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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Trials 2020

Now that we are in 2021 it is appropriate to reflect on 2020.

A year to remember! A year where cars sat in driveways. A year of social distancing and face mask mandates, covid testing and quarantines, empty restaurants, no contact food deliveries, and hugs and handshakes only memories.

Making it through 2020 (a lot did not) was a journey.

But trying as 2020 was, it made a household word out of epidemiology (no longer a skin disorder back in Sleepy Eye) and underscored the importance of medical research and trials, enough to put Tony Fauci on the cover of People Magazine.

What would you regard as important features of the 2020 sojourn as a trialist? My list is below.

Responsiveness of the trials research enterprise

There are almost 2,500 COVID-19 trials registered, virtually all started in 2020. The number includes several vaccines now in use throughout the world – An extraordinary accomplishment at warp speed for which all humankind is grateful.

Importance of modeling

Modeling with regard to the direction and scope of the pandemic has been uncanny in accuracy. Although they told us things we did not want to hear, the information is useful.

Counts of COVID cases and deaths

Enter COVID and country in Google and you likely will get a tracing of COVID cases and deaths over time for that country. The information, even if of varying accuracy, is useful in characterizing the pandemic. Thanks.

The primary source of information for the US is via the CDC. Under state disease reporting laws, hospitals, healthcare providers, and laboratories must report confirmed or probable COVID-19 cases and deaths to state or local health departments and from there to the CDC.

Flexibility

The research enterprise is not known for its flexibility. It can take months to get funding to do a trial and months more to get IRB and other approvals to start a trial. Those delays have, thanks to all concerned, have been shortened for the pandemic. Thanks.

Virtual consents and virtual patient visits

The rule of thumb for most trials is face-to-face consents and ditto for data collection, with IRBs unlikely to approve other forms except in special circumstances. Now in the COVID pandemic they have been more accommodating and flexible. Let us hope it continues.

Zooming

Zoom, is a video communications tool, founded by Eric Yuan (born in China; moved to Silicon Valley 1997); company went public in spring 2019; stock has quadrupled in price in 2020.

Before it was conference telephone, now it is Zoom with the features of conference telephone but with video hookups.

Resilience of the research enterprise

The research enterprise, worldwide, has shown remarkable resilience in addressing the COVID medical crisis. It should be comforting regardless of where we live.

Importance of registration of trials

There would not be anyway of tracking COVID trials without registration or any way to knowing results without postings when trials are finished.

Transition from office to home as workplaces

Thousands of people, used to the ritual of “going to work”, now, during the pandemic, are able to work in their PJs with a commute of 50 feet from bed room to “office” but the appeal wears thin with children and distance learning.

Adaptability of IRBs

Normally, it can take months to clear IRBs so a trial can start. Often IRBs are stumbling blocks in the startup and execution processes. They have shown remarkable flexibility in the COVID age. One can only hope that trend continues after the pandemic.

In writing this I asked my colleague, fellow trialist, Steve Piantadosi, what he regarded as noteworthy attributes and accomplishments of the trialist enterprise in the 2020 COVID pandemic. Below is what he wrote:

1. Excellent core values, even heroism, in clinical providers, researchers, and regulators
2. Successful responses to pressures to innovate in key areas, including by private enterprise
3. Disorganized but well meaning research efforts globally
4. Astonishing defects in political leadership at all levels without exception
5. The worst media coverage in human history
6. Gross deficiencies evidently for generations in science education in the public
7. Some disgusting individual selfishness based on greed, need, or stupidity