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GREG HORNE: Hello, and welcome to *The Health Pulse,* a podcast exploring how analytics in the health and life sciences industry is growing and its repercussions in all our lives. So my name is Greg Horne, and I am your host for this series, as always, and I will be joined by my expert guest to discuss a topical subject.

And on this week's episode, we're going to turn our attention to pharmaceutical clinical data. And this is our first external guest today. Andrew Friedman will be joining us.

But before we get to that, the last episode that we did, we heard a lot about pharmaceutical data in the commercial space with Patrick. And we're still looking to get your feedback on that episode and any questions that you may have. Send those questions through to thehealthpulsepodcast@SAS.com. So that's thehealthpulsepodcast@SAS.com.

So without any further ado, let's get started on today's episode. And let me introduce Andrew. Andrew, could you give us a little bit of background and tell us a bit about yourself, please?

ANDREW FRIEDMAN: Sure. Hi, Greg. So I'm Andrew Friedman.

I was formerly head of medical policy at GlaxoSmithKline, where I led governance for our clinical study disclosure commitments. And I arrived at that kind of position through a long career at GlaxoSmithKline, which included bench science, medical affairs, corporate communications, and policy.

GREG HORNE: I want to know what bench science is. So can you just expand on that, please?

ANDREW FRIEDMAN: So bench science, yeah, it's kind of a--

GREG HORNE: Oh, bench science.

ANDREW FRIEDMAN: --a summary for wearing a white coat and doing things with test tubes to identify, at the time, it was anti-hypertensive agents we were looking for in the lab that we hope we'd take through to the clinic. Unfortunately, in that project, we didn't find anything, which just points to the fact that pharmaceutical discovery is quite a difficult endeavor. And a lot of projects, unfortunately, fall by the wayside. And it's only the very few that get taken to the clinic, and then fewer still that actually make it to patients.

GREG HORNE: Brilliant. And, Andrew, one of the things we ask all our guests is just to tell us a little bit about yourself outside of the world of pharmaceuticals. So when you're not doing your science, what do you like to do?

ANDREW FRIEDMAN: You know what? I have many interests. I like to keep fit. I'm doing some volunteering around the pandemic at the moment.

I've also signed up to do a 26-mile hike along the Thames path in July to raise money for Macmillan Cancer Support. Having been on a few afternoon walks recently to try and get into shape for that. I realize that 26 miles is a heck of a long way.

So if anybody feels like wanting to encourage me with some sponsorship, please feel free. You can find me on justgiving.com website under fundraising. So if anybody wants to encourage me and get those miles into my legs, then please do.

I think my other main interest outside work interest is cricket, which is probably a turn-off for your US listeners right there. But it's a sport I played all my life. I now coach at my local club. And actually, it's related to our current discussion.

It's a sport rich in data. There's lots of data on every aspect of the game, lots of stats. And my son, actually, is a computer science undergraduate at Loughborough University, and he's doing an internship on player analysis of Derby County Cricket Club.

And I'm using him to try and teach me some of these newfangled technologies, AI methodologies, in particular. I'm a policy guy, and I'm really interested in how these new technologies can be applied to data. So I'm getting him to show me how it works with cricket data to see if I can pick up some insights as to how it can be used in health care.

GREG HORNE: Fantastic. Yeah, I'm the same. When I ride my bike, there's data coming at me from all kinds of directions. And I find it incredibly interesting to look at.

But let's move on. And we're going to come to our first question. And, Andrew, we're seeing now a lot of evidence that real-world data is really important from a clinical research point of view. So what's your view on the availability of results from clinical research?

ANDREW FRIEDMAN: I mean, my view is very straightforward. And that is that the results of clinical studies in humans should be made available. It's very simple.

For me, there are kind of three compelling reasons for that. Firstly, there is a science reason. Publication of scientific theories and the data which supports them enables others to identify errors, to support, or reject, or refine those theories, and to reuse that information to generate further insights. So there's a fundamental science reason why we need to make information available from our clinical studies.

And secondly, I think there's an ethical dimension. So when patients participate in clinical research, they do so on the understanding that their data is going to help develop scientific knowledge. And so publishing is a way of ensuring that their data is used to maximum effect in the creation of those new insights.

And then thirdly, when the research relates to health care interventions that are used in patients, for me, it's really important that all the evidence on the benefits and risks of those interventions are available so health care providers, professionals, and patients can make informed choices about the most appropriate course of action. Now, I think great strides have been made over the years around making results available. In particular, you can point to the registration of trials and posting results on web-based registers, such as clinicaltrials.gov, which has helped ensure the results are in the public domain. And it's important that I think there's continued scrutiny on researchers, and by regulators, and others to make sure that results are registered.

But I think there are other aspects to availability of data that need to be thought through. For me, there are too many papers, scientific papers, that sit behind journal paywalls. Should patients be charged $30 to $50 to read the latest research about a medicine that may be used to treat them?

Now, I recognize it's not as simple as that, and journals and publishers need to make a return on investment. But it seems to me there are open access journals that seem to be viable. I think there's a compelling reason as to why information needs to be made available.

But for me, it's also about usability of that data. I don't think it's good enough to just dump data. If ever you've been on clinicaltrials.gov and looked at the results, you will realize that it's not always easy to understand the data. There's a lot of tabular information, and interpreting that data can become more difficult.

So I think it's more that we can do to make that data relevant and usable to those who might be looking for and wanting to utilize the data. For example, I mean, how many research papers have a summary that can be readily understood by a general audience or a patient so that can actually read that paper and then go with that paper about latest information, have a discussion with their doctor and physician? I think very few. So I think there's a range of usability of data, which goes from a researcher wanting to reanalyze a single clinical trial or combine data across clinical trials through to the patient who wants to understand, well, what's the latest information that's out there that could help treat me in the disease or condition that I've got? So compelling reasons for availability, but I think there's more that we can do in making that data usable.

GREG HORNE: And, Andrew, I want to pick up on a point you made about halfway through there, where you talked a bit about patient attitude as well. Because this is something that-- and we'll touch more on the pharma side in just a second. But from a patient perspective, I see very much two trains of thought here.

The first one is, I don't want to share my data with big pharma, big government, big whatever, because it's personal, and I worry about it. But the same people then go on social media and write a Facebook post that will outline everything about their condition. How do we get patients to be a little bit more consistent in that approach?

ANDREW FRIEDMAN: Yeah, I mean, I think there are a number of different aspects and dimensions that you can think about to try and get to a better place around the question that you pose there, Greg. I mean, fundamentally, I think that data can be shared in ways where the privacy is protected, or at least the risk of identification is reduced considerably, without undermining the research value of those data. So data can be anonymized, for example, which is what we did when we share patient-level data from our clinical trials.

You can put in agreements, contractual agreements, which mean that researchers can attempt to identify individuals. And you can also make sure that the data is available in a secure environment. So there's lots of things that you can do to protect data, and I think it's important that those protections are communicated to patients to reassure them that their data is going to be used in a responsible way. It's going to be used to help further scientific endeavor, and ultimately, benefit future patients down the line.

GREG HORNE: Great. And so you are at the forefront of an industry initiative to make patient-level data from clinical trials available for the research purposes. So why did companies want to do that? Why did you want to do that?

ANDREW FRIEDMAN: Yeah. I mean, obviously, I was at GlaxoSmithKline when we decided to launch our system. So I can only really speak with authority about the thinking that was taking place at GlaxoSmithKline at that time.

And, Greg, fundamentally we believe that scientific benefits could come from all clinical trial data-- I emphasize all clinical trial data-- being shared to further research, and that that would give rise to patient and health benefits. I mean, at the time, we believed that if we took a first step and put in place a system to do that, it would help catalyze data sharing across the industry and academia. We believe that the risks could be well-managed. We've already touched on the privacy risk around patients being identified, and we believe we could manage that.

There are also risks around the data being misused, whether that be inadvertently or nefariously. And we manage that risk by putting together an independent review panel to look at proposals to use the data and make the decision on whether we should provide access. We also require teams to have expertise. So we needed them to have a qualified statistician to be part of the team so they could utilize the data appropriately.

So I think they were the main reasons at GSK. More broadly, there are a number of developments that I also think encourage companies to share data. The pharmaceutical industry in July 2013 issued a commitment to share anonymized patient data with other researchers and members of the trade associations, through that commitment had an obligation to do so.

There were reports. There's one from the Institute of Medicine in the United States, 2015, calling for data sharing to be the norm. And journal editors have also played a role in requiring data sharing or data sharing statement to be included in publications.

So I think all these aspects come together-- the benefits, the effective management of risks, the expectation setting by external groups, such as journal editors. And, of course, companies also like to improve their reputation, and increasing transparency of data helps achieve that aim. Although, I do have a little bit of a note of caution, in that you can set up a system to share data, tick that reputation box, if you like, but put in place too many controls or too many caveats, such that you don't effectively share.

So I think that reputation benefit needs to go hand in hand with the desire for the data to be used for further research. And it can't be just on its own, because I think that drives you in a different direction, which I don't think is necessarily beneficial.

GREG HORNE: That's really interesting. Now, I think what you've laid out there are some really nice examples of the kind of theory. And you've kind of described very well what the point of doing this is and why you would want to achieve certain things.

But I think from a business point of view, I think I want to understand a little bit more about what this has meant in the case of actual breakthroughs. So when you look back at the research that's been done with patient-level data that's been shared, and aggregated, and the like, can you point to some breakthroughs? Can you point to things that have happened purely and simply because of data sharing?

ANDREW FRIEDMAN: Yeah, I mean, that's a really, really good question, an important question, to continually ask around initiatives, such as sharing data. I mean, if I kind of take a stepwise look at this, I mean, if I look at what we aimed to do in the first instance, which was to catalyze data sharing across industry and academia, I say we were successful. If I look at the two main platforms that are used today, clinicalstudydatarequest.com and Vivly, there are 30 to 40 organizations who have committed to share their data. I think that in itself is a breakthrough compared with where we were pre-2013.

Now, as to the research that has been conducted, I mean, I think it's important that research has been done. We used to nervously joke when we were setting up our system that we'd open up our shop and nobody would come in. Tumbleweed would come in through the door, and that would be that, and nobody would be interested in accessing the data.

But when I left GSK, we were getting two to three research proposals a month. And on the two data sharing platforms that I mentioned, when I looked yesterday, there were over 100 publications and presentations that had been recorded. Now, your question was specifically, have there been any breakthroughs? Now, the answer to that is, I don't know.

I don't think there have been any breakthroughs, because I think I would have heard about them. And the research, of course, covers many different diseases and different aspects of research, and I'm not an expert in all of those to be able to assess the significance. But what you can say, of course, is that journals have made the determination that the research is of interest to their readers, which I think in itself shows it has merit and it is a worthwhile contribution.

And, of course, science generally progresses incrementally. There are breakthroughs, obviously, but that's not kind of the normal course of science. Progress is incremental with experiments and findings building on one another.

And, of course, what we're talking about here is reanalysis or analysis of data that's already been collected. And many of the experiments or analyses are set up to be exploratory, pointing to further research that needs to be conducted. So I think if you take it in the round, I think, yeah, maybe nothing astounding has been discovered because we've made data available. But that's not to say that the research hasn't been worthwhile and unimportant.

GREG HORNE: OK, that's great. And I'd like to think now about where this is going to go then. Because you set a very interesting foundation in this whole process. And I'm thinking now about what you see as future challenges and opportunities in sharing data, and for a more broad disclosure of data, and a use of real-world evidence that's shared amongst other companies

ANDREW FRIEDMAN: Yeah, thanks, Greg. I mean, I think there are a number of challenges and opportunities with regard to data sharing. I mean, on the theme of usability, which we referred to earlier, I think there's the challenge of different central secure systems through which researchers access data.

And if I can give an example, fictitious example, so say a researcher wants to access Pfizer data through the Vivly platform, where the data is on a Microsoft de jure platform, and let's say Sanofi data, which is accessible through clinicalstudydatarequest.com, where the data is on a SAS platform, that's going to be a problem. I think it's also a problem if the researcher wants to use software that's not provided in the central platform. And one potential solution to that, which we've put forward, is that the secure environment should be provided by the researcher rather than data provider. So the data is securely downloaded to the researcher from the different platforms, and the researcher can use the data with whatever software they like. So it's a different model, which we believe can address some of the usability issues.

On the opportunity side, at present, the data sharing model on clinicalstudydatarequest.com and Vivly is one where the data requester conducts their research independently from the original researchers. And I think they'll always be a space for this type of model, but I think there are opportunities to set up more data collaborations, where researchers and data providers come together to share data and conduct research. So, for example, through learned societies, can key research questions be identified, where already collected data could provide insight? Can these questions be prioritized with funding, and those that hold the relevant data come together to answer the questions with experts in the relevant technologies and techniques? Or perhaps the data could be made available in a data challenge kind of model to find answers to those questions.

So I think there's an opportunity for greater collaboration. I also think there are opportunities to share more data. Now, as I've already described, I think the privacy risks and risks of misuse can be managed, but they can't be totally eliminated. And I think this can inhibit data sharing.

So I think there's a need to explore different models. So one model that's been put forward is what's described as a federated model, in which the data never leave the organization that holds it. Instead, the data is visited and computed answers are brought back. It looks great on a nice PowerPoint slide, but can that be implemented practically?

I mean, that remains to be seen. And I'm not a technical expert, but that's the kind of model, different models of data sharing, I think need exploration. We shouldn't rest on our laurels of where we are today.

So overall, I think we've made a good start in data sharing. But as we use AI techniques more and more, which need bigger volumes of data, I think we need to do more to make data sharing easier, and to make it easier to combine data from different trials and from different sources. You mentioned real-life data-- being able to combine real-life data sources with clinical trial data sources. All of these data sources, I think, present enormous opportunities to actually use data to deliver health care, and of course, patient benefits.

GREG HORNE: Brilliant. Thank you. So you've got me thinking there. And I've got one last question I want to ask you, because what you just said inspired this in me, which is to ask you this, Andrew.

We are currently undergoing the world's biggest clinical trial, and there's a lot of data being collected in this clinical trial. And a lot of it seems to be very much in the public domain for people to look at. It's creating this idea of the citizen pharmaceutical expert almost, in terms of what does has efficacy mean?

And what is a clinical trial? And what is "approved for emergency use" mean-- and lots of other questions. Andrew, can you comment generally on this ginormous clinical trial and how you see that fitting into the work that you've done in the past?

ANDREW FRIEDMAN: Yes, you're right. I guess it is an enormous clinical trial. I mean, from my perspective, I see the benefits in terms of people and populations being very interested in research and the outcomes of research. I mean, if I look at the UK media, for example, everybody now knows what an r value is. Whereas, probably two years ago, they wouldn't have a clue what that was.

People are more inquiring about models in epidemiology. I think this all points to a benefit in people wanting to understand more about research, wanting to participate in research, which I think is important as well. So for me, there's an opportunity, actually, to build on what people's interest in COVID and the vaccines that have been researched, to build on that interest in other disease areas-- cancer, diabetes. Can we actually build on the momentum and interest that's been created in science and research to encourage more participation, more engagement, in other areas as well?

GREG HORNE: Fantastic. That is really interesting, and I'm sure our listeners will have lots to kind of think about with that one as well. So thank you, Andrew, for your insights today and for joining us. And I'm sure we will get that feedback through thehealthpulsepodcast@SAS.com.

I think that the subject of sharing clinical trial data is really interesting for a lot of people right now, because they see that drug development has been slow, and they can see what can be done when people really put their heads together. So please do let us know your thoughts on this subject. And we hope to bring those questions and comments in a later episode.

So all that remains now is for me to say, thank you for joining *The Health Pulse* today. I've been your host, Greg Horne. Please like and subscribe to receive future episodes, and we hope to be bringing more to you very soon. Thank you very much.

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