Scientific Oversight Committee (SOC)

- **What Does the SOC Do?**
  - Solicits and reviews scientific projects and programs
    - Projects typically yield a White paper
  - Develops and facilitates research teams dedicated to each approved project
    - Team has a project lead (full CSRC member or employed by a company that is a CSRC member)
    - Teams may include members from industry, academia and regulatory authorities

Have a Proposal
Submit to: cardiacsafety@dm.duke.edu
## Ongoing CSRC Projects

<table>
<thead>
<tr>
<th>Project</th>
<th>Team Leader</th>
<th>Purpose</th>
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<tr>
<td>Restricted Mean Survival Time (RMST) statistical analysis approach for analyzing Cardiovascular Outcomes Trials</td>
<td>David Manner, PhD (Eli Lilly)</td>
<td>To evaluate the utility of the RMST method (vs traditional HR) in diabetes CVOTs as RMST considers both events and exposure</td>
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<tr>
<td>Arrhythmia Normal Limits Combined Holter/12 Lead ECG Analysis</td>
<td>Polina Voloshko, MD (BioTelemetry Research)</td>
<td>To determine the incidence and variability of various arrhythmias during continuous ECG recordings in healthy adult clinical research volunteers</td>
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| Prevention of Sudden Cardiac Death in the Young: National Cardiac Screening Warehouse Pilot Study | Salim Idriss, MD (Duke) & Theressa Wright, MD (CSRC; Lilly)         | • To develop and implement uniform collection of a core screening dataset  
• To demonstrate feasibility of data collection comparing paper and electronic methods and feasibility of long term outcome collection |
| Regenerative Medicine Working Group Development                         |                                                                    |                                                                        |
| CSRC/DIA Collaboration: Real World Evidence & CV Safety Educational Curriculum | Brian Bradbury, PhD (Amgen) Raleigh Malik (DIA) & Mary Jane Geiger, MD, PhD (CSRC; ICON) | To education physicians with regards to key design elements and critical interpretation of real world evidence studies |
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