**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

**Short Name**
EPIC Observational

**Specimens Currently Available to Other Researchers**
Yes

**Current Study Status**
Closed

**Study Timeline Metrics**

<table>
<thead>
<tr>
<th></th>
<th>Planned</th>
<th>Actual (Sponsor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begin Enrollment</td>
<td></td>
<td>11/01/2004</td>
</tr>
<tr>
<td>Complete Enrollment</td>
<td>02/15/2008</td>
<td>01/01/2009</td>
</tr>
<tr>
<td>Study Complete</td>
<td>06/30/2009</td>
<td>06/30/2009</td>
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**Number of Patients Planned**
1700

**General Study Information**

**Study Type**
Observational

**Intervention Type**
CF Foundation Specimen Banking

**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**

**Primary Manuscript Citation**
Pediatr Pulmonol 2010;45(9):934-44

**Eligibility Criteria**

<table>
<thead>
<tr>
<th>Age</th>
<th>1 Days to 12 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1</td>
<td>No FEV1 requirement</td>
</tr>
<tr>
<td>P. aeruginosa status</td>
<td>Negative</td>
</tr>
<tr>
<td>B. cepacia status</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Visit #</th>
<th>Time from Baseline</th>
<th>Specimens Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+0 Days</td>
<td>serum</td>
</tr>
<tr>
<td>2</td>
<td>+1 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>3</td>
<td>+2 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>4</td>
<td>+3 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>5</td>
<td>+4 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>6</td>
<td>+5 Years</td>
<td>serum, buccal DNA, PA isolates</td>
</tr>
</tbody>
</table>

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CF Foundation Specimen Banking 1 of 3
CONFIDENTIAL
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)

Specimens Currently Available to Other Researchers: Yes

Current Study Status: Database Locked

Study Timeline Metrics

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<thead>
<tr>
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<td>04/01/2009</td>
<td>02/17/2009</td>
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<tr>
<td>Complete Enrollment</td>
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Number of Patients Planned: 1780

General Study Information

Study Type: Observational

Intervention Type: CF Foundation Specimen Banking

Control Type: No

Blinded: No

Randomized: No

Duration of Subject Participation: 5 Years

Endpoints Evaluated: Spirometry, Exacerbations, LRT Microbiology, Growth


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.

<table>
<thead>
<tr>
<th>Visit #</th>
<th>Time from Baseline</th>
<th>Specimens Collected</th>
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</thead>
<tbody>
<tr>
<td>7</td>
<td>+6 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>8</td>
<td>+7 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>9</td>
<td>+8 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>10</td>
<td>+9 Years</td>
<td>serum, PA isolates</td>
</tr>
<tr>
<td>11</td>
<td>+10 Years</td>
<td>serum, PA isolates</td>
</tr>
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</table>
### 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

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<tr>
<th>Metric</th>
<th>Planned</th>
<th>Actual (Sponsor)</th>
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### 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

#### 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