Clinical Development of Sentio - Then, Now, and Future

Presenter: Marianne Philipsson

Hi everybody, thank you for listening in. My name is Maria Philipson. I work as the senior clinical trial manager for Oticon Medical. My background is within audiology and I'm a trained audiologist and I have been working for optical medical for quite some years now, actually mostly with clinical development of our various devices, but also lately and for quite many years with the development of Sentio. So I'm really excited here today to tell you about the clinical development of Sentio and all of the clinical data that we have gathered so far on our device.

So after this course, participants will be able to explain the benefits and adjustability of the Senchio implant. I after this course, participants will be able to discuss how to use the information presented to adequately support patients when counseling about the clinical data conducted thus far. After this course, participants will be able to describe the clinical data supporting the SEN till one minisund processor and the SeN Tio Ti implant.

So let's take a look at the agenda for today. This presentation will cover first just a brief introduction to bas and the Sentio system. I will guide you through the key clinical evidence that supports performance, safety and product claims for Sentio. I will present the design, setup and outcomes of the Sentio pivotal clinical study, and we will look at how the Sentio clinical data compares to similar prompt devices and the implications of Sentio outcomes for the everyday life of the user. I will also share the future research plans and opportunities for Sentio, but let's start with an overview over different bone conduction devices.

As you know, these devices transfer sound through the cochlea through vibration in the bone. However, there are two fundamental different ways to do this. We talk about direct sound transmission and we talk about skin transmission. Let's start by looking at the direct sound transmission. That is when we have vibration directly to the bone.

Firstly, we have the active transcutaneous devices where we have the transducer in the implant. That is what kind of device Sentio is. We also have the percutaneous devices. That is when the transducer is in the external sound processor, but connected to the bone through an implant and an abutment. Both of these are directly contacted either by the transducer or by an abutment and an implant implanted to the skull.

If we move over to the skin transmission devices, we firstly have the non surgical solution. Typically there are different devices, but typically it's a softband. And the softband, you attach a sound processor to that and it's pressed to the skin. This solution is typically used for children that are too young to get an implant or patients actually trialing a bone anchor device, deciding if they want to undergo surgery. What we also have over in the skin transmission devices is the passive transcutaneous device.

They're not that commonly used anymore, or getting less and less commonly used, but sometimes they're actually confused with the active transcutaneous. I think it's worth bringing it up because they are completely different. With the passive transcutaneous you have the implanted magnet, but the transducer is in the external sound processor. The magnet is only used to hold the device and the vibration is lead to transmitted through the skin. The non surgical like the softband and the passive transcutaneous, they have actually similar performance.

But when we look over at the direct sound transmission, where we have direct contact to the bone, we have a much better and stronger performance. And that you will see in this presentation as we move along and look at the results.

I also want to give you a brief introduction to Sentio. Let's start with our sound processor. The Sentio one mini.

The Sentio one mini sound processor is actually the smallest transcutaneous sound processor out there on the market. It comes in six different colors as you can see on the screen, and have a push button on the top to operate volume and prior change. Also you can see an led on the front, a visual indicator that helps the user guiding on what the sound processor does. If you're familiar with our Ponto system, the easiest way of explaining what Sentio is, is actually to say the proven Ponto system in a transcutaneous options. Overall stem tur has the same ontological features and fitting procedure as our Ponto.

So if you can fit a ponto, you can fit a Sentio.

Lets also take a look at the Sentio implants. Its small and flexible and powerful. Its also the smallest transcutaneous implant on the market. You can see the dimension on the left and actually compared to one and compared to two. The center Ti implant, its 5.3 mm high and 20.3 wide.

And it's actually the first 1st competitor is actually 14% larger. And the second competitor here on the screen is actually 39% larger.

The Sentio Ti implant is also flexible and easy to install. This we actually have heard from firsthand experience from the surgeons that have experienced with it. But by design it has a flexible, so it actually can twist or turn maximum 30 degrees in each direction both left and right and actually back and forth. So that makes it easier for the surgeon when they are to place it that they actually can get a good fit and get it into the pocket under the skin. It also has flexible fixation bands.

We know that this patient group, they might have abnormal anatomy due to syndromes, or they may have had previous, previous surgery in the area. But with this flexible solution, with the little fixation span that you actually can cross over the transducer in which direction you prefer, make it easy to find a spot where that you actually can fit the device.

Okay, let's move over to the development. Let's start with actually development of medical devices.

Okay, so let's talk about the development of medical device and take a look at the generic process of developing a medical device. It all starts with preclinical work. This is a natural first, low risk step. And I emphasize low risk because when we develop medical device, low risk and safety profile is always the driver. So first you will look into what kind of technical measurements or bench tests you can do.

You will then, depending on if it's. Depending on which device it is, look into if it's necessary to perform animal testing of cadaver studies. This is all, like I said, depending on which device, and they are only performed as necessary. And of course, it's highly, highly regulated.

You will then move over to a pilot study, and that is where you test the early safety and performance of the device. And you will involve maybe 20 to 30 human subjects. And then if the results are in line with what you expect, you then would scale up to a pivotal study.

In the pivotal study, you will involve more human subjects. And here you put your hypothesis and test in a highly controlled clinical trial context.

When you have your results and approved from all of these three initial steps, you will be able to get permission to sell or get FDA clearance or approval. And this is when you start selling the device, and the device is starting to be wider, broader use out in the market. But very important here, not to forget, is that this is actually not where the interest, or at least not the obligations of doing research on the device stops. We also have a post market phase, and that because that is where we can investigate the long term effectiveness and safety in the general population. And there you scale up to over 100 subjects.

Okay, so let's take a look again at the generic model of clinical development and apply all of the research that we have done on STEM geo. On this model, there is actually more than ten studies on different aspects of the development that classify as preclinical work. In this presentation, I will dig into the details of two of these studies. Also, thanks to Professor Bill Hortenseson, Bill Hortenseson was actually the inventor of the complete bone anchor system back in the seventies. But he is also the father of the BCI system, which is a system that is the same basic principles and have a lot of similarities to the STEM T system.

So it's based on the BCI that the stem geo system works. And he did a pilot study. They started already in 2012 with six patients, two clinics in Sweden, and thanks to this pilot said, we actually have five years follow up of a system that is, like I said, the same system over the basis of the system that Sentio is.

Like I said, they started this in 2012. And we know what happens with patients. We know what happened with hearing aid development, we know what happened with patients devices. These patients, of course, needed sound processor upgrades. We have two different pilots that actually cover audiological aspects and physical aspects of the sound procedure.

And then of course, we have our pivotal study. It's ongoing, it's fully recruited and we have concluded the first endpoints, which is the basis for our approvals, but it's still ongoing. We have implanted 51 patients in six clinics in three countries in total. We follow them for two years and it's estimated to end in November 2025.

I will also share with you our post market plans because we have three studies in active planning. Two of them focus on pediatrics with the aim to extend our indication. And we also have a bigger research program going on where we follow real world evidence and long term data with the Sentio device.

Let's take it from the start and look into the pre clinical studies.

Okay, so the first study we would like to highlight is the study exploring the benefit of size and adjustable implantation of the stem cell implant. It was published in 2021 by Ron et al and it's a retrospective, non interventional study that explores fictitious implantation of the center implant based on CT scans. The study includes a total of 197 CT scans, which of 132 were from adults and 65 of them were from children. The children were also, as you can see on the slide, split up in five different age group where there were 13 scans per age group. What the researchers did was based on the bone thickness indicated from the CT scans and the dimension and flexibility of Sentio.

They looked if. Okay, can a Sentio implant be placed on this specific patient just based on the information on the CT scan? So you could say they did pre op planning on these patients based on the CT scan to see. Okay, would it be feasible to place an implant in this specific skull and looking at the results? The results plotted the minimum bone thickness in the recess area, the recess area that is under the implant.

Wherever you drill a little bone bed where you place the implant, they plotted that and also plotted the placement of the two fixation screws, because of course, the fixation screws also go down in the bone. So it's important to see that there is enough bone both to drill the recess and to use the two fixation screws. So. And what it actually could be seen is that it could be implanted without previous CT scanning in patients from the age of nine years and above. Currently, the initial regulatory clearance is centered of twelve years of age and older.

So we have a good range there. Also, what you can see was that actually in all CT scans, except for one scan, and that was of a 16 month old child, the new bone conduction device, that is Sentio, could be implanted in at least one of the fixation band position analyzed. And if you remember when I talked about the flexibility of the band that you could twist and then you could choose where to place it. In this study, it was shown that, okay, you can actually place the dip at least in one position. This gives us a

little bit, like I talked about before, when we looked at the flexibility of the implant, that we actually, it can safely be placed from twelve years of age and older, and most likely for younger children in the future.

The second study that I would like to highlight is when we look at the performance of the Sand G one sound processor. This is work that was published by Goncalves et al in 2022. And it's a preclinical prospective study on five human cadaver heads. So five human heads, and that gives ten ears that they measured on.

They implanted these heads with punctuation sensor implants. And then they used a method using laser Doppler vibration to validate different output levels from the two sound processor and the location using a method called cochlear promontory vibration. And the implants that were placed according to the surgical manual and wherever and according to clinical practice, where they would expect to place this implant.

The results from this study showed many interesting findings, but one of the central takes away that has been helping us a lot in further development was actually that at frequencies above 500 transcutaneous device. Again, that is Sentio provided similar output levels to the perfect tedious device. And this is a really important finding. As in many ways, as I previously said, Sentio has similarities to Ponto. And Ponto is a benchmark for personal performance outcome.

And like a little bit, I talked about before is if you can fit a Sentio, if you can fit Ponto, you can then fit a Sentio and expect the same output.

So this is proven by this study. And of course also for the result, let's dig further into our pilot study.

Let's start with one of the first publications of clinical experience from the BCI pilot study. This was publishing published by Hawker Sonnet Al in 2019 and he spoke research group at Chalmers

University in Gothenburg. The study describes the one year follow up of the 16 patients that were implanted with the BCI. At this slide you can see the cohort demographic presented in detail. For example, the BNH is about 40, ranging from 18 years to 74 years.

They were followed through four standardized measurement appointments at one, three, six and twelve months. What you can also see on this slide is actually the similarities between the BCI implant and the Sentio implant. So you can see that it's the same design with a coil and you can see the little neck and then you can see the transducer.

Another publication from the same group is even more interesting. It was published by Reinfeld et al. Again, the research group at Chalmers University and this publication actually follow the long term follow up for the original BCI cohort. And even if this is labeled as a five year follow up, the true implant time ranges between six and nine years. Because the patients were implanted sequentially, you didn't do everybody at once.

You first did one patient and then continued with the others. Actually by the time of this publication, accumulated implant time is actually 113 years. And as this was published in 2022, we are now even more accumulated implant time.

Looking at the performance, what is important here, and also very reassuring is that you can see stable performance throughout the study. For the patient measured, the functional gain was 29.5 decibels PTA four and the effective gain was -12.4 decibels PTA. And this is, like I said, very similar to the results that they previously published. And more importantly is actually during all of this accumulated time, there are no serious adverse events reported, which brings reliability and robustness with the safety profile of Sentioe. Like I said, as BCI and Sentio share the same basic principle, we expect the same stable long term performance over time and the same beneficial low risk safety profile for the Sentio.

As for the BCI.

Another important pilot study with very important results come from the STO one Milli study. So in this study the subjects with the BCI implant were offered some processor upgrade, some physical performance use and preference were explored after one month, one month's use. The results clearly indicate the same level or even slightly better, actually functional and effective gain as previously reported for the BCI.

Also interesting to look at, what do the patients say when the patients were asked for their preference of either Sentio, one mini or the previous sound processor? Seven out of ten preferred Sentio and two out of ten they were based. They were more or less neutral. This study provides support for patient preference for the Sentio 1 minute sound processor and all of its associated features.

So now it gets really interesting because now we'll take a look at the pivotal study. And like I mentioned before, this is the first time where the final design of the Sentio. So the Cynthia that is out there on the market, that is what was studied in this study. The study includes 51 patients implanted.

Every patient is followed for 24 months through ten clinical visits. The main analysis of data are done after three, six and 24 months after surgery. Performance measures are aided thresholds, speech recognition and different type of pro, that is patient reported outcomes. And the study includes six medical centers. You can see them on the right hand side.

We have two centers in Holland with Professor Mirtha hall as the coordinating investigator and also Professor Emmanuel Milano in Radboud in UK. We have two centers also. We have University of Hospital in Burmatown, Queen Elizabeth, where we have Doctor Peter Monksfield. We also have Cambridge University Hospital and also known as the Edinburgh Hospital led by doctor James Heidel.

And then of course we have the two german sites, one site in Freiburg led by doctor the professor, doctor Susan Arndt and also in Hanover in Germany where led by professor doctor Thomas Lennartz.

So if we look at the demography for the patients in this study, we have a mean age of 50 years ranging from 24 to 77 years. We have 63 female participants, 63% female participants and 37% male participants. Looking at the type of hearing losses, we have about half 51% conductive hearing loss and we have one four of mixed and one fourth of SSD. So covering the complete indication for the sentient system, the group is a little bit mixed when looking at what they have come from. 33 of them have had no hearing solution on their implanted ear and they have never had one for the one of them have had some kind of previous solution and 26 of them have a current solution, current solution being an AC hearing aid across a by cross.

So looking at some of the surgery data to start with, surgery duration, on average the surgery was performed in 58 minutes ranging from 23 minutes to 85 minutes and we can see an overall downward trend over time. The shortest with 23 was not the first area that was done after some time. So this is also something we can expect out there. Of course, we have some cases that are a little bit more tricky and some cases that are easier, but overall expect surgery well below 1 hour after surgeons are getting acquainted with the system. Also interesting, let's look at anesthesia.

We can see that 96% were performed under general anesthesia and two cases were performed under local anesthesia. So it's indicating that it's possible to do in local anesthesia however we do, and it can give further development options. However, we expect general anesthesia to be the clinical practice in most cases. Of course, the study also concludes that the Sentio can be safely implanted without preoperative imaging. This of course we looked on earlier before when we talked about the Vaughn study, but here we have real world or clinical data supporting it.

And what we can see is actually that 55% of the surgeries was done without any pre op imaging. There were no aborted surgery due to insufficient bone thickness and or expected anatomy. So it was not that they had to cancel a surgery after started because something popped up. And actually what is worth mentioning here is actually that 37 of the sites they had preoperative planning as a part of their clinical routine. So they did not perform it just because of the Sentio.

They always do it, no matter which transcutaneous device work with. So, but if we remove these centers, we can actually see that more than 85% was done without pre imaging.

Of course post operative complication, but through monitored in the study using several measurements. In general, no severe complications were observed and the surgical wound was healed within two weeks as expected. There were initial reports of pain, swollen skin, numbness after surgery as indicated by the IPS score in this graph. And the IPS stands for inflammation, pain and skin height and numbness. And it's a standard based way of measuring skin complications after surgery.

So as you can see, a little peek from the baseline, that is of course before surgery and then surgery is performed. And of course there is an increase in inflammation as there would be after surgery, but you can see that it declines. And after three months, basically all of these three factors are down to serial. Again and again, no major complication was seen. And this study actually, if you look at the accumulated implant time for this study, we actually have 47 to 60 implant years.

Let's dig a little bit more into the safety and potential complication. When we talk about are adverse events and safety. Because the sentient system is safety use as intended. What is the baseline for that? How can we say that?

And that is our safety reporting. And this is done in a clinical investigation. You actively look for side effects. This means that in any interaction between research subject and healthcare professional, you

ask about experience problems, complication or any untoward medical incident. These are called adverse events.

And in contrast to spontaneous reporting, actively adverse event reporting generates a lot of different events. And I mean an event can be complication related to the surgery or use of the product, but it could also be completely unrelated. You gather everything. You either gather if they have had a cold or if they have the sprained ankle. Everything is gathered and then analyzed to see if it's related to the system or nothing.

And what we can see is that in the study at the three months follow up there were 53 adverse events related to the surgery or product reported by 24 of the subjects.

None of these were serious, no major complications. Minor events were seen such as numbness, swelling and pain, headache and dizziness. Very reasonable, very common side effects when you have undergone surgery. But in the events, like I said, they were all minor and in most cases they have been resolved.

Let's look at the performance data. How do the patients actually hear? That is what we're interested in, of course.

And the primary objective of the center study was to investigate the difference between the unaided and aided sound field threshold for the 500,000, 2000, 4000 Hz, or as we refer to them, the PTA four. So the difference between uninitiated PTA four is referred to as the measurement functional gain. If we take a look at the graph, you can see that we have noted the unaided threshold. So that is sound field threshold measured with the non implanted ear blocked, that is 59 decibels prior to implantation. If we then redo the measurement after getting a central implant, again blocking the non implanted ear with the aided threshold of 26.2, that gives us a significant improvement of 32.8 decibels.

And when comparing this, the functional gain, as it is a very common way of evaluating bone anchored hearing aids, when we compare it to the range report of similar devices and those devices is all transcutaneous active devices out there. So it's bone with anosmia center fits right in the range because the range is between 19 and 59. So we've fit right in this range.

Why this range, one might ask, and I think it should be noted that functional gain is very dependent on the study population. So that is basically the type of hearing loss, or more specifically, how big the air-bone gap is, will mean that functional gain will difference. So the bigger airborne gap, the bigger the functional gain. So a more representative measurement is therefore the effective gain that corresponds to the difference between the aided thresholds and the on and bone conduction, or BC threshold.

So we actually see, when we measure the aided threshold, we actually see, okay, how close to the patient's bone conduction threshold can you actually get? How well does this system bridge the airborne gap? So a measurement or a value as close to zero is, the better. And you can see that the range reported here in similar devices is between minus six and three decibels. So the value of nine decibels is actually a very good value and a good indication that center is doing what it's supposed to do and that we are on par with different treatment options.

Let's get a little bit more.

I will take this from the top as well.

Okay, let's look at the improved hearing when we look at speech in quiet, a little bit better evaluation of how the patients actually hear. So again, we measured with a non ear implanted and a speech signal coming from the front. So what we can see here is that unaided, before getting the implant and fitting with Sentio, the unaided valley was 46%. After getting the implant, the aided value was 98%. And this is

very high value.

We can see in the range report of similar devices that there is a range between 58 and 100%. So you can make it a little bit easier and just say that with the Sentio, you go from hearing about what I have, what is that? To hearing about everything that is said with the 52% improvement. And again, highly significant.

Let's look into speech in noise, a better and more relevant outcome, of course, because as we know, speech in noise, that is where the patients with hearing losses really struggle to understand.

Again, plugging the non implanted ear, a speech signal coming from the side and noise from the front. And what you do here is actually that you keep the speech fixed and then you will adapt the noise based on correct answers from the patient. So you aim to find a level where the subject can repeat 50% of what is said. Here. The center was compared to a pont on a soft bend, and the SNR improvement went from -6.7 decibels when using a ponzo on a soft bend to -9.6 decibels when aided by Sentio.

And this corresponds to a change in improvement of almost three decibels, 9.2 to be exact.

We also, if you remember, there was one fourth of SSD patients in this group. And we of course, this is a specific group and we of course, need to look at them separately to see, okay, how do they cope with, how do they perform, what the stem to your device and what we do here, we do a separate setup with speech coming from the aided side and noise from the non implanted side. And here we do not block the ear because this setup represents the most challenging and relevant situation for the subjects without help due to the head shadow effect. So here, center is expected to make a big difference, helping to overcome the head shadow and routing the signal to the hearing side. And that is exactly what we can see.

We see a significant change from 0.9 decibels unaided to -4.5 decibels when aided by Sentio. So this corresponds to a change of 5.4 decibels improvement of SNR with the esSentiol.

Now let's move over to what the patient says, and let's do that first by looking at the patient reported outcomes.

I will take this one from the top as well.

Okay, now we move over to patient reported outcomes and the most relevant one to ask the participant subjects about the perceived quality of life. We use several methods to explore this and one of the generic measurements is the Glasgow benefit inventory. GBI is an 18 item questionnaire that measures precede quality of life from an intervention. The score can be between -100 that is indicating a worsening via zero. That would represent no effect to plus 100, which is maximum positive benefit from the intervention.

And it's different aspects of quality life. It's 18 questions, like I said, and they're covering quite broad aspects of quality of life. For example, have the results of the sentry implantation made your overall life better or worse since you had a central implantation? Do you catch colds or infection more or less often? Since you had the center implantation, have you been able to participate in more of your social activities?

And what we can see is that as many as 97 reports an improvement of their quality of life.

The score was 29 out of the maximum positive effect of 100. And as indicated by the graph and the substance of scores for statistical and social TBI, center will not solve all of your problems in life and it's not expected to. If you recall the question I just read out loud with, if it has affected the ability to catch cold or not. That is of course not something that we by any means claim that Sentio would, but it's a

part of this general. So we don't expect with this system to have 100 of score, but this general impact is still significant as represented by the general and total GBI scores.

Okay, let's look at patient benefit from one of our other pros, this speech spatial and hearing qualities, or as we call it, just the SSQ. This is a twelve item questionnaire of perceived benefit from intervention, with questions like, can you follow a conversation in a busy restaurant? Can you tell direction from a specific sound? Does music sound clear and natural? Or.

And so on. And each question is answered on a scale between zero and ten, where zero represents being unable and ten represents being perfectly able. For complete agreement to the posted question.

For this questionnaire, we can actually see that 100% of this participant subject reported benefits and the total score went from 3.4 to six, which is the significant improvement. Also, when we looked at the sub scores for speech spatial inequalities, respectively, we saw a change of more than two steps on the scale. And worth mentioning here is actually that in the scientific literature, it's reported that any change more, equal to or greater than one step of the scale is clinically relevant. So this indicates that we have both a clinically relevant and statistically significant improvement with Sentio.

We also measured very specific patient reported outcomes that evaluate the features of the Sentio system. Sentio is a specific, it's a somewhat new type of device. The standardized questionnaires that we have, they are very generic. So we just needed another tool to be able to measure some of the aspects that is specific and interesting to know. Looking at the Sentio system, one of the things that we wanted to look at was the magnet retention.

Sentio has an exchangeable magnet. It has. It comes with a default magnet, but then you can actually exchange the magnet. So if the patient perceives that the sound processor fallen off, you can change it to a stronger. And if they perceive it being a little bit uncomfortable, you can change it to a softer.

So these two questions, we actually can see that the strengths that we have to offer with the stem gel system give a good balance of does the stem processes stay in place and how does it feel against the skill? Is it uncomfortable or is it comfortable? And this is actually shown already at three months after surgery. So this is really nice that the audiologist had been able to find a good fit for most of the patient that quick looking at the details, you can see that 90 96% report that the sound processor generally or always stays in place and 94% find it either acceptable or comfortable to wear. Worth mentioning here is that we recommend usage of safety line.

So if it's dropped, it's not dropped completely, it just falls off and then the patient can put it in place again. Also, looking at this, remember, like I said, this is at three months. And that magnet replacement happens also after this visit to ensure comfortable use of the sound processor. And this is something that we monitor through all of the study. How is the comfort, how is the retention and which magnet has been used?

And nothing. Let's look at the sound quality.

These two charts show different aspects of sound quality. And here I believe we have some of our strongest results. When rating the sound quality at three months, 94% finds it acceptable or natural. And remember here, this is not natural sound. It is actually digital process sound through the sound processor.

So it's really strong that we have these nice results with so many people saying that it actually is a natural and acceptable sound.

Also worth to emphasize is the very rare course of feedback. In fact, at three months, we only see one subject reported recurrent feedback problems. And this I can actually share with you, that this was

actually resolved at six months. So in other words, thanks to fine tuning and open sound optimizer, we can confidently say that cento is unlikely to cause feedback issues.

Okay, let's look at some further patient reported outcomes where we come to use and satisfaction. Last but not least, we ask center users how much they use their sound processor and how satisfied they are with the center system. Most users use sound processor for the full day, as seen in the chart to the left. And when it comes to satisfaction, actually 100% are either neutral or satisfied with the treatment as presented in the chart to the right. And remember here, this treatment is actually a quite extensive clinical program where they sign up for a clinical study, they sign an informed consent, and so on and so on, and they undergo surgery.

And actually, all of the patients have either a satisfied or at least a neutral experience with the central system.

But. So let's stop looking at charts and let's hear what the patients actually say. So this is patient quotes coming directly from the clinical trial. This is a UK patient, and it was gathered by doctor Peter Monksfield. And the patient here actually says, without the sound processor, it feels like the right half of my head has gone dead.

So the site is brought to life when he puts his Sentio processor on.

I don't think it can get much better than this. A patient just undergoing surgery fitting with the device. And the quote is, when can I get the other side implanted? This is one of our dutch patients in Monksfield.

And then lastly also a dutch patient who states that my life changed completely when they got the stem jail.

So that was this center clinical development up to approval to market. Let's return a little bit to this overall slide where we see the different faces. And like I said, now we have approval to the market. We have heard about the first surgeries out there. But like I said, our obligation and our interest of performing and gather data for clinical percentile does not stop here.

We also have our post market activities.

And what we have in active planning right now is firstly a pediatric study under twelve years. This is a study that will be carried out in Europe, focusing, like I said, on children below the year twelve and with the aim to be able to extend our indication for the Sentio system. As you remember when I talked about the results from et al, it could be shown that on these fictive ct scans you could place an implant in children, in young children. But of course we need the clinical data to support that. And that is what this first research activity aims on doing.

We also have a pediatric study implanting phase in the US that is between twelve and 18 years. That is a post market follow up where we would like to get clinical data on this group as the group in the pivotal study. We're all above 18 years. We also have the SENS study. The SENS study stands for Sentiosystematic evaluation.

It's a study that followed clinical practice according to the labeling. But this is how the surgeons, how the audiologist would use this system out in their clinics. And we worked again with gathering this real world data on esSentiol and also it enables us to gather long term follow up.

Thank you so much for listening. If you have any questions, you see my email on the screen. I don't know if you have any question from the people listening in right now. Thank you so much for listening.

Oh, we have a question here from in the chat from from Melissa. Thank you so much. Melissa wonders what is the primary goal of the pilot phase in Sentius development. Well, the primary goal of the pilot phase in censure development is gather information on safety and efficacy. Thank you for that question.

Oh great. Thank you so much. We also have a question here about our pilot study de bunch at Alphaa in 2022. What was the primary outcome measure in this study? The primary outcome measure in this study, that was the cadaver study is vibration of the cochlear promontory.

Thank you so much for that question.

Is commonization a phase in the clinical development of esSentiol. No, it's not. Commonization is just a term we use when we can sell the device. So all of the data that we gather, that is data that we gather to be able to commercially sell the device.

Okay. Thank you so much for listening and thank you for all of your questions. If you have any more questions, you can see my email on the screen. Please feel free to reach out with any questions you might have or any comments. Thank you again for listening.

Thank you so much. Marianne. At this time, we're going to go ahead and close down the recording. If you'll be taking the exam on audiology online, please. Please go ahead to your course details page to take the exam there.

Thank you so much. In a world filled with beautiful moments, sound is our unseen companion painting vibrant moments of connection. Okay.

Tranquility and energy. Are you ready? Yes. Let's go. Giving us a sense of belonging, he was the great empowerment.

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