Media Conference on COVID-19 Vaccines
19 August 2020

Resource speakers:
Dr. Jaime C. Montoya - Executive Director, DOST-Philippine Council for Health Research and Development
Dr. Lulu Bravo - Executive Director, Philippine Foundation for Vaccination
Dr. Eric Domingo - Director General, Food and Drug Administration

***Guests*:**
Sec. Fortunato T. Dela Peña - Secretary, Department of Science and Technology (DOST)
Usec. Rowena Cristina Guevara - Undersecretary for Research and Development, DOST
Dr. Nina Gloriani - Chair, DOST Vaccine Expert Panel
ASec. Leah Buendia - Assistant Secretary for International Cooperation, DOST

Moderators:
Dr. Isagani Padolina - R&D Head, Pascual Laboratories**,**
Dr. Ma. Liza Antoinette Gonzales - Associate Dean for Faculty and Students, University of the Philippines Manila

Dr. Ma. Liza Antoinette Gonzales:
Good morning everyone, thank you for joining the Media Conference on COVID-19 Vaccines. My name is Dr. Ma. Liza Antoinette Gonzalez.I am an Associate Dean and a Professor at the University of the Philippines - Manila (UPM, and I will be moderating today's press conference together with Dr. Gani Padolina. We are hosting this conference in behalf of the Sub-Technical Working Group on Vaccine Development to which multiple government agencies are involved including the DOH, DOST, FDA, DFA, NDC and DTI.Today's online conference is a response to the demand for up-to-date and credible information on the status of the government's unprecedented efforts on COVID-19 vaccine research and collaborations. Joining us in our online conference today are three resource speakers who are directly involved in our negotiations with our international partners and vaccine developers. Now before we proceed, let us first hear from the Department of Science and Technology (DOST) Secretary Hon. Fortunato dela Peña for his message.

Sec. Fortunato T. Dela Peña
Thank you, Dr. Gonzales. Good morning everyone, welcome to this media conference on COVID-19 vaccines. I would like to greet Director General Eric Domingo of the Food and Drug Administration (FDA), Dr. Lulu Bravo, the Executive Director of the Philippine Foundation for Vaccination, we also have Dr. Rontgene Solante, Chair of the Adult Infectious Diseases and Tropical Medicine Center of the San Lazaro Hospital, I can see Dr. Isagani Padolina from Pascual Pharma, I would also like to recognize, I'm sure she is here, Dr. Nina Gloriani, and of course we have USec. Rowena Cristina Guevara of DOST, Executive Director Dr. Jaime Montoya of the DOST-Philippine Council for Health Research and Development, other members of our expert panel, we welcome you today in this online media conference as a response to the urgent need for up-to-date and credible information on our current initiatives and ongoing discussions with our partners for COVID-19 vaccine research and collaborations.

The queries and sometimes the misimpressions that reach me, I requested our group, the DOST, to come up with a Frequently Asked Questions (FAQs) material. Actually they did, but it was a better idea that a media conference be held so that we can tackle the various issues.

As a highly-communicable disease, COVID-19 has challenged the way our communities and systems work. To help save lives and to stem the virus' transmission, we rely on solutions that are brought about by science, technology and innovation. From hospital management to boosting the economy, we at the Department have been mobilizing our resources and capacities to respond to the pressing challenges brought about by the pandemic. We actually report every week on what we have been doing and we follow the suggested categorization given to us by our communications office - that we follow the 4K categories. So we report our efforts on *Kalusugan,* and that definitely includes what we have been doing with regards to collaborations. We also report in *Kaayusan*, or anything that hopes to improve the

systems and the management of services that are related to addressing COVID-19. We also include a report on *Kabuhayan*, and definitely this is very important - particularly now. We also made a report on *Kinabukasan* or our preparations for the future.

Recognizing how vaccine development requires infrastructure, expertise, resources, and a lengthy and rigorous process, we evaluate possible partnerships with other countries with the most advanced candidates as the first short-term approach in securing a potential supply of vaccines. The ones we approached are the countries where we have bilateral agreements on Science and Technology. Together with the Department of Health (DOH), we also commit to support the country's participation in the WHO vaccine solidarity trials. This is a global action to develop a vaccine against COVID-19 and participation in these WHO clinical trials ensures that the country will secure equitable access to the global supply of the potential vaccine.

While we are called to work faster to provide the needed solutions, we commit to advancing Science for the benefit of the Filipino people - without compromising processes, research results and the welfare of human participants in research. We rely a lot of course on the expertise of our Vaccine Expert Panel, we have our Sub-Technical Working Group on Vaccine Development under the IATF for Emerging Infectious Diseases, and of course we rely heavily also on our different ethics committees or ethics board because this will all require human participation.

Allow me to thank therefore, all of you - our resource speakers, and of course our co-organizers here and the media who are present here today for being our partners in disseminating reliable and relevant information. We hope that you will utilize this platform as an opportunity to raise your questions and clarify your concerns on our COVID-19 initiatives,

Now more than ever, we are called to build on solidarity to bring solutions closer to our communities and to our people. Muli, maraming salamat sa inyong lahat. Thank you.

Dr. Ma. Liza Antoinette Gonzales:
Thank you Sec. Dela Peña, and now for the most awaited part of the program, we proceed to the question and answer portion. Just a little housekeeping before we start, we gathered the frequently asked questions from the media. Our resource speakers will provide the answers to each unique query. We tried to categorize the questions into six general questions so that we will have a smooth transition during the Q&A. Joining us today are DOST-PCHRD Executive Director Dr. Jaime C. Montoya, Philippine Foundation for Vaccination Executive Director Dr. Lulu Bravo, and Food and Drug Administration Director General Dr. Eric Domingo. Welcome to our three panelists.

As the moderator, and I have a co-moderator, which is Dr. Gani Padolina who will be helping me field out the questions. So we will start asking our panelists the first set of questions to which a panel member will answer. In case any of you have follow-up questions, please type them in the Q&A panel.Take note that you have to mention who your question is for. I'll put them on the list and we'll do our best to accommodate everyone's questions. Without further ado, let's start with the Q&A part. For the first question, this question is for Dr. Jaime Montoya. May I please ask Dr. Gani Padolina to please ask the first question.

Dr. Isagani Padolina:
Good morning everyone, this first question is for Dr. Jaime Montoya, Executive Director of PCHRD: Why is it that only rich countries like the USA, Germany, Japan, Russia, China and other European countries can make vaccines, while a poor country like us cannot make one, or is not able to make one?

Dr. Jaime Montoya:
Yes, good morning to everyone, thank you for the question, Dr. Padolina. As I understand it, vaccine development and production requires huge investments and resources. Once the Philippines has already been classified as a low-middle income country, we do admit that we still have a lot of things to do and to upgrade and enhance in order to attain this ability to manufacture vaccines. For example, R&D for vaccine development would require significant scientific talent

development involving several disciplines, planning, infrastructure, capacity building for the state of the art laboratory facilities and training sufficient human resources. As far as I know, we also have to upgrade our whole value chain, as far as vaccine availability is concerned. We really have to do a lot of development, but I assure the public that the government is already doing a lot of negotiations and discussions and grants in order to achieve some degree of vaccine sufficiency so that we are able to respond to the pandemic such as what we are experiencing now. Thank you.

Dr. Ma. Liza Antoinette Gonzales:
Thank you very much Dr. Montoya. The second question is how much is the cost to make a vaccine and is that why we cannot make one? Dr. Montoya?

Dr. Jaime Montoya:
Well, you know as I was saying, there's a lot of investments required to make a vaccine and most companies will tell you that they actually factor in the cost from R&D, proof of concept to marketing. All of that has to be built in to the final cost of the product. So we imagine that for this COVID-19 pandemic vaccine, it would really be expensive. However, a lot of initiatives have already been started by the WHO for example through what we call the COVAXX facility to make sure that vaccines are actually affordable and available to all countries. Based on the arrangements with that particular facility of which the Philippines is participating, the vaccine will roughly approximately cost about $10 per vial. Of course, this is an average cost - it may be higher or lower than this but the important thing is there is a global effort to bring down the cost of the vaccine so that most countries including the low-middle-income countries will be able to afford and buy.

Dr. Ma. Liza Antoinette Gonzales:
In a related question Dr. Montoya, in producing a vaccine, is it the cost or the highly-qualified scientists, researchers and other members of Science that determine its discovery and production?

Dr. Jaime Montoya:
Actually all of those factors are important. As I was saying, when you imagine a factory line of vaccine production - it starts from the concept to the final product, which is actually distributed to the people who will use it. From the proof of concept, you need a scientist, you need the people who think about the development of the vaccine - how it's going to be tested then you have to go to the trials. For example, if you've gone through the proof of concept stage, you have to subject them to trials. We have what we call pre-clinical and clinical trials that will be discussed later. And then after the clinical trial phase, you have to actually submit or have the product registered with the regulatory agencies. So depending on how good the results are from the clinical trials, then you will get an approval or product registration and afterwhich, the product will be made available to the public. So that is the whole value chain, when it leaves the production line, it has to end up with the eventual user. For example the value chain, the cold chain, should be there - how to make it intact and viable until it reaches its eventual customer is very important. So we should actually have a clear idea of the whole value chain and that is taken into consideration for developing a vaccine and maybe to some extent, to how much a vaccine would cost.

Dr. Ma. Liza Antoinette Gonzales:
Dr. Montoya, is the Philippines working on a vaccine? And if we are not working on a vaccine, why not? So I guess this relates to again the COVID-19 vaccine.

Dr. Jaime Montoya:

Maybe if it is alright I would refer that to the chair of our Sub-Technical Working Group on Vaccines, Undersecretary Rowena Guevara to answer the question, because she has a more holistic view of the problem and the situation. Thank you.

Usec. Rowena Cristina Guevara:
Currently, we do not have the research facility to undertake the research in developing a vaccine, but we have been working on establishing a Virology Science and Technology Institute of the Philippines. We already got the funding for the R&D. we're starting next year. This will not just deal with human viruses but also viruses against animals and plants. The why not is because, we are just starting but we are very fortunate that we have started developing the human resource since 2007, so we have the MS and the PhDs in all the right fields, and we have the MD-PhDs who will help us undertake and develop vaccines for the future pandemics. But for now, we don't have it.

Dr. Ma. Liza Antoinette Gonzales:
Thank you very much Usec. Guevara. The next set of questions is actually regarding the processes or procedures in the development of vaccines. This talks about pre-clinical testing and clinical trials. I'd like to call on Dr. Gani Padolina, my co-moderator to please ask the next set of questions.

Dr. Isagani Padolina:
The next set of questions is for Dr. Lulu. Good morning, Dr. Lulu. There are two sets of questions related to each other, the first one is - what are the necessary processes needed to be completed before a vaccine could be administered to the public, and related to that, what is pre-clinical testing?

Dr. Lulu Bravo:
Thank you very much Dr. Padolina. That is a subject we can discuss for many hours, because it really takes many years to really develop a vaccine from the time that you were able to identify.. Alam mo na kung ano yung iyong mikrobyo. Hahanapin doon ng mga scientist yung part ng mikrobyo na kukunan nila para gawing bakuna. And that takes a long time. You know the protein substance that is in that organism, yung mismong mikrobyo hahanapin nila don, anong parte ng mikrobyo na magiging good enough to do a vaccine from. And true enough sito sa COVID-19, medyo na-shortcut doon. Kasi China was able to identify that and shared it with the world. Actually I think, it was sometime early January or December na ibinigay ng China yung genetic material ng COVID-19 having been able to identify it right and shared it to the world, so na shortcut ngayon ang vaccine development. Well as it may take years and years, yun iyong tinatawag nating laboratory, yun ang proof of concept, ano doon sa mikrobyo ang gagawin mong unit or kukunin mo ba yung buong mikrobyo at gagawin mo nalang… papatayin mo nalang, yung tinatawag na killed vaccines diba? Yung buong mikrobyo, what we call inactivated, at iyon nalang ang ibibigay mo para maging bakuna because there are many ways of vaccine developmen. So ang nangyari sa COVID na shortcut iyon, we were able to get the genetic composition and now, from January up to now, it was going to be a race to go from animal studies, kukunin nila iyong unit na iyon at ibibigay sa animals tapos kung safe sa animals at nakaka produce ng vaccine or ng antibodies puwedeng ng gawin sa humans and that is where the human clinical trial starts. Okay?

So before the humans are involved in the trial, that is what we call pre-clinical trial, from the time na kumuha ng mikrobyo na gawin kung pwede yang maging bakuna, pwede yang gawing ganito, marami yang ways… sabi nga natin so many ways of killing the cat ano. Ganun din yan, hindi parepareho ang pag gawa ng bakuna, so there are now more than two hundred vaccines in development by different companies. They are racing against time and trying to outdo each other to go from the clinical to the manufacturing and I guess this is what is happening now. In the Philippines, I heard a question earlier 'Bakit daw ang Pilipinas ay'… si Dr. Guevarra nga sinagot niya yan. Napaka laking investment ang gumawa ng bakuna from the time that you need to do laboratory identification and testing to the time of clinical trials.

Dito sa COVID, nandito na tayo sa Phase 3 dahil marami ng bansa at marami ng manufacturers ang gumawa ng Phase 1 at Phase 2. In fact, iyon ang ating ma ico-contribute dito sa COVID-19, that we are ready to undertake what we call Phase 3 na marami na ang bibigyan ng bakuna. Kasi sabi nga natin, yung clinical human trial starts with Phase 1, konti lang iyon, ite-test mo lang sa mga bibigyan mo ng bakuna right? Ang tawag doon ay safety phase 1, checkin mo kung

walang mangyayaring masama sa mga pasyente or sa mga binigyan mo, mga less than 100 lang ang binibigyan noon. In fact, yung iba 45 lang then yung iba 50 lang or 70. Pag dating sa Phase 2, titignan mo na kung hindi lang safe kung hindi nakaka develop sa katawan ng tao ng antibodies right? Once you are sure na mayroong antibodies, okay mayroon napoproduce na bakuna sa katawan, and that usually takes about a hundred or about a thousand subjects to do. MAs maraming bigyan ng bakuna, mas maganda ang confidence mo doon sa bakuna diba? Kasi makikita mo na marami ang sumasali… kasi alam mo iba iba ang reaction na tao sa bakuna, walang pareho, maski yung level ng antibodies hindi parepareho iyan, mayroong mas konti mayroong mas marami mayroong middle lang, so pinag aaralang mabuti ano yung average, ano iyong karamihan… 50 percent of those big given ay ganito ang level ng kanilang antibodies. Then we are now on Phase 3, iyan ang pinaka magagawa natin ngayon at iyan ang ino-offer sa atin... I think DOST is now ready to do that, yung maramihan na, hing lang isang daan kung hindi libo-libo ang pwedeng mabigyan ng bakuna to test na the safety rin… syempre all the way lagi iyan, tine-test yung saftey na walang mangyayaring masamasa mga babakunahan at titignan na kung iyong bakuna ay talagang makakapag protect sa mga tao laban sa COVID. Iyon ang tinatawag na efficacy trial dahil ang efficacy trial mo, bibigyan mo ang isang grupo ng bakuna, yung isang grupo walang bakuna… ang tawag dun ay palcibo or saline lang or tubig lang or bibigyan mo ng tinatawag na comparator vaccine or ibang bakuna. Hindi alam noong nabigay o nag iimbistiga o ng pasyente kung ano ang natanggap niya dahil kailang na pareho sila na alam natin na kapag finallowup yung na iimbestiga, hindi siya bias, wala siyang bias… uy ito may bakuna dapat ganito ang mangyayari. Hindi dapat ganon, wala sila dapat alam. Blinded ang tawag doon, hindi nila alam kung sino ang nag karoon ng bakuna at sino ang walang bakuna. And during the next one year, hopefully, six months to one year sabi nga nila, the longer it takes for you to follow them up, doon mo makikita kung mag kakaroon sila ng COVID o hindi. Doon mo ikukumpara kung iyong mga nabigyan mo ng bakuna ay nailigtas sa COVID at iyong walang bakuna ay iyon ang mga nag kaka COVID. And that is when you compute now kung effective, or efficacious not effective, efficacious yung bakuna, anong percentage ang ma poprotektahan ng bakuna. So iyon ang Phase 3, once you have a good study, you submit it to FDA.. andiyan na si Dr. Domingo na mag sasabi sa inyo kung aaprubahan niya, base… base, the basis is the study, the data that you produce from Phase 1, Phase 2, Phase 3, dapat iyan isinasubmit sa FDA natin para sila ang mag approve kung maganda at efficacious at mapapakinabangan natin, ligtas ang bakuna para mabigyan nila ng lisensiya para maibigay yan o rollout sa mga tao for public use. Now Phase 4, tinatawag nating post-marketing, iyan na iyong maski bago, lalo na kung bago yung bakuna, continuously minomonitor yan para makita kapag milyon milyon na ang binibigyan mo ng bakuna, mayroon ka paring posibleng makitang side effect na hindi mo nakita noong ginagawa iyong trial sa libo libo lang kasi iba yung makikita mong trial kapag… ay makikita mong effect kapag milyon milyon na ang binibigyan. So that in a short way, I can describe what the vaccine development is all about.

Thank you Dr. Padolina.

Dr. Isagani Padolina: Salamat po Dr. Lulu. Uhm, question din ito para sa inyong dalawa ni Dr. Jimmy. Uhm, balikan po natin… salamat pumunta narin kayo doon sa different phases, balikan lang po natin iyong isang tanong na paano po nirerecruit iyong mga volunteers para doon sa Phase 3 trials. Ito nga Ma'am yung tinatawag nating mga bayani talaga dahil sila yung mag vo-volunteer doon sa Phase 3. Paano po iyon nire-recruit?

Dr. Jaime Montoya: Sisimulan ko yung pag sagot Dr. Isagani if it's allright then dadagdagan nalang ni Dr. Lulu.

Ang pagkukuha ng mga lalahok sa pagsusuri sa clinical trial ay una base sa isang set of selection criteria. Ito iyong mga panuntunan kung ano ang mga kailangang characteristic ng mga pasyente o mga tao na sasali sa clinical trial at ito ay base sa protocol na dinedevelop ng vaccine developer. So kaniya kaniya po iyan, at base po doon makikita ninyo, pwedeng na pwedeng naka saad doon iyong age, kung anong age ang isasama doon sa clinical trial, kasi depende po sa bakuna, mayroon silang mga target na age groups. Pwede rin kasing makita doon kung anong mga klase ng tao ang kanilang target, halimbawa pwedeng healthcare worker, mga fontliner, nag tatarabaho sa mga ospital, o pwedeng mga nasa komunidad. So pwede iyon.

At tingin ko ang napaka halaga dito ay kailangan randomized iyon. Ano ba yung sinasabing randomized? Ibig sabihin, lahat ng mga sasali ay may equal chances magkaroon ng pagkakataong sumali kasi para lahat ng kategorya, lahat ng klase ng tao ay mapapasama at hangga't maari doon sa clinical trial.

Of course, bago sila sumali, ang pinaka importante na tingin ko ay sasabihin din ni Dr. Lulu ay iyong tinatawag nating pre-prior informed consent. So ito yung FPIC, ano ba ito? Ipaliliwanag sa mga lalahok ano yung clinical trial, iyong ano 'yung produkto, anong posibleng epekto nito, bakit ito ibinibigay, at ano ang maaaring mangyari pag ikaw ay lumahok. So ito ay para malaman ng mga lalahok kung ano ba ang mga pwedeng mangyari sa kanila pag sila ay sumali dahil boluntaryo ito, hindi sila pwedeng pilitin. So kung sila ay papayag, naiintindihan nila kung ano ang pag aaral na gagawin at sila ay lalagda dito sa informed consent. So pwede na silang lumahok. So yun po ang sa madaling salita, iyon po ang pamamaraan kung paano sumali sa clinical trial.

Ewan ko, Dr. Lulu baka gusto mong dagdagan ng iba pang detalye.

Dr. Lulu Bravo: Thank you Jimmy. Ang tanong kasi nila, paano tayo nag rerecruit. Gusto ko lang sabihin na ang Pilipinas ay isa sa mga bansa sa ASIA pacific na paborito ng mga manufacturers na gumawa ng trials kasi magagaling ang ating mga scientist na gumagawa nito diba? Ang paano tayo nag rerecruit? Magaling kaming mag paliwanag sa mga pasiyente kung ano ang papasukan nilang trial. For example, whether it is a flu trial, whether it is a polio, whether it is in yung mga hepatitis B. Alam mo almost 40 years na akong gumagawa ng vaccine trials since the 90s and laging importante yung sinabi mo, informed consent. Hindi tayo yung kagaya noong panahon ni Hitler diba na basta ka nalang kukuha tapos gagwin mo yung gusto mong mngyari. Hindi ganoon. We spend time trying to inform all our subjects kung ano ang mangyayari sa kanila from beginning to end, anong mahihita nila. Kung minsan sasabihin mo nga, anong benepisyo. Sa ngayon, wala ka pang masasabi na benefit na mangyayari sa bakuna kasi hindi pa talaga natin alam. Part yan ng ating study, ang makukuha lang nilang benefits ay number one, kung sakali na talagang magaling ang bakuna edi benefit na iyon. In fact, isa yan sa mga ginagawa nating information na kung sakali na makita na beneficial o magaling yung bakuna, yung grupo na hindi nabigyan ng bakuna… di ba may isang grupo na hindi bakuna ang ibibigay mo diba? Ibang bakuna or placibo. Pwede silang mag request o mabigyan ng bakunang iyon. Kung mapatunayan natin na maganda yung bakuna, yung grupo na hindi nabakunahan, pwede silang mabigyan kung gusto nila kasi makikita mo kapag binuksan mo na yung resulta ng study na wow yung mga nabakunahan pala, ang ganda ng naging resulta, hindi sila nagkaroon ng COVID tapos ito iyong mga hindi nabakunahan tapos sila yung mga nag ka COVID. Isang benepisyo yan diba?

And of course, ang isang magandang nakikita namin diyan, na aalagaan namin ng husto ang mga subjects para silang may private physician na puros eksperto pa. Diba kapag sumali ka sa isang research, marami ngang sumasali sa research ng malignancy sa cancer sa ganon diba, sumasali sila kasi nabebenipisyohan sila in terms of the check up. Para silang may private [doctor] na aalagaan sila throughout the follow up at nabibigyan sila ng konting… may sakit sila, wow, dito na agad, bibigyan sila ng check up, bibigyan sila ngtest para malaman kung ligtas sila. Alam mo, in fact, sa totoo lang, iyan ang isa sa napaka gandang benepisyo na sometimes nakaka inganyo sa kanila na sumali din kasi alagang alaga natin ang mga nasa trial. And mind you, I think the Philippines is very good at this kasi maganda ang rapport natin sa mga subjects natin eh. MArami na kami, naku libo libo na siguro in the last 30 years na nagawa naming vaccine trails, wala kaming nag karoon talaga ng.. I will tell you this ha, honestly, marami na kaming nakita na trials and trialist, wala pa ni isa na nag karoon ng problema, ng issue tungkol diyan sa ginawang trial na subject. Wala pa kaming subject na nag karoon ng problema, lahat sila ay maganda ang nagiging resulta.

So yun lang. Thank you very much Jimmy.

Dr. Isagani Padolina: Dr. Lulu at tska Dr. Jimmy, maraming mga questions eh na dumarating dun sa chat group at marami ring related dito. So ita-try long imoderate para matanong na natin ngayon habang napag uusapan na natin ng mabuti.

Doon sa pag recruit Ma'am Lulu, may bayad po ba iyon, yung mga ni-rerecruit natin na mga pasyente? Tanong po ito ni Caroline Bonquin.

Dr. Jaime Montoya: Sagutin ko yan kasi Ethical Issue yan. Ako kasi ay may kaunting nalalaman tungkol sa Ethics. So ang importante kasi diyaan, dapat ang mga lalahok sa isang clinical trial ay hindi ma distorbo. Kumbaga dapat ay kung sila man ay sasali sa isang clinical trial, isang araw na mawawala sa kanilang trabaho kunwari, at siya kunwari ay nag tatrabaho, o isang ina na nag aalaga ng mga anak sa bahay, syempre mauubos ang oras nila sa pag lahok sa clinical trial. Yan po ay tinatawag nating compensation, para ito sa oras na sila nadoon sa clinical trial. So yan po ay binibigyan,

pati po yung pagkain kung kinakailangan, at iyong transporation kung sila kailangan pumunta sa isang lugar na medyo malayo sa kanilang bahay, iyan po ay bibigyan sila ng kaunting halaga. Pero kailangang isipan na itong halagang ito ay hindi malaki. Ito ay compensation lamang para doon sa oras na kanilang iginugugol sa clinical trial.
Bakit? Ayaw naming magbibigay, o yung mga trialist, hindi pwedeng mag bigay ng malalaking halaga. Bakit? Kasi baka yung mga tao ay sumasali hindi dahil naiintindihan nila yung makukuha nila sa trial o boluntaryo nilang gagawin kung hindi, ginagawa nila dahil may bayad at malaki. So that is what we call undu inducement sa clinical trial, iniiwasan natin yan. So enough compensation ang ibinibigay. Yun lang. At of course, pasasalamat na sila ay sumali sa clinical trail.

Oh Dr. Lulu, baka gusto mo dagdagan.

Dr. Lulu Bravo: Tama yan Jimmy. Actually that is correct. Hindi tayo dapat magbigay ng sobra sobra na magiging undue. Nakasulat yan sa informed consent natin. Pero alam mo, different times nakakatuwa kasi if you listen to CNN, ang sabi sa CNN… alam mo yan ang favorite kong source ngayon ng mga vaccine trials sa abroad. Sa US daw, 350, 000 na ang nag enlist para sumali sa clinical trial, they only need 100, 000 pero 350, 000 na raw ang nag enlist. DIba ang dami daming gusto sumali sa trial? At marami diyan doctor pa ha, mga frontliners. So ibig sabihin naiintindihan nila kung ano ang magiging benepisyo kung sakali sumali sa trial. Kasi may kaklase nga ako na doktor eh, sumali siya na mabigyan ng bakuna. 350,000. Pero eto ang sinasabi ko, ang sabi ng CNN or sabi nung vaccine trialist, I think it was Moderna, yung kay Dr. Fauci, ang sabi nila, yung 350,000 na nag enlist, only about 10 percent are blacks and latinos. Ibig sabihin, yan yung mga hindi masyadong maganda ang estado sa buhay diba? Yung income group. ANg gusto nga nila ang mas marami ay yung katino at mga blacks, yung mga colored kasi yun ang mga mas delikado sa COVID but ang nakita nila ang mas marami nanag e-enroll or nag e-enlist ay mga puti at tska nasa taas, you know, frontliners.

So anong ibig sabihin noon? Hindi naman iyong inducement lang.

[40:01 - 60:00] CJ

Dr. Lulu Bravo: Nasa 350 000, pero ito ang sinasabi ko. Ang sabi ng vaccine trialist, I think yung sa moderna, yung kay Dr. Faucci, ang sabi nila, yung 350 000 na nagenlist, only about 10% are blacks and latinos, ibig sabihin, yan yung mga hindi masyado maganda ang buhay, yung mga income group, kasi ang gusto nga nila mas marami ang Latino at mga blacks, yung mga colored, kasi yun ang mas delikado sa COVID. But ang nakita nila, mas marami ang nag eenroll na mga puti at frontliners, so ano ang ibig sabihin non? Hindi naman yung inducement plan. Ang malaking nakikita ng mga tao sa pagsali sa trial is yung maaring benepisyo. At yon, pag naiintindihan mo yon, at ipinaliwanag sa iyo ng husto ng mga trialists, I think ay napakagandang ano yan, hindi lang yung pera, I doubt if it is just the money, and mind you, yung sinet aside ng ERB na pera, kulang na, dahil wala tayong transportation. Kailangan mag-grab ka, eh magkano ang Grab? Isang distance lang 500 na e pano pabalik? O another 500. Yan ang problema namin ngayon kasi ang laki na nag kulang dun sa tinatawag mo Jimmy kanina na compensation, kasi yung sinet aside o in-approve ng ERB na ibibigay na transportation, sa nanahon ngayon, kulang. [laughs] Sorry ha, we have to amed that kasi sa Grab lang 500 na para pumunta ang pasyente doon sa site.

Dr. Isagani Padolina: Ma'am, so maraming tanong na...gusto ko lang sabihan kila Maria Catherine Cruz, Kristine Sabillo na nakita namin yung mga tanong nyo at itatanong namin as soon as it is appropriate. Ma'am last na tanong, kasi meron akong tanong rito para kay DG Domingo sa FDA, so para kina Dr. Jimmy at saka Dr. Lulu ulit. Yung mga dinadala nating volunteers, ini-infect ba natin yan ng virus? Ganun ba ang ating mode? Baka gusto nyong iexplain kung paano naeexpose.

Dr. Jaime Montoya: Okay, kailangan nating linawin ano, ang pinag-uusapan natin ay bakuna. Ang bakuna ay binibigay sa mga taong wala pang sakit at ito ay ibinibigay para maproteksyonan ka sa sakit. So ibig sabihin, kung ito ay ating i-tetest, sa isang clinical trial, ito ay para sa malulusog, o yung mga taong wala pang sakit, kasi hindi ito gamot. Ang gamot binibigay kapag maysakit ka, pag binigyan ka gagaling ka. Ito, kailangan walang sakit ang bibigyan ng bakuna. At usually ginagawa ito sa isang lugar na may transmission na tinatawag o yung maraming kaso ng COVID. Bakit? Dahil kailangang malaman natin kung ang isang tao ay naexpose, o nagkaroon ng pagkakataon na mai-harap sa isang

nakakahawang virus. Sya ay hindi magkakaroon ng sakit dahil binigyan sya ng bakuna. Yung bakuna ang nag-stimulate at nagpasigla ng kanyang immune system para laban yung impreksyon. So klaruhin natin na ang bakuna ay ibinibigay sa walang sakit. At ito ay ibinibigay para maproteksyunan sya para sa sakit o doon sa sa virus.

Dr. Isagani Padolina: Kaya po siguro importante na kailangan natin ma-elaborate na ang ating mga clinical studies ay nandun sa mga high prevalence areas. Pwede po ba ninyo i-elaborate iyon?

Dr. Jaime Montoya: Well yes, bibigyan ko lang ng introducksyon utong Solidarity Trial, kasi yung trial na gagawin natin sa Pilipinas na committed tayong i-support, ay isa iyon sa pinakamahalagang criterion para gawin. Gagawin iyon sa isang lugar na maraming kaso, dahi ibig sabigin, merong nangyayaring transmission dyan o pagpapasa pasa noong virus sa populasyon na iyon. Doon magandang subukan ang bakuna dahil doon natin makikita kung epektibo. Although may mga test pang gagawin.

Dr. Lulu Bravo: Merong mga pagkakataon na merong human challenge, na magbibigay ka ng bakuna, pagkataps, iinfect mo. Madalas ginagawa yon sa preclinical, sa mga animasl, sa mga monkey, guinea pigs para maging sigurado na nakakatulong yung bakuna. Sa humans, the ethic review commitee, I doubt, will do that. Kasi sabi nila para mapabilis yung resulta, para malaman mo agad kung talagang makakapag protect yan sa tao, edi gawin mo. I-challenge mo or bugyan mo ng COVID-19, pero the ethics review committee will never do that, dahil walang gamot sa COVID. Alam mo sa malaria ginawa yan e noong araw, pero sa COVID, hindi mangayayri yun an bigyan mo ng sakit para malaman kung ang nabakunahan ay naprotektahan o hindi, per yun ang pinaka mabilis na paraan para malaman mo talaga kung naka protekta yung bakuna o hindi.

Dr. Jaime Montoya: Linawin ko lang ano, kasi baka akala ng ating mga kababayan e gumagawa tayo ng human challenge. Sa Pilipinas, hindi natin ipahihintulot yung ganong pamamaraan ng pag-aaral, dahil that is a violation of human rights, dahil kahit sya ay pumayag pa, alam nating wala namang gamot para sa COVID-19 sa ngayon. Walang ethics review board na mag-aapprove sa Pilipinas para payagan ang ganoong pag-aaral.

Dr. Isagani Padolina: Central po ang FDA regulatories dito sa pagaaral natin sa COVID-19 vaccine. Sir Eric, will the manufacturer finish Phase IV trial before he can distribute? Kailan po ba iaapprove ng FDA ang pag distribute ng vaccine?

Dr. Eric Domingo: Katulad po ng in-explain ni Dr. Lulu Bravo kanina, yung Phase I, II and II clinical trial na po ang nagseset ng safety at efficacy ng bakuna. So after the Phase II trial, makikita na po natin yung safety profile nya tsaka yung efficacy at maari na po syang i-register. Ibig sabihin, maari na po syan i-approve ng FDA for distribution pero for monitored release. Ibig sabihin, maari na po syang ibenta at gamitin, pero yun hong manufacturer at distributor ay binabantayan po at nirereport sa FDA kung may makikita pong adverse effect o side effects. Yun pong Phase IV CT, tinatawag pong post-marketing surveillance o post authorization, ibig pong sabihin, nalisensyahan na at pwede na po syang ibenta, at binabantayan natin for the next two to three years kung meron pa tayong makikita na possible side effects sa matagal na panahob bago lumabas, o kaya pag milyon miyon na yung nabakunahan, yung mga very rare na possible adverse events na pwede nating makita. Pero yun po, post marketing na po yung Phase IV, ibig sabihin sa Phase III, lisensyado na at pwede na po syang magamit at maibenta with strict monitoring.

Dr. Ma. Liza Antoinette Gonzales: Question po from Ms. Carolyn Bonquin. The government plans to have a vaccine manufacturing facility in the Philippines, which areas will these be established? And how soon can we set these up?

Dr. Jaime Montoya: Marami tyaong mga eksperto ngayon na naandito, at tingin ko ay bigyan natin sila ng pagkakataon na sagutin itong tanong na ito. Nakikita ko dito si Asec Leah Buendia, baka po pwede natin ipaliwanag sa kanila ang ating ginagawa.

Asec Leah Buendia: Actually in the short term, the manufacturing of vaccine will just be a fill in finish, ito po yung una naming plano with the SubTWG of which maraming agencies ang members. Dahil kung fill in finish, ay pinakamabilis, at pangalawa, private sector are willing to collaborate with us on this. But in the long term, I think a manufacturing facility by which we will have already the capacity to produce, will hopefully be in place. Also, there will be a research and development component, of which yun po yung sinasabi ni Usec Guevara na vaccine S&T institute of the Philippines. This will support the manufacturing site of the vaccine itself, and not only for COVID, but other vaccine on the virus side like plants and animals will be included.

Dr. Ma. Liza Antoinette Gonzales: How many vaccine developers are we talking to right now? Does this include the frontrunners? Are there any updates with the discussions with them?

Asec Leah Buendia: May I turn over it to Dr. Gloriani, the head of technical panel?

Dr. Nina Gloriani: Good morning everybody, remember we announced na meron pong IATF approval to collaborate with China, pero doon sa lima, dalawang companies pa lamang ang nasa taas ng landscape, na nasa Phase II na sila, ito po yung Sinovac at Sinopharma, but there are other negotiations or talks with Pfizer at Moderna, even Oxford, ito po yung anim na nasa top list na advanced stage sila ng development at Phase III. Number 1 there is Oxford Astra Senica, Number 2 is SInovac, Number 3 and 4 yun Sinopharma kasi dalawa nag kanilang vaccines, and we have Moderna and Pfizer. Meron pa pong iba pero Phase II pa lang sila and I think eventually they will move up to Phase III. So hindi natin alam sino dun yung sasali sa WHO Solidarity Trial, but right now, yun po yung mga kausap natin. Salamat po.

Dr. Ma. Liza Antoinette Gonzales: Follow up po, about the Sputnik V Russian Vaccine. Ano po ba nag updates natin doon?

Dr. NIna Gloriani: Meron na kaming nakuhang kaunting information, synopsis, but we require the complete technical dossier. Until that happens, hindi po namin mafufully evaluate yung kanilang product. Mayroon pong very strict requirements ang FDA about that.

Dr. Ma. Liza Antoinette Gonzales: Ma'am ano po ba ang clinical qualifications na pwedeng sumama sa Russian vaccine?

Dr. Nina Gloriani: Lahat ng information that they have, yung preclinical development nila, maraming mga data doon that we need, safety, immunogenicity, efficacy tapos human trial kung meron na sila. We will be very strict with that. FDA will have the final approval, meron na silang tinitgnan na minimum standard fo this pandemic vaccine, susundan po lahat iyon, we have to assure the public that there will be rigorous evaluation of the vaccines sa lahat.

Dr. Ma. Liza Antoinette Gonzales:: Do the volunteers for the CT have to test negative from a PCR test before having them included in the trial?

Dr. Nina Gloriani: May ibang mga pag-aaral abroad that includes yung mga trial ng seropositive, about 10%. Sa ibang trials, may seropositive na sinali, may antibody pero iba ang analysis non. Technically what we want for trials here are seronegative, walang COVID, at walang antibody, yun po ang ating uunahin.

Dr. Chette: From Ms. Melly Tenorio, papaano kung namatay ang nag-undergo ng trial? Siguro this is regarding vaccine safety po and adverse effects, Ma'am Lulu, ano po ba ang gagawin pagka may nangyaring adverse effect, death is of course considered a severe adverse effect.

60:00-80:00 [Yana]

Dr. Lulu Bravo:
Well, thank you, Chet. Actually, sa isang clinical trial, sabi nga natin, lahat ng nngyayari sa pasyente ay minomonitor. From the time na binigyan sila ng bakuna, for 1 year, 2 years, 3 years, pwede pang 5 years; talagang binabantayan sila. And mayroon talagang namamatay. Iniimbestiga at tinigtingnan noong principal investigator kung ano ang kadahilanan ng pagkamatay. Kasi lahat ng 'yon, yung namatay, yung naospital, yung nagkaroon ng seizure; yung lahat ng nangyari sa kanya, dinidetermine or pinagaaralan noong principal investigator- and usually, eksperto at espesyalista ang mga principal investigator- dinidetermine nila ano ang dahilan ng pagkamatay. At kung yan ay related sa bakuna, itatala nila yan. Ito ba ay dahil sa bakuna kaya namatay? Ito ba ay dahil sa ibang paraan? Like, baka naman mayroon syang sakit na TB, nahawa sya sa TB, wala namang relasyon yung TB doon sa bakuna. Or sya ba ay nagkaroon ng tinatawag natin na cancer? Pwede rin makita kung yan ba ay--

Dr. Jaime Montoya:
Or ano, tumatawid ng kalye, nabangga, namatay.

Dr. Lulu Bravo:
Yes, so lahat ng yan ay iniimbestigahan para malaman kung ano ang naging dahilan. At kung makita na yan ay may kinalaman sa bakuna, mayroong tinatawag na liability clause. Lahat ng clinical trial natin, kung may nakitang hindi magandang epekto, na mdetermine galing sa bakuna, yan ay sinasagot ng isang klase ng tinatawag nating- it's like an insurance- it's like a liability. Mayroong clause yan. Mayroong allotment dyan ang kompanya, mayroong allotment dyan ang ERB. Pagka chineck mo yan sa ERB, lagi yan nakasama sa informed consent din. Sinasabi din yan sa mga pasyente kaya importante na lahat yan alam ng mga pasyente bago sila sumali.
Pero ang sabi ko nga kung naalala nyo kanina, sinabi ko na so far, so far, you know, knock on wood- sa tinatagal tagal ng vaccine trials dito sa Pilipinas, more than 30 years now, wala pa po tayong nangyaring ganyan na namatay dahil sa bakuna. Wala po kayong makikitang naging kaso na habang nasa clinical trials sya, nagkaroon sya ng- namatay sya or something na nangyaring ganon. Mayroon po mga side ffects kagaya ng nagkaroon ng konting- well, tinatawag po nating side effects, marami po yan, chinecheck talaga, nagkaroon ng-

Dr. Jaime Montoya:
Lagnat.

Dr. Lulu Bravo:
Yung mga side effect-

Dr. Jaime Montoya:
Oo, lagnat, masakit doon sa injection side, pero mga minor lang yan.

Dr. Lulu Bravo:
Yeah, so wala pa po sa lahat ng- at masasabi ko po, daan-daan na po ang mga nagawang clinical trials sa Pilipinas. Mula pa po noong 1990s. Sa vaccine trials po, masasabi ko po sa inyo, ako po ay nag pioneer. Kasama ko po yung aming mga pediatrician.

Dr. Jaime Montoya:
O, nabibisto ka, nabibisto ka, Dr. Lulu... Na bata ka pa.

Dr. Ma. Liza Antionette Gonzales:
Sige, thank you Ma'am Lulu, marami pa po tayong tanong. So from several- may several questions po tayo from the chatbox, si Ms. Mariz Umali, meron din related si Nes Aguilar, the Philippines Event News TV. At marami pa pong nagtatanong so maybe ano nalang, short answer nalang.

Dr. Jaime Montoya:
O, ang sasagot nyan ay si Undersecretary Guevara. Ma'am, tinatanong kung kailan daw magiging available ang- Ano ba 'to yung unang bakuna o yung Russian ano- yung unang bakuna sa Pilipinas?

USec. Rowena Cristina Guevara:
If we are talking about the availability in masss, we believe this is going to be happening in the second quarter of next year. Pero if we are talking about the clinical trials, it will start in the third- in the fourth quarter of this year. Yun lang po.

Dr. Maria Liza Antionette Gonzales:
Okay, thank you Ma'am. Tapos po, to the FDA so kay Dr. Montoya, "How are we going to be assured that the vaccines that would be delivered in the country for the clinical trials would be safe and effective?"

Dr. Jaime Montoya:
Okay, si DG Director General Domingo.

Dr. Maria Liza Antoinette Gonzales:
From Mr. Red Mendoza yan, the Manila Times.

Dr. Eric Domingo:
Yeah, hi Chet, I'm Eric ah, not Jimmy, from FDA.

Dr. Maria Liza Antoinette Gonzales:
Ay okay, hi Dr. Domingo.

Dr. Eric Domingo:
Yeah, well first of all, katulad po ng sinabi kanina, pag clinical trial phase 3, hindi naman po yan natin tatanggapin for a phase 3 dito sa atin kung hindi naprove sa phase 1 at phase 2 yung safety and some level of ano noh, efficacy po na ito ng isang bakuna. So dumaan na sya sa trial- phase 1 and phase 2- bago natin sya tanggapin pagkatapos gagawin naman natin yung isang masusing pagaaral- technical review by our experts, ng lahat po ng dokumento noong kanilang mga naunang phases- the earlier phases- including the pre-clinical studies bago natin iapprove.
And at the same time, very strict nga yung ating mga ethics ano noh, ethics boards dito sa Pilipinas. Titignan muna nila talaga kung- talagang mayroon tayong safeguards for all the participants, talagang hindi sa mapupunta sa ano noh, in any dangerous situation or hindi sila mapapahamak in any way.
So sisiguraduhin po natin yung screening na yan bago naman natin magpayag dito ng isang phase 3 trial. Ngayon po pagdating naman po sa pag talagang bakuna na, halimbawa, approved na tapos bumibili na ang either ang pamahalaan or ang private sector, ang bawat dating po, bawat shipment po ng bakuna mayroon po yang ano noh batch certification at tsaka lot certification. Sinusuri po muna natin lahat ng papeles, lahat ng dokumento to make sure na dumaan sya- na hindi sya nadaan sa maling temperatura. Pagkatapos kung may kailangan pong tests na gagawin just to make sure yung bakuna ay nasa tamang kondisyon, ginagawa rin po yan bago irelease.
So before every batch or lot of vaccines are released, nacheck na po ng FDA yan na siguradong wala na pong problema.

Dr. Maria Liza Antoinette Gonzales:
Thank you Dr. Domingo, now this is uh- mayroon pong mga- nako, napakadami po hindi ko po alam kung mababasa ko lahat. Pero babasahin ko po tong mga iba na medyo related. So questions about the Dengvaxia from Mr. Greg Gregorio TV5, similar question from Dhel Nazario and maybe- meron pang mga iba pero they were asking about yung Dengvaxia controversy and we know that it caused fear among some Filipinos and has been said to be a factor in the loss of confidence in vaccines and low immunization rates. So the question is, okay, so how can we assure or what is the government doing to allay these fears? So sino po ang gustong mag answer ng question na to?

Dr. Jaime Montoya:
Maganda sana isang taga Department of Health ang sumagot nyan pero siguro kung I would be allowed- Lulu, kasi alam ko ay mahaba ang iyong karansaan sa mga pagbabakuna, ikaw muna ang suamgot dito at sasagot din kami kung may oras pa.

Dr. Lulu Bravo:
Pwede naman, emotional ako pag tungkol sa Dengvaxia eh Kasi mahabang pagaaral ang ginawa sa Dengvaxia vaccine diba, sa RITM, at hindi lang- sa buong mundo, maraming trial yan. Sabi ko nga, walang nakita na nagkaroon ng- namatay or nagkaron ng talagang, you know, weird- kaya yan naaprubahan in the first place. And right now talaga namang sabi ng WHO pwedeng magbigay ng dengue vaccine sa mga countries na endemic or mataas ang incidence ng dengue. In fact, andyan si Dr. Eric pero talagang isa yan sa mga pinaglalaban namin na dapat ang Pilipinas, magkaroon na ulit nung dengue vaccine dahil tayo ang pinakamataas na may burden ng dengue sa Asia Pacific. Mas mataas na tayo sa Indonesia, sa Vietnam.
Ngayon ang sinasabi natin kagaya nga ng papaano natin marerestore ang public trust dahil nasira yan nung 2018 at yan ang madalas kong sabihin na importante para magkaroon tayo ng public trust, kagaya ng mga nangyayari ngayon, nagpapainterview kayo, nagbibgay tayo ng mga kaalaman, nagbibgay tayo ng mga media conference like this para sa masabi sa madling tao, sa ating mga mamamayan ang kahalagahan ng pagbabakuna.
Actually nga, natutuwa ako dahil ngayon, marami nang gustong makaalam tungkol sa bakuna napakadami na ang kailangan nating matutuhan. Narerealize nila na hindi pala simple yung pagaaral ng bakuna, na napakadami palang dapat malaman dyan diba? Yan ang tinatawa natin na science and vaccine literacy kasi noong araw pa, noong magumpisa yang Dengvaxia na controversy, talaga namang- hirap na hirap tayong magpaliwanag kung ano ang ibig sabihin ng- bakit clinical trial, bakit yan naaprubahan ng FDA, bakit ganito. Ngayon, unti-unti na nilang natutuhan, and sana hindi lang sa ngayon, I am willing- and I'm sure you too, from the Department of Science and Technology- pwede tayong magkaroon ng regular press conference tungkol sa pagbabakuna. Lalo ngayon at kailangang kailangan ng mga tao ng kaalaman dahil little knowledge is dangerous. Pagka hindi ka nagcommunicate well, hindi ceffective ang communication mo, yan ang isang papatay sa mga tao- hindi mo ba alam yon, na importante magaling at mahusay ang komunikasyon natin dahil deadly din yung mga tinatawag nating misconceptions, myth na tinatawag- mga kung anu-anong naniniwala sa sabi-sabi. Sabi ko nga, isa sa pinakamagandang maipapayo natin sa ating mga mamamayan, pwede ba making kayo sa mga scientist, sa mga eksperto. Doon dapat nakikinig ang mga tao, hindi sa kung anu-anong sabi-sabi, walang bait sa sarili. Yun lang, thank you.

Dr. Maria Liza Antoinette Gonzales:
Okay, so maybe last, last questions na lang and let's just focus on the DOST's vaccine initiative. So ano po ba- pwede po bang isummarize lang or sabihin ang timelines with regards to clinical trials for COVID vaccines? Kailan ba talaga, ano po bang vaccine ang uunahin, by next year ba, may ibang vaccine ba, ano pa ba- basta yung regarding the plans on clinical trials and the timelines on the DOST's vaccine initiatives. Dr. Montoya?

Dr. Jaime Montoya:
Oo, alam mo, sisikapin kong sagutin yang tanong na yan. Mahirap yan sagutin dahil maraming mga ifs and buts yan, pero sasagutin ko noh as best as I can. Unang-una, yung pagbibigay ng timeline kasi depende sa anong klaseng bakuna at kung saan manggagaling na bakuna. Ang pinakaimportante nating isipin ay hindi tayo magkakaroon ng timeline until maaprubahan ng isang FDA ng isang bansa usually yung bansa kung saan ginagawa yung bakuna bago tayo makapagsasabi kung ano ba talaga yung timelines na involved.
Now, itong sa Russia for example, kasi naglabas sila na, yun nga, na sila ay handa na magphase 3, may timeline silang sinet kaya alam natin kung kalian yan mangyayari. Halimbawa, nanggaling sa kanila na ang clinical trial ay magisismula by Semptember noh, ngayong September and it will take 3-6 months. Kaya alam natin na matatapos yan mga Enero. So kung ano man ang mga bansa na sasali doon sa phase 3, alam natin na matatapos lahat yan by January of next year. Pagkatapos noon, katulad ng sinabi ni Director General Domingo, itong mga resulta na ito ay pag aarala noh. Iipunin lahat ng vaccine developer kasi ito'y ginawa sa iba-ibang bansa- pagaaralan, at kapag ito ay nakitang maganda ang resutla, isusubmit nila ngayon ito sa kanilang Food and Drug Administration. Sabihin na nating isang buwan bago nila mapag-aralan lahat yung mga datos, so that means end of- first quarter of next year, most likely nasubmit na nila yan sa kanilang FDA- sa Russia- for example, nasubmit na nila at nabigyan na yan, siguro, ng approval kung

magaganda ang resulta- nakumbinsi ang mga awtoridad ng kanilang FDA. Doon palang sila magbibigay o magsusubmit ng mga dokumento sa mga FDA ng mga iba't-ibang bansa katulad ng Pilipinas.
So, assume natin na naapprove yan ng- end of first quarter, isusubmit nila yan sa mga iba't ibang bansa, first month, mga April of the 2nd quarter. Dadalhin yan- kunwari sa Pilipinas, sa FDA, mga isang buwan yan na pagaaralan, siguro, ng ating FDA. Maririnig natin si Dr. Domingo kung ano ang kanyang timeline, at siguro, by the end of the 2nd quarter mga- April, May, June noh- May o June, pwedeng lumabas ng yung approval ng FDA natin, which means pwede na syang ipagbili o pwede na syang gamitin ng mga pIlipino. So example lang yon, so lagi tayong bibilang kung kailan matatapos yung phase 3- o kung kailan magsisimula, kalian magsisimula, tatlo hanggang anim na buwan, matatapos noon, magbigay ka ng isang buwan para yun ay pagaralan yung mga datos, Isusubmit nila sa kanilang FDA, doon sa kung saan sya ginagawa at pag yon naaprubahan, at tsaka nila isusubmit sa mga FDA ng iba't ibang bansa kasama na ang Pilipinas. Magbigay ka ulit ng isang buwan para pagaralan yan ng mga FDA ng kanya-kanyang bansa at pag nagrelease sya after 1 month, doon pwedeng ipagbili na yung nasabing bakuna.
Dr. Maria Liza Antoinette Gonzales:
Dr. Jim, in relation ba dyan, kasama ba dyan ang WHO Solidarity vaccine trial?

Dr. Jaime Montoya:
Oo, kasama dyan, at ang solidarity trial, nasusupervise ng WHO ay isasailalim din sa ganoong pamamaraan. Hindi sya exception. Ang kagandahan lang ng solidarity trial, maraming bakuna ang kasama doon sa pagaaral na yon, hindi lang isang klase ng bakuna. At ito'y magtatagal din ng mga tatlo hanggang anim na buwan pero kailangan pa din syang aprubahan ng FDA ng iba't ibang bansa kung saan gagawinn yung trial bago ito simulant.

Dr. Maria Liza Antoinette Gonzales:
Okay so thank you very much, Dr. Montoya. Nako, napakadami pa pong tanong pero pasensya nap o kayo medyo napapagsabihan na po ako na I have to start wrapping up. So before that, may mga announcements ako later na important but maybe we'd like to hear from USec. Guevara for her- please give your closing remarks po, Ma'am, can we hear from USec. Guevara?

USec. Rowena Cristina Guevara:
Secretary Fortunato dela Peña of the Department of Science and Technology (DOST), Director General Eric Domingo of the Food and Drug Administration (FDA), Dr. Nina Gloriani, chair of our Vaccine Expert Panel, Dr. Rontgene Solante, Chair of the Adult Infectious Diseases and Tropical Medicine Center of the San Lazaro, Dr. Lulu Bravo, Executive Director of the Philippine Foundation for Vaccination, Assistant Secretary Leah Buendia, our hosts, Dr. Maria Liza Antoinette Gonzales and Dr. Isagani Padolina, Executive Director Dr. Jaime C. Montoya of the Department of Science and Technology-Philippine Council for Health Research and Development (DOST-PCHRD), our friends from the media, ladies and gentlemen, good morning.
Allow me to extend our gratitude to our guest speakers and all our media attendees today, for being our partners in disseminating reliable information, especially on all our efforts to address the COVID-19 pandemic. Media has always played a vital role in science and technology, by ensuring that research-based solutions and innovations reach our communities.
Undeniably, COVID-19 brought unprecedented challenges in our healthcare, economic and social welfare systems. As we face these times of uncertainty, the solidarity among our communities and organizations is key to alleviating the burdens the global health crisis has brought upon us. Rest assured, that we, at the DOST, are committed to advancing science and technology in the country's quest to provide high-quality and accessible solutions for the Filipinos. As we move forward in building our network and establishing partnerships to ensure access to the potential COVID-19 vaccine, we hope you will all continue to support us.
To the best of our abilities, we will continue to provide up-to-date information, not only on our COVID-19 initiatives, but for the rest of our science, technology and innovation efforts. We need our friends in media to ensure that the correct information reach our *kababayans* to dispel their fears and anxiety in this time of COVID-19. Help us communicate science to the people. Correct information is the key to fighting COVid-19. With science and technology on our side, we will overcome the COVID-19 pandemic, and we will heal as one. Thank you very much.

Dr. Maria Liza Antoinette Gonzales:

Thank you very much USec. Guevara. So thank you also to our expert resource speakers, Dr. Montoya, Dr. Bravo, Dr. Domingo, Dr. Gloriani, Dr. Buendia, our partners in media, my co-host. Thank you for attending this Media Conference on COVID-19 vaccines. A recorded video of this conference will be available on DOST-PCHRD Facebook page. The frequently asked questions we have presented today and those which have not been answered will also be uploaded on this website flashed on your screen. The FAQs will also be updated every week so you may visit the site if you have additional questions. You may also send us your queries by messaging PCHRD's Facebook page also flashed on your screen. On behalf of the TWG on vaccine development and our presenters, thank you for joining us today. And have a great rest of your day!

--end--