# CAS CLINICAL TRIAL AND REGISTRY UPDATE

<table>
<thead>
<tr>
<th>Study</th>
<th>Sponsor</th>
<th>Sample Size</th>
<th>Stent</th>
<th>Embolic Protection Device</th>
<th>Study Design</th>
<th>Target Vessel Size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Risk</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARCHeR</td>
<td>Abbott Vascular</td>
<td>N=581</td>
<td>Archer 1: Acculink OTW; Archer 2: Acculink OTW; Archer 3: RX Acculink</td>
<td>Archer 1: none; Archer 2: Accunet OTW; Archer 3: RX Accunet</td>
<td>High-risk registry</td>
<td>Stent: 4 to 9; EPD segment: 3.25 to 7</td>
</tr>
<tr>
<td>ARMOUR</td>
<td>Invatec</td>
<td>N=228</td>
<td>Any FDA-approved carotid stent</td>
<td>Mo.Ma</td>
<td>Multicenter prospective US and EU study in high surgical risk population</td>
<td>Any vessel size compatible with FDA-approved carotid stents</td>
</tr>
<tr>
<td>BEACH</td>
<td>Boston Scientific Corporation</td>
<td>N=747</td>
<td>Carotid Wallstent Monorail Endoprosthesis</td>
<td>FilterWire EX Embolic Protection System; FilterWire EZ Embolic Protection System</td>
<td>High-risk registry</td>
<td>Stent: 6.8, 10; EPD segment: 3.5 to 5.5</td>
</tr>
<tr>
<td>CABERNET</td>
<td>EndoTex, now a Boston Scientific company</td>
<td>N=488</td>
<td>NexStent Carotid Stent</td>
<td>FilterWire EX Embolic Protection System; FilterWire EZ Embolic Protection System</td>
<td>High-risk registry</td>
<td>Stent: 4 to 9; EPD segment: 3.5 to 5.5</td>
</tr>
<tr>
<td>CREATE</td>
<td>ev3</td>
<td>N=419</td>
<td>Protégé GPS, straight and tapered</td>
<td>Spider OTW</td>
<td>High-risk registry</td>
<td>Stent: 4.5 to 9; EPD segment: 4 to 7</td>
</tr>
<tr>
<td>CREATE</td>
<td>SpiderRX Arm</td>
<td>N=160</td>
<td>Acculink; RX Acculink</td>
<td>SpiderRX</td>
<td>High-risk registry</td>
<td>Stent: 3.6 to 9.1; EPD segment: 4 to 7</td>
</tr>
<tr>
<td>EMPIRE</td>
<td>Gore &amp; Associates</td>
<td>N=320</td>
<td>Any FDA-approved carotid stent</td>
<td>Gore Neuro Protection System</td>
<td>High-risk registry</td>
<td>Stent: 4 to 9</td>
</tr>
<tr>
<td>EPIC US</td>
<td>Lumen Biomedical</td>
<td>N=30</td>
<td>Guidant Acculink</td>
<td>FiberNet EPD</td>
<td>Multicenter, US-based, prospective, feasibility study in high-risk patients</td>
<td>EPD segment: 2.5 to 7</td>
</tr>
<tr>
<td>EPIC EU</td>
<td>Lumen Biomedical</td>
<td>N=50</td>
<td>Any approved carotid stent</td>
<td>FiberNet EPD</td>
<td>Multicenter, prospective European feasibility study in high-risk patients</td>
<td>EPD segment: 2.5 to 7</td>
</tr>
<tr>
<td>EPIC Pivotal Trial</td>
<td>Lumen Biomedical</td>
<td>N=254</td>
<td>Any approved carotid stent</td>
<td>FiberNet EPD</td>
<td>Multicenter, prospective, pivotal study in high-risk patients</td>
<td>EPD segment: 2.5 to 7</td>
</tr>
<tr>
<td>MAVErIC I &amp; II</td>
<td>Medtronic</td>
<td>N=99 (phase I); N=399 (phase II)</td>
<td>Exponent</td>
<td>GuardWire</td>
<td>High-risk registry</td>
<td>Stent: 5.5 to 9.5</td>
</tr>
<tr>
<td>MAVErIC III</td>
<td>Medtronic</td>
<td>N=413</td>
<td>Exponent</td>
<td>Interceptor Plus</td>
<td>High-risk registry</td>
<td>Stent: 5.5 to 9.5</td>
</tr>
<tr>
<td>MO.MA</td>
<td>Invatec</td>
<td>N=157</td>
<td>Any</td>
<td>Mo.Ma</td>
<td>Multicenter EU registry (75% of the final population was at high risk)</td>
<td>Mean ICA reference diameter: 6.28</td>
</tr>
<tr>
<td>PASCAL</td>
<td>Medtronic</td>
<td>N=113</td>
<td>Exponent</td>
<td>Any CE Mark-approved device</td>
<td>Outside US high-risk registry</td>
<td>Stent: 5.5 to 9.5</td>
</tr>
<tr>
<td>PRIAMUS</td>
<td>Invatec</td>
<td>N=416</td>
<td>Any</td>
<td>Mo.Ma</td>
<td>Multicenter Italian registry (63.5% symptomatic patients)</td>
<td>Mean diameter stenosis: 80%±9.8</td>
</tr>
<tr>
<td>PROTECT</td>
<td>Abbott Vascular</td>
<td>N=320</td>
<td>Xact Carotid Stent</td>
<td>EmboShield Pro Embolic Protection System</td>
<td>High-risk registry</td>
<td>Stent: 4.8 to 9.1; EPD segment 2.5 to 7</td>
</tr>
<tr>
<td>SAPPHIRE</td>
<td>Cordis Endovascular</td>
<td>N=724*</td>
<td>Precise (5.5 F, 6 F)</td>
<td>AngioGuard XP</td>
<td>Randomized (CEA and CAS) multicenter trial of high-risk patients; evaluated by multidisciplinary team</td>
<td>Stent: 4 to 9.5; EPD segment: 3.5 to 7.5</td>
</tr>
</tbody>
</table>

Prepared by the editors of Endovascular Today in conjunction with the device manufacturers.
<table>
<thead>
<tr>
<th>30-Day Results</th>
<th>Final Results</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>All death, stroke, MI=8.3%</td>
<td>Final 1-y data: all death, stroke, MI within 30 d and all ipsilateral stroke from 31 d to 1 y=9.6%; weighted historical control=14.5%</td>
<td>FDA approval received August 2004</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrollment begins September 2007</td>
</tr>
<tr>
<td>MAE=5.6%</td>
<td>1-y results: non-Q–wave MI: 0 to 24 hrs; stroke, death, Q-wave MI: 0 to 30 d; ipsilateral stroke, neurological death: 31 to 360 d=9.1%</td>
<td>Pending FDA approval</td>
</tr>
<tr>
<td>MAE=3.9%</td>
<td>Primary endpoint 1: 1-y results: all death, stroke, MI 0 to 30 d, and ipsilateral stroke and any death related to ipsilateral stroke 31 to 365 d: 4.7%. Primary endpoint 2: 1-y results results, all death, stroke, MI 0 to 365 d=11.9%</td>
<td>FDA approval received December 2006</td>
</tr>
<tr>
<td>MACE=6.3%</td>
<td>Primary endpoint: 30-d composite MI, ipsilateral stroke, procedure-related contralateral stroke, and death, and ipsilateral stroke from 31 to 365 d=7.8%</td>
<td>FDA approval received January 2007</td>
</tr>
<tr>
<td>MACE=5.6%</td>
<td>n/a</td>
<td>510(k) clearance</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Completed enrollment</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>30-d all MACE=5.7%</td>
<td>n/a</td>
<td>Active</td>
</tr>
<tr>
<td>30-d results MAE=8%</td>
<td>n/a</td>
<td>Completed, published</td>
</tr>
<tr>
<td>30-d all stroke and deaths=4.5%; 30-d MI=0%</td>
<td>n/a</td>
<td>Enrollment completed</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Completed, published</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>4.4% total MAE; 0% major stroke rate</td>
<td>Key Randomized Results: 1-y results: stent patients: death, stroke, MI rate=12%; surgical patients: death, stroke, MI rate=19.2% Precise lesion success &lt;30%=99.4%; AngioGuard XP success rate=98.1% 2-y results: TLR=1.4%</td>
<td>Trial completed; 1-y results published in N Engl J Med, October 2004; 3-y results pending publication</td>
</tr>
</tbody>
</table>

*Randomized N=310; stent registry (surgical refusal)=407; surgical registry (stent refusal)=7. †Abbott Vascular provides product support.
### High Risk (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sponsor</th>
<th>Sample Size</th>
<th>Stent</th>
<th>Embolic Protection Device</th>
<th>Study Design</th>
<th>Target Vessel Size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECURITY</td>
<td>Abbott Vascular</td>
<td>N=305</td>
<td>Xact Carotid Stent</td>
<td>EmboShield Embolic Protection System</td>
<td>High-risk registry</td>
<td>Stent: 4.8 to 9.1; EPD segment: 2.8 to 6.2</td>
</tr>
<tr>
<td>VIVA</td>
<td>Bard Peripheral Vascular</td>
<td>N=400</td>
<td>Vivexx</td>
<td>Industry partner</td>
<td>High-risk registry</td>
<td>Stent: 3.5 to 11</td>
</tr>
</tbody>
</table>

### Normal Risk

<table>
<thead>
<tr>
<th>Study</th>
<th>Sponsor</th>
<th>Sample Size</th>
<th>Stent</th>
<th>Embolic Protection Device</th>
<th>Study Design</th>
<th>Target Vessel Size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT I</td>
<td>Abbott Vascular</td>
<td>N=1,658</td>
<td>Xact Carotid Stent</td>
<td>EmboShield Pro; EmboShield Gen3 Embolic Protection System</td>
<td>Randomized, multicenter trial for asymptomatic, CEA-eligible patients</td>
<td>Stent: 4.8 to 9.1; EPD segment: 2.5 to 7</td>
</tr>
<tr>
<td>ACST-2</td>
<td>NHS Health Technology Assessment Programme &amp; BUPA Foundation</td>
<td>N=5,000</td>
<td>Any CE Mark-approved device</td>
<td>Optional, but any CE Mark-approved device</td>
<td>Randomized, multicenter trial for asymptomatic, CEA-eligible patients</td>
<td>Not specified; any asymptomatic carotid stenosis that is considered to warrant intervention</td>
</tr>
<tr>
<td>CARES</td>
<td>Cordis Endovascular</td>
<td>N=2,200</td>
<td>Precise RX</td>
<td>AngioGuard RX</td>
<td>Multicenter, non-high-risk, pivotal study</td>
<td>Stent: 4 to 9.5; EPD segment: 3.5 to 7</td>
</tr>
<tr>
<td>CREST</td>
<td>NIH/NINDS, UMDNJ†</td>
<td>N=2,500</td>
<td>RX Acculink</td>
<td>RX Accunet</td>
<td>Randomized (CEA and CAS) multicenter trial of low to moderate risk patients evaluated by multidisciplinary team</td>
<td>Stent: 4 to 9; EPD segment: 3.25 to 7</td>
</tr>
<tr>
<td>EVA-3S</td>
<td>Multiple devices used</td>
<td>N=527</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Multicenter, randomized, noninferiority</td>
<td>Symptomatic stenosis &gt;60%</td>
</tr>
<tr>
<td>SPACE</td>
<td>Multiple devices used</td>
<td>N=1,200</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Randomized, noninferiority trial</td>
<td>Stenosis &gt;70%</td>
</tr>
<tr>
<td>TACIT</td>
<td>n/a</td>
<td>N=3,700</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Randomized (CEA, CAS, and medical therapy) multicenter trial</td>
<td>Stenosis &gt;60%</td>
</tr>
</tbody>
</table>

### Postmarket Surveillance

<table>
<thead>
<tr>
<th>Study</th>
<th>Sponsor</th>
<th>Sample Size</th>
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<th>Embolic Protection Device</th>
<th>Study Design</th>
<th>Target Vessel Size (mm)</th>
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<tr>
<td>CAPTURE</td>
<td>Abbott Vascular</td>
<td>N=1,500</td>
<td>RX Acculink</td>
<td>RX Accunet</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4 to 9; EPD segment: 3.25 to 7</td>
</tr>
<tr>
<td>CAPTURE 2</td>
<td>Abbott Vascular</td>
<td>N=10,000</td>
<td>RX Acculink</td>
<td>RX Accunet</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4 to 9; EPD segment: 3.25 to 7</td>
</tr>
<tr>
<td>CASES</td>
<td>Cordis Endovascular</td>
<td>N=1,500</td>
<td>Precise</td>
<td>AngioGuard XP</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4 to 9.5; EPD segment: 3.0 to 7</td>
</tr>
<tr>
<td>CHOICE</td>
<td>Abbott Vascular</td>
<td>N=5,000</td>
<td>RX Acculink/Xact Carotid Stent</td>
<td>RX Accunet/EmboShield Embolic Protection System</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4 to 9.1; EPD segment: 2.8 to 7</td>
</tr>
<tr>
<td>CREATE PAS</td>
<td>ev3</td>
<td>N=1,500</td>
<td>Protégé RX</td>
<td>SpiderFX</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4.5 to 9.5; EPD segment: 3 to 7</td>
</tr>
<tr>
<td>CRISTALLO</td>
<td>Invatec</td>
<td>N=124</td>
<td>Cristallo Ideale</td>
<td>Any</td>
<td>Multicenter EU</td>
<td>Target vessel diameter: 5 to 9</td>
</tr>
<tr>
<td>EXACT</td>
<td>Abbott Vascular</td>
<td>N=1,500</td>
<td>Xact Carotid Stent</td>
<td>EmboShield Embolic Protection System</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4.8 to 9.1; EPD segment: 2.8 to 6.2</td>
</tr>
<tr>
<td>SAPPHIRE WW</td>
<td>Cordis Endovascular</td>
<td>N=10,000</td>
<td>Precise; Precise RX; Precise Pro RX</td>
<td>AngioGuard XP; AngioGuard RX</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4 to 9.5; EPD segment: 3 to 7</td>
</tr>
<tr>
<td>SONOMA</td>
<td>Boston Scientific Corporation</td>
<td>N=1,500</td>
<td>NexStent</td>
<td>FilterWire EZ</td>
<td>Multicenter, high-risk, postmarketing surveillance study</td>
<td>Stent: 4 to 9; EPD segment: 3.5 to 5.5</td>
</tr>
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<th>Final Results</th>
<th>Status</th>
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<tr>
<td>All death, stroke, MI=7.5%</td>
<td>Final 1-y data: all death, stroke, MI within 30 d, plus all ipsilateral stroke from 31 d to 1 y=8.5%</td>
<td>FDA approval received September 2005</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>All death, stroke, and MI</td>
<td>30-d: all death, stroke, MI, plus all stroke and death to 5 years</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a; pending publication</td>
<td>IDE approved</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>Stroke or death: post-CAS: 9.6, post-CEA: 3.9</td>
<td>6-mo incidence of any stroke or death: CEA=6.1, CAS=11.7</td>
<td>Stopped prematurely</td>
</tr>
<tr>
<td>Ipsilateral ischemic stroke and death: CAS: 6.84, CEA: 6.34</td>
<td>See 30-d results</td>
<td>Completed</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a; pending publication</td>
<td>Completed; results to be published</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>30-d MAE (death, stroke, MI) rate of 5%; 30-d results published in CCI, August, 2007</td>
<td>Completed; published in CCI, August 2007</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>MANE=0%</td>
<td>MANE=0%</td>
<td>Completed; results to be published</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrollment closed; 1-y follow-up ongoing</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>Enrolling</td>
</tr>
</tbody>
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*Randomized N=310; stent registry (surgical refusal)=407; surgical registry (stent refusal=7). †Abbott Vascular provides product support.*