Participant Information Leaflet

Study title: Perspectives of stakeholders on the integration of adverse drug withdrawal events reporting in the pharmacovigilance system: a qualitative interview study

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Principal investigator's title:	Postdoctoral researcher, School of pharmacy and biomolecular science, RCSI, 123 St Stephens Green, Dublin 2, Ireland
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Co-investigator's name:	Dr. Frank Moriarty
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Co-investigator's name:	Dr. Anais Essilini
Co-investigator's title:	Postdoctoral Researcher, School of pharmacy and biomolecular science, RCSI, 123 St Stephens Green, Dublin 2, Ireland

Data Protection

Data controller's Identity:	The Royal College of Surgeons in Ireland (RCSI)
Data Protection Officer's Identity:	Mr Dónall King, RCSI Data Protection Office
Contact Details:	dataprotection@rcsi.ie

You are being invited to take part in a research study to be carried out by a team of researchers at the Royal College of Surgeons in Ireland.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with others. Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision. If

you have any questions about the material contained in this information leaflet, or would like more information, please contact Dr Zakir Khan by telephone (087-0395605) or email (zakirkhan@rcsi.ie).

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as ‘Informed Consent’.

You don't have to take part in this study. You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out, without having to give a reason.

Why is this study being done?

Medication harm is a significant and growing challenge for health systems, designated as the current WHO Global Patient Safety Challenge. The World Health Organization-Uppsala Monitoring Centre (WHO-UMC) coordinates and supports the global pharmacovigilance system, which currently includes 160 full member countries and 22 associate members. Pharmacovigilance plays an important role in post-marketing drug safety surveillance and relies on spontaneous reporting of adverse drug reactions (ADRs) to inform regulatory actions and clinical practice.

Deprescribing, reducing or stopping unnecessary or harmful medications, is an important strategy to reduce risk of medication harm. Its implementation into routine practice is impeded by barriers, including clinician and patient fear of adverse consequences, and a perceived lack of evidence on the effects of stopping a medication. One key aspect of this is adverse drug withdrawal events (ADWEs) which are poorly captured and inconsistently reported in routine practice, potentially due to a lack of awareness or guidance on how to identify and report ADWEs. Despite the established role of pharmacovigilance systems in monitoring and reporting of ADRs, there is limited use of this systems for ADWEs. Increased use of the pharmacovigilance system to record ADWEs can support generation of evidence on deprescribing safety. It is important to understand the perspectives of those working in the pharmacovigilance sector (e.g. key stakeholders involved in national, regional, and global pharmacovigilance regulatory bodies) on integration of ADWEs.

This study is being done to understand the views and perspectives of stakeholders on the integration of ADWE reporting in the pharmacovigilance system.

Who is organising and funding this study?

The researchers who are conducting this research are all listed on the first page of this leaflet and are based in the Royal College of Surgeons in Ireland. This research is funded by the European Union through the Marie Skłodowska-Curie Actions programme (Project acronym: HEAD-P; Project number: 101149577)

Why am I being asked to take part?

We are interested in interviewing you because you are an important stakeholder with respect to pharmacovigilance nationally and/or internationally, and we would like to learn more about your perspectives.

How will the study be carried out?

If you consent to participate in this study, you will be asked to take part in a one to one interview to share your views and perspectives on the importance of gathering evidence on ADWEs, mechanisms to gather evidence on ADWEs and what are the potential barriers and enablers to integrate ADWE reporting in the pharmacovigilance system. This interview will take place online via Microsoft Teams. The interview will take place at a time and date that is convenient for you.

You do not have to answer all of the questions if you do not want to. Following consent, the interview will be audio-recorded and transcribed. The researcher will inform you when the audio recording is about to start, and when recording is completed. During the analysis stage, all identifying information will be removed from the data so that your confidentiality is assured.

What will happen to me if I agree to take part?

If you consent to being contacted by the research team for this study, you will receive an email to confirm your interest in taking part. The researcher will arrange the interview for a time that suits you. The interview will last approximately 30-45 minutes.

What will happen to the audio recording of my interview?

Following the completion of the interview the audio recording will be transcribed prior to analysis. For interviews conducted on Microsoft Teams, the automatic transcribing function will be used to produce an initial transcript, which will reviewed by the researcher. The transcript of your interview will be pseudo-anonymised, which means that any identifying information will be removed and a unique study ID will be assigned.

You will be given the opportunity to review and edit your transcript after it has been transcribed and before it has been analysed. Once the transcript is finalised, both the audio recording and the link between your personal information and unique study ID will be deleted, so that your transcript is anonymous. Selected quotes from your transcript may be used to illustrate points in any resulting publications but any data used for these purposes will be de-identified.

What are the benefits?

There are no direct benefits to you by taking part in this study. However the knowledge gained through this interview study will be disseminated, and may improve our understanding about ADWEs and possible ways to integrate ADWE reporting in the pharmacovigilance system.

What are the risks?

There are no foreseeable harms associated with your participation in this research. We will ensure best practices in data management and do not intend to collect or store any sensitive personal data. However, if you have any concerns or wish to discuss any aspect of this study, please feel free to discuss these concerns with the lead researcher (Zakir Khan) or the co-investigators (Anais Essilini and Frank Moriarty) of the study at any time.

Is the study confidential?

Yes. If you consent to participate in this study all information you provide will be pseudo-anonymised, and then anonymised once your interview transcript is finalised.

This means any identifying information will be removed and a unique study ID will be assigned to you.

All electronic data will be stored on a secure RCSI storage network (hosted on OneDrive) with restricted access to relevant members of the research team. Participant identifiers will be kept in a separate folder restricted to the lead researcher and co-investigators. Audio files and the link between participant information and unique study ID will be destroyed once your interview transcript has been finalised. Consent forms and transcripts will be destroyed five years after publication of study results, in line with research best practice. Any published versions of the research will not identify you in such a way that individual responses or contributions can be attributed to you.

Data Protection Information

We must provide you with the following information, as a legal requirement under data protection law

1. Data gathered during interviews will be used to support our work to learn more about your perspectives on the integration of adverse drug withdrawal events (ADWEs) reporting in the pharmacovigilance system.

2. The legal basis under which we are processing your data is your consent, based on article 6(1)(a) and article 9(2)(a) of the General Data Protection Regulation 2016.

3. Only researchers named in this participant information leaflet will have access to your data, with only the researcher conducting the interviews (Zakir Khan and Anais Essilini) having access to the link between your identity and audio file/transcript. This link, and the audio files, will be deleted once your transcript is finalised.

4. Consent forms and anonymised transcripts will be retained for 5 years after the final publication and then destroyed.

5. Your participation in this project does not carry any anticipated risks. When any personal data is held by another person or organisation, there is a potential risk that a data breach might occur. However, because of the security measures in place to ensure your data is stored securely and remains confidential, this is unlikely to occur. Your data will be de-identified by the researcher conducting the interviews as early as possible. You will be assigned a unique study ID when you consent to participate in the study. In all subsequent documents, you will be referred to according to your unique participant ID. The key linking your data to identifying information (e.g. contact details) will be destroyed once your transcript is finalised.

6. If you wish to withdraw consent you can do so by contacting the principal investigator or co-investigator, without offering any explanation. If you wish to have your data withdrawn from the study, this can be done any time before your transcript is finalised, three weeks after your interview. As the link between your

details and your transcript will be destroyed at this point, it will not be possible to identify your transcript after this.

7. If you have a complaint about how your data is being used as part of this study, you have the right to lodge a complaint with the Data Protection Commission who can be contacted here: (https://www.dataprotection.ie/en/contact/how-contact-us.

8. You have the right to request access to your data and obtain a copy of your personal data for your own use. You can request to move, copy or transfer your personal data from the RCSI computers to another data controller.

9. You have the right to restrict or object to processing of your data, up to the point where your transcript is anonymised.

10. You have the right to have any inaccurate information corrected or deleted. You will have the opportunity to review your interview transcript after it has been transcribed. You may request that inaccurate information is corrected or deleted.

11. You have the right to have your personal data deleted, up to the point where your transcript is anonymised.

12. Data analysis will be carried out using qualitative research methods by the principal investigator. Automated processing of data, sometimes referred to as profiling, will not be carried out as part of this study.

13. The questions included in the interview topic guide have been compiled to capture only information relevant to the objectives of this research. Your data will not be processed for any other purposes.

14. Your data will be stored on RCSI secure cloud storage (OneDrive) within the EU, and will not be transferred elsewhere

Where can I get further information?

If you need any further information now or at any time in the future, please contact:

Principal investigator: Zakir Khan zakirkhan@rcsi.ie Tel no: +353-87-0395605

Co-investigators: Anais Essilini anaisessilini@rcsi.ie; Frank Moriarty frankmoriarty@rcsi.ie

Thank you for reading this information sheet and for taking an interest in this study.