

Current Participant Retention

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15 VOICE Sites – 11 in South Africa



□ UGANDA

- Makerere Univ./JHU, Kampala (1 site)

□ ZIMBABWE

- UZ-UCSF, Harare (1 site)
- UZ-UCSF, Chitungwiza (2 sites)

□ SOUTH AFRICA (DURBAN AREA)

- Medical Research Council (7 sites)
- CAPRISA eThekweni (1 site)

□ SOUTH AFRICA (JOHANNESBURG AREA)

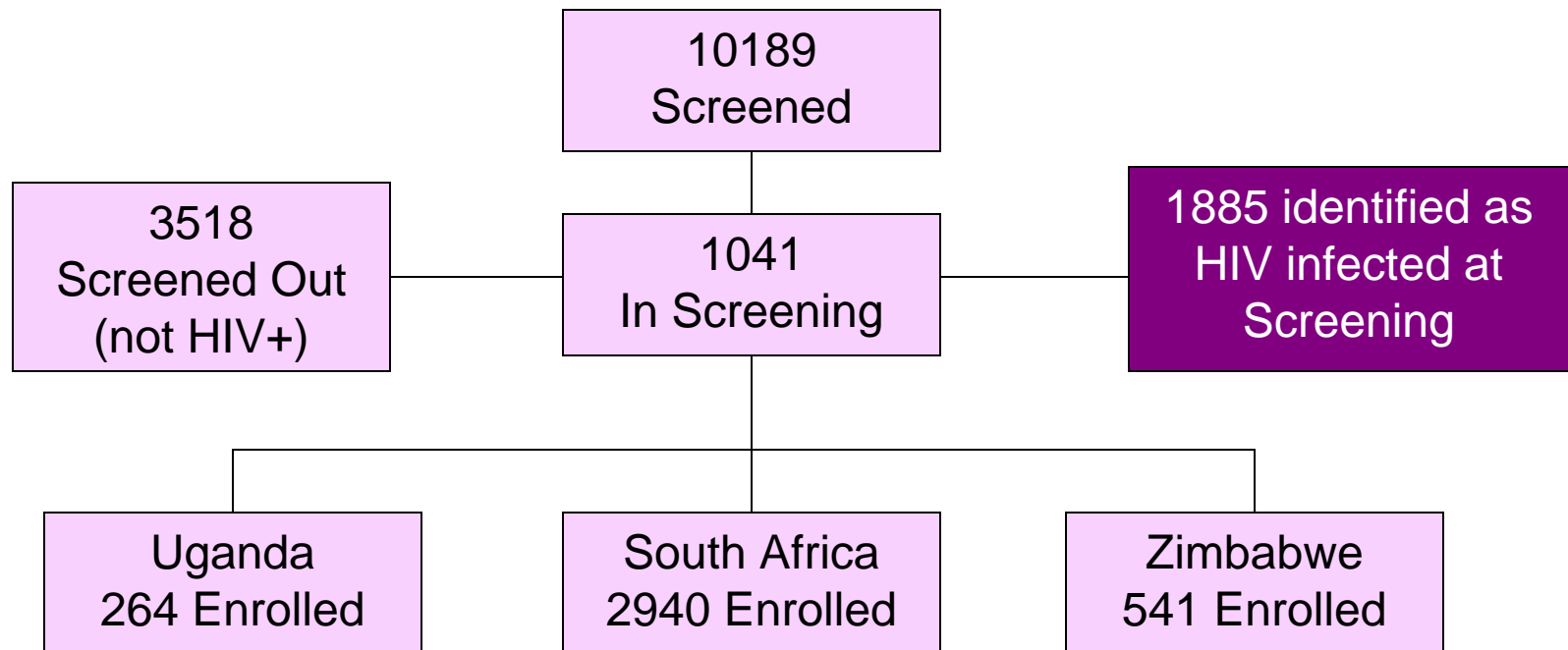
- RHRU Research and Training Centre (1 site)
- PHRU Soweto (1 site)

□ SOUTH AFRICA (KLERKSDORP AREA)

- Aurum Institute (1 site)

VOICE - Current Status

As of 18 March 2011



Total Enrollment = 3745
Overall Screen to Enroll Ratio = 2.4:1



Retention in VOICE Study

- Two retention measures are used:
 - Monthly retention: participants who completed scheduled visits within the allowable visit window
 - End of the study retention: participants complete HIV testing at PUEV
- For VOICE, annual retention target is:

95%



Retention in VOICE Study

- Retention rate will be used as a key study performance measure
- Each site will make every effort to retain each participant enrolled/randomized in VOICE by carefully monitoring scheduled follow-up (f/u) visits to minimize possible bias associated with loss to f/u



Why is Retention so Critical

- We will not know if participants who are loss to f/u are HIV-infected or HIV-uninfected
- This could lead to potential interpretation that each loss to f/u results in an unobserved HIV infection (assumed sero-converter)
- Regulators will often add all potential unobserved endpoints into active arm as worse case scenario therefore biasing the results outcome for efficacy of product
- Loss to f/u rates should not exceed the incidence rate of primary endpoint



Retention In VOICE Study

- Each site has established SOPs to describe site-specific retention procedures undertaken to meet the study retention goal of 95% per year.
- Each site will present their strategies to maintain this critical 95% target

VOICE Retention Targets

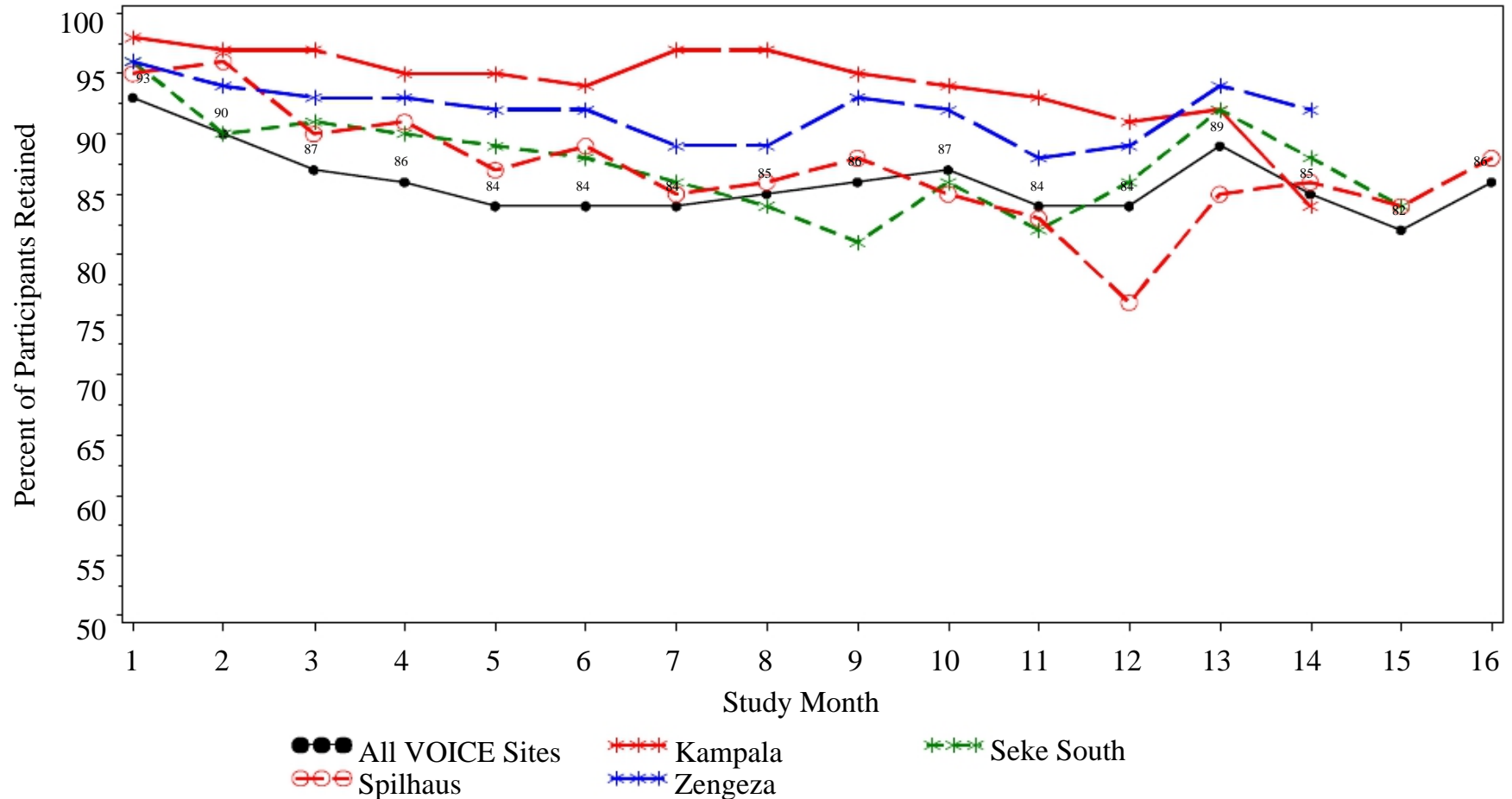
Study Visit	Target % Retained		Study Visit	Target % Retained
Month 1	99.62		Month 20	92.33
Month 2	99.23		Month 21	91.95
Month 3	98.85		Month 22	91.56
Month 4	98.47		Month 23	91.18
Month 5	98.08		Month 24	90.79
Month 6	97.7		Month 25	90.41
Month 7	97.32		Month 26	90.03
Month 8	96.93		Month 27	89.64
Month 9	96.55		Month 28	89.26
Month 10	96.16		Month 29	88.88
Month 11	95.78		Month 30	88.49
Month 12	95.4		Month 31	88.11
Month 13	95.01		Month 32	87.73
Month 14	94.63		Month 33	87.34
Month 15	94.25		Month 34	86.96
Month 16	93.86		Month 35	86.58
Month 17	93.48		Month 36	86.19
Month 18	93.1			
Month 19	92.71			

Study month, Target, Actual, Difference

Study Month	Target	Actual	Difference
Month 1	99.62%	93%	7%
Month 2	99.23%	90%	9.23%
Month 3	98.85%	86%	12.85%
Month 4	98.47%	85%	13%
Month 5	98.08%	84%	14.08%
Month 6	97.70%	84%	13.70%
Month 7	97.32%	84%	13%
Month 8	96.93%	85%	11.93%
Month 9	96.55%	85%	11.55%
Month 10	96.16%	87%	9%
Month 11	95.78%	85%	10.78%
Month 12	95.40%	85%	10.40%
Month 13	95.01%	89%	6%
Month 14	94.63%	86%	8.63%
Month 15	94.25%	81%	13.25%

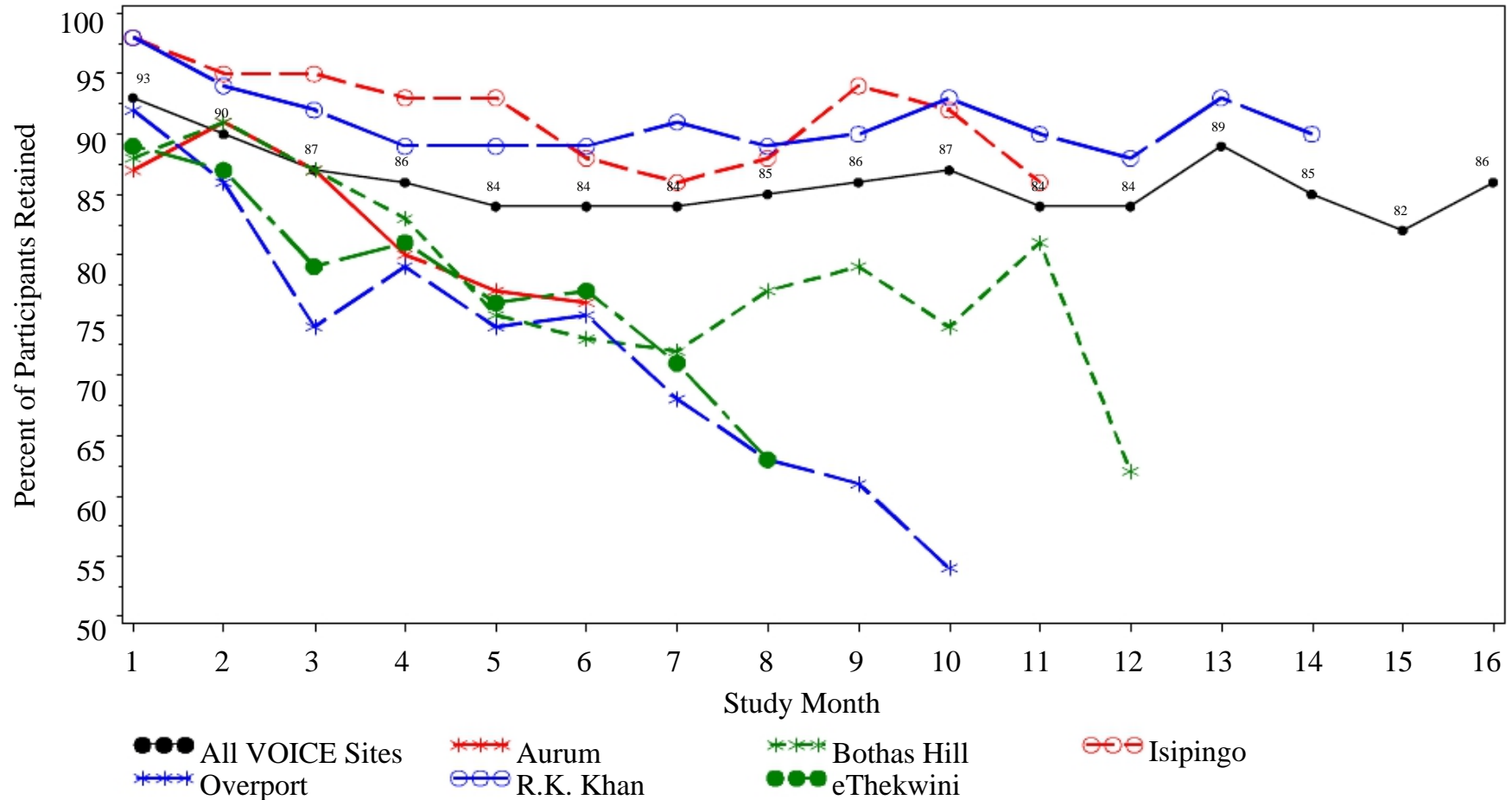
Percent of VOICE Participants Retained during Follow-up

Overall and by Non-South African Sites



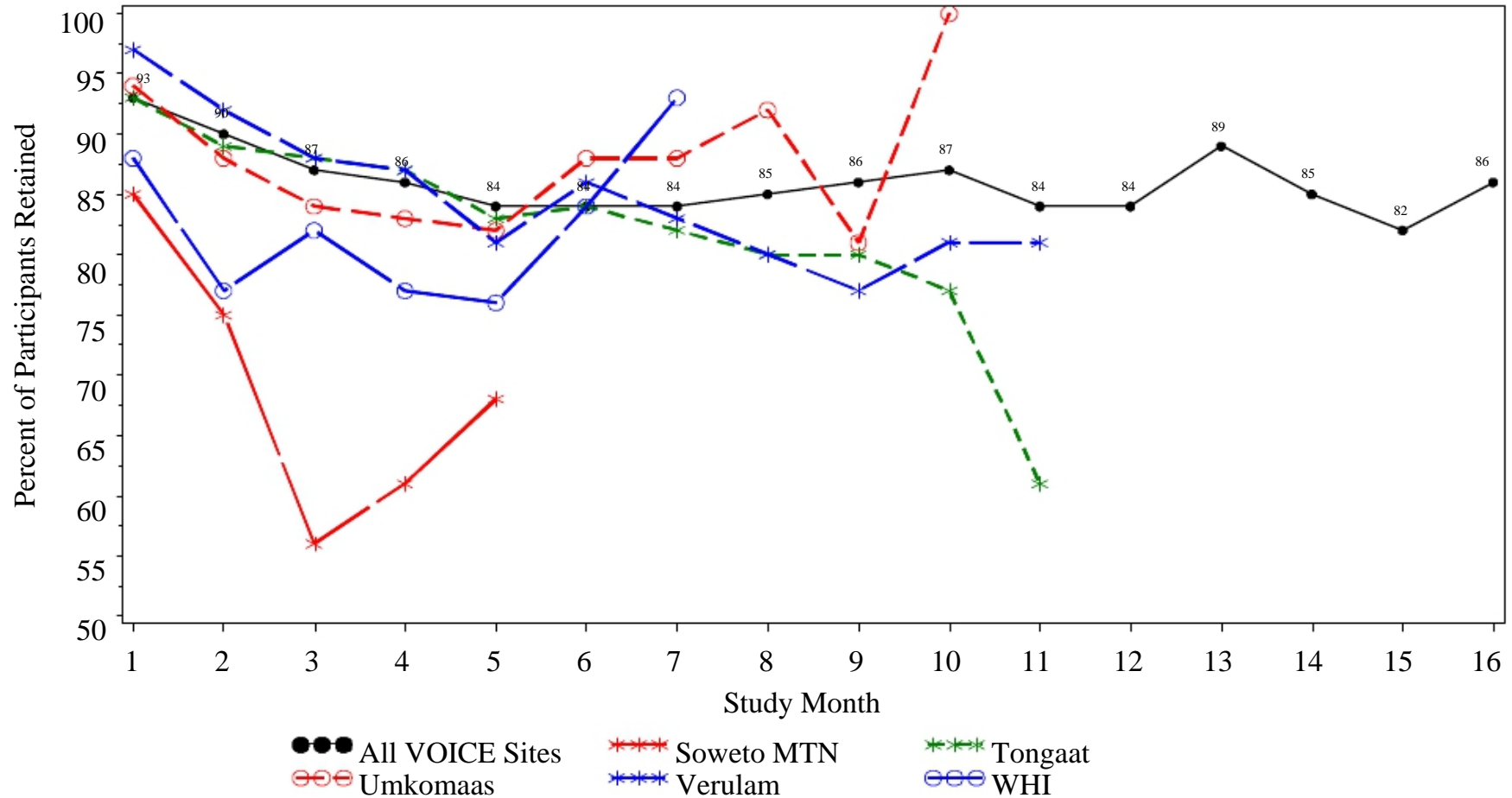
Percentages reported where at least 20 participants were expected that month for follow-up at the site

Percent of VOICE Participants Retained during Follow-up Overall and by South African Sites (Group 1)



Percentages reported where at least 20 participants were expected that month for follow-up at the site

Percent of VOICE Participants Retained during Follow-up Overall and by South African Sites (Group 2)



Percentages reported where at least 20 participants were expected that month for follow-up at the site



Retention Strategies: sec 8 SSP

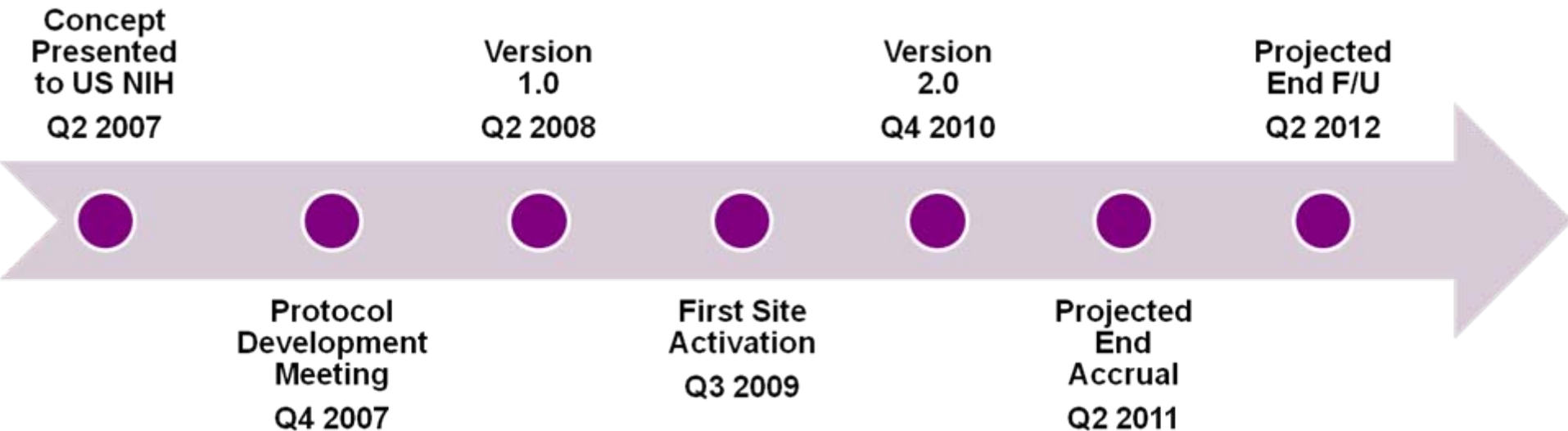
- Obtain accurate locator information
 - At all visits, ensure locator information is updated
- During the IC process, ensure participants understand the importance of attending all study visits
- Work with outreach team and CAB to identify the most applicable contact and retention strategies
- Use tracking systems to identify when participants' scheduled visits are due and/or overdue. If visits are missed, address immediately
- Develop rapport and ensure participants feel welcome and comfortable during their visits
- Organize retention activities, including retention meetings with participants, partners, and CAB



Next Steps

- Each site needs to review their retention numbers and meet as a group to assess if current retention methods are adequate and if changes are needed.
- Once an updated retention plan has been established, sites should communicate the updated plan with management team and protocol chairs.
- Management team will follow-up with each site as needed about future steps (e.g. updating SOPs, ad-hoc conference calls)

Timeline



- DSMB First review of HIV endpoints in Q2 2011
- Study results anticipated available in Q1 2013

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