Study title: *MyDiabetes IQ: safety and efficacy testing of a diagnosis and precision medicine tool for diabetes management.*

Study Researcher: Dr Nicholas Conway

We are inviting you to take part in a research study

Before you choose whether or not to take part, we want you to understand why we are doing the study. We also want to tell you what it will involve if you agree to take part. Please take time to read this information carefully. You can ask us any questions you have and talk to other people about it if you want. We will do our best to answer your questions and give you any more information you ask for. You do not have to decide straight away.

We would like to invite you to take part in testing a new version of MyWay Clinical. The existing system uses a decision support engine called *MyDiabetesIQ*, which is a Class 1 CE marked medical device, and offers only 'low risk' decision support. The new system that we are asking you to take part in testing will cover 'higher risk' decision support, such as advice around how patients are likely to respond to different drug regimes, and likelihood of diabetes subtype misdiagnosis. We need users' input in order to test the safety and usability of the new system. We will be asking four GP surgeries in Greater Manchester to use the system in their diabetes clinics. However, before *MyDiabetesIQ*-generated advice is released to GPs in the testing phase, the advice will need to be screened by diabetes experts like you, to ensure that the advice is both sensible and reasonable. Your participation would involve you viewing the outputs from the *MyDiabetesIQ* system and validating each piece of advice. Any advice that you deem to be questionable will not be released to the GPs who are testing the system, and would instead be returned to the research team for interrogation. Only once the system has been rigorously tested in this way will it be tested in the real world (in a future phase of this project).

We'd be grateful if you would consider taking part.

What is the purpose of the study?

More people are being diagnosed with Diabetes than ever before. A patient-facing system, Diabetes MyWay, has been developed to allow people with diabetes to access their own healthcare record and to improve communication with their diabetes team. Systems like Diabetes MyWay have been shown to improve diabetes care.

MyWay Clinical is a clinician-facing dashboard that uses data from Diabetes MyWay to provide healthcare professionals (HCPs) with an overview of their patient population. We are trying to find ways of improving MyWay Clinical so that it can provide users with additional information that may help with the care of diabetes patients. This might be identifying patients who may have been misdiagnosed (e.g. suggesting that they may be of a different diabetes subtype such as MODY or LADA) or optimising drug combinations, with a view to reducing risk of complications. Testing the new system means asking clinicians to use it (after first ensuring that the advice the system gives to users is accurate and safe by passing it through clinical validators before it reaches participants).

Why am I being invited to take part?

We are looking for expert diabetologists to act as 'clinical validators' of *MyDiabetesIQ* decisions/advice as part of this user testing exercise.

Do I have to take part?

No. It is up to you to choose, taking part in this study is entirely up to you. You can choose to take part or choose not to take part. If you choose to take part, you can stop the study at any time. You do not have to give a reason for not taking part or for stopping.

Whatever you choose it's important that you are happy with your decision and it is not the role of the study team to help decide for you.

What will happen if I take part?

You will have time to decide if you would like to take part in the study and you can contact us directly to

discuss further (email available at the bottom of this leaflet). We will do our best to answer any questions you have if you are interested, and we will assess your eligibility at the same time.

If you decide to take part in the study, we will ask you to give your consent by completing a consent form.

You would be invited to an initial (remote) meeting, where a researcher will show you the MyWay Clinical system. You will be provided with a link and login for the new system. You will then be asked to pre-screen the clinic attendee record for each diabetes clinic, and check the acceptability of *MyDiabetesIQ* advice.

The data we collect during the study will be 'pseudonymised', so that your name would be replaced with an identifying number. It would be possible for certain members of the study team to identify you by looking at this number and comparing it to a cipher or key, but it would not be possible for anyone else to identify you.

What are the possible benefits of taking part?

We anticipate that the new MyWay Clinical system, underpinned by new *MyDiabetesIQ* functionality, will be a more powerful tool for managing diabetes compared with the current system. This user testing phase will provide you with the opportunity to make MyWay Clinical/*MyDiabetesIQ* better for all users in the future.

You will be renumerated (£50 per hour, up to an agreed number of hours per month) for the time you spend on these validation activities.

What are the possible disadvantages to taking part?

You may decide to leave the study before it is finished, and you can withdraw from the study if you change your mind.

We do not anticipate any risks in taking part in this study.

Will what I say in this study be kept confidential?

Identifiable information about you and the information collected about you during the study will be stored by the University of Dundee. Only specified members of the research team will have access to this information.

Your pseudonymised coded study information will be stored securely on a password-protected database in the University of Dundee.

Your information will be kept securely for five years after the end of the study. After five years it will be destroyed. If you would like to be informed about future studies that you might wish to participate in, we will ask you to sign a consent form to allow us to hold your contact details.

Information which identifies you will not be published or shared. Your study information (with any information which identifies you removed) may be shared with other researchers in the UK.

We may use quotes from your responses to validation questions, with your permission, but any publication as a result of this study will not make it possible for you to be identified.

What should I do if I want to take part?

If you wish to take part in this study, please contact the researcher via the email provided at the end of this leaflet. You will then be contacted with further information.

If you decide you would not like to take part in this study, but would like the opportunity to take part in further research in this area, please contact the research team via the email address at the bottom of this leaflet.

What will happen to the results of the research study?

The results from the study will be used to develop *MyDiabetesIQ* for HCPs caring for people with diabetes in the UK and elsewhere. The results will also

be published as journal articles and presented at conferences. The results will help improve our understanding of how digital tools like MyWay Clinical/*MyDiabetesIQ* can be improved. If you wish to obtain a copy of any publications, please contact the researcher directly.

Who is organising and funding the research?

The study is being conducted as part of a project funded by the National Institute for Health Research (NIHR) AI in Health and Care Award. It is a joint project between the University of Dundee and MyWay Digital Health Ltd. MyWay Digital Health Ltd. Is a company created to commercialise My Diabetes My Way (the Scottish version of Diabetes My Way) for use outside of Scotland. This study is sponsored by MyWay Digital Health Ltd., and is organised by Dr Nicholas Conway of the University of Dundee.

What if something goes wrong?

If you have a complaint about your participation in the study, first of all you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to MyWay Digital Health.

If you think you have come to harm due to taking part in the study there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice but you might have to pay for your legal costs.

Insurance

MyWay Digital Health Ltd. are sponsoring the study. MyWay Digital Health Ltd holds insurance against claims from participants for injury caused by their participation in the clinical investigation. Participants may be able to claim compensation if they can prove that MyWay Digital Health Ltd has been negligent. However, as this clinical investigation is being carried out in primary care setting with health care professionals, the participants' employers continues to have a duty of care to the participant of the clinical investigation. MyWay Digital Health Ltd does not accept liability for any breach in the employer's duty of care, or any negligence on the part of employees. This applies whether the employer is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical investigation without the need to prove negligence on the part of MyWay Digital Health Ltd or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

MyWay Digital Health Ltd have indemnity arrangements in place, to cover the malfunction and breakdown of the device.

Who has reviewed the study?

This study has been reviewed and approved by xxxxxx Research Ethics Committee (TBC), who are responsible for reviewing research conducted in humans. The Research Ethics Committee does not have any objections to this study going ahead. (TBC)

Data Protection Privacy Notice

How will personal information be used?

We will only use your personal information to carry out this study.

MyWay Digital Health Ltd. are the sponsors for this study and are based in the United Kingdom. Researchers at the University of Dundee will be conducting the study, and will be using information from you in order to undertake this study. The University of Dundee will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. The University of Dundee will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To protect your rights, we will use the minimum amount of information which is personably identifiable as possible.

Directly collected data

The University of Dundee will use your name and contact details to contact you about the study. They will use this information to make sure that relevant information about the study is recorded and to check the quality of the study. The only people in the University of Dundee who will have access to information that identifies you will be people who need to contact you with details about the user testing or to check how the information is collected. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The University of Dundee will keep identifiable information about you from this study for 5 years after the study has finished.

Lawful reason for using your information

It is lawful for the The University of Dundee to use your personal data for the purposes of this study. The legal reason for using your information is that using it is necessary for the research which is carried out in the public interest.

Legally, we must ensure we have technical and organisational processes in place to respect your rights when we use your information.

You can find out more about how we will use your information at:
https://www.dundee.ac.uk/information-governance/dataprotection/

If you wish to raise a complaint on how the research team at the University of Dundee have handled your personally-identifiable information, you can contact The University of Dundee Data Protection Officer, who will investigate the matter
dataprotection@dundee.ac.uk

If you are not satisfied with our response or believe we are processing your personally-identifiable information in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) https://ico.org.uk/

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