>> GOOD MORNING, AND WELCOME TO THOSE ATTENDEES JOINING, AS WE JUST OPENED THE MEETING, WE'RE JUST WAITING FOR THOSE ATTENDEES TO BE ABLE TO COME INTO THE MEETING AND WE SHOULD START THE CONFERENCE JUST SHORTLY IN A FEW MINUTES. THANK YOU.
OKAY.
I THINK WE'RE GOING TO GO AHEAD AND GET STARTED.
THERE ARE STILL SOME PEOPLE JOINING THE MEETING, BUT WE HAVE A FULL AGENDA.
AND WANT TO MAKE SURE WE CAN GIVE EVERYONE THE AMOUNT OF TIME.
SO, HELLO, AND THANK YOU FOR JOINING THE MEETING.
MY NAME IS SARAH WHITE, I'M THE EXECUTIVE DIRECTOR HERE AT MULTI-REGIONAL CLINICAL TRIALS CENTER, BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD AND DELIGHTED TO WELCOME YOU TO THE SECOND PART OF OUR CONFERENCE, REIMAGINING CLINICAL TRIALS, LEARNINGS FROM COVID-19.
NEXT SLIDE, PLEASE.
THE MRCT CENTER IS AN ACADEMIC RESEARCH AND POLICY CENTER FOCUSED ON ADDRESSING THE CONDUCT, 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 THIS BY ENGAGING A DIVERSE GROUP OF STAKEHOLDERS, INCLUDING INDUSTRY, ACADEMIA, GOVERNMENT, NONPROFIT ORGANIZATIONS, AND PATIENT TO PATIENT ADVOCACY TO IDENTIFY AND DEFINE THESE EMERGING ISSUES AND THEN MOVE TO CREATE ETHICAL, ACTIONABLE AND PRACTICAL SOLUTIONS.
AND OVER THE PAST DECADE, THE MRCT CENTER'S EFFORTS HAVE RESULTED IN IMPLEMENTATION OF BEST PRACTICES, GREATER TRANSPARENCY AND IMPROVED SAFETY FOR RESEARCH PARTICIPANTS.
NEXT SLIDE.
SO TODAY'S MEETING IS THE SECOND PART OF THE CONFERENCE.
THE CONFERENCE IS A PRODUCT OF DISCUSSIONS WE'VE HAD WITH THE MRCT CENTER'S EXECUTIVE AND STEERING COMMITTEE.
THEY REALLY CHALLENGED US TO THINK LONG-TERM ABOUT THE CHANGES THAT CAN AND SHOULD BE MADE TO SUSTAIN CLINICAL TRIALS IN THE FUTURE.
LAST WEEK WE HEARD ABOUT THE FLEXIBILITIES IN STUDY CONDUCT AND THE REIMAGINED WORKFORCE, WE DISCUSSED FLEXIBILITY BY DESIGN, THE NEED FOR COLLABORATION, AND THE NEED TO APPLY THE SAME URGENCY WE SAW IN DEVELOPING COVID VACCINES FOR ALL DISEASES.
WE RECOGNIZE THE NEW TECHNICAL NEEDS OF THE WORKFORCE AND THAT THEY SHOULD BE TRAINED TO EXCEL IN THIS NEW DECENTRALIZED AND HYBRID RESEARCH ENVIRONMENT.
WE RECOGNIZED THAT WE NEEDED TO START LOOKING AT OUR COMMUNITY ORGANIZATIONS AS MORE OF A PARTNER, AND WE ALSO RECOGNIZED THAT THE REVIEW DECISIONS MADE OVER THE NEXT 12 MONTHS WILL REALLY BECOME A BAROMETER OF RISK AND FLEXIBILITY WITH RESPECT TO THE APPROVAL.
THE RECORDING FOR THE JUNE 16TH MEETING IS POSTED AND I THINK TOWARDS THE END OF TODAY MAYBE THE LAST SLIDE WE'VE GOT THE LINK POSTED FOUR BUT YOU CAN CERTAINLY FIND THAT ON OUR WEBSITE.
TODAY WE ARE GOING TO FOCUS ON REGULATORY FLEXIBILITIES AND INTERNATIONAL COOPERATIVITY

IN AND GOVERNMENTS.
NEXT SLIDE.
THESE ARE THE GOALS FOR THE MEETING.
WE REALLY WANT TO LOOK INTO THE FUTURE.
OUR SPEAKERS AND OUR PANELISTS ARE GOING TO DISCUSS WHAT'S THE VISION FOR HOW MULTI SITE, MULTINATIONAL CLINICAL TRIALS SHOULD BE CONDUCTED.
WHAT WORKED BUT ALSO WHAT DIDN'T WORK AND WHAT DO WE STILL NEED MORE INFORMATION AND ANALYSIS ON.
AND REALLY TO THINK ABOUT THE HOW, HOW DO WE BUILD ON THIS EXPERIENCE OF CLINICAL TRIALS DURING COVID-19 AND BE PREPARED FOR THE FUTURE.
NEXT SLIDE.
THIS IS THE AGENDA FROM LAST WEEK.
AND ON THE NEXT SLIDE YOU'LL SEE THE AGENDA FOR TODAY.
AFTER THE KEYNOTE FROM FERGUS SWEENEY AND AN EXAMPLE FROM GINNY BEAKES-READ, YOU'RE GOING TO HEAR FROM A DIVERSE SET OF PANELISTS AND OUR MODERATORS TODAY BARBARA BIERER AND MARK BARNES WILL REALLY FACILITATE TO 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 FUNCTION AND THE Q&A ARE OPEN.
AND WE'LL DO OUR BEST TO ADDRESS WHAT WE CAN VIRTUALLY AND THEN OUR MODERATORS, IF THEY ARE ABLE TO KIND OF FIND THE QUESTIONS THAT ARE BEING ASKED AT THE SAME TIME WE'LL ALL TRY TO BRING THEM TOGETHER AND HOPEFULLY INCORPORATE THEM INTO THE Q&A DURING THE PANEL ITSELF.
SO NEXT SLIDE.
BEFORE I INTRODUCE TODAY'S KEYNOTE SPEAKERS ON BEHALF OF THE MRCT CENTER I'D LIKE TO SAY THANK YOU TO THE PLANNING COMMITTEE FOR THIS CONFERENCE.
THEIR NAMES ARE LISTED ON THIS SLIDE.
NEXT SLIDE, PLEASE.
IT IS MY PLEASURE TO INTRODUCE FERGUS SWEENEY.
FERGUS IS THE HEAD OF THE CLINICAL STUDIES AND MANUFACTURING TASK FORCE AT THE EUROPEAN MEDICINES AGENCY AND IN THIS CAPACITY HE COVERS THE CLINICAL TRIAL INFORMATION SYSTEM, BIOLOGICAL HEALTH THREATS AND VACCINE STRATEGY AND SUPPORT STRATEGY DEVELOPMENT IN MANUFACTURING AND PERSONAL DATA PROTECTION IN HEALTH RESEARCH ON MEDICINES.
HE'S BEEN INCREDIBLY BUSY AS YOU CAN IMAGINE OVER THE LAST 18 MONTHS, AND WE ARE INCREDIBLY GRATEFUL FOR HIM TO BE HERE TO GIVE THIS KEYNOTE.
OVER TO YOU, FERGUS.
>> THANK YOU VERY MUCH, SARAH, AND GOOD MORNING, GOOD AFTERNOON TO EVERYBODY.
IT'S A GREAT PLEASURE OF.
I'VE INTERACTED ON MULTIPLE OCCASIONS NOW WITH THE MRCT CENTER AND I THINK IT'S ALWAYS BEEN A REALLY ENRICHING DISCUSSION SO IT'S AN HONOR AND PRIVILEGE TO BE ABLE TO JOIN YOU TODAY.

I'M HAPPY TO BE PART OF THIS.
I WANT TO TALK ABOUT REIMAGINING CLINICAL TRIALS, LEARNING FROM COVID.
SO I'LL GO STEP BACK A LITTLE BIT AND SEE WHERE WE COME FROM OVER LAST YEAR AND WHAT WE HAVE ACHIEVED IN MANY RESPECTS, BUT THEN HOW CAN WE TRANSLATE SOME OF THOSE LESSONS FOR THE FUTURE.
I'VE PICKED A FEW PARTICULAR POINTS WHICH I'LL COVER IN ADDRESSING THAT BUT WHICH I THINK ARE OF PARTICULAR IMPORTANCE.
NEXT SLIDE.
DISCLAIMER IS NEXT.
SO LOOKING BACK AT THE LAST YEAR, IT'S ABOUT 18 MONTHS SINCE WE FIRST STARTED TO HEAR TALK OR MAYBE 19 MONTHS, OF THE OUTBREAK OF THE CORONAVIRUS.
AND THEN QUICKLY THAT SPREAD.
SO WHO DECLARING THE PANDEMIC IN THE FIRST QUARTER OF LAST YEAR END OF FEBRUARY, AND USING OUR HEALTH THREATS PLANNING, THE EU AND SIMILAR REGIONS, WE BASED ON THE 2009 FLU PANDEMIC HAD REVISED OUR PLANS AND LAUNCHED OUR EXPERT TASK FORCE.
SO THIS IS EMA EXPERT TASK FORCE BRINGS TOGETHER EXERCISE FROM ACROSS THE REGULATORY NETWORK.
EMA BUT ALL THE NATIONAL MEDICINES AGENCIES AND KEY EXPERTISE COVERING THE DIFFERENT ASPECTS FOR BOTH VACCINES AND THERAPEUTICS.
WE ALSO REACHED OUT INTERNATIONALLY AND I'LL SPEAK A LITTLE BIT ABOUT THAT WITH PARTICULARLY THE ICMRA.
EARLY ON THE FOCUS WAS ON PROVIDING GUIDANCE TO DEVELOPERS EARLY, RAPID SCIENTIFIC ADVICE TO GET THINGS MOVING AND IN PART ON REPURPOSING BUT ALSO ALL THE EARLY GUIDANCE ON VACCINE DEVELOPMENT GETTING THROUGH THE HUMAN TRIALS AND ON WARDS TO SEE WHAT WOULD BE THE MOST EFFECTIVE WAY OF DESIGNING THESE TRIALS SO THAT WE COULD MOVE QUICKLY THROUGH THE DEVELOPMENT PROCESS BUT STILL OBTAIN ROBUST EFFICACY AND SAFETY INFORMATION.
SHORTAGES WERE A KEY POINT IN THE EARLY DAYS.
IN PARTICULAR, A LOST WORK DONE TO REJOIN THE DIFFERENT PIECES OF THE SUPPLY CHAIN IN A WORLD THAT WAS LOCKING DOWN VERY DRAMATICALLY.
AND VERY IMPORTANTLY TRANSPARENCY AND OUTREACH IN THIS RAPID PERIOD OF DEVELOPMENT WITH HUGE PUBLIC CONCERN AND ALSO CONCERN ABOUT VACCINES HISTORICALLY STILL BEING PRESENT, IT'S REALLY IMPORTANT TO ENGAGE THE PUBLIC AND ENSURE THEIR CONFIDENCE AND THAT THE SYSTEM, THE REGULATORY PROCESS AND DATA DECISIONS ARE AVAILABLE AND UNDERSTAND.
AND THAT'S BROUGHT US FOUR VACCINES WITH MARKETING AUTHORIZATION IN EUROPE AND A LOT OF PROGRESS ON THERAPEUTICS UNDER WAY AS WELL.
NEXT SLIDE.
SO ON THE LEFT WE HAVE A SNAPSHOT, THE TRADITIONAL STANDARDS DEVELOPMENT TIME FOR VACCINES WHICH CAN SPAN TEN OR MORE YEARS.
AND ON THE RIGHT FOR COVID VACCINES WE'VE EFFECTIVELY COMPRESSED THAT INTO A LITTLE UNDER A YEAR TO THE FIRST VACCINE AUTHORIZATIONS.
AND THAT'S BEEN AN ENORMOUS EFFORT, HUGE INVESTMENT BY DEVELOPERS, BY REGULATORS,

ACADEMIA, SCIENTISTS, RESEARCHERS, CLINICIANS, AND INDEED ALL OF THE PEOPLE WHO PARTICIPATED IN THESE CLINICAL TRIALS.
ENORMOUS EFFORTS.
BUT ENABLED THAT STILL MAINTAINING THE HIGH STANDARDS OF QUALITY, MANUFACTURING CONTROL, EFFICACY, LARGE CLINICAL TRIALS, BIGGER THAN THOSE FOR MANY OTHER VACCINES IN THE END, AND GOOD SAFETY DATA AND CONTINUING OVERSIGHT AFTER AUTHORIZATION.
NEXT SLIDE.
THANK YOU.
AND THE REGULATORY PROCESS HAS BEEN ACCELERATED FOR US IN EUROPE USING A SYSTEM OF ROLLING REVIEW CYCLES.
SO NORMALLY IF YOU FOLLOW THE STANDARD APPROACH, COMPANIES WOULD HAVE DEVELOPED THEIR PRODUCT AND ASSEMBLED ALL THE DIFFERENT ELEMENTS OF THEIR DOSSIER, MANUFACTURING QUALITY, SAFETY, EFFICACY, AND THEN SUBMITTED THE WHOLE PACKAGE AND THEN WE WOULD HAVE GONE INTO THE REVIEW PROCESS BUT FOR THE ROLLING REVIEW WE ANALYZE AND EVALUATE EACH ELEMENT AS IT BECOMES AVAILABLE.
MEANING THAT BY THE TIME THE FULL DOES YEAH FOR MARKETING AUTHORIZATION WAS AVAILABLE, WE ONLY HAVE TO LOOK AT THE DELTA REMAINING ON THE DOSSIER WORKING SEVEN DAYS A WEEK, PEOPLE ANSWERING EMAILS AT THREE IN THE MORNING.
IT'S BEEN TOUGH ON THE INDUSTRY SIDE AND TOUGH ON THE REGULATORY ASSESSORS AND ALSO REMEMBER FOR THE ASSESSORS IN AN INDIVIDUAL COMPANY YOU WANT TO MAYBE THREE PRODUCTS, REGULATOR SIDE WITH THE WHOLE PORTFOLIO ALL THE TIME RUNNING SO IT'S CHALLENGING AND WHILE WE CAN LEARN FROM THIS OBVIOUSLY IN A NEW FUTURE WE HAVE NEED TO DEVELOP A SUSTAINABLE APPROACH.
BUT HOPEFULLY WITH A GREATER DEGREE OF DIALOGUE AND INTERACTION SO WE CAN PROGRESS.
NEXT SLIDE.
FINALLY WITHOUT GOING INTO DETAILS, JUST TO EMPHASIZE THAT WITH THE EUROPEAN PROCESS WHAT WE'VE DELIVERED FOR THE FOUR VACCINE AND IS ARE WORKING THROUGH FOR THERAPEUTICS ALSO AND FURTHER VACCINES IS A MARKETING AUTHORIZATION SO BRINGS IN ALL THE CONTROLS, POST AUTHORIZATION, WHICH ENABLES US TO CONTINUOUSLY MANAGE THESE PRODUCTS AS WE WOULD ANY OTHER PRODUCT ON THE MARKET. AND THIS IS REALLY IMPORTANT, IMPORTANT FOR PUBLIC CONFIDENCE BUT ALSO IMPORTANT TO ENSURE THAT WE DO HAVE PROPER REGULATORY CONTROL ACROSS THE BOARD.
CONDITIONAL MARKETING AUTHORIZATIONS, EARLIER WITH DATA BEING PROVIDED, OBLIGATIONS POST AUTHORIZATION, BUT HAVE TO BE ABLE TO SHOW THE BENEFITS OUTWEIGH THE RISKS AT THE TIME OF AUTHORIZATION.
AND IT'S FORE SEEN IN THE LEGISLATION AS THE TOOL TO USE IN PUBLIC HEALTH EMERGENCIES.
SO ON THE INTERNATIONAL COOPERATION, ICMRA IS THE INTERNATIONAL COALITION OF MEDICINES REGULATORY AGENCIES, ABOUT 30 COUNTRIES INVOLVED, AND THEN THE DOOR IS OPEN, MORE MAY JOIN AND YOU CAN SEE ON THE MAP THE SPREAD OF COUNTRIES INVOLVED.
RIGHT ACROSS NORTH AMERICA, SOUTH AMERICA, AND EUROPE AND ASIA AND AFRICAN COUNTRIES AS WELL JOINING.
REALLY IMPORTANT OPPORTUNITY FOR REGULATORS TO CHANGE, DEVELOP GUIDANCE, BIWEEKLY

POLICY, REGULAR WORKING GROUPS ON A RANGE OF ACTIVITIES EARLY IN COVID, EXCHANGING INFORMATION ON EARLY VACCINE TRIALS, NON-CLINICAL REQUIREMENTS FOR VACCINES AND FURTHER INTO CLINICAL AND ON TO THE PHARMACOVIGILANCE NETWORK WE BUILT UP AND MANY OTHER ISSUES.
REALLY IMPORTANT AND ALSO CREATES CONTEXT WHICH ENABLE OUR BILATERAL OR MULTI LATERAL DISCUSSIONS AND EXCHANGES INCLUDING MORE DETAILED EXCHANGES WHERE CONFIDENTIALITY ARRANGEMENTS ARE IN PLACE.
THIS IS IMPORTANT.
HAPPENED TO BE CHAIRING THIS WHEN COVID BROKE OUT SO IT'S AN IMPORTANT OPPORTUNITY ALSO FOR US TO WORK WITH GLOBAL REGULATORS AND KEEP US ALL -- BE ALL ALIGNED AND ALSO ALIGNED IN THE WAY WE RELATE TO THE PUBLIC ABOUT HOW WE'RE PROGRESSING ON PHARMACOVIGILANCE AND SAFETY AND EFFICACY.
SO VERY, VERY IMPORTANT.
AND YOU CAN SEE THE WORKSHOPS PROGRESSING ON VARIANTS, INCLUDING PREGNANT AND LACTATING WOMEN AND REINFORCING PHARMACOVIGILANCE.
WE'VE ALSO COMMENCED TOWARDS THE END OF LAST YEAR AN OPEN INITIATIVE WHERE WE'VE OPENED OUR PROCEDURES TO A NUMBER OF COUNTRIES AND PLUS WHO HAVE JOINED AND THIS ENABLES THEIR ASSESSORS TO BE PART OF THE SCIENTIFIC DISCUSSIONS ON MARKETING AUTHORIZATIONS FOR THE VACCINES AND THERAPEUTICS THAT WERE PROGRESSING THROUGH OUR EMERGENCY TASK FORCE AND THROUGH THE COMMITTEE FOR HUMAN PRODUCTS, THE CHMP.
THAT CAN THEN, THEY CAN JOIN THE DISCUSSION AND BENEFIT FROM THE DISCUSSION.
THIS HAS BEEN HUGELY IMPORTANT ALSO IN PROGRESSING THE AUTHORIZATION OF VACCINES ON A MORE GLOBAL BASIS.
NEXT SLIDE.
STEPPING BACK THEN TO CLINICAL TRIALS AND THE BEGINNING OF COVID, WE HAD TO GENERATE GUIDANCE BECAUSE CLEARLY BOTH TRIALS THAT MIGHT INVESTIGATE COVID TREATMENTS OR VACCINES, BUT ALSO ALL THE CLINICAL TRIALS THAT WERE ONGOING IN ALL SORTS OF INDICATIONS, WE HAVE TO TRY AND ENABLE CONTINUATION OF TREATMENT FOR THE PARTICIPANTS, FOR THE PATIENTS, ENSURE SAFETY REPORTING, BUT ALSO ENSURE THAT THE VALUE OF THE TRIAL RESULTS, THE RELIABILITY AND AS MUCH AS POSSIBLE TO ENABLE THE COLLECTION OF THE DATA BUT MITIGATING THE BURDEN ON SITE STAFF AND FACILITIES AND PARTICIPANTS IN A LOCK DOWN SOCIALLY DISTANCED WORLD.
HOW CAN WE ACHIEVE THAT.
IT'S INVOLVED APPLICATION OF RISK ASSESSMENT AND THIS ANTICIPATES A GREATER USE OF SENSE OF PROPORTIONALITY AND RISK ASSESSMENT IN FUTURE CLINICAL TRIALS, BUT ALSO CHANGES TO INFORMED CONSENT PROCESSES AND OTHER WAYS OF THE INVESTIGATOR INTERACT WITH PATIENTS DOWN THROUGH THE TRIAL VISITS.
OFTEN USING REMOTE TOOLS, SKYPE OR OTHER ACTIVITIES RATHER THAN FACE TO FACE VISITS, DISTRIBUTION OF IMP WHERE POSSIBLE DIAGNOSTICS ALSO AND OF COURSE THE MONITORING AND AUDITING TO SUPPORT THE CONDUCT OF THE TRIAL.
WE'VE HAD DO THIS REACTIVELY AND NOW WE HAVE THE OPPORTUNITY TO REINVENT AND DO THIS BY DESIGN FOR FUTURE TRIALS.

SO RAPID RESPONSES AND REGULATORY FLEXIBILITIES WITH PANDEMIC STILL ONGOING AND EVOLVING.
WE'RE LEARNING FAST.
AND ADAPTING.
BUT IT'S AN EVOLVING REGULATORY LANDSCAPE.
USE OF DIGITAL TOOLS, WE WERE ALREADY TALKING ABOUT BUT THIS IS REALLY ACCELERATED.
AND PUSHED -- I THINK ALL THE PARTIES BEYOND THEIR COMFORT ZONE AND MEANT THAT WE'RE LEARNING, LEARNING BASED ON REAL EXPERIENCE. DIALOGUE HAS BEEN SIGNIFICANTLY INCREASED ALONG THE DEVELOPMENT PATHWAY, AS I'VE INDICATED IT'S RESOURCE DEMANDING SO WE NEED TO PICK OUT HOW BEST TO ACHIEVE THAT BUT I THINK IT'S A VERY USEFUL PROCESS SO WE NEED TO FIND WAYS OF IMPROVING HOW TO DO THAT IN A MORE LET'S SAY RESOURCE RESILIENT WAY AND REFLECT ON EXPERIENCE, IMPROVE SELECT HOW IT WORKS, OTHER THINGS MAY HAVE BEEN GOOD FOR A YEAR FOR TWO YEARS, BUT CAN'T BE SUSTAINED OVER THE LONG-TERM AND WE NEED TO FIND OUT HOW WE CAN WORK BUT IT WILL BE A NEW, DIFFERENT LANDSCAPE FOR THE FUTURE.
AND WE CAN CHANGE NOW TO ACT BY DESIGN AND LESS WHICH REACTION BOTH IN NORMAL CIRCUMSTANCES AND IN ANTICIPATION OF FUTURE EMERGENCIES WHICH WILL COME.
WE NEED TO KEEP REGULATORY STANDARDS HIGH ALONG WITH SPEED AND INNOVATION.
A NUMBER OF KEY DEVELOPMENTS ONGOING IN PARALLEL AND, AGAIN, THE SITUATION REVEALS THAT THE NEED TO IMPROVE AND REFLECT THE COMPLEX CLINICAL TRIALS, MASTER PROTOCOLS, PLATFORM TRIALS, KEY IN COVID AS WELL.
AND WE'VE BEEN DISCUSSING THOSE A LOT IN ANY CASE AND THE LESSONS WE LEARNED FROM COVID WILL BE ALL THE MORE IMPORTANT AND LIKEWISE DECENTRALIZED CLINICAL TRIALS WHEN YOU'RE IN A SOCIAL DISTANCED WORLD AND PEOPLE CAN'T NECESSARILY COME TO THE CLINICS, YOU NEED TO FIND ANOTHER WAY OF DOING THAT.
BUT CLEARLY THAT DOES OPEN THE DOOR TO BETTER WAYS OF DOING TRIALS IN ANY CASE IN THE FUTURE.
NEXT, PLEASE.
WE NEED TO REDESIGN APPROACH TO ENABLE INNOVATION IN A RAPIDLY INVOLVING ECOSYSTEM.
SET THE FOUNDATIONS AND ENABLE INNOVATION BY DESIGN.
NOT BY REACTION.
I WANT TO TOUCH ON THREE AREAS WHICH ARE KEY AND WE'VE BEEN CARRYING THESE INTO THE PANEL DISCUSSION.
FIRST IS DIGITALIZATION WHICH HAS BEEN GREATLY ACCELERATED BY THE COVID SITUATION.
ENSURING SUFFICIENTLY LARGE, POWERFUL -- POWERED LARGE TRIALS WHERE LARGE TRIALS ARE WHAT IS NEEDED.
AND ENABLING PLATFORM TRIALS IN A BETTER WAY AND ON A LARGER INTERNATIONAL SCALE.
OF COURSE IN THE INTERNATIONAL COLLABORATION AND DISCUSSION THE ICH, GCP WE KICKED OFF AT THE LAST FACE-TO-FACE MEETING IN SINGAPORE, THREE OR FOUR MONTHS BEFORE THE -- NOT EVEN THREE MONTH BEFORE THE COVID PANDEMIC STARTED, AND IT'S ENABLING US TO BUILD INTO THAT DISCUSSION WE ALREADY ANTICIPATED THE NEED TO DISCUSS DIGITALIZATION, NEW TECHNOLOGIES, DECENTRALIZED TRIALS, FOR EXAMPLE, AND OF COURSE NOW THIS IS VERY MUCH MORE BUILT ON REAL EXPERIENCE AND IS REALLY IMPORTANT.

WE'VE RENOVATED THE ICH GENERAL CONSIDERATIONS ON CLINICAL TRIALS TO ESTABLISH GOOD RISK BASED PROPORTIONATE APPROACHES FOCUSING ON QUALITY BY BUILDING QUALITY INTO DESIGN AND THEN IN E6 MODERNIZING APPROACH TO TRIAL CONDUCT SO WE'RE READY FOR THE FUTURE IN A MUCH BETTER WAY.
AND THIS INVOLVING NOW REGULATORS FROM ALL THE REGIONS WHO HAVE BEEN IMPACTED BY THE COVID.
AND JUST TO ILLUSTRATE THAT WE'VE PUBLISHED THE DRAFT PRINCIPLES FOR GOOD CLINICAL PART OF THE GCP RENOVATION AS AN INTERIM DRAFT.
SO NOT YET FOR PUBLIC CONSULTATION BUT FOR TRANSPARENCY ON THE PROCESS AND I JUST -- YOU CAN FIND THIS ON THE ICH WEBSITE.
I JUST PICKED OUT THE PRINCIPAL TEN, CLINICAL TRIALS SHOULD GENERATE RELIABLE RESULTS BECAUSE THIS PRINCIPLE IS WHERE WE ADDRESS DIGITALIZATION AND YOU CAN READ WHAT'S THERE, BUT WE NEED SYSTEMS AND PROGRESSIONS PROPORTIONATE TO THE RISK TO PARTICIPANTS AND RELIABILITY OF RESULTS.
TOOLS FITTED FOR PURPOSE AND CAN CONFORM TO PRINCIPLES THAT ENSURE RELIABLE RESULTS AND SYSTEMS, DIGITAL SYSTEMS USED NEED TO CONSIDER THE FACTORS THAT ARE CRITICAL TO THEIR QUALITY.
WE NEED TO DEVELOP THE APPROACH TO THOSE THAT CAN BE APPLIED IN A PROPER WAY ACROSS THE DIFFERENT DIGITAL SYSTEMS BEING USED.
NEXT SLIDE.
ONE BACK.
PROGRESSES THE SAME SET REALLY AND FURTHER SETTING OUT HIGH LEVEL PRINCIPLES IN THE 1GCP WHAT MORE WE CAN DETAIL IN TERMS OF WAYS OF ASSURING THE VALIDITY OF DIGITAL TOOLS AND THE DIFFERENT KINDS OF TOOLS.
AND CHALLENGES THERE BEING TO ESTABLISH TRUST IN DATA PROVIDENCE SWELL TECHNICAL AND SCIENTIFIC VALIDITY TO LOOK AND BE OPEN TO NEW DATA SOURCES AND IT WON'T BE A ONE SIZE FITS ALL FOR THOSE.
ESTABLISH GOOD PERSONAL DATA PROTECTION TO ENSURE PROTECTION OF TRIAL PARTICIPANTS PRIVACY WHILE ENABLING CLINICAL DATA TO BE USED AND I THINK BOTH ARE LEGITIMATE EXPECTATIONS OF TRIAL PARTICIPANTS.
IF YOU JOIN A TRIAL IT'S TO ENABLE YOUR DATA TO BE USED.
BUT YOU STILL WANT YOUR PRIVACY TO BE PROTECTED.
THIS IS CHALLENGING TO ACHIEVE BUT WE CAN FIND WAYS OF DOING THIS IN A PROPER WAY AND NEED TO ESTABLISH THAT AND NEED SETS OF STANDARDS THAT CAN SUPPORT THIS ARE UNIVERSALLY APPLICABLE IN FUTURE PROOF AND AS AN EXAMPLE, WE'VE JUST RELEASED A DRAFT GUIDANCE ON COMPUTERIZED SYSTEMS AND ELECTRONIC DATA.
THIS ISN'T FROM ICH, THIS IS FROM THE EUROPEAN GCP INSPECTORS BUT OPEN FOR CONSULTATION AND CERTAINLY WELCOME COMMENTS, DETAILS, MORE THAN ONE WOULD EXPECT I THINK IN ICH BUT GOOD TO SEE COMMENTS ON THAT ALSO TO WHAT'S REALLY GOOD AND WHAT CAN BE OF BENEFIT.
JUST A FEW WORDS ON LARGE SCALE RANDOMIZED CLINICAL TRIALS.
WE RECOGNIZE VERY QUICKLY THE FRAGMENTED NATURE OF CLINICAL TRIALS.
MANY SMALL TRIALS STARTING FROM ACADEMIA EVEN FROM INDUSTRY ON DIFFERENT INITIALLY ON

REPURPOSING AND TRYING OUT EXISTING PRODUCTS FOR TREATMENTS OF DIFFERENT ASPECTS OF COVID DISEASE, BUT ALSO IN SOME PARTS FOR NEWER PRODUCTS.
IT WAS GOOD TO SEE THE RECENT G7 STATEMENT ON COVID WHICH IS EMPHASIZING THE NEED TO REALLY SUPPORT THE INFRASTRUCTURES FOR LARGE CLINICAL TRIALS.
AND THERE I THINK KEY THINGS ARE BUILDING AND MAINTAINING LARGE INVESTIGATION NETWORKS AND SUSTAINING THEM LINKING THEM TOGETHER ACROSS REGIONS IS IMPORTANT AND NOT JUST WITHIN COUNTRIES OR REGIONS BUT ENABLING FUNDING INFRASTRUCTURE FOR THEM AND THIS, AGAIN, WAS ALSO ADDRESSED IN THE G7 AND EUROPEAN RESEARCH AND DEVELOPMENT FUNDS ARE BEING USED TO BUILD THESE INFRASTRUCTURES.
BUT ALSO ENABLING PUBLIC AND PRIVATE SPONSORS TO WORK TOGETHER AND I THINK THIS COMES BACK IN THE PLATFORM TRIALS AS WELL.
ENABLE TRIALS INVOLVING BOTH BUILD INFRASTRUCTURE FOR HEALTH BODIES TO SPONSOR INTERNATIONAL TRIALS ACROSS DIFFERENT JURISDICTIONS IS IMPORTANT.
AND ALSO ADDRESS THE DRIVERS OF SMALL TRIALS, BECAUSE IS IT LACK OF FUNDING, LACK OF NETWORK OPPORTUNITY OR NOT BEING LINKEDIN, IS IT BECAUSE OF FOCUSING ON PUBLICATION AND NEED FOR ACADEMIC RECOGNITION?
I'M SURE THERE ARE MULTIPLE ASPECTS INVOLVED BUT WE NEED TO ADDRESS THAT.
AND HOW TO, LET'S SAY, REFER SMALL TRIALS TO THE POSSIBILITY OF JOINING A LARGER TRIAL RATHER THAN SETTING OUT AS A SMALL TRIAL.
NEXT.
AND THEN FINALLY ON PLATFORM TRIALS, THERE HAVE BEEN CLEAR SUCCESSES DURING COVID BUT ALSO CHALLENGES IN PARTICULAR RUNNING PLATFORM TRIALS ACROSS MULTIPLE COUNTRIES AND REGIONS HAS BEEN CHALLENGING BECAUSE OFTEN THERE'S A MASTER PROTOCOL BUT THEN THE POSSIBILITY OF ADAPTING THAT AT INDIVIDUAL NATIONAL LEVEL AND FOR A NUMBER OF THEM THE SPONSOR, LET'S SAY A MASTER SPONSOR, BUT THEN INDIVIDUAL PUBLIC HEALTH BODIES IN DIFFERENT COUNTRIES ASS ACTING AS SPONSOR WITH THE REGULATOR WHICH CAN MAKE THE PROCESS COMPLICATED AND KEEPING THE PROTOCOL FOCUSED AND HARMONIZED CAN BE CHALLENGING.
SO WE NEED TO LOOK AT HOW WE CAN ADVANCE THE METHODOLOGIES AND SCIENCE, THERE ARE CHALLENGES FROM THE STATISTICAL POINT OF VIEW FOR INSTANCE, ON EXACTLY HOW MUCH AND WHAT DATA DO YOU NEED TO COLLECT NOT MAKING IT COMPLEX AND WHAT SOURCES OF DATA CAN YOU USE TO GENERATE THE RESULTS.
BUT THERE ARE ALSO ISSUES OF MEDICINE REGISTRATION VERSUS REPURPOSING YOU NEED DIFFERENT KINDS OF DETAIL OF DATA FOR THOSE OBJECTIVES.
INFRASTRUCTURE AND TRIAL MANAGEMENT, REALLY IMPORTANT.
AND THINKING OUT OF THE BOX.
ARE THESE SINGLE CLINICAL TRIAL PROTOCOL APPLICATION OR A SET OF TRIAL DIFFERENT CLINICAL TRIAL AUTHORIZATIONS, PROTOCOLS, WHICH ARE GROUPED IN A SINGLE OVER LAYING SCIENTIFIC CONCEPT OF TRIAL WHOSE RESULTS ARE ANALYZED TOGETHER.
A LOT OF IT IS, IT'S ABOUT CHANGING THE WAY WE WORK, DON'T JUST ADD MORE TO THE STATUS QUO AND IN SOME RESPECTS CHANGE MANAGEMENT IS GOING TO BE THE GREATEST CHALLENGE GETTING PEOPLE TO BE CONFIDENT IN DIGITAL SYSTEMS AND OTHER WAYS OF WORKING AND RELYING ON DIFFERENT KINDS OF CONTROLS TO SUPPORT QUALITY OR TO SUPPORT PARTICIPANT SAFETY.

AND ADJUSTING OUR BEHAVIORS AND ATTITUDES AND KIND OF EMBEDDED TEN, 20, 30 YEARS OF PRACTICE IS ONE WAY TO MOVE IT TO A DIFFERENT WAY.
TWO QUOTES I LIKED TO BRING OUT.
PERFECTION IS ACHIEVED NOT WHEN THERE'S NOTHING MORE TO ADD BUT WHEN THERE'S NOTHING LEFT TO TAKE AWAY.
FOCUS ON THE ESSENTIAL.
EINSTEIN, EVERYTHING SHOULD BE MADE AS SIMPLE AS POSSIBLE.
MEDICINE AND SCIENCE ARE COMPLEX BUT WE SHOULD NOT MAKE THEM COMPLICATED.
AND THEN JUST FINAL CONCLUSIONS, WE NEED TO DEVELOP GOOD STANDARDS FOR DIGITAL TOOLS USED IN CLINICAL TRIALS.
THEY ARE ROBUST BUT ENABLE USE OF THOSE TOOLS.
PROTECTING THE VALIDITY OF DATA AND PARTICIPANT PRIVACY.
ENSURE PROPERLY POWERED LARGE RANDOMIZED TRIALS AND LARGE WHERE THEY NEED TO BE LARGE OBVIOUSLY, ENABLE LARGE INVESTIGATION NETWORKS AND LINKED NETWORKS AND SUPPORT THEM AND DEVELOP THE SCIENCE AND REGULATORY MODELS FOR PLATFORM TRIALS, ENABLE THEM TO WORK ACROSS COUNTRIES AND REGIONS.
MRPCT IS SOMETHING TO FURTHER AIM FOR.
I THINK THAT'S MY LAST SLIDE.
THANK YOU VERY MUCH.
BACK TO YOU, SARAH.
>> THANK YOU SO MUCH, FERGUS.
I THINK WHAT WE SHOULD DO IS WE'RE GOING TO MOVE TO GINNY AND THEN IF WE HAVE TIME AT THE END OF THIS SESSION THEN WE CAN COME BACK FOR SOME QUESTIONS.
I HAVE SEE ONE QUESTION IN THE Q&A.
BUT LET'S -- SO I'M DELIGHTED TO INTRODUCE GINNY BEAKES-READ WHO IS THE EXECUTIVE DIRECTOR OF GLOBAL REGULATORY AND R&D POLICY AT AMGEN.
IN THIS POLICY GINNY WORKS TO SHAPE THE REGULATORY ENVIRONMENT IN WAYS THAT SUPPORT INNOVATIVE DRUG DEVELOPMENT AND PATIENT ACCESS TO NEW THERAPIES.
GINNY, DELIGHTED TO HAVE YOU HERE TO SHOW US SOME EXAMPLES FROM THE FIELD.
SO OVER TO YOU.
>> THANK YOU.
BEFORE -- POLICY FOR ABOUT 15 YEARS, BEFORE THAT I WAS AT FDA AND CDER AS A REGULATORY POLICY LAWYER AND CRITICAL CARE NURSE.
HEARING FERGUS'S VISION FOR THE FUTURE IS REALLY INSPIRING.
SO THANK YOU FERGUS, FOR YOUR THOUGHTS.
I'M GOING TO BRIEFLY TAKE US BACK TO WHERE FERGUS STARTED, MARCH OF 2020.
AND IT'S PAINFUL AS IT IS FOR SOME OF US TO REMEMBER, WE WERE HAVING THIS GUIDANCES THAT FERGUS MENTIONED, AND JUST GOING TO ADDRESS THE CLINICAL TRIAL PART OF IT.
THOSE GUIDANCES.
BUT WE WERE GETTING GUIDANCES FROM REGULATORS GLOBALLY ALL THE TIME.
AND THEY WERE REALLY GREAT.
SO I'M LOOKING -- MY TALK IS ABOUT ALIGNING GLOBAL CLINICAL TRIALS AND WHAT WE LEARNED

FROM ALL THE GUIDANCES LEADS TO MY DISCUSSION ABOUT THAT NEED.
WE HAD DOZENS AND DOZENS OF REGULATORS GIVING US GREAT GUIDANCE THAT HELPED US TO NAVIGATE THAT IMPACT FERGUS TALKED ABOUT SHUTTING DOWN COUNTRIES AND CITIES AND THAT MEANT SITES ALSO WHERE THE SITES NEEDED TO TAKE CARE OF COVID PATIENTS OR PARTICIPANTS COULDN'T MAKE IT TO SITES.
THERE WAS A HUGE IMPACT.
WITHOUT THE GUIDANCE FROM REGULATORS HELPING US TO THINK ABOUT FLEXIBLE APPROACHES TO CONTINUE THE TRIALS AS SAFELY AS POSSIBLE, WE WOULD NOT HAVE BEEN ABLE TO CONTINUE AS MUCH AS WE WERE ABLE TO SOME REGULATORS LIKE EMA AND FDA CONTINUED TO REFINE THAT GUIDANCE, AS THEY WERE LEARNING ADDED MORE INFORMATION OR MORE GUIDANCE TO US ABOUT HOW TO USE TELEMEDICINE APPROPRIATELY OR DIRECT TO PATIENT SHIPMENT.
USE THE DIGITAL TOOLS.
USE OF GLOBAL, LOCAL LABS INSTEAD OF CENTRAL LABS, FOR EXAMPLE.
THAT WAS REALLY LOTS OF INFORMATION COMING AT US.
BUT WHAT I WANT TO TALK ABOUT SOME OF THE DIFFERENCES WE SAW.
ALL THE GUIDANCE WAS BASED ON PRINCIPLES OF GCP.
NEEDING TO MITIGATE RISK TO SUBJECTS, NEEDING TO ENSURE TRIAL DATA INTEGRITY, AND HAVING TO BE REACTIVE MEANT THAT THERE WASN'T TIME FOR ALL REGULATORS TO DISCUSS THINGS BUT I WANT TO TALK ABOUT SOME OF THE DIFFERENCES AND SHINE A LIGHT ON THAT A BIT SO WE CAN THINK ABOUT HOW WE MOVE FORWARD TOGETHER GLOBALLY, COLLECTIVELY, AS BEST AS POSSIBLE TO MOVE TOWARD THAT VISION THAT FERGUS OUTLINED.
WE CAN GO TO MY NEXT SLIDE, PLEASE.
NEXT ONE, SORRY.
SO YOU CAN IMAGINE INDUSTRY AND STAKEHOLDERS WERE GRAPPLING WITH THESE DIFFERENT VERY HELPFUL AND INFORMATIVE REGULATORY GUIDANCES, GETTING SEVERAL A TIME AT DIFFERENT TIMES.
SO WE'RE TRYING TO FIGURE OUT HOW TO PROVIDE INFORMATION TO OUR TEAMS SO WE COULD MOST SUCCESSFULLY CONTINUE OUR TRIALS.
WE ENDED UP, PEOPLE WERE USING SPREADSHEETS, WE ENDED UP DEVELOPING A DATABASE, SMART SHEET TOOL, TO HANDLE THE RAPID VOLUME OF INFORMATION COMING OUR WAY.
AND THEN ADDING OUR OWN INTERPRETATION TO THIS REGULATORY GUIDELINES TO BE MOST INFORMATIVE TO OUR TEAM.
SO WHAT YOU'RE GOING TO SEE IS A CHART AND A COUPLE OF SLIDES FROM NOW THAT VISUALLY ILLUSTRATES WHAT WE SAW IN THOSE GUIDANCES IN AMGEN'S INTERPRETATION.
AND THAT MAY HAVE BEEN ABOUT PROCESS, WHAT KIND OF PROCESS WAS NEEDED OR WHETHER THERE'S ANY GUIDANCE AT ALL WHEN THERE'S NOT GUIDANCE IT MAKES IT MORE CHALLENGING TO EXECUTE IN AREAS.
AND THEN WHERE THERE WAS MORE OF A FLEXIBLE APPROACH.
NEXT SLIDE, PLEASE.
SO THIS IS OUR DASHBOARD THAT WE CREATED THAT DRAWS FROM THAT DATABASE WHICH IS SHOWN UP IN THE RIGHT-HAND CORNER.
WE COLLECTED INFORMATION AND CREATED REPORTS SO WE COULD PUSH THAT OUT TO THE TEAM AND ALSO TO MANAGEMENT LOOKING AT OUR GLOBAL CLINICAL TRIALS AND UNDERSTANDING THE

IMPACT OF THE TRIALS -- IMPACT TO OUR TRIALS GLOBALLY.
YOU CAN SEE TWO OF THE FOUR AREAS WHERE WE CAPTURED SPECIFIC TOPICS THAT WERE IMPORTANT TO THE COMPANY.
BUT WHAT I WANT TO SHOW IS A COMPARISON CHART IN A MINUTE AS YOU CAN SEE UP IN THE UPPER LEFT-HAND SIDE WE LOOKED AT OUR PRIORITY TOPICS AND WE COMPARED ALL THE -- WE WOULD LOOK AT ALL COUNTRIES OR WE WOULD FOCUS ON A REGION, YOU CAN DRAW UPON THE DATA HOWEVER YOU WANTED TO.
INTERCONTINENTAL AND AMGEN TERMS.
FERGUS TALKED -- PREPARED REPORTS TO LOOK AT.
AND I'M GOING TO TAKE US TO THE NEXT SLIDE TO KEY HEALTH AUTHORITY REPORTS.
THIS IS JUST A VISUAL OF AMGEN'S INTERPRETATION OF SEVEN OF THE TOPICS THAT WERE IMPORTANT TO OUR TEAMS.
AND THE GUIDANCE THEY PROVIDED ON THIS TOPIC.
AND THIS IS A HEAT MAP.
AND AS YOU WOULD EXPECT, THE DARKER GREEN MEANS MORE FLEXIBLE APPROACHES AND RED IS CHALLENGES ASSOCIATED WITH MORE PROCESS ASSOCIATED WITH ADDRESSING REGULATORY FLEXIBILITY IN A CERTAIN COUNTRY.
AND I WANT TO BE REALLY CLEAR HERE THAT I THINK WE ALL IN INDUSTRY AND ANYBODY IN THIS SPACE UNDERSTANDS THERE ARE REASONS FOR DIFFERENCES, IT'S NOT LIKE WE EXPECT THAT THERE WILL BE HARMONIZATION GLOBALLY ON ALL THESE DIFFERENT APPROACHES GOING FORWARD.
THERE ARE DIFFERENT LOCAL NEEDS.
BUT FROM MY PERSPECTIVE, WHAT I THINK ABOUT IS TAKING A DRILLING DOWN INTO EACH OF THESE AREAS AND SAYING WHAT IS THE PURPOSE FOR THAT DIFFERENCE?
AND IF THERE'S A PURPOSE THAT MAKES SENSE AND AS REGULATORS AND OTHERS TALK ABOUT DIFFERENT THINGS, THEN THAT'S CERTAINLY APPROPRIATE.
BUT TO THE EXTENT THAT WE CAN HARMONIZE THE APPROACHES GOING FORWARD AND THIS IS REALLY A SNAPSHOT IN TIME OF KIND OF A REACTIVE MODE BUT AS WE TAKE THE APPROACH ABOUT HOW DO WE WANT TO REIMAGINE CLINICAL TRIALS LET'S LOOK AT OUR EXPERIENCE WHY WE HAD CERTAIN DIFFERENCES AND THINK ABOUT WHAT WE THINK WOULD BE MOST EFFECTIVE FOR THE FUTURE, UNDERSTANDING THERE WILL BE DIFFERENCES.
YOU'LL HEAR FROM THE PANEL THE IMPACT WE WERE ABLE TO EXECUTE AGAINST EVEN A MORE ONEROUS REQUIREMENTS HERE, BUT THAT HAD AN IMPACT ON THE ABILITY TO CONTINUE TRIALS AS EFFICIENTLY AS POSSIBLE, WHICH AFFECTS INNOVATION AND THE PARTICIPANTS BEING ABLE TO BE INVOLVED AS WELL AS POSSIBLE IN THOSE TRIALS.
SO WITH -- I GUESS THE OTHER THING I'D LIKE TO SAY IS AS WE MOVE TOWARD THE FUTURE, AS FERGUS SAID, THERE ARE GOING TO BE THINGS THAT WE'RE LOOKING AT THAT AREN'T ON THIS CHART.
WE'RE GOING TO BE COLLECTING A LOT OF DATA.
WE ARE IN INDUSTRY AND REGULATORS ARE TOO AND WE NEED TO UNDERSTAND THE IMPACT OF SOME OF THESE FLEXIBILITIES ON THE TRIAL.
IF WE WERE ABLE TO SAFELY -- ABLE TO MITIGATE RISK AND DIDN'T AFFECT THE DATA INTEGRITY, THEN THOSE ARE THE KINDS OF FLEXIBILITIES THAT CLEARLY WANT TO TRY TO LEVERAGE AND TAKE FORWARD IN THE FUTURE.

BUT WE ALL NEED TO PARTNER TOGETHER TO UNDERSTAND VARIATIONS AND TO PROVIDE THE DATA THAT SUPPORT NEW INNOVATIVE APPROACHES GOING FORWARD.
WITH THAT, SARAH, I'LL TURN IT BACK TO YOU.
>> THANKS, GINNY.
REALLY INCREDIBLE VIEW OF THAT GRID AND, YOU KNOW, I REMEMBER SEEING THAT GRID, I WAS VERY GRATEFUL TO GET THAT EXPOSURE DURING THE HEIGHT OF COVID.
IF YOU HAD TO THINK AS FAR AS PREPAREDNESS IN THE FUTURE AND HOW TO THINK ABOUT COOPERATION AND HOW PEOPLE HOPEFULLY CAN INTERPRET THINGS TOGETHER, LIKE WHAT WOULD BE KIND OF ONE OF THE MOST IMPORTANT WAYS FORWARD IN STARTING TO THINK ABOUT THE INTERPRETATIONS IN THE SAME WAY?
HOW CAN COMPANIES START TO INTERPRET IN THE SAME WAY?
>> RIGHT.
I THINK THIS GOES BACK TO FERGUS'S CLOSE, IT'S SIMPLE.
THE THING TO ME THAT IN POLICY OR IN DEVELOPING NEW PROGRAMS IS COMMUNICATION.
AND WE DIDN'T HAVE TIME TO -- WE IN POLICY WERE SHARING OUR INTERPRETATION WAS GUIDANCE OR SHARING GUIDANCES GOING FORWARD AND REGULATORS WERE CERTAINLY TALKING A LOT ABOUT WHAT THEY COULD DO TO GATHER AND TRY TO HARMONIZE.
AND I THINK -- I HEARD PEOPLE SAY THAT WE ARE -- WE'RE KIND OF ADDRESSING SOME OF THESE ISSUES CONSISTENTLY AS REGULATORS AND TO THE EXTENT THAT WAS OF COURSE CORRECT.
I'M TALKING ABOUT ISSUES SOMETIMES OUT OF -- PARTICULARLY WITH SOME OF THE MONITORING ISSUES.
BUT IT'S LOOKING AT THE DATA AND THE EXPERIENCE AND TALKING ABOUT IT AND HAVING A DIALOGUE, WHETHER THAT'S THROUGH THE POLICY GROUPS, WHETHER IT'S THROUGH MRCT, IT'S SPONSORS BEING COMFORTABLE ADDRESSING SOME OF THE REGULATORY FLEXIBILITIES.
TAKES ALL OF US TO HAVE THAT DIALOGUE ABOUT UNDERSTANDING WHAT WOULD BE ACCEPTABLE THAT'S ALWAYS AN ISSUE FOR INDUSTRY IS AT THE BACK END, WILL, EVEN IF A GUIDANCE SAYS SOMETHING IS PERMISSIBLE WILL AN INSPECTOR BE COMFORTABLE WHEN THEY ARE REVIEWING THEIR DATA THAT THAT WAS A CORRECT APPROACH.
SO I THINK SO MUCH OF IT GOES BACK TO DIALOGUE AND COMMUNICATION, ENSURING OF THE DATA, PROVIDING THAT TO REGULATORS, WHAT WE'RE COLLECTING IN TERMS OF DATA VARIABILITY OR LACK THEREOF OR HOW WE ADDRESSED THE MISSING DATA OR JUST DIFFERENT WAYS IT WAS COLLECTED AND HOW WE CAN ESTABLISH THAT THOSE DATA ARE RELIABLE.
.
>> FERGUS, IF I COULD JUST ASK YOU ONE QUESTION.
YOU TALKED ABOUT IN YOUR PRESENTATION ABOUT HOW THE RESPONSE DURING COVID WAS ALL ABOUT BEING REACTIVE AND NOW THERE'S AN OPPORTUNITY TO DO THIS BY DESIGN.
AND I WONDER IF YOU HAD A PICK LIST OF THREE OF THE BIGGEST OPPORTUNITIES THAT YOU WANT TO MOVE FORWARD FIRST, LIKE WHAT WOULD THEY BE?
>> I THINK A KEY IS REALLY TO GET THE PROCESS AND THE STANDARDS FOR DIGITAL TOOLS IN PLACE, AND THE CONFIDENCE ACCEPTED FOR THESE BOTH BY REGULATORS AND SPONSORS AND CLINICAL INVESTIGATORS AND TRIAL PARTICIPANTS AND WE'VE HEARD A LOT OF POSITIVE REACTION AND DIFFERENT MEETINGS ALSO FROM PATIENTS WHO HAVE BEEN IN TRIALS AND BEEN ABLE TO STAY IN

THE TRIALS AT HOME.
STAY PROTECTED BUT STILL RECEIVE THEIR TREATMENT.
AND CONTINUE WITH THIS.
SO IT'S -- AS I SAID, IT'S ABOUT SHIFTING FROM OUR OLD COMFORT POSITIONS INTO THE NEW WORLD AND CHANGE MANAGEMENT BUT ALSO GOOD TECHNICAL STANDARDS BECAUSE THERE IS A WEALTH OF DIGITAL TOOLS OUT THERE AND THEY'RE NOT ALL THE SAME.
THEY ARE USED IN DIFFERENT WAYS OF THE PROCESS AND IF -- ONE THING AS A DATA COLLECTION TOOL, ELECTRONIC CRF PERHAPS AND ANOTHER THING IS HOW DO YOU ACHIEVE CONSENT IN INTERACTING WITH THE TRIAL PARTICIPANT BUT THEN HOW DO YOU DOCUMENT THAT IN A VALID WAY WHICH COMES BACK TO THE DIGITAL PROOF BUT IF YOU'RE USING A FIT BIT TO MEASURE AN ENDPOINT IF IT'S WHATEVER HEARTBEAT MONITOR, THE PARTICIPANT HAS FROM ONE OF THE PROVIDERS THAT THEY GET, CAN YOU DO THAT CAN YOU MIX AND MATCH THE RESULTS BOTH DIFFERENT VERSIONS OF THE SAME PRODUCT AS WELL AS OTHERS OR DO YOU NEED TO STANDARDIZE ON THE SAME PRODUCT?
ALL THESE THINGS NEED TO BE INVESTIGATED AND THAT'S MORE ABOUT SCIENTIFIC VALIDITY AND ESTABLISHING THE DATA CHAIN.
AND THE OTHER THINGS I SAID ABOUT INVESTIGATOR NETWORKS, BUILDING THE INFRASTRUCTURE FOR RESEARCH AND BUILDING IT INTERNATIONALLY AND ALSO FOR THE PLATFORM TRIALS.
FOR ME, THREE OF THE BIG THINGS.
THERE'S A LOT ELSE THE SCIENCE AND METHODOLOGY AND STEPS, USE OF REAL WORLD EVIDENCE OR DATA COLLECTED EVEN IF IT'S PROSPECTIVELY COLLECTED IN INTERVENTIONAL TRIALS FROM HEALTH RECORDS RATHER THAN RECORDING A CRF.
MANY DIMENSIONS BUT THE DIGITAL THING I THINK WILL LIBERATE US THE MOST.
>> THANK YOU.
THANK YOU BOTH FERGUS AND GINNY.
THIS IS A GREAT START TO THE MORNING.
I THINK IT GIVES ALL OF US AND THE PANELISTS AND OF MODERATORS SOMETHING TO REALLY JUMP FROM AS WELL.
AT THIS MOMENT I'M GOING TO INTRODUCE BARBARA BIERER WHO IS THE FACULTY DIRECTOR OF THE MRCT CENTER AND SHE IS GOING TO BE MODERATING THIS FIRST PANEL ON ENABLING REGULATORY FLEXIBILITIES IN A GLOBAL ENVIRONMENT.
OVER TO YOU, BARBARA.
>> THANK YOU, SARAH, THANK YOU, GINNY, AND THANK YOU, FERGUS FOR JUST A TERRIFIC INTRODUCTION SETTING THE STAGE FOR THIS PANEL.
I HAVE TO SAY, I CAN'T THINK OF A BETTER INTRODUCTION, AND TO THE COMPLEXITY AT MULTIPLE LEVELS FOR COORDINATING THIS KIND OF RESPONSE.
THE FIRST THING I WANT TO SAY BEFORE I SAY ANYTHING ELSE IS A HUGE APPRECIATION TO OUR REGULATORS AROUND THE WORLD WHO REALLY HAVE BEEN IN RECEIPT OF INNUMERABLE INQUIRIES AND BEEN RESPONSIBLE FOR VERY COMPLEX DECISION MAKING AND FIGURING OUT HOW TO MAKE THIS A SUSTAINABLE OPERATION, AS YOU SAID, FERGUS, SUCH THAT WE'RE NOT REINVENTING THE WHEEL EACH TIME AND WE'RE USING THIS EXPERIENCE TO LEARN GOING FORWARD IS IMPRESSIVE AND IMPORTANT.

THE DEGREE OF COOPERATION AND COORDINATION THAT WE'VE SEEN, MANY ARE NOW CALLING FOR THAT TO BE PART OF HOW WE FUNCTION GOING FORWARD, AND NOT JUST FOR THE EMERGENCY THAT WE'VE GONE THROUGH.
SO I THINK EVERYTHING YOU ALL HAVE SAID SETS UP THIS PANEL BRILLIANTLY, AND, GINNY, THE ADVANTAGE OF FLEXIBILITY AT THE POLICY LEVEL BECOMES THE DISADVANTAGE OF TRYING TO OPERATIONALIZE FLEXIBLE STANDARDS.
THOSE ARE THE KINDS OF QUESTIONS WE'RE GOING TO DIG INTO NOW ON THE PANEL.
AND I'LL INTRODUCE EVERYONE SO THAT WE CAN BRING EVERYBODY UP AND THEN ASK EACH TO MAKE SOME COMMENTS.
TARAS CARPIAC IS A THE EXECUTIVE DIRECTOR OF INNOVATION AND PROCESS IMPROVEMENT IN AMGEN AND ACTUALLY WAS ONE OF THE TEAM RESPONSIBLE FOR IMPLEMENTING THE COMPLEX ARRAY OF STANDARDS AND GUIDELINES THAT GINNY JUST ENUMERATED IN KEEPING UP WITH THE VERY CHALLENGING PIECES OF WORK IN MULTIPLE JURISDICTIONS.
LAUREN HARTSMITH WILL THEN SPEAK.
LAUREN IS THE DIRECTOR OF REGULATORY AFFAIRS AT ADVARRA, AND FILLING IN FOR MICHELE RUSSELL WHO CANNOT BE HERE, BUT IS -- WE ARE DELIGHTED TO WELCOME LAUREN.
RICH MOSCICKI IS CMO AND EVP OF SCIENCES AND REGULATORY ADVOCACY AT PHRMA HAVING LEFT THE VA TO RUN THAT DIVISION OF PHRMA AND WILL GIVE US INSIGHT INTO THE GLOBAL VIEW FROM PHRMA.
NEVINE ZARIFFA IS THE PRINCIPAL AND FOUNDER OF THE NMD GROUP AND WILL SPEAK TO US ABOUT THE EXTENSION OF THIS WORK AND HOW WE CAN THINK ABOUT A FUTURE ORIENTED COLLABORATIVE NETWORK AS WELL.
SO IF I COULD ASK EACH OF YOU TO COME ON SCREEN SO WE COULD BE IN THE GALLERY VIEW AND TAKE DOWN THE SLIDES, THAT WOULD BE IDEAL.
GREAT.
AND I THINK THE ORDER THAT I'D LIKE TO INVITE YOU TO SPEAK, TARAS, IF YOU COULD INITIATE THIS, THAT WOULD BE GREAT.
>> SURE.
BARBARA, DID YOU HEAR ME OKAY?
>> I CAN.
>> GREAT.
THANKS, EVERYONE.
GOOD MORNING.
GOOD AFTERNOON.
I'M REALLY PLEASED TO BE PART OF THIS ENGAGEMENT TODAY.
I COME HERE FROM CLINICAL OPERATIONS LENS SO JUST BY WAY OF QUICK INTRODUCTION, I LEAD INNOVATION CENTER OF EXCELLENCE WITHIN DEVELOPMENT OPERATIONS AT AMGEN.
SO I WORK CLOSELY WITH GINNY AND AS BARBARA SAID, RESPONSIBLE REALLY FOR TRIAL OPERATIONAL DELIVERY, ENSURING OUR STUDYING COMPLY WITH THE GUIDANCE THAT GINNY'S TEAM HELP SYNTHESIZE FOR US THAT YOU SAW.
WHY AM I EXCITED TO BE HERE TODAY?
LIKE THE MAJORITY OF US, I ASSUME HAVE BEEN PRIVILEGED TO SUPPORT THE EFFORT OVER THE LAST

15, 16 MONTHS TO NAVIGATE THE IMPACT OF THE PANDEMIC AND DEVELOP THE APPROACHES THAT HELPED US TO CONTINUE TO OPERATE OUR TRIAL PORTFOLIO.
ENSURING WE COULD KEEP PATIENT SAFE DATA INTEGRITY CONSIDERATIONS FRONT OF AND CENTER AND REALLY HAVE THE CHANCE TO SEE FIRSTHAND FROM A SPONSOR PERSPECTIVE JUST HOW QUICKLY THE PACE OF INNOVATION PICKED UP ACROSS THE CLINICAL TRIAL ENTERPRISE AND ACROSS THE BOARD BUT DATA MANAGEMENT AND SITE MANAGEMENT AND BIOSTATS AND BATS PROGRAMMING AND A LOT OF EXAMPLES THAT I'M SURE ALL OF US SHARE USE OF DATA AND ANALYTICS TO TRACK THE IMPACT OF THE PANDEMIC AND SUPPORT DECISION MAKING ON THINGS LIKE ENROLLMENT PAUSES OR RESTARTS.
CERTAINLY THE DIRECT TO PATIENT AND DECENTRALIZED TECHNIQUES THAT HAVE BEEN DISCUSSED HERE AT LENGTH AND ARE SO IMPORTANT AND WHICH BENEFITTED IMMENSELY FROM THE REGULATORY FLEXIBILITIES AND GUIDANCE THAT WAS PROVIDED.
IT WAS VERY HELPFUL.
AND I'M PARTICULARLY PROUD OF HOW TECHNIQUES LIKE CENTRALIZED STATISTICAL MONITORING HERE AT AMGEN WERE ADAPTED AND ENCOURAGED BY GUIDANCE SUCH AS WHAT FERGUS JUST TALKED ABOUT A FEW MINUTES FROM EMA.
SO FOR US THAT WAS TAKING APPROACHES THAT WE HAD IN PLACE FOR IDENTIFYING SITES THAT MIGHT BE STRUGGLING WITH THE PROTOCOL THAT TRADITIONAL MONITORING PERHAPS WOULDN'T BE ABLE TO DETECT AS QUICKLY.
AND THEN EXTENDING AND ADAPTING THOSE TO TAKE INTO ACCOUNT THE PANDEMIC'S IMPACT ON THINGS LIKE DATA FLOW AND OTHER FACTORS.
AND I THINK THE POINT I'LL MAKE IN THE INTRODUCTION IS WE HAVE A KEEN INTEREST TO CONTINUE TO BUILD ON THESE CAPABILITIES AND INVEST IN THESE APPROACHES.
MAKE THEM DURABLE, PART OF HOW WE WORK GOING FORWARD.
AND COCHLEAR WHAT GINNY SAID, VERY APPRECIATIVE OF THE FLEXIBILITIES AFFORDED TO US OVER THIS PERIOD, BUT ACKNOWLEDGE SOME OF THE CHALLENGES IN NAVIGATING SOME DIFFERENCES THERE IN PARTICULAR FOR OUR GLOBAL TRIALS.
AND SO WOULD CERTAINLY ATTEST WE WOULD BENEFIT ON THE OPERATIONS SIDE FROM CONTINUED ALIGNMENT AND COMMUNICATION AND TRANSPARENCY AND ULTIMATELY HARMONIZATION AND THAT'S REALLY WHY I'M SO PLEASED TO BE PART OF THIS CONVERSATION.
THANKS, BARBARA.
>> THANK YOU.
THANK YOU SO MUCH.
AND GREAT INTRODUCTION.
LAUREN, THANK YOU FOR BEING HERE.
MAYBE YOU COULD BEGIN AND START.
>> THANK YOU SO MUCH.
AGAIN, MY NAME IS LAUREN HARTSMITH, AND I'M THE DIRECTOR OF REGULATORY AFFAIRS AT ADVARRA.
HEAR ME OKAY?
DURING MIGHT HAVE INTRO TODAY I'M GOING TO BE FOCUSING ON WHAT ARE THE CURRENT BARRIERS TO THE EFFICIENT IRB REVIEW OF INTERNATIONAL RESEARCH AND WHERE ARE AREAS OF

REGULATORY FLEXIBILITY SPECIFICALLY IN THE IRB REVIEW CONTEXT.
SO MY SHORT ANSWER HERE, IT'S NOT SO SHORT, BUT SHORT FOR TODAY, THERE'S SOME REGULATORY FLEXIBILITY, BUT THERE ISN'T A TON WHEN WE'RE TALKING ABOUT IRB REVIEW OF RESEARCH ACTIVITIES.
BUT THAT BEING SAID, THE FLEXIBILITY THAT WE HAVE HASN'T REALLY BEEN FULLY UTILIZED SO IT'S HARD TO EVEN ASSESS DO WE HAVE SUFFICIENT FLEXIBILITY IN THE REGS RIGHT NOW BECAUSE WHAT WE HAVE ISN'T BEING USED AS BROADLY AS IT COULD BE.
MOTIVATES FLEXIBILITY THAT EXISTS IN PATENT REGULATIONS RIGHT NOW WOULD REALLY HELP FOSTER AND FACILITATE THINGS LIKE SURVEILLANCE ACTIVITY, SPECIFICALLY PUBLIC HEALTH SURVEILLANCE, AND DIFFERENT DATA SHARING ACTIVITIES.
AND THERE ARE OTHER REGULATORY FLEXIBILITIES THAT COULD POTENTIALLY ASSIST WITH THE ISSUE THAT IRBS NOW HAVE TO MANAGE MULTIPLE SETS OF REGULATORY CRITERIA, ESPECIALLY IN THE INTERNATIONAL CONTEXT.
AND SO AGAIN, THERE'S SOME FLEXIBILITIES THERE BUT WE HAVEN'T REALLY SEEN THAT BE PUSHED OR UTILIZED.
SO ULTIMATELY I THINK, AND I THINK EVERYONE HERE WOULD AGREE, THAT WE NEED TO DEVELOP COLLABORATIVE MODELS FOR HOW REVIEW OF RESEARCH THAT WILL TAKE PLACE IN MORE COUNTRIES CAN OCCUR AND ULTIMATELY I THINK THAT IN ORDER TO FOSTER THESE TYPES OF MODELS TO BE DEVELOPED, THIS INTERNATIONAL RESEARCH AND INTERNATIONAL CLINICAL TRIALS, IT REALLY WOULD NEED TO BECOME A NATIONAL PRIORITY.
AND SOMETHING THAT IS SPECIFICALLY PROBABLY HHS WOULD REALLY NEED TO START CHAMPIONING TO FULLY TAKE ADVANTAGE OF REG FLEXIBILITIES AND TO REALLY FOSTER THE EFFICIENT AND ETHICAL REVIEW OF RESEARCH ACTIVITIES.
SO AN EXAMPLE AND I'LL TALK ABOUT THIS MORE LATER, IS AT LEAST IN THE U.S. WHAT WE'VE EXPERIENCED WITH THE SINGLE IRB POLICIES.
IT STARTED AS SOMETHING THAT INDIVIDUALLY DIFFERENT INSTITUTIONS DIFFERENT GROUPS WERE WORKING TOWARDS, BUT REALLY WE'VE SEEN, I THINK, A MUCH -- A VERY BIG UPTICK IN INSTITUTIONS NEEDING TO FIGURE OUT HOW TO ADDRESS THE NEED FOR SINGLE IRB BECAUSE OF HHS'S EMBRACING OF THAT PARTICULAR APPROACH AND THAT PARTICULAR POLICY.
SO I THINK WE DO HAVE EXAMPLES IN THIS SPACE OF HOW SOMETHING BECOMING A NATIONAL PRIORITY CAN REALLY PUSH THE IRB WORLD IN ONE DIRECTION OR ANOTHER.
SO NOW -- SO LET'S QUICKLY LOOK AT HOW THINGS ARE WORKING IN THE IRB WORLD OR IRB LAND AS I CALL IT.
WHAT ARE SOME OF THE ISSUES TO IRB REVIEW -- WHAT ARE SOME OF THE ISSUES IN IRB REVIEW OF THESE INTERNATIONAL ACTIVITIES.
SO RIGHT NOW I THINK THE TYPICAL IRB'S APPROACH IS YOU SEE AN INTERNATIONAL STUDY COME IN, STEP ONE MAKE SURE THERE'S SOME KIND OF LOCAL ETHICS COMMITTEE ASSESSMENT THAT YOU HAVE ON FILE.
SO TYPICALLY IRBS ARE NOT THE FIRST GROUP THAT'S LOOKING AT A STUDY.
BUT FROM THERE, IF THERE'S ALSO TO THE EXTENT POSSIBLE AND PRACTICABLE IRBS WILL TRY TO BRING IN EXTRA EXPERTS TO HELP WITH THE -- HELP THE IRB MAKE THE DETERMINATIONS NECESSARY BUT THEN AFTER ALL OF THAT KIND OF REVIEW OF THE INTERNATIONAL FRAMEWORK, WHAT THE IRB

TENDS TO BE MOST FOCUSED ON IS REVIEWING AN ACTIVITY UNDER THE U.S. REGULATORY FRAMEWORKS AND ALSO THE U.S. PARTICULAR FOCUS ON THE ETHICAL ISSUES ARTICULATED IN THE BELMONT REPORT.
AND THAT MAY OR MAY NOT BE HOW OTHER ETHICAL FRAMEWORKS ARE SET UP.
AND SO THERE'S THAT TENSION THERE.
SO SOME OF THE ISSUES THAT WE SEE IN OUR CURRENT APPROACH, AGAIN, GOING BACK TO THE FACT THAT THIS TYPE OF RESEARCH IN ORDER FOR US TO FIND THESE EFFICIENCIES AND CREATE THESE COLLABORATIVE MODELS, IT NEEDS TO BE A NATIONAL PRIORITY, AND NEEDS TO BE A PRIORITY WITHIN INSTITUTIONS AND BECAUSE RIGHT NOW IT'S NOT NECESSARILY A BIG PRIORITY FOR INSTITUTIONS NATIONALLY, THERE'S NOT A LOT OF RESOURCES BEING PUT INTO THIS AREA.
SO THAT'S ONE THING.
AND THEN WITH RESPECT TO THE ACTUAL REVIEWS IT CAN BE VERY DIFFICULT FOR U.S.-BASED IRBS TO MAKE THE REQUIRED DETERMINATIONS SO, FOR EXAMPLE, IT CAN BE DIFFICULT FOR IRBS TO LOOK AT WHETHER THE RECRUITMENT PROCEDURES ARE APPROPRIATE IN THE LOCAL CONTEXT WHERE THE STUDY MIGHT BE TAKING PLACE.
IT MIGHT BE A CHALLENGE TO ASSESS THE RISKS, THE PROSPECTIVE BENEFITS, AND AGAIN GOING BAG TO THE LOCAL CONTEXT, IT CAN BE A CHALLENGE TO ASSESS THE LOCAL CONTEXT ISSUES EVEN WITH CONSULTANTS IN TERMS OF CONSULTANTS, IT CAN BE DIFFICULT TO FIND THE RESOURCES OR THE PEOPLE NECESSARY TO PROVIDE THE EXPERTISE BASED ON THE POPULATIONS THAT MIGHT BE PROSPECTIVELY INVOLVED IN THE RESEARCH.
AND THEN YOU ALSO RUN THE RISK, IRBS RUN THE RISK OF TOKENISM, SO HAVING ONE PERSON WHO MIGHT HAVE ONE VERY PARTICULAR PERSPECTIVE ABOUT A COMMUNITY RELYING JUST ON THAT ONE PERSPECTIVE WHEN YOU'RE MAKING THESE DECISIONS THAT COULD IMPACT THOUSANDS OF PEOPLE.
SO THOSE ARE JUST SOME OF THE PROBLEMS.
AND THEN, OF COURSE, THE DIFFERENCES BETWEEN THE REGULATORY FRAMEWORKS THAT MIGHT BE APPLIED.
I THINK THIS IS LIKELY MORE OF AN ISSUE FOR STUDIES CONDUCTED OR SUPPORTED BY HHS OR OTHER AGENCIES AND SPECIFICALLY THERE, I THINK THE BIG PROBLEM IS THAT HHS AND OTHER COMMON ROLES THEY HAVE YET TO INDICATE THAT THERE ARE ANY OTHER INTERNATIONAL FRAMEWORKS THAT WILL BE DEEMED EQUIVALENT TO THE COMMON RULE SO THAT CAN BE A HUGE BARRIER FOR IRBS BECAUSE THEN THEY HAVE THE ISSUE OF WE NEED TO APPLY 45CFR46 AND THE FRAMEWORK THERE BUT ALSO YOU NEED TO BALANCE THAT AGAINST OTHER INTERNATIONAL FRAMEWORKS AND WHAT THE LOCAL COMMITTEES ARE SAYING.
SO THAT CAN BE A CHALLENGE.
>> THANK YOU.
.
>> SORRY.
>> NO PROBLEM.
GREAT.
WONDERFUL INTRODUCTION TO THE COMPLEXITY THAT WE FACE WITH IRBS AND RESEARCH ETHICS REVIEW.
RICH, OPENING COMMENTS?

>> THANKS FOR THE INVITATION --
>> DO YOU WANT TO GO NEXT OR DID YOU WANT NEVINE TO GO NEXT.
>> I THINK WE HAD A LITTLE EXCHANGE BEFORE AND SUGGESTED MAYBE NEVINE TALK ABOUT THE DATA SCIENCE ASPECTS AND THEN I CAN -- COME BACK.
>> THAT WOULD BE GOOD.
I'M SORRY.
NEVINE?
>> HAPPY TO BE WITH ALL OF YOU.
APOLOGIZE IN ADVANCE IF YOU HEAR THE PHONE RINGING, THESE ARE BIRTHDAY WISHES COMING IN ALTHOUGH I CAN THINK OF NO BETTER WAY TO SPEND MY BIRTHDAY THAN WITH ALL OF YOU.
>> WE WON'T INTERRUPT TO SING, BUT HAPPY BIRTHDAY.
>> THANK YOU.
THANK YOU.
SO AS WE'RE THINKING OF THE FUTURE, I WANTED TO TAKE JUST A LITTLE STROLL BACK THROUGH HISTORY AND REMIND US THAT IN 1954, THE BRILLIANT MINDS AT THE RAND CORPORATION CREATED THE FIRST LARGE-SCALE COMPUTER TO HELP IN THE NASA MISSIONS.
AND HAD THIS PREDICTION.
THE PREDICTION WAS THAT IT WAS VERY EXPENSIVE, VERY BIG, AND UNLIKELY THAT THERE WOULD BE THIS KIND OF COMPUTING POWER IN EVERY HOUSEHOLD.
SO THAT WAS 1954.
WHAT DID WE HAVE 50 YEARS FORWARD IN 2004?
WE HAD THESE.
SO WHAT WE ARE TALKING ABOUT IN THE WORLD OF DATA SHARING IS LET'S MOVE BEYOND THE ONE POINT ZERO, 1954 VERSION AND GET OURSELVES TO THE IPHONE VERSION OF DATA SHARING.
AND WHY WOULD THAT MATTER?
SO I'M GOING TO PUT THE CASE TO YOU, I'LL TELL YOU ABOUT OUR EXPERIENCE AND THEN I'M GOLDEN THE SOAP BOX PIECE WHERE I TELL YOU EXACTLY WHAT HAS TO BE DONE TO GET TO THE TWO POINT ZERO AND YOU'LL ALL TELL ME IF I'M IN THE ZONE WHEN WE GO INTO DISCUSSION.
SO IF I THINK ABOUT THE PANDEMIC AND THE IMMENSE AMOUNT OF ENERGY THAT WENT INTO THE STUDY OF DRUGS WE ALREADY HAD HANDY, FIRST OF ALL, THANK YOU TO ALL OF YOU WHO WORKED ON THIS.
SECOND OF ALL, LET'S IMAGINE WE HAD OUR IPHONE VERSION OF DATA SHARING TWO POINT ZERO, WHAT COULD WE DO WITH THAT?
MY THOUGHT IS WE COULD ACTUALLY GET CLARITY ON THE STATE OF KNOWLEDGE OF WHAT WE DO AND DON'T KNOW ABOUT WHAT THE TREATMENTS DO OR DON'T DO IN VARIOUS SEGMENTS OF OUR POPULATION.
WE COULD ALSO HAVE EASY AT OUR FINGERTIPS INFORMATION AROUND HOW TO BEST DESIGN THE TRIALS THAT WOULD NOW BE NEEDED TO ADDRESS THE REMAINING UNCERTAINTIES.
WHERE WE DON'T HAVE CLARITY.
HOW DO WE DO ALL OF THAT?
THROUGH DATA.
WE DO IT THROUGH DATA IN A USABLE FORMAT.

I THINK WE ALL KNOW THAT.
AND THAT IS ESSENTIALLY WHAT ICODA SET OUT TO DO, TO ANSWER THE RESEARCH QUESTIONS THAT COULDN'T POSSIBLY BE ADDRESSED BY A SINGLE TRIAL.
NOW, ICODA IS A LOT MORE THAN RANDOMIZED CONTROL TRIAL DATA.
IT HAS REGISTRY COHORT, GENOMICS, YOU NAME IT BUT I FOCUSED ON THE RCT PART OF IT.
WHAT WE NEEDLED TO UNDERSTAND QUICKLY AND YOU WAS SOURCES OF HETEROGENEITY ACROSS TRIALS FOR AND YOU CLEARLY NEED GLOBAL TRIALS DONE AROUND THE VARIOUS REGIONS OF THE GLOBAL OTHERWISE YOU DON'T GET A FULL VIEW.
HENCE GETTING BEYOND THE BORDERS.
GETTING THE TRIALS TOGETHER IS THE ONLY WAY TO REALLY UNDERSTAND SUBGROUPS AND SECONDARY ENDPOINTS BECAUSE YOU VERY RARELY GET CLARITY FROM A SINGLE TRIAL ON THESE POINTS.
AND THEN YOU'VE GOT THE BRIGHT CREATIVE INNOVATIVE DATA RESEARCHERS WHO MIGHT GENERATE ADDITIONAL SCIENTIFIC INSIGHTS SHOULD THE DATA BE AVAILABLE TO THEM.
WE DO BETTER TRIALS NEXT TIME AROUND.
AND GUESS WHAT?
REGULATORS, POLICYMAKERS, THEY GET ALL THIS INFORMATION AVAILABLE TO THEM TO INFORM THEIR DECISIONS.
A LOT OF THIS WORK CAN BE DONE PERFECTLY WELL WITH SUMMARY LEVEL DATA.
THAT'S WHAT WE DID IN ICODA GOT THE PHARMACEUTICAL EXPERTS AND ACADEMIC EXPERTS AND DESIGNED A DATA DICTIONARY SO THE DATA WOULD BE HARMONIZED ACROSS TRIALS.
WE HAVE SOME MODERN TOOLS TO SEE THE DATA, VISUALIZE AND ALSO ANALYZE IT.
AND WE THOUGHT THIS APPROACH OF SUMMARY LEVEL DATA WOULD BE SUPER QUICK BECAUSE IT'S UNENCUMBERED BY PATIENT PRIVACY.
YET, DESPITE A PANDEMIC, AND DESPITE THE STRATEGY OF GETTING BEYOND WHAT MIGHT BE ENCUMBERED BY PATIENT PRIVACY WE HAVE HIT A LOT OF ROADBLOCKS AND AT ONE YEAR OF EFFORT WE'RE NOT WHERE WE WANTED TO BE WHAT WE HAD ENVISIONED.
HERE'S THE SOAP BOX.
WHAT IS IT THAT IS IN THE DATA SHARING 2.0, WHAT REALLY MOVES THE NEEDLE TO GET US THERE?
THREE THINGS.
MAYBE A FOURTH ONE AT THE END TO TIE IT AROUND WITH A RIBBON.
FIRST, THOSE WHO CONDUCT TRIALS, YOUR JOB ISN'T DONE UNTIL YOU'VE SHARED THE DATA FROM YOUR TRIAL.
THAT'S HOW WE GET MAXIMUM VALUE FROM THE INVESTMENT THAT'S BEING MADE.
TWO, THOSE WHO FUND THE TRIALS MUST HAVE MECHANISMS TO HOLD THEIR FUNDEES ACCOUNTABLE AND SUPPORT THEM ASK, THREE, THOSE LIKE ME WHO WORK WITH DATA OR SET UP DATA SYSTEMS THAT ARE BASED ON PROVISIONING OF DATA, WE HAVE TO MAKE THIS SUPER EASY AND STRAIGHTFORWARD, AND WE SHOULD BE WORKING ON HOW TO ENABLE RELIABLE INFERENCE, THE MOST BEAUTIFUL DATA RESEARCH LAB DOES NOTHING FOR US IF THE RESULTS COMING OUT ARE MISREPRESENTED THE DATA.
AND SO ONE GROUP THAT'S REALLY KEY IN ALL THIS THAT I'VE HEARD MENTION OF DURING THE CONVERSATION TODAY BUT ESPECIALLY IN OTHER VENUES, THE PATIENT GROUPS, THE PROFESSIONAL

MEDICAL ASSOCIATIONS, AND WHAT I'M ASKING THEM TO DO IS SIMPLE.
YOU KEEP ASKING THE QUESTIONS YOU CARE ABOUT BECAUSE INVARIABLY THEY CALL FOR THIS KIND OF DATA SHARING SO WE CAN SYNTHESIZE KNOWLEDGE SO WE CAN GET YOU THE ANSWERS TO THOSE QUESTIONS.
AND, BARBARA, THAT'S IT FOR MY OPENING COMMENTS, THANK YOU.
>> GREAT.
I CAN'T WAIT TO DIG INTO THE SOAP BOX.
EVEN ON YOUR BIRTHDAY.
AND NOW, RICH, OVER TO YOU.
>> THANKS VERY MUCH.
AND JUST REITERATE MY HONOR TO PARTICIPATE IN TODAY'S DISCUSSION, APPRECIATE THE INVITATION, BARBARA.
SO WHEN THE PANDEMIC HIT, PHARMA VERY MUCH WORKED WITH OUR MEMBER COMPANIES TO CATALOG ALL OF THE ISSUES THAT WERE ARISING.
AND OBVIOUSLY WITH TWO DIFFERENT THOUGHT STREAMS.
ONE WAS THE IMPACT OF THE PANDEMIC ON THE ONGOING CLINICAL TRIALS.
ESSENTIALLY WE HAD A WHOLE GENERATION OF NEW MEDICINES NOW AT RISK AS CLINICAL TRIAL SITES WERE CLOSING DOWN AROUND NOT JUST THE NATION BUT THE WORLD.
AND ON THE OTHER HAND, WE HAD AN EFFORT TO SEE WHAT COULD BE DONE TO REALLY SPEED THE DEVELOPMENT OF COVID-RELATED THERAPEUTICS AND VACCINES AND HOW COULD WE REALLY ACCELERATE THAT AS WELL.
AND SO THIS LED TO THE LESSONS LEARNED, AND OUR PUTTING TOGETHER OF DOCUMENTS THAT NOT ONLY LOOK AT WHAT THE ISSUES WERE BUT WHAT PROPOSED SOLUTIONS COULD BE, AND WE WERE VERY HAPPY TO SHARE THAT WITH FDA AND VERY PLEASED AT FDA'S RESPONSE TO IT AND WORKED WITH OUR SISTER ORGANIZATIONS, SUCH AS FPIA IN EUROPE AND IFP ON A GLOBAL SCALE TO PROMULGATE WHAT THOSE SUGGESTIONS COULD BE FOR -- TO ADVANCE.
AND OF COURSE WE'RE VERY INTERESTED THAT THOSE CONTINUE POST-PANDEMIC WHEREVER POSSIBLE.
SO ON THAT LIST, WHAT ROSE TO THE TOP WAS CENTRALIZED CLINICAL TRIAL TYPE OF MODES OF OPERATION.
AND A LOT OF TIME HAS BEEN SPENT ON THAT AND SO I'M NOT GOING TO GO INTO THE DETAILS OF WHAT WE MEAN WHEN WE SAY DECENTRALIZED CLINICAL TRIAL APPROACHES.
BUT THERE ARE ALSO CLEARLY MANUFACTURING ISSUES.
ASIDE FROM THE CLINICAL TRIALS.
SO SUCH AS INSPECTIONS THAT GROUND TO A HALT AND REALLY INHIBITED DRUG DEVELOPMENT TREMENDOUSLY.
AND SO WE WORKED HARD TO MAKE RECOMMENDATIONS AROUND HOW TO DO REMOTE ASSESSMENTS OF MANUFACTURING FACILITIES, AND THEN THERE WAS THE NEED TO RAPIDLY MANUFACTURE ON A VERY QUICK AND BROAD SCALE THE COVID THERAPEUTICS AND VACCINES.
AND SO IN ORDER TO DO THAT, THERE WASN'T TIME TO BUILD NEW FACILITIES, AND SO WE WERE VERY MUCH FOCUSED ON ASKING THE REGULATORY AUTHORITIES TO LOOK AT THE WAYS THAT WE WOULD PROPOSE TO RAPIDLY REPURPOSE OTHER MANUFACTURING FACILITIES.

NOW, I MENTION THOSE BECAUSE THEY ALSO SORT OF ILLUSTRATE SOME OF THE APPROACHES THAT WE THINK CAN BE TAKEN TO ALIGN ON A GLOBAL SCALE THE IMPLEMENTATION OF THESE KEEPERS FROM OUR LESSONS LEARNED AS WE GO FORWARD.
WHEN REGULATORY AUTHORITIES DID ISSUE GUIDANCE, WE WERE REALLY PLEASED TO SEE THAT THEY OFTEN REFLECTED MANY OF THE SUGGESTIONS THAT WE HAD SUBMITTED TO THEM.
FERGUS SWEENEY HAS ALREADY INTRODUCED TWO OF THE MAJOR ORGANIZATIONS THAT ALLOW GLOBAL ALIGNMENT ON THESE KINDS OF ISSUES SUCH AS THE INTERNATIONAL COALITION OF MEDICINES, REGULATORY AUTHORITIES, OR AS EVERYBODY CALLS IT ICMRA.
AND THAT'S A GROUP THAT I THINK IS VERY IMPORTANT IN MANY WAYS, VERY IMPORTANT IN THIS SETTING BECAUSE IT REALLY EXISTED AND EXISTED TO SHARE THIS KIND OF INFORMATION AND TO CREATE ALIGNMENT ON STRATEGY.
IT'S NOT REALLY -- ITS PURPOSE ISN'T TO ACTUALLY FORM POLICY ON A GLOBAL SCALE BUT IT DOES ALLOW THE RIGHT DISCUSSIONS TO OCCUR AT A GLOBAL LEVEL.
AND SO TOGETHER WITH OUR SISTER ORGANIZATIONS, WE WERE ABLE TO WORK WITH ICMRA AND PUT FORWARD MANY OF THESE LESSONS LEARNED IDEAS TO THEM.
AND IN PARTICULAR -- AND I DO WANT TO MENTION ANOTHER THING ABOUT ICMRA THAT WE DIDN'T MENTION BEFORE, AND THAT IS THAT IT ALSO INCLUDES THE EU MEMBER STATES THAT ARE PART OF EMA, WHICH IN EUROPE AGAIN IS VERY IMPORTANT I'M SURE AS FERGUS WOULD POINT OUT, BECAUSE THEY HAVE AN IMPORTANT RESPONSIBILITY IN THE CONDUCT OF CLINICAL TRIALS.
AND SO ICMRA ALSO SERVES A PURPOSE TO BE ABLE TO HAVE RAPID CONVERSATIONS THAT WOULD INCLUDE THEM AS WELL.
SO WE HAVE BEEN ABLE TO HAVE THESE DISCUSSIONS WITH ICMRA, AND THEY HAVE PUT OUT A NUMBER OF STATEMENTS THAT FERGUS HAS REFERRED TO.
AND I THINK THEY'VE ALSO HELD WORKSHOPS ON THINGS LIKE CLINICAL TRIAL ENDPOINTS AS WELL AS FOR REALWORLD EVIDENCE AND OBSERVATIONAL STUDIES.
AND NOW THEY'RE GOING TO HOST A WORKSHOP WITH REPRESENTATIVES ALSO FROM INDUSTRY TO DISCUSS ISSUES ON THE MANUFACTURING CAPACITY THAT I SPOKE OF INITIALLY.
AND I THINK THIS TYPE OF WORKSHOP, WITH ICMRA, SETS A REAL PRECEDENT FOR FUTURE OPPORTUNITIES OF HOW WE CAN GAIN GLOBAL ALLIANCE ON THESE CLINICAL TRIAL ISSUES.
AND CAN PLAY A REALLY IMPORTANT ROLE AS WE MOVE FORWARD.
FOR EXAMPLE, ON DECENTRALIZED CLINICAL TRIAL APPROACHES AND HOW TO REALLY GET THE ADOPTION THAT WE'RE LOOKING FOR GOING FORWARD.
ICMRA ALSO SERVES AS A PREMIER ORGANIZATION, I'M SORRY -- I MEANT TO SAY ICH AS FERGUS MENTIONED IS THE PREMIER ORGANIZATION FOR ACTUAL POLICY OF HARMONIZATION OF THESE APPROACHES.
AND FERGUS HAS ALREADY MENTIONED THE E-EIGHT AND E6 AS TO YOU FERTILE AREAS THAT ARE RELEVANT FOR US TO LOOK AT AND TRY TO GET GLOBAL ALIGNMENT ON THESE APPROACHES.
I'M GOING TO FOCUS ON E SIX, R3, A GUIDELINES ON GOOD CLINICAL PRACTICES.
AND WE THINK THIS IS THE GOLDEN OPPORTUNITY TO REALLY MEMORIALIZE THESE LESSONS LEARNED AND MAKE THEM REAL AS WE MOVE FORWARD.
WHILE THERE ARE SEVERAL UNDER PIECES THAT ARE TERMED ANNEXES.
ANNEX2 IS UNDERWAY THAT WILL ADDRESS CONSIDERATIONS FOR NON-TRADITIONAL

INTERVENTIONAL CLINICAL TRIALS SUCH AS PRAGMATIC AND DECENTRALIZED CLINICAL TRIALS AS WELL AS THOSE THAT INCORPORATE REAL WORLD DATA SOURCES.
SO WE THINK THIS IS THE GOLDEN OPPORTUNITY TO REALLY TRY TO MOVE FORWARD AND GET THIS.
I ALSO THERE'S A BROAD IMPACT TO THE E6 GUIDELINE SOME OF THE GUIDELINES ARE OFTEN HIGH LEVEL.
AND SO I THINK ONE OF THE APPROACHES THAT ICH HAS ALREADY TAKEN ON TO CREATE A GREATER DEGREE OF ALIGNMENT IN THE IMPLEMENTATION OF ICH GUIDELINES IS THROUGH TRAINING.
AND AN INVESTMENT IN TRAINING RESOURCES THAT CAN HELP PEOPLE UNDERSTAND WHAT THE GUIDELINES WERE INTENDED TO ACTUALLY DO AND TO TRY AND GAIN A MUCH GREATER DEGREE OF ALIGNMENT FROM ALL OF THOSE WHO FOLLOW THE ICH GUIDELINES.
I THINK ANOTHER UNIQUE ASPECT OF THIS IS THAT ICH RARELY GOES OUT AND GETS EXTERNAL STAKEHOLDER INVOLVEMENT.
BUT BECAUSE OF THE IMPORTANCE OF GCP IN CLINICAL TRIALS, I THINK THIS IS AN AREA THAT ACTUALLY ICH HAS GONE OUT FORWARD TO LOOK AT EXTERNAL STAKEHOLDERS AND HAS ASSEMBLED SEVERAL SUCH SESSIONS.
AND I THINK THIS IS ANOTHER PLACE WHERE WE CAN CONTINUE TO GIVE INPUT AND ADVICE TO ICH ON HOW TO INCORPORATE THESE NEW APPROACHES IN PARTICULAR THOSE RELATED TO DECENTRALIZED CLINICAL TRIALS.
SO I REALLY THINK IT'S THROUGH COLLABORATION WITH ICMRA AND THE REVISION OF THE E6, R3 GUIDELINES THAT WE CAN HAVE A GOLDEN OPPORTUNITY TO TIE IN THESE LESSONS LEARNED AND SUPPORT OUR CLINICAL TRIAL CONDUCT REFORMATION GOING FORWARD.
OBVIOUSLY, IT'S GOING TO REQUIRE AN ADDITIONAL SPIRIT OF COLLABORATION, SHARING EXPERTISE, ESTABLISHING COMMON UNDERSTANDING OF THIS RELATED SCIENCE.
BUT I THINK IT DOES PROVIDE US WITH A REAL PATHWAY TO ACHIEVE THIS GOING FORWARD.
>> THANK YOU.
AND THANK YOU FOR THE ENDING ON A POSITIVE NOTE TOWARDS THE FUTURE.
I THINK THAT IT IS INTERESTING, BECAUSE FOR LOTS OF REASONS.
I THINK THERE ARE WONDERFUL OPPORTUNITIES OF FLEXIBILITIES, PARTICULARLY SINCE CASES LIKE THE PANDEMIC HIT DIFFERENT COUNTRIES, DIFFERENT CITIES, AND EVEN DIFFERENT HOSPITALS DIFFERENTLY AT DIFFERENT TIMES.
BUT IN AFFORDING THOSE FLEXIBILITIES YOU GET A PATCHWORK THAT MAKE OPERATIONS REALLY DIFFICULT.
AS WE HEARD FROM TARAS AND NEVINE WHO SPENT SOME TIME CREATING A DATA INFRASTRUCTURE ON SO THERE CAN BE INTEROPERABILITY WHY NOT JUST DECIDE AT THE BEGINNING HERE ARE THE ENDPOINTS WE'RE GOING TO MEASURE OR DATA AND HERE'S HOW IT SHOULD BE CODED AND COLLECTED SO WE DON'T HAVE TO DO THE REWORK.
AMGEN PUT TOGETHER THIS INCREDIBLY BEAUTIFUL SMART -- WHAT DID GINNY CALL IT -- SMART SCREEN OR WHATEVER, THE COLOR CODED -- EVERY INSTITUTION AND EVERY PHARMA COMPANY PUT TOGETHER SOMETHING LIKE THAT POSSIBLY NOT AS BRILLIANTLY AS -- BUT WE DIDN'T SHARE IT ACROSS EACH OTHER.
IRBS ARE WORKING IN THEIR FOX HOLES WITHOUT PICKING UP THE PHONE AND SAYING HOW DID YOU SORT OF REVIEW THIS AND WHAT WERE YOUR THOUGHTS WHEN YOU SAW THIS?

SO ONE QUESTION IS HOW DO WE BRING THIS FORWARD.
ICMRA INVITES PHARMA, PHARMA IS NOT AT THE TABLE.
IT'S A REGULATORY ASSOCIATION.
HAS TO BE.
I GET T THEY NEED A SAFE PLACE TO TALK.
IN THE ONES THAT YOU'VE MENTIONED, ICMRA AND ICH, PATIENT TO PATIENT ADVOCATES AREN'T THERE, ACADEMIC TO CLINICAL RESEARCHERS AREN'T THERE.
THE NONPROFIT FUNDERS AREN'T THERE.
SO AT WHAT LEVEL SHOULD THIS COORDINATION REALLY BE OCCURRING?
AND HOW DO YOU ENVISION THE GOVERNANCE ABOUT THAT?
>> IF I COULD TAKE A STAB AT IT, I THINK WHAT I WAS TRYING TO IMPLY IS THAT ALTHOUGH REGULATORS DO NEED THEIR SPACE, ICMRA DOES FOR THE FIRST TIME INVITE EXTERNAL INPUT.
AND THROUGH THIS WORKSHOP, FOR EXAMPLE, THAT'S GOING TO TAKE PLACE ON THE MANUFACTURING ISSUES RELATED TO COVID.
AND I THINK THAT WE NEED TO GET ICMRA TO DO THE SAME THING FOR CLINICAL TRIALS HERE AND MAKE SURE THAT THAT CAN BE ANOTHER WAY TO HAVE THE RIGHT CONVERSATION WITH THE RIGHT PEOPLE AT THE TABLE.
I THINK ON THE ICH FRONT, THEY ARE INVITING EXTERNAL STAKEHOLDERS TO PLAY A ROLE, AND THOSE CAN BE THE EXTERNAL STAKEHOLDERS THAT WE ADVANCE THE NEED TO INCLUDE THEM IN THESE DISCUSSIONS.
AND ICH IS A PLACE WHERE INDUSTRY HAS A SEAT AT THE TABLE, INDUSTRY'S VERY KEENLY INTERESTED IN MOVING THESE FORWARD.
AND SO, YOU KNOW, I HAVE THIS HOPE THAT THESE THINGS -- BUT THEY TAKE TIME.
WE PROBABLY WILL SEE ANNEX TWO OF E3 OR E6R3 PROBABLY GET STARTED VERY SOON, BUT PROBABLY NOT BE COMPLETED UNTIL 2023.
SO BUT TO DO THIS RIGHT PROBABLY WILL TAKE TIME.
>> IT WILL TAKE TIME.
AND JUST TO COUNTER AND SAY, WELL, TO SUPPORT THAT ICH DOES PUT THAT OUT FOR PUBLIC COMMENT.
SO PEOPLE DO HAVE AN OPPORTUNITY TO DO THAT.
NOT AT THE TABLE, BUT HAVE AN OPPORTUNITY TO BE HEARD.
>> YOU KNOW, I ALSO THINK THAT NOTHING PRECLUDES US FROM FORMING A COALITION OF ALL OF OUR VOICES AND USING THAT COALITION OF VOICE TO ALSO SEND INPUT INTO THESE OPPORTUNITIES FOR HARMONIZATION.
>> YES.
YES.
AND I WOULD BE REMISS TO SAY THAT ROPES & GRAY ON BEHALF OF MRCT CENTER OR WITH US PUT TOGETHER SOME OF THE COUNTRY-SPECIFIC REGULATIONS NOT WITH THE DETAIL THAT WE SAW THIS MORNING, AND IT WASN'T MAINTAINED AT THE LEVEL OF EACH INDIVIDUAL PIECE OF THAT.
AN INCREDIBLE AMOUNT OF WORK, QUITE USEFUL, BUT THAT WORK WAS REDUPLICATED BY MANY, MANY FOLKS.
TARAS, DID YOU WANT TO SAY SOMETHING?

>> I WAS JUST THINKING, AGAIN, THROUGH THE LENS OF SOMEONE RESPONSIBLE FOR THE TRIAL DELIVERY, IS FROM THE BIG PICTURE I SEE WE'RE JUST VERY THANKFUL OF THE NIMBLENESS OF THE GUIDANCE DELIVERED AT THE FRONT.
IT HELPED US TO KNOW WHAT WE COULD DO, WHAT FLEXIBILITIES WE HAD, HOW WE NEEDED TO THINK ABOUT THE STEWARDSHIP THAT HAVE DATA AND WE'RE IN THE POSITION NOW OBVIOUSLY OF HARMONIZATION, LINKING THIS TOGETHER, AND BEING ABLE TO SUPPORT THIS AT SCALE GOING FORWARD.
BUT I THINK THAT'S A GOOD PROBLEM TO HAVE GIVEN THAT WE WERE ABLE TO OPERATE VERY QUICKLY AND GET SOME CLEAR STEER.
SO WE TOOK AN EFFICIENCY TAX, THAT'S WHAT WE'RE TALKING ABOUT WITH SOME DIFFERENCES.
BUT I'LL TAKE THAT.
AND THANKFUL FOR HOW QUICK THAT GUIDANCE CAME AND NOW WE HAVE A CHANCE TO TIGHTEN THOSE LACES.
THAT'S THE LENS I VIEW IT THROUGH.
>> NEVINE?
>> I WAS THINKING GOING FORWARD, THERE'S A LOT OF POWER IN STORIES.
SO CASE STUDIES ON A PARTICULAR TOPIC FOLLOWED BY THE WORKSHOP THAT RICH MENTIONED WHERE YOU CAN HEAR ALL THE DIVERSE VIEWS AND THEN A DRAFT GUIDELINE, BECAUSE ONCE IT'S DRAFTED, EVEN THOUGH IT'S OPEN FOR PUBLIC COMMENT, THEY DON'T OFTEN MOVE ALL THAT MUCH.
SO YOU'VE GOT TO GET THE CONCERTED VOICES, EXAMPLES, THOUGHTS, IDEAS, INTO THAT REGULATORY FRAMEWORK THINKING EARLIER.
>> LAUREN?
>> I THINK THAT'S A GREAT POINT.
SO THERE ARE -- IN MY EXPERIENCE ANYWAY I'VE SEEN THERE ARE SOME COMMENTS THAT ARE GIVEN DURING PUBLIC COMMENT PROCESSES THAT ARE ABLE TO REACH THE EARS OF PEOPLE BETTER THAN OTHER COMMENTS.
AND SO I THINK CREATING KIND OF GROUPS OF VOICES, SHOWING THAT THERE'S A BIG COALITION OF PEOPLE WHO AGREE WITH THE SAME PERSPECTIVE AND ALSO MAKING SPECIFIC SUGGESTIONS AND NOT JUST SAYING YES, WE GENERALLY AGREE WITH THE PROPOSAL, BUT OFFERING SPECIFIC LANGUAGE SUGGESTIONS AND THAT SORT OF THING CAN DEFINITELY HELP MOVE THE PROCESSES ALONG.
>> SO LET ME PIVOT TO SOMETHING THAT I'M CURIOUS ABOUT.
WHAT LESSONS HAVE WE LEARNED THAT WE DON'T WANT TO SEE GO FORWARD?
WHAT WERE THE PROBLEMS THAT WE WANT TO REALLY ADDRESS?
I CAN PROBABLY GIVE YOU OFF-HAND TEN.
SO WONDERING WHAT FLOATS TO YOUR TOP.
>> I HAVE ONE, BARBARA, AN IT'S IN THE AREA OF REPURPOSING OF DRUGS AND HAVING AN END TO END SYSTEM FOR FIGURING OUT, LOOK, I HAVE SOME SIGNALS THIS COULD BE WORTH LOOKING AT.
OH, THEY'RE FROM REALWORLD DATA SOURCES, MY GOSH.
WHAT DOES THAT REALLY MEAN?
THEN HOW DO I STUDY THEM AND SO ON.

THAT MIGHT BE A GREAT POSITIVE STEP FORWARD TO HAVE THAT END TO END ON REPICKING UP OF DRUG THAT TOUCHES DATA SHARING, HOW DO YOU ADJUDICATE SIGNALS, PLATFORM TRIALS, AND THEN ONWARD COMMUNICATION.
>> END TO END WHAT?
INFRASTRUCTURE?
OR END TO END PROCESS OR --
>> PROCESS.
THE INFRASTRUCTURE DIFFERS DEPENDING ON WHICH COMPONENT YOU'RE IN.
IF YOU'RE A PLACE WHERE YOU'VE DECIDED IRAMECTIN SHOULD BE STUDIED, I'M JUST SAYING, FOR WHATEVER REASON, THEN THERE SHOULD BE A PLATFORM TRIAL AVAILABLE TO DO THAT STUDY.
THAT'S A DIFFERENT KIND OF ARCHITECTURE OR STRUCTURE THAN IT WOULD BE TO GET THE SIGNALS FROM REALWORLD DATA TO BEGIN WITH.
>> I WOULD ADD, I DO THINK WE NEED BETTER ORGANIZATIONAL STRUCTURES FOR CLINICAL TRIALING IN A PUBLIC EMERGENCY.
I THINK JANET WOODCOCK SPEAKS TO THE FACT THAT ONLY 5% OF THE THOUSANDS OF CLINICAL TRIALS THAT WERE LISTED AS COVID TRIALS IN CLINICALTRIALS.GOV WERE ACTUALLY OF A NATURE THAT COULD PRODUCE MEANINGFUL INFORMATION.
AND SO THERE WAS A TREMENDOUS ABUNDANCE OF THE TECHNICAL TERM I THINK IS SCT OR SMALL CRAPPY TRIALS, AND MANY OF THESE IN ACADEMIC CENTERS OR EVEN OUTSIDE OF ACADEMIC CENTERS, BUT NEVER COULD ACHIEVE ADEQUATE POWER TO ANSWER ANY OF THE QUESTIONS AND WHAT THE HARM OF THAT IS ONLY IT GUMS UP THE REGULATORY SYSTEM AS THEY TRY TO ADDRESS ALL OF THESE CLINICAL TRIALS AND TRY TO PROVIDE THE RIGHT SUPPORT FOR AN IND THAT MIGHT VOICE THESE TRIALS.
AND THE OTHER PART TO THAT, OF COURSE, IS THAT FOR THOSE WHO HAVE DESIGNED LARGE-SCALE MEANINGFUL TRIALS, THEIR ABILITY TO IMPLEMENT IS SLOWED BY THE FACT THAT MANY INSTITUTIONS ARE NOW OCCUPIED WITH THESE SCT'S.
SO I'M LOATHE TO SAY WE NEED A NATIONAL SYSTEM THAT CONTROLS ACCESS TO CLINICAL TRIALS BECAUSE I DON'T THINK THAT'S HOW INNOVATION WORKS BEST.
BUT I THINK UNDER THE CONDITIONS OF SOMETHING LIKE A PANDEMIC, THAT MIGHT BE A MOMENT WHERE WE CAN ACTIVATE A CLINICAL TRIAL ORGANIZATION ASPECT THAT WOULD ALLOW A BETTER SELECTION OF AGENTS AND BETTER SELECTION OF TRIALS AND I THINK THAT'S WHAT ACTIVE WAS IN PART ESTABLISHED TO ACHIEVE.
>> AND THERE IN SORT OF ELIMINATING OR PROVIDING MUCH MORE RIGOROUS OVERSIGHT AND -- A REAL ROLE OF THE IRB AND WE DIDN'T SEE THAT.
IF IT WAS EVALUATED MUCH MORE ON THEIR INDIVIDUAL BENEFIT RISK AND WHETHER THIS HAD SCIENTIFIC -- SOME SCIENTIFIC MERIT RATHER THAN WITH THESE, WITH THE DATA, REALLY BE CONTRIBUTE AND HOW DO WE GET TEETH INTO THAT.
>> WELL, I THINK THAT TO HAVE THAT DONE AT A GLOBAL SCALE INCREASES THE COMPLEXITY, BUT MAYBE YOU START AT A NATIONAL SCALE AND WITH AN APPROPRIATE DEGREE OF PANDEMIC PREPAREDNESS THINKING AND ORGANIZATION.
>> UH-HUH.
SO I HAVE TO SAY THAT THE PUBLIC NOW -- MANY PEOPLE THAT I SPEAK TO SAY, WELL, YOU KNOW,

FOR EVERY INDIVIDUAL, THEIR DISEASE IS AN EMERGENCY.
WHY IS THIS -- WHY ARE WE RESERVING THE KIND OF INFRASTRUCTURE AND COORDINATION FOR PUBLIC HEALTH EMERGENCIES AND NOT FOR ALL DISEASES?
AND WHY DON'T WE HAVE THAT PRESSURE, GIVEN THIS SORT OF SIGNIFICANT DISEASE BURDEN THAT NOW EXISTS?
WHAT CAN WE APPLY?
SEEMS TO ME THAT THE DATA INFRASTRUCTURE SHOULD BE THERE.
THE OPPORTUNITY FOR PHARMA TO MOVE FORWARD MORE EFFICIENTLY AND BETTER SHOULD BE THERE.
THE COORDINATION SHOULD BE THERE.
SO WHAT'S STOPPING US?
>> WELL, I THINK ANOTHER LESSON LEARNED WAS WHEN COMPANIES PUT ASIDE COMPETITION AND TURNED TO COLLABORATION DURING THE PANDEMIC.
AND THERE MAY BE SOMETHING THERE FOR US TO CONSIDER ON OTHER PLANES AND WITH OUR THERAPEUTIC HEARINGS.
>> ONE WAY TO THINK ABOUT YOUR QUESTION IS WHERE DOES BE VARIABILITY OR VARIETY HELP US AND WHERE DOES IT GET IN THE WAY?
SO DIVERSE VIEWS ON HOW TO SOLVE A COMPLEX PROBLEM THAT'S NEVER BEEN SOLVED, THAT SOUNDS LIKE A PLUS.
BUT ONCE YOU GET TO A PLACE WHERE THAT'S GOING TO BE AN OPTIMAL DECISION, THEN LET'S NOT REINVENT ANOTHER SOLUTION.
A PLACE WHERE VARIABILITY DOESN'T HELP US, ENDPOINT DEFINITION.
DOESN'T HELP US ONE BIT.
WE DON'T KNOW WHAT THE HECK WE'RE LOOKING AT FROM ONE STUDY TO THE NEXT BUT MIGHT HELP IN THE BEGINNING WHEN WE ARE TRYING TO LEARN ABOUT SOMETHING NEW.
SO PIECE WORK THAT'S COORDINATED THAT YOU OPEN THE FUNNEL, A PROCESS TO GET TO THAT HARMONIZED ENDPOINT THEN EVERYBODY USE THAT IS GOING FORWARD.
THAT'S THE KIND OF FRAMEWORK THAT I LIKE TO THINK OF TO ANSWER YOUR QUESTION.
I DON'T KNOW IF IT'S HELPFUL, BUT I OFFER IT.
>> TARAS, YOU LOOKED LIKE YOU WERE GOING TO SAY SOMETHING.
>> JUST A BIT OF A VARIATION.
BY THE WAY, I MUST CONFESS IN THE BRIEF INTERVAL BETWEEN WHEN RICH USED SCT AND ATTEND I WAS WRACKING MY BRAIN FOR WHAT THAT ACRONYM MEANT.
I'M GLAD HE DIDN'T WAIT TOO LONG. THE WAY I LOOK AT IT IS BIT IS THE RESPONSE TO THE PANDEMIC AND THE NIMBLENESS HOW WE ADAPTED IN MANY WAYS I SEE IT AS A LARGE EXPERIMENT IN BECOMING TRULY PATIENT CENTRIC IN THE TRIALS.
DIFFERENT PATIENTS NEEDED TO ENGAGE WITH THE TRIAL ENTERPRISE IN VERY DIFFERENT WAYS JUST SOME BY NECESSITY BECAUSE OF THE INSTITUTIONS THEY WERE WORKING WITH THEMSELVES HAD SIGNIFICANT DISRUPTIONS, SOME BECAUSE OF WELL-UNDERSTOOD FEARS ABOUT TAKING AN ALREADY COMPROMISED SITUATION AND PUTTING FURTHER RISK.
AND WE LEARNED A LOT THROUGH THAT AROUND A DIFFERENT LEVERS AND TECHNIQUES WE HAVE TO BE ABLE TO BRING THE TRIALS TO PATIENTS TO WORK WITHIN THEIR ALREADY COMPROMISED

LIFESTYLES, ET CETERA.
AND I THINK THE CHALLENGE FOR US NOW WHERE WE'VE THE OPPORTUNITY TO LINE UP IS WE ARE EAGER TO SAY LET'S MAKE THAT DURABLE BUT MAKE SURE WE'RE CONFIDENT HOW HANDLE VARIABILITY AND WHAT THAT MEANS WHEN THE DATA IS PERHAPS COLLECTED IN DIFFERENT WAYS.
THAT WORKS FOR THE PATIENTS, BUT IT CREATES A CHALLENGE FOR US IN TERMS OF BEING ABLE TO BE TRANSPARENT, UP FRONT, DESCRIBE HOW WE'RE INTENDING TO COLLECT THAT, HOW WE'RE INTENDING TO ENSURE THAT THE RESULTS WE ULTIMATELY SUBMIT ARE SOUND.
BUT THAT'S KIND OF THE LENS I LOOK THROUGH THAT A LITTLE BIT, BARBARA, IS WE HAD A VERY LARGE EXERCISE IN PATIENT CENTRICITY OVER THIS TIME, AND WHAT IT SHOWED US THERE'S GOING TO BE DIVERSITY IN APPROACHES GOING FORWARD AND HOW WE COLLECT THE DATA AND HOW THEY ENGAGE WITH IT IF WE REALLY WANT TO BE GOOD STEWARDS OF THEIR PARTICIPATION IN TRIALS AND HOW WE NAVIGATE THAT GOING FORWARD GOING THE CALL TO ACTION FOR US.
>> I COULDN'T AGREE MORE.
I ALSO THINK WE REALLY WANT TO THINK ABOUT HOW TO LEVERAGE NOT ONLY THE COOPERATION AND COLLABORATION BUT THE INTERNATIONAL EXCHANGE OF INFORMATION AND IF WE CAN GET TO A PLACE WHERE THE REGULATORS AND INSTITUTIONS AND PATIENTS CAN SAY WHY THEY NEED SOMETHING DIFFERENT WHEN THEY NEED SOMETHING DIFFERENT WILL BE ABLE TO WORK WITH THAT.
I THINK ONE OF THE REAL CHALLENGES FOR US IS THAT A LOT OF THE DIFFERENCES IN SORT OF FLEXIBILITIES COME DOWN WITHOUT AN EXPLANATION OR THE REGULATORS MAKE DECISIONS THAT APPEAR TO DIFFER, MAY NOT DIFFER, BUT MAY DIFFER, AND WE DON'T UNDERSTAND WHY THESE EVALUATIONS ARE DIFFERENT BASED ON SIMILAR DATA OR IDENTICAL DATA.
WITHOUT HAVING THE INFORMATION, WE, AS CONSUMERS, CAN'T SORT OF REALLY SORT OF IMPROVE THE NEXT TIME AROUND OR POINT OUT THE ISSUES.
AND TO YOUR POINT, NEVINE, WE DON'T HAVE A PROCESS WHERE THERE'S SOME GOD IN THE SKY WHO SAYS OKAY, THE FUNNEL HAS GOTTEN TO WHERE WE NOW KNOW AND THIS IS WHAT WE'RE GOING TO USE GOING FORWARD.
MAYBE THAT SHOULD BE SOMETHING WE STAND UP TOGETHER AND THINK ABOUT WHO WOULD BE THAT BODY THAT ORGANIZATION, MAYBE THAT'S ICMRA, MAYBE THAT'S WHO IN CERTAIN INSTANCES.
IT'S NOT -- THEY'RE NOT THE OPERATIONAL DETAILS WHICH ICH SORT OF STRATEGIZES OR LAYS THE GROUNDWORK FOR.
IT'S MUCH MORE THERAPEUTIC AREA-BASED AND SPECIFIC.
BUT REALLY INTERESTING CHALLENGE.
AND IT'S ALSO INTERESTING TO ME THAT IN THIS MORNING'S SESSION, WHO DIDN'T COME -- WASN'T MENTIONED.
SO, YOU KNOW, THAT SAYS SOMETHING TO US ABOUT HOW WE NEED TO WORK TOGETHER.
>> BARBARA, TO GO BACK TO SOMETHING ELSE THAT YOU WERE TOUCHING ON, YOU ASKED ABOUT WHAT ARE OTHER LESSONS LEARNED ON CLINICAL TRIALS DO WE NEED TO REALLY THINK ABOUT.
I DIDN'T MENTION IT BEFORE BECAUSE IT'S MORE DIFFICULT AT A GLOBAL SCALE TO TACKLE BUT I THINK IT'S DIVERSITY IN OUR CLINICAL TRIALS.
I THINK THE EVENTS OF 2020 BOTH FROM A RACIAL JUSTICE POINT OF VIEW AS WELL AS THE IMPACT OF THE PANDEMIC ITSELF ON CERTAIN COMMUNITIES, I THINK, RAISED TO THE FORE THE HEALTH EQUITY ISSUES AND THE NEED TO PROVIDE DIVERSITY IN OUR CLINICAL TRIALS.

AND SO TO ME, THAT'S ALSO A REALLY IMPORTANT LESSON THAT WE NEED TO FOCUS ON AND I THINK BROUGHT TO THE FORE THE IMPORTANCE OF COMMUNITY-BASED APPROACHES AND INVOLVEMENT OF THOSE PARTICULAR COMMUNITIES IN OUR CLINICAL TRIAL ENTERPRISE.
>> AND INTEREST IN RESEARCH.
YEAH.
WELL, WE ARE AT TIME, I BELIEVE, AND THE TIME HAS FLOWN FOR US.
SO THANK YOU SO MUCH.
THANK YOU, TARAS, NEVINE, RICH, AND LAUREN.
REALLY INTERESTING PERSPECTIVES AND A LOT OF WORK TO DO AHEAD OF US.
THANK YOU.
>> THANK YOU.
APPRECIATE IT.
>> THANK YOU.
>> SARAH?
ARE WE TAKING A BREAK NOW?
>> WE ARE NOW TAKING A TEN -- WE'RE GOING TO TAKE AN EIGHT-MINUTE BREAK SO WE CAN MAKE SURE THAT THIS SECOND PANEL GETS ALL THE TIME.
SO WE WILL SEE YOU ALL BACK HERE AT 11:50.
THANK YOU.
(BREAK)
.
>> WELCOME BACK FROM THE BREAK.
WE ARE GOING TO START RIGHT ON TIME AGAIN.
AND AT THIS TIME, I'D LIKE TO JUST INTRODUCE MARK BARNES FROM THE MRCT CENTER AND PARTNER AT ROPES & GRAY WHO WILL BE THE MODERATOR OF THIS SECOND PANEL.
SO MARK, I WILL TURN IT OVER TO YOU.
>> THANK YOU, SARAH, VERY MUCH.
AND THANKS TO YOU AND BARBARA AND ALL THE FOLKS WHO PUT TOGETHER THIS SESSION AS WELL AS THE SESSION THAT OCCURRED LAST WEEK.
SO WE HAVE -- WE'RE GOING TO TALK ABOUT INTERNATIONAL COOPERATION IN THIS SESSION WHICH WE'VE TOUCHED ON IN THE BRIEF SESSION AND FERGUS TOUCHED ON IT AS WELL IN HIS OPENING REMARKS AS DID GINNY.
THE FOLKS WHO ARE GOING TO BE TALKING ON THE BE PANEL TODAY INCLUDING THE FOLLOWING.
DR. KHAIR ELZARRAD FROM THE OFFICE OF MEDICAL POLICY AND CDER AT FDA.
OWEN FIELDS THE VICE PRESIDENT FOR REGULATORY STRATEGY R&D AT PFIZER, STEVE KERN DEPUTY DIRECTOR OF QUANTITATIVE SERVICES AT THE GATES FOUNDATION AND FERGUS SWEENEY IS ALSO AGREED TO SIT ON THIS PANEL AS WELL.
I THINK THE ORDER WE'RE GOING TO TAKE THIS IN IF IT'S ALREADY WITH FOLKS IS OWEN FOR YOU TO GO FIRST AND THEN KHAIR AND THEN STEVEN AND THEN FERGUS TO OPEN THIS SESSION TODAY AND FERGUS CAN BE THE LAST SPEAKER FOR THIS SESSION IF THAT'S OKAY.
WITH THAT, I THINK I'LL TURN IT OVER TO YOU, OWEN.
>> OKAY.

THANK YOU.
I'M DOING AN AUDIO CHECK.
>> YES, IT'S FINE.
>> OKAY.
BEAUTIFUL.
I'M GOING TO DISCUSS SOME ACTUAL REALWORLD EXPERIENCES, CLINICAL TRIAL EXPERIENCES, THAT IS, THAT PFIZER HAS HAD WITH THESE CONCEPTS.
THIS IS GOING TO INCLUDE FLEXIBILITY IN TRIAL CONDUCT, WHAT WE THINK WORKED THERE AND WHAT WE THINK SHOULD GO FORWARD AS A PERMANENT POLICY AFTER THE PANDEMIC.
I'M GOING TO TALK ABOUT DECENTRALIZED TRIAL BRIEFLY WE'RE RUNNING CURRENTLY.
BUT AS I'LL TELL YOU, IT IS ONLY BEING RUN IN THE U.S. AND THAT'S BECAUSE WE NEED SOME GLOBAL HARMONIZATION IN THAT AREA.
THEN I'LL TALK ABOUT SOME PLATFORM TRIALS THAT WE ARE RUNNING WHICH I THINK PROVIDE SOME LESSONS IN WHAT IS CURRENTLY EASY TO DO VERSUS WHAT IS STILL PRETTY HARD TO DO.
SO WITH THAT, I'LL START.
SO I'M GONNA TALK ABOUT TWO ACTUAL EXPERIENCES IN MAJOR MRCT PROGRAMS.
THESE ARE DESIGNED TO MEET ICHE17, FULLY GLOBAL SITES IN THE U.S., CHINESE, JAPAN, ESSENTIALLY ALL OF THE MAJOR MARKETS.
THE FIRST ONE THE EXTENSION OF EXTENSION TRIAL, SO THE FIRST ONE IS A COMPLICATED PROGRAM WITH MULTIPLE PIVOTAL STUDIES ALL OF WHICH FEED STUDIES INTO THE EXTENSION.
THE EXTENSION IS LARGELY THERE FOR SAFETY PURPOSES AS WELL AS TO MONITOR CONTINUED RESPONSE TO THE DRUG AND LOOK AT PATIENT REPORTED OUTCOMES.
SO THE PANDEMIC INTERRUPTED, BECAUSE I DON'T KNOW A DIFFERENT WORD TO USE FOR IT, THE LARGELY THE EXTENSION.
SO WE GOT LUCKY IN THAT PROGRAM, OF THAT PROGRAM, AND SO WE VERY RAPIDLY ON A GLOBAL BASIS ARRANGED DIRECT TO PATIENT SHIPPING, WE ALREADY HAD THE PATIENT REPORT THE OUTCOMES COLLECTED REMOTELY AND WE SET UP A SYSTEM FOR REMOTE SAFETY DATA COLLECTION OVER THE PHONE GENERALLY.
INTERESTINGLY, THERE HAVE QUESTIONS ABOUT WHETHER REMOTE SAFETY DATA COLLECTION PROVIDE SIMILAR RESULTS TO COLLECTION AT A BRICK AND MORTAR SITE AND THIS PROGRAM WE COULD DO A TIME CONTROL.
SO WE COULD LOOK AT SAFETY DATA FROM THE STUDY PRIOR TO THE SHUTDOWN VERSUS SAFETY DATA COLLECTED AFTER THE SHUT DOWNS AND DID THAT WITH THAT -- IT WAS A VERY LARGE DATABASE AND FRANKLY, WE SAW NOTHING PRE- AND POST THE VIRTUALIZATION OF THE TRIAL.
NO MEANINGFUL DIFFERENCES IN THE SAFETY DATA COLLECTED.
I THINK THAT PROVIDES SOME GOOD PRECEDENCE AND FACTS SUPPORTING DATA THAT FOR EXTENSION TRIALS, IT PROBABLY IS APPROPRIATE TO ALLOW VERY EXTENSIVE USE OF VIRTUAL VISITS.
NOW, KEEP IN MIND EXTENSION TRIALS ARE A SPECIFIC CONTEXT.
TYPICALLY THEY'VE ALREADY BEEN TRAINED ON HOW TO ADMINISTER THE DRUG.
THEY HAVE TO HAVE TOLERATED THE DRUG AND NOT HAD MAJOR ADVERSE EVENTS DURING THE MAIN STUDY.
THEY GENERALLY HAVE RESPONDED WELL TO THE DRUG AND VOLUNTARILY JOIN THE EXTENSION.

SO TO ME, THIS EXAMPLE IS ONE THAT'S ACTUALLY QUITE EASY FROM A REGULATORY POLICY PERSPECTIVE IN TERMS OF MAKING THE CASE THAT THIS KIND OF FLEXIBILITY SHOULD BE PERMANENT.
THE SECOND MULTI REGIONAL CLINICAL TRIAL EXPERIENCE WE HAD IS WITH A DERMATOLOGY PRODUCT AND THE PRIMARY STUDY PERIOD WAS HEAVILY AFFECTED.
SO WE IMMEDIATELY HAD DISCUSSIONS WITH AGENCIES AND THIS WAS LITERALLY DURING THE TIME THE GUIDANCES WERE BEING ISSUED AND SOME CASES WE GOT AHEAD OF THE GUIDANCE, IN SOME CASES WE COULD RELY ON THE GUIDANCE.
AND IN THIS CASE WE ALSO ARRANGED FOR DIRECT TO PATIENT DELIVERY OF DRUG.
BUT AGAIN, THIS IS AFTER THEIR INITIAL STUDY VISITS TYPICALLY.
SO THEY HAD BEEN GIVEN TRAINING ON THE DRUG AND THEY HAD SIGNED INFORMED CONSENTS AT A SITE.
AND WE ALSO ARRANGED FOR THE PATIENTS, BECAUSE IT'S A DERMATOLOGICAL CONDITION, ARRANGED FOR THE PATIENTS TO PHOTOGRAPH THEIR DISEASE ACTIVITY.
AND WE HAVE AN AGREEMENT FROM REGULATORY AGENCIES THAT WILL NOT BE USED AS THE PRIMARY ANALYSIS BUT WHEN THEY LOOK AT MISSING DATA AND THEY DID AGREE IT COULD BE CONSIDERED MISSING RANDOM IN THIS CASE THEY CAN GO BACK AND DO A SENSITIVITY ANALYSIS AND TAKE THOSE PATIENT-TAKEN DIGITAL PHOTOGRAPHS GENERALLY WITH A SMARTPHONE AND WE WILL HAVE THOSE AVAILABLE FOR THEIR INSPECTION WHEN WE FILE FOR THIS.
AGAIN, I THINK THIS IS A LITTLE BIT ASKING A BIT MORE BECAUSE IT'S DURING THE MAJOR STUDY PERIOD.
BUT I ALSO THINK THIS KIND OF FLEXIBILITY SHOULD BE CONSIDERED APPROPRIATE POST-PANDEMIC AT LEAST IN THE CONTEXT IS APPROPRIATE.
OKAY.
SO WE'RE ALSO CURRENTLY RUNNING A FULLY DECENTRALIZED TRIAL.
THERE ARE NO SITE VISITS AND THERE ARE IN FACT NO PHYSICAL SITES.
IT IS AN APPROVED DRUG BUT WE'RE RUNNING THE DECENTRALIZED TRIAL IN A NEW INDICATION TO SUPPORT A NEW INDICATION.
THERE HAVE BEEN SEVERAL FULLY DECENTRALIZED TRIALS RUN, I BELIEVE MOST OF THEM HAVE BEEN RUN IN A SETTING WHERE THE INDICATION BEING STUDIED IS ALREADY APPROVED.
WE ARE DOING THIS IN COLLABORATION WITH VERILY, BUT THE MAIN POINT TO MAKE IS WE'RE ONLY DOING THIS IN THE U.S. BECAUSE NEITHER WE NOR VERILY THOUGHT WE HAVE ENOUGH CLARITY GLOBALLY, CANADA, EUROPE, JAPAN, CHINA, TO ACTUALLY CONDUCT THE TRIAL AND OTHER COUNTRIES.
SO WE HAVE MADE THIS WORK IN THE U.S.
WE'RE DOING FULLY VIRTUAL INFORMED CONSENT.
WE ARE DOING DIRECT TO PATIENT SHIPMENT.
WE'VE HAD EXTENSIVE DISCUSSIONS WITH FDA, WE WENT THROUGH 21CFR PART 312 WHICH TALKS ABOUT IND STUDIES AND WE HAVE WORKED OUT STATE TELEHEALTH AND MEDICAL PRACTICE REQUIREMENTS.
BUT I THINK LOOKING TO THE FUTURE, WE'RE GOING TO NEED TO GLOBALIZE THE ABILITY TO DO THESE STUDIES TO MAKE THEM REALLY A MAJOR PART OF CLINICAL DEVELOPMENT GOING FORWARD.
SO WE ARE CURRENTLY WORKING WITH INTERNATIONAL AGENCIES AND WE'RE SUPPORTING A

NUMBER OF EFFORTS TO GLOBALIZE THE ABILITY TO DO DECENTRALIZED TRIALS.
SO ONE THING I'M OFTEN ASKED ABOUT IN THE AREA OF DECENTRALIZED TRIAL IS LIKE WHEN IS IT THE APPROPRIATE CONTEXT OF USE?
WHAT IS AN APPROPRIATE SETTING TO DO A DECENTRALIZED TRIAL?
SO I THOUGHT I'D GO OVER THAT FOR THIS PARTICULAR TRIAL THAT WE'RE RUNNING.
SO THIS TRIAL IS ON A TOPICAL ANTI-INFLAMMATORY AND IT'S IN A DISEASE CALLED STASIS DERMATITIS.
THE REASON WE CHOSE THIS DRUG IN THIS SETTING FOR A FULLY DECENTRALIZED TRIAL COMES IN MULTIPLE PARTS.
FIRST THE DRUG IS A VERY SIMPLE SAFETY PROFILE, IT'S APPROVED, ONE OF THE SHORTEST LABELS IN RECENT HISTORY.
PATIENTS DO NOT NEED TRAINING ON ADMINISTERING THE DRUG.
IT'S A TOPICAL ADMINISTERED TWICE A DAY.
THEY'VE ALREADY BEEN USING THIS KIND OF PRODUCT.
THE EFFICACY ENDPOINTS ARE COMPLETELY DOCUMENTABLE BY DIGITAL PHOTOGRAPHY.
SO THAT'S ANOTHER FEATURE THAT MAKES IT APPROPRIATE FOR FULLY DECENTRALIZED TRIAL.
THERE'S NO CENTRAL LABS NEEDED.
THE LABS ARE BASICALLY DONE FOR SAFETY PURPOSES AND THE DRUG REALLY DOESN'T HAVE ANY EFFECT ON LABS.
AND FINALLY SOMETHING THAT A LOT OF PEOPLE FORGET THIS IS A POPULATION THAT THERE'S ACTUALLY SOMETHING IN IT FOR THE PATIENTS SO THIS IS UNIVERSALLY AN ELDERLY POPULATION AND THEY WILL BENEFIT A LOT FROM NOT HAVING TO GO TO CENTERS.
THAT'S WHY WE CHOSE THIS SETTING TO DO THE DECENTRALIZED TRIAL IN A NEW INDICATION DEVELOPMENT.
THEIRS OTHER CONTEXTS WE THINK ARE APPROPRIATE FOR PARTIALLY DECENTRALIZATION.
ONE IS LONG-TERM EXTENSIONS AND I DESCRIBED THE PURPOSE OF THOSE, LARGELY FOR SAFETY PURPOSES.
YOU OFTEN COLLECT PATIENT REPORTED OUTCOMES ON THOSE.
AND ANOTHER ONE IS WHAT I THINK OF AS INTERMEDIATE VISITS IN MAIN PIVOTAL TRIALS WHERE YOU'RE NOT LOOKING AT THE PRIMARY ENDPOINT OR KEY SECONDARY ENDPOINT.
SO I THINK AS E6 IS AMENDED I THINK ONE OF THE TRICKIEST THINGS THEY WILL NEED TO DO IS COME UP WITH A SCOPE STATEMENT AS TO WHAT'S THE -- WHAT ARE THE SETTINGS IN WHICH A FULLY OR PARTIALLY DECENTRALIZED TRIAL IS APPROPRIATE.
SO THE LAST THING I'M GOING TO MENTION IS REGARDING PLATFORM TRIALS.
AGAIN, IT'S RELATED TO OUR ACTUAL EXPERIENCE.
SO WE ARE EITHER RUNNING OR HAVE RUN AND I'M RESPONSIBLE FOR INFORMATION AND IMMUNOLOGY AND WE HAVE QUITE A FEW ASSETS IN DEVELOPMENT AND IN THAT THERAPY AREA, IT'S COMMON TO HAVE MULTIPLE MECHANISMS THAT WORK IN MULTIPLE CONDITIONS.
SO WE ARE RUNNING OR HAVE RUN FOUR INTRA COMPANY PLATFORM TRIALS.
SO THESE ARE TRIALS WITH TWO COMPOUNDS OR THREE COMPOUNDS, ALL OF WHICH ARE OURS.
WE HAVE DONE THESE GLOBALLY.
SO THESE HAVE ALL BEEN MULTI-REGIONAL CLINICAL TRIALS.

THE MAIN MESSAGE IS INTRA COMPANY WHEN YOU'RE DEALING WITH THE SAME OPERATIONAL PLATFORM, SAME DATABASE, IT'S ACTUALLY NOT THAT DIFFICULT.
THERE WAS SOME DIFFICULTY MESHING UP THE PROCEDURES GLOBALLY.
SO IN THE U.S., THE IND SYSTEM IS SPECIFIC TO COMPOUND AND INDICATION.
YOU HAVE AN IND FOR EACH SEPARATE INDICATION FOR EACH COMPOUND.
IN EUROPE AND JAPAN AND CANADA THE CTA SYSTEM IS SPECIFIC TO THE TRIAL.
SO IF YOU THINK ABOUT A PLATFORM TRIAL THAT HAS TWO OR THREE COMPOUNDS, YOU SEE THAT THE STRUCTURE OF YOUR REGULATORY SUBMISSIONS DIFFER SOMEWHAT AND IT DID ADD SOME COMPLEXITY TO DO THIS AND PULL THIS OFF HAVING MULTIPLE COMPOUNDS IN THE SAME STUDY.
BUT WE DID IT.
SO I GUESS MY MESSAGE TO THE GROUP IS THIS CAN BE DONE.
I THINK THE MORE COMPLICATED THING ABOUT INTERCOMPANY PLATFORM TRIALS AND THEY ARE CLEARLY A DESIRABLE LONG-TERM GOAL, IS THAT THERE ARE A BUNCH OF OTHER COMPLEXITIES COMING IN SUCH AS WHO OWNS THE DATA, CONFIDENTIALITY ISSUES, THE FACT THAT THE OTHER COMPOUND IN THE TRIAL COULD ACTUALLY BE IN YOUR COMPETITOR, AND THEN THERE'S CLINICAL OPERATIONAL DETAILS AND DATABASE DETAILS WHICH ARE NOT REALLY MY EXPERTISE.
SO WITH THAT, I THOUGHT -- I THINK I WILL TURN IT BACK OVER TO MARK.
>> OKAY.
THANK YOU, OWEN. I HAVE A COUPLE QUESTIONS FOR BUT I'LL SAVE THEM UNTIL THE QUESTION AND ANSWER PERIOD.
SO KHAIR, DO YOU WANT TO GO NEXT?
>> SURE THING.
THANK YOU AGAIN FOR THE OPPORTUNITY TO BE WITH YOU TODAY.
I ARRIVE AT THIS TOPIC FROM A POLICY PERSPECTIVE.
THE WORK OF MY OFFICE OF MEDICAL POLICY IS A FASCINATING FUNCTION ANTICIPATING INNOVATION, CHANGES, AND THE WHOLE THERAPEUTIC DEVELOPMENT ECOSYSTEM AND HOW TO PREPARE TO BE RESPONSIVE IN ADDRESSING ANY REGULATORY NEED.
THAT CAME VERY FAST AT US DURING THE PANDEMIC.
SO THE PANDEMIC REALLY FUNCTIONED AS A CATALYST, TO ACCELERATE THE WORK THAT WERE ONGOING, A FEW EXAMPLES OF THAT.
FACILITATING MORE EFFICIENT CLINICAL TRIAL CONDUCT INCLUDING -- DIGITIZATION AND DATA SHARING WHEN APPROPRIATE.
LOOKING AT THE POTENTIAL OF DECENTRALIZED CLINICAL TRIALS PLATFORM TRIALS OR TRIALS EMBEDDED IN HEALTHCARE SETTINGS AND HOW CLARITY CAN BE HELPFUL IN FACILITATING TRIALS.
ADDITIONAL HEALTH TOOLS.
IT'S LIMITING TO THINK OF HOW WE DEFINE THE DIGITAL HEALTH TOOLS.
I THINK THE FIELD IS MOVING IN SUCH A FAST RATE THAT EVEN WHAT WE CONSIDER INNOVATIVE FEW MONTHS AGO HAS BEEN CHALLENGED ALREADY.
WE'RE SEEING ALGORITHMS BE USED.
SO IT'S AN ECOSYSTEM OF EXPONENTIAL TECHNOLOGY THAT IS THE POTENTIAL TO SHIFT A LOT OF THE BURDENS WE'RE SEEING AND NEED TO BE READY FOR THAT FROM A REGULATORY PERSPECTIVE.
ALSO HOW TO HAVE AN INFRASTRUCTURE AND REGULATION NEEDED TO EXPLORE FIT FOR PURPOSE

DATA SHARING AND GOVERNANCE STRUCTURES.
RECOGNIZING THAT GLOBALLY THERE ARE DIFFERENT NEEDS, PERSPECTIVES AND RESOURCES.
AND DETAILS HAVE TO BE REALLY IRONED OUT IN THE EFFORT OF GLOBAL COLLABORATION IN THAT SENSE.
A KEY QUESTION IS HOW TO HELP ESTABLISH THE NEEDED NEW NORMS AND BE RESPONSIVE TO THE CHANGING PUBLIC HEALTH DEMANDS EVEN OUTSIDE OF THE PANDEMIC CONTEXT.
I KNOW WE TALK ABOUT THE PANDEMIC VERSUS NON-PANDEMIC BUT ARE THERE NORMS THAT HAVE TO BE EMBEDDED IN OUR STANDARD PRACTICES THAT POTENTIALLY CAN BE ACCELERATED DEPENDING ON PUBLIC HEALTH NEEDS.
SO IT'S NOT JUST LEARNING FROM THE PANDEMIC BUT HOW TO TAKE THE OPPORTUNITY TO BUILD A BETTER SYSTEM AND APPROACHES IN GENERAL.
I HEARD GINNY EARLIER PRESENTATION MENTIONING THE OPPORTUNITY TO MOVE FROM BEING REACTIVE TO PROACTIVE AND I THINK THAT'S REALLY A CRITICAL UNDERLYING ASPECT HERE.
HOW TO CONSIDER THE TOTALITY OF AVAILABLE EVIDENCE AS WE MOVE INTO EXPLORING THE UTILITY OF REALWORLD EVIDENCE DATA AND EVIDENCE.
THE PROGRAM IS AN EXAMPLE HERE.
I WOULD HIGHLIGHT INCREASING DIVERSITY OF WHAT WE WOULD CONSIDER REALWORLD DATA AND I THINK THAT'S VERY MUCH VERY DIVERSE AREA, INCREASINGLY BECOMING DIVERSE AND I THINK WE REALLY NEED TO WORK TOGETHER GLOBALLY TO UNDERSTAND THE POTENTIAL OF REALWORLD EVIDENCE AND HOW TO BETTER APPROPRIATE PARAMETERS AND UNDERSTAND APPROPRIATE PARAMETERS FOR BASIC ISSUES LIKE TRANSPARENCY AND DOCUMENTATION.
I KNOW THE DISCUSSION TODAY IS ABOUT CLINICAL TRIALS, WHEN YOU START USING OBSERVATIONAL DATASETS OR, WHAT WOULD THE TRANSPARENCY AND DOCUMENTATION PARAMETERS EVEN THAT IS SOMETHING ARE TO US TO PROVIDE CLARITY ON.
GLOBAL POLITICAL COOPERATION AND EFFECTIVE COMMUNICATION IS REALLY NO LONGER NICE TO HAVE BUT A NECESSITY.
EVEN BEYOND THE PANDEMIC.
EXAMPLE OF WHERE THIS ENGAGEMENT CAN BE HELPFUL FOR US AND I KNOW FERGUS MENTIONED SOME EXAMPLES BEFORE, BUT SUPPORTING EFFICIENT CLINICAL TRIAL DESIGN CONDUCT IN ICH E-EIGHT AND E6 AND PROVIDING CLARITY NEEDED FOR DECENTRALIZED CLINICAL TRIALS OR TRIALS WITH ELEMENTS IS ESSENTIAL.
PROACTIVELY PROVIDING NEEDED CLARITY GLOBALLY SHOULD BE A STANDARD GOAL I BELIEVE.
HOW CAN WE PROVIDE SUCH CLARITY IN A REASONABLE TIMEFRAME WHICH INCLUDES MULTIPLE CHALLENGES AND THE PANDEMIC WAS REALLY A FORCE TO MAKE US REALIZE MAYBE WE NEED TO LOOK INWARD.
THIS IS MY LAST POINT I WILL LIKE TO MAKE.
INNOVATION FOR REGULATORY PROCESSES AND PLATFORMS ARE REALLY NEEDED HERE.
MODERNIZING DATA AND TECHNOLOGY PLATFORMS AND AGAIN THIS IS FROM A REGULATORY PERSPECTIVE WITHIN THE REGULATORY AGENCY.
TAKING ADVANTAGE OF A CLOUD-BASED DATA FLOW AND ANALYTICS WE RECENTLY ESTABLISHED AI STEERING COMMITTEE BECAUSE WE REALIZED THERE'S AN INCREASED USE OF ALGORITHMS AND WANT TO BE PROACTIVE IN BOTH PROTECTING PUBLIC HEALTH AND ALSO SUPPORTING INNOVATION

HERE.
MECHANISMS TO PROVIDE CLARITY AROUND USE OF NEW TOOLS AND APPROACHES NEED TO BE THOUGHT.
WE ALWAYS THINK OF THAT IN THE CONNECT OF GUIDANCE BUT ARE THERE TIMES WHEN POTENTIALLY A FRAMEWORK OR A DIFFERENT MODE OF COMMUNICATION WILL BE APPROPRIATE TO PROVIDE FASTER ENGAGEMENT WITH THE COMMUNITY.
THE OTHER ASPECT IS LINKING POLICY DEVELOPMENT TO IMPLEMENTATION AND ACROSS STAKEHOLDERS.
I HEARD RICH TALKING ABOUT TRAINING AND IMPLEMENTATION, FOR EXAMPLE.
SO IT'S NOT JUST PROVIDING GUIDANCE AND POLICY BUT ALSO THINKING ABOUT HOW TO CARRY THE ENGAGEMENT THROUGHOUT IMPLEMENTATION TO MAKE SURE WE'RE ALL IMPLEMENTING WITH THE SAME SPIRIT OF THE DEVELOPMENT ITSELF.
SO I THINK THAT'S SOMETHING THAT'S REALLY IMPORTANT MOVING FORWARD.
LINES OF COMMUNICATION GLOBALLY WITH A VARIETY OF STAKEHOLDER GOING FORWARD I THINK IS ESSENTIAL AND I'M GOING BEYOND THE CLASSIC FORM IN BIOTECH.
WE'RE ALL SEEING TECHNOLOGY SECTORS AND SECTORS WE WOULD NOT CONSIDER HAVE ANYTHING TO DO WITH HEALTH PROVIDE INNOVATION HOW CAN WE ENGAGE FOR ICH WE FOUND ENGAGEMENT WITH PATIENT ADVOCATES TO BE EXTREMELY USEFUL AND THE MANAGEMENT COMMITTEE THAT ICH MANAGEMENT COMMITTEE EVERY TIME WE ASK TO -- WE WERE ABLE TO PUT OUT THE DRAFT PRINCIPLES, MAKE THEM AVAILABLE TO THE PUBLIC AND WE'RE EXCITED ABOUT THIS CONTINUED ENGAGEMENT.
I'M GOING TO STOP HERE AND TURN IT BACK TO YOU, MARK.
THANK YOU.
>> THANKS SO MUCH.
THAT WAS GREAT.
THANK YOU SO MUCH.
STEVE, WOULD YOU LIKE TO TAKE IT FROM HERE?
>> THANKS, MARK.
I'LL FOLLOW ON FROM THE COMMENTS THAT KHAIR MENTIONED AND TOUCH ON SOME OF THE INTERESTING OBSERVATIONS AND EXPERIENCES FROM OWEN BUT ALSO TALK ABOUT IN PREVIOUS SESSIONS.
FOR ME THE BIGGEST FOCUS I'VE HAD AS MARK INTRODUCED ME I'M HEAD OF QUANTITATIVE SCIENCES AT THE GATES FOUNDATION AND WE PAY A LOT OF ATTENTION TO DATA FLOW AND THE FUEL OF THESE KINDS OF CHANGES WE'RE ASKING TO MAKE.
THAT'S ONE OF THE BIGGEST CHALLENGES WE'VE SEEN AS A FUNDER IS HOW CAN DATA FLOW IN A WAY PEOPLE CAN USE IT TO MAKE SMART DECISIONS, ANTICIPATORY PREEMPTIVE DECISIONS AS OPPOSED TO REACTIVE DECISIONS.
BECAUSE IF WE THINK ABOUT THIS IN THE CONTEXT OF A PANDEMIC, WE WANT TO GET A HINT OF WHAT'S LOOKING LIKE IT'S STARTING TO HAVE SOME IMPACT OR EFFECT SO WE CAN START PLANNING ACCORDINGLY FOR THAT EFFECTIVE THERAPEUTIC OR VACCINE OR WHATEVER THE INTERVENTION IS TO BE AVAILABLE TO COMMUNITIES THAT ARE GOING TO NEED IT.
ONE OF THE THINGS I'VE SEEN IN MY OWN EXPERIENCE COLLABORATING WITH NEVINE ZARIFFA IS THAT

THIS PANDEMIC DID INSTILL A SENSE OF WILLINGNESS OF COOPERATION AND COLLABORATION AMONG INDIVIDUALS.
SO PEOPLE INDIVIDUALLY FELT THAT WAY.
NOW AGGREGATE THAT INDIVIDUAL RESPONSE UP TO AN INSTITUTION AND NOW YOU START GETTING INTO PROBLEMS AND THE PROBLEM ISN'T THAT THE INSTITUTIONS ARE AGAINST IT BUT THE CHALLENGE COMES TO IN MY MIND A HUGE ISSUE OF RISK.
PEOPLE, ORGANIZATIONS WEREN'T SURE WHO'S RESPONSIBLE FOR AT RISK FOR THE SAFETY OF DATA IF WE'RE GOING TO START TO SHARE IT.
NEVINE MENTIONED THIS WORKBENCH THAT WE HAD SET UP THAT WE GOT TREMENDOUS RESPONSE FROM THE PHARMACEUTICAL INDUSTRY TO GIVE US SUMMARY LEVEL DATA.
BUT THEN FIGURING OUT THE METHODS OF HOW TO DO THAT, THAT'S WHERE I SEE THERE'S A MASSIVE GAP IN GOVERNANCE.
WE'RE ALL STRANGLED BY GDPR BECAUSE WE DON'T KNOW HOW TO RESPOND IN WAYS THAT MAKE PEOPLE FEEL LIKE I'M NOT GOING TO BE AT RISK.
SO THE APPROACH TO TAKE A CAUTIOUS NO RISK I DON'T WANT TO THE MAKE A DECISION OR BE THE LEADER IN THAT STEP.
SO I THINK THERE'S AN ISSUES WE HAVE TO LOOK AT NOT TO PRIVACY IS A BAD ISSUE, IT'S AN IMPORTANT ISSUE, BUT YOU WHO DO WE ACT IN THIS AND DO SOMETHING BETTER IN TERMS OF SHARING DATA AND HAVE THIS FUEL TO HAVE THESE KINDS OF DECISIONS WE WANT TO MAKE GLOBALLY FROM A REGULATORY PERSPECTIVE.
REGULATORS CAN LEAD THAT ROLE.
I SAW SOME HESITATION ABOUT CREATING SOME MANDATE ABOUT HOW WE'RE GOING TO GOVERN WHO, WHO GETS TO DO TRIALS AND HAVING A CENTRALIZED ORGANIZATION.
WITHOUT SOME DEGREE OF CENTRALIZATION AND COOPERATION AROUND WHERE DATA GOES HOW PEOPLE CAN ACCESS IT WHO CAN LOOK AT IT.
I THINK WE'RE JUST GOING TO BE STUCK.
WE ALSO HEARD A CONVERSATION ABOUT WHY WOULDN'T WE ACT THIS WAY DIFFERENTLY IN A NON-PANDEMIC SITUATION.
IN FACT, THAT'S HAPPENING AROUND US.
TO ME ONE OF THE COGENT EXAMPLES ABOUT FOUR YEARS AGO I WAS INTRODUCED TO THE LAMB FOUNDATION, IT WAS BASICALLY THIS SELF-ORGANIZED GROUP OF WOMEN BECAUSE LAMB IS A DISEASE THAT PRIMARILY AFFECTS WOMEN EARLY IN THEIR LIFE AT THE PRIME OF THEIR LIFE.
AND THEY ALL WERE BASICALLY BEING TREATED BY PHYSICIANS WHO HAD AN N OF 1 POPULATION SO THEY SELF-ORGANIZED AS A GROUP AND GOT THEIR PHYSICIANS TO SHARE DATA AND BANDED TOGETHER TO SAY WE'RE GOING TO HAVE TO SETTLE THIS OURSELVES BECAUSE WE'RE TOO SMALL OF A DISEASE.
THEY MOTIVATED TO THE POINT OF HAVING RAP AN MYCIN.
SO THAT WAS SOMETHING, THEY DIDN'T ASK ANYONE'S PERMISSION TO DO THAT.
THEY DIDN'T GO GET APPROVAL FROM REGULATORY AUTHORITIES.
THEY STARTED TO BIND TOGETHER AND WORK THROUGH THE SYSTEM FROM A GRASSROOTS UP.
SO I THINK WE HAVE TO THINK ABOUT WHAT ARE SOME OF THOSE LESSONS WE CAN LEARN AND THEN HOW DO WE SAFELY IMPLEMENT THOSE INTO A PROGRAM WHERE WE CAN ACTUALLY FACILITATE THIS

WILLINGNESS AND COLLABORATION.
I THINK THERE'S A NUMBER OF LEVELS THAT CAN HAPPEN AT.
IT CAN HAPPEN AT THE LOCAL LEVEL.
MARK AND BARBARA IT WOULD BE INTERESTING IF HARVARD SAID WE'RE GOING TO ONLY RUN ONE COVID TRIAL, ALL INVESTIGATORS HAVE TO PARTICIPATE IN ONLY ONE INSTITUTIONAL TRIAL, THAT'S IT.
THE IRB AND HARVARD JUST ONLY APPROVED ONE AND IF YOU WANT TO BE IN IT YOU GOTTA JOIN, YOU CAN ADD AN ARM FOR YOUR THERAPEUTIC, BUT ONE TRIAL.
BECAUSE ONE OF THE THINGS WE RAN BOO IS EVEN WITHIN BIG RESEARCH INSTITUTIONS, INVESTIGATORS WERE COMPETING WITH EACH OTHER WITHIN THE INSTITUTION FOR PATIENTS.
SO THAT'S WHERE WE GET TO THIS -- THE SCT ALGORITHM MENTIONED IN THE FIRST SESSION TRYING TO GET AWAY FROM THAT.
I THINK FROM A GOVERNANCE STANDPOINT IF WE CAN WORK ON WAYS TO GET DATA TO FLOW INTO A COOPERATIVE PLACE WHERE PEOPLE CAN SEE IT, AGGREGATE IT, BUILD ON IT, THAT ACTUALLY IS GONNA HELP US MAKE SMARTER DECISIONS OVERALL IN A PANDEMIC.
AND I WOULD AGREE THAT THAT CAN ACTUALLY TRANSLATE INTO THE WAYS WE CAN WORK IN EVERYDAY LIFE.
OWEN GAVE A GREAT EXAMPLE OF HOW PFIZER IS APPROACHING IT AND AS OWEN WAS TALKING ABOUT THE CONDITIONS, THE SITUATION, THE IMAGE THAT WAS COMING TO MIND WAS BABY STEPS, RIGHT?
TAKING BABY STEPS FORWARD.
IT'S THE RIGHT THING TO DO BECAUSE YOU WANT TO MITIGATE YOUR RISK FROM THE STANDPOINT OF WHAT YOU'RE WORKING ON AS A COMPANY BUT CAN WE DO THINGS THAT ENABLE COMPANIES THAT WANTED TO BE MORE PROGRESSIVE TO TAKE BIGGER THAN BABY STEPS AS THEY MOVE INTO THIS PROCESS.
I'LL STOP THERE.
>> THAT WAS GREAT.
JUST BEFORE I TURN IT OVER TO FERGUS, JUST A COUPLE OF BRIEF COMMENTS.
ONE IS THAT DATA SHARING OVER THE PAST, LET'S SAY, SEVEN OR EIGHT YEARS, MANY OF US HAVE BEEN INVOLVED IN THE ADVOCACY FOR DATA SHARING AND FERGUS KNOWS THAT ROSSI WAS A PROPONENT OF IT. BUT WE TALKED ABOUT DATA SHARING AS A KIND OF -- AS SHARING DATA FOR TRIALS THAT ARE OVER AND DONE WITH.
AND THEN SHARING THEM ON A PLATFORM WHICH IS WHY BARBARA AND I AND OTHERS WERE INVOLVED WITH SETTING UP BIBLI.
YOU'RE TALKING ABOUT THE IDEA OF A DYNAMIC SHARING, THAT SHARING REAL TIME DATA NOT JUST DATA FOR TRIALS THAT ARE COMPLETED WITH ALL THE COMPLEXITIES.
THAT LEADS ME TO THE SECOND POINT THAT I WANTED TO MAKE, AND THAT IS WE DO KNOW THAT, AND I KNOW THAT EMA IS AWARE, EMA IS NOT RESPONSIBLE FOR GDPR BUT EMA IS AWARE OF THE ISSUES AND THERE ARE THESE CHALLENGES BOTH ABOUT THE LEGAL THEORY FOR THE SECONDARY USE OF PERSONAL DATA AS WELL AS THE PROBLEMS IN THE TRANSNATIONAL SHIPMENT OF DATA. AND FOR BETTER OR WORSE, THE FACT IS THAT JAPAN HAS ADOPTED A PRIVACY ACT THAT'S CLOSELY MODELED ON GDPR AND OTHER JURISDICTIONS ARE FOLLOWING SO THESE PRIVACY RULES WHICH WERE NEVER REALLY MEANT TO BE SPECIFIC TO CLINICAL TRIALS BUT SWEEP US INTO IT, THEY POSE

SOME REAL OBSTACLES TO DOING WHAT YOU'RE TALKING ABOUT.
AND SO IN TERMS OF DEFINING THE PROBLEM, THAT'S A PROBLEM THAT WE HAVE.
FERGUS, I'M GOING TO TURN IT OVER TO YOU.
>> THANKS VERY MUCH, MARK.
GOOD AFTERNOON.
JUST LISTENING TO THE TALKS IN THIS SESSION AND THE PREVIOUS ONE, I THOUGHT I'D JUST HIGHLIGHT TWO ASPECTS WHICH I THINK ARE IMPORTANT.
ONE IS THE CONCEPT OF MULTI STAKEHOLDER DISCUSSION, WHICH HAS BEEN SPOKEN TO ALREADY BY KHAIR AND OTHERS IN THIS SESSION, THE PREVIOUS.
IT IS REALLY IMPORTANT BECAUSE IF YOU -- IT'S PART OF HUMAN NATURE, BUT IF YOU HAVE LIKE MINDED PEOPLE TALKING TO EACH OTHER WHETHER THEY'RE PRIVACY EXPERTS OR SOME OTHER KIND OF EXPERT, THEY WILL TEND TO REINFORCE THEIR OWN POSITION AND YOU ACTUALLY GET A CENTRIFUGAL OPINION FORMING WHICH MAKES IT MORE DIFFICULT TO MOVE.
SO YOU NEED TO BRING THE MULTIPLE VIEWS TOGETHER OF AT THE TABLE AND KHAIR SAID WITH THE ICH NOW WITH THE E-EIGHT AND E6, WE'VE BEEN ABLE TO REACH OUT TO ACADEMIA AND PATIENTS AND WE NEED TO BUILD MORE ON THAT TO GET THEIR INPUT AND IT'S ALWAYS ENRICHING.
WE HAVE PATIENTS AND HEALTHCARE PROFESSIONAL REPRESENTATIVES IN OUR COVID-19 EMERGENCY TASK FORCE WHO ARE PRESENT DURING THE PROTOCOL DISCUSSIONS DURING THE ROLLING REVIEWS AND CONTRIBUTE AND OFTEN HAVE VERY GOOD AND INCISIVE INSIGHT WHICH IS DIFFERENT.
SO BUILDING THE PLATFORMS AND THE HAS TO BECOME PART OF OUR GOVERNANCE OF CLINICAL TRIALS OF DATA MANAGEMENT, OF THE WAY WE OPERATE ACROSS INSTITUTIONS AND YOU REFER TO INSTITUTIONS, STEVE, AND THEY KIND OF RETREAT AND PULL UP THE DRAW BRIDGES AND WE NEED TO GET THAT MULTI-STAKEHOLDER INPUT TO OPEN THE DOORS AND GET THE DRAW BRIDGES BACK DOWN AND PEOPLE MINGLING AND SHARING.
A SECOND PART OF THAT, I THINK, AND COVID HAS GIVEN US THIS TO A DEGREE AS WELL, BUT WE NEED TO BUILD ON IT, IS REALLY TO INCREASE THE NON-COMPETITIVE SPACE IN RESEARCH AND CLINICAL TRIALS.
SO BECAUSE IN THE END, THE MORE YOU SHARE IDEAS, THE MORE YOU SHARE DATA, THE FASTER INNOVATION WILL GO, THE FASTER YOU WILL MAKE PROGRESS IN REVEALING NEW THERAPIES OR BETTER USES OF EXISTING ONES.
AND I THINK THAT'S BEEN INHIBITED FOR DIFFERENT COMPETITIVE REASONS, WHETHER COMMERCIAL OR ACADEMIC, AND SOME OF IT ALSO IS BUILT UP AROUND THE CLINICAL TRIAL PROCESS RATHER THAN EVEN THE MOLECULE AND MEDS AND THIS BE BROUGHT FORWARD. SO I REALLY THINK ENABLING AND WORKING TO BREAK DOWN THE KIND OF COMPETITIVE BARRIERS SO THAT WE HAVE A LARGER AND MORE INTERACTIVE NON-COMPETITIVE OR PRECOMPETITIVE SPACE, HOWEVER WE CAN CALL IT, WITHOUT DESTROYING INTELLECTUAL PROPERTY PER SE, BUT JUST ENABLING PEOPLE TO ACTUALLY MOVE THAT FORWARD FASTER, BECAUSE I THINK WE WOULD -- I THINK IN TERMS OF THE WAY WE BUILD GOVERNANCE BUILDING ON THE COVID EXPERIENCE, I WOULD SEE THESE AS TWO THINGS WHICH I THINK ARE REALLY IMPORTANT.
THANK YOU.
>> THANKS, FERGUS.
LET ME START WITH -- IF YOU HAVE QUESTIONS FEEL FREE TO EMAIL THEM IN THE Q&A SECTION.

OWEN, LET ME ASK YOU A COUPLE QUESTIONS.
IN THESE FULLY DECENTRALIZED TRIALS, WHAT'S THE FUNCTION OF THE INVESTIGATOR?
DOES THE COMPANY BECOME THE INVESTIGATOR IN THOSE TRIALS?
IS THIS AN ENTIRELY NEW THING?
IS IT LIKE RUNNING AN INTERNAL PHASE 1 UNIT?
THESE THINGS ARE BYPASSING OUR TRADITIONAL STRUCTURES.
>> IT ACTUALLY IS ANALOGOUS TO A PHASE 1 UNIT IN A WAY ALTHOUGH THOSE ARE BRICK AND MORTAR FOR GOOD REASON BECAUSE THEY TYPICALLY RUN FIRST IN HUMAN AND CLINICAL PHARMACOLOGY STUDIES. THEIR ROLE IS TO HAVE THE SAME INTERACTIONS THE PATIENTS THAT THEY WOULD IF THEY WERE IN AN OFFICE.
BUT THEY'RE DOING IT VIRTUALLY.
THEY CONSISTENT WITH U.S. REGULATIONS, OKAY THE SHIPMENT OF DRUG TO PATIENTS AND THEY ESSENTIALLY DO WHAT THEY WOULD DO IF THEY WERE IN THE OFFICE, BUT THEY DO IT VIRTUALLY.
NOW, THE OTHER THING ABOUT THE TRIAL IS THAT FDA ASKED US TO ADD AN IN-PERSON ELEMENT TO IT SO THAT THEY COULD COMPARE IN-PERSON ASSESSMENT VERSUS IN FULLY DIGITAL CENTRALIZED ASSESSMENT BY A PANEL OF READERS AND WE DID THAT.
SO WE ACTUALLY HAVE A HOME HEALTHCARE WORKER WHO GOES TO THEIR HOME I BELIEVE THREE TIMES AND THEY GO THERE FOR THE BASELINE AND THE PRIMARY ENDPOINT AND THEY GO THERE TO GET THEM SET UP AS WELL.
SO WE HAVE THAT ELEMENT BUILT INTO THE TRIAL AS WELL.
GOING FORWARD, WE PROBABLY WOULD NOT HAVE THREE SUCH VISITS.
WE WOULD PROBABLY JUST HAVE ONE.
SO THE ROLE OF THAT PERSON, OF THE INVESTIGATOR, IS TO HAVE THE SAME INTERACTIONS WITH THE PATIENT THAT THEY WOULD IF THEY WERE IN A BRICK AND MORTAR SITE BUT THEY DO IT VIRTUALLY.
WE HAVE THE QUESTIONS ABOUT WHAT'S THE IMPLICATIONS ON INSPECTIONS.
A FULLY VIRTUAL TRIAL IS MORE INSPECTABLE THAN A NON-CENTRALIZED TRIAL IN SOME WAYS.
SO WHEN THE DISCUSSION BETWEEN THE INVESTIGATOR AND PATIENT ON ADVERSE EVENTS IS HAPPENING THAT'S RECORDED.
THE ENDPOINT DATA IS CENTRALLY RECORDED.
SO AN AGENCY CAN GO IN OR AN INSPECTOR CAN GO IN AND LOOK AT THE ACTUAL HONEST TO GOD RAW DATA WHEREAS IN OTHER PROGRAMS WE HAVE THINGS LIKE TEN DIFFERENT SWOLLEN JOINT COUNTS WHICH IS SOMETHING A DOCTOR DOES WITH THEIR HANDS AND THEY WRITE IT DOWN OR PUT IT ON A COMPUTER.
SO IT'S ACTUALLY IN SOME WAYS MORE INSPECTABLE THAN IS A TRADITIONAL CLINICAL TRIAL.
>> THANK YOU.
THANKS.
HAVE YOU GUYS THOUGHT ABOUT THE IDEA OF -- IF ENROLLMENT CAN BE REMOTE, THEN WHY NOT HAVE PI'S INSIDE THE COMPANY INSTEAD OF EXTERNAL PI'S?
>> THAT'S A VERY GOOD QUESTION.
I THINK THERE'S A -- THERE'S A CULTURE THAT YOU WANT THE PI TO BE OUTSIDE THE COMPANY DUE TO CONCERNS OVER CONFLICT OF INTEREST.
BUT THAT'S AN EXCELLENT QUESTION.

WHY COULDN'T IT BE SOMEBODY IN THE COMPANY?
>> RIGHT.
I'M WONDERING THAT LONG-TERM WHETHER WE'RE SEEING A BLURRING OF THE ROLES OF THE INVESTIGATOR IN THE COMPANY BECAUSE THE COMPANY IS SO SOLVED IN THE -- IN VIRTUAL ENTIRELY REMOTE TRIALS.
>> EXACTLY.
YEAH.
>> FERGUS, LET ME ASK YOU ABOUT THIS.
STEVE HAD BROUGHT UP THE ISSUE OF GDPR.
CAN YOU GIVE US AN UPDATED ON WHAT YOU THINK IS GOING ON ABOUT ALLOWANCE FOR THESE TEMPORAL DATA SHIPMENTS AND THE REALWORLD EVIDENCE IMPLICATIONS OF GDPR.
I KNOW YOU GUYS HAVE BEEN WORRIED ABOUT IT AND THERE SEEMS TO BE SOME BREAKING OF THE ICE BY THE DATA PROTECTION AUTHORITY.
.
>> THERE'S AN INCREASING DISCUSSION AND ENGAGEMENT WITH THE ISSUE OBVIOUSLY THE GDPR IS HUGE AND COVERS ALL INDUSTRY SECTORS.
AND AS YOU RIGHTLY SAY, IT WASN'T DESIGNED PARTICULARLY TO TACKLE RESEARCH.
IT WAS AIMED AT OTHER THINGS OR PROBLEMS.
SO I THINK FOR ME THE KEY IS REALLY FINDING THE PATH TO ALIGN THE REQUIREMENTS IN A POSITIVE WAY.
AND TO ENSURE THAT WE CAN PUT IN PLACE PROCESSES THAT ENABLE DATA EXCHANGE BUT PROTECT THE PRIVACY OF THE PERSON THAT THE DATA AND SUBJECT AT THE SAME TIME.
AND THAT DOES REQUIRE CAREFUL CONSIDERATION.
I THINK ALSO THE ABILITY FOR SECONDARY DATA USE FOR POSITIVE PURPOSES IN AND HEALTHCARE PURPOSES IN A GOOD WAY I THINK NEEDS TO BE SUPPORTED.
IF PEOPLE ARE WILLING, AS TRIAL PARTICIPANTS, AS INDIVIDUALS, TO SHARE THEIR INFORMATION OR TO ENABLE THEIR INFORMATION TO BE SHARED, I THINK THEY -- THAT NEEDS TO BE DONE SO THE BEST VALUE IS TAKEN FROM IT.
BUT NOT TO THE POINT WHERE THEN IT DOES BECOME PROBLEMATIC.
AND ACHIEVING THAT IS CHALLENGING IN THE WORLD WE HAVE AND GETTING THE TECHNIQUES TO PROTECT THAT IS CHALLENGING.
BUT THERE'S A LOT OF DISCUSSION ONGOING NOW.
I KNOW FOR INSTANCE, IN INDUSTRY ASSOCIATIONS ARE WORKING ON CODE OF CONDUCT TO ADVANCE THIS AND BRINGING IT THROUGH THE DATA PROTECTION AUTHORITIES AND WE'RE DISCUSSING ACROSS THE DIFFERENT GROUPS TO ADVANCE THIS ALSO WITH THE BIO BANKING GROUPS AS WELL.
AND COLLEAGUES ARE BUILDING THAT UP.
BUT IT'S -- IN A SENSE, I SUPPOSE, ALSO, THERE'S A CERTAIN LEVELLING NEEDED ACROSS DIFFERENT PARTS OF THE WORLD WHERE SOME PARTS ARE LESS PROTECTIVE AND THEN WE CAN MEET IN THE MIDDLE ON A MORE EQUAL WAY AND THAT WILL ALSO ENABLE BETTER EXCHANGE I BELIEVE.
IT'S DEFINITELY VERY CHALLENGING AND WE NEED TO TAKE CARE THAT IT DOESN'T DAMAGE RESEARCH OR HEALTHCARE.

>> IF WE COULD HAVE INDUSTRY-WIDE CODES OF CONDUCT THAT ACTUALLY COULD BE -- COULD BE ACCEPTABLE TO THE DATA PROTECTION AUTHORITIES IN MANY DIFFERENT COUNTRIES BUT WOULD ALSO BE ACCEPTABLE TO THE INDUSTRY PARTNERS WHO AGREED TO THE SAME COVID CONDUCT, THAT'S A WAY OF STANDARDIZING THIS AND ACTUALLY PROVIDING PROTECTION BUT ALSO FACILITATING DATA EXCHANGE.
>> MARK THE OTHER THING -- BECAUSE IN OUR THERAPEUTIC ACCELERATOR CONSORTIUM AT THE GATES FOUNDATION PARTICIPATED IN INCLUDED MASTER CARD WHO'S NOT A NORMAL BIO MEDICAL RESEARCHER.
BUT INTERESTINGLY MASTER CARD DEALT WITH THIS IN THE FINANCIAL SERVICES AND FINANCIAL SERVICES HAVE DEALT WITH THIS BECAUSE THEY NEEDED TO KEEP THEIR BUSINESSES BY SETTING UP DATA TRUSTS. ONE OF THE CHALLENGES IS ALL OF HOUSE WANT TO BE PARTICIPATING IN THIS, WE'RE DOING ALL THESE OTHER THINGS AND DATA SHARING.
SO WE HAVE THIS OTHER ANCILLARY THING, DATA SHARING, WE DON'T KNOW WHAT THE RISK AND HOW IT'S GOING TO IMPACT US BECAUSE IT'S NOT OUR BREAD AND BUTTER.
YOU SET UP A DATA TRUST WHO'S FUNCTION IS TO MEET THOSE REQUIREMENTS OF SAFETY AND TO BE ABLE TO ENABLE THE TRANSFER OF DATA AND NOW YOU HAVE THE POSSIBILITY AND I THINK FERGUS JUST MENTIONING BIOBANK I HADN'T THOUGHT ABOUT THAT, THAT'S A GREAT POTENTIAL CATALYST, PLACES WHERE YOU'RE GOING TO START TO AGGREGATE SAMPLES FOR THE SAKE OF REPEAT ANALYSES MIGHT BE THE PLACE TO BUILD THINGS LIKE A DATA TRUST THAT THEN IS SOLELY TASKED WITH MAINTAINING THE SECURITY AND PRIVACY AND THEN ALLOWS OTHERS TO HAVE ACCESS.
THAT COMPLIMENTED WITH CODE OF CONDUCT COULD BE A VERY FEASIBLE SOLUTION.
>> AS FERGUS SAID, THE INTERNATIONAL SOCIETIES, INTERNATIONAL SOCIETY FOR BIOBANKING THAT'S BEEN VERY INVOLVED IN THESE DISCUSSIONS BECAUSE OBVIOUSLY -- SPECIMENS ARE NOT THEMSELVES COVERED BY GDPR BUT THE -- WITHOUT WHICH THE SPECIMENS ARE USELESS IS COVERED BY THESE PRIVACY REGULATIONS.
>> MARK, WANT TO ADD TO, GOING BEYOND A LITTLE BIT THE GDPR, WHAT WE'RE DISCUSSING DATA FLOW AND USE, I THINK THERE ARE MULTIPLE OTHER CHALLENGES THAT WE SHOULD ADDRESS SIMULTANEOUSLY, I FEEL LIKE WE HAVE A WAY TO GO, UNDERSTANDING HOW TO MAKE BEST USE OF THIS DATA, THE FORMAT OF THE DATA, STANDARDIZATION, HOW TO STILL, A LOT OF THAT YET TO BE ANSWERED AND SHOULD BE ANSWERED AS WELL AS THE DISCUSSIONS AROUND THE GDPR AND OTHER --
>> HOW DO WE ANSWER THAT, THOUGH?
WHAT'S THE FORUM?
IT NEEDS TO BE SORT OF A RESEARCHER, INVESTIGATOR SITE GOVERNMENT AGENCY AND INDUSTRY DISCUSSION, BUT IT'S GOT TO BE -- WE'RE ALL IN SORT OF OUR SILOS AND TRADE ASSOCIATION OR ASSOCIATIONS OF COMMON INTEREST THAT DON'T CUT ACROSS THESE THINGS EASILY.
>> I THINK IT COMES A BIT TO THIS MULTI-STAKEHOLDER THINKING THAT WE NEED TO BUILD ON AND FIND THE PLACES WHERE THEY CAN HAVE, HOW CAN I SAY, I DON'T KNOW IF IT'S A LEGAL PERSONALITY BUT A LEGITIMACY THAT THEN HAS REAL IMPACT INTERNATIONALLY AS WELL AS REGIONALLY OR NATIONALLY.
AND WE HAVE A PHARMACEUTICAL INDUSTRY WORKING ON CODE OF CONDUCT AND PERHAPS BRINGING THOSE ELEMENTS TOGETHER INDIVIDUAL ACADEMIC OR HOSPITAL INSTITUTIONS ARE GOING

TO STRUGGLE WITH THIS OR EVEN INDIVIDUAL COMPANIES BECAUSE IT'S -- EVERYBODY IS TRYING TO REINVENT THE WHEEL WITH A DIFFERENT PERSPECTIVE AND UNDERSTANDING OF WHAT A WHEEL MIGHT BE.
IT'S INTELLECTUALLY VERY CHALLENGING AS A WHOLE NEW THING.
THE MORE WE CAN BRING A COMMON DISCUSSION TOGETHER, I THINK, AND I DO THINK TECHNICALLY THERE ARE APPROACHES AND I GUESS STEVE -- PART OF MANY OF THESE DISCUSSIONS WHERE YOU CAN FED RATE THE WAY THE DATA IS HEALTH AND INTERROGATED AND WHAT YOU COLLECT TO YOUR CENTRAL ANALYSIS IS PRACTICAL SENSE ANONYMOUS AND STILL REAL AND -- IN ITS ORIGINAL HOSPITAL FILE OR WHATEVER.
I'M SURE THERE ARE TECHNICAL SOLUTIONS, BUT IT DOES REQUIRE PEOPLE WORKING TOGETHER TO A RELATIVELY COMMON APPROACHES BECAUSE OTHERWISE WE'LL END UP WITH A HUGE DIVERSITY WHICH WON'T BE MANAGEABLE.
>> STEVE, LET ME ASK YOU THIS, BUT THIS IS ALSO FOR THE OTHER PANELISTS.
ONE OF THE THINGS THAT WAS TALKED ABOUT LAST SESSION WAS THE SO CALLED SCT'S AND THE QUESTION REALLY IS -- YOU GAVE AN EXAMPLE AND AS AN INSTITUTION, DANA-FARBER OR MD ANDERSON OR CITY OF HOPE OR ANY OF THESE PLACES, THEY COULD CHOKE OFF THE SMALL CRAPPY TRIALS WITHIN THEIR OWN INSTITUTIONS, RIGHT, BY PUTTING OUT ESSENTIALLY INTELLECTUAL RULES ABOUT WHAT'S APPROPRIATE AND NOT APPROPRIATE.
HOW DO WE -- THAT'S POSSIBLE.
BUT THAT'S ONLY WITHIN ONE INSTITUTION OR MAYBE A CONSORTIUM OF CANCER CENTERS OR HOSPITALS.
HOW DO WE CHOKE OFF THESE -- AT A LARGE SCALE, HOW DO WE CHOKE OFF THESE TRIALS AND COMBINE EFFORTS FOR EFFICIENCY?
>> I THINK IF WE PUT IN THE STRUCTURE TO TELL PEOPLE THESE ARE THE RULES OF THE GAME.
WHEREVER IT IS WAVES THE FLAG THAT SAYS THIS IS A PUBLIC HEALTH EMERGENCY THAT HAS TO BE DEALT WITH, WE SWITCH TO THOSE OPERATING RULES.
BECAUSE I THINK THE REASON WE END UP WITH SO MANY SMALL CRAPPY TRIALS IS BECAUSE SO MANY PEOPLE WANTED TO HELP.
LOOK AT HOW MANY PEOPLE WERE PRINTING 3-D MASKS AND SHIELDS.
YOU HAD THIS DESIRE OF INDIVIDUALS TO WANT TO HELP, THEY KNEW I KNOW HOW TO RUN A STUDY AND JUMP IN AND DO IT.
INSTEAD OF IF YOU SAID YOU WANT TO HELP HERE'S HOW I NEED YOU TO HELP AND PUT THAT STRUCTURE IN PLACE I DON'T THINK WE'LL GET RESISTANCE.
SO WHAT WE JUST NEED IS A HIERARCHICAL ORGANIZATION.
YOU DO IT AT THE INSTITUTION LEVEL THAT ROLLS UP PERHAPS ACROSS PROFESSIONAL SOCIETIES OR ACADEMIC STANDARDS, COLLABORATING TOGETHER.
I DON'T THINK WE NEED TO PROSCRIBE THAT BUT YOU START TO BUILD THESE KINDS OF STRUCTURES AND IF THEY ARE IN PLACE PEOPLE WILL FOLLOW THEM.
I THINK IT WAS RARE PEOPLE'S EGO SAID I WANT TO RUN MY OWN TRIAL FORGET YOU.
IT WAS MORE ABOUT THIS IS WHAT I KNOW HOW TO DO.
EVERYBODY HAS TO BE FAST LET'S ALL RUN.
IN A FIRE DRILL IF WE DON'T HAVE AN ORGANIZED WAY TO DO IT WE ALL RUN INTO EACH OTHER AND

THAT'S KIND OF WHAT HAPPENED.
>> I'M KIND OF HESITANT TO SAY THIS BUT REGULATORY AGENCIES CAN PLAY A ROLE AS WELL.
FDA HAS EXPLICIT LEGAL AUTHORITY TO PLACE A CLINICAL HOLD ON A TRIAL THAT DOESN'T HAVE A FIRM SCIENTIFIC BASIS.
SO IF IT'S UNCONTROLLED, IF IT'S BADLY UNDERPOWERED, THEY HAVE AUTHORITY TO DO THAT.
I DON'T BELIEVE THEY USE THAT AUTHORITY VERY MUCH, BUT THEY COULD HAVE.
YOU CAN SEE WHY WORKING IN INDUSTRY AND -- I WAS HESITANT TO SAY THAT.
WE ALSO SAW IN EUROPE THIS PLETHORA OF UNCONTROLLED TRIALS AND AT ONE POINT BOTH SPAIN AND ITALY SAID WE'RE NOT ACCEPTING THE CTA SYSTEM UNCONTROLLED TRIALS ANYMORE.
SO THERE IS A ROLE FOR REGULATORS.
I THINK ESPECIALLY EARLY ON.
THEY REALLY WERE NOT -- THEY WERE VERY HESITANT TO APPLY THAT AUTHORITY, BUT I THINK THAT'S PROBABLY A LEARNING FOR NEXT TIME.
WE ALL THINK THERE WILL BE A NEXT TIME.
>> WELL, I THINK IT'S THAT IF YOU LOOK AT THE ECOSYSTEM OF CLINICAL TRIALS, IT'S VERY DIVERSE.
YOU HAVE ACADEMIC CLINICAL TRIALS, SMALL SPONSORS, SO IT'S NOT REALLY EASY TO PUT EVERYTHING IN THE SAME BASKET AND SAY HERE'S WHAT REGULATORY AGENCIES WILL LOOK AT.
I AGREE WE HAVE A ROLE TO PLAY AND A SUBSTANTIAL ROLE TO PLAY.
BUT I THINK PART OF WHAT'S NEEDED IS LOOK, FOR EXAMPLE, DECENTRALIZED CLINICAL TRIALS, I THINK YOU'RE ENGAGED WITH THE FDA AND ENGAGED WITH REGULATORS AND HAVE A SHARED UNDERSTANDING AND ALSO PROVIDING EVIDENCE OF YOU MENTIONED, FOR EXAMPLE, THE DIFFERENCES BETWEEN REMOTE VERSUS IN-PERSON.
I THINK THAT IS NEEDED FROM THE COMMUNITY AT LARGE.
I THINK THAT CANNOT BE DONE JUST BY THE REGULATORS.
I THINK THAT TYPE OF ENGAGEMENT IS NEEDED.
ONE EXAMPLE I WOULD GIVE I FOUND TO BE USEFUL AND USEFUL NOT JUST FOR OUR STAKEHOLDERS BUT ALSO TO EDUCATE INTERNALLY IS THE REALWORLD EVIDENCE SUBCOMMITTEE WE HAVE WHERE WE ENGAGING AT EARLY STAGES WITH ANYBODY FROM OUTSIDE, ANY STAKEHOLDERS WHO WERE THINKING ABOUT UTILIZING REALWORLD EVIDENCE AND THEY -- PRESENT ON THEIR WORK AND WE HAVE THIS DIALOGUE THAT'S OUTSIDE OF THE REGULATORY DECISION MAKING.
AND I THINK THE MORE WE PROVIDE CLARITY IN THOSE AREAS AND THAT'S A COLLECTIVE MISSION I BELIEVE THAT -- IN ADDITION TO OUR ROLE WE PLAY DIRECTLY, GUIDANCE AND COMMUNICATION.
>> OWEN I'M GLAD IT WAS YOU TO SAID REGULATORS TO PLAY A ROLE.
BECAUSE I THOUGHT THAT YOU PROBABLY WOULDN'T SAY IT.
THANK YOU FOR SAYING IT.
FUNDERS CAN PLAY A ROLE AS WELL.
NIH CAN PLAY A ROLE, GATES FOUNDATION, ALL THESE FUNDERS OF RESEARCH COULD, NATIONAL SCIENCE FOUNDATION OF CHINA COULD PLAY A ROLE, THEY COULD ALL PLAY A ROLE IN THIS REGARD AS WELL, RIGHT?
>> ABSOLUTELY.
>> ANYTHING ELSE YOU GUYS WOULD LIKE TO COMMENT ON BEFORE WE CLOSE HERE?
>> I CAN RAISE AN ISSUE THAT FERGUS RAISED AS A POTENTIAL QUESTION TO BRING UP, WHICH IS

HOW CAN REGULATORS FACILITATE MULTI-REGIONAL PLATFORM TRIALS.
AND I TOLD YOU IN OUR EXAMPLES THAT WE HAVE DONE AT INTRA COMPANY, BUT I DO THINK IF YOU WENT TO A MULTI-COMPANY SETTING AND BECAME EVEN MORE GLOBAL, IT WOULD GET MORE DIFFICULT.
AND I THINK THE MAIN THING WE WOULD NEED FROM REGULATORS IS A MECHANISM FOR THE MAJOR AGENCIES IF NEEDED, TO COME TOGETHER QUICKLY AND HARMONIZE.
AND THE REASON I RAISE THAT IS BECAUSE WE TYPICALLY RUN NEARLY ALL OF OUR TRIALS AS MULTI-REGIONAL OR GLOBAL TRIALS FROM PHASE 2 ON THESE DAYS AT LEAST IN MY THERAPY AREA.
IT'S VERY COMMON TO HAVE A LACK OF HARMONIZATION BETWEEN MAJOR AGENCIES ON A PROTOCOL THAT HAS A SINGLE COMPOUND IN IT.
SO THEY HAVE A DIFFERENT PERSPECTIVE ON THE TOX DATA AND DIFFERENT PERSPECTIVE ON THE PREVIOUS CLINICAL DATA.
WHEN YOU THEN MOVE TO A PLATFORM TRIAL THAT HAS TWO OR THREE OR EVEN FOUR AS SOME OF THE MASTER PROTOCOLS WOULD, THE CHANCES THAT YOU'RE GOING TO HAVE REGIONAL DISHARMONY GO UP THEY'RE SQUARED OR EVEN GO UP HIGHER THAN THAT.
OF SO AT SOME POINT TO MAKE THIS WORK, ESPECIALLY ACROSS MULTIPLE COMPANIES WHEN YOU GET OVER, SAY, TWO COMPOUNDS AND MAY BE FLIPPING ENDPOINTS AS YOU MOVE FROM COMPOUND COULD COMPOUND AND SOME OF THESE MASTER PROTOCOLS, SOME MECHANISM FOR ARRIVING AT SOME HARMONIZATION WOULD BE GOOD.
BECAUSE OF COURSE, A MULTI REGIONAL TRIAL CANNOT TRULY BE A MULTI REGIONAL TRIAL IF YOU HAVE DISHARMONY AMONG THE MAJOR REGULATORS.
>> BEFORE FERGUS RESPONDS TO THAT OR KHAIR LET ME ASK YOU, THE REGULATORY AGENCIES IS ONE ASPECT AND THE TRANSNATIONAL HARMONIZATION.
BUT COMPANIES WOULD HAVE PROBLEMS TOO IN INTERCOMPANY PLATFORM TRIALS BECAUSE OF ISSUES THAT WE TALKED ABOUT IN REGARD TO DATA OWNERSHIP, DATA USE RIGHTS, COMPETING COMPOUNDS WITHIN ONE PLATFORM TRIAL.
SO TO WHAT EXTENT HAVE YOU GUYS BEEN ABLE TO ANSWER THOSE QUESTIONS OR COULD THERE BE THE POSSIBILITY OF HAVING A PHARMA, BIO, ALL OF THEM, YOU COULD HAVE DEVICE PLATFORM TRIALS AS WELL I SUPPOSE.
BUT I JUST WONDER ABOUT HOW DO WE ACHIEVE, BEFORE WE GET TO THE REGULATORY ISSUES HOW DO WE DEAL WITH THE IP ISSUES AND THE RIVALRY ISSUES?
>> THAT'S KIND OF BEYOND MY COMPETENCE A BIT.
I THINK THOSE ARE THE MAIN ISSUES.
THE NIAID TRIAL WHAT WAS AT THE ACTT TRIAL, I MIGHT BE MIXINGS UP THE ACRONYMS, ACTUALLY MOVED MULTIPLE COMPOUNDS IN AND OUT OF THE STUDY PRETTY RAPIDLY.
THE THING THAT ALLOWED THAT I THINK WAS THAT NIH WAS A CENTRAL ENTITY RUNNING IT.
NOW, THERE ARE MAJOR GLOBAL CRO'S WHO CAN BE A CENTRAL ENTITY RUNNING IT.
AND THEY COULD WORK OUT DATA EXCLUSIVITY, DATA CONFIDENTIALITY, AND COMPETITION ELEMENTS, I THINK.
SO I THINK THE MAJOR CROS AS WELL AS THE MAJOR ORGANIZATIONS LIKE NIH'S OF THE WORLD AND THE WHOS COULD PROBABLY HELP QUITE A BIT THERE.
AND I ALMOST THINK IN MY PAST I'VE COME ACROSS THINGS CALLED MODEL REGULATIONS.

SO THERE'S A REGULATION THAT THERE'S A MODEL ELECTRICAL CODE FOR THE ENTIRE UNITED STATES, FOR EXAMPLE, AND STATES ADOPT THAT.
IT'S ALMOST AS IF SOMEBODY NEEDS, A GROUP NEEDS ON TO SIT DOWN AND COME UP WITH A MODEL, I WON'T CALL IT A MODEL REGULATION BUT A MODEL WAY OF WORKING FOR THESE KIND OF PLATFORM TRIALS.
IT WOULD LAY OUT WHO OWNS THE DATA AND DO THAT BEFORE THE NEXT PANDEMIC OR PUBLIC HEALTH CRISIS HITS.
SO THAT'S JUST MY THOUGHTS.
BUT, AGAIN, THAT'S SORT OF OUTSIDE MY BAILIWICK SOMEWHAT.
>> FERGUS AND KHAIR AND STEVE, DID YOU GUYS WANT TO COMMENT ON THE ISSUE?
>> I WOULD JUST GO AHEAD AND ADD ONE THING, AND I AGREE WITH ACTUALLY THE PREMISE OF WHAT YOU'RE STARTING REGARDING COMPETITION AND I THINK THERE ARE A LOT OF FACTORS HERE AT PLAY.
ONE ITEM THAT I'M ALWAYS REMINDED OF, I THINK MIGHT BE A LITTLE BIT LESS SEVERE BUT IT'S AN IMPORTANT ITEM NONETHELESS IS THE RISK AVERSION AND GOOD ENOUGH.
SO WHY CHANGE?
SOMEBODY MENTIONED THAT.
HOW TO SHIFT FROM THAT.
I THINK THE PANDEMIC IS A GOOD CATALYST FOR THAT, BUT HOW LONG THAT EFFECT IS GOING TO LAST CAN BE BUILT OUT ON THIS INFRASTRUCTURE WE NEED TO MOVE FORWARD WITH A CHANGE OF MENTALITY.
HESITANT TO BRING IT UP BUT I'VE BEEN HEARING MORE ABOUT IT, IS THAT A WAY AT LEAST TO ALLOW FOR ADDITIONAL RISKS TO BE TOLERATED AND HOW CAN WE ADDRESS THAT COLLECTIVELY.
EVEN AREAS THAT ARE WELL ESTABLISHED LIKE TAKE, FOR EXAMPLE, SPACE MONITORING, SOMETHING THAT THERE'S AN AGREEMENT ON AND THERE'S HESITATIONS, HOW TO OVERCOME THAT BEHAVIOR AND THINKING.
JUST WANT TO MENTION THAT AS ANOTHER CHALLENGE.
BACK TO YOU, FERGUS, PROBABLY FOR COMMENT.
>> THANK YOU.
I THINK THIS IS A REALLY KEY PART BECAUSE WE'VE HAD SOME VERY GOOD PLATFORM TRIALS, BUT SOME OF THE BEST ONES HAVE BEEN RUN IN A SINGLE LEGISLATURE AND POSSIBLE DATA ECOSYSTEM AND BUILDING A PROCESS THAT CAN ENABLE THAT ACROSS MULTIPLE COUNTRIES AND REGIONS GOES FROM THE POINT OF VIEW OF LEGISLATION AND REGULATION GUIDANCE, BUT ALSO THE WAY THAT DATA IS AVAILABLE, HANDLED, STORED AND COLLECTIBLE NEEDS ADDRESSING.
AND I'D COME BACK TO WHAT I SAID ABOUT BUILDING THE NON-COMPETITIVE SPACE.
ONCE YOU GET TWO OR THREE COMPANIES INVOLVED IN A PLATFORM TRIAL, I'VE BEEN IN SOME SUPER COMPLICATED DISCUSSIONS ABOUT YOU CAN'T SEE THAT OR YOU CAN'T SHOW YOU THAT AND SO ON.
WE CAN ONLY GIVE IT TO SOME EXPERTS AND NOT TO OTHERS.
AND THAT DISABLES THE -- THE THING PEOPLE ARE TRYING TO SET OUT TO ACHIEVE THEY DISABLE IT ALMOST BY DESIGN BECAUSE OF THE COMPLEXITY AROUND THE IP AND OTHER ASPECTS.
SO AND THE RESPONSIBILITIES.

WHO DOES PHARMACOVIGILANCE DRUG SAFETY ACROSS A PLATFORM TRIAL.
AND I DON'T THINK WE SHOULD JUST THINK IN PANDEMIC TERMS.
THESE ARE EXTENSIVELY USED FOR ONCOLOGY AND I'M SURE THERE ARE OTHER AREAS ALSO.
NEUROLOGICAL AREAS THAT WOULD BENEFIT ENORMOUSLY FROM THIS KIND OF PROCESS AS WELL.
SO WE NEED TO BUILD UP AND I'M LOOK AT MRCT, I THINK THAT M -- MAYBE THERE'S A ROLE THERE TO FACILITATE OR AT LEAST CATALYZE THIS DISCUSSION AND THEN REACHING OUT TO ORGANIZATIONS LIKE ICMRA AND OTHERS AND THE INDUSTRY AND PERHAPS EVENTUALLY WITHIN ICH WE CAN DO SOME THINGS AS WELL.
BUT WE NEED TO CREATE THE COMMON AREA BUT ALSO THE INFRASTRUCTURE THAT ONE OF THE DIFFICULTIES WE'VE SEEN IS THE ABILITY OF -- TO HAVE THE SAME SPOKESPERSON TALK TO EACH REGULATOR ON BEHALF OF THE MASTER PROTOCOL RATHER THAN INDIVIDUAL, LET'S SAY, NATIONAL HEALTH INSTITUTES, FOR EXAMPLE, AND YOU END UP WITH A FRAGMENTED APPROACH AND END UP WITH DIFFERENT PROTOCOLS IN DIFFERENT PLACES.
I THINK IT'S BUILDING AN ENTITY.
YOU TALKED ABOUT INTERNATIONAL CROS BUT SOME KIND OF PUBLIC-PRIVATE ENTITY OR A MODEL, WHAT YOU SAID ABOUT MODEL RULES, A MODEL WAVE DOING THESE THINGS THAT COULD THEN BE ADOPTED BY PEOPLE WOULD BE A MODEL CONTRACTS, ET CETERA.
>> ALL OF YOU WERE TOO KIND TO OBSERVE THE PRIMARY OBSTACLE TO MANY OF THESE EFFORTS IS THE LAWYERS WITHIN THE INSTITUTIONS BECAUSE THEY'RE THE MOST CONSERVATIVE.
THEY ALWAYS SAY NO.
THEY'RE SCARED OF EVERYTHING.
>> THE OBJECT IS NOT TO TAKE THE RISK THAT'S FINE.
WE SHOULD REACH OUT, MARK, TO THE REMAP CAP FOLKS BECAUSE THEY BASICALLY IMPLEMENTED THIS IN REALTIME AND MY UNDERSTANDING IS EARLY ON THEY RAN INTO THESE ISSUES, THEY COULDN'T TRANSFER DATA BETWEEN THEIR SITES.
AND THEY'RE TRYING TO MAKE DOWN-REGULATION DECISIONS DROPPING ARMS AND SO I THINK THERE MIGHT BE SOME INTERESTING LEARNING LESSONS THERE.
SORRY.
DIDN'T MEAN TO CUT YOU OFF.
>> I'M GLAD FERGUS BROUGHT UP THE COMPLEXITIES OF PHARMACOVIGILANCE AND THESE MULTI COMPANY PLATFORM TRIALS.
I'VE BEEN INVOLVED WITH MANY MARKETED DRUG COLLABORATIONS, AND THE PHARMACOVIGILANCE AGREEMENTS BECAUSE IT'S COMPLIANCE RELATED, YOU HAVE CERTAIN TIMEFRAMES IF IT'S IN ONE CATEGORY YOU HAVE TO HIT THE TIMEFRAME OR YOU'RE OUT OF COMPLIANCE.
THOSE CAN RUN HUNDREDS OF PAGES AND GET EXTRAORDINARILY COMPLICATED.
BUT I THINK HAVING ONE ENTITY AND ALSO THE OTHER THING THAT FERGUS RAISED WHICH IS HAVING ONE FACE TO THE AGENCY AND DOING THAT GLOBALLY A COMPANY THE SIZE OF PFIZER COULD DO THAT IF WE WERE PARTNERED WITH ANOTHER COMPANY BUT IF WE'RE NOT PARTNERED WITH THEM I'M NOT SURE HOW WE WOULD WORK THAT OUT FRANKLY.
THERE ARE MAJOR GLOBAL CRO'S WHO HAVE REGULATORY INFRASTRUCTURE IN ALL THE MAJOR MARKETS AND THEY COULD BE ABLE TO DO THAT IN A MULTI REGIONAL SETTING.
SO.

>> WELL, I THINK WE'LL CLOSE HERE UNLESS ANY OF YOU WANT TO MAKE A FINAL COMMENT ABOUT ANYTHING.
>> JUST ONE THING I WANT TO SAY, MARK, ON BEHALF OF THE PANEL I WAS GOING TO APOLOGIZE TO ALL THE WOMEN ON THE -- BECAUSE WHEN WE HAD TO PREP FOR THIS MEETING WE HAD CARMEN, SARAH AND WE HAD GINNY ON THE PHONE AND MARK ALL IN THE SCREEN, MARK, YOU WERE ON THE PHONE AND I LOOKED AT THE GROUP AND I THOUGHT OH, THIS IS GREAT, IT'S A SPLIT OF MEN AND WOMEN AND THEN WHEN THE FIVE OF US SHOWED UP I THOUGHT OH, GOD WE'VE CREATED A MANHOLE.
APOLOGIZE TO THE LADIES WE SHALL BE CAREFUL FOR THAT AND THANK YOU FOR OF REST OF YOU COMING ON BECAUSE THIS IS WHAT IT LOOKED LIKE BEFORE.
>> SARAH AND I ALREADY HAD THAT CONVERSATION OFFLINE.
WHAT HAPPENED?
WE REALLY, REALLY APPRECIATE YOUR DISCUSSION TODAY AND I JUST WANT TO ADD THAT IN ADDITION TO ONCOLOGY, THERE ARE OTHER PLACES LIKE PEDIATRICS THAT WOULD BENEFIT FROM THIS AND THERE ARE LOTS OF EXAMPLES WHERE WE COULD TAKE SMALL STEPS AND BUILD THAT COLLABORATION.
>> PEDIATRICS IS AN EXCELLENT EXAMPLE BECAUSE THE MARKET ISN'T THAT BIG TYPICALLY.
SO THE COMPETITIVE ISSUE IS FRANKLY NOT THERE.
AND IT IS INCREASINGLY HARD TO DO PEDIATRIC STUDIES IN AREAS THAT ALREADY HAVE DRUGS APPROVED.
IT CAN ALSO BECOME IMPOSSIBLE, I CAN TELL YOU IN IMMUNOLOGY THERE ARE AREAS BECOMING EXTRAORDINARILY DIFFICULT TO DO THESE STUDIES.
>> AND JUST AS YOU WERE SPEAKING ABOUT A DATA TRUST, THINKING ABOUT WHO IS THE TRUSTED CONVENER, BOTH FOR THE, QUOTE, MODEL AND THEN FOR THIS ADVANCING THE PRECOMPETITIVE AND MULTI-STAKEHOLDER GROUP IS ANOTHER QUESTION THAT WE SHOULD CONTINUE TO PUSH ON.
GREAT.
DO YOU WANT TO SAY THANK YOU TO YOUR TEAM?
OR DO YOU WANT TO CLOSE?
>> ARE YOU TALKING TO ME, BARBARA?
>> YEAH.
>> HOW DO YOU WANT DO THIS?
>> I'LL JUST SAY THANK YOU VERY MUCH TO THE PANEL THAT WAS THE MANHOLE.
WHEN YOU GUYS GOT ON THE THING I THOUGHT OH, MY LORD WHAT'S THIS?
YOU GUYS DID A GREAT JOB AND THANK YOU VERY MUCH FOR SHARING YOUR DIFFERENT PERSPECTIVES AND OWEN, THANK YOU FOR SPEAKING UP ON BEHALF OF REGULATORS.
>> YOU'RE WELCOME.
I USED TO BE ONE WAY BACK WHEN.
I WORKED AT FDA WAY BACK WHEN, SO --
>> A LOT OF GRADUATES OF REGULATORY AGENCIES AROUND THE WORLD.
>> BARBARA, BACK TO YOU TO CLOSE.
>> SO I JUST WANT TO THANK EVERYONE TODAY AND LAST WEEK.
I THINK THAT COLLECTIVELY WE'VE HEARD A LOT OF IDEAS.

AND NOW THE REAL QUESTION IS HOW TO WE USE THIS TO USE THE MOMENT AND NOT LET A GOOD PANDEMIC GO TO WASTE, AN IT WERE.
WE DID A LOT OF OVER THE LAST YEAR AND A HALF, AND I'M REALLY WORRIED THAT WE'RE GOING TO LOSE A LOT OF THOSE LEARNINGS AND WE'LL SORT OF MAKE CHANGES AT THE EDGES BUT NOT REALLY DRIVE CHANGE IN A WAY THAT IS GOING TO BENEFIT PUBLIC HEALTH IN A MAJOR WAY.
AND THAT IS, YOU KNOW, REALLY CONCERNING TO ALL OF US, I THINK.
OF COURSE, THERE WILL BE ANOTHER PANDEMIC AND CERTAINLY EPIDEMICS AND WE'VE NOT PUT IN INFRASTRUCTURE FOR PANDEMIC PREPAREDNESS, THE ELEMENTS OF WHICH CAN THEN BE USED FOR RARE DISEASES, ULTRA RARE DISEASES, OTHER COMMON DISEASES ONCE WE GET COMFORTABLE IN THE WAY OF DOING BUSINESS, I THINK IS -- WOULD BE A REAL LOSS TO SOCIETY AND HUMANITY.
I ALSO -- I THINK THAT WE NEED TO BRING -- I'M PERSONALLY, AND I DON'T SPEAK FOR ANYBODY ELSE, I THINK ONE OF THE MAJOR CHALLENGES THAT I FELT OVER THE LAST YEAR OR THE FIRST YEAR WAS THE POLITICALIZATION OF SCIENCE IN MEDICINE.
AND THAT WAS PARTICULARLY TRUE IN AMERICA AND I THINK WE HAVE TO MAKE SURE WE DO WHATEVER WE CAN TO PROTECT THE SCIENCE OF EVIDENCE AND DATA AND BUILD BACK TRUST THAT WE NEED GOING FORWARD.
AND I DO THINK THAT THIS QUESTION OF HOW DO WE BUILD AN INTERNATIONAL MULTI-STAKEHOLDER COMMUNITY DEDICATED TO DOING THIS WORK AT A TIME WHEN WE'RE NOT IN CRISIS AND THEN FIGURING OUT HOW TO FUND THAT SO THAT PEOPLE WHO ARE WORKING 15 HOURS, 24/SEVEN, 365, MANY OF WHICH WE'RE LOOKING AT ON THE SCREEN TODAY, ARE RESOURCED APPROPRIATELY SO THAT WE CAN KEEP THE INFRASTRUCTURE ALIVE AND WARM AS WE SORT OF DO BUSINESS AS USUAL AND THEN CAN SCALE AT TIMES OF CRISIS.
SO I CAN'T THANK YOU ENOUGH NOT ONLY FOR TODAY AND LAST WEEK BUT ALSO FOR YOUR EFFORTS IN THE LAST 18 MONTHS AND YOUR COMMUNICATION, COLLABORATION, FRIENDSHIP, AND GIFTS TO ALL.
SARAH?
MARK?
>> I WOULD JUST REALLY LIKE TO SAY THANK YOU.
I DON'T THINK I HAVE ANY OTHER WORDS OF WISDOM BEYOND, BARBARA, WHAT YOU'VE JUST SAID.
WE'RE DEFINITELY IN AN OPPORTUNITY, MOMENT OF OPPORTUNITY, THAT WE SHOULD ALL SEIZE.
I THINK AT THIS MOMENT WE CAN SAY THANK YOU TO ALL OF THE PANELISTS BOTH DAY ONE AND DAY TWO.
THANKS TO THE MODERATORS, THANK YOU FERGUS AND GINNY FOR SPEAKING EARLIER TODAY.
AND THANKS TO ALL THE ATTENDEES FOR BEING WITH US ON BOTH DAYS.
>> PROCEEDINGS AND THE --
>> CARMEN HAS A SLIDE THAT HAS THE LINK TO THE RECORDING FROM THE FIRST DAY, WHICH WILL LIKELY ALSO BE THE LINK TO THE SECOND DAY.
ACTUALLY, THE RECORDINGS WILL BE AVAILABLE SOONER THAN THE PROCEEDINGS.
DAY ONE IS ALREADY AVAILABLE, IT'S LIKELY THAT TODAY'S PROCEEDINGS WILL BE AVAILABLE BY THE END OF THE WEEK.
AND THEN PROCEEDINGS WILL FOLLOW SHORTLY.
AND THEN WITH THAT, WE CAN CLOSE THE MEETING.

THANK YOU SO MUCH, EVERYONE.

>> THANK YOU.

>> THANK YOU.

>> THANK YOU.

>> THANKS, ALL.

>> THANK YOU.