A MULTI-CENTER, RANDOMIZED, CONTROLLED, DOUBLE-BLIND STUDY OF THE EFFECTS OF AN ANTIOXIDANT-ENRICHED MULTIVITAMIN SUPPLEMENT ON INFLAMMATION AND OXIDATIVE STRESS IN CYSTIC FIBROSIS PATIENTS

Specimens Currently Available to Other Researchers: Yes

Current Study Status: Database Locked

### Study Timeline Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Planned</th>
<th>Actual (Sponsor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Begin Enrollment</td>
<td>07/15/2013</td>
<td>09/10/2013</td>
</tr>
<tr>
<td>Complete Enrollment</td>
<td>06/30/2015</td>
<td>06/30/2015</td>
</tr>
<tr>
<td>Study Complete</td>
<td>12/31/2015</td>
<td>10/31/2015</td>
</tr>
</tbody>
</table>

### Eligibility Criteria

- **Age**: \( \geq 10 \) Years
- **FEV1**: 40 to 100 Percent Predicted
- **P. aeruginosa status**: Not Applicable
- **B. cepacia status**: Not Applicable

### Biorepository Specimen Information

The purpose of this randomized, controlled study was to evaluate the effects of a modified formulation of AquADEKs® (AquADEKs-2) on markers of inflammation, antioxidant levels, and oxidative stress. Plasma, serum and sputum will be banked.

<table>
<thead>
<tr>
<th>Visit #</th>
<th>Time from Baseline</th>
<th>Specimens Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>+0 Days</td>
<td>serum, EDTA plasma</td>
</tr>
<tr>
<td>4</td>
<td>+16 Weeks</td>
<td>serum, EDTA plasma</td>
</tr>
</tbody>
</table>

### General SPECIMEN Information

**Study Long Title**: A MULTI-CENTER, RANDOMIZED, CONTROLLED, DOUBLE-BLIND STUDY OF THE EFFECTS OF AN ANTIOXIDANT-ENRICHED MULTIVITAMIN SUPPLEMENT ON INFLAMMATION AND OXIDATIVE STRESS IN CYSTIC FIBROSIS PATIENTS

**Short Name**: AquADEKs-2 Phase 2

**Current Study Status**: Database Locked

**Control Type**: Active

**Blinded**: Yes

**Randomized**: Yes

**Endpoints Evaluated**: Spirometry, Exacerbations, Sputum Inflammatory Mediators, Blood Inflammatory Mediators

**Trial Specific Link on ClinicalTrials.gov**: [http://clinicaltrials.gov/show/NCT01859390](http://clinicaltrials.gov/show/NCT01859390)

**Primary Manuscript Link**

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**CONFIDENTIAL**

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