Fall 2020 SWOG DIGITAL ENGAGEMENT CMTE Meeting – Virtual

SUMMARY

Date: Wednesday, September 23, 2020
Time: 2:30 – 4:00 PM CT

Attending: See roll call at 0:01:37.

Agenda:

Welcome and Agenda Overview – Don Dizon, MD, chair

Roll Call – Wendy Lawton, liaison

Blue Note Therapeutics – Blue Note + the team

Leaders from Blue Note Therapeutics, a California-based, venture-backed company providing digital mental health interventions to patients, including a COVID cancer program currently in testing for treatment of stress and anxiety. We get a brief presentation and ask questions.

Strategy Update – Wendy Lawton, liaison

We get the status on the social media tool kit, plain language initiative and other elements in our social media strategic plan. Be prepared to ask and answer questions and talk about moving projects forward.

Cancer Briefs Update – Jonathan Sommers

We get an update on our Hope-funded video project.

Digital Engagement Future – Don

What's our value proposition? Our committee has evolved tremendously over time, work that has included running our own projects, providing strategic communication advice, and reviewing and approving SWOG surveys. What tasks should we keep, and what new work can we do, to improve our cancer clinical trials?

Next Steps and Adjourn

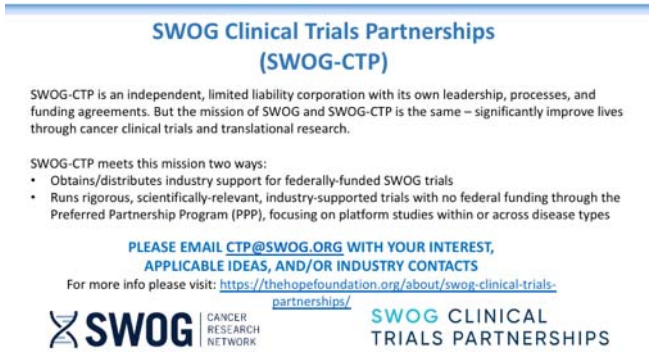
Additional Information

[Chat Record]

0:00:00

Don Dizon noted that several of the Digital Engagement Committee (DEC) members are on the SWOG Clinical Trials Partnership (SWOG-CTP) advising committee.

- CTP trying to do cancer clinical trials in its broadest definition
- Also translational research
- Looking for partners to design, develop, and run trials of mutual interest
- Anyone interested should reach out to Wendy Lawton and Dizon
- DEC members should be aware of this
- Kathy Albain, leader of CTP, is always interested in discussing partnerships and development of innovative trials



SWOG Clinical Trials Partnerships (SWOG-CTP)

SWOG-CTP is an independent, limited liability corporation with its own leadership, processes, and funding agreements. But the mission of SWOG and SWOG-CTP is the same – significantly improve lives through cancer clinical trials and translational research.

SWOG-CTP meets this mission two ways:

- Obtains/distributes industry support for federally-funded SWOG trials
- Runs rigorous, scientifically-relevant, industry-supported trials with no federal funding through the Preferred Partnership Program (PPP), focusing on platform studies within or across disease types

PLEASE EMAIL CTP@SWOG.ORG WITH YOUR INTEREST, APPLICABLE IDEAS, AND/OR INDUSTRY CONTACTS

For more info please visit: https://thehopefoundation.org/about/swog-clinical-trials-partnerships/

SWOG CANCER RESEARCH NETWORK

SWOG CLINICAL TRIALS PARTNERSHIPS

Welcome and Agenda Overview

0:01:10

Dizon welcomed members to the DEC meeting and noted it was an open session with all invited.

- Started with roll call with Lawton: DEC members first, then others

Digital Engagement Committee
AGENDA
Sept. 23, 2020
2:30-4:00 p.m. Central Time
(Note we're going with Chicago time for all group meeting sessions)

2:30 p.m.	**Welcome and agenda overview**	Don Dizon, MD, chair
2:35 p.m.	**Roll call**	Wendy Lawton, liaison
2:40 p.m.	**Blue Note Therapeutics**	Blue Note + the team
	Leaders from Blue Note Therapeutics, a California-based, venture-backed company providing digital mental health interventions to patients, including a COVID cancer program currently in testing for treatment of stress and anxiety. We get a brief presentation and ask questions.	
3:10 p.m.	**Strategy Update**	Wendy Lawton, liaison
	We get the status on the social media tool kit, plain language initiative	

Roll Call

0:01:37

Lawton took roll call. Those present included the following:

- Sanjay Aneja
- Lisa Barnstrom
- Don Dizon
- Zeynep Eroglu
- Mike Fisch
- Amy Geschwender
- Krishna Gunturu
- Julie Gralow
- Dan Hertz
- Becky Johnson
- Jennifer Klemp
- Mark Lewis
- Jennifer Maeser
- Ginny Mason
- Anne Marie Mercurio
- Erin McCaig
- Craig Nichols
- Lynn Nguyen
- Kanwal Raghav
- Heloisa Soares
- Jonathan Sommers
- Dana Sparks
- Saad Usmani

0:05:15

Dizon asked those joining from SWOG but not members of the committee (but very welcome) to introduce themselves. The following did:

- Norb Strauss, Ops
- Michelle Kirschner, U Cincinnati

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3:10 p.m.	**Strategy Update** We get the status on the social media tool kit, plain language initiative	Wendy Lawton, liaison

- Jeff Berenberg
- Kathy Crew, Columbia
- Allison Rosen, AYA Community Advocate
- Eileen Fuentes, Latinx Community Advocate

Dizon and Lawton also welcomed

- Whitney Leslie (running the slides)
- Betsy Barnick, Carle NCORP
- Beth Pallante, Heartland NCORP
- Judy Hancock, CCDR Lead, Ozarks NCORP

The following were deemed not present at time of roll call:

- Morgan Cox
- Jo Horn
- Kara Smigel
- Sarah Mougalian
- Neema Navai
- Mina Sedrak
- Mindy Whisnant

0:06:42
Dizon encouraged those visitors with questions to use the Chat. He then introduced Blue Note Therapeutics.

Blue Note Therapeutics

0:07:00

Mark Elfers from Blue Note Therapeutics introduced CEO Geoff Eich to present.

- Eich asked to jump to slide 3 of the Blue Note set

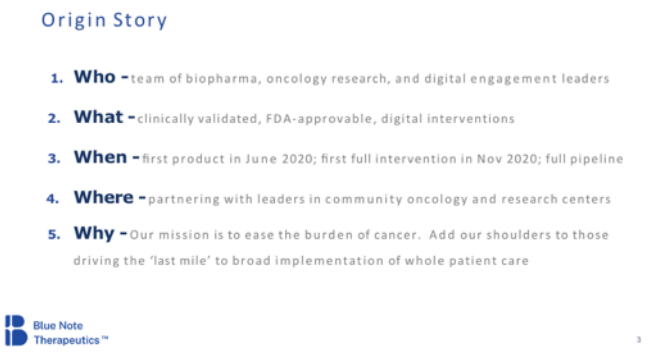
0:07:45

Eich introduced colleagues with him:

- Dr. Diane Shumay, clinical psychologist with focus in oncology
- Laura Chavaree, clinical social worker with experience at Genentech and in other entrepreneurial areas to help patients have access to oncology medicines
- Mark Elfers, head of finance and operations
- Michael Malecki, heading up access and reimbursement work

Eich gave some background on Blue Note:

- Small company
- Founded 2019 to contribute to oncology care through digital media
- Most of team came from roles in oncology research via pharma or digital engagement
- Came together to try to create FDA-approvable Class 2 digital medical device that could help in adjunct care with cancer patients to address, among other things, anxiety and depression
- Saw Institute of Medicine report in 2008
- Met Patty Ganz and others who had done much of that work
- Also saw distress guidelines and reviewed number of interventions that were in use for cancer patients in leading cancer centers in US and Europe
- Eich joined from Copenhagen for three reasons:



    - Would be leading in application of digital therapeutics in cancer care
    - Would be seeking clinical validation through trials and FDA approval as medical device
    - Would seek conventional coverage and reimbursement
        - Meant their device would not contribute to financial toxicity of cancer and could help address needs of cancer patients, including in underserved communities
    - Has remained their focus
- Have moved quickly to license, through Dr. Michael Antoni's work at U Miami, well-researched interventions
- Worked with multidisciplinary team to create digital version of those interventions
- Result: cancer patient not able to access mental health care at cancer center could access similar virtual experience through digital device

Eich said Blue Note launched in last few months their first basic product:

- Free tool for cancer patients during COVID
- Team have had number of family members with cancer
- Worked with FDA and received breakthrough device designation for their lead intervention
- That product under public health emergency will become available to cancer patients this fall
- Proud of fact that through Diane and Laura's work cancer patients have reviewed all content of intervention, and their feedback has been incorporated to ensure device is accessible to all patients
- Have established pipeline of interventions ranging from those for early cancer in outpatients to more specific care for inpatients and noncurative care and survivorship care

Eich said they would like to share more about company because each intervention will require research partnership to move forward to FDA approval.

- Have committed with NRG to work on lead intervention

- Series of additional interventions coming into development over next 6–8 months
- Interested in continuing collaboration
- Had great welcome from oncology and psych-oncology communities.
- Would like opportunity to work with SWOG to tailor products to benefit patients

Eich asked for questions.

Dizon noted not everyone may be aware of Antoni's work. Give brief overview? Eich agreed.

Eich said lead intervention is called cognitive behavioral stress management (CBSM).

- Combines relaxation training with cancer-specific cognitive behavioral therapy (CBT) regimen
- In face-to-face form, it's a group dynamic of 10 sessions, each teaching different set of skills
- Chose this intervention to start because of amount of research done on it in range of populations
    - Breast cancer patients
    - Prostate cancer patients
- Also dismantling studies to understand separately the effects of relaxation training and cancer-specific CBT
- Also adaptations for underserved populations with promising results
- Went to FDA with existing evidence and info on what evidence Blue Note wants to generate to earn FDA approval
    - Evidence that virtual group experience would give patients same benefits
- CBSM has been shown in preliminary work to improve overall cancer care and outcomes
    - Certainly want to pursue this, but not seeking it as part of label initially

    - But really interested in work done with biomarkers and epigenetics to understand if their intervention is mediating pro-inflammatory signals by reducing stress
- Near-term benefit is reduction of symptoms of anxiety and depression in cancer patients

Dizon asked whether their pipeline is strictly in psychosocial space.

- Eich said it is
- Want to focus on easing burden of cancer for patients to improve physical health and behaviors

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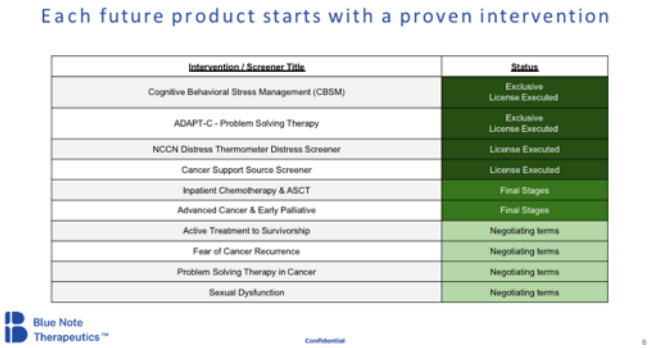
0:16:57

0:16:58

0:16:59

Eich noted slide 6 shows some of the progress on their pipeline to date.

- Interested in how immersive digital experience can increase access for patients not able to seek care in a physical setting
- Also excited about "win/win/win": easing burden of cancer for patients, improving patient self-efficacy, while also giving providers option for intervention that is evidence-based and FDA-approved
    - Also to help health systems reduce unnecessary treatment expenses and suboptimal outcomes
- Said in their experience, there are few cases where win is provided for patient, provider, and payer – all three
- Have worked with several institutions and payers, in addition to extensive work with patients



0:18:26

Craig Nichols asked for a higher level view:

- Blue Note a hardware or software company?
- Eich said software as a medical device
    - Still a question whether at some point during company's evolution they would want to adopt hardware to improve access
    - Also, to improve physical health, is there a role for some in-house technology that could enhance benefits?
- Eich said today they are software as a medical device, and conversations with FDA today are for Class 2 prescription medical device adjunct to oncology care
- Said person who will write Rx for lead product would be interdisciplinary team member—oncologist, nurse practitioner, or PA

Nichols asked whether they were hardware-agnostic and EMR-agnostic.

- Eich confirmed both were correct
- Targeting both Android and iOS for tablets and phones
- For COVID tool, they've used a web-based browser (covidcancercare.com), but everything forward will be mobile-based

- They will ensure there's an Rx and fulfilment system available
- Will also help to personalize onboarding patients into the digital experience

Nichols asked what their business plan is and who their customer is.

- Eich said they've determined there is good product market fit in between time of screening that first recognizes distress and when there is availability for consult in cancer centers
- Second important area is patient transition out of active treatment to survivorship
    - Seeing lot of demand here
- They anticipate that, with lead product they will launch under public health emergency, they will want to engage with set of cancer sectors that can help them refine the market fit and their ability to integrate with existing care pathways
    - What is the amount of information that needs to be shared between device and the prescriber re patient's continuation?
    - Past work suggested more integration was better
    - But their work has shown them that oncologists, psychologists, and patients were all uninterested in extensive amount of information interoperability
    - Instead, were specific bits of information that need to be conveyed at specific times
    - Need to explore and refine this with partner organizations

Nichols said he assumes they will sell to large integrated health care systems rather than providers or patients.

- Eich concurred
- Excited about progress they've made in working directly with number of payers
- Payers immediately recognize benefits and that product should be used coincident with diagnosis and treatment of cancer
- Recognize that this is not part of a mental health benefit but part of the cancer benefit for patients

- Blue Note anticipates it will become part of patient benefit under either Medicare or private insurance

Nichols asked whether using this system to capture patient voices and PROs is on their agenda.

- Eich said yes—using cutting edge PROs in their clinical studies
- Have also worked with FDA and want to see ClinROs as well (clinician-reported outcomes) to compare them to PROs
- He identified one of most exciting opportunities as ability to study tens to hundreds of thousands of cancer patients on use of a consistent, well-controlled intervention to understand drivers that mediate health behavior, positive affect, adherence to therapy
- They feel strongly about use of this data to perform research
- Patients respond well to having their anonymized data used for research
- Not talking about inappropriate use or sale of data
- Now looking at 150–200 patients and testing few aspects, but will be able to test many more in many more patients

Dizon asked whether others had questions.

Dawn Hershman asked about getting CMS to pay for some basic things:
1) what would charge be exactly for enrolling patient in program like this and 2) has it been studied in randomized fashion to assess efficacy on population level?

- Eich confirmed it's been studied in number of randomized trials
    - One of the reasons they chose this lead intervention
    - First studies published in 2006 …
- Hershman stepped in to focus question on Blue Note's device in particular rather than CBT studies generally
- Eich said their studies they will work on this fall with FDA will depart from face-to-face intervention
- They will run a pilot study this fall and a registration study staring Q1 2021 for data for FDA approval outside of public health emergency

- Payment model:
    - Medicare already pays through CPT codes for subset of these types of services face-to-face
    - They know from other therapy areas that through CMS they can convert CPT codes, and there's proposed rule for breakthrough devices such as this that they will give 4 years of coverage on FDA clearance
    - Also can work with Medicare Advantage payers
    - Will look at each segment—private payers, fee-for-service Medicare, and Medicare Advantage—to ensure it is covered

Jennifer Klemp had two questions:

- 1) Will they have ability to white-label the product as well?
- 2) Feedback loop to organization: How do they get feedback to organization? Discrete data?
- Eich said in response to white-labeling question they will want to customize device to certain institutions
    - E.g., in stepped-care model, important that lower and upper steps connect seamlessly into organization's care pathways
- Not considering true open label or white label at this time, as it's more difficult to do this with FDA, which wants to see that active treatment part is locked down and clinically validated
- As for data, Eich said two aspects they think will be important:
    - 1) What information about patient's progress through this intervention comes back to physician prior to visit?
        - Have heard everything ranging from limited information that patient has started intervention all the way to lab values in the EHR that patient had discontinued, is continuing, or is not yet initiating
    - 2) Also envision on research side tremendous value to institutions to be able to see aggregated results for cohort participating with the device

- Blue Note is also excited about idea of providing win/win/win in terms of cost offsets and adherence to treatment and allowing institutions to see, on aggregate level, the benefit of this

0:32:04
Question from Anne Marie Mercurio:

- 1) Does patient have dominion over their own data as they're inputting it?
- 2) How can we make sure we're not creating new category within diversity situation: people in rural areas with limited Internet access or elderly challenged by digital devices?
- Eich answered second question first:
    - Working with groups to evaluate: get lots of patient cocreation up front from groups of patients diverse in every way: SES, access, comfort, age, ethnicity, language, etc.
    - Building these aspect in from start, with idea that access is equal to getting care in top cancer centers
    - In clinical development work, studying digital version with underserved populations so they can understand how they're doing and where to improve
    - They also know that, e.g., Spanish-speaking patients have steeper route to getting care. Want to translate experience into Spanish ASAP and study that in Spanish-speaking populations
- Eich addressed data security:
    - Doing everything possible to be EU-compliant with data (similar to California level of law). Concept is individual citizens have ownership of their data
    - Their privacy statement tells patients exactly what their objectives are, sources of data, how they're used
    - Need to be very explicit with patients

Becky Johnson asked about patient interface. Looks impressive, but are users interacting with people, either group leader or other patients? Or just with computer?

- Eich said there's core active ingredient which is locked and all patients experience. Includes group dynamics that include archetypal patients in group to emphasize certain skills or circumstances
- As product evolves over next 6 months, will also incorporate content outside locked core where patients will have ability for asynchronous communication
    - Patient research has strongly guided them to this: have to find a way to do this
    - Not simple, and also need to figure out how to moderate it
    - Good examples of this in consumer products (Peloton, Strava, etc.) to help them understand how to do this

Dizon noted group in this meeting included leaders from multiple arenas, including patient advocates, AYA group, chair of symptoms and survivorship, head of NCORP. Wanted to encourage conversation going forward.

- Told Blue Note about CTI and will put them in touch
- Group members are investigators at heart and would be interested in evidence-based interventions Blue Note's trying to transition to digital space to help investigators' own patients
- Sees digital engagement as conduit to bring them and investigators on disease site teams together
- Encouraged all to think about this
- Spoke highly of his experience engaging with Blue Note at Lifespan Cancer Institute
    - Been exceptionally willing to engage and really interested in feedback
    - Have well-rounded, engaged, evidence-based team
- Asked if SWOG can engage with them in implementation work or clinical research work?
- Happy to provide introductions. Anyone who wants introductions should speak to Lawton
- Encouraged chairs and liaisons on call to take this message back to their committees

Eich thanked group for contributions to patients, said they enjoy following a number of members on Twitter.

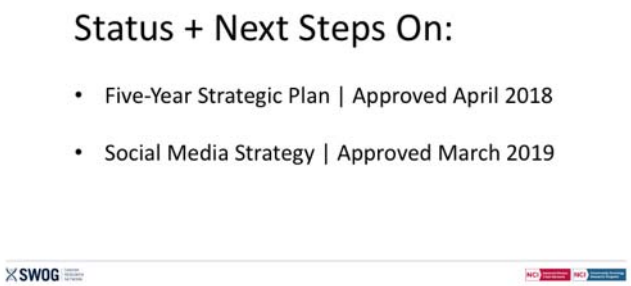
Strategy Update
0:40:25
Dizon introduced Lawton with Strategy Update.

0:40:40
Lawton thanked group for attending.

- In 2018 and 2019, DEC approved plans; Lawton was checking in with progress report

0:41:27

- In April 2018 DEC approved 5-year strategic plan
- Last year DEC approved social media strategy
- Important for accountability, as team and for Lawton personally, to check in
- Doing well, but much has changed in the world
- COVID, but also plain language
- DEC approved both plans before SWOG moved on plain language efforts



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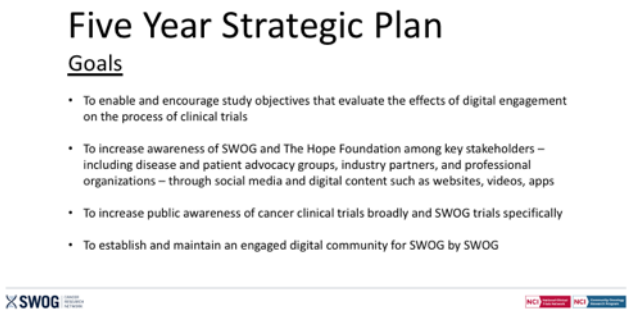
Lawton said she would walk group through plans and progress.

- Five-year strategic plan had goals listed in slide
- Focus was on
    - Evaluating digital tools and how they work in trials
    - Increasing awareness of SWOG and Hope
    - Increasing awareness of clinical trials
    - Establishing and maintaining engaged digital community



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DEC then developed action plan. Report of status:

- Streamlining informed consent procedures: have not moved on this
- Agreed to do surveys, but have not moved on this
- Grow social media presence
    - Have been doing this in spades
    - Twitter in particular: now 9,400+ followers
- Explore private virtual spaces with private Facebook group
    - Closed after 1-year test
- Establish presence in research committees
    - Have established liaison positions

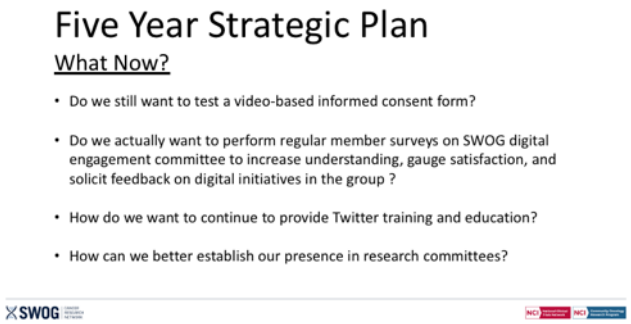
0:43:52

Last part of strategic plan listed critical measures of success.

- Testing video-based informed consent
  - Not moved on
- Working with entertainment partners to launch web-based video project
  - Well in progress with Jonathan Sommers
  - Approaching finish line
- Helping SWOG committee launch trial to evaluate digital tool
  - Been doing this
  - Taking on Heloisa and her project
- Tried and closed private Facebook group
  - Wanted to grow to at least 500 members
  - After a year was clear it would not meet goal
  - Considered it a negative trial
- Increasing SWOG followers
  - Already exceeded 5-year goal with Twitter
  - Have not yet approached goals with LinkedIn and YouTube, but moving the needle
- Great administrative support from Whitney Leslie, thanks to Casey Dawson
- Also completed, thanks to Lisa and colleagues, Twitter training for members

0:45:48
Big questions in 5-year plan:

- Does DEC still want to test video-based informed consent?
- Perform regular member surveys on digital engagement?
- How does DEC continue to provide Twitter training?
    - Started in fall 2019
    - Not able to do it this virtual meeting
    - Want to continue, but how?
- How does DEC better establish presence in research committees?
    - Looking at liaison roles



0:46:44
Social media (SM) strategy goals:

- Create SM toolkit for every new trial
- Form SM partnership with NCI Contact Center
    - 1-800-4-CANCER
- Improve and expand SM platforms
- Outline content strategy
- Create tracking system to produce key metrics
- Host SM training

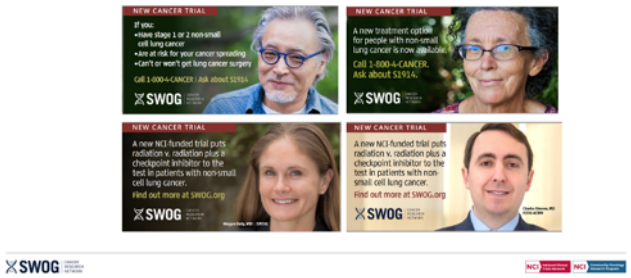
0:47:20
SM toolkit in progress:

- Lawton wrote first plain language summary

0:47:34

- Have SM graphics and social posts
- Test trial is lung trial just activated: S1914
    - Radiation trial
- Lawton's personal goal is plain language summaries for all trials open in 2020 (10+)
    - Get these posted to a page on SWOG website
    - Send out tweets
    - Do this even though no plain language writer on board
        - Because of OHSU hiring freeze
        - Probably won't be able to hire until well into 2021
    - Thinks plain language is one thing that can have significant impact on trials and patients, so a priority for Lawton

S1914



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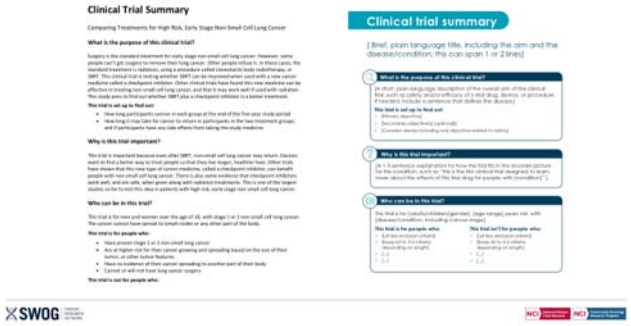
- Plain language summary:
    - S1914 plain language text at left in slide
    - Magic of design will make website presentation look like template at right



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SM strategy “yes” zone:

- In May formed partnership with NCI Contact Center
- Included in grant request
- Good 5-year partnership with them
- Can use 1-800-4-CANCER info on swog.org and in tweets
- Important because for those with questions about our trials, missing link has been customer service
    - Who can they call?
    - Can print plain language summary, call 1-800-4-CANCER, and discuss with them
        - Eligibility?
        - Local?
- Have launched SM training

0:50:41
SM strategy goals in progress:

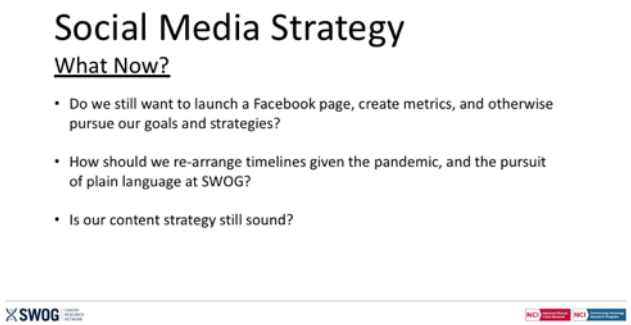
- Improving and expanding SM platforms
    - Supposed to launch public Facebook page
    - Need to expand LinkedIn and YouTube presence
- Growth of SWOG Twitter platform is amazing
    - But progress still to come on Facebook and other channels
- Have content strategy outlined in social plan
    - Lawton would like to revisit with DEC

0:51:37
SM strategy goals that have not moved:

- Key metrics tracking

0:51:49
SM strategy questions:

- Does DEC still want to launch Facebook page?
- Still want to do metrics?
- How to rearrange timelines, given pandemic?
- Pursuit of plain language at SWOG?
- Some of the goals in this realm got run over by COVID
- Important to reconfigure timelines
- Is content strategy for Twitter still sound?



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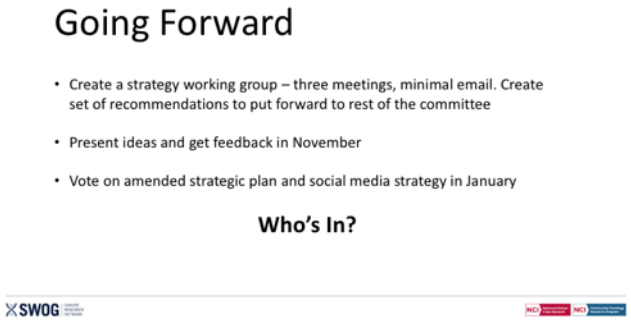
Going forward:

- Lawton wants to create small strategy working group
    - Few meetings, minimal email
- Revisit documents and create recommendations to bring to DEC
- Get feedback on next DEC call in November
- Vote formally on amended strategic plan and social strategy in January

Encouraged members to email her if they want to be part of working group.

Dizon pointed out that DEC has evolved significantly since its formation.



- DEC has huge task with few resources
- Reminded DEC that Lawton has charge of running all communications for SWOG
    - Whitney will now assist, but asking one person with other responsibilities to manage SM engagement is daunting challenge

Questions and comments.

Dawn Hershman thanked Lawton, agreed with revisiting strategic plan, given pace of change around us.

- Many recent changes will become permanent
- Don't know best practices yet
- Doing much virtually with technologies, so not question of can we but how can we do it better
    - How can we help sites?
    - How can we learn from each other?
- Gone from "do we?" to "how do we do this better?"
- Lawton agreed and noted days of video consent are here, based on NCI allowances
    - Does this group still want to make this a project?

Lawton noted agreement in Chat to revisit Facebook, as that world and brand have changed.

Volunteers for Lawton's working group included

- Anne Marie Mercurio
- Jonathan Sommers
- Lisa
- Heloisa Soares
- Lynne Nguyen (maybe)
- Others encouraged to sign up as well

Dizon followed up on Hershman's comment:

- What is within purview of DEC?
- And what has become part of mission of other SWOG committees?
- Digital consenting is good example of this
- World has evolved quickly

Craig Nichols invoked overall SWOG strategic plan. With all going forward, SWOG needs to revisit overall plan.

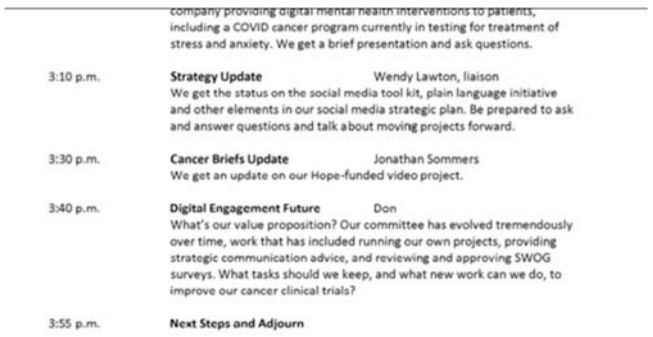
- Hope to bring this to a working group end of year or early next year
- Has discussed with Hershman: expects digital engagement will be important aspect in reimagining SWOG strategic plan
- Will happen on multiple levels
- Group will be depending on DEC

Lawton thanked group for insights and offers of help.

Cancer Briefs Update
0:59:10
Dizon introduced Jonathan Sommers.

Sommers provided update on Cancer Briefs project.

- Episode 1 is done
    - Episode goal is to increase awareness of cancer clinical trials overall
- Episode 2 has been shot and is being edited
    - Topic is cancer disparities
    - Can send around a rough cut for those who want to see it
- Episode 3 meant to increase awareness of a specific trial: S1501
    - Had been about to start production March 15, 2020
    - Had IRB-approved script, talent, etc.
    - COVID shut everything down
- Advice of TV4 [Sommer's organization] marketing department was that launching product during pandemic would produce false numbers
    - Fear of COVID meant public did not have appetite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3:55 p.m. **Next Steps and Adjourn**

    - Current politics also argue against launch now
- Will continue producing Episode 2
- No need to edit Episode 3 script
    - One issue was using generic name
    - Workaround in that shot was to use [inaudible 1:04:40] rather than having to edit script
- In mid- to late October will film Episode 3
    - Los Angeles filming opening back up under set guidelines
- As time goes on, people learning to live—and film—with COVID, for example:
    - Every person will have their own script copy
    - Everyone on set has temperature taken
    - Those not being filmed are wearing masks
    - Rethinking shooting:
        - Need two people in frame, or do with just one?
        - Film all of one character's scenes in one day?
    - Trying to minimize issues
- Looking forward to filming
- Locking down sound stage for interior shots
- Have exterior shots of home and garden
- Expects this to be most exciting and fun episode

Dizon asked whether any episode was yet in final form.

- Sommers said by late 2020 would be ready to go
- Lawton asked whether all three would be ready late 2020
- Sommers confirmed yes
    - Needs approval from SWOG and Hope
- Dizon wants to see all three

Digital Engagement Future

1:04:58

Dizon discussed conversation he had had with Nichols and Lawton about what DE has done and is doing.

- What is DEC future?
- Wants to wrap up discussion in 10 minutes to have time for open business.

1:05:42

Value DEC brings to digital engagement:

- Provide expertise in SM, text messaging
- Can bring folks to table in web and mobile apps space
- Can be bridge for SWOG investigators to digital therapeutics
- Apply expertise not only to DEC work but hope to inform trials under development

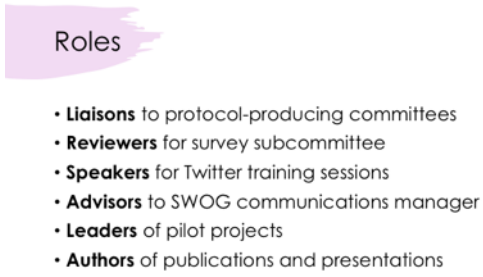
1:06:21

Current mission discussed (Lawton already reviewed):

- Advise
- Train
- Provide approval for survey projects
- Can try to launch pilot projects
    - Have one with Cancer Briefs
- Provide leadership for SWOG, NCI, broader research community
    - The last through papers published
    - Shout out to Krishna for second DEC paper
- Through publications and presentations making mark outside of SWOG

1:07:11
What DEC has done:

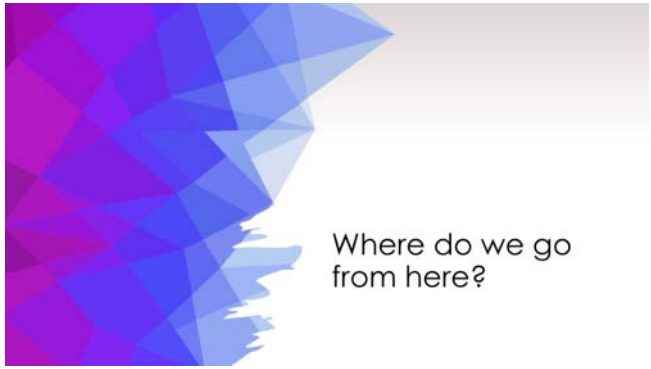
- Brought on disease-site liaisons to provide very early bridge on trial development
    - If they're considering app or digital tool to help recruitment or retention or to collect novel data
- Reviewers in subcommittees
    - Zeynep and Mindy done much heavy lifting here
- Provided training sessions
    - Lisa and others
- Advisers to Lawton
- Led pilot projects
- Authored publications



1:08:02
Results so far:

- Have created four policies in SWOG
- Have successfully had Coltman Fellow on social media topic
    - Mina Sedrak
- Two peer-reviewed publications
- Had funded projects
    - Facebook trial (closed)
    - Cancer Briefs
    - More recent one with Hope support to bring technology partners to SWOG and make introductions

1:08:41
Where does DEC go?



1:08:45
Dizon echoed Hershman: COVID has brought rapid need to evolve—in clinic, in trials. Much work DEC thought about conceptually has become critical in practice.

Going forward:

- Way for DEC to frame what it does within SWOG
- Wants thoughts from group:
    - Should Nichols and Dizon take conversation to executive committee and other research support committees?
- Doesn't see DEC as research support committee but as partner committee to disease sites
- DEC contributions are as important as the PIs defining those trials
- Sees DEC bringing partners such as Oura or Blue Note to disease sites—not to let them run with it but to partner to create quality that can be tested
- Sees DEC moving away from advise and consent role within disease committees and to partnering
    - Could be partnering with Symptom Control & QoL Committee to approach fear of recurrence using Blue Note platform
    - Or, as Saad's doing, partnering with Myeloma Committee but engaging Oura to collect biomarker data to be mined
- These are good examples of where DEC can bring project forward and develop as partner with disease site

- Also allows DEC flexibility to run trials as PIs within DEC
    - Not funded to do this
    - Don't have statistical support to do this
- Perhaps DEC does not run trials but looks at implementation strategies and projects
- Should be place where digital health partnerships are introduced and vetted within SWOG
- Should also be introducing orgs like Blue Note to SWOG-CTI
- DEC should not be thinking solely as novel drug developers
    - This is what cooperative groups have done successfully
- DEC should look more broadly at what it can do and whether it involves traditional therapeutics

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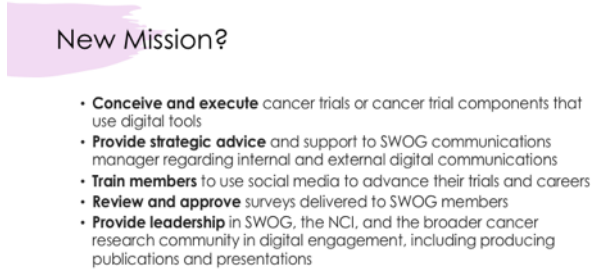
1:11:42

Raises question of mission, which Lawton's working group will strategize on. What should DEC broad platform be?

- Still provide strategic advice
    - But perhaps not begin with research tool that's digital therapeutic or new app
    - Instead, could begin in Melanoma Committee, with Zeynep bringing to DEC to help think through whether it's duplicative or platform is already available
    - This remains the same
- Can—does DEC want to?—still provide survey feedback for all SWOG
- Can still become leaders within committees
- Should be place where ONS reaches out to identify speaker on digital engagement in cooperative groups
- Can be place where AACR asks for key opinion leaders (KOLs)
- Dizon looks at all DEC members as KOLs in this space, whether or not member is on Twitter, TikTok, or Facebook
- Members are leaders because they can approach all of these things objectively



- But perhaps DEC can also (1st bullet) conceive and execute trial components or clinical trials themselves that use digital tools

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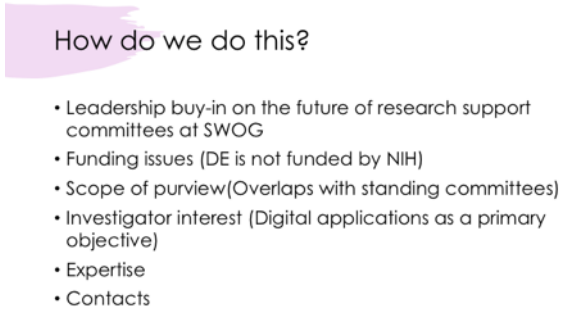
1:13:30
How does DEC do this?

- Elevating research support committees to researcher partners requires leadership
- Requires funding, but maybe not own funding line, which is almost impossible with NCI and NCTN
- Could be agreement that if DEC proposes and it's in territory of disease site committee, DEC can claim leadership level
- Are funding issues: DEC not funded by NIH
    - Dizon doesn't envision requesting this in any cooperative group budget
- Have to consider question of purview and overlap with standing committees
- Not looking to replace any committee
- Dizon's vision:
    - If SWOG is far enough along, DEC could not exist in 10 years because digital engagement would be inherent in all committees
- Can evolve DEC mission to meet needs of SWOG
    - Thinks this is Hershman's charge to DEC
- DEC can be place investors come with interest in digital apps—not as tool to measure but to ask question raised by Hershman today:
    - Is platform useful (even if evidence basis is accepted)?
    - A question DEC can ask
- DEC can also provide contacts into this space



1:15:30
Comments and questions?

Nichols noted other research support committees are going through same exercise.

- These committees have value to SWOG
- Challenge is how to maximize value of these committees and their expertise
- Highly enthusiastic about taking on this effort to bring exceptional value to SWOG

Hershman added that all cancer control and prevention committees have at least one trial that integrates either EMR and patient or site and EMR and provider.

- Examples:
    - Electronic capture of PROs
    - EMR-based decision-aid tool
- Any idea from DEC can be brought to these committees and will be welcomed
- If idea is good, SWOG is committed to figuring out best place to get it done
- May assign to a committee, but whoever has idea leads the study
- Then up to SWOG to identify best statistician, funding source, etc.
- At end of day, it's about having a good idea

Dizon concurred and cited a level of collaboration within SWOG that's to be applauded.

- Asked for input from Becky Johnson or Mark Lewis or Mike Fisch on this

Mark Lewis replied as one having helped run a research support committee.

- Can approach chairs of tissue-focused groups, but they also have to be aware of DEC and want to work with us
- Largely issue of funding: support committees often must apply piecemeal to fund projects and get statistics support
- Tumor-centric groups much better structured, so they must approach DEC at least as much as vice versa

Becky Johnson agreed funding is key issue.

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3:55 p.m. **Next Steps and Adjourn**

- Not something that fits organically
- Hershman's idea that whoever has good idea gets funding is great; optimally it would work this way
- But research support committees operate at deficit because they lack statistical support and funding

Hershman said almost every prevention, control, and care delivery study has grant funding behind it—beyond NCORP funding. No pool of money for these studies either.

- Most money for disease sites comes from pharma

Dizon asked attendees to think about this and follow up at next meeting. Asked Hershman to provide her update.

1:21:42
Hershman provided update on trial with company Proteus [*not* PROTEUS Consortium trial].

- A cautionary tale
- Particularly important for DEC
- Had study looking at Proteus's digital medication platform for opiate use
    - Had Hope funding
    - Had matching funds from Proteus for pilot feasibility study
- Had regulatory issues because it was an opiate trial
- COVID hit as trial was about to open
- When COVID hit, Proteus went from a $1.5-billion company to bankruptcy
- Platform collected data centrally
    - Data was then to be transferred to SWOG
- But bankruptcy means no control over patient-level data
- Study was put on hold
- Company then bought by Otsuka Pharmaceuticals for $15 million
- Otsuka wants to focus on Abilify link only

Small biotech companies can seem solid—Proteus had FDA approval—but can tank quickly.

- Study now closed
- Learned much
- But issue is what to do with patient-level data with these companies that may be transient
- How do we protect our research data?
- Didn't have policy for this

Task for DEC: think about safeguards for data as SWOG engages with these companies.

Dizon agreed this was a digital engagement issue and was sobering lesson.

- Something DEC should advise SWOG on

Mercurio asked from patient perspective if patients have some ownership over their data; is that a back door means of getting data back to trial?

- Goes to much larger questions
- Relates to data collection problems with the BRCA Sisterhood data leak and Facebook
    - All about ownership of data by patients

Hershman noted that a company that goes bankrupt is no longer a company.

Mercurio asked whether patient has access to their data as company is accumulating it.

Dizon noted this was part of Hershman's question to the DEC.

- SWOG's legal team is looking at this as well
- Might be more significant debriefing based on this experience
- Asked to have DEC member as part of this debrief, so DEC in the future could not only help with solutions but also help specify the questions

Hershman noted this wasn't an issue because trial was closed early enough.

- Data was transmitted on a daily basis, so SWOG didn't lose it
- But did not know what would happen going forward

Lawton acknowledged this was important issue and project that could include people from Data and Safety Monitoring Committee, Statistical Center, CRAB, DEC, and staff attorneys to get policy.

Dizon noted Geoff Eich from Blue Note had written in Chat that this needs to be solved in contracts; companies should have a data tail policy in place in case they close operations.

- Need to learn from others as well

Next Steps and Adjourn
1:28:25

Dizon hoped for an in-person meeting at some point and adjourned the meeting.

Chat Record

2:25 PM – Wendy Lawton: Hi everyone! Thanks for being here.

2:26 PM – don dizon: I see folks from BlueNote have joined. Welcome to SWOG! We will make sure everyone gets a chance to introduce themselves!

2:36 PM – Krishna Gunturu: Wendy, Krishna is here

2:37 PM – Betsy Barnick - Carle NCORP: Hi, I'm Betsy Barnick from the Carle NCORP.

2:37 PM – beth pallante: hi, Beth Pallante Heartland NCORP

2:37 PM – Judy Hancock - Ozarks NCORP: This is Judy Hancock CCDR Lead from Ozarks NCORP

2:37 PM – Whitney Leslie: Happy to be here! :)

2:37 PM – Kristie Conder: This is Kristie Conder from PCRC NCORP

2:38 PM – Anne Marie Mercurio: Welcome visitors, hello teammates!

2:38 PM – Eileen Z. Fuentes: Hey Eileen from Columbia U. and community advocate

2:38 PM – Anita Cheung: Hi! I'm Anita from HI MU NCORP

2:38 PM – Wendy Lawton: Welcome! We've got 69 souls on this call. It's a big one!

2:38 PM – Gabriela Mora: Good afternoon everyone. This is Gabriela Mora from INCan Mexico.

2:38 PM – Desiree: Good afternoon, Desiree Walker from RRC & PAC

2:38 PM – Wendy Lawton: Hey! Welcome Desiree!

2:39 PM – jlm2809: Jennifer Mose from Heartland NCORP here!

2:39 PM – Wendy Lawton: Hi Jennifer!

2:39 PM – Desiree: Thx Wendy!

2:39 PM – UC-NCORP, Kamara Mertz-Rivera: Kamara Mertz-Rivera with UC-NCORP here

2:39 PM – don dizon: Welcome welcome all!! Shout out to Desiree!!!!!

2:39 PM – Wendy Lawton: Welcome Kamara!

2:39 PM – Desiree: Hi Don!

2:40 PM – Cindy Haguewood: hello from Cindy Haguewood, UC- NCORP

2:41 PM – Anne Marie Mercurio: Patty Ganz and the late Jimmie Holland, two leaders in this field!

2:41 PM – Kelsey Bridges: UC-NCORP: Good afternoon, Kelsey Bridges with Upstate Carolina present.

2:45 PM – Allison Rosen: dle poll

2:45 PM – Allison Rosen: sorry please ignore that typo

2:46 PM – Belenda Slate SCOR: I have no sound and the slides are not moving?

2:47 PM – Belenda Slate SCOR: Is there an issue someone please answer.

2:48 PM – don dizon: Belinda- no slides moving; he's going to slide 6 now. But, might want to check audio controls on your end.

2:48 PM – Anne Marie Mercurio: No issues on my side. Slide isn't moving. Try changing the view screens in the upper corner?

2:52 PM – Anne Marie Mercurio: Mobile and tablet based is great but are we creating a disparity for those who have limited access (rural/elderly).

2:53 PM – Amy Geschwender: Definitely a point to consider.

2:54 PM – don dizon: If you have a question, please speak! Raise your hand, Wendy and I will recognize you!

2:58 PM – don dizon: Jen, you got it.

3:00 PM – Laura Chavaree, LCSW: Great comments about accessibility and its importance. For our product design process, we are using a co-design model. We have prioritized diversity in our patient codesigners. We are adapting versions every day to better serve patients. It will require constant iteration as you already know. Thanks for your engagement and great questions!

3:07 PM – Anne Marie Mercurio: Thanks very much for that!

3:07 PM – Mark Elfers: Thanks for such great questions!

3:08 PM – Laura Chavaree, LCSW: One thing I would add to Geoff's answer to Anne Marie's question is that there is an accessibility challenge with access to Cancer-specific mental health support. Many community cancer centers need to refer out for support. Blue Note's products allow for immediate access to support, whether waiting for their psycho oncology appointment or as a support to their medical care even if they are not seeking a therapist or group therapy experience.

3:10 PM – Laura Chavaree, LCSW: So grateful for these questions and inspired by this group's leadership.

3:10 PM – Mark Elfers: We'll follow up with a thank you note - please feel free at send any additional thoughts or questions to me at marke@bluenotetx.com.

3:11 PM – Mark Elfers: We'd be more than happy to do that!

3:11 PM – Dawn Hershman: Thank you for your interesting presentation

3:11 PM – Dianne Shumay PhD: Thanks for having us and all the great questions.

3:15 PM – Mark Elfers: we built a COVID-19, cancer-specific tool for cancer patients which is available now to any person, on any device with internet access - the link is here:

3:15 PM – Mark Elfers: https://www.covidcancercare.com

3:16 PM – Anne Marie Mercurio: Now may be the time to see if we can advance video based consent.

3:16 PM – Mark Elfers: Please feel free to share with your patients or your colleagues

3:17 PM – Jeff Berenberg: I agree that the video base concert is critical to clinical trial recruitment success in this Covid era

3:18 PM – Anne Marie Mercurio: A number of places are already taking stabs at video consents - partnership possible? Rather than having to reinvent the wheel from scratch?

3:19 PM – Jeff Berenberg: Need NCI and CIRB support

3:19 PM – Anne Marie Mercurio: Congrats!!! That's awesome.

3:19 PM – Anne Marie Mercurio: Yes, NCI and CIRB for eConsent or video consenting but Dr. Sharpless has stated he wants that to be a "covid lesson" to carry forward.

3:20 PM – Dawn Hershman: We need to think about how to bridge the virtual research world - and help sites figure out what can be done remotely and how to do it well

3:20 PM – Anne Marie Mercurio: Yes, Dawn!!

3:21 PM – Lynne Nguyen: Kudos on those plain language/plain design study summaries Wendy!

3:23 PM – Mark Lewis (privately): Facebook as a trustworthy platform for open engagement (i.e. not closed or secret groups) looks quite different now in terms of palatability compared to when we first proposed this

3:23 PM – Mark Lewis: Facebook as a trustworthy platform for open engagement (i.e. not closed or secret groups) looks quite different now in terms of palatability compared to when we first proposed this

3:23 PM – Anne Marie Mercurio: Thanks Mark for reading my mind. Agree re: FB!

3:24 PM – Krishna Gunturu: Great work, Wendy, Don and DE team. I would say to rest FB proposal.

3:24 PM – Anne Marie Mercurio: Wendy: I'm in.

3:24 PM – Heloisa Soares: Happy to help!

3:25 PM – Jonathan Sommers: I'd love to help. Well done, Wendy!

3:25 PM – Lynne Nguyen: On the other hand, FB is more popular among boomers and older generation, the group at highest risk for cancer.

3:26 PM – beth pallante: In today's world of Artificial Intelligence for marketing using social media especially Facebook it seems we need to tread lightly

3:27 PM – Kelsey Bridges: UC-NCORP: Great presentation Wendy! Something to be cognizant of as you're considering what social media platforms to pour more effort into is what populations are are trying to reach. Professionals vs potential patients, what age groups etc. For instance Gen Z age are most likely not on Facebook and LinkedIn and are utilizing YouTube and Instagram.

3:28 PM – Lynne Nguyen: yes, please add me to your posse

3:28 PM – Mark Lewis: Post-Cambridge Analytica, the BRCA Sisterhood leak, and our own "negative trial" trying to get SWOG investigators to use FB I'm just less enthused to use it now vis a vis patient contact -- I'm happy to contribute to this group

3:28 PM – Kelsey Bridges: UC-NCORP: I'm in to help!

3:28 PM – Wendy Lawton: Thanks Lynne!

3:28 PM – Eileen Z. Fuentes: I'd love to join the DE committee, Wendy

3:28 PM – Allison Rosen: I would love to help Wendy

3:28 PM – Gabriela Mora: I have seen that Facebook is quite more polite than tweeter

3:29 PM – Gabriela Mora: I am sorry. Twitter

3:29 PM – Wendy Lawton: Thanks, Kelsey, Allison and Eileen. I will add you to my working group. Will be in touch about adding you on formally - if you want to and if we have room!

3:30 PM – Anne Marie Mercurio: Thank you, Wendy.

3:30 PM – Wendy Lawton: You all are great. Thank you.

3:30 PM – masonvirginia@msn.com: Wendy...I'm willing to help with the "revisit" project, if needed.

3:30 PM – Wendy Lawton: Thanks Ginny! Def adding you.

3:32 PM – Anne Marie Mercurio: To say nothing of the fact that many centers, at least in NY, closed trials in March.

3:37 PM – Wendy Lawton: Excellent! You're in.

3:39 PM – craig nichols: Should add visionaries to the Roles slide

3:41 PM – Anne Marie Mercurio: Are we now a "bridge" committee between the digital world and the disease committees?

3:42 PM – Wendy Lawton: Yes - we are true research support. We don't have the capacity to run trials or trial components.

3:42 PM – Anne Marie Mercurio: COVID changed everything because of the urgent need to use virtual tools in every aspect of life.

3:44 PM – judyjohnson.519@gmail.com: Today's Patient Advocate Committee ranked top 4 NCI COVID clinical trial adaptations for patients to be: localize study activities, ship oral agents to patients, telemedicine, and remote informed consent. Not sure if this offers opportunity, but it may.

3:44 PM – Michael J. Fisch: This notion of DE as research partner as opposed to the traditional "research support" entity makes perfect sense to me. We are already realizing this way of being, and there is more that can be done

3:44 PM – Anne Marie Mercurio: AGREE, Judy!! There's a ton of crossover from what we discussed in the PAC

3:45 PM – Wendy Lawton: Great input and feedback, Judy and Mike.

3:46 PM – Betsy Barnick - Carle NCORP: We would just need to be aware that many rural folks and certainly elderly have struggled with all the new telemedicine approaches. I believe there is a real opportunity for us to address that though.

3:47 PM – Wendy Lawton: Thanks Betsy. Our patient advocates talked a lot about the need for telemedicine to not make disparities worse for rural/elderly/poor, etc.

3:48 PM – judyjohnson.519@gmail.com: Patient choice of methods is key.. and access.

3:50 PM – Anne Marie Mercurio: Excellent point, Dawn. Thank you for sharing that.

3:55 PM – Mark Lewis: https://www.fiercehealthcare.com/tech/proteus-digital-health-could-exit-bankruptcy-15m-stalking-horse-from-otsuka

3:56 PM – Michael J. Fisch: Of note, what Dr. Hershman is discussing in terms of the company Proteus is not linked to the Proteus Consortium:--where the acronym stands for "Patient-Reported Outcome Tools: Engaging Users & Stakeholders." This is something that Dr. Claire Snyder will discuss on the SCQOL meeting on Friday afternoon

3:56 PM – masonvirginia@msn.com: Thanks for sharing this Dawn...important to know.

3:57 PM – Krishna Gunturu: Is there a way to change SWOG's legal agreement that if company goes under, we would get out data back? Novice question.

3:57 PM – Wendy Lawton: Super important to consider! Protecting patient data - and also generally managing risk with companies in terms of our info sharing and our investment. General question: How do we protect SWOG and our patients?

3:58 PM – Geoff Eich: Yes - this is a good issue to solve in contract terms. Companies should have data 'tail policy' in place if they close out operations

3:59 PM – Geoff Eich: Anne Marie is correct - patient would have access to their data

3:59 PM – Geoff Eich: thank you all - have a great day and please feel free to reach out with any questions or ideas. Geoff geich@bluenotetx.com and @GeoffreyEich

3:59 PM – Dawn Hershman: THANK YOU!!!

3:59 PM – Heloisa Soares: Thank u

3:59 PM – Michael J. Fisch: Great job on the digital meeting!