

TRANSCRIPT

Module 6: Accessing clinical trials

- Hello, and welcome to Module 6, where we will be talking today about accessing clinical trials and addressing some potential barriers to participation. We're going to look at some things to consider when accessing trials, some methods to locate trials for you, what to do when you do find a clinical trial that you might be interested in, some potential barriers that might come up to that participation. And as always, we're going to have some video interviews with experts on hand where we're going to discuss the MS Trials Network in Australia and how to find trials. And we're going to also talk about how to become involved in trials, what to look for, what to ask, and we're also going to talk about the importance of including regional, rural, and remote access for people living with MS. When looking at access, there are a few factors to consider. Firstly, finding out which clinical trials are actively recruiting and what we mean by this is what clinical trials are actually enrolling patients into the study right now. That's very important to know because some trials that you might see advertised may have closed, so getting in contact with those researchers to find out if they're still recruiting actively is really important. The second thing is identifying potential barriers to your clinical trial participation, the things that get in the way even though you really want to take part. We're going to talk about ways to overcome those barriers, and finally, we're going to look at the concept of regional, rural, and remote areas being involved in clinical trials and look at some of the exciting new developments in that area. So now we're going to look at some methods to locate clinical trials. First up, there's your usual MS healthcare team, so that's your usual neurologist and MS nurse. They may be conducting clinical trials at your particular site where you go in to see them in clinic, or they may have collaborators or colleagues who are recruiting for clinical trials that might suit you. That's quite a passive way to find out about trials. If you're after something that's a bit more active, a good way is to scan the MS Australia clinical trials network website. Now, we're going to talk to some experts from MS Australia about this website later on, but it's a good way to find out which trials are actively recruiting, and they're set out for different states. You can put in details to look at clinical drug trials or other types of trials that might be happening in allied health. So it's a really great resource where everybody comes together, people looking for trials and researchers looking to recruit patients for trials. Contact details provided here allow you to contact the researcher to obtain the participant information sheet for more details and a summary of the proposed research. Other types of clinical trial registries include the Australian New Zealand clinical trial registry and also ClinicalTrials.gov, which is a US website but it does list studies from all over the world. And more rarely, you might see on the news or in newspaper advertising, people calling out for particular clinical trials. So now we're going to hear from a clinical trial expert from MS Australia. We're going to discuss the MS Clinical Trials Network website, how you can use it, what you can find in there, and just get some tips for finding what you're after. Hi again, and welcome as we talk about the MS Australia Clinical Trials Network and how to locate clinical trials and different types of research studies. So today, we're joined by Dr. Jo Gamble from MS Australia. Thank you, Jo, for coming to talk to us, and we're going to find out something that's a really important step in getting into clinical trials, and that is how do I find them and how do I know what's happening where and when. So most people find out about clinical trials from their neurologist, their MS nurse, and their MS healthcare team but sometimes there's other avenues and Jo's going to fill us in on all of those details, how to navigate that both

nationally and internationally. So thank you, Jo. So we'll get started with can you tell me a little bit about your role in looking after clinical trials at MS Australia?

- Yeah, so essentially my role is all about being that bridge between our fabulous, dedicated researchers and our amazing people living with MS and they might be interested in participating in the trials. So as part of that role, I collaborate really closely with the researchers who are conducting these trials or studies related to MS or other demyelinating conditions. And once they're ready to recruit, I will work with them to list their trial or study on our website, and I can also spread the word about that on our social media platforms, which is really helpful. So then there's a lot of information about ongoing trials, eligibility, and how they can get involved.

- Okay, so that's by accessing a clinical trials website, which we'll have listed in our resources, but what sorts of other things can you find on there?

- So there's a comprehensive list of trials and studies related to the different forms of MS. So whether you have relapsing remitting MS, primary progressive MS, secondary progressive MS, or progressive relapsing MS, you can find relevant clinical trials and potential opportunities to participate in your region.

- So you can search, so what you're saying is you can search both by your State or region and by the type of MS that you have.

- Absolutely. So the clinical trials website, mstrials.org.au, and it allows users to search for trials in multiple ways, and that makes it convenient for potential participants to find relevant trials. And when you combine these search criteria, individuals with MS or their caregivers can easily find clinical trials not only relevant to their region but also really tailored to the specific type of MS they have.

- And you've brought up two great things there, Jo. I just want to just tease out a little bit more. So firstly, it's that it's not just clinical trials but other types of research are listed on this as well.

- Yeah, so there are studying surveys that people can answer questionnaires about, and it just really kind of puts into the mix of everything that's going on for people with MS.

- Yeah.

- We can really understand how they're living and their quality of life.

- And I guess you're not obligated at that point, are you? You're just information gathering.

- Yeah.

- Yeah, great. And the second thing that you brought up, which was a really good point, was although we're concentrating on people living with MS, you mentioned caregivers and other different types of research that people who are living with someone with MS or caring for

someone with MS can also be involved in special types of trials and research just around them.

- Yeah, I think caregivers are a really important part of the whole thing really. You know, they also need support as well as the person living with MS. It's really nice to be very inclusive of that.

- Yeah, and it's nice to know that there is actually research going on for carers as well, so a really important point.

- Yeah, absolutely. And so that's nationally for Australia but internationally, what's available for people with MS who might be interested in keeping an eye on what's happening overseas and globally?

- Yeah, so there are a number of ways to look at what's happening internationally. There are a number of resources that will be listed in these modules and that people can go and look on the website. Off the top of my head, there's the national clinical trials website where all the global trials are listed, and also we do actually have a few international surveys on our own website. So we're kind of, you know, into the international stuff as well as locally.

- Now, that's good to hear. And finally, this question is a little off track but still related to what we're talking about, and that's a question about the AHSCT registry which MS Australia is heavily involved with. So for those that don't know, we're referring to the autologous haematopoietic stem cell therapy or what people call stem cell therapy in MS, and we host a registry, Jo, that I know you are heavily involved with. So what is this registry and how does it fit in with helping with clinical trials?

- Okay, so this was to help contribute to the international efforts and to just really increase our understanding of this treatment or technique that's used to treat MS. And it was settled together with haematologists and neurologists to make a registry to collect detailed data on treatment regimes, pre and post treatment, following people who've had this treatment either within Australia or overseas. And we can collect this data and it really does inform, you know, future directions of trials but also looking at safety and efficacy of the treatment, if it's actually working, and maybe even just increasing that global understanding of the treatment that benefits patients and healthcare professionals and researchers.

- Yeah, because you said that it's not just for people that have participated in the clinical trial in Australia, but people who've gone overseas to have their treatment as well, whether that was in a clinical trial or not in a clinical trial. So we're gathering all that information together in one place so that we can hopefully answer the questions that is still outstanding about stem cell therapy in MS. So that's really good to know.

- Yeah.

- So thank you, Jo. Thanks for joining us today and exploring all of that a little bit deeper for us. Thank you. So what happens when you do find a clinical trial that you may be interested

in participating in. So first up, you usually have to get more information, so you need to get a copy of the participant information sheet, you need to read a summary, you need to go through that very carefully. You need to look at the eligibility that's listed. That will be the list of people that can be included, for example, that might be the specific type of MS that they're looking for and they may be looking for people who are on specific therapies or have had specific things happen to them. You need to contact the researcher for more information. A good rule of thumb here to know is that by contacting the researcher, that doesn't mean that you're signing up for the study. There's still many steps to happen before we get to that point. So please feel free to contact the researchers if something is not clear or if you have questions, or you would just like more information about the study. That's absolutely fine and there's no obligation to participate at that point. And you could also check in with your neurologist and MS healthcare team just for their advice and thoughts, particularly if you're going to a clinical trial that's outside of their healthcare system. It's a good idea just to run it by them so that everybody's on the same page. Now we're going to talk to a clinical trial expert who's a research nurse in MS on how to become involved in trials and what to look for and what to ask for. Hello and welcome to Module 6, and today I have a very special guest, Vanessa Maxwell from Adelaide. And Vanessa's going to talk to us about why accessing clinical trials is so important in MS and some ways that we can do that and things that we need to consider. So firstly, welcome, Vanessa. We're so excited to have you here today. Vanessa is a clinical trial coordinator but also an MS nurse. So often those two things go together, don't they, Vanessa? But firstly, can you tell us a little bit about yourself and what type of work that you do?

- I'm at the Lyell McEwin. We have a neurology department with MS clinic. We have probably 470 patients currently in our clinic. My job role is a mixture of both research and clinical. When clinical trials come through, we review them and see whether they would benefit our patients and whether we have time to be able to do those trials. So it's really important for us to know that we can actually offer our patients trials if we can. So this role's probably three quarters MS nurse and a quarter research.

- So you work in a hospital which also does, as you said, the clinical work plus also research and trials where you can. How do the patients find you, Vanessa? How do they come into your clinic and then be helping in the clinical trials?

- The clinical trials, mostly patients are identified, I guess, with the clinic, with the patients that we already have. So if a clinical trial comes to us, we look at the patient population that we would have that could go into that clinical trial. So we sort of determine whether we could actually do our best in that clinical trial and offer as many patients as they would, you know, would make it worthwhile to run. So we would look at, we have really good spreadsheets with all our patients in terms of patients that have relapsing remitting MS, primary progressive, and things like that. So we go through our list to sort of see whether or not we have patients that we think would benefit from the clinical trials.

- Yeah, because I guess what you're saying is you really want the trials to, A) benefit the patients that are already in your care and, B) you want to go into that clinical trial knowing that you can recruit successfully and bring the best for your patients, don't you?

- Yeah, absolutely. Yeah.

- Yeah. So I guess if we look at it a little bit more broadly, why is it so important, Vanessa, for people living with MS to have access to clinical trials as a treatment option?

- We know that the treatment that we have for MS is far greater than it was 10, 20 years ago, but we know it's not perfect and we know that we can do better. So I think trials that come through are really important because something that I give a patient now for treatment, somebody did research on 10 and 20 years ago. So patients are benefiting from the research participants that we had 10 and 20 years ago. It's exciting to know that something that you've done eventually is being clinically used for patients. So I think it's really important that we offer our patients holistic care because if we don't offer them every opportunity of what's out there, then we're not giving them the best care.

- Yeah, and I guess at the end of the day, we don't have a cure for MS yet, do we? So we've got ways that we can stop relapses but progression still happens behind the scenes. So until we can remyelinate and neuro protect, we still don't have that holy grail, so that's where trials help us out to try and get towards that. So if people with MS find a clinical trial, however that may be, that they might be interested in, what are the next steps that they should do before they jump into something?

- I really hope that they give us a call, that we can discuss it with them, that we can offer as much information about that and help them get as much information about that trial as possible. I think to look at whether or not we think that that would benefit the patient, that it doesn't contraindicate the current therapy that they're on as well and also whether they actually meet the inclusion criteria to that study.

- So are there any training or educational things that you know about that might help people who want to do, to look into it a little bit more deeply?

- Yeah, there is a really good website called the Australian Clinical Trials Alliance, which have a lot of information for patients. I've realised that my patients are more informed than me at times.

- Great. Well, thank you, Vanessa. I think one of the best things to get out of today is for the MS community to realise just how far, but the MS nurses, the neurologists, the researchers work on their behalf behind the scenes as well. Thank you for all that you do.

- Thank you very much. Appreciate it. Thank you.

- Now we're going to look at addressing potential barriers to participating in clinical trial. The first of these is time. That's probably going to be one of the big issues for everybody who's considering a clinical trial. Are you able to devote the required time to the study? Is the study schedule too onerous? How often are the visits? How long do they go for? Are they spaced far enough apart? Will you need time off work? These are things to think about, particularly with how flexible you can be with your normal life. And it's also good to ask about if any of the visits can be virtual or if they can be done by telehealth, or if they can be

done more locally, because that might be a big barrier for you that can be quite easily overcome. The second thing to think about is the assessments and tests that are being asked of you to participate in the clinical trial. Now, many trials in MS will use the same sorts of tests, and some of these are what we use in normal clinical practice, so it's not going to be too much of a push for you to do that. But some trials do ask a lot in a way of assessments and tests and these could be longer tests such as an MRI, or it could be having specific new tests for you, such as eye tests or certain types of blood tests. So you need to be willing to perform all of the tests asked for you and just think about whether that could be a potential barrier. The third consideration on my list is prior experiences with research. So if you've been involved in research or a clinical drug trial previously and you didn't have a good experience with that, it's something that you could discuss with the study team. Just to think about things that didn't work for you the last time, can they be avoided or can they be planned for better this time so that you have a good experience in the clinical trial. Looking at regional, rural, and remote locations is a really exciting new area of addressing potential barriers because for people living in those country areas, that can be a barrier in itself because they're not close to the research site. But we have some very exciting new initiatives, which we're going to talk about in a little bit more detail at the end of this module, that open that up for people living with MS so that they can be included in clinical trials. Now in MS, we know that there's other forms of isolation. This could be financial, social, cultural, it could be isolation from disability, from the immunosuppression from some of the drugs that we use in MS care, or it could be from symptoms such as bladder incontinence. I think people who suffer from bladder incontinence know that going to new centres or going to new places can be really stressful if they don't know what the toilet situation is like. So even speaking to the study staff about what the location is like and how access is for them to toileting facilities can make the world of difference. So it really is worth exploring a little bit more with the study team, what the situation is like to potentially overcome a barrier for you that might actually be quite easy to solve. And just a note for people in whom English is a second language, interpreters are often used, particularly through the consent process and through those early questions, and they're professional interpreters that the clinic and medical staff can use so that there's no wrong messages and that everybody's on the same page. So now we're going to dig a little bit deeper into addressing regional, rural, and remote access in clinical trials. Every Australian should have access to clinical trials. It should not be something that's withheld or only offered to certain people. We need this treatment option, especially in rare diseases and particularly in diseases such as MS that do not have a cure. So what are teletrials? This is a really exciting new area to hit Australia, and it will be rolled out in coming months and years. So they're new ways to promote enrolment and to maintain participation for people living in regional, rural, and remote areas. They're often excluded just by the fact that they can't often travel long distances and get to metropolitan locations to participate in what's needed. So this has been created especially for those people to improve their access. And what's going to happen is that in each state that will have their own jurisdiction where primary clinical trial investigators in sites can be linked to satellite centres further afield. Now it's already rolled out in Queensland and other states and territories are following shortly. So huge benefits because people can be seen closer to home in their satellite centre which means that when they participate in a clinical trial, they can have the support of their family, community, and their local healthcare support. Obviously, there's going to be a reduction in travel and accommodation costs, but more importantly, it gives equity of access to all Australians to

clinical trials and improved access to potential new therapies. An indirect benefits for the local area are that people working in those areas can broaden their skills as well, and it's all going to be done in a supported fashion with education and resources provided. So if you reside in these regional, rural, and remote areas and you find a trial that you think may suit you, please ask your MS healthcare team, neurologist, or MS nurse if teletrials might be an option for you. Now we're going to talk to one of our industry partners about ways to promote enrolment and maintain participation for regional, rural, and remote participants. Hi again, and thanks for joining us today. I have Serena King, who is the clinical and country site lead here in Australia for Biogen. We're going to be discussing something that's very close to both of our clinical trial hearts, and that's diversity and inclusion in clinical trials. Now, Serena, firstly, can you tell us a little bit about your role at Biogen?

- My role at Biogen is to oversee the clinical research programme for global clinical operations in Australia and New Zealand.

- Why is it so important for us to look beyond what appears to be sometimes the easiest way to recruit patients into clinical trials, which is just people that are local to the hospital or the clinic or already known to them. Why is it important for us to look beyond that?

- Well, that is important to, wherever possible and practical, to expand clinical trials to include different communities and ethnicity so that data collected represents diverse cultures, which is a true representation of our broader population. And as individuals like you and me, we are not the same, we're but different genetic makeup, and people may respond differently to the same medicines or products even within close family members. So it's important to capture this information to learn more about the safety and effectiveness of medicine across many different groups of people. And this can also lead to improvement in health equity and provide early access to more communities who would benefit from medicines as well as advancing health sites in general.

- Now, we know that for some in our MS community, they would love to be involved in a clinical trial, but because of distance or being away from a site, there's not really the capacity to do that. So what are some things that we can do to work around that?

- I mean, as you know, COVID has really impacted the way we work and many companies had to reassess and how to think, how to manage their business including our sector, clinical trials. So the majority of our trials are conducted by the main site, and it's what we call centralised clinical trials, and on the other end of the scale, there's a model called decentralised clinical trials. And that's been around for a number of years which allows study activities to be conducted away from the main site, so it's a bit more convenient for the patient.

- Yeah, and it would save a lot in costs too with travelling and all those sorts of things. So special consideration in what we call the three R communities. Got to get this right, it's regional, rural, and remote communities. It's becoming increasingly important and I think you've started to touch on some of the reasons why that might be.

- Yeah. In Australia, we have a population of just under 27 million and just about a third, just less than 30% live in the R three region, that's the regional, rural, remote, and may include many diverse community. So this group face a number of challenges due to their geographic location, including access to just basic services like education and healthcare, and results in a poorer health outcome overall than people in the major city. And we can see this health disparity between the two groups, the metro and the R three groups, and which is why it's important that we expand our region to the R three communities just to increase clinical trial awareness and access to provide the same level of clinical trial opportunities.

- I guess, and you've mentioned disparity and inequity and I think that's for when we're dealing with a disease like MS that does not have a cure and we're doing all of these support measures, that becomes even more important because it should be an option for people when they're living with that. Now, we've heard about teletrials earlier in the module and how the government has funded the teletrials program to bring clinical trials to these communities, the rural, regional, and remote communities, how will it work, how does that set up?

- Yeah, the government has really invested heavily in this program, which is fantastic to see. So each State establishes their own regional clinical trial coordinating centre, the RCCC, to provide support for any sites who wish to set up a teletrial model. So there's a number of sites involved. There is a primary site which is led by a principal investigator who is very experienced in clinical trials, and that person is usually located in the metro area, and then you've got these smaller sites called satellite sites and they are located in the R three region so that the trials can be conducted closer to home or in that region. And there's a partnership between the primary and the satellite sites, and all site staff are properly trained prior to any study activity and would be under the supervision of the primary site. So it depends on the study protocol and the requirements and the setup, and also the experience of the satellite sites. So people living in the R three region may have a majority of their studies conducted locally and then some that can't be done locally will be done at the primary site. So it's just bringing the study closer to home. And this would save a lot of time and effort and travel, and also they'll have the support from their families, friends, and the local healthcare, which is a real big bonus. So this in turn can potentially lead to access better interventions and treatment earlier and potential health benefits for people living in the R three region, so it's a win for all.

- Well, thank you, Serena, for bringing us up to date with all of our three R community efforts, and thank you for everything that you're doing through Biogen to help promote health equity for all. Thank you for joining us today for Module 6. It certainly has been a big one. We have a full list of resources and references available at the end of this module if you wish to explore these concepts a little more deeply. Also remember to take the short quiz just to check what you've learned during this module. Please join us next for Module 7, where we're going to be talking to some of our national advocates from MS Australia about the types of clinical trials that they've taken part in and what the experience was like for them. Thanks for joining us.