**NHS TRUST PARTICIPANT INFORMATION SHEET**

**Study Title: MicroGuide-2** - A randomised controlled trial of the impact of MicroGuide™ computerised decision support modules on antimicrobial prescribing behaviours and clinical outcomes.

**Chief Investigator:** Dr Philip Scott, Reader in Health Informatics, University of Portsmouth.

**Sponsor:** Merck Sharp & Dohme (UK) Limited (MSD).

**IRAS ID number**: 295323

**Invitation and brief summary**

We would like to invite your NHS Trust to participate in our MicroGuide2 study. To help inform your decision, we have provided this Participant Information Sheet which details why the study is being conducted as well as what this will mean for your NHS Trust. A member of our research team is also available to go through the information sheet with you and answer any questions that may arise. We would anticipate that this should take around 30 minutes.

**What is involved?**

The World Health Organisation (WHO) declared antimicrobial resistance (AMR) as one of the ten most significant global public health threats facing humanity. Thus, the United Kingdom (UK) government currently has in place a 5-year national action plan (2019-2024) and long-term vision (20 years) for AMR by 2040.

The UK government’s long-term vision and the NHS Long Term Plan advocate the use of clinical decision support (CDS) tools to optimise antimicrobial treatment.

CDS is defined as an electronic tool or software, which incorporates an underlying algorithm to support clinical decision-making at the point of care. It combines patient-specific data with evidence-based guidelines and knowledge of antibiotics. Thus, a well-designed and well-implement CDS represents a potential digital solution for improving antimicrobial prescribing practices by promoting adherence to guidelines and thereby reducing AMR.

MicroGuide™ is a software application (app) available for portable electronic devices or via a web browser. This is currently available at your NHS Trust, providing prescribers with quick and easy to access locally adaptable antimicrobial treatment guidelines and infection management advice for common infections. MicroGuide™ can create clinical *decision support modules* (DSMs) for specific conditions. By using the DSM feature on MicroGuide™, prescribers are guided to answer a series of conditional questions such as disease severity, allergies, resistance risk and pregnancy status. Answers to the conditional questions will generate a recommended antibiotic treatment plan or, in some cases, to seek further microbiology specialist advice.

The purpose of this study is to assess whether CDS, delivered through the widely adopted MicroGuide™ app, can improve the clinical effectiveness and appropriateness of antimicrobial prescribing. We aim to determine whether there are statistically and clinically significant changes in patterns of carbapenem prescribing caused by implementation of DSMs for five common infections: community-acquired pneumonia; hospital-acquired pneumonia; urinary tract infection; cellulitis; and biliary tract infection.

**What would taking part involve?**

NHS Trusts who agree to participate in the study will be randomised to either:

* use MicroGuide™ with computerised DSMs for five common infections, or
* continue using the standard ‘browse’ version of MicroGuide™.

Participation will last 12 months.

The individual responsible for administration of the MicroGuide app at each NHS Trust will be required to work with the study team to develop and test DSMs based on NICE guidelines

and local hospital policies and promote implementation of the DSMs within their NHS Trust. DSM development is a relatively simple task, with full training and support from the study team. Based on prototyping work, we anticipate that each DSM will take no more than four hours to iteratively build and test with a group of local prescribers. Access to the DSMs will be limited to your NHS Trust and will be controlled by use of a PIN.

Consent for local implementation of the DSMs for five common infections within MicroGuide™ and removal of the ‘browse’ version of guidance for these five common infections within the app must be secured through a suitable internal governance process such as the Trust Antimicrobial Stewardship Committee or Drug & Therapeutics Committee or appropriate equivalent.

The NHS Trust will need to provide consent for releasing data that are identifiable by organisation (not by individual patient or staff member). These data sets are:

* MicroGuide™ app use statistics (from Horizon Strategic Partners)
* Aggregated monthly data on Trust-level antibiotic dispensing (from RxInfo Define software)

Publicly available data on antibiotic prescribing and resistance from the Public Health England website will also be analysed, along with data on length-of-stay, 30-day readmission, ICU admission and in-hospital mortality from NHS Digital.

No data will be provided to MSD, the sponsor of the study, beyond what is publicly available. No data will be provided to Horizon Strategic Partners, the suppliers of MicroGuide™, beyond what they already access under their commercial agreement with your NHS Trust.

Publication and other dissemination of results will not name participating NHS Trusts.

If your NHS Trust is randomised to use MicroGuide™ computerised DSMs, then following implementation and after at least six months, a sample of 2-3 healthcare professionals (comprising of junior and senior doctors, and nurse prescribers) per Trust will be invited to consent and participate in interviews. One-to-one interviews will be conducted at a time convenient to the participant and during their personal time. Interviews are expected to take for up to 45-minutes and they will be digitally audio-recorded. Health care professionals who participate in the study interviews will be offered compensation with a £30 Amazon® voucher.

Data obtained from interviews or surveys with DSM users will be anonymised and the identity of interviewees and survey respondents will not be published or available to Horizon Strategic Partners or MSD.

**What are the possible benefits of taking part?**

This is an opportunity for your NHS Trust to participate in an innovative research project using a digital solution to combat AMR. As AMR is a global threat, research like this has the potential to inform government policy; both in the UK and internationally.

**What are the possible disadvantages and risks of taking part?**

For NHS Trusts randomised to the intervention group, MicroGuide™ with computerised DSMs will be applied and mandated. Consequently, there will be no access to the pre-existing standard ‘browse’ version of MicroGuide™.

Like any technological change, it is anticipated there may be initial clinician scepticism or fear of loss of autonomy leading to resistance of the CDS system. This could potentially result in avoidance of the CDS system and possibly poor adherence to local antimicrobial prescribing guidelines. To combat this risk, the research team will incorporate signposts within the app to direct prescribers to guideline documents hosted electronically on your hospital’s intranet.

**Who has reviewed this study?**

Merck Sharp & Dohme (UK) Ltd is the sponsor and funder of the above study. This has been reviewed by the sponsor’s global review committee.

All research in the NHS is looked at by an independent expert group, called a Research Ethics Committee. This study has been reviewed and given favourable opinion by East Midlands Nottingham 2 Research Ethics Committee.

**Further information**

If you would like to participate, please complete the ‘NHS Trust Participant Consent Form’ (Version 3.1, dated 21/06/2021). The NHS Trust has the right to withdraw from the study at any point.

The results of this study will be available to participants and will contribute to publications in academic journals, reports at conferences and dissemination through patient forums, social and mainstream media and NHS organisational channels. Patient and family/carer representatives will be involved in the dissemination of our findings. The findings of this study will inform future grant application(s) and may be used in future ethically reviewed and approved research studies

**Thank you for taking the time to read this NHS Trust Participant Information Sheet.**