

An application for smartphone in a safety observational study



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KAPPA SANTE

E-TOOLS AND SOCIAL NETWORKS FOR EPIDEMIOLOGY

Post authorization safety study

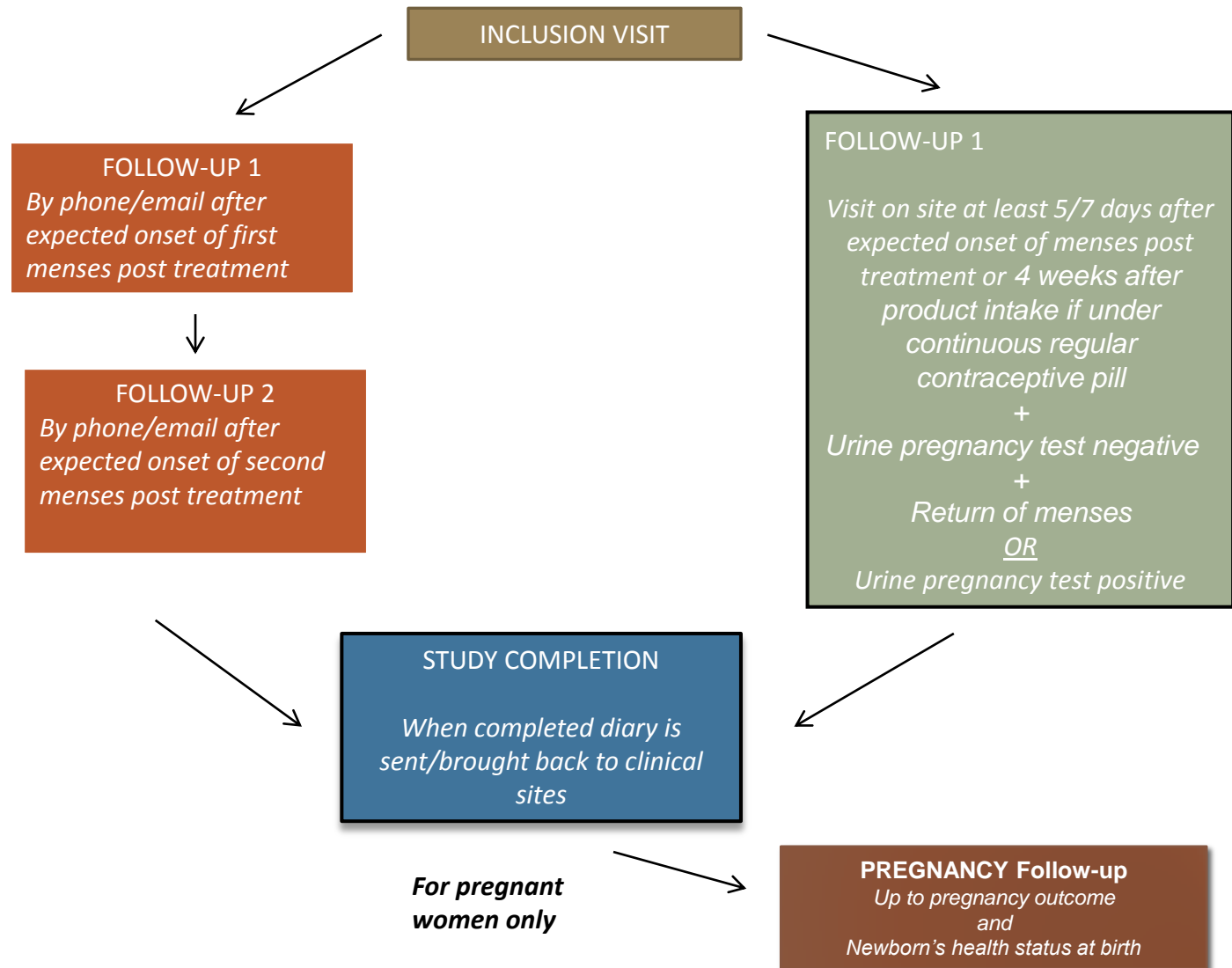
An observational study focusing on the safety, tolerability and efficacy of a product in women under 18, to respond to a request from the EMA

- Primary objective
 - To assess the safety and tolerability of product[®] in routine conditions of use for emergency contraception in postmenarcheal adolescents and adult women in particular menorrhagia, metrorrhagia, dysmenorrhea and effect on menstrual cycles.
- Secondary objectives
 - To assess the pregnancy rate observed after taking product[®] in routine conditions in postmenarcheal adolescents and adult women.
 - To follow-up pregnant women throughout the pregnancy (check of potential complications) including fetal and neonatal follow-up.

Study design

- Prospective, observational, single arm, open-label, multicentre study (Sweden, UK, France, Germany & USA)
 - ✓ Enrolment visit
 - ✓ Follow-up 1
 - ✓ Follow-up 2
 - OR 1 visit on site
 - ✓ Study completion
- Between 30 and 40 sites overall

Study flow chart



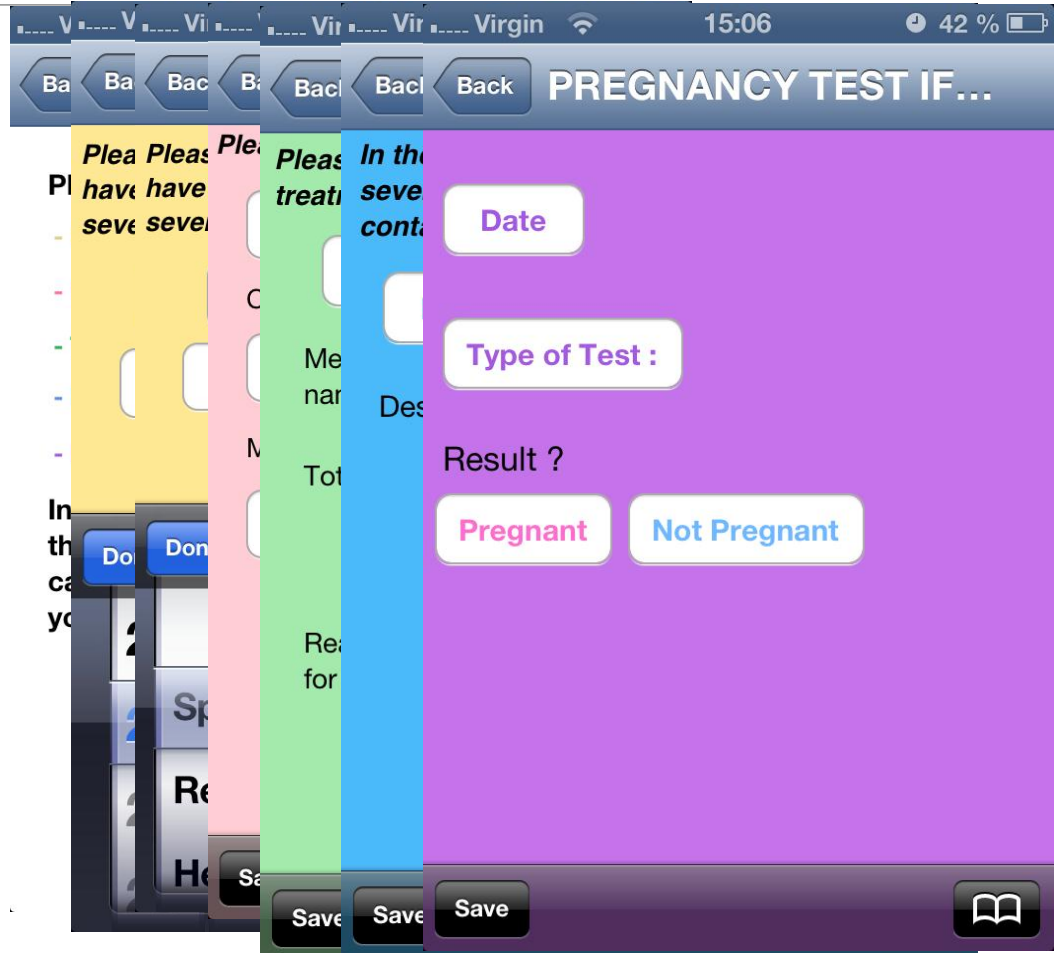
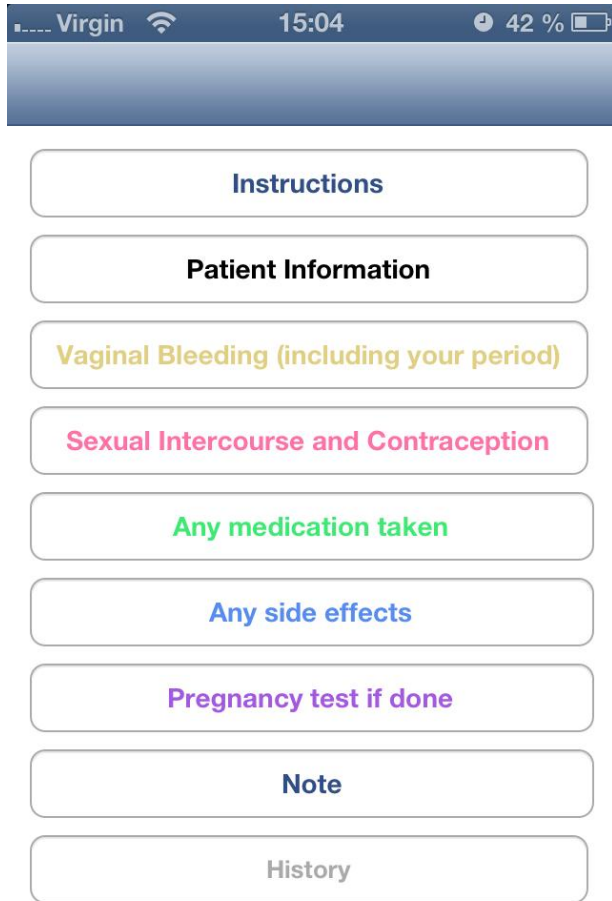
Key data for safety and tolerability

- Adverse events recorded in the diary & in the Phone calls/email follow-up
- Concomitant medications
- Sexual intercourse & contraception use
- Bleeding profiles recorded in the diary & in the Phone calls/email follow-up
- Pregnancy follow-up (up to outcome/delivery)

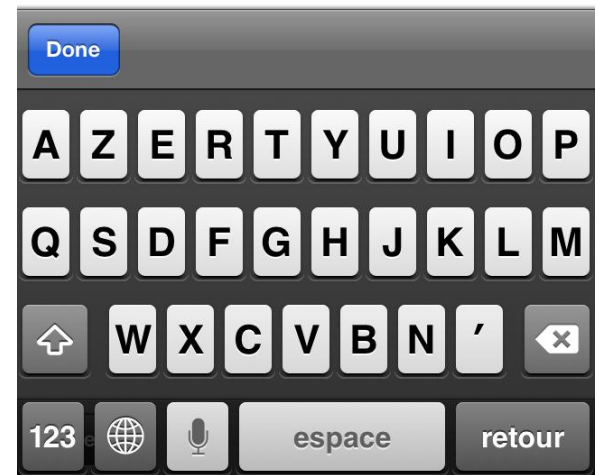
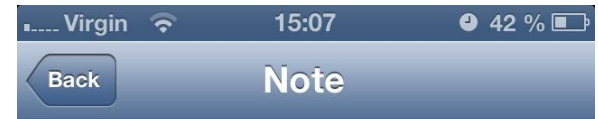
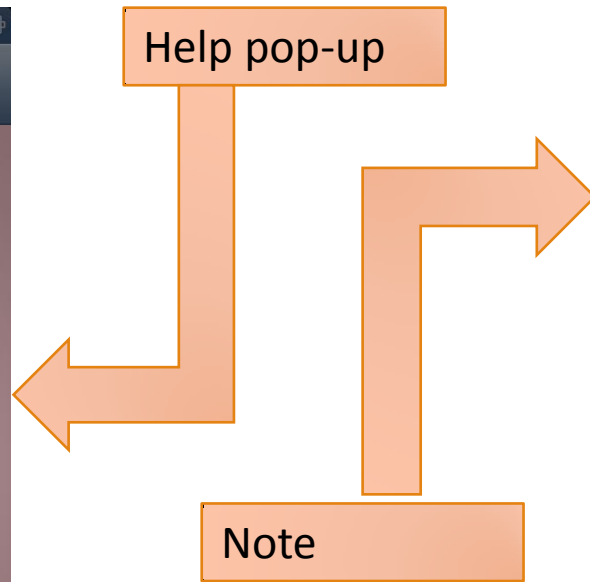
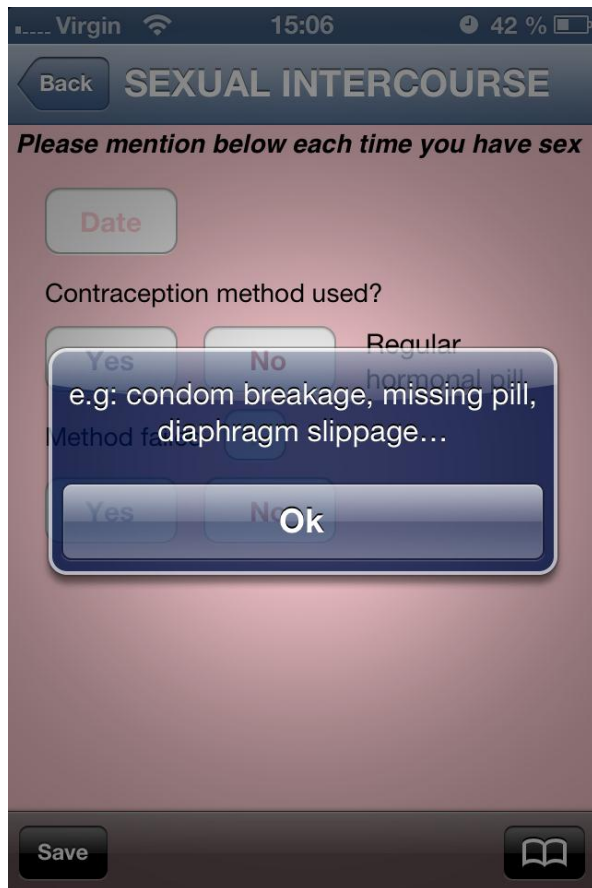
Application

- First option was to use a paper questionnaire but it soon appeared inefficient (target population, sensitive questionnaire...). It was decided to replace the paper version by a smartphone application
- The application
 - Developed for iOS and Android
 - Available in 3 languages : English, Deutsch, Sweden
 - At the inclusion visit, a card was given to the patient with the instructions to download the application.
 - Downloadable from appstore and playstore

An electronic diary on the smartphone



Some specific functions



Some specific functions

Virgin 17:58 20 %

Back HISTORY

You have the possibility to change the information below, however the modified data will not be saved.If you wish to save the changes, you should come back to the previous pages.

Patient Information :
Patient Number :123 - 45
Patient Initials : ab - re

Vaginal Bleeding :
6 oct. 2012 Heavy
30 mai 2012 Spotting
27 oct. 2012 Regular
30 janv. 2013 Heavy
18 mars 2013 Regular

Sexual Intercourse :
20 avr. 2013 method used : Female condom
No Failure

Medication Taken :

Send Data



Virgin 17:58 20 %

Annuler STEella Study,... Envoyer

À :

Cc/Cci, De : redhouane.a@gmail.com

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Questions for the immediate future

- Better compliance with e-tools?
- Decrease the number of lost of follow up or missing data?
- Same metrology as others « classical » way to collect data?
- Acceptation by health authorities?
- Data privacy?