Protocol No.	Site No.	Participant No.	Participant Initials	Visit				
EPIC-001				Baseline				
PROTOCOL	PROTOCOL INFORMED CONSENT Date of Visit:/							
Date Informed	Consent Signed:/	/						
DATABANK	DATABANK INFORMED CONSENT							
97 Databank	Informed Consent not obt	ained						
Date Informed Consent Signed:/								
SPECIMEN BANKING INFORMED CONSENT								
97 Specimen Banking Informed Consent not obtained								

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1

Final: March 9, 2005

Date Informed Consent Signed: ____/

See Version 2 of the CRF at the end of this document.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

INCLUSION CRITERIA

	Note: Any "No" response in this section disqualifies the subject from approval has been obtained from the sponsor.	m the stud	ly, unles:	s prior
		No	Yes	N/A
1.	Male or female ≥ 1 year and ≤ 12 years of age	0	1	
2.	 Confirmed diagnosis of Cystic Fibrosis: sweat chloride > 60 mEq/L by quantitative pilocarpine iontophoresis; and/or a genotype with two identifiable mutations consistent with CF or an abnormal nasal transepithelial potential difference and 	0	1	
3.	 one or more clinical features consistent with CF *Participants >15 months of age: New onset of Pa positive respiratory culture within 6 months prior to Baseline Visit: 			98
	 a) first lifetime documented <i>Pa</i> positive culture; <u>OR</u> b) <i>Pa</i> recovered after at least a 2 year history of <i>Pa</i> negative respiratory cultures (≥ 1 culture/year) 	0	1	98 98 98
4.	*Participants 12-15 months of age: at least one documented Pa positive respiratory tract culture since birth or CF diagnosis	о	1	98
5.	Clinically stable: no evidence of significant respiratory symptoms and/or physical or chest radiograph findings at screening that would require administration of IV anti-pseudomonal antibiotics, oxygen, and/or hospitalization	0	1	
6.	Signed informed consent by parent or legal guardian and applicable assent.	0	1	

*Select appropriate age criteria for participant. If participant is >15 months of age, also select either subcriteria a) or b). Any non-applicable age or subcriteria should be marked "N/A".

2

EPIC-001				Baseline
Protocol No.	Site No.	Participant No.	Participant Initials	Visit

EXCLUSION CRITERIA

Not	Note: Any "Yes" response in this section disqualifies the subject from the study, unless prior approval has been obtained from the sponsor.					
		No	Yes			
1.	History of aminoglycoside hypersensitivity or adverse reaction to inhaled aminoglycoside.	0	1			
2.	History of hypersensitivity or adverse reaction to ciprofloxacin or other fluoroquinolone.	0	1			
3.	History of persistent, unresolved hearing loss documented by audiometric testing on at least two occasions and not associated with middle ear disease or an abnormal tympanogram.	0	1			
4.	Abnormal renal function at Baseline Visit (serum creatinine > 1.5 times the upper limit of normal for age).	0	1			
5.	Abnormal liver function tests at Baseline Visit (ALT and/or AST > 2 times the upper limit of normal range).	0	1			
6.	Administration of any investigational drug within 30 days prior to the Baseline Visit.	0	1			
7.	Administration of loop diuretics, phenytoin, warfarin, theophylline or other methyl-xanthines ≤ 30 days prior to Baseline Visit.	0	1			
8.	Administration of more than one course (at least 10 continuous days of therapy) of IV anti-pseudomonal antibiotics or more than one course (at least 28 continuous days of therapy) of inhaled anti-pseudomonal antibiotics. Antibiotics must be completed > 30 days prior to the Baseline Visit.	0	1			
9.	Chronic macrolide use (more than 90 day duration) within 3 months prior to the Baseline Visit.	0	1			
10.	Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the Participant or the quality of the data.	0	1			
TI	ne CRF data below was not submitted					
I cert	ify that I have reviewed source documentation and that all inclusion / exclusion informatio	n is accur	ate.			
Sign	ature: Date:/_	/dd	уууу			

Protocol No.	Site No.	Participant No.	Participant Initials	Visit		
EPIC-001				Baseline		
DEMOGRAF	PHICS					
Date of Birth:	// 	Sex:	₁☐ Male	₂☐ Female		
Race/Ethnicit	y (check one):					
Caucasian (not of Hispanic origin) African-American (not of Hispanic origin) Asian or Pacific Islander American Indian or Alaskan Native Other, specify:						
REPRODUCTIVE STATUS						
Female is:	₁□ Pre-mena	rche 2 Post-m	nenarche 98 N/A			
DIAGNOSIS]					
Sweat Chloric	de Test 97 Not Done	Dat	e of Test:/	/		
Result:	mEq/L					
CF Genotype	97 ☐ Not Done	Dat	e of Test:/	<u>/</u>		
Mutation #1.	Delta F508 Unidentified Other, specify:	submitted.	pe data has not be			
Mutation #2.	Delta F508 Unidentified Other, specify:					

EPIC-001			•	Baseline
Protocol No.	Site No.	Participant No.	Participant Initials	Visit

MEDICAL HISTORY

Med	ication Allergies:	₀☐ Check if None			
1		5	 		
2		6	 		
3		7	 		
4		8	 		
No.	*Body System *Indicate Body System only if "Other" is used	Details	Resolved	Inactive	Active
1.			0	1	2
2.			0	1	2
3.			0	1	2
4.			0	1	2
5.			0	1	2
6.			0	1	2
7.			0	1	2
8.			0	1	2
9.			0	1	2
10.			0	1	2
11.			о	1	2
12.			0	1	2

Please ensure all significant medical history and medical procedures are reviewed for the following body systems:

01=General Appearance 02=Skin 03=Lymph Nodes 04=HEENT 05=Respiratory

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06=Cardiovascular 07=Gastrointestinal 08=Urinary 09=Neurologic 10=Hematologic 11=Endocrine 12=Musculoskeletal 13=Surgical 99=Other

EPIC-001				Baseline
Protocol No.	Site No.	Participant No.	Participant Initials	Visit

HISTORY OF ANTI-PSEUDOMONAL ANTIBIOTIC USE (Regardless of Indication) from birth to Baseline Visit

₀ None

Line #	Medication	Route (IV, INH, PO)	Start Date (mmm/dd/yyyy)	Stop Date (mmm/dd/yyyy)
1.			/	
2.				
3.				
4.				
5.				
6.				
7.				//
8.				
9.			//	
10.				

HISTORY OF CHRONIC MACROLIDE USE (> 90 days of continuous therapy) from birth to Baseline Visit

lт	N	_	n	е
ш	Ν	O	П	е

Line #	Medication	Route (IV, PO)	Start Date (mmm/dd/yyyy)	Stop Date (mmm/dd/yyyy)
1.			/	
2.				
3.			/	
4.			/	/
5.			/	/
6.			/	
7.				
8.				
9.			/	
10.				

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

PSEUDOMONAS AERUGINOSA CULTURE HISTORY ≤ 3 YEARS PRIOR TO BASELINE VISIT

	rticipant's qualifying doo y culture prior to EPIC	•	Date:/
	he participant's first doo a positive respiratory cu		mmm dd yyyy 1 ☐ Yes
	No , please list the part 3 years prior to the EP		re results (Pa positive or Pa negative)
Line #	Culture Date (mmm/dd/yyyy)	Pa Results	
4		П., . П.	

Line #	Culture Date (mmm/dd/yyyy)	Pa Results		
1.		0 ☐ Negative 1 ☐ Positive		
2.		0 ☐ Negative 1 ☐ Positive		
3.		0 Negative 1 Positive		
4.		0 ☐ Negative 1 ☐ Positive		
5.		0 ☐ Negative 1 ☐ Positive		
6.	/	0 Negative 1 Positive		
7.		₀☐ Negative 1☐ Positive		
8.		0 ☐ Negative 1 ☐ Positive		
9.		0 Negative 1 Positive		
10.		0 Negative 1 Positive		
11.		0 Negative 1 Positive		
12.		0 ☐ Negative 1 ☐ Positive		
13.		₀☐ Negative 1☐ Positive		
14.		₀☐ Negative 1☐ Positive		
15.	/	₀☐ Negative ₁☐ Positive		

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Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

	OMONAS AERUGI Y ≤ 3 YEARS PRIC	NOSA CULTURE OR TO BASELINE VISIT	
respirator Was this this thickness of the second se	articipant's qualifying doc y culture prior to EPIC the participant's first doc a positive respiratory cu	-001 Baseline Visit: Discumented	
	3 years prior to the EP		o (r a positivo er r a negativo
Line #	Culture Date (mmm/dd/yyyy)	Pa Results	
1.	/	₀☐ Negative ₁☐ Positive	
2.		₀☐ Negative 1☐ Positive	
3.	/	₀ Negative 1 Positive	
4.		0 ☐ Negative 1 ☐ Positive	
5.	/	0 ☐ Negative 1 ☐ Positive	
6.		0 ☐ Negative 1 ☐ Positive	
7.	/	0 ☐ Negative 1 ☐ Positive	
8.	/	0 ☐ Negative 1 ☐ Positive	
9.	/	0 ☐ Negative 1 ☐ Positive	
10.	/	0 ☐ Negative 1 ☐ Positive	
11.		0 ☐ Negative 1 ☐ Positive	
12.	/	0 ☐ Negative 1 ☐ Positive	
13.	/	₀ Negative 1 Positive	
14.		□ Negative □ Positive	

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15.

 $_0$ Negative $_1$ Positive

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

PSEUDOMONAS AERUGINOSA CULTURE HISTORY > 3 YEARS PRIOR TO BASELINE VISIT

Has the participant had any <i>Pa</i> positive respiratory cultures > 3 years prior to the EPIC-001 Baseline Visit?	o□ No	₁□ Yes	96 Unknown
If Yes, please list dates of all prior Pa positive re > 3 years prior to the EPIC-001 Baseline Visit.	espiratory cultur	e results	

Line #	Culture Date (mmm/dd/yyyy)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	

EPIC-001				Baseline
Protocol No.	Site No.	Participant No.	Participant Initials	Visit

PSEUDOMONAS AERUGINOSA CULTURE HISTORY > 3 YEARS PRIOR TO BASELINE VISIT

Has the participant had any <i>Pa</i> positive respiratory cultures > 3 years prior to the EPIC-001 Baseline Visit?	o□ No	₁ ☐ Yes	96 Unknown
If Yes, please list dates of all prior Pa positive res > 3 years prior to the EPIC-001 Baseline Visit.	spiratory cultur	e results	

Line #	Culture Date (mmm/dd/yyyy)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	

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Protocol No.		Site No.	Partic	ipant No.	Part	icipant Initials	Visit
EPIC-001	_				_		Baseline
VITAL SIGNS 97 Not Done							
Heart Rate (per min)		spirations (per min)		Pressure		Tem	nperature
	_			_/			1 □ °C • 2 □ °F
HEIGHT AN	D WEI	GHT					
Height ₉₇ [Not D	cm 1	Standing Prone				
Weight 97	Not [kg 1	Standing				
Is the participant	transitio	oning to stand	ling? o□N			record second i	measurement below.
Height 98	□ N/A 1 □ 	cm 1	Standing				
Weight 98		kg 1[Standing				
PREGNANCY TEST							
Was a pregna	ncy test	·	₀□ No	1			
If test required	If Yes, record the results: 0 Negative 1 Positive 97 Not Done *If test required and not done, a comment is required in the Investigator Comment Log.						

	Cystic Fibrosis Therapeutics, Inc.									
Protocol No.		Site No.		Particip	ant No.	Participant Initia	ls	Visit		
EPIC-001								Baseline		
PHY	SICAL E	EXAM] ₉₇ 🗆 P	hysical Ex	cam Not	Done				
Body Code	Body S	ystem	Normal	Abnorma	Not Done		Specify Abno	ormality		
1.	General		0	1	97					
2.	Skin		0	1 🗌	97					
3.	Lymph N	lodes	0	1	97					
4.	HEENT		o 🗌	1	97					
5.	Respirate Chest	ory/	o 🗌	1 🔲	97					
6.	Cardiova	ascular	0	1 🔲	97					
7.	Gastroin	testinal	0	1 🔲	97					
8.	Genitour	inary	0	1	97					

97

97

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0

9.

10.

Musculoskeletal

Neurologic

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

JOINT EXAM 97 Not Done
Joint Exam Findings
0 ☐ Normal 1 ☐ Abnormal*
*If checked abnormal, describe findings and contributing factors:

Note: Chronic joint disease, such as JRA, may disqualify participant from study eligibility under exclusion criteria #10.

				•						
Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit			
EPIC-001				· 			Baseline			
SPIROMETRY 97 Not Done 98 N/A										
Spirometry	Spirometry									
FVC:	(L)	FEV ₁ : _		(L)	FEF 25-75%	%: .	(L/sec)			
MICROBIOL	.OGY									
Specime	n Type	Was Specimer Collected?		Date Specimen Collected (mmm/dd/yyyy)			Pa Result**			
OP Swab		₀□ No* ₁□ Yes		/			0 ☐ Negative 1 ☐ Positive 98 ☐ NAV			
Expectorated Sputum 0 1				/	_/		0 ☐ Negative 1 ☐ Positive 98 ☐ NAV			
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. * Pa results from CHRMC Core Microbiology Laboratory.										
TREATMENT										
Treatment pres	Treatment prescribed: 0 No 1 Yes Date prescribed:/									

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

SERUM CHEMISTRY

Was the specimen collected? □ No* □ Yes										
*If a specimen was not collected, a comment is required in the Investigator Comment Log.										
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***			
Creatinine	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes				
GGT	98		U/L		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes				
AST (SGOT)	98		U/L		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes				
ALT (SGPT)	98		U/L		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes				

RESEARCH LABS

Serum for Serology / Banking *If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log. Tube 1 0.01-0.25 2 0.26-0.50 Volume $_0 \square 0.00$ One Tube 1 0.01-0.25 Volume ₀ □ 0.00 2 0.26-0.50 Two Tube 4 0.76-1.00 з 0.51-0.75 1 0.01-0.25 2 0.26-0.50 Three Volume $_0 \square 0.00$ Tube 1 0.01-0.25 2 0.26-0.50 4 0.76-1.00 Volume $_0 \square 0.00$ з 0.51-0.75 Four

^{**} According to investigator's opinion

^{***} Please complete Medical History CRF.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

HEMATOLOGY

Was the specime	en collecte	d? ₀□	No*	₁ ☐ Yes	3		
*If a specim	en was no	t collected	, a comm	ent is req	uired in the	Investigator C	comment Log.
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***
RBC	98		x10 ⁶ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Hematocrit	98 🔲		%		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Hemoglobin	98 🗆		g/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes	
Platelets	98 🗆		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
WBC	98 🔲		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Differential:							
Neutrophil Segs	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Neutrophil Bands	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Neutrophils (Combined Segs/Bands)	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Lymphocytes	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Monocytes	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Eosinophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Basophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Other:							
C-Reactive Protein	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes	

^{**} According to investigator's opinion
*** Please complete Medical History CRF.

EPIC-001				Baseline
Protocol No.	Site No.	Participant No.	Participant Initials	Visit

	 	Basellile
CHEST RADIOGRAPH 97 Not Done		
Chest radiograph findings: One Normal Abnormal; not clinically significa Abnormal; clinically significant*	Radiograph:	
*If checked abnormal, describe findings:		

Prote	ocol No.	Site	No.	Participa	Participant No.		Initials	Visit			
EP	IC-001							Baseline			
AUD	AUDIOLOGY 97 Not Done 98 N/A (at Site) Date tested: // // mmm dd yyyy										
Wer	Were the results interpretable? 0 ☐ No 1 ☐ Yes										
		, indicate the t									
							Π _{Δ1} ,	14			
	1 V I	isual Reinford		• •	,	Normal 1	∐Abnorm	iai"			
		^If Abnorma		the informati		ш \	\neg				
		500 Hz	1000 Hz	ones in Sour		<u> </u>	,				
		d			_		<u>-</u> lb				
			•			<u> </u>					
2 ☐ Play Audiometry Left Ear: □ ☐ Normal Right Ear: □ ☐ Normal □ Abnormal* *If Abnormal, complete the information below:											
ſ		*If Abnorma	•	the informati	1 ☐ Abnor	mal*	<u>ynt</u> Lai.				
[EAR	*If Abnorma	Pure Tone	the informati	₁□Abnor ion below: tion Thresh	mal* olds (dBHL)	6000 Hz	1 ☐ Abnormal*			
	EAR Right		•	the informati	1 ☐ Abnor	mal*		Abnormal*			
		500 Hz	Pure Tone	the informati Air Conduct 2000 Hz	1 Abnorion below: tion Thresh 3000 Hz	olds (dBHL)	6000 Hz	Abnormal* 8000 Hz db			
	Right Left	500 Hz db db	Pure Tone 1000 Hz db db ometry	the informati e Air Conduct 2000 Hz db	1 Abnor ion below: tion Thresh 3000 Hz db db	mal* colds (dBHL) 4000 Hz db db	6000 Hz	Abnormal* 8000 Hz db			
	Right Left	500 Hz db db	Pure Tone 1000 Hz db db ometry	the informati e Air Conduct 2000 Hz db db Left Ear:	1 Abnor ion below: tion Thresh 3000 Hz db db	mal* olds (dBHL) 4000 Hz db db al Rimal*	6000 Hz dk	Abnormal* 8000 Hz db db			
	Right Left	500 Hz db db	Pure Tone 1000 Hz db db ometry	the information of the informati	1 Abnor ion below: tion Thresh 3000 Hz db db	mal* olds (dBHL) 4000 Hz db db al Rimal*	6000 Hz dk	Abnormal* 8000 Hz db db			
	Right Left 3 Se	500 Hz db db tandard Audi *If Abnorma	Pure Tone 1000 Hz db db ometry al, complete Pure Tone	the information of the informati	1 Abnor ion below: tion Thresh 3000 Hz db db 0 Norma 1 Abnor ion below: tion Thresh	mal* colds (dBHL) 4000 Hz db db al Rimal* colds (dBHL) 4000 Hz	6000 Hz db db ght Ear:	Abnormal* 8000 Hz db db Normal Abnormal*			
	Right Left 3 Si	500 Hz db db tandard Audi *If Abnorma	Pure Tone 1000 Hz db db ometry al, complete Pure Tone 1000 Hz	the information of the informati	1 Abnor ion below: tion Thresh 3000 Hz db 0 Norma 1 Abnor ion below: tion Thresh	mal* colds (dBHL) 4000 Hz db db al Rimal* colds (dBHL) 4000 Hz db	6000 Hz db db ght Ear:	Abnormal* 8000 Hz db db Normal Abnormal*			

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

PARTICIPANT FOLLOW-UP CONTACT

Baseline Visit plus 3 Days (+/- 2 Days)

Was the Participant randomized?	o□ No	₁ ☐ Yes
	If Yes,	1 ☐ Cycled 2 ☐ Culture-based
Was the Participant contacted?	o□ No	1 ☐ Yes
	If Yes,	Date:/

Start of Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	o□ No	₁ ☐ Yes
	If Yes,	Date://
Date study treatment started (I		dd yyyy

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Cystic Fibrosis Therapeutics, Inc.								
Protocol No.	Site N	No.	Participant	No.	Participar	nt Initials Visit		Visit
EPIC-001						Visit 2		
MICROBIOL	_OGY				Date of '	Visit:	/	/
Specimen Type	Was Specimen Collected?	Specime	Date n Collected n/dd/yyyy)	Co	Specimen ollected Hr Clock)	<i>Pa</i> Resi	ult**	Isolate sent to: CHRMC Micro Lab
OP Swab	₀ ☐ No* ₁ ☐ Yes	/		/:		0 ☐ Neg 1 ☐ Pos 98 ☐ NA\	itive	₀□ No ₁□ Yes
Expectorated Sputum	₀□ No ₁□ Yes				_:	I 1 I Positive I		₀□ No ₁□ Yes
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from Site Microbiology Laboratory. LAST DOSE OF TOBI								
Date (mmm/dd/		Time (24-Hr Clo	ock)					
		:_						
TREATMENT								
Treatment pres	scribed: 0	□ No 1[Yes	Date	prescribed:	/_ 	/_ d	уууу

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 2

PARTICIPANT FOLLOW-UP CONTACT

Visit 2 plus 3 Days (+/- 2 Days)

Was the Participant contacted?	o ☐ No	₁ ☐ Yes
	If Yes,	Date:/

Start of Visit 2 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	о□ №	₁ ☐ Yes	98 N/A
	If Yes,	Date:/_	/

Visit 2 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted?	о□ №	₁ ☐ Yes
	If Yes,	Date:/

Protocol No.	Site No.	Partici	pant No.	Part	icipant Initials	Visit
EPIC-001						Visit 3
VITAL SIGNS	S ₉₇ Not Done	·		Da	te of Visit:	
Heart Rate (per min)	Respirations (per min)		Pressure nm Hg)		Tem	perature
			_/			1 □ °C • 2 □ °F
HEIGHT ANI	D WEIGHT					
Height ₉₇		Standing				
Weight ₉₇ [Standing				
Is the participant	transitioning to stand	ding? o□ No			record second r	measurement below.
Height 98	□ N/A 1 □ cm 1 2 □ in	Standing				
Weight 98	□ N/A 1 □ kg 1 2 □ lb	Standing				
PREGNANCY TEST						
Has fertility sta	atus changed for fem	ale participant′ ₀	? 0 □		₁ ☐ Yes	98 N/A
	If Yes, record	the results:	₀□Negati	ve	₁ Positive	

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Prot	otocol No.		Site No.		Participant No.		Participant Initials	Visit
EP	IC-001	_						Visit 3
PH	/SICAL I	EXAM	97 🗆 I	Physical E	xam Not Do	one		
Dodu				Cha	nge		Only Comment	If Changed
Body Code	Body Sy	stem	No Change	Improved	Worsened*	Not Done	From Previo (Improved or V	us Visit
1.	General		0	1	2	97		
2.	Skin		0	1	2	97		
3.	Lymph No	odes	о	1	2	97		
4.	HEENT		0	1	2	97		
5.	Respirato Chest	ory/	0	1	2	97		
6.	Cardiovas	scular	о	1	2	97		
7.	Gastrointe	estinal	0	1	2	97		
8.	Genitourir	nary	0	1	2	97		
9.	Musculos	keletal	о	1	2	97		
10.	Neurologi	С	0	1	2	97		

^{*}If worsened, record AE.

EPIC-001				Visit 3
Protocol No.	Site No.	Participant No.	Participant Initials	Visit

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT BASELINE VISIT

Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml		vials	vials
Cipro/ placebo	Tablets 2 250 mg BID 3 250 mg TID 4 500 mg BID 5 750 mg BID		tablets	tablets
	3 Suspension 6 100 mg/ 1 ml BID 7 150 mg/ 1.5 ml BID 8 200 mg/ 2 ml BID 9 250 mg/ 2.5 ml BID 10 375 mg/ 3.75 ml BID 11 500 mg/ 5 ml BID 12 750 mg/ 7.5 ml BID		mls	(Estimate liquid volume from side of Rx bottle for suspension)

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 2

Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml		vials	vials

22

98 N/A

				<u> </u>					
Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit		
EPIC-001				· 			Visit 3		
SPIROMETRY 97 Not Done 98 N/A									
Spirometry	Spirometry								
FVC:	FVC: (L) FEV ₁ : (L) FEF 25-75%: (L/sec)								
MICROBIOLOGY									
Specime	Specimen Type		Was Specimen Collected?		Date Specimen Collected (mmm/dd/yyyy)		Pa Result**		
OP Swab		₀□ No* ₁□ Yes					0 ☐ Negative 1 ☐ Positive 98 ☐ NAV		
Expectorated Sputum				/			□ Negative □ Positive □ NAV		
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from CHRMC Core Microbiology Laboratory.									
TREATMENT									
Treatment prescribed: 0 No 1 Yes Date prescribed: // // // // // // // // // // // // //									

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 3

PARTICIPANT FOLLOW-UP CONTACT

Visit 3 plus 7 Days (+/- 2 Days)

Was the Participant contacted?	₀□ No	₁ ☐ Yes
	If Yes,	Date://

Start of Visit 3 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	o□ No	₁ ☐ Yes	98 N/A
	If Yes,	Date:/_	dd yyyy

Visit 3 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted?	₀□ No	₁□ Yes
	If Yes,	Date:/

Protocol No.	Site No.	Partici	pant No.	Part	icipant Initials	Visit		
EPIC-001						Visit 4		
VITAL SIGNS	VITAL SIGNS Property Not Done Date of Visit:/							
Heart Rate (per min)	Respirations (per min)		Pressure nm Hg)		Tem	perature		
			_/		1□°C ———•— 2□°F			
HEIGHT AND WEIGHT								
Height ₉₇		Standing						
Weight ₉₇ [Standing						
Is the participant	transitioning to stand	ding? o□ No			record second r	measurement below.		
Height 98	□ N/A 1 □ cm 1 2 □ in	Standing						
Weight 98	□ N/A 1 □ kg 1 — 2 □ lb	Standing						
PREGNANCY TEST								
Has fertility sta	atus changed for fem	ale participant′ ₀	? 0 □		₁ ☐ Yes	98 N/A		
	If Yes, record	the results:	₀□Negati	ve	1 ☐ Positive			

Protocol No.		Site No. Partici		Participa	ant No. Participant In		t Initials	Visit		
EPIC-001 _									Visit 4	
PHYSICAL EXAM 97 Physical Exam Not Done										
Pody				Cha	nge			Only	Comment	If Changed
Body Code	Body Sys	stem	No Change	Improved	Worsened*	Not Done	From Previous Visit		ous Visit	
1.	General		0	1	2	97				
2.	Skin		0	1	2	97				
3.	Lymph No	odes	0	1	2	97				
4.	HEENT		0	1	2	97				
5.	Respirato Chest	ry/	0	1	2	97				
6.	Cardiovas	cular	0	1	2	97				
7.	Gastrointe	estinal	0	1	2	97				
8.	Genitourir	nary	0	1	2	97				
9.	Musculos	keletal	0	1	2	97				
10.	Neurologi		0	1	2	97				

^{*}If worsened, record AE.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 4

JOINT EXAM 97 Not Done							
Joint Exam Findings							
o ☐ Normal 1 ☐ Abnormal⁴* • • • • • • • • • • • • • • • • • • •							
⁴Is this worsened from previous visit? 0 No 1 Yes *If checked abnormal, describe findings and contributing factors:							
Referred to Rheumatology? □ No	₁ ☐ Yes						
If Yes,	Date examined:/						

[•]Please record AE if new findings or if worsened

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 4

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 3

Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml		vials	vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID			
	5 ☐ 750 mg BID	/	tablets	tablets
	3 Suspension 6 100 mg/ 1 ml BID 7 150 mg/ 1.5 ml BID 8 200 mg/ 2 ml BID 9 250 mg/ 2.5 ml BID 10 375 mg/ 3.75 ml BID 11 500 mg/ 5 ml BID	/		(Estimate liquid volume from side of Rx bottle for suspension)
	12 750 mg/ 7.5 ml BID	/	mls	mls

				•				
Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit	
EPIC-001							Visit 4	
SPIROMETRY 97 Not Done 98 N/A								
Spirometry								
FVC: (L) FEV ₁ : (L) FEF 25-75%: (L/sec)								
MICROBIOLOGY								
Specimen Type		Was Specimen Collected?		Date Specimen Collected (mmm/dd/yyyy)		Pa Result**		
OP Swab		₀□ No* ₁□ Yes		/			0 ☐ Negative 1 ☐ Positive 98 ☐ NAV	
Expectorated	₀□ No ₁□ Yes					0 ☐ Negative 1 ☐ Positive 98 ☐ NAV		
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from CHRMC Core Microbiology Laboratory.								
TREATMENT								
Treatment prescribed: 0 No 1 Yes Date prescribed: //								

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 4

SERUM CHEMISTRY

Was the specimen collected? □ No* □ Yes								
*If a spec	imen was n	ot collecte	d, a com	nment is r	equired in the	Investigator C	omment Log.	
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***	
Creatinine	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes		
GGT	98		U/L		1 ☐ Low 2 ☐ Normal 3 ☐ High	0□ No 1□ Yes		
AST (SGOT)	98		U/L		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes		
ALT (SGPT)	98		U/L		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes		

RESEARCH LABS

Serum for Serology / Banking								
*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.								
Tube One	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50				
Tube Two	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50				
Tube Three	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50	з 🗆 0.51-0.75	4 0.76-1.00		
Tube Four	Volume	0.00 □ 0	1 0.01-0.25	2 0.26-0.50	з 🗆 0.51-0.75	4 0.76-1.00		

^{**} According to investigator's opinion

^{***} Please complete AE form

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 4

HEMATOLOGY

Was the specimen collected? ₀☐ No* 1☐ Yes								
*If a specimen was not collected, a comment is required in the Investigator Comment Log.								
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***	
RBC	98 🔲		x10 ⁶ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Hematocrit	98 🔲		%		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Hemoglobin	98 🗆		g/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes		
Platelets	98 🔲		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
WBC	98 🔲		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Differential:								
Neutrophil Segs	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Neutrophil Bands	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Neutrophils (Combined Segs/Bands)	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Lymphocytes	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Monocytes	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Eosinophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Basophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		
Other:								
C-Reactive Protein	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes		

^{**} According to investigator's opinion
*** Please complete AE form

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 4

PARTICIPANT FOLLOW-UP CONTACT

Visit 4 plus 7 Days (+/- 2 Days)

Was the Participant contacted?	о□ №	₁ ☐ Yes
	If Yes,	Date://

Start of Visit 4 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	o□ No	₁ Yes	98 🗆 N/A
	If Yes,	Date:/_	/

Visit 4 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted?	₀□No	₁□ Yes
	If Yes,	Date://

Protocol No.	Site No.	Partici	pant No.	Part	icipant Initials	Visit		
EPIC-001						Visit 5		
VITAL SIGNS	VITAL SIGNS Property Not Done Date of Visit:/							
Heart Rate (per min)	Respirations (per min)		Pressure nm Hg)		Tem	perature		
			_/			1 □ °C • 2 □ °F		
HEIGHT ANI	D WEIGHT							
Height ₉₇		☐ Standing						
Weight ₉₇ [Standing						
Is the participant	transitioning to stand	ding? o□ No			record second r	measurement below.		
Height 98	□ N/A 1 □ cm 1 2 □ in	Standing						
Weight 98	□ N/A 1 □ kg 1 2 □ lb	Standing						
PREGNANCY TEST								
Has fertility sta	atus changed for fem	ale participant′ ₀	? 0 □		₁ ☐ Yes	98 🗌 N/A		
	If Yes, record	the results:	₀☐Negati	ve	1 ☐ Positive			

Protocol No.		Site No.		Participant No.		P	articipant I	nitials	Visit	
EPIC-001 _									Visit 5	
PH	PHYSICAL EXAM 97 Physical Exam Not Done									
Pody				Cha	nge			Only Co	omment	If Changed
Body Code	Body Sys	stem	No Change	Improved	Worsened*	Not Done		From Previous Visit (Improved or Worsened)		
1.	General		о	1	2	97				
2.	Skin		0	1	2	97				
3.	Lymph No	odes	0	1	2	97				
4.	· HEENT		о	1	2	97				
5.	Respirator Chest	ry/	о	1	2	97				
6.	Cardiovas	cular	о	1	2	97				
7.	Gastrointe	estinal	0	1	2	97				
8.	Genitourin	nary	0	1	2	97				
9.	Musculosi	keletal	0	1	2	97				
10	Neurologic			1						

^{*}If worsened, record AE.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 5

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 4

Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml		vials	vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID			
	5 ☐ 750 mg BID	/	tablets	tablets
	3 Suspension 6 100 mg/ 1 ml BID 7 150 mg/ 1.5 ml BID 8 200 mg/ 2 ml BID 9 250 mg/ 2.5 ml BID 10 375 mg/ 3.75 ml BID 11 500 mg/ 5 ml BID	/		(Estimate liquid volume from side of Rx bottle for suspension)
	12 750 mg/ 7.5 ml BID	/	mls	mls

		•		•	<u> </u>			
Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit	
EPIC-001				· 			Visit 5	
SPIROMETR	RY 97	Not Done		98 N/A				
Spirometry								
FVC: (L) FEV ₁ : (L) FEF 25-75%: (L/sec)								
MICROBIOLOGY								
Specimen Type		Was Specimen Collected?		Date Specimen Collected (mmm/dd/yyyy)			Pa Result**	
OP Swab		₀□ No* ₁□ Yes		/			0 ☐ Negative 1 ☐ Positive 98 ☐ NAV	
Expectorated	l -	₀□ No ₁□ Yes				0 ☐ Negative 1 ☐ Positive 98 ☐ NAV		
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from CHRMC Core Microbiology Laboratory.								
TREATMENT								
Treatment pres	Treatment prescribed: 0 No 1 Yes Date prescribed: // mmm dd // yyyy							

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 5

PARTICIPANT FOLLOW-UP CONTACT

Visit 5 plus 7 Days (+/- 2 Days)

Was the Participant contacted?	₀□ No	₁ ☐ Yes
	If Yes,	Date://

Start of Visit 5 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	о□ №	₁ ☐ Yes	98 🗆 N/A
	If Yes,	Date:/_	/

Visit 5 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted?	o□ No	1 ☐ Yes
	If Yes,	Date://

Protocol No.	Site No.	Partici	pant No.	Part	icipant Initials	Visit	
EPIC-001						Visit 6	
VITAL SIGNS	S 97 Not Done			Da	te of Visit:		
Heart Rate (per min)	Respirations (per min)	Blood Pressure (mm Hg)			Temperature		
			_/			1 □ °C • 2 □ °F	
HEIGHT ANI	O WEIGHT						
Height ₉₇		Standing					
Weight ₉₇ [Standing					
Is the participant	transitioning to stand	ding? o□No			record second r	measurement below.	
Height 98	□ N/A 1 □ cm 1 2 □ in	Standing					
Weight 98	□ N/A 1 □ kg 1 2 □ lb	Standing					
PREGNANCY TEST							
Has fertility sta	itus changed for femancy test done?	ale participant? ₀□ No	? 0 ☐ 1 ☐		₁ ☐ Yes	98 N/A	
	If Yes, record	I the results:	₀□Negati	ve	1 ☐ Positive		

Prot	Protocol No. Site No.		Participant No.		Participant Initial	s Visit		
EP	IC-001	_						Visit 6
PHY	SICAL I	EXAM	97 F	Physical E	xam Not D	one		
Body				Cha	nge			ent If Changed
Code	Body Sy	stem	No Change	Improved	Worsened*	Not Done		evious Visit or Worsened)
1.	General		0	1	2	97		
2.	Skin		0	1	2	97		
3.	Lymph No	odes	0	1	2	97		
4.	HEENT		о	1	2	97		
5.	Respirato Chest	ory/	о	1	2	97		
6.	Cardiovas	scular	0	1	2	97		
7.	Gastrointe	estinal	0	1	2	97		
8.	Genitourir	nary	0	1	2	97		
9.	Musculos	keletal	0	1	2	97		

Neurologic

10.

^{*}If worsened, record AE.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 6

JOINT EXAM 97 Not Done
Joint Exam Findings
0 ☐ Normal 1 ☐ Abnormal [△] *•
[△] Is this worsened from previous visit? 0 No 1 Yes *If checked abnormal, describe findings and contributing factors:
Referred to Rheumatology? 0 No 1 Yes
If Yes, Date examined:/

[•]Please record AE if new findings or if worsened

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 6

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 5

				_
Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml		vials	vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID 5 ☐ 750 mg BID	/	tablets	tablets
	3 Suspension 6 100 mg/ 1 ml BID 7 150 mg/ 1.5 ml BID 8 200 mg/ 2 ml BID 9 250 mg/ 2.5 ml BID 10 375 mg/ 3.75 ml BID 11 500 mg/ 5 ml BID 12 750 mg/ 7.5 ml BID	/	mls	(Estimate liquid volume from side of Rx bottle for suspension)

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		•		•			
Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit
EPIC-001							Visit 6
SPIROMETRY 97 Not Done 98 N/A							
Spirometry							
FVC:	(L)	FEV ₁ : _		(L)	FEF 25-759	%: . _	(L/sec)
MICROBIOL	OGY						
Specime	n Type	Was Spe Collect			men Collected /dd/yyyy)		Pa Result**
OP Swab		0 □ N 1 □ Y		/	/		0 ☐ Negative 1 ☐ Positive 98 ☐ NAV
Expectorated Sputum O No 1 Yes O Negative 1 Positive 98 NAV						1 Positive	
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from CHRMC Core Microbiology Laboratory.							
TREATMEN	Т						
Treatment pres	scribed: o	☐ No 1[Yes	Date	prescribed:	/ mm dd	

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 6

SERUM CHEMISTRY

Was the specimen collected? □ No* □ Yes								
*If a specimen was not collected, a comment is required in the Investigator Comment Log.								
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***	
Creatinine	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes		
GGT	98		U/L		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes		
AST (SGOT)	98		U/L		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes		
ALT (SGPT)	98		U/L		1 Low 2 Normal 3 High	₀□ No ₁□ Yes		

RESEARCH LABS

Serum for Serology / Banking							
*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.							
Tube One	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50			
Tube Two	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50			
Tube Three	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50	з 🗆 0.51-0.75	4 0.76-1.00	
Tube Four	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50	з 🗆 0.51-0.75	4 0.76-1.00	

^{**} According to investigator's opinion

^{***} Please complete AE form

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 6

HEMATOLOGY

Was the specime	n collecte	d? ₀□	No*	₁ ☐ Yes	S		
*If a specime	*If a specimen was not collected, a comment is required in the Investigator Comment Log.						
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***
RBC	98		x10 ⁶ /uL		1 Low 2 Normal 3 High	0□ No 1□ Yes	
Hematocrit	98		%		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes	
Hemoglobin	98		g/dL		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes	
Platelets	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
WBC	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Differential:	1						
Neutrophil Segs	98		x10 ³ /uL		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes	
Neutrophil Bands	98		x10 ³ /uL		1 ☐ Low 2 ☐ Normal 3 ☐ High	o□ No 1□ Yes	
Neutrophils (Combined Segs/Bands)	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Lymphocytes	98		x10 ³ /uL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes	
Monocytes	98		x10 ³ /uL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0□ No 1□ Yes	
Eosinophils	98		x10 ³ /uL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0□ No 1□ Yes	
Basophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	
Other:							
C-Reactive Protein	98 🔲		mg/dL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes	

^{**} According to investigator's opinion
*** Please complete AE form

Protocol No		Site	No.	o. Particip		Participant Initials		Visit
EPIC-001								Visit 6
AUDIOLOGY 97 Not Done 98 N/A (at Site) Date tested://								
Were the results interpretable? 0 ☐ No 1 ☐ Yes								
		•		ng performed	d:			
1	Visu	ı al Reinford	rement Audi	ometry (VRA	ا ∟ د	Normal 1	Abnorm	nal*
				• `	,	nation below		iai
				nes in Soun				
		500 Hz	1000 Hz				z	
		d	b d	b d	lb (db d	lb	
2	Play	Audiomet	ry	<u>Left</u> Ear:	0 ☐ Norma 1 ☐ Abnor		g <u>ht</u> Ear:	0 ☐ Normal 1 ☐ Abnormal*
2			al, record AE	and comple	1 ☐ Abnori	mal* mation below		
2 EAR			al, record AE		1 ☐ Abnori	mal* mation below		
		If Abnorma	al, record AE Pure Tone	and comple	1 ☐ Abnori	mal mation below olds (dBHL)	:	1 Abnormal*
EAR		flf Abnorma	al, record AE Pure Tone 1000 Hz	and comple Air Conduct 2000 Hz	1 Abnorr	mal* mation below olds (dBHL) 4000 Hz	6000 Hz	Abnormal* 8000 Hz db
EAR Right	Stan	500 Hz db db	Pure Tone 1000 Hz db db ometry	and comple Air Conduct 2000 Hz db db	ate the information Thresholds 3000 Hz db db	mation belowed blds (dBHL) 4000 Hz db db	: 6000 Hz db db	Abnormal* 8000 Hz db
EAR Right Left	Stan	500 Hz db db	Pure Tone 1000 Hz db db ometry	and comple Air Conduct 2000 Hz db db	te the information Thresholds 3000 Hz db db Normation Thresholds db	mation belowed the second seco	: 6000 Hz db db	Abnormal* 8000 Hz db db
EAR Right Left	Stan	500 Hz db db	Pure Tone 1000 Hz db db ometry	and comple Air Conduct 2000 Hz db db Left Ear:	te the information Thresholds 3000 Hz db db Normation Thresholds db	mation belowed the second seco	: 6000 Hz db db	Abnormal* 8000 Hz db db
EAR Right Left	Stan	500 Hz db db adard Audie	Pure Tone 1000 Hz db db ometry Al, record AE	and comple Air Conduct 2000 Hz db db Left Ear: and comple	te the information Thresholds O Normation Thresholds te the information Thresholds te the information Thresholds	mal* mation below olds (dBHL) 4000 Hz db db db I Rimal* mation below olds (dBHL)	db db ght Ear:	Abnormal* 8000 Hz db Mormal Normal Abnormal*

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 6

PARTICIPANT FOLLOW-UP CONTACT

Visit 6 plus 7 Days (+/- 2 Days)

Was the Participant contacted?	o□ No	₁ ☐ Yes
	If Yes,	Date://

Start of Visit 6 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	₀□ No	₁ ☐ Yes	98 N/A
	If Yes,	Date:/_	dd yyyy

Visit 6 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted?	o□ No	₁□ Yes
	If Yes,	Date://

Protocol No.	Site No.	Particip	oant No.	Part	icipant Initials	Visit	
EPIC-001						Visit 7	
VITAL SIGNS	97 Not Done			Da	te of Visit:		
Heart Rate (per min)	Respirations (per min)		Pressure m Hg)		Tem	perature	
			_/			1□°C 2□°F	
HEIGHT AND	WEIGHT						
Height 97	Not Done 1 □ cm 1	☐ Standing					
Weight ₉₇ [☐ Standing					
Is the participant	transitioning to stand	ding? ₀☐ No			record second r	measurement below.	
Height 98	N/A 1 □ cm 1 — 2 □ in	Standing					
Weight ₉₈	□ N/A 1 □ kg 1 2 □ lb	Standing					
PREGNANCY TEST							
Has fertility sta	tus changed for femons	ale participant? ₀☐ No	0 0		₁ ☐ Yes	98 N/A	
	If Yes, record	the results:	₀ ☐ Negati	ve	₁ Positive		

Prot	Protocol No. Site No. Participant No.		ant No.	Participant Initials	Visit			
EPIC-001						Visit 7		
PH	/SICAL	EXAM] 97 I	Physical E	xam Not Do	one		
Dadu				Cha	nge		Only Comment	If Changed
Body Code	Body Sy	/stem	No Change	Improved	Worsened*	Not Done	From Previ (Improved or '	ous Visit
1.	General		o 🗌	1	2	97		
2.	Skin		0	1	2	97		
3.	Lymph N	odes	о	1	2	97		
4.	HEENT		0	1	2	97		
5.	Respirato Chest	ory/	0	1	2	97		
6.	Cardiovas	scular	0	1	2	97		
7.	Gastroint	estinal	0	1	2	97		
8.	Genitouri	nary	0	1	2	97		
9.	Musculos	skeletal	о	1	2	97		
10.	Neurolog	ic	0	1	2	97		

^{*}If worsened, record AE.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 7

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 6

Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml	/		
	1 🗀 300 mg/ 3 mi	/	vials	vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID	/		
	5 ☐ 750 mg BID	/	tablets	tablets
	3 Suspension 6 100 mg/ 1 ml BID 7 150 mg/ 1.5 ml BID 8 200 mg/ 2 ml BID 9 250 mg/ 2.5 ml BID 10 375 mg/ 3.75 ml BID 11 500 mg/ 5 ml BID			(Estimate liquid volume from side of Rx bottle for suspension)
	12 750 mg/ 7.5 ml BID	/	mls	mls

Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit	
EPIC-001							Visit 7	
SPIROMETRY 97 Not Done 98 N/A								
Spirometry								
FVC:	(L)	FEV ₁ : _		(L)	FEF 25-75%	%: .	(L/sec)	
MICROBIOL	MICROBIOLOGY							
Specimen Type		Was Specimen Collected?		Date Specimen Collected (mmm/dd/yyyy)			Pa Result**	
OP Swab		₀□ No* ₁□ Yes					0 ☐ Negative 1 ☐ Positive 98 ☐ NAV	
1 –		0 □ N 1 □ Y		/			0 ☐ Negative 1 ☐ Positive 98 ☐ NAV	
* If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from CHRMC Core Microbiology Laboratory.								
TREATMENT								
Treatment pres	Treatment prescribed: 0 No 1 Yes Date prescribed: // // // // // // // // // // // // //							

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Visit 7

PARTICIPANT FOLLOW-UP CONTACT

Visit 7 plus 7 Days (+/- 2 Days)

Was the Participant contacted?	o□ No	₁ ☐ Yes
	If Yes,	Date://

Start of Visit 7 Treatment plus 14 Days (+/- 2 Days)

Was the Participant contacted?	₀□ No	₁□ Yes	98 N/A
	If Yes,	Date:/_	dd yyyy

Visit 7 plus 6 Weeks (+/- 1 Week)

Was the Participant contacted?	₀□ No	₁□ Yes
	If Yes,	Date://

Protocol No.	Site No.	Particip	ant No.	Part	icipant Initials	Visit
EPIC-001				_		End of Study Visit
VITAL SIGNS	97 Not Done			Da	te of Visit:	///
Heart Rate (per min)	Respirations (per min)		Pressure m Hg)		Tem	perature
			./			1 □ °C •— 2 □ °F
HEIGHT AND	WEIGHT					
Height 97	Not Done 1 □ cm 1 2 □ in 2	☐ Standing				
Weight 97	_ `	☐ Standing				
Is the participant	transitioning to stand	ding? o□ No			record second r	measurement below.
Height 98	☐ N/A 1 ☐ cm 1 — 2 ☐ in	Standing				
Weight ₉₈ [□ N/A 1 □ kg 1 2 □ lb	Standing				
PREGNANC	Y TEST					
Has fertility sta	tus changed for fem	ale participant? ₀☐ No	o 🗆 1 🔲		₁ ☐ Yes	98 N/A
	If Yes, record	the results:	₀ ☐ Negati	ve	₁ Positive	

Protocol No.		Site No.		Participant No.		Participant Initials	Visit			
EPIC-001							End of Study Visit			
PHY	PHYSICAL EXAM 97 Physical Exam Not Done									
				Cha	nge		Only Commer	nt If Changed		
Body Code	Body Sy	stem	No Change	Improved	Worsened*	Not Done	From Prev (Improved or	ious Visit		
1.	General		0	1	2	97				
2.	Skin		0	1	2	97				
3.	Lymph No	odes	0	1	2	97				
4.	HEENT		0	1	2	97				
5.	Respirato Chest	ory/	0	1	2	97				
6.	Cardiovas	scular	0	1	2	97				
7.	Gastroint	estinal	0	1	2	97				
8.	Genitourii	nary	0	1	2	97				
9.	Musculos	skeletal	0	1	2	97				
10.	Neurologi	С	о	1	2	97				

^{*}If worsened, record AE.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				End of Study Visit

JOINT EXAM 97 Not Done
Joint Exam Findings
o ☐ Normal
1 ∐ Abnormal [△] *•
⁴Is this worsened from previous visit? 0 □ No 1□ Yes *If checked abnormal, describe findings and contributing factors:
in checked agricimal, accorded infamige and contributing lactors.
Referred to Rheumatology? 0 No 1 Yes
If Yes, Date examined:/

[•]Please record AE if new findings or if worsened

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				End of Study Visit

PARTICIPANT DRUG ACCOUNTABILITY FOR STUDY DRUG PRESCRIBED AT VISIT 7

Medication	Formulation and Dose Prescribed	Start Date Stop Date (mmm/dd/yyyy)	# / Amount Dispensed (from Rx container label)	# / Amount Returned
ТОВІ	1 ☑ Vials 1 ☐ 300 mg/ 5 ml	/		
	1 🗀 300 mg/ 3 mi	/	vials	vials
Cipro/ placebo	2 ☐ Tablets 2 ☐ 250 mg BID 3 ☐ 250 mg TID 4 ☐ 500 mg BID	/		
	5 ☐ 750 mg BID	/	tablets	tablets
	3 Suspension 6 100 mg/ 1 ml BID 7 150 mg/ 1.5 ml BID 8 200 mg/ 2 ml BID 9 250 mg/ 2.5 ml BID 10 375 mg/ 3.75 ml BID 11 500 mg/ 5 ml BID			(Estimate liquid volume from side of Rx bottle for suspension)
	12 750 mg/ 7.5 ml BID	/	mls	mls

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Protocol No.	Site I	No.	Parti	cipant No.	Participant Ir	nitials	Visit		
EPIC-001							End of Study Visit		
SPIROMETRY 97 Not Done 98 N/A									
Spirometry									
FVC:	(L)	FEV ₁ : _		(L)	FEF 25-759	%: .	(L/sec)		
MICROBIOLOGY									
Specime	n Type	Was Spe Collect			nen Collected /dd/yyyy)		Pa Result**		

o ☐ Negative

1 ☐ Positive

o ☐ Negative

□ Positive

98 🗆 NAV

98 NAV

0 ☐ **No***

₁ ☐ Yes

 $_0\square$ No

₁ ☐ Yes

OP Swab

Expectorated Sputum

^{*} If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log. ** Pa results from CHRMC Core Microbiology Laboratory.

Protocol No.		Site No.	Participant No.	Participant Initials	Visit End of Study Visit	
-	EPIC-001				Elia di Study Visit	

SERUM CHEMISTRY

Was the specimen collected? ₀ ☐ No* ₁ ☐ Yes								
*If a spec	imen was n	ot collecte	d, a com	nment is r	equired in the	Investigator C	omment Log.	
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***	
Creatinine	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes		
GGT	98		U/L		1 ☐ Low 2 ☐ Normal 3 ☐ High	0 ☐ No 1 ☐ Yes		
AST (SGOT)	98		U/L		1 Low 2 Normal 3 High	0□ No 1□ Yes		
ALT (SGPT)	98		U/L		1 Low 2 Normal 3 High	0 ☐ No 1 ☐ Yes		

RESEARCH LABS

Serum	Serum for Serology / Banking								
*If a specimen was not collected (all tube volumes are marked 0.00), a comment is required in the Investigator Comment Log.									
Tube One	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50					
Tube Two	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50					
Tube Three	Volume	₀□0.00	1 0.01-0.25	2 0.26-0.50	з 🗆 0.51-0.75	4 0.76-1.00			
Tube Four	Volume	0.00 □ 0	1 0.01-0.25	2 0.26-0.50	з 🗆 0.51-0.75	4 0.76-1.00			

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^{**} According to investigator's opinion

^{***} Please complete AE form

Protocol No.		Site No.	Participant No.	Participant Initials	Visit End of Study Visit	
-	EPIC-001				Elia di Study Visit	

HEMATOLOGY

Was the specimen collected? □ No* □ Yes									
*If a specime	*If a specimen was not collected, a comment is required in the Investigator Comment Log.								
Analyte	Result Not Available	Value	Unit	Unit if Other	Comparison to Lab Normal	Clinically Significant?**	Comment (if result is Both Abnormal <u>and</u> Clinically Significant)***		
RBC	98		x10 ⁶ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Hematocrit	98		%		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Hemoglobin	98 🗆		g/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes			
Platelets	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
WBC	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Differential:									
Neutrophil Segs	98 🗆		x10 ³ /uL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes			
Neutrophil Bands	98		x10 ³ /uL		1 Low 2 Normal 3 High	o□ No 1□ Yes			
Neutrophils (Combined Segs/Bands)	98		x10 ³ /uL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes			
Lymphocytes	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Monocytes	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Eosinophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Basophils	98		x10 ³ /uL		1 Low 2 Normal 3 High	₀□ No ₁□ Yes			
Other:									
C-Reactive Protein	98		mg/dL		1 ☐ Low 2 ☐ Normal 3 ☐ High	₀□ No ₁□ Yes			

^{**} According to investigator's opinion
*** Please complete AE form

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				End of Study Visit

CHEST RADIOGRAPH 97 Not Done	
Chest Radiograph Findings Chest radiograph interpretation:	Date of Radiograph://
0 Normal 1 Abnormal; not clinically significant* 2 Abnormal; clinically significant* *If checked abnormal, describe findings:	
Comparison to Baseline:	

[•]Record AE if worsened since Baseline

Protocol No.	Site I	Vo.	Participa	ant No. Participant I		t Initials Visit			
EPIC-001							End of Study Visit		
AUDIOLOGY 97 Not Done 98 N/A (at Site) Date tested://									
	Were the results interpretable? 0 No 1 Yes If Yes, indicate the type of testing performed:								
	•					П.,			
1	isual Reinforc		• ,	,	Normal 1	∐Abnor	mal*		
	^If Abnorma				mation below	/: 			
	500 Hz	1000 Hz	nes in Soun			7			
	dk					db dt			
2 P	lay Audiometr *If Abnorma	I, record AE	Left Ear: and comple Air Conduct		mal* mation below	ght Ear: /:	o ☐ Normal 1 ☐ Abnormal*		
EAR	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 H	z 8000 Hz		
Right	db	db	db	db	db	(db db		
Left	db	db	db	db	db	(db db		
₃□ s	Standard Audiometry Left Ear: 0 Normal Right Ear: 0 Normal 1 Abnormal* 1 Abnormal* *If Abnormal, record AE and complete the information below:								
			Air Conduct		olds (dBHL)				
EAR	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 H			
Right	db	db	db	db			db db		
Left	db	db	db	db	db	(db db		

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Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001			

		Protocol No.	Site No.	· 0	Participant No.	Participant Initials	
		EPIC-001					
위	HOSPITALIZATION	o No Hospitalization	ılization				
Line No.	Admission Date (mmm/dd/yyyy)		Discharge Date (mmm/dd/yyyy)			Diagnosis	
,				1 Pulmo	Pulmonary Exacerbation		
.				99 🔲 Other	☐ Other <i>(describe)</i> :		
(1 🔲 Pulmo	Pulmonary Exacerbation		
.i				99 🔲 Other	Other (describe):		
(1 🔲 Pulmo	Pulmonary Exacerbation		
				99 🔲 Other	Other (describe):		
,				1 🔲 Pulmo	Pulmonary Exacerbation		
4.				99 🔲 Other	Other (describe):		
Ļ				1 Pulmo	Pulmonary Exacerbation		
ი				99 🔲 Other	Other (describe):		
(1 Pulmo	Pulmonary Exacerbation		
o				99 🔲 Other	☐ Other <i>(describe)</i> :		
ı				1 Pulmo	☐ Pulmonary Exacerbation		
				⁹⁹ ☐ Other	Other (describe):		

ŀ	Protocol No.	Site No.	Participant No.	Participant Initials
l	EPIC-001			

CONCOMITANT MEDICATIONS AND THERAPIES

Record any medication or therapy the Participant is using \leq 30 days prior to the Baseline Visit. Record any changes to or new medications or therapies (excluding study medications) that occur during the course of the study.

Line No.	Medication / Therapy (Brand or Generic)	Indication	Dose	Units	Frequency ^a	Route⁵	>30 Days ^c	Start Date Stop Date
					If "99=Other" please specify	If "99=Other" please specify		(mmm/dd/yyyy) mark box (\checkmark) if continuing ψ
1.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other					1	
2.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other					1	
3.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other					1	
4.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other					1	
5.		1 ☐ Pulmonary Exacerbation 2 ☐ Prophylaxis 99 ☐ Other					1	

^a Frequency:	1 = QD, 2 = BID, 3 = TID, 4 = QID, 5 = QHS, 6 = QOD, 7 = PRN, 99 = Othe
-------------------------	---

bRoute: 1 = Oral, 2 = Intravenous, 3 = Subcutaneous, 4 = Intramuscular, 5 = Nasal, 6 = Topical, 7 = Gastrointestinal Tube, 8 = Nasogastric, 9 = Rectal, 10 = Inhaled,

^{11 =} Intradermal, 12 = Vaginal, 13 = Intra-articular, 14 = Opthalmic, 15 = Intralesional, 99 = Other

c>30 Days: Check box if start date is more than 30 Days prior to the date of the Baseline Visit and leave start date blank.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001			

ADVERSE EVENTS

Has tl	ne participant experie	nced any adverse events?	٥	No1[Yes	If Yes, des	cribe below.		
Line No.	Adverse Event	Start Date Stop Date	Outcome	Any Treatment Required?	Severity	Study Agent Action	Relation To Study Drug	Was Event Serious? ^b	Hospitalized?*
	(List one event per line)	(mmm/dd/yyyy)	1 = Unresolved 2 = Resolved 3 = Resolved w/Sequelae 4 = Death	0 = None 1 = Concomitant Medications 2 = Non-Drug Therapies 3 = Concomitant Medications	1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening	0 = None 1 = Discontinued 2 = Stopped and Restarted	1 = Unrelated 2 = Possibly 3 = Probably 4 = Definitely	0 = No 1 = Yes	0 = No 1 = Yes
		mark box (✓) if continuing ↓		and Non-Drug Therapies					
1.									
2.									
3.									
4.									

^aPlease refer to protocol for severity definitions.

^bPlease refer to protocol for serious adverse event (SAE) definitions. If "Yes" is marked, an SAE form must be completed. *Please complete Hospitalization CRF.

Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001			

INVESTIGATOR COMMENT LOG

This form is to be used for explaining any relevant events occurring during the course of the study that are **NOT** noted elsewhere.

CRF Page	Visit	Comment

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Protocol No.	Site No.	Participant No.	Participant Initials
EPIC-001			

STUDY TERMINATION

Did the	Participant complete the study $_0$ \square No $_1$ \square Yes If No, Date of Withdrawal: $ $
	Select one reason (below) for withdrawal:
1 🔲	Screening failure
2	Participant discontinued due to an adverse event. Record adverse event on AE page. Specify:
3	Participant decision (e.g., voluntary withdrawal, withdrawal of consent, compliance with study procedures), specify:
4	Physician decision, specify:
5	Lost to follow-up
6	Death
99	Other, specify:

This CRF data was not submitted

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	
EPIC-001				

INVESTIGATOR STATEMENT	
I certify that I have carefully examined all entries on the Case Report entered on these pages is correct.	Forms and that all information
Principal Investigator's Signature:	Date://

Protocol No.	Site No.	Participant No.	Participant No. Participant Initials	
EPIC-001				Supplemental

MICROBIOLOGY

Study Visit this Supplemental CRF page is associated with (e.g., Visit 3): ___

Specimen Type	Was Specimen Collected?	Date Specimen Collected (mmm/dd/yyyy)	Pa result**
OP Swab	0	/	o Negative 1 Positive 98 NAV
Expectorated Sputum	₀□ No ₁□ Yes	/	o ☐ Negative 1 ☐ Positive 98 ☐ NAV

^{*}If an OP Swab specimen was not collected, a comment is required in the Investigator Comment Log.

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^{**}Pa results from CHRMC Core Microbiology Laboratory.

Protocol	No.	Site N	No.	Participa	ınt No.	Participant	Initials	Visit
EPIC-0	01							Supplemental
AUDIOL	_OGY	97 Not	t Done	₉₈	Site)	Date teste	ed:	//
	Were the results interpretable? 0 ☐ No 1 ☐ Yes If Yes, indicate the type of testing performed:							
'		·	•					
1	ı∐Vis	sual Reinforce		• `		Normal 1	∐Abnor	mal*
		*If Abnormal				mation below	ν: 	
		500 H-		nes in Soun			_	
		500 Hz	1000 Hz		_		\dashv	
		u.) dl	b d	υ <u> </u>	db c	lb	
	2 Play Audiometry Left Ear: 0 Normal Right Ear: 0 Normal 1 Abnormal* *If Abnormal, record AE and complete the information below: Pure Tone Air Conduction Thresholds (dBHL)							
E	AR	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	z 8000 Hz
Righ	ht	db	db	db	db	db	c	lb db
Left		db	db	db	db	db	c	lb db
Standard Audiometry Left Ear: 0 Normal Right Ear: 0 Normal 1 Abnormal* *If Abnormal, record AE and complete the information below:								
			Pure Tone	Air Conduct	ion Thresh	olds (dBHL)		
E	AR	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	z 8000 Hz
Righ	ht	db	db	db	db	db	c	lb db
Left								
		db	db	db	db	db	С	lb db

68.____

See version 2 of this page at the end of the document

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Supplemental

SIGNS AND SYMPTOMS OF A PULMONARY EXACERBATION

Check a response for each criteria or si	Check a response for each criteria or signs/symptoms:					
 Major criteria: Decrease in FEV1 Decreased Oxygen saturation New lobar infiltrate or atelectas Hemoptysis 	is		0 No 0 No 0 No 0 No	1 Yes 1 Yes 1 Yes 1 Yes 1 Yes	98 NAV 98 NAV 98 NAV 98 NAV	
Minor Signs/symptoms: Increased work of breathing/res New or increased adventitial so Weight loss Increased cough Decreased exercise tolerance of Increased chest congestion or	ounds on lung e	ty	0 No 0 No 0 No 0 No 0 No 0 No	1 Yes	98 NAV 98 NAV 98 NAV 98 NAV 98 NAV 98 NAV	
Duration Criteria:						
• Duration of sign/symptoms ≥5	days		o ☐ No	₁ ☐ Yes	98 NAV	
Do the criteria, signs/symptoms, and do the definition of pulmonary exacerbation			o□No	₁ ☐ Yes		
		If Yes, date	of diagnosis:	/	_/	
Was the participant hospitalized?	o□ No	₁☐Yes*	date:/		<i>yyyy</i> <u>yyy</u>	
Were intravenous antibiotics required?	o ☐ No	₁ ☐ Yes**				
	Date IV a	intibiotic the	rapy started:	/_ 	_/	
Were oral antibiotics required?	₀ □ No	₁ ☐ Yes**				
	Date oral a	antibiotic the	rapy started:	/ mmm dd	_/	
Were inhaled antibiotics required?	o ☐ No	₁☐Yes**				
	Date inhaled a	antibiotic the	rapy started:	/ mmm dd	_/	

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^{*} Please record on Hospitalization CRF

^{**} Please record on Conmeds CRF

ŀ	Protocol No. Site No. Participant No.		Participant Initials	Visit	
-1	EPIC-001				Supplemental

PHYSICIAN INITIATED TREATMENT DISCONTINUATION

Study drug discontinuation:
1□TOBI ^Δ
*Date discontinued://
1 ☐ Temporary 2 ☐ Permanent
⁴ If TOBI has been discontinued, please record Ciprofloxacin discontinuation.
*Please describe reason for discontinuation:
₂☐ Ciprofloxacin/placebo
*Date discontinued://
1 ☐ Temporary 2 ☐ Permanent
*Please describe reason for discontinuation:

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The CRF data for this page was not submitted.

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Supplemental

EPIC OBSERVATIONAL STUDY (EPIC-002)

Has the participant enrolled in the EPIC Observational Study (EPIC-002)?	₀□ No	₁ ☐ Yes
If Yes, Date of Enrollment:	mmm dd	/
Observational Study ID number:		

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Baseline

INCLUSION CRITERIA

		No	Yes	N/A
1.	Male or female ≥ 1 year and ≤ 12 years of age	٥	1	
2.	 Confirmed diagnosis of Cystic Fibrosis: sweat chloride > 60 mEq/L by quantitative pilocarpine iontophoresis; and/or 	0	1	
	 a genotype with two identifiable mutations consistent with CF or an abnormal nasal transepithelial potential difference and one or more clinical features consistent with CF 			
3.	*Participants >15 months of age: New onset of <i>Pa</i> positive respiratory culture within 6 months prior to Baseline Visit:			98
	a) first lifetime documented <i>Pa</i> positive culture; OR	0	1	98
	 b) Pa recovered after at least a 2 year history of Pa negative respiratory cultures (≥ 1 culture/year) 	0	1	98
4.	*Participants 12-15 months of age: at least one documented Pa positive respiratory tract culture since birth or CF diagnosis	0	1	98
5.	Clinically stable:	0	1	
	 no evidence of significant respiratory symptoms and/or physical or chest radiograph findings at screening that would require administration of IV anti-pseudomonal antibiotics, oxygen, and/or hospitalization 			
6.	Signed informed consent by parent or legal guardian and applicable assent.	0	1	

^{*}Select appropriate age criteria for participant. If participant is >15 months of age, also select either subcriteria a) or b).

Version 2 of Pulmonary Exacerbation signs and symptoms

Cystic Fibrosis Therapeutics, Inc.

Protocol No.	Site No.	Participant No.	Participant Initials	Visit
EPIC-001				Supplemental

SIGNS AND SYMPTOMS OF A PULMONARY EXACERBATION

	Date Symptoms Started://						
Check a response for each criteria or signs/symptoms:							
Major criteria: Decrease in FEV1 Decreased Oxygen saturation New lobar infiltrate or atelectasis Hemoptysis			0 No 0 No 0 No 0 No	1 Yes 1 Yes 1 Yes 1 Yes 1 Yes	98 NAV 98 NAV 98 NAV 98 NAV		
 Minor Signs/symptoms: Increased work of breathing/respiratory rate New or increased adventitial sounds on lung exam Weight loss Increased cough Decreased exercise tolerance or level of activity Increased chest congestion or change in sputum 			0 No 0 No 0 No 0 No 0 No 0 No	1 Yes	98 NAV 98 NAV 98 NAV 98 NAV 98 NAV 98 NAV		
Duration Criteria:							
 Duration of sign/symptoms ≥5 days 			₀∐No	₁∐ Yes	98 LI NAV		
Do the criteria, signs/symptoms, and duration listed above meet the definition of pulmonary exacerbation per the study protocol? 0 No 1 Yes							
		If Yes, date	of diagnosis:	:/	_/		
Was the participant hospitalized?	₀□No	₁□Yes*	n date:	/ /			
		, tarriloolor	n date:	dd y	/yy		
Were intravenous antibiotics required?	o ☐ No	₁ Yes*	k				
Date IV antibiotic therapy started://							
Were oral antibiotics required?	o□No	₁ ☐ Yes*					
Date oral antibiotic therapy started://							
Were inhaled antibiotics required?	₀ No	₁ ☐ Yes*	*				
Date inhaled antibiotic therapy started:///					_/		
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^{*} Please record on Hospitalization CRF

^{**} Please record on Conmeds CRF