Clinical trial case studies
What has worked well and what lessons have been learned?

THE MEDICINES COMPANY
Reducing complexity and cost

1. design
2. set up
3. implement
4. analyze
Reducing complexity and cost

1. design
2. set up
3. implement
4. analyze
Align design with practice

Keep it simple...

<table>
<thead>
<tr>
<th>Practice</th>
<th>Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI patient population</td>
<td>SA/ UA/ NSTEMI/ STEMI</td>
</tr>
<tr>
<td>Clopidogrel loading</td>
<td>300 or 600 mg</td>
</tr>
<tr>
<td>Clopidogrel timing</td>
<td>After angiography</td>
</tr>
<tr>
<td></td>
<td>Before or after PCI start</td>
</tr>
<tr>
<td>Minutes lapsed to treat</td>
<td>0</td>
</tr>
</tbody>
</table>
Site selection matters

Pick winning sites...

<table>
<thead>
<tr>
<th></th>
<th>NEJM-1</th>
<th>NEJM-2</th>
<th>NEJM-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>13,000</td>
<td>18,000</td>
<td>11,000</td>
</tr>
<tr>
<td>Sites</td>
<td>707</td>
<td>650</td>
<td>150</td>
</tr>
<tr>
<td>Rate (pt/site/mo)</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Enrollment period (mos)</td>
<td>26</td>
<td>29</td>
<td>20</td>
</tr>
</tbody>
</table>
Move the 12-lead ECG machine into the cath lab…

Tape the blinded study meds to the patient record…

Attach the post PCI blood sample orders to the outgoing gurney…

Promote a learning culture

God is in the details…

4. Implement
Restrain data exuberance

Data variable counts $\alpha$ data acquisition cost

$R^2 = 0.86$
Restrain data exuberance

Data variable counts modestly $\alpha$ queries

Data queries per patient vs. Data variables per patient

- PHOENIX (N~11,000)
- REPLACE-2 (N~6,000)
- PCI-PLAT (N~14,500)
- ACUITY (N~13,800)

$R^2 = 0.33$
Restrain data exuberance

Trial complexity may drive costs of data + queries

Data + query cost per patient

$0

$1,000

$2,000

$3,000

Data variables per patient

PCI-PLAT (N~14,500)

ACUITY (N~13,800)

PHOENIX (N~11,000)

REPLACE-2 (N~6,000)

R² = 0.77

4. analyze
4%
35
98.2%
Reducing complexity and cost

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3. implement
4. analyze
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