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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Why does it take so long to do trials?

The question comes from a conversation with a colleague associated with someone who wants to reduce the time it takes to do trials. Good luck on that.

Doing a trial is like constructing a building. It takes a long time for anything visible to happen and when digging finally starts it takes a long time for the building to come out of the ground.

Planning for the Freedom Tower started soon after 9/11/2001. Construction started April 2006. It was two years after that before the building came out of the ground. It was another five years before it was topped off and a year and half after that before the first tenant moved in.

As a trialist, I feel like my Cousin Vinny (played by Joe Pesci) when Marisa Tomei was stomping back and forth on the porch with her biological clock running.

> *Lisa, I don't need this. I swear to God, I do not need this right now, okay? I've got a judge that's just aching to throw me in jail, an idiot who wants to fight me for two hundred dollars, slaughtered pigs, giant loud whistles. I ain't slept in five days. I got no money, a dress code problem, and a little murder case which, in the balance, holds the lives of two innocent kids, not to mention your biological clock; my career, your life, our marriage, and let me see, what else can we pile on? Is there any more shit we can pile on to the top of the outcome of this case?! Is it possible?!*
>
> *Maybe it was a bad time to bring it up.*

We keep piling things on trials and then wonder why it takes so long to do them. I provided a list of things that trialists have to do in a memo dated 31 May 2013, *So you want to run a trial, do you?* (available on trialsmeinertsway.com under the tab "musings"). The list was long!

Lind, onboard the Salisbury at sea, on the 20th of May 1747 rounded up twelve sailors with scurvy for his trial and observed that the two men receiving limes were fit for duty six days later.

It would take at least a year to do the same thing today. Lind would need a written, approved, protocol, IRB review and approval, and an approved consent form before starting. He would need an IND since one of the treatments was a "drug" (elixir vitriol). He and his

attendants would have to take training modules to be HIPAA and IRB certified and would have to be exposed to videos to be informed of insider trading, would have to register the trial before starting to be able to publish, would have to provide tabular results on ClinicalTrials.gov within one year of finishing to avoid being fined, and would be expected to share data within a year of finishing even if results not yet published.

The “typical” timetable for trials is depicted below.

Activity	Time range in yrs			"Usual" time
Conception to funding	1.00	to	4.00	2.50
Funding to start of enrollment	0.75	to	1.50	1.00
Start of enrollment to end of data collection	0.50	to	10.00	5.00
End of data collection to finished dataset	0.50	to	1.00	0.75
Finished dataset to finished manuscript	0.50	to	1.00	0.50
Finished manuscript to publication	0.50	to	3.00	1.50
Total	**3.75**	to	**20.50**	**11.25**

Basically, the only time amenable to investigator control is from start of enrollment to end of data collection. Good luck on cutting that time. Usually it takes longer than planned to reach enrollment goals.

The only way to "save" time is by cutting the front and back times by reducing administrative and operational overheads. Good luck there also.