

**Lung Health Study
Data and Coordinating Center
University of Minnesota, Minneapolis, MN**

Coded Variables

<u>Variable</u>	<u>Value</u>	<u>Description</u>
All yes/no variables	1	yes
	2	no
SIA	1	if participant is in the Special Intervention + Atrovent group
	0	otherwise
SIP	1	if participant is in the Special Intervention + Placebo group
	0	otherwise
U_C	1	if participant is in the Usual Care group
	0	otherwise
RGROUP	1	SIA, Special Intervention + Atrovent group
	2	SIP, Special Intervention + Placebo group
	3	UC, Usual Care group
DAYS2DED		This variable gives the number of days from randomization to the date of death of the participant
YEAREduc	4	less than or equal to 8th grade
	8	trade school instead of high school
	10	some high school
	12	high school graduate
	14	trade school after high school or some college
	16	bachelor's degree
	18	some graduate education
20	graduate degree	
BMI		$(\text{wt in kg.})/(\text{ht. in meters})^2$
SEX	1	male
	2	female
"Triage" smoking status variables	1	quitter
	2	intermittent smoker
	3	smoker

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<u>Variable</u>	<u>Value</u>	<u>Description</u>
"Quad" smoking status variables	1 2 3 4	sustained quitter intermittent smoker who has now quit intermittent smoker who is now smoking continuous smoker
RQUIT*		The RQUIT1 - RQUIT5 series of variables cover self-reported quit status for smoking cigarettes at annual visits 1 - 5.
	0 1	not quit quit smoking cigarettes
PCQUIT*		The PCQUIT1 - PCQUIT5 series of variables cover self-reported quit status for smoking cigarettes, pipes and cigars at annual visits 1-5.
	0 1	not quit quit
VQUIT*		The VQUIT1 - VQUIT5 series of variables cover quit status for cigarettes, validated by either salivary cotinine or carbon monoxide levels.
	0 1	not quit quit
F060PHYS- F560PHYS	0 1 2 3	none private physician HMO, naming specific doctor name of HMO or clinic only
S3STATUS	0	OK
A5STATUS	1 2 3	did not do methacholine challenge test unanalyzable stopped early
F80PD01 - F80PD14	1 2 3 4 5 6 7 8 9	myocardial infarction angina ischemic heart disease congestive heart failure coronary revascularization other coronary heart disease unspecified coronary heart disease stroke TIA

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Variable Value Description

10	arrhythmia
11	pulmonary embolism
12	hypertension
13	other cardiovascular disease
14	unspecified cardiovascular disease
15	lung cancer
16	other cancer
17	cancer with unknown primary
18	COPD
19	asthma
20	pneumonia
21	other respiratory disease
22	unspecified respiratory disease
23	other disease
24	documentation refused
25	unknown

F32CAF6

F32TCAF6 If version 3 or 4, use F32TCAF6 only.
 If version 1 or 2, and F32CAF6 = 1 and F32TCAF6 = 1, then did use 2 cups
 of coffee or equiv. caffeine in past 6 hours.
 If version 1 or 2, and F32CAF6 = 1 and F32TCAF6 = 2, then NO, the
 participant did not use two or more cups of coffee in the past 6 hours. If
 version 1 or 2 and F32CAF6 = 2, then NO.

F33SMK1Y Version 1 of F33

Do you expect that one year from now you will be smoking:
 1 = more cigarettes
 2 = same number of cigarettes
 3 = fewer cigarettes
 4 = no cigarettes at all

F060DRKW drinks per week (computed variable)

AV1LCIGM computed from data on form

SUMCIGS1 computed from data on form

F541COLL was any serum or plasma collected? 1=yes, otherwise blank

F541SERM number of serum samples collected

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<u>Variable</u>	<u>Value</u>	<u>Description</u>
F541PLAS		number of plasma samples collected
F541WHIT		were white cells collected? 1=yes, 0=no
F32MCCOD	00	regular protocol followed
and/or	01	test discontinued because of symptoms
F32MCCOM	02	computer or spirometer problems occurred during challenge
	03	severe symptoms occurred but test was continued - problems may affect test or dose given
	04	fewer than 5 breaths given, but FEV1 drop was $\leq 14\%$ and no severe symptoms occurred
	05	failed to return to 10% of baseline FEV1 after 2 doses of 2 puffs isuprel
	06	failed to return to 20% of baseline FEV1 after 2 doses of 2 puffs isuprel
	07	FEV1 drop was $< 10\%$ - isuprel was given anyway
	08	protocol was followed but less than 5 breaths were given
	09	test was discontinued early - no reason given
	10	mild symptoms occurred
	11	FEV1 decline was apparently due to fatigue - there was no apparent reaction to methacholine
	12	participant asked to stop test or refused to continue testing
	13	additional bronchodilator was given, other than isuprel
	14	FEV1 drop was $\geq 10\%$ - no isuprel was given
	15	protocol indicates 3 breaths to be given but 5 breaths were actually given
	16	other protocol error
	17	symptoms occurred after leaving clinic
F060TDCC		
F260TDCC		
F360TDCC		
F460TDCC		
F560TDCC	001	perspiration
	002	back ache
	003	joint pain, stiffness
	004	ear aches
	005	sinus problems
	006	kidney stones
	007	heartburn
	008	tiredness
	009	hematoma
	010	“catch in throat”
	011	hernia

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<u>Variable</u>	<u>Value</u>	<u>Description</u>
	012	cough
	013	gas
	014	urinary urgency
	015	laryngitis
	016	belching
	017	stomach discomfort
	018	hearing difficulty
	019	wheezing
	020	diarrhea
	021	headache
	022	poor eyesight
	023	epitoxis
	024	hemorrhoids
	025	swollen, watery eyes
	026	clogged nose
	027	cold
	028	adult acne
	029	excessive phlegm
	030	anxiety
	031	hot flashes
	032	chills easily
	033	shortness of breath, difficulty breathing
	034	depression
	035	gall bladder pain
	036	tension
	037	hiatal hernia
	038	alcoholism/recovery/treatment
	039	constipation
	040	teeth and gums sore
	041	teeth loose
	042	heart rate rapid
	043	duplicate of 060
	044	skin rash
	045	pulled out partials
	046	dry throat
	047	muscle spasm/pain
	048	sneezing
	049	benign essential tremors
	050	numb arm, leg, extremities
	051	pinched nerve
	052	bone spurs on feet
	053	dizziness
	054	itching

Variable Value Description

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055	increased forgetfulness
056	hay fever-like problems
057	varicose veins
058	sore ribs
059	bladder infection
060	bad taste in mouth
061	malformed gums
062	bronchospasm
063	unusual dreams
064	biting tongue
065	gum sticks to dentures
066	chest tightness
067	sinus problems
068	duplicate of 020
069	hoarseness
070	duplicate of 031
071	colitis
072	sweats
073	dysmenorrhea
074	groin pain
075	angina
076	duplicate of 074
077	fever/mouth blisters
078	nose bleeds
079	ear wax build-up
080	hives
081	addiction to nicotine gum
082	teeth cracking/breaking
083	vomiting
084	throat pain/ache
085	tinnitus, ringing in ears
086	unspecified pain, burning, soreness
087	lip soreness/swelling/dryness/numbness
088	tooth/denture problems
089	nose pain
090	blood clot
091	inflammation of bowel
092	duplicate of 053
093	ear congestion
094	duplicate of 060
095	rectal soreness
096	agoraphobia
097	nausea
098	incontinence

Variable Value Description

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099 gags on inhaler
 100 bloating/edema/swelling of limbs
 101 diverticulitis
 102 duplicate of 069
 103 cold extremities, circulation problems
 104 runny nose
 105 ulcer pain/symptoms
 106 difficulty swallowing
 107 overweight, obesity
 108 teeth sensitive to hot and cold
 109 neck injury
 110 sleep apnea
 111 gout
 112 duplicate of 093
 113 high blood pressure
 114 nephritis, kidney pain
 115 sensitivity to noise
 116 Ménière's syndrome
 117 allergies
 118 underactive thyroid
 119 jaw problems, TMJ, popping
 120 throat clearing, excess mucous
 121 acid stomach
 122 urinary infection
 123 diabetes
 124 serious cuts
 125 herpes, genital
 126 herniated disc
 127 nose sores
 128 bowel movements - increased frequency
 129 perspiration increase
 130 choking feeling
 131 bronchitis
 132 speech impediment
 133 equilibrium, loss of
 134 congestion, general
 135 acute allergic reaction
 136 bad breath
 137 fever
 138 low blood pressure
 139 fungal infections
 140 prostate problems
 141 high cholesterol level
 142 retinal hemorrhage

Variable Value Description

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143	back surgery
144	neck pain
145	seizure
146	flushed face
147	eczema
148	insomnia
149	low blood sugar
150	pancreatitis
151	Parkinson's Disease
152	hepatitis
153	cardiovascular problem requiring treatment
154	glaucoma
155	psychological/mental illness
156	urinary retention
157	chest pain
158	excess salivation
159	heat intolerance
160	hiccups
161	irritability
162	loss of appetite
163	moody, mood changes
164	bursitis
165	hydrocele
166	foot/leg/limb pain
167	skin cancer
168	neurological disorder
169	anemia
170	impotence
171	flu, flu-like symptoms
172	high liver enzymes
173	exophthalmia
174	liver disease
175	swollen glands
176	inflammatory disease, Weber-Christian disease
177	ingrown toenail
178	floaters
179	broken bone
180	Lyme disease
181	mitral valve prolapse
182	hemorrhaging (site unknown)
183	fibromas
184	appendicitis
185	duplicate of 046
186	loss of sense of smell or taste

Variable Value Description

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187	alopecia, hair loss, baldness
188	PMS
189	pneumonia
190	bloody stools
191	duplicate of 002
192	transglobal amnesia
193	foot surgery
194	eye twitching/tic
195	appetite, increase in
196	carpal tunnel syndrome
197	shingles
198	lung irritation due to a chemical irritant
199	chronic dislocation, right shoulder
200	duplicate of 190
201	narcolepsy
202	breast lump
203	duplicate
204	lungs feel full of water
205	spots in mouth or throat
206	intestinal blockage
207	plantar warts
208	“unmotivated to use”
209	duplicate of 044
210	cataracts
211	duplicate of 155
212	slow heart beat
213	tonsillitis
214	sunburn
215	receding gums
216	aortic aneurysm
217	hip surgery/replacement
218	duplicate of 035
219	phlebitis
220	wounds do not heal
221	localized infection
222	pancreas division
223	benign tumors in mouth
224	duplicate of 202
225	heart palpitations
226	blackouts, fainting spells
227	duplicate of 193
228	bladder tumors
229	coughing up blood
230	blood in urine

Variable Value Description

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231	mononucleosis
232	ringworm
233	stroke
234	dental decay
235	bladder problems
236	cancer, all types
237	hyperactive thyroid
238	optic neuritis
239	inflamed duodenum
240	Crohn's disease
241	sty in eye
242	osteoporosis
243	duplicate of 109
244	supranuclear palsy
245	heart pounding harder but not faster
246	hemiplegia
247	duplicate of 091
248	congestive heart failure
249	eye injury
250	deviated septum
251	weight loss
252	stomach virus
253	weakness
254	strep throat
255	bowel problem
256	pleurisy
257	bacterial heart infection
258	polymyalgia rheumatica
259	incisional pain
260	atrial fibrillation
261	chemotherapy problems, unspecified
262	eye infection
263	transient ischemic attack
264	nasal polyps
265	stomach distention
266	impetigo
267	hyperventilation
268	mental functions not as quick
269	adrenal tumor
270	collapsed vein
271	panic disorder
272	bladder problems
273	lactose intolerance
274	multiple sclerosis

Variable Value Description

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275 thyroid infection
276 body aches
277 papilloma
278 aneurysm (any but aortic)
279 numbness to one side of face
280 numbness or pain on one side of body
281 blood platelet count low
282 endocrine disorder, any type
283 blood, difficulty retrieving
284 night sweats

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Miscellaneous

Dates All dates have been converted to the number of days from randomization. As a result, dates for some of the screening visits appear as a negative number of days.

Height,
Weight In accordance with our instructions, height and weight have been removed from the data file, but we have added body mass index at baseline (named BMI) and at the annual visits (named BMI1 - BMI5).

Hospitalization
Codes Reasons for hospitalizations and similar coded fields are given in standard ICD-9-CM codes.

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Pulmonary Function Variables

Pulmonary function testing in LHS1 was done at 9 visits:

Number	Description
0	Screen 1
1	Screen 2: baseline and post-BD
2	Screen 3: baseline and methacholine
3	Month 4: (SI participants only) baseline and post-inhaler
4	Year 1: baseline and post-BD
5	Year 2: baseline and post-BD
6	Year 3: baseline and post-BD
7	Year 4: baseline and post-BD
8	Year 5A: baseline and post-BD
9	Year 5B: baseline and methacholine

Screen 1 spirometry involved testing with non-standardized equipment in a variety of settings (worksites, shopping malls, satellite clinics, and others). Up to 6 maneuvers were done. Participants were excluded if

- a) their FEV₁ percent of predicted was < 50% or > 90%,
- b) their FEV₁/FVC % was > 75%.

The only variables on the analysis file from the Screen 1 visit are:

F10MFEV (maximum FEV₁)
F10MFVC (maximum FVC)

Screen 2 and subsequent spirometry was performed using study-standardized equipment and a uniform protocol. Spirometry sessions were of 3 types:

Type	Description
1	Baseline
2	Post-bronchodilator or post-inhaler (the latter done only at Month 4)
3	Methacholine

For baseline and post-BD sessions, up to 8 maneuvers were performed. The analysis file includes a subset of the data from these 8 maneuvers.

The file includes data on maximum values from acceptable maneuvers (those meeting ATS acceptability criteria), and maximum values from all maneuvers, regardless of acceptability.

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The specific variables and prefixes of their names on the file are as follows:

<u>Description</u>	<u>Variable Names</u>	
	<u>For ATS-Acceptable Maneuvers</u>	<u>For All</u>
<u>Maneuvers</u>		
Max FEV ₁	FEVAC1xy	ALFEV1xy
2nd Max FEV ₁	FEVAC2xy	ALFEV2xy
Max FVC	FVCAC1xy	ALFVC1xy
2nd Max FVC	FVCAC2xy	ALFVC2xy
PEFR from Max FEV ₁	PFRAC1xy	ALPFR1xy
PEFR from 2nd Max FEV ₁	PFRAC2xy	ALPFR2xy
PEFT from Max FEV ₁	PFTAC1xy	ALPFT1xy
PEFT from 2nd Max FEV ₁	PFTAC2xx	ALPFT2xy
Max FEV ₃	FEV3ACxx	ALFEV3xx
Max FEV ₆	FEV6ACxy	ALFEV6xy
Max FEV ₁ % pred	FEVPACxy	ALFEVPxy
Max PEFR	MPEFR1xy	—
2nd Max PEFR	MPEFR2xy	—
PEFT from Max PEFR	PRPFT1xy	—
PEFT from 2nd Max PEFR	PRPFT2xy	—
Number of Maneuvers	NUMACxy	NUMMANxy
FEF 25-75 (Redline)	FEF25xx	—
FEF 25-75 for Max FEV ₁	FEFAC1xx	ALFEF1xy
FEF 25-75 for 2nd Max FEV ₁	FEFAC2xx	ASFEF2xy
Extrapolated Volume	EXTVACxy	ALEXTVxy

Additional Session Variables:

<u>Description</u>	<u>Variable</u>
Days from Randomization to Session	SPEDATxy
Time (Hours) of Session Start	SPHOURxy
Time (Min.) of Session Start	SPMINSxy
Flow Grade (0-4) Quality Score	FGRADExy
Volume Grade (0-4) Quality Score	VGRADExy

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The two last digits in variables such as FEVAC1xy are defined as follows:

x = 1 for “baseline” or pre-BD sessions
2 for post-BD sessions

y = visit number, 1-9, as defined above

Note: The FEV3 and FEV6 variables are sometimes set to 0. This occurred when the forced expiratory times were less than 3 seconds or 6 seconds (resp.). **These values should be regarded as missing.**

Methacholine Data

Methacholine reactivity testing was done at Screen 3 and again at Annual Visit 5B. The methacholine testing protocol is described in detail in Tashkin et al, *Am J Respir Crit Care Med* 153:1802-1811, 1996. The specific variables and prefixes of their names on the file are as follows:

<u>Description</u>	<u>Variable Names</u>	
	<u>Screen 3</u>	<u>AV 5B</u>
Status 0 = OK A5STATUS	S3STATUS	
1 = Did not do test		
2 = Unanalyzable		
3 = Stopped early		
Diluent response (0=no, 1=yes) (Abs change in FEV ₁)/(log ₁₀ (cumdose +1))	S3DILRES	A5DILRES
Abs change in FEV ₁ /(cum dose)	S3SLOP1A	A5SLOP1A
Abs change in FEV ₁ /log ₁₀ (conc +1)	S3SLOP2A	A5SLOP2A
Abs change in FEV ₁ /final concentration	S3SLOP3A	A5SLOP3A
O'Connor two-point slope: (% drop FEV/cumdose) S5OCONNR	S3SLOP4A	A5SLOP4A
Two-point slope: origin to last data vs. concentration	S3OCONNR	
Cum dose (abs. scale) drop to 80.5% diluent	S3PAC2	A5PAC2
Cum dose (log ₁₀ scale) drop to 80.5% diluent	S3PD20	A5PD20
Cum dose (abs. scale) drop to 85.5% dil	S3PD20L	A5PD20L
Cum dose (log ₁₀ scale) drop to 85.5% dil	S3PD15	A5PD15
Cum dose (abs. scale) drop to 90.5% dil	S3PD15L	A5PD15L
Cum dose (log ₁₀ scale) drop to 90.5% dil	S3PD10	A5PD10
Conc. (abs. scale) drop to 80.5% dil	S3PD10L	A5PD10L
Conc. (log ₁₀ scale) drop to 80.5% dil	S3PC20	A5PC20
	S3PC20L	A5PC20L

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Conc. (abs. scale) drop to 85.5% dil	S3PC15	A5PC15
Conc. (log ₁₀ scale) drop to 85.5% dil	S3PC15L	A5PC15L
Conc. (abs. scale) drop to 90.5% dil	S3PC10	A5PC10
Conc. (log ₁₀ scale) drop to 90.5% dil	S3PC10L	A5PC10L
Conc. abs scale uninterr drop to 80.5% dil	S3PCUN20	A5PCUN20
Conc. abs scale uninterr drop to 85.5% dil	S3PCUN15	A5PCUN15
Conc. abs scale uninterr drop to 90.5% dil	S3PCUN10	A5PCUN10
Pre-diluent max FEV ₁	S3BL	A5BL
Post-diluent max FEV ₁	S3DIL	A5DIL
Max FEV ₁ after 3 breaths 1 mg conc.	S3C1B3	A5C1B3
Max FEV ₁ after 5 breaths 1 mg conc.	S3C1B5	A5C1B5
Max FEV ₁ after 3 breaths 5 mg conc.	S3C5B3	A5C5B3
Max FEV ₁ after 5 breaths 5 mg conc.	S3C5B5	A5C5B5
Max FEV ₁ after 3 breaths 10 mg conc.	S3C10B3	A5C10B3
Max FEV ₁ after 5 breaths 10 mg conc.	S3C10B5	A5C10B5
Max FEV ₁ after 3 breaths 25 mg conc.	S3C25B3	A5C25B3
Max FEV ₁ after 5 breaths 25 mg conc.	S3C25B5	A5C25B5
Log ₁₀ (.681 - 2-point abs. slope)	LOGPACS3	
LOGPACA5		
Methacholine testing days from randomization	S3SDATE	SPEDAT91

F32MFEVT: Trans Max FEV₁ —
of acceptable FEV₁s or the

MFVCT
MFVCT
MPEFR

This is either the maximum

maximum of all FEV₁s if there were no acceptables.
Similar for FVC, FEV₁/FVC and PEFR.

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Mortality and Morbidity Data on the LHS Analysis File

Deaths: Deaths among LHS1 participants are accurately recorded up to five years (1827 days) after randomization. Mortality follow-up is incomplete and unreliable after 1827 days, and should not be used for statistical tables or analyses.

Codes for causes of death are recorded in two variables, one of which is a collapsed version of the other:

1. DEADCODE: 33 categories
2. DTHCAUSE: 7 categories

The relationship between these two variables can be summarized as follows:

DEADCODE		DTHCAUSE	
Code	Description	No. Deaths in 5 Years	Code Description
1	Myocardial infarction	10	1 Coronary heart disease
2	Ischemic heart disease	4	1 Coronary heart disease
3	Congestive heart failure	0	2 Cardiovascular disease, not
CHD			
4	Coronary revascularization	0	1 Coronary heart disease
5	Other CHD	0	1 Coronary heart disease
6	Unspecified CHD	0	1 Coronary heart disease
7	Stroke	4	2 Cardiovascular disease, not
CHD			
8	Transient ischemic attack	0	2 Cardiovascular disease, not
CHD			
9	Arrhythmia	1	2 Cardiovascular disease, not
CHD			
10	Pulmonary embolism	1	2 Cardiovascular disease, not
CHD			
11	Hypertension	0	2 Cardiovascular disease, not
CHD			
12	Other CVD	0	2 Cardiovascular disease, not
CHD			
13	Unspecified CVD	0	2 Cardiovascular disease, not
CHD			
14	Sudden cardiac	11	1 Coronary heart disease
15	Other sudden death	5	6 Other cause
16	Lung cancer	57	3 Lung cancer
17	Other cancer	29	4 Other cancer
18	Cancer unknown site	4	4 Other cancer
19	COPD	0	5 Respiratory, not cancer

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20	Asthma	1	5	Respiratory, not cancer
21	Pneumonia	0	5	Respiratory, not cancer
22	Other respiratory	0	5	Respiratory, not cancer
23	Unspecified respiratory	0	5	Respiratory, not cancer
24	Diabetes	0	6	Other cause
25	Liver disease	1	6	Other cause
26	AIDS	2	6	Other cause
27	ARC	0	6	Other cause
28	Drug dependency	0	6	Other cause
29	Suicide	3	6	Other cause
30	Homicide	2	6	Other cause
31	Accident	2	6	Other cause
32	Other causes	4	6	Other cause
33	Unknown	2	7	Unknown

Morbidity

Morbidity in the LHS1 was ascertained in essentially three stages:

1. On annual visit forms 60, 260, 360, 460, and 560, participants were asked if they had been hospitalized in the past year (e.g. F260HOSP, with 1 = yes, 2 = no), and, if yes, how many times (e.g., F260HTMS). Clinic center personnel attempted to obtain hospital records for all hospitalizations other than those for psychiatric illnesses, alcohol abuse, or drug abuse.
2. Central coding of the causes of hospitalization for all record-sets was done by a trained coder with expertise in ICD-9 and other coding, at the Data Coordinating Center
3. All records for which there was any indication of the presence of respiratory disease, cardiovascular disease, or cancer, were sent to the MMRB (a panel of 3 physicians with expertise in pulmonary disease, oncology, and cardiovascular disease) for coding. The MMRB assigned exactly **one primary** cause for the hospitalization, and any number of co-existing conditions.

The MMRB's findings were summarized on Form 80. Participants could have multiple Form 80s, corresponding to multiple hospitalizations. The maximum number of Form 80s was 14. Form 80 variables are linked to the form by the form-variables documentation.

Note that Form 80 is **not** useful for counting hospitalizations for conditions other than respiratory, cardiovascular, or cancer.

Note that **most** Form 80s are completely blank for **most** participants; only 754 participants have even one Form 80, only 119 have two, etc.

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Each Form 80 includes an admission time and a discharge time (both as days since randomization).