

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Recruitment Support & Study Timeline

Christiana E. Hall MD, MS

and

Claudette Lohr, RN, CCRC



Recruitment

Brief historic footnote for comparison:

- In the GRASP 2 center mid-phase trial
 - UVA stroke population ~ 300 annually
 - MCG stroke population ~ 300 annually

- Recruited ~76 in just < 18 months
 - that's 50/ yr
 - 25 per site/ yr
 - 4.25 pts per site/ month



Recruitment

- One of the most important measures of any clinical trial's success
- Now more important than ever
- SHINE Trial was designed for success
 - Proven track record of NETT
 - Independent sites hand picked for high quality
 - Recruitment estimates for each Hub or Site scientifically derived **then halved!**



Recruitment

- SHINE Trial was designed to:
- Complete recruitment in 3.5 years !
- There are those that say: *It can't be done*
- I say: *just watch all of us go !*



Recruitment

- All SHINE has to do is:
- Recruit 33.66 patients per month
 - And of course retain them
- Sounds easy, but we all know its really really hard work
- It will happen if:



Recruitment

SITE	Per year	Per month
U Arizona	13	1.08
U Cincinnati	3	0.25
UCSF	19	1.6
Columbia	22	1.83
Emory	11	0.91
Henry Ford	14	1.16
U Kentucky	18	1.5
U Maryland	6	0.5
U Minnesota	21	1.75
U Pennsy	34	2.83
OHSU	18	1.5
Stanford	8	0.666
U TX - Houston	20	1.66
VCU	8	1.5

SITE	Per year	Per month
Wayne State	59	4.92
Temple	30	2.5
MC Wisconsin	19	1.6
GHSU (MCG)	6	0.5
U TX - SW	9	0.75
UVA	7	0.59
Baylor	12	1
Mayo Jacks'ville	8	1.5
OSF ST Francis	5	0.42
St Louis Univ	7	0.583
U of Utah	6	0.5
Penn State U	12*	1
B-U: Mayo AZ	6	0.5
B-U: Clev Clinic	9	0.75

Recruitment

- Don't let these targets:
 - *Hold you back...*
 - *Many capable of higher enrollment*
 - *Reimbursement follows recruitment*
 - *Excess is good*



Recruitment

Recognition:

- Highest absolute enrollers
- Highest proportional enrollers (over target)



Recruitment

- Tremendous expertise & know-how at sites
- Collaboration with NINDS recruitment expert and Clinical Trials Specialist
 - Jamie Roberts, MA, CCRP
- SHINE has 2 other secret weapons:
 - Recruitment PI
 - Chris Hall, MD, MS
 - Recruitment Nurse Specialist
 - Claudette Lohr, RN, CCRC



Recruitment

Hall & Lohr roles:

- Support YOU!
- Pledge not to hassle you when your doing great
 - except to provide well-deserved pats on the back & cheers
- We're there in case the going gets tough
 - to be a sounding board & thinking partner
 - To help develop updated recruitment strategies
 - To teleconference
 - Even to visit



Recruitment

Hall & Lohr roles:

- Look at recruitment progress each week
- We'll report to you every quarter (feedback)
- We're on the monthly NETT coordinator calls
- Host a quarterly SHINE recruitment telecon to start
 - These could go away if it becomes clear performance is way above expectation
 - This could happen!



Recruitment

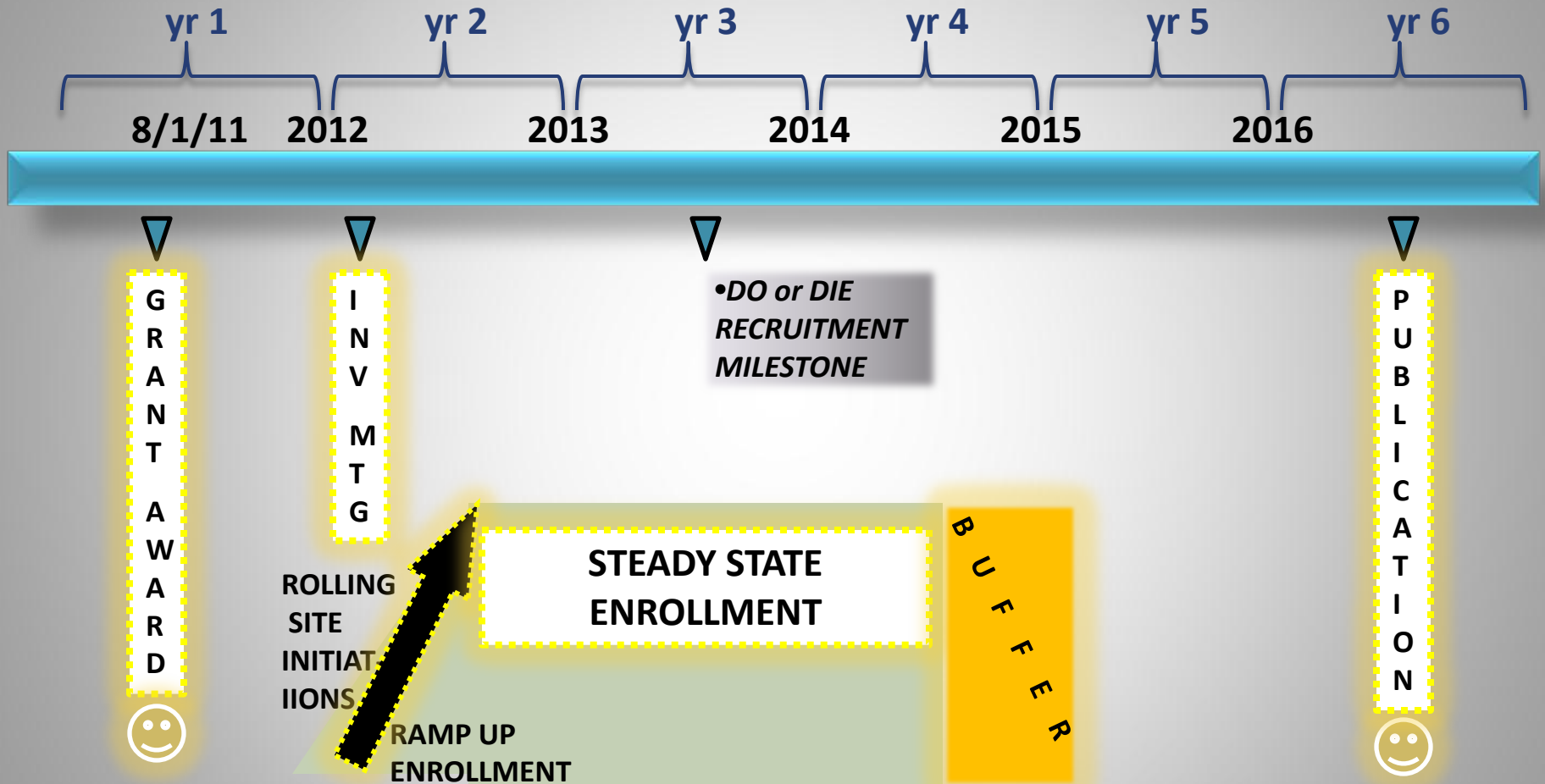
Hall & Lohr *ask* from you:

- Brief summary of baseline planned recruitment strategy for SHINE at your site (1/2-1 pg)
 - just so we're familiar w/ how your team operates
- If you see a tsunami coming let us know when you know – maybe we can help
- Call or email anytime you have question
- Our pledge is never have you feel we're hassling -- so tell us if that ever, ever happens
 - and also you tell us how best we can help you
 - Every site's an individual & strong



Timeline

SHINE Recruitment Lifecycle – 3.5 yrs



POST-AWARD-----3.5 yr (42 MO) ENROLLEMENT-----Follow ups
 10 MONTH START UP

Close out
 Data Analysis

