**Sonya Chowdhury**

Welcome everybody to the DecodeME webinar. I've got to start with an apology, which is never good, but I'm so sorry for those people that were hoping to watch this live and be able to ask questions. There is an issue with zoom and streaming to Facebook, YouTube, and any other option that we've explored. So what we're going to do is to run through the three presentations that we've got and take a handful of questions.

And then as soon as we can, we will hold another Q+A hopefully sometime next week. So for those of you that don't know me, my name is Sonya Chowdhury I'm chief executive of Action for M E. I've been involved with the decodeME study in lots of different ways. And also chair the management group. I will ask my colleagues to introduce themselves, and then we'll head into the presentations.

So we'll start with Andy then Sadie then Chris.

**Andy Devereux-Cooke**

Hi everyone. I'm Andy Devereux-Cooke , patient of 40 years and I'm on the management group as well as obviously being a patient on the PPI steering group as well.

**Sadie Whittaker**

Hi everyone. I'm Sadie Whittaker and I'm the chief scientific officer at Solve ME , I'm happy to be on the call today.

**Chris Ponting**

Hi, I'm Chris Ponting. I'm joining you from the university of Edinburgh. Well, my home in Edinburgh, I'm a human geneticist and I'm one of the investigators on the DecodeME project. . Thank you very much.

**Sonya Chowdhury**

So we'll start now with the first presentation.

**Chris Ponting**

Do you want me to kick off Sonya? So if you can allow me to share my screen . I have some slides which should just take five minutes. Okay. Here we go. So This is a co-production as you, may know, between investigators, such as myself and, , people with ME and carers and the public, and we have, five steps for a successful co-production.

So step one is we're going to ask people to complete a questionnaire from home. Here is, a person , James in Wales, and they're interested in participating. so they log on to our website, and he is asked to complete a questionnaire. He can stop at any time that he wishes, and come back to complete the rest of the questionnaire as many times as he wishes.

so what is the questionnaire? The questionnaire allows us to implement, the criteria, the Canadian consensus and the IOM criteria. We will ask whether people have had a professional diagnosis of ME and we will ask people, if they're more than 16 years of age, of course, we welcome participation from anyone in the UK with mild, moderate, or severe ME

and or CFS or CFS. so that information goes to us in Edinburgh. And here's another person here's Jane, out in the outer Hebrides. And she, has greater difficulties in, completing the electronic, questionnaire. we do allow people to help others electronically to complete questionnaires.

But if, if that's not suitable for Jane, then there is a paper questionnaire but we will ask people if at all possible they can do it electronically online. Because the paper questionnaire has quite a lot of overhead, but of course we'd be very happy to receive a completed paper questionnaire.

They will come to us. In Edinburgh. So we will launch in September this year. And of course our hope and intent is to get at least 20,000 people who pass the criteria that we show here. And we have all of their details. we will keep all of your information incredibly securely.

Step two, we will send you a package from a vendor and they will go to your home address. So we will have your home address details. In the package will be this device, which is a saliva collection device. You spit into the tube, you collect the saliva in the tube, on the right there, and then pop it into an envelope that we will provide. And it will go into a normal postbox. And then that will go from our participants to the biosamples center in Milton Keynes, our partner in this project who will extract the DNA from the two samples, the many samples, the DNA will be sent to our partners. Thermo Fisher scientific in California, who will read out the DNA letters at almost a million positions across the genome. Now half of the DNA will be kept in Milton Keynes to allow us to do at a later point in time when we have sufficient funds, whole genome sequencing, which is different from what Thermo Fisher provides us with.

Afterwards, step four, the data will be sent to us again, in Edinburgh. We will have all of the data and again, we will hold it always incredibly securely. We will do the data analysis. We're looking for DNA letters that are more common in people with ME than in controls, because we have already accumulated in the UK biobank. We already have 500,000 people's DNA information from UK individuals.

We are in this first instance, asking people with ME in the UK for their samples and again, at least 20,000. So we all find hopefully one or more, hopefully many DNA letters that predict, significantly predict whether someone has ME over being a control individual. Our hope is that we will generate biomedical evidence that subsequently capitalized evidence-based experiments that we will study, whether the genetics of ME overlaps or not with the genetics for other diseases. And we intend there to be societal changes in the perception of people's ME or CFS, because of what we find.

So, what are we doing now? We're spending a huge amount of time ensuring that all of our procedures are done to the very best of our ability, both the electronic questionnaire, which is enormously aided by our partnership and collaboration with Solve ME and the paper questionnaire.

And we're going through the ethics procedure through the research ethics committee locally here. We are putting into place procurement and contracts with our partners, for example, Thermo Fisher and the NIHR Bio sample center, we are going through procurement for the saliva sample kits, and we're ensuring that we have in place systems that allow us to track everyone's samples and everyone's packages on the journey that I've previously shown you. So that is where we're at with DecodeME and I would be delighted if you could join us to ensure that we have at least 20,000 people with ME in the UK, who can participate.

**Sonya Chowdhury**

Thank you, Chris. We're now going to hand over to Sadie.

**Sadie Whittaker**

So thanks, Chris. We're excited to partner with you on the DecodeME study. What I thought I would do in my presentation is go through a couple of slides about the registry, and then talk about how that registry infrastructure is going to be used in the DeocdeME study. So we launched this registry back in the summer of last year.

And in December, we opened it to the long COVID community. So it's a registry and biobank. We have patient reported data and biological samples and you'll see how it works on this circle here. So if you start on the top right around one o'clock people sign up to a desktop portal, enter information through self-report information, they complete surveys, and then they can download a symptom tracking app to do longitudinal data capture.

That information is aggregated together and then combined with data from everybody else who's in the registry to form the dataset and then patients will be asked to provide a biological sample. And all of that information together will be made available to research. So overall, that's kind of how our registry works in terms of how that it's going to work with DecodeME.

Chris and his team are working with us to use some of our infrastructure and some of the ways that we're collecting data, such that the participants in the who are part of the DecodeME study are entering information and will be given the option to subsequently participate in the registry.

And I'm going to go through that in a couple of slides. I mentioned that there is a symptom tracking app. I have a few slides just to show you guys what this looks like. So this is the home screen. You can enter information on your general wellness. And that showed it as a score around the edge of the circle.

You see its shown as a 38, and you can personalize this by putting your photograph in. You'll also get a flag when it's time to do a tracking, you see that orange banner at the top that talks about when it's time to deal with tracking. And then you can track your symptoms or you see on the left-hand side, the sliders where you can drag your symptoms from zero to four depending on how you feel.

You can also remove symptoms add different symptoms and prioritize, which ones are the most important to you. You see on the right hand side here, we're also collecting information on treatments, life events, you know, did you have a stressful day? Did you exercise? And then a general wellness score slider, and this is the slider that when you add a school here, it shows on that home screen.

So just to go back to this , that slider is the number that shows here on this circle. You can graph you symptoms over time, so you can pick which symptoms are important to you to graph, and you can show them over time. And you can also see on the right hand side here, that the general wellness score over time can be graphed

so you can monitor, you know, what things might be affecting, how you're feeling whether that's, you know, physical exertion or medications that you might be using, you're able to more closely monitor what's happening to your health. So I mentioned, we opened in the summer of last year. This is our enrollment dashboard.

So on the left-hand side, you see here, we have the numbers of participants. So we're at 3,148. We're actually, this was from yesterday. We're actually at 3,155 today. We have 2285 people with ME CFS. 343 controls and 520 with COVID. That COVID is long COVID and not long COVID. But a majority of it right now about 80% is made up of long .

The statistics you see kind of on the right hand side here, all just for the ME/CFS cohort. So you see, it's probably not the great deal of surprise, but we have a majority female in the registry. The average age is 52. We have a range of 18 years to 94 years. And then you see in the middle panel here, this shows how much impairment people have in their day to day functioning.

So a majority have severe to moderate impairment shown in this yellow and gray here. We do capture whether people were diagnosed by a provider or self-diagnosed and you see those numbers there. So 90% were diagnosed by a provider and 10% of self-diagnosed. We have this very small percentage, 1% who had had ME CFS, but now consider themselves recovered.

So that's just a data snapshot of where we're at with enrollment. The next slide just gives you a sense of where we are at geographically. So right now for the ME/CFS cohort, we're only open in the US. We've just launched a collaboration with emerge in Australia to open to Australian enrollment. And we are planning to open globally in the June timeframe in the U S we have representation across all of the States and you see, we do have some clusters in California.

Florida, Texas. And I don't know what this state is. I've lived here for 20 years and I still don't know the geography of the United States. But you can see, we do have fairly good representation across the whole country. In terms of opening up globally and how that relates to the partnership with decode me.

I mentioned that the DecodeME study is going to use our data infrastructure to collect data. That data will be housed at the university of Edinburgh with Chris's group. But after signing up for the study, participants will be given the option to join the registry and contribute their data to this bigger effort that we're undergoing with the registry.

Similarly if we have opened the registry and you're already part of the registry and you want it to be part of the decode me study, you'll be given and kind of an easy option to sign up for that study. We're currently exploring now with our software developers, how we make sure that obviously with your consent data, that you've already entered either as part of the registry or as part of the DecodeME

if you join the other effort, that data that you've already entered will be transferred across with your permission. So you won't be asked to enter the same information twice. And that's really one of the benefits that we see in this collaboration, this stability to amplify each other's efforts and to do more with the information that you're providing.

So we can really help to not only be successful with decode, but to continue to drive research in other areas. So that's the end of my presentation and I'm looking forward to answering any questions.

**Sonya Chowdhury**

Thanks very much Sadie and thanks for clarifying the fact that the You+ME portal is not yet available in the UK and also in other parts of the world.

It's also important that people understand that for the DecodeME study, you will just be required to complete the questionnaire. And give your consent to participate in the study and then provide a saliva sample from home. You won't need to travel anywhere. And that will be posted back so that you can be included in the study. The symptom tracker, and all the other wonderful benefits that you can access will be a choice.

There are lots of different things you can be part of, or you could just be part of different aspects of that. So thank you, Sadie. That was, that was really helpful. Andy you're not going to tell us a little bit about how people with lived experience of ME are participating in every aspect of this study.

**Andy Devereux-Cooke**

I am indeed. Unfortunately thank you to my colleagues for their presentations I don't have slides to share. So you'll just have me as a talking head I'm afraid. So I'll be describing how people with lived experience of ME and their carers have the ability to influence decode ME.

But first I thought I'd set a bit of a scene as to patient and public involvement. So PPI And research. So without being an expert in it I think it's fair to say that historically inclusion of patients and, and all the public and their ability to influence research is really only a, a relatively new development in terms of research projects.

Previously research very much was something that happened almost to patients. Obviously samples would be taken, but their ability to have a say on what might be in their opinion or wrong or right way to do things. It was very much you know, it just didn't happen, but in recent times the importance of including the views and opinions of patients and the public and carers Has become more and more obvious.

And so the inclusion of involvement has started to grow. Often that takes the form of a small group of patients who might be consulted once or twice over the course of a research project. And, or a steering group who might, be asked to give their opinion on various aspects on a couple of times.

That as far as I'm aware is often more the case nowadays. But Decode ME takes that approach and builds on it quite dramatically. So we do have a PPI steering group, which I and Sonya are part of as patient and carer and charity representative. So the PPI steering group meets once a month to review the progress of the project to discuss and express opinion, view whatever is needed for anything that crops up.

But we've also taken the further step of basically embedding Patients and their, and or carers into the different delivery groups of DecodeME. So delivery groups will be working on different aspects of the study. So one is the cohort delivery team. Cohort in this case basically meaning the 20,000 people or more, or who will take part by sending in their saliva samples.

So we have those people with that direct lived experience working as part of those teams able to give a necessary opinion, the insight into the condition that they can give daily, you know, so it can, it doesn't need to come back to be reviewed and suffers a months long delay.

Those insights can directly feed into the progress that is made by those individual teams. And. Obviously in that regard speeds up the process. But equally in the regard as to taking the appropriate care and concern as to their condition, that naturally slows things down. Because as I'd imagine the vast majority of those of you watching this know the impact of overexertion that that can be had by those who suffer ME can be extreme. So obviously what we're trying to do is, and achieve a balance of having them involved, gaining insight gaining those valuable inputs into our process, but at the same time, respecting their health. And taking things forward in a way where and that's a speed that enables that.

So unfortunately, that's one of the reasons why we have had to push the launch date back to September. Obviously really particularly our patients. We would ideally love to have launched in may, In conjunction with ME awareness day. But for the health of the project most importantly, the health of, of our PPI representatives,

we took the decision to push that launch date back. Thankfully because of everybody's enthusiasm to take part by signing up we really do not see that as risking the project. So say in order to maintain that valuable input all the way through a delay was we believe warranted. So that's all scene setting.

And I will say at this point, that we do have a webinar planned to cover the PPI aspects. So I don't really want to dive into giving intimate details of what exactly has been changed. What has, what has been influenced. But obviously with that Hands-on input from people with ME, with lived experience, the two aspects that have that have been influenced in that way, the design of, of all of our output.

So the emails that you get , the website, the, portal from solve ,how to make that more accessible in terms of font coloring, all of those things to try and make that accessible to all of those people with ME and especially to take into account the light sensitivities, the difficulties that people with ME will often encounter in that regard and the language used because we're all aware that scientists can often fall into jargon and long words.

So when people with ME almost always suffer cognitive issues, then making that language friendly to those of you out there, that's, vitally important. So the insight that our PPI representatives on the teams offer has improved the language that we are using and we'll be using in our documentation immensely.

I won't give any more detail. Like I say, we have an upcoming webinar. So, I don't know if I've hit my five minutes, but I'll leave it there.

**Sonya Chowdhury**

Thanks Andy. And without wanting to reveal things that we'll be covering in our next webinar, Chris, if I asked you just in a nutshell to describe the value of PPI to you as the scientist in this study could you just give us a flavor of that?

**Chris Ponting**

The value has been huge. We are motivated, but of course we are even more motivated when we work alongside people with ME. We see the huge impact that ME is put people under and that motivation to make an impact on people's lives is of course tremendous, not just for me, but the whole academic team.

Now it's far more than that, however, it's that I have not experienced ME and I do not know many things about ME, so I'm not an expert, but therefore having the ability to work alongside people with ME with lived experience ensures that we have the very best expertise. To ensure that as Andy was saying that the language that is used is comprehensible.

And eventually what that is going to do is to maximize the number of people in this cohort, the number of people who will be signing up for our study. And that's really important, scientifically because with more people, we can have greater power to find things. So better language, better understanding of what we're doing will translate directly to better science and greater power to find important things for you.

People with ME and carers.

**Sonya Chowdhury**

Thank you, Chris. And as Andy mentioned, we have delayed the start. So we are hoping to launch our recruitment, actual recruitment towards the end of September, but I'm really pleased to report that we've gotten over 24,000 people already signed up through the website for updates who are over the age of 16, based in the UK and have said that if they meet the research criteria that we're applying for this study, they would like to take part, that's phenomenal. That's fantastic. But we still need more people. So please do spread the word. Do encourage people to sign up for updates.

I can promise you now that you will be first in line to be able to take part, you will get the information before we go live with it. So it really is worth you signing up to get the updates. You'll also get lots of blogs and other information that will help you keep updated on our progress. We know that there are many people globally that have signed up for updates. And we're so pleased that you've done that.

We want this to be a whole community effort. And we know that you'll understand that at this point, we're only going to be recruiting people from the UK, but we have been working hard to find collaborators and to think about how we can develop this study further so that everybody that wants to participate can. But for our first phase, it is going to be for people in the UK only.

We've had over 457 questions in advance of our failed webinar this evening. And we're not going to have time to get through all of those. And just going to pick out a couple, to answer now. And of course, when we do have a webinar, hopefully in the next week or so, we'll be able to answer more of them. But I would recommend that you look at the frequently asked questions on the DecodeME website. There's lots of information in there about what research criteria we're using. And that actually was decided based on feedback we had from hundreds and hundreds of people, thousands, actually, people with ME who responded to a survey.

You'll find out more about what participating in the study will involve. You'll find out more about the time and the effort that's required in that, particularly for people who are concerned, whether they can participate if they have severe ME. So just a couple of questions. The first question, I think Chris, I'm going to direct to you as well.

Will everyone who signs up to the study, be able to take apart.

**Chris Ponting**

That is not the case. Not everyone who will sign up will take part, will be sent a saliva kit. And the reason for that is that there are criteria that we have to use, internationally recognized criteria, that we went to the funders and we used to persuade them that this was important for us.

This study was important to do. So we have to apply criteria and by the very nature of criteria, it means that not everyone will pass those criteria. But we will value everyone's contributions and everything that people via informed consent allow us to know will be useful for researchers down the line. If you give your consent.

**Sonya Chowdhury**

Thank you, Chris. And Sadie one of the real benefits as you highlighted is that potentially people will be able to sign up for other studies, be able to use the symptom tracker within the you and me portal and have their data collected in the registry. Are you doing work with others to broaden the potential use of the information and the access that people signing up can get to being involved in other studies?

**Sadie Whittaker**

Yeah. So the goal with the registry, unlike decode me which is a very specific study, the goal with the registry and biobank is to establish this research repository really that people can apply that they can submit a research proposal and ask us if we would agree to let them use the data and the bio specimens that we're collecting.

So we will have a review committee that sits over those requests. And people, individuals with the disease and, and care partners will be part of that decision-making committee. But there will be opportunities for researchers to use the information related to additional studies that people in the registry can participate in.

We have a section of the portal which highlights open research studies, and we will be posting different research opportunities within there. People within the registry can have the opportunity to sign up for those specific studies, the benefit being that you don't have to reenter all of that kind of baseline information, the surveys and the house information that you may have to, if you signed up for a study at a university, for example, all of that information is baked in and will be with your consent will be transferred over to a specific study.

And then you may have to answer some additional questions or do some additional Components for a specific study.

**Sonya Chowdhury**

Fantastic. So I think it's really important that people can see how we're working so collaboratively to give other opportunities for people with lived experience or people with ME, but also for researchers.

So we're hoping that this is just going to grow and it will create additional benefit. And so for me, that's quite magical, really having Solve's involvement in this project.

**Sadie Whittaker**

I think it's lovely. I mean, that's the beauty for me too. So, you know, people who are part of DecodeME have the option to sign up and have that data be part of this registry that then could maybe fuel, you know, 10, 15, 20, 50, a hundred other research projects.

The exciting thing is now we're starting to get interest from some more commercial organizations who want to develop drugs. And so we're looking at what does that look like? Because ultimately we want new therapies. We want treatments for this disease.

And so there's a lot more also translational interest in the data as well.

**Sonya Chowdhury**

That's fantastic. I mean, that's what everybody wants. We want treatments that are personalized and are going to start improving lives and making real difference for people. So just going to finish off by just saying thank you to my colleagues here and everybody working behind the scenes because Sam and James have been working hard and putting alternatives in place for us.

When we weren't able to get the webinar up and running. We will let you know, as soon as possible, hopefully in the next day or so about when we will hold another webinar so that we can answer the questions that you've got. There's going to be a huge amount of activity over any awareness month. So next month we would really love it if you could help promote the study, retweet comment, ask others to comment. We are going to be recruiting social media ambassadors, to work with us as part of our team who will help spread the word, help us recruit. We'll also be helping by doing that in terms of driving people to the You + ME registry as well.

So that's just really amplifying the impact that this study is going to have, and that you will have by being part of our team. So thank you again for your patience in terms of the difficulties we've had this evening with the webinar, we look forward to receiving questions in the next week or so at our next webinar.

And of course do go to the decode ME website, www.decodeme.org.uk where you can find out lots of answers to questions you may have. And of course you can sign up to get the updates. Don't forget you will be first in line. And that means you're more likely to be able to participate in our study, which actually is not just our study. It's also your study. Thank you very much.