Kinexions

Insights for Translating Life Sciences into Solutions

A Note from the CEO

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Welcome to the Spring 2023 edition of *Kinexions*!

The 4th quarter of last year was a busy one for us for conferences. In October, we held our annual ***Targeting Metabesity*** conference, virtually. All recordings of the sessions, including the Emerging Company Showcase, have been posted at the Kitalys Institute website and can be found here.

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A Note from the Chairman

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The opening and closing sections of Carl Orff's iconic, monumental choral work *Carmina Burana* are entitled *Fortuna Imperatrix Mundi* ("Fortune, Empress of the World"). As I look back upon my career, which has been rich in good fortune and serendipity, I realize that I have been far more fortunate than my efforts devised or merited. In other words, *Fortunatior quam bonus fui (*I have been more lucky than good).

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A Biographical Interview with Kinexum Founder and Executive Chairman, Zan Fleming

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Kinexers Thomas Seoh and Georgina Xanthou conducted this personal interview of Zan last year for *Kinexions*. Zan has resisted this project at every turn, but the interviewers relentlessly wore him down into agreeing to the following excerpts being published.

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Groundwork for Draft Healthspan Legislation at Metabesity 2022

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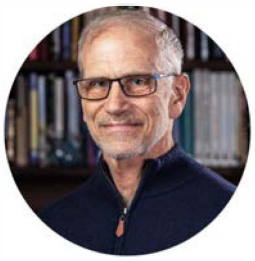
One of the most often-cited challenges to the translation of advances in aging research into products that prevent chronic diseases and extend healthy longevity is the lack of a clear regulatory pathway. Key stakeholders, including pioneer scientists in the aging research field, regulatory experts and legislators participated in a unique, far-

Obesity Pharmacotherapy: New Era, New Opportunities? (Part 2)



Michael Zemel, PhD
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The opening installment of this article focused primarily on the progress and promise of GLP-1 agonists such as semaglutide, incretin polyagonists such as tirzepatide and related combinations targeting hunger and satiety pathways. While the importance and impact of these central targets in obesity cannot be overstated, especially with their robust efficacy and safety profile and associated cardiometabolic benefits, there are nonetheless significant limitations associated with controlling obesity by targeting ingestive behavior through satiety and hunger control mechanisms.

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How Medical Device Control Helps the Startup

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ranging discussion that took place during the "***Achieving Evidence to Support Healthy Longevity Therapeutics & Products***" session on Day 1, October 9, 2022, of the Targeting Metabesity conference.

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You received seed money for the development of your medical device idea. You know that time is money and you have limited funding so you don't want to waste time. You probably know that the US FDA requires you to develop a medical device following the Design Control process, but what is Design Control? Is it just more unnecessary government regulation requiring filling out of a stack of forms or is it a useful and helpful aid to producing a product on time and within budget?...

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The Thrill of The Chill

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We are proud to announce that our Kinexer, Joy Cavagnaro, once again took the Icy Plunge and [Went] for the Cold! Coach Joy has been involved with the Special Olympics Organization for over 20 years, not only as a polar plunger, but as a multi-sport coach in her local area, Loudoun County, VA and as a national swim coach for Team Virginia at USA Games in 2014, 2018 and 2022. She is mentoring her 5th Global Messenger, a leadership program for athletes helping spread the mission and vision of Special Olympics.

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Continuation of the Above Articles

A Note from the CEO (cont.)

It was an embarrassment of riches in terms of learning opportunities, and to call out certain sessions does a disservice to those left out…but **Ken Dychtwald**'s opening keynote presentation, and Zan's afternoon sessions on what evidence we should want for healthspan products on Day 1; **Bill Haseltine**'s session on lessons from the COVID-19 pandemic on Day 2; and the marathon Commercialization roundtable with executives from Novo, Lilly and Pfizer, PepsiCo and Mars Edge, emerging companies and funders, on Day 3, were the types of sessions uniquely available at Metabesity. The conference for this year is being rebranded the ***Targeting Healthy Longevity*** conference and will be held not as a one-time conference over several days, but in a series of webinars over a period of months, starting in 2Q 2023, and culminating in an in-person workshop in Washington, DC near the end of the year.

In November, Zan and I spoke on separate panels at **BioFuture** in NYC, put on by the organizers of the Biotech Showcase conference that is held during JP Morgan Healthcare conference week in January in Union Square, San Francisco.

In December, we attended the **Milken Institute Future of Health summit** in Washington, DC, during which we participated in a private 6-hour Action for Healthy Aging roundtable on private sector initiatives for healthy brain aging organized by UsAgainstAlzheimer's and the Milken Institute.

I just want to comment on one of the most fascinating BioFuture sessions, featuring **Leroy Hood** of the Institute of Systems Biology, and Scott Penberty, Director of Applied AI at Google. Lee, in his hale eighties, is one of America's National Living Treasurers in life sciences (see his Wikipedia entry linked above). He mentioned that he has had four paradigm shifts in his professional career: 1. automated gene sequencing, 2. the Human Genome Project (HGP) that such technology enabled, 3. Systems Biology, and most recently, 4. precision population health. Further to this last epiphany, Lee is now leading the Human Phenome Initiative (HPI) to capture Vast amounts of data in a million persons over 10 years.

(Analogous to the genome and proteome, which represent an organism's genes and proteins, respectively, the phenome represents the sum of an organism's phenotypic traits, which result from all of the interactions of nature and nurture, including behavior and environment.)

As much a 'moonshot' project as the HGP represented at the turn of the century, the HPI represents a next generation project that is orders and orders of magnitude more complex than the HGP, to capture and correlatemultiomic (e.g., incorporating data on the genome, proteome, transcriptome, epigenome and microbiome), behavioral, environmental, and other data into a trajectory of an individual's phenome from time to time throughout their life. To illustrate the Vast amount of data they want to gather and correlate with respect to a drop of blood, Scott noted that it would approximate the volume of data on the entire internet circa 2012. The aim of such a detailed record is **to treat diseases with medicines that each individual patient knows will help them, and beyond that, to predict and prevent diseases for each such**

person. Just as in the case of the HGP, Lee is seeking massive government funding through vehicles like ARPA-H to drive the cost of capturing the phenome to affordable levels.

Lee gave two examples of what such an amalgamation of data could enable. First, say there are at least about 7,000 rare genetic diseases…but 30% of Americans in the aggregate suffer from at least one of them, and most won't know it until the disease presents and they complete an often-tortuous path to diagnosis, if ever. **Lee anticipates that the HPI should lead to our ability to identify most mutations and predict, or diagnose in the pre-disease state, such rare diseases.** As another example, the phenome affects not only proclivity to disease, but response to molecules that may help or hurt: in an early population study, Lee discovered that he had low vitamin D, so he started supplementation with 1000 IUs, only to discover that this had no effect; it turned out his metabolic reaction to vitamin D was such that he needed 15,000 IUs to normalize and remain there. The HPI is intended to identify many, many such actionable insights applicable to each individual.

Collection of these Vast quantities of data is one part; another is processing such data and teasing out actionable insights. AI techniques, incorporating advances from tensor mathematics to techniques for finding minerals on the moon, are being applied to handle manifold dimensional correlations to an extent that there is a legitimate debate among theorists on whether a difference in such quantity leads to a difference in quality – where **correlation of a Vast enough set of data points infers causality, as a practical matter.**

The future of human health as articulated by these visionaries is bracing. Readers interested in learning more can research Phenome Health and wait for Lee Hood and Nathan Price, The Age of Scientific Wellness, due to be released by Harvard University Press in April 2023.

- Thomas

Back to Top

A Note from the Chairman (cont.)

The most important and enduring gifts that come to us in life are relationships—starting, of course with family, but extending to hundreds, if not thousands of friends and colleagues, and even to those who could be seen as adversaries. Often, those seeming adversaries do us the favor of making us better or closing off a path or door that would have led to wasted time or disaster.

Kinexum was founded and named on the basis of making connections (L., nexum) and doing so with exuberance—energy (Gr., Kine). The unmerited fortune is that the nearly 1000 companies that Kinexum has touched over two decades has resulted in perhaps 10- or 20,000 kindled relationships. Some of these personal relationships endure to this day. Kinexum has been built almost entirely on the good fortune of meeting the right person at, more or less, the right time. We have never put out a help wanted sign or sought the help of a headhunter. We have simply encountered, *Fortuna gratias*, people who we like and admire, and asked them to join us.

I could name hundreds of treasured personal relationships and list them in an appendix, but instead of risking leaving off so many beloved people, I will focus on just one dear friend who has

been much in our thoughts.

Several months ago, we learned from his daughter, Ute Saalasti, that one of Kinexum's most esteemed and beloved members, Knut Zellerhoff, passed away after a difficult struggle with mesothelioma. Ute was by his side during his last hours. Despite his diagnosis in November 2021 and recurring crises, Knut was still able to live a fulfilling year with his large, beautiful family. He kept busy with projects, which included his rediscovered hobby of ship model building. He lived with hope of being able to outsmart the disease, but he was fully aware of the prognosis.

Knut was one of the most knowledgeable and effective pharmaceutical scientists with whom I have ever worked. His long career at Bayer involved key roles in the development of Cipro (ciprofloxacin) and over a dozen other approved drugs, which contributed to Bayer's success. Though he rose to head Bayer's global regulatory department, Knut was first and foremost a highly skilled scientist. He had expertise across a broad range of technologies involving small and large molecules. He became highly skilled in regulatory compliance and strategy across multiple disciplines. Following his years at Bayer, he was invited to support a start-up project for a therapy aimed at the autoimmunity of type 1 diabetes. It was at that project that Knut and I met. This fortunate encounter led to Knut becoming Kinexum's senior pharmaceutical scientist and one of our busiest, most sought after colleagues.

Knut then joined a Kinexum project that involved a biosynthetic enzyme targeting hepatoma. The developer of this treatment was based in Hong Kong, which led to an unforgettable trip with Knut to that city and several cities in China. Knut was already a seasoned world traveler and world class photographer. The bonus of that and other trips with Knut was his stunning photography, which provided mementoes of those adventures.

Karen Wolfe-Kerker, Kinexum's Chief Regulatory Officer, reacted to his passing by saying:
Knut was so much more than a knowledgeable colleague to many of us. He was a wonderful gentleman and friend. When my husband Phil and I travelled to Germany the past couple of times, he provided great advice and suggestions for navigating public transportation/trains between several cities and places to not be missed around Cologne, Bonn and Frankfurt, so we were comfortable travelling on our own. He patiently allowed me to practice my German language skills, too. During the past 12 or so years I knew him, he also gave solid pharmaceutical development advice and privately answered my regulatory questions since my CMC knowledge is limited. Knut never made me feel uncomfortable in asking questions. He was a great photographer, and he and Phil shared pictures of the full solar eclipse from 4 ½ years ago that was able to be seen completely from my home and from the Pacific Northwest where Knut traveled to see it. We had hoped that Knut would be able to visit us for the April 8, 2024 total eclipse, when we will again be in the path of the total eclipse, so the ring of fire surrounding the moon will be full.

Many other Kinexers offered similar reminiscences. We have all enjoyed his travelogs, spectacular photography, and friendship. Because Knut and I shared the hobby of ship model building, I will treasure the photo that Ute sent me of Knut working on his ship model during his last months. It was of the U.S.S. Constitution—"Old Ironside"—my first ship model. Like Old Ironside, which was so named because cannonballs fired at it bounced off as if the ship were built of iron, Knut was always unflappable, standing with full command of the relevant knowledge in any discussion. Yet, he was also gentle and collegial in every case. Over his career, Knut had a major role in putting many medicines in service to patients, while being a kind and gentle friend to many.

Recently, Kinexum has benefited from an extraordinary coach and guide, who has been helping us to make some simple but very important changes in how we work together within Kinexum. He has helped us, among other things, to understand that "we" can do anything we want; we just can't do everything we want. It is our individual decision to decide what we want to do and what we should leave aside. When surrounded by so many alluring choices largely provided by good fortune, it can be almost paralyzing to decide what to do and to don't. What I now realize is that when the choice is between things and people, the choice is people.

It goes back to what my mother use to sing to me when I was a little boy:
"Make new friends but keep the old; one is silver and the other gold."[1] [continued next page]
To your health and good fortune,
-Zan

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[1] The origin of this expression is not entirely clear, but it is believed to be an adaptation of an old English folk song or poem. The earliest known version of the saying was published in a children's magazine called St. Nicholas in 1908

Back to Top

Obesity Pharmacotherapy: New Era, New Opportunities? (Part 2) (cont.)

Key among these are: (a) difficulties in maintaining lost weight and reaching weight plateaus prior to achieving target weight, both of which may in the future be addressed with combination therapies; and (b) significant loss of lean mass. Although estimates vary somewhat, adipose tissue loss typically represents only ~70-75% of weight loss, with the remaining ~25-30% being lean mass. This can result in substantial decreases in energy expenditure, further contributing to weight regain, most of which is comprised of adipose tissue. Repeated weight loss-regain cycles then result in a progressively higher percentage of body fat and a correspondingly lower energy expenditure at any given BMI. Accordingly, there is a clear need for additional therapeutic modalities that target peripheral metabolism to target energy expenditure rather than focusing solely on ingestive behavior. While several are under development, most are in very early nonclinical stages and will not be discussed here.

2,4-dinitrophenol (DNP) was a popular and effective OTC weight loss drug prior to 1938, when the FDA withdrew it due to its narrow therapeutic index, which led to predictable side effects (e.g., hyperthermia) and death secondary to systemic mitochondrial uncoupling. However, there has been resurgent interest in controlled-release versions, prodrugs and tissue targeted mitochondrial uncoupling agents that can substantially broaden the therapeutic index and be safely utilized in obesity and related cardiometabolic diseases. While most of these remain in nonclinical development, HU6 (Rivus Pharmaceuticals) has demonstrated a favorable safety and tolerability profile in phase 1, with increases in resting energy expenditure and dose-dependent weight loss reported. A recent [MZ1] phase 2A eight-week trial of HU6 showed dose-dependent weight loss in the absence of a dietary or exercise regimen. Notably, the weight loss was comprised primarily of fat loss with preservation of lean mass and was accompanied by improvements in cardiometabolic

endpoints. While the durability of these effects remains to be demonstrated in longer-term trials, controlled metabolic uncoupling does appear to be a promising approach for obesity with preservation of lean mass.

BAM15 (Continuum Biosciences) is a mitochondrial protonophore-based uncoupler with potency comparable to DNP, showing considerable anti-obesity promise with preservation of muscle mass and salutary cardiometabolic benefits in animal models, although no clinical data are available to date. Similarly, other mitochondrial uncoupling agents that rely on similar protonophore-based mechanisms show promising results in non-clinical studies but are not yet in clinical trial.

Another approach to uncoupling is to target non-shivering thermogenesis via UCP1 in brown/beige adipose tissue (BAT). While this remains a topic of early-stage investigation, promising rodent data has not translated well to humans, possibly due an insufficient mass of brown adipose tissue in humans to elicit clinically meaningful effects. On the other hand, b3-adrenergic receptor agonists (e.g. mirabegron) do show BAT activity at high doses, possibly mediated by off-target b-2 AR activity, but is not practical as an obesity therapeutic due to effects on blood pressure and heart rate. Nonetheless, b-2 AR agonists are considered by some to have therapeutic potential for obesity.

NS-0200 (NuSirt Biopharma) is a combination of approved drugs with the amino acid leucine designed to activate the Sirt1-AMPK axis. Phase 2a data show significant progressive weight loss in the absence of lifestyle modification over 24 weeks accompanied by improvements in insulin sensitivity, blood pressure, lipids and liver fat. Notably, the combination exerted a markedly greater effect (~2.5-fold) on these parameters among African-Americans, suggesting potential to address a significant disease burden that falls disproportionately on this population.

Most other promising nonclinical approaches to develop anti-obesity medicines based on increasing peripheral energy expenditure have not succeeded in clinical translation either due to safety signals or minimal efficacy.

An exception is bimagrumab (Versanis Bio), which represents a unique approach to obesity therapeutics. Bimagrumab is an anti-activin type II receptor human monoclonal antibody that inhibits the binding of myostatin and activin A, thereby effectively attenuating a negative regulator of muscle mass and growth. A recent [MZ2] 48-week phase 2 trial demonstrated a 20.5% (7.5 kg) decrease on fat mass while increasing lean mass by 3.6% (1.7 kg) vs. a 0.4 kg loss in the placebo group. While the mechanism of action on lean mass is clear, there is considerable mechanistic uncertainty regarding effects on adiposity, although there is some data to suggest a linkage to BAT activation. Regardless, this degree of adipose tissue loss is consistent with that found with best-in-class approaches and was accompanied by improvements in HbA1c and other cardiometabolic parameters, although the weight loss was necessarily more modest (6.5%) due to the offsetting gain of lean mass. This approach holds considerable promise, especially with its unique ability to increase lean mass, although the long-term functional implications of this property remain to be seen and the broad applicability of the present formulation may be limited by the need for monthly intravenous infusion of the antibody.

Although most peripheral/bioenergetic targets of obesity pharmacotherapy have fallen short in clinical translation due to safety issues, efficacy, or both, there are now several promising clinical-stage drugs that present a realistic alternative and/or complement to targeting hunger and satiety pathways in obesity. As the field matures and obesity pharmacotherapy is more broadly adopted,

combination therapies that more fully exploit both the hunger/satiety and bioenergetic mechanisms could become the next horizon for more sustained and broadly applicable control of weight and associated cardiometabolic risk.

[MZ1] https://www.rivuspharma.com/wp-content/uploads/2022/09/RIVUS_PHARMACEUTICALS_ANNOUNCES_POSITIVE_DATA_FROM_PHASE_2A_CLINICAL_TRIAL_OF_LEAD_CANDIDATE_HU6.pdf
[MZ2]: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774903

- Michael

Back to Top

A Biographical Interview with Kinexum Founder Zan Fleming (cont.)

Interviewer (I): Zan, what three things do most people not know about you that they might find interesting, surprising, even shocking?

Zan (Z): <laugh> well, I am a shocking kind of person…It might be of interest that I love making things with my hands—furniture making, model ship building, and home renovation. I've built a fair number of reasonably good furniture pieces – a Chippendale style highboy chest, for example.

I: Do you recreate them or do you re refurbish them, or…?

Z: No, I start from scratch with mahogany or cherry boards. I have also restored some furniture, and I've also made a few musical instruments, including a harpsichord and a clavichord. Those were from kits. Haven't done much lately, but ironically, I did most of it when I was in medical school. I had more time then.

I: <laugh> What would you say was the genesis of your interest?

Z: My grandfather had a workshop and I loved to go down and watch him make stuff. He gave me his tools and that got me started.

Z: I also love music, which will not be a surprise to those who have viewed our Metabesity conferences in which we have included shoutouts and performances from world-class musicians. I have been told I'm a pretty good singer but not in my father's class. He was an outstanding soloist. Few people know that I've written the lyrics to a piece that was composed by Allen Pote, who's a world-famous composer. Long story there, but just to say I would like to get back to doing some music and lyrics composing in the future. I also enjoy supporting local concerts and music festivals.

I: You and Sir Anthony Hopkins, who has YouTube videos of his music…and the third?

Z: I am a leader in my local church and denomination-the United Methodist Church. I have

served as the lay leader in the three churches to which Deborah and I belonged over the past 35 years. I have given dozens of sermons, commentaries, and lectures in those two large and one small church. I have served in different ways to support the Wesley Theological Seminary in Washington, D.C.

I: Not to give you whiplash, but how did you end up at the FDA?

Z: That is a well-known story because I often tell it. I give credit to our dear Kinexum colleague, Art Santora, who went to the same medical school that I did, at Emory. He was a year ahead, but he was in a MD/PhD program and he ended up a year behind. But he preceded me to NIH where I went after my endocrine fellowship at Vanderbilt. He then went to FDA for a period of time before he went on to Merck. As Art was leaving FDA, he thought of me, about a particular need they had for a clinical reviewer. So, he suggested I apply. I did, thinking it would be a good sabbatical that I would stay for a year maybe, and then go back to NIH or academia.

I jokingly say that I found that I was much better critiquing other people's data than generating data myself in the lab. But it was true…I was not cut out to be a basic investigator. Although I spent four years doing that at NIH, which was a great experience, I found my niche at FDA. It's because of Art Santora that I ended up there for 12 years.

I felt like I had the best job in the Agency because I lucked into reviews of landmark approvals and was involved in multiple Agency innovations. My first NDA review was the first statin. At the time, I didn't even know what NDA stood for, <laugh> much less how to review clinical data in a sophisticated way. But in my naive way, I pushed to complete the review in what turned out to be record time. I pushed my colleagues and, in some cases, ruffled some feathers, but we set the land speed record for approving an NDA. At that time, the average time was about 40 months. We approved the lovastatin NDA in about 10 months. This led to the center director holding up that NDA review as a model for everybody else at CDER to follow. But I would hate for anybody to see my first NDA review.

That was just an example of sheer dumb luck that led to other lucky things, like the opportunity to be stationed in Geneva at WHO for a year and a half, which was a wonderful, mind-expanding experience. My assigned project was in China, which led to multiple adventures in Shanghai, Shenzhen, and Beijing, that included eating scorpions and other exotic banquet food.

Other opportunities I had at FDA included Leading Reviewer training and education, and this allowed me to get to know people all through not just CDER, but CBER and CDRH. We made that a socializing process as well, like a weekly CDER-wide seminar, and that was a good opportunity to also have some fun and get to know each other. I used to bring refreshments and play music before the start of the program. We could get just about any speaker we wanted. I also co-founded CDER's Virtual Journal of Regulatory Science. It died after I left, but I believe it might have been one of the scientific world's first online journals.

Another thing I did was to demonstrate the first use of the internet for regulatory communication, and that is another interesting story. The first transmission during this pilot project was when I was in Taiwan on an FDA educational mission, and I arranged to receive a small, maybe 15 kilobyte file, by internet dial up - probably took, 15 minutes to get it. But the point is, this was the very first example of an FDA regulatory transmission over the internet related to a review project. It was just my dumb luck to be in the position to be on the cutting edge of that technology at FDA.

I: Before we leave the FDA, we have heard you say that you had to fight for the approval of metformin for treatment of type 2 diabetes?

Z: That's a surprising story because there was so much controversy and even resistance within the Agency at the time. Metformin has since become the first line treatment for T2D. Another closely related biguanide drug, phenformin, had previously been removed from the market because it led to serious cases of lactic acidosis. It was actually the only case in which FDA preemptively removed a drug in contrast to the usual case in which the company removes its product "voluntarily." Then Secretary of Health, Education and Welfare, Joseph Califano cited the imminent hazard provision, and phenformin was removed from the market the next day.

This experience led to very strong opinions in the expert community that the US should never have another biguanide on the market. However, metformin had been used widely throughout the world since the mid 1950's and its effectiveness was well-established. There were an enormous amount of controlled trial and epidemiologic data that showed metformin was not associated with a risk of lactic acidosis except in people with renal failure, in whom the drug could accumulate. The data were compelling to me, but even one of my clinical reviewers violently disagreed. We let him present his opinion at a dramatic advisory committee hearing, but he persuaded no one. We put together an Agency working group to prepare for a storm of criticism. The group included CDER director, Janet Woodcock, who was key for engaging known critics. The storm never came. Metformin remains a major T2D therapy, and now it is one of the favored interventions for slowing the aging process and reducing risks of multiple chronic diseases.

I: Perhaps ironic is not the right word, but isn't metformin one of the safer or safest drugs out there?

Z: There is that irony. As mentioned, metformin is a favorite candidate for targeting healthy longevity. There is this trial that may get started soon called TAME, or Targeting Aging with Metformin that in part is based on the drug's excellent safety profile. Metformin's safety makes it one of the few drugs that could be tested in a healthier population, for preventing multiple chronic diseases, in contrast to treating a single disease.

I: Let us give you whiplash again and ask how you would describe the family culture in which you were raised? Your dad was a cardiologist? Do you come from a line of doctors? How were you and your siblings raised?

Z: Well, I came from a unique household. My father was a wonderful model for being a practicing physician, but he was much more than that. He was a great innovator and was very much on first name basis with the leading cardiologists of his day and did a lot of things for medicine in the region in which we lived. My mother was a force to be reckoned with, an accomplished writer and a great practitioner of hospitality. She and my dad were quite a formidable couple, and they brought a who's who of famous people to our house for dinner, Christian Barnard, Michael DeBakey, and many other famous physicians, Eudora Welty, Roy De Groot, Frank Reynolds, the ABC news anchor, a whole host of authors, and politicians.

I: This all in the Florida panhandle?

Z: Pensacola, 674 miles from Miami.

I: That wouldn’t be surprising if you're talking about Manhattan, but that seems so surprising in Pensacola.

Z: That was another thing my dad did, put on regular conferences, which influenced me to do the same thing. He brought world famous people to speak to local physicians. This was very unusual for a relatively small city in the deep South. Being an old naval town and its over 400-year history made Pensacola unique. My parents wrote together with noted composer, Allen Pote, a musical based on the true and fascinating story of a squadron of large seaplanes based at NAS Pensacola, which made the first transatlantic flight. Unlike Lindbergh, the flight was not non-stop and has largely been forgotten. The play was performed over 50 times, including at the Kennedy Center.

I: If you had not become an MD, what field would you have liked to have gone into? Or was that never a question?

Z: I always wanted to be an architect growing up and it was only when I got into high school that there was a future doctor's club and I thought, what the heck I'll join it. Once I joined it, I figured I'll just go with being a doctor <laugh>, which was probably a good thing because I'm not a good artist. You need to be a good artist to be an architect.

I: Do you have any advice for young scientists and MDs from your vantage point?

Z: Be curious about everything and keep an open mind. There is something to be said about doggedly pursuing a childhood obsession to be a neurosurgeon or astronaut, but chances are that curiosity, an open mind, and persistence will lead to the right place. There are just so many opportunities in science and medicine that the challenge is choosing among many good choices and not stiving with blinders on to achieve a preconception. Science is a great discipline with which to prepare for a career, even it does not directly involve science. Never stop learning about the world you live in.

I: Another whiplash question: would it be fair to call you an Anglophile?

Z: Well, I love England, but I also love Western civilization, but also Oriental culture. I don't know why England stands out other than that's probably my historical roots, at least, going back four or five centuries, before my Flemish ancestors left Holland. I did spend a year there while my father did a sabbatical at St. George's hospital in London, and that was such a great experience. It was a life changing experience that gave me a love of British culture, music (the Beatles were just catching on), and history.

I: On Zoom calls, including this one, you often have model ships on the wall behind you. <laugh> Are you a sailor, or other sea enthusiast?

Z: Well, I love ships. I used to go down to the harbor in Pensacola just to watch the ships. In fact, I took a job one summer unloading heavy bags of fish meal in the holds of freighters, which was the worst job you can imagine. <laugh>. I just loved the idea of ships in general and sailing ships in particular, but it's also ironic that my family will occasionally rib me about this: even though I love ships, I'm not a very good sailor. I was famous for having run a sailboat, aground <laugh> in Chesapeake Bay, near Annapolis. It required a commercial towing company to take us off the sand bar. It’s a story I'll never live down in my family.

I: Was this when you were young, a teenager?

Z: The fish meal loading was when I was a teenager. The long shipwreck story short is that this was a surprise that my daughters gave me for my umpteenth birthday. They rented the sailboat, and we set out with the idea that we would sail to where we were staying outside of Annapolis, and a big storm came up and it led to some confusion. Not on my part, but, uh, the map makers were confused when they <laugh>, uh, they drew the map. Despite my best efforts, the shoreline kept coming at us.

I: So lightning round, are you a dog or a cat person?

Z: <laugh> Both. First a dog person. Deborah and I both had dachshunds before we knew each other. More recently, we had a pair who both lived more than 20 years. We became cat persons along the way. We also claim as our own the pair of eagles who nest over the Potomac behind our house.

I: I believe that you're on the board of a Methodist seminary. How do you think faith and science should relate to each other?

Z: Well, I think they relate to each other because human beings need both, even though they're entirely different enterprises. I do believe we can accept that scientists can be people of faith and people of faith can be scientists and that science and scientists need not be hostile to religion or faith. A good example of that is Francis Collins, who founded the organization, BioLogos, which is primarily aimed at helping Evangelical Christians accept that science is not hostile to their beliefs. That there doesn't have to be a conflict between those who believe in the more literal interpretation of scripture and what modern science is telling us about the universe and about biology and disease. I do see the desperate need to help evangelicals to trust in the methods and findings of science.

I think whether you practice a religious faith or not, human beings have the instinct to believe in something that's greater than themselves. That's where we can all find common ground. We don't have to accept a particular set of beliefs about God or even whether God exists, but we can live our lives enriched by the appreciation of principles that go beyond what is found in scientific books.

I: From the sacred to the profane: what are your short- and long-term ambitions for Kinexum?

Z: I've always said that Kinexum is a means to an end. That was particularly true when I founded it, thinking that the end would be to identify particularly important opportunities to develop therapies or other life science assets. We did that in the early days: we founded a company aimed at stimulating islet regeneration in people with diabetes and long story short, that effort failed. We then went back to making Kinexum more of an end than just a means - a particular model for offering important needed solutions for small and large organizations that are involved in development of life science assets.

My hope is that Kinexum will be not just a firm, but an important resource that will keep going long after me. To a significant extent, it has developed into an organization that's far beyond what I ever envisioned, and I hope that it will just keep on its trajectory to be a substantial force and resource for catalyzing the development of important products that treat or prevent disease.

I: Just a couple more questions. Do you have a guilty pleasure?

Z: <laugh> I love chocolate. I take some satisfaction in evidence that flavonoids and other constituents of chocolate have health benefits <laugh> but only in large quantities, which cannot be practically consumed in chocolate alone. So I think we have to call chocolate a guilty pleasure *and* not a safe and effective intervention. <laugh>

I: What are you most looking forward to learning before the end of this decade?

Z: I hope to see substantial progress in preventing multiple chronic diseases, particularly diabetes. Preventing type 2 diabetes is eminently achievable now. Preventing is not quite the right word. Let's use the word preempting or reducing the risk of developing the disease. I do think what we can make substantial strides in actually slowing the progression of multiple chronic diseases among people across the globe.

Back to Top

How Medical Device Design Control Helps the Startup (cont.)

I was involved in the management of design and development of medical devices for many years at companies ranging from startups to Fortune 100. I earned five patents. As I'm sure you do, I preferred to have my people design and work in the lab instead of filling out paperwork. It slows you down and is annoying. Who wants to chase document signatures? Who wants to explain in writing the obvious?

Well, after many years of design and development experience, I came to see that the use of design controls actually shortened development times and made life easier for the entrepreneur, while facilitating FDA approval.

When I left the corporate world and began consulting with medical device companies, my first engagement was with a Boston medical device startup company that had prototypes being tested in several Boston area hospitals. At one point, they realized that each of these prototypes was different, but they didn't know what the differences were. They had lots of marked up drawings and red lined specifications, but couldn't relate these to any specific prototype. My first task was to put on my Engineer hat and figure out what the differences were. Then, I created a design control system for them so this wouldn't happen in the future.

WHAT ARE DESIGN CONTROLS?

Design controls for a medical device is a system of procedures and documentation relating to its design and development that are required by the FDA for Class II and Class III (and certain Class

I) devices. These are not detailed instructions that you follow, but requirements relating to early, middle-stage and later activities of product development. How you meet the requirements is left to your judgement. FDA may reject your judgment if they feel you do not have adequate control of the design process. Thus, it is helpful to work with employees, collaborators and/or consultants who are familiar with FDA requirements from early on in the process of invention and development.

PLANNING

Planning for integration of design controls should be integrated at the beginning of a project to develop a medical device. A plan defines responsibilities – who is responsible for what and who is not. It defines the interfaces between groups – who are the interfaces with Engineering and what information gets transferred. It defines the documentation required – who creates it, who approves it. It takes time and effort to write a good plan. But, the written plan will help you and protect you. It will help justify the allocation of your efforts to your investors. If you don't have a good plan, FDA could conclude that your development was haphazard and reject your submission.

REQUIREMENTS

Of course, you know what you want to develop. Who knows better than engineering professionals what device features are needed in the marketplace? Let the manufacturing experts figure out later how to make the medical device and how to make it at a reasonable cost. That's not your concern. Just start designing; we will fill out the paperwork as we go.

The above scenario is a recipe for disaster.

Perhaps Engineers don't know market needs that well. Fun fact: the first subway was built in London long ago. The subway engineers, logically designed the subway cars without windows because there was nothing to see. They soon had to redesign the cars. People refused to ride in windowless cars. Maybe our ideas will result in a product that costs too much and can't compete. Maybe that device can't be manufactured using existing equipment, tooling and processes. If we spend some time upfront defining the users, their profiles, characteristics, and what the product should do, in consultation with marketing and other groups, you will avoid headaches downstream. A good detailed user and functional requirements list, in addition to avoiding the above problems, will help generate an accurate cost/time/resource estimate that will help you avoid a subsequent crisis with investors. FDA will expect you to have documentation tracing each requirement to a successful test.

Documented and approved design outputs protect you. They confirm that you completed the design process accurately, on-time and within budget, and produced the product that everybody agreed they wanted. Or, such documentations will demonstrate that variances were made for good reasons.

DESIGN INPUT

Design inputs set forth the initial requirements of the planned medical device.

DESIGN OUTPUT

Design outputs include specifications, manufacturing process and inspections, and need to be directly traceable to design inputs.

DESIGN REVIEW

Design review is a formal review of the design by function (such as engineering, manufacturing, marketing and sales, IP, etc.).

It takes much time to prepare a design review. Presenting a design review can be scary. But, it's better to learn now if you are off track than later when it will be more painful to fix the design. Frequent design reviews with an interdisciplinary audience lessens the impact of any problem.

Design reviews, like other elements of Design Controls, need to be documented in the Design History File (DHF, see below), including review date, participants, design version/revision reviewed and review results.

DESIGN VERIFICATION

Design verification is the process that confirms that the design outputs conform to the design inputs, and needs to demonstrate that the specifications are the correct specifications for the design.

DESIGN VALIDATION

Design validation ensures that the device conforms to defined user needs and intended uses under actual or simulated use conditions. This can include software validation and risk analysis.

DESIGN TRANSFER

Design transfer is the process whereby the device design is translated into production, distribution and installation specifications. Changes in design or manufacturing would necessitate documentation of this and the other elements of Design Controls.

DESIGN CHANGES

Design changes is the process in which design changes are identified, justified, tested, approved and documented.

I have seen many projects where verbal undocumented design changes led to several product prototypes different from each other. Getting design changes documented, tested and approved may appear to slow you down, but it actually helps save time by avoiding a potential disaster later in the process. FDA expects a detailed change control process, especially when contract developers and contract manufacturers are involved.

DESIGN HISTORY FILE

The Design History File (DHF) is a formal document or index of documents that memorializes each of the above elements, the dates of formal meetings, participants and processes and outcomes, which can trace the development of the medical device from invention to submission of

the application for FDA licensure.

You accomplished all this good work. Where is the documentation? Can anybody find it in a few months or a few years when it's time for an upgrade? Are you relying on your memory? The time to create a numbered organized file of documents is well worth it to avoid confusion at a later time. This is especially true in the context of regulatory reviews when you must quickly produce requested documentation to an FDA auditor.

It is necessary but not sufficient to have test data showing the device is safe and effective. FDA, based on review of years of field problems, recalls, etc., has come to require Design Controls, documented in a DHF, to minimize the chances of unanticipated problems that might otherwise show up in the field.

CONCLUSION

Design Controls are a requirement for regulatory approval of Class II and Class III (and select Class I) medical devices. Far from 'check the boxes' documentation to be gathered at the point of submitting a licensing application, these processes need to be planned, documented and integrated into the development of the medical device in real time, from beginning to end. But more than simply a bureaucratic or administrative record keeping requirement, Design Controls can avoid unnecessary delays and increase the quality of your medical device product candidate, both in terms of performance and safety. This is why it is extremely important and valuable to work with employees, consultants and vendors who have familiarity with the development of regulated medical devices. Kinexum consultants will be happy to help you to plan, implement and document Design Controls that are optimized for favorable review by the FDA.

- Edwin

Groundwork for Draft Healthspan Legislation at Metabesity 2022 (cont.)

One of the most often-cited challenges to the translation of advances in aging research into products that prevent chronic diseases and extend healthy longevity is the lack of a clear regulatory pathway. Key stakeholders, including pioneer scientists in the aging research field, regulatory experts and legislators participated in a unique, far-ranging discussion that took place during the "***Achieving Evidence to Support Healthy Longevity Therapeutics & Products***" session on Day 1, October 9, 2022, of the Targeting Metabesity conference.

Moderated by **David Fox, JD**, Partner, Hogan Lovells, and **Alexander Fleming, MD**, Founder and President of the Kitalys Institute and Executive Chairman of Kinexum, the discussants included:

Steven Austad, PhD, Senior Scientific Director of the American Federation of Aging Research (AFAR)

Tom DiLenge, JD, Senior Partner, Flagship Pioneering, and former President, Advocacy, Law and Policy of BIO

Martin Hahn, JD, Partner, Hogan Lovells

Ellis Unger, MD, Principal Drug Regulatory Expert, Hyman Phelps & McNamara, PC and former Director, Office of Drug Evaluation-I, CDER, FDA

The following questions initiated panel discussions:

- *Do we need a universal system for Healthspan products, or do we need a system that breaks Healthspan products out into different categories (such as foods/supplements, drugs and devices)?*

- *What types of rules and evidentiary standards should govern science to support the marketing of Healthspan products?*

- *How much uncertainty should we be willing to accept in the evidence?*

- *What type of incentives are going to be needed to back the development of Healthspan products?*

- *What is the appropriate role of surrogate markers, molecular biomarkers or clinical endpoints for the assessment of aging?*

The following key points made by the moderator and the discussants were noted:

- Healthspan products can be defined as those "*intended to reduce the risk or delay the onset of age-related disability or the occurrence of multiple chronic age-related conditions*".

- In regulatory science, there are standards of evidence based on statutes about the types of products that can be marketed, the claims that can be made and about how much uncertainty people are willing to accept to allow interventions to be available sooner rather than later.

- A major distinction between Healthspan products from the types of products that FDA approves as therapeutics is that they are upstream in the unfolding of the disease or involve multiple systems that may lead to distinct diseases, while FDA usually approves products that target one specific disease.

- When targeting something as deeply rooted in biology as aging, Healthspan products will face the risk of developing side effects (though the acceptability of such side effects would depend on the countervailing benefits).

- The possibility of millions of healthy people taking a Healthspan product regularly for decades to prevent the development of age-related diseases means drug safety is paramount. Hence, researchers in the aging field are proposing to repurpose existing drugs, whose safety has already been proven, as Healthspan products.

- From the food perspective, there are no incentives to do research or clinical trials on dietary supplements and food products as companies may spend millions of dollars to prove that their interventions decrease the risk of disease development, but no proprietary value can back this claim and, therefore, any company with a similar product can benefit from the same claim. Similar risks may be faced by developers of repurposed drugs that are used as senescence-retarding products in healthy longevity trials.

- In addition to safety, Healthspan products need to be followed for a large number of years to demonstrate efficacy.

- Scientists need to identify molecular biomarkers of aging that can show efficacy of an intervention in shorter timeframes.

- Scientists and VCs, such as, Flagship Pioneering support the use of AI and ML to mine large databases in biobanks for correlations and causal relationships between biomarkers and aging, though the FDA will need to be convinced of their applicability, aided by Congressional encouragement and increased funding from new entities, such as ARPA-H.

- Geroscientists and sponsors should work early and often with the FDA to agree on the validation of AI and ML.

- In a model where a composite endpoint of the first appearance of one or another age-related chronic disease is used, then the event rate would come sooner in effect on average, and one would be able to identify within three to five years a change in the composite.

- If investigators can show improvement across a few domains, that are seemingly unrelated to each other, but related to aging, then a regulatory approval with aging as an indication may be obtained.

- Indicative clinical endpoints that can be utilized to prove Healthspan drug effects on prevention or reversal of aging may include the six-minute walk, the curve of the spine and muscle strength and others.

- If aging is considered as a fatal disease, then the accelerated approval pathway may be appropriate for Healthspan projects.

- If geroscientists can demonstrate to people that there is an 80%-90% risk of developing a chronic disease because of the changes occurring in their body, then people would be willing to accept certain risks to get some type of intervention.

- Private enforcement, instead of relying on the FDA to take action, can help developers of generics preserve their economic incentives for generating new data that support healthy longevity.

- A predictable and coherent system is needed to create a vibrant commercial market that is based on strong clinical evidence and calibrated on the risks and benefits of Healthspan products.

The panelists further discussed the need to develop a **Healthy Resiliency and Healthy Longevity Interventions (HRHLI) Act.** The **HRHLI Act** would establish a framework to oversee and incentivize the development of products regulated by the Food and Drug Administration (FDA) that are intended to lengthen the period of life during which individuals remain in good health, free from the chronic diseases and conditions responsible for most mortality and disability in the general population.

A recording of the session is available here**.**

The thrill of The Chill, (cont.)

Special Olympics is much more than sports - it is a global movement helping transform the lives of children and adults with intellectual disabilities and build communities of respect, inclusion, and unity. Joy currently serves as Chair of the Board for Special Olympics VA.

As a distinguished scientist, Joy gets a thrill assisting in the translation of novel therapies into the clinic. This past fall, Dr. Cavagnaro received the American College of Toxicology's Distinguished Scientist Award for her "*involvement in important public health issues of the last 30 years; service to the public, pharmaceutical industry, scientific and regulatory literature, and public*

health regulatory policy; and pivotal contributions, in the field of biologics." Dr. Cavagnaro's early contributions to the field of biopharmaceutical safety advocation for science-based, case-by-case evaluations, has formed the basis for all subsequent testing in this area.

Remarkably, Joy recently received another prestigious award: the American Society of Cell and Gene Therapy (ASGCT) Catalyst Award. The award recognizes an ASGCT member that has had **an extraordinary impact on the translation of gene and cell therapies** and has contributed in biomarker identification, endpoint development, manufacturing and scale-up, policy, or regulatory science. The ASGCT Catalyst Award will be given to Joy in the context of the annual ASGCT meeting in May 16-20, 2023, in Los Angeles, CA.

https://impact.specialolympicsva.org/fundraiser/4313504

Back to Top

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Other News

The Kitalys Institute organized the 5th Edition of the Targeting Metabesity Conference 2022 which was broadcasted live from Harper's Ferry! The conference was held virtually on October 10-12th and included an Emerging Company Showcase on October 13th.

Once more this year the conference was highly successful and hosted top academics, Directors of NIA , former FDA commissioners, the former prime minister of New Zealand, the Dean of Harvard Medical School, White House

representatives, legislative and other policy makers, senior executives at Big Pharma and Big Food and venture capitalists.
The theme of the conference focused on how to accelerate the translation of emerging science into public health to prevent chronic diseases.

Kinexum is proud to welcome 10 new Kinexers during the past year!

Jennifer Ahearn, PhD: Pharmaceutical and medical device regulatory compliance expert with former roles as an FDA domestic and international investigator, technical liaison for FDA's Office of Criminal Investigations, and member of FDA's National Training Cadre. She has worked to resolve technical and FDA compliance issues for pharmaceutical dosage forms and medical device classes.

Michelle Baron-Romans, MD, FACE: Global clinical and regulatory development and medical affairs in cardiometabolic diseases. Former roles include CMO Intarcia, VP Metabolism Medical Unit and VP Diabetes at Sanofi-Aventis US, and Diabetes Section Leader at Novartis. Michelle holds the position of an Assistant Professor of Medicine at SUNY New York. Michelle is board-certified in Internal Medicine and Endocrinology and Metabolism and earned her BA in biology from Johns Hopkins University and her MD from Howard University College of Medicine.

Elaine Chiquette, Pharm.D.: Medical and Regulatory Affairs within the pharmaceutical, biotechnology and medical device industries with a focus on cardiometabolic diseases. Elaine held leadership positions at Hoffman La Roche, Amylin Pharmaceuticals, Aegerion, GI Dynamics and Gelesis. Elaine completed her pharmacy degree at Laval University in Quebec and a Pharm.D. At University of Texas Health Science Center at San Antonio.

Elizabeth Cho-Fertikh, PhD: Drug development, spanning preclinical, GLP and GMP studies, regulatory affairs and program management. Additional expertise with financing biotech startup activities including nondilutive and dilutive funding and providing technical due diligence for angel investors and venture capitals. Assets have included small molecules, monoclonal antibodies, vaccines and gene therapy for Macrogenics, RegenXBio, VLP Therapeutics and

Enterin, Inc. Elizabeth received her BA from Johns Hopkins University, her PhD in Development Biology from Thomas Jefferson Medical School and completed her postdoctoral studies at NIH and Harvard Medical School.

Lydia Gilbert-McClain, MD: Broad expertise in drug development programs in pulmonary diseases, Critical Care, allergic disorders, and inflammation. Lydia has served as a Primary clinical reviewer, Clinical Team Leader, Cross-Discipline Team Leader and Deputy Division Director in the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) in FDA. Lydia completed internship and residency training in Internal Medicine at the Howard University hospital and fellowship training in Pulmonary and Critical Care medicine at Indiana University School of Medicine and Affiliated hospitals.

Kimberly Guedes, RN, BSN, MBA: Experienced clinical development professional across multiple areas of drug development; operations, and project management. Former roles include Vice President of Global Clinical Operations at pharmaceutical, start-up biotech companies and CROs at Keiferx, Centrexion Therapeutics, Merck Pharmaceuticals, Bristol Myers-Squibb, and Mitsubishi Pharmaceuticals. Kim received her BS in Nursing from Salve Regina University and her MBA from The University of Dayton, OH.

Alexander Klonoff, MD, MBA: Regulatory, digital health, and clinical practice experience, with prior experience working at FDA in the Center for Devices and Radiological Health. Alex maintains his clinical practice of medicine as an internist in both the inpatient and outpatient settings. Alex serves on the executive board of the Metro Los Angeles IEEE Engineering in Medicine and Biology Society (EMBS) section, which brings together industry and academic leaders from institutions including USC, UCLA, Caltech, and NASA/JPL, to foster collaboration and innovation in healthcare technology. Alex earned his BA, MD, and MBA degrees at University of Southern California and completed internship and residency training in Internal Medicine at USC/LAC+USC Medical Center.

Bart Van der Schueren, MD, PhD: An Associate Professor in Endocrinology at the University of Leuven, Belgium, Bart is also responsible for the obesity and lipid clinic at the University Hospital. He served as the Belgian member of the committee for medicinal products for human use (CHMP) and a member of the cardiovascular working party (CVWP) at the European Medicines Agency (EMA) and is the president elect of the Belgian Association for the Study of Obesity (BASO). Bart obtained his medical degree at the University of Leuven, Belgium, wherein he was also trained as a Specialist in Internal Medicine and Endocrinology.

Mitchell R. Smith, MD, PhD: Experience in clinical trials of lymphoma, leukemia and myeloma targeted therapies. Mitchell is the Chief Medical Officer of the UK-based non-profit Follicular Lymphoma Foundation, while prior appointments include Associate Cancer Center Director for Clinical Investigations and Chief of the Division of Oncology & Blood Disorders at the

Cancer Center in Washington DC. Mitchell earned his Medical Degree and PhD at Case Western Reserve University School of Medicine, Cleveland, OH, completed his internship in Internal Medicine at the Long Island Jewish Hospital, NY, spent 3 years in Pathology at Washington University, in St. Louis, MO, then another year in Internal Medicine at the Jewish Hospital of St. Louis.

Georgina Xanthou, PhD: Associate Professor in Immunology at the Biomedical Research Foundation of the Academy of Athens, Greece and Visiting Professor at the Division of Digestive Diseases, David Geffen School of Medicine at UCLA. Her research studies focus on investigating the cellular and molecular mechanisms underlying T cell immune responses in allergic, autoimmune diseases and cancer. Georgina has published more than 50 peer-reviewed articles in leading scientific journals and has received numerous prestigious international awards. Georgina completed her studies at the Department of Biology (University of Athens), received her PhD in Immunology, at the Medical School (University of Athens) and completed her postdoctoral studies with a scholarship from the European Molecular Biology Organization at the Division of Biomedical Sciences in Imperial College, London, UK.


Jennifer Ahearn


Michelle Baron-Romans


Elaine Chiquette


Elizabeth Cho-Fertikh


Lydia Gilbert-McClain


Kimberly Guedes


Alexander Klonoff


Bart Van der Schueren


Mitchell R. Smith


Georgina Xanthou

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Please submit suggestions to georginaxanthou@kinexum.com

Back to Top

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Kinexum provides strategic regulatory, clinical, non-clinical, manufacturing, and other translational advisory services for life science product development.

Our experts have decades of experience in government, industry, and/or academia and have broad experience with a range of modalities (including small and large molecules, devices, and digital health) and therapeutic areas (including diabetes, cardiovascular, GI, oncology, neurology, and wound healing). We manage complex assignments, file regulatory submissions, and negotiate with the FDA and agencies in other major markets.

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