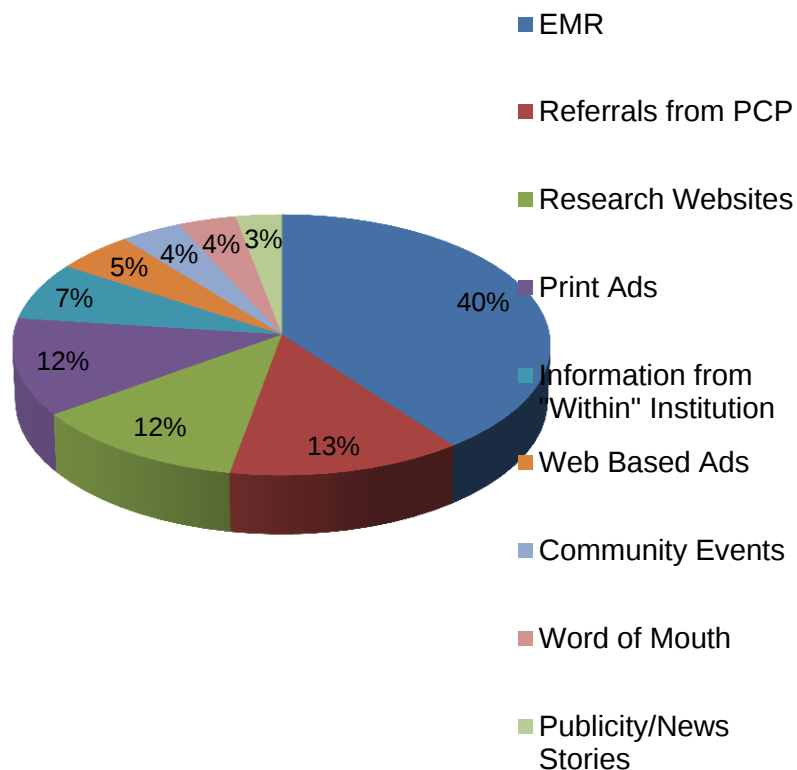

D2d Recruitment and Retention Update

Vanita Aroda, MD
MedStar Health Research Institute

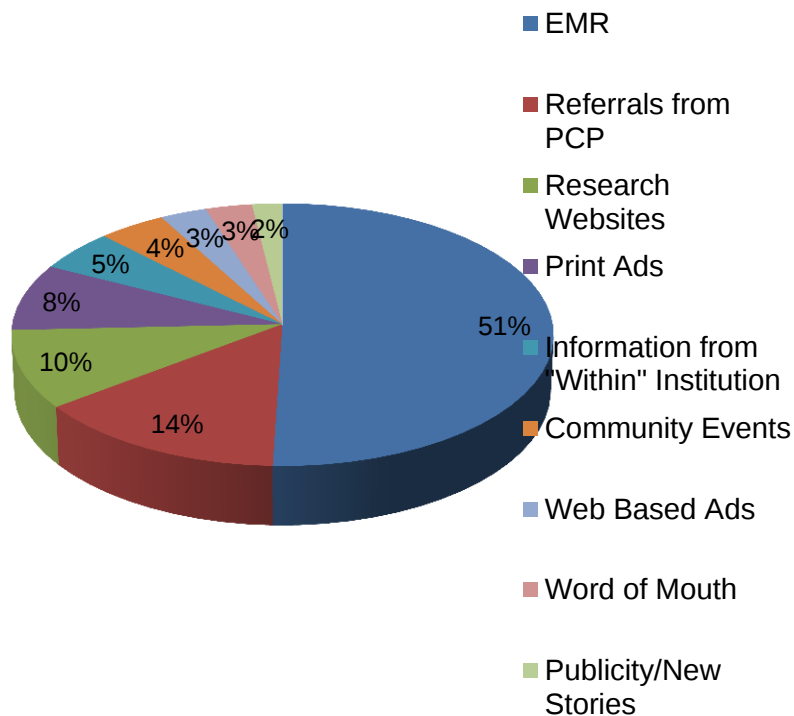
Recruitment & Retention Subcommittee	Site
Rincy Varughese	Atlanta VA Medical Center
Erica Caravana (CC Liaison)	Coordinating Center
Taso Pittas	Coordinating Center
Patty Sheehan	Coordinating Center
Chhavi Chadha	HealthPartners Research Foundation
Shelly Cook	HealthPartners Research Foundation
Sarah Serafin-Dokhan	Los Angeles Royal Comprehensive Health Center
Irwin Brodsky (Vice Chair)	Maine Medical Center Research Institute
Vanita Aroda (Chair)	MedStar Health Research Institute
Myrlene Staten	NIDDK
George Bray (former Vice Chair)	Pennington Biomedical Research Center
Sarah Gunn	Tufts Medical Center
Miranda Oullette (Vice Chair)	University of Kansas Medical Center

Where are our Current Participants Coming from

Screened

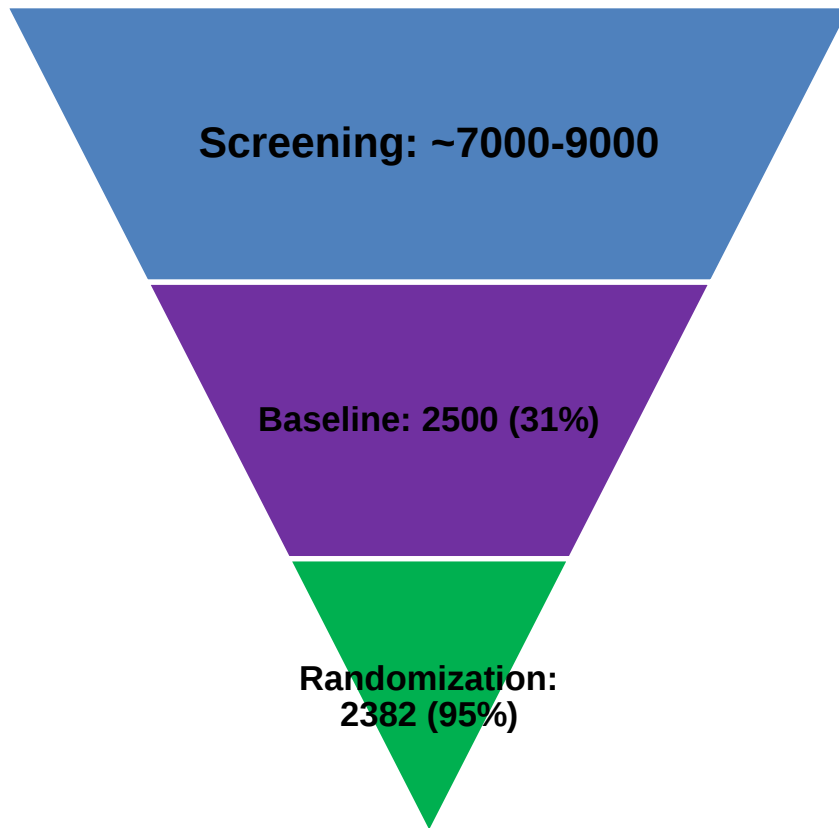


Randomized

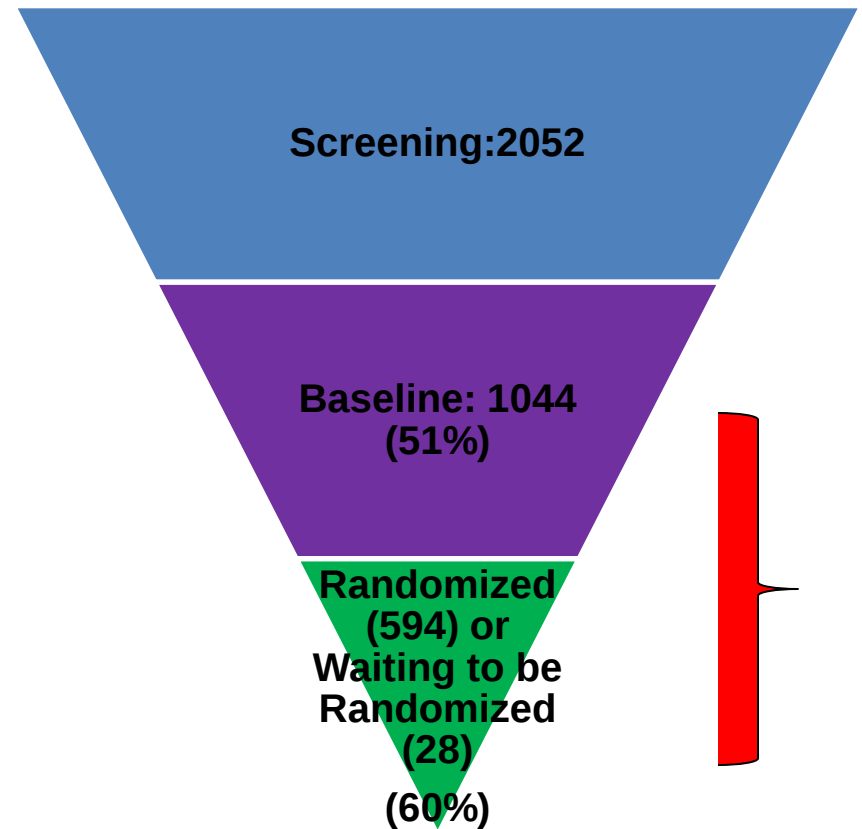


Recruitment and Enrollment Goals

Projected at Study Start

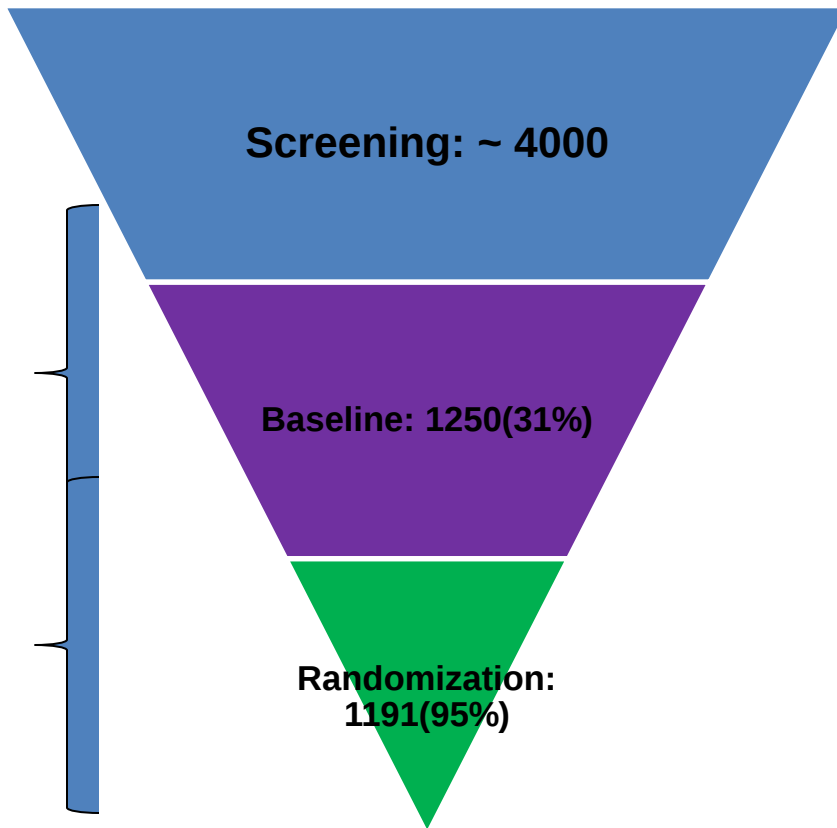


Current, Actual

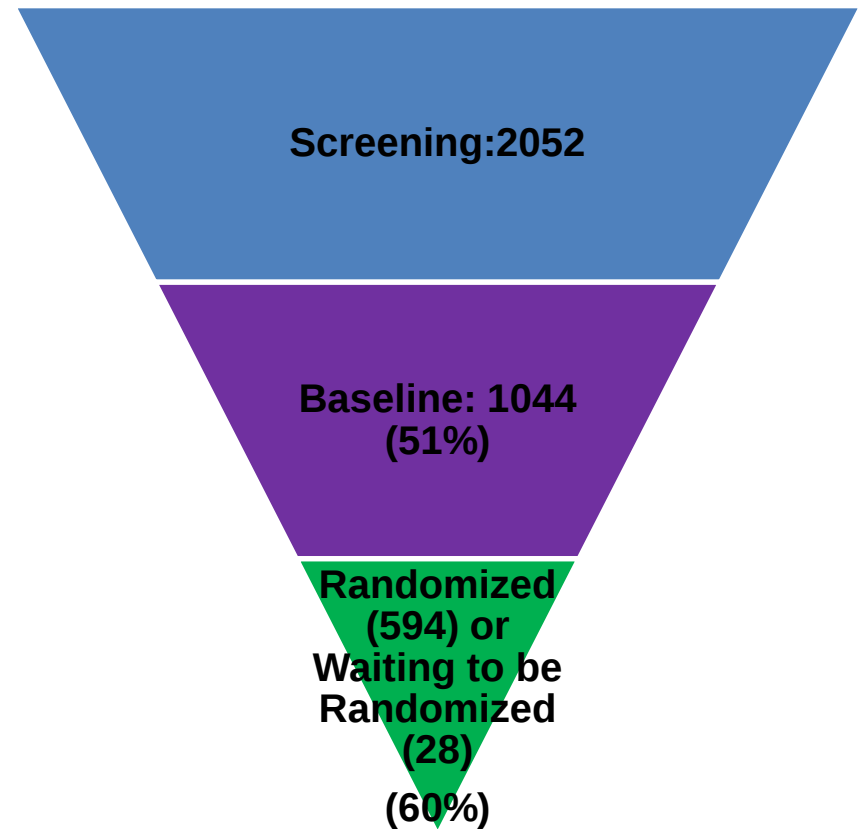


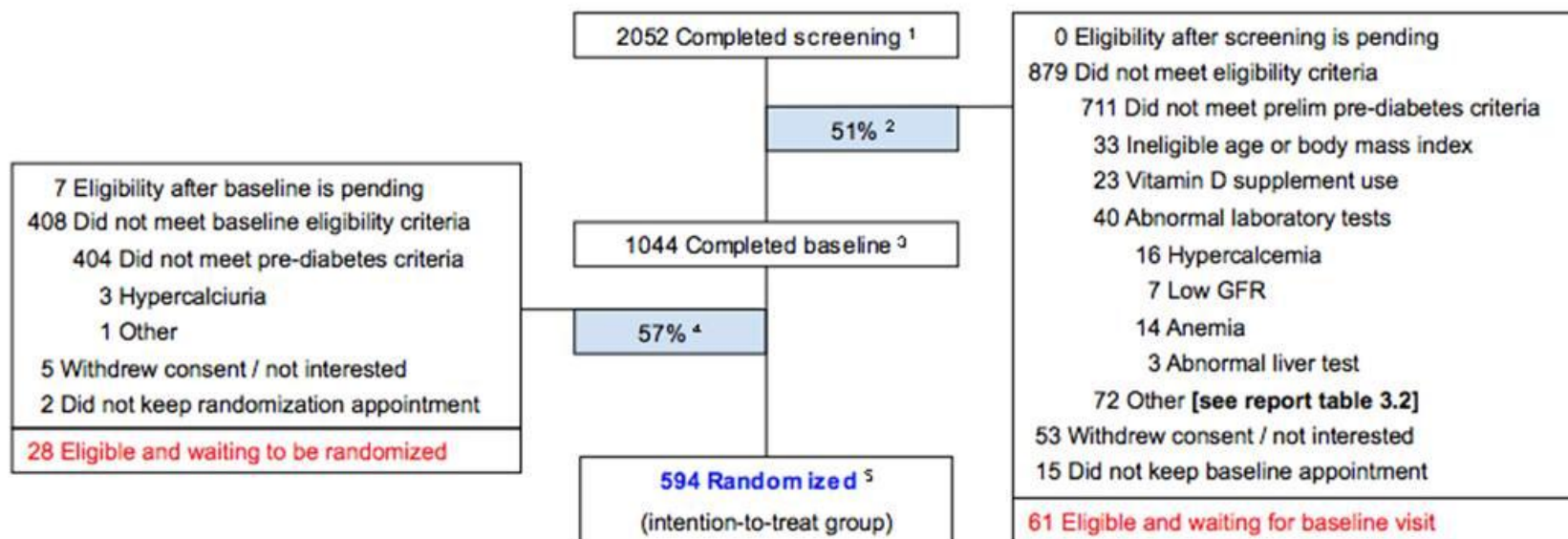
Recruitment and Enrollment Goals

Projected for Current (Midway)



Current, Actual





¹Completed screening = had a screening visit date, i.e., [screening visdat] date entered in EDC

²Percent of those that completed screening visit that qualified and completed BAS visit.

³Completed baseline = has a baseline visit date, i.e., [baseline visdat] entered in EDC

⁴Percent of those that completed BAS visit that were randomized.

⁵Randomized = (NEWBTLYN=1 [yes] in randomization)

An Anecdote (MedStar Health team)

September 2014:

A funnel chart illustrating the progression of patients through three stages. The top stage is blue and labeled 'Screening: 19'. The middle stage is purple and labeled 'Baseline: 15 (79%)'. The bottom stage is green and labeled 'Randomization: 6 (40%)'. The funnel shape indicates a decreasing number of patients at each subsequent stage.

Stage	Count	Percentage
Screening	19	
Baseline	15	79%
Randomization	6	40%

Screening: 19

Baseline: 15 (79%)

Randomization: 6 (40%)

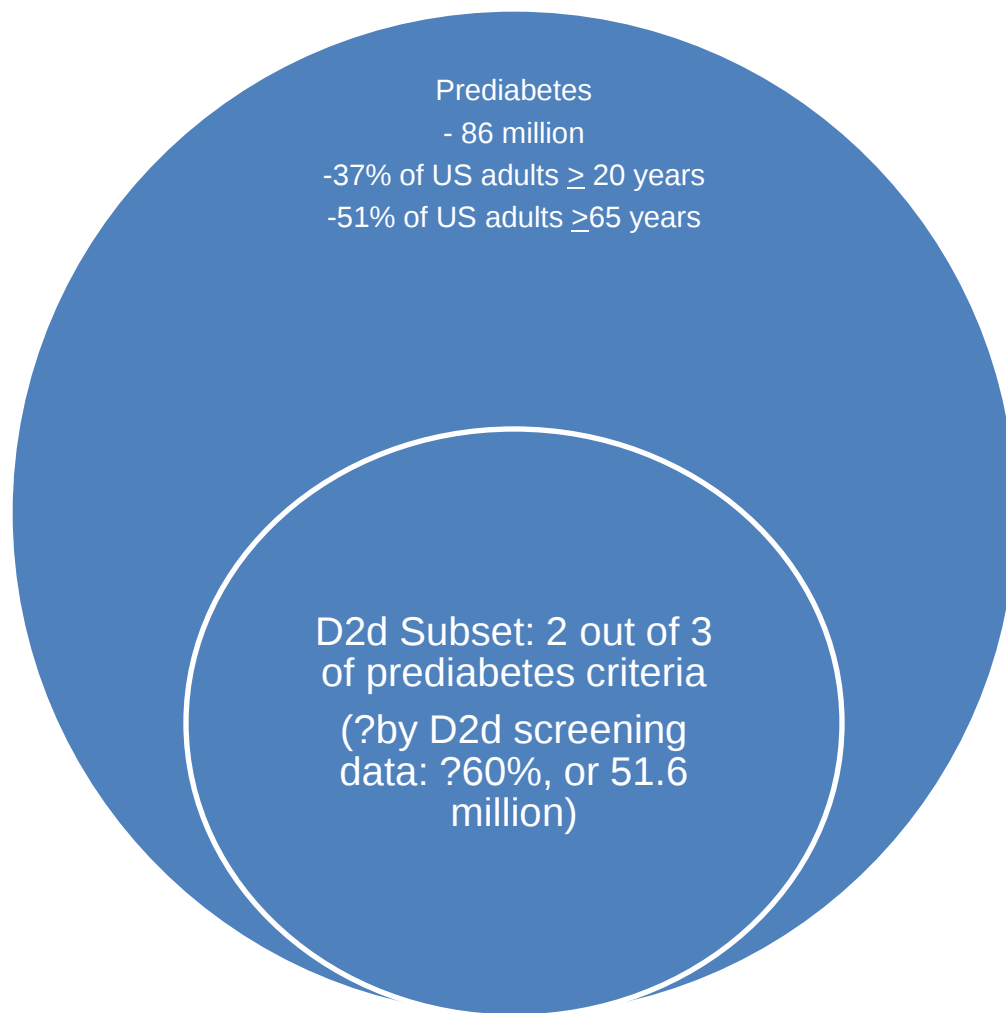


Teachable Moment?

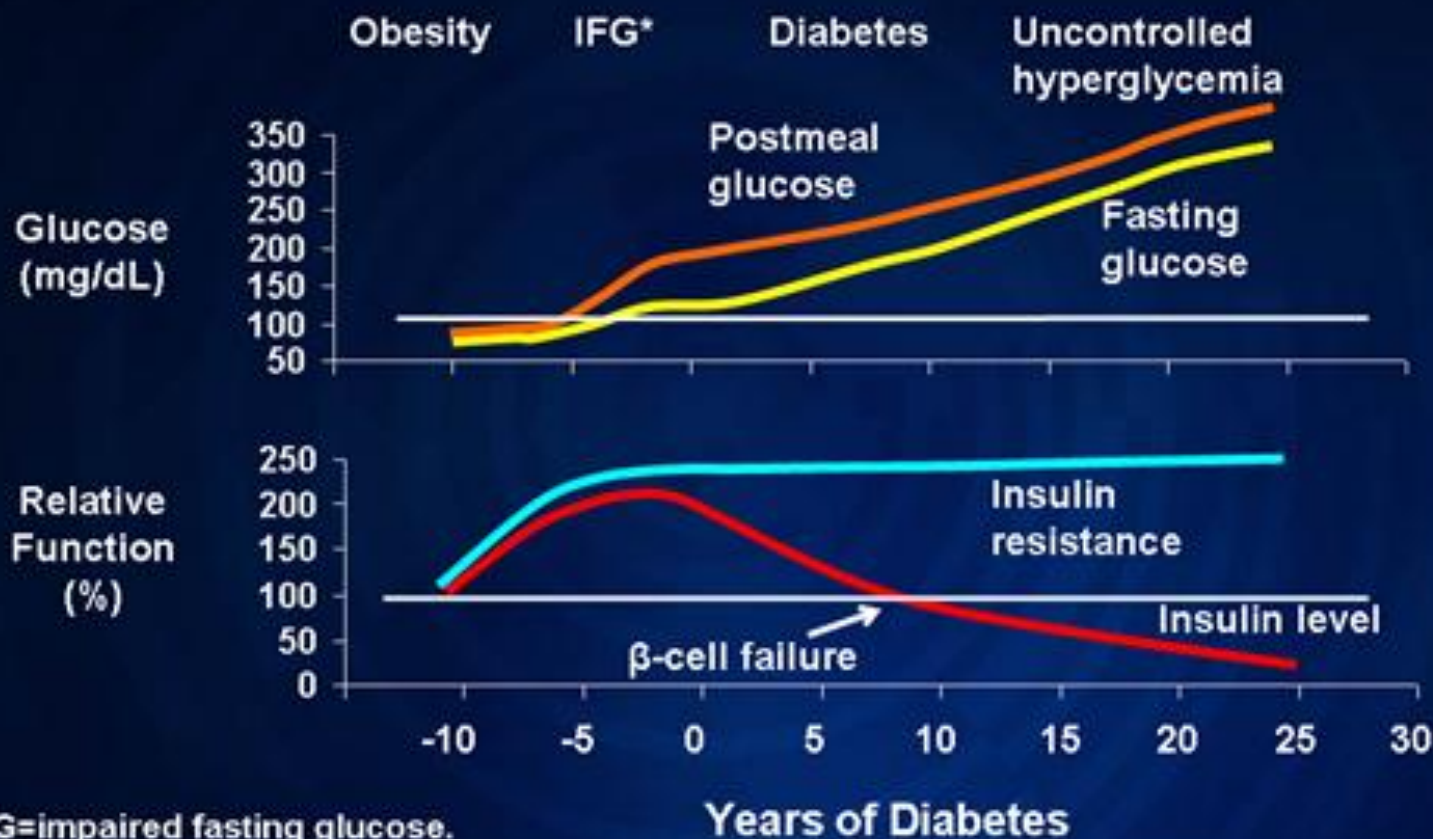


	Screening (local labs)		Baseline (central)			Baseline (repeat, prn)		
	A1c%	FPG mg/dl	A1c%	FPG mg/dl	2h glu mg/dl	A1c %	FPG mg/dl	2 h glu mg/dl
Pt 1	6.2	97	5.5	101	119	5.7	87	137
Pt 2	6.1	98	5.5	97	128			
Pt 3	6.0	97	5.8	92	72	6.0	89	47

D2d Universe is a Subset of the Prediabetes Universe



Natural History of Type 2 Diabetes



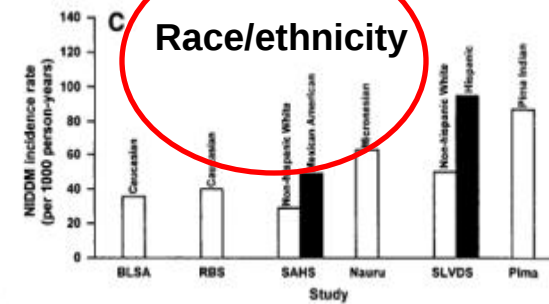
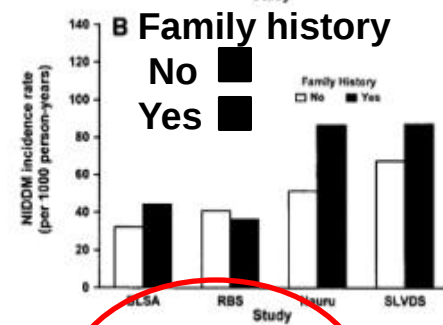
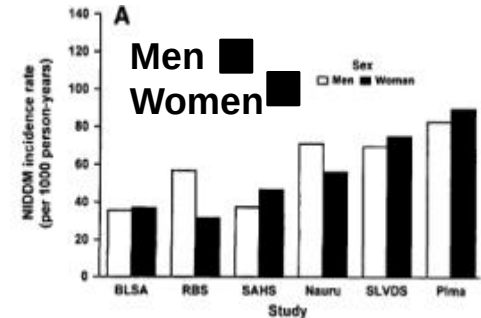
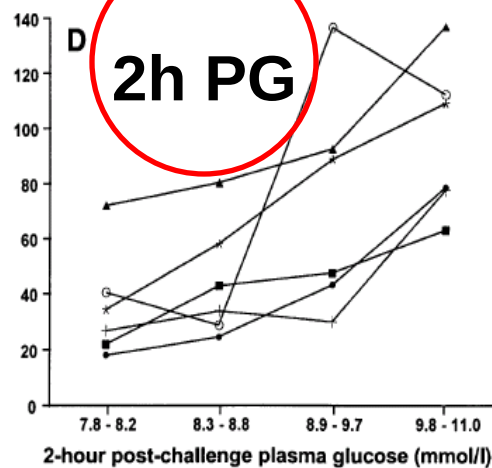
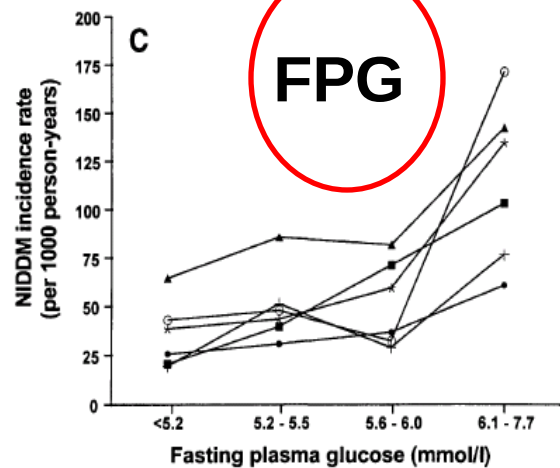
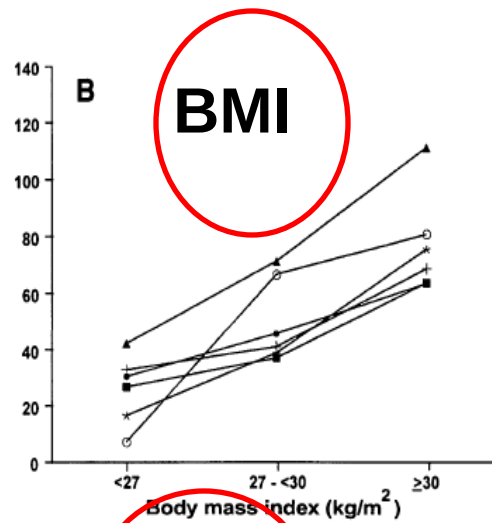
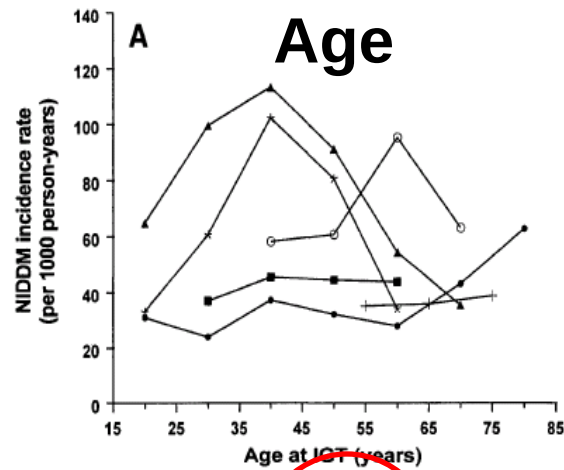
*IFG=impaired fasting glucose.

Adapted from International Diabetes Center (Minneapolis, Minn).



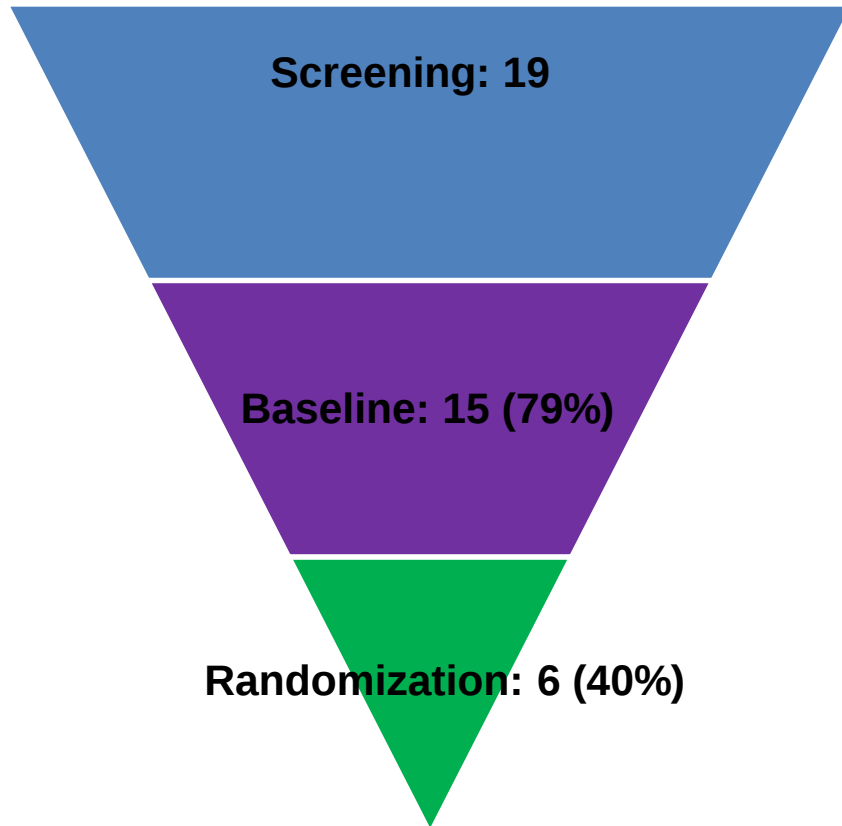
Predictors of Progression From Impaired Glucose Tolerance to NIDDM:

An Analysis of Six Prospective Studies

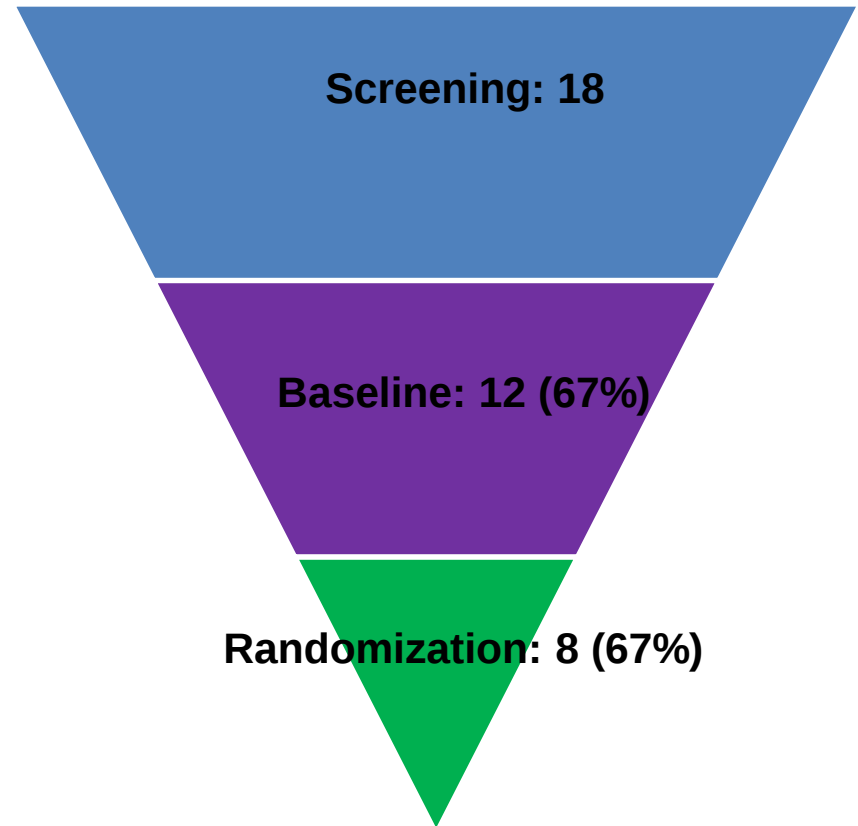


Working smarter, not harder?

Of patients screened in Sept 2014



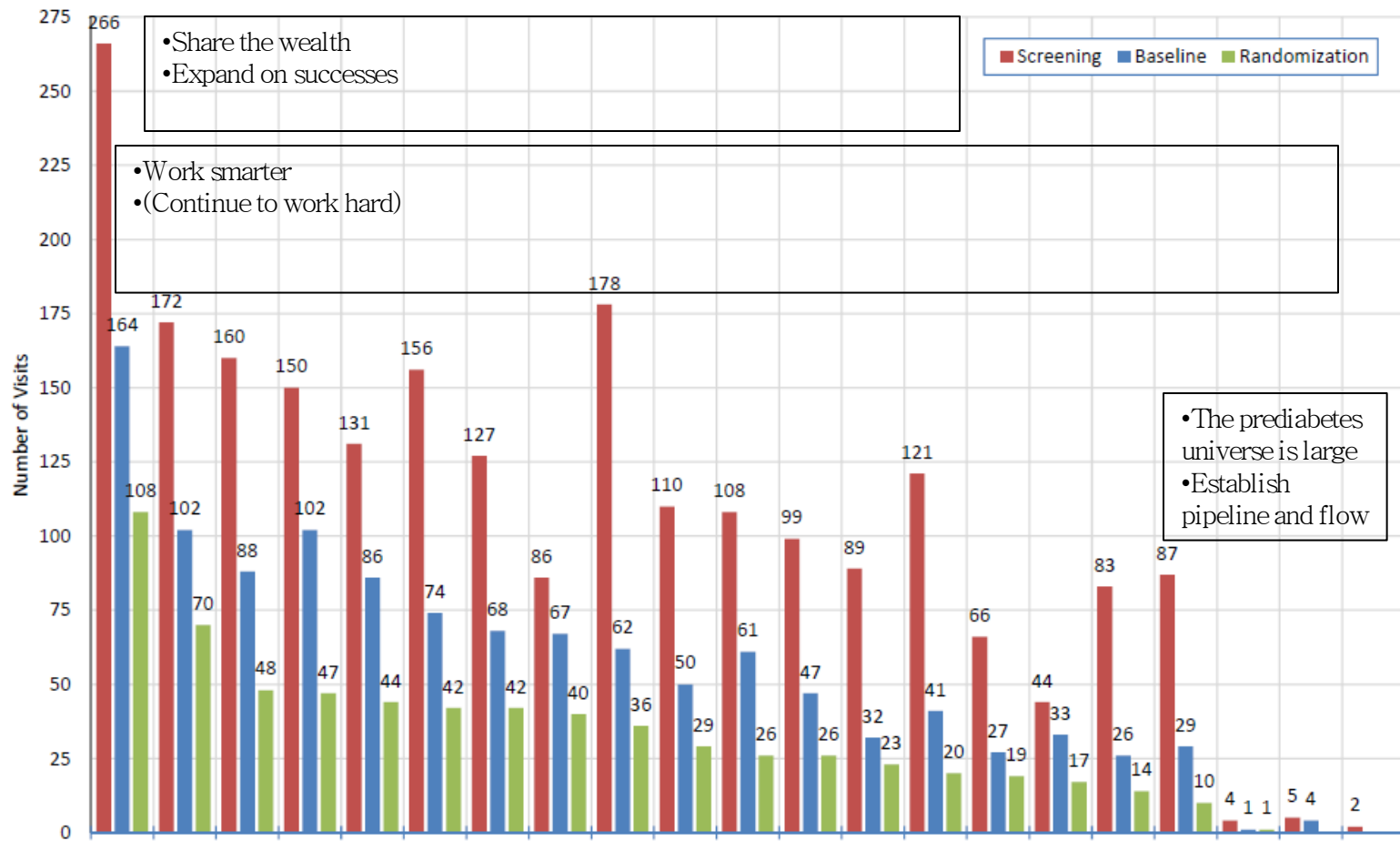
Of patients screened in Oct 2014



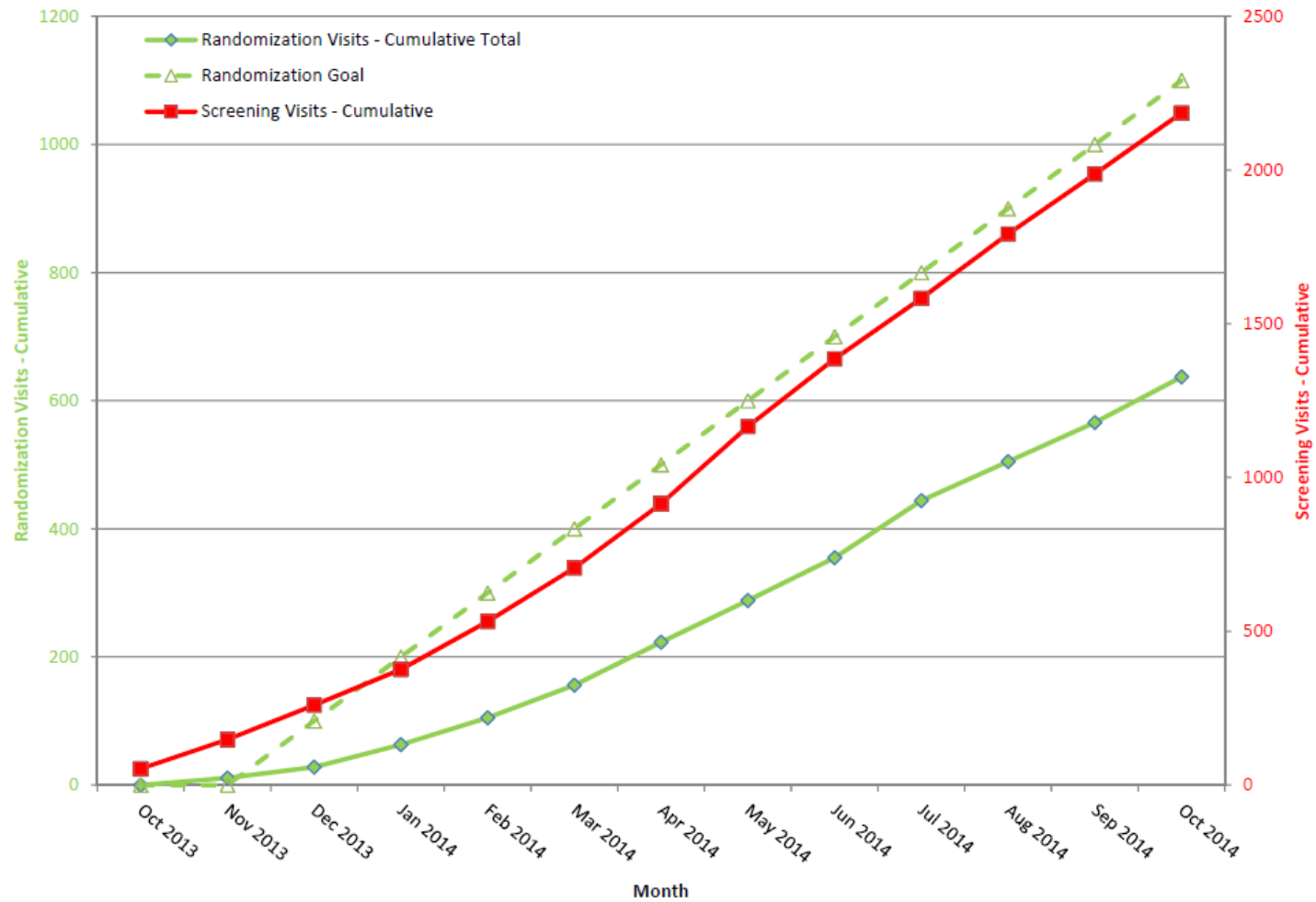
Study-wide: Prediabetes Criteria Fulfilled in Randomized Participants

Met all 3 criteria	201 (30%)
Met FPG and HbA1c	352 (52%)
Met FPG and 2hPG	48 (7%)
Met HbA1c and 2hPG	70 (10%)
Total	671

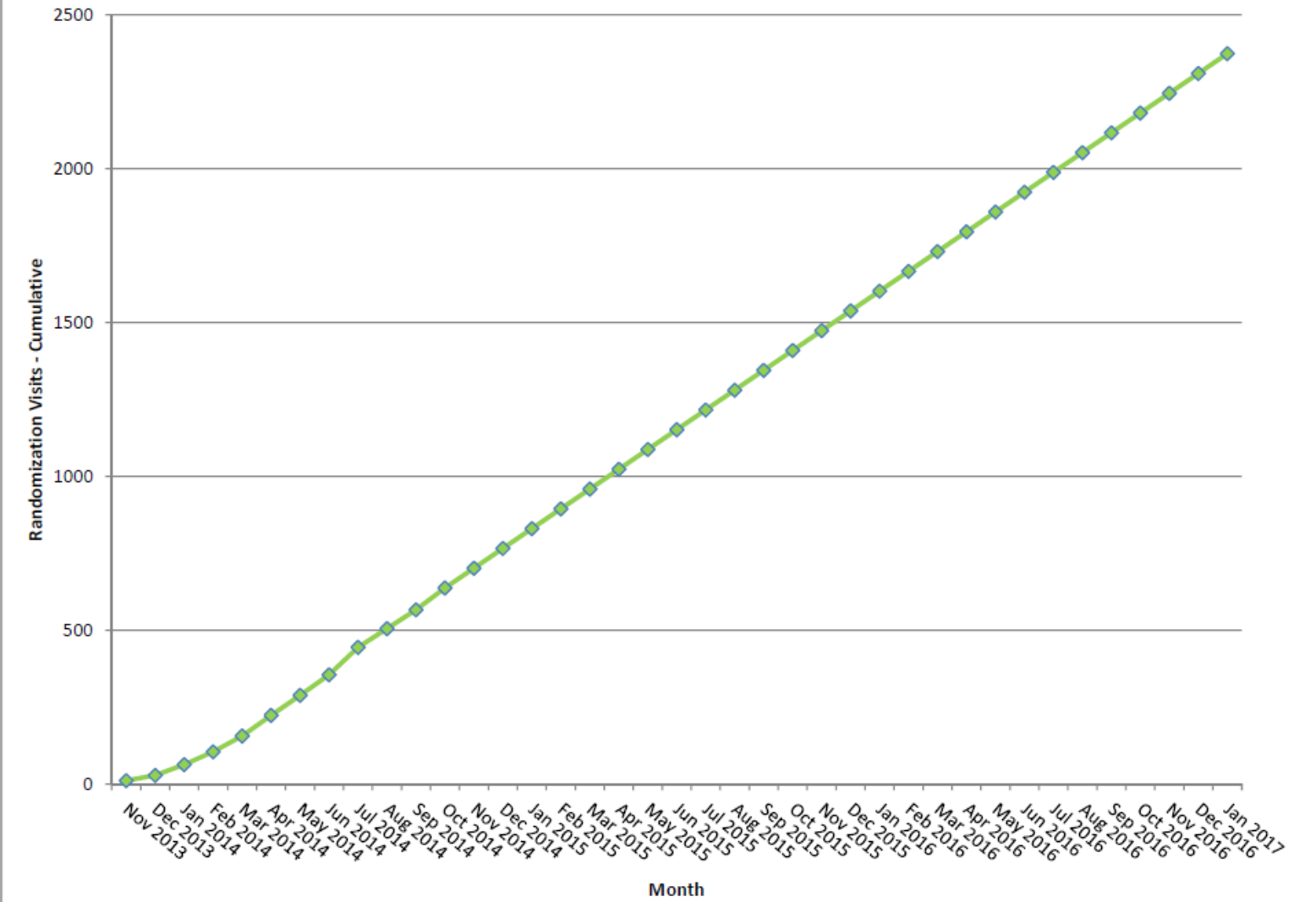
D2d Visits by Site - Cumulative



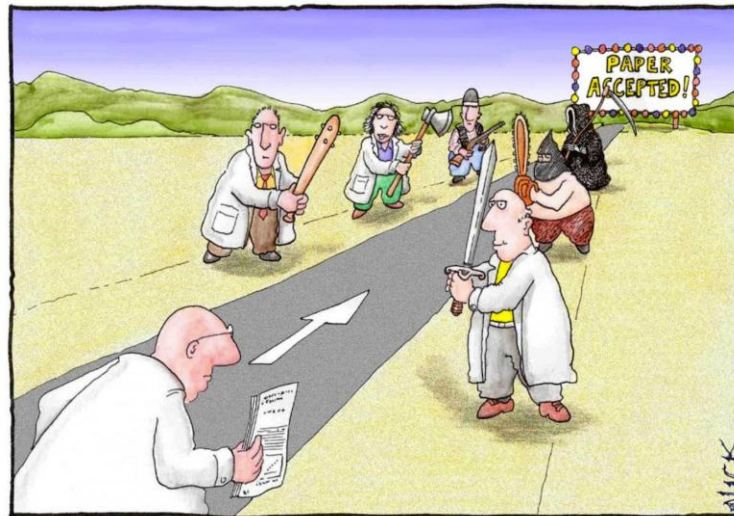
Cumulative Screening and Randomization Visits by Month



Cumulative Randomizations (if status quo is maintained)



“Recruitment Rounds”, AKA: Speed Dating meets Attending Rounds meets CONSTRUCTIVE Peer Review and Influence



Most scientists regarded the new streamlined peer-review process
as “quite an improvement.”

With each site Randomizing + 2 compared to the average in the last 3 months, and the 3 new sites (welcome aboard!) meeting said goals

