INSTITUTIONAL PERSPECTIVES ON
CANCER COMMUNITY ACTIVATION TIMES

FORTE OnCore™

BACKGROUND

- Cancer Centers are under pressure to decrease trial time to activation
- NCI expects protocols to be activated in <u>8 to 12 weeks</u>
- Cancer Centers want to know
  - Are we competitive with our peers?
  - Are these timelines achievable?

METHODS

- Forte Benchmarks database queried:
  - Cancer Centers
  - Treatment Intervention Protocols
  - December 2018 – May 2019

Sarah Stewart, BS
University of Wisconsin Carbone Cancer Center
Assistant Director of Clinical Research
sarah.stewart@wisc.edu

Wendy Tate, PhD, MS, GStat
Forte Research Systems
Director of Analytics
wendy.tate@forteresearch.com

Laura Hilty, BS
Forte Research Systems
Vice President, Product Management & Strategy
laura.hilty@forteresearch.com

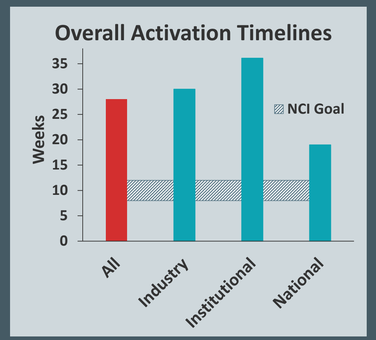
RESULTS

Activation Metric	Sponsor Type	# Orgs	# Protocols	Turnaround Times (days)		
				25th %ile	Median	75th %ile
Overall	**All protocols**	**19**	**548**	**124**	**196**	**273**
	Industry	18	267	153	210	278
	Institutional	17	79	178	253	378
	National	19	165	76	133	231
PRMC	**All protocols**	**19**	**713**	**8**	**20**	**42**
	Industry	19	370	13	28	47
	Institutional	18	100	8	22	64
	National	18	172	3	9	19
IRB	**All protocols**	**19**	**556**	**6**	**21**	**61**
	Industry	17	299	9	26	66
	Institutional	18	73	26	53	81
	National	19	145	1	3	22
IRB-Open	**All protocols**	**19**	**530**	**21**	**57**	**127**
	Industry	17	256	28	58	102
	Institutional	17	77	34	69	161
	National	19	161	10	46	152
Open-FPI	**All protocols**	**18**	**375**	**27**	**70**	**189**
	Industry	18	198	24	61	137
	Institutional	16	63	21	51	128
	National	17	93	30	122	383
Budget	**All protocols**	**7**	**83**	**64**	**103**	**150**
	Industry	7	78	72	106	152
Contract	**All protocols**	**7**	**71**	**93**	**132**	**188**
	Industry	7	56	101	136	189
Contract-Open	**All protocols**	**10**	**119**	**14**	**54**	**91**
	Industry	9	91	14	53	83

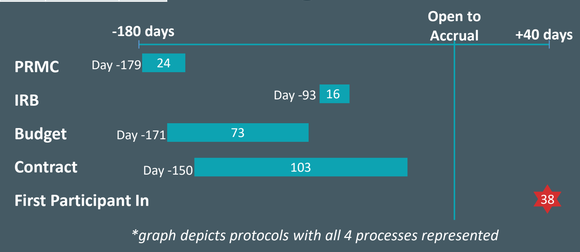
- Median time between the **last major process completed** and the **open to accrual** date is <u>**50 days**</u>

KEY TAKE-AWAYS

- Activation timelines are much slower than NCI goals



- <u>NO centers</u> have a median activation time under 12 weeks
  - Fastest averages ~3 months
  - 2/3 of centers have fewer than 10% activating in 12 wks
- Protocols with **concurrent** PRMC and IRB processes (9% of protocols) activated on average **53 days faster** than ones with sequential processes (161 v. 218)
- Of protocols that closed in this timeframe, **25%** were **zero-accruing**



**graph depicts protocols with all 4 processes represented*

DISCUSSION

- 8-12 weeks is possible for **individual trials**, but it's not a realistic metric for Cancer Centers to achieve **TODAY**
- Significant effort spent on zero-accruing trials – for what gain?
- **What can Cancer Centers do?**
  - Decrease National Group study activation to **30 days –** possible?
  - Concurrent processes (e.g., PRMC/IRB)
  - Minimize '**gap time**' between last major process and opening
    - SIV scheduling / sponsor activation
    - Institutional processes (e.g., financial, chemo orders, institutional review, calendar build)
    - Dedicated activation staff
    - Manage workload and number of trials in activation

FORTE Benchmarks™