Stanford MEDICINE

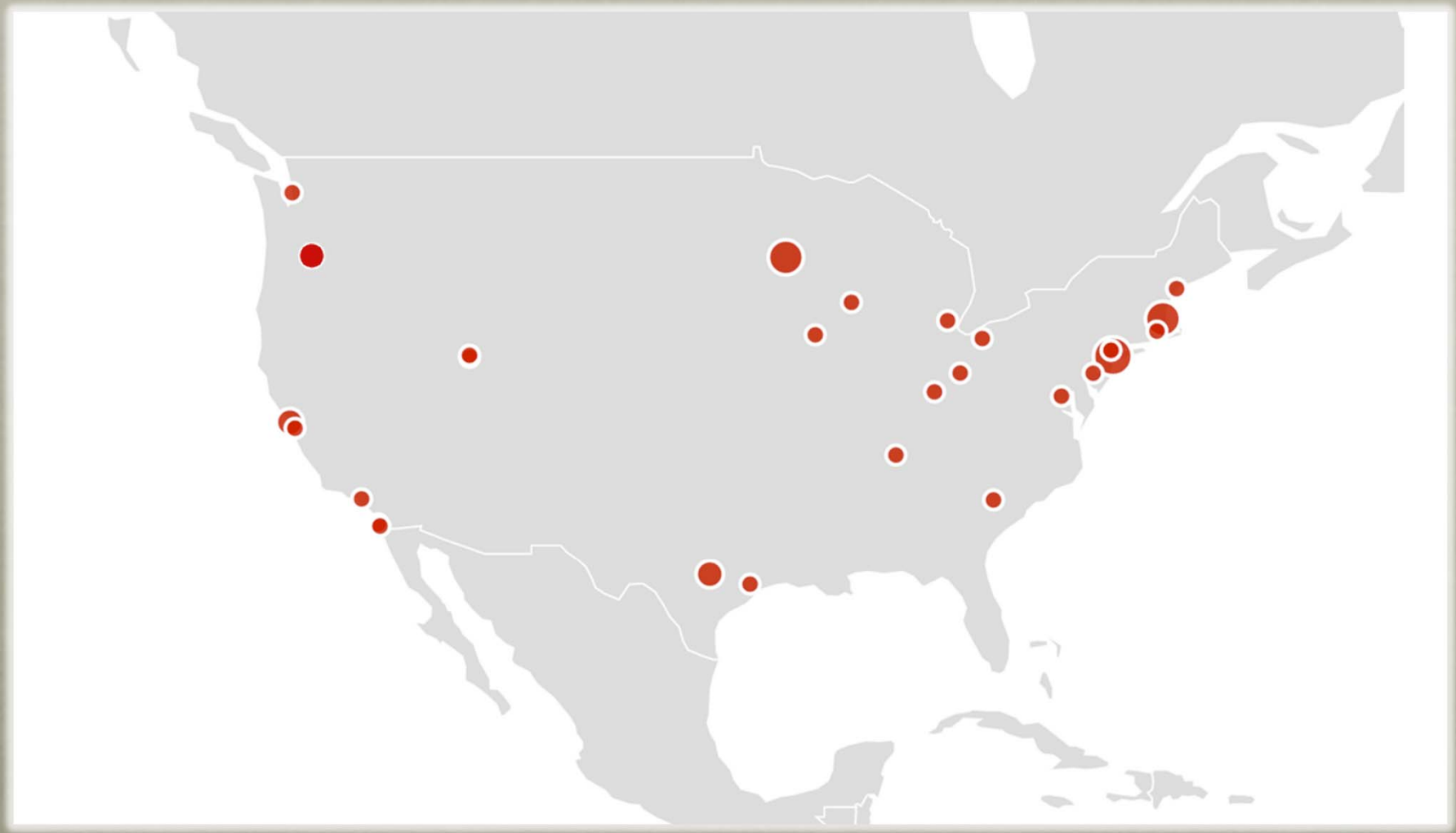
defuse·3

NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

Funded by a Grant from the National Institutes of Health

DEFUSE 3 Sites

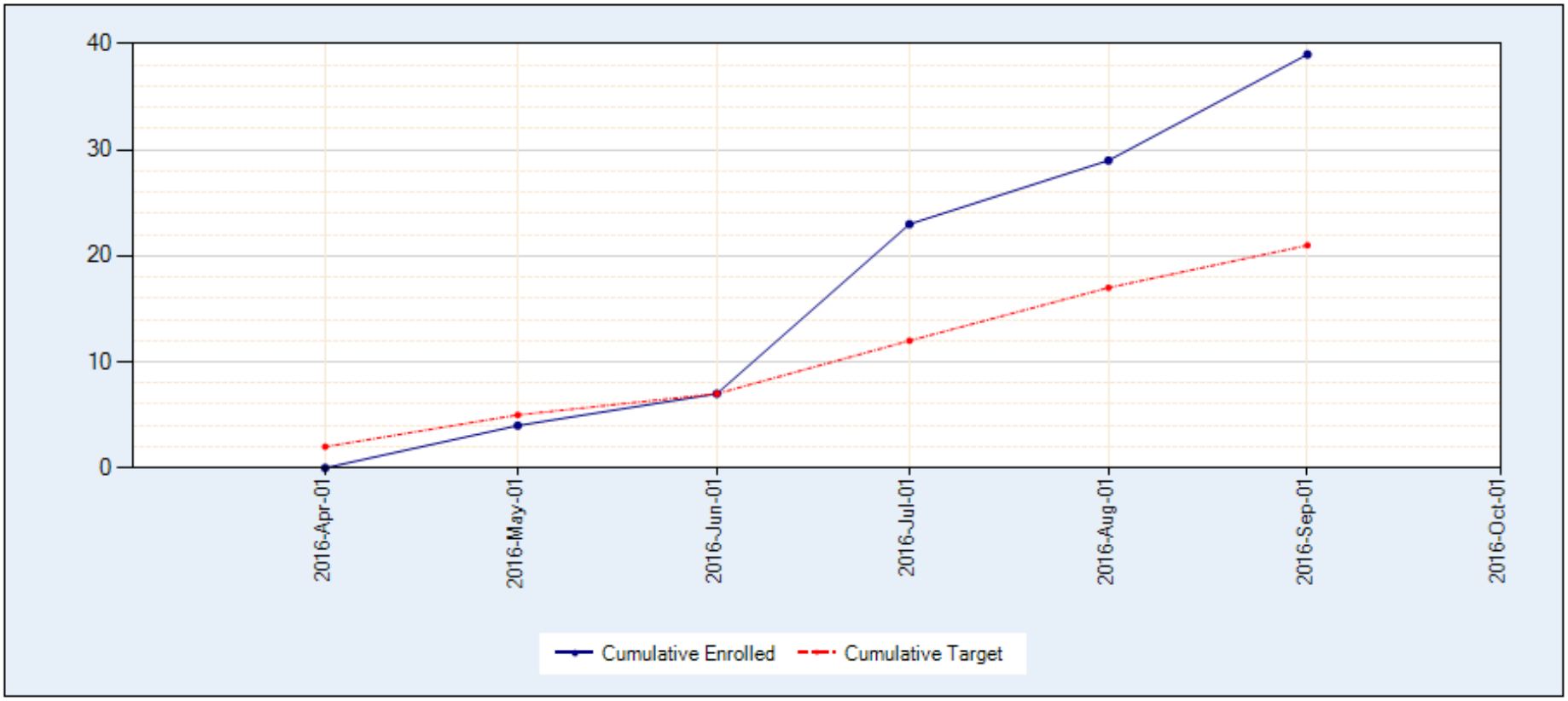


DEFUSE 3 STUDY SITES

Number of sites selected 45

Number of sites with Protocol Trial Agreement	39
Number of sites with CIRB approval	36
Number of site visits completed	35
Number of sites with RAPID installed	36
Number of sites with RAPID approved scanners	35
Number of sites activated to enroll	32

DEFUSE3 Cumulative Enrollment Summary - By Month

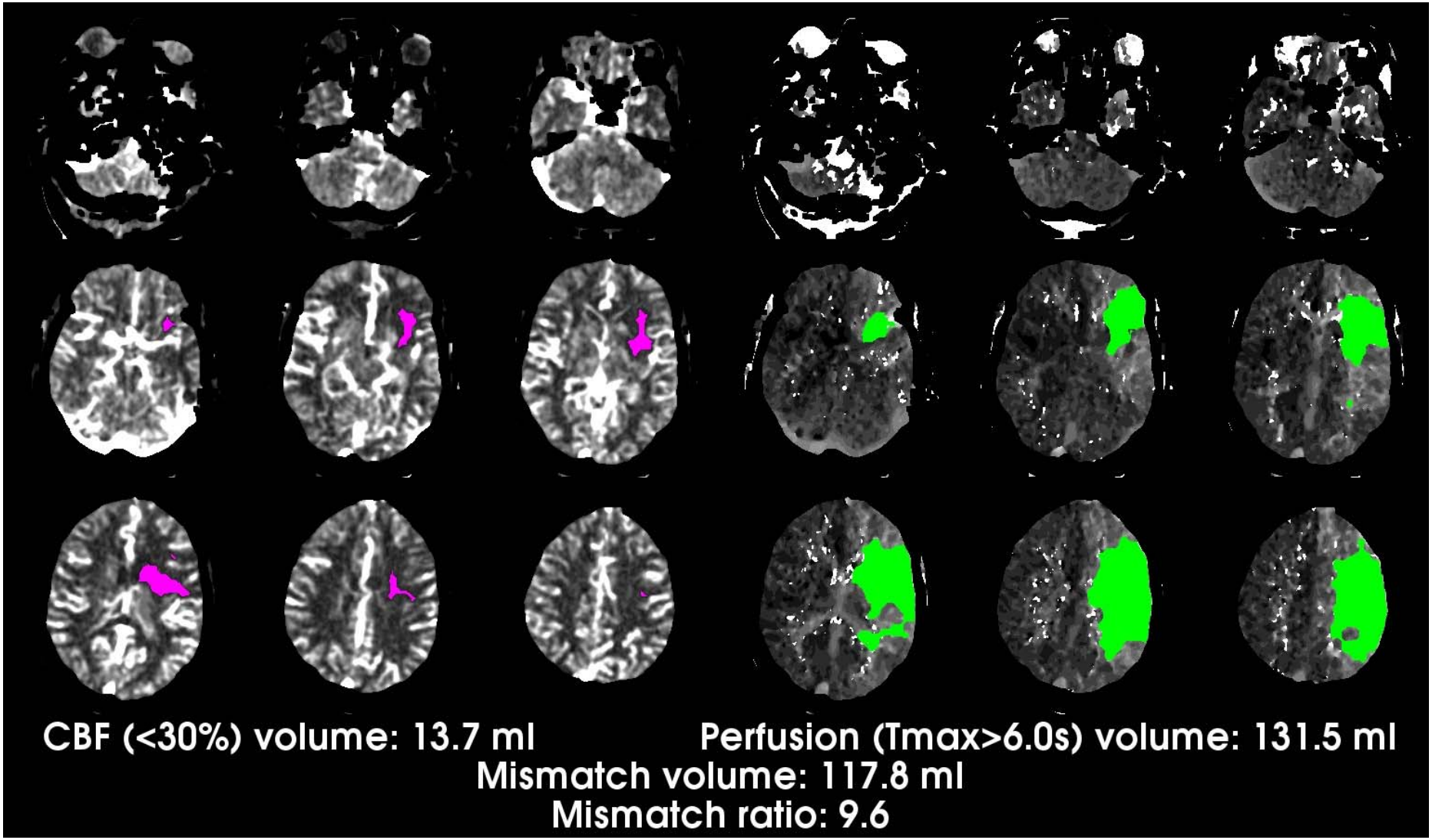


DEFUSE 3 PATIENT ENROLLMENT

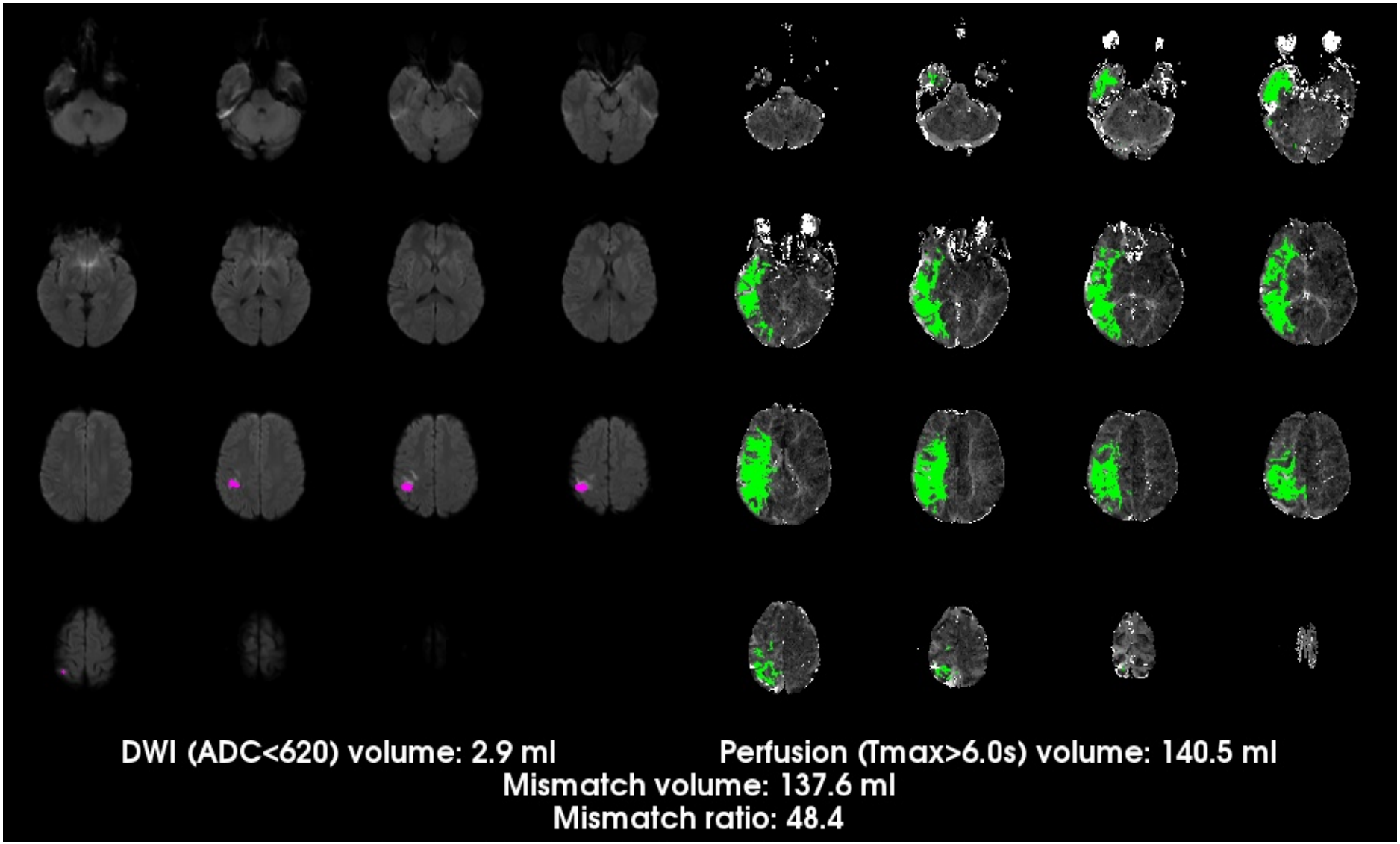
As of September 22, 2016: 40 enrolled

	# Randomized
University of Iowa Hospitals & Clinics, Iowa City, IA	7
Stanford University Medical Center, Stanford, CA	4
Keck Hospital of USC, Los Angeles, CA	4
Rhode Island Hospital, Providence, RI	3
OSU Wexner Medical Center, Columbus, (Ohio State)	3
Hennepin County Medical Center, Minneapolis, MN	3
University of Pennsylvania, Philadelphia, PA	3
Valley Hospital, Ridgewood, NJ	2
UCSD Medical Center - Hillcrest Hospital, San Diego, CA	1
University of Cincinnati Medical Center, Cincinnati, OH	1
University of Wisconsin, Madison, WI 4/26/2016	1
University of Utah Healthcare, Salt Lake City, UT	1
Intermountain Medical Center, Murray, UT	1
Northwestern Memorial Hospital, Chicago, IL	1
Oregon Health & Science University Hospital, Portland, OR	1
Mount Sinai Medical Center, New York, NY	1
Cornell, New York, NY	1
Memorial Herman, Houston, TX	1
University of Michigan, Ann Arbor, MI	1

CTP from Iowa



MRI from Rhode Island Hospital



Consented but Not Randomized (N=31)

Reason	N	# to Endovascular
Time Window (w/in 6 hours)	1	1
Occlusions in multiple vascular territories	2	2
No ICA or M1 occlusion	7	2
NIHSS < 6	1	1
No target Mismatch	14	1
Basilar	1	1
ASPECT score <6	1	0
Other	4	0
TOTAL	**31**	**8**

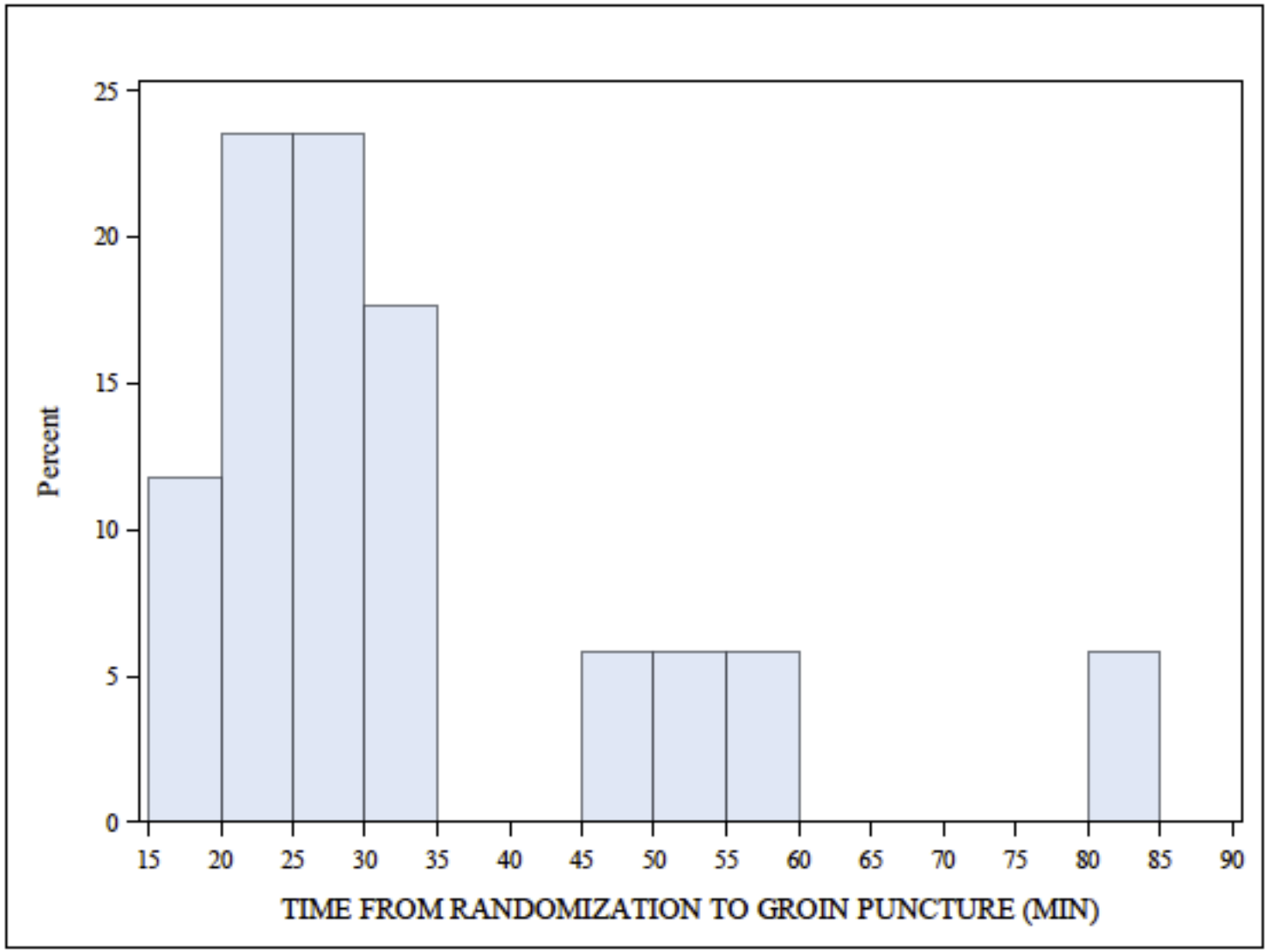
Screen Failures

(endovascular therapy 6-16 hrs; not consented for D3)

Reason	**N**
mRS> 2	2
Age >90	3
NIHSSS <6	1
No ICA/M1 Occlusion	2
Multiple Vascular Territories	1
Severe Sustained HTN	1
Unable to obtain consent	1
Other: 1 Inmate; 2 Investigator Judgement	3
TOTAL	14

Baseline Data

Mean Age	69 years
Median NIHSS	15
Baseline core (mean)	13 ml
Onset to Randomization	11 hrs
Randomization to puncture	27 minutes



TOTAL SUBJECTS	MEAN	MEDIAN	MINIMUM	MAXIMUM
17	33	27	15	84

Protocol Amendment

New Exclusion Criterion:
Any other condition that, in the opinion of the investigator, precludes an endovascular procedure or poses a significant hazard to the subject if an endovascular procedure was performed.

Clarification of Neuroimaging Exclusion #6:
Subjects with *acute symptomatic* arterial occlusions in more than one vascular territory *confirmed on CTA/MRA* (e.g., bilateral MCA occlusions, or an MCA and a basilar artery occlusion).

New Time Criterion:
In patients randomized to endovascular therapy, the goal for femoral artery puncture will be within 45 minutes of randomization; femoral artery puncture must occur *within 90 minutes of the completion of the qualifying imaging*.

Informed Consent Issues

Six violations to date

- outdated version of consent form
- unapproved foreign language short form
- no written consent prior to randomization
- no consent prior to perfusion imaging (n=2)
- no consent prior to sending images to RAPID

EDUCATE

- Make sure to train all research staff about the *consent process* and what the CIRB has approved. **Know your local policies!**

  Do you have approved foreign language consent forms?
  Who can provide consent (legally authorized representatives?)
  Is remote telephone consent discussion followed by faxed/email consent allowed?
  Who is allowed to obtain consent at your site?

USE CORRECT FORMS

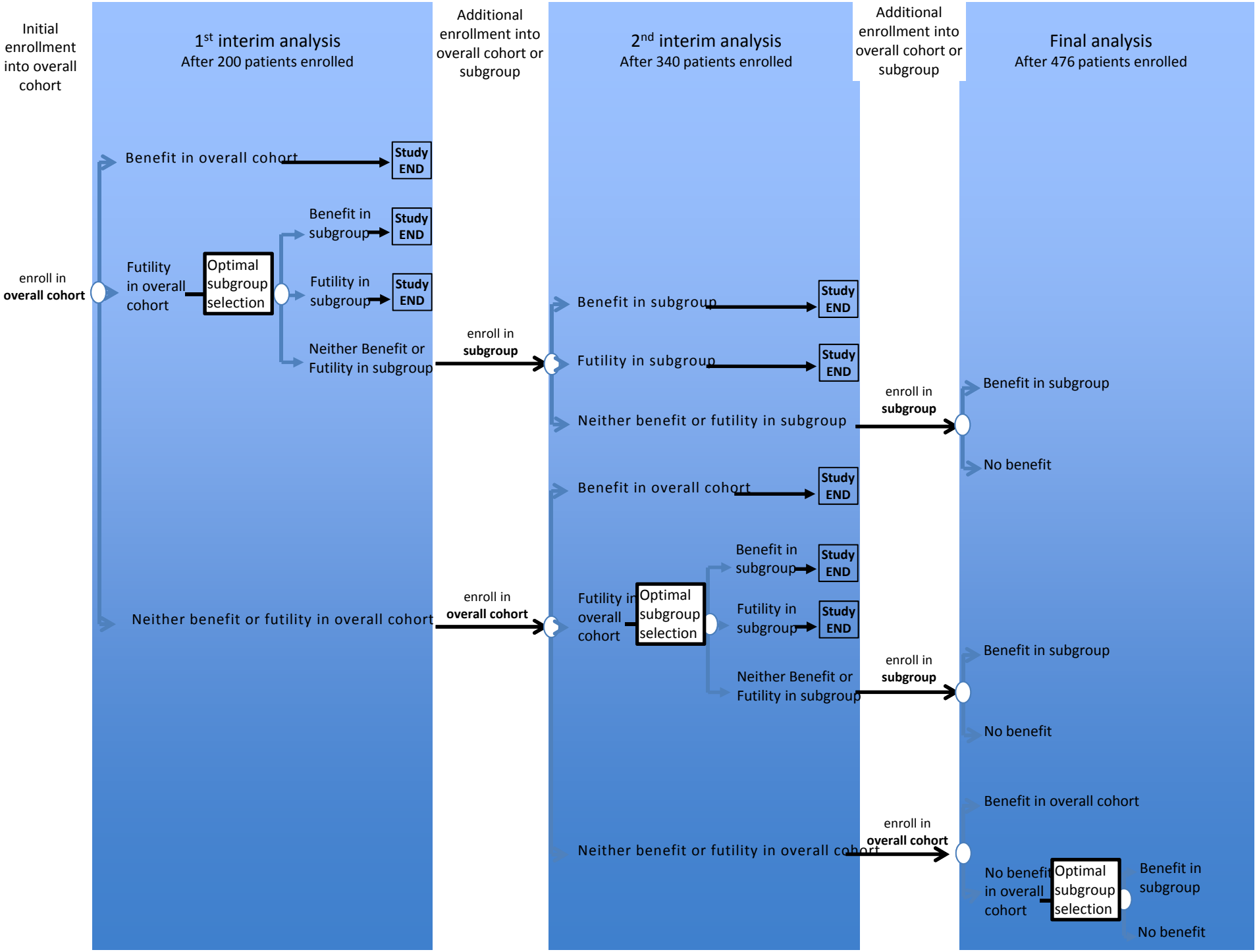
- Check the approval and expiration dates prior to giving consent to participant/LAR
- Establish local practices for accessing CURRENT versions at the time of screening

REVIEW FOR COMPLETENESS

- Verify that participant complete *all applicable lines* on the consent form.
- Verify participant signature and *dates* are complete and legible
- Verify that participant signs and dates *HIPAA Authorization*, if applicable
- Check the consent form for completeness and accuracy before randomization!
-

PROCEED

- Do not randomize or perform any study-related items without **WRITTEN** consent
- Verify that each participant is given a signed *and* dated copy of the consent form at the time of initial consent


Initial enrollment into overall cohort
1st interim analysis
After 200 patients enrolled
Additional enrollment into overall cohort or subgroup
2nd interim analysis
After 340 patients enrolled
Additional enrollment into overall cohort or subgroup
Final analysis
After 476 patients enrolled
enroll in overall cohort
Benefit in overall cohort
Study END
Futility in overall cohort
Optimal subgroup selection
Benefit in subgroup
Study END
Futility in subgroup
Study END
Neither Benefit or Futility in subgroup
enroll in subgroup
Benefit in subgroup
Study END
Futility in subgroup
Study END
Neither benefit or futility in subgroup
enroll in subgroup
Benefit in subgroup
No benefit
Benefit in overall cohort
Study END
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Questions?