# SCLERODERMA PROGRAM

<table>
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<tr>
<th>Study Name/ Organ</th>
<th>Description</th>
<th>Inclusion Criteria</th>
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<th>Contact/ PI</th>
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| **Celgene**       | Lungs       | A Phase 2, Proof-of-Concept, Multi-Center, Randomized, double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of Pomalidomide (CC-4047) in Subjects with Diffuse Cutaneous Systemic Sclerosis with Interstitial Lung Disease. | - Diagnosis of SSc defined by ACR criteria  
- Onset of first non-Raynaud’s manifestation of SSc within 7 years of Screening  
- Must meet at least one of the following – FVC readings ≥45% and <70% at screening and baseline without FVC decline of fibrosis score – or  
  FVC readings ≥70% and ≤80% at screening and baseline with a documented history of either or both 1. ≥5% decrease in FVC in 24 months prior to baseline 2. | - SpO2 < 92% at screening and baseline  
- Known diagnosis of obstructive lung disease as defined by FEV1/FVC ratio < 0.7  
- Diagnosis of PAH requiring treatment | Jennelle Shaw  
734-936-4555  
jdsh@med.umich.edu  
PI: Dr. Schiopu |
| **Scleroderma Registry/ Pathogenesis of SSc** | Database and bio-repository of UM Scleroderma patients  
- Develop an observational cohort of patients with systemic sclerosis (Scleroderma; SSc) seen at the University of Michigan Scleroderma Program | - Diagnosed with SSc  
- Over 18 | - Subjects who are unable to give consent  
- Subjects who cannot complete written surveys in English | Jennelle Shaw  
734-936-4555  
jdsh@med.umich.edu  
PI: Dr. Khanna |

### Inclusion Criteria:
- Diagnosis of SSc defined by ACR criteria
- Onset of first non-Raynaud’s manifestation of SSc within 7 years of Screening
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### Exclusion Criteria:
- SpO2 < 92% at screening and baseline
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<td><strong>ASC01</strong>&lt;br&gt;Rituximab&lt;br&gt;NIH</td>
<td>Randomized, Double-blind, Placebo-Controlled, Phase II Multicenter Trial of a Monoclonal Antibody to CD20 (Rituximab) for the Treatment of Systemic Sclerosis-Associated Pulmonary Arterial Hypertension (SSc-PAH)</td>
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| - Ages 18 – 75  
- Diagnosis of SSc-PAH within the past 5 years  
- Mean PVR of >3 wood units  
- NYHA Functional Class II, III, or IV  
- Must be able to maintain an O2 saturation of >90%  
- Must be treated with background medical therapy for PAH | - PAH >5 years  
- Measurement of meanPAP >25mmHg by Right Heart Catheterization  
- Persistent hypotension with systolic blood pressure <90mmHg  
- History of CAD, or any significant ventricular tachy-arrrhythmia, stent replacement, CAGB, or MI within 3 years of randomization  
- Treatment of a DMARD within 4 weeks prior to randomization.  
- Prior treatment with rituximab or exposure to any lymphocyte depleting agent | Jennelle Shaw  
734-936-4555  
jdsh@med.umich.edu  
PI: Dr. Khanna  
Co-PI: Dr. McLaughlin |
| **LOTUSS** | An Open-Label, Randomized, Phase 2 Study of the Safety and Tolerability of Pirfenidone when Administered to Patients with Systemic Sclerosis–Related Interstitial Lung Disease | - Ages 18 – 70  
- Diagnosis SSc- ILD  
- FVC ≥ 50%  
- DLCO ≥ 40% | - Treatment for PAH  
- Smoking with 3 months  
- Underlying liver disease | Jennelle Shaw  
734-936-4555  
jdsh@med.umich.edu |