

## PARTICIPANT INFORMATION SHEET

### **Study MMZ-001 – Semi-Structured Interviews with Subject Matter Experts; Preparation for a Research Project to Examine Pedagogical Methods for Understanding the Medicine Development and Regulatory Review Process**

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for reading this.

#### **1. What is the purpose of this research project?**

It is important that students of pharmacy and biomedical science develop a basic understanding of the medicine development and regulatory review process. The MeduMaZe® board game was originally developed by the researcher to help teach this topic and has been used as an educational tool within the School of Pharmacy and Pharmaceutical Sciences at Cardiff University for a number of years. However, it is now due for an update to address changes within industry and education.

The goal of this overall research project is to examine methods for helping students to understand the medicine development and regulatory review process, including use of the MeduMaZe board game. As part of this project, we are seeking input from subject-matter experts to assure that the updates to the scientific/regulatory affairs content reflect the latest knowledge in this area and are engaging to current students.

#### **2. Why have I been invited to take part?**

You have been invited to take part because you are qualified by training or experience (3 years or more) to represent a subject matter area within the pharmaceutical industry, regulatory agencies or contract research industry, or involved in higher education activities related to drug development with students of pharmacy and biomedical science.

#### **3. Do I have to take part?**

No, your participation in this research project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part, we will be happy to discuss the research project with you. If you respond to say that you are interested in taking part, we will ask you to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights.

You are free to withdraw your consent to participate in the research project at any time, without giving a reason. If you choose to withdraw your consent after you have signed the consent form and/or after you have participated in the interview, you can withdraw your data up until the point it has been de-identified for analysis as it will then no longer be possible to identify your contribution to the data.

**4. What will taking part involve?**

If you agree to take part, you will be asked to take part in a one-to-one semi-structured interview. The interview will consist of you giving your personal opinions and sharing your experiences in relation to current and future themes and topics about new medicine development and regulatory affairs, and how it should be addressed in higher education in pharmacy and biomedical science. You do not have to answer any questions you do not wish to answer.

The interview will be held at a time that suits you and will take place online via MS Teams. The interview is expected to take between 45-60 minutes. Please arrange to join the online interview from a suitable location to assure privacy and minimise interruptions. The interview will be recorded with your consent (you can choose to have your camera on or off); only the audio stream recording will be used for the purposes of transcription. Recordings made through the MS Teams software will be deleted 60 days after the call, once the interview has been typed up and checked for accuracy.

Within 4 weeks of the interview, the interviewer will send you a Draft Interview Report to review, based on a transcript, so that you have an opportunity to clarify, correct, delete or add to the information collected.

**5. Will I be paid for taking part?**

No, you will not be paid for taking part in this project. Any information you share will be as a gift and you will not benefit financially now or in the future, even if this project leads to the development of a new educational tool.

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

While there are no direct benefits to you from participating, the information you provide will help the education of students by ensuring that updates to educational materials reflect the latest scientific and regulatory knowledge and educational practices.

**7. What are the possible risks of taking part?**

There are no perceived risks associated with taking part in this study.

**8. Will my taking part in this research project be kept confidential?**

All information that you share about your views and opinions during the interview associated with this research project will be kept confidential by the research team. Your name, and the name of your employer, will not be included in the Interview Report. Any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information.

**9. What will happen to my Personal Data?**

By participating in this project, you will be providing us with some Personal Data, including name and contact email. These data will not form part of the reported output but will be collected to support the logistics of organising interviews with a range of relevant experts.

The interview recording will be stored on a secure Cardiff University digital folder on MS Teams, which can only be accessed by members of the research team (Alison Bowers and Dr Louise Hughes). The recording will be deleted 60 days after the interview. As soon as

possible after the interview, the audio recording will be used to prepare an Interview Report. At this stage, any information which could potentially identify you as an individual will be removed (de-identified), however your area of subject matter expertise, and job title or seniority level, as provided by you during the interview, will be retained for context. A draft of your Interview Report, including verbatim quotes transcribed from the audio recording, will be provided to you for a single round of review, should you wish to modify, correct, delete or add to the information collected. This review period, and your opportunity to comment, will end 4 weeks after the Draft Interview Report is provided to you. The only personal information that will remain in the Final Interview Report is your area of subject matter expertise and job title or seniority level. A copy of your de-identified Final Interview Report will be provided to you.

Although the overall findings of this project may be reported (including direct quotes from the interviews, attributed to subject discipline/area of expertise for context), all information will be made anonymous i.e. no personal details which could identify you will be reported, and quotes will not be attributable to any specific identifiable individual.

Cardiff University is the Data Controller for this project and is committed to respecting and protecting your Personal Data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- your rights
- the University's Data Protection Policy and broad data management principles; and
- how to contact the University's Data Protection Officer and/or the Information Commissioner's Office

can be found at

<https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>

The University's overarching Data Protection Notice for research participants is available at:

<https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection/research-participants-data-protection-notice>

If you do not have access to the internet and/or otherwise require this information in another format, please let us know.

In accordance with Data Protection legislation, we are required to inform you of our lawful basis for collecting and processing your Personal Data. The lawful basis we are relying on as part of the research project is article 6(1)(e) of the UK GDPR, namely that the processing of your Personal Data is necessary for the performance of our public task.

After 2 months, the research team will de-identify the Personal Data it has collected from, or about, you in connection with this research project, with the exception of your consent form. Your consent form, which will include your name, will be retained securely for the current academic year (2024-2025) + 5 years.

The de-identified Interview Report will be retained securely for the current academic year (2024-2025) + 5 years, or after publication of any findings based upon the data (whichever is later), and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities.

As noted in section 3 above, if you choose to withdraw from this project your Personal Data collected up until the point of participant withdrawal from the research project will be deleted. If you choose to withdraw prior to signing the consent form, the only record retained will be that 'MMZ-001-Subject-001 (no-identifier), with expertise in scientific/regulatory area A (subject area identified), declined to participate'. If you choose to withdraw your consent after you have signed the consent form, the original consent and documentation of the withdrawal of consent will be retained as described above and will be reported as 'MMZ-001-Subject-001 (no-identifier), with expertise in scientific/regulatory area A (subject area identified), withdrew consent prior to conduct of the interview'. If you choose to withdraw your consent after you have participated in the interview or before the Interview Report is finalised, you can withdraw your data up until it has been de-identified, as it will then no longer be possible to identify your contribution to the data. In this instance, the data will be reported as 'MMZ-001-Subject-001 (no-identifier), with expertise in scientific/regulatory area A (subject area identified), withdrew consent prior to completion of the report of their interview'.

#### **10. What happens to the data and results at the end of the research project?**

Information relating to interviewee consent information will be kept in a secure manner for the current academic year (2024-2025) + 5 years, and then deleted. The de-identified data and Interview Reports will be kept in a secure manner for the current academic year (2024-2025) + 5 years, but the derived pseudonymised information may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research or educational purposes.

The data and results of this project will be used as part of my thesis and available to specific members of teaching staff within Cardiff University and examiners. It is also our intention to publish the de-identified results of this research project in academic journals or other similar forums and to present findings at conferences. If, following participation, you would like to receive a report of the key findings or copies of any related publications, please let the research team know.

#### **11. What if there is a problem?**

If you have any concerns or questions about how you have been approached or treated during this research, please contact Alison Bowers: [BowersAC@cardiff.ac.uk](mailto:BowersAC@cardiff.ac.uk) in the first instance. If your concern or complaint is not managed to your satisfaction, please contact the project supervisor Dr. Louise Hughes, [HughesML@cardiff.ac.uk](mailto:HughesML@cardiff.ac.uk), who will address the issue. If you remain unhappy and wish to complain formally to someone independent from the research team, you can do this by contacting the Director of Research, at Cardiff School of Pharmacy and Pharmaceutical Sciences on <mailto:phrmyresoffice@cardiff.ac.uk>

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

**12. Who is leading and funding this research project?**

The research is being led by Alison Bowers of the School of Pharmacy and Pharmaceutical Sciences at Cardiff University, under the supervision of Dr Louise Hughes, Dr Jenna Bowen, Dr Stephen Hiscox and Professor James Coulson of Cardiff University. The project has not received external funding.

Cardiff University is committed to protecting the safety, rights and dignity of research participants and insists that all research conducted by its staff and students is underpinned by the highest ethical standards. Further information about Research Ethics and Research Integrity (good research practice) at Cardiff University can be found at <https://www.cardiff.ac.uk/research/our-research-environment/integrity-and-ethics>

Declaration of interest: The researcher (Alison Bowers) is creator of MeduMaZe and a Director of Xenofate Limited, which provides support to the pharmaceutical industry (Regulatory Affairs & Medical Writing).

**13. Who has reviewed this research project?**

This research project has been reviewed by the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee, Cardiff University and has been granted a favourable ethical opinion.

**14. Further information and contact details**

Should you have any questions relating to this research project, you may contact me during normal working hours using the details below:

Alison Bowers, c/o School of Pharmacy and Pharmaceutical Sciences, Redwood Building, King Edward VII Avenue, Cardiff CF10 3NB.

Telephone (direct): 029 2087 6432.

Email [BowersAC@cardiff.ac.uk](mailto:BowersAC@cardiff.ac.uk)

**Thank you for considering taking part in this research project.**

**If you would like to take part, please email:** [BowersAC@cardiff.ac.uk](mailto:BowersAC@cardiff.ac.uk)

**I will provide you with a copy or link to a Consent Form to review, sign and return electronically.**

**I will contact you to arrange a convenient date for the interview.**

**You will also receive an electronic copy of the completed Consent Form for your records.**