Less than a year to develop a COVID vaccine: Here's why you shouldn't be alarmed

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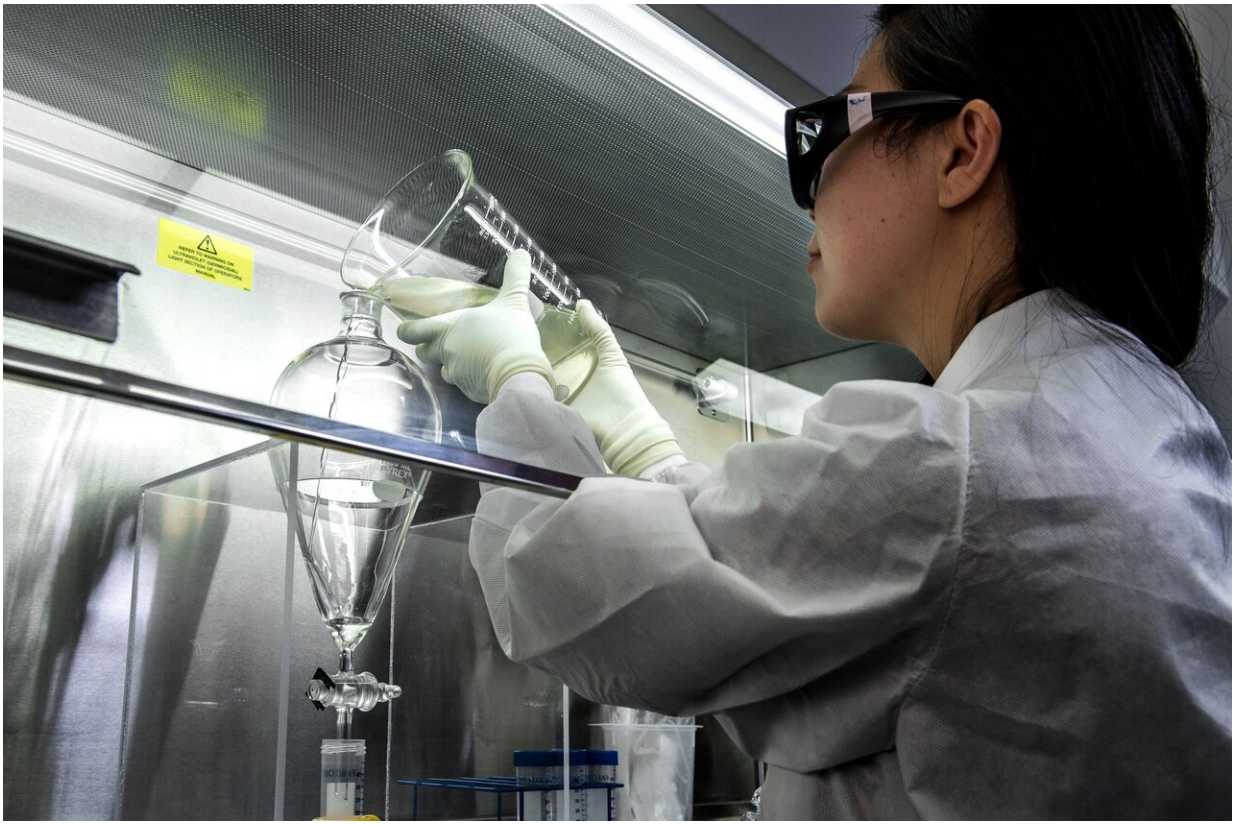

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I'm a clinical trials geek. I keep hearing people talk about the seven to ten years it takes to make a vaccine and how dangerous speeding this up might be. The word that keeps popping up is "rushed", and it is making

the average person nervous about vaccine safety. So, as a clinical trials doctor, I am going to tell you what I do for most of those ten years—and it is not very much.

I'm not lazy. I submit grants, have them rejected, resubmit them, wait for review, resubmit them somewhere else, sometimes in a loop of doom. When I am lucky enough to get trials funded, I then spend months on submitting to ethics boards. I wait for regulators, deal with personnel changes at the drugs company and a "change of focus" away from my trials, and eventually, if I am very lucky, I spend time setting up trials: finding sites, training sites, panicking because recruitment is poor, finding more sites. I then usually have more regulatory issues and, finally, if my big pot of luck is not used up, I might have a viable therapy—or not.

At this point, it might get delayed because of questions over profitability or any number of other obstacles. I'm not even going to go into the years it normally takes to get the "preclinical" studies, the ones before the human trials, done.

Ten years to develop a vaccine is a bad thing

So next time somebody expresses concern at the astonishing speed the vaccine trials have happened at, point out to them that ten years isn't a good thing, it's a bad thing. It's not ten years because that is safe, it's ten hard years of battling indifference, commercial imperatives, luck and red tape. It represents barriers in the process that we have now proved are "easy" to overcome. You just need unlimited cash, some clever and highly motivated people, all the world's trial infrastructure, an almost unlimited pool of altruistic, wonderful trial volunteers and some sensible regulators.

With all of this and the clock ticking on a global pandemic killing people

by the second, it turns out we can do amazing things. The vaccine trials have been nothing short of a miracle. A revolution in how we do trials that when you think about it is perhaps not that surprising given our ability to innovate when we really need to.

And we really need to—necessity being the mother of invention. Safety has not been compromised. All trials have been through the correct "phases" or process of any normal drug or vaccine. Hundreds of thousands of the very best of us volunteered and had an experimental vaccine. The world watched so closely that when a single person fell ill, we were all debating it.

To date, there has not been a single associated death related to COVID vaccines and only a handful of potentially serious events. Just imagine watching everybody in a small city for six months and reporting every single heart attack, stroke, neurological condition or anything that might be judged serious. How astonishing is this? It has been a triumph of medical science.

I haven't even touched on the lucky confluence of timing that meant this all happened at a time when sequencing all the genes in a person or virus is so routine nobody bats an eyelid. This turbocharged the early preclinical science needed as the foundation stone of several new technologies at the right point to be exploited.

At this time, three vaccines have already broken cover and demonstrated efficacy higher than we had ever hoped. The bar was set by regulators at around 50%. Both Moderna and Pfizer reported 95% efficacy, and Oxford University reported 90% efficacy for a particular dosage regimen. Safety data is still to follow, but the track record of vaccines is excellent, and I am an optimist.

None of this is to downplay the challenges still ahead. It is also not to say

vaccines are without safety questions still to be answered. It has been, however, a triumph of good process and great people. I am confident that when regulators pore over the safety and efficacy data, closely followed by every interested scientist in the world, that vaccines will only be used if their benefits clearly outweigh the risks—and you should be confident too.

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