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31 October 2022

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: COVID and trials

As people, we have lived through dozens of pandemics, but COVID is the first since launch of ClinicalTrials.gov, providing an opportunity to assess the impact of the pandemic on trials.

ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The act required the U.S. Department of Health and Human Services (HHS), through the National Institutes of Health (NIH), to establish a registry of clinical trials. The site was launched in 2000.

A key question is whether COVID trials are in addition to trials normally done or whether they take away from the usual mix of trials. The numbers in Table 1 suggest the latter. The only decrease in trials relative to previous years occurred in year 2020. The numbers in the 2nd and 3rd columns show a decline in the number of COVID trials undertaken since the 1st half of 2020.

Indications are that COVID trials are larger than other trials as seen in Table 2. Median sample sizes for COVID trials were about twice those for non COVID trials.

A higher percentage of COVID trials were randomized compared to non COVID trials (Table 3).

Tables 4, 5, and 6 give number of multicenter trials (Table 4), randomized and multicentered (Table 5), and trials having DSMBs (Table 6). Slightly more COVID trials are randomized than their counterpart non COVID trials. More COVID trials are randomized and multicentered and more have DSMBs.

Table 7 gives a breakdown by funding source. The notable finding is funding from US federal agencies is less for COVID trials than for other trials.

Table 8 shows breakdown by phase of trial. More COVID trials are phase 3 or 4 than non COVID trials.

Table 1: CT.gov registrations by year

Yr registered	COVID trials		All other trials		All trials	
	No.	% of all	No.	% of all	No.	% change in no. reg
1 st half 2019	6	0.05%	11,935	99.95%	11,941	
2 nd half 2019	10	0.09%	11,152	99.91%	11,162	-6.98%
1 st half 2020	1,234	12.36%	8,748	87.64%	9,982	-11.82%
2 nd half 2020	1,160	9.29%	11,325	90.71%	12,485	20.05%
1 st half 2021	918	6.82%	12,544	93.18%	13,462	7.26%
2 nd half 2021	672	5.46%	11,646	94.54%	12,318	-9.29%
1 st half 2022	452	3.59%	12,152	96.41%	12,604	2.27%

Table 2: Median sample size (SS) and inter quartile (IQ) range

Yr registered	COVID trials			All other trials		
	No.	Mdn SS	IQ range	No.	Mdn SS	IQ range
2020	1,741	100	10-304	20,103	60	30-150
2021	1,050	144	50-490	24,514	64	30-150

Table 3: Randomized trials

Yr registered	COVID trials			All other trials			All trials		
	No. registered	No. randomized	% randomized	No. registered	No. randomized	% randomized	No. registered	No. randomized	% randomized
2018	40	31	77.50%	22,084	14,370	65.07%	22,124	14,401	65.09%
2019	83	68	81.93%	22,488	14,662	65.20%	22,571	14,730	65.26%
2020	2,543	1,854	72.91%	19,302	12,331	63.88%	21,845	14,185	64.93%
2021	1,770	1,319	74.52%	23,794	15,174	63.77%	25,564	16,493	64.52%

Table 4: Multicentered trials

Yr registered	COVID trials			All other trials			All trials		
	No. registered	No. multicenter	% multicenter	No. registered	No. multicenter	% multicenter	No. registered	No. multicenter	% multicenter
2018	40	20	50.00%	22,084	6,594	29.86%	22,124	6,614	29.90%
2019	83	23	27.71%	22,488	6,656	29.60%	22,571	6,679	29.59%
2020	2,543	970	38.14%	19,302	6,269	32.48%	21,845	7,239	33.14%
2021	1,770	695	39.27%	23,794	8,954	37.63%	25,564	9,649	37.74%

Table 5: Randomized and Multicentered trials

Yr registered	COVID trials			All other trials			All trials		
	No. registered	No. Rz & multicenter	% Rz & multicenter	No. registered	No. Rz & multicenter	% Rz & multicenter	No. registered	No. Rz & multicenter	% Rz & multicenter
2018	40	14	35.00%	22,084	4,113	18.62%	22,124	4,127	18.65%
2019	83	20	24.10%	22,488	4,120	18.32%	22,571	4,140	18.34%
2020	2,543	787	30.95%	19,302	3,825	19.82%	21,845	4,612	21.11%
2021	1,770	542	30.62%	23,794	5,708	23.99%	25,564	6,250	24.45%

Table 6: Randomized and multicentered having data and safety monitoring boards (DSMBs)

Yr registered	COVID trials			All other trials			All trials		
	No. registered	No. having DSMB	% having DSMB	No. registered	No. having DSMB	% having DSMB	No. registered	No. having DSMB	% having DSMB
2018	40	10	25.00%	22,084	1,817	8.23%	22,124	1,827	8.26%
2019	83	11	13.25%	22,488	1,816	8.08%	22,571	1,827	8.09%
2020	2,543	787	30.95%	19,302	3,825	19.82%	21,845	4,612	21.11%
2021	1,770	331	18.70%	23,794	2,314	9.73%	25,564	2,645	10.35%

Table 7: Funding agency

Yr registered	COVID trials		All other trials		All trials	
	No.	%	No.	%	No.	%
2020						
US fed	100	2.30%	1,535	5.22%	1,635	4.84%
Industry	764	17.56%	6,186	21.04%	6,950	20.59%
Other	3,488	80.15%	21,678	73.74%	25,166	74.56%
Total	4,352		29,399		33,751	
2021						
US fed	125	4.20%	2,025	5.57%	2,150	5.47%
Industry	704	23.65%	7,827	21.54%	8,531	21.70%
Other	2,148	72.15%	26,488	72.89%	28,636	72.83%
Total	2,977		36,340		39,317	

Table 8: FDA phase of trial

Yr registered	COVID trials		All other trials		All trials	
	No.	%	No.	%	No.	%
2020						
Phase 2 or less	1,632	34.33%	8,521	27.76%	10,153	28.64%
Phase 3 or 4	1,430	30.08%	4,738	15.44%	6,168	17.40%
Phase not applicable	1,692	35.59%	17,434	56.80%	19,126	53.96%
Total	4,754		30,693		35,447	
2021						
Phase 2 or less	874	26.71%	10,923	28.67%	11,797	28.51%
Phase 3 or 4	880	26.89%	5,291	13.89%	6,171	14.92%
Phase not applicable	1,518	46.39%	21,888	57.45%	23,406	56.57%
Total	3,272		38,102		41,374	