

WEBVTT

NOTE duration:"00:17:38.2830000"

NOTE language:en-us

NOTE Confidence: 0.9057229

00:00:00.000 --> 00:00:02.115 Thank you for the opportunity.

NOTE Confidence: 0.9057229

00:00:02.115 --> 00:00:05.151 I will briefly talk about what we

NOTE Confidence: 0.9057229

00:00:05.151 --> 00:00:07.266 went through with the clinical

NOTE Confidence: 0.9057229

00:00:07.266 --> 00:00:09.290 trials during the pandemic.

NOTE Confidence: 0.9057229

00:00:09.290 --> 00:00:11.980 Um, related to COVID-19 vaccines.

NOTE Confidence: 0.9057229

00:00:11.980 --> 00:00:15.557 These are my disclosures I have in

NOTE Confidence: 0.9057229

00:00:15.557 --> 00:00:18.953 an investigator at the vaccine and

NOTE Confidence: 0.9057229

00:00:18.953 --> 00:00:21.305 Treatment Evaluation Unit founded

NOTE Confidence: 0.9057229

00:00:21.305 --> 00:00:25.630 by NIH from 2015 to 2020 until my

NOTE Confidence: 0.9057229

00:00:25.630 --> 00:00:29.174 relocation to Yale mid Pandemic in 2020.

NOTE Confidence: 0.9057229

00:00:29.174 --> 00:00:35.239 I'm a member of mRNA 1270 three study group.

NOTE Confidence: 0.9057229

00:00:35.240 --> 00:00:38.628 I'm discussing only what we have publicly

NOTE Confidence: 0.9057229

00:00:38.628 --> 00:00:41.959 available and I have no idea my dear.

NOTE Confidence: 0.9057229

00:00:41.960 --> 00:00:44.195 If you or approval for

NOTE Confidence: 0.9057229

00:00:44.195 --> 00:00:45.536 my current presentation,

NOTE Confidence: 0.9057229

00:00:45.540 --> 00:00:48.234 I had received funding through my

NOTE Confidence: 0.9057229

00:00:48.234 --> 00:00:50.549 institution to conduct clinical trials

NOTE Confidence: 0.9057229

00:00:50.549 --> 00:00:52.317 through from different companies

NOTE Confidence: 0.9057229

00:00:52.317 --> 00:00:54.950 and the bodies as listed here.

NOTE Confidence: 0.9057229

00:00:54.950 --> 00:00:58.088 I will briefly talk about the

NOTE Confidence: 0.9057229

00:00:58.088 --> 00:01:01.000 trial phases and then I will.

NOTE Confidence: 0.9057229

00:01:01.000 --> 00:01:03.382 Discuss what we did differently with

NOTE Confidence: 0.9057229

00:01:03.382 --> 00:01:06.637 the code 19 vaccine trials and I will

NOTE Confidence: 0.9057229

00:01:06.637 --> 00:01:08.622 share some pandemic challenges that

NOTE Confidence: 0.9057229

00:01:08.622 --> 00:01:11.229 we faced during during this time.

NOTE Confidence: 0.9057229

00:01:11.230 --> 00:01:14.362 So the term vaccinology or vaccination

NOTE Confidence: 0.9057229

00:01:14.362 --> 00:01:18.509 was first used by Doctor Edward Jenner.

NOTE Confidence: 0.9057229

00:01:18.510 --> 00:01:21.870 As many of you would know,

NOTE Confidence: 0.9057229

00:01:21.870 --> 00:01:23.030 Great Britain,

NOTE Confidence: 0.9057229

00:01:23.030 --> 00:01:25.930 although the idea of protecting  
NOTE Confidence: 0.9057229

00:01:25.930 --> 00:01:29.476 unimpacted using some sort of transferred  
NOTE Confidence: 0.9057229

00:01:29.476 --> 00:01:32.336 immunity from the infected individuals  
NOTE Confidence: 0.9057229

00:01:32.336 --> 00:01:35.870 has been had been around for awhile.  
NOTE Confidence: 0.9057229

00:01:35.870 --> 00:01:39.056 We have documentation from the 10th  
NOTE Confidence: 0.9057229

00:01:39.056 --> 00:01:42.360 century that shows that variolation.  
NOTE Confidence: 0.9057229

00:01:42.360 --> 00:01:45.846 Which is different form of transferring  
NOTE Confidence: 0.9057229

00:01:45.846 --> 00:01:49.760 immunity had been used in China and  
NOTE Confidence: 0.9057229

00:01:49.760 --> 00:01:52.742 then in 16th century in automating  
NOTE Confidence: 0.9057229

00:01:52.742 --> 00:01:56.088 prior but doctor Jenner had no tist  
NOTE Confidence: 0.9057229

00:01:56.088 --> 00:01:58.826 in 18th century was the milkmaids  
NOTE Confidence: 0.9057229

00:01:58.826 --> 00:02:01.066 who are often getting infected  
NOTE Confidence: 0.9057229

00:02:01.066 --> 00:02:04.318 with the car parks were somehow  
NOTE Confidence: 0.9057229

00:02:04.318 --> 00:02:06.746 protected against against smallpox.  
NOTE Confidence: 0.9057229

00:02:06.750 --> 00:02:09.400 They were either not getting  
NOTE Confidence: 0.9057229

00:02:09.400 --> 00:02:12.550 the disease or when they got.

NOTE Confidence: 0.9057229

00:02:12.550 --> 00:02:14.266 The disease they were,

NOTE Confidence: 0.9057229

00:02:14.266 --> 00:02:17.460 they were mild cases compared to other

NOTE Confidence: 0.9057229

00:02:17.460 --> 00:02:20.130 individuals who were dying quickly,

NOTE Confidence: 0.9057229

00:02:20.130 --> 00:02:22.944 like 30% mortality rate almost and

NOTE Confidence: 0.9057229

00:02:22.944 --> 00:02:26.299 the huge scars that they would have.

NOTE Confidence: 0.9057229

00:02:26.300 --> 00:02:29.444 So based on this information or

NOTE Confidence: 0.9057229

00:02:29.444 --> 00:02:32.030 observation Doctor Jenner collected pass

NOTE Confidence: 0.9057229

00:02:32.030 --> 00:02:35.294 from illusion of Milk Maid who had cowpox,

NOTE Confidence: 0.9057229

00:02:35.300 --> 00:02:37.670 then an inoculated that pass

NOTE Confidence: 0.9057229

00:02:37.670 --> 00:02:40.040 to an 8 year old.

NOTE Confidence: 0.9057229

00:02:40.040 --> 00:02:41.916 Otherwise healthy young men.

NOTE Confidence: 0.9057229

00:02:41.916 --> 00:02:45.330 And then after a couple of weeks,

NOTE Confidence: 0.9057229

00:02:45.330 --> 00:02:48.011 he this time in equated the same

NOTE Confidence: 0.9057229

00:02:48.011 --> 00:02:50.256 young man named James Phipps

NOTE Confidence: 0.9057229

00:02:50.256 --> 00:02:52.280 Phipps with the smallpox.

NOTE Confidence: 0.9057229

00:02:52.280 --> 00:02:54.584 And then Luckily dreams that very  
NOTE Confidence: 0.9057229

00:02:54.584 --> 00:02:57.409 well and seeing how we rank Doctor  
NOTE Confidence: 0.9057229

00:02:57.409 --> 00:02:59.839 General went on other people and  
NOTE Confidence: 0.9057229

00:02:59.839 --> 00:03:02.210 practice this on many other people.  
NOTE Confidence: 0.9057229

00:03:02.210 --> 00:03:04.190 As far as we know,  
NOTE Confidence: 0.9057229

00:03:04.190 --> 00:03:06.185 Doctor Jenner had the permission  
NOTE Confidence: 0.9057229

00:03:06.185 --> 00:03:09.026 from the parents of this young man  
NOTE Confidence: 0.9057229

00:03:09.026 --> 00:03:11.336 who were actually working for him.  
NOTE Confidence: 0.9057229

00:03:11.340 --> 00:03:13.972 So many of the things that was done  
NOTE Confidence: 0.9057229

00:03:13.972 --> 00:03:17.280 for this will not always do fly in our  
NOTE Confidence: 0.9057229

00:03:17.280 --> 00:03:19.893 day because Luckily we have ministrat  
NOTE Confidence: 0.9057229

00:03:19.893 --> 00:03:22.767 regulations to make sure that we're  
NOTE Confidence: 0.9057229

00:03:22.767 --> 00:03:25.300 maximizing the safety of the parts.  
NOTE Confidence: 0.9057229

00:03:25.300 --> 00:03:27.310 Once in our clinical trials,  
NOTE Confidence: 0.9057229

00:03:27.310 --> 00:03:28.510 including vaccine trials,  
NOTE Confidence: 0.9057229

00:03:28.510 --> 00:03:30.910 and we are maximizing our transparency,

NOTE Confidence: 0.9057229

00:03:30.910 --> 00:03:33.367 this I think the most important part

NOTE Confidence: 0.9057229

00:03:33.367 --> 00:03:36.317 of this is we are really diligent

NOTE Confidence: 0.9057229

00:03:36.317 --> 00:03:38.592 about informed consent process so

NOTE Confidence: 0.9057229

00:03:38.592 --> 00:03:41.415 that we don't repeat the same mistakes

NOTE Confidence: 0.9057229

00:03:41.415 --> 00:03:44.143 that we have done within the last

NOTE Confidence: 0.9057229

00:03:44.143 --> 00:03:46.148 century with the clinical trials.

NOTE Confidence: 0.9057229

00:03:46.150 --> 00:03:47.754 So typical vaccine trial,

NOTE Confidence: 0.9057229

00:03:47.754 --> 00:03:48.556 clinical trial,

NOTE Confidence: 0.9057229

00:03:48.560 --> 00:03:51.768 or we see comes after the laboratory on

NOTE Confidence: 0.9057229

00:03:51.768 --> 00:03:55.310 the anyone studies where we have an antigen.

NOTE Confidence: 0.8304252

00:03:55.310 --> 00:03:57.908 That would be the candidate vaccine,

NOTE Confidence: 0.8304252

00:03:57.910 --> 00:04:01.420 and we test the safety and the ability to

NOTE Confidence: 0.8304252

00:04:01.420 --> 00:04:04.839 provoke an immune response in animal studies.

NOTE Confidence: 0.8304252

00:04:04.840 --> 00:04:07.864 And then based on the animal challenge

NOTE Confidence: 0.8304252

00:04:07.864 --> 00:04:10.466 studies, we come up with a suggested

NOTE Confidence: 0.8304252

00:04:10.466 --> 00:04:13.929 those we apply to FDA under investigation.

NOTE Confidence: 0.8304252

00:04:13.930 --> 00:04:16.020 Only drag application and then

NOTE Confidence: 0.8304252

00:04:16.020 --> 00:04:19.080 we can go to humans phase one

NOTE Confidence: 0.8304252

00:04:19.080 --> 00:04:21.714 which is first in human studies,

NOTE Confidence: 0.8304252

00:04:21.720 --> 00:04:23.890 are usually less than 100.

NOTE Confidence: 0.8304252

00:04:23.890 --> 00:04:25.786 Otherwise completely healthy individuals.

NOTE Confidence: 0.8304252

00:04:25.786 --> 00:04:28.630 It is non blinded operate open

NOTE Confidence: 0.8304252

00:04:28.698 --> 00:04:31.830 label study design. It can be age,

NOTE Confidence: 0.8304252

00:04:31.830 --> 00:04:34.180 the escalation or those escalation.

NOTE Confidence: 0.8304252

00:04:34.180 --> 00:04:37.000 What we did with the model.

NOTE Confidence: 0.8304252

00:04:37.000 --> 00:04:38.302 NIH moderner trial.

NOTE Confidence: 0.8304252

00:04:38.302 --> 00:04:41.895 We started with 18 to 55 year old

NOTE Confidence: 0.8304252

00:04:41.895 --> 00:04:45.122 individuals and we started between 5 UG

NOTE Confidence: 0.8304252

00:04:45.122 --> 00:04:48.118 and once we have central participant

NOTE Confidence: 0.8304252

00:04:48.118 --> 00:04:52.064 skipping 25 UG did fine once we saw

NOTE Confidence: 0.8304252

00:04:52.064 --> 00:04:55.920 that we went 200 UG and then making.

NOTE Confidence: 0.8304252  
00:04:55.920 --> 00:04:58.416 After seeing that those two cohort,  
NOTE Confidence: 0.8304252  
00:04:58.420 --> 00:05:00.838 the sentiment cohorts with 25 and  
NOTE Confidence: 0.8304252  
00:05:00.838 --> 00:05:03.820 100 that well in terms of safety,  
NOTE Confidence: 0.8304252  
00:05:03.820 --> 00:05:07.384 we went to 250 UG with the safety and  
NOTE Confidence: 0.8304252  
00:05:07.384 --> 00:05:10.709 extent of the immune response information  
NOTE Confidence: 0.8304252  
00:05:10.709 --> 00:05:14.539 that we collected from phase one trial.  
NOTE Confidence: 0.8304252  
00:05:14.540 --> 00:05:15.821 Enrolled 120 individuals  
NOTE Confidence: 0.8304252  
00:05:15.821 --> 00:05:18.383 we went to phase two trial.  
NOTE Confidence: 0.8304252  
00:05:18.390 --> 00:05:21.138 This time 600 individuals and again  
NOTE Confidence: 0.8304252  
00:05:21.138 --> 00:05:24.259 we were looking for more data on  
NOTE Confidence: 0.8304252  
00:05:24.259 --> 00:05:27.059 safety and we were trying to figure  
NOTE Confidence: 0.8304252  
00:05:27.145 --> 00:05:30.001 out the dosing for the phase three  
NOTE Confidence: 0.8304252  
00:05:30.001 --> 00:05:32.550 trial and then with the phase  
NOTE Confidence: 0.8304252  
00:05:32.550 --> 00:05:35.190 three trial which followed the 600  
NOTE Confidence: 0.8304252  
00:05:35.190 --> 00:05:37.220 individuals from phase two trial,  
NOTE Confidence: 0.8304252



00:05:37.220 --> 00:05:39.788 we enrolled more than 30,000 individuals.  
NOTE Confidence: 0.8304252

00:05:39.790 --> 00:05:41.930 We similar to other studies.  
NOTE Confidence: 0.8304252

00:05:41.930 --> 00:05:43.316 It was randomized.  
NOTE Confidence: 0.8304252

00:05:43.316 --> 00:05:45.164 We had a civil.  
NOTE Confidence: 0.8304252

00:05:45.170 --> 00:05:48.306 We were still looking for the safety because  
NOTE Confidence: 0.8304252

00:05:48.306 --> 00:05:51.349 our phase one and phase two trials were  
NOTE Confidence: 0.8304252

00:05:51.349 --> 00:05:54.189 not powered to catch rare side effects,  
NOTE Confidence: 0.8304252

00:05:54.190 --> 00:05:56.927 but this was the first time officially,  
NOTE Confidence: 0.8304252

00:05:56.930 --> 00:06:00.002 the outcome was the efficacy of the vaccine  
NOTE Confidence: 0.8304252

00:06:00.002 --> 00:06:03.195 as defined for the modern NIH Moderna trial.  
NOTE Confidence: 0.8304252

00:06:03.200 --> 00:06:05.986 It was defined as this symptomatic COVID-19  
NOTE Confidence: 0.8304252

00:06:05.986 --> 00:06:08.298 infection 14 days after those two,  
NOTE Confidence: 0.8304252

00:06:08.300 --> 00:06:10.260 and then with that information,  
NOTE Confidence: 0.8304252

00:06:10.260 --> 00:06:12.492 or we should be at the  
NOTE Confidence: 0.8304252

00:06:12.492 --> 00:06:14.959 company went to FDA got April.  
NOTE Confidence: 0.8304252

00:06:14.960 --> 00:06:16.920 What can follow up there?

NOTE Confidence: 0.8304252

00:06:16.920 --> 00:06:20.240 This is phase four trials which is not.

NOTE Confidence: 0.8304252

00:06:20.240 --> 00:06:23.138 Industry if the manufacturer wants in,

NOTE Confidence: 0.8304252

00:06:23.140 --> 00:06:26.996 you know as if they have the funding.

NOTE Confidence: 0.8304252

00:06:27.000 --> 00:06:29.898 They can continue to test the

NOTE Confidence: 0.8304252

00:06:29.898 --> 00:06:31.832 vaccine for safety, effectiveness,

NOTE Confidence: 0.8304252

00:06:31.832 --> 00:06:33.760 and other potential users.

NOTE Confidence: 0.8304252

00:06:33.760 --> 00:06:36.420 This process from identification are

NOTE Confidence: 0.8304252

00:06:36.420 --> 00:06:39.699 the valid validation of the antigen

NOTE Confidence: 0.8304252

00:06:39.699 --> 00:06:42.359 in animal models to completion

NOTE Confidence: 0.8304252

00:06:42.359 --> 00:06:45.124 of the regulatory process usually

NOTE Confidence: 0.8304252

00:06:45.124 --> 00:06:47.320 takes almost two decades.

NOTE Confidence: 0.8304252

00:06:47.320 --> 00:06:49.684 We just heard from Doctor Grace

NOTE Confidence: 0.8304252

00:06:49.684 --> 00:06:52.430 about the about the Ebola vaccine,

NOTE Confidence: 0.8304252

00:06:52.430 --> 00:06:55.454 but I think many of us can remember

NOTE Confidence: 0.8304252

00:06:55.454 --> 00:06:57.700 the rotavirus which was implemented

NOTE Confidence: 0.8304252

00:06:57.700 --> 00:07:00.526 to try with immunization in 2006.  
NOTE Confidence: 0.8304252

00:07:00.530 --> 00:07:03.086 It took more than three decades  
NOTE Confidence: 0.8304252

00:07:03.086 --> 00:07:04.790 for the hepatitis B.  
NOTE Confidence: 0.8304252

00:07:04.790 --> 00:07:06.915 This was about two decades  
NOTE Confidence: 0.8304252

00:07:06.915 --> 00:07:08.615 and again for Zika.  
NOTE Confidence: 0.8304252

00:07:08.620 --> 00:07:12.028 It is still an ongoing process with HIV.  
NOTE Confidence: 0.8304252

00:07:12.030 --> 00:07:14.760 It is still an ongoing process  
NOTE Confidence: 0.8304252

00:07:14.760 --> 00:07:17.489 and with murr's the same way.  
NOTE Confidence: 0.8304252

00:07:17.490 --> 00:07:20.040 Have the vaccine up there couple  
NOTE Confidence: 0.8304252

00:07:20.040 --> 00:07:22.610 years and even longer with Zika.  
NOTE Confidence: 0.8304252

00:07:22.610 --> 00:07:25.172 We did better with the most  
NOTE Confidence: 0.8304252

00:07:25.172 --> 00:07:26.453 recent influenza pandemic,  
NOTE Confidence: 0.8304252

00:07:26.460 --> 00:07:28.926 which was item and identified in  
NOTE Confidence: 0.8304252

00:07:28.926 --> 00:07:31.812 2009 and by October in the United  
NOTE Confidence: 0.8304252

00:07:31.812 --> 00:07:34.134 States we got the vaccines but  
NOTE Confidence: 0.8304252

00:07:34.134 --> 00:07:36.469 with the influenza pandemic H1N1

NOTE Confidence: 0.8304252  
00:07:36.469 --> 00:07:39.265 it was using the same platform.  
NOTE Confidence: 0.7910958  
00:07:39.270 --> 00:07:41.405 It was almost like a  
NOTE Confidence: 0.7910958  
00:07:41.405 --> 00:07:43.540 proving for any big litters.  
NOTE Confidence: 0.7910958  
00:07:43.540 --> 00:07:45.875 Have review process was similar  
NOTE Confidence: 0.7910958  
00:07:45.875 --> 00:07:47.743 to seasonal influenza vaccine.  
NOTE Confidence: 0.7910958  
00:07:47.750 --> 00:07:49.754 What happened with COVID-19  
NOTE Confidence: 0.7910958  
00:07:49.754 --> 00:07:51.257 was quite impressive.  
NOTE Confidence: 0.7910958  
00:07:51.260 --> 00:07:53.570 They the after the identification  
NOTE Confidence: 0.7910958  
00:07:53.570 --> 00:07:56.510 and reporting of the first unusual  
NOTE Confidence: 0.7910958  
00:07:56.510 --> 00:07:59.270 pneumonia cases late December 2019.  
NOTE Confidence: 0.7910958  
00:07:59.270 --> 00:08:03.689 It took less than two weeks for the China  
NOTE Confidence: 0.7910958  
00:08:03.689 --> 00:08:07.788 CDC to share the genome of the Navy,  
NOTE Confidence: 0.7910958  
00:08:07.790 --> 00:08:09.886 identified coronavirus and impressively  
NOTE Confidence: 0.7910958  
00:08:09.886 --> 00:08:13.609 it took almost two months from having  
NOTE Confidence: 0.7910958  
00:08:13.609 --> 00:08:16.615 this information to having our first  
NOTE Confidence: 0.7910958

00:08:16.615 --> 00:08:19.099 participant get getting the vaccine.  
NOTE Confidence: 0.7910958

00:08:19.100 --> 00:08:22.058 And for for Phase one trial,  
NOTE Confidence: 0.7910958

00:08:22.060 --> 00:08:25.636 this is 5 days after the  
NOTE Confidence: 0.7910958

00:08:25.636 --> 00:08:28.020 Bleacher calling in pandemic.  
NOTE Confidence: 0.7910958

00:08:28.020 --> 00:08:30.384 And then I guess even more  
NOTE Confidence: 0.7910958

00:08:30.384 --> 00:08:31.960 impressive is after consenting,  
NOTE Confidence: 0.7910958

00:08:31.960 --> 00:08:35.326 this young man for Phase one I got my  
NOTE Confidence: 0.7910958

00:08:35.326 --> 00:08:38.446 first dose of inage modern vaccine here  
NOTE Confidence: 0.7910958

00:08:38.446 --> 00:08:42.137 at yeah less than nine months after it.  
NOTE Confidence: 0.7910958

00:08:42.140 --> 00:08:42.646 Um?  
NOTE Confidence: 0.7910958

00:08:42.646 --> 00:08:45.176 And the whole process from  
NOTE Confidence: 0.7910958

00:08:45.176 --> 00:08:47.200 identification of the SARS,  
NOTE Confidence: 0.7910958

00:08:47.200 --> 00:08:48.788 Co E22 vaccine rollout,  
NOTE Confidence: 0.7910958

00:08:48.788 --> 00:08:51.170 at least in the United States,  
NOTE Confidence: 0.7910958

00:08:51.170 --> 00:08:53.558 was a year or even less.  
NOTE Confidence: 0.7910958

00:08:53.560 --> 00:08:56.122 So there are a couple of things

NOTE Confidence: 0.7910958

00:08:56.122 --> 00:08:59.026 that were unique to quit 19 and how

NOTE Confidence: 0.7910958

00:08:59.026 --> 00:09:01.840 we ran clinical trials and how we

NOTE Confidence: 0.7910958

00:09:01.840 --> 00:09:03.876 identified our vaccine candidate.

NOTE Confidence: 0.7910958

00:09:03.880 --> 00:09:06.256 First of all, we had tryouts.

NOTE Confidence: 0.7910958

00:09:06.260 --> 00:09:09.436 We had SARS, we had the first one.

NOTE Confidence: 0.7910958

00:09:09.440 --> 00:09:10.601 We had Merce,

NOTE Confidence: 0.7910958

00:09:10.601 --> 00:09:12.923 so we were very familiar with

NOTE Confidence: 0.7910958

00:09:12.923 --> 00:09:14.640 the corner viruses.

NOTE Confidence: 0.7910958

00:09:14.640 --> 00:09:17.832 And we were lucky to have Doctor

NOTE Confidence: 0.7910958

00:09:17.832 --> 00:09:20.281 Korba and Doctor Graham who

NOTE Confidence: 0.7910958

00:09:20.281 --> 00:09:23.239 had been working on Murs Spike

NOTE Confidence: 0.7910958

00:09:23.239 --> 00:09:26.306 protein and they had item fight

NOTE Confidence: 0.7910958

00:09:26.306 --> 00:09:28.786 that died in animal studies.

NOTE Confidence: 0.7910958

00:09:28.790 --> 00:09:30.814 The antibodies against spike

NOTE Confidence: 0.7910958

00:09:30.814 --> 00:09:33.344 protein were protective and they

NOTE Confidence: 0.7910958

00:09:33.344 --> 00:09:36.009 were inducing niessing response.

NOTE Confidence: 0.7910958

00:09:36.010 --> 00:09:38.410 So this part was fast.

NOTE Confidence: 0.7910958

00:09:38.410 --> 00:09:41.074 We already had the antigen to

NOTE Confidence: 0.7910958

00:09:41.074 --> 00:09:43.690 be included in the vaccine.

NOTE Confidence: 0.7910958

00:09:43.690 --> 00:09:45.845 The second unique feature of

NOTE Confidence: 0.7910958

00:09:45.845 --> 00:09:49.099 this pandemic is we had a huge

NOTE Confidence: 0.7910958

00:09:49.099 --> 00:09:51.629 federal initiative that is called

NOTE Confidence: 0.7910958

00:09:51.629 --> 00:09:54.205 Operation Warp Speed that targeted

NOTE Confidence: 0.7910958

00:09:54.205 --> 00:09:57.127 914 months for the whole process.

NOTE Confidence: 0.7910958

00:09:57.130 --> 00:10:00.106 This initiativ came with a large.

NOTE Confidence: 0.7910958

00:10:00.110 --> 00:10:00.930 Large funding,

NOTE Confidence: 0.7910958

00:10:00.930 --> 00:10:03.390 but I guess the most important

NOTE Confidence: 0.7910958

00:10:03.390 --> 00:10:06.439 thing that they were able to do was

NOTE Confidence: 0.7910958

00:10:06.439 --> 00:10:09.178 bringing many people who are on the

NOTE Confidence: 0.7910958

00:10:09.178 --> 00:10:12.048 networks together to work on COVID-19 Maxine.

NOTE Confidence: 0.7910958

00:10:12.050 --> 00:10:14.160 These individuals who had been

NOTE Confidence: 0.7910958

00:10:14.160 --> 00:10:16.270 doing vaccine trials for decades

NOTE Confidence: 0.7910958

00:10:16.345 --> 00:10:17.617 they had the reach.

NOTE Confidence: 0.7910958

00:10:17.620 --> 00:10:20.804 They did not have to run clinical trials.

NOTE Confidence: 0.7910958

00:10:20.810 --> 00:10:22.795 They were very familiar with

NOTE Confidence: 0.7910958

00:10:22.795 --> 00:10:23.986 the regulatory process,

NOTE Confidence: 0.7910958

00:10:23.990 --> 00:10:26.456 so they came under the umbrella

NOTE Confidence: 0.7910958

00:10:26.456 --> 00:10:28.370 of COVID-19 Prevention Network Co.

NOTE Confidence: 0.7910958

00:10:28.370 --> 00:10:30.480 BPN, and it was not.

NOTE Confidence: 0.7910958

00:10:30.480 --> 00:10:32.152 Only in Indiana State,

NOTE Confidence: 0.7910958

00:10:32.152 --> 00:10:35.350 but it was a global global effort.

NOTE Confidence: 0.8210816

00:10:37.590 --> 00:10:40.490 And then we all watched.

NOTE Confidence: 0.8210816

00:10:40.490 --> 00:10:44.599 I guess online or once on news

NOTE Confidence: 0.8210816

00:10:44.599 --> 00:10:48.589 outlets that within 10 to 1213 months.

NOTE Confidence: 0.8210816

00:10:48.590 --> 00:10:51.490 All of this was completed.

NOTE Confidence: 0.8210816

00:10:51.490 --> 00:10:55.459 What was different in addition to the

NOTE Confidence: 0.8210816



00:10:55.459 --> 00:10:58.420 preclinical phrases and the network  
NOTE Confidence: 0.8210816

00:10:58.420 --> 00:11:01.906 creation about code 19 vaccine trials,  
NOTE Confidence: 0.8210816

00:11:01.910 --> 00:11:05.414 was this unique approach in a  
NOTE Confidence: 0.8210816

00:11:05.414 --> 00:11:07.750 regular traditional vaccine trial.  
NOTE Confidence: 0.8210816

00:11:07.750 --> 00:11:10.516 Usually phrase one completes its enrollment,  
NOTE Confidence: 0.8210816

00:11:10.520 --> 00:11:13.558 then the data is under review for  
NOTE Confidence: 0.8210816

00:11:13.558 --> 00:11:16.882 awhile and then once it is locked  
NOTE Confidence: 0.8210816

00:11:16.882 --> 00:11:19.292 and the analysis are completed,  
NOTE Confidence: 0.8210816

00:11:19.300 --> 00:11:20.896 we start phase two.  
NOTE Confidence: 0.8210816

00:11:20.896 --> 00:11:24.380 So it is 123 in a stepwise.  
NOTE Confidence: 0.8210816

00:11:24.380 --> 00:11:26.750 But with the COVID-19 trials what  
NOTE Confidence: 0.8210816

00:11:26.750 --> 00:11:29.930 we did it was overlapping faces,  
NOTE Confidence: 0.8210816

00:11:29.930 --> 00:11:32.235 not skipping faces by overlapping  
NOTE Confidence: 0.8210816

00:11:32.235 --> 00:11:33.618 them telescope fashion.  
NOTE Confidence: 0.8210816

00:11:33.620 --> 00:11:36.428 So we had phase two before  
NOTE Confidence: 0.8210816

00:11:36.428 --> 00:11:37.832 we complete started.

NOTE Confidence: 0.8210816

00:11:37.840 --> 00:11:40.276 Before we had Phase one completed

NOTE Confidence: 0.8210816

00:11:40.276 --> 00:11:42.946 and the other important feature was

NOTE Confidence: 0.8210816

00:11:42.946 --> 00:11:45.371 the companies with the guaranteed

NOTE Confidence: 0.8210816

00:11:45.371 --> 00:11:47.610 funding from Operation Warspeed.

NOTE Confidence: 0.8210816

00:11:47.610 --> 00:11:50.340 They did not wait for the results

NOTE Confidence: 0.8210816

00:11:50.340 --> 00:11:53.236 of Phase three trial to start

NOTE Confidence: 0.8210816

00:11:53.236 --> 00:11:55.976 manufacturing large amounts of vaccine.

NOTE Confidence: 0.8210816

00:11:55.980 --> 00:11:59.700 I know we still with the regulatory bodies,

NOTE Confidence: 0.8210816

00:11:59.700 --> 00:12:03.558 everything was done on fast track.

NOTE Confidence: 0.8210816

00:12:03.560 --> 00:12:07.080 But we did not see any phrase again,

NOTE Confidence: 0.8210816

00:12:07.080 --> 00:12:09.660 the information that we were supposed

NOTE Confidence: 0.8210816

00:12:09.660 --> 00:12:12.798 to collect from each phases were there.

NOTE Confidence: 0.8210816

00:12:12.800 --> 00:12:16.760 We show with the phase one that the larger,

NOTE Confidence: 0.8210816

00:12:16.760 --> 00:12:18.364 the higher the dose.

NOTE Confidence: 0.8210816

00:12:18.364 --> 00:12:20.770 The second dose had been correlated

NOTE Confidence: 0.8210816

00:12:20.849 --> 00:12:23.359 with the higher reactivation state,  
NOTE Confidence: 0.8210816

00:12:23.360 --> 00:12:26.798 and then we did see that they saw and  
NOTE Confidence: 0.8210816

00:12:26.798 --> 00:12:30.254 after the second dose has a nice human  
NOTE Confidence: 0.8210816

00:12:30.254 --> 00:12:34.029 response and we have it threatening affect.  
NOTE Confidence: 0.8210816

00:12:34.030 --> 00:12:35.332 With 250 UG,  
NOTE Confidence: 0.8210816

00:12:35.332 --> 00:12:37.936 so the decision was made on  
NOTE Confidence: 0.8210816

00:12:37.936 --> 00:12:40.547 the safety and the email.  
NOTE Confidence: 0.8210816

00:12:40.550 --> 00:12:43.400 Jenna City information to go with  
NOTE Confidence: 0.8210816

00:12:43.400 --> 00:12:46.283 hundred UG for the Phase three  
NOTE Confidence: 0.8210816

00:12:46.283 --> 00:12:49.405 trial as it was going to happen.  
NOTE Confidence: 0.8210816

00:12:49.410 --> 00:12:52.300 Work in regular traditional vaccine  
NOTE Confidence: 0.8210816

00:12:52.300 --> 00:12:56.054 trials and we had this nice graph  
NOTE Confidence: 0.8210816

00:12:56.054 --> 00:12:59.785 at the end of at the end of I  
NOTE Confidence: 0.8210816

00:12:59.785 --> 00:13:02.177 think December showing that.  
NOTE Confidence: 0.8210816

00:13:02.180 --> 00:13:05.589 The vaccine was effective more than 90%.  
NOTE Confidence: 0.8210816

00:13:05.590 --> 00:13:08.894 If efficacious, more than more than 99%.

NOTE Confidence: 0.8210816  
00:13:08.900 --> 00:13:11.265 So there are unique challenges  
NOTE Confidence: 0.8210816  
00:13:11.265 --> 00:13:13.157 about how things went.  
NOTE Confidence: 0.8210816  
00:13:13.160 --> 00:13:16.464 One of them was as a researcher.  
NOTE Confidence: 0.8210816  
00:13:16.470 --> 00:13:18.358 We were always late.  
NOTE Confidence: 0.8210816  
00:13:18.358 --> 00:13:20.246 There were that lines,  
NOTE Confidence: 0.8210816  
00:13:20.250 --> 00:13:23.141 and we were always trying to catch  
NOTE Confidence: 0.8210816  
00:13:23.141 --> 00:13:25.543 up something and then everything  
NOTE Confidence: 0.8210816  
00:13:25.543 --> 00:13:28.765 outside were changing on daily basis.  
NOTE Confidence: 0.8210816  
00:13:28.770 --> 00:13:30.706 The transportation was different.  
NOTE Confidence: 0.8210816  
00:13:30.706 --> 00:13:34.179 We had stay at home orders that  
NOTE Confidence: 0.8210816  
00:13:34.179 --> 00:13:36.115 prevented our participants to  
NOTE Confidence: 0.8210816  
00:13:36.115 --> 00:13:38.535 show up for their visits.  
NOTE Confidence: 0.8210816  
00:13:38.540 --> 00:13:41.000 We had cancellation of commercial  
NOTE Confidence: 0.8210816  
00:13:41.000 --> 00:13:44.311 flights which caused way to get the  
NOTE Confidence: 0.8210816  
00:13:44.311 --> 00:13:47.006 study product from NIH to our site.  
NOTE Confidence: 0.8210816

00:13:47.010 --> 00:13:48.794 And then, you know,  
NOTE Confidence: 0.8210816

00:13:48.794 --> 00:13:51.024 we didn't have enough masks.  
NOTE Confidence: 0.8210816

00:13:51.030 --> 00:13:53.706 You would not have this challenge  
NOTE Confidence: 0.8210816

00:13:53.706 --> 00:13:56.758 with any other study, but remember,  
NOTE Confidence: 0.8210816

00:13:56.758 --> 00:13:59.928 this is March 2020 and.  
NOTE Confidence: 0.8210816

00:13:59.930 --> 00:14:01.614 Masking or masking mandates  
NOTE Confidence: 0.8210816

00:14:01.614 --> 00:14:03.719 are we're not that common.  
NOTE Confidence: 0.8210816

00:14:03.720 --> 00:14:06.744 Then we were staying in the same room  
NOTE Confidence: 0.8210816

00:14:06.744 --> 00:14:10.457 with the participant for two to three hours,  
NOTE Confidence: 0.8210816

00:14:10.460 --> 00:14:12.132 and we have masks,  
NOTE Confidence: 0.8210816

00:14:12.132 --> 00:14:14.640 but we don't know when they're  
NOTE Confidence: 0.8210816

00:14:14.726 --> 00:14:17.590 going to last and how are we going  
NOTE Confidence: 0.8210816

00:14:17.590 --> 00:14:20.290 to have additional masks so we  
NOTE Confidence: 0.8210816

00:14:20.290 --> 00:14:22.660 didn't have any PPE accept.  
NOTE Confidence: 0.8210816

00:14:22.660 --> 00:14:25.600 Accept the gloves and the  
NOTE Confidence: 0.8210816

00:14:25.600 --> 00:14:28.540 homemade masks for awhile an.

NOTE Confidence: 0.8210816

00:14:28.540 --> 00:14:31.110 The other biggest challenge that

NOTE Confidence: 0.8210816

00:14:31.110 --> 00:14:35.361 we did not really plan for was two

NOTE Confidence: 0.8210816

00:14:35.361 --> 00:14:38.535 schools and childcare settings and how.

NOTE Confidence: 0.65800613

00:14:38.540 --> 00:14:41.650 Lockdown effective.

NOTE Confidence: 0.65800613

00:14:41.650 --> 00:14:43.806 Functioning society function manual

NOTE Confidence: 0.65800613

00:14:43.806 --> 00:14:45.962 fire participants didn't have

NOTE Confidence: 0.65800613

00:14:45.962 --> 00:14:48.317 grandparents who were available to

NOTE Confidence: 0.65800613

00:14:48.317 --> 00:14:50.729 take care of the younger individuals.

NOTE Confidence: 0.65800613

00:14:50.730 --> 00:14:54.554 Given the high risk with the code 19.

NOTE Confidence: 0.65800613

00:14:54.560 --> 00:14:57.670 Many of our staff members

NOTE Confidence: 0.65800613

00:14:57.670 --> 00:15:00.780 did not have backup plans.

NOTE Confidence: 0.65800613

00:15:00.780 --> 00:15:02.980 And I guess most right,

NOTE Confidence: 0.65800613

00:15:02.980 --> 00:15:04.740 most impressively, or Interestingly,

NOTE Confidence: 0.65800613

00:15:04.740 --> 00:15:07.380 we were online all the time.

NOTE Confidence: 0.65800613

00:15:07.380 --> 00:15:10.299 There was a huge social media an

NOTE Confidence: 0.65800613

00:15:10.299 --> 00:15:12.660 interest in what we're doing,  
NOTE Confidence: 0.65800613

00:15:12.660 --> 00:15:15.940 what we're not doing, we.  
NOTE Confidence: 0.65800613

00:15:15.940 --> 00:15:18.050 This was something that we  
NOTE Confidence: 0.65800613

00:15:18.050 --> 00:15:20.160 were not really prepared for.  
NOTE Confidence: 0.65800613

00:15:20.160 --> 00:15:21.306 To be honest,  
NOTE Confidence: 0.65800613

00:15:21.306 --> 00:15:23.980 this young man again here giving his  
NOTE Confidence: 0.65800613

00:15:24.059 --> 00:15:26.717 blood Lisa Ann guitar student nurses  
NOTE Confidence: 0.65800613

00:15:26.717 --> 00:15:29.869 are with the homemade masks and gloves.  
NOTE Confidence: 0.65800613

00:15:29.870 --> 00:15:31.554 Nothing else was available.  
NOTE Confidence: 0.65800613

00:15:31.554 --> 00:15:33.238 And then you know,  
NOTE Confidence: 0.65800613

00:15:33.240 --> 00:15:35.949 after our wizard he is on CNN  
NOTE Confidence: 0.65800613

00:15:35.949 --> 00:15:38.115 with Doctor Sanjay Gupta telling  
NOTE Confidence: 0.65800613

00:15:38.115 --> 00:15:40.420 about how I consented him.  
NOTE Confidence: 0.65800613

00:15:40.420 --> 00:15:43.675 What I told him and what was  
NOTE Confidence: 0.65800613

00:15:43.675 --> 00:15:46.175 in the consent form. Um?  
NOTE Confidence: 0.65800613

00:15:46.175 --> 00:15:51.140 Which is which is in a way a good thing,

NOTE Confidence: 0.65800613  
00:15:51.140 --> 00:15:52.828 because this young man,  
NOTE Confidence: 0.65800613  
00:15:52.828 --> 00:15:55.360 as we heard from the CNN,  
NOTE Confidence: 0.65800613  
00:15:55.360 --> 00:15:57.470 is an MD PhD student.  
NOTE Confidence: 0.65800613  
00:15:57.470 --> 00:16:00.654 He has the you know he can consent  
NOTE Confidence: 0.65800613  
00:16:00.654 --> 00:16:04.170 and he can process work or we see  
NOTE Confidence: 0.65800613  
00:16:04.170 --> 00:16:07.179 what we are trying to tell him.  
NOTE Confidence: 0.65800613  
00:16:07.180 --> 00:16:10.176 But there were many other messages out  
NOTE Confidence: 0.65800613  
00:16:10.176 --> 00:16:13.560 there that we had no control and our  
NOTE Confidence: 0.65800613  
00:16:13.560 --> 00:16:16.979 participants were on TV or on social media.  
NOTE Confidence: 0.65800613  
00:16:16.980 --> 00:16:18.680 We don't talking with us.  
NOTE Confidence: 0.65800613  
00:16:18.680 --> 00:16:20.370 We were supposed to have  
NOTE Confidence: 0.65800613  
00:16:20.370 --> 00:16:21.722 conversations with them about,  
NOTE Confidence: 0.65800613  
00:16:21.730 --> 00:16:23.758 you know, do you have pain?  
NOTE Confidence: 0.65800613  
00:16:23.760 --> 00:16:26.514 But we would hear it from news outlet before  
NOTE Confidence: 0.65800613  
00:16:26.514 --> 00:16:29.180 we hear it from from our participants.  
NOTE Confidence: 0.65800613



00:16:29.180 --> 00:16:31.441 So there are couple of things I  
NOTE Confidence: 0.65800613

00:16:31.441 --> 00:16:33.249 think remaining as a challenge.  
NOTE Confidence: 0.65800613

00:16:33.250 --> 00:16:35.290 You need to quit 19 first.  
NOTE Confidence: 0.65800613

00:16:35.290 --> 00:16:37.746 One is like what is going to happen  
NOTE Confidence: 0.65800613

00:16:37.746 --> 00:16:40.019 with the placebo recipients for the  
NOTE Confidence: 0.65800613

00:16:40.019 --> 00:16:42.876 phase three trial you I'm sure you  
NOTE Confidence: 0.65800613

00:16:42.876 --> 00:16:45.264 have heard about the unblinding and.  
NOTE Confidence: 0.65800613

00:16:45.270 --> 00:16:46.810 I'm providing vaccines based  
NOTE Confidence: 0.65800613

00:16:46.810 --> 00:16:48.350 on what is recommended.  
NOTE Confidence: 0.65800613

00:16:48.350 --> 00:16:49.890 Recommended with the VA.  
NOTE Confidence: 0.65800613

00:16:49.890 --> 00:16:52.200 We have not included any children,  
NOTE Confidence: 0.65800613

00:16:52.200 --> 00:16:53.932 pregnant women or transplant  
NOTE Confidence: 0.65800613

00:16:53.932 --> 00:16:56.530 recipients to our trials and we  
NOTE Confidence: 0.65800613

00:16:56.603 --> 00:16:59.123 don't know how it is going to work.  
NOTE Confidence: 0.65800613

00:16:59.130 --> 00:17:01.518 And you know with the vaccines  
NOTE Confidence: 0.65800613

00:17:01.518 --> 00:17:04.517 that are shown to be more than 90%

NOTE Confidence: 0.65800613  
00:17:04.520 --> 00:17:07.306 efficacious it is going to be a  
NOTE Confidence: 0.65800613  
00:17:07.306 --> 00:17:09.680 different error to test another vaccine  
NOTE Confidence: 0.65800613  
00:17:09.680 --> 00:17:13.758 and we will see how it is going to play out.  
NOTE Confidence: 0.65800613  
00:17:13.760 --> 00:17:16.904 I want to end by saying none of.  
NOTE Confidence: 0.65800613  
00:17:16.910 --> 00:17:18.962 This would happen if we did  
NOTE Confidence: 0.65800613  
00:17:18.962 --> 00:17:21.100 not have all into yourself.  
NOTE Confidence: 0.65800613  
00:17:21.100 --> 00:17:23.767 I want to thank each of them,  
NOTE Confidence: 0.65800613  
00:17:23.770 --> 00:17:25.675 and if you're still interested  
NOTE Confidence: 0.65800613  
00:17:25.675 --> 00:17:26.437 in volunteering,  
NOTE Confidence: 0.65800613  
00:17:26.440 --> 00:17:28.340 please go to this website.  
NOTE Confidence: 0.65800613  
00:17:28.340 --> 00:17:30.825 We have studies with the  
NOTE Confidence: 0.65800613  
00:17:30.825 --> 00:17:32.813 vaccines and treatment options  
NOTE Confidence: 0.65800613  
00:17:32.813 --> 00:17:35.820 and we still need one tears and  
NOTE Confidence: 0.65800613  
00:17:35.820 --> 00:17:38.283 thank you for having me today.