“Educating Cancer Patients and Caregivers about Drug Discovery and Development” (Kevin Freiert) [#96]

Brad Power
May 8, 2024

“When I left Pfizer I started Salem Oaks to teach patients how pharmaceutical R&D really works, so that they can have a greater impact as they approach companies, academic researchers, or the FDA. It's a lot easier to win the game if you know how the game is played.” – Kevin Freiert

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Meeting Summary

About 70% of cancer patients and caregivers are educating themselves about their disease and engaging in their medical decisions, but they are confronted with many challenges as they try to navigate their care, including their consideration of clinical trials:

- **An increasingly complex cancer landscape**: With a 94% increase in the number of cancer treatments available over the last five years, it is becoming more difficult for both patients and providers to stay up-to-date on rapidly evolving guidelines. The continuous approval of new tests and therapies means that what you know becomes obsolete every six months or so.
- **Preconceptions about clinical trials**: Many patients and caregivers consider clinical trials to be higher risk than standard treatments. They don't want to be lab rats in an unproven experiment.
- **Difficulties in understanding the process of clinical trials**: Drug discovery and development consists of multiple layers filled with dependencies, hidden risks, and changing policies. It's like a transportation system with land, sea, and air routes for various activities.
- **Information overload**: Patients and families have unprecedented access to information (97% of patients use Google), yet are overwhelmed due to the lack of information curation and medical education to interpret complex test results, treatment options, and molecular biology
- **Limited time with doctors**: Cancer patients have on average only 23 minutes with their oncologist, and healthcare providers are seeing an increased number of cancer patients. Tools for shared-decision making are essential to make that limited time as efficient as possible.

Kevin Freiert, Owner and CEO of Salem Oaks, a healthcare education services company, is uniquely qualified to lead a discussion about the challenges and solutions for educating patients and caregivers about clinical trials. During his 30-year career with Pfizer, Kevin acquired a broad and deep understanding of the drug discovery and development process. He is a recovered rare cancer patient. He educated colleagues and others about pharmaceutical R&D, including establishing and running Pfizer Research University. Salem Oaks builds educational

resources about pharmaceutical research and development tailored to the specific needs of patients. They have mapped out all the on ramps, roundabouts, express routes and service stations along the drug discovery and development journey. Kevin is the host of three podcasts: Raising Rare, LEMS Aware, and Improbable Developments.

He has many educational sessions in his development roadmap. He wanted to learn about the biggest educational content gaps that patients and caregivers experience.

What information gaps about drug development can hinder you from selecting your best treatment options?

Evaluating Treatment Options

- Finding credible sources to evaluate treatments, assessing the credibility of research literature and claims about treatments, and quickly skimming literature and evaluating a treatment’s potential value. For example, reviewing information about the background to a clinical trial, such as the research on an animal model that led to the trial.
- Comparison of standard of care treatments versus treatments available through clinical trials
- Potential trade-offs that come with clinical trials, such as treatment limitations and consequences, or more frequent scans and blood tests. For example, if I join this clinical trial, will it limit me in my future treatments? Am I locked into this? What are the consequences if I drop out of the trial or do something different? Might I be prevented from pursuing other courses?

Accessing Treatments

- Navigating the FDA regulatory process, especially for access, such as expanded access, compassionate use, and right to try
- Reviewing eligibility criteria to see whether you can qualify for clinical trials; knowing what the prerequisites are can change your decision tree
- How to access drugs off-label, e.g., drugs indicated by genomics rather than the cancer setting (tissue of origin)
- Assessing the timing of the availability of a drug through a clinical trial and weighing that against the likelihood of disease progression in the meantime

Behaviors

- How to ask tough questions, how to advocate for yourself, e.g., how to make your voice heard if you don't meet the eligibility criteria for a clinical trial
- Examples of patient journeys, such as how a patient successfully advocated for themselves

What resources should be available to educate patients and caregivers about cancer and drug development?

- Content available through multiple media: video, audio, written
- Bite-sized learning modules
- Online discussion board: a place to ask questions, lasting records of discussions

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- Flexible and self-paced learning opportunities, tailored to individual pathways and needs
- Include examples to illustrate concepts

What can you do to educate yourself about drug development?

- Explore Salem Oaks’ Atlas platform and provide feedback

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Meeting Notes

KEYWORDS

question, clinical trials, cancer, drug discovery, drugs, patients, trial, put, work, courses, biotechs, cancer patient, oncology, treatments, information, kevin, process, company, access, pfizer

SPEAKERS

Kevin Freiert (69%), Brad Power (13%), Brian McCloskey (7%), David Plunkett (4%), Robert Gurmankin (3%), Sherrie Arsenault (2%), Cheryl Middleton (1%), Roger Royse (0%)

SUMMARY

Kevin Freiert discussed the challenges of navigating clinical trials and drug development for rare cancers and his personal experience. He explored the differences between clinical trials and standard of care, highlighting their potential benefits and drawbacks. Drug discovery has evolved and personalized medicine has increased, especially the importance of genomics in redefining diseases and fast-tracking drug approvals. There are many challenges in providing education in drug discovery and development, especially the need for personalized education tailored to individual learners' needs and pathways.

OUTLINE

Patient education on drug development and clinical trials.

- Kevin Freiert has a problem: prioritizing education materials for rare disease patients.
- He explains his experience in drug discovery and development, offering a subscription service with courses for those interested.
- Participants discuss their experiences with clinical trials and drug discovery, sharing sources of information such as Cancer Patient Lab and clinical trials.gov.
- Patients and caregivers should know where drugs come from to make informed decisions about clinical trials.

Drug development challenges and personalized learning solutions.

- Kevin Freiert discusses challenges in developing educational content for rare disease organizations due to lack of funding.
- He identifies knowledge gaps and information overload in drug discovery and development.
- Solution proposed: bite-sized learning modules tailored to individual pathways and needs.
- He describes a subscription-based online learning platform with various features, including written resources, discussion board, and bi-weekly office hours.
- The platform aims to provide flexible and self-paced learning opportunities for members, with a focus on practical applications and lasting records of discussions.

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- He outlines complex processes for drug discovery and development, emphasizing interdependencies and complexity.
- He explains the drug development process, including FDA regulations and company acquisitions.

Cancer clinical trials and eligibility criteria.

- Patients should ask about potential treatment limitations and consequences before joining a clinical trial.
- Kevin Freiert discusses eligibility criteria for clinical trials, emphasizing the importance of making your voice heard if you don't meet criteria.
- He showcases the courses available on their website, offering exclusive content for members and a subscription program for access to more courses.
- He describes drug discovery and development, highlighting key concepts, such as phase 2 trials confirm drug efficacy and safety, while phase 3 expands on safety database.
- He shares personal experiences and insights from his career in the pharmaceutical industry, including the importance of understanding the regulatory view and clinical pharmacology.

Cancer treatment options, including clinical trials and standard of care, with a focus on the advantages and disadvantages of each.

- Patients face a decision between standard of care and clinical trials, with pros and cons of each.
- Patients seek to understand trade-offs, such as more frequent scans and blood tests with clinical trials.
- Kevin Freiert discusses drug discovery and development in oncology, highlighting the importance of building on existing knowledge and using examples to illustrate key points.
- He discusses the use of artificial intelligence in drug discovery, highlighting its potential to analyze complex genomic data and identify specific cancer mutations.
- He believes pharmaceutical companies will adopt AI in clinical settings gradually, allowing the technology to mature first, and their current projects have been in development for years.

Cancer drug development, patient education, and literacy.

- Kevin Freiert discussed the importance of evaluating research papers and understanding their methods and conclusions.
- He emphasized the need for patients to be able to quickly skim literature and evaluate its credibility.
- He highlights the complexity of cancer, with over 16,000 different diseases to consider.
- The group discusses the importance of asking tough questions and seeking credible sources of information.

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TRANSCRIPT

Brad Power
This is the Cancer Patient Lab.

We're pleased today to have Kevin Freiert of Salem Oaks to talk with us. I ran into Kevin at a recent conference here in Boston which he was attending. He focuses on rare diseases. It was a rare disease conference. We've known each other for several years. I got to know Kevin as someone who'd come out of Pfizer and the clinical trials process, and through a set of circumstances got into the business of helping patients understand how the clinical trials process works.

He told me that the challenge he's facing is that he could develop 50 different modules of education materials for patients, but doesn't know where to prioritize, where to start. I sometimes call our community “focus group as a service”, that we are a ready-made market research forum that can give feedback to startups, as we've done many times, or to someone like Kevin, who's got these kinds of questions.

This is for information purposes only, it is not medical advice. Consult your doctor. We're trying to help arm patients with information they can bring to their doctors and their medical teams.

Cancer Patient Lab is a patient-led nonprofit learning community. We depend on the kindness of people who make donations of time and money. This is just a reminder that we would appreciate any donations that you can make.

Kevin Freiert 2:33
Thank you for the opportunity to speak today with you. Brad mentioned to me that you were a group of people who know what's going on. It was clear just from hearing one of the patient’s introductions before we started recording. I heard you're really tuned into your healthcare, your cancer, and the treatments you go through.

I am a recovered rare cancer patient. I had a liposarcoma that was removed in 1998. That seems like a long time ago. The only liposarcoma patients I've talked to since then were in much worse situations than I was, and I haven't been able to follow up with them. I think that we're primarily terminal.

I spent 30 years at Pfizer, and a lot of that time was spent teaching people how drug discovery and development works. My scope is larger than clinical trials. My thing at Pfizer was I knew how the whole puzzle fit together. I helped people understand how they depended on each other to get things done. When I left Pfizer I started Salem Oaks to teach patients how pharmaceutical R&D really works, so that they can have a greater impact as they approach companies, academic researchers, or the FDA. It's a lot easier to win the game if you know how the game is played. That's what I set out to do.

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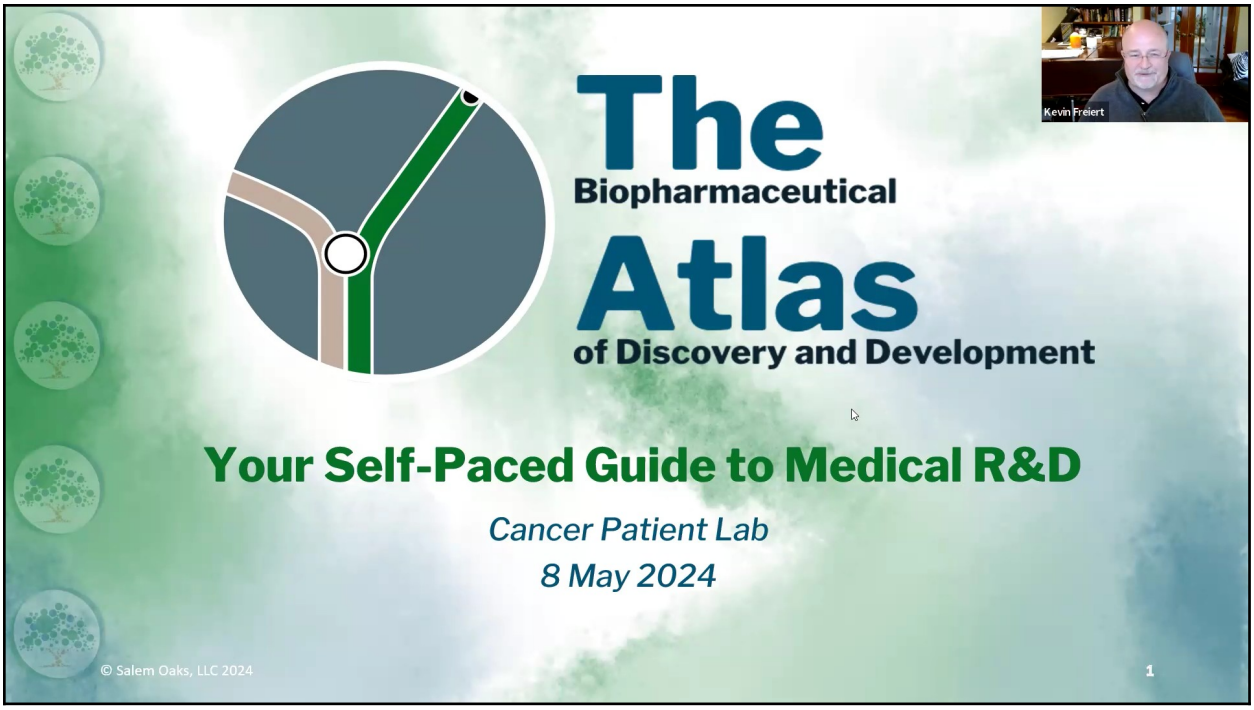
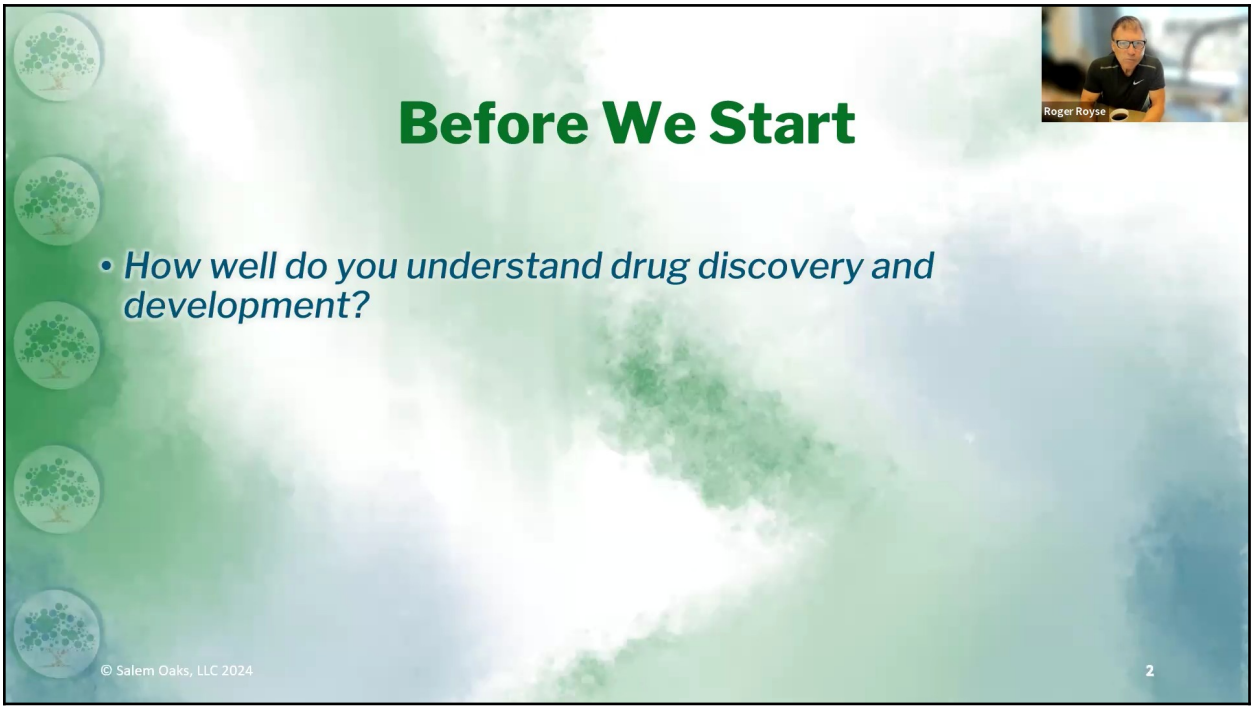
I'm trying to get some feedback from you, and also offer to you a service that we put together. I want to give you a little bit of background on it. We call it “The Atlas”.



The long name is “The Biopharmaceutical Atlas of Discovery and Development”. It's a subscription service where we're offering courses to people at the pace that they need it.



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I will just dive in and ask you guys some questions first. The first question I have for you is in general, how well do you guys already understand drug development, drug discovery, and development? For example, how many of you have been in clinical trials?

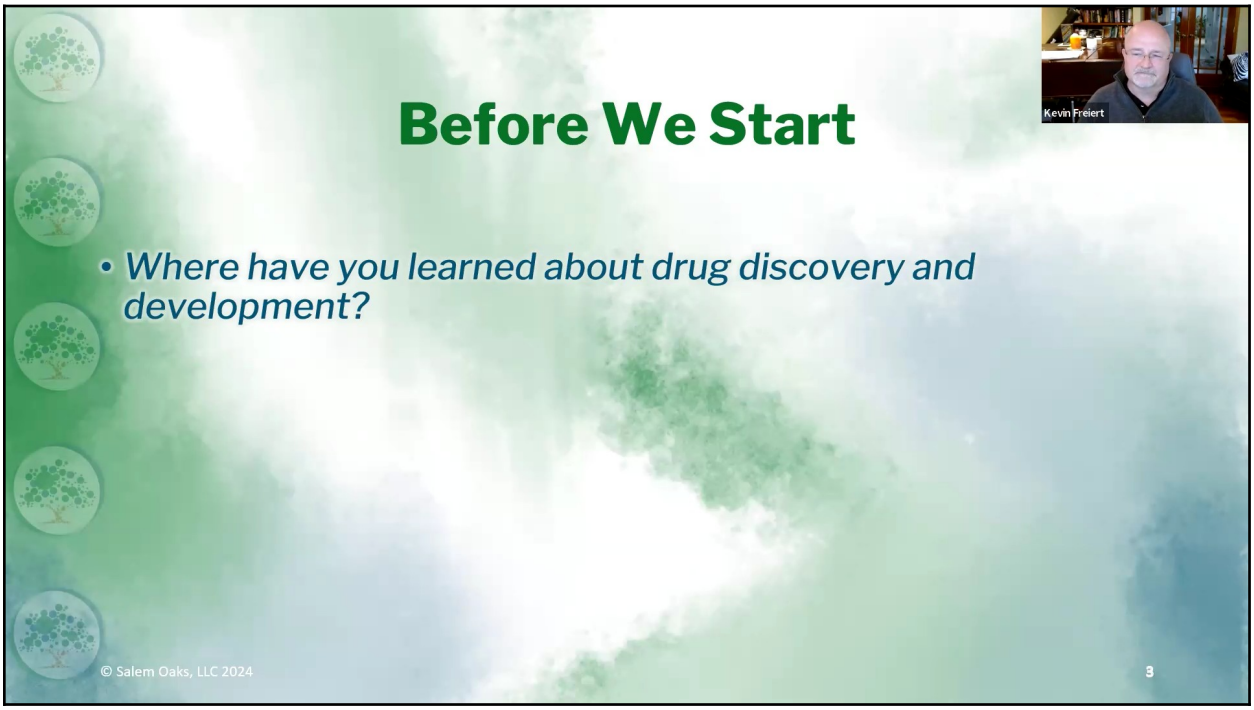
Have any of you met with the FDA or any other regulatory authorities talking about your situation, your diagnosis, or the treatments available?

How about meeting with academic researchers? Anybody tried to get people starting to look at treatments that may not exist yet?

Do any of you invest in the biopharmaceutical market?

Roger Royse 6:33
I'll just offer that I'm currently part of an FDA expanded access application. It's not a clinical trial, but it is a clinical research study. I'm getting a vaccine under that program.

Kevin Freiert 6:50
Knowing what expanded access is knowing what the difference is between a study and a trial.



Where have you learned about drug discovery and development before? Where do you get your information?

Cheryl Middleton 7:18

I get most of my information from this and other organizations. My brother has prostate cancer, and our father died of it. I've had breast cancer, and I'm being watched for multiple myeloma. So I sign up for information from those sites. But that's about it.

Brad Power 7:40
At Cancer Patient lab, we use Massive Bio, which is a free service. If you give them consent to give them access to your medical records, they will tell you about clinical trials. They look at clinical trials.gov, and you define a geography that you're willing to travel. Then they give you the best clinical trials for you. We get similar services from Cancer Commons. Similarly, you release your medical records, and they come back and tell you about either standard treatments or clinical trials. That's the way I and many others have gotten information about what's available in clinical trials.

David Plunkett 8:29
I'm more of an end user. I just took the recommendations of my medical oncologist and discuss things with her.

Kevin Freiert 8:39
Fantastic. David, have you been in a clinical trial?

David Plunkett 8:41
Yes, I'm currently enrolled in the CHAARTED 2 trial (Cabazitaxel with abiraterone versus abiraterone alone randomized trial for extensive disease following docetaxel). That's due to conclude I'm told later this year.

Kevin Freiert 8:49
I hope it's going well for you.

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One more question before I start dumping my brain.
How important do you think it is for patients and caregivers to understand where drugs come from? And why do you think that's important?

Robert Gurmankin 9:15
I think it's important because in many ways, if you join a clinical drug trial, it's a leap of faith. And it would be nice to know a little more information so it's not quite as big a leap. You see so many first-in-human studies. What came before that? They're able to get at least either the mouse or whatever model to humans.

Brian McCloskey 9:57
This isn't really a comment regarding this particular question. It's an overall comment, which is that for a lot of our patients, they're doing a lot of advanced diagnostics. They're trying to redefine their disease using these diagnostics. When you redefine your disease, it can open up drugs that may not be approved or used in your particular cancer setting. But they may work very well in other cancer settings. If you have, for example, the gene expression, the gene makeup alterations, etc., that looks like patients that might be receiving a drug in a different cancer setting, then why not pursue those other drugs?

That's a challenge that we have: how do we fast track drugs, using genomics, rather than just using the cancer setting?

Kevin Freiert 11:09

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Wow, that's a really deep question. That'll be one of the upcoming courses I've put together. It touches on a number of things: the prevalent off-label use of drugs in oncology, more so than in other areas. It gets into some of the subtleties, particularly in the oncology world.

Let me talk a little bit about how we got to what we're at today. We've tried to put together education for people. All the goodwill in the world. I've got a career's worth of stuff in my brain. I've got experts I can tap into to build things that I don't know as well. As I said, I know how to put the puzzle together. But I need to talk to the puzzle pieces to go deeper, where needed. We tried to just build things, put them out there retail, and see if people would come. No one did. There's no reason for someone to come find us.

We started working with some of the organizations. As Brad mentioned, I work in rare diseases. That's more of a tendency than a boundary that we have. I have fallen in love with the rare disease community. I also serve on the Board of Rare New England as part of that. Rare diseases upset the applecart of drug development. So it's an interesting place to go, because there's a lot of breakthroughs there. But we started working with rare disease organizations, and putting together projects for them. That worked pretty well. However, they have to go find funding. The funding they can get doesn't compensate us for the amount of time we're putting into it and the value of the knowledge that's there. They're not where the funds really accumulate. It works well, and we always will work with an organization if they have a project we want to do.

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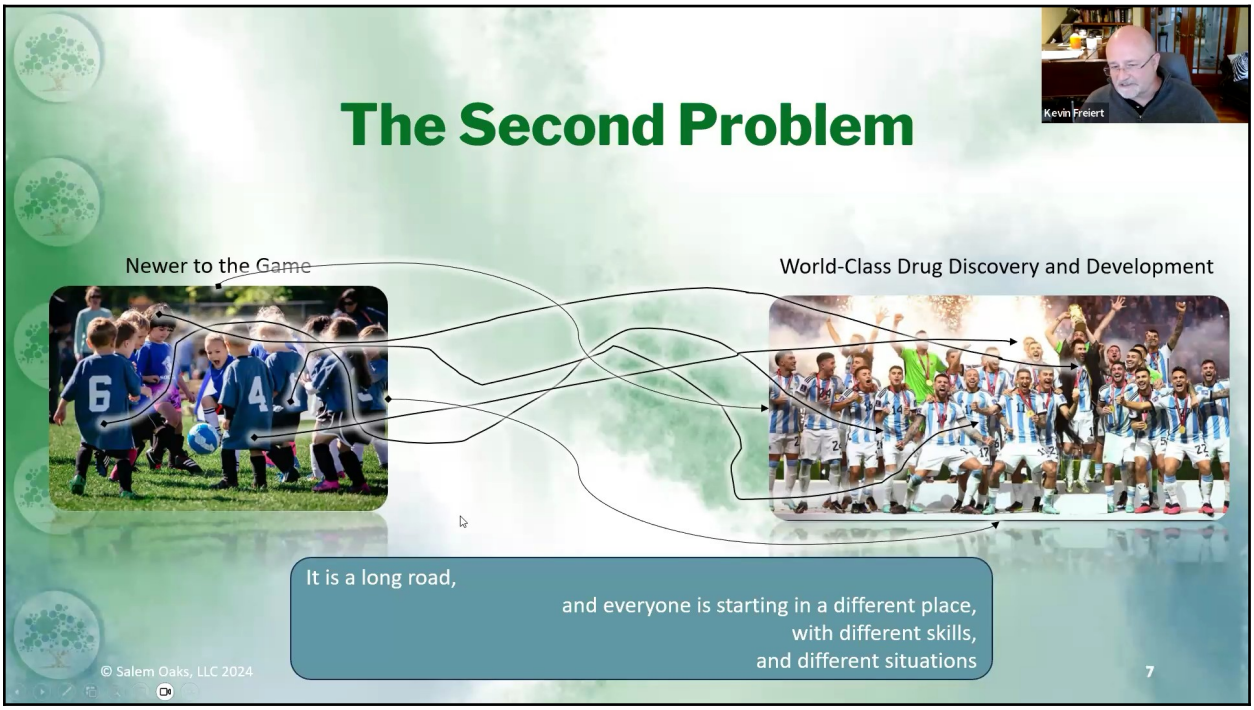
We noticed that there's a problem here. The problem is that we've got people who are really specialized in understanding this very well. I've always seen this, even when I was at Pfizer. There were people who are experts in tiny little things, who didn't know how they fit in the big picture. But they really knew their stuff. Then you've got your average Joe out there. I'm trying to talk to this person. It's a big gap. The knowledge gap is bigger. It's variable, but it's bigger than I originally anticipated.



The second problem is, everybody jumps in. As Brian said, you want to fast track things. You want to go faster. Everybody wants that world class discovery and development. But actually, they're newer to the game. They probably just got thrown into this because of a diagnosis. And it's a really long road. You hear the statistics of 12 to 15 years to find a drug. Well, what does that mean? Everybody who's doing this is starting at a different place. They have different skills. They've got different life experiences, and they're in different situations. It was really hard for us to say, “Here's what we need to do for somebody.”

The third thing is drug discovery and development, just clinical trials, is just too much to eat at once. What you get is people who come in and just give you the very superficial and don't go deep where you need it, or they go so deep and they try to put it all into one 45-minute session, and you just can't swallow it quickly, and, therefore, you're not learning. It bounces off of you.

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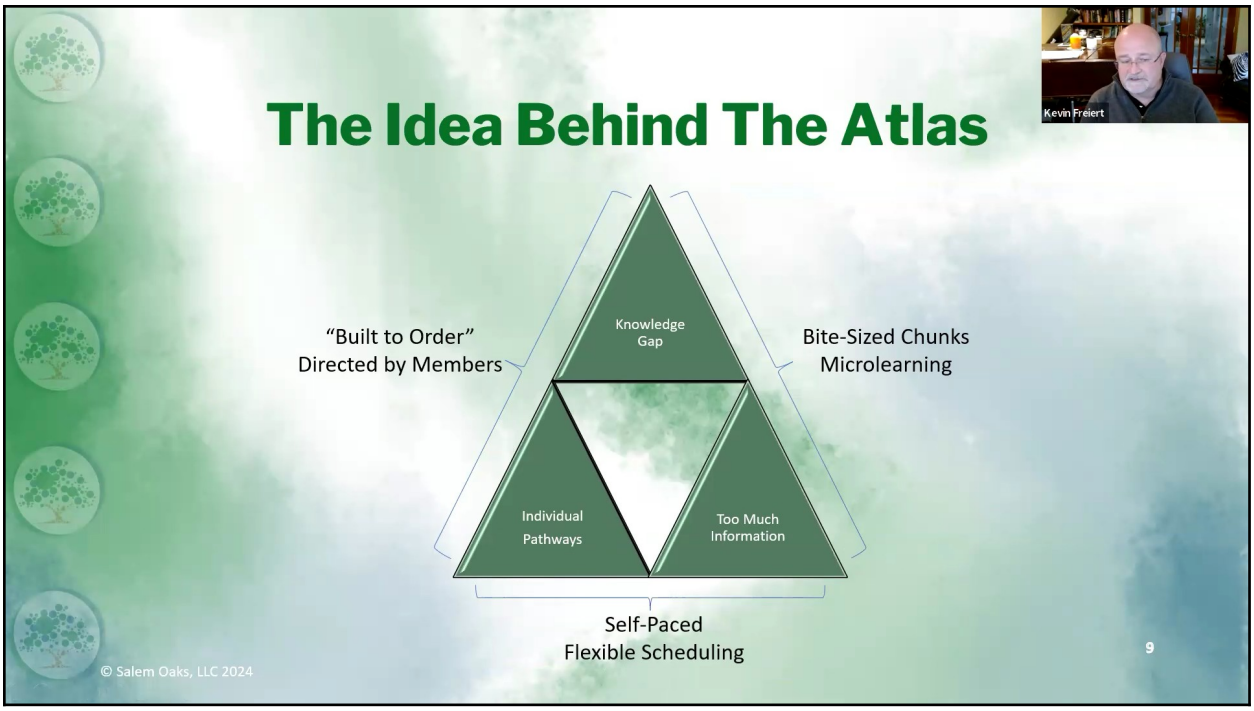

As we looked at these three problems, we said, “Well, if you've got individual pathways, and people have knowledge gaps, why don't we ask them what they need to know next? Is there a way to talk to people, much like I just did with you, to figure out where you're at first, and then build to order what you need?” People who are very early in the process need things that are different from people who are trying to get an Investigational Drug through the FDA that started its journey 10 years before they started.

This access to the knowledge gap and too much information: we're going to start building bite-sized things. I was getting very good at building these big long courses that no one would ever do. They're just too long. We don't have that much time to devote at once. So we're doing bite-sized chunks.

Then there's individual pathways and too much information: we wanted to make this self-paced and flexible. So it's less about when I can show up, and more about when people can show up and dive into what they're doing.

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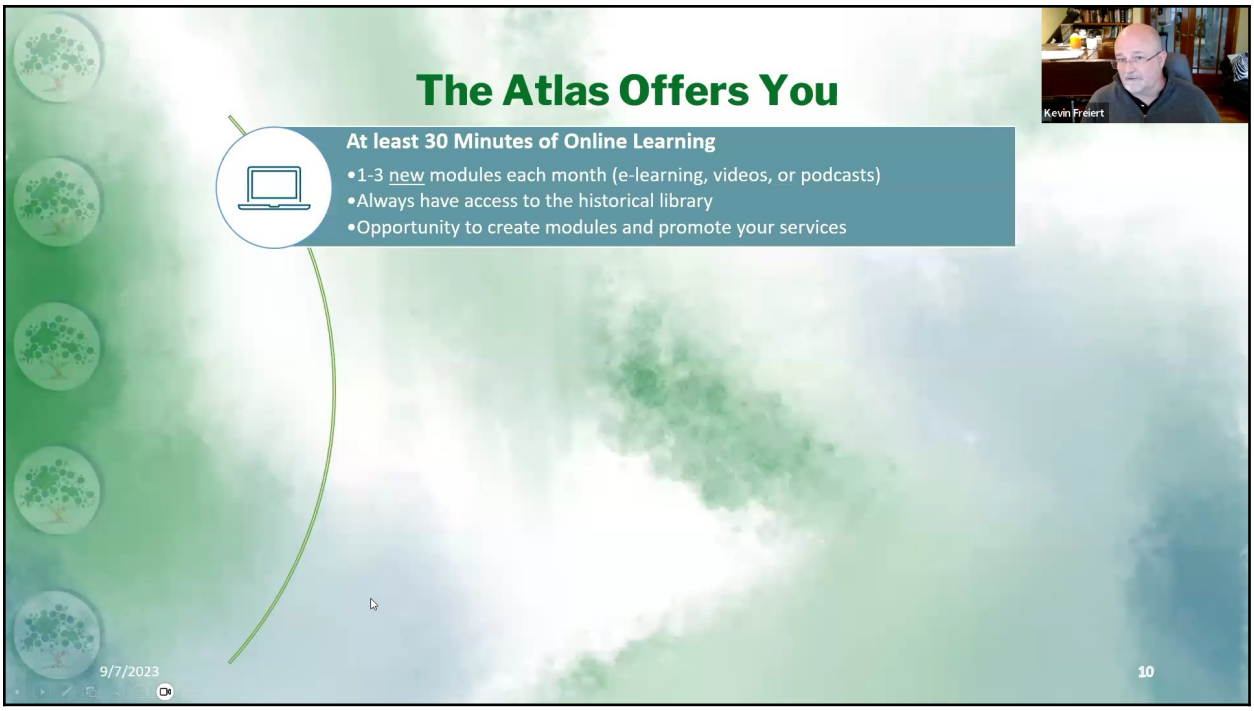
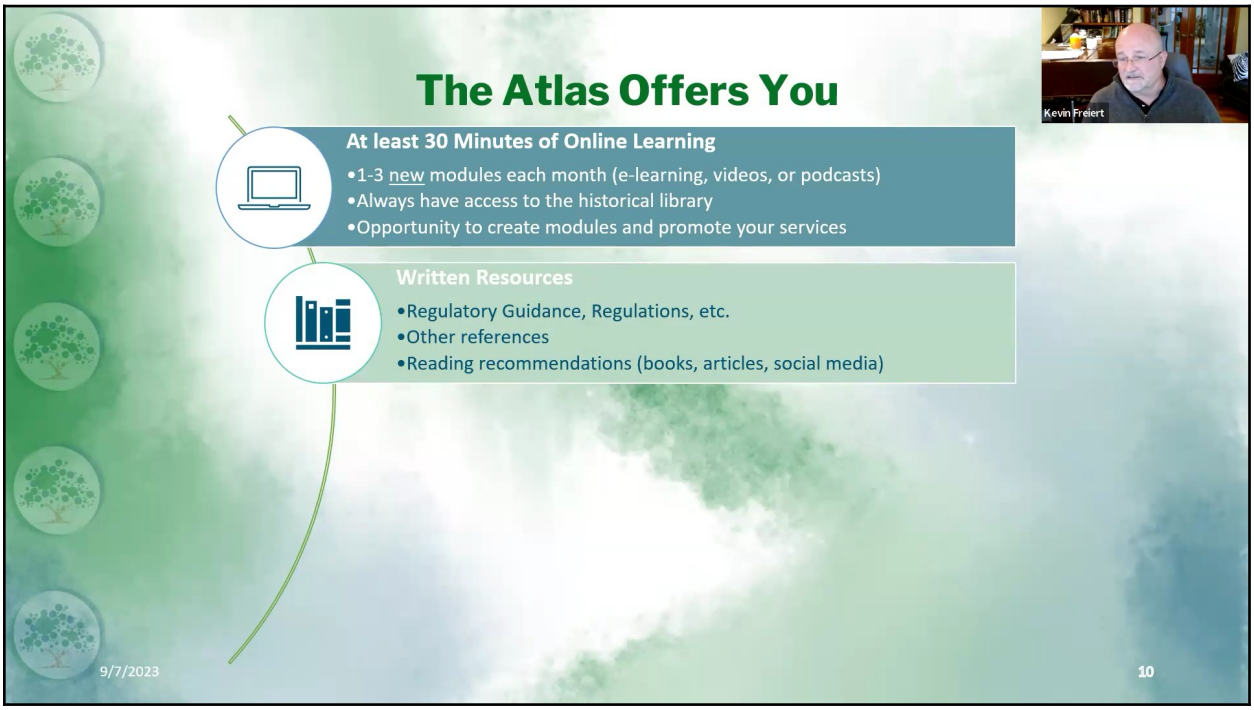


With this framework in mind, we started with a blank sheet of paper. We came up with a subscription model. Where we're going to put out at least 30 minutes of online learning – we usually do a bit more than that – each month. People can come in and use those each month as they go through. They also have the opportunity to let us know what they need. And if there's somebody who's doing something, one of my expert friends or something, it's a place for them to show off what they do.



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We provide written resources. I've just done a couple of courses on some regulatory guidances that have come out, but we provide the guidance so you shouldn't have to go digging through fda.gov to find something, because it's actually really hard. You have to learn how they've organized their information base, and it's not always obvious. Then other references. We've got recommendations for books and things that we've read along the way, or people that we know have authored.

We have a discussion board. We went kind of old school here. We wanted people to start conversations and be able to track those conversations, and by the way, create a lasting record of those discussions. That way people can go in, and they might be able to search for something and find the other people in the community who have used it, or who have had experience with it.

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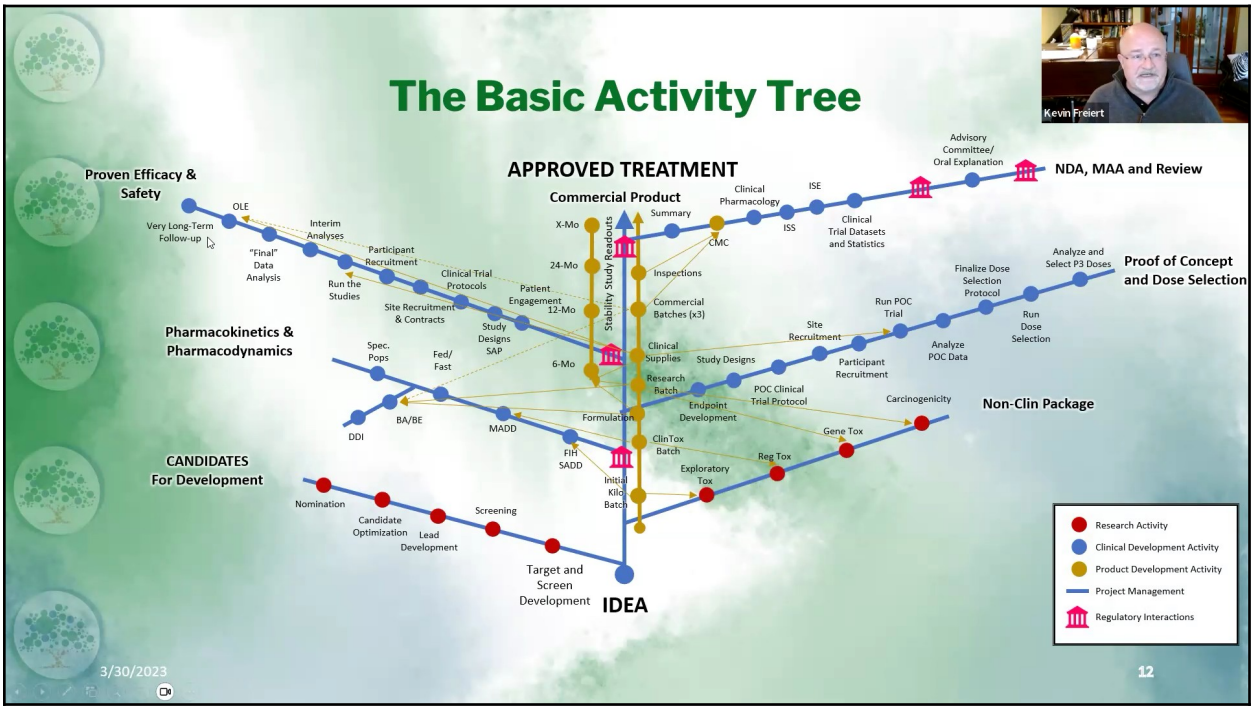
We offer biweekly office hours. This is a time when we're available to answer questions, whether it's about the learnings that were out there or just anything else. It's almost complimentary consulting time for those who show up for it.

When we started to say, well, what are we going to put into this? What's the content? This is where we started with a blank sheet of paper. I often see people put a timeline out there and

say, “This is the process.” The problem with that is it's very linear and doesn't capture the complexity and the interdependency of things. And it doesn't actually tell you about the outcomes. It tells you about the timing of things.



Every time I put this picture up, I warn people that it might make your head hurt. But this is what's in my brain of how I think about this whole process. What you see here is a number of major arms of the work that's going on, that need to happen. This is taking you from, “Gee, I have an idea for something,” all the way through to an approved treatment. Each of these little nodes is a course that I could build in my mind. I know I need to build them at a basic, intermediate, and advanced level. So if I add all these things up, there are about 400 courses that I could build.

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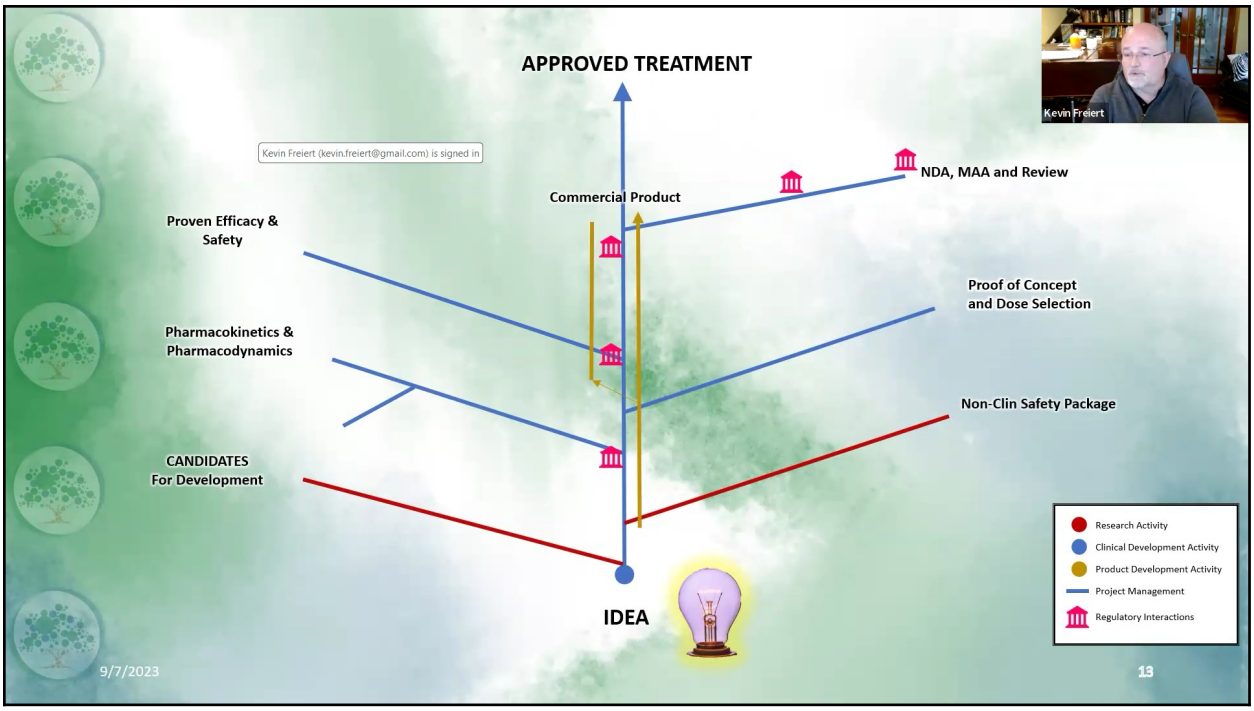

It takes me about a week to do each one. It's going to take me years to get there, which is where we come back to, “Well, what do people need next?” This is the framework that we're building. These are the types of things that get learned through the process. Then we go and have a conversation and ask people: “Where are you now? Where are you in the process?” I forget who mentioned expanded access. That's not even on here. It's beyond the drug discovery development process, but it's a big part of it. We will be working on courses about that as well.

I can show you some of what we have, but I want to get the idea of the concepts wrapped up a little bit first.

Cheryl Middleton 20:46
Is this germane to a particular type of cancer, or is this generic enough that it can be used for a variety of cancers?

Kevin Freiert 21:02
It's not even limited to cancer.

Cheryl Middleton 21:05
Can you elaborate on that?

Kevin Freiert 21:07
People have other diseases, and there are people looking for drugs for those diseases. That's where I work in the rare disease space. I work with the Friedreich’s Ataxia Research Alliance. They're looking for drugs for Friedrich’s ataxia, Duchenne muscular dystrophy, but even things like less rare diseases. Things like multiple sclerosis. There's a lot of work going on trying to find

drugs. I'm not bringing disease knowledge. I'm bringing the process, no matter what disease you're looking at, you're going to have to follow it in some way, shape, or form.

I already mentioned that oncology is slightly different than if you're looking at an anti-infective or something for headaches. There is a slightly different process that is taken, but the basic bones are the same. You still have to show that it's safe, it's effective, that you can make it consistently purely and to the strengths and qualities that you say you're making it. And it all is regulated. So you've got to deal with the FDA and all of that.

Robert Gurmankin 22:28
It's not really related to what you've been talking about. But you'd be a good person to ask since you know the field. I'm five weeks into a clinical trial. And within the first week, the drug that I am taking was bought out by Novartis.

How common is a big company buying out a drug that's in phase 2, or whatever phase? And is there a cause for concern going from a small biotech to this big giant company?

Kevin Freiert 23:13
There's lots of details behind that that I don't know. But to answer your question, “Yes. This is very common.” In fact, when I started in the industry, we did everything. We did some of the basic research. We looked for drugs. We selected those drugs. We moved them forward. We got them into clinical trials. We went all the way through the whole process. Now the industry works more where the biotechs do that early stage work, and get it to a point where it's an attractive investment for the bigger companies, who then have the wherewithal to take them over the goal line. Because the small biotechs usually don't have all of the regulatory horsepower, the manufacturing horsepower, the experience and the processes to make this happen. It's actually been a real boon for the whole system, because the biotechs can work really quickly in that early stage, which fails a remarkably high percentage of the time. So they can churn very quickly. Then once things become promising, a big company buys it up. It seems like that company has expressed some interest. The things you may notice are less of a personal touch. I don't know how close the biotech was to you, but it's a big company. It's got lots of things going on. Things may get more systematic. Things that felt like they were falling through the cracks and stuff will stop because the big company knows if we don't tighten the ship, and we don't do this well, then we're never going to get that approval. And if we don't get that approval, we've just wasted our investment. So that's one view of it.

I don't know how big the small company was, how many assets that were taken up in the acquisition, or if it was just one. If it was many, then you're at the, “Which one did they really buy the company for?”

Robert Gurmankin 25:33
It was just one. It happens to be the drug that I'm on.

Kevin Freiert 25:40

I'd say that's a promising sign.

Sherrie Arsenault 26:00
I am in between. My last treatment is no longer working. My tumors are growing. I had a zoom consultation with my clinical trial oncologist two weeks ago. She said the approval for INSIGhT (INdividualized Screening trial of Innovative Glioblastoma Therapy) was going to be funded any day. I know my tumors are growing. My concern is, “How do I know whether this is going to happen in the next few weeks?” Or do I go back to my oncologist and say, “Let's go for something different.”? I want to be proactive with my care, but I don't want to nudge too much and drive them crazy. But knowledge is power for me. That's my question.

Kevin Freiert 27:00
This is where Brad’s disclaimer about medical advice comes in. I have no qualifications to give you any medical advice, so I can't even do it. My advocacy advice would be, “Don't worry about the nudging.” You're dealing with your life and your body here. So go to your oncologist. The place where you can find things would be clinical trials.gov.

Sherrie Arsenault 27:34
I've been there.

Kevin Freiert 27:37
Look for what's there.
But the question you should ask your oncologist is something like, “What are my other options?” And, “Why wouldn't you have recommended that in the first place?” Dig a little.

There's a friend of mine, Rob Weker. You may know him. He pushed back on his oncologist who said, “We can't give you that because it's just too hard to dose.” And he said, “I work in the pharmaceutical industry in the dosing world. What don't you think I can do?” Sometimes people make assumptions about your ability to do a treatment. Don't let that happen. Just keep digging. What's the objection? Can we manage it?

Brian McCloskey 28:27
As a rule of thumb, Sherrie, it's always good to have parallel paths. Because there are so many reasons why a drug or combinatorial that you are pursuing may not actually happen. It may be that you can't get access to it, or you're not going to get insurance reimbursement. There are a lot of different things that you need to have, multiple irons in the fire, to be able to navigate this.

David Plunkett 28:59
A continuation of that point is that when a clinical trial was first suggested to me, one of my first questions for my oncologist was, “Does this limit me in my potential treatments? Am I locked into this? What are the consequences if I drop out of the trial or do something different? Might I be prevented from pursuing other courses?” And I was very relieved, at least in my case, to learn that, “No. I wasn't locked into anything.” So I could change.

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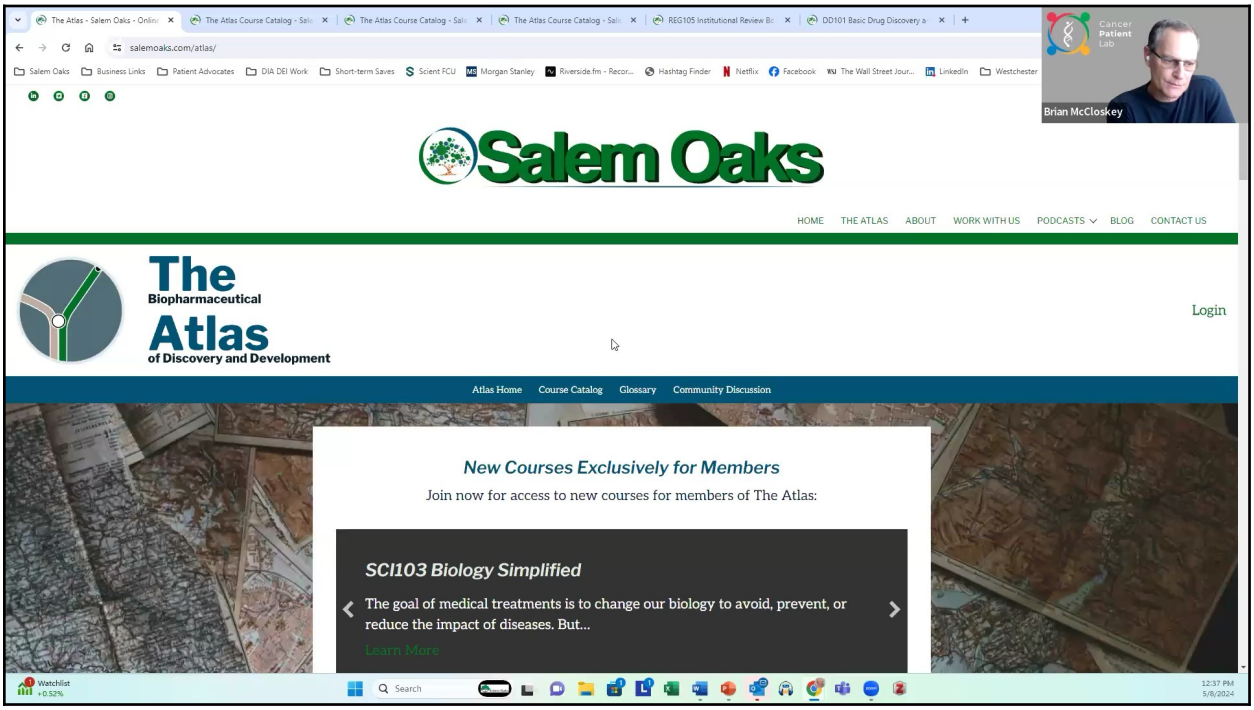
But one of the questions that came up for a friend of mine with colon cancer was the qualifications needed for the trial that she was interested in. In her case, she found out about a new trial about three days before she was due to start a chemo session that would have disqualified her. So knowing what the prerequisites are can change your decision tree. And that's worth knowing in advance.

Kevin Freiert 30:12
The eligibility criteria are really important. Your inclusions and exclusions in a study are because you're trying to control an experiment. There are things which would disqualify you, or as David asks, would this disqualify me for something in the future? It's hard, though, because you're trying to anticipate something you're trying to anticipate. How am I supposed to know what the eligibility criteria are if I don't know what the trial is that I'm looking for? But it is important.

Again, that's a place where you can push back a little. You may not get the immediate answer you want. But I know that when companies start hearing, “Gee. People are not enrolling in this trial because they're not meeting criteria over and over and over again.” They go back and look at their criteria and say, “Do we really need that? Can we be flexible?” So it's important to make your voice known if you're seeing something like that.



Kevin Freiert 31:53
The Atlas is just on our website, Salem Oaks. We offer exclusive courses for members. We've also got some free courses that will be put out there, but it's up to us what goes out as free.

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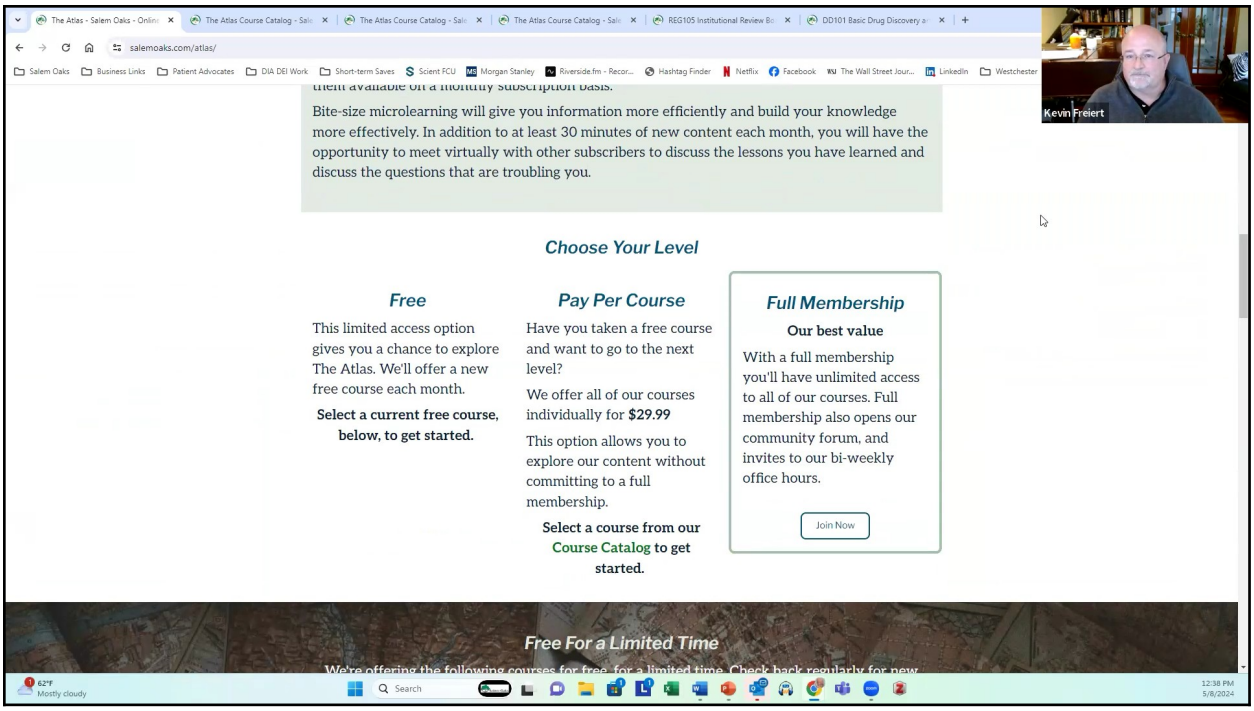
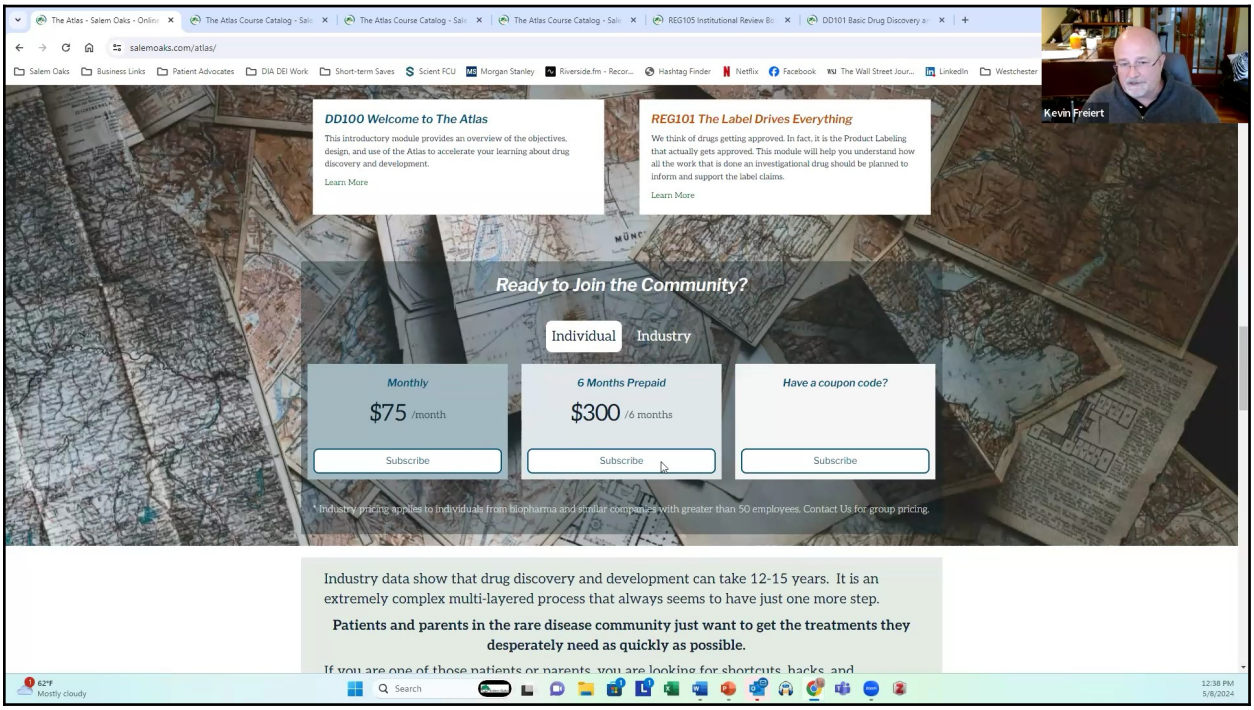


Then we've got a way to pay for it by the course. Some people may not want to jump into our subscription program. But the subscription program for the value you get is fairly valued, or a fairly good bargain. It's worth the money.



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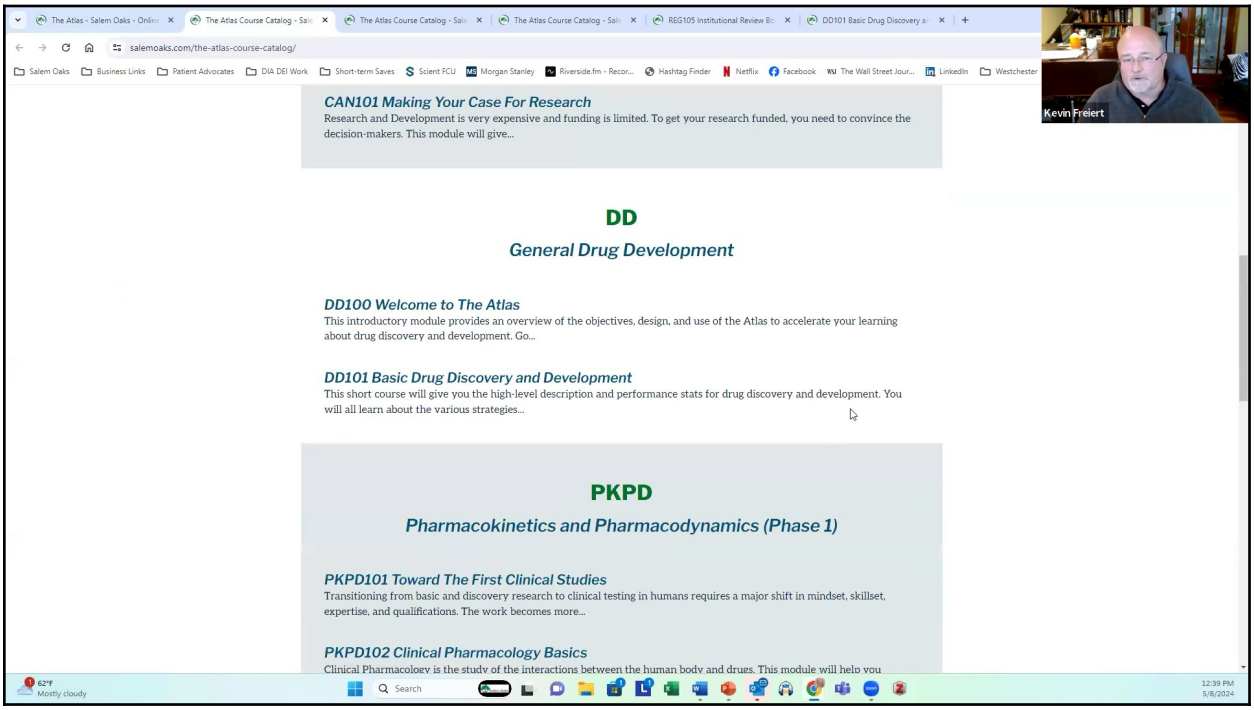
It's $75 a month. Or if you pay in six month increments, it's $300. So it’s somewhere between $300 and $900 a year. I'm telling you those details not because I’m a pitch man. I’m not good at this. But I'm trying to get some feedback from you as well.



What we have in our course catalog, which people can always see, I've got 15 courses that I've built so far. These are the various topic areas, those bars that you saw on that tree I showed before. Then the courses that are built in there. How do you make your original case for research? What is the Atlas? How does this work? What is basic drug discovery and development? What's the big picture look like?

When you get into pharmacokinetics and pharmacodynamics, that's where I spent most of my career, how do you get to those first clinical studies? What's required? Where has this drug been before? I'm taking it. If you think about the first clinical study. I remember an FDA person that came to speak to us. They talked about the first-in-human trial for an FDA decision-maker. “Do I give them the okay to go forward with this or not? Let me see, no one's ever had this in their body before. I'm going to be held accountable for the very first human being ever being exposed to this.” That's a very weighty decision for them. They don't take it lightly. That's what this course teaches you. Well, what do they need to look at if they haven't seen it in people?

Then we have a course on just clinical pharmacology, different things around the regulatory view, the fact that the label, the end game of drug discovery and development is that thing that you unfold out of your prescription. That's the label, the package insert. That's the product. It's not the chemicals. It's not the pill. It's not the liquid. It's what do we know about that, and how does it work? And how do we use it?

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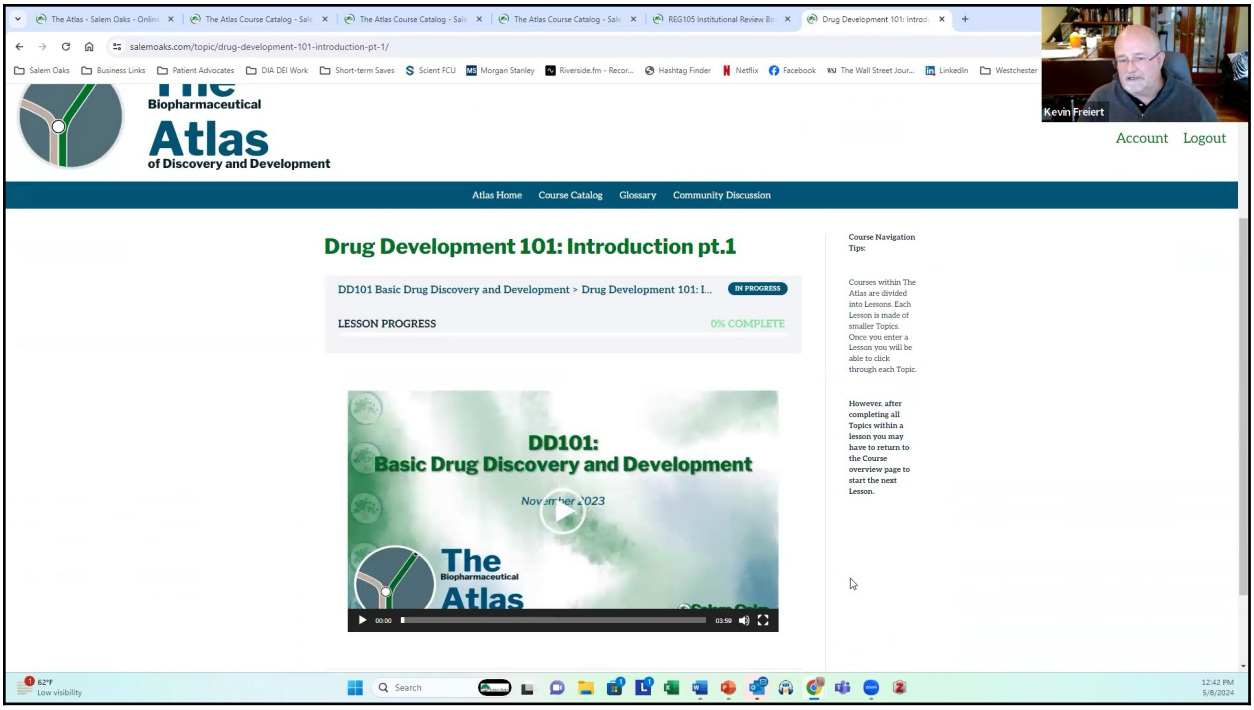
We have a course on IRBs (Institutional Review Boards) and how they oversee clinical trials. And recently, we've got the guidances on benefit, risk and rare disease.

Some of our early members said, “We need to know basic things like, How does a scientist think?” I'm not a scientist, I'm an interior designer. How do scientists think? So we built something there.

The other thing is you find yourself reading lots of papers, and it can be overwhelming. There are ways to efficiently digest papers, and knowing what those papers are, and how they're structured. What they do is very helpful.

And then people wanted to know just the basic biology. How do things work?

So that's our current catalog.



What does one of these things look like? Here's the basic drug discovery and development one. We've got it organized into lessons and things so that you can take a look at it, and many of them are in video format. So you just walk your way through. This lesson is a little under four minutes.

Sherrie Arsenault 36:41
How do we access it? Do we just go to Atlas?

Kevin Freiert 36:47
It's at Salemoaks.com/atlas. It will take you to the opening page.

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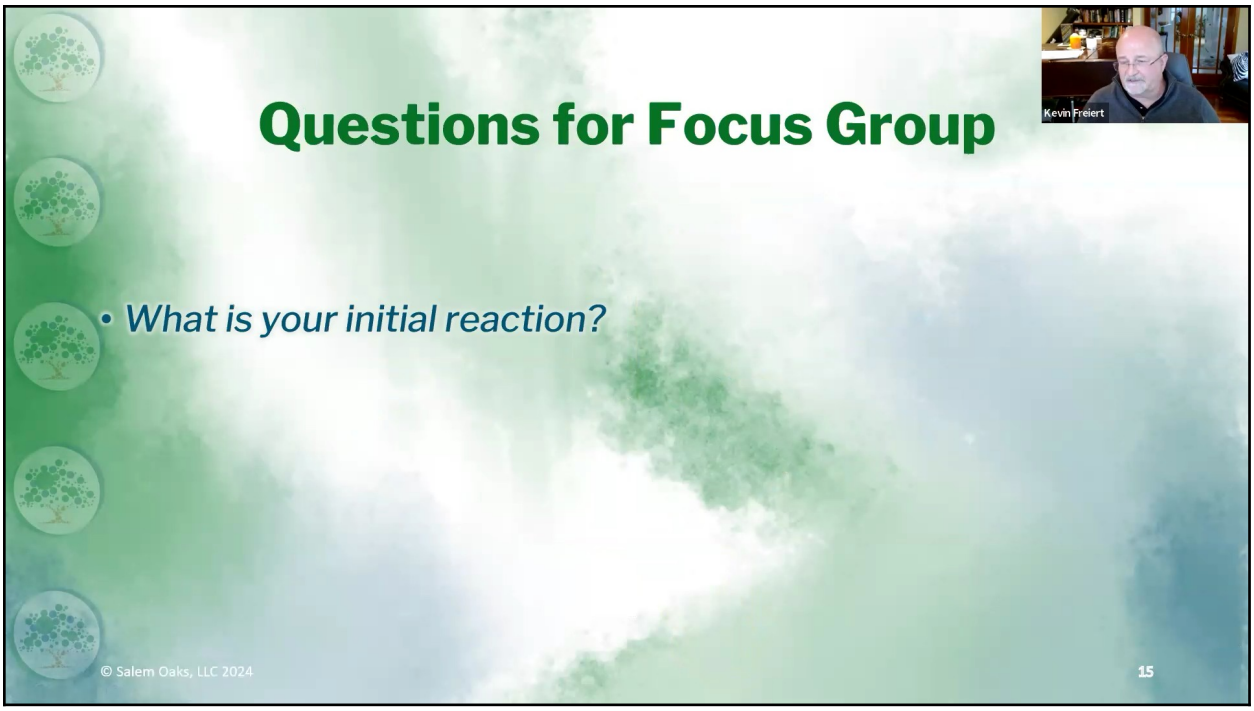

Kevin Freiert 37:30
I had some questions as the focus group that Brad sold you as. You're much more than that. You're a fun group to talk to as well.
But what's your initial reaction just to the idea?

Brad Power 37:59
If I can access a phase 2 or phase 3 trial, how should I feel about the difference?

Kevin Freiert 38:11
The difference between the two is that we call the phase 2 trials “the learning trials”. What you're doing in phase 2 is you're trying to find out, “Does this drug work?” Phase 3 are the confirming trials. You're confirming that what you saw in phase 2 was true, and you're expanding on it and building a larger safety database. All these drugs are targeted to do something, and if it's efficacious, it's doing what you expected it to do. They all have off-target issues. It's just whenever you put anything into your body, food, water included, you can have adverse reactions to it. When you're doing a phase 3 trial, you're trying to get a large enough group that you're casting a net, that you're going to pick up some of those rare adverse events. That's the difference between the two. In phase 2, you're still looking for adverse events. But you're asking the question, “Does it work?” For oncology phase 1 usually answers that question to some extent. Pfizer didn't always have oncology. It was not until about 1997 or 1998 that we started to dive into oncology. When all those oncologists came on, we put phase 1 right into patients. They had to because they were talking about chemotherapies that had known toxic effects. You can't go into somebody who's “healthy” and give them something like that when they really have no benefit from it, particularly since many chemotherapies can cause other cancers, or other mutations. Phase 1 in oncology is like phase 2 in normal drug development.

Phase 3 is really now they're getting into, what can we combine this with? And what can we really know about this product?

Brad Power 40:46
For our patients, it's not understanding the process, per se, as a process, it's understanding how it relates to their decision-making. The decision-making that patients have to make is step one. I can get a standard of care treatment, or I can get a clinical trial. What are the trade-offs between those two? What are the pluses and minuses of standard of care and clinical trials?

I’ll give you my answer to that question. I know that the cancer vaccine that I'm getting now in a clinical trial has the standard of care built into it. So I'm getting a standard of care plus, which gives me one more shot at possibly getting a good response. The cancer vaccine is working. It's not the other treatments. Maybe that'll give me a long-term, more durable response. I'm getting access to an enhanced possibility.

Another positive is I'm getting tested like crazy. I had 13 vials of blood taken from me today. And I'm getting scans. There was a scan at six weeks or something normally, they don't scan as frequently. They don't take as much blood. There's a lot more monitoring of me, which is more data, which is a good thing.

On the other hand, I went to my doctor and I said, “Can I try this? I heard about one of these alternative therapies that would be complementary to a vaccine. Could I try, for example, intravenous vitamin C?” He said, “No. You can't do that.” Because they want to control the boundaries around the clinical trial.

A module that I would encourage you to develop would be just the basic, “I'm faced with a choice between the standard of care and a clinical trial – what are the pluses and minuses of each?”

Kevin Freiert 42:49
Thank you for that. That's really good. Our society doesn’t do a good job of preparing us all to ask ourselves those questions. That's a high level of critical thinking around your own healthcare.

What's the difference? You just gave some great examples of the pluses and the minuses of, of taking a clinical trial over standard of care.

In oncology there are a lot of those additive trials. They're always trying to advance a little bit and the way the company would approach something is they'd do an add on to standard of care, then the next trial would be, “Let's see. If we can do it without the standard of care, can it become a first line treatment? Can it replace the standard of care?” But that's a different sequence of logic you have to go through. You don't just jump to “Let's give somebody something we think might work,” when there's something that already will help them. There's a constant building on each other's shoulders.

David Plunkett 44:03
The first thing that occurs to me when looking at your diagrams is that for each of those lessons, I would be looking for examples to be included. If there are multiple examples, then I'd be interested in comparing and contrasting them. Whereas a few minutes of lecture would not hold my attention nearly as well as if I had something to apply it to.

Kevin Freiert 44:32
That's really good feedback. I'm a storyteller. I always try to use examples.

Brian McCloskey 44:47
How is drug discovery changing with the advent of multi-omics, which is really all about redefining cancer, that part of the equation, in terms of selecting or targeting drugs, selecting patients, et cetera?

Kevin Freiert 45:19
It absolutely is. As I mentioned before, chemotherapies were just kind of a shotgun approach. It was just like, “We're going to take care of this cancer.” Now things are very specific. You can see that with something like Ibrance for breast cancer (Ibrance - palbociclib - is an FDA-approved oral combination treatment for hormone receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer - HR+, HER2- mBC - a targeted therapy), which is a very specific mutation, or a very specific genetic profile. It won't work in the other things as well because it was targeted for this genetic profile. In drug discovery, where this has really taken off, as they're starting to do the genomes of cancers, genomes of solid tumors, and understanding the differences, and then you can do in vitro work on that, and you can move into models that are closer related to those specific cancers.

In other disease areas, not in cancer, they're doing the same things. They're looking at the genomics and proteomics and metabolomics, and all the multi-omics. All the things that you can measure in the body. It's one of these places where artificial intelligence will make a huge difference. There's too much data for scientists living off the backs of NIH grants to just go through and go, “There it is. There's the answer.” The patterns are too complex and too subtle. Artificial intelligence is starting to help the discovery world come up with what are the right approaches to these various differences that we see in people where we might be able to intervene.

Finding patients builds off the back of that. This is just me being cynical about my own career and history. Pharmaceutical companies aren't going to jump into AI in clinical areas right away. They will want to let this settle and become a mature technology first, and then they'll start to use it.

By the way, the things that they're working on today have been in progress for years. It's a little late for anything that's in the clinic to shift. The things that are in the clinic today were probably thought of or envisioned back in 2010. They're quite a ways along.

There's a lot of work going on around this. I just talked to some people from the Broad Institute yesterday. They're doing a study called Count Me In. They're looking for cancer patients to provide genomic data and medical health record data so that they can start to come up with those patterns targeting several tumors right now. I'm not sure if, if any of yours are there. There's another study called All of Us, where they're trying to get a million people signed in from all health statuses, so that they can start to draw the picture or sketch out the picture of the phenotypes that come from the genotypes. What are people's lives like, and what's their health status?

Brad Power 49:22
Patients will want the ability to evaluate literature at some level. You had mentioned that it was on your list of existing modules, but if people want to be able to guide their treatment and be partners and copilots with their medical team, they need, at some level, to be able to quickly skim some literature that describes the results of a clinical trial.

Robert Gurmankin 49:57
More than that, being able to evaluate any clinical research paper. Is this a good paper or not? Because, unfortunately, there's a lot of, for lack of a better term, “crap,” out there.

Kevin Freiert 50:18
Yes. There is no better term. It's crap. There's a lot of misinformation that can easily seep in.

The barrier is that when you jump from something that's like advertising for public consumption to the research papers, it's a big shift. Research papers by necessity, and intentionally, are rather thick to read. You have to go into what the methods were. You've got to go into how you're analyzing the results. Now, does that mean you have to read all those details? Maybe not. Not at first blush. That's where I go in my courses. Read the introduction; read the conclusions. If you're still interested, go in and dig back to where you can maybe ask questions on whether it's real or not. But all those details can just be overwhelming to a lot of people.

We have a scientific literacy and a health literacy problem, and those come together here. People aren't paying attention to a lot of this stuff until they're finding themselves needing to.

Brad Power 51:49
A quick example we had the week before last was a discussion of mushrooms. There was a Memorial Sloan Kettering site, which cited some research studies that show that Turkey Tail mushrooms are effective and have anti-cancer effects. Then Allen Morris, a pathologist who's in our community said, “Is it from a phase 2 trial? Or a phase 3 trial? Is it cell lines? Or is it animal models? Where's the source of that information?” “Is it in humans? Is the information source credible? How credible is it?” Another question is, “Is that for everybody? Is that for all all cancers? Or is it a complementary therapy, if you're getting chemotherapy, or radiation, whatever?” All of that nuance, we bump into all the time.

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Kevin Freiert 52:51
It's too easy for proclamations of “This is helpful.” They're not asking those tough questions. Because it's not simple. Cancer is not a simple disease. There are over 16,000 of them – the last that I've heard. That's a lot of different diseases that need to be looked at.

Brian McCloskey 53:29
We're going to publish this on our YouTube channel. We'll also put it on our Circle community forum. There could be further engagement and questions that come in through the community collaboration platform. So look for that.

Kevin, thank you so much for your time and for educating us on what you do. It is important for our patients to understand the drug development process and to get educated about it. It's complementary to our other topics.

A gentle reminder that we are a donation-based community, and any donations are much appreciated. You can go to our website at cancerpatientlab.org and hit the “Donate” button and that will go right to a Zephy form. We would greatly appreciate it.