In-depth interviews with stakeholders

Participant Information Sheet

Title: Perceived facilitators and barriers to Plant Molecular Farming product development and marketing in the EU
Name of Researcher: Sebastian Fuller, Chief Investigator

We are inviting you to take part in a recorded interview about your thoughts and opinions of Plant Molecular Farming, a new technology that uses plants to produce medical products. Before you decide on your potential participation we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully. You will be given the opportunity to discuss the information in this document and ask any questions that you may have.

What is the purpose of this study?

This study is part of the EC-funded project PharmaFactory, which aims to advance a new technology called Plant Molecular Farming (PMF). This is the process by which plants are modified to produce medical products (i.e. pharmaceuticals and diagnostic products). For more information on the project visit: www.pharmafactory.org

In this part of the project, researchers from St George’s, University of London (SGUL), in collaboration with colleagues from the University of the Arts London (UAL), are looking to gain a better understanding of the perceptions and opinions of different stakeholders, such as patients, healthcare professionals and members of the general public on PMF.

Specifically, during one-on-one interviews, we are looking to explore your personal experiences of diagnosis/treatment, and how these might change with the new diagnostics/therapies being developed.

There are no right or wrong answers to the topics that we will discuss; this is about your thoughts on these issues.

Why have I been invited?

You have been invited to participate because:

- You are a member of an organisation/group that is of significant relevance to the field of PMF, and the products that arise with the technology. We would like to engage in discussions with individuals belonging to these groups in order to identify the issues and priorities around the technology and products that are relevant to you.

  OR

- You are a carer or family member of a patient belonging to an organisation/group that is of significant relevance to the field of PMF, and the products that arise with the technology.
Do I have to take part?

It is up to you to decide whether or not to take part. Refusal to participate will not affect you negatively in any way. If you decide to take part in the interview, you will be given this information sheet to keep. We will be asking for your verbal consent prior to the start of the interview. You are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

If you agree to take part, please let us know and a member of our research team will contact you to organise a time for the interview that is suitable for you.

We expect the interview to take approximately 1 hour. We will audio record the interview so that the research team can be sure to accurately describe participants’ thoughts later on. The digital audio file of your interview will then be transcribed so that we can have a written account of the discussion. The digital audio file of your interview will be sent via secure electronic portal to a professional transcription service that is compliant with UK Data Protection Act and the EU General Data Protection Regulations (GDPR) to protect your confidentiality. If your interview is taking place in a language other than English, we will also use a professional translation service that is compliant with UK Data Protection Act and the EU GDPR to have your interview translated into English.

Prior to the interview taking place, we will ask you to agree to all compulsory aspects of the consent form. This includes everything on the consent form except for consent to our mailing list. We will also invite you to our mailing list, to invite you to attend future activities. You can refuse to consent to this and still take part in the interview.

You will be given a gift voucher (£30) for your participation in the interview.

What are my benefits for participating?

Your participation in this study will not benefit you personally.

Results from this project are expected to guide the production and commercialization of new and innovative high-value biopharmaceutical products. We believe the involvement of patients and other stakeholders will increase the value of these products to other end-users. However, we are unsure of how our work will impact product development and commercialisation, and when these new products will be made available.

However, results from this project are expected to accelerate commercialization of new and innovative high-value biopharmaceutical products to the market. These will be of great benefit to patients and other end-users, which may include you or someone in your group/community.

How will my privacy be protected?

What you say in this interview will be kept confidential (private). That means that your personal information (e.g. name, contact information, organisation/group name) will not be attached to the record of the interview. We will assign a unique code (study identification number) to each person participating in the research.

The consent taking process will be recorded in a separate file than the audio file for the interview. The two files will be de-linked, and any transcripts sent to professional transcription services will not have your name on it.
Your personal details will be linked in a list connected to your study ID. This will allow us to link the transcript of your interview to you. This linking list will be kept on access-controlled password-protected computers at St George’s University of London. We will keep this linking list until the end of the study only. We are keeping this link so that if you, or anyone else that participates, changes their minds and would like to withdraw from the study, we are able to identify their interview transcript and delete it.

The digital audio recordings and transcript of the interview will also be given a unique code (study identification code). The audio recordings and transcript of the interview will be solely identified by this study identification code in order to keep the identity of the participants and organisation/group private.

The audio recordings, written transcript, as well as your contact details (if you consent to the mailing list), will be kept on password-protected computers at St George’s University of London, and at the University of the Arts London, and only the researchers involved in this study will have access to these.

We may use some of what you say in this interview when we write publications about this study. Any publications or presentations using your words will not identify you as the speaker, or your organisation/group. All details that might identify you will be deleted or changed in order to protect your privacy. We ask that, where practical, you refrain from using full names and exact locations, in order to help us keep your identity confidential.

In the unlikely chance that you discuss criminal activity or anything that can put you or others at risk of serious harm during this interview, please be aware that we are under a statutory requirement of the local laws where we are holding the activity. This means that we may be required to share this information with the relevant authorities. If it is mandated that we share your information we will make every reasonable attempt to discuss with you whom we will report to and what information will be shared. We ask that you refrain from discussing criminal activity, where possible.

Interview recordings will be deleted after final analysis. All the other data collected will be retained by SGUL for up to 10 years before being deleted or destroyed.

**What are my potential risks for participating?**

There are no personal risks associated with your participation in this study.

**What will happen if I don’t want to carry on with this study?**

You can withdraw your participation at any time and there will be no negative consequence if you choose to do so. We will withdraw your comments and remove your contact information and any other personal information we have for you in our files.

To withdraw from the study, you must contact the CI or the Research Assistant, whose contact details are listed below.

**What will happen to the results of the research study?**

We will present the findings of this study to other institutions involved in the project, in peer-reviewed publications, and at professional conferences.

**Who has reviewed this study?**
This study has been reviewed and given favourable opinion by the St George’s University of London (UK) Research Ethics Committee, reference number: 2018.0143

Who is organising and funding this study?

This study has been sponsored by St George’s, University of London and funded by Horizon 2020 (Reference 774078 — PharmaFactory).

St George's University of London sponsored research:

St Georges, University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the study. We would not be bound to pay compensation where the injury resulted from a drug or procedure outside the trial protocol and/or the protocol was not followed. These arrangements do not affect your right to pursue a claim through legal action.

Questions or complaints about the research:

If you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you can speak with the chief investigator of the study, who will do his best to answer your questions or concerns:

Dr Sebastian Fuller  
Social Science Lead  
Applied Diagnostic Research and Evaluation Unit  
Tel.: +4420 8725 2823  
Email: sf Fuller@sgul.ac.uk

Sara Albuquerque  
Research Assistant  
Applied Diagnostic Research and Evaluation Unit  
Tel.: +44(0)77 5310 1156  
Email: smesquit@sgul.ac.uk

If you are still not satisfied with the response, you may contact the Joint Research and Enterprise Office at St George’s:  
Tel: +4420 8725 4986  
Email: sgulrec@sgul.ac.uk