther_ipfcdd:ADJTRK1.BLDOBTAN / Blood Obtained) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date blood obtained Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.BLDOBDT / Blood Date)
8. Was research BAL obtained during the date range of interest	(ace_ipfcdd:ADJTRK1.BALOBTAN / BAL Obtained) (panther_ipfcdd:ADJTRK1.BALOBTAN / BAL Obtained) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date BAL obtained Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.BALOBBDT / BAL Date)
Adjudication Docs Submission	
9. Identify all the known types of treatment facilities during the date range of interest	(ace_ipfcdd:ADJTRK1.TRTFAC01 / Facility Local doctor) (panther_ipfcdd:ADJTRK1.TRTFAC01 / Facility Local doctor) [1] <input type="checkbox"/> Local physician/clinic (ace_ipfcdd:ADJTRK1.TRTFAC02 / Facility IPF Clinic) (panther_ipfcdd:ADJTRK1.TRTFAC02 / Facility IPF Clinic) [1] <input type="checkbox"/> IPF clinic (ace_ipfcdd:ADJTRK1.TRTFAC03 / Facility Local ER) [1] <input type="checkbox"/> Local ER (ace_ipfcdd:ADJTRK1.TRTFAC04 / Facility IPF ER) (panther_ipfcdd:ADJTRK1.TRTFAC04 / Facility IPF ER) [1] <input type="checkbox"/> IPF ER (ace_ipfcdd:ADJTRK1.TRTFAC05 / Facility Local Hospital) (panther_ipfcdd:ADJTRK1.TRTFAC05 / Facility Local Hospital) [1] <input type="checkbox"/> Local hospital (ace_ipfcdd:ADJTRK1.TRTFAC06 / Facility IPF Hospital) (panther_ipfcdd:ADJTRK1.TRTFAC06 / Facility IPF Hospital) [1] <input type="checkbox"/> IPF hospital
10. Admission/Discharge Summary available?	(ace_ipfcdd:ADJTRK1.DISSUM / Discharge Summary) (panther_ipfcdd:ADJTRK1.DISSUM / Discharge Summary) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.DISSUMDT / Date Summary Report(s) Sent) (panther_ipfcdd:ADJTRK1.DISSUMDT / Date Summary Report(s) Sent)
11. Lab report(s) available?	(ace_ipfcdd:ADJTRK1.LABRPT / Lab Reports)

		<input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.LABRPTDT / Date Lab Report(s) Sent) (panther_ipfcdd: ADJTRK1.LABRPTDT / Date Lab Report(s) Sent)
12.	Transfusion report(s) available?	(ace_ipfcdd: ADJTRK1.TRFUS / Transfusion) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.TRFUSDT / Date Transfusion Reprt Sent)
13.	X-ray report(s) available?	(ace_ipfcdd: ADJTRK1.XRAYRPT / X-Ray) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.XRARPTDT / Date X-Ray Report(s) Sent)
14.	Respiratory culture report(s) available?	(ace_ipfcdd: ADJTRK1.RSPCLTRP / Respiratory Culture) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.RSPCLTDT / Date Resp Culture Rept Sent) (panther_ipfcdd: ADJTRK1.RSPCLTDT / Date Resp Cult Report Sent)
15.	Pulmonary function test report(s) available?	(ace_ipfcdd: ADJTRK1.PULMRPT / Pulmonary Function Test) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.PLMRPTDT / Date PFT Report(s) Sent)
16.	Blood culture report(s) available?	(ace_ipfcdd: ADJTRK1.BLDRPT / Blood Culture) (panther_ipfcdd: ADJTRK1.BLDRPT / Blood Culture) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.BLDRPTDT / Date Blood Cult Report Sent)
17.	Bronchoscopy report(s) available?	(ace_ipfcdd: ADJTRK1.BRONRPT / Bronchoscopy) (panther_ipfcdd: ADJTRK1.BRONRPT / Bronchoscopy) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.BRNRPTDT / Date Broncho Report(s) Sent)
18.	Pulse oximetry report(s) available?	(ace_ipfcdd: ADJTRK1.PULOXRPT / Pulse Oxymetry) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.PULOXTDT / Pulse Oxymetry Report Sent)
19.	CT scan available (important)?	(ace_ipfcdd: ADJTRK1.HRCTSCAN / CT Scan) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.HRCTSNDT / Date CT Scan Sent) (panther_ipfcdd: ADJTRK1.HRCTSNDT / Date CT Scan Sent)
20.	Surgical lung biopsy slide available?	(ace_ipfcdd: ADJTRK1.SLBSLIDE / Lung Biopsy Slide) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.SLBSLDDT / Date Lung Biopsy Slide Sent)
21.	Arterial Blood Gas report(s) available?	(ace_ipfcdd: ADJTRK1.ABGRPT / ABG) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.ABGRPTDT / Date ABG Report(s) Sent)
22.	Echocardiogram available?	(ace_ipfcdd: ADJTRK1.ECHOGRM / Echo) (panther_ipfcdd: ADJTRK1.ECHOGRM / Echo) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.ECHOGMDT / Date Echo Sent) (panther_ipfcdd: ADJTRK1.ECHOGMDT / Date Echo Sent)
23.	Clinic / hospital records available?	(ace_ipfcdd: ADJTRK1.HOSPREC / Hospital Records) <input type="radio"/> No <input checked="" type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd: ADJTRK1.HOSRECDT / Date Hospital Records Sent)

24.	Physician and nurse progress notes available?	(ace_ipfcdd:ADJTRK1.MDNOTES / Progress Notes Available) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.MDNOTEDT / Date Progress Notes Sent)	
25.	Autopsy report(s) available?	(ace_ipfcdd:ADJTRK1.AUTOPSRT / Autopsy) [97] <input type="radio"/> NA [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date report sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.AUTOPSDT / Date Autopsy Report(s) Sent) (panther_ipfcdd:ADJTRK1.AUTOPSDT / Date Autopsy Report(s) Sent)	
26.	Death certificate available?	(ace_ipfcdd:ADJTRK1.DTHCERT / Death Certificate) [97] <input type="radio"/> NA [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date report sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.CERTDATE / Date Death Certificate Sent)	
27.	Death narrative available?	(ace_ipfcdd:ADJTRK1.DTHNRT / Death Narrative) [97] <input type="radio"/> NA [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date report sent for adjudication Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK1.DTHNRDT / Date Death Narrative Sent) (panther_ipfcdd:ADJTRK1.DTHNRDT / Date Death Narrative Sent)	
Adjudication Docs Tracking			
28.*	Source Document Verification Completion	(ace_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:	(ace_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	Date returned from reviewer
30.			
30.a	Reviewer	A30 (ace_ipfcdd:ADJTRK2.ADJRVR / Reviewer)	
30.b	Date sent to reviewer	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK2.ADJRVSDT / Date Sent to Reviewer)	
30.c	Date returned from reviewer	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJTRK2.ADJRVSDT / Date returned from reviewer)	
* Item is not required			

Column Name	Column Data Type	Design Note
CASEID	STRING(20) - A20	
MMERLDT	DATE - DDMONYYYY	
MMLTEDT	DATE - DDMONYYYY	
MMADJAE	NUMERIC	
MMADJDT	NUMERIC	
MMADJHS	NUMERIC	
MMADJBL	NUMERIC	
PIADJAE	NUMERIC	
PIADJDT	NUMERIC	
PIADJHS	NUMERIC	
PIADJBL	NUMERIC	
PIADJNR	TEXT(255) - A2000	
BLDOBTAN	NUMERIC	
BLDOBDT	DATE - DDMONYYYY	
BALOBTAN	NUMERIC	

BALOBDT	DATE - DDMONYYYY	
TRTFAC01	NUMERIC	
TRTFAC02	NUMERIC	
TRTFAC03	NUMERIC	
TRTFAC04	NUMERIC	
TRTFAC05	NUMERIC	
TRTFAC06	NUMERIC	
DISSUM	NUMERIC	
DISSUMDT	DATE - DDMONYYYY	
LABRPT	NUMERIC	
LABRPTDT	DATE - DDMONYYYY	
TRNFUS	NUMERIC	
TRNFUSDT	DATE - DDMONYYYY	
XRAYRPT	NUMERIC	
XRARPTDT	DATE - DDMONYYYY	
RSPCLTRP	NUMERIC	
RSPCLTDT	DATE - DDMONYYYY	
PULMRPT	NUMERIC	
PLMRPTDT	DATE - DDMONYYYY	
BLDRPT	NUMERIC	
BLDRPTDT	DATE - DDMONYYYY	
BRONRPT	NUMERIC	
BRNRPTDT	DATE - DDMONYYYY	
PULOXRPT	NUMERIC	
PULOXTDT	DATE - DDMONYYYY	
HRCTSCAN	NUMERIC	
HRCTSNDT	DATE - DDMONYYYY	
SLBSLIDE	NUMERIC	
SLBSLDDT	DATE - DDMONYYYY	
ABGRPT	NUMERIC	
ABGRPTDT	DATE - DDMONYYYY	
ECHOGRM	NUMERIC	
ECHOGMTDT	DATE - DDMONYYYY	
HOSPREC	NUMERIC	
HOSRECDT	DATE - DDMONYYYY	
MDNOTES	NUMERIC	
MDNOTEDT	DATE - DDMONYYYY	
AUTOPSRT	NUMERIC	
AUTOPSDT	DATE - DDMONYYYY	
DTHCERT	NUMERIC	
CERTDATE	DATE - DDMONYYYY	
DTHNRT	NUMERIC	
DTHNRTDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	
ADJSTAT	NUMERIC	

CDD: ace_ipfcdd Table: ADJTRK2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ADJRVR	STRING(30) - A30	
ADJRVSDT	DATE - DDMONYYYY	
ADJRVRDT	DATE - DDMONYYYY	

CDD: panther_ipfcdd Table: ADJTRK1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CASEID	STRING(20) - A20	
MMADJHS	NUMERIC	

PIADJHS	NUMERIC	
BALOBTAN	NUMERIC	
TRTFAC02	NUMERIC	
TRTFAC04	NUMERIC	
TRTFAC05	NUMERIC	
PIADJDT	NUMERIC	
RSPCLTDT	DATE - DDMONYYYY	
BLDRPT	NUMERIC	
MMERLDT	DATE - DDMONYYYY	
HRCTSNDT	DATE - DDMONYYYY	
ECHOGMTD	DATE - DDMONYYYY	
MDNOTES	NUMERIC	
MMADJAE	NUMERIC	
PIADJAE	NUMERIC	
PIADJNR	TEXT(255)	
DISSUM	NUMERIC	
ADJSTAT	NUMERIC	
PULOXRPT	NUMERIC	
TRNFUS	NUMERIC	
BALOBDT	DATE	
SLBSLDDT	DATE	
MMLTEDT	DATE - DDMONYYYY	
ECHOGRM	NUMERIC	
TRTFAC06	NUMERIC	
DISSUMDT	DATE - DDMONYYYY	
AUTOPSRT	NUMERIC	
BRONRPT	NUMERIC	
AUTOPSDT	DATE - DDMONYYYY	
LABRPTDT	DATE - DDMONYYYY	
BLDOBAN	NUMERIC	
DTHNRDT	DATE - DDMONYYYY	
ABGRPT	NUMERIC	
TRTFAC01	NUMERIC	
ABGRPTDT	DATE	

ace_ipf : Adjudication Report (ADJRPT)	
Adjudication Case	
1. Case ID	A20 (ace_ipfcdd:ADJRPT.CASEID2 / Case ID) (panther_ipfcdd:ADJRPT.CASEID2 / Case ID)
Acute Exacerbation Adjudication	
2. Was a suspected acute exacerbation adjudicated?	<p>(ace_ipfcdd:ADJRPT.ADJACEX / Exacerbation Adjudicated) (panther_ipfcdd:ADJRPT.ADJACEX / Exacerbation Adjudicated)</p> <p>[0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes</p> <p>Date of onset Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2016) (ace_ipfcdd:ADJRPT.ADJAEDT / Exacerbation onset date) (panther_ipfcdd:ADJRPT.ADJAEDT / Exacerbation onset date)</p> <p>(ace_ipfcdd:ADJRPT.ADJAEOUT / Adjudication Outcome) (panther_ipfcdd:ADJRPT.ADJAEOUT / Adjudication Outcome)</p> <p>Outcome [1] <input type="radio"/> Treated as outpatient [2] <input type="radio"/> Hospitalized, not mechanically ventilated [3] <input type="radio"/> Hospitalized and mechanically ventilated</p> <p>(ace_ipfcdd:ADJRPT.ACEXCOFF / Productive Cough) (panther_ipfcdd:ADJRPT.ACEXCOFF / Productive Cough)</p> <p>During this episode of acute worsening, did the subject have</p> <p>Productive cough? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p> <p>(ace_ipfcdd:ADJRPT.ACEXFVR / Fever) (panther_ipfcdd:ADJRPT.ACEXFVR / Fever)</p> <p>Fever? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p> <p>(ace_ipfcdd:ADJRPT.ACEXHEAD / Headache) (panther_ipfcdd:ADJRPT.ACEXHEAD / Headache)</p> <p>Headache? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p> <p>(ace_ipfcdd:ADJRPT.ACEXCONG / Congestion) (panther_ipfcdd:ADJRPT.ACEXCONG / Congestion)</p> <p>Congestion? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p> <p>(ace_ipfcdd:ADJRPT.ACEXACHE / Achiness) (panther_ipfcdd:ADJRPT.ACEXACHE / Achiness)</p> <p>Achiness? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p> <p>(ace_ipfcdd:ADJRPT.ACEXST / Sore Throat) (panther_ipfcdd:ADJRPT.ACEXST / Sore Throat)</p> <p>Sore throat? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown</p> <p>(ace_ipfcdd:ADJRPT.ADJDYSPN / Clinical A Met) (panther_ipfcdd:ADJRPT.ADJDYSPN / Clinical A Met)</p> <p>Clinical: A Unexplained worsening of dyspnea or cough within 30 days, triggering unscheduled medical care (e.g., clinic, study visit, hospitalization):</p> <p>[1] <input type="radio"/> Met [2] <input type="radio"/> Not Met [3] <input type="radio"/> Data Insufficient to Judge</p> <p>(ace_ipfcdd:ADJRPT.ADJDVT / Clinical B Met) (panther_ipfcdd:ADJRPT.ADJDVT / Clinical B Met)</p> <p>Clinical: B No clinical suspicious or overt evidence of cardiac event, pulmonary embolism, or deep venous thrombosis to explain acute worsening of dyspnea:</p> <p>[1] <input type="radio"/> Met [2] <input type="radio"/> Not Met [3] <input type="radio"/> Data Insufficient to Judge</p> <p>(ace_ipfcdd:ADJRPT.ADJPNEU / Clinical C Met) (panther_ipfcdd:ADJRPT.ADJPNEU / Clinical C Met)</p> <p>Clinical: C No pneumothorax:</p> <p>[1] <input type="radio"/> Met [2] <input type="radio"/> Not Met [3] <input type="radio"/> Data Insufficient to Judge</p> <p>(ace_ipfcdd:ADJRPT.ADJXRA / Radiologic A Met) (panther_ipfcdd:ADJRPT.ADJXRA / Radiologic A Met)</p> <p>Radiologic/Physiologic: A Bilateral radiographic change including new ground glass opacity or consolidation on chest X-ray or CT scan:</p> <p>[1] <input type="radio"/> Met [2] <input type="radio"/> Not Met</p>

[3] Data Insufficient to Judge
 (ace_ipfcdd:ADJRPT.ADJPAO2 / Radiologic B Met)
 (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
 (ace_ipfcdd:ADJRPT.ADJINFCT / Microbiologic A Met)
 (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
 (ace_ipfcdd:ADJRPT.ADJLRT / Microbiologic B Met)
 (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
 (ace_ipfcdd:ADJRPT.ADJBLD / Microbiologic C Met)
 (panther_ipfcdd:ADJRPT.ADJBLD / Microbiologic C Met)
 Microbiologic: C Lack of positive pathogen in blood cultures:

[1] Met
 [2] Not Met
 [3] Data Insufficient to Judge
 (ace_ipfcdd:ADJRPT.ADJFINAL / Final Diagnosis)
 (panther_ipfcdd: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 (ace_ipfcdd:ADJRPT.ADJFNLOT / Final Diagnosis, Specify)
 Other (specify): (panther_ipfcdd:ADJRPT.ADJFNLOT / Final Diagnosis, Specify)

Hospitalization Adjudication

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

(ace_ipfcdd:ADJRPT.ADJHOSP / Hosp During Adjudication)
 (panther_ipfcdd:ADJRPT.ADJHOSP / Hosp During Adjudication)
 [0] No
 [1] Yes
 Date of admission | Req / | Req / | Req (2009-2016) (ace_ipfcdd:ADJRPT.ADJHOSDT / Hospital admission date)
 (panther_ipfcdd:ADJRPT.ADJHOSDT / Hospital admission date)

(ace_ipfcdd:ADJRPT.ADJHOSRS / Hospitalization Cause)
 (panther_ipfcdd:ADJRPT.ADJHOSRS / Hospitalization Cause)
 Was hospitalization primarily attributed to:

[1] Bleeding event
 [2] Acute exacerbation
 [98] Other (ace_ipfcdd:ADJRPT.ADJHSRSP / Hospital Cause, Specify)
 Other (specify): (panther_ipfcdd:ADJRPT.ADJHSRSP / Hospital Cause, Specify)

Death Adjudication

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

(ace_ipfcdd:ADJRPT.ADJDIE / Death During Adjudication)
 (panther_ipfcdd:ADJRPT.ADJDIE / Death During Adjudication)
 [0] No
 [1] (ace_ipfcdd:ADJRPT.ADJDICSE / Primary Cause of Death)
 (panther_ipfcdd:ADJRPT.ADJDICSE / Primary Cause of Death)
 Yes
 If Yes: Was death primarily attributed to:

[1] Cardiovascular event
 [2] Acute exacerbation
 [98] Other (ace_ipfcdd:ADJRPT.ADJDICSP / Cause of Death, Specify)
 Other (specify): (panther_ipfcdd:ADJRPT.ADJDICSP / Cause of Death, Specify)

Bleed Adjudication

5. Was a suspected bleed adjudicated?

(ace_ipfcdd:ADJRPT.AJJBST / Bleed Adjudicated)
 [0] No
 [1] Yes
 Date of onset | Req / | Req / | Req (2009-2016) (ace_ipfcdd:ADJRPT.AJJBST / Bleed onset date)
 (ace_ipfcdd:ADJRPT.AJJBSTE1 / Access Site Bleed)
 Site/type of bleed
 [1] Access site
 (ace_ipfcdd:ADJRPT.AJJBSTE2 / Genitourinary Bleed)

	<p>[1] <input type="checkbox"/> Genitourinary (ace_ipfcdd:ADJRPT.ADJBSTE3 / Hematuria Bleed) [1] <input type="checkbox"/> Gross hematuria (ace_ipfcdd:ADJRPT.ADJBSTE4 / Hemarthrosis Bleed) [1] <input type="checkbox"/> Hemarthrosis (ace_ipfcdd:ADJRPT.ADJBSTE5 / Hematermesis Bleed) [1] <input type="checkbox"/> Hematemesis (ace_ipfcdd:ADJRPT.ADJBSTE6 / Hematoma Bleed) [1] <input type="checkbox"/> Hematoma (ace_ipfcdd:ADJRPT.ADJBSTE7 / Intraarticular Bleed) [1] <input type="checkbox"/> Intraarticular (ace_ipfcdd:ADJRPT.ADJBSTE8 / Intramuscular Bleed) [1] <input type="checkbox"/> (ace_ipfcdd:ADJRPT.ADJCMPSN / Compartment Syndrome) Intramuscular Compartment syndrome? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:ADJRPT.ADJBSTE9 / Intraocular Bleed) [1] <input type="checkbox"/> (ace_ipfcdd:ADJRPT.ADJSECHG / Vision Change) Intraocular Vision change? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (ace_ipfcdd:ADJRPT.ADJBST10 / Intraspinal Bleed) [1] <input type="checkbox"/> Intraspinal (ace_ipfcdd:ADJRPT.ADJBST11 / Nosebleed) [1] <input type="checkbox"/> Nosebleed (ace_ipfcdd:ADJRPT.ADJBST12 / Retroperitoneal Bleed) [1] <input type="checkbox"/> Retroperitoneal</p>
<p>6.* If bleed adjudicated, conclusion per ACE protocol criteria</p>	<p>(ace_ipfcdd:ADJRPT.ADJRST / Type of Bleed) [1] <input checked="" type="radio"/> Major (ace_ipfcdd:ADJRPT.ADJMJR01 / Fatal Bleed) [1] <input type="checkbox"/> Fatal bleeding (ace_ipfcdd:ADJRPT.ADJMJR02 / Symptomatic Bleed) [1] <input type="checkbox"/> Symptomatic bleeding in a critical area or organ (ace_ipfcdd:ADJRPT.ADJMJR03 / Bleed Requiring Transfusion) [1] <input type="checkbox"/> Bleeding leading to transfusion of 2 or more units of whole blood or red blood cells [2] <input type="radio"/> Minor [3] <input type="radio"/> Minimal [4] <input type="radio"/> No bleed [5] <input type="radio"/> Data Insufficient to Judge</p>

* Item is not required

CDD: ace_ipfcdd Table: ADJRPT Key Type: PATIENTVISIT

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

ADJHOSDT	DATE - DDMONYYYY	
ADJHOSRS	NUMERIC	
ADJHSRSP	STRING(100) - A100	
ADJDIE	NUMERIC	
ADJDICSE	NUMERIC	
ADJDICSP	STRING(100) - A100	
ADJBST	NUMERIC	
ADJBLDT	DATE - DDMONYYYY	
ADJBSTE1	NUMERIC	
ADJBSTE2	NUMERIC	
ADJBSTE3	NUMERIC	
ADJBSTE4	NUMERIC	
ADJBSTE5	NUMERIC	
ADJBSTE6	NUMERIC	
ADJBSTE7	NUMERIC	
ADJBSTE8	NUMERIC	
ADJCMPSN	NUMERIC	
ADJBSTE9	NUMERIC	
ADJSECHG	NUMERIC	
ADJBST10	NUMERIC	
ADJBST11	NUMERIC	
ADJBST12	NUMERIC	
ADJRST	NUMERIC	
ADJMRO1	NUMERIC	
ADJMRO2	NUMERIC	
ADJMRO3	NUMERIC	

CDD: panther_ipfcdd Table: ADJRPT Key Type: PATIENTVISIT

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

ace_ipf : Computer Tracker (COMPTRKR)		
Computer Tracker Tracker		
1.	Did the subject receive a computer?	(ace_ipfcdd:COMPTRKR1.COMPUTER / Computer Received) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
	Serial Number	Date dispensed Date returned
2.		
2.a	Serial Number	<input type="text" value="A50"/> (ace_ipfcdd:COMPTRKR2.PCSERLNO / Serial Number)
2.b	Date dispensed	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2010) (ace_ipfcdd:COMPTRKR2.PCDISDT / Date Computer Dispensed)
2.c	Date returned	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2010) (ace_ipfcdd:COMPTRKR2.PCRTNDT / Date Computer Returned)

CDD: ace_ipfcdd Table: COMPTRKR1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
COMPUTER	NUMERIC	

CDD: ace_ipfcdd Table: COMPTRKR2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PCSERLNO	STRING(50) - A50	
PCDISDT	DATE - DDMONYYYY	
PCRTNDT	DATE - DDMONYYYY	

ace_ipf : INR Monitors Tracker (INRTRKR)		
INR Monitor Tracker		
1.	Did the subject receive an INR monitor?	(ace_ipfcdd: INRTRKR1.INRMONTR / INR Monitor Received) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
	Serial Number	Date dispensed Date returned
2.		
2.a	Serial Number	<input type="text" value="A50"/> (ace_ipfcdd: INRTRKR2.INSERTLNO / Serial Number)
2.b	Date dispensed	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2010) (ace_ipfcdd: INRTRKR2.INDISDT / Date Monitor Dispensed)
2.c	Date returned	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2010) (ace_ipfcdd: INRTRKR2.INRTNDT / Date Monitor Returned)

CDD: ace_ipfcdd Table: INRTRKR1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
INRMONTR	NUMERIC	

CDD: ace_ipfcdd Table: INRTRKR2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
INSERTLNO	STRING(50) - A50	
INDISDT	DATE - DDMONYYYY	
INRTNDT	DATE - DDMONYYYY	

ace_ipf : Survival Status Form (LTF)		
Survival Status		
1.	Date of survival check	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:LTF.LTFDFT / Survival Check Date)
2.	What is the current status of the subject ?	(ace_ipfcdd:LTF.SURVIVAL / Current Subject Status) [0] <input type="radio"/> Unknown [1] <input type="radio"/> Alive [2] <input type="radio"/> Dead If Dead: Date of death: Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2016) (ace_ipfcdd:LTF.LTFDTHDT / Death Date)
3.*	Source Document Verification Completion	(ace_ipfcdd:LTF.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: ace_ipfcdd	Table: LTF	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
LTFDFT	DATE - DDMYYYY	
SURVIVAL	NUMERIC	
LTFDTHDT	DATE - DDMYYYY	
SDVSTAT	NUMERIC	

ace_ipf : Unscheduled Visit Status (UNSCVIST)		
Unscheduled visit		
1.	Contact Date	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2016) (ace_ipfcdd:UNSCVIST.CONTDT / Contact Date)
2.	Type of Contact	(ace_ipfcdd:UNSCVIST.CONTACT / Type of Contact) [1] <input type="radio"/> (ace_ipfcdd:UNSCVIST.UNSCRSN / Unscheduled Reason) Unscheduled Visit [1] <input type="radio"/> Acute Exacerbation [2] <input type="radio"/> Other (ace_ipfcdd:UNSCVIST.UNSCOTHR / Unscheduled Reason, Other) Specify Other A50
3.*	Source Document Verification Completion	(ace_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
CONTDT	DATE - DDMONYYYY	
CONTACT	NUMERIC	
UNSCRSN	NUMERIC	
UNSCOTHR	STRING(50) - A50	
SDVSTAT	NUMERIC	

ace_ipf : Signature Completion (SIGN)		
Signature		
1.	Casebook Ready for Signature	(ace_ipfcdd: SIGN.PISIGN / PI Signature Present) [1] <input type="checkbox"/> Yes
2.*	Source Document Verification Completion	(ace_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		

CDD: ace_ipfcdd Table: SIGN Key Type: PATIENTVISIT		
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.