## INFORMATION SHEET FOR GP PRACTICES

**Project title:**

# Post-authorisation passive enhanced safety surveillance of seasonal influenza vaccines: Pilot study in England

### Overview

We invite you to take part in a research study. Please take time to read the following information. The proposed study represents a pilot to explore the use of routinely collected data in England to provide timely and relevant information on influenza vaccine safety. The research is carried out by the Department of Clinical and Experimental Medicine, University of Surrey, in collaboration with GlaxoSmithKline Biologicals.

### Background and Rationale

The European Medicines Agency (EMA) has set out new requirements for influenza vaccine safety surveillance that all Marketing Authorisation Holders (MAHs) providing vaccines in the EU must address. The key objective of the EMA enhanced safety surveillance is to rapidly detect a significant increase in the frequency and/or severity of expected reactions (local, systemic or allergic reactions) that may indicate a potential or more serious risk, as exposure to the vaccine increases.

The objective of the study is to conduct a pilot assessing adverse event of interest (AEI) frequencies among flu-vaccinated subjects using routinely collected data in ten primary care practices. Our primary surveillance is of 7-day AEI, post vaccination, but we will not exclude events recorded outside this window, which will be analysed separately.

### What is the design of the study?

We have recruited ten practices representing urban and rural localities across England, and the three major computerised medical record (CMR) suppliers in the UK. The anticipated start date for data collection will be in September 2017.

The method and governance procedure has been developed by the University of Surrey as part of previous work with the Royal College of General Practitioners Research and Surveillance Centre (RCGP RSC) and Public Health England (PHE), using an approved provider, Apollo Medical Software Solutions Ltd. Apollo extracts data using the Apollo automated extraction system. Communication is via a SOAP (Simple Object Access Protocol) web service, no special firewall configuration is needed. These arrangements may change from time-to-time and we will notify members if any changes occur. Patients will be given AEI reporting cards by practice staff to complete; the data from completed cards will be entered in the CMR by practice staff.

Data extractions will be conducted in accordance with the Research Group's standard operating procedures in data extraction, pseudonymisation, and transfer. All data are stored and managed by the University of Surrey. The information security policies and procedures of the Research Group have been approved by the

NHS Health and Social Care Information Centre (HSCIC). Details of the departmental information governance policies and procedures can be found in:
http://www.clininf.eu/about/information-governance.html

**Why have I been invited to take part?**

The study is part of a research programme which aims to explore cases of adverse events of interest following flu immunisation. You have been invited because your practice has expressed interest in becoming part of a research network within the RCGP RSC, and because you meet representativeness criteria (geographic location and computerised medical record system) for this study.

**What will happen if I take part?**

You will be contacted by RCGP RSC and Apollo Medical Software Solutions Ltd to sign data extraction agreements. The GP practices will be supported by the RCGP RSC and the Research Team led by Prof Simon de Lusignan. The responsibilities of the GP practices are outlined below.

**What are my responsibilities?**

If you agree to take part in the study, you will be required to provide such support as may be reasonably required to achieve its aims. Practices will be required to facilitate access for data extraction and staff will be required to distribute AEIs reporting cards to patients and to enter the data from these into the system.

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

The proposed study will help assess the feasibility of an influenza vaccine safety monitoring system using routine data collected in primary care, which will help patients receiving influenza vaccines.

**Who can I contact for more information?**

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