<table>
<tr><th>Prescription Drugs</th><th>Medical Devices (primarily FDA Class III)</th></tr>
<tr><td>Phase 1 Trial

• To demonstrate safety and tolerance
• Healthy volunteers (20-100 subjects)
• Determine dosing and major adverse effects</td><td rowspan="2">Pilot Trial

• Smaller population with the disease or condition (10-30 subjects)
• Determine preliminary safety and performance information</td></tr>
<tr><td>Phase 2 Trial

• To demonstrate safety and efficacy
• Small population (50-200 subjects) with the target disease or condition
• Confirm dosing and adverse effects</td></tr>
<tr><td>Phase 3 Trial

• To demonstrate safety and efficacy
• Large population (100s to 1000s of subjects) with the target disease or condition
• Determine drug-drug interactions and adverse effects</td><td>Pivotal Trial

• Larger population with the disease or condition (150-300 subjects)
• Determine effectiveness and adverse effects</td></tr>
<tr><td>Phase 4 Trial

Post-approval study

• Collect long-term data and adverse effects</td><td>Post-Approval Study

• Collect long-term data and adverse effects</td></tr>
</table>

Rx trials tend to be characterized by large samples, randomized and blinded group assignment/membership as well as the use of control and alternative treatment groups, including placebo treatment.

Medical device trials for Class III products typically involve smaller sample sizes and often do not involve randomization, placebos, or blinded group assignment/membership.