

WEBVTT

NOTE duration:"00:12:49.5680000"

NOTE language:en-us

NOTE Confidence: 0.85142773

00:00:02.120 --> 00:00:04.316 OK, my name is Dana Mcpartland.

NOTE Confidence: 0.85142773

00:00:04.320 --> 00:00:06.155 Thanks for the opportunity to

NOTE Confidence: 0.85142773

00:00:06.155 --> 00:00:07.990 participate in this data blitz.

NOTE Confidence: 0.85142773

00:00:07.990 --> 00:00:10.114 I am a clinical psychologist by

NOTE Confidence: 0.85142773

00:00:10.114 --> 00:00:12.352 training the research that I do

NOTE Confidence: 0.85142773

00:00:12.352 --> 00:00:13.860 is social neuroscience research.

NOTE Confidence: 0.85142773

00:00:13.860 --> 00:00:15.700 I'll tell you about today.

NOTE Confidence: 0.85142773

00:00:15.700 --> 00:00:17.535 I direct the autism clinic

NOTE Confidence: 0.85142773

00:00:17.535 --> 00:00:19.370 at the Child Study Center.

NOTE Confidence: 0.85142773

00:00:19.370 --> 00:00:21.422 I run a lab and then I also direct

NOTE Confidence: 0.85142773

00:00:21.422 --> 00:00:23.573 a consortium around the country

NOTE Confidence: 0.85142773

00:00:23.573 --> 00:00:25.425 called the Autism Biomarkers

NOTE Confidence: 0.85142773

00:00:25.425 --> 00:00:27.439 Consortium for clinical trials,

NOTE Confidence: 0.85142773

00:00:27.440 --> 00:00:29.864 and I'll tell you about all

NOTE Confidence: 0.85142773

00:00:29.864 --> 00:00:31.480 of those things today.

NOTE Confidence: 0.85142773

00:00:31.480 --> 00:00:32.443 Put really simply,

NOTE Confidence: 0.85142773

00:00:32.443 --> 00:00:34.690 my the work in our lab is

NOTE Confidence: 0.85142773

00:00:34.771 --> 00:00:36.671 designed to address this problem

NOTE Confidence: 0.85142773

00:00:36.671 --> 00:00:39.671 that when we are in the lab we

NOTE Confidence: 0.85142773

00:00:39.671 --> 00:00:41.717 can do use these amazing tools.

NOTE Confidence: 0.85142773

00:00:41.720 --> 00:00:44.536 We do a lot of work with EG.

NOTE Confidence: 0.85142773

00:00:44.540 --> 00:00:47.717 We do a lot of work with eye tracking.

NOTE Confidence: 0.85142773

00:00:47.720 --> 00:00:50.303 We do some work with PET and MRI and

NOTE Confidence: 0.85142773

00:00:50.303 --> 00:00:52.308 functional near infrared spectroscopy.

NOTE Confidence: 0.85142773

00:00:52.310 --> 00:00:53.718 Lots of interesting powerful

NOTE Confidence: 0.85142773

00:00:53.718 --> 00:00:55.126 ways to understand autism,

NOTE Confidence: 0.85142773

00:00:55.130 --> 00:00:57.980 which is primarily what we study.

NOTE Confidence: 0.85142773

00:00:57.980 --> 00:00:59.960 But when I'm in the clinic,

NOTE Confidence: 0.85142773

00:00:59.960 --> 00:01:02.615 I have one to my my clinical lens and

NOTE Confidence: 0.85142773

00:01:02.615 --> 00:01:04.730 that's really the same tool that's
NOTE Confidence: 0.85142773

00:01:04.730 --> 00:01:07.220 been used in the history of autism.
NOTE Confidence: 0.85142773

00:01:07.220 --> 00:01:09.860 I think that if we had more objective,
NOTE Confidence: 0.85142773

00:01:09.860 --> 00:01:11.172 sensitive tools like biomarkers,
NOTE Confidence: 0.85142773

00:01:11.172 --> 00:01:13.526 we would be in a better place
NOTE Confidence: 0.85142773

00:01:13.526 --> 00:01:15.136 to help people with autism.
NOTE Confidence: 0.85142773

00:01:15.140 --> 00:01:16.870 And that's really the problem
NOTE Confidence: 0.85142773

00:01:16.870 --> 00:01:19.428 that we try to solve in the lab.
NOTE Confidence: 0.85142773

00:01:19.430 --> 00:01:21.452 There are many different purposes for
NOTE Confidence: 0.85142773

00:01:21.452 --> 00:01:23.390 biomarkers cohorts that we work with.
NOTE Confidence: 0.85142773

00:01:23.390 --> 00:01:25.700 Are, you know, school age and up,
NOTE Confidence: 0.85142773

00:01:25.700 --> 00:01:27.415 so the kinds of biomarkers
NOTE Confidence: 0.85142773

00:01:27.415 --> 00:01:28.787 that I'm interested in.
NOTE Confidence: 0.85142773

00:01:28.790 --> 00:01:30.590 Really are related to stratification.
NOTE Confidence: 0.85142773

00:01:30.590 --> 00:01:33.414 The idea that you can take a very
NOTE Confidence: 0.85142773

00:01:33.414 --> 00:01:34.902 heterogeneous group of people

NOTE Confidence: 0.85142773

00:01:34.902 --> 00:01:37.050 and find markers either in genes,

NOTE Confidence: 0.85142773

00:01:37.050 --> 00:01:37.774 brain function,

NOTE Confidence: 0.85142773

00:01:37.774 --> 00:01:39.584 patterns of visual attention to

NOTE Confidence: 0.85142773

00:01:39.584 --> 00:01:41.734 subgroup in ways that are meaningful

NOTE Confidence: 0.85142773

00:01:41.734 --> 00:01:43.738 for figuring out who's going to

NOTE Confidence: 0.85142773

00:01:43.738 --> 00:01:45.659 respond to treatment for prognosis.

NOTE Confidence: 0.85142773

00:01:45.660 --> 00:01:48.980 For for purposes like that.

NOTE Confidence: 0.85142773

00:01:48.980 --> 00:01:51.633 This is a a biomarker that we've

NOTE Confidence: 0.85142773

00:01:51.633 --> 00:01:53.180 been extremely involved with.

NOTE Confidence: 0.85142773

00:01:53.180 --> 00:01:55.085 This is a brain electrophysiological

NOTE Confidence: 0.85142773

00:01:55.085 --> 00:01:55.466 biomarker.

NOTE Confidence: 0.85142773

00:01:55.470 --> 00:01:57.380 It's an event related potential,

NOTE Confidence: 0.85142773

00:01:57.380 --> 00:01:59.290 which just means signal processing

NOTE Confidence: 0.85142773

00:01:59.290 --> 00:02:00.818 applied to the electroencephalogram.

NOTE Confidence: 0.85142773

00:02:00.820 --> 00:02:03.235 Produces a marker that tells us something

NOTE Confidence: 0.85142773

00:02:03.235 --> 00:02:05.409 specific about a cognitive process.
NOTE Confidence: 0.85142773

00:02:05.410 --> 00:02:06.601 In this case,
NOTE Confidence: 0.85142773

00:02:06.601 --> 00:02:08.586 the cognitive process is face
NOTE Confidence: 0.85142773

00:02:08.586 --> 00:02:10.543 perception which is really interesting
NOTE Confidence: 0.85142773

00:02:10.543 --> 00:02:13.091 to us in autism because faces are
NOTE Confidence: 0.85142773

00:02:13.160 --> 00:02:15.386 a key source of social information
NOTE Confidence: 0.85142773

00:02:15.386 --> 00:02:18.590 and a pretty reliably affected.
NOTE Confidence: 0.85142773

00:02:18.590 --> 00:02:21.698 Area function in people with autism.
NOTE Confidence: 0.85142773

00:02:21.700 --> 00:02:24.325 This negative peak around 170
NOTE Confidence: 0.85142773

00:02:24.325 --> 00:02:27.547 milliseconds is called the N 170
NOTE Confidence: 0.85142773

00:02:27.547 --> 00:02:30.037 and this represents the brain
NOTE Confidence: 0.85142773

00:02:30.037 --> 00:02:32.580 recognizing a face as such,
NOTE Confidence: 0.85142773

00:02:32.580 --> 00:02:36.222 so the first face specific stage
NOTE Confidence: 0.85142773

00:02:36.222 --> 00:02:38.043 of face processing.
NOTE Confidence: 0.85142773

00:02:38.050 --> 00:02:40.367 Work that we did now some time
NOTE Confidence: 0.85142773

00:02:40.367 --> 00:02:42.599 ago showed us that in people

NOTE Confidence: 0.85142773

00:02:42.599 --> 00:02:44.529 with autism is very early.

NOTE Confidence: 0.85142773

00:02:44.530 --> 00:02:46.530 Marker is significantly delayed that

NOTE Confidence: 0.85142773

00:02:46.530 --> 00:02:48.896 people with autism show inefficiency at

NOTE Confidence: 0.85142773

00:02:48.896 --> 00:02:51.010 this very early stage of face perception,

NOTE Confidence: 0.85142773

00:02:51.010 --> 00:02:52.306 since doing this study,

NOTE Confidence: 0.85142773

00:02:52.306 --> 00:02:54.250 we've done a number of different

NOTE Confidence: 0.85142773

00:02:54.315 --> 00:02:55.799 studies to really understand

NOTE Confidence: 0.85142773

00:02:55.799 --> 00:02:58.025 whether this could be a potentially

NOTE Confidence: 0.85142773

00:02:58.084 --> 00:02:59.648 useful biomarker in autism.

NOTE Confidence: 0.85142773

00:02:59.650 --> 00:03:01.450 The kinds of things that

NOTE Confidence: 0.85142773

00:03:01.450 --> 00:03:02.890 we've tried to understand,

NOTE Confidence: 0.85142773

00:03:02.890 --> 00:03:03.626 you know?

NOTE Confidence: 0.85142773

00:03:03.626 --> 00:03:06.202 Coming from that first study that showed

NOTE Confidence: 0.85142773

00:03:06.202 --> 00:03:09.276 us that it's sensitive diagnostic status.

NOTE Confidence: 0.85142773

00:03:09.280 --> 00:03:11.500 The intergroup mean differences between

NOTE Confidence: 0.85142773

00:03:11.500 --> 00:03:13.720 people that some people without
NOTE Confidence: 0.8369112

00:03:13.784 --> 00:03:16.276 we've seen that it N 170 responses
NOTE Confidence: 0.8369112

00:03:16.276 --> 00:03:17.848 correlated with autism severity
NOTE Confidence: 0.8369112

00:03:17.848 --> 00:03:20.470 in other kinds of autism symptoms
NOTE Confidence: 0.8369112

00:03:20.470 --> 00:03:22.200 like difficulty recognizing faces.
NOTE Confidence: 0.8369112

00:03:22.200 --> 00:03:23.840 It's functionally specific that
NOTE Confidence: 0.8369112

00:03:23.840 --> 00:03:25.890 these relationships we see with
NOTE Confidence: 0.8369112

00:03:25.950 --> 00:03:27.850 social function are not generic
NOTE Confidence: 0.8369112

00:03:27.850 --> 00:03:30.298 relationships with all aspects of visual
NOTE Confidence: 0.8369112

00:03:30.298 --> 00:03:32.218 function or cognitive performance.
NOTE Confidence: 0.8369112

00:03:32.220 --> 00:03:34.621 So really, it's not just telling us
NOTE Confidence: 0.8369112

00:03:34.621 --> 00:03:37.251 something that a brain is performing
NOTE Confidence: 0.8369112

00:03:37.251 --> 00:03:39.806 differently is telling something specific.
NOTE Confidence: 0.8369112

00:03:39.810 --> 00:03:43.415 About this social circuitry of the brain.
NOTE Confidence: 0.8369112

00:03:43.420 --> 00:03:45.160 We've seen that it's applicable
NOTE Confidence: 0.8369112

00:03:45.160 --> 00:03:45.856 across development.

NOTE Confidence: 0.8369112

00:03:45.860 --> 00:03:47.732 We see these differences in the

NOTE Confidence: 0.8369112

00:03:47.732 --> 00:03:50.050 end 170 in very young children,

NOTE Confidence: 0.8369112

00:03:50.050 --> 00:03:50.953 autism through adults,

NOTE Confidence: 0.8369112

00:03:50.953 --> 00:03:52.759 we see that it's robust to

NOTE Confidence: 0.8369112

00:03:52.759 --> 00:03:54.240 variation behavior manipulating,

NOTE Confidence: 0.8369112

00:03:54.240 --> 00:03:55.239 where a person,

NOTE Confidence: 0.8369112

00:03:55.239 --> 00:03:58.080 how a person with ASD looks at faces,

NOTE Confidence: 0.8369112

00:03:58.080 --> 00:03:59.940 which is an important control

NOTE Confidence: 0.8369112

00:03:59.940 --> 00:04:02.175 because people with autism tend to

NOTE Confidence: 0.8369112

00:04:02.175 --> 00:04:04.005 look at faces in different ways,

NOTE Confidence: 0.8369112

00:04:04.010 --> 00:04:06.446 doesn't make worse or fix this delay.

NOTE Confidence: 0.8369112

00:04:06.450 --> 00:04:07.686 In the end, 170,

NOTE Confidence: 0.8369112

00:04:07.686 --> 00:04:10.291 and we've also seen that this N 170

NOTE Confidence: 0.8369112

00:04:10.291 --> 00:04:12.343 is responsive to change in clinical

NOTE Confidence: 0.8369112

00:04:12.343 --> 00:04:15.250 status as children with autism get better.

NOTE Confidence: 0.8369112

00:04:15.250 --> 00:04:17.623 In treatment we can see this latency
NOTE Confidence: 0.8369112

00:04:17.623 --> 00:04:20.399 difference in the end when 70 become reduced.
NOTE Confidence: 0.8369112

00:04:20.400 --> 00:04:22.969 So having done many of these studies
NOTE Confidence: 0.8369112

00:04:22.969 --> 00:04:25.865 and next goal has been to try to get
NOTE Confidence: 0.8369112

00:04:25.865 --> 00:04:28.529 the kind of data that we could use
NOTE Confidence: 0.8369112

00:04:28.529 --> 00:04:30.984 to qualify a biomarker with the FDA.
NOTE Confidence: 0.8369112

00:04:30.984 --> 00:04:33.042 And this is the work that we've
NOTE Confidence: 0.8369112

00:04:33.042 --> 00:04:34.850 accomplished in the context of
NOTE Confidence: 0.8369112

00:04:34.850 --> 00:04:36.390 the Autism Biomarkers Consortium
NOTE Confidence: 0.8369112

00:04:36.390 --> 00:04:37.545 for clinical trials.
NOTE Confidence: 0.8369112

00:04:37.550 --> 00:04:39.643 This is a multi site 5 autism
NOTE Confidence: 0.8369112

00:04:39.643 --> 00:04:41.036 research centers around the
NOTE Confidence: 0.8369112

00:04:41.036 --> 00:04:42.347 country naturalistic study,
NOTE Confidence: 0.8369112

00:04:42.350 --> 00:04:45.260 meaning we don't administer intervention we.
NOTE Confidence: 0.8369112

00:04:45.260 --> 00:04:47.409 We we have now concluded the first
NOTE Confidence: 0.8369112

00:04:47.409 --> 00:04:49.937 phase in which we worked with a large

NOTE Confidence: 0.8369112

00:04:49.937 --> 00:04:52.283 group of children 280 with autism and

NOTE Confidence: 0.8369112

00:04:52.283 --> 00:04:54.133 119 with typical development between

NOTE Confidence: 0.8369112

00:04:54.133 --> 00:04:56.445 the ages of 611 and with a range

NOTE Confidence: 0.8369112

00:04:56.445 --> 00:04:58.168 of Iqs from in the intellectually

NOTE Confidence: 0.8369112

00:04:58.168 --> 00:05:00.910 disabled range to well above average.

NOTE Confidence: 0.8369112

00:05:00.910 --> 00:05:03.234 We took a battery of well studied,

NOTE Confidence: 0.8369112

00:05:03.240 --> 00:05:04.588 promising biomarkers from the

NOTE Confidence: 0.8369112

00:05:04.588 --> 00:05:06.610 modality of e.g and eye tracking

NOTE Confidence: 0.8369112

00:05:06.664 --> 00:05:08.239 and then study them overtime,

NOTE Confidence: 0.8369112

00:05:08.240 --> 00:05:10.430 so seeing children over three time

NOTE Confidence: 0.8369112

00:05:10.430 --> 00:05:13.082 points of baseline to six weeks so we

NOTE Confidence: 0.8369112

00:05:13.082 --> 00:05:15.513 get a sense of stability in the short

NOTE Confidence: 0.8369112

00:05:15.513 --> 00:05:17.886 term and we don't anticipate that too

NOTE Confidence: 0.8369112

00:05:17.886 --> 00:05:19.346 much intervention related change.

NOTE Confidence: 0.8369112

00:05:19.346 --> 00:05:21.206 Or developmental change should have

NOTE Confidence: 0.8369112

00:05:21.206 --> 00:05:23.193 happened and then again at 24 weeks

NOTE Confidence: 0.8369112

00:05:23.193 --> 00:05:24.642 where we might expect more changes

NOTE Confidence: 0.8369112

00:05:24.642 --> 00:05:26.559 to give us a chance to see how these

NOTE Confidence: 0.8369112

00:05:26.560 --> 00:05:28.680 biomarkers might track change.

NOTE Confidence: 0.8369112

00:05:28.680 --> 00:05:31.384 We also drew blood on all these children,

NOTE Confidence: 0.8369112

00:05:31.390 --> 00:05:33.358 so we have genetic genotypic data

NOTE Confidence: 0.8369112

00:05:33.358 --> 00:05:35.460 that we have yet to analyze,

NOTE Confidence: 0.8369112

00:05:35.460 --> 00:05:38.502 but will be able to do in the future.

NOTE Confidence: 0.8369112

00:05:38.510 --> 00:05:41.214 So in this first phase of the study,

NOTE Confidence: 0.8369112

00:05:41.220 --> 00:05:43.460 we actually got the kind of data that

NOTE Confidence: 0.8369112

00:05:43.460 --> 00:05:45.541 we needed in terms of demonstrating

NOTE Confidence: 0.8369112

00:05:45.541 --> 00:05:47.361 that we replicated the effects

NOTE Confidence: 0.8369112

00:05:47.361 --> 00:05:48.679 that we anticipated.

NOTE Confidence: 0.8369112

00:05:48.680 --> 00:05:50.320 We demonstrated stability overtime in

NOTE Confidence: 0.8369112

00:05:50.320 --> 00:05:51.960 these biomarkers and we demonstrated

NOTE Confidence: 0.8369112

00:05:52.009 --> 00:05:53.429 relationship with the phenotype.

NOTE Confidence: 0.8369112
00:05:53.430 --> 00:05:54.258 With that information,
NOTE Confidence: 0.8369112
00:05:54.258 --> 00:05:56.190 we took two biomarkers to the FDA
NOTE Confidence: 0.8369112
00:05:56.248 --> 00:05:57.829 biomarker qualification program.
NOTE Confidence: 0.8369112
00:05:57.830 --> 00:06:00.646 The M170 that I've described to you already.
NOTE Confidence: 0.8369112
00:06:00.650 --> 00:06:03.306 And the second was an eye tracking marker,
NOTE Confidence: 0.8369112
00:06:03.310 --> 00:06:05.404 looking at how much time people
NOTE Confidence: 0.8369112
00:06:05.404 --> 00:06:07.455 with autism spend looking at faces
NOTE Confidence: 0.8369112
00:06:07.455 --> 00:06:08.639 or people on screen.
NOTE Confidence: 0.8369112
00:06:08.640 --> 00:06:10.656 The Ocular Motor index of gays
NOTE Confidence: 0.8369112
00:06:10.656 --> 00:06:12.000 to human faces or
NOTE Confidence: 0.83372533
00:06:12.079 --> 00:06:14.422 the Omi. We submitted these in the form
NOTE Confidence: 0.83372533
00:06:14.422 --> 00:06:17.128 of letter of intent to the FDA biomarker
NOTE Confidence: 0.83372533
00:06:17.128 --> 00:06:19.306 qualification program and they were both
NOTE Confidence: 0.83372533
00:06:19.368 --> 00:06:21.629 accepted in Maine 2019 and March 2020.
NOTE Confidence: 0.83372533
00:06:21.630 --> 00:06:23.628 This is a first for autism,
NOTE Confidence: 0.83372533

00:06:23.630 --> 00:06:26.123 but this is also a first for the field
NOTE Confidence: 0.83372533

00:06:26.123 --> 00:06:28.748 of psychiatry and that these are the
NOTE Confidence: 0.83372533

00:06:28.748 --> 00:06:31.348 first biomarkers to be except for any.
NOTE Confidence: 0.83372533

00:06:31.350 --> 00:06:33.583 Psychiatric condition to be accepted if into
NOTE Confidence: 0.83372533

00:06:33.583 --> 00:06:35.689 the FDA's biomarker qualification program.
NOTE Confidence: 0.83372533

00:06:35.690 --> 00:06:37.370 The context of use that we
NOTE Confidence: 0.83372533

00:06:37.370 --> 00:06:39.580 described was to use these markers
NOTE Confidence: 0.83372533

00:06:39.580 --> 00:06:41.119 as stratification biomarkers.
NOTE Confidence: 0.83372533

00:06:41.120 --> 00:06:43.752 The idea that if you see this distribution
NOTE Confidence: 0.83372533

00:06:43.752 --> 00:06:46.381 here that people with autism their their
NOTE Confidence: 0.83372533

00:06:46.381 --> 00:06:48.730 histogram values are shown in green.
NOTE Confidence: 0.83372533

00:06:48.730 --> 00:06:51.112 The typically developing children are shown
NOTE Confidence: 0.83372533

00:06:51.112 --> 00:06:54.516 in blue and you can see that this is this.
NOTE Confidence: 0.83372533

00:06:54.520 --> 00:06:56.844 This would not be a good diagnostic
NOTE Confidence: 0.83372533

00:06:56.844 --> 00:06:59.218 biomarker in that there's much overlap,
NOTE Confidence: 0.83372533

00:06:59.220 --> 00:07:01.110 but there's a portion of

NOTE Confidence: 0.83372533

00:07:01.110 --> 00:07:02.244 children with autism.

NOTE Confidence: 0.83372533

00:07:02.250 --> 00:07:03.725 Crucial values that don't overlap

NOTE Confidence: 0.83372533

00:07:03.725 --> 00:07:05.570 it off with the typical range,

NOTE Confidence: 0.83372533

00:07:05.570 --> 00:07:07.992 and the idea is that this group

NOTE Confidence: 0.83372533

00:07:07.992 --> 00:07:09.850 of children may represent.

NOTE Confidence: 0.83372533

00:07:09.850 --> 00:07:13.035 A subgroup that may be more similar,

NOTE Confidence: 0.83372533

00:07:13.040 --> 00:07:16.680 you know, typically or may have more common,

NOTE Confidence: 0.83372533

00:07:16.680 --> 00:07:18.520 more consistent neuropathology that.

NOTE Confidence: 0.83372533

00:07:18.520 --> 00:07:21.280 By selecting these children and selectively

NOTE Confidence: 0.83372533

00:07:21.343 --> 00:07:23.298 admitting them to clinical trials,

NOTE Confidence: 0.83372533

00:07:23.300 --> 00:07:25.981 clinical trials would have greater power to

NOTE Confidence: 0.83372533

00:07:25.981 --> 00:07:27.929 determine whether treatments are effective.

NOTE Confidence: 0.83372533

00:07:27.930 --> 00:07:30.849 We are continuing to work through the

NOTE Confidence: 0.83372533

00:07:30.849 --> 00:07:32.950 biomarker qualification process with the FDA,

NOTE Confidence: 0.83372533

00:07:32.950 --> 00:07:33.979 which is extensive.

NOTE Confidence: 0.83372533

00:07:33.979 --> 00:07:36.380 We're now in the stage of developing
NOTE Confidence: 0.83372533

00:07:36.442 --> 00:07:38.552 a biomarker qualification plan which
NOTE Confidence: 0.83372533

00:07:38.552 --> 00:07:40.662 would guide our data collection,
NOTE Confidence: 0.83372533

00:07:40.670 --> 00:07:42.760 Towards preparing a biomarker qualification
NOTE Confidence: 0.83372533

00:07:42.760 --> 00:07:45.605 package based on which an FDA FDA
NOTE Confidence: 0.83372533

00:07:45.605 --> 00:07:47.669 colleagues would make a decision about
NOTE Confidence: 0.83372533

00:07:47.669 --> 00:07:50.209 whether a biomarker could be qualified.
NOTE Confidence: 0.83372533

00:07:50.210 --> 00:07:52.254 This is a very exciting time for
NOTE Confidence: 0.83372533

00:07:52.254 --> 00:07:54.498 us and that being in this cutting
NOTE Confidence: 0.83372533

00:07:54.498 --> 00:07:57.147 edge space where the FDA is learning
NOTE Confidence: 0.83372533

00:07:57.147 --> 00:07:59.037 about psychiatric biomarkers.
NOTE Confidence: 0.83372533

00:07:59.040 --> 00:08:00.512 As we're learning about
NOTE Confidence: 0.83372533

00:08:00.512 --> 00:08:01.248 psychiatric biomarkers,
NOTE Confidence: 0.83372533

00:08:01.250 --> 00:08:03.756 it's been a very exciting time to
NOTE Confidence: 0.83372533

00:08:03.756 --> 00:08:06.338 partner with the FDA in the course
NOTE Confidence: 0.83372533

00:08:06.338 --> 00:08:08.486 of several grants that permit us

NOTE Confidence: 0.83372533

00:08:08.562 --> 00:08:10.422 to have ongoing discussions as

NOTE Confidence: 0.83372533

00:08:10.422 --> 00:08:13.026 to think about how to refine our

NOTE Confidence: 0.83372533

00:08:13.026 --> 00:08:14.130 biomarkers towards qualification.

NOTE Confidence: 0.83372533

00:08:14.130 --> 00:08:17.066 We were renewed for second phase in July.

NOTE Confidence: 0.83372533

00:08:17.070 --> 00:08:19.314 The second phase will consist of

NOTE Confidence: 0.83372533

00:08:19.314 --> 00:08:20.810 three studies of confirmation.

NOTE Confidence: 0.83372533

00:08:20.810 --> 00:08:23.316 Study very similar to the first one,

NOTE Confidence: 0.83372533

00:08:23.320 --> 00:08:25.474 but with a more balanced ratio

NOTE Confidence: 0.83372533

00:08:25.474 --> 00:08:26.910 of children with autism.

NOTE Confidence: 0.83372533

00:08:26.910 --> 00:08:28.065 Typically developing children

NOTE Confidence: 0.83372533

00:08:28.065 --> 00:08:30.375 follow-up study in which will evaluate

NOTE Confidence: 0.83372533

00:08:30.375 --> 00:08:32.777 the original cohort 2 1/2 to four

NOTE Confidence: 0.83372533

00:08:32.777 --> 00:08:34.081 years after initial enrollment,

NOTE Confidence: 0.83372533

00:08:34.090 --> 00:08:36.918 and then a feasibility study in which

NOTE Confidence: 0.83372533

00:08:36.918 --> 00:08:39.008 will determine whether these biomarkers

NOTE Confidence: 0.83372533

00:08:39.008 --> 00:08:41.432 can be applied in younger children

NOTE Confidence: 0.83372533

00:08:41.432 --> 00:08:43.858 three to five year old children.

NOTE Confidence: 0.83372533

00:08:43.860 --> 00:08:46.844 I want to talk about a few other

NOTE Confidence: 0.83372533

00:08:46.844 --> 00:08:49.381 studies going on the lab that will

NOTE Confidence: 0.83372533

00:08:49.381 --> 00:08:51.980 be active in the next few years.

NOTE Confidence: 0.83372533

00:08:51.980 --> 00:08:53.936 One is really designed to improve

NOTE Confidence: 0.83372533

00:08:53.936 --> 00:08:56.612 the reach of this line of biomarker

NOTE Confidence: 0.83372533

00:08:56.612 --> 00:08:58.787 research and really broad biomarker

NOTE Confidence: 0.83372533

00:08:58.787 --> 00:09:01.051 research using e.g an eye tracking

NOTE Confidence: 0.83372533

00:09:01.051 --> 00:09:03.043 in general and autism at present

NOTE Confidence: 0.83372533

00:09:03.050 --> 00:09:04.301 almost all research,

NOTE Confidence: 0.83372533

00:09:04.301 --> 00:09:06.386 almost all neuroscience research in

NOTE Confidence: 0.83372533

00:09:06.386 --> 00:09:08.555 autism exclude children who have

NOTE Confidence: 0.83372533

00:09:08.555 --> 00:09:10.670 any kind of significant intellectual

NOTE Confidence: 0.83372533

00:09:10.670 --> 00:09:12.227 disability simply because it's

NOTE Confidence: 0.83372533

00:09:12.227 --> 00:09:14.165 really hard to to collect data.

NOTE Confidence: 0.83372533

00:09:14.170 --> 00:09:16.861 So what we've tried to do is develop a

NOTE Confidence: 0.83372533

00:09:16.861 --> 00:09:19.057 basically a behavior modification setup

NOTE Confidence: 0.83372533

00:09:19.057 --> 00:09:21.342 that's governed by machine learning.

NOTE Confidence: 0.8442333

00:09:21.350 --> 00:09:23.942 That's automated, and so when we have a

NOTE Confidence: 0.8442333

00:09:23.942 --> 00:09:26.773 person in the lab where basically monitoring

NOTE Confidence: 0.8442333

00:09:26.773 --> 00:09:29.290 everything they do where they look,

NOTE Confidence: 0.8442333

00:09:29.290 --> 00:09:31.558 whether where their head is oriented,

NOTE Confidence: 0.8442333

00:09:31.560 --> 00:09:34.199 whether their bodies and body is moving

NOTE Confidence: 0.8442333

00:09:34.199 --> 00:09:36.472 or still, and we basically create

NOTE Confidence: 0.8442333

00:09:36.472 --> 00:09:38.740 automated thresholds for these levels too,

NOTE Confidence: 0.8442333

00:09:38.740 --> 00:09:41.044 that we then downward adjust during

NOTE Confidence: 0.8442333

00:09:41.044 --> 00:09:43.394 periods of natural rust natural rest

NOTE Confidence: 0.8442333

00:09:43.394 --> 00:09:45.638 so that we can essentially shape.

NOTE Confidence: 0.8442333

00:09:45.640 --> 00:09:48.125 Person to look at the screen sits

NOTE Confidence: 0.8442333

00:09:48.125 --> 00:09:49.603 still maintain their orientation

NOTE Confidence: 0.8442333

00:09:49.603 --> 00:09:51.997 towards the screen as in order to
NOTE Confidence: 0.8442333

00:09:51.997 --> 00:09:54.328 keep a preferred video playing.
NOTE Confidence: 0.8442333

00:09:54.330 --> 00:09:57.392 So this is really put simply, these are
NOTE Confidence: 0.8442333

00:09:57.392 --> 00:10:00.164 the the this is applied behavior Now.
NOTE Confidence: 0.8442333

00:10:00.170 --> 00:10:01.904 Behavior modification, the kind of things
NOTE Confidence: 0.8442333

00:10:01.904 --> 00:10:03.644 that are used behaviorally, not ISM.
NOTE Confidence: 0.8442333

00:10:03.644 --> 00:10:05.688 The idea here is really to automate
NOTE Confidence: 0.8442333

00:10:05.688 --> 00:10:07.968 it so that we can collect EG data.
NOTE Confidence: 0.8442333

00:10:07.970 --> 00:10:09.758 An eye tracking data.
NOTE Confidence: 0.8442333

00:10:09.758 --> 00:10:11.099 And it works.
NOTE Confidence: 0.8442333

00:10:11.100 --> 00:10:13.753 These are pilot data that this is
NOTE Confidence: 0.8442333

00:10:13.753 --> 00:10:15.941 an ongoing study that's actually
NOTE Confidence: 0.8442333

00:10:15.941 --> 00:10:18.376 been slowed because of covid,
NOTE Confidence: 0.8442333

00:10:18.380 --> 00:10:20.948 but the system works were able
NOTE Confidence: 0.8442333

00:10:20.948 --> 00:10:23.090 to get children with Iqs,
NOTE Confidence: 0.8442333

00:10:23.090 --> 00:10:26.086 is lowest 22 to tolerate our procedures

NOTE Confidence: 0.8442333

00:10:26.086 --> 00:10:29.509 to yield valid eye tracking and EEG data,

NOTE Confidence: 0.8442333

00:10:29.510 --> 00:10:32.576 and so we're actually we plan actually

NOTE Confidence: 0.8442333

00:10:32.576 --> 00:10:35.182 to to begin seeing participants

NOTE Confidence: 0.8442333

00:10:35.182 --> 00:10:37.578 post covid next week.

NOTE Confidence: 0.8442333

00:10:37.580 --> 00:10:39.120 Another application of this line

NOTE Confidence: 0.8442333

00:10:39.120 --> 00:10:41.149 of research is to think whether

NOTE Confidence: 0.8442333

00:10:41.149 --> 00:10:43.319 these biomarkers could provide us

NOTE Confidence: 0.8442333

00:10:43.319 --> 00:10:45.055 information about potential treatment

NOTE Confidence: 0.8442333

00:10:45.115 --> 00:10:47.323 targets and so we're interested in

NOTE Confidence: 0.8442333

00:10:47.323 --> 00:10:48.795 direct brain stimulation really.

NOTE Confidence: 0.8442333

00:10:48.800 --> 00:10:49.548 Right now,

NOTE Confidence: 0.8442333

00:10:49.548 --> 00:10:51.044 autism is treated purely

NOTE Confidence: 0.8442333

00:10:51.044 --> 00:10:52.166 by behavioral treatments.

NOTE Confidence: 0.8442333

00:10:52.170 --> 00:10:54.830 There are no medications to treat the

NOTE Confidence: 0.8442333

00:10:54.830 --> 00:10:56.650 core social difficulties in autism.

NOTE Confidence: 0.8442333

00:10:56.650 --> 00:10:58.520 We understand the brain regions
NOTE Confidence: 0.8442333

00:10:58.520 --> 00:11:00.016 that underpin these difficulties.
NOTE Confidence: 0.8442333

00:11:00.020 --> 00:11:02.476 We know that they are the brain region
NOTE Confidence: 0.8442333

00:11:02.476 --> 00:11:04.509 targeted by behavioral treatments,
NOTE Confidence: 0.8442333

00:11:04.510 --> 00:11:06.538 and So what we're interested in
NOTE Confidence: 0.8442333

00:11:06.538 --> 00:11:08.438 doing is targeting them directly
NOTE Confidence: 0.8442333

00:11:08.438 --> 00:11:10.358 with direct brain stimulation.
NOTE Confidence: 0.8442333

00:11:10.360 --> 00:11:10.635 Specifically,
NOTE Confidence: 0.8442333

00:11:10.635 --> 00:11:11.735 we're interested in targeting
NOTE Confidence: 0.8442333

00:11:11.735 --> 00:11:13.110 this theory of temporal sulcus.
NOTE Confidence: 0.8442333

00:11:13.110 --> 00:11:15.520 Here you can see me.
NOTE Confidence: 0.8442333

00:11:15.520 --> 00:11:17.944 Demonstrating what a stimulation
NOTE Confidence: 0.8442333

00:11:17.944 --> 00:11:20.368 looks like we are.
NOTE Confidence: 0.8442333

00:11:20.370 --> 00:11:21.396 At this stage,
NOTE Confidence: 0.8442333

00:11:21.396 --> 00:11:23.106 less interested in whether they
NOTE Confidence: 0.8442333

00:11:23.106 --> 00:11:24.575 would work therapeutically and

NOTE Confidence: 0.8442333

00:11:24.575 --> 00:11:27.095 more in terms of proof of concept.

NOTE Confidence: 0.8442333

00:11:27.100 --> 00:11:29.473 If we target the brain regions that

NOTE Confidence: 0.8442333

00:11:29.473 --> 00:11:31.278 we believe underpin these biomarkers

NOTE Confidence: 0.8442333

00:11:31.278 --> 00:11:33.819 that end 170 and attention to faces,

NOTE Confidence: 0.8442333

00:11:33.820 --> 00:11:35.914 can we see movement in these

NOTE Confidence: 0.8442333

00:11:35.914 --> 00:11:37.724 constructs in the direction that

NOTE Confidence: 0.8442333

00:11:37.724 --> 00:11:39.782 we would hypothesize that would be

NOTE Confidence: 0.8442333

00:11:39.782 --> 00:11:41.947 beneficial to a person with autism

NOTE Confidence: 0.8442333

00:11:41.947 --> 00:11:44.439 and we do even in typically developing

NOTE Confidence: 0.8442333

00:11:44.440 --> 00:11:46.120 controls we see that stimulating

NOTE Confidence: 0.8442333

00:11:46.120 --> 00:11:48.340 the STS decreases in 170 latency,

NOTE Confidence: 0.8442333

00:11:48.340 --> 00:11:50.458 so there anyone 70 gets faster,

NOTE Confidence: 0.8442333

00:11:50.460 --> 00:11:52.875 which is what we would want to

NOTE Confidence: 0.8442333

00:11:52.875 --> 00:11:54.929 see in people with autism.

NOTE Confidence: 0.8442333

00:11:54.930 --> 00:11:57.657 And we also see that the when we look

NOTE Confidence: 0.8442333

00:11:57.657 --> 00:12:00.683 at the amount of time a person spends

NOTE Confidence: 0.8442333

00:12:00.683 --> 00:12:03.190 fixating on the eyes of the face,

NOTE Confidence: 0.8442333

00:12:03.190 --> 00:12:06.095 we see it being increased in these

NOTE Confidence: 0.8442333

00:12:06.095 --> 00:12:07.340 typically developing individuals

NOTE Confidence: 0.8442333

00:12:07.404 --> 00:12:09.182 in response to TMS to the SDS

NOTE Confidence: 0.8442333

00:12:09.182 --> 00:12:10.750 and less to confuse you,

NOTE Confidence: 0.8442333

00:12:10.750 --> 00:12:13.158 I TBS just refers to a particular

NOTE Confidence: 0.8442333

00:12:13.158 --> 00:12:14.190 kind of TMS.

NOTE Confidence: 0.8442333

00:12:14.190 --> 00:12:16.255 So that's the information that

NOTE Confidence: 0.8442333

00:12:16.255 --> 00:12:18.919 I want to tell you in my.

NOTE Confidence: 0.8442333

00:12:18.920 --> 00:12:21.230 Brief datablitz I want to

NOTE Confidence: 0.8442333

00:12:21.230 --> 00:12:24.042 acknowledge the people who who make

NOTE Confidence: 0.8442333

00:12:24.042 --> 00:12:26.520 this all happen in the clinic.

NOTE Confidence: 0.8442333

00:12:26.520 --> 00:12:28.060 In the ABC T.

NOTE Confidence: 0.8442333

00:12:28.060 --> 00:12:30.370 And in the in the lab,

NOTE Confidence: 0.8442333

00:12:30.370 --> 00:12:32.140 one of the downsides of this

NOTE Confidence: 0.8442333

00:12:32.140 --> 00:12:33.320 virtual asynchronous format is

NOTE Confidence: 0.8622538

00:12:33.374 --> 00:12:35.114 that I don't get to entertain

NOTE Confidence: 0.8622538

00:12:35.114 --> 00:12:36.578 the excellent questions that I

NOTE Confidence: 0.8622538

00:12:36.578 --> 00:12:37.828 usually get from this group.

NOTE Confidence: 0.8622538

00:12:37.830 --> 00:12:39.558 So please, please consider emailing me,

NOTE Confidence: 0.8622538

00:12:39.560 --> 00:12:40.620 check out our website,

NOTE Confidence: 0.8622538

00:12:40.620 --> 00:12:43.124 pick Yale and I hope I have the opportunity

NOTE Confidence: 0.8622538

00:12:43.124 --> 00:12:45.580 to work with you all in the future.

NOTE Confidence: 0.8622538

00:12:45.580 --> 00:12:47.795 Thanks so much for listening

NOTE Confidence: 0.8622538

00:12:47.795 --> 00:12:49.567 to the talk today.