

CF Foundation Specimen Banking			
<b>Study Long Title</b>	Multi-center, Multi-national, Randomized, Placebo-Controlled Trial of Azithromycin in Subjects with Cystic Fibrosis 6 - 18 years old, Culture Negative for Pseudomonas aeruginosa.		
<b>Short Name</b>	AZ0004 (Randomized)		
<b>Specimens Currently Available to Other Researchers</b>	Yes		
<b>Current Study Status</b>	Closed		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment	12/01/2006	02/21/2007	
Complete Enrollment	12/31/2008	01/14/2009	
Study Complete	06/30/2009	07/14/2009	
<b>Number of Patients Planned</b>	300		
General Study Information			
<b>Study Type</b>	Interventional		
<b>Intervention Type</b>	Anti-Infective		
<b>Study Drug (Primary)</b>	Azithromycin		
<b>Study Drug (Non-Primary)</b>	Azithromycin		
<b>Control Type</b>	Placebo		
<b>Blinded</b>	Yes		
<b>Randomized</b>	Yes		
<b>Duration of Subject Participation</b>	24 Weeks		
<b>Endpoints Evaluated</b>	Spirometry, Exacerbations, Blood Inflammatory Mediators, LRT Microbiology, Growth		
<b>Trial Specific Link on ClinicalTrials.gov</b>	<a href="http://www.clinicaltrials.gov/ct/show/NCT00431964?order=1">http://www.clinicaltrials.gov/ct/show/NCT00431964?order=1</a>		
<b>Primary Manuscript Link</b>	<a href="http://jama.jamanetwork.com/article.aspx?articleid=185799">http://jama.jamanetwork.com/article.aspx?articleid=185799</a>		
<b>Primary Manuscript Citation</b>	JAMA 2010;303(17):1707-1715		
Eligibility Criteria			
<b>Age</b>	6 Years to 18 Years		
<b>FEV1</b>	>= 50 Percent Predicted		
<b>P. aeruginosa status</b>	Negative		
<b>B. cepacia status</b>	Negative		
<b>Other Primary Eligibility Requirements</b>	Eligible subjects must be negative for P aeruginosa for one year prior to screening (documented by at least 2 negative cultures)		
Biorepository Specimen Information			
<b>General Specimen Information</b>			
Specimens were collected at baseline and at 4 weeks and 24 weeks after treatment with 3 times weekly azithromycin.			
Visit #	Time from Baseline	Specimens Collected	
1	+0 Days	serum, Lith-Hep Plasma	
3	+4 Weeks	serum, Lith-Hep Plasma	
5	+24 Weeks	serum, Lith-Hep Plasma	