

# MONITORING ACRUAL

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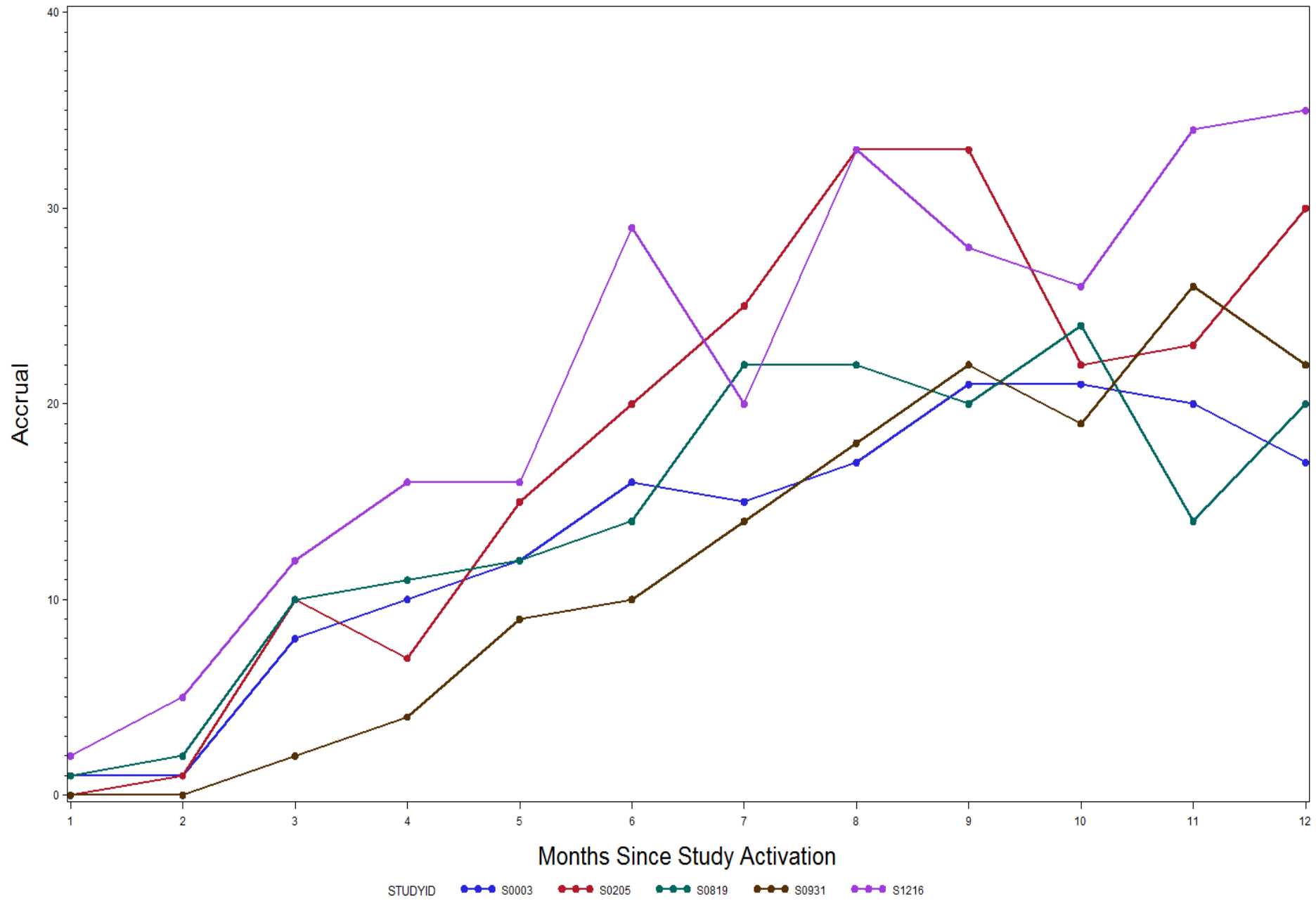
On the SWOG LUNG Master Protocol  
(Lung MAP)

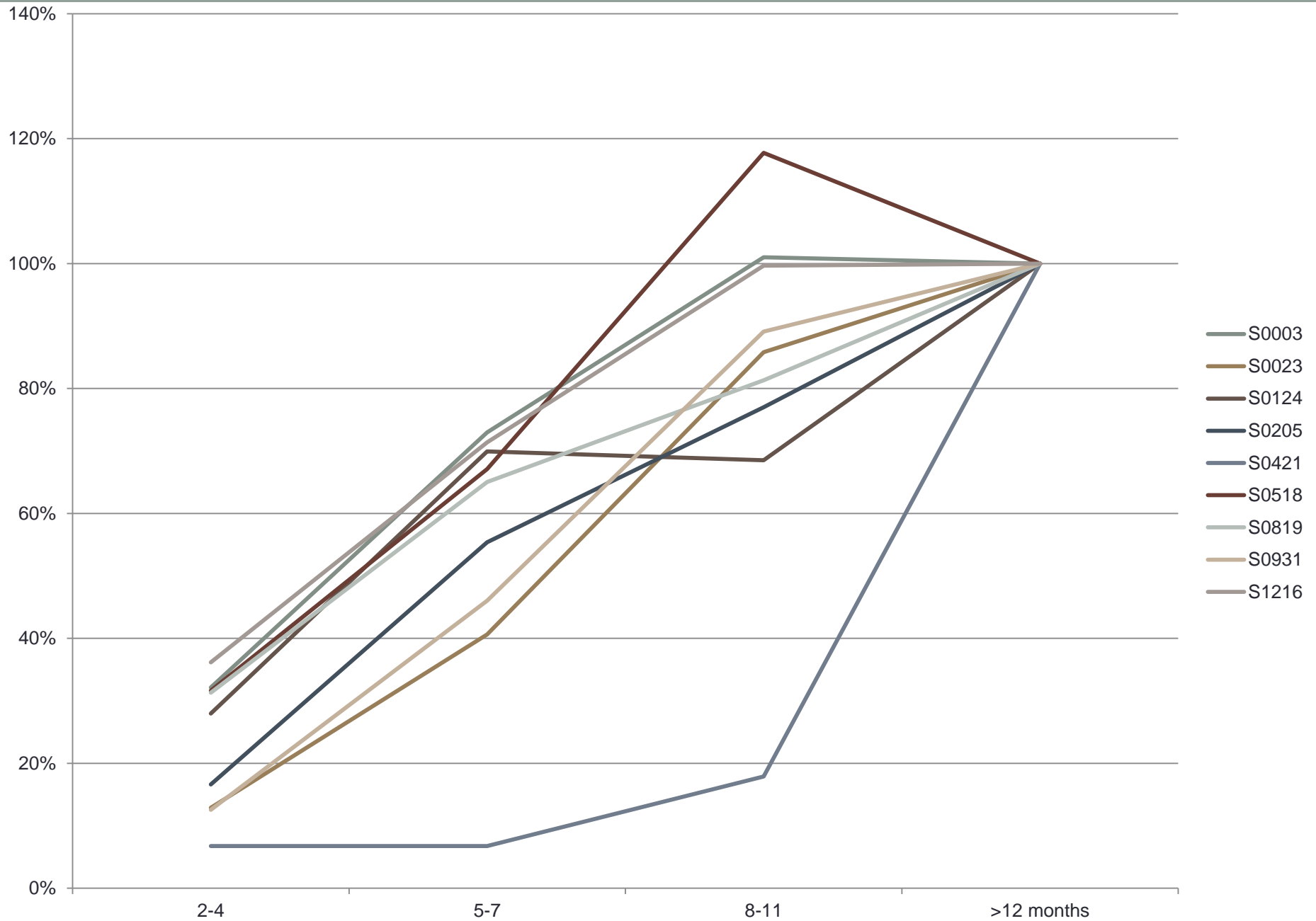
# Accrual ramp-up period in cooperative group trials

Cooperative group studies typically have very few patient accruals in the 1st couple of months after study activation.

- IRB approval required at each site
- Some sites have additional regulations/procedures

E.g. Scientific Review Committee

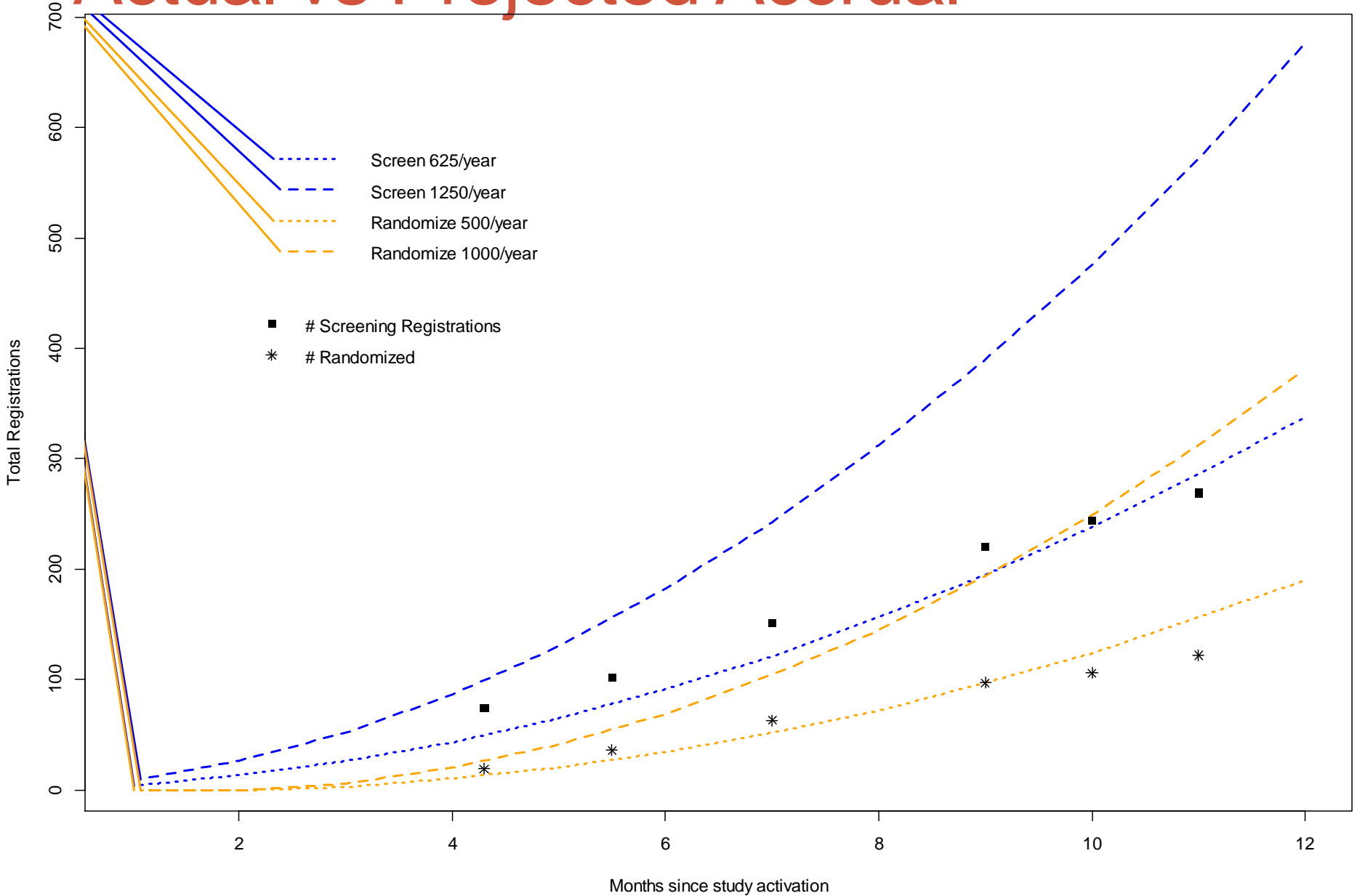




# SWOG experience: Accrual Ramp-up

	2-4 months	5-7 months	8-11 months
<b>25% percentile</b>	<b>13%</b>	<b>43%</b>	<b>73%</b>
<b>50% percentile</b>	<b>28%</b>	<b>65%</b>	<b>86%</b>
<b>75% percentile</b>	<b>32%</b>	<b>71%</b>	<b>100%</b>
<b>Average</b>	<b>23%</b>	<b>55%</b>	<b>82%</b>

# Actual vs Projected Accrual



# Effect on Study Design

- Phase III study designs assume uniform accrual
- Ramp-up period usually has negligible effect because:
  - Interim analyses occur later on in study
  - Accrual estimate is the average accrual over the entire study period.

# Effect on Study Design

- Unique features of Lung-MAP
  - Delay between screening, sub-study assignment, sub-study enrollment.
  - Interim analyses based on earlier endpoints: response, PFS
- Study completion may end up approximately 5 months longer than if these studies had no ramp-up period.

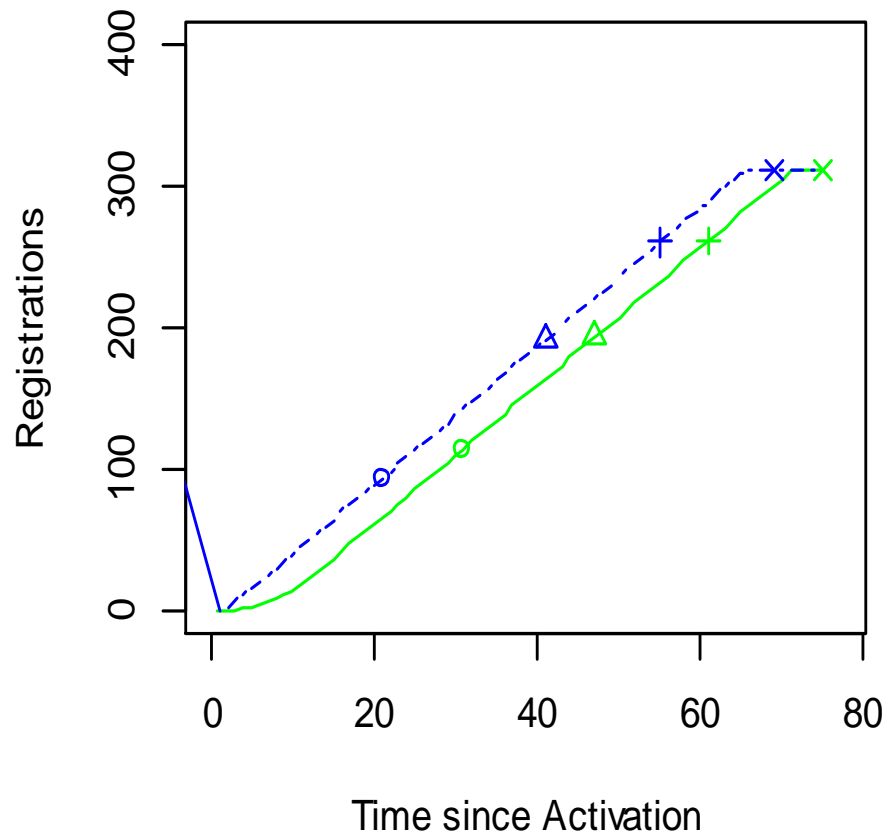


# Example: S1400C

	Ramp Up		Deaths	% Deaths	PFS events	% Accrual	No ramp up		
	Time	Accrual					Time	Accrual	difference
<b>500 patients/year</b>									
Phase 2 interim	29	104	51	20	56	33	19	83	10
Phase 2 report	31	114	59	23	63	37	21	93	10
Interim 1	47	193	128	50	121	62	41	191	6
Interim 2	61	261	193	75	172	84	55	260	6
Final(OS)	75	312	256	100	292	100	69	312	6
Final(PFS)	74	312	252	98	289	100	68	312	6
<b>1000 patients/year</b>									
Phase 2 interim	20	121	44	17	57	39	13	107	7
Phase 2 report	22	141	55	21	68	45	15	126	7
Interim 1	32	238	126	49	134	76	27	242	5
Interim 2	40	312	190	74	251	100	35	312	5
Final(OS)	51	312	255	100	299	100	46	312	5
Final(PFS)	47	312	237	93	290	100	42	312	5

# Effect on Study Timing

**S1400C @ 500/year**



**S1400C @ 1,000/year**

