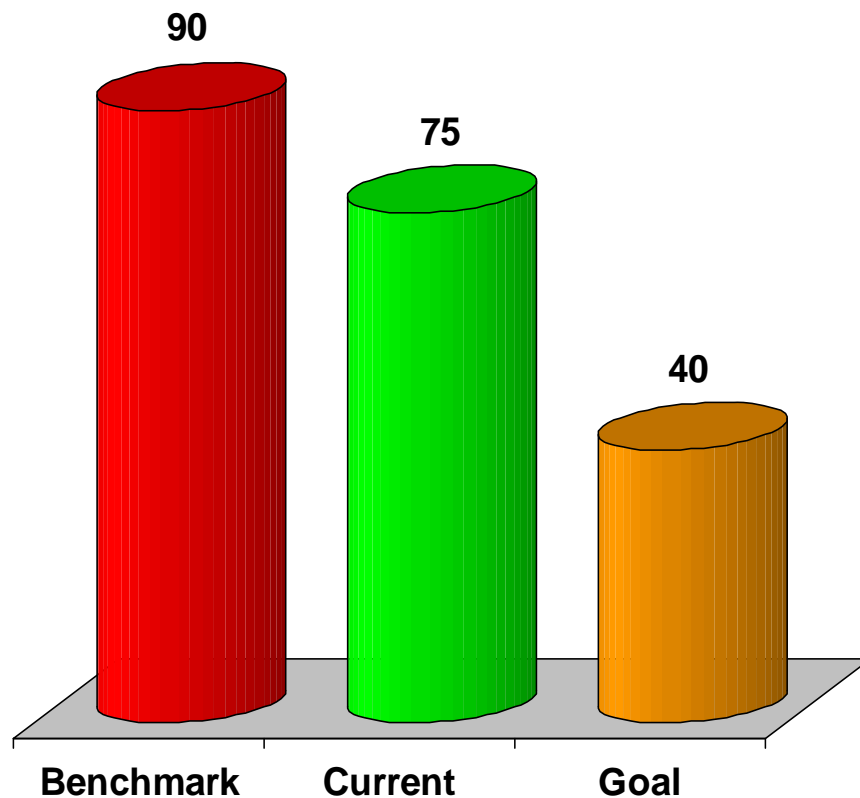


Mean Site Contract Process Times



Continuous Improvement: Site Contract Process

Challenge:

Trial timeline is 3 months longer than desired

Trial Goal:

Save 3 months on timeline

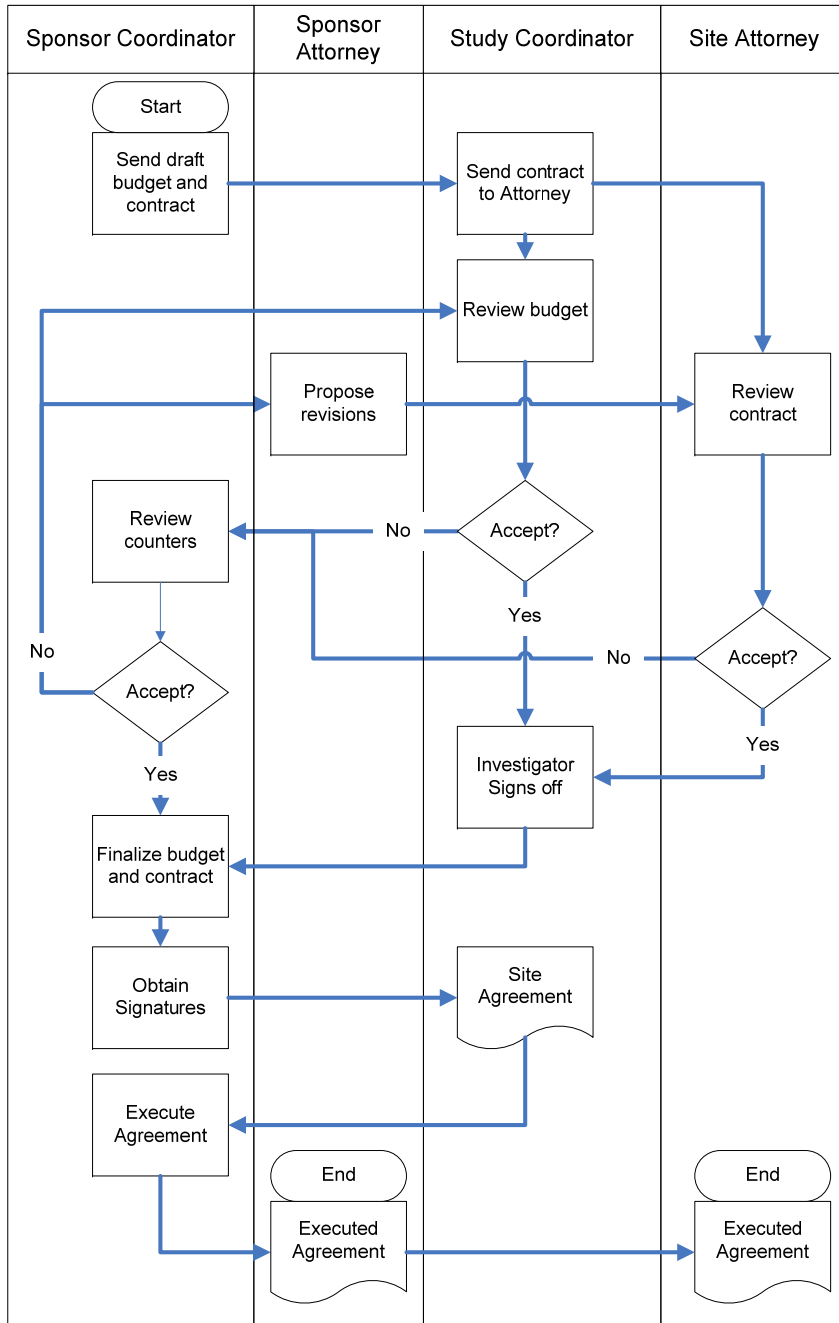
Process Goal:

Expedite enrollment by reducing time to First Patient Enrolled (**FPI**)

Current cycle time is 75 days

Reduce contract cycle time to 40 days (~50% reduction);

1 months savings



Site Contract Approval Process

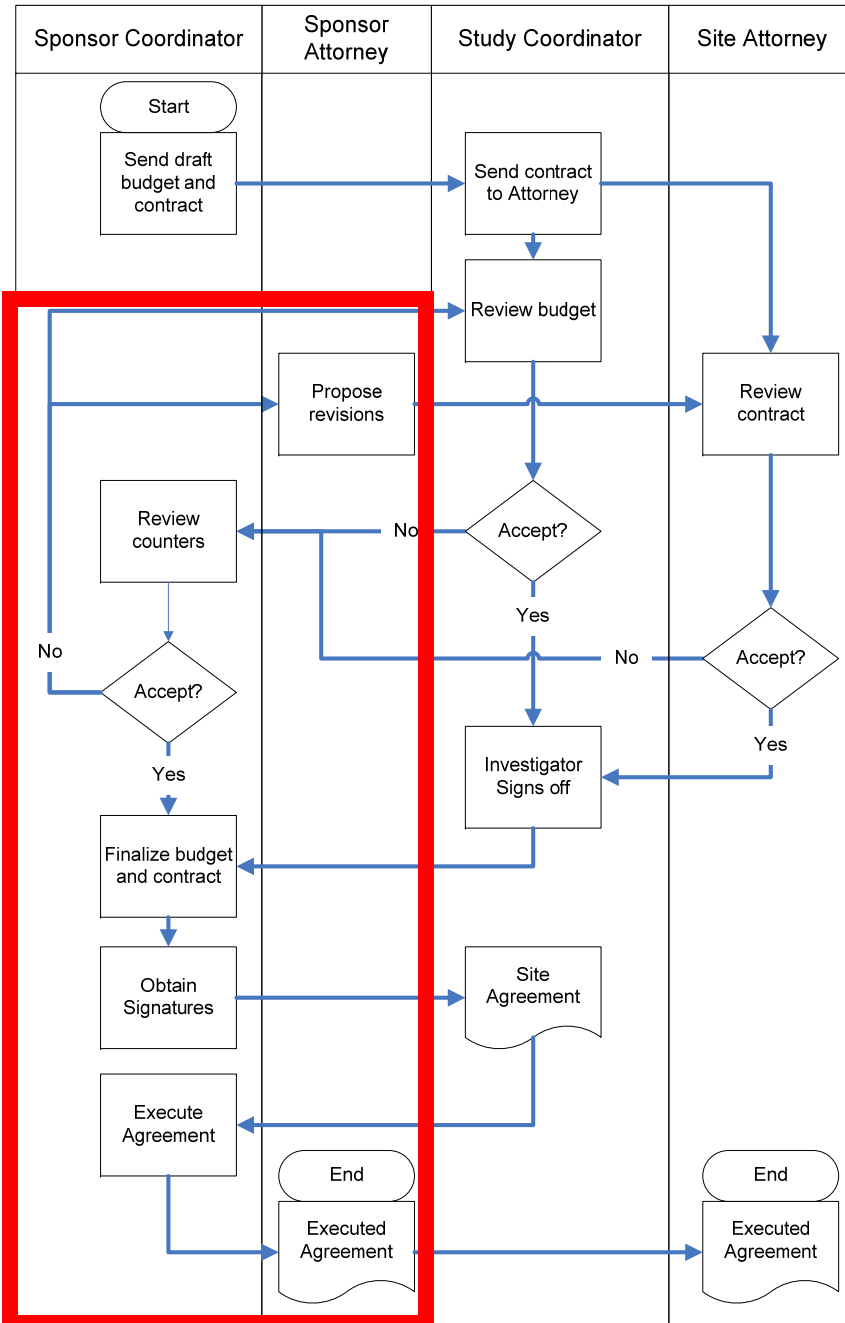
2 interdependent cycles:
 Terms & conditions approval (**Contract**)
 Budget approval (**Budget**)

(days)	No. (n=44)	Contract	Budget
May	16	57	54
July	28	87	81
Change	12	30	27

Critical Path Assumption

Contract approval is in the critical path to first patient enrolled (**FPI**)

Shortening site contract cycle time can expedite enrollment start



Sponsor Cycle Times

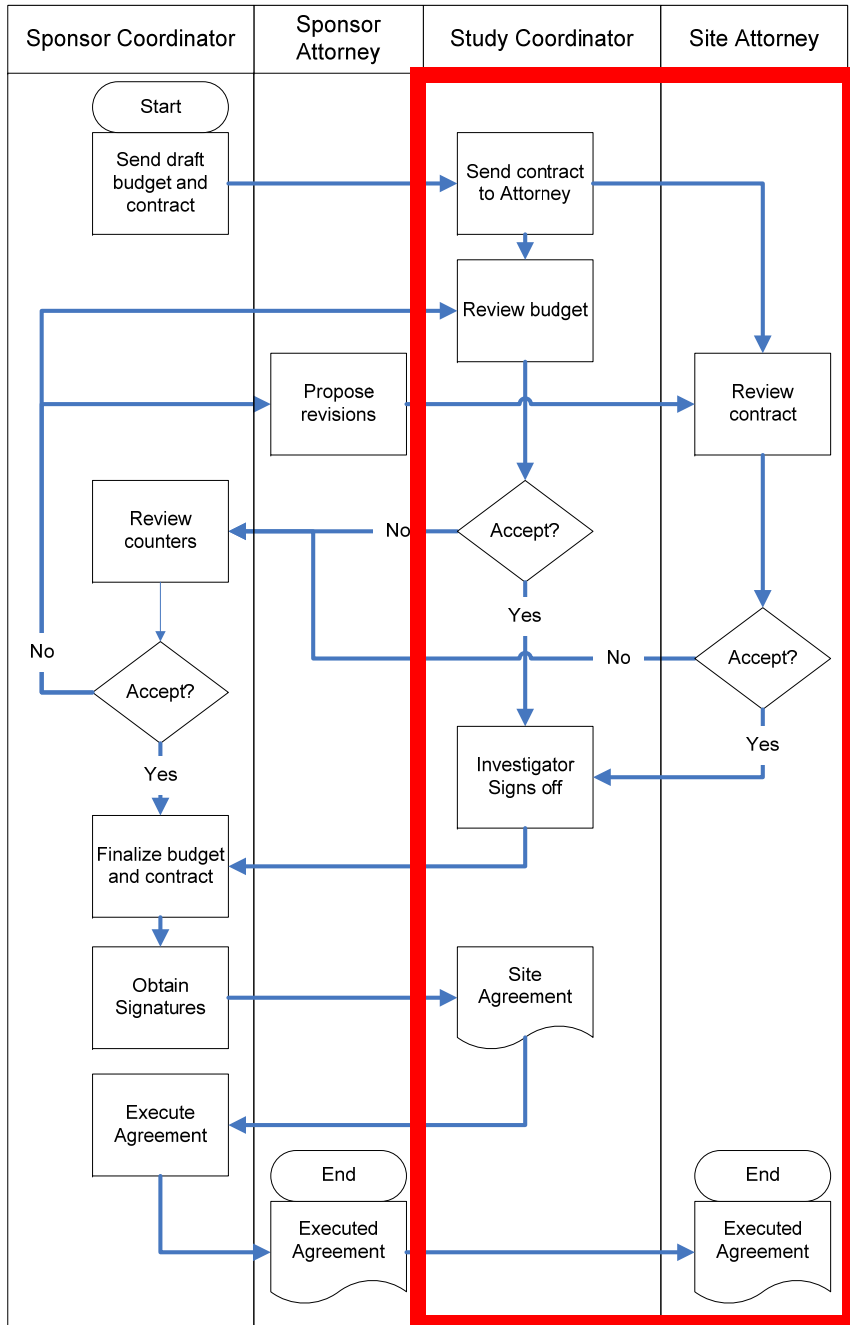
Review and approval cycle times at sponsor comprise the **minority** of the approval time

(days)	No. (n=44)	Contract	Budget
May	16	7	4
July	28	5	8
Change	12	-2	4

Next Steps

Opportunities to reduce cycle times at sponsor don't seem as significant compared to site cycle times

Target site cycle times



Sites Cycle Times

Review and approval cycle times at sites comprise the majority of the approval time

(days)	No. (n=44)	Contract	Budget
May	16	44	46
July	28	73	67
Change	12	29	21

Next Steps

Shortening site review and approval cycle times is **BIG** opportunity

Avoid prolonged negotiations on budgets and terms

Site Cycle Times

(days)	Wait for IRB Approval	Review Budget & Contract	Wait for Meeting	Negotiate Budget & Contract	Wait for Approvals	Execute Agreement	Total
Budget	> 30	1	4	1	2	1	> 39
Contract	> 30	1	10	1	2	3	> 47

Lapsed Time (days)	Waiting	Effort	Total	Tactic
Budget	36 (90%)	3 (10%)	39 (100%)	<p>Persuade site to NOT wait for IRB approval before initiating reviews; save 30 days (~60%)</p> <p>Do not negotiate with sites on budget and contract; save 5 days (~10%)</p>
Contract	42 (90%)	5 (10%)	47 (100%)	