

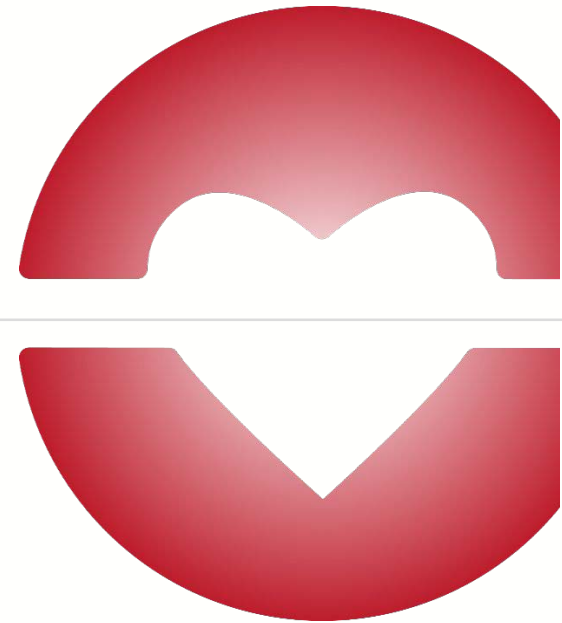
ADAPTABLE

The Aspirin Study

*Greater Plains Collaborative
2018 Learning Engagement Conference*



Adaptable
The Aspirin Study

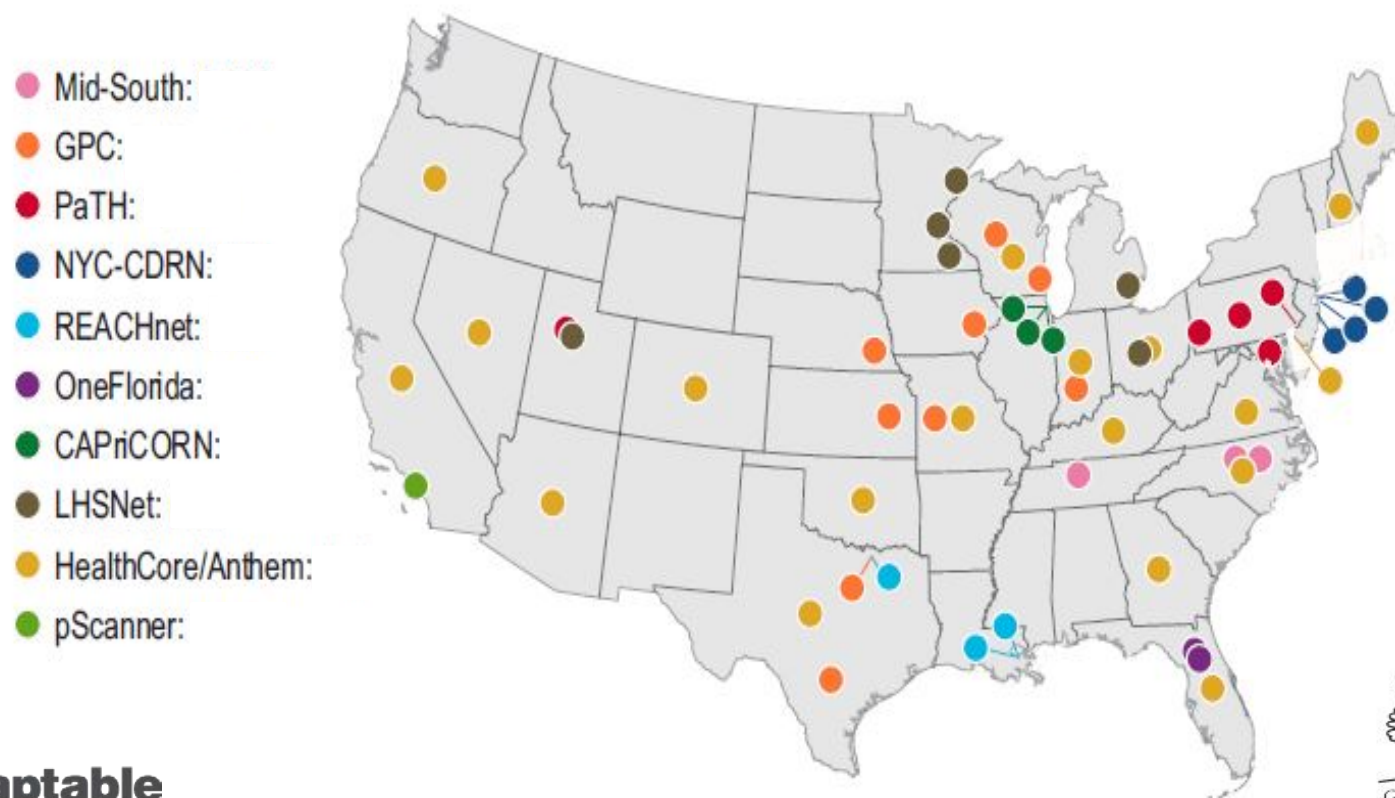


Agenda for Today

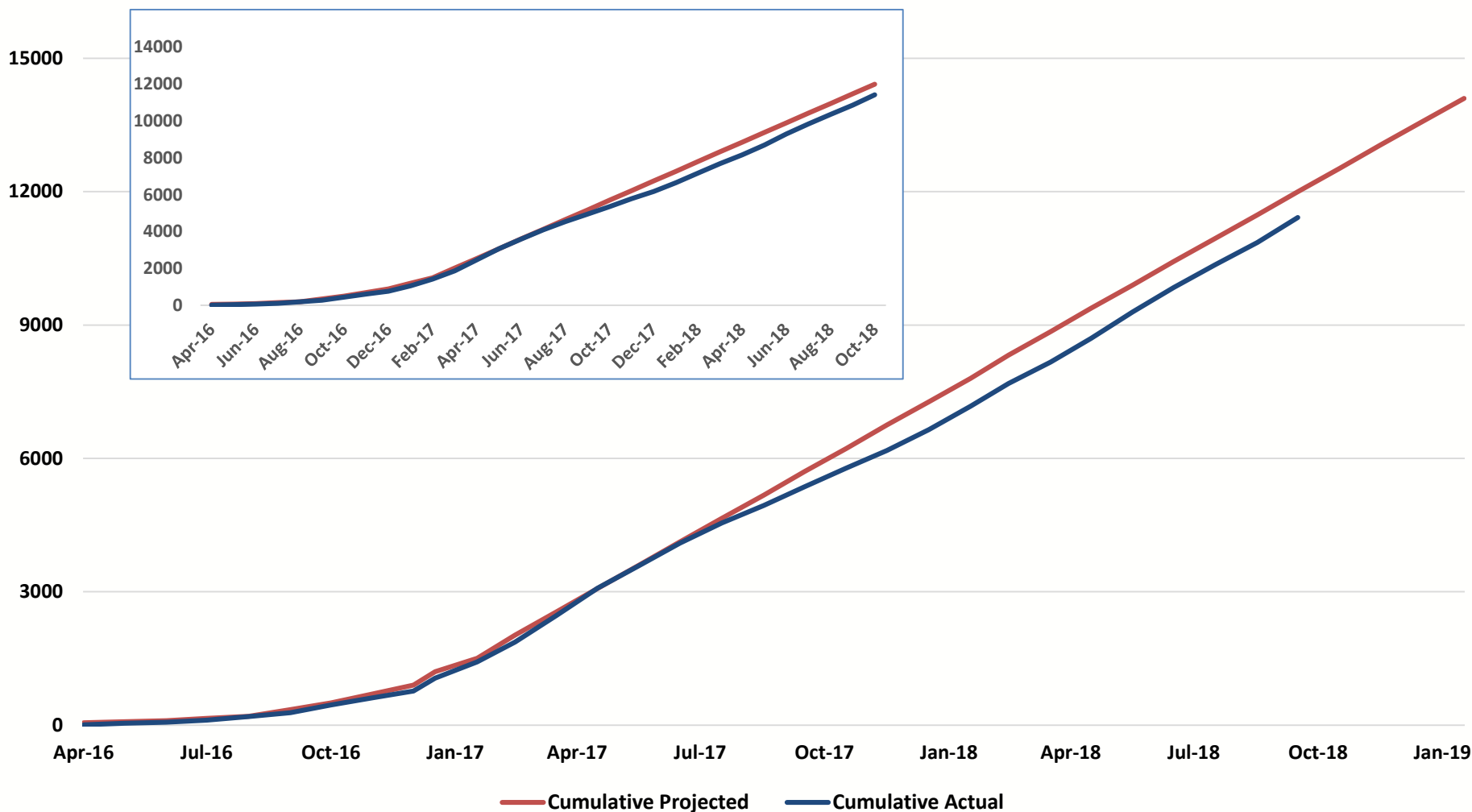
- Enrollment Update
- Recruitment Strategies
- Follow-up and Retention
- Open Discussion

Trial Activation and Enrollment

- 41 sites currently active, 40 enrolling
 - 423,747 of 671,957 of total eligible approached
 - 11,754 subjects randomized



Updated ADAPTABLE Enrollment Curve



GPC Site Approach and Enrollment Update

Site	Total Eligible	Total Approached	% Eligible Approached	Golden Tickets Entered	% Golden Tickets entered per Approached	Total Enrolled	# Non-Internet Enrolled	% Enrolled per Approached	% Enrolled per Golden Ticket Entered
Indiana	9,597	4,325	45%	326	7%	176	5	4%	53%
Iowa	18,911	14,178	75%	835	6%	450	117	3%	54%
KUMC	21,944	13,507	62%	920	7%	490	15	4%	52%
Marshfield	14,949	10,704	72%	564	5%	246	10	2%	44%
MCW	12,220	11,049	90%	966	8%	342	2	3%	34%
Missouri	8,267	3,608	44%	239	6%	104	2	3%	44%
UNMC	3,475	3,777*	109%	192	5%	80	4	2%	42%
UTHSCSA	1,055	2,078*	197%	61	3%	28	0	1%	46%
UTSW	2,459	1,096	45%	49	4%	26	0	2%	53%
TOTAL	92,877	64,322	69%	4,152	6%	1,942	155	3%	47%

GPC Monthly Enrollment

2016

Site	Aug 2016	Sep 2016	Oct 2016	Nov 2016	Dec 2016
Total Enrolled	8	1	16	31	1
# of Sites Enrolling	1	1	1	2	2

2017

Site	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017
Total Enrolled	10	117	54	140	107	76	62	43	22	28	83	39
# of Sites Enrolling	3	4	6	7	7	7	7	7	8	8	8	9

2018

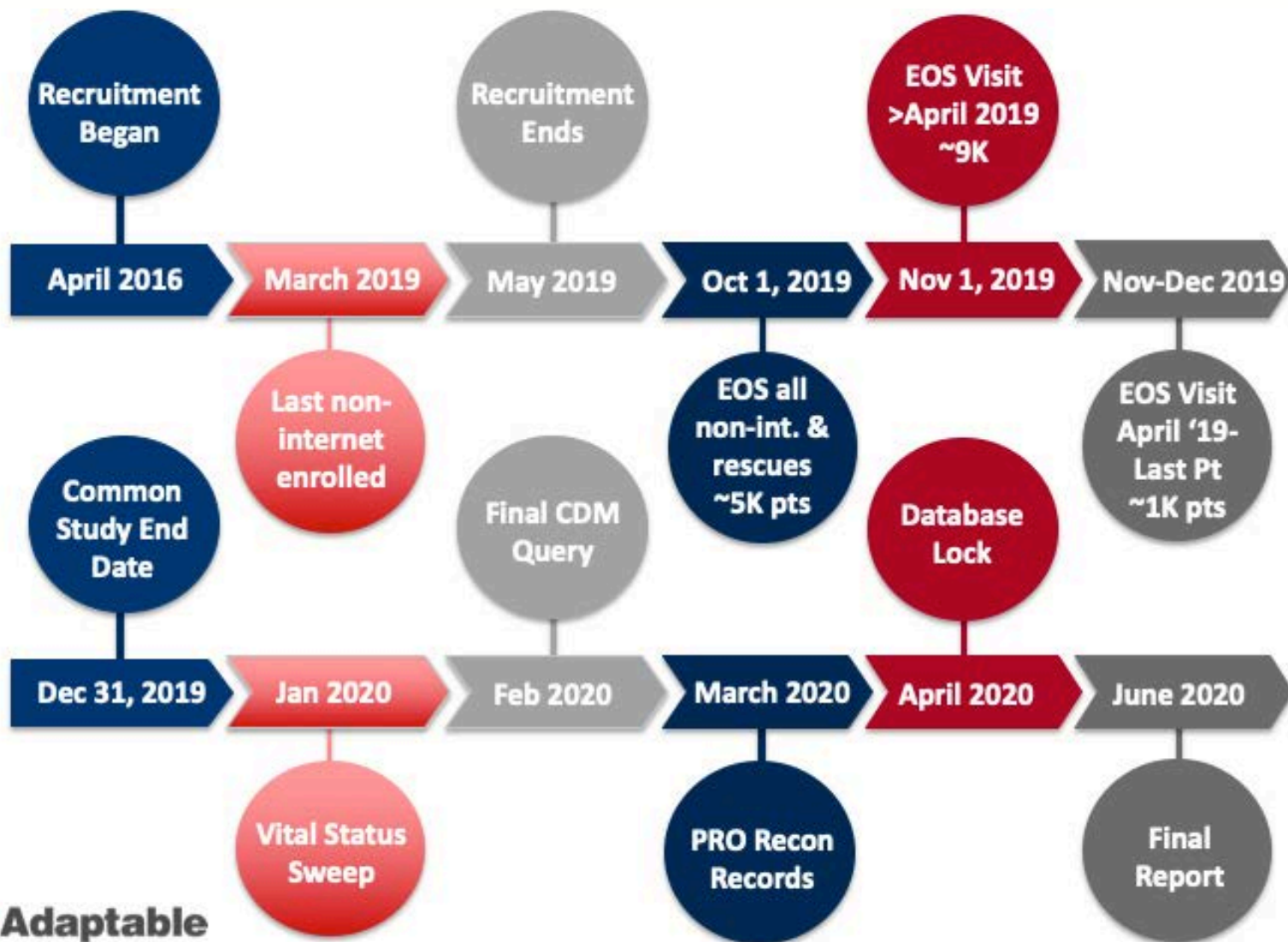
Site	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018
Total Enrolled	46	40	85	78	149	121	134	114	85	112	98
# of Sites Enrolling	9	9	9	9	9	9	9	9	9	9	9

Average monthly enrollment for last 6 months= 111/month

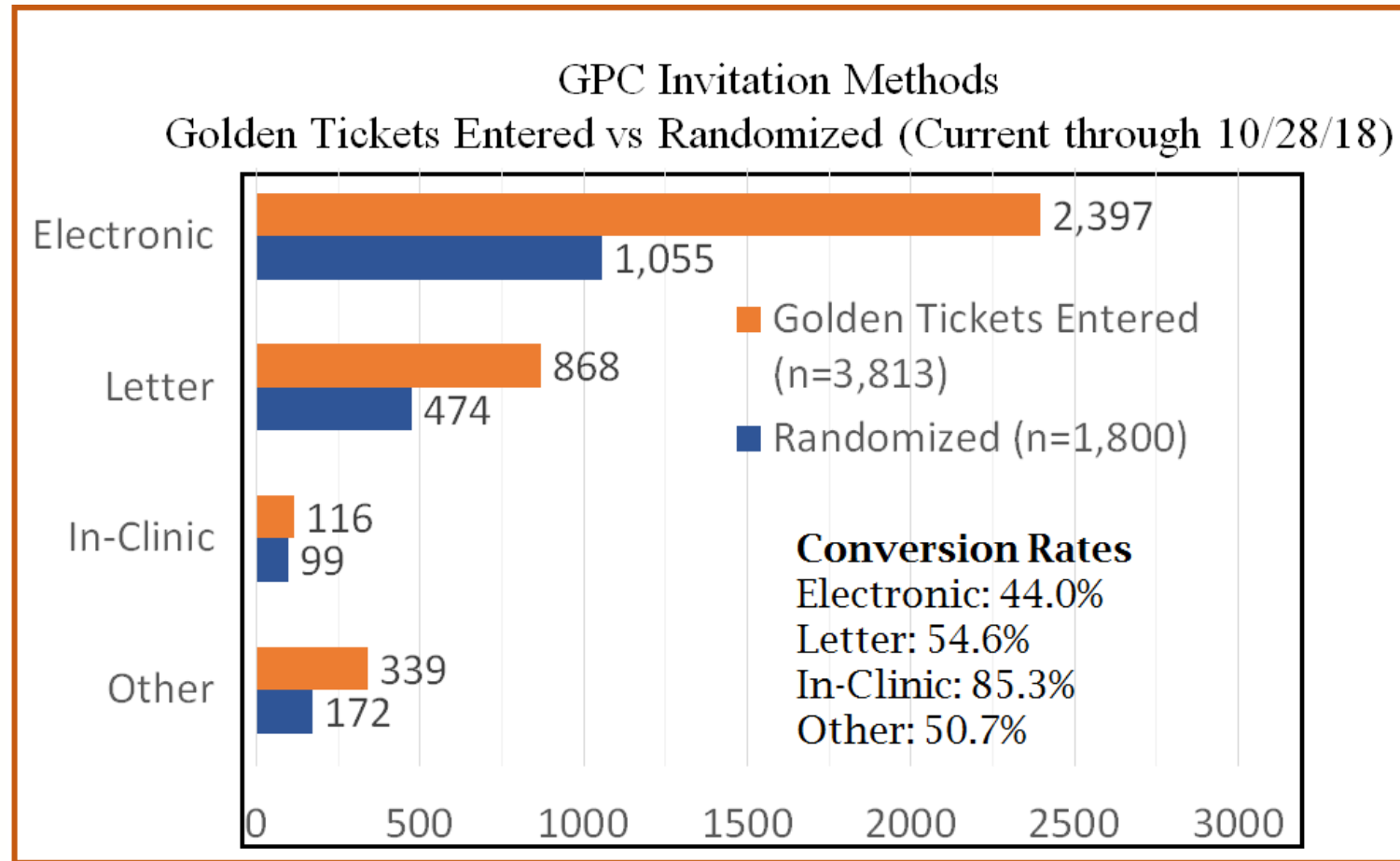
GPC Enrollment Demographics (n=1800)

	N	%
Age (years)		
<45	49	2.7
45-54	181	10.0
55-64	424	23.6
65-74	743	41.3
>75	403	22.4
Sex		
Male	1,127	62.6
Female	673	37.4
Race		
White	1,512	84.0
Black	54	3.0
Other	56	3.0
Not Specified	178	9.9

ADAPTABLE Study Timeline



GPC Recruitment Strategies



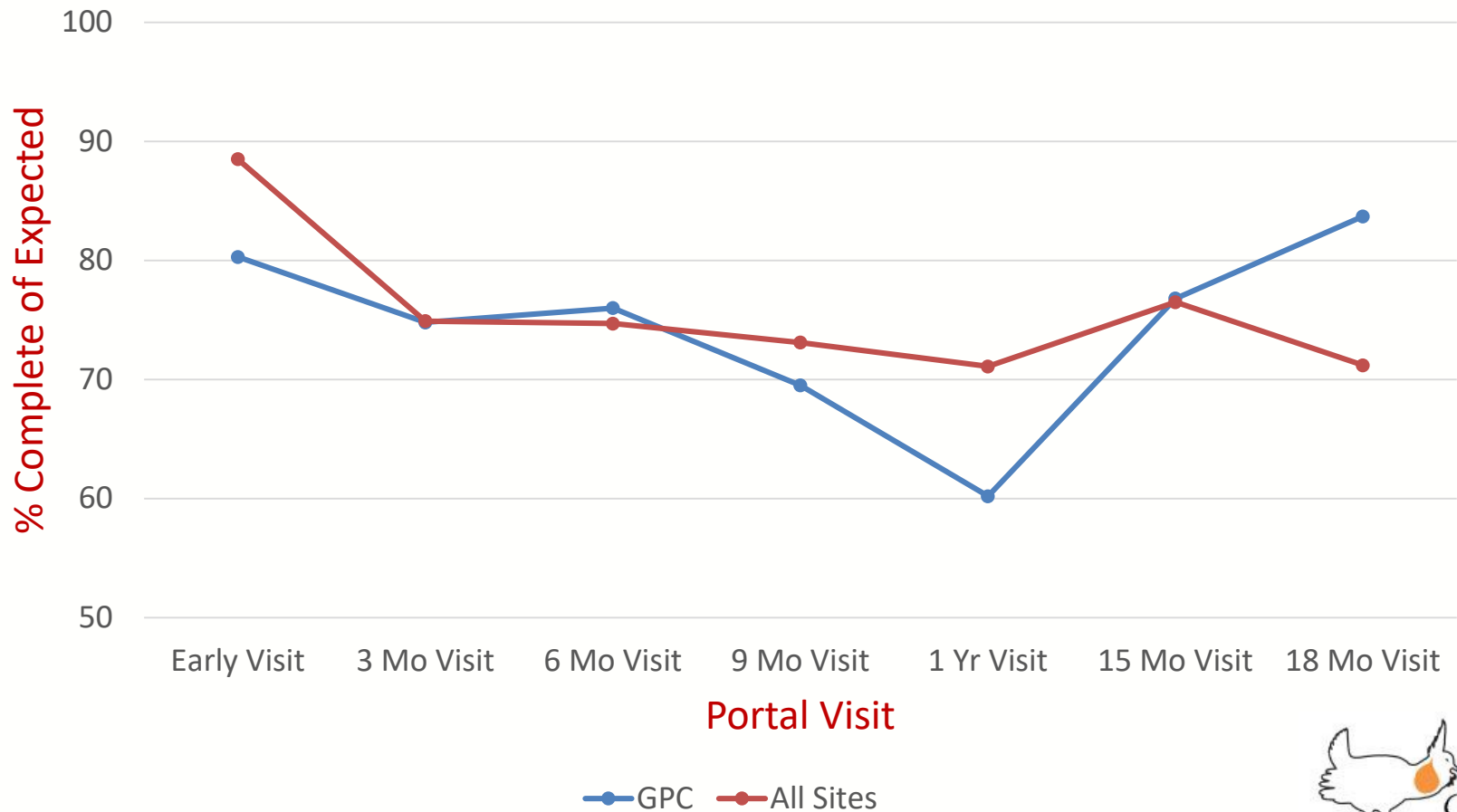
Completing Recruitment by May 2019

- Approach entire eligible population
 - Refresh CP if nearing end of current pool
 - Revisit previously approached patients
 - Monitor average approach numbers each month to ensure all patients approached at least once
- Engagement and Recruitment Fatigue
 - Team effort
 - Encourage communication
 - Retain current staff
 - Diversity of activities

GPC Retention



Visit Completion Rates



Withdrawn Consent and Limited Participation

CDRN	Randomized	%WDC	% Limited Participation
C11 PaTH	1,260	2.7%	0.7%
C13 OneFlorida	566	4.1%	1.8%
C2 Mid-South	3,803	0.9%	1.5%
C3 pSCANNER	131	3.1%	-
C4 GPC	1,605	1.2%	0.7%
C6 REACHnet	743	2.3%	1.1%
C8 NYC CDRN	693	2.2%	0.7%
C9 CAPriCORN	511	3.9%	0.2%
HPRN	356	1.1%	-
LHSNet	692	0.6%	2.3%
Grand Total	10,360	1.7%	1.1%

- Median time to WDC: 97 Days
Range (0,587)
- Most common reasons reported for changing participation level:
 - #1 Medication/Health issues
 - #2 Privacy concerns

Follow-up

- Site expectations

- **Data team:**

- Minimize data latency
 - Respond to queries

- **Coordinators:**

- Help to minimize WDC
 - Support participants continuing on randomized dose
 - Update contact info for participants to ensure follow-up
 - Phone number, Mailing address, Race/ethnicity (if available)
 - Help with collection of outcomes data not in CDM
 - These are limited in scope, but will be more at EOS when current CDM data is not available
 - New report coming: Participants with no follow-up post EV
 - Look more closely at this group as our potential lost to follow-up group (PLTFU)
 - This will start in January

Important Reminders

- Upcoming Calls
 - GPC 1:1 with DCRI on Monday, December 17th, 1:00-2:30PM CST
 - GPC Internal Call on Thursday, January 10th, 9:00-10:00AM CST
 - ADAPTABLE All-CDRN on Monday, January 14th, 1:00-2:00PM CST
- Adaptable Query
 - Next query released on Monday, February 25th
 - Includes all patients through February 1st
 - August 2019
 - February 2020

Questions?