

# ADNI3 CLINICAL CORE

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# ADNI3 Cohorts

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- CN
- MCI
- Mild AD

# CN Eligibility Criteria

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- Age initially 65-90, but may adjust to match other cohorts
- With or without subjective memory complaints
- CDR=0
- MMSE 24-30
- Logical Memory
  - $\geq 9$  for 16+ years of education
  - $\geq 5$  for 8-15 years of education
  - $\geq 3$  for 0-7 years of education
- No cholinesterase inhibitors or memantine

# MCI Eligibility Criteria

4

- Age 55-90
- Subjective memory concern by participant, study partner or clinician
- CDR=0.5
- MMSE 24-30
- Logical Memory
  - ▣  $\leq 11$  for 16+ years of education
  - ▣  $\leq 9$  for 8-15 years of education
  - ▣  $\leq 6$  for 0-7 years of education
- Stable cholinesterase inhibitors and memantine allowed

# Mild AD Eligibility Criteria

5

- Age 55-90
- Subjective memory concern by participant, study partner or clinician
- CDR=0.5 or 1
- MMSE 20-26
- Logical Memory
  - ▣  $\leq 8$  for 16+ years of education
  - ▣  $\leq 4$  for 8-15 years of education
  - ▣  $\leq 2$  for 0-7 years of education
- Diagnosis of probable AD
- Stable cholinesterase inhibitors and memantine allowed

# ADNI3: Schedule of Events

## Rollover and New Subjects

	Baseline	12 month	24 month	36 month	48 month
CN	CV, MRI, Tau, AMY, LP	CV, MRI, <b>Tau (+/-)</b> OR Phone Check	CV, MRI, <b>Tau (+/-)</b> , AMY, LP	Phone Check	CV, MRI, Tau, AMY, LP
MCI	CV, MRI, Tau, AMY, LP, FDG	CV, MRI, <b>Tau (+/-)</b>	CV, MRI, <b>Tau (+/-)</b> , AMY, LP	CV, MRI	CV, MRI, Tau, AMY, LP
AD	CV, MRI, Tau, AMY, LP, FDG	CV, MRI, Tau	CV, MRI, Tau, AMY, LP	Phone Check (Neuropath only)	Phone Check (Neuropath only)

# New components of ADNI3

- MINT (instead of Boston naming)
- Cogstate
- FCI-SF
  
- BHR

# Multilingual Naming Test (MINT)

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- The MINT is a test of object picture naming designed to include items that are comparable across English, Spanish and other languages.
- It replaces the Boston Naming Test in the Uniform Data Set of the NIA-funded AD centers because the BNT contains items that are not of the same level of difficulty for Spanish and English speakers.

# ADNI2 Cogstate Pilot: Preliminary analysis (from Bruce Albala)

- Approximately 80% of participants who completed an in-clinic baseline assessment (N=98) also completed a follow-up at-home assessment (N=78).
- Based on qualitative feedback, participants most often encountered difficulties in relation to accessing the website. A small proportion of participants also had difficulty remembering to use the D and K buttons.
- Assessments take ~15 minutes in-clinic or at-home
- Similar results in-clinic and at-home on all 4 tests
- Performance on the CBB was worse among patients with MCI when compared with cognitively normal controls.
- Participants who were amyloid positive (but not diagnosed with MCI) performed worse on the One Card Learning test when compared with participants who were amyloid negative (but not diagnosed with MCI).

# Cogstate in ADNI3

- CN and MCI
- Administered via Cogstate web site
- In clinic and quarterly unsupervised

# Improvements in CBB Testing Going Forward into ADNI3

- Simpler website URL – [adni3.cogstate.com](http://adni3.cogstate.com)
- A more inviting and motivating landing page
- Reminders within the website
  - ▣ Appropriate testing environment
  - ▣ What to expect, including availability of a brief participant demonstration video
- Simpler username & password combinations
- CBB remains exactly the same

# Financial Capacity Instrument – Short Form (FCI-SF, Dan Marson)

- The FCI-SF is a brief performance measure of everyday financial skills, comprised of 37 performance items which evaluate four constructs of monetary calculation, financial conceptual knowledge, use of a checkbook/register, and use of a bank statement.
- The FCI-SF also includes six variables measuring time to completion (in seconds) of four FCI-SF tasks.
- The FCI-SF takes 15 minutes or less to administer.
- FCI-SF performance and timing results discriminate between amyloid-positive and -negative controls, as well as control vs MCI vs mild AD groups.

# BHR in ADNI3

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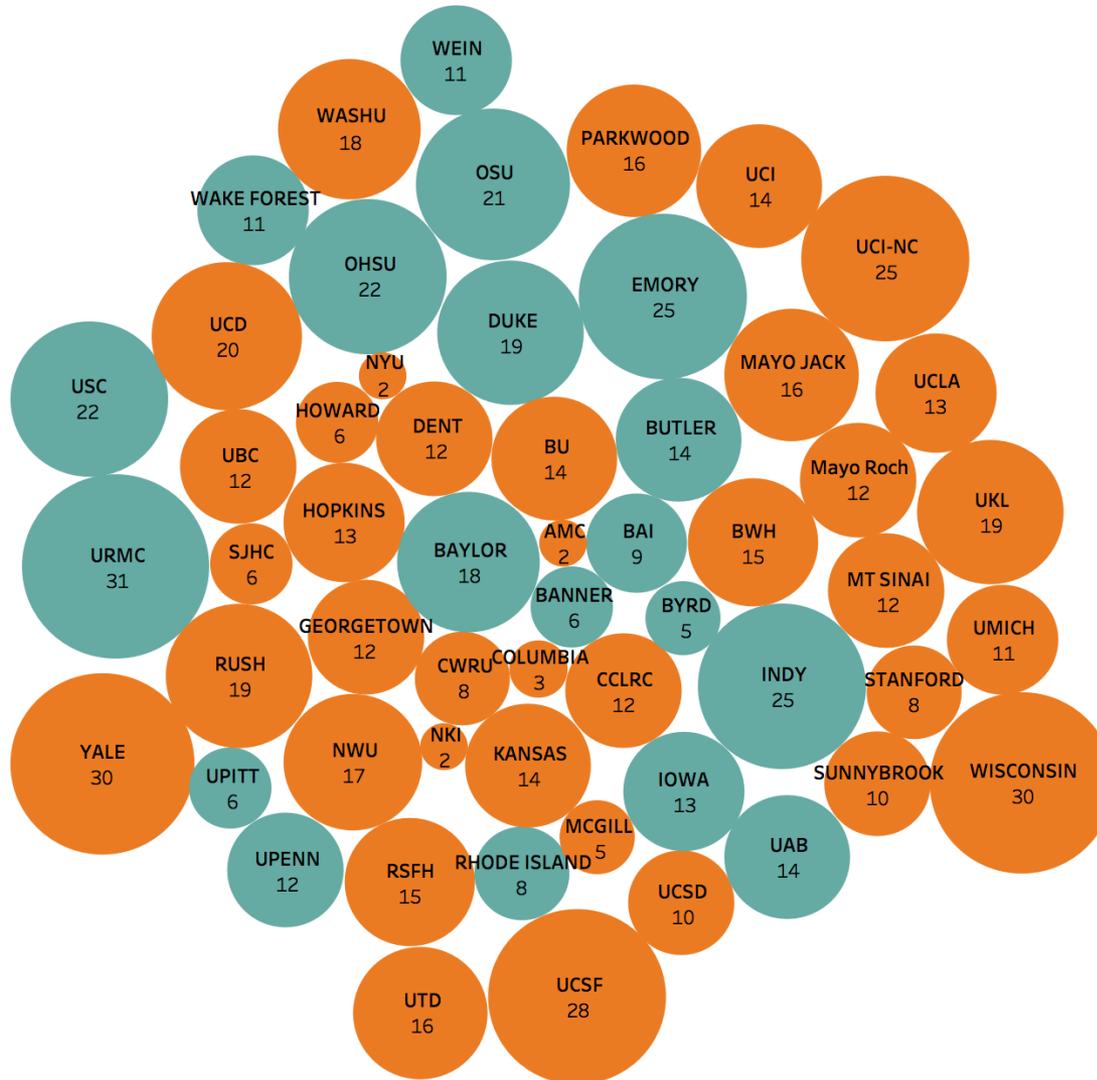
- Recruitment
- All ADNI3 CN and MCI participants invited to join BHR

# ADNI3 start-up progress



# Orange Sites are not yet Approved (19/59 approved)

Potential Rollover Participants



Site and sum of Potential Rollovers. Color shows details about In / Out of Approved. Size shows sum of Potential Rollovers. The marks are labeled by Site and sum of Potential Rollovers.

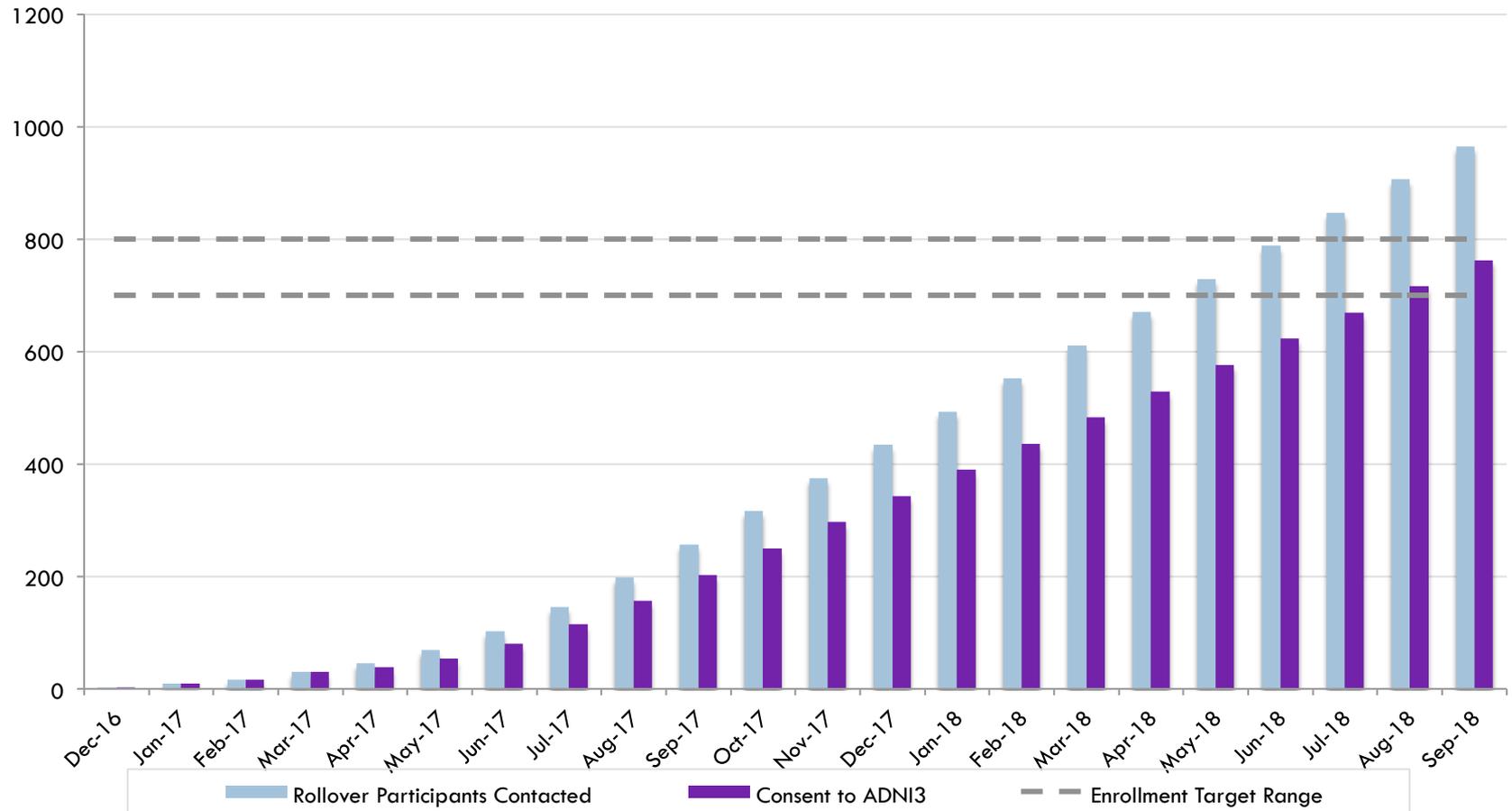
# Time to start-up

Site No	Site Name	Site PI	Date IIP sent	Approval Date	Days in startup	Months in startup
27	University of Rochester Medical Center	Porsteinsson	5/27/2016	10/27/2016	153	5.10
129	Banner Alzheimer's Institute	Burke	5/27/2016	12/23/2016	210	7.00
16	Wien Center	Duara	5/27/2016	12/13/2016	200	6.67
24	University of Pittsburgh	Lopez	5/27/2016	1/9/2017	227	7.57
37	Indiana University	Farlow	5/27/2016	1/11/2017	229	7.63
99	Banner Sun Health Research Institute	Zamrini	5/27/2016	1/11/2017	229	7.63
22	University of Pennsylvania	Wolk	5/27/2016	1/25/2017	243	8.10
2	Oregon Health and Science University	Silbert	5/27/2016	2/8/2017	257	8.57
137	Wake Forest University Health Sciences	Sink	5/27/2016	2/10/2017	259	8.63
32	Emory University	Levey	5/27/2016	2/28/2017	277	9.23
21	Duke University Medical Center	Doraiswamy	5/27/2016	3/8/2017	285	9.50
3	University of Southern California	Schneider	5/27/2016	3/13/2017	290	9.67
141	Rhode Island Hospital	Ott	5/27/2016	3/15/2017	292	9.73
135	University of Iowa	Miller	5/27/2016	3/22/2017	299	9.97
130	Ohio State University	Scharre	5/27/2016	3/27/2017	304	10.13
19	University of South Florida Health Byrd Alzheimer's Institute	Smith	5/27/2016	3/31/2017	308	10.27
12	University of Alabama at Birmingham	Geldmacher	5/27/2016	4/10/2017	318	10.60
941	Butler Hospital Memory & Aging Program	Salloway	5/27/2016	4/11/2017	319	10.63
9	Baylor College of Medicine	Kass	5/27/2016	4/13/2017	321	10.70
						<---Average months it takes to approve someone 8.81

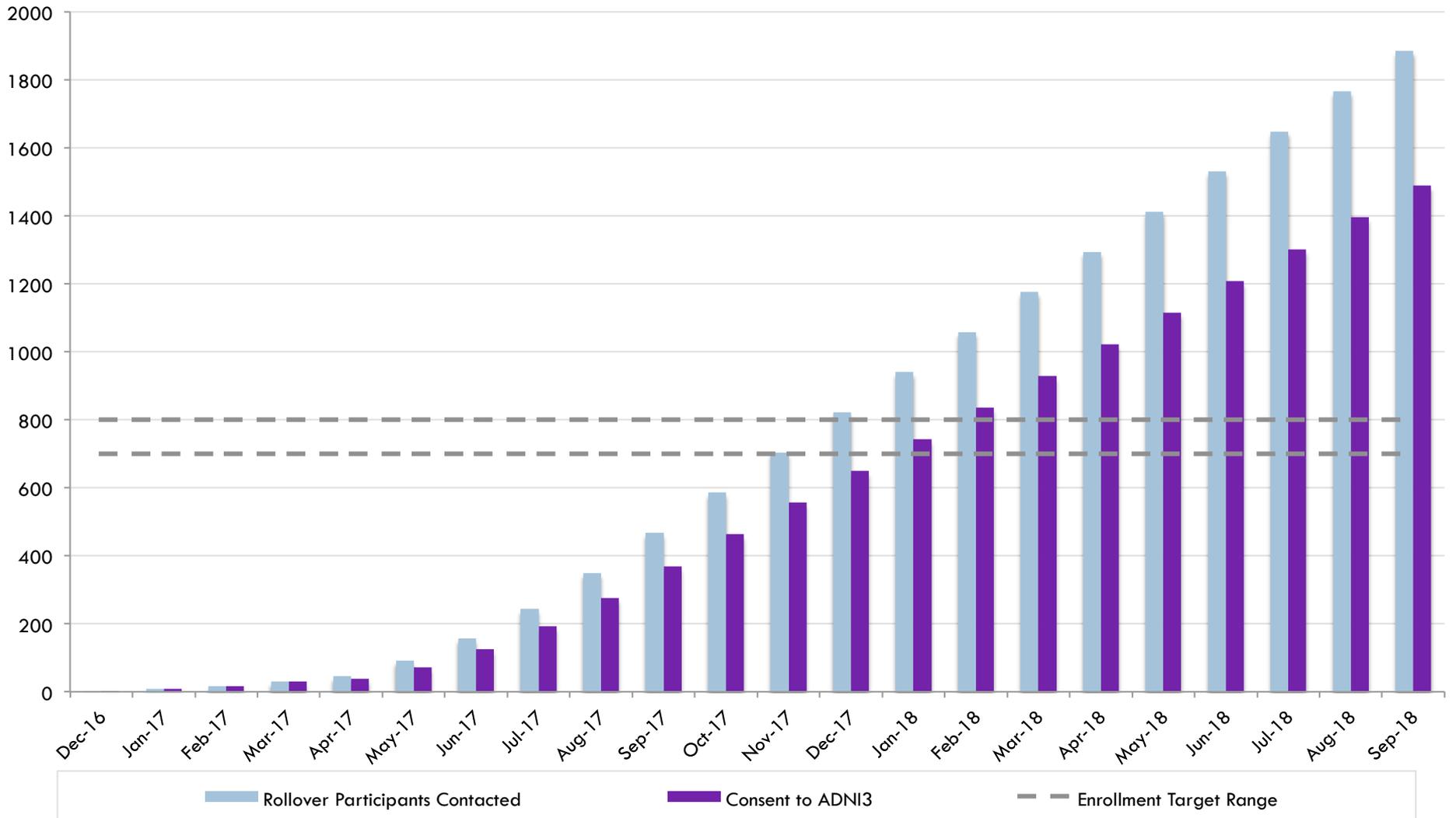
# A slice of start-up tracker

Site No	P. Sheets	ADAS	EDC	Protocol training	CBB	FCI	MRI Certification	IRB Approval Date	Reg. File Approval Date	Contract Exec Date	PET Recert	MRI Notes
7	12	2	2	4	3	2	4/5/2017	2/10/2017	3/13/2017	4/3/2017		complete
116	11	1	2	3	3	1	3/30/2017	11/14/2016	partial	1/23/2017		complete
98	11	1	4	2	1	1	3/30/2017	12/6/2016	2/17/2017	1/30/2017		complete
70	11	1	5	2	2	1	11/3/2016	03/15/2017	11/9/2016	1/3/2017		complete
41	11	5	2	3	4	3		03/28/2017	11/9/2016	1/10/2016		4/19 update
67	12	2	5	3	2	2		09/20/2016	11/17/2016	1/12/2017		volunteer sc
82	11	1	3	5	2	1		09/15/2016	11/22/2016	11/2/2016		4/19 Bret to
6	11	1	8	3	3	1		11/10/2016	3/20/2017	3/24/2017		working on s
123	12	2	5	3	3	1		11/11/2016	11/16/2016	11/2/2016		4/19 phanto
168	11	3	3	5	1	1		01/04/2016	11/28/2016	3/3/2017		Protocol was
36	11	2	4	3	1	1		2/10/2017	3/30/2017	3/31/2017		Protocol was
31	11	2	3	4	2	2		03/27/2017	11/15/2016	11/8/2016		Working on
10	11	1	3	3	1	1		02/01/2017	3/21/2017	1/18/2017		4/19 upgrad
109	11	1	3	3	3	1		2/1/2017	4/13/2017	4/12/2017		4/19 need to
18	12	1	2	3	2	2		03/13/2017	partial	3/16/2017		4/19 not res
114	12	3	2	3	3	1		03/11/2017	3/28/2017	3/16/2017		Working on
5	6			5	1	1		12/8/2016	3/8/2017	12/19/2016		Volunteer sc
131	10		1	1	1			02/01/2017	partial	3/1/2017	NEEDED!	Volunteer sc
127	12	1	2	3	2	1	11/3/2016		2/17/2017	10/18/2016		complete
73	11	1	2	2	2	1			partial	1/31/2017		

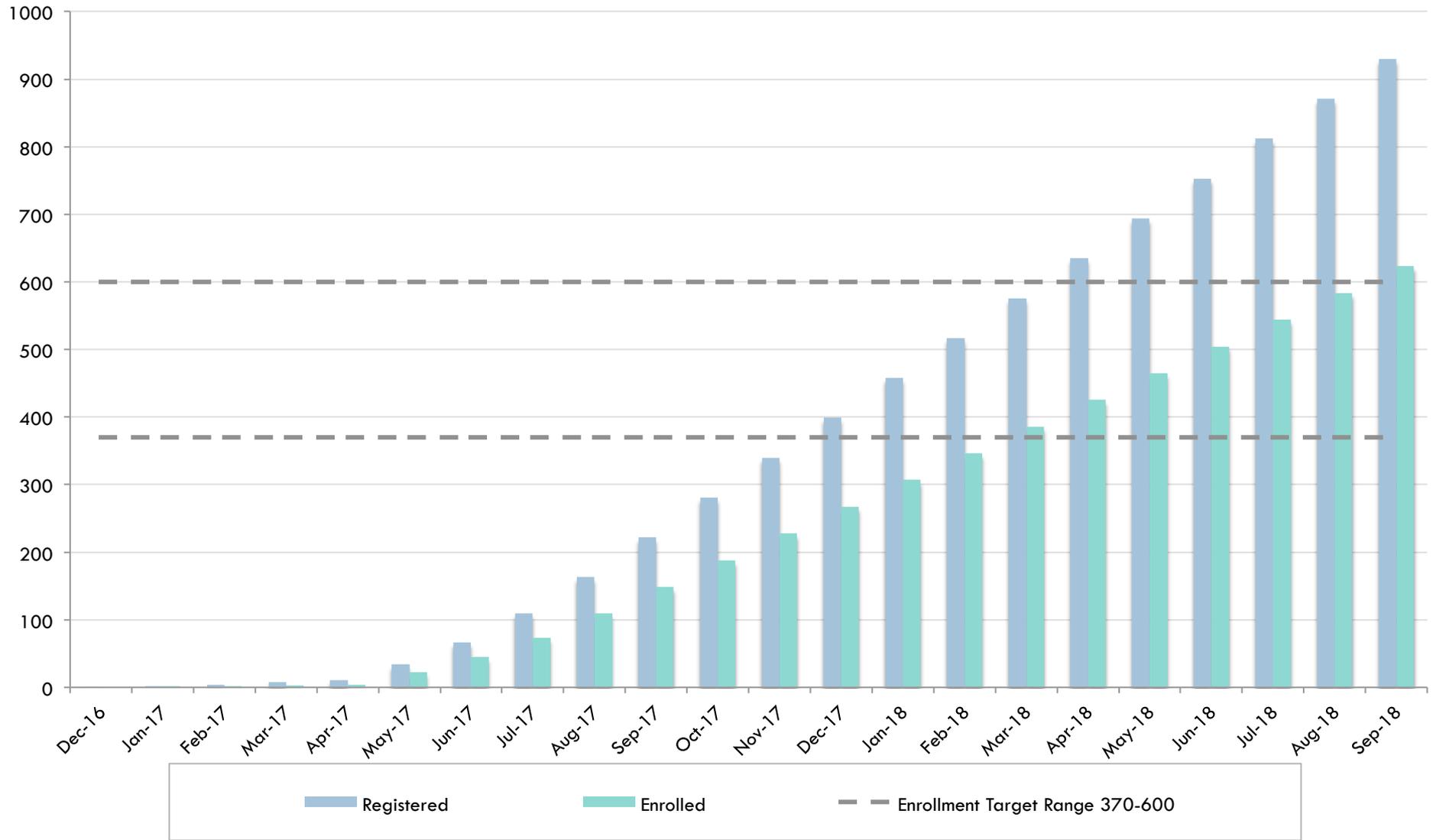
# Rollovers, 1 contacts/site/month



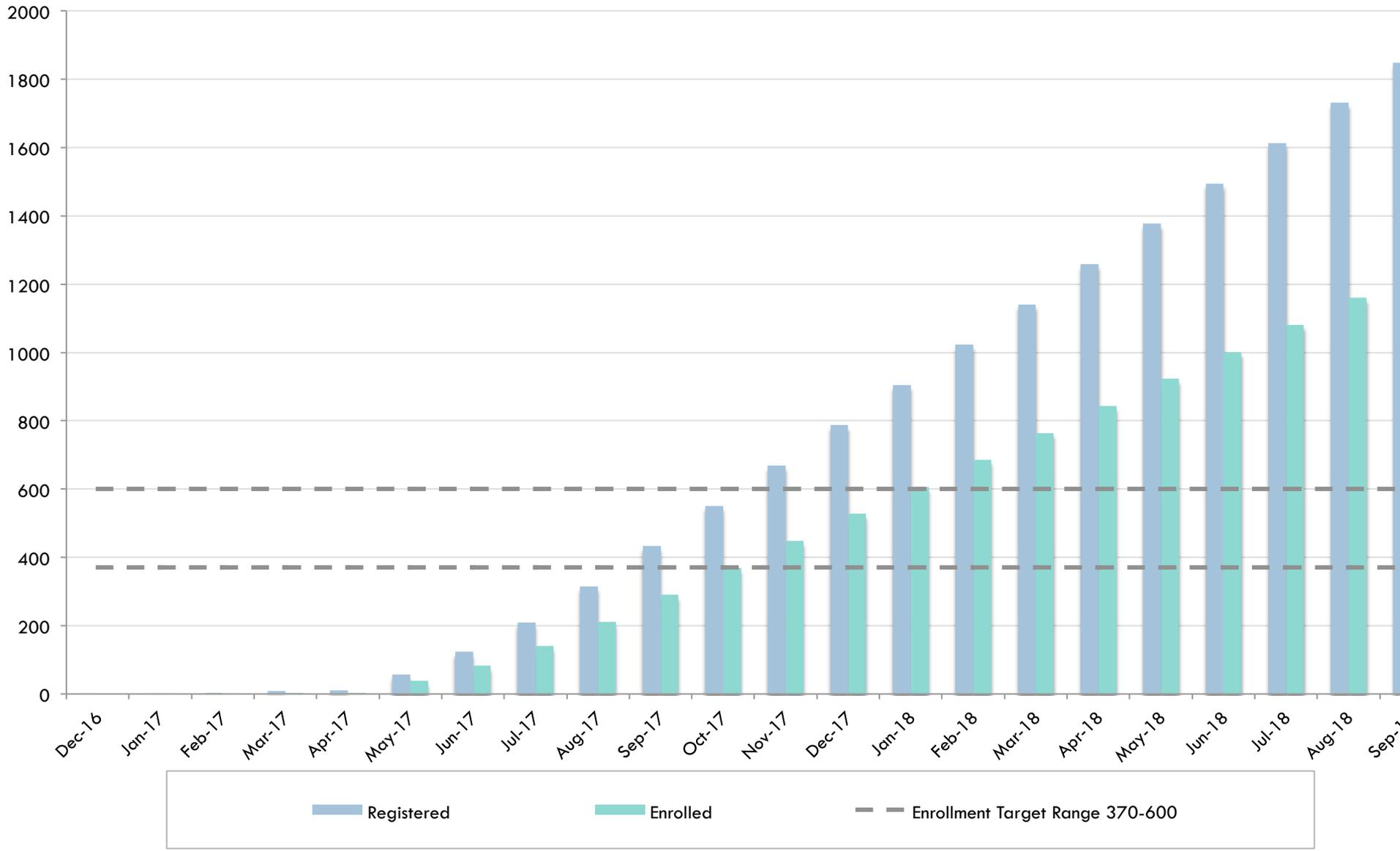
# Rollovers, 2 contacts/site/month



# New subject projection, 1 scrns/site/mo



# New subject projection, 2 scrns/site/mo



# Major Focus of Clinical Core

- Site start-up
  - ▣ Only 19 of 59 so far
- Maximizing:
  - ▣ Rollovers (only 38 so far)
  - ▣ Recruitment of new subjects (only 4 so far)
  - ▣ Retention
- Adjusting FCI-SF data capture