

CF Foundation Specimen Banking			
Study Long Title	The EPIC Observational Study: Longitudinal Assessment of Risk Factors for and Impact of Pseudomonas aeruginosa Acquisition and Early Anti-Pseudomonas Treatment in Children with CF		
Short Name	EPIC Observational		
Specimens Currently Available to Other Researchers	Yes		
Current Study Status	Closed		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment		11/01/2004	
Complete Enrollment	02/15/2008	01/01/2009	
Study Complete	06/30/2009	06/30/2009	
Number of Patients Planned	1700		
General Study Information			
Study Type	Observational		
Intervention Type			
Control Type			
Blinded	No		
Randomized	No		
Duration of Subject Participation	5 Years		
Endpoints Evaluated	Spirometry, Exacerbations, LRT Microbiology, Growth		
Trial Specific Link on ClinicalTrials.gov	http://www.clinicaltrials.gov/ct2/show/NCT00676169?term=EPIC+and+cystic+fibrosis&rank=3		
Primary Manuscript Link	http://onlinelibrary.wiley.com/doi/10.1002/ppul.21279/full		
Primary Manuscript Citation	Pediatr Pulmonol 2010;45(9):934-44		
Eligibility Criteria			
Age	1 Days to 12 Years		
FEV1	No FEV1 requirement		
P. aeruginosa status	Negative		
B. cepacia status	Not Applicable		
Other Primary Eligibility Requirements			
Subjects eligible for this trial will have had no prior isolation of Pa from respiratory cultures (documented as negative in at least 1 culture in 24 months prior to enrollment), or if prior isolation of Pa from respiratory cultures, at least a two-year history of Pa negative cultures. In addition, patients enrolled in the EPIC Clinical trial will automatically be enrolled in the EPIC Observational trial after completion of EPIC Clinical.			
Biorepository Specimen Information			
General Specimen Information			
Blood was collected annually for banking for 2.5 to 5 years (depending on when patients were enrolled). OP cultures were also evaluated annually and if P. aeruginosa was isolated, the isolates were sent to Seattle Children's for banking. A single collection of a buccal swab for DNA was added at the Year 5 timepoint.			
Visit #	Time from Baseline	Specimens Collected	
1	+0 Days	serum	
2	+1 Years	serum, PA isolates	
3	+2 Years	serum, PA isolates	
4	+3 Years	serum, PA isolates	
5	+4 Years	serum, PA isolates	
6	+5 Years	serum, buccal DNA, PA isolates	

CF Foundation Specimen Banking			
Study Long Title	The EPIC Observational Study: Longitudinal Assessment of Risk Factors For and Impact of Pseudomonas aeruginosa Acquisition and Early Anti-Pseudomonal Treatment in Children with CF (5 year Extension)		
Short Name	EPIC Observational Extension Years 6 to 10		
Specimens Currently Available to Other Researchers	Yes		
Current Study Status	Database Locked		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment	04/01/2009	02/17/2009	
Complete Enrollment	12/31/2009	12/31/2011	
Study Complete	12/31/2013	12/31/2013	
Number of Patients Planned	1780		
General Study Information			
Study Type	Observational		
Intervention Type			
Control Type			
Blinded	No		
Randomized	No		
Duration of Subject Participation	5 Years		
Endpoints Evaluated	Spirometry, Exacerbations, LRT Microbiology, Growth		
Trial Specific Link on ClinicalTrials.gov	http://www.clinicaltrials.gov/ct2/show/NCT00676169?term=EPIC+observation&rank=2		
Primary Manuscript Link	http://www.sciencedirect.com/science/article/pii/S1569199314001544		
Primary Manuscript Citation	J Cyst Fibros 2014;13(5):542-9		
Eligibility Criteria			
Age	1 Days to 12 Years		
FEV1	No FEV1 requirement		
P. aeruginosa status	Not Applicable		
B. cepacia status	Not Applicable		
Other Primary Eligibility Requirements	This study is an extension of the EPIC Observational study.		
Biorepository Specimen Information			
General Specimen Information			
This study represents a 5 year extension to the original EPIC Observational study. Blood was again collected annually (Years 6 - 10) and OP cultures were obtained annually with any isolated P. aeruginosa send to Seattle Children's for Banking.			
Visit #	Time from Baseline	Specimens Collected	
7	+6 Years	serum, PA isolates	
8	+7 Years	serum, PA isolates	
9	+8 Years	serum, PA isolates	
10	+9 Years	serum, PA isolates	
11	+10 Years	serum, PA isolates	

CF Foundation Specimen Banking			
Study Long Title	The EPIC Observational Study: Longitudinal Assessment of Risk Factors For and Impact of Pseudomonas aeruginosa Acquisition and Early Anti-Pseudomonal Treatment in Children with CF (Years 11-15)		
Short Name	EPIC Observational Years 11-15		
Specimens Currently Available to Other Researchers	Not Yet		
Current Study Status	Enrolling		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment	01/01/2014	01/02/2014	
Complete Enrollment	06/01/2015		
Study Complete	12/31/2018		
Number of Patients Planned	1400		
General Study Information			
Study Type	Observational		
Intervention Type			
Control Type			
Blinded	No		
Randomized	No		
Duration of Subject Participation	5 Years		
Endpoints Evaluated	Spirometry, Exacerbations, LRT Microbiology, Growth		
Trial Specific Link on ClinicalTrials.gov			
Primary Manuscript Link	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948320/		
Primary Manuscript Citation	Contemp Clin Trials ;DOI 10.1016		
Eligibility Criteria			
Age	1 Days to 17 Years		
FEV1	No FEV1 requirement		
P. aeruginosa status	Not Applicable		
B. cepacia status	Not Applicable		
Other Primary Eligibility Requirements	Must have participated in EPIC Observational Study.		
Biorepository Specimen Information			
General Specimen Information			
Visit #	Time from Baseline	Specimens Collected	
12	+11 Years	serum, EDTA plasma, buffy coat	
13	+12 Years	serum, EDTA plasma, buffy coat	
14	+13 Years	serum, EDTA plasma, buffy coat	
15	+14 Years	serum, EDTA plasma, buffy coat	
16	+15 Years	serum, EDTA plasma, buffy coat	