



Wow! or Yeow?! 2026 Zoom Chat Transcript

00:29:13 Kyle Butler: Hi guys!!!

00:29:48 Kyle Butler: Is this not like an Meeting so cant we turn on our own cams?

00:29:50 Thomas Seoh: Hello Kyle!

00:30:44 Andrea Miller: Andrea Miller InnoPath

00:30:46 BethWeinberg: hi everyone - in snowy and cold Boston!

00:30:50 Helen Cheung: Hi.

00:30:52 Myriam Triest: Hi, from Montreal

00:30:52 David Wood: Hi, I'm from the Longevity Escape Velocity Foundation (LEVF), and am connecting from London

00:30:55 lex van der ploeg: Hi Boston: VDP II LLV dba RIFFIT

00:31:01 Helen Cheung: Hi from Philly

00:31:05 Kenneth Moch: Well, Hi all. Kenneth Moch, Regerna Therapeutics, from lovely Chapel Hill, North Carolina

00:31:07 Irene Schauer: Hello from Colorado!

00:31:09 Darya Vasilyeva: Hi! New York Mount Sinai

00:31:10 Patrick Noonan: Hi from Boston

00:31:10 John Jenkins: Good morning

00:31:11 JClark: Howdy! Jennifer from Calgary

00:31:12 Kaiping.Deng: Hi from Chicago

00:31:13 Kyle Butler: Cant we on Turn our cams?

00:31:13 Eric Mbunwe: Hello from very cold Lunenburg, MA

00:31:42 Dr Michael Zemel: Hello from (frozen) Nashville.



00:31:46 Fiona Miller: ... and from very cold Littleton MA

00:31:49 Poul Strange: Hi from Princeton

00:31:54 Helen Cheung: It's cold 🥶 here too. Lol

00:32:02 Sarah.Sims: Hi from Northern Virginia where it needs to warm up

00:32:02 Jerrold Shapiro: Here's my contact info:

Jerry Shapiro, President, Floelle Inc., Acton, MA

Invented, patented and successfully clinically tested a medical device to block the unwanted urine leaks that define female urinary incontinence and restore these women's dignity, joy and quality of life.

<https://floelle.com>

shapiro@floelle.com

<https://www.linkedin.com/in/jerroldmshapiro/>

TAM: 750 million women, 1.3 Trillion US dollars of annual sales

NEED: \$3 million for pivotal clinical trial and FDA, EU market

clearance.NEED: \$3 million for pivotal clinical trial and FDA, EU market clearance.

\$4 million for education & training of doctors to use it.

ASK: Your help introducing me to investors you know.

00:32:35 Kyle Butler: Can we turn on our cams?

00:32:50 Kinexum Services: Hi Kyle! Attendees will not be able to turn on microphones or cameras, but feel free to communicate with the cha

00:32:56 Kinexum Services: *chat

00:34:07 Susan Abossein: Hello, Dr. Susan Abossein from Ohio.

00:36:54 Thomas Seoh: @Kyle, this is a function of the Zoom Webinar platform, which can't show tiles from hundreds of attendees. This is distinct from the Zoom Meeting platform which is designed for a more intimate meeting.

00:42:45 Thomas Seoh: Could everyone pls mute your mics, to prevent feedback?
Thanks!

00:53:51 Julie's iphone: Stay the same should be an option for the poll

00:56:40 Thomas Seoh: @Julie, noted!



00:57:35 John: with so much safe and efficient stem cell/progenitor cell studies, why no FDA approval for autoimmune and degenerative conditions that show cures in many diseases. Why not?

01:04:15 John: Is the peer review panel sometime unduly influenced

01:05:19 Lisa Yanoff, M.D.: hi Peter!

01:06:57 Thomas Seoh: 1st time for Peter on Wow or Yeow. But Peter has been on one of our Metabesity panels on regulatory issues on the development of healthspan products.

01:09:43 Sam McDonald: Should we allow people to die whilst we wait for scientific evidence which is often biased and time consuming, outdated, etc etc - also why no preventative measures towards wellbeing as opposed to illness? Further, systemic approaches to understand why 8 billion are suffering with illness without recognising globalisation, including extensive spillover creating both NCDs and communicable diseases with a direct correlation to what has typically been term "mental illness" - has to take some accountability, surely? Are not the approaches no longer fit for purpose?

01:14:42 John: Why would PRP be denied coverage for "regenerative medicine but covered by Medicare and other insurance. It does cure pain.

01:17:45 Sam McDonald: Are there any women on this panel?

01:18:06 Sam McDonald: Any people of colour?

01:18:15 Robert Gump (FDA): unfilled as no permanent vs acting

01:18:41 Annie: Jodi Scott is speaking and she is a woman of asian descent

01:19:16 Sam McDonald: 🙏

01:22:10 Helen Cheung: Hi Sarah and everyone 😊🙏❤️

01:24:17 Thomas Seoh: @Sam - those are big issues, beyond the year in review and a long ahead to 2026. Your first point goes to where society today wants to set the bar on the gradient of innovation and evidence/public health/safety. On your second point of wellness vs. disease treatment, our not-for-profit Kitalys Institute has proposed the THRIVE Act, which proposes a regulatory pathway, evidentiary tiers and incentives for healthspan products. Your third point also is very broad - what evolution in approaches for changes in the circumstances, globalization included.



01:28:27 Sam McDonald: Love the concept of a 'Thrive' Act - this won't be before its time

01:28:41 Thomas Seoh: @Sam: we had 3 women who were conflicted from joining the panel today...bad luck.

01:30:40 Thomas Seoh: See current draft of the THRIVE Act at www.kitalys.org.

01:35:03 Sam McDonald: 🙏

01:39:00 John: CLRs would help other applicants to fulfill requirements. Even if applicant was omitted.

01:40:21 Sam McDonald: My only concern is the lack of preventative measures. I'm particularly interested in early intervention, systemic change & how policy, education, and organisational design can create conditions where people are supported to thrive rather than managed once harm has occurred.

01:42:35 Poul Strange: Jodi: why is it a strategic advantage for a company to choose a de novo path?

01:43:13 Sam McDonald: Free download of a book entitled "The last Economy" does not see us running towards AI as positive but rather as a move towards the demise of humans. It has a very interesting perspective that should not be taken lightly.

01:47:19 Jodi K. Scott: @Poul, Choosing De Novo if it's appropriate, gives a company first-mover advantage—you create the new device category, set the regulatory benchmarks competitors must follow, and reach market faster than a PMA would ever allow

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01:50:52 Julie's iphone: Happy to know I am not the only one who still remembers GGPs.

01:54:24 Poul Strange: I get that, but they also make it very easy for competitors to enter, which may weigh heavier over time.01:54:34 John: 21st Century Cures Act money was not really spent on regenerative cures. Just pure research.



01:59:28 Thomas Seoh: @Poul, sponsors can 'elect' to go the PMA route even if it might be able to avail the de novo pathway...but those are very specific strategic circumstances; most would prefer the quicker, less expensive route.

02:00:15 Susan Abossein: Thank you so much for this informative meeting. Wow

02:00:28 Christine Kirk: Thanks!

02:00:54 Pat Furlong: Many thanks for an enlightening discussion.

02:00:55 Sam McDonald: Thank you - please connect if there's an interest
<https://www.linkedin.com/in/samantha-are-you-willing-to-have-your-beliefs-challenged-97b4a924>

02:01:51 Fang Li: Thank you! Hope we all have a good year and FDA keeps doing what they have done in the past being a science-based organization!

02:02:19 Roberta Anderson: Thank you! Great program!

02:02:44 Helen Cheung: Great work Thank you

02:02:44 Saad HARTI: Thank you !

02:03:09 Thomas Seoh: Thanks all!

02:03:15 William Carter: Thank you, everyone.

02:03:49 Gargi Mahapatra: Thank you for the terrific discussion. It was eyeopening! Please feel free to connect if you're interested: [linkedin.com/in/gargi-mahapatra1985-phd](https://www.linkedin.com/in/gargi-mahapatra1985-phd)

02:09:24 lex van der ploeg: Enjoyed discussion! Have to go. Greetings, Lex

02:09:51 Timothy R. Franson: Thanks Zan, Thomas, fellow panelists, Emma, Kristi and for the great audience interactions. We all need to continue a collaborative approach for improving development and care practices for patient unmet needs. I need to drop off for another commitment.

02:10:32 Thomas Seoh: Thanks Tim!

02:15:17 John Jenkins: The commissioner seems to suggest a lower p value for the one trial since he keeps referring to it as a "math" issue.

02:18:34 John: RWE



02:21:02 Thomas Seoh: RA Fisher's $1/20$ due to chance multiplied, if independent trials, to $1/400$