



EMERGEN

Meredith Todd

THE **MEDICINES** COMPANY

LST Expert Meeting, May 13-14 2013

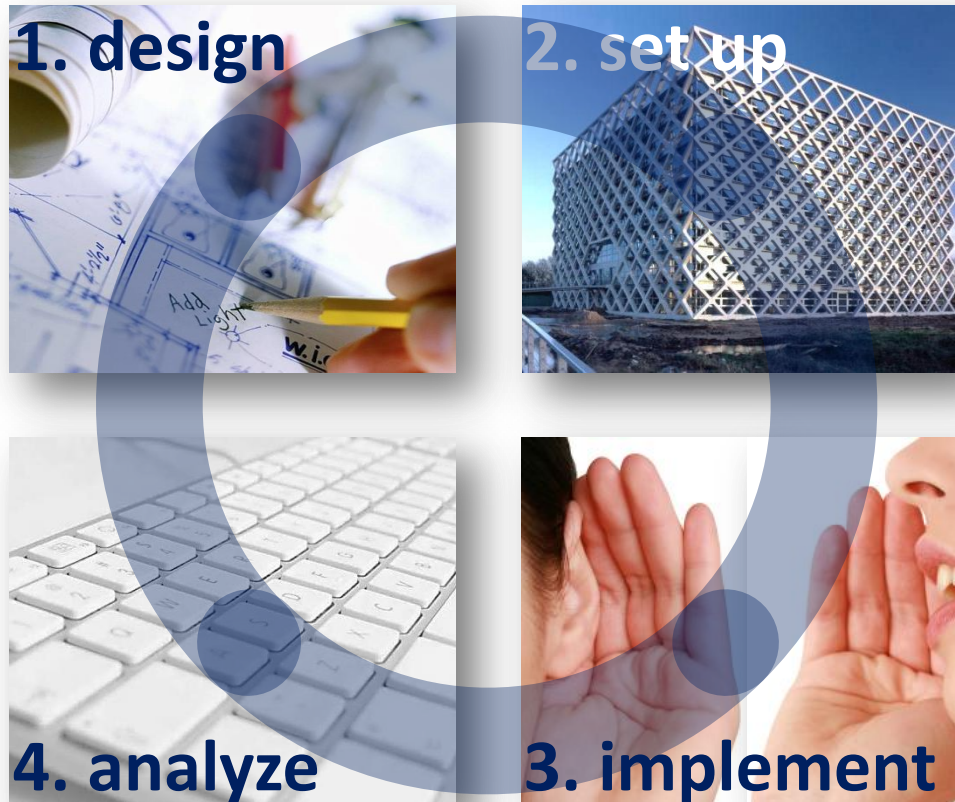
Clinical trial case studies

What has worked well and what lessons have been learned?





Reducing complexity and cost



Reducing complexity and cost





Align design with practice

Keep it simple...

	Practice	Protocol
PCI patient population	SA/ UA/ NSTEMI/ STEMI	<input checked="" type="checkbox"/>
Clopidogrel loading	300 or 600 mg	<input checked="" type="checkbox"/>
Clopidogrel timing	After angiography	<input checked="" type="checkbox"/>
	Before <i>or</i> after PCI start	<input checked="" type="checkbox"/>
Minutes lapsed to treat	0	12



Site selection matters

Pick winning sites...

NEJM-1 NEJM-2 **NEJM-3**

Patients	13,000	18,000	11,000
Sites	707	650	150
Rate (pt/site/mo)	1	1	4
Enrollment period (mos)	26	29	20

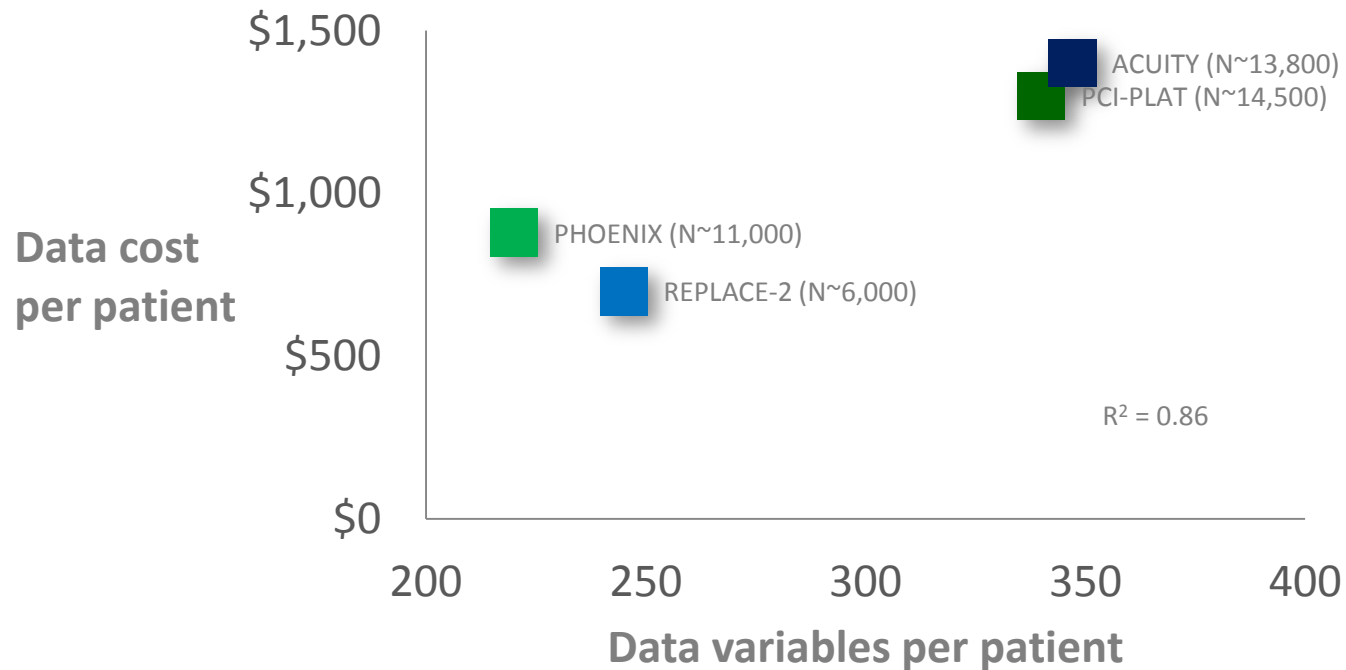






Restrain data exuberance

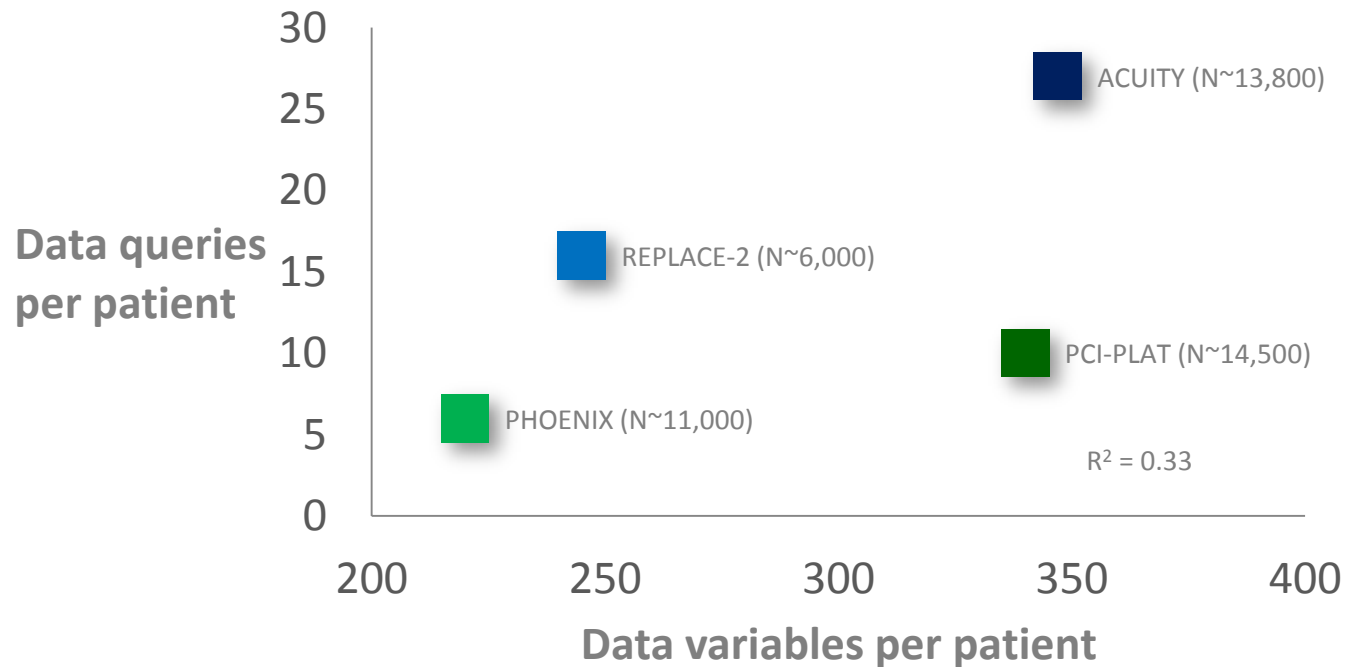
Data variable counts \propto data acquisition cost





Restrain data exuberance

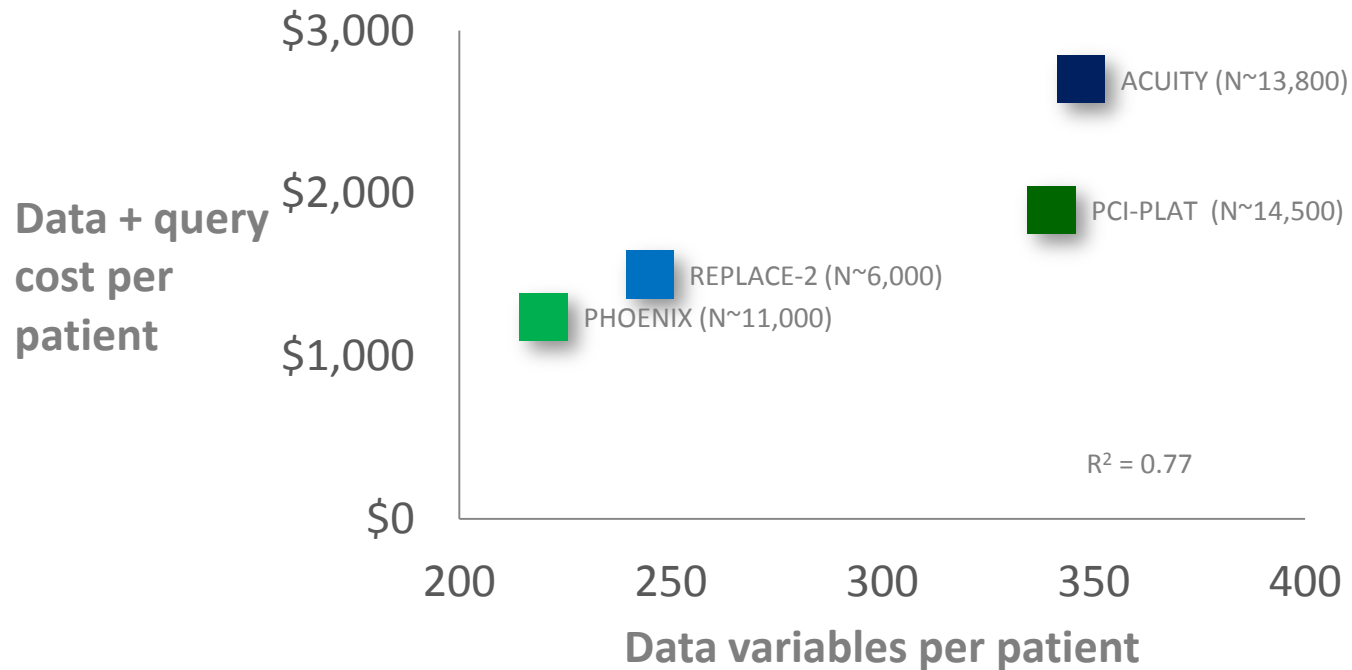
Data variable counts modestly α queries





Restrain data exuberance

Trial complexity may drive costs of data + queries



4%

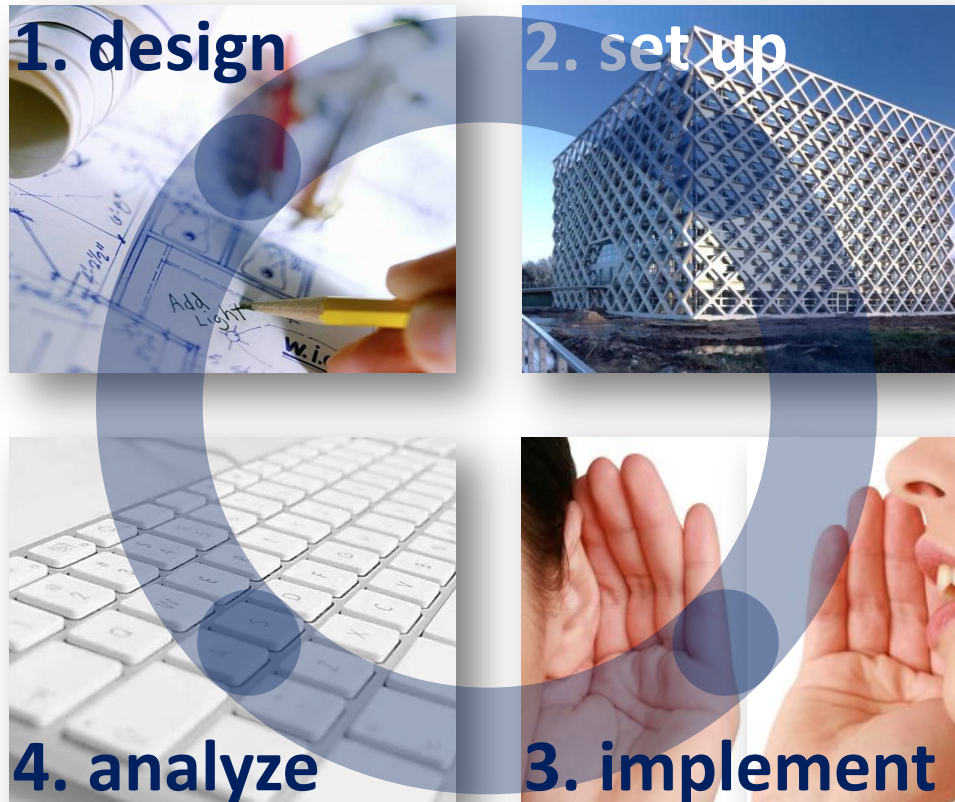
35

0%

98.2%

\$6,500

Reducing complexity and cost





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