>> GOOD MORNING, EVERYONE.
THANK YOU FOR JOINING.
WE ARE JUST SEEING PEOPLE STILL ENTERING THE WEB MEETING.
SO WE'RE GOING TO WAIT JUST ONE MORE MINUTE AND THEN WE'LL GO AHEAD AND GET STARTED.
THANK YOU SO MUCH FOR JOINING TODAY.
GOOD MORNING, EVERYONE.
MY NAME IS SARAH WHITE, I'M EXECUTIVE DIRECTOR HERE AT THE MULTI-REGIONAL CLINICAL TRIALS OF BRIGHAM AND WOMEN'S HOSPITAL IN HARVARD.
AND I'M DELIGHTED TO WELCOME YOU ALL TO THE CONFERENCE REIMAGINING CLINICAL TRIALS LEARNINGS FROM COVID-19.
NEXT SLIDE, PLEASE.
MRCT IS A POLICY CENTER FOCUSED ON ADDRESS THE CONDUCT OVERSIGHT, ETHICS AND REGULATORY ENVIRONMENT OF GLOBAL CLINICAL TRIALS.
OUR VISION IS TO IMPROVE THE INTEGRITY, SAFETY AND RIGOR OF GLOBAL CLINICAL TRIALS AND WE DO OUR WORK BY ENGAGING AND CONVENING A MULTI STAKEHOLDER GROUP INCLUDING INDUSTRY, ACADEMIA, GOVERNMENT, NONPROFIT, PATIENT AND PATIENT ADVOCATES TO COME TOGETHER TO DEFINE EMERGING ISSUES AND CREATE AND IMPLEMENT ETHICAL ACTIONABLE AND PRACTICAL SOLUTIONS.
AND OVER THE PAST DECADE, MRCT CENTER'S EFFORTS RESULTED IN THE IMPLEMENTATION OF BEST PRACTICES, GREATER TRANSPARENCY AND IMPROVED SAFETY FOR PARTICIPATES.
NEXT SLIDE.
WE HAVE SEEN A LOT OF INNOVATION, RESILIENCE AND HARD WORK OVER THE LAST 16 MONTHS RELATED TO RUNNING CLINICAL TRIALS.
THE COVID PANDEMIC HAS OPENED OUR EYES TO WHAT COULD AND SHOULD BE POSSIBLE FOR CLINICAL TRIALS.
AND IN EARLY 2021, THE MRCT CENTER'S EXECUTIVE AND STEERING COMMITTEE CHALLENGED US TO THINK LONG-TERM ABOUT THE CHANGES THAT SHOULD AND COULD BE MADE TO SUSTAIN CLINICAL TRIALS IN THE FUTURE.
AND THIS CONFERENCE IS THE RESULT OF THAT.
THERE HAVE BEEN A NUMBER OF CONFERENCES ON LESSONS LEARNED BUT WHAT WE'RE INTERESTED IN DOING HERE IS TO REALLY THINK ABOUT A LONG-TERM VISION.
HOW ARE WE PREPARING FOR CLINICAL TRIALS OF THE FUTURE, WHAT ARE THE POSSIBILITIES, THE FLEXIBILITIES, COMPLEXITIES AND THE BARRIERS.
WE HAVE TWO MEETINGS AS PART OF THIS CONFERENCE.
TODAY WE'LL TALK ABOUT FLEXIBILITIES, CONDUCT AND COORDINATION, AND THEN ALSO GOING TO

THINK ABOUT THE IMPLEMENTATION -- IMPLICATIONS OF THE CLINICAL TRIAL WORKFORCE AND NEXT THURSDAY WE'LL FOCUS ON THE REGULATORY FLEXIBILITIES AND INTERNATIONAL COOPERATIVITY AND GOVERNANCE.
NEXT SLIDE.
OUR GOAL IN THESE MEETINGS IS TO REALLY LOOK INTO THE FUTURE.
OUR SPEAKERS AND PANELISTS ARE GOING TO DISCUSS WHAT IS THE VISION FOR HOW MULTI-SITE, MULTINATIONAL CLINICAL TRIALS ARE GOING TO BE CONDUCTED, WHAT WORKED BUT ALSO WHAT DIDN'T WORK, AND WHAT WE NEED, STILL NEED MORE INFORMATION AND ANALYSIS ON.
AND WE'LL ALSO THINK BEYOND CATALOGING AND THINK ABOUT THE HOW, HOW DO WE BUILD THE EXPERIENCE OF CLINICAL TRIALS DURING -- THAT WE'VE LEARNED ABOUT DURING THE COVID-19 PANDEMIC AND BE PREPARED FOR THE FUTURE.
NEXT SLIDE, PLEASE.
HERE IS OUR AGENDA FOR TODAY'S MEETING.
AFTER TODAY'S KEYNOTE YOU'LL HEAR FROM A DIVERSE SET OF PANELISTS AND OUR MODERATORS TODAY HAVE BEEN ASKED TO FACILITATE AND PUSH THE CONVERSATION TOWARDS THAT LONG-TERM VISION OF THE FUTURE OF CLINICAL TRIALS.
NEXT SLIDE.
WE DO HAVE CLOSED CAPTIONING AVAILABLE AND YOU CAN VIEW IT BY CHANGING YOUR SETTINGS AND THE CHAT AND Q&A FUNCTION ARE OPEN AND WILL BE MONITORING THEM ON OUR END.
NEXT SLIDE.
BEFORE I TURN IT OVER TO BARBARA TO INTRODUCE TODAY'S KEYNOTE SPEAKER ON BEHALF OF THE MRCT CENTER, I'D LIKE TO SAY A BIG THANK YOU TO THE PLANNING COMMITTEE FOR THIS CONFERENCE WHO HAVE BEEN TREMENDOUS IN THE DEFINE AND DEVELOPMENT OF THE PANEL TODAY AND NEXT THURSDAY AND THEIR NAMES ARE LISTED ON THE SLIDE.
I'D LIKE TO INTRODUCE BARBARA BIERER FACULTY DIRECTOR OF THE MRCT CENTER.
OVER TO YOU, BARBARA.
>> THANK YOU, THANK YOU, SARAH, AND THANK YOU, EVERYONE, WHO IS JOINING AND LET ME ADD MY WELCOME TO EVERYONE AND MY THANKS TO THE PLANNING COMMITTEE.
I HAVE TO SAY I'M REALLY THRILLED TO BE ABLE TO INTRODUCE OUR KEYNOTE SPEAKER ESTHER KROFAH WHO IS THE EXECUTIVE DIRECTOR OF FASTERCURES, WHICH IS A CENTER OF THE MILKEN INSTITUTE WHICH I'M SURE EVERYONE IS FAMILIAR WITH.
FASTERCURES IS A REALLY DEDICATED TO THE -- TO ACCELERATING PATIENT-CENTERED AND TREATMENTS AS RAPIDLY AS POSSIBLE, DECREASING BARRIERS, ET CETERA, AND ESTHER HAS BEEN INCREDIBLY INVOLVED OF LATE IN DEVELOPING AN ACTION PLAN FOR THE U.S. GOVERNMENT IN TERMS OF THINKING ABOUT WHAT WE NEED TO PUSH FORWARD.
ESTHER WAS PREVIOUSLY THE DIRECTOR OF PUBLIC POLICY LEADING GLAXCO'S -- (AUDIO BUFFERING) -- WORKED AT PROGRAM AT THE NATIONAL GOVERNOR'S, I THINK IT'S REALLY AN HONOR AND PLEASURE TO INTRODUCE ESTHER.
I THINK WE FIRST MET WHEN SHE WAS ABOUT A WEEK OLD AT FASTERCURES WHEN IN-PERSON MEETINGS WERE STILL POSSIBLE AND WE WERE DOWN IN WASHINGTON, D.C., BUT SINCE THEN WE'VE BECOME REALLY WONDERFUL COLLEAGUES AND I CAN'T SAY ENOUGH ABOUT WHAT A PLEASURE IT IS TO HEAR FROM HER TODAY.

SHE'LL PRESENT A LOT OF THE WORK THAT SHE'S BEEN DOING AND LEADING OVER THE LAST MANY MONTHS TO POSITION US FOR THE FUTURE AND I THOUGHT IT WAS IMPORTANT TO GROUND SOME OF THESE CONSIDERATIONS FOR THE CONFERENCE TODAY IN A MORE U.S. VISION WITH THE EYE TOWARDS HOW TO EXTEND THIS TO MULTINATIONAL AND MULTI-SITE, MULTI REGIONAL TRIALS W THAT, ESTHER, WE LOOK FORWARD TO HEARING FROM YOU AND THANK YOU SO MUCH FOR JOINING US.

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>> WHAT A WARM WELCOME.

I DO RECALL WHEN YOU AND I MET IN-PERSON AND OUR WASHINGTON, D.C. OFFICE AND WE WERE ALREADY FAST FRIENDS.

PARTLY BECAUSE I HAD TWO OF MY KIDS AT BRIGHAM AND WOMEN'S AND WE'VE BECOME GREAT COLLEAGUES AND COLLABORATORS OVER THE LAST SEVERAL MONTHS IN PARTICULAR.

I'M DELIGHTED TO BE WITH ALL OF YOU TODAY, WHAT AN INCREDIBLY EXCITING TOPIC.

VERY.

VERY RELEVANT FOR WHERE WE ARE AS A COUNTRY, AS WE'RE IN THESE WANING DAILIES HOPEFULLY FROM THE PANDEMIC.

BUT WE CERTAINLY RECOGNIZE THE HUNDREDS OF THOUSANDS OF LIVES THAT WERE LOST DUE TO THIS PANDEMIC, AND IT'S ABSOLUTELY APPROPRIATE THAT WE SHOULD TALK ABOUT LESSONS LEARNED AND WE WILL HAVE A LOT OF LESSONS LEARNED ACROSS THE ENTIRE PUBLIC HEALTH RESPONSE TO COVID-19, BUT VERY PERFORM, THIS CONVERSATION THAT WE'RE HAVING TODAY ABOUT THE FUTURE OF CLINICAL TRIALS IS EXTREMELY RELEVANT AS WELL AS THE ROLE OF OUR CLINICAL TRIAL INFRASTRUCTURE AND OUR CLINICAL TRIAL ENTERPRISE REALLY CAME TO THE FOREFRONT.

WHY DON'T WE TURN TO THE SLIDE DECK PRESENTATION.

SO WHAT I'M GOING TO SHARE WITH YOU TODAY IS REALLY INFORMED AS BARBARA MENTIONED, BY OUR EFFORTS AT FASTERCURES TO DOCUMENT THE LESSONS LEARNED COMING OUT OF COVID-19 AND ACCELERATING BIOMEDICAL RESEARCH.

IN FACT OUR WHITE PAPER ON THIS TOPIC WAS RELEASED EARLIER THIS YEAR.

AND IF YOU CAN BELIEVE IT OR NOT, WE WERE DOCUMENTING LESSONS LEARNED AT THE HEIGHT OF THE PANDEMIC ABOUT THIS TIME LAST YEAR, WE WERE HAVING A SERIES OF INTERVIEWS WITH KEY LEADERS FROM DR. FRANCIS COLLINS TO DR. TONY FAUCI AND LEADERS WITHIN FDA INDUSTRY, PATIENT-LED DISEASE ORGANIZATIONS, AND MANY OTHER STAKEHOLDERS AS WELL THAT INFORMED THAT EFFORT.

THE REASON WHY WE WANT TO CAPTURE THINGS IN REALTIME, BECAUSE WE RECOGNIZED HOW EASY IT IS TO FORGET THINGS WHEN YOU MOVE AWAY FROM THE ACUTE PAIN POINTS THAT YOU'RE EXPERIENCING.

THIS TALK IS ALSO INFORMED BY MY EFFORTS WITH THE NATIONAL ACADEMIES, I'VE BEEN CO CHAIRING AN EFFORT WITH STEVEN ON AMGEN ON A SERIES AROUND TRANSFORMING THE CLINICAL TRIAL ENTERPRISE 2030 AND ALSO MY INVOLVEMENT IN THE RECENT U.S. GOVERNMENT-LED EFFORT TO UNDERSTAND LESSONS LEARNED FROM COVID-19 THERAPEUTIC TRIALS AND ALSO ENGAGING WITH MULTIPLE STAKEHOLDERS INCLUDING MASTER PROTOCOLS LEADING 19 TREATMENT TRIALS.

SO A LOT OF CONVERSATIONS HAVE BOILED INTO SOME TAKEAWAYS WE CAN GLEAN FROM THIS BUT

ALSO LOOK FORWARD TO THE REST OF THE DISCUSSIONS TODAY.
NEXT SLIDE.
I THOUGHT I WOULD BEGIN BY TAKING A GIANT STEP BACK.
WHEN WE THINK ABOUT OUR CLINICAL TRIAL INFRASTRUCTURE IN THIS COUNTRY, I THINK IT'S IMPORTANT FOR US TO UNDERSTAND HOW IT'S SITUATED WITHIN OUR HEALTHCARE ECOSYSTEM.
OUR HEALTHCARE ECOSYSTEM WHEN YOU THINK ABOUT THIS IN THE CONTEXT OF COMPARISONS WITH OUR PEERS AND OUR HIGH INCOME COUNTRIES, THE U.S. SPENDS NEARLY TWICE AS MUCH AS THE AVERAGE OECD COUNTRY ON HEALTHCARE AS A SHARE OF ITS ECONOMY, LARGELY DRIVEN BY MEDICAL TECHNOLOGIES AND HIGHER PRICES.
NEXT SLIDE.
WE ALSO DESPITE UNFORTUNATELY THAT LEVEL OF INVESTMENT, HAVE THE LOWEST RANKING IN TERMS OF HEALTHCARE OUTCOMES.
WHEN WE LOOK AT LIFE EXPECTANCY IN THE U.S., AGAIN, COMPARED TO OUR PEERS, OUR LIFE EXPECTANCY AT BIRTH IS TWO YEARS LOWER THAN OECD AVERAGE.
IF YOU GO TO THE NEXT SLIDE, THIS, OF COURSE, DOES NOT IMPROVE WHEN WE START TO TALK ABOUT CHRONIC DISEASE BURDEN.
WE HAVE THE HIGHEST CHRONIC DISEASE BURDEN AND OBESITY AMONG OUR PEERS ACCORDING TO THE CDC SIX IN TEN ADULTS HAVE CHRONIC DISEASE, ONE, FOUR IN TEN ADULTS HAVE TWO OR MORE.
THIS INCLUDES HEART DISEASE, CHRONIC LUNG DISEASE, ARE DIABETES, AND THE LIST GOES ON.
IF YOU GO TO THE NEXT SLIDE, WE ALSO SPEND THE MOST OF OUR PEERS IN INVESTMENT AND BIOMEDICAL R&D PUBLIC AND PRIVATE SECTOR SPENDING.
AND WHAT YOU SHOULD BE COMMENDED IN TERMS OF OUR LEADERSHIP AND INVESTMENT IN R&D, HOWEVER, AS WE'LL TALK ABOUT TODAY, DESPITE THIS LEVEL OF INVESTMENT AS YOU CAN SEE WITH OLD AND MULTIPLE LEVELS OF SPONSORS OF INVESTMENT IN R&D, OUR ECOSYSTEM IS INEFFICIENT AND SILOED AND FRAGMENTED.
THIS SILOED NATURE AND FRAGMENTATION OF OUR CLINICAL TRIAL ECOSYSTEM AND R&D ECOSYSTEM WAS VERY MUCH REVEALED DURING COVID-19, HUNDREDS OF INVESTIGATORS LAUNCHED PRECLINICAL OR CLINICAL TRIALS INVESTIGATING ANTIVIRALS, ANTIBODIES, MRNA REPURPOSED DRUGS FROM OTHER CONDITIONS, NUMEROUS OTHER COMPOUNDS, TECHNOLOGIES AND DEVICES THAT COULD BE A POTENTIAL USE MITIGATING THE DISEASE.
I HAD MANY, MANY PHONE CALLS IN THE BEGINNING OF PANDEMIC WHEN WE LAUNCHED OUR COVID-19 TREATMENT AND VACCINE TRACKER WITH MANY DIFFERENT COMPANIES AND/OR INVESTIGATORS WANTING TO MAKE SURE THEIR STUDIES WERE DOCUMENTED THERE.
ACADEMIC RESEARCH INSTITUTIONS OF COURSE ALSO LAUNCHED THEIR OWN EFFORTS AS DID INDUSTRY, ALL FOR GOOD CAUSE, TRYING TO BE AS RESPONSIVE AS POSSIBLE WITH REGARD TO COVID-19.
THE CHALLENGE, HOWEVER, IS THAT WE HAD VERY LITTLE ALIGNMENT IN TERMS OF RESEARCH PRIORITY ACROSS ALL OF THOSE TYPES OF RESEARCH INVESTIGATORS, WHERE SHOULD WE HAVE THE APPROPRIATE LEVEL OF INVESTMENTS, AND RESOURCES, TO ANSWER THE MOST URGENT QUESTIONS.
WHICH OF TREATMENTS WERE MOST EFFECTIVE FOR HOSPITALIZED PATIENTS THOSE WHO ARE MILD OR MODERATE DISEASE, AND IN SOME CASES, WE ALSO EXPERIENCED COMPETITION FOR PATIENTS ENROLLING INTO TRIALS DESPITE THOUSANDS OF PATIENTS ALL OVER THE COUNTRY INFECTED WITH

COVID-19 AS YOU CAN SEE FROM THIS DATA AND DR. WOODCOCK ADD FDA REFERENCED THIS MANY TIMES BASED ON THEIR ANALYSIS, ONLY FIVE PERCENT OF COVID-19 CLINICAL TRIAL ARMS WILL YIELD GENERALIZABLE INFORMATION ON SAFETY AND EFFICACY EITHER GIVEN SMALL ENROLLMENT OR POOR DESIGN IN A VAST MAJORITY OF TRIALS.
WHILE WE SHOULD BE COMMENDED IN TERMS OF THE MEDICAL RESEARCH RESPONSE FROM COVID-19 ON THE THERAPEUTIC SIDE, WE REALLY DID SUFFER FROM THAT FRAGMENTATION AND LACK OF ALIGNMENT.
IF YOU GO TO THE NEXT SLIDE, THIS IS ONE OF THE REASONS WHY.
I TOOK THIS MAP FROM
CLINICALTRIALS.GOV.
IT DOES A NICE JOB SHOWING US WHERE STUDY ARMS ARE LOCATED AROUND THE COUNTRY GEOGRAPHICALLY.
THE RED STATES ARE WHERE WE SEE THE MOST NUMBER OF STUDIES UNSURPRISINGLY, WE SEE VERY SIGNIFICANT HUBS IN THE NEW ENGLAND, NORTHEAST REGION AND THEN, OF COURSE, THE WEST COAST AND THEN SOME SCATTERING AROUND THE COUNTRY.
HOWEVER, VERY VIEW NETWORKS EXIST IN COMMUNITY BASED SETTING.
VAST MAJORITY OF WHERE CLINICAL TRIAL NETWORKS ARE SITUATED ARE IN ACADEMIC RESEARCH INSTITUTIONS.
AND EVEN FOR THOSE COMMUNITY-BASED SETTINGS THAT ARE INVOLVED IN CLINICAL TRIALS, THE BARRIERS TO ENTRY ARE QUITE HIGH.
BARRIERS GIVEN DATA SYSTEMS THAT NEED TO BE UPGRADED OR DEVELOPED A NEW WORKFORCE CHALLENGES, ADEQUATE TRAINED REIMBURSEMENT AND THE APPROPRIATE EXPERTISE TO CONDUCT THOSE TRIALS.
IF YOU GO TO THE NEXT SLIDE, ANOTHER LEARNING COMING OUT OF COVID, OF COURSE, HAS BEEN OUR LACK OF REPRESENTATION AND HEALTH EQUITY ISSUES ACROSS OUR HEALTHCARE SYSTEM.
IT'S ALSO VERY MUCH NOTABLE AROUND CLINICAL TRIALS.
WHEN WE LOOK AT REPRESENTATION IN CLINICAL TRIALS, WE DON'T NECESSARILY SEE CONSISTENTLY THAT TRIALS REFLECT THE BURDEN OF DISEASE.
WHEN WITH LOOK AT CARDIOVASCULAR, FOR EXAMPLE, 2.9 PERCENT WERE BLACK PARTICIPANTS.
WE SEE THE SAME DELTA WITH OUR DISEASE CONDITIONS, DIABETES AND VARIOUS CANCERS WHEN WE LOOK AT MULTI MY LOAM IN A 20% OF PATIENTS ARE BLACK BUT 4.5 PERCENT OF PATIENTS PARTICIPATE IN CLINICAL TRIALS WITH DATA STARTING IN 2003.
THE BRIGHT SPOT OUT OF THIS DATA, HOWEVER R THE COVID-19 VACCINE TRAILS PARTICULARLY MODERNA AND PFIZER AND THE OTHERS WHO MADE A CONCERTED EFFORT TO ENROLL POPULATIONS THAT WERE DISPROPORTIONATELY AFFECTED BY THE DISEASE.
A LOT OF THAT CAME BECAUSE OF THE CHALLENGES AND THE FORESIGHT TO THINK ABOUT LEVELS OF VACCINE ACCEPTANCE IF THOSE POPULATIONS WERE NOT INCLUDED IN THE CLINICAL TRIALS.
AND MANY CASES THOSE TRIALS SLOWED DOWN TO ENSURE ENROLLMENT MET POPULATIONS THAT WERE REFLECTIVE OF THOSE GROUPS GENERALLY SPEAKING.
SO WE DID PAUSE AND WE DID DO A NICE JOB THERE AND I THINK WE HAVE A LOT OF LEARNINGS TO TAKE AWAY FROM THAT.
IF YOU GO TO THE NEXT SLIDE, ALL OF THIS HAS CULMINATED INTO REALLY A REEMERGED FOCUS

AROUND DESIGNING A BETTER CLINICAL TRIAL SYSTEM THAT WE SHOULD NOT LET COVID-19 GO TO THE WAYSIDE AND NOT USE IT AS A CATALYST OPPORTUNITY FOR US TO THINK ABOUT THE SYSTEM ANEW.
EMERGING FROM A NATIONAL ACADEMIES WORKSHOP SERIES THERE ARE A FEW KEY THEMES THAT CAME OUT OF THE BREAKOUT DISCUSSIONS A NUMBER OF THE SPEAKERS THAT WE HAD, AS PART OF THAT I'LL TOUCH ON THESE THREE THEMES AROUND A NEW SYSTEM THAT'S FOCUSED ON EFFICIENCY, ENGAGEMENT, AND COORDINATION.
IF WE FIRST TURN TO EFFICIENCY ON THE NEXT SLIDE, WE ALL KNOW THAT CLINICAL TRIALS ARE BECOMING INCREASINGLY COMPLEX.
STUDIES ARE LOOKING FOR NARROWER PATIENT POPULATIONS, STRINGENT INCLUSION AND EXCLUSION CRITERIA.
HOWEVER WE DID SEE THAT IT'S POSSIBLE FOR US TO HAVE SIGNIFICANT ENROLLMENT AND PRAGMATIC TRIALS.
FOR EXAMPLE, BRIGHT SPOT IS THE UK RECOVERY TRIAL.
THEY DEMONSTRATED THAT YOU CAN HAVE A SIMPLE PROTOCOL EMBEDDED WITHIN A CLINICAL RESEARCH NETWORK AS PART OF A NATIONAL HEALTH SERVICE THERE IN THE UK.
WHEN I LOOKED AT THE DATA JUST RECENTLY THEY'VE HAD OVER 40,000 PATIENTS ENROLLED IN THOSE TRIALS IN THAT TRIAL AND 181 ACTIVE SITES THAT INCLUDE COMMUNITY BASED SITES THEY WERE ABLE TO GENERATE FASTER ANSWERS AND THERAPIES AND NEGATIVE ANSWER AND IS HYDROXYCHLOROQUINE AND HELPFUL INFORMATION FOR CLINICAL IMPLICATIONS FOR PATIENTS SUFFERING FROM COVID-19.
THE NATIONAL INSTITUTES OF HEALTH ACTIVE TRIAL WHICH ALSO LEVERAGES A MASTER PROTOCOL HAS ALSO BEEN QUITE HELPFUL IN ESTABLISHING MULTI STUDIES TO LOOK AT THERAPEUTICS AND GREAT OTHER EXAMPLES AS WELL AS REMAP CAP ESTABLISHED FOR COMMUNITY ACQUIRED PNEUMONIA AND PIVOTED TOWARD COVID.
WHEN WE LOOK AT THE RIGHT-HAND SIDE WHAT ARE SOME THEMES AND APPROACHES EMERGING AROUND EFFICIENCY THAT GOING FORWARD WE NEED TO FOCUS ON STREAMLINING TRIALS STARTUP, ENROLLMENT, SIMPLIFYING CONTRACTING, IRB APPROVALS AND STARTUP COSTS, EARLY IN COVID, PROCESSES THAT WILL NORMALLY TAKE SIX MONTHS TO A YEAR WERE HAPPENING IN A WEEK, HAPPENING WITHIN TWO WEEKS, AS THE URGENCY OF THE MEMO WAS RECOGNIZED.
UNFORTUNATELY WE'RE ALREADY STARTING TO GO BACKWARDS IN TERMS OF HOW QUICKLY WE CAN WORK THROUGH ISSUES LIKE CONTRACTING AND IRB.
THIRD, SIMPLIFYING DATA COLLECTION FOR MULTIPLE SOURCES.
WE DO NOT HAVE A VERY STREAMLINED PROCESS OF INTEGRATING CLINICAL TRIAL DATA INTO CLINICAL CARE DATA ENHANCING DATA CAPTURE INCLUDE DATA COMING OUT OF CLINICAL CARE.
DATA, INFORMATION, KNOWLEDGE EXCHANGE AMONGST STAKEHOLDERS.
HARKENS BACK TO MY COMMEND AROUND FRAGMENTATION WE DON'T HAVE AN EFFICIENT WAY OF DOING SO.
I WILL SAY A BRIGHT SPOT CAME OUT THAT WE'RE ABLE TO CREATE A PLATFORM IN C3 TO ALLOW FOR MORE ROBUST DATA SHARE AND THAT'S A PATH FOR THE FUTURE.
WE NEED TO BETTER CLARIFY THE ROLE OF TECH ENABLED RESEARCH TO SUPPORT INNOVATION SO WE'RE NOT DIMINISHING THE OPPORTUNITIES FOR NEW TOOLS TO COME FORWARD FOR PATIENTS.

AROUND ENGAGEMENT, A LOT OF THE DISCUSSIONS EMERGED HAVE BEEN HOW DO WE ENSURE THAT MORE PEOPLE CAN PARTICIPATE IN A ENTERPRISE AND MORE DIVERSE REPRESENTATION IN OUR CLINICAL ENTERPRISE SWELL THAT GOES ALL THE WAY DOWN TO COMMUNITY-LEVEL PARTICIPATION THAT REFLECTS THE NEEDS OF THOSE COMMUNITIES THAT WE SHOULD HAVE CLINICAL TRIALS THAT ARE FOCUSED ON THESE KEY APPROACHES THAT ARE HIGHLIGHTED HERE, ENHANCING A USER-FRIENDLINESS AND ABRIDGING THE TECHNICAL DIVIDE.

I THINK MANY TIMES PARTICULARLY WHEN WE HAVE NEW USES OF TELEMEDICINE OR TELEHEALTH WE HAVE TO BE COGNIZANT OF INCREASING HEALTH LITERACY ARE AND THE ACCESS TO THESE TECHNOLOGIES SO WE DON'T LEAVE ENTIRE COMMUNITIES BEHIND.

EXTENDING THE REACH AND RELIABILITY AND REPORTABILITY OF CLINICAL TRIALS, USING INFORMATION AND INSIGHTS GENERATED FROM THOSE CLINICAL TRIALS TO INFORM THE COMMUNITIES IN TERMS OF ISSUES AND AREAS OF PRIORITY TO THEM.

HAVING PROCESSES AND DECISION MAKING TOOLS FOR PARTICIPATING INCLUDING HAVING PATIENTS PARTICIPATING ACROSS THE ENTIRE ECOSYSTEM ALL THE WAY FROM THE DESIGN OF THE CLINICAL TRIAL AND EVEN TO THE CLINICAL TRIAL PARTICIPATION ITSELF LOWER BARRIERS TO RECRUITMENT.

WORKING ON MORE DIVERSE REPRESENTATION, INCLUDING FROM RURAL AREAS AND FOR OLDER PATIENTS AS WELL.

AND VERY KEY TO THIS IS HAVING AN ENGAGING MORE DIVERSE CLINICAL TRIAL WORKFORCE WE'RE ALL AWARE THAT THERE ARE SOME TIMES CULTURAL BIASES THAT PREVENT US FROM ASKING ANY AND ALL ELIGIBLE PATIENTS WHETHER THEY WOULD BE INTERESTED IN PARTICIPATING.

IF WE GO TON ON THE THIRD SLIDE AROUND COORDINATION, WHICH IS THAT A NEW VISION IS EMERGING AROUND A NEED FOR A ROBUST COMMUNITY-BASED CLINICAL TRIAL NETWORK.

WHICH IS GOING TO BE DEPENDENT ON HAVING CRITICAL INVESTMENT IN LOCAL INFRASTRUCTURE AND THE APPROPRIATE GOVERNANCE TO ENSURE THAT NETWORK WILL RESPOND WITH LIMITED RESOURCES TO KEEP PUBLIC HEALTH NEEDS.

AND THAT IF WE GO FORWARD WITH SUCH APPROACH IN TERMS OF COORDINATION, IT WILL REALLY ENABLE US TO ADOPT THESE KEY APPROACHES ENABLING MORE EFFICIENT INFORMATION SHARING THAT BRINGS IN DIVERSE VOICES AND STAKEHOLDERS, COLLABORATIVE TRIAL DESIGNS HAVING APPROPRIATE LEVEL OF CONDUCT AND ANALYSIS, DEVELOPING TOOLS TO EFFICIENTLY ALLOCATE RESOURCES, THAT OF COURSE WILL NEED A STRONG GOVERNANCE STRUCTURE, HOW DO WE IDENTIFY THE CRITICAL PUBLIC HEALTH NEEDS IN AN APPROPRIATELY ALLOCATE RESOURCES THERE AND ENABLING COMMUNITY BASED PARTNERSHIPS, COMMUNITY BASED PARTNERS ARE EQUAL PARTNERS AND THERE'S AN EQUAL SHARE IN THE VALUE OF THAT RESEARCH INFORMATION, ESTABLISHING INFRASTRUCTURE, TRAINING, AND OPPORTUNITIES AGAIN, ALL EMERGED AS KEY THEMES ON THAT TOPIC.

IF WE GO TO THE NEXT SLIDE, I REFERENCED EARLIER THAT ANOTHER EFFORT I'VE BEEN PART OF HAS BEEN A U.S. GOVERNMENT LED EFFORT TO EXAMINE THE LESSONS LEARNED FROM COVID-19 THERAPEUTIC TRIALS.

THIS WAS SPURRED BY THE U.S. GOVERNMENT'S INVOLVEMENT IN OPERATION WARP SPEED WORKING ON THERAPEUTICS, THIS WAS OUTSIDE OF THE VACCINE PROCESS, THIS IS THE CONFIGURATION OF THOSE THAT ARE INVOLVED IN THIS EFFORT AND KEY ROLES HERE.

WE HAVE AT FASTERCURES LED ONE OF THE WORKING GROUPS AROUND INFRASTRUCTURE AND

RESOURCING, MRCT PARTICIPATED THROUGH BARBARA AS WELL AS A NUMBER OF OTHER PARTNERS.
NOT AN EXHAUSTIVE LIST BUT SOME OF THOSE ARE IDENTIFIED HERE AS WELL THAT INCLUDE BOTH INDUSTRY AND THOSE OUTSIDE OF INDUSTRY.
SO ALL OF THAT HAVE IS LED TO A FEW THEMES I WANTED TO HIGHLIGHT ON THE NEXT SLIDE THAT EMERGED FROM THIS U.S. GOVERNMENT EFFORT.
ONE IS THE NEED FOR CLEAR COMMUNICATION AND ENGAGEMENT TO ALL STAKEHOLDERS ACROSS A CLINICAL TRIAL LANDSCAPE.
PARTICULARLY RESEARCHERS, PATIENTS, AND DEVELOPERS.
WHAT WE LEARNED IS EARLY IN COVID IN PARTICULAR WHICH IS REALLY A SYMPTOM OF HOW OUR CLINICAL TRIAL ENTERPRISE IS, THAT WE REALLY DID NOT HAVE AN EFFICIENT WAY OF COMMUNICATING.
WHERE RESEARCH STUDIES WERE HAPPENING, HOW PATIENTS COULD ENGAGE IN THOSE RESEARCH STUDIES WHICH WERE A PRIORITY FOR WHAT TYPE OF PATIENTS, ALL OF THAT WAS NOT SHARED IN AN EFFICIENT WAY FOR THE GENERAL PUBLIC.
THAT WE NEED TO BUILD A CLINICAL TRIAL INFRASTRUCTURE, NETWORKS AND PARTNERSHIPS AND KEEP THEM WARM ON THE OTHER ISSUES THAT ARE CRITICAL OUTSIDE OF PUBLIC HEALTH EMERGENCIES.
NIH DID A NICE JOB IDENTIFYING NETWORKS, ACADEMIC, SCIENCE AND OTHERS THAT COULD BE HELPFUL FOR THEIR ACTIVE STUDIES.
HOWEVER, AS WE ALL KNOW WHAT TYPICALLY HAPPENS IN CLINICAL TRIALS IS THAT WE FORM A TEAM, WE COME TO A SIDE, EXECUTE A CLINICAL TRIAL, AND THEN IT'S DISBANDED.
SO THE CRITICAL NEED HERE IS HOW DO WE KEEP THOSE NETWORKS FOCUSED ON OTHER PUBLIC HEALTH PRIORITIES OUTSIDE OF A PUBLIC HEALTH EMERGENCY SO THAT WHEN WE ARE EXPERIENCING A PUBLIC HEALTH EMERGENCY, THEY ARE READY TO GO.
THE THIRD IS SETTING STRATEGIC PRINCIPLES, PROVIDING TOOLS, GUIDELINES FOR CLINICAL TRIAL DESIGN, I MENTIONED EARLIER THE VERY EFFECTIVE PLATFORMS TURNED OUT TO BE PRAGMATIC TRIALS OR MASTER PROTOCOLS.
BUT WHAT ARE THE TOOLS AND GUIDANCE THERE AND OF COURSE FDA HAS RECENTLY COMMENTED AROUND THAT.
TO ENSURE THE RESPONSES CAN BE QUICKLY SHAPED FROM PUBLIC HEALTH INCEPTION SO WE'RE NOT WAITING TO GET JUST OUR DUCKS IN A ROW BEFORE WE STARTING TO.
THE OTHER IS DEVELOPING AND DISSEMINATING TOOLS AND BEST PRACTICES TO IMPROVE CLINICAL TRIAL EXECUTION.
ONE OF THE CHALLENGES THAT BECAUSE OF OUR LOCATIONS OF THE VAST MAJORITY OF OUR CLINICAL TRIAL NETWORKS BEING REALLY SITUATED ON BOTH COASTS, WHEN WE HAVE OPPORTUNITIES FOR NEW TRIAL SITES TO BE UP AND RUNNING, THEY DON'T HAVE ALL OF THE TOOLS THAT THEY NEED.
EVEN HAVING A MODEL CONTRACTS AND INDEMNIFICATION CLAUSES, UNDERSTANDING WHERE AND HOW TO TAP INTO VARIOUS TYPES OF REIMBURSEMENT STRATEGIES.
ALL OF THOSE KINDS OF TOOLS AND BEST PRACTICES NEED TO BE DEVELOPED AND CONSISTENTLY DEPLOYED.
ESTABLISHING MECHANISMS AND TOOLS FOR DATA COLLECTION AND SHARING ACROSS THE U.S. CLINICAL TRIAL ECOSYSTEM.

THIS WILL NEED A QUARTER BACK.
WE DON'T HAVE A SINGLE ENTITY U.S. GOVERNMENT ENTITY, RESPONSIBLE FOR THE CLINICAL TRIAL ENTERPRISE IN THIS COUNTRY.
WHAT'S NEEDED FROM THAT PERSPECTIVE TO ENABLE US TO SHARE INFORMATION IN A SEAMLESS WAY.
AND FINALLY, PRIORITIZING AND RESOURCE PARTNERING WITH THE INTERNATIONAL COMMUNITY WHICH IS VERY MUCH RELEVANT FOR THIS GROUP IN A JOINT EFFORT ACROSS REGULATORY BODIES THAT WHERE FLEXIBILITIES ARE PROVIDED THEY CAN BE EXTEND BY OTHERS BECAUSE WHEN WE'RE DEALING WITH COMPANIES IN PARTICULAR, NOT JUST OPERATE IN ONE GEOGRAPHY.
SO ALL OF THIS HAS CULMINATED BOTH OUR EFFORTS IN TERMS OF OUR LESSONS LEARNED AT FASTERCURES AS WELL AS THE NATIONAL ACADEMIES EFFORTS AND U.S. GOVERNMENT EFFORT INTO SOME TWO BROAD AREAS THAT I THINK THAT WE NEED TO CONSIDER IN TERMS OF A VISION FOR THE FUTURE.
SHOULD WE AND HOW CAN WE MOVE TOWARD A NATIONAL NETWORK OF CLINICAL TRIALS EMBEDDED IN COMMUNITY PRACTICE.
WHAT ENTITY SHOULD BE THE ONE TO PRIORITIZE THIS.
IF IT IS A NEW ENTITY WHAT SHOULD IT LOOK LIKE, WHERE WILL FUNDING AND SUPPORT FOR THIS ENTITY COME FROM.
THIS WILL ALLOW US TO ACHIEVE THOSE THREE THINGS THAT I TALKED ABOUT IN TERMS OF EFFICIENCY AND COORDINATION ENGAGEMENT, LEVERAGING OUR EXISTING ECOSYSTEM, BUILDING POINT TO BRING IN MORE COMMUNITY TRIAL SITES.
IMPORTANTLY WE NEED A TRUE NORTH.
WE NEED TO UNDERSTAND WHAT ARE OUR CONCRETE GOALS, THE METRICS THAT WE'RE GOING TO ASSIGN TO GUIDE US TOWARD THAT NORTH STAR.
THE FDA TRACKS DIVERSITY AND INCLUSION METRICS.
BUT AS AN ECOSYSTEM, WE CAN CERTAINLY DO MORE BUT WHAT ARE THOSE METRICS WE CAN ALL ALIGN ON SO WE DON'T HAVE SEGMENTATION BY INDUSTRY, BY COMMUNITY BASED ORGANIZATIONS, BY ACADEMIC SPONSORED TRIALS OR INDEPENDENT INVESTIGATOR LED TRIALS BUT THAT WE'RE ALL MARCHING TOWARD A COMMON BEAT AND FOCUSED ON KEY PUBLIC HEALTH ISSUES AND CHALLENGES.
JUST FINALLY TO CLOSE OUT, I AM INCREDIBLY ENCOURAGED BY THE EFFORTS THAT WE'RE ALREADY SEEING.
WE'RE SEEING THIS ACCELERATED MOVE TOWARDS DECENTRALIZED AND HYBRID TRIALS.
THIS CAME OUT OF THE EFFORTS FOR ONGOING TRIALS TO STAY RELEVANT AND TO STILL BE OPERATIONAL AND LEVERAGING REMOTE MONITORING AND OTHER TOOLS TO ENABLE AND KEEP GOING.
HOW DO WE MOVE TOWARD THAT IN THE FUTURE.
WE HAVE SEEN AN INDUSTRY FOCUS ON DIVERSITY IN CLINICAL TRIALS AND THAT SHOULD CERTAINLY BE APPLAUDED AND ENCOURAGED.
CRO'S ARE BUILDING MORE DIVERSE TRIAL NETWORKS.
MANY WERE STOOD UP IN RESPONSE TO THE MODERNA AND PFIZER EFFORTS AND OTHERS TO TRY TO DIVERSIFY THE COVID-19 VACCINE TRIALS.

HOW TO WE CONTINUE TO BUILD UPON THAT MOMENTUM.
DR. FRANCIS COLLINS AT NIH IS ANNOUNCED AN INITIATIVE CALLED UNITE.
THAT COULD CERTAINLY BE HELPFUL AS WE THINK ABOUT A MORE DIVERSE WORKFORCE.
ASKING QUESTIONS THAT ARE RELEVANT TO THE APPROPRIATE COMMUNITIES.
AND THEN THE OTHER AREA HERE BEFORE THE LAST IS THE U.S. GOVERNMENT'S EFFORT TO EVALUATE THE COVID-19 THERAPEUTIC TRIALS ALSO SHOULD BE APPLAUDED AS THE U.S. GOVERNMENT IS TAKING A STEP BACK AND CONSIDERING WHAT HAPPENED, WHAT DO WE NEED TO DO BETTER IN THE FUTURE THAT'S RELEVANT NOT JUST FOR THE NEXT ONCE IN A LIFETIME EVENT, BUT IT'S ALSO RELEVANT FOR OUR ONGOING CLINICAL TRIAL NETWORK.
AND CERTAINLY VERY ENCOURAGED TO SEE THESE KINDS OF PUBLIC WEBINARS AND WORKSHOPS BEING PUT ON BY MULTIPLE ORGANIZATIONS BECAUSE IT'S HELPING US TO REALLY START TO SEE WHERE ARE CONSENSUS DEVELOPING AND WHERE IS THE COMMUNITY MOVING AND HOW WE CAN CREATE A NEW VISION FOR THE FUTURE.
SO THANK YOU SO MUCH.
I HOPE THIS WAS HELPFUL AND LOOK FORWARD TO ANY QUESTIONS.
>> THANK YOU SO MUCH, ESTHER.
BARBARA IS HAVING SOME CONNECTIVITY ISSUES SO I'M PITCH HITTING FOR HERE.
REALLY APPRECIATE YOUR THOUGHTS, INCREDIBLY THOUGHT FUNDAMENTAL PILLARS OF EFFICIENCY, ENGAGEMENT AND COORDINATION.
AND VERY MUCH APPRECIATE YOUR COMMENTS TOWARDS THE END ON METRICS, SOMETHING THAT MRCT CENTER IS THINKING A LOT ABOUT RIGHT NOW.
WANTED TO JUST ASK ONE QUESTION BEFORE WE MOVE TO THE FIRST PANEL.
KIND OF THE EXTENSION OF THE GOALS OF EFFICACY AND THE NETWORK OF CLINICAL TRIALS.
DO YOU HAVE SUGGESTIONS TO INTERNATIONAL TRIALS AND GLOBAL PREPAREDNESS?
>> YES A VERY INTERESTING QUESTION.
I THINK A LOT OF THE CONVERSATION WE'VE HAD TODAY IS RELEVANT IN THE U.S. CONTEXT.
I THINK THERE ARE LEARNING OPPORTUNITIES THE SOLIDARITY TRIAL, FOR EXAMPLE, DID A NICE JOB GETTING A LOT OF COUNTRIES SIGNED UP FOR THAT TRIAL.
WHAT HAPPENS, HOWEVER, IT DOES SLOW THINGS DOWN A BIT AS ANSWERS NEED TO COME FORWARD BUT AS THEY COME FORWARD THERE ARE MORE RELEVANT IN THOSE REGIONAL LOCATIONS AS WELL BECAUSE THEY'RE REFLECTIVE OF THOSE PATIENTS WHO WERE ENGAGED.
SO DESPITE THE CONTEXT HERE BEING SHAPED AROUND THE U.S., I DO THINK THIS MOVEMENT TO HOW WE EMBED TRIALS IN COMMUNITIES THAT ARE ASKING QUESTIONS THAT ARE RELEVANT TO COMMUNITIES CERTAINLY HAS INTERNATIONAL IMPLICATIONS.
>> ESTHER, THANK YOU SO MUCH.
VERY MUCH ENJOYED THIS TALK.
AND NOW I'M GOING TO MOVE TO THE FIRST PANEL, AND INTRODUCE DR. PAUL KLUETZ, WHO IS A MEDICAL ONCOLOGIST AND DEPUTY DIRECTOR OF THE ONCOLOGY CENTER OF EXCELLENCE AT THE U.S. FDA.
AND PAUL IS GOING TO LEAD THE GROUP THROUGH THIS FIRST PANEL, THINKING ABOUT USEFUL AND PERMISSIBLE FLEXIBILITIES TO STUDY CONDUCT.
SO PAUL, OVER TO YOU.

>> THANK YOU, SARAH.
MY NAME IS PAUL KLUETZ, AGAIN, AND I'M WITH THE ONCOLOGY CENTER OF EXCELLENCE AT THE FDA.
I'M GOING TO SEE IF WE CAN GET BACK ON SCHEDULE A LITTLE BIT BY REDUCING MY INTRO REMARKS BECAUSE WE HAVE A GREAT PANEL AS YOU CAN SEE.
REALLY ACROSS A GROUP OF STAKEHOLDERS THAT WE WANT TO HEAR FROM PATIENTS TO COMMERCIAL INDUSTRY TO ACADEMIC RESEARCHER AND TO FOLKS ON THE OPERATIONAL SIDE HELPING OUT DESIGN CLINICAL TRIALS.
SO I GUESS I WOULD JUST MENTION FROM THE FDA SIDE THAT WHAT I'M VERY INTERESTED IN AS WELL AS WHAT SOUNDS LIKE THE ENTIRE GROUP, IS TO NOT GO BACK TO BUSINESS AS USUAL AND TO LEARN FROM WHAT THE EFFICIENCIES AND PATIENT CENTEREDNESS THAT WERE DONE DURING THE COVID PANDEMIC.
THE ONE ISSUE WE SAW VERY EARLY WAS THAT THERE WAS SOME UNCERTAINTY WITH RESPECT TO THE REGULATORY BARRIERS TO DOING THINGS LIKE REMOTE ASSESSMENTS AND I THINK WE ADDRESSED THAT ISSUE RAPIDLY WITH THE COVID-19 CLINICAL TRIALS GUIDANCE.
AND I THINK THAT OPENED UP AN UNDERSTANDING TO WHERE WE COULD DEPLOY SOME OF THESE REMOTE ASSESSMENTS KEEPING SAFETY AND DATA INTEGRITY AT THE FOREFRONT.
AND I THINK A LOT OF TRIALS NOW AS EVERYONE KNOWS, ARE BEING CONDUCTED IN A HYBRID MANNER, WHICH I THINK HAS LONG BEEN OF INTEREST TO DRUG DEVELOPMENTS, HOW CAN WE MOVE CLINICAL TRIALS OUT MORE TO WHERE PATIENTS LIVE AND SO THAT'S BEEN OBVIOUSLY ONE BIG BENEFIT OF COVID-19 WAS REALLY PUSHING EVERYONE OUT OF THEIR COMFORT ZONES TO DEPLOY THOSE ASSESSMENTS.
SO I THINK TO START I'D LIKE TO HEAR SOME OPENING REMARKS FROM THE PANELISTS, BLADED OF HOUSEKEEPING, WE DO -- WE WOULD LOVE TO SEE QUESTIONS COME IN AND WE'LL TRY TO ANSWER THEM AS THEY COME IN.
WE WON'T GET TO THEM ALL BUT I HOPE WE'LL BE ABLE TO REVIEW ALL THE QUESTIONS AFTERWARDS SO WE CAN IDENTIFY ISSUES.
I THINK I'D LIKE TO STARTED WITH VALEN, A PATIENT ADVOCATE AND HEAR FROM HER ABOUT WHAT HER PRIORITIES ARE AND WHAT SHE'D LIKE TO SEE POST-PANDEMIC.
VALEN?
>> IT'S AN HONOR TO BE HERE TODAY WITH ALL OF YOU.
I'VE BEEN A PATIENT MOST OF MY LIFE.
STARTED ADD FIVE YEARS OLD WITH EPILEPSY AND POLYCYSTIC KIDNEY SKIS AND HAD A CHALLENGE JOURNEY BUT GRATEFUL TO SAY THIS SUMMER I'M CELEBRATING 19 YEARS POST KIDNEY AND THREE YEARS POST LIVER TRANSPLANT AND GRATEFUL EVERY DAY TO BE ALIVE.
DURING COVID OF COURSE, IT'S BEEN VERY CHALLENGING TO BE IMMUNO EXPRESSED AND I'M CLOSELY CONNECTED WITH THE KIDNEY AND TRANSPLANT COMMUNITY IT'S BEEN A JOURNEY FOR ALL OF US.
BUT I'VE BEEN LUCKY TO BE ABLE TO PARTICIPATE IN A STUDY DURING COVID AND I'VE LEARNED A LOT FROM IT TO BE ABLE TO DO ALL OF IT FROM HOME AND BE SAFE AND ESPECIALLY WITH THE CONCERNED OF BEING HIGH RISK AND DURING THE THICK OF COVID AND NOT GOING OUT AND BEING ABLE TO BE SAFE, I'VE LEARNED A LOT FROM IT.
I THINK A COUPLE THINGS THAT WORKED REALLY WELL TO SHARE IS THAT THEY SENT ME A BLOOD

DRAW KIT AT HOME, AND MADE ME THE ACCESS TO BE ABLE TO PARTICIPATE REALLY EASY AND SAFE.
SO IT WAS A WONDERFUL EXPERIENCE OF BEING ABLE TO DO THAT ON MY OWN AND THEY SCHEDULED PICKUP AND EVERYTHING WAS DONE VIRTUALLY, AND ALL OF THE INFORMATION WAS SHARED VIA WEBINARS, WHICH I THINK WAS REALLY AMAZING THAT IF I THINK BACK TO TIMES PRE-COVID THAT PROBABLY WOULDN'T HAVE TAKEN PLACE.
SO WE'VE BEEN KEPT UP TO UPDATE AND FELT VERY PART OF THE STUDY AND I THINK THE PARTICIPATION BEING ABLE TO BE REALLY EASY AND THE COMMUNICATION I THINK HAS BEEN JUST A REALLY WONDERFUL EXPERIENCE FOR US PATIENTS.
I LEARNED A LOT, OF COURSE, FROM THIS OF HOW IMPORTANT RESULTS ARE TO PATIENTS, WHICH I FELT THAT WAY MY ENTIRE JOURNEY.
BUT I THINK BEING ABLE TO HAVE IT SHARED WITH THE COMMUNITY IN AN EASY TO UNDERSTAND LANGUAGE HAS BEEN REALLY EMPOWERING FOR ALL OF US.
AS WE'VE LEARNED THE RESULTS AND FEELING VERY IN COMMUNICATION WITH THE STUDY TEAM, I THINK WE HAVE FELT LIKE WE'RE PARTNERS VERSUS PATIENTS, AND I THINK I'VE SEEN THAT SHIFT OF HOW GOOD THAT'S BEEN FOR THE COMMUNITY OF FEELING LIKE WE'RE A PART OF THIS, WE'RE IMPORTANT, WE'RE FEELING APPRECIATED, WE'RE LEARNING INFORMATION, IT'S EMPOWERING, AND THE THING THAT'S BEEN REALLY NEAT TO WITNESS IS THE COMMUNITY'S COME TOGETHER SURROUNDING THIS STUDY.
THERE'S NOW SOCIAL MEDIA GROUPS ABOUT IT, PATIENTS ARE TALKING, AND IN TURN, BY A REALLY GOOD EXPERIENCE AND COMMUNICATING ONLINE ABOUT THIS, RECRUITMENT IS NATURALLY HAPPENING FROM PATIENTS TALKING ABOUT IT TO OTHER PATIENTS.
MY THOUGHT MOVING FORWARD, THINKING OF GOING THROUGH A DECENTRALIZED STUDY DURING COVID AND WITH THE COVID CLINICAL TRIALS AND JUST BEING IMMUNO SUPPRESSED IS MAKES ME THINK MOVING FORWARD ON PARALLEL STUDIES.
I FEEL LIKE THE IMMUNO SUPPRESSED COMMUNITY WE FEEL MONTHS BEHIND THE GENERAL PUBLIC BECAUSE OF NOT BEING INCLUDED IN THE INITIAL COVID TRIALS.
SO WE DIDN'T HAVE ANY INFORMATION ON SAFETY OR EFFICACY OF THE VACCINE AND IT LEAVES US NOW THAT JUST SEVERAL MONTHS AGO WE LEARNED THAT IT'S NOT AS EFFECTIVE IN OUR COMMUNITY, AND NOW, YESTERDAY, I LIVE IN CALIFORNIA, AND ALL MANDATES WERE LIFTED FOR MASKS AND SOCIAL DISTANCING AND I FEEL LIKE I'M MONTHS BEHIND THAT BECAUSE WE'RE STILL LEARNING HOW TO PROCEED MOVING FORWARD AND WHAT'S SAFE TO INTEGRATE OURSELVES BACK INTO SOCIETY.
SO I THINK IT WOULD HAVE BEEN AMAZING IF THERE COULD HAVE BEEN -- THAT WE COULD HAVE BEEN INCLUDED, IF THERE WOULD HAVE BEEN AN OPTION TO DO MAYBE A PARALLEL STUDY WITH A GENERAL PUBLIC AND THOSE THAT HAVE A COMPROMISED IMMUNE SYSTEM.
AND I THINK THAT -- I THINK THROUGH THE BIG THING THROUGH ALL OF THIS IS JUST WITNESSING, I THINK, THE POWER OF PARTNERSHIPS WITH PATIENTS AND STUDY TEAMS AND I'M JUST REALLY GRATEFUL TO BE ABLE TO SHARE THE PATIENT PERSPECTIVE TODAY AND I HOPE THAT IT HELPS MOVING FORWARD TO CREATE POSITIVE CHANGE.
>> THANK YOU, VALEN.
NOW I THINK WE'LL MOVE OVER AND HEAR SOME OPENING REMARKS FROM ISAAC RODRIGUEZ-CHAVEZ WHO'S A FORMER FDA COLLEAGUE AND FRIEND OF MINE AND NOW HAS MOVED

OVER TO MORE THE OPERATIONS SIDE WITH PRAHEALTHSCIENCES.
ISAAC, OPENING REMARKS?
>> THANK YOU, PAUL.
AND THANK YOU ALL THE ORGANIZERS OF THIS EVENT FOR THE OPPORTUNITY TO BE WITH ALL OF YOU HERE.
WELCOME ALL OF YOU PARTICIPANTS TO THIS CONFERENCE AND EVENT.
I'M DELIGHTED TO BE HERE.
WE'RE IN A TRANSFORMATIONAL TIME WITH RESEARCH.
THESE ARE EXCITING TIMES FOR EVERYONE TO BE ENGAGED IN INVESTIGATIONS AND ESSENTIALLY THE FUTURE IS REALLY BRIGHT.
THERE ARE OPPORTUNITIES TO THINK OUTSIDE OF THE BOX AND WHAT I LOOK FORWARD IS WE ARE JUST AT THE BEGINNING OF MANY, MANY GOOD AND EXCITING THINGS TO HAPPEN FROM THE CLINICAL RESEARCHER STANDPOINT THAT WILL DEFINITELY BENEFIT ALL THE STAKEHOLDERS, CLEARLY THE PATIENTS.
THE SPONSORS, THE SCIENCE, INVESTIGATORS, THE DIFFERENT HEALTHCARE PROVIDERS ENGAGED IN THE CLINICAL INVESTIGATIONS, THIS IS A GREAT OPPORTUNITY TO DELIVER AT A VERY HIGH CALIBER, QUALITY, MAINTAIN THE SAFETY, THE PARTICIPANTS, AND HAVE REALLY THE INTEGRITY OF THE DATA THAT IS NEEDED FOR ASSESSING THE SAFETY AND EFFICACY OF THE MEDICAL PRODUCTS ON THE INVESTIGATION.
SO THE FUTURE IS REALLY BRIGHT, AND I'M LOOKING FORWARD TO BEING PART OF THIS.
THANK YOU.
>> THANKS, ISAAC.
I WILL TURN IT OVER NOW FOR A LITTLE BIT OF AN ACADEMIC INVESTIGATOR INSIGHT BY LINDSEY BADEN AND I THINK LINDSEY, IT'S INTERESTING, PENNY HAS THE SAME PERSPECTIVE, I'M SPECIFIC TO ONCOLOGY, BUT YOU HAVE A BROAD RANGE OF THERAPEUTIC AREA INTERESTS WITH RESPECT TO CLINICAL TRIALS SO I KNOW THE CONTEXT IS IMPORTANT.
OPENING REMARKS FROM YOU, LINDSEY?
>> THANK YOU, AND I'D LIKE TO THANK THE ORGANIZERS FOR BRINGING US TOGETHER FOR THIS TERRIFIC AND IMPORTANT DISCUSSION.
AND I'M GOING TO AMPLIFY WHAT'S BEEN SAID BECAUSE I THINK WE TOUCHED ON A LOST THE HE KEY ISSUES.
ON THE PI OF THE NIH MODERNA STUDY.
OVER THE LAST 18 MONTHS, SPENT A LOT OF TIME WATCHING THINGS UNFOLD AND HELPING FIGURE OUT HOW DO WE DO SOMETHING THAT HASN'T BEEN DONE BEFORE IN THE SHADOW OF A PANDEMIC THAT SHUT DOWN SOCIETY, SHUT DOWN HOW WE INTERACT AND WE WERE ALL FEARFUL FOR OUR OWN HEALTH AND NEEDED TO RESPOND TO THIS.
WE DIDN'T UNDERSTAND THE PATHOGEN.
I THINK PART OF THE LESSONS TO JUST HIGHLIGHT A COUPLE OF KEY LESSONS, DATA SHARING.
BACK ON JANUARY 10, '11, 2020, HAVING THE SEQUENCE AVAILABLE GLOBALLY MADE A DIFFERENCE TO EVERYBODY IN THINKING ABOUT HOW TO RESPOND AND THAT DATA SHARING IS A VERY IMPORTANT ELEMENT WE HAVE TO THINK ABOUT.
THE REGULATORY FRAMEWORK, HOW DO WE DO STUDIES, HOW TO WE THINK ABOUT IT?

ARE THE DIFFERENT CONSIDERATIONS BE THEY VACCINE, MONOCLONAL, SMALL MOLECULES, ANTI-INFLAMMATORIES, DO THEY REALLY HAVE THE SAME ISSUES.
IN FACT DO WE EVEN UNDERSTAND THE DISEASE PATH OWE GENESIS TO KNOW WHICH OF THOSE THINGS MATTERED IN OUR RESPONSE.
DO WE HAVE DIAGNOSTIC TESTS, ANTIBODY, PCR, WE'RE STILL IMPROVING THAT.
I THINK THAT WE HAD TO FIGURE OUT HOW TO DESIGN THE STUDIES, WHAT WOULD THE CLINICAL TRIALS LOOK LIKE, HOW WOULD WE DO HOME ASSESSMENTS AND WHAT CAN WE DO THROUGH THE MAIL OR IN-PERSON TO MAKE SURE WE KEEP THE VOLUNTEERS SAFE WHILE WE ANSWERED THE QUESTIONS WITH THE TECHNOLOGY AVAILABLE BECAUSE WE UNDERSTOOD THE DISEASE.
I THINK THAT'S A VERY IMPORTANT ELEMENT IS THE UNDERSTANDING THE PATHOGEN AND RAPIDITY OF ENGAGING THE CLINICAL TRIALS NETWORK AND STAKEHOLDERS AND THIS WAS A PARTNERSHIP BETWEEN ACADEMIA, GOVERNMENT, THE INDUSTRY, THE REGULATORY AND COMMUNITY AND WE ALL RALLIED TOGETHER WITH MUCH UNCERTAINTY TO SAY WHAT ACTUALLY MAKES SENSE TO GO FORWARD TO BE ABLE TO DO THE PIVOTAL STUDIES, MANY OF THE STUDIES DIDN'T YIELD THE RESULT WE WANTED.
SOME OF THEM DID YIELDED RESULT WE WANTED AND WE HAVE TO BE PREPARED FOR BOTH SUCCESS AND FAILURE.
THERE WILL BE A LOT MORE FAILURE THAN SUCCESS IN TERMS OF THINGS WORKING.
AND HOW DO WE ENABLE, ENGAGE, AND ACCELERATE THAT ITERATIVE PROCESS.
AND THEN THE LAST COMMENT IS JUST EQUITY WHICH I THINK WE ALL ARE REFLECTING ON IN TERMS OF DISPROPORTIONALITY OF DISEASE IMPACT BUT ALSO OF HOW WE DO OUR STUDIES TO MAKE SURE IT'S RELEVANT TO THE COMMUNITIES THAT ARE IMPACTED AS DR. KROFAH ELOQUENTLY FRAMED IN THE OPENING REMARKS.
BUT I THINK THERE'S A LOT THAT WE CAN DO TOGETHER AND HAVE DONE TOGETHER.
AND I THINK THERE'S MUCH FOR US TO THINK ABOUT AND LEARN FROM THIS.
>> THANKS, LINDSEY.
I THINK IT'S SO IMPORTANT THE POINT YOU MADE THAT THERE ARE MANY MORE FAILURES THAN THERE ARE SUCCESSES IF YOU'RE DOING SCIENCE CORRECTLY.
AND THE QUESTION IS HOW CAN WE GET TO THOSE RESULTS AS FAST AS POSSIBLE SO THAT WE CAN SCREEN THROUGH ALL THE FAILURES TO FIND THOSE TRULY EFFECTIVE THERAPIES.
AND THE OTHER POINT I THINK IS COLLABORATION AND DATA SHARING.
WHAT ARE THE INCENTIVES FOR THAT MOVING FORWARD IS IMPORTANT.
SO WE'RE GOING TO END AS FAR AS THE INTRODUCTIONS WITH PENNY CARLSON WHO IS WITH TAKEDA.
WHAT'S BEEN YOUR PERSPECTIVE?
WHAT DO YOU THINK ABOUT THE COVID-19 PANDEMIC AND WHAT WE CAN LEARN?
>> THANKS FOR HAVING ME.
I THINK WHAT EVERYONE HERE IS HEARING IS THAT NO MATTER THE PERSPECTIVE WHETHER IT BE AN INVESTIGATOR FROM A CRO OR REGULATOR PATIENTS OR SOMEONE FROM A SPONSOR COMPANY IS I SEE OPPORTUNITY EVERYWHERE.
I THINK IT TOOK AS YOU A LITTLE BIT TO TURN THOSE INTO OPPORTUNITIES ALL OF YOU HAVE MENTIONED A LOT OF THOSE OPPORTUNITIES WE HAVE SEEN SIGNIFICANT FOCUS AND OPPORTUNITY

IN TERMS OF DIVERSITY IN CLINICAL TRIALS AND THAT'S DIVERSITY OF ALL SORTS OF.
WE'LL TALK THROUGH SOME OF THAT THROUGHOUT THE PANEL TODAY.
THOSE OPPORTUNITIES FOR COLLABORATION WHICH WE DIDN'T SEE PRIOR TO THE PANDEMIC IN THE SAME WAY.
THAT'S ABOUT HOW WE COLLABORATED WITH EACH OTHER AS SPONSOR COMPANIES, FOR EXAMPLE, HOW WE COLLABORATED WITH SITES AND COLLABORATED WITH REGULATORS.
I THINK WE'VE ALL LEARNED SO MUCH.
I THINK AS A HUMAN BEING, AS A PARENT, AS AN EMPLOYEE OF A SPONSOR COMPANY, ALL THOSE PERSPECTIVES ARE IMPORTANT IN TERMS OF WHAT IT IS WE'VE DONE TO RESPOND TO THE PANDEMIC.
BUT WE HAVE A LONG WAY TO GO.
I THINK WE HAVE A LOT TO DO TO TAKE EVERYTHING WE'VE DONE ALL THE WAYS IN WHICH RESPONDED TO THE PANDEMIC AND KEEP THAT MOMENTUM GOING AND REALLY CHANGE THE WAY WE WORK.
THAT COULD BE ABOUT HOW IT IS WE WORK WITH SITES TO GET READY TO DO RESEARCH FASTER, COULD BE ABOUT HOW WE OFFER ACCESS TO CLINICAL TRIALS TO PATIENTS WHO REALLY NEED A DIFFERENT KIND OF ACCESS TO HEALTHCARE, AND IT COULD BE ABOUT HOW QUICKLY WE'RE ABLE TO GET INFORMATION TO REGULATORS IN ORDER TO GET TO THE NEXT PHASE AND GIVE A MUCH BROADER POPULATION ACCESS TO THE TREATMENTS OR THE VACCINES.
>> THANK YOU VERY MUCH.
SO WHAT I'D LIKE TO DO IS OPEN THIS UP TO MORE OF A PANEL DISCUSSION.
WE'LL ALSO TAKE SOME QUESTIONS AND ANSWERS.
ONE HAS COME IN THAT'S INTERESTING THAT COULD MAYBE GET US STARTED.
I THINK WE CAN ALL COMMENT ON.
SURROUNDING INCENTIVES.
WHAT'S THE INCENTIVE TO CONTINUE TO DO THINGS AS THEY WERE DONE?
THAT COULD BE WITH RESPECT TO DATA SHARING, COULD BE WITH RESPECT TO COMPANIES COLLABORATING ON SORT OF TRIALS WITH A SHARED CONTROL ARM, THAT'S A CHALLENGE IN ONCOLOGY WE LOVE TO SEE IMPROVE.
HE THE QUESTION SPECIFICALLY IS PATIENTS AND WHEN WE'RE DOING REMOTE ASSESSMENTS OR DELIVERING REMOTE INVESTIGATIONAL PRODUCTS WHICH HAS HAPPENED DURING COVID, HOW CAN WE INCENTIVIZE PATIENTS TO TAKE THE DRUG AS IT WAS PRESCRIBED OR TO FILL OUT THAT THE ELECTRONIC PATIENT REPORTED OUTCOME OR WHATEVER THE CLINICAL OUTCOME ASSESSMENT IS THAT'S BEING DONE REMOTELY.
I'LL START WITH VALEN.
WHAT DO YOU THINK AS A PATIENT WOULD INCENTIVIZE, BECAUSE A LOT OF THIS IS GOING TO BE PUT ON PATIENTS AND IT'S GOING TO BE SO REMOTE, WHAT DO YOU THINK WILL MOTIVATED PATIENTS TO TRY TO COMPLETE THE ASSESSMENTS AND MAKE SURE THEY ARE TAKING THE DRUG AS PRESCRIBED, ET CETERA?
I THINK YOU'RE MUTED, VALEN.
>> THANK YOU.
I HAVE SEEN HOW IMPORTANT IT IS FOR PATIENTS TO HEAR FROM PATIENTS.
AND I THINK IF THERE'S AN INITIATIVE AND IT OPENS UP SOME TYPE OF A COMMUNITY AND I THINK IF

THERE'S SOME TYPE OF A CONNECTION, LIKE IF I WAS PARTICIPATING IN A CLINICAL TRIAL BUT I WAS ABLE TO TALK TO MAYBE OTHER PATIENTS THAT WERE DOING IT OR I WAS EVEN ABLE TO BE EDUCATED ON IT FROM OTHER PATIENTS, I THINK THAT ONE-ON-ONE IS SO IMPORTANT FOR US TO BE ABLE TO HEAR FROM SOMEONE ELSE.
SOMEONE ELSE THAT'S GOING THROUGH THE SAME THING.
SO I THINK IF IT'S ALMOST LIKE YOU'RE, IT'S AN OPPORTUNITY, YOU CAN PARTICIPATE IN A CLINICAL TRIAL AND YOU'RE ALSO OPENING UP THIS COMMUNITY YOU'RE GOING TO BE PART OF.
AND YOU FEEL LIKE YOU'RE PART OF SOMETHING BIGGER THAN YOURSELF AND YOU SEE THE OUTCOME AND HOW YOU CAN HELP, I THINK THAT THAT'S REALLY POWERFUL.
I THINK THAT WOULD BE REALLY IMPORTANT AND I THINK THAT'S WHAT PATIENTS WANT RIGHT NOW.
WE WANT TO BE PART OF SOMETHING BIG SO WE KNOW WE'RE CREATING POSITIVE CHANGE FOR FUTURE GENERATIONS SO THEY DON'T HAVE TO GO THROUGH WHAT WE'RE GOING THROUGH.
>> ISAAC, AS SOMEONE WHO'S RESPONSIBLE FOR DATA QUALITY WITHIN CLINICAL RESEARCH ORGANIZATION LET'S SAY, WHAT ARE SOME THINGS YOU'VE DONE TO HELP MONITOR AND MAKE SURE THAT FOR INSTANCE ADHERENCE TO AN ELECTRONIC PRO OR SOME PATIENT GENERATED DATA IS HIGH QUALITY?
>> IT WILL TAKE ME TWO WEEKS TO ANSWER YOUR QUESTION BUT LET ME GIVE YOU A QUICK INTRODUCTION TO IT.
THANK YOU, PAUL FOR THE QUESTION.
VERY IMPORTANT.
IN THE FIRST PLACE, I COULD SAY WHEN YOU LOOK AT THE INCENTIVES AND LET ME GO BACK TO YOUR INITIAL QUESTION OR PREVIOUS QUESTION, WHEN YOU LOOK AT THIS FROM THE DIFFERENT MULTIPLE -- DIFFERENT AND MULTIPLE STAKEHOLDERS, THE PATIENT PERSPECTIVES ARE DIFFERENT COMPARED TO THE SPONSOR'S PERSPECTIVES AND THE SCIENCE PERSPECTIVES, AND EACH OF THESE STAKEHOLDERS HAVE IMPORTANT INCENTIVES IN PLACE TO DO THINGS IN A DIFFERENT WAY.
PATIENTS WANT SOMETHING THAT'S TRANSFORMATIVE.
SOMETHING THAT'S MEANINGFUL.
SOMETHING THAT'S LESS INTRUSIVE.
SOMETHING THAT'S REALLY GOING TO PROVIDE A BENEFIT FOR THEM THAT IS TANGIBLE.
NOW, WE'RE TALKING ABOUT PATIENTS IN CLINICAL TRIALS.
WE ALSO HAVE HEALTHY PEOPLE IN CLINICAL TRIALS.
THINK ABOUT THE -- THESE INDIVIDUALS ARE JUST NOT INFECTED WITH HIV, SORRY, WITH COVID-19, THEY ARE JUST BEING VOLUNTEERS, IF YOU WILL, IN CLINICAL INVESTIGATIONS AND THEY MAY SEE THE BENEFITS, BUT THESE ARE PARTICIPANTS, THESE ARE NOT NECESSARILY PATIENTS.
SO THERE ARE DIFFERENT INCENTIVES CREATED FOR DIFFERENT SECTORS OF PEOPLE INVOLVED AND STAKEHOLDERS INVOLVED IN THE CLINICAL INVESTIGATION.
THE SPONSORS ARE LOOKING FOR SOMETHING THAT'S MORE TANGIBLE, MORE EFFICIENT AND ALL THE STEPS OF THE CLINICAL INVESTIGATION THAT IS COST-CONTROLLED IF NOT CHEAPER, AND THAT MAINTAINS THE SAFETY AND EFFICACY OF -- MAINTAINS THE SAFETY AND THE DATA QUALITY OF THE CLINICAL INVESTIGATION.
THE SCIENCE ARE LOOKING FOR HOW DO WE GENERATE REVENUE WHEN WE HAVE LESS PEOPLE AND CAN WE DO THIS IN A MEANINGFUL WAY SO THAT IT DOESN'T REPRESENT LOSSES BECAUSE

OTHERWISE, OUR SILVER LINING IS COMPROMISED.
NOWADAYS MANY SIDES UNDERSTAND THAT THE MORE EFFICIENCY AND INTEGRATION LIMITING OR ELIMINATING THE GEOGRAPHIC BARRIERS REPRESENT MORE OPPORTUNITIES.
AND SO THERE'S A TRANSFORMATION OF THE EXPENSES AND REVENUE GENERATION AT THE SITE LEVEL THAT'S DIFFERENT, FOR EXAMPLE, IN DECENTRALIZED TRIALS COMPARED TO WHAT HAPPENS IN A TRADITIONAL CLINICAL INVESTIGATION.
DIFFERENT EFFICIENCIES AND DIFFERENT WAYS OF -- ACCESSIBILITY OF MULTIPLE ACTIVITIES IN CLINICAL RESEARCH AND THE DIGITAL HEALTHCARE ENTERPRISE SO THAT THINGS CAN BE TRANSFORMED.
THAT'S WHY I USE THE WORD TRANSFORMATIONAL IN ALL SENSES.
GOING BACK TO YOUR SECOND QUESTION, I COULD SAY WE NEED TO ENABLED BY DIGITAL HEALTH TECHNOLOGIES, OFFER A UNIQUE OPPORTUNITY HISTORICAL OPPORTUNITY TO DO THINGS DIFFERENTLY.
THERE IS A LOT MORE INTEGRATION OF MULTIDISCIPLINARY TEAMS WITHIN AN ORGANIZATION AND THERE'S A LOT MORE INTEGRATION OF DIFFERENT ORGANIZATIONS AND STAKEHOLDERS TO PUT TOGETHER A SIMPLE, AND PENNY ALLUDED TO THIS.
THE COLLABORATION AND THE LEVEL OF COLLABORATION AND TYPES OF COLLABORATIONS NOWADAYS HAS TO BE PUT IN PLACE TO DELIVER QUALITY, EXCELLENCE, CONTROL, THE QUALITY AND INTEGRITY OF THE DATA AND MAINTAIN THE SAFETY OF THE PARTICIPANTS IS UNPRECEDENTED.
AND ALL OF THIS NEEDS TO BE MAPPED OUT VERY CAREFULLY EARLY ON EVEN BEFORE A TRIAL IS -- PROTOCOL IS WRITTEN.
SO THERE'S A WHOLE DECK OF PEOPLE AND STAKEHOLDERS, MEDICAL, SCIENTIFIC, QUALITY CONTROL, QUALITY ASSURANCE, REGULATORY, LEGAL, OPERATIONS, THAT HAVE TO REALLY WORK IN SYNCHRONY TO MAKE IT HAPPEN.
ANOTHER THING IS IN ALL OF THIS, WE ENGAGE EARLY ON WITH THE PARTICIPANTS, BECAUSE PARTICIPANTS BEING PARTICIPANTS AND PATIENTS, BECAUSE NOWADAYS IT'S MORE THAN EVER A PARTNERSHIP.
IT'S NOT THE PASSIVE POSITION OF THE PARTICIPANTS IN THE TRADITIONAL CLINICAL TRIALS.
IT'S MORE OF AN EMPOWERMENT POSITION.
THEY ARE VESTED IN UNDERSTANDING WITH ALL OF THE TECHNOLOGIES THAT EXIST WHAT IS HAPPENING WITH THEIR HEALTH, WHAT IS THE RESULT OF THE CLINICAL LABORATORY THAT WAS AN ENDPOINT OR IS AN ENDPOINT FOR THE CLINICAL INVESTIGATION THAT'S HAPPENING.
SO -- ALL OF THIS IS VERY IMPORTANT.
MAPPING OUT THE DATA FROM THE END, THE BEGINNING TO THE VERY END AND HOW THE DATA WILL FLOW AND WHAT IS THE HEALTH JOURNEY THAT THE PARTICIPANTS WILL FOLLOW, WHAT KIND OF TECHNOLOGIES WILL BE CUSTOMIZED AND ADAPTED FOR THE SPECIFIC NEEDS OF THAT TRIAL, WHAT KIND OF DIGITAL ENDPOINTS WILL BE UTILIZED, CAN THEY BE UTILIZED, TO MEET THE SPECIFIC NEEDS OF THAT SPECIFIC --
>> THERE'S NO DOUBT THAT THERE'S GOING TO NEED TO BE A LOT OF INFRASTRUCTURE.
THAT WAS ACTUALLY BROUGHT UP A LITTLE BIT IN THE INTRODUCTORY COMMENTS THAT I THOUGHT WERE GREAT.
I'D LOVE TO SEE THE SLIDE DECK FROM OUR SPEAKER.

IT WAS FANTASTIC: FOR LINDSEY AND FOR PENNY, THE WHOLE IDEA OF DECENTRALIZED TRIALS AND PATIENTS PARTICIPATING MORE IS AN EXCITING OPPORTUNITY.
BUT WHAT ARE THE DATA INTEGRITY ISSUES WE HAVE TO THINK ABOUT.
THE MORE THAT YOU PUT SOME OF THESE VERY HIGHLY CONTROLLED ENDPOINTS AND DATA SOURCING TO PATIENTS, THERE'S NOTHING FOR FREE.
YOU MAY GET SOME VARIABILITY, YOU MAY HAVE SOME CHALLENGES THERE.
WHAT ARE SOME OF THE THINGS THAT WOULD BE CONSIDERATIONS FOR THE PATIENTS GENERATED DATA AND HOW DO YOU OVERCOME THAT IN SOME OF THE TRIALS YOU'VE DONE.
WE'LL TART WITH LINDSEY AND THEN GO TO PENNY.
>> I THINK THAT UNDERSTANDING THE PERSPECTIVE OF THE OTHER, WHICH IS WHAT YOU'RE GETTING AT WITH INCENTIVE, IS FOR YOU TO PARTICIPATE IN MY TRIAL, I HAVE TO UNDERSTAND YOUR PERSPECTIVE, WHAT MOTIVATES YOU, WHAT YOU'RE ABLE TO DO, WILLING TO DO, INTERESTED IN DOING, AND WE HAVE TO ALIGN THE INCENTIVES SO EVERYBODY WINS.
AND THERE'S NO REASON NOT TO.
SO THAT'S THE MACROSCOPIC DO THE INCENTIVES ALIGN IN WAY THAT LEAD US ALL TO A VIRTUOUS RESOLUTION AND THEN WHAT YOU'RE GETTING AT, PAUL; THE ISSUE OF ADVANCING TECHNOLOGY.
NOW THAT WE ALL HAVE -- NOW THAT MANY OF US HAVE SMART PHONES AND SMART PHONES ARE CHEAP ENOUGH THAT THEY CAN BE INCORPORATED INTO CLINICAL STUDIES WE CAN DO -- OXYGEN LEVEL MONITORING, HEART RATE MONITORING, ONLINE QUESTIONNAIRES, DAILY DIARIES, CDC VACCINE SURVEILLANCE AFTER -- JUST EXAMPLES OF THINGS WHICH COULD NOT HAVE EXISTED 20 YEARS AGO THAT NOW I AM AN INVESTIGATOR BUT I'M ALSO A PATIENT, A PARTICIPANT, A VACCINE RECIPIENT, BECAUSE I'M AT RISK FOR COVID LIKE THE REST OF US ON THIS CALL.
AND SO BEING ABLE TO ENGAGE ME IN A WAY WHERE I CAN RESPOND IN A WAY THAT FITS MY LIFESTYLE BUT ADDS TO THE DATA ROBUSTNESS, COMPLETENESS, AND BEING ABLE TO ENGAGE ALL OF US.
AND I THINK THAT'S REALLY IMPORTANT.
I THINK WE HAVE TO ADAPT TO THE TECHNOLOGIES AND GET BACK TO THE EQUITY CONCEPT IN THAT THERE ARE THOSE COMMUNITIES THAT DON'T HAVE ACCESS TO SOME OF THESE DEVICES, AND THAT IS SOMETHING WE HAVE TO BUILD INTO HOW WE THINK ABOUT DOING THESE STUDIES, BECAUSE WE REALLY, FOR THINGS THAT AFFECT ALL OF US, WE HAVE TO ENGAGE ALL OF US AND WE NEED TO LEVERAGE TECHNOLOGY TO ENGAGE ALL OF US, AND THAT'S DOABLE.
WE JUST HAVE TO THINK IT THROUGH.
I THINK ENGAGING THE TECHNOLOGY AND MAKING IT PART OF THE STUDY DESIGN AND HAVING THE VOLUNTEERS, PARTICIPANTS, BE THOUGHT ABOUT IN THE CREATION OF THOSE DATA ACQUISITION ELEMENTS SO WE'RE ABLE TO INCLUDE THE RURAL COMMUNITIES THAT DON'T HAVE VERY GOOD WIFI, CERTAIN COMMUNITIES THAT DON'T HAVE SMART DEVICES, THAT'S ALL SOLVABLE.
WE JUST HAVE I THIS TO THINK IT THROUGH.
>> I WOULD MENTION THAT THERE ARE SOME THINGS THAT ARE WITHIN OUR REGULATORY PURVIEW AND A LOT OF THINGS WE HAVE TO DO AS A COUNTRY AND AS A SORT OF ECOSYSTEM TO IMPROVE.
ONE OF THEM IS JUST DIGITAL INFRASTRUCTURE.
BUT THERE'S ALSO THESE EFFICIENCIES LIKE IRB AND CONTRACTING WHICH IS SORT OF ALSO OUTSIDE OF OUR WHEELHOUSE.

PENNY, TELL ME ABOUT WHEN YOU'RE RUNNING A TRIAL AND YOU'RE GOING TO BE PUTTING IN SIGNIFICANT RESOURCES TO GET AN ANSWER THAT'S ROBUST ENOUGH TO PRESENT TO THE AGENCY, HOW DO YOU THINK ABOUT INCENTIVIZING AND HOW DO YOU THINK ABOUT WHAT LINDSEY WAS SAYING THAT NOW WE MAY HAVE MANY, MANY MORE DATA SOURCES AND MAYBE THERE WILL BE MORE DIRECTIONAL BUT NOT AS MUCH PURE RIGOR WITHIN A SINGLE SOURCE?
>> I THINK THIS IS A QUESTION THAT WAS RELEVANT EVEN BEFORE COVID-19.
WHEN WE THINK ABOUT THE NUMBER OF INDICATIONS WHERE PATIENT REPORTED OUTCOMES ARE SO CRITICAL TO UNDERSTAND EFFICACY OR THE ULTIMATE ENDPOINT OF A PARTICULAR CLINICAL TRIAL, IT'S ONLY INTENSIFIED AND I THINK PART OF THE INCENTIVIZATION HAS TO BE JUST ABOUT APPEALING TO HUMANITY.
I HAVE TO ASSUME THAT WAS A SIGNIFICANT PART OF WHY THESE VACCINE TRIALS WERE ABLE TO ENROLL AS QUICKLY AS THEY WERE, IT WAS ABOUT THE GREATER GOOD AND A LITTLE BIT ABOUT HAVING ACCESS TO SOMETHING BEFORE THE GENERAL POPULATION, SOME OF THEM MIGHT HAVE BEEN ABOUT ACCESS.
AT LEAST A CHANCE AT ACCESS.
WE CAN'T GUARANTEE EFFECTIVENESS AND CAN'T GUARANTEE WHICH OF THE VACCINES OR PLACEBO YOU WOULD GET.
BUT I THINK THERE'S A SIGNIFICANT HUMANITY PART AND I THINK ALSO HELPING PATIENTS UNDERSTAND WHY A PARTICULAR PIECE OF DATA MIGHT BE IMPORTANT WOULD ALSO BE HELPFUL.
I DON'T THINK ANYBODY, ANY HUMAN WANTS TO GO INTO THE EFFORT OF DOING SOMETHING AND GO INTO A HOSPITAL, IN BOSTON, TRYING -- AND THEN FIND OUT THAT YOU DIDN'T GET THE RIGHT DATA TO ANSWER THE QUESTIONS YOU NEEDED TO ANSWER.
SO I THINK SOME OF THAT IS APPEALING TO BASIC HUMANITY AND MAKING SURE PATIENTS TRULY UNDERSTAND WHAT THEY ARE GETTING INTO AND WHY THEIR PARTICIPATION AND THAT DATA POINT IS SO IMPORTANT BECAUSE I THINK MANY OF US ARE IN INDICATIONS IN THERAPEUTIC AREAS WITHOUT THAT PATIENT REPORTED DATA WE HAVE NOTHING.
THAT'S IN TERMS OF -- IN TERMS OF DATA INTEGRITY I THINK THAT'S THE ONE BIG QUESTION, SORT OF THE BIG BLACK BOX OUT THERE IN TERMS OF WHAT WILL THIS LOOK LIKE IN A YEAR OR TWO IN TERMS OF DATA INTEGRITY.
WHEN WE THINK ABOUT CAPTURING INFORMATION VIA TELEHEALTH IS THERE VARIABILITY WE DON'T YET UNDERSTAND IN TERMS OF HOW IT IS A PHYSICIAN WOULD ASSESS A PATIENT VIA TELEHEALTH VERSUS ACTUALLY HAVE PATIENT IN YOUR OFFICE.
LINDSEY WOULD BE MUCH BETTER EQUIPPED TO ANSWER THAT THAN I.
I HAVE TO ASSUME THERE WOULD BE -- WE HAVE TO UNDERSTAND THAT AND WE NEED TO COLLABORATE AS SPONSOR COMPANIES AND WORK WITH REGULATORS TO UNDERSTAND WHAT THE CHALLENGE FOR THAT VARIABILITY IS.
AND THEN THE LAST POINT I WOULD MAKE IS WE AS AN INDUSTRY HAVE BEEN FOCUSED ON QUALITY BY DESIGN FOR A LONG TIME AND I THINK WE NEED TO SHIFT AND ADD TO THAT LIST FLEXIBILITY BY DESIGN AND UNDERSTAND IS THERE A PATIENT WHO WOULD MUCH PREFER TO GO ON A SITE EVERY TIME BECAUSE THEY WANT ACCESS TO THAT PHYSICIAN AND THOSE NURSES OR IS THERE SOMEBODY WHO LIVES FIVE HOURS AWAY AND WANTS ACCESS TO THE CLINICAL TRIAL AND WANTS TO PARTICIPATE AND GIVE THEIR TIME BUT CAN'T POSSIBILITY GET IN THERE EVERY TIME.

THAT GOES BACK TO THE VARIABILITY QUESTION.
THAT'S WHY THE COLLABORATION IS SO IMPORTANT BETWEEN PATIENTS, SPONSORS AND REGULATORS.
>> VALEN, DO YOU WANT TO RESPOND BRIEFLY TO WHAT I THINK WAS REALLY INTERESTING POINT WHICH IS SOMETHING THAT WE ALWAYS THINK WE KNOW WHAT PATIENTS WANT UNTIL WE ASK PATIENTS AND THEN THEY SURPRISE US 50% OF THE TIME.
ONE OF THE THINGS I THOUGHT PATIENTS WANTED WAS OF COURSE YOU WANT TO STAY AT LOAM AND HANG WITH YOUR OWN HOME HEALTHCARE SYSTEM AND IT'S GOING TO BE SO MUCH MORE CONVENIENT BUT WE HAVE HEARD THAT'S ABSOLUTELY NOT TRUE.
SOME PATIENTS REALLY DO VALUE THAT FACE TO FACE CONTACT AT THE SITE.
SO WHAT DO YOU THINK ABOUT THAT?
WHAT'S YOUR PERSPECTIVE?
>> I AGREE.
I FEEL LIKE I'M DOING THIS THE WHOLE TIME BECAUSE ALL OF YOU WERE SAYING I'M LIKE YES, YES, AND YES.
I DO THINK -- I LOVE PENNY WHAT YOU SAID ABOUT FLEXIBILITY.
BECAUSE I THE VALUE OF DATA AND INTEGRITY OF THAT BUT I DO THINK WE'RE ALL HUMANS SO WE'RE NATURALLY HAVE DIFFERENT DESIRES.
I THINK IF THERE COULD BE A BIT MORE FLEXIBILITY IT WOULD BE HUGE BECAUSE AS AN EXAMPLE, I HAD TO TRAVEL OUT OF STATE TO GET MY LIVER TRANSPLANT AFTER A YEAR I WAS ABLE TO KEEP MY CARE IN CALIFORNIA.
I STILL TRAVEL THERE BECAUSE I TRUST THEM SO MUCH AND I WANT THAT IN-PERSON.
SO YOU HAVE GOING TO FIND PEOPLE THAT WANT THAT IN-PERSON HUMAN CONNECTION AND THEN YOU'RE GOING TO FIND PEOPLE THAT WANT TO PARTICIPATE BUT MIGHT BE TOO SICK AND CAN'T TRAVEL AND IT'S REALLY IMPORTANT FOR THEM TO BE PART OF THIS STUDY.
IT COULD BE A DRUG FOR INSTANCE WITH PKD THAT'S GOING TO SLOW THE PROGRESSION OF THEIR DISEASE, BUT THEY'RE TOO SICK TO DO THE TRAVEL IN-PERSON.
SO IT'S REALLY IMPORTANT FOR THEM TO PARTICIPATE TOO.
SO I THINK IF WE CAN EVOLVE INTO SOME FORM OF JUST GREATER FLEXIBILITY BUT STILL TRY AND OF COURSE HAVE INTEGRITY IN OUR DATA, I THINK THAT WOULD BE HUGE SUCCESS.
YOU'RE GOING TO REACH THE MOST AMOUNT OF PEOPLE AND I REALLY THINK IT'S KEY IF YOU CAN HAVE PATIENTS INVOLVED FROM THE BEGINNING.
JUST FIGURE OUT WHAT'S IMPORTANT TO THEM.
AND I THINK THE EDUCATION IS HUGE.
THEY NEED TO BE EDUCATED AND UNDERSTAND THE VALUE OF IT, AND WHY IT'S IMPORTANT FOR NOT ONLY THEMSELVES BUT LIKE WAS SAID HUMANITY AS A WHOLE, AND JUST ALL OF THIS IS JUST SO GREAT.
I'M EXCITED FOR THE FUTURE.
IT'S JUST BEEN AMAZING TO BE A PATIENT FROM A CHILD TO NOW AND SEE ALL THAT'S EVOLVED AND NOW THE PATIENT VOICE MATTERS.
IT DIDN'T WHEN I WAS A KID.
THIS IS JUST EXCITING.

THE FUTURE IS EXCITING.
.
>> I THINK THIS DISCUSSION IS EXCITING.
I BELIEVE THAT THE BEAUTY OF THIS -- ONE OF THE BEAUTIES OF THIS IS THEY OFFER THE OPPORTUNITY TO THINK OUTSIDE OF THE BOX AND ADD LEVELS OF FLEXIBILITIES TO THE TRIALS, ACCOUNTING FOR VARIABILITIES OR SOURCES OF VARIABILITIES AND CUSTOMIZING TECHNOLOGIES TO MAKE IT FIT FOR PURPOSE AND ESSENTIALLY ACCOUNTING FROM THE VERY BEGINNING UNTIL THE END ALL OF THESE FACTORS SO THAT THERE ARE OPPORTUNITIES TO DO THINGS IN A DIFFERENT WAY.
AGAIN, THIS IS A HISTORICAL TRANSFORMATION AND WE ARE ABLE TO MAKE IT.
IT'S AN EXPERIMENT THAT WE ARE ALL PART OF THIS EXPERIMENT.
I THINK IT'S ON OUR HANDS TO ACCOUNT FROM THE VERY BEGINNING THOSE FLEXIBILITIES, BUILD THOSE FLEXIBILITIES IN THE PROTOCOLS, OTHERWISE IT'S JUST NOT GOING TO HAPPEN, AND THEN HOW DO YOU ACCOUNT FOR SOURCES OF VARIABILITIES, SOURCES OF BIAS AND, AT THE SAME TIME, AS LINDSEY MENTIONED, WE NEED TO THINK ABOUT ENHANCING DIVERSITY POOL IN THE CLINICAL INVESTIGATIONS.
THAT IS ALSO AN IMPORTANT FACTOR.
AND THE EXPECTATION REALLY IS FROM THE FDA AS A FORMER COLLEAGUE AND OFFICIAL REALLY IS TO ENHANCE THE DIVERSITY OF THE POOL PARTICIPATING IN CLINICAL TRIALS.
IT DOESN'T HAPPEN FOR FREE.
IT REALLY HAS TO BE PLANNED PROACTIVELY.
AND STREAMLINED PROCESSES AND PROCEDURES ADAPTING TECHNOLOGIES SO WE ENHANCE THE PARTICIPATION OF EVERYONE.
EQUITY IS IMPORTANT WITH FLEXIBILITIES.
THANK YOU.
>> LINDSEY, GO AHEAD.
>> I THINK IT'S GETTING THE ISSUE OF COMMUNICATION.
AND WE HAVE TO REALLY THINK DEEPLY ABOUT THAT.
BECAUSE IT'S NOT ONE SIZE FITS ALL.
THERE ISN'T ONE PROTOTYPIC PATIENT FOR COVID.
AND SOMETHING WE LEARNED IS AS WE WERE DOING THE VACCINE STUDIES, THERE ARE VERY EDUCATED COMMUNITIES WHO WERE BEATING DOWN THE DOOR.
SO NO COMMUNICATION WAS NECESSARY.
THEY WERE FRONT AND CENTER.
AND THEN THERE WERE COMMUNITIES THAT ARE VERY SUSPICIOUS OF THE ESTABLISHMENT.
AND FOR US TO BE SUCCESSFUL, ALL COMMUNITIES WHO ARE AT RISK FOR THIS DISEASE, WHICH IS ALL OF US, HAD TO BE ENGAGED WHICH MEANT THE COMMUNICATION WAS VERY DIFFERENT AND REQUIRED VERY DIFFERENT STRATEGIES, PERSONNEL, AND TACTICS TO BE ABLE TO OVERCOME SOME OF THE HISTORICAL HOSTILITIES THAT I COULD ARGUE WE HAD NEED TO DO WITH BUT HAD EVERYTHING TO DO WITH.
AND I THINK THAT COMMUNICATION IS PART OF WHAT WE HAVE TO THINK THROUGH DEEPLY TO MAKE SURE THAT WHEN WE DO OUR STUDIES, WE REALLY ENGAGE IN ALL THE COMMUNITIES AT RISK FOR THE DISEASE AND THEREFORE HELP US UNDERSTAND THAT THE SOLUTIONS WE COME UP WITH

REALLY WORK FOR THE COMMUNITIES AFFECTED AND NOT JUST THE COMMUNITIES WHO ARE MOST ACCESSIBLE.
>> LINDSEY WHAT YOU SAID IS REALLY IMPORTANT.
WHERE I WORK WE ACTUALLY FOLLOW MULTI PRONGED APPROACH OR APPROACHES TO REACH DIVERSE COMMUNITIES AND ACTUALLY ADD CULTURAL COMPETENCIES.
AND THAT IS WHAT YOU'RE SAYING.
IT'S JUST NOT ON REACHING EVERYONE WITH ONE SIZE FITS ALL BUT IT'S ACTUALLY ADDING THAT MEANINGFUL COMMUNICATION PIECE TO DIFFERENT COMMUNITIES WITH DIFFERENT SOCIAL BEHAVIORS SO THAT IF THEY MESSAGE RESONATES WITH DIFFERENT COMMUNITIES IN DIFFERENT PLACES.
AND DOING IT IN MULTIPLE WAYS IN DIFFERENT MULTIMEDIA, USING DIFFERENT APPROACHES.
>> COUPLE INTERESTING -- SOME ARE COMMENTS, SOME ARE QUESTIONS -- COMING IN THROUGH THE Q&A.
ONE OF THE THINGS THAT CAME TO MY MIND AS WELL AS VALEN WAS TALKING ABOUT HOW THE PATIENT COMMUNITIES WANT TO SPEAK TO EACH OTHER AND WANT TO BECOME A COMMUNITY WHILE THEY ARE ON A CLINICAL TRIAL.
THAT HAS BENEFITS IN THAT PATIENTS FEEL INVESTED, PATIENTS MAY ACTUALLY ENCOURAGE EACH OTHER TO -- ON COMPLETION AND ADHERING TO PROTOCOLS, ET CETERA.
BUT WHAT ARE THE CHALLENGES TO BIAS AND TO AFFECTING POTENTIALLY OUTCOMES, BECAUSE THERE COULD BE SOME, AND I WAS GOING TO SEE MAYBE IF PENNY AND LINDSEY WANTED TO COMMENT ON THAT.
>> I'M HAPPY TO COMMENT FIRST.
AND PENNY CAN FILL IN.
HAVING PATIENTS COMMUNICATE WITH EACH OTHER, SUPPORT EACH OTHER, COMMUNICATE WITH THE INVESTIGATIVE TEAM TO IMPROVE THE STUDY, VERY IMPORTANT.
BUT THERE ARE HUGE PRIVACY CONSIDERATIONS.
AND THE REAL CHALLENGES BECAUSE DURING THE COURSE OF A STUDY, SURPRISES MAY EMERGE AND INDIVIDUALS MAY OR MAY NOT WANT THAT SHARED WITH OTHERS.
SO ONE HAS TO BE VERY THOUGHTFUL TO ENABLE COMMUNICATION SO WE CAN IMPROVE THE SUPPORT OF THE PARTICIPANTS AS WELL AS HELP US IMPROVE THE STUDY, MAYBE THE WAY IN WHICH WE'RE SAMPLING SOMETHING CAN BE DONE BETTER AND WE CAN ACTUALLY DO A PROTOCOL CHANGE TO IMPROVE HOW THE STUDY IS CONDUCTED.
BUT WE HAVE TO BE INCREDIBLY SENSITIVE TO INDIVIDUAL PRIVACY AND UNEXPECTED ISSUES THAT MAY EMERGE THAT WE HAVE TO BE VERY RESPECTFUL OF.
>> YEAH, I AGREE WITH THAT COMPLETELY.
I THINK, I WOULD ARGUE IN FACT THIS MAY HAPPEN INFORMALLY ANYWAY, SO IRRESPECTIVE IF IT'S SANCTIONED BY THE FOLKS RUNNING THE CLINICAL TRIAL THERE'S RISK IN THAT.
EMPLOYEES PEOPLE ARE REALLY TRYING TO UNDERSTAND HOW DO YOU UNDERSTAND SOMETHING THAT MIGHT BE SHARED ON A FORUM OR FACEBOOK OR SOCIAL MEDIA RELATIVE TO A CLINICAL TRIAL.
AND I THINK WE SEE IT ON A REGULAR BASIS.
SO I DO THINK THE PRIVACY ISSUE IS ONE THAT SHOULD BE NOTED.
THAT'S REALLY IN ALL AREAS OF WHAT WE'RE TALKING ABOUT HERE AS WE THINK ABOUT NEW

TECHNOLOGY, INNOVATION, TELEHEALTH VISITS, TRANSFERRING DATA FROM AN APPLE WATCH TO SOME OTHER DEVICE THAT GOES TO AN ULTIMATELY TO A SPONSOR DO WE HAVE THE RIGHT MECHANISMS TO ENSURE DATA PRIVACY PARTICULARLY IN AREAS OF THE WORLD WHERE DATA PRIVACY REGULATIONS ARE EVEN STRONGER THAN THEY ARE HERE IN THE U.S.
WE TOUCHED ON A LOT OF TOPICS HERE THAT ARE IMPORTANT TO WHAT WE'RE TALKING ABOUT.
>> ON THE SHARING AND WHAT CAN WE LEARN SIDE OF THINGS, I THINK YOU THOUGHT UP SOMETHING THAT'S VERY INTERESTING, PENNY, AN INTEREST OF MINE.
WHEN THE RUBBER HITS THE ROAD INDUSTRY'S BIG CONCERN IS VARIABILITY ESPECIALLY AS RELATES TO THE PRIMARY EFFICACY ENDPOINT OF A CLINICAL TRIAL.
AND I THINK WE SHOULD ALL BE CONCERNED ABOUT THAT BECAUSE WE DON'T WANT AN EFFECTIVE DRUG BEING SHOWN TO BE INEFFECTIVE OR WE DON'T WANT SOME BIAS INTRODUCED THAT SHOWS AN INEFFECTIVE DRUG BEING EFFECTIVE THE PRIMARY ENDPOINT IS SO IMPORTANT.
WHAT ARE FOLKS DOING, INDUSTRY, CRO'S, ACADEMIA, TO LOOK AT THE INFORMATION THAT'S COMING FROM THIS GRAND EXPERIMENT OF HYBRID DECENTRALIZATION AND HOW CAN WE LOOK AT THAT DATA TO SEE WHERE IS THE VARIABILITY.
IN ONCOLOGY, ONE OF THE THINGS IS GETTING CT SCANS LOCALLY VERSUS AT MEMORIAL SLOAN-KETTERING FOR INSTANCE.
WHAT ARE YOU GIVING UP?
MOST PEOPLE HAVE HIGH TECHNOLOGY CT SCANS AT THIS POINT BUT ARE THERE SOME SCANS THAT DON'T GO LOW ENOUGH AND THEREFORE BECOME UNINTERPRETABLE.
I THINK THAT'S AN OPPORTUNITY FOR THE WHOLE SYSTEM TO LOOK AT THEIR DATA.
HAVE YOU BEGUN TO LOOK AT THAT LINDSEY, PENNY AND, ISAAC?
>> PAUL, JUST TO FRAME IT, IF YOU LOOK AT THE PRIMARY SCALE FOR COVID OUTCOME, THE WHO, SEVEN POINT SCALE, MAYBE THE NIH EIGHT POINT SCALE, BOY, IS IT CRUDE.
IT'S CRUDE.
DO YOU NEED OXYGEN, ARE YOU IN THE ICU?
ARE YOU FULLY FUNCTIONAL?
IT'S VERY QUALITATIVE AND THE QUESTION IS HOW IS THAT ENDPOINT OR THAT SCALE TO BE USED?
IS IT USED GLOBALLY FOR TRIALS EVERYWHERE WHERE THERE MAY BE NO STRUCTURE AND ELECTRICITY IS UNCERTAIN?
IS IT ONLY AT HIGH -- HIGH RESOURCED ACADEMIC CENTERS?
AND I THINK THAT ALL OF THE ABOVE CAN MAKE SENSE, BUT THEN THEY REQUIRE DIFFERENT SCALES AND DIFFERENT WAYS OF ASSESSING, AND IS THE OUTCOME IS MORTALITY, THAT'S EASIER TO ASSESS IN ANY CONTEXT.
IF THE OUTCOME IS YOUR DEGREE OF HYPOEMIA THAT CAN BE DONE AT HOME AND IN A RELIABLE WAY BUT DOES IT REFLECT THE DISEASE PATH OWE GENESIS THAT'S INTERRUPTIBLE WITH THE INTERVENTION OF INTEREST.
SO I THINK IT'S AN IMPORTANT QUESTION.
ONCOLOGY AND INFECTIOUS DISEASE HAVE METRONOMES AND GLOBAL ASSESSMENT HAVE DIFFERENT CHALLENGES.
AND THAT JUST HAS TO BE INCORPORATED INTO WHAT IS THE STUDY TRYING TO DO.
AND WHAT IS ASSESSABLE IN A TIMEFRAME THAT'S RELEVANT.

>> THOSE ARE REALLY EXCELLENT POINTS.
I THINK THAT MOST OF THE COMPANIES ARE GOING TO PROBABLY REPRESENTED HERE ARE ASKING THROWS SAME QUESTIONS.
I THINK WE ALMOST HAVE A STUDY WITHIN OUR STUDIES RIGHT NOW.
WHAT WE TRIED TO DO AT TAKEDA WAS FOR ANY STUDY THAT WAS IMPACTED BY COVID WHICH WAS ALL OF THEM ESSENTIALLY IN ONE WAY OR ANOTHER, IF THERE WERE ASSESSMENTS THAT NEEDED TO BE DONE LOCALLY THAT WOULD ORDERLY HAVE BEEN DONE IN A CENTRAL LAB, FOR EXAMPLE, OR CENTRAL IMAGING COMPANY OR CENTRAL RADAR, WE TRIED TO UNDERSTAND AND COLLECT DATA ABOUT HOW THOSE ASSESSMENTS WERE COLLECTED DURING THE PANDEMIC SO WE CAN GO LOOK DO WE HAVE VARIABILITY, DO WE UNDERSTAND ANY DIFFERENCES WE MIGHT OBSERVE BASED ON THE METHOD OF ASSESSMENT IF IT WAS LOCAL OR BASED ON THAT CENTRAL IMAGING VENDOR.
I THINK WE DON'T HAVE THAT INFORMATION JUST YET.
BUT I THINK IT'S A QUESTION WE'RE ACTIVELY ANSWERING AND, AGAIN, THAT'S ONE OF THINGS WE'LL ALL LEARN AND HOPEFULLY SHARE WITH EACH OTHER ABOUT WHAT IS THAT VARIABILITY WE OBSERVED DURING THE PANDEMIC AND DOES IT MATTER IN IS IT IMPACT FULL IN TERMS OF OVERALL ENDPOINTS ACROSS ANY NUMBER OF INDICATIONS OF THERAPEUTIC AREAS.
>> IN MY CASE WE HAVE DATA SCIENTISTS AND WE HAVE ANALYTICS IN PLACE FOR EACH OF THESE TRIALS SO WE CAN ACTUALLY ASSESS THE PROTOCOL IN REALTIME.
WHEN THERE IS AN OUTLIER AND INVESTIGATE THE REASONS FOR THAT OUTLIER TO BE HAPPENING.
THE OUTLIER CAN BE A SAFETY SIGNAL OR THE OUTLIER CAN BE A BAD HEALTH OUTCOME JUST BECAUSE THERE WAS AN ERROR IN PROCESSING OR IN LAB ENDPOINT.
SO WE INVESTIGATE IN AS REAL TIME AS POSSIBLE AND WE HAVE THE CAPACITY TO DO SO, BECAUSE THERE'S DATA INTEGRATION THROUGH THE TECHNOLOGY THAT WE USE AND THERE'S A FOUNDATIONAL TECHNOLOGY THAT'S UTILIZED AND AS I SAID, IT'S ALL MAPPED OUT HOW THE DATA WILL FLOW FROM THE BEGINNING TO THE END AND HOW THE DATA IS LOOKED AT SO THAT WE CAN ACTUALLY TAKE CORRECTIVE MEASURES IN ALMOST REAL TIME AND ESSENTIALLY UNDERSTAND THE SOURCES OF THE VARIABILITY, THE SOURCES OF THE REASONS WHY AN OUTLIER MIGHT BE HAPPENING AND PUT IN PLACE CORRECTIVE MEASURES BEFORE TOO LONG.
DOING IT TIMELY, DOING IT PER PROTOCOL IS IMPORTANT.
BUT ALSO DOING IT ON A HOLISTIC BASIS, BECAUSE THE SERVICES ARE OFFERED FROM END TO END, IT'S NOT JUST A POINT SOLUTION, NOT JUST LOOKING AT ONE PARTICULAR OUTLIER.
ONE OF THE BEAUTIES OF THIS REALLY IS THAT WE HAVE THE OPPORTUNITY TO COLLECT DATA MORE CONTINUOUSLY OR 24/7, DEPENDS ON WHAT IS DECIDED FOR PROTOCOL AND THAT AND THE IDEA OF SPECIFIC HEALTH OUTCOMES GIVES US THE OPPORTUNITY TO HAVE A MORE HOLISTIC VIEW FROM THE HEALTH PERSPECTIVE FOR EACH OF THE PARTICIPANTS AS COMPARED TO, FOR EXAMPLE, THE EPISODIC DATA WE USED TO GET WITH TRADITIONAL CLINICAL INVESTIGATIONS.
THAT IS VERY POWERFUL.
THAT CAN NEVER BE OBTAINED IN TRADITIONAL CLINICAL INVESTIGATIONS.
AND EVEN IF THERE WILL BE SOURCES OF VARIABILITY AND SOME LEVEL OF VARIABILITY, WE CAN ACCOUNT FOR THOSE LEVELS OF VARIABILITY AND WE NEED TO UNDERSTAND WHAT WILL BE ACCEPTABLE BY THE REGULATORY AGENCIES BECAUSE ALL OF THESE TESTING WAR DOING FOR SAFETY AND EFFICACY HAS THE CONVENIENCE OF THE PARTICIPANTS IS HAPPENING IN THE REAL WORLD

SETTINGS.
>> LET ME MENTION THIS.
I THINK -- I DO WANT TO REORIENT EVERYONE TO THE TIME.
IT'S GOING TO BE 11:25 AND WE'RE SUPPOSED TO END ADD 11:30 AND TO BE A FUN EXERCISE TOWARDS THE END TO HAVE EVERYONE FOCUS ON THE ONE THING THEY HOPE WILL BE MAINTAINED AND THEN MAYBE ONE CHALLENGE YOU THINK THAT'S IN THE WAY OF IT BEING MAINTAINED.
LET ME JUST WRAP UP A COUPLE OF THEMES I THOUGHT WERE INTERESTING.
ISAAC'S POINT, CONTINUOUS MONITORING IS ACTUALLY SOMETHING THAT IS PROBABLY GOING TO BE HAPPENING WITH DECENTRALIZATION IF YOU'RE USING MORE DIGITAL TECHNOLOGIES YOU'RE GOING TO HAVE SIGNALS IN BETWEEN CLINIC VISITS.
SO WHAT'S MOST IMPORTANT IS THAT WE RANDOMIZED IF WE'RE DOING A HYBRID DESIGN AND SORT OF BEING FLEXIBLE AND LETTING PATIENTS ONE VISIT BE IN CLINIC AND THE NEXT REMOTE, WHICH IS HAPPENING AND I THINK THAT'S FINE.
IT NEEDS TO BE RANDOMIZED AND WHAT WE WILL LOOK AT AND SHOULD LOOK AT IS THAT IT'S BALANCED.
BECAUSE IT'S CLEARLY GOING TO BE DIFFERENT.
IF YOU'RE -- IT'S ASCERTAINMENT BIAS IF YOU'RE GOING TO ASK SOMEONE EVERY DAY HOW THEY ARE FEELING VERSUS ONCE A MONTH.
WHAT PERCENTAGE OF PATIENTS HAD REMOTE ASSESSMENTS ON EACH ARM AND MAKE SURE IT'S BALANCED.
THAT'S SOMETHING WE CAN DO.
SECOND IS WHAT DO WE LEARN FROM THE DATA WE'RE GETTING AS WE GET IT IN.
IF EVER THERE WAS A TIME TO DATA SHARE, TO LINDSEY'S POINT, IT WOULD BE WHAT DO WE KNOW ABOUT THE VARIABILITY OF DIFFERENT KINDS OF REMOTE ASSESSMENTS AND HOW CAN WE ALL LEARN FROM THAT BECAUSE I THINK WHAT WE'RE GONNA FIND IS IN COVID, WHATEVER THE VARIABILITY IS PROBABLY THE WORST IT'S GOING TO BE BECAUSE WE WERE DEPLOYING THESE ON THE FLY, WE DIDN'T TRY TO MITIGATE THINGS AND KNOW WHAT WE WERE GOING TO BE RUNNING UP AGAINST.
AND THE LAST IS I WANT TO SAY TO VALEN'S POINT I DO THINK THAT THE RIGHT APPROACH IS PROBABLY A FLEXIBLE APPROACH TO ALLOW THE PATIENTS TO DETERMINE WHETHER THEY WANT TO COME TO CLINIC OR WANT TO STAY REMOTELY.
AGAIN, AS LONG AS IT'S ALL RANDOMIZED AND THAT THERE'S EQUAL ASSESSMENTS.
LAST ONE IS A PLUG.
WE'RE INTERESTING IN LEARNING FROM COVID AND ASKED INDUSTRY WHO ARE SUBMITTING CANCER CLINICAL TRIAL DATASETS TO STANDARDIZED SOME OF HOW THEY'VE DONE REMOTE VERSUS CLINIC VISITS SO WE CAN START TO LOOK AT AND AGGREGATE OUR DATA AND MAYBE HELP THE COMMUNITY BY PROVIDING SOME INSIGHTS AND THAT'S ON THE ONCOLOGY CENTER OF EXCELLENCE WEBSITE LEARNING FROM DECENTRALIZED TRIALS.
TO END AND MAYBE WE'LL BE JUST SLIGHTLY OVER, BUT I'D LOVE TO HEAR FROM EACH PERSON THE ONE THING THEY WOULD LOVE TO MAINTAIN FROM WHAT WE HAD TO DO DURING COVID-19 AND ONE OF THE ISSUES THAT MAYBE A BARRIER THAT WE SHOULD START TO WORK ON TO OVERCOME IT.
AND I THINK WE'LL AS ALWAYS START WITH THE PATIENT, VALEN.
>> OKAY.

SO ONE THING TO MAINTAIN GOING FORWARD, I THINK THE EASE OF PARTICIPATION.
I'VE SEEN HOW POWERFUL THAT WAS, HOW MANY PEOPLE COULD BE ABLE TO GET INVOLVED IN THE STUDY BECAUSE IT WAS ACCESSIBLE TO THEM FROM HOME, NOT HAVING TO GO ANYWHERE, COMPLETELY SAFE.
NO QUESTIONS ASKED.
IT WAS -- WE ALL WANTED TO BE PART OF IT.
AND JUST PARTNERSHIPS WITH PATIENTS.
IT'S JUST -- IT'S HUGE.
IT'S WHAT'S GOING TO EVOLVE TO AS MANY PEOPLE AS POSSIBLE BEING ABLE TO BE A PART OF IT TO SUCCESSFUL TRIALS, BECAUSE YOU'RE GOING TO TALK TO PATIENTS RIGHT OFF THE BAT AND KNOW WHAT THEY WANT AND JUST -- IT WILL -- THE SUCCESS OF IT WILL BE HUGE.
I THINK AN OPPORTUNITY, I'LL SAY, GOING FORWARD.
I THINK THERE'S A GREAT OPPORTUNITY TO BUILD ON EDUCATION.
WHEN YOU THINK OF THIS PAST YEAR, THE WHOLE WORLD HEARD ABOUT TRIALS.
IT WAS IN THE FOREFRONT OF ALL OF US, IN THE NEWS, AND SO PEOPLE THAT DON'T EVEN HAVE ANY HEALTH ISSUES LEARNED SOMETHING ABOUT IT.
SO WE'VE GOT THIS PLATFORM NOW, I THINK WE SHOULD JUST BUILD UPON THAT AND BE ABLE TO EDUCATE OTHERS ON THE IMPORTANCE OF IT AND TO REACH DIFFERENT COMMUNITIES, BECAUSE I FELT EARLIER WHAT WAS SHARED IS HOW I FEEL, IS THAT I'M ACTIVE IN THE COMMUNITY.
SO I STAY UP TO DATE.
BUT WHAT ABOUT THE TRANSPLANT RECIPIENTS WHO AREN'T ACTIVE?
HOW DO I REACH THE PATIENTS THAT RANT PART OF THE ORGANIZATIONS I'M INVOLVED WITH THAT NEED THIS INFORMATION AND NEED TO KNOW CLINICAL TRIALS ARE AVAILABLE TO, THEY NEED TO KNOW THE RESULTS?
SO I THINK SO MANY AMAZING THINGS WERE DONE, LISTEN TO ALL OF YOU HAVE FULL CONFIDENCE WE'RE ABLE TO DO ANYTHING WITH EXTRAORDINARY PEOPLE LIKE YOU IN THE POSITIONS TO HELP PATIENTS.
AND I'M JUST REALLY GRATEFUL AND I REALLY THINK THERE'S A BRIGHT FUTURE AHEAD FOR PATIENTS AND I'M EXCITED TO STILL BE ALIVE TODAY TO WITNESS IT ALL AND HOPEFULLY PLAY A POSITIVE ROLE IN ALL OF IT SO THANK YOU FOR INCLUDING THE PATIENT VOICE TODAY.
I'M REALLY HONORED TO BE HERE.
>> ISAAC, TAKE A DEEP BREATH, ONE QUESTION, YOU CAN ONLY DO IT IN ONE BREATH, THOUGH.
>> VERY QUICKLY, SO I WOULD SAY ONE THING THAT WE HAVEN'T DISCUSSED TODAY IS, AND THAT I WOULD LIKE TO SEE GOING FORWARD, IS THE MAINTENANCE OF THE UNIFICATION OF UTILIZATION OF THE STANDARD HEALTHCARE SYSTEM AND CLINICAL RESEARCH AS AN OPTION.
WHY?
BECAUSE OUR HEALTH JOURNEY IS ONE.
WE PARTICIPATE IN CLINICAL RESEARCH, WE PARTICIPATE AND WE TAKE ADVANTAGE OF THE STANDARD HEALTHCARE SYSTEM.
IF WE DO THIS AS CLINICAL RESEARCH OPTION AND INTEGRATE IT WITH THE STANDARD HEALTHCARE SYSTEM, WE AS HUMANS WILL BE BETTER SERVED.
>> THAT'S GREAT.

>> IN TERMS OF THE CHALLENGES AND THIS IS SOMETHING THAT WE ARE IMPLEMENTED IN PRAHEALTHSCIENCES, BUT IT'S SOMETHING THAT THE FIELD AS LARGE WOULD PROBABLY EMBRACE, BECAUSE OUR HEALTH AS INDIVIDUALS IS ONE.
IT'S NOT DIVIDED INTO CLINICAL RESEARCH AND STANDARD HEALTHCARE SYSTEM.
THE CHALLENGE MOST DEFINITELY IS THE REGULATORY CHALLENGE.
BECAUSE WE HAVE TO -- WE NEED TO HAVE HARMONIZE THE DIFFERENT REGULATORY FRAMEWORKS ACCORDING TO DIFFERENT REGULATORY AGENCIES TO BE ABLE TO CONDUCT THIS IN A MORE MEANINGFUL WAY GLOBALLY.
THE GDPR IN EUROPE IS A CHALLENGE.
APAC IS UP AND COMING.
41% OF NEW TRIALS SINCE 2018 ARE CONDUCTED IN THE ASIA PACIFIC REGION.
YET WE NEEDED REGULATORY LANDSCAPE THERE.
>> THAT'S JUST TO REITERATE, IT'S A GLOBAL CLINICAL TRIAL ENTERPRISE THAT WE'RE IN AND WE WILL CONTINUE TO BE IN.
AND THERE'S ONE FDA THAT SPEAKS FOR U.S. AND MANY OTHER REGULATORY AGENCIES AND THAT'S A GREAT POINT.
PARTICULARLY HARD TO OVERCOME CHALLENGE.
BUT I THINK WE'RE ALREADY INTERACTING GLOBALLY WITH REGULATORS.
>> THANK YOU FOR THE OPPORTUNITY.
AND THANK YOU FOR SHARING ALL OF THIS INFORMATION WITH ALL OF YOU.
HOPEFULLY WE'LL GET TO HARMONIZE ALL OF THE REGULATORY FRAMEWORKS ACROSS DIFFERENT AGENCIES AND CONDUCT THIS GLOBALLY.
>> THANKS, ISAAC.
WHAT'S YOUR GRAND HOPE AND THE CHALLENGE WE HAVE TO OVERCOME TOGETHER.
>> WE WERE ABLE TO CREATE THERAPIES IN UNDER A YEAR.
SO ALL OF THE CHALLENGES WE'VE TALKED ABOUT WERE OVERCOME.
PERIOD.
WE NEED THAT SAME URGENCY FOR ALL THE OTHER DISEASES.
WE HAVE TO STEP BACK FROM SARS-COV-2 EXCEPTIONALISM TO WHAT CAN WE DO AND WHAT HAVE WE LEARNED THAT WE CAN BRING TO BEAR FOR ALL THE OTHER THINGS OUR PATIENTS ARE SUFFERING FROM AND HAVE THAT SAME SENSE OF URGENCY AND TO LEVERAGE WHAT WAS DONE BECAUSE IT DEMONSTRATES WHAT CAN BE DONE.
SO I THINK THAT WE HAVE TO SAFETY AND SPEED ARE NOT AT ODDS.
THEY CAN AND HAVE BEEN DONE TOGETHER.
AND WE NEED TO COMMUNICATE.
SO WE NEED TO COMMUNICATE OUR ABILITY TO DO WHAT WE HAVE DONE AND TO CONTINUE TO BUILD ON IT.
SCIENCE WORKS, SAFETY AND SPEED WORK TOGETHER, AND WE NEED TO HAVE THAT COLLECTIVE SENSE OF URGENCY TO OVERCOME AND ADDRESS THE DISEASES OUR PATIENTS HAVE.
>> WELL SAID.
PENNY?
LAST PANELIST STANDING.

>> I'LL TRY TO BE BRIEF.
I THINK THERE'S ONE WORD THAT SUMS IT UP AND THAT'S THE COLLABORATION BECAUSE IT COVERS WHAT WE DID WITH PATIENTS, WHAT WE'VE DONE WITH REGULATORS, DONE AS SPONSORS WORKING WITH EACH OTHER, WHAT WE'VE DONE WORKING WITH OUR VENDORS.
IT SPEAKS TO THE COMMUNICATION WITH THE MEDIA, SPEAKS TO CROSS BORDER COLLABORATION AND I THINK IT WAS UNPARALLELED, WE'VE NEVER SEEN THAT KIND OF COLLABORATION BEFORE.
WE'VE NEVER SHARED DATA WITH EACH OTHER THE WAY WE HAVE IN THE LAST YEAR AND A HALF.
I THINK THAT IT'S REALLY OPENED THE INDUSTRY'S EYES IN TERMS OF WHAT'S POSSIBLE.
WAYS IN WHICH WE SHOULD BE WORKING NOT JUST BECAUSE WE HAD TO BUT BECAUSE WE CAN AND WE SHOULD.
SO IT'S COLLABORATION EVERY STEP OF THE WAY.
>> WELL, THANK YOU.
I WANT TO THANK THE CONVENERS OF THIS FOR INVITING ME AND MY FELLOW PANELISTS.
I THINK YOU GUYS DID A GREAT JOB.
I FELT WE LEARNED A LOT AND I WILL STOP SO THAT PEOPLE CAN GET A COFFEE AND A SEVEN MINUTE BREAK BEFORE THE NEXT SESSION.
>> THANK YOU SO MUCH.
AND VALEN, PENNY, ISAAC AND LINDSEY, THANK YOU SO MUCH FOR THE THOUGHTFUL DISCUSSION AND THE QUESTIONS AND THE CONVERSATION.
IT'S REALLY BEEN A WONDERFUL HOUR.
SO AS PAUL SAID, WE'RE GOING TO TAKE A TEN-MINUTE BREAK NOW AND SO WE WILL SEE YOU ALL BACK HERE AT 11:44.
SEE YOU IN TEN MINUTES.
(BREAK)
.
>> OKAY.
WELCOME BACK, EVERYONE.
WE HOPE YOU HAD A GOOD TEN-MINUTE BREAK AND KIND OF LET ALL OF THE AMAZING CONVERSATION DIGEST FROM THE FIRST PANEL.
I AM VERY PLEASED TO INTRODUCE OUR MODERATOR FOR OUR SECOND PANEL, IF WE COULD JUST PUT THE SLIDES ONE MORE AHEAD.
THANK YOU.
PERFECT.
THE SECOND PANEL IS REALLY GOING TO DISCUSS AND THINK ABOUT THE IMPLICATIONS FOR AND THE NEED TO REIMAGINE THE WORKFORCE.
AND I AM VERY PLEASED TO INTRODUCE CRAIG LIPSET WHO IS THE CO-CHAIR OF THE VICE CHAIR OF MEDSTAR HEALTH RESEARCH INSTITUTE AND VICE PRESIDENT FOR FOUNDATION FOR RESEARCH AND EDITORIAL BOARD FOR THERAPEUTIC INNOVATION AND REGULATORY SCIENCE.
OVER TO YOU, CRAIG.
>> THANK YOU SO MUCH.
IT'S SUCH A PLEASURE AND AN HONOR TO BE HERE AND ESPECIALLY TO BUILD ON THE FANTASTIC CONVERSATION THAT WE'VE HAD SO FAR WITH BOTH ESTHER AS WELL AS THE FIRST PANEL TODAY.

CLEARLY THE CHANGES COMING OUT OF CLINICAL TRIALS AFTER THE PANDEMIC ARE REAL AND THEY'RE HERE.
AND AS WE'VE BEEN DISCUSSING SO FAR WHETHER THOSE HIT ON DECENTRALIZATION, FLEXIBILITY FOR PARTICIPATION, OR SPORE AREAS SUCH AS HOW WE MONITOR OUR TRIALS IN FRESH AND DIFFERENT WAYS.
AS ESTHER OPENED WITH, HOW DO WE ENHANCE OUR SUPPORT FOR DIVERSITY AND INCLUSION IN OUR TRIALS.
BUT ONE THING WE DO KNOW IS THAT CHANGE DOES NOT SUSTAIN SIMPLY BECAUSE WE DID IT WITH URGENCY DURING A PANDEMIC.
WE KNOW THAT CHANGE REQUIRES COMMITMENT IN TERMS OF LOOKING AT OUR POLICIES, LOOKING AT OUR PARTNERS, LOOKING AT OUR CULTURE, AND IMPORTANTLY, LOOKING AT OUR WORKFORCE.
WITH THOSE SUSTAINING CHANGES -- THERE'S NO CONFIDENCE WE'RE NOT JUST GOING TO GO BACK TO THE COMFORT OF HOW WE'VE DONE THINGS BEFORE.
I'M LOOKING FORWARD TO A DISCUSSION ON HOW WE BUILD ON MORNING SO FAR AND START TO TALK ABOUT REIMAGINING OUR WORKFORCE AND WHILE I'M OF COURSE LOOKING FORWARD TO OUR PANELISTS I'M WILLING LOOKING FORWARD TO HEARING FROM ALL OF YOU AND SO PLEASE KEEP YOUR QUESTIONS COMING AND WE'LL BE SURE TO WEAVE THOSE INTO THE CONVERSATION TOGETHER.
I WOULD LIKE TO WELCOME THE INDIVIDUALS SEE ON YOUR SCREEN NICHOLAS BROOKE, FOCUSED WITH PATIENT FOCUSED MEDICINE DEVELOPMENT, ANDREA FERRIS, PRESIDENT AND CEO OF LUNGEVITY AND ANDY LEE SEER VICE PRESIDENT AND HEAD OF GLOBAL CLINICAL TRIAL OPERATIONS AT MERCK, AND HARPREET SINGH, WHO IS WITH THE DIVISION OF ONCOLOGY AT THE U.S. FDA, WELCOME TO YOU ALL.
TO GET OUR CONVERSATION STARTED, AND I WILL -- I WANT TO MAKE SURE -- THIS WILL BE MY CASUAL WAY OF MAKING SURE THAT MY PANELISTS ARE ALL CONNECTED AND THEIR MICROPHONES ARE ALL WORKING.
I'D LIKE TO INVITE EACH OF YOU TO SHARE AN OPENING PERSPECTIVE OF TWO OR THREE MINUTES ON THE TOPIC OF REIMAGINING OUR WORKFORCE TO SUPPORT THE FUTURE OF CLINICAL TRIALS, NICHOLAS, WOULD YOU MIND GETTING US STARTED?
>> THANK YOU, CRAIG.
AND HI, EVERYBODY.
PLEASURE TO BE WITH YOU ALL TODAY.
SO YES, I'M IN PFMD AND OUR FOCUS IS TO DESIGN THE BEST WAY TO INTEGRATE THE PATIENT VOICE AT OWL STAGES OF MEDICINE SO THAT PERSPECTIVE THAT I COME TO THE THIS PANEL.
AND I THINK WE HEARD IT SEVERAL TIMES, LINDSEY FINISHED HIS CLOSING REMARKS WITH THAT COMMENT.
AND YOU SAID IT JUST NOW, CRAIG.
IT'S NOT US MAKING THE CHANGE.
CRISIS PUSHED US TO MAYBE THIS CHANGE HAPPEN.
IT'S A KEY QUESTION IN TERMS OF THE SKILLS AND WORKFORCE BECAUSE WE DIDN'T DO IT BECAUSE HE WE WANTED TO DO IT BUT BECAUSE WE HAD TO DO IT.
THE FIRST QUESTION IS THAT WE DISCUSSED THAT WE HAVE TO MAINTAIN AND SUSTAIN THE CHANGE

WE'VE REACHED AND CAN WE EXTEND IT.
YES, WE HAVE GREAT PROGRESS.
IT'S BEEN VERY WELL ARTICULATED ACROSS THE PREVIOUS SESSION.
TELEMEDICINE, COMPLEX DECENTRALIZED TRIALS, ALL THE DIGITAL ASPECTS OF IT SHIFT TO PATIENT CENTRICITY AND A SHIFT TO USER CENTRICITY TO USE MORE OF A DIGITAL LANGUAGE.
SO YES, ALL OF THAT IS HAPPENING.
WE DON'T KNOW YET HOW IT WILL CRYSTALLIZE.
AND WHAT WILL BE THE NEXT NORMAL, BECAUSE WE HEAR PLENTY OF PEOPLE THAT WANT TO BUILD ON THAT.
AND WE HEAR PLENTY OF PEOPLE THAT WANT TO GET BACK TO NORMAL.
SO I THINK THAT REALLY SOME KEY QUESTIONS WE NEED TO ACT UPON IF WE WANT TO MAKE SURE THAT WE ANCHOR THE PROGRESS WE'VE MADE TO DATE.
AND SO I THINK WHAT I WITNESSED IS THAT WE ARE FACING CONVERGING TRENDS, DIGITAL, WHOLE NEW SPACE TO MAKE IT HAPPEN, MANY NEW QUESTIONS, AND ALL THE ASPECTS OF REMOTE TRIALS, ALL OF THAT IS NEW AND WHAT WE'RE DOING IS WE'RE ADDING TO THE COMPLEXITY THAT WAS ALREADY IN PLACE BEFORE THE CRISIS AND THE PANDEMIC.
SO WHAT I'D LIKE TO SEE AND DISCUSS TODAY IS HOW WE WILL CHECK HOW WE'RE -- ARE WE MAINTAINING THE SOLUTIONS WE'VE PUT IN PLACE AND SCALE TO OTHER CONDITIONS.
THAT'S ONE.
HOW WE CONTINUE TO ADDRESS ISSUES THAT WERE THERE BEFORE THAT ARE STILL THERE TODAY, DIVERSITY, DATA SHARING, ACCESS TO CLINICAL TRIALS, ALL THESE QUESTIONS THAT ARE STILL VERY TRUE.
AND SO THEN, I KNOW WE DISCUSSED THAT LATER BUT WHAT TYPE OF AGILITY WE NEED AND AS A TRIGGER AND AS I MENTIONED A NORTH STAR EARLIER IN THE INTRODUCTION AND I BELIEVE THE NORTH STAR AND OUR AGILITY WOULD HAVE TO BE QUALIFIED THROUGH THE PATIENT LENS.
THAT'S WHAT I WOULD LIKE TO DISCUSS FURTHER TODAY.
>> THANK YOU, NICHOLAS.
FABULOUS POINTS THERE.
I LOVE THIS CALL-OUT THAT WHILE THERE ARE A NUMBER OF IMPORTANT AND TECHNICAL CAPABILITIES WE'LL BE DISCUSSING AS PART OF OUR WORKFORCE GOING FORWARD, WHAT ARE THOSE OTHER MINDSETS AND OTHER CHANGES THAT WE NEED SO THAT WE CAN ADAPT QUICKLY FOR OTHER CAPABILITIES WE SIMPLY CAN'T ANTICIPATE TODAY.
BUT CERTAINLY SAW HOW IMPORTANT THAT CAPABILITY WAS OVER THE LAST YEAR.
ANDREA, DO YOU HAVE TWO OR THREE MINUTES OF OPENING PERSPECTIVE ON THIS TOPIC OF WORKFORCE FOR THE EMERGING CLINICAL TRIAL LANDSCAPE?
>> SURE.
THANK YOU.
THANK YOU FOR HAVING ME.
AS YOU MENTIONED, I'M PRESIDENT AND CEO OF LUNGEVITY FOUNDATION A U.S. BASED LUNG CANCER PATIENT ADVOCACY GROUP AND I LIKE WHAT NICHOLAS WAS TALKING ABOUT IN TERMS OF AN AGILE WORKFORCE BUT I THINK ALSO AS WE'RE THINKING ABOUT DECENTRALIZING CLINICAL TRIALS AND BRINGING THEM CLOSER TO THE PATIENT, FOR A VARIETY OF REASONS, MOST PATIENT

CENTRICITY AND ENGAGEMENT OF DIVERSE AND UNDERSERVED POPULATIONS AS WELL, I THINK FROM A WORKFORCE PERSPECTIVE, WE NEED TO THINK MORE BROADLY ABOUT WHAT THAT WORKFORCE IS. IT'S NOT JUST THE PEOPLE DESIGNING THE CLINICAL TRIALS, THE CLINICIANS IMPLEMENT BEING IT BUT ALL THE DIFFERENT PLAYERS AND REALLY AND STAKEHOLDERS WHO INTERACT WITH PATIENTS AS WELL AND CAN HELP TO ENABLE OR NAVIGATE THROUGH THE SYSTEM.
SO I THINK AS WE'RE TALKING ABOUT DECENTRALIZING TRIALS AND REIMAGINE BEING THE WORKFORCE I ENCOURAGE ALL OF US TO HAVE A MUCH MORE AMPLE MINDSET WHEN THINKING ABOUT WHAT THAT WORKFORCE IS AND WHO THAT ENCOMPASSES.
>> GREAT PERSPECTIVE.
THANK YOU, ANDREA.
SOME GREAT POINTS: ANDY LEE, WELCOME.
DO YOU HAVE OPENING THOUGHTS ON THE WORKFORCE FOR OUR FUTURE GIVEN SOME OF THE THESE CHANGES?
I'M NOT SURE IF ANDY WAS ABLE TO RECONNECT AFTER THE BREAK.
SO I WILL -- LET'S SEE IF SARAH AND TEAM CAN CHECK ON ANDY AND HIS WHEREABOUTS AND SHIFT TO HARPREET.
OPENING PERSPECTIVE?
>> THANKS SO MUCH FOR HAVING ME.
I'M HARPREET SINGH A MEDICAL ONCOLOGY AND I DIRECT ONE OF OUR THREE SOLID TUMOR DIVISIONS WITHIN THE FDA.
MY DIVISION IN PARTICULAR HOUSES ALL THE THORACIC CANCER SO AN ACTIVE AREA OF INVESTIGATION.
WHEN WE -- I WANTED TO PULL FROM PANEL 1 AND THEN TO TAKE THAT INTO THIS IDEA OF REIMAGINING THE RESOURCES.
ONE THING THAT I'VE HEARD A TERM I'VE HEARD A LOT IS AGILITY AND FLEXIBILITY.
WE CERTAINLY NEED THAT WHEN THINKING ABOUT WHAT THE WORKFORCE LOOKS LIKE.
BUT JUST TO BACK IT UP FOR A MOMENT, ONE THING WE NEED FROM THIS GRAND EXPERIMENT IS DATA.
HARD DATA ON WHAT WE CAN MOVE FORWARD WITH IN TERMS OF A NEW NORMAL, A BETTER NORMAL.
AND SO JUST TO PLUG SOMETHING THAT DR. KLUETZ WAS SAYING AT THE END OF HIS REMARKS IS AN EFFORT THAT WE ARE EMBARKING ON IN TERMS OF FDA ASKING FOR VERY SPECIFIC DATASETS REGARDING REMOTE ASSESSMENTS IN CLINICAL TRIALS AND REALLY HOPING TO LEARN FROM WHAT HAS GONE ON SINCE THE START OF THE PANDEMIC AND MOVING FORWARD.
AND ON THAT, AT THE BEGINNING OF THE PANDEMIC, MARCH OR SO OF LAST YEAR, THE FDA ISSUED A RAPID GUIDANCE ON BASICALLY HOW TO SAFELY CONDUCT DECENTRALIZED OR HYBRID APPROACH TRIALS TO KEEP PATIENTS SAFE.
AND JUST A LITTLE BIT OF BACKGROUND ON THAT.
THE FDA FOR A VERY LONG TIME HAD ALREADY BEEN THINKING ABOUT DECENTRALIZATION OF TRIALS, THERE WAS AN INTERNAL WORKING GROUP BUT AS GOVERNMENT BUREAUCRACIES GO IT WAS TAKING A WHILE TO TRICKLE THROUGH AND REACH AGREEMENT ON SOME OF -- MANY OF THE KEY ASPECTS AND DETAILS.

MUCH OF THAT INFORMATION AT THE TIME OF THE PANDEMIC WAS JUST RAPIDLY PUT OUT WITHOUT ANY TIME FOR PUBLIC COMMENT, JUST BECAUSE OF THE REALLY THE SEVERITY OF THE PANDEMIC AND THE URGENT NEED TO KEEP PATIENTS SAFE.
NOW THERE'S AN EFFORT TO REVISIT THAT SAME GUIDANCE THAT MAYBE IS THE NEXT STEP FORWARD, HOW DO WE DECENTRALIZE TRIALS MOVE FORWARD AND ONE ISSUE IS THIS NOTION OF THE 1572 FORM, WHO IS AN INVESTIGATOR AND THAT'S SOMETHING I HOPE WE CAN GET INTO IN THE PANEL BECAUSE GOING BACK TO THE AGILITY ISSUE, IT'S FEEDBACK THAT WE'VE RECEIVED THAT DOES SEEM TO CAUSE CONFUSION, CONCERN, AND PERHAPS LIMIT THE FLEXIBILITY OF A DECENTRALIZED APPROACH.
.
>> LET'S COME BACK TO THAT ON THIS TOPIC OF THE 1572, BECAUSE TO ME, THERE'S A QUESTION IN THERE ABOUT OUR EXPANDED AND AUGMENTED WORKFORCE THAT SUPPORTS THE CLINICAL TRIAL SPACE AND HOW DO WE ENSURE THAT WE'RE BEING INCLUSIVE, ESPECIALLY AS WE TRY TO REACH COMMUNITIES BUT NOT NECESSARILY PRESCRIPTIVE THAT EVERYBODY NEEDS TO BE AN INVESTIGATOR, SUB INVESTIGATOR ON A 1572.
GREAT TOPIC.
AND ANDY, I SEE THAT WE HAVE YOU HERE.
WELCOME.
DO YOU HAVE MAYBE TWO OR THREE MINUTES OF OPENING PERSPECTIVE ON THIS TOPIC AROUND OUR WORKFORCE AND READINESS NOR THIS FUTURE WE'VE BEEN TALKING ABOUT THIS MORNING?
>> GOOD MORNING, EVERYONE.
THANKS FOR HAVING ME.
MY RESPONSE TO RUN ALL OF THE INPATIENT CLINICAL TRIALS, IT'S ABOUT 300 MERCK SPONSORED CLINICAL TRIALS AND ABOUT 200 COLLABORATIVE TRIALS LARGELY IN ONCOLOGY WITH COMBINATION THERAPIES WITH MULTIPLE DIFFERENT SPONSORS.
SO ABOUT 500 CLINICAL TRIALS IN THE SORT OF PERIMETER OF WHAT WE'RE DOING.
WE OPERATE IN APPROXIMATELY 60 COUNTRIES, FOOTPRINT IN ABOUT 47.
WORKFORCE IS ABOUT EIGHT AND A HALF THOUSAND PEOPLE, 45% OF THOSE ARE MERCK BADGES AND OTHERS WORK IN AN IN SOURCED FUNCTIONAL SERVICE PROVIDER MODEL.
EVERYTHING IS RUN IN OUR TOOL SYSTEMS PROCESS OPERATING PROCEDURES.
WE WORK WITH ABOUT 15 TO 20,000 DIFFERENT CLINICS AND SITES AROUND THE GLOBE AND HAVE ABOUT 60,000 ACTIVE PATIENTS.
SO IT'S A BIG MACHINE AND IT'S A LOT OF WORK.
MANY OF THOSE TRIALS WERE STARTED THREE, FOUR, FIVE YEARS AGO IN A DIFFERENT ERA, DIFFERENT WORLD, DIFFERENT MODEL.
WE HAVE MAINTAINED THE PHILOSOPHY DURING COVID THAT WE ARE OPEN FOR BUSINESS, WE HAVE NOT CLOSED ANY STUDY ADAPTED ANY PROTOCOL, OR MADE SIGNIFICANT CHANGES.
AND WE HAVE FOCUSED ON NO PATIENT LEFT BEHIND AND NO COLLEAGUE LEFT BEHIND.
THESE ARE TWO MANTRAS WE TALK ABOUT EVERY SINGLE DAY.
IN 2020 WE LOCKED APPROXIMATELY 300 DATABASES, WE DIDN'T MISS A SINGLE DATABASE LOCK, THEY WERE DELIVERED ON TIME AND WE DELIVERED 97% OF OUR CORPORATE MILESTONES IN SPITE OF THE PANDEMIC.

THERE WERE OBVIOUSLY SOME STUDIES THAT WERE IMPACTED ADVERSELY, PARTICULARLY THOSE AROUND ELECTIVE SURGERIES AND MANY THAT SURPRISINGLY ACCELERATED.
HIV STUDIES THAT GREW QUICKER THAN EXPECTED.
OUR THEMES HAVE FOCUSED TO BE A LITTLE BIT DIFFERENT.
OF COURSE PATIENT CENTRICITY IS IMPORTANT AND THE DECENTRALIZED CONCEPT HAS COME UP AS WE'VE SEEN GUIDANCES CHANGED AND ADOPTED IN DIFFERENT SHAPES AND FORMS BECAUSE WE ADOPT THEM DOESN'T MEAN HOSPITALS, COUNTRIES AND SITES ADOPT THEM NECESSARILY.
SO THE YEARS OF STANDARDIZATION HAVE ACTUALLY COME TO A HEAD AND IT'S NOW THE TIME OF FLEXIBILITY AND WE HAVE TO SEE THE ESPECIALLY SODIC FLOW OF THE PANDEMIC AROUND THE WORLD AND SEE THE DIFFERENT AGENCIES AROUND DIFFERENT FLEXIBILITIES.
SO OUR MONITORS IS MONITORS CANNOT MONITOR LIKE THEY USED TO.
THEY HAVE TO DO REMOTE MONITORING AND HAVE ACCESS TO ELECTRONIC HEALTH RECORDS.
THERE'S A MASSIVE EVOLUTION THAT'S DIFFERENT IN U.S. WHERE WE SEE GREATER ACCESS COMPARED TO ASIA AND EUROPE WHERE THERE'S LIMITED ACCESS.
OUR DATA CURATION AS WE LOOK AT SOURCES OF DATA THROUGH DIGITIZATION, TELEHEALTH THROUGH HOME NURSING, WE HAVE TO THINK ABOUT CURATION OF DATA AND WHAT'S THAT MEAN FOR OUR DATA, WHICH IS OUR CURRENCY.
THAT'S HOW WE LOCK DATABASES WE MAKE SURE THE DATA IS CREDIBLE.
IT'S CHANGED OUR THINKING OF THE WORKFORCE AROUND DATA CURATION AND SECURING THE FIDELITY THAT HAVE DATA AND THEN WE NEED TO LOOK AT THE UNITED OF WORK THAT PROCESS KITES A TRIAL IN A CLINICAL SITE.
WE DON'T DO ANY CLINICAL TRIAL WORK IN THE HEADQUARTERS OF MERCK OR ANYTHING.
IT'S ALL DONE IN REGIONS, COUNTRIES AND HOSPITALS. MANY OF OUR WORK IS SPECIALTY CARE WHICH REQUIRES VERY COMPLEX INFUSIONS, COMPLEX PROCEDURES.
BUT NOT ALL TRIALS ARE LIKE THAT.
AND WHERE WE HAVE THOSE COMPLEX PROCEDURES, THOSE ARE BEST DONE IN THE HANDS OF SCIENCE.
WHERE WE CAN DO REMOTE WORK AND DO IMAGING, COLLECTION OF DATA, WE DO THAT.
AND IT'S ADDED A COMPLEXITY TO HOW YOU RESOURCE AT THE SITE.
HOW DOES THE STUDY COORDINATOR COORDINATE THAT WORK TO ENSURE THAT WE'RE NOT MISSING DATA AND IT'S COLLECTED AT THE RIGHT TIME IN THE RIGHT MANNER.
SO WE NOW HAVE HAD TO DUPLICATE WORK AND WE HAVE TO GET SOURCE OF DATA FROM A SOURCE INTO A SOURCE AT THE HOSPITAL WHICH IS INSPECTED.
WE UNDERSTAND GO APPROXIMATELY A HUNDRED REGULATOR INSPECTION AS YEAR AROUND THE GLOBE AND IT'S ONE THING COMING WITH A THEORY THE PRACTICE OF THE DEFENDING INSPECTIONS AND CREDIBILITY OF DATA IS REALLY IMPORTANT.
SO THOSE ARE THE THEMES I'VE HAD ABOUT MONITORING, DATA CURATION AND THE TRIAL UNIT THAT ACTUALLY GETS THE UNITS OF WORK DONE.
ALL CHANGING.
>> LET'S STAY WITH YOU FOR A MOMENT, ANDY, AND TALK A BIT SPECIFIC TO THE WORKFORCE.
WHAT TYPES OF TECHNICAL NEEDS OR GAPS ARE YOU SEEING IN THE WORKFORCE AS YOU TALKED ABOUT, THERE'S DIFFERENT TYPES OF DATA NEEDS WITH THE DIVERSITY OF DATA YOU'RE TRYING TO

MANAGE AND CURATE.
THERE'S DIFFERENT TYPES OF MONITORING APPROACHES YOU'RE EMBEDDING.
ARE YOU FINDING THE WORKFORCE AVAILABLE THAT YOU NEED.
ARE THERE GAPS IN SKILLS OUT THERE TODAY?
>> IT'S A GREAT QUESTION.
SO ONE OF THE CHALLENGES WE'VE SEEN IN THE ECOSYSTEM AT LARGE FOR ALL OF SPONSORS IS THAT THEY ARE STRUGGLING WITH STUDY STARTUP IS TAKING LONGER AS MANY HOSPITALS ARE IMPACTED THROUGH THE PANDEMIC.
SO THEY ARE FOCUSING THEIR ATTENTION ON SAVING LIVES OF PEOPLE WHO ARE COVID IMPACTED.
SO THE RESOURCES AVAILABLE TO RESEARCH ARE LESS AVAILABLE NOW.
THEY'RE LIMITED.
SIMILARLY WHAT'S HAPPENED IS SPONSORS THEN DO THE USUAL THING AND SAY I'M GOING TO ADD IN 20% MORE SITES TO HEDGE MY BET SO YOU NEED MORE SITES AND MORE MONITORS.
WE'VE CREATED A DEMAND FOR RESEARCH CAPABILITY IN COUNTRIES AND IN SPONSORS.
AND SO THAT'S NOT A GOOD THING.
AND SO WE'VE ALSO THEN SEEN THAT THERE'S A DIFFERENT APPROACH TO WHAT'S GOING ON.
IT'S IN CHINA WE'RE BACK TO WORKING THE WAY WE DID PREPANDEMIC.
IN THE U.S. IT'S VERY, VERY DIFFERENT IN OR WORKFORCE.
WE'VE HAD TO LOOK AT WE'VE MAINTAINED THIS CONCEPT OF NO COLLEAGUE LEFT BEHIND.
WE'VE LOOKED AT WAYS WE SUPPORT PEOPLE TO WORK FROM HOME, NEW TECHNOLOGIES, ALL GOT UPGRADES IN TECHNOLOGY BUT WORKED COLLABORATIVELY WITH SITES TO ACCESS ELECTRONIC HEALTH RECORDS AND THIS ALLOWS FOR MONITORING AND WE'RE LOOKING AT NEWER HOW CAN WE SHARE DOCUMENTS THAT ARE PRIVACY PROTECTED THAT ACTUALLY ARE ROBUST ENOUGH THAT WE CAN USE ELECTRONIC DIGITIZATION.
THAT REQUIRES TRAINING OF STAFF AND REQUIRES NEW WAYS OF WORKING TO INTRODUCE TELEHEALTH MEDICINE, HOW DO YOU MONITOR A TELEHEALTH VISITED.
PERHAPS YOU DON'T.
SO YOU NEED TO LOOK AT SOURCE AND HOW THAT GETS INTO THE SOURCE.
HOW DO YOU MONITOR THE VISITS OF A HOME NURSE AND GET THAT PRIVACY DONE.
WE'RE INTRODUCING NEW SKILL SETS AROUND MONITORS IN THE FIELD AND THEN SIMILARLY FOR DATA MANAGERS WE'RE REQUIRING THEM TO DO A LOT MORE WORK UP FRONT ON DATA INTEGRITY OF THE COLLECTION DEVICES.
AND WE DO THAT IN UAT TESTS LONG BEFORE WE IMPLEMENT IN A TRIAL AND OUR CHALLENGE, IT'S NOT SCALABLE ACROSS AN ENTERPRISE OF 500 CLINICAL TRIALS.
WE HAVE TO LOOK AT NEW STUDY STARTS AND PICK OUT THE STUDIES THAT REALLY NEED THE TECHNOLOGY.
WE CANNOT INDUSTRIALIZE AT THIS AT THIS POINT BECAUSE WE CANNOT SCALE NOR CAN THE SUPPLIERS SCALE THAT.
THE WORKFORCE IS CHANGING QUICKLY TO A MORE DIGITIZED WAY OF WORKING AND WAYS TO INTEGRATE DATA FROM DISTAL SOURCE INTO CENTRAL SOURCES.
>> HARPREET, YOUR ORGANIZATION MUST BE SEEING SOME OF THESE CHANGES AS WELL AS ANDY WAS MENTIONING THE DIVERSITY OF DATA TYPES PEOPLE ARE RAPIDLY EMBRACING, THE SHIFTING

LOCATION OF WHERE DIFFERENT TYPES OF PROCEDURES MAY BE HAPPENING MUST IMPACT EVERYBODY FROM REVIEWERS TO INSPECTORS TO EVERYBODY HANDLING DATA IN BETWEEN.
HOW DO YOU SEE REGULATORY AUTHORITIES NEEDING TO EVOLVE THEIR WORKFORCE?
>> I THINK THAT'S A MULTI LAYERED QUESTION.
SO FIRST OF ALL, LET ME JUST START BY SAYING I REPRESENT THE U.S. FDA.
AS WE HEARD EARLIER TODAY, ALL CLINICAL TRIALS, PARTICULARLY ONCOLOGY, REALLY ARE GLOBAL ENDEAVORS.
AND I CAN HONESTLY SAY THAT THERE ARE DISTINCT DIFFERENCES AND THERE WERE THAT WE OBSERVED DURING THE PANDEMIC THAT COMPANIES TOLD US ABOUT IN WHICH THEY WERE TRYING TO IMPLEMENT SOME OF THE ELEMENTS OF THE COVID GUIDANCE IN DECENTRALIZING TRIALS THEY WEREN'T ABLE DO IN OTHER PARTS OF THE WORLD BASED ON THOSE REGULATORY AUTHORITIES.
SO IN TERMS OF HOW I SEE THIS IMPACT BEING THE FDA WORKFORCE AND OUR REGULATORY WORK WHICH I THINK MAYBE PART OF THE QUESTION, FOR THE MOST PART, FROM THE CLINICAL PERSPECTIVE WE'RE ABLE TO DO MUCH OF OUR WORK REMOTELY BUT ONE OF THE KEY ISSUES THAT'S COME UP IS INSPECTIONS OF FACILITIES.
PEOPLE THINK THAT A DRUG APPROVAL, I THINK, IS JUST THE CLINICAL DATA, HERE'S THE TRIAL NOW APPROVE THE DRUG.
IT'S REALLY NOT THAT SIMPLE.
WE HAVE TO MAKE SURE PARTICULARLY FOR NEW DRUGS THEY'RE SAFE AND BEING MANUFACTURED APPROPRIATELY AND THAT REQUIRES A LOST INTERNATIONAL TRAVEL AND THAT'S BEEN A CHALLENGE IN THE SETTING OF THE PANDEMIC.
AND ONCOLOGY AND THROUGHOUT THE FDA, THERE HAVE BEEN DELAYS OF APPROVALS AS A RESULT OF THIS.
I THINK THAT WE ARE KIND OF MOVING TO SOME VIRTUAL INSPECTIONS, BUT SOME THINGS JUST ARE REALLY CHALLENGING TO DO VIRTUALLY, AND THEY WILL REQUIRE SOME IN-PERSON INSPECTIONS OR VISITS.
SO THAT'S SOMETHING THAT WE'RE WORKING TOWARDS.
NOW, I THINK ANOTHER PART OF YOUR QUESTION IF I UNDERSTOOD IT, WAS JUST ALSO HOW WE'RE INTERPRETING YOU ALL THE DATA COMING IN TO US FROM CLINICAL TRIALS.
>> IF YOU HAVE THE RIGHT PEOPLE FOR THESE.
I THINK EVERY ORGANIZATION IS HAVING TO RETHINK THE TYPES OF PEOPLE THEY HAVE IN THEIR ORGANIZATIONS GIVEN THE DIVERSITY OF DATA THAT WE'RE ALL STARTING TO REALIZE IN THESE STUDIES.
>> SO IN TERMS OF THE TYPES OF PEOPLE THAT WE HAVE TO ASSESS THE DATA THAT'S COMING IN, THE ONCOLOGY GROUP IS PRETTY PROGRESSIVE IN TERMS OF WHO WE HIRE.
SO, FOR EXAMPLE, WE HAVE SOMEONE DEDICATED TO LOOKING AT EXTERNAL DATA LIKE REALWORLD DATA, EXTERNAL CONTROLS, THAT TYPE OF THING.
BUT IN TERMS OF REMOTE ASSESSMENT AND WHETHER OR NOT THOSE BASICALLY IMPACT THE BOTTOM LINE, WHICH IS THE PRIMARY EFFICACY ENDPOINT, THAT'S SOMETHING THAT WITH THE HELP OF OUR BIOSTATISTICS CAL COLLEAGUES WHICH ARE VERY ROBUST AT THE FDA, AS A GROUP, WE ARE, ACE MENTIONED AT THE TOP OF THE PANEL, WE ARE BASICALLY SEEKING PARTICIPATION AFTER PARTICIPATION FROM INDUSTRY TO PUT THAT IN A TABULAR FORMAT SO WE CAN AGGREGATE THE

DATA TO ASSESS WHAT IMPACT REMOTE LABS, REMOTE IMAGING, ET CETERA, REMOTE CLINICAL ASSESSMENTS HAD ON CLINICAL TRIAL INTEGRITY.
THAT MAY REQUIRE SOME OUTSOURCING FOR STAFF OR PERHAPS SOME CONSULTING, I DON'T THINK WE'RE THERE YET.
BUT RIGHT NOW, I THINK WE DO HAVE THE INFRASTRUCTURE TO HELP ASSESS SOME OF THAT DATA COMING IN.
>> THAT WAS CLEARLY A VERY PROGRESSIVE VIEW OF THE ONCOLOGY CENTER.
IT'S GOING TO BE INTERESTING TO SEE IF OTHER DIVISIONS IN FDA MAKE SIMILAR ASKS AND IF OR REGULATORY AUTHORITIES AROUND THE WORLD DO BECAUSE THAT IS AREA WHERE WE ALL NEED TO KEEP LEARNING AND SHARING.
I'D LOVE TO TURN TO ANDREA.
I'M THINKING, ANDREA, ABOUT OBSERVATION THAT VALEN SHARED IN THE FIRST PANEL ABOUT THE IMPORTANCE OF EXPERIENCE.
AND I'M CURIOUS, AS YOU SEE THESE DIFFERENT COMMITMENTS THAT RESEARCH SPONSORS HAVE BEEN MAKING RELATED TO IMPROVING THE EXPERIENCE OF PARTICIPANTS IN RESEARCH, ARE THERE NEW TYPES OF ROLES, NEW TYPES OF WORKFORCE CAPABILITIES, THAT ARE NEEDED TO FILL THE GAPS IN ORDER FOR US TO BETTER MEET PATIENTS WHERE THEY ARE, BETTER ADDRESS LITERACY FOR PATIENTS WHERE THEY ARE?
>> I DON'T KNOW IF THERE'S NEW OR WE JUST NEED MORE.
AND SO I THINK THAT THERE'S DEFINITELY AN INCREASED NEED FOR CERTAIN DISCIPLINES.
FOR EXAMPLE, PARTICULARLY AS TRIALS MOVE MORE INTO THE COMMUNITY OR ALSO AS WE'RE TRYING TO ENGAGE UNDERREPRESENTED POPULATIONS IN TRIALS, THE ROLE OF NAVIGATORS AND PATIENTS NAVIGATORS AND NURSE NAVIGATORS, CLINICAL TRIAL NAVIGATORS, I THINK HAS BEEN WELL DOCUMENTED, BUT THERE ARE NOT VERY MANY OF THEM.
AND ALSO CURRENTLY THEY'RE NOT REIMBURSED GENERALLY ALSO.
SO THERE'S A POLICY ELEMENT THAT IMPACTS THE WORKFORCE AS WELL WITH RESPECT TO THAT.
BUT I DO THINK THAT THE ROLE OF NAVIGATION WILL CONTINUE TO INCREASE AS WE ENGAGE MORE BROADLY AS WELL AS MORE DIVERSELY IN CLINICAL RESEARCH.
AND THEN ABSOLUTELY AS WELL, WITH RESPECT TO HEALTH LITERATE MATERIALS I DO THINK THERE'S AN INCREASED NEED AND PROBLEM NOT ENOUGH PRACTITIONERS WHO ARE REALLY WELL VERSED AT CREATING HEALTH LITERATE CULTURALLY SENSITIVE AND LINGUISTICALLY APPROPRIATE MATERIALS TO COMMUNICATE ABOUT WHAT A CLINICAL TRIAL IS AND HOW TO ENGAGE WITH THAT.
I THINK THAT THERE ARE ALSO OTHER LEVELS OF COMPLEXITY WITH THAT, FOR EXAMPLE, CREATING SIMPLIFIED INFORMED CONSENT FORMS.
SO THAT REQUIRES A TECHNICAL EXPERTISE IN ADDITION TO THE HEALTH LITERACY PIECE IN ADDITION TO PEOPLE WHO ARE USED TO ENGAGING WITH THE PATIENT COMMUNITIES TO BRING THEIR VOICE TO BEAR ON THINGS OF THAT NATURE.
SO I THINK THAT THERE ARE A LOT OF AREAS WHERE WE NEED MORE HIGHLY QUALIFIED PRACTITIONERS IN THESE FIELDS THAT ENGAGE WITH PATIENTS DIFFERENT.
>> ANDREA, THERE'S GREAT CONNECTION THERE THAT YOU'RE MAKING THAT I JUST WANT TO MAKE SURE I'M CALLING OUT, BECAUSE I THINK IT'S EYE OPENING FOR ME.
YOU'RE CALLING OUT THE IMPORTANCE, FOR EXAMPLE, OF NURSE NAVIGATORS, BUT MAKING SURE

THOSE ROLES ARE BEING REIMBURSED AND SUPPORTED.
SO VERY OFTEN RESEARCH SPONSORS AND CRO'S INVOLVED IN SITE LEVEL BUDGETS FOR MULTI CENTER TRIALS HAVE A LOST TEMPLATES AND A LOT OF LEGACY BUDGET MODELS THAT WE RELY ON. WE HAVE ALL SORTS OF METRICS FOR WHAT EACH TASK SHOULD LOOKING BUT AS YOU'RE NOTING HERE, THERE MAY BE NEW TASKS, THERE MAY BE NEW CONTROLS THAT WE HAVE TO MAKE SURE WE'RE SUPPORTING.
>> I THINK IT'S BEYOND THAT, CRAIG, AND I THINK THAT WE HAVE SO GET AN AWAY FROM THIS RINSE AND REPEAT OF TRIAL PROTOCOLS AND BLOW UP HOW WE'VE DONE IT IN THE PAST BECAUSE WE'RE IN A DIFFERENT ERA OF SCIENCE ALSO.
WE KNOW MORE.
AND WHEN IT'S -- WHEN YOU HAVE THE ABILITY TO MODEL THINGS DIFFERENTLY USING AI OR MACHINE LEARNING AND HAVE THE ABILITY TO DO INCORPORATE REALWORLD DATA I THINK WE NEED TO RETHINK THE WHOLE PARADIGM FROM A PATIENT PERSPECTIVE AND THEN BACK INTO WHAT IS, IF YOU COME AT IT FROM THE PATIENT JOURNEY AND HOW THEY'RE GOING TO PARTICIPATE, BECAUSE REALLY IN MANY DISEASES AND I CAN -- HARPREET TALK ABOUT THE ONCOLOGY CENTER OF EXCELLENCE, I CAN TALK ABOUT THE PATIENT COMMUNITY, BUT IN MANY OF THE CANCERS NOW, CLINICAL TRIALS ARE PART OF CLINICAL CARE, NOT A RESEARCH VEHICLE OF LAST RESORT ANYMORE. MANY OF THEM ARE FIRST LINE AND MANY PATIENTS ARE ON FOUR, FIVE, SEVEN CLINICAL TRIALS WHERE ALL THE ASSESSMENTS THAT WE USED TO DO TO GATHER AS MUCH SCIENTIFIC DATA AS POSSIBLE NEED TO BE RETHOUGHT BECAUSE IS THAT REALLY GOOD FOR THE PATIENT AND GOING TO HELP THEM DOWNSTREAM?
I THINK WE JUST NEED TO APPROACH IT DIFFERENT.
IF YOU COME AT IT FROM THE PATIENT JOURNEY MANY WORK WITH REGULATORS TO UNDERSTAND WHAT'S NECESSARY TO DEMONSTRATE SAFETY AND EFFICACY AND WHAT'S SORT OF NICE TO HAVE. AND THEN THE PROBABLY THE BIGGEST HURDLE IS DEALING WITH YOUR OWN LEGAL AND ETHICS AND COMPLIANCE INTERNALLY AT THE INSTITUTION LEVEL OR AT THE SPONSOR LEVEL.
BUT THEY ARE PROBABLY THE MOST INERT GROUP OF PEOPLE TO BE STEREOTYPICAL IN A CLASSIFIERS INDIVIDUALS BUT THAT'S PROBABLY GOING TO BE ONE OF THE BIGGEST HURDLES TO GET THINGS TO SHIFT.
>> IF I BREAK THAT DOWN, ANDREA, IN TERMS OF WORKFORCE THINKING, YOU HAVE ME THINKING ABOUT DO I HAVE THE RIGHT PEOPLE INSIDE OF MY ORGANIZATION AS A SPONSOR CRO OR OTHERWISE TO ACTIVELY ENGAGE WITH PATIENTS FOR INSIGHTS AND PLANNING FOR MY STUDIES, THE RIGHT LEGAL AND COMPLIANCE COLLEAGUES ALIGNED TO THE STRATEGY OF THE ORGANIZATION THAT THIS IS WHERE WE WANTED TO GO AND WE'LL WORK WITH THOSE COLLEAGUES IN A WAY TO FIND A WAY TO SAY YES RATHER THAN THE LEGACY MINDSET OF PROTECT THE ORGANIZATION AT ALL COSTS.
DO WE HAVE THE RIGHT STATISTICIANS AND OTHERS IN STUDY DESIGN TO FULLY EMBRACE PLATFORM TRIALS AND OTHER MODELS THAT WE KNOW CAN BETTER INTEGRATE RESEARCH AND HEALTHCARE RATHER THAN TREATING STUDIES AS A ONE BY ONE DISRUPTIVE INSTANCE TO HOW CARE IS BEING DELIVERED.
DID I MAP SOME OF YOUR IDEAS?
>> I'M GOING TO SAY YES BUT I THINK WE ALSO NEED TO BE REALISTIC THAT WE CAN'T GO BLOW UP EVERYTHING.

IF YOU CAN PUT HARPREET OR PAUL IN ANY SPOT, I THINK WE'LL BE IN GOOD SHAPE.
BUT I KNOW THAT'S NOT REALISTIC IN AN IDEAL WORLD I WOULD SAY ABSOLUTELY YEAH.
BUT REALISTICALLY HOW DO WE TAKE THOSE BABY STEPS TOWARDS THAT.
YOU EAT AN ELEPHANT ONE BITE AT A TIME.
WHAT ARE THE BITES WE CAN ATTACK TO MOVE IN THE RIGHT DIRECTION.
>> I THINK THAT SETS UP NICELY SOME OF THE PERSPECTIVE THAT NICHOLAS WAS SHARING FROM THE OUTSET.
HOW DO WE MAKE SURE THAT WE ARE SHIFTING TO A WORKFORCE AND EMBRACING A WORKFORCE THAT'S READY TO BE AGILE?
AND READY TO ADAPT TO SOME OF THESE CHANGES?
BECAUSE WE CAN TALK ABOUT THINGS LIKE DECENTRALIZED, BUT DECENTRALIZED WAS 2020.
THAT WAS OUR RESPONSE TO THE LAST PANDEMIC.
WHO KNOWS WHAT THE APPROACH IS IF WE'RE GOING TO HAVE TO RAPIDLY EMBRACE AND EVOLVE FOR WHATEVER ELSE THE WORLD THROWS AT OUR CLINICAL TRIAL ENTERPRISE.
NICHOLAS, CAN YOU DOUBLE DOWN ON THIS THINKING?
WHAT TYPE OF PERSPECTIVE DO WE NEED AS WE'RE THINKING ABOUT AGILITY, BEYOND JUST THINKING ABOUT SPEED?
>> SO I WOULD LIKE TO -- ANDREA WAS MENTION BEING THE NEED TO SHIFT TO PATIENT CENTRICITY AND I UNDERSTAND THE ANALOGY OF THE ELEPHANT BUT I BELIEVE IT'S NOT THAT DIFFICULT TO HAVE PATIENT CENTRICITY.
I THINK SIMPLY TO HAVE PATIENTS AT THE TABLE AND THE RIGHT PATIENT PROFILE AND WE SOMETIMES HAVE THE NEED FOR MAKE SURE EXPERIENCE OR PATIENT EXPERTISE WITH PATIENTS WITH A GOOD UNDERSTANDING OF HEALTH SYSTEM OR LIFECYCLE OF DRUG DEVELOPMENT, FOR EXAMPLE.
AND THERE'S A SCIENCE OF THAT.
GOOD PRACTICES ARE VERY GOOD EXAMPLE IN EVEN DURING COVID, I HEARD MANY CASES THAT COULD MAKE A FAST SHIFT TO REMOTE TRIALS BECAUSE THEY WERE ADDRESSING POTENTIAL ISSUES WITH PATIENTS FROM THE OUTSET.
AND SO YES, IT'S NOT ONLY -- I TOTALLY SUPPORT THE NAVIGATOR APPROACH BUT I ALSO WOULD LIKE TO SEE PATIENTS AT THE TABLE WHEN WE DESIGN THE CLINICAL TRIAL, WHEN WE DESIGN TARGETED PRODUCT PROFILE, WHEN WE TRY TO UNDERSTAND NEEDS AND DESIGN THE DATA SO THE PATIENT EXPERIENCE DATA WE DESIGN ACTUALLY REFLECTS PATIENT EXPERIENCE.
WHICH IS ONE OF THE KEY CHALLENGES TODAY.
SO I THINK FROM MY PERSPECTIVE, I CAN SEE MANY PRACTICES EVOLVING IN THAT DIRECTION, I CAN ALSO SEE REGULATORS AND FDA BUT ALL OTHER REGULATORS ACROSS THE GLOBE MOVING IN THAT DIRECTION AND RAISING THE BAR IN TERMS OF EXPECTATION AND HOW AND WHEN PATIENTS ARE INVOLVED IN THE PROCESS.
I BELIEVE THERE'S A WAY THERE AND I REALLY BELIEVE THAT WAS ONE OF THE MISSING KEYS WHY WE DIDN'T ADDRESS ISSUES IN THE PAST.
I THINK WE WILL PROBABLY CONTINUE NOT TO ADDRESS THESE ISSUES EVEN WITH NEW TECHNOLOGIES AND THE DIGITAL POTENTIAL IF WE DON'T SOLVE THAT SPECIFIC ASPECT.
BECAUSE I CAN SEE US JUGGLING MANY, MANY BALLS BUT IF WE DON'T CHOOSE THE RIGHT BALLS THE

PATIENT PERSPECTIVE IN MIND, I THINK WE'RE JUST ADDING COMPLEXITY AND THE ONLY THING WE'RE DOING IS TO GO, I THINK THE SAME WORLD BUT MAYBE EVEN FASTER BECAUSE IT'S MORE COMPLEX, AND WITH MORE BURNED OUT PEOPLE IN THE PROCESS.
I THINK THAT'S REALLY FOR ME THE AGILITY THAT I WOULD LIKE TO EXPLORE IS NOT THE AGILITY JUST TO DO MORE WITH LESS BUT ALSO TO BETTER CHOOSE PRIORITIES AND THE OUTCOMES WE'RE TARGETING BECAUSE WE WORK WITH THE PATIENT FROM THE OUTSET.
>> NICHOLAS, IS SOME OF THAT A WORKFORCE CHALLENGE OR OPPORTUNITY?
SOME OF THAT CULTURE AS COMPARED TO DIFFERENT TYPES OF SKILLS OR MINDSETS WE SHOULD BE HIRING?
>> SO IN MY EXPERIENCE WITH THE ORGANIZATION I WORK WITH, WHATEVER STAKEHOLDER GROUP WE TALK ABOUT, IT'S MORE OF QUESTION OF CULTURE CHANGE AND LEGACY OF THE PROCESS TO TOOLS AND PRACTICES.
BUT I HAVE SEEN PEOPLE AGAINST THE IDEA AND PEOPLE THAT TRIED AND WERE DISAPPOINTED BUT IT.
PATIENTS WERE ALWAYS ABLE TO BRING VALUE AT THE END BUT STILL A VALUABLE PROCESS.
SO I THINK IN MY MIND IT'S MUCH MORE A QUESTION OF ORGANIZATION CULTURE SHIFT AND PEOPLE MINDSET WILLINGNESS TO DO IT.
>> ANDY, NICHOLAS IS BRINGING UP SOME INTERESTING POINTS AROUND AGILITY AND IT REMINDS ME OF HOW SO MANY OF THE TOPICS THAT WE'RE TALKING ABOUT IN PANEL ONE, THESE AREN'T INNOVATIONS, THEY'VE BEEN AVAILABLE FOR US FOR A VERY LONG TIME.
YOU AND I, ANDY, WORKED ON THE FIRST FULLY REMOTE TRIAL 15 YEARS AGO NOW, I BELIEVE.
SO THIS IS REALLY A STORY OF ADOPTION, IT SEEMS, RATHER THAN INNOVATION.
HOW DO YOU SEE EMBRACING THAT TYPE OF AGILITY IN AN ORGANIZATION LIKE YOURS THAT'S BIG, THAT'S COMPLEX, YOU'VE GOT COLLEAGUES ALL OVER THE WORLD.
HOW DO YOU SEE EMBRACING SOME OF THE AGILITY THAT NICHOLAS IS DESCRIBING?
>> I THINK WE START WITH APPROACH OF WHAT'S THE OUR OBJECTIVE.
WE REVERSE ENGINEER AND WHAT ARE TECHNOLOGIES AND CAPABILITIES WE NEED TO ACHIEVE THAT.
AND CLEARLY GETTING PATIENT INPUT AND INSIGHT INTO HOW DISEASE IS MANAGED, WHAT'S THEIR PREFERENCE, HOW THEY WOULD PREFER TO GO TO SITE OR NOT IS REALLY IMPORTANT FOR US TO BUILD INTO OUR DESIGN.
BUT ULTIMATELY WHAT WE HAVE TO FOCUS ON IS NOT ONLY COLLECT THE DATA BUT WE HAVE TO GET THE PRODUCT APPROVED.
AND SO THERE'S A STEP BEYOND JUST RUNNING A TRIAL.
AND THERE'S A STEP BEYOND JUST USING COOL AND SEXY TECHNOLOGY.
WHAT YOU HAVE TO DO IS GET IT APPROVED.
SOME OF THE THINGS WE'VE USED TECHNOLOGY GET HIGHLY SCRUTINIZED AND RIGHTLY SO.
WE WANT TO MAKE SURE THAT WHEN YOU'VE USED A DEVICE TO COLLECT A ENDPOINT, THAT HOW THAT DATA IS CURATED AND THAT'S WHY I MENTIONED THE DATA CURATION, IT'S DONE CORRECTLY.
WE'VE HAD INSPECTIONS ON THE ALGORITHMS USED BY THE VENDOR ON HOW THEY TRANSFORM THAT ELECTRONIC DATA INTO A MEANINGFUL CLINIC OUTPUT.
IT'S VERY COMPLEX AND IT'S, WE HEARD EARLIER IN THE PANEL BEFORE US ABOUT USING THE CELL PHONE.

EVERYONE HAS A SMARTPHONE BUT IF YOU'VE WATCHED THE NEWS YOU'VE SEEN THE NUMBER OF SIGN ATTACKS AND THE USE OF CRYPTO CURRENCY TO PAY RANSOM.
WE HAVE 5 MILLION ATTACKS ON OUR DATA SYSTEM A WEEK.
SO THE INTEGRITY OF A CELL PHONE USED BY A COORDINATOR OR CELL PHONE USED BY A VISITING NURSE IS A POTENTIAL FOR A PRIVACY BREACH AND POTENTIAL TO GET INTO YOUR DATA SYSTEMS.
COULD BE AN ENTRY POINT.
SO I THINK WE HAVE TO THINK HOLISTICALLY ABOUT THIS, HOW DO WE LOOK AT THIS.
OUR BIGGEST CHALLENGE IS MAKING SURE THE SECURITY OF OUR DATA AND THAT WHAT YOU DO THAT MAKES IT EASY FOR A PATIENT CAN BE TRANSFORMED INTO THE TRIAL.
WE'VE GOT THIS CONFLICT OF AS WE HEARD FROM ANDREA IS THAT MANY CANCER PATIENTS, THEIR CLINICAL CARE IS THEIR CANCER CARE AND IS THEIR TRIAL BUT IN OR WORLDS, I'VE EXPERIENCED THE LAST 18 MONTHS I'VE HAD TO HAVE SOME PHYSICIAN VISITS AND SOME I'VE BEEN QUITE HAPPY.
I COULD CARE LESS ABOUT MY PRIVACY ON GETTING HIT IN THE EYE BY A TWIG WHILE CYCLING, I JUST WANT IT FIXED.
I DON'T SEE THAT AS A PRIVACY ISSUE BUT IF I HAVE HAD A GYNECOLOGICAL CANCER I THINK I WOULD BE VERY CONCERNED ABOUT MY PRIVACY BECAUSE THE STIGMATIZATION ASSOCIATED WITH THOSE THINGS.
I THINK WE HAVE TO AVOID THE GENERALIZATION AND OUR APPROACH IS TO SAY WHAT DO WE NEED FOR THE OUTPUT THAT HAVE TRIAL.
CERTAIN STUDIES WE CAN ACTUALLY ADOPT A VERY BROAD APPROACH IF IT'S A STUDY FOR CANCER WITH THE CANCER IS BEING REMOVED PEOPLE ARE SUPPOSED TO DOILY DISEASE FREE AND WE TRACK THEM TEN YEARS IF YOU MISS A SCAN AND YOU CAN DO THAT THREE MONTHS LATER OR DO ONE DISTALLY AND IF IT'S POSITIVE YOU GO IN CENTRALLY WON'T AFFECT THE OUTCOME OF THE TRIAL IT ENABLES THE TRIAL AND ENABLES RETENTION IN THE STUDY.
IF YOU'RE DOING A TREATMENT WHERE YOU'RE LOOKING AT PROGRESSION FREE SURVIVAL AND LOOKING AT CHANGE FROM SIX MONTHS TO NINE MONTHS WHICH IS A BIG DIFFERENCE IN CERTAIN CANCERS, IT'S REALLY IMPORTANT THAT YOU GET THE PRECISION OF THAT MEASUREMENT DONE WITH THE PRECISION OF THE MACHINERY AND DONE REPEATEDLY SO YOU HAVE THE DATA.
SO WHAT I'M SAYING HERE IS THAT I THINK WE HAVE TO LOOK AT EACH CASE INDIVIDUALLY NOT HAVE BROAD PAINTBRUSH STROKES AND SAY SUDDENLY DECENTRALIZE EVERYTHING.
COMPONENTS IN A TRIAL YOU CAN SHIFT OUT AND SAY THAT CANNING CENTRALIZED AND IS THIS THAT IS TO BE DONE A CERTAIN WAY AND TEASE THAT OUT AND LOOK AT IN CERTAIN TRIALS DOES IT LEAN THIS WAY AND NOT THAT WAY.
WE'VE BEEN DONE PATIENT REPORTED OUTCOMES REMOTELY FOR A LONG TIME.
DOING A LOST ASSESSMENTS REMOTELY.
DIDN'T HAVE THE SMARTPHONE IN THE OLD DAYS WE HAD A LEG PHONE AND DID TELEPHONE VISITS IN CARDIOVASCULAR OUTCOME STUDIES 20 PLUS YEARS AGO AND USING A LOT OF THE STUFF.
LET'S TAKE THE PATIENT NEEDS AND ALSO LOOK AT THE ECOSYSTEM NEEDS OF PROTECTING THE INTEGRITY OF DATA, CYBERSECURITY, PRIVACY AND BRING THOSE FACTORS AND DO THAT INEST PLANNING BEFORE WE EXECUTE ON A CLINICAL TRIAL.
IT'S COMPLEX, IT'S NOT THE SAME, IT'S NOT COOKIE CUTTER APPROACH.
>> I THINK AS WE'VE BEEN TALKING ABOUT THE IMPORTANCE OF STARTING BY LISTENING, IT'S ALWAYS

BEEN MY BELIEF THAT BURDEN IS NEITHER CREATED OR DESTROYS, IT JUST GETS SHIFTED AROUND.
SO IF WE'RE ASPIRING TO REMOVE BURDEN FROM ONE STAKEHOLDER WE HAVE TO BE PREPARED TO MANAGE AND ABSORB IT SOMEWHERE ELSE IN THE ECOSYSTEM.
BUT REST ASSURED IT WAS SOMEBODY'S BURDEN BEFORE IT GOT SHIFTED AND IT WAS PROBABLY THE PATIENT AND THE SITES UP FRONT.
THAT REMINDS ME, ANDREA, WHEN ESTHER WAS SPEAKING SHE SHARED SOME PERSPECTIVE ON THE IMPORTANCE OF BRINGING TRIALS INTO THE COMMUNITY.
AND I'M CURIOUS, IN YOUR MIND, ANDREA, WHERE SHOULD COMMUNITY BASED ORGANIZATIONS FIT INTO THIS STORY AS WE'RE STARTING TO THINK OF ALMOST THE AUGMENTED AND ENHANCED WORKFORCE THAT'S SUPPORTING CLINICAL RESEARCH GOING FORWARD?
>> I THINK TO ANDY'S POINT WE COULD NEED TO BE CAREFUL OF WHAT KIND OF TRIALS GO WHERE AND WHETHER IT'S TRULY DECENTRALIZED OR IF IT'S JUST CERTAIN ASSESSMENTS ARE LOCAL VERSUS CENTRALLY DONE AS WELL.
BUT WITH RESPECT TO THAT ALSO, AND BRINGING SOME OR ALL OF THE TRIAL INTO THE COMMUNITIES, I THINK WE NEED TO START LOOKING AT COMMUNITY BASED ORGANIZATIONS, THE COMMUNITY BASED OUTREACH OF CONTROL CANCER CENTERS AS MORE OF A PARTNER IN THE CLINICAL TRIAL ECOSYSTEM THAN PERHAPS THEY HAD BEEN LOOKED TO BEFORE.
BECAUSE OFTENTIMES THEY ARE THE TRUSTED PARTNER OF THE PATIENT.
AND THEY ARE THE AREA WHERE PEOPLE GO TO LOOK FOR INFORMATION OR A COMMUNITY OR RESOURCES TO HELP THEM EITHER NAVIGATE THROUGH OR WITH THE CLINICAL TRIAL OR TO DECIDE TO PARTICIPATE IN IT OR NOT.
I THINK THAT WE NEED TO JUST HAVE A DIFFERENT VIEW PERHAPS OF COMMUNITY BASED ORGANIZATIONS AND IDENTIFY THOSE THAT TRULY ARE INTERACTING WITH THE POPULATION YOU'RE LOOKING AT FOR YOUR CLINICAL TRIAL AND ARE TRUSTED PARTNERS AND RESOURCES FOR THOSE AND THEN ENGAGE WITH THEM FULLY TO HELP THEM HELP THE PARTICIPANTS IN THE TRIAL AS WELL.
>> ANDREA, CAN YOU GIVE AN EXAMPLE FOR FOLKS OF AN ENGAGEMENT WITH A COMMUNITY BASED ORGANIZATION DONE RIGHT?
>> I WOULD HAVE TO GO BACK, THERE'S SO MANY.
DEPENDS ON THE TRIAL.
QUITE HONESTLY, I HAVE NOT YET SEEN A TRIAL IN A COMMUNITY SETTING TO BE ABLE TO RELATE IT DIRECTLY TO THAT.
THAT SAID, ONE OF THE THINGS THAT WE DO AT LUNGEVITY, WE HAVE CLINICAL TRIAL AMBASSADOR PROGRAMS WHERE WE ACTUALLY MATCH PATIENTS WITH ANOTHER PATIENT WHO HAS BEEN -- SOMEBODY CONSIDERING A CLINICAL TRIAL, WE WILL MATCH THEM WITH SOMEBODY WHO'S BEEN ON A CLINICAL TRIAL SO THEY CAN UNDERSTAND WHAT TO EXPECT.
WE MATCH THEIR CAREGIVERS WITH CAREGIVERS AS WELL.
SO IT'S NOT -- WHILE IT'S NOT LOCAL FEET ON THE GROUND, IT'S VIRTUAL, IT IS ONE WAY TO ENGAGE WITH COMMUNITY BASED ORGANIZATIONS FOR HOW THEY'RE ENGAGING WITH THE CONSTITUENTS YOU'RE TRYING TO REACH AND HEALTH LITERATE MATERIALS AND PROVIDING THAT INFORMATION.
DO YOU HAVE AN EXAMPLE?
>> I WANTED TO CIRCLE BACK TO SOMETHING ANDY WAS SAYING, BUT --
>> GO FOR IT.

>> CRAIG, I FEEL LIKE ANDY INVOKED THE FDA BY TALKING ABOUT THE ULTIMATE GOAL OF APPROVAL.
AND HE'S ABSOLUTELY RIGHT.
AND THERE IS A CULTURE, PARDON ME, I HOPE IT'S OKAY TO SAY THAT WITHIN INDUSTRY OF DERISKING, RIGHT?
YOU WANT THE DRUG TO BE APPROVED.
THAT'S WHAT'S BEST FOR EVERYONE, IN PARTICULAR OUR PATIENTS.
AND SO WHEN YOU TALKED, CRAIG, ABOUT ADAPTATION OR ADOPTION, RATHER THAN INNOVATION, THAT IS THE EXACT SENTIMENT BUT YOU HAVE TO ASK, WE HAVE TO ASK OURSELVES WHY?
WHY WAS THIS NOT ADOPTED?
NOBODY EVER SAID THE FDA NEVER SAID YOU CAN'T DO REMOTE ASSESSMENTS, YOU CAN'T INVOKE THE USE OF TECHNOLOGY OR REMOTE MONITORING IN CLINICAL TRIAL CONDUCT.
INDUSTRY AND INVESTIGATORS, INVESTIGATOR LED TRIALS, SAID WE DON'T WANT TO TAKE THAT RISK BECAUSE OUR BOTTOM LINE IS THE PRIMARY ENDPOINT.
AND I THINK WHAT WE ARE GOING TO SEE, WHICH IS INEVITABLE IN THE NEXT MAYBE SIX MONTHS TO A YEAR IS ALL THE DATA COMING IN FROM ALL THE TRIALS THAT WERE ABLE TO CONTINUE SAFELY IN THE WAKE OF THE PANDEMIC AND THAT THE FDA AND AWAY PLAY WELL IN THE SANDBOX AND WE'LL SHARE ALL OF THIS INFORMATION, HOW IT DID OR DID NOT IMPACT THE BOTTOM LINE WHICH IS APPROVAL, AND ACCESS TO NOVEL THERAPIES FOR PATIENTS.
AND SO THE DATA CAN'T LOOK ANY WORSE MOVING FORWARD THAN IT'S GOING TO COME INTO US IN THE NEXT, AS IT'S ALREADY COMING IN IN THE NEXT SIX MONTHS TO A YEAR.
SO I THINK THE ADOPTION IS GOING TO BE DRIVEN BY INFORMATION WHICH IS GOING TO BE DRIVEN BY THE DATA THAT WE RECEIVE WHICH, AGAIN, IS WHAT TRIGGERED THIS CALL FOR A MORE HARMONIZED APPROACH SO THAT WE CAN LOOK AT THIS DATA IN A MORE KIND OF AGGREGATE WAY.
SO I COMPLETELY AGREE WITH THIS KIND OF AN IDEA THAT WE'RE NOT INNOVATING HERE, WE'RE ASKING PEOPLE TO ADOPT.
AND THAT IS GOING TO STEM FROM DATA AND SUBSEQUENT APPROVALS.
AND THEN ON ANDY'S POINT ABOUT SELECTING THE RIGHT TRIAL OR THE RIGHT ELEMENTS OF A TRIAL THAT COULD BE DECENTRALIZED, 1,000 PERCENT AGREE WITH HIS SENTIMENTS BUT EVEN SOMETHING LIKE A NEW DRUG VERSUS A SUPPLEMENTAL INDICATION, RIGHT?
IF WE KNOW ALREADY THE SAFETY PROFILE OF A THERAPY, IT'S MUCH EASIER, I THINK, TO KIND OF HAVE PATIENTS BEING MONITORED REMOTELY WHEN YOU'VE YOU ALREADY HAVE A SENSE OF WHAT TO LOOK FOR RATHER THAN A FIRES IN HUMAN TRIAL IN WHICH YOU ACTUALLY DON'T KNOW WHAT THE TOXICITIES MAY LOOK LIKE AND THEY MAY NEED TO BE MONITORED BY SOMEONE WHO KNOWS WHAT TO EXPECT.
BEFORE WE LOST THAT I WANTED TO FOLLOW UP AND SORRY, ANDREA, DIDN'T MEAN TO --
>> LET ME GO TO A LEVEL DEEPER ON THAT ONE WITH YOU.
I AGREE WITH YOU.
I THINK THE ADOPTION THIS YEAR WAS NOT DONE BY AN ASPIRATION TO INNOVATE.
IT WAS ALL AROUND RISK MITIGATION SO THINGS THAT WERE AVAILABLE BECAME RISK MITIGATION STRATEGIES.
I WOULD ARGUE, THOUGH, THAT THE REVIEW DECISIONS THAT WILL BE MADE OVER THE NEXT 12 TO 24 MONTHS BY REGULATORY AUTHORITIES IN ALL THERAPEUTIC AREAS ARE GOING TO BECOME THE

BAROMETERS OF ACCEPTABILITY AND RISK.
BECAUSE YOUR TEAMS ARE MAKING DECISIONS OVER THE NEXT YEAR TO TWO TO THREE YEARS BASED ON STUDIES THAT WERE RUNNING IN THE YEAR 2020.
AND EACH APPROVAL OR LACK THEREOF IS GOING TO BE BASED BOTH ON THE DRUG AND METHODS THAT WERE FOLLOWED AROUND IT.
SO SHOULD WE ALL BE WATCHING WITH ANXIETY FOR EACH DECISION TO GET A SENTIMENT OF THE LEVEL OF RISK IN CONTINUING TO EMBRACE THESE APPROACHES GOING FORWARD?
>> THAT'S A GREAT QUESTION.
YOU'RE PUTTING ME ON THE SPOT HERE.
I THINK IT WILL BE IMPORTANT TO WATCH HOW WE DISSEMINATE INFORMATION ABOUT THE DATA.
WE ARE ACTIVELY WORKING FOR EVERY APPROVAL IN MY DIVISION AND EVERY APPLICATION WE HAVE IN HOUSE, WE DO SPEND TIME AT LOOKING AT WHAT WAS INCLUDED REGARDING COVID-19 MODIFICATIONS, HOW THAT IMPACTED THE BOTTOM LINE, AND I THINK YOU WILL SEE FROM US AT LEAST THE ONCOLOGY GROUP, DISSEMINATE THAT INFORMATION.
YOU KNOW, YOU HAVE TO LOOK AT ONCOLOGY IN A DIFFERENT CONTEXT, I THINK, BECAUSE WE'RE TALKING ABOUT LIFE-THREATENING DISEASES, POTENTIALLY LIFESAVING, LIFE EXTENDING THERAPIES.
SO THE FLEXIBILITY THAT WE MAY EXTEND MAY BE VIEWED DIFFERENTLY ACROSS OTHER THERAPEUTIC AREAS.
BUT I DO THINK YOU COULD SAFELY WATCH OUR APPROVALS IN THE NEXT 12 TO 18 MONTHS AS SOMEWHAT OF A BAROMETER.
I DON'T KNOW.
I CAN TELL YOU WE HAVEN'T ENCOUNTERED ANYTHING YET THAT HAS PRECLUDED AN APPROVAL BASED ON COVID, BUT WE'RE STILL VERY EARLY HERE.
I DID MENTION WE'VE HAD DELAYS DUE TO COVID THAT ARE COMPLETELY INDEPENDENT OF CLINICAL DATA AND HOW IT WAS ACQUIRED, BUT, RATHER, THE INSPECTION ISSUE.
SO IT'S VERY MULTIFACTED, BUT I'M NOT GOING TO GIVE YOU A HARD YES OR NO ON THAT BECAUSE THAT'S JUST NOT WHAT REGULATORS DO.
I'M GOING TO HEDGE IT.
>> WOULDN'T EXPECT OTHERWISE.
[LAUGHTER]).
>> AT LEAST YOUR CONSISTENT.
>> WE WILL SHARE.
WE WILL SHARE FOR SURE.
>> ANDY, DID YOU WANT TO REACT TO SOME OF PREPARE THE'S PERSPECTIVE?
>> ABSOLUTELY.
SO LET'S BE REAL.
THE SUBMISSIONS THAT HAVE BEEN MADE THE LAST 12 MONTHS, MANY OF THOSE STUDIES STARTED PRE-COVID.
SO THE TAIL END OF THOSE TRIALS WAS IMPACTED BY COVID POTENTIALLY IMPACTED.
AND WE ASK THREE FUNDAMENTAL QUESTIONS.
HAVE WE MAINTAINED, WE DID A SURVEY OF TEN COUNTRIES IMPACTED BY COVID INCLUDING CHINA AND ITALY AND THESE COUNTRIES THAT HAD THE BIGGEST IMPACT AT THE BEGINNING.

AND WE SURVEYED THE COUNTRIES IN OUR CANCER STUDIES AND WE PROVIDED THIS TO OCE AS FEEDBACK.
WE LOOKED AT DID PATIENTS MAINTAIN THEIR VISITS, HAVE THEIR DOSING SCHEDULE AND PROCEDURES MAINTAINED.
AND THE DOSING SCHEDULE WAS IN THE 95% MAINTAINED AND SO WAS THE PROCEDURE AND THE VISITS WAS THE SAME.
FOR THOSE WHO MISSED, WE GOT THEM BACK ON SCHEDULE QUICKLY AND WE LOOKED AT INFORMED CONSENT.
WE HAD LOWER WITHDRAWAL OF INFORMED CONSENT IN COVID THAN OF BEFORE.
ONE TENTH OF ONE PERCENT IN OUR STUDIES WITHDREW CONSENT.
LOWER THAN BEFORE.
SO WHAT HAPPENED IS PEOPLE WHO ARE SICK AND CANCER STUDIES REALLY WANTED TO MAKE SURE THEY STAYED IN THEIR CANCER TREATMENT AND THERAPIES.
IT MAY NOT BE THE SAME FOR SOMEONE WHO'S GETTING TREATED FOR SOMETHING THAT'S NOT AS SERIOUS AS CANCER WHERE PEOPLE DIE IF THEY DON'T GET TREATMENT.
WE HAVEN'T LOOKED AT OTHER STUDIES. WHAT WE DID LOOK AT IS ALL THE GUIDANCES AROUND THE GLOBE AND CHANGED ABOUT TEN OF OUR GUIDANCE.
JUST ROUNDED THAT OFF.
I CAN GIVE THE EXACT NUMBER.
WE LOOKED IN THOSE TEN COUNTRIES WE SURVEYED WHO WAS WILLING TO ADOPT THE CHANGES.
FOR SOME OF THEM, NONE WILL WILLING TO ADOPT.
DOCTORS WERE NOT COMFORTABLE WITH SHIPPING INFUSED MEDICINES THAT ARE UNDER THEIR CONTROL TO SOMEONE'S HOME.
AND THAT WAS FINE.
FOR A TABLET, WHICH IS ORAL MEDICATION THAT'S HEAT STABLE THERE'S WILLINGNESS TO SHIP FROM THE SITE TO A PATIENT'S HOME BUT NOT ALL PATIENTS WANTED IT THAT WAY.
DEPENDING ON THE DISEASE, YES OR NO, THEY WOULD OR WOULD NOT TAKE THAT.
SO WE ASSUMED EVERYONE WANTS THE SAME, IT'S NOT TRUE LIKE THAT.
WE LOOKED AT A LOT OF DIFFERENT THINGS.
I'LL GIVE ONE.
THE ECOSYSTEM --
>> WE'RE GOING TO RUN OUT OF TIME.
SO I WANT TO BOUNCE OVER TO QUICKLY TO ANDREA.
I THINK SHE HAD A --
>> I HAD A QUESTION FOR BOTH ANDY AND HARPREET AND NICHOLAS FEEL FREE TO JUMP N LISTENING TO YOU IN TERMS OF ALL OF THE CHANGES THAT ARE HAPPENING DUE TO COVID AND THE ADAPTABILITY.
SO TO BRING IT BACK TO THE WORKFORCE AND REIMAGINING THE WORKFORCE, FROM BOTH WITHIN THE FDA AND WITHIN INDUSTRY, DO YOU THINK THAT GOING FORWARD THE PEOPLE WHO YOU WILL CONTINUE TO HIRE AND CONTINUE TO EXCEL ARE THOSE THAT CAN ADAPT TO THE NEW SITUATIONS?
SO HISTORICALLY GOING BACK 20 YEARS, THEY WERE NOT THE MOST FORWARD THINKING PEOPLE GENERALLY HARPREET, THAT WAS -- IT WAS VERY PROCESS DRIVEN BUT NOW OCE PARTICULARLY, YOU,

PAUL, OTHERS, ARE WILLING TO BE MORE PROBLEM SOLVERS THAN JUST PROCESS PEOPLE.
IN INDUSTRY, SOUNDS LIKE ANDY FROM WHAT YOU'RE SAYING PEOPLE HAD TO PIVOT AND FIGURE OUT HOW YOU CAN MAINTAINED TRIALS AND KEEP ENROLLMENT.
FROM A WORKFORCE PERSPECTIVE, IS THAT HOW IT'S GOING TO CONTINUE TO DEVELOP WITHIN REGULATORY AND WITHIN INDUSTRY, DO YOU THINK?
>> ABSOLUTELY.
FIRSTLY, I'D LIKE TO SECOND WHAT YOU SAID.
THE AGENCY HAS BEEN VERY PROGRESSIVE AND COLLABORATIVE AND WORKED TOGETHER WITH MANY SPONSORS.
THAT'S A GOOD NEWS SCENARIO.
AND WE'VE ALWAYS BEEN ADAPTIVE TO THE CHALLENGES THAT AWAY FACED.
WHEN WE DEVELOPED AN EBOLA VACCINE WE HAVE TO BE CREATIVE IN HOW THAT GETS DONE.
WE DO DIFFERENT THERAPEUTIC AREAS WE HAVE TO THINK CREATIVELY WHAT'S THE WORKFORCE WE NEED TO THINK DIFFERENTLY AND TO CONDUCT THE TRIALS IN DIFFERENT ENVIRONMENTS, DIFFERENT MANNERS.
SO I WOULD SAY YES, WE HAVE TO KEEP ADAPTING AND WHAT WE HAVE TO DO IS TAKE THE VERY EXPERIENCED PEOPLE WE HAVE AND CHANGE THEIR MINDSET AND RESKILL THEM AND HIRING NEW SKILLS.
SOME OF THE NEWER SKILLS ARE MORE DIGITALLY ENABLED AND -- 15-YEAR-OLD KIDS ARE FAR BETTER AT PROGRAMMING THE GADGETS IN OUR HOME THAN I AM.
BUT THEY CAN DO IT INTUITIVELY AND DON'T EVEN KNOW WHAT MANUALS ARE.
I DON'T KNOW HOW THEY KNOW BUT THEY KNOW.
FOR ME IT'S A MANUAL WORLD.
I HAVE TO READ UP HOW TO CHANGE AND PROGRAM THE TV AND ALL THAT STUFF.
>> WE'RE GETTING -- HARPREET, DO YOU HAVE A PERSPECTIVE ON ANDREA'S QUESTION?
>> LOOK, I THINK WE ARE A PROGRESSIVE PART OF THE FDA AND WE HAVE BEEN PROBABLY FOR -- RICK JOINED IN 1999.
SO I'D SAY PROBABLY SINCE THEN, I THINK WE'LL CONTINUE THAT.
WE'RE GUIDED BY PATIENT CENTRICITY, WE'RE GOVERNMENT EMPLOYEES, OUR DUTY IS TO THE PUBLIC HEALTH AND IN THIS CASE, AS ONCOLOGISTS, THE HEALTH OF PATIENTS WITH CANCER IN THE UNITED STATES.
SO THAT'S WHAT DRIVES US.
THAT'S WHAT MOTIVATES US.
AND I DO THINK YOU'RE GOING TO SEE A CONTINUED MOVE TOWARDS A MORE PROGRESSIVE AGENDA PARTICULARLY ON THIS TOPIC.
>> NICHOLAS, ANY THOUGHTS ON ANDREA'S QUESTION?
>> NO, JUST CONFIRMING FOR THE LAST FEW YEARS I'VE SEEN QUITE A SHIFT FROM THE FDA IN TERMS OF ENGAGING PATIENTS AND DESIGNING GUIDANCES THAT ARE RAISING QUESTIONS BUT CREATING QUESTIONS BECAUSE WE GET TO IT AND ACTUALLY QUESTIONS ARE BEING ADDRESSED AS WE EXPLORE FURTHER AND THE FDA MOVEMENT HAS A RIPPLING EFFECT GLOBALLY SO I THINK I JUST WANTED TO SECOND THAT AND TO GIVE IT MORE OF A GLOBAL PERSPECTIVE AS A RIPPLING EFFECT OF THESE EFFORTS.

THAT'S THE ONLY THING I CAN ADD TO THAT.
>> JUST FOR THE RECORD, IT WAS THE FDA STAKEHOLDERS AT CITY THE CLINICAL TRIALS TRANSFORMATION INITIATIVE THAT LAUNCHED THE TRIALS INITIATIVE INCLUDING THE DCT RECOMMENDATIONS BACK IN 2018.
IT WASN'T INDUSTRY DRAGGING REGULATORS IT WAS KIND OF THE OTHER WAY AROUND AND THOSE ARE GETTING UPDATED WITH CITY RIGHT NOW.
ONE QUICK LAST QUESTION I WANTED TO COME BACK TO YOU, HARPREET, BECAUSE AT THE OUTSET YOU TALKED ABOUT THE 1572.
AND THERE'S A GREAT CONNECTION HERE TO ME AROUND OUR THINKING OF WORKFORCE, WE WERE TALKING EARLIER ABOUT GETTING THINGS GOING IN THE COMMUNITY BETTER.
WE CAN'T EXPECT A FUTURE WHERE EVERY PHYSICIAN IN THE COMMUNITY NEEDS TO BE LISTED ON A 1572 FOR EVERY STUDY IN ORDER TO ENSURE ACCESS AND EDUCATED FOR ALL.
SO WHAT ARE CURRENT THINKING AROUND 1572S?
>> I THINK THERE'S FLEXIBILITY HERE.
AGAIN, WE'VE HEARD EXTENSIVELY THAT IS A POINT OF CONFUSION AND MAYBE EVEN CONTENTION.
I THINK THE TAKE-HOME POINT IS THE GENERAL FEELING RIGHT NOW WITHIN THE AGENCY IS THAT THE DECISION TO INCLUDE INDIVIDUALS AS SUB INVESTIGATORS, THEREBY REQUIRING 1572S ARE THOSE WHO ARE CONDUCTING TRIAL RELATED ACTIVITIES THAT CONTRIBUTE DIRECTLY AND SIGNIFICANTLY TO STUDY DATA.
THERE'S A LOT OF GRAY AREA THERE.
AND I THINK THAT IS THE SPACE FOR KIND OF INDIVIDUAL QUESTIONS ABOUT YOUR PROTOCOL, ABOUT WHO WOULD QUALIFY DIRECTLY TO THE AGENCY.
I THINK THE REST SO KIND OF LOCAL HEALTHCARE PROVIDERS THAT ARE CONDUCTING ACTIVITIES THAT FALL WITHIN THE SCOPE OF THEIR MEDICAL PRACTICE COULD BE LISTED, FOR EXAMPLE, ON A TASK LOG AS OPPOSED TO BEING ON A 1572.
BUT THIS IS A VERY ACTIVE ISSUE OF DISCUSSION AND WE'RE OPEN TO FEEDBACK ABOUT THIS.
>> I THINK THAT IS TREMENDOUS TO HEAR.
BECAUSE AS WE THINK ABOUT ACCESS IN THE COMMUNITY AND THE DECENTRALIZED IT DOESN'T MEAN TRIALS AT HOME.
IT JUST MEANS OPENING UP MORE ACCESS POINTS.
AND THAT CAN START TO OPEN DOORS FOR ACCESS WITH ALMOST ANY DOCTOR'S OFFICE WITH REMOTE INVESTIGATORS BEING ENGAGED USING VIDEO TO MANAGE THE PROTOCOL INTERACTIONS, BUT PROVIDING AN ALTERNATIVE TO THE HOME AS A TRUSTED LOCATION THAT MAY BE MORE ACCESSIBLE AND CONVENIENT FOR PATIENT.
WHETHER WE'RE THINKING ABOUT IMAGING THAT'S LOCAL, USING LOCAL LABS PERHAPS WITH CENTRAL REVIEW OR SOME OF THESE OTHER ALTERNATIVES IT WILL BE INTERESTING TO SEE MORE SPONSORS AND CROS AND INVESTIGATORS ENGAGING WITH THE FDA AROUND THE 1572 RATHER THAN MAKING ASSUMPTIONS ABOUT WHAT WE CAN AND CAN'T DO HERE.
>> I THINK THAT'S THE KEY IS THAT ANY QUESTIONS, EVEN AROUND WHAT I JUST MENTIONED AS KIND OF GENERAL LINES OF THOUGHT, SHOULD BE COMMUNICATED DIRECTLY WITH THE AGENCY AND THE DIVISION RESPONSIBLE FOR THE STUDY FOR REALLY MORE DIRECT GUIDANCE ON THAT.
DON'T MAKE ASSUMPTIONS.

>> HARPREET, NICHOLAS, ANDREA, AND ANDY WHY YOU ARE FABULOUS VOICES ON THIS TOPIC AND I'M GRATEFUL TO HAVE YOU HERE WITH US FOR THIS LAST HOUR.
AND WE'LL TURN THE BATON BACK TO YOU, SARAH.
>> THANK YOU SO MUCH, CRAIG, ANDY, NICHOLAS, ANDREA AND HARPREET.
THAT WAS REALLY, REALLY INTERESTING TO HEAR.
I THINK AT THIS TIME WE'RE GOING TO SHIFT TO WRAPPING UP TODAY'S SESSION AND I'LL ASK PAUL TO COME BACK ON, CRAIG, I KNOW IS GOING TO STAY ONLINE AND HAS TO -- HE'S GOING TO START MOVING BUT WE'RE GOING TO BE ABLE TOO HEAR HIS VOICE HOPEFULLY STILL.
>> STILL HERE.
FOR THE RECORD, MY DAUGHTER GOT A RIDE HOME SO I'M NOT RACING OFF IN THE CAR.
>> GOOD.
OKAY.
THEN WE GET BOTH YOUR VOICE AND YOUR FACE.
BARBARA HAS BEEN ON THE -- THERE SHE IS.
SHE'S BEEN HAVING SIGNIFICANT INTERNET CONNECTIVITY.
BUT SHE HAS BEEN FOLLOWING THE CONVERSATION WITHOUT BEING ABLE TO BE HERE.
SO THANKS, BARBARA, FOR JOINING BACK ON.
SO WHAT WE WOULD LIKE TO DO FOR THE LAST 15 MINUTES IS REALLY JUST THINK TOGETHER ABOUT WHAT WE HEARD AS WE WRAP UP.
AND I WOULD LOVE FOR PAUL, PAUL, YOU'VE ALREADY KIND OF CONCISELY BROUGHT YOUR THOUGHTS TOGETHER.
BUT MAYBE IF YOU COULD JUST COME BACK TO SOME OF THE MOST IMPORTANT POINTS OF THE PANEL FIRST AND THEN CRAIG, WE'LL TURN IT OVER TO YOU.
>> GREAT.
THANK YOU.
I REALLY ENJOYED THAT LAST PANEL.
IT'S SO FUN TO SEE DR. SINGH ANSWER SOME TOUGH QUESTIONS.
CRAIG, HOW ARE WE GOING TO ANSWER WHAT ARE OUR APPROVAL DECISIONS GOING TO BE IN THE NEXT TWO YEARS?
I THINK THAT WAS A GOOD QUESTION.
I THINK WHAT -- I WANT TO RESPOND TO THAT.
IT'S NOT SO MUCH ABOUT THE DECISIONS WE MAKE, BECAUSE THOSE ARE ALWAYS GOING TO BE BASED ON THE SCIENCE AND THE EVIDENCE THAT WE RECEIVE AND STRENGTH THAT HAVE EVIDENCE.
BUT IT'S THE TRANSPARENCY AND THE DESCRIPTION OF HOW AND WHY WE MADE A DECISION THAT'S GOING TO BE SO CRITICAL TO YOUR POINT, IN THE FUTURE BECAUSE IT'S -- WE WILL RECEIVE DATA AS YOU RIGHTLY POINT OUT THAT WILL HAVE WITHIN CONDUCTED FOR 50% OF THE TIME WITHIN COVID.
RIGHT NOW WE'VE BEEN RECEIVING DATASETS THAT WERE CONDUCTED MAYBE A MONTH OR TWO OR THREE INTO THE PANDEMIC WHERE THE REMOTE ASSESSMENTS WERE BEING CONDUCTED.
SO I THOUGHT THAT WAS AN INTERESTING AND IMPORTANT QUESTION.
>> GREAT POINT BECAUSE THAT TRANSPARENCY IS GOING TO BE SO INFORMATIVE TO THIS COMMUNITY.
THIS IS HOW THEY'RE GOING TO UNDERSTAND WHAT'S ACCEPTABLE AND WHERE THEY NEED TO GO

BACK AND REENGINEER AND RETHINK PROCESSES.
IT'S NOT THAT EVERYTHING IS YES AND NO AND CLEARLY ACCEPTABLE AND CLEARLY NOT, BUT WHERE DO THINGS HAVE TO BE ADJUSTED TO MAKE SURE WE'RE GETTING IT RIGHT.
AND WE'RE GOING TO HAVE THAT KIND OF FEEDBACK I BELIEVE HOPEFULLY ON A GLOBAL BASIS.
>> AND THERE MAY BE DIFFERENCES AS EVERYONE HAS BEEN SAYING, IN THE GLOBAL REGULATORY DECISION MAKING BECAUSE THEY OPERATE ON VERY DIFFERENT OFTENTIMES LAWS AND EVEN REGULATIONS.
SO TO WRAP UP I GUESS MY PANEL FROM WHAT I HEARD, I WOULD -- ONE WAS EDUCATION AND I THOUGHT IT WAS IMPORTANT AS PATIENTS ARE BROUGHT MORE INTO THE CONDUCT OF CLINICAL TRIALS, I KNOW THAT IT WAS MENTIONED THAT THE UP FRONT EDUCATION OF THE PATIENT ON HOW VITAL LET'S SAY THEIR ELECTRONICALLY CULTURED PRO IS OR THEIR ABILITY TO BE INVOLVED IN THE TELEMEDICINE ASPECTS OF FOLLOW-UP WILL BE IMPORTANT.
INFORMED CONSENT AND UP FRONT TRAINING OF PATIENTS ABOUT WHAT TO EXPECT IS GOING TO BE MORE IMPORTANT.
AND THAT'S THE SAME ALSO FOR LOCAL HEALTHCARE PROVIDERS IF THEY ARE PART OF THE PERSONNEL.
NUMBER TWO ON THE COLLABORATION DATA SHARING AND TRANSPARENCY THIS IS A LITTLE BIT ABOUT WHAT WE WERE TALKING ABOUT.
ALL OF US HAVE A ROLE AT COLLABORATING AND BEING TRANSPARENT ABOUT THE FINDINGS THAT WE HAD WITH RESPECT TO HOW REMOTE ASSESSMENTS WERE CONDUCTED, BEST PRACTICES, HOW WE CAN DO IT BETTER MOVING FORWARD.
I MENTIONED AND HARPREET MENTIONING I THINK WHAT WE'RE GOING TO SEE IS THE WORST CASE SCENARIO ON DATA VARIABILITY BECAUSE THESE WERE DEPLOYED IN A RAPID EMERGENCY SITUATION, WHAT CAN WE LEARN AND THEN WE CAN DEPLOY THEM IN WAYS TO MITIGATE THAT VARIABILITY UP FRONT IF WE DEPLOY THEM IN A MORE PROSPECTIVE MANNER.
WE TOUCHED ON GLOBAL REGULATORY COLLABORATION, HOW IMPORTANT IT'S GOING TO BE FOR US TO MAINTAIN CONTACT WITH EACH OTHER AND GLOBAL REGULATORY ENVIRONMENT TO SEE WHERE THERE ARE OPPORTUNITIES TO HARMONIZE AS WE'VE DONE IN THE PAST.
AND I KNOW THERE'S A BIG INTEREST IN GLOBAL REGULATORY COLLABORATION TO PROJECT ORIVS AND SOME PROJECTS.
LASTLY AND MOST EXCITINGLY TO ME IS AS WE MOVE THINGS OUT INTO THE COMMUNITY IN THE TRIAL SCENARIO, IN DCT AND HYBRID DCT, NATURALLY STANDARD HEALTHCARE PROVIDERS ARE GOING TO START TO SEE THE VALUE AND UNDERSTAND NOR ABOUT CLINICAL TRIALS.
I THINK THAT'S GOING TO BE SO IMPORTANT TO WHAT'S GOING TO BE NEEDED FOR LEARNING, TRUE LEARNING HEALTHCARE SYSTEMS.
CAN WE GET THAT INFRASTRUCTURE AND THAT TALENT AND THAT UNDERSTANDING OF SCIENCE OUT ALL ACROSS THE U.S. TO WHERE WE CAN DEPLOY PROSPECTIVE RANDOMIZED PRAGMATIC OR PRACTICAL TRIALS TO DO THINGS IN A MORE EFFICIENT WAY.
I THINK THAT'S VERY EXCITING TO ME.
I'LL END THERE.
>> THANKS, PAUL.
BARBARA, DID YOU WANT TO ADD ANYTHING TO PAUL'S COMMENTS?

YOU'RE ON MUTE.
>> WHY DON'T WE HEAR FROM CRAIG.
>> SURE, GO FOR IT, CRAIG.
>> AND THEN I CAN TALK.
>> ALL RIGHT.
WELL, THAT WAS A FABULOUS PANEL FOR US TO BE ABLE TO DRAFT OFF OF AND BUILD UPON, BECAUSE FOURS TO TALK ABOUT WORKFORCE CHANGES, WE HAVE TO UNDERSTAND WHAT THE CHANGES ARE THAT WE'RE ADAPTING TO EVOLVE AROUND.
IT WAS FASCINATING TO HAVE THIS GROUP COME TOGETHER AND TO ME, START TO BREAK OUT THREE DIFFERENT CATEGORIES OF WORKFORCE EVOLUTION.
ONE SEEMED TO CENTER AROUND THE SKILLS OF OR WORKFORCE WHEN WE'RE THINKING ABOUT OUR STATISTICIAN AND IS OTHERS WHO ARE INVOLVED IN STUDY DESIGN, TO THINK EXPANSIVELY AROUND MASTER PROTOCOLS AND PLATFORM TRIALS.
DO WE HAVE THE RIGHT PEOPLE TO BE ABLE TO HANDLE AND MANAGE AND NAVIGATE WITH DIVERSITY OF DATA THAT WE'RE LOOKING TO INCLUDE.
EVEN AWAY FROM JUST THE DIGITAL ASPECTS OF OUR WORKFORCE, MAKING SURE THAT WE HAVE THE RIGHT PEOPLE IN PLACE TO ACTIVELY LISTEN, ENGAGE, AND PARTNER WITH PATIENTS AND OTHER CRITICAL VOICES TO EMBED AND MAKE SURE THAT WE HAVE THE RIGHT PEOPLE THAT CAN KEEP OUR WALLS POROUS AND MAKE SURE WE DON'T DRIFT BACK INTO THE IVORY TOWERS OF THE PAST.
AFTER SKILLS, THERE SEEMED TO BE THIS INTERESTING DISCUSSION ABOUT NEW STAKEHOLDERS, NEW PEOPLE IN OUR WORKFORCE, WHETHER WE'RE THINKING ABOUT CARE NAVIGATORS AND OTHER RESOURCES IN THE COMMUNITY, STRAIGHT THROUGH TO THE IMPLICATIONS OF RETHINKING OUR 1572 AND WHAT ARE THE OTHER STAKEHOLDERS BEYOND THE CONVENTIONAL BOUNDARIES OF A 1572 THAT WE CAN NOW START TO ENGAGE AND INCLUDE IN THE COMMUNITY LOCAL TO THE PATIENT, TRUSTED FACES AND VOICES AND ALMOST AUGMENT THE MINDSET OF THE PAST AROUND WHO IS IN OUR WORKFORCE AND WHO ISN'T.
AND THEN FINALLY, AFTER THINKING ABOUT OUR SKILLS AND THE PERHAPS ADDITIONAL PEOPLE IN OUR WORKFORCE, WHAT'S THAT NEW MINDSET.
THE MINDSET THAT SUPPORTS THE COLLABORATION AND TRANSPARENCY THAT THE FIRST PANEL REALLY UNPACKED SO WELL, BUT AS NICHOLAS SET US UP WITH IN THE SECOND PANEL, THE MINDSET OF AGILITY.
THESE TECHNICAL AREAS THAT WE'RE PROBING RIGHT NOW ARE ALL THE DOWNSTREAM SOLUTIONS FROM THE COVID PANDEMIC.
I DON'T KNOW WHAT THE NEXT CRISIS IS GOING TO BE, AND I DON'T KNOW WHAT THE SOLUTIONS WILL BE NEEDED TO ADDRESS THAT CRISIS.
BUT AS NICHOLAS CALLED OUT, WE HAVE TO HAVE A WORKFORCE THAT CAN ADAPT, THAT UNDERSTANDS HOW TO PROPERLY BALANCE RISK AND HOW TO BE ABLE TO PICK UP AND EVOLVE WITH DIFFERENT SOLUTIONS ALONG THE WAY.
I THINK WITH THESE TYPES OF WORKFORCE SHIFTS, WE CAN HAVE SOME GREATER CONFIDENCE THAT WE'RE NOT NECESSARILY GOING BACK TO JUST THE WAYS OF THE PAST, BUT WE CAN ACTUALLY CHART A PATH FORWARD.
>> REALLY TERRIFIC.

SO SARAH, IF I GO IN AND OUT, PLEASE INTERRUPT AND TAKE OVER, BUT I THOUGHT THAT THIS WAS A WONDERFUL, WONDERFUL THREE HOURS TO SPEND.
AND A COUPLE OF SALIENT POINTS CAME OUT TO ME.
ONE IS THAT I THINK THERE IS A DIFFERENCE BETWEEN PREAPPROVAL NEW DRUGS AND POST-APPROVAL THAT WE CAN INTRODUCE RATHER READILY WHEN WE KNOW A LOT ABOUT THAT DRUG OR PRODUCT BEFORE.
AND I FEEL LIKE AS I WAS LISTENING, I KEPT THINKING ABOUT WHEN ARE WE DEPLOYING REALLY NEW SCIENCE, NEW SAFETY QUESTIONS, NEW EFFICACY QUESTIONS VERSUS SOMETHING THAT WE KNOW A LOT ABOUT AND THEN CAN DEPLOY FOR NEW INDICATIONS AS WE SAW WITH THE RECOVERY TRIAL FOR DEXAMETHASONE.
EVERYBODY KNOWS ABOUT DEXAMETHASONE AND WHAT WAS INTERESTING IS TO THINK ABOUT HOW WELL THEY DID THAT WORK EMBEDDED IN THE COUNTRY.
AND THEN ADVANCE THE QUESTIONS ABOUT HYDROXYCHLOROQUINE THAT WE STUMBLED UPON AND CONTINUE TO TRIP OVER OURSELVES WHICH IS ANOTHER ONE THAT WE COULD HAVE DONE SO, SO MUCH BETTER.
I THOUGHT IT WAS INTERESTING THAT THE FIRST 15 OR 20 MINUTES OF THE WORKFORCE PANEL, AS IT WERE, REALLY SPENT A LOT OF TIME TALKING ABOUT THE DATA INTEGRITY AND HOW THE WORKFORCE HAS TO FOLLOW FROM THE DATA AND THE NEED FOR UP SKILLING NEW VOICES, NEW MINDSETS, AS CRAIG WAS SAYING, COMES FROM MAKING SURE THAT IN THE END OF THE DAY, OUR RESEARCH ENTERPRISE DELIVERS RELIABLE DATA TO ANSWER THE QUESTIONS THAT WE NEED TO ADDRESS.
IT IS CERTAINLY, AS WE THINK ABOUT THE KINDS OF THINGS THAT WE NEED MORE TIME TO ANALYZE AND WHERE DATA WILL BE SO HELPFUL, THE NEXT NUMBER OF MONTHS, I THINK WE NEED DATA ABOUT WHAT WORKED AND WHAT DIDN'T IN THE NEW MODELS OF TRIALS THAT WERE UNDERTAKEN.
AND THAT WE SHOULDN'T JUMP TOO QUICKLY TO SEEING THAT SOLUTION AS, YES, BECAUSE DECENTRALIZED TRIALS OR HYBRID TRIALS ARE MORE PATIENT CENTRIC, THAT IN -- WE NEED TO ABANDON MUCH OF WHAT WE THINK IN ORDER TO SORT OF EFFECTUATE THOSE.
WE NEED TO UNDERSTAND AS ANDY WAS SAYING, WHEN WE CAN AND WHEN IT'S PROBLEMATIC.
AND I THINK COLLECTING THAT DATA FROM THE UNIVERSE OF EXPERIENCE THAT WE HAVE BOTH FOR FDA AND OTHER REGULATED TRIALS AS WELL AS OTHER TRIALS WILL BE VERY, VERY HELPFUL TO US.
SO -- AND I ALSO WANT TO END WITH THIS IDEA THAT, FIRST OF ALL, THE DEGREE OF COLLABORATION AND COOPERATION OVER THE LAST 16 MONTHS HAS BEEN UNIQUE AND SOMETHING WE CANNOT LOSE.
AND THAT IN THE END, WHAT LINDSEY SAID ABOUT WE CAN HAVE SPEED AND EFFICIENCY AND SAFETY, AND THAT WE SHOULD BE STRIVING FOR THAT AND NOT SATISFIED WITH ANYTHING LESS BECAUSE FOR EVERY INDIVIDUAL PATIENT, THEIR DISEASE IS THE MOST IMPORTANT DISEASE TO THEM.
AND WE'VE MADE HUGE ADVANCES IN OUR THINKING, OUR FLEXIBILITY, OUR AGILITY, AND OUR TRUST IN ONE ANOTHER AND THE ABILITY TO COOPERATE.
WE SHOULDN'T LOSE THAT.
AND OUR NEXT SESSION IS GOING TO BE ABOUT GLOBAL COOPERATION BECAUSE I THINK WE REALLY NEED TO FIGURE OUT HOW TO BOTH LEVERAGE WHAT WE'VE LEARNED OVER THE LAST 18 MONTHS, BUT ALSO SUPPORT IT.
THERE IS NO FUNDING FOR THE KIND OF INTELLECTUAL AND REGULATORY COLLABORATION IN THE

WAY THAT WE NEED TO MAKE SURE THAT WE EMBED AS PART OF THE INFRASTRUCTURE OF HOW WE DO OUR WORK.
SO I JUST THOUGHT IT WAS AN INCREDIBLY INTERESTING, FAR-REACHING DISCUSSION TODAY, AND I THANK YOU.
>> THANKS, BARBARA.
AND THANKS, PAUL AND CRAIG AND I THINK TWO OF THE THOUGHTS THAT I WAS REALLY LEFT WITH AT THE END OF THE PANELS WERE IN THE FIRST ONE, REALLY SEEING THIS AS A GREAT OPPORTUNITY AND NOT LETTING KIND OF WHAT HAS HAPPENED, THE ACCOMPLISHMENTS THAT HAVE HAPPENED IN THE PAST GO TO WASTE.
REALLY MOVING FORWARD WITH THAT OPPORTUNITY AND JUST THE INTERESTING COMMENT ABOUT, WHICH I THINK WE ALL EXPECTED OF FDA SERVING AS THE BAROMETER OVER THE NEXT YEAR OR TWO AND SEEING WHAT RIPPLE EFFECT WILL BE.
HAYAT, IF ASK YOU TO PULL UP SLIDE DECK AND WE CAN JUST LOOK AT THE AGENDA FOR NEXT WEEK.
I JUST WANT TO SHARE THIS WITH ATTENDEES JUST SO YOU CAN SEE WHAT THESE TOPICS ARE THAT WILL BE DISCUSSED NEXT THURSDAY.
THE 24TH.
SO YOU CAN SEE HERE WE HAVE A NUMBER OF SPEAKERS AT THE BEGINNING AT 10:00 O'CLOCK AND THEN THE FIRST PANEL WILL LOOK AT ENABLING REGULATORY FLEXIBILITIES IN THE GLOBAL CONTEXT AND THE SECOND PANEL WILL LOOK AT REGULATORY COOPERATION AND COMMUNICATION AND ISSUES OF GOVERNANCE IN THE GLOBAL PANDEMIC.
SO HOPE YOU CAN ALL ATTEND FOR THAT.
JUST ANOTHER VERY BIG THANK YOU TO PAUL AND CRAIG FOR REALLY MODERATING AND FACILITATING SUCH GREAT PANELS AND THANK YOU TO ALL THE PANELISTS AND, AGAIN, ANOTHER THANK YOU TO THE PLANNING COMMITTEE.
THANKS, EVERYONE, FOR JOINING, AND WE WILL HOPEFULLY SEE YOU NEXT WEEK.
>> THANK YOU.
>> THANKS, SARAH.