Wearable EEG’s in Clinical Trials - Now and Beyond

Ensuring technology is viable for clinical studies is the team from Advanced Brain Monitoring with their new product – wearable EEGs. Tune in and learn how this innovative product aids in the study of psychological and neuropsychological conditions that have their roots in the brain, the psyche and the physiology.

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Priya : Hello, everyone, and welcome to the Cure Panel Talk Show on Health Tech. I am Priya Menon, Scientific Media Editor at Cure Talk, and I welcome all of you this evening to a discussion on wearable EEGs in clinical trial, now and beyond.

This is the 23rd episode of the Cure Panel Talk Show and today’s show is featured on Blog Talk Radio. Before we begin with today’s introduction, I would like to share the fact that in August Cure Panel Talk Show is celebrating its first anniversary. We launched Cure Panel Talk Show in August 2012 with our monthly series on multiple myeloma and we have grown over the year to conduct talk series on a variety of topics including prostate cancer, yoga, nanotechnology, and cancer and nutrition. This August, we will be launching our new talk series on breast cancer. Please visit our website www.trialx.com/curetalk for information regarding our show and you can always mail me, priya@trialx.com if you would like to be featured on our show.

Coming back to today’s panel, we are excited to have with us the team from Advanced Brain Monitoring, CEO and Co-founder, Chris Berka, who has over two decades of brain research and technology development leadership experience; Vice-President, Manufacturing, Gene Davis, who is an expert on International EEG Regulatory Compliance and ensures technology is viable for clinical studies. Advanced Brain Monitoring specializes in the development of interfaces that can be easily applied by the user without assistance to obtain neuro, cardio, and respiratory signals equivalent to those obtained in the laboratory. The company aims at developing innovative uses of physiology for clinical research, refining them through old applications and ultimately manufacturing end-user friendly technology.

We also have with us Dr. Ajay Verma. Dr. Verma is currently Global Vice-president at Biogen Idec for neurology and experimental medicine. Dr. Verma is an MD and PhD from the John Hopkins University and has trained in neuroscience in the laboratory of Dr. Soloman Snyder. He was also a tenured Professor in neurology and neuroscience at the Uniformed Service University of the Health Sciences, the US Military and Medical School.

Next on the panel is Dr. Kamran Fallahpour, Director of Brain Resource Center. Dr. Fallahpour is a clinical psychologist. His clinical practice and research activity are focussed on health psychology, applied neuroscience, and computer-human interphase. Dr. Fallahpour has years of experience in assessment and treatment of various psychological and neuropsychological conditions that have their roots in the brain, the psyche and the physiology. I extend a hearty welcome to all the experts.

Today’s show is co-hosted by Kimberly Blozie. Ms. Blozie is a Senior Chemical Research professional and

entrepreneur. She is currently working in business development at Nanotronics Imaging and is writing a science fiction trilogy. Hi, Kim, and welcome to the show.

Today, the panel will discuss wearable EEG in clinical trials, now and beyond. The electroencephalogram, EEG, is a classic noninvasive method for measuring a person's brain wave and is used in a large number of fields, from epilepsy and sleep disorder diagnosis to brain computer interphases. Electrodes are placed on the scalp and to detect the microvolt-sized signal that is felt on synchronized neuronal activity within the brain. Wearable EEG is envisioned as a evolution of ambulatory EEG units from the bulky limited lifetime devices available today. Small devices present only on the head that can record EEGs for days, weeks, or months at a time. We actually learned about wearable EEGs in the New York Times article that was published on March 27th, which talked about researches at University of Edinburgh who attached portable EEGs to the scalp of 12 healthy young adults to study the cognitive impact of these phases. They asked each volunteer to take a short walk of 1.5 miles that included walking through a park and urban congested areas so that they could detect the brain-based pattern as the walk progressed through different sections. The study found that green spaces lessened brain fatigue and we thought this would be something useful to discuss as part of our Nanotech and Innovative Health Tech Cure Panel TV. We are actually very excited about this technology and so we invited the executive team from Advanced Brain Monitoring to talk about it. Before I hand over to Kim, I would like to remind all listeners that we will be talking, taking calls, live questions at the end of the discussion. Listeners who have a question for our panel can press 1 on their keypad and we will bring you live on air to ask your question. Kim, you are live on air.

Kimberly : All right. Thanks so much, Priya, and thanks for bringing me back to host. I really enjoy doing this and welcome to our panel and thanks everybody for joining us. Before starting on the questions, I just wanted to say how excited I am specifically to be discussing EEGs, wearable EEGs, not only because they can help monitor our health and our emotional state and, you know, give us insight into the brain and our moods and emotions, but they can also help us interact with our environment in terms of reducing the gap between us and technology, which is always something that is fascinating to me. So, very excited to be here. My first question I will ask is for Gene Davis and I first want to discuss a bit about what is EEG and how they are traditionally applied and then what aspects of wearable EEGs have recently changed?

Gene Davis : That's a great question. The standard that many people are used to seeing probably involves something on a TV show where there are a number of leads and cables and there is a lot of goop that they put in the hair. They have to abrade the scalp to get it down to a low impedance. All of this so that they can get a good quality signal to start wiring in. Also, traditionally, they are not wireless but in fact wire to plug into a wall. Some of the more recent changes that you have seen is obviously the wireless aspect of it and then there are a number of dry technologies as well. In fact, the as well, but probably the biggest change is the aspect of mobility with a wireless with our sensory system with a higher impedance being acceptable. You can now actually study people in a more natural environment.

Kimberly : Great, and just to probe a bit further here and again I am speaking with Gene, the VP of Manufacturing at Advanced Brain Monitoring. Going off on what you are saying, can you explore a little bit more how EEGs our emotional states and measure the emotional states, as Priya was mentioning the New York Times article about people's brain patterns being accepted and measured by, you know, walking through green spaces. So, can you provide a little insight on how EEGs can help us gain insight into depression or anger or emotions like that?

Gene Davis : Certainly. Chris Berka may jump in as well to add to whatever I say, but there's been a lot of recent research in looking at the there are quite a few publications as well. Taking about certain aspects of the EEG where they are able to tap into and detect the emotional aspect of the individual with a specific, where you could maybe specifically tell if angry or maybe frustration and maybe a number of other aspects, but its certainly something that you are seeing more of in research and publication. Often times will also leverage other physiological sensors like ECG, sometimes GSR as well and those tend to be a little bit lower and physically the EEG would be something that would be able to find faster response.

Kimberly : That's great! Thank you very much for that. I am going to switch over to Chris Berka. Again, Chris is CEO and Co-founder of Advanced Brain Monitoring. Chris, I was wondering if you could tell us a bit about wearable EEGs. When were they first developed and I would love to hear a little bit more about how you got started and why you think wearable EEGs is so important?

Chris Berka : Sure. First of all, let me just take the pleasure to be here and this is one of my favorite topics. So, I really appreciate the opportunity to get this panel together. So, EEG is probably one of the oldest bio-medical technologies in existence. We have, you know, over a century of work backing us up, but its only recently in the last 20 to 30 years with the advent of increased processing capability, miniaturization of electronics, ability to store or produce and merge and analyze large data sets that we are really starting to see a whole in the field of EEG analysis and technology. So, there's been many attempts at mobile systems over the last 20 to 30 years and this is our area of specialty and expertise and go on designing these systems as to how the least intrusive, unobtrusive systems as possible. We want them to be comfortable and light weight and as Gene said, you know, the end goal is to have someone perform their normal daily activities or go to bed at night and sleep and be monitored continuously and not necessarily be aware of that monitoring. So, on top of the sensor technology and the electronics, we need to layer in very specific algorithms for identifying potential artifacts so the EEG, as Priya stated earlier, is a and you need to be able to identify that you have, in fact, measured EEG and biological artifacts or environmental contaminants and so, lot of the work that's been done over the last 30 years has been evolving algorithms that can identify and distinguish EEG from all of those other potential artifacts and then if the artifact is detected, you may need to give the person an alarm to say, your sensor fell off, for example, and ask them to continually do this by voice messages so that we can make sure that we can continuously collect clean data where the EEGs are derivable.

Kimberly : Okay and as far as I recall, EEGs still are… I mean they are not huge, they are maybe half a penny or so sized, that would sit on the scalp at various places and can either be worn as like a cap or they are placed maybe in a and then wires go back into a wireless kind of transplant or that's worn in a pocket or in a belt, something like that. Is that right?

Chris : Well, our current systems both for sleep and for daytime assessment, everything is worn on the head…

Kimberly : Okay.

Chris : …and you may have a sensor array that is anywhere from two or three sensors which is all we need to stage sleep at night up to 24 or 32 sensors that allow us to give a complete neural map and depending on what your application is you only may need two or three sensors or you may need more extensive yet. What we have been able to do is and then we have a blue tooth on board, so we are sending everything live. We put everything on the head and its very comfortably worn system that is 2 or 3 ounces even for the denser array and then that communicates wirelessly with a smartphone or tablet or computer and you could be 30 feet away because of the wireless communication. So, you don't even have to have the receiver on your person. It could be sitting close to you or even, you know, in a room located nearby.

Kimberly : Okay. Great! Very cool. Thanks for that and I would love to kind of keep going on it in this direction of future and how wearable EEGs are changing and I wanted to target this question to Dr. Verma who again is the Global Vice-President at Biogen Idec for Neurology and Experimental Medicine. In terms of clinical trials, how are portable or wearable EEGs being used and how are they also kind of being experimented with and changing to help this whole technology move forward?

Dr. Verma : Great! Thanks for the question and thanks for having me on. I think one broad perspective from the standpoint of neurological health is that, you know, we have been struggling to have biomarkers for the healthy brain and our field has suffered, you know, compared to, let's say, the cardiovascular field where we have cholesterol or blood pressure or blood sugar and so on. You know, we don't have that brain number, you know, for an individual and its kind of a transformative concept because once you have that number, that

biomarker, then it will actually change its management. In fact, in many of those diseases where we treat the blood pressure number, the blood glucose number rather than the disease itself because we know it will ward off disease and so we desperately needed more convenient biomarkers and we are hoping that by making EEGs which are robust biomarker brain function, you know, more accessible and available to the mobile population at large, this will, you know, create one of the biomarkers that we need. Imagine if you had to have a catheter every time you measured blood pressure, you know, it wouldn't be a very useful biomarker.

That's right.

Dr. Verma : Whereas we know going into a Cydia Store and just getting your blood pressure, you know, measured is terrific. So…

Right.

Dr. Verma : This convenience is that the ABM technologies offer, you know, can't be underestimated. I think if you add to that the comfort, the ease of use, and you know, without compromising their quality, you know, it really adds a lot. As far as how this is being used, in clinical practice EEGs are largely used to study epileptic phenomenon or sleep physiology, but in drug development they are being used in a number of different diseases, neurodegenerative diseases like Alzheimer's and Parkinson's, ADHD. You may have heard recently there was an EEG device actually approved for even, you know, treatment in ADHD, but to look at drug responses and the EEG provides a very robust signal for a variety of drug classes, hypnotics, alerting agents agents and so on and that's a very key problem that we have early on clinical development is how to set our dose, what is the measure that we use to know that we are making an impact on the brain and that's where I see, at least in what I do, you know, the impact of this technology.

Kimberly : Right. That is fascinating! I used to work in cancer clinical research, so of course, we would take all the circling biomarkers of the various cancers that we work with to look at their, you know, there being… if the drug was efficacious on the cancer or not or what not. So, that is fascinating in terms of looking at, you know, brain responses in terms of biomarkers and you know, in terms of treatment of different drugs and such. Now, that is fascinating. I also wanted to ask you if you had heard about or know about EEGs that are now worn just through the ear and so, you know, I am sure there are only specific kinds of measurements that can be done in the ear, but do you see EEG technology evolving so that its just going to be one or maybe two electrodes being placed where the algorithms extract more valuable information or what are your thoughts on that?

Dr. Verma : You know there is an emerging, you know, movement of these single-lead EEGs. Many of them are actually being used as entertainment devices right now whereby one can regulate, you know, one's level of attention or meditation and change their EEG signal and the blue tooth, you know, connection, you can actually, for example, move a cursor or something on a computer or change the color of something.

Ah, right.

Dr. Verma : And so, there are number of these gaming technologies now. Those often use single-lead EEGs because that's where the signal is most, you know, robust. If you know ahead of time, you know, where to look, where on the scalp, because the brain does have regional specialization and different parts of the surface of the brain, you know, are involved in different diseases and drug responses. Initially, we didn't know where to look. You would want to have as complete a set of data as possible…

Right.

Dr. Verma : …but I could imagine it wouldn't be possible that once you know what you are looking at and where could use one of the other models with less leads or even down to one lead. I am not as familiar more familiar with the ear thing. I do know, you know, for certain type of epileptic, you know,

syndromes, often we need to get electrode very close to the source of the seizure, let's say, and there are some needle electrodes and so on, but again this can be customized, you know, based on the problem that one's trying to study and then how best you get the data.

Chris : Right. I would agree with AJ on that. I think that there is quite a bit that you can do. For example, full sleep staging, full quantitative objective sleep staging as I said with two or three sensors on and we have some alertness and drowsiness that can also be run with just two sensors, one on the top of the head and the emotion classifiers and the empathy metrics that will examine what we were looking at also require just a handful of sensors, but you need to know exactly where to put them and for some of these more compact disorders where looking at depression or neurological disease, trying to distinguish between some of the subtypes, dimensions, there we need the more complete map first to the number sensors.

Kimberly : Right. Okay. Great. Yeah. Thanks for waiting in there, Chris.

Chris : Its kind of like an EKG, you know, when you want to know a full… You can get a full EKG to look at all your conduction issues and your heart issue or if you just want to get a simple rhythm strip, you just need one lead, you know, so it depends on what you are looking for.

Kimberly : I see. Yeah, that's very clarifying. Umm… I want to return to this topic. It particularly excites me, but I want to bring in Dr. Fallahpour and again Dr. Fallahpour is clinical psychologist and director of the Brain Resource Center, New York. Kamran and I have had the pleasure of working together on a project about a year or so ago, so I am actually friends with Kamran and very happy to be seeing him again. Its been a little while for us. Kamran, welcome to the show. I just wanted to kind of ask you just to kind of on this and ask, I know you use EEG technology all the time in your work and would love to hear how you use it and how you think its innovation can help evolve just or help our knowledge about our emotions and brain health in general?

Dr. Fallahpour : Well, thank you, Kimberly. First of all, thanks for the invitation. Its great to have you as a moderator. Its been a while since I have seen you, so its good to hear your voice.

Kimberly : Yeah. Likewise.

Dr. Fallahpour : Thank you. So, you know, we have been involved with EEG and physiological monitoring in multiple levels. We use it in biomarker studies where we have looked at basically biomarkers looking at depression population, testing various antidepressants, and basically drug response. Same with ADHD. We have also been involved with, some years ago actually we developed some blue tooth device for monitoring EEG remotely, which we have used in both clinical setting and some research setting, but I have also been privileged in a field where I can actually apply these to patients today and see how we can utilize the research in neuroscience and kind of used as not only for monitoring what goes on but also to give real time feedback so patients can actually change their state in real time…

Kimberly : Right.

Dr. Fallahpour : …as they go through a task. So, with that in a number of clinical situations, we have used also EEG and I think that the advancements with, you know, the portable EEG and other physiologic measures is really opening a new door both for research and also for human brain interphase, clinical applications, etc., etc. So, its very exciting. There are a number of challenges that of course are involved, which I am glad both… I think Chris alluded to them and I think other panelists also mentioned about, you know, teasing out what's really clear signal with movement artifact, with muscular artifact, which you know, when you go to faster activities is very difficult to detect and what is eye movement artifact, etc., etc., and I think we are getting better and better at those. Devices are getting smaller, more comfortable to use. We have tested a number of devices. I happen to have been involved in developing some devices that do remote monitoring but also kind of consulted various companies on such development. So, I have seen development of these devices becoming more robust and becoming more user friendly and I think the future

of both research and clinical use is quite exciting.

Kimberly : Right. Right and I would love for you to describe too how, you know, because this is kind of a two-way street with the kind of research you are working with and the kind of way that you work with patients. Its not just monitoring. You monitor, but then you take that information and allow it to participate in the data that you receive from the EEG monitoring to…

Yes.

…you know, either change brain chemistry or connection so that they experience less depression or less stress. I would love for you to share a little bit about how that works.

Dr. Fallahpour : Yeah, sure. So, we have done lots of brain mapping using EEG and concentrated EEG and there are certain profiles that are associated with certain disorders. For instance, not all but most kids and adults with ADHD happen to have an increased slow activity, mostly in the face ranging the frontal lobe and once that's identified and the exact location and the frequency band is figured out, we can design paradigms where in real time we can measure activities with just a single or double-channel EEG and actually teach children by way of giving feedback and reinforcements, teaching them how to inhibit the increased amplitude or power of those waves that brain activity, which is really neuronal firing in synchrony in real time and sort of bring their behavior, which in this case is the neuronal activity and the behavior of the brain closer to the norm in real time and what we observe is this model of kind of self regulation through monitoring and rewarding brain activity seems to work really well for a number of disorders and its also very exciting because not only the data is available for research and seeing how people go through various stages of that but also in terms of making actual changes in real time that once its reinforced over and over again becomes somewhat of the activity of that person's brain and they sort of learn how to operate on that level.

Kimberly : Umm. Ah, yes. Very cool. I wanted to just briefly open this up to either Chris or Dr. Verma or Gene to comment on if the Advanced Brain Monitoring group will be working in a similar way or, you know, has any ideas or thoughts about the two-way street using the EEG data to help patients heal.

Gene : Sure. Sure. We have done a number of devices on our own. One of them is called the Adaptive Peak Performance Trainer where we characterize an expert state in worksmanship, golf, and other athletic performance including archery and then we provide the feedback or intermediate and train them to produce the expert brain state before they picked up the rifle or the bow and arrow or the golf club and accelerated skilled training by training them first to produce the state of an expert, accelerated skilled training by a factor of 200%.

Ah!

So, you know, the vision to, you know, helping overcome diseases can also help accelerate normal performances in some of the, you know, simple skilled and then we partnered up with Dr. Bob Thatcher on a fairly large neuro feedback project he developed just over the last 30 years and have the normative database, fairly substantial normative database and that uses the 20-channel to characterize the normative brain state and then allow you to load up the normative characteristics and then move an abnormal brain closer to the normative data through a variety of feedback. So, we are keenly interested in the area of neuro feedback training.

Kimberly : Oh, great! Great to hear and Dr. Verma, any comment from Biogen, you know, moving forward this kind of information exchange regarding EEGs?

Dr. Verma : Oh, I think the… You know, again making these robust devices, you know, available to the mobile are going to lead to new users, you know, that we probably didn't expect before. You know the EEGs can be very useful assistive devices for people that are handicapped, for example, you know, if they can learn to control their…

Definitely.

…brain wave. I have seen in the wheelchair, for example, whereby you know, if you sort of concentrate or meditate you move forward to backwards. If you blink your left eye or right eye, you could turn left or right. There are ways to, you know, read random letters on the screen and once you see the letter you want, a certain potential is triggered, so thereby you can just type, you know…

Yeah.

…and just by looking at certain letters on the screen and the EEG response to that…

Yeah.

So, I think its really up to the creative inventors now how to use it and previously with the bulky devices obviously that was very limiting, but you know, that the convenience of these devices may open up a whole field of new users.

Kimberly : Great! That's very, I personally kind of get very passionate about this where its best to paralyze people. People with locked in condition can begin with simply think and start to communicate and exchange information, you know, turn on the lights without help and wheelchair move around like you are saying, that's something I… Anyways, I am very, very excited about that. I wanted to talk a little bit now about kind of a map in the outdoors and hand all this which are just as important as the technology itself and I kind of like to just ask each of our panelists or at least those with the different kind of companies that are represented here, so Dr. Verma, we will start with you since you are talking already on… What do you find in terms of the algorithms and how they are developed? Do you need to hire, you know, specialist IT people who know about brain waves and things like that or can you hire any IT person how critical is it to really have a good IT team develop and figure out these algorithms?

Dr. Verma : Well, its the art of extracting meaningful signals, you know, from EEG is really an art and it takes a lot of insight, skills and you do have to know a lot about signal analysis how to clean up the signals, you know, what is noise, what is not.

Yeah.

You also have to know some neuro biology whether something makes sense, so its sort of multidisciplinary cultivated art in my opinion and its not trivial to do. Maybe for simple things, you know, like inattention or a meditative state or sleep, you know, its possible but there's such a rich amount of data to be had in what's happening in cortical activity that we have not found it easy. I have used EEG at several other companies that I have worked and, you know, it does take a certain rigor of having the hardware just right, the controls just right, the noise, you know, low, being able to extract the features and we . A lot of the stuff that happens under the hood is the most important stuff and the sensors and electronics have definitely advanced, but I think Chris remarked on this earlier. The analysis is where I think that the biggest gains are to be made, you know, and there are various ways to look at this. Many, many different ways to look at EEG signals and there may even be more ways that are being invented soon, especially as we try to couple EEG activity to functional imaging activity, for example, on MRI and so on to make better sense of what the EEG signals mean.

Right.

But, I think Chris is certainly the expert on the analysis here, so maybe I will let her comment further on that.

Yeah.

Chris : Well, I am supported by a pretty sophisticated team of PhD level engineers here at Advanced Brain

Monitoring. We have the electrical engineers, biomedical engineers. We have several experts processing and signal detection, algorithm development and then we have neuroscientists and several psychophysiologists, clinical psychologists. So, we have a pretty good range of expertise, you know, starting at the engineering level and working up to the, you know, human clinical trials and neuroscience level and it takes that team really to kind of study the problem and all the different levels and develop, you know, algorithms and then also develop ways to deal with artifacts, so you know, you are always going to catch some signals that you are recording that are larger than the EEG signals. So, what do you do with those? In many cases, there is qualified EEG riding on top of those signals and you can work around them and extract them and all of that is kind of a, you knowbut then on top of that you want to layer in the connections between all of the different channels of the brain and you are mapping so that it maps to the neuroscience and then there is psychology that we understand the different regions of the brain and then on top of that, we have done a lot of work with large databases. So, first of all you want a normative database that you can map against and that database has to be perfectly clean and validated and you want to make sure that you have reproducible results so that you can take an EEG on someone, day 1, day 2, day 3, and make sure that, you know, there is some consistency across the measures that you are looking at to replicate and then a lot of what we have been doing is looking at ways to even in group situations, so whether its a small team interacting or a one-on-one situation, we have a look at some of these metrics at a more level and say, you know, how are two people communicating by looking at the brain, the neurometrics in real time and this is kind of… Data sets are large and challenging, you know. Often we are bringing in mathematics and do a lot of very sophisticated mathematics, always with an eye towards can we run this in the real time environment. So, its a big, big problem and a great challenge to ask.

Kimberly : Definitely. Very complex and large amount of data that needs to be passed out and some need to be sorted as slow waves, some need to be sorted as a repeatable, reliable signal and indicator of things. Kamran, I want to ask you about this as well. Whenever I have visited you and your office is in New York, I see mainly clinical staff, nurses, and coordinators and things like that. Do you also, you know, have a whole math lab where you have people kind of analyzing this data, breaking it down, or do you rely on kind of algorithms? How do you handle this great data problem here?

Dr. Fallahpour : Yeah. I think most panelists really alluded to this. So, to repeat again, you know, from our side, we had a team of physicists, neuroscientists, mathematicians, physicians, and neurologists, and neuropsychologists who all contributed to basically developing algorithms to make sure that the artifacting and other aspects of the database, basically the algorithms that go into it are robust and of course, these databases, you know, I was involved. There was a team of kind of international consortium of neuroscientists involved in developing what I believe may be now the largest database of not only EEG but also ERPs which are, you know, event-related potential and number of activation tasks and also neurocognitive data such as attention, memory, auditory, visual, so a whole neuropsychological battery as well and some genetic data and also a number of dozens of questionnaires and scales are normally used in research, all leading to one database, where then this database has to be of course, validated and standardized as I believe, again Chris alluded to this, that this is just not something you put together and say its done…

Yeah. Yeah.

…It has to go through all kinds of validation and standardization and then once that's done, then you can compare patient populations to it and so then it becomes a very powerful tool not only for looking at individual data sets but also groups of people and also looking at drug responses and obviously now, you know, the foreign companies have been interested. We have drawn a couple of trials already using not only EEG but a number of other physiological measures and also neuropsyche data in the biomarker area, which is quite exciting.

Kimberly : Right. Yeah. There is… I actually first didn't know that there was kind of a collective database that was regulated and standardized, that had a lot of answers to these kind of signal clean signal versus not. What oversight bodies and what kind of regulatory bodies help to monitor that?

Dr. Fallahpour : Umm… Well, there are a number of ways. One is that validation standardization needs to be done through, you know, you need to publish in scientific journals and have again as was recommended before, its not just one study, there needs to be a number of studies showing validation standardization, repeated EEGs on different days, showing that the normative database, the features and all the elements are actually standardized and then depending on which country basically this is going to be used in, there are, you know, stay regulations. There are scientific and regulatory bodies that look into this, but I am sure the other panelists have other opinions or aspects of this they want to discuss.

Yeah. I would like to bring Gene Davis, again is the VP of Manufacturing at Advanced Brain Monitoring, who has expertise in international EEG regulatory compliance. I would love to hear your thoughts on kind of the regulatory oversight body, what kind of…, how standards are arrived at, you know, if they have to pass a certain kind of governing body? I would love for you to tell us a little bit about that.

Gene : Yeah, absolutely. The perspective, well, each country has its own specific aspect that they may focus on. Just by way of example, for medical devices item 6 of 601-1, which is just a broad-handed ethical regulation and that is an international group that comes together to decide on what those specific requirements are and it covers everything from safety for both the patient and the technician at the hospital using it as well as noise radiated by the device as well as how robust the device has to be in a normal environment. For EEG, there is a specific substandard or particular standard they call it, which is actually, 601-2-2 set. That covers specific aspects of EEG itself and whether the standard of the International European Union derivatives of that, the US derivatives, there are Canadian derivatives. More or less every country has, you know, their own specific… You speak to that country or you need to add specific aspect of what their infrastructure might

Kimberly : Okay. Great! Thanks very much for that. Anyways, I personally regulatory bodies, the oversight bodies and it just helps to standardize and kind of confirm validity and the reliability of these tests. So, that is critical.

Gene : So, they have the standards which is also requirement for you to then go through a certified testing body. So, its not just that someone can say, hey, our device meets these standards because we say so. You generally have to go through a certified testing body to get that taken care of and thereafter you go through FDA for medical. For insurance, there is also an additional standard or that also comes in and audits our facility as well to make sure we are following our operating procedures that we are in compliance.

Kimberly : Okay. Great! Kind of on the flip side of this, what happens, you know, and I would love to hear from everybody on this. What are the major difficulties that come up with in terms of using wearable EEGs, you know, not only in the algorithms but just in people complying. I would love to hear just some of the hurdles you have faced in extracting that, you know, viable data from wearable EEGs and, Gene, if you want to comment, we can start with you and then go around the panel.

Gene : Certainly. You know, depending on the study you are doing, there is a wide scope of issues to overcome sometimes depending on environment, sometimes depending on patient acceptance. You know what I really found to be the bigger hurdle is even just on the current medical community where they have been using the old Columbian you know, getting _____ there is a bit of disbelief that this technology is even something that is wearable is something like science fiction. So, I still am surprised even to this day on some of the push back we get on the new technology from the .

Kimberly : Right. Chris, you want to add anything to that in terms of challenges or difficulties

Chris : Sure. Sure. One of the things that we deal with everyday is we are generally running anywhere from 500 to 1000 human subject studies here every year and one of the first things that comes up is privacy concerns and also sort of the added concern of, you know, not just the health privacy issue which personally have to be HIPAA compliant and make sure that we protect and treat all people's data, you know, with the utmost privacy and protection, but also the concern that we are trying to read people's minds. That is a very

common, you know, subject coming in for the first time, you know, thinks that we are putting these sensors on their head and we are going to be able to tell, you know, what they are thinking or what they did last night and of course, that's not the case.

Sure.

What it is you know, privacy issues are important for both the health concerns as well as just overcoming the initial responses, you know, you are reading my mind and that's questionable we are doing, but it is important to overcome any of those concerns and fears.

Kimberly : Sure. Dr. Verma, I would love to hear from you any, you know, let's say advice from these perceived challenges from either potential users or critics and what are some practical roadblocks or road bumps you come up with in regard to wearable EEGs?

Dr. Verma : You know, most of my experience has been in using it in clinical trials and those are very controlled settings, so we can force people to wear on

concerns, that is.

] That's right. That's right. I think its just the analysis and the robustness of the data and that's been a challenge in some studies. You know, some of the EEG systems in the past have really been susceptible to noise, you know, from other electronics and on the floor for example and the newer technologies have really made it a lot easier. I have some of these mobile, you know, single-lead headsets that are more sort of entertainment and my 8-year-old daughter actually wears them and plays games on the computer with them, (laughter) so I think that shows you how acceptable its becoming from being this cumbersome, you know, spool of wires in the past, but for me its really been about the quality of the data and…

Yeah.

the viability and the repeatability. That's been a challenge and to find a good system and laboratory that, you know, that assures good quality of data is paramount for us.

Kimberly : Yeah. Yeah. Definitely! Great! And then Dr. Fallahpour, not only are you dealing with just monitoring, you are dealing with people responding, getting re-monitored responding. What has been some of those, the challenges you face in the research you do?

Dr. Fallahpour :] Sure. I will be happy to talk about that. But, generally, I think EEG is a fantastic signal, but its a very fragile signal. There are number of ways that it can be effective, some of which sometimes we may not pay attention to, even the type of lighting you have or sources of electronic devices, I think Gene just mentioned that, or what equipment you have around you. All of those things can be impacted. So, in my experience, mostly with work electrodes, meaning using gel or paste, one of the ways we are able to really secure a good signal with lot of impedance is the U-gel or paste and not everyone likes that, its a very messy problem in a way. So, you know, people don't like doing it, although we try to really make it, you know, minimal and we have developed methods to make it easier. I have tried a number of other more dry options, dry electrodes. Personally, I have not liked any of them. I am actually eager to try some of the dry electrodes that I think have been developed and I believe if I am not mistaken, some of the panelists have been involved with developing. I am very curious and looking forward to trying those. So, I think from an end-user point of view, I think the comfort, because, you know, when you go to gaming or things like that, its easy because the accuracy of data may not be that important, but when you are in a clinical situation or research situation, the signal and basically the quality of the signal is everything. As the engineers say, its garbage in, garbage out. If the signal you are getting in is contaminated, basically interpretation you have also is not really good. Therefore, in order to get good signal, often we have to go through these messy processes and some of their patient subjects are not very compliant with it, especially if you have to do it several times or many times, but I am looking forward to the future of dry electrodes and other ways of actually getting the

data that can be both accurate and very comfortable.

Kimberly : Hmm… Right. Great! Well, I want to be respectful of our time period. If you want to open up the line to listeners, I have one more question I can ask everybody; if not, then let me know what's best.

Priya : You can ask your question, Kim, and then we can proceed.

Kimberly : Okay. Great!

Yeah.

So, this is my clear question. I am happy I get to ask it. I wanted to hear from everyone in regards to the future of wearable EEGs and, you know, of course this can help us as Dr. Verma was saying in terms of this is another biomarker that's just allowing us to hear biological-based feedback about our health in response to drugs. There are situations, environments, but you know, doesn't that willing to help around or beyond, where do each of the panelists feel or get excited about the future of wearable EEGs in terms of technology or the paralyzed being able to drive cars or whatever it is, I would love to hear from each of you what you feel the potential is here. So, let's start with Chris. Would love to hear your thoughts on this.

Chris : Sure. Well, I think everything is going to get smaller and smarter and faster. So, the sister technology that we are using today is already five years, you know, out of date in comparison to consumer electronics. So, we can count on material science and whether its nanotechnology or other material science, allowing us to access these signals easier and still of high quality as well as . What's exciting for me is that, you know, I really envision a very near-term future where where an EEG becomes part of a standard physical and standard physical being done at home or, you know, having to go anywhere to get a physical done. An EEG will just become part of that. So, you will be tracking your brain from the time that you had your first checkup maybe at birth until you die and so we will have, you know, longitudinal data on the brain as it develops that we can then map to some of these databases that are now growing, which will allow us earlier and earlier detection of things like, you know, early stage of dementia and as we all know one of the most coming out, hopefully sooner rather than later, but we need to be able to assess and diagnose little bit earlier so that the treatments can be made available and then assess treatment outcomes, but I think all of these things you will see far off distant future.

Yeah.

Dr. Verma : Yes. Just to add to that. This is Ajay Verma. You know when you collect an EEG on an individual under controlled settings, if you do that over and over again in the same settings, you actually find that the EEG is actually like a biometric signature of that person. In fact, there are these studies done where your children will have, you know, some similarities. In fact, twin studies show some resting EEG similarities between the two individuals. So, its much like a fingerprint or an iris scan. It could be considered a biometric of the way your brain, you know, sort of runs under certain states and if one can map that to echo with what Chris is saying, during a healthy baseline, you know, you might find that this instrument is exclusively sensitive to deterioration from, you know, from health. So, it could be an early warning system potentially that, you know, you need to go get some help or something like that and I am hoping it can rise to the level of that type of biomarker for the, you know, wire messes and just be used when you actually have the illness but hopefully use it to identify early signs of illness and ward them off.

Kimberly : That's great and that would be such even like Chris, you were saying, do yourself at home, type of way that patients could take their own baseline and see whether they have to send it to their health care provider. So, I think that's a great idea. Gene, do you want to add anything to this?

Gene : Yeah. I think… I am kind of excited about the consumer aspect of this in that I think there is a large amount of I should say patients will benefit most from this, but I think that when you get into the masses that you will start to get more people involved, more funds will come in when there is money for other companies

to chase after that I think in the end will benefit those that truly need it while at the same time giving a better quality of life to normative or healthy patients that as well as the biomarker aspect.

Kimberly : Right. And, Kamran, I would love to hear your thoughts about the future.

Dr. Fallahpour : Sure. A lot of what I had in mind was already discussed, but maybe we can say that we have done repeated quantitative EEGs on a range of population including people who are in peak performance mode to the end of the spectrum with, you know, patients in vegetative states and the repeated EEGs show very solid results that this is actually a biomarker as was discussed before and we have already done biomarker studies basically focused on the EEG and ERPs. So, I think the time for that has already come. We already have patients who do this routinely once a year just to make sure that, you know, we have a baseline, but we are also monitoring improvement, etc., and I agree that this will be one of the measures in the future that will be part of your yearly physical and it would be easier and easier to use and would be more readily available for the masses, yeah.

Kimberly : Right. Really, really great! Well, thanks very much and I really enjoyed co-hosting. I am actually going to turn the meeting, I guess, this broadcast over to Priya who is going to take it from here.

Priya : Thank you, Kim. Thank you very much. That was really a great discussion. We have received lot of questions, couple of questions from our participants. I would quickly go over them. The first one is, does wearable EEGs make a breakthrough in mind-body research and provide solid evidence for effective spiritual practices. Dr. Fallahpour?

Dr. Fallahpour : Well, I think that's a difficult question because we need to kind of define almost every word in that question. (Laughter) You know, but I do believe that human beings have a, you know, very wide range of experience and those states are certainly a part of that and there is already a body of research going on using EEG, looking at meditative space and how, you know, meditation correlates to meditative states and EEG and various states of consciousness that we have been able to clearly show and I think we can continue to look at that and we also know the impact of these sort of practices, mindfulness or being in a state where you are totally relaxed, you know, alpha-theta space that traditionally have been called and the relationship to your health and relationship to various kind of states of consciousness that we have a lot of reports from, you know, people who enter into these states, who talk about how they feel their body is in a state of healing or there is the mind-body paradigm that, you know, is being discussed in some of the. I think there is a lot to explore there and its an exciting area.

Priya : Thank you, Dr. Fallahpour. Chris, I think you can take the next one. Does the EEG only record surface brain signals or can it pick up signals from structures that are buried in the brain, such as the limbic system that regulates emotional responses? Are there signature pattern for each emotion status?

Chris : That's an excellent set of questions and so, if you have a fairly large ray of sensors placed on the surface of the scalp, you can at least get some indication of what is going on in some of the deeper structures of the brain, but we are primarily looking at cortical activity when we are recording from the surface. There are some reflections of what's going on in the deeper structures and this is an area of some controversy as to how closely and how many sensors you need and what type of mathematics you need to model some of the deeper structures. And, as far as mapping emotional states, I think this is still very early in the exercise, particularly for normative populations, but we have been working on this problem ourselves for almost 10 years and because there's so much variation across individuals with regard to emotions that there are some broad emotional states that everyone but I think there is still a lot of work that needs to be done for mapping emotional states using surface EEG.

Priya : Thank you, Chris. The next question is, can we annotate what we are doing in wearable EEGs to better correlate a brain signal with our activities? Dr. Verma?

Dr. Verma : Yeah, I think so. First of all, the clearest example of that is probably sleep. There are very

characteristic change in the EEG pattern with that activity; however, I assume the caller is asking about wake activity and that's where I think some of these cutting edge experiments that were mentioned about, performance, you know, during the sporting event, during a task, and how the EEG signal is, you know, reporting whether you are in optimal performance or not. That's a whole new area that I think is going to be very exciting to watch and much like biofeedback, it may actually be a form a feedback for enhancing one's own performance.

Priya : Thank you, Dr. Verma. I think we are almost over time now. That was a wonderful discussion. I thank the panel for being with us today. Thank you all for your support and we look forward to having all of you join us for the next Cure Panel Talk Show on August 8th to be inspired by young adult cancer survivor stories. For more details of our upcoming shows, please visit trialx.com/curetalk. The link for today's show will be sent via email to all participants. Thank you.

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