

CK Huang: co-hosts can set "mute on entry" or something like that in the draw-down...

Aaron King: yeah its important

Jeannie Baumann: Reacted to "co-hosts can set "mu..." with 👍

Nancy Tepper: it seems the presentation began before the start time, or am I missing something?

Jill Baron: Reacted to "co-hosts can set "mu..." with 👍

Anne Tseng: Reacted to "co-hosts can set "mu..." with 👍

Thomas Seoh: @Nancy - the Commissioner arrived a couple minutes early, We just started.

Steve Daly: Hi Nancy - the session started about 3 minutes early. This is the first question response.

Sarah Karlin-Smith: can you repeat what the question was

Thomas Seoh: FDA typically reviews interventions for diseases - aging is not a disease, at least not nominated as such for now - what sort of endpoints should FDA use for healthspan products?

Thomas Seoh: For those who are willing, please say hello in the chat and indicate where you are listening from...?

Thomas Vasicek: Hello from Minneapolis!

Ricardo Pacheco: Hi, this is Ricardo from Switzerland

Scot faulkner: Hello from the PBM Foundation at Shepherd University, Shepherdstown, WV!

Bill Kole: Greetings from Providence, R.I.

Nir Barzilai's iPhone: Nir Barzilai, Bronx, NY

Mark Osabutey: Hi, I am joining in from Rochester, NY. University of Rochester Medical Center.

Nancy Tepper: Greetings from Tucson, University of Arizona Cooperative Extension 🌵 🌿

Thomas Hattier: Hello from Cleveland, OH

Elizabeth Holt: Greetings from LifeScan. I am joining from Durham, NC

Steve Daly: Orange County CA here

Janet Nunziata: Greetings from Burlington, VT

Jim Cummins: Jim Cummins, retired biologist, hello from near Harpers Ferry.

Paul Abrams: Greetings to all from Seattle

Erwin Tan: Erwin Tan of AARP joining from Washington DC

Joining from the Marcus Institute for Aging Research, Hebrew SeniorLife and Harvard Medical School

Irene Crowell: Hi there, Irene Crowell, PharmD, Consultant Pharmacist with Coordinated Medication Team in Oregon

Evelyne Bischof: Evelyne Bischof, Shanghai, China

Phil Frankino: I'm Phil from Loyal (Cellular Longevity, Inc). Hello from Bay Area, California!

Rita Effros: Hello from Portland OREGON

Monica Feldman: Hello from Phoenix, Arizona.

Jim O'Neill: Mill Valley, California

Brian Chen: Los Angeles, CA

Kira Jones: Hello from Haddon Heights, NJ!

Gary Scott: Hello from Fort Worth, Texas: "where the West begins"

Giovanni Greatti: Hi to all from Italy

Hien: Greetings from Germany, Hien Nguyen

Thomas Vasicek: Tom Vasicek here in Minnesota at Gila Therapeutics

Paul Abrams: Greetings to all from Paul from Seattle. Oncologist and cancer researcher

Philip Home: Good evening from Newcastle, UK

Ravi Kiron: Ravi Kiron from EMD Serono Silicon Valley Innovation Hub, San Jose, CA
(ravi.kiron@emdserono.com)

Amanda Adler: Oxford, England - friends from the MRC Clinical Trials Unit, London, will listen in tomorrow

Rafael Vivas: Reacted to "Oxford, England - f..." with 🤔

Greg Wu: Hello from Greg Wu, San Francisco, CA

Alan Rogol: Can someone centrally be sure that all microphones are off except for those actually contributing?

Andrew Wong: Hi. Andrew Wong Edmonton Canada-family physician

Karl Pflieger: Intros in chat is a terrible idea. It means no one can use the chat to discuss what is being said because too much else scrolls by.

Karl Pflieger: There's a participants list and the value of people sharing where they are is tiny compared to the value of discussing the content via the chat.

Jim O'Neill: Reacted to "There's a participan..." with 👍

Dr Kim Kuebler: Hi Kim Kuebler Director of Multiple Chronic Conditions Resource Center

Aaron King: For questions - do we just raise our hand?

Thomas Seoh: Hey Karl, pls feel free to make substantive comments. In our experience, people who want to engage do, and I am certainly looking for questions to pass through to Jay and Zan

Eugene Major: Will a recording be available? thanks

Thomas Seoh: @Aaron, with a couple hundred attendees, it's going to be difficult to recognize hands raised. Pls put questions in the chat, and we'll put it to the speakers.

Aaron King: My question - has Robert seen a database of biomarkers that do and don't change with age, does this exist somewhere? I'm currently building this but it seems like the FDA should already have something similar.

Karl Pflieger: Accelerated approval is great. It's the only way we're going to get long (eg multi-decade) follow-up.

Thomas Seoh: Yes, every registrant will receive a link to the YouTube video recording in a couple days, **as well as a transcript.**

Bill Kole: A question for the commissioner: How does he feel about approaching aging as a treatable disease -- something David Sinclair at Harvard and others argue should be done?

Thomas Seoh: Transcript could take a couple weeks because we ask speakers to comment on the transcript.

Joe Balavage: Is the resistance for supplement update because of back pressure from pharma?

Paul Abrams: Cardiology question: more and more people are getting calcium scores. A study of the impact of cholesterol levels on improvement of calcium scores might be a window into at least one aspect of aging. I am told that Europeans have lower targets than we do in the US.

Nir Barzilai's iPhone: Because so many supplements may have a role in aging, we need the FDA to distinguish between supplements clinical studies and other studies. We need to encourage supplements to do clinical studies like that other wise it's hope and not promise

Jim O'Neill: Reacted to "Because so many supp..." with 👍

Paul Abrams: But, the question for FDA is, suppose such a study were done, and showed a benefit in lower cholesterol levels in improving calcium scores, would that be an acceptable surrogate marker?

Thomas DiLenge: would he appoint one or more folks from FDA to participate in such a convening?

Steven Grossman: Replying to "Is the resistance fo..."

Not to my knowledge. The DS field is an active area for small business (natural food stores, etc.) and opposition to rationalizing regulation is similar to other areas with small local businesses. Congress listens to those folks.

Dan Elton: add 👍

Jim O'Neill: Reacted to "Not to my knowledge...." with 👍

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Nir Barzilai's iPhone: Because so many supplements may have a role in

Karl Pflieger: Tangential but supplement trials are notorious for being poorly designed. Especially when the supplement supplies something also provided by diet or environment trials often fail to account for controls also getting it, and baseline & achieved levels are often not taken into account even for trials where measurement of body levels is easy. See this paper by Heaney that published guidelines for nutrient trials for example: <https://pubmed.ncbi.nlm.nih.gov/24330136/> We need fewer bad supplement trials.

Thomas Seoh: Should there be a center or division or office for healthy longevity?

Saima Khan: Reacted to "Should there be a ce..." with 👍

Dan Elton: add 👍

Noah Rosenberg: Reacted to "Should there be a ce..." with 👍

Teri Mascuch: @steven grossman and Joe Balacavage, supplements are covered under DSHEA and also not sold in small local businesses. WalMart, CVS etc are not small local businesses.

Jim O'Neill: Reacted to "Should there be a ce..." with 👍

Stuart Fitzgerald: Reacted to "Should there be a ce..." with 👍

Kira Jones: Reacted to "Should there be a ce..." with 👍

Steven Grossman: Replying to "@steven grossman and..."

Teri--go into any natural foods store in America.....the father of DSHEA was from Utah and the industry is very strong there.

Teri Mascuch: Aren't we talking about healthy longevity being to avoid or postpone chronic illnesses associated with aging?

Monica Feldman: @Teri Mascuch - I agree, In fact the largest CPG companies Nestle and Procter & Gamble sell dietary supplements and have a lot of corporate power.

Susan Szathmary: We need early biomarkers

Teri Mascuch: Replying to "We need early biomar..."

Agree!

Mahdi Moqri: Reacted to "We need early biomar..." with 👍

Mahdi Moqri: Removed a 👍 reaction from "We need early biomar..."

Bill Kole: Reacted to "Should there be a ce..." with 👍

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Mahdi Moqri: Replying to "We need early biomar..."

Agree!

Jim O'Neill: NIA is largely focused on Alzheimer's specifically. It would be great to have a large office of geroscience at NIH that could fund development of causal biomarkers of aging.

Thomas DiLenge: Replying to "We need early biomar..."

agree but we also need a rapid process to validate such markers

Steven Grossman: Replying to "@Teri Mascuch - I ag..."

Nestle and P&G are indeed large CPG, but not sure they own any of the vitamin manufacturers....and in any case the political clout is local and retail.

Steven Grossman: Replying to "@Teri Mascuch - I ag..."

....and libertarian

Mahdi Moqri: Replying to "We need early biomar..."

Indeed, validated biomarkers are the key

Gary Scott: yes causal biomarkers of aging, not aging's artifacts/symptoms

Karl Pflieger: I think fatty thymus disease should be a clinical indication, similar to fatty liver disease. Similarly I think accumulation of persistent senescent cells should be considered to be a disease (plenty of evidence it causally leads to bad clinical outcomes in many areas). What organization should be doing the work to get these kinds of things established as new clinical indications? Is that something the NIA (or Jim's suggested just above large NIH office focused on geroscience) would do?

Gregory Fahy: Hear, hear!

Jim O'Neill: Reacted to "I think fatty thymus..." with 👍

Dan Elton: add 👍

Karl Pflieger: Reacted to "I think fatty thymus..." with 👍

Teri Mascuch: Reacted to "I think fatty thymus..." with 👍

Saima Khan: How has FDA considered ways to improve clinical trials and regulatory frameworks currently not 'fit for purpose' in meeting needs of elderly patients:

Underrepresented in clinical studies, inadequate characterisation of drug effects e.g. those caused by 'age' vs underlying conditions common in, but not unique, to elderly patients. (i.e. Diversity in Clinical Trials)

Ineligible to participate in studies due to restrictive inclusion/exclusion criteria (e.g. concomitant drugs)

Elderly patients/carers reluctance to participate in clinical trials due to logistical difficulties e.g. travelling, OR health literacy issues, ethical considerations and risk perceptions. (i.e. improving access via e.g. Decentralised Trials)

Clinical study endpoints may have less relevance to elderly patients. e.g. QoL more important to elderly patients vs extending life. (PFDD)

Clinicians and regulators not clearly prioritising 'unmet medical needs' and outcomes in elderly patients. This results in delays in clinical trials, and for

Sally Zheng: Replying to "Because so many supp..."

Bob mentioned that he thinks the legislation on supplements need an update and didn't get through the congress. Is it possible to create a separate category? Not waiting for the congress.

Saima Khan: Reacted to "How has FDA consider..." with 👍

Evelyne Bischof: Healthy longevity medicine is shaping up as a medical discipline, and while there is already a huge demand from patients seeking educated physicians in the field, the sick-care departments/specialties also benefit from longevity medicine diagnostics/approaches. Educating medical students and professionals is detrimental, yet it is very difficult to bring longevity medicine into med school curricula. Are there any approaches to facilitate those attempts?

Mahdi Moqri: Replying to "yes causal biomarker..."

Of course! Mechanistic biomarkers as surrogate endpoints

Aaron King: ... what.

Nir Barzilai's iPhone: Epidemic preparedness: Metformin in many associations and clinics studied prevented 50% hospitalization, death and long Covid, maybe that should be discussed in congress as example how to save the elderly ❤️ 👍

Susan Szathmary: Biomarkers that are participating in aging early on.

Susan Szathmary: Also, the animal models we are working on could speed up the developments

Savva Kerdemelidis: There are payment models to help fund generic drug and nutraceutical repurposing and get better and faster longevity interventions e.g. advance market commitments / paying for successful clinical trial data. FDA can encourage CMS establish such novel payment models (eg new CPT code to reimburse a repurposed generic at a higher price subject to successful clinical trials).

Mahdi Moqri: Reacted to "Biomarkers that are ..." with 👍

Patricia Heyn, PhD, FGSA, FACRM: Cardiorespiratory exercise has been showing consistently the most effective treatment for many chronic diseases including diabetes, sarcopenia, and dementia. Unfortunately, there is not the same funding interest in enhancing the roadmap for us to truly come up with precision exercise medicine prescription for healthy longevity as we do with our drug trials.

Thomas Seoh: @Nir, Rob did say when there is broad consensus (not just within the geroscience silo), FDA would have to figure out how to handle a new animal if an agent can help healthy people live longer healthier...

Aaron King: I feel like we all just got catfished

Aaron King: Have fun, I'm going back to work, this is all stuff I've heard before

Phil Frankino: Reacted to "I feel like we all j..." with ?

Phil Frankino: Removed a ? reaction from "I feel like we all j..."

Thomas Seoh: @Aaron, we knew Rob was not going to unveil a Guidance, it's early conversations. The Roundtable has practitioners thinking about the challenges and opportunities

Phil Frankino: Reacted to "@Aaron, we knew Rob ..." with 👍

Gregory Fahy: Regarding SK, if aging is the outcome, aging clocks would be a biomarker to measure it.

Jim O'Neill: Reacted to "Regarding SK, if agi..." with 👍

Paul Abrams: There is also a beta thyroid receptor agonist, Resmetirom, in very late stage clinical trials. No toxicity has been reported. It activates fat metabolism, improves lipid profiles, and the function of mitochondria in the liver. It is being developed as a NASH drug. Because of its toxicity profile, it seems as if it might be a good candidate for anti-aging

Teri Mascuch: Replying to "Cardiorespiratory ex..."

I like your points Patricia. I agree with them. I wonder if there is not as much funding interest for precision exercise medicine because what \$ or profit is there in this arena of good science and medicine. Private funding might be the best way to gain financial interest.

Bill Kole: Reacted to "Cardiorespiratory ex..." with 👍

Paul Abrams: If we had a decent House of Representatives, we might consider adding coverage for cardiorespiratory exercise

Jim O'Neill: Replying to "If we had a decent H..."

What would coverage for exercise mean?

Teri Mascuch: Reacted to "Cardiorespiratory ex..." with 👍

Teri Mascuch: Removed a 👍 reaction from "Cardiorespiratory ex..."

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Nancy Tepper: Reacted to "If we had a decent H..." with 👍

Todd Lorenz: Replying to "Cardiorespiratory ex..."

As a former practicing endocrinologist who treated many T2Ds, I can say that recommendations for exercise are vital, but fall short of what is needed to increase public health.

Patricia Heyn, PhD, FGSA, FACRM: Replying to "Cardiorespiratory ex..."

I have been in this field for over 30 yrs and if we had a drug that will generate the same outcomes that prescribed exercise does, the funding and drive will be unheard. My conclusion, ironically, is that we will not achieve longevity just because we are not smart enough :-)

Teri Mascuch: Reacted to "I have been in this ..." with 👍

Gary Scott: She makes great point about metabolic dysfunction, and glucose hypo-metabolic energy loss, as common link of aging and dementias

Todd Lorenz: Do we really have access to the medical records of all 340 million Americans as Dr. Califf said? If not, perhaps an "opt-out" system, where patients who do NOT want their medical records shared as they are in the UK could specify this.

Nora Norback: Fascinating. This may be off track but it's hard not to ask, "what are the likely socioeconomic and psychical implications of more people living longer?"

Teri Mascuch: It helps to have public health for all as in UK. Helps provide data and direction including AI opportunities for health and policy and impact metrics

Susan Szathmary: Takes 10-20 years for a new disease definition to get down to the practicing physician

Steven Grossman: Replying to "It helps to have pub..."

I believe he said 120 million Americans with electronic health records. The number is certainly growing but that is consistent with what I have been told.

Patricia Heyn, PhD, FGSA, FACRM: Reacted to "If we had a decent H..." with 👍

Gregory Fahy: I fully agree with Karl Pleger's comments: there is no logical rebuttle to the idea that physiological changes that lead to pathological outcomes should be recognized as candidates for intervention. To answer his question as to who needs to push for this, I think this falls to industry: those with drugs that may address such changes need to make the case and hope the FDA will listen.

Rohan Gidvani: Could make the cancer analogy to NGS testing (or even family history) for BRCA, other HRD mutations, Lynch, EGFR, NTRK, etc., etc. -- this doesn't mean you treat with platinum chemo, but the patient is at high risk, and in many situations does take preventive steps before confirmed diagnosis of cancer (could be a longevity intervention). This can apply to non-genetic biomarkers as well.

Rohan Gidvani: Reacted to "I fully agree with K..." with 👍

Bill Kole: Reacted to "I fully agree with K..." with 👍

Nora Norback: Replying to "It helps to have pub..."

Yes, but US has yet to build an infrastructure to allow providers to both get new data entered (aka charting) and spend time providing care.

Nora Norback: Replying to "@steven grossman and..."

Karl Pflieger: Reacted to "Could make the cance..." with 👍

Nora Norback: Reacted to "I think fatty thymus..." with 👍

Tina Woods: This is what we are trying to do to create a 'world test bed for health' in the Quantum Healthy Longevity Innovation Mission as set out in the Lancet here:

[https://www.thelancet.com/journals/lanhl/article/PIIS2666-7568\(22\)00267-7/fulltext](https://www.thelancet.com/journals/lanhl/article/PIIS2666-7568(22)00267-7/fulltext)

Steven Grossman: Replying to "@steven grossman and..."

correct....comparatively small manufacturers, lots of natural foods stores, strong libertarian culture. It was a winner for him back home.

Jim O'Neill: Reacted to "This is what we are ..." with 👍

Tina Woods: Worth looking at Our Future Health who we are working with on the Innovation Mission-<https://ourfuturehealth.org.uk/>. Linking all these trusted research environments / databases is at the heart of our mission

Nora Norback: How do I get the cat notes after this is over?

Thomas Seoh: @Nora, each registrant will get the link to the YouTube video, probably within a couple days. A transcript could take a couple weeks, because we run then by the speakers for QC. The chat we typically post at Kitaly with the foregoing as an archive of this event.

Thomas Seoh: Sorry Lucy, going to 4 p.m., but we'll have a video

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Tina Woods: I have to leave now but a fascinating discison and look forward to continuing and furthering shared endeavours to help people like healthier for longer around the world

Rohan Gidvani: ODD has been fantastic for drug development in the past 2 years and going forward, particularly rare diseases, rare cancers, etc.. Great point David is making.