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<tr>
<th>STUDY</th>
<th>DESCRIPTION</th>
<th>CONTACT/PI</th>
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<td><strong>SKIN</strong></td>
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<td><strong>ASSET</strong></td>
<td><strong>A phase 2 study to evaluate subcutaneous abatacept vs. placebo in diffuse cutaneous systemic sclerosis – a double-blind, placebo-controlled, randomized controlled trial.</strong>&lt;br&gt;• 48 week Double Blind&lt;br&gt;• 24 week Open Label&lt;br&gt;• 86 subjects, 25 centers across US, Canada and UK&lt;br&gt;• Weekly 125 mg abatacept/placebo sub cutaneous injection.&lt;br&gt;• Disease duration: ≤36 months&lt;br&gt;• Background therapies are d/c but escape therapy allowance provided at 3 months</td>
<td><strong>Currently Recruiting</strong>&lt;br&gt;Melanie Woods&lt;br&gt;734-232-2119&lt;br&gt;<a href="mailto:mewoods@med.umich.edu">mewoods@med.umich.edu</a>&lt;br&gt;PI: Dr. Khanna</td>
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<td><strong>FocuSSed</strong></td>
<td><strong>A phase 3, multicenter, randomized, double-blind placebo–controlled, parallel-group study to assess the efficacy and safety of Tocilizumab vs. placebo in patients with systemic sclerosis.</strong>&lt;br&gt;• 48 week Double Blind&lt;br&gt;• 48 week Open Label&lt;br&gt;• 210 subject, 120 global sites&lt;br&gt;• Weekly 162mg TCZ/placebo sub cutaneous injection&lt;br&gt;• Disease duration: &lt;60&lt;br&gt;• Escape therapy allowance starting at 24 weeks.</td>
<td><strong>Currently Recruiting</strong>&lt;br&gt;Aaron Rankin&lt;br&gt;734-763-4866&lt;br&gt;<a href="mailto:rankina@med.umich.edu">rankina@med.umich.edu</a>&lt;br&gt;PI: Dr. Khanna</td>
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<td><strong>GSK2330811</strong></td>
<td><strong>A multi-centre, randomized, double-blind (sponsor open), placebo-controlled, repeat-dose, proof of mechanism study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and explore efficacy of GSK2330811 in participants with diffuse cutaneous systemic sclerosis.</strong>&lt;br&gt;• 12 week Double Blind/ 16 week follow up&lt;br&gt;• 20-40 subjects&lt;br&gt;• Some background therapies including mycophenolate and low dose oral corticosteroids all allowed.&lt;br&gt;• Bi-weekly 100/300 mg of GSK2330811 or placebo sub cutaneous injections&lt;br&gt;• Disease duration: &lt;60</td>
<td><strong>Not yet Recruiting – Spring</strong>&lt;br&gt;Melanie Woods&lt;br&gt;734-232-2119&lt;br&gt;<a href="mailto:mewoods@med.umich.edu">mewoods@med.umich.edu</a>&lt;br&gt;PI: Dr. Young</td>
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<td><strong>tofacitinib</strong></td>
<td><strong>Evaluation of tofacitinib in early diffuse cutaneous systemic sclerosis (dcSSc): A phase I/II two center safety and tolerability study</strong>&lt;br&gt;• 24 week Double Blind/ 24 week follow up&lt;br&gt;• 20-40 subjects&lt;br&gt;• Some background therapies including mycophenolate and low dose oral corticosteroids all allowed.&lt;br&gt;• Daily tofacitinib/placebo, 5mg, oral tablets&lt;br&gt;• Disease duration: &lt;60</td>
<td><strong>Not yet Recruiting – Spring</strong>&lt;br&gt;Erica Bush&lt;br&gt;734-936-5615&lt;br&gt;<a href="mailto:ebush@med.umich.edu">ebush@med.umich.edu</a>&lt;br&gt;PI: Dr. Khanna</td>
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<td><strong>ACT14604</strong></td>
<td><strong>Efficacy and safety of SAR156597 in the treatment of diffuse cutaneous Systemic Sclerosis (dcSSc): A randomized, double-blind, placebo-controlled, 24-week, proof of concept study</strong>&lt;br&gt;• 24 week Double Blind/ 24 week follow up&lt;br&gt;• 94 subjects&lt;br&gt;• Some low dose background therapies are allowed.&lt;br&gt;• Weekly SAR156597 200 mg/ placebo sub cutaneous injections&lt;br&gt;• Disease duration: ≤36&lt;br&gt;• Choice of visiting nurses for injections to limit travel time.</td>
<td><strong>Not yet Recruiting – Spring</strong>&lt;br&gt;Erica Bush&lt;br&gt;734-936-5615&lt;br&gt;<a href="mailto:ebush@med.umich.edu">ebush@med.umich.edu</a>&lt;br&gt;PI: Dr. Young</td>
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## DIGITAL ULCERS

### RESCUE
Pilot study to assess the efficacy and safety of riociguat vs. placebo in scleroderma – associated digital ulcers
- 16 week double blind (8 week titration/8 week dose maintenance
- 16 week Open Label
- 20 subjects, 5 centers
- TID dosing of riociguat/placebo titrated up beginning with 1mg to 2.5 mg (0.5 is also available should tolerance be an issue)
- Diagnosis of SSc and one visible, active, ischemic DU at baseline located at or distal to the proximal interphalangeal joint, and that developed or worsened within 8 weeks prior to screening.

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## LUNG FIBROSIS

### STRATUS
A phase II, randomized, double-blind, placebo-controlled, parallel group, multicenter trial to evaluate the efficacy and safety of abituzumab in subjects with systemic sclerosis-associated interstitial lung disease.
- 104 week double blind treatment period with a 12 week safety follow up
- 175 subjects, 60 centers
- Abituzumab(1500 or 500mg)/placebo administered as an intravenous infusion over 1 hour once every 4 weeks with last dose at week 100
- Stable Mycophenolate is required up to 3 grams a day
- Diagnosis of SSc with disease duration of <7 years from first non-Raynaud’s
- DLCO > 30% predicted, FVC 40%-85% predicted and ratio of FVC% predicted to DLCO % predicted <1.8. If these criteria are met the HRCT will be performed and must show 5% fibrosis for the subject to be eligible.

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### SENSICS
To investigate the efficacy and safety of 150 mg bid nintedanib in patients with systemic sclerosis associated interstitial lung disease.
- 52 weeks Double blind (primary endpoint). Continuation of blinded treatment for up to 100 weeks.
- 520 subjects
- Nintedanib 150 mg/placebo BID with possibility to reduce to 100mg to manage adverse events.
- Diagnosis of SSc with disease duration of first non-Raynaud’s symptom within 5 years V1
- Extent of fibrotic disease in the lung ≥10%; FVC ≥40% predicted; DLCO 30%-89% predicted

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### SLS 3
Combining the anti-fibrotic effects of pirfenidone (PFD) with mycophenolate (MMF) for treating scleroderma-related interstitial lung disease.
- 18 month double blind
- 150 subjects
- Mycophenolate 250mg capsules + Pirfenidone 267mg capsules or placebo. The dosage will escalate if tolerated over a monthly 4 step titration plan.
- Diagnosis of SSc with disease duration of first non-Raynaud’s symptom within 5 years V1
- FVC-% of <80% at screening
- Disease duration of ≤84 months

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## JOINT CONTRACTURES

### REACT
Novel Strategies to Improve Arm Function in Patients with Scleroderma
- Aim to improve arm function in scleroderma patient with upper extremity contractures.
- 8 weeks of occupational therapy treatment.
- Participant stipend and travel reimburse available.
- Participants must have a contracture of the hand and other joint in at least one arm, such as wrist, elbow, or shoulder, with the ability to demonstrate active range of motion in that arm.

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