An application for smartphone in a safety observational study

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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

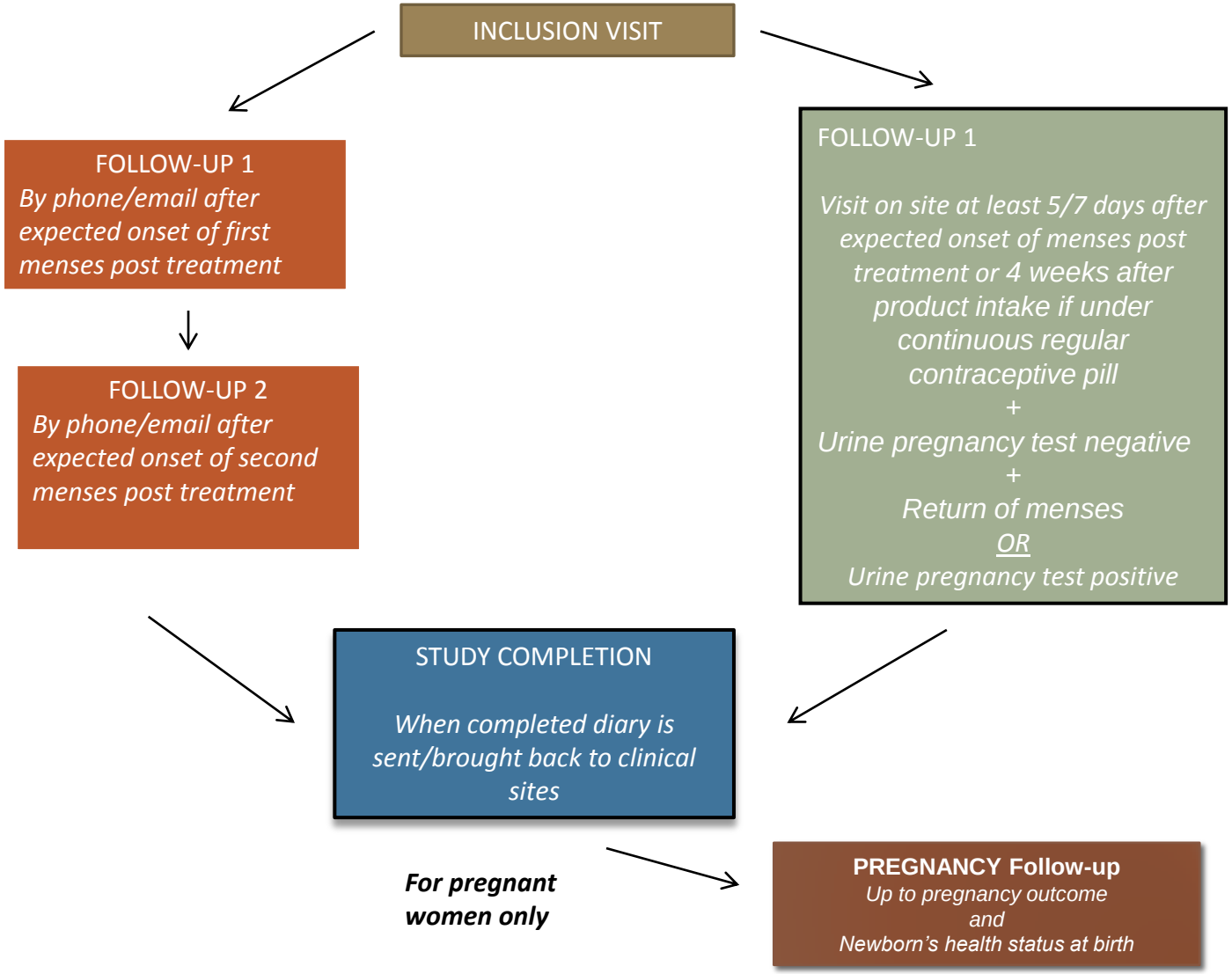
- Primary objective
  - To assess the safety and tolerability of product® in routine conditions of use for emergency contraception in postmenarcheal adolescents and adult women in particular menorraghia, metrorrhagia, dysmenorrhea and effect on menstrual cycles.
- Secondary objectives
  - To assess the 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

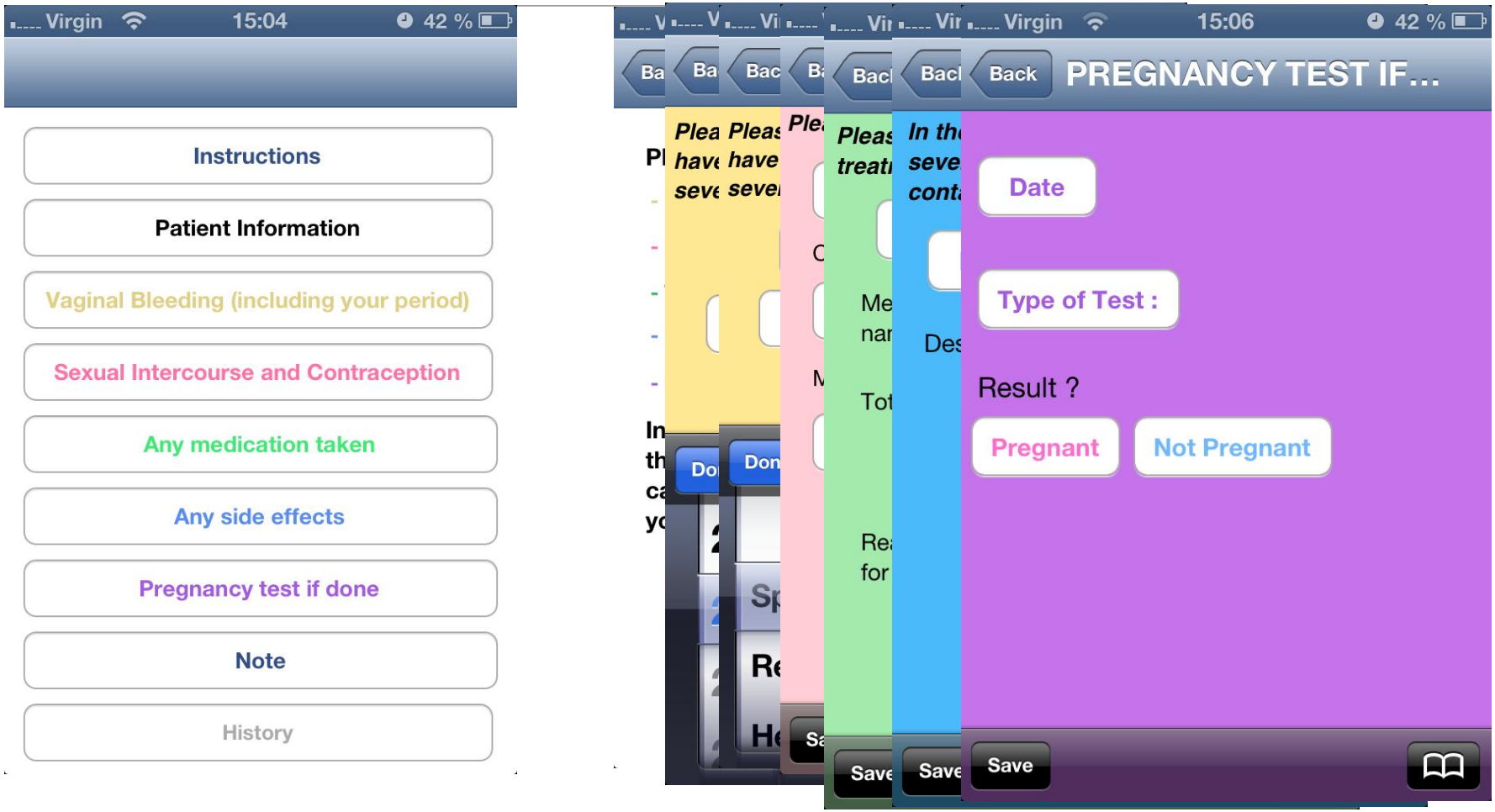
- Adverse events recorded in the diary & in the Phone calls/email follow-up
- Concomitant medications
- Sexual intercourse & contraception use
- Bleeding profiles recorded in the diary & in the Phone calls/email follow-up
- Pregnancy follow-up (up to outcome/delivery)

Application

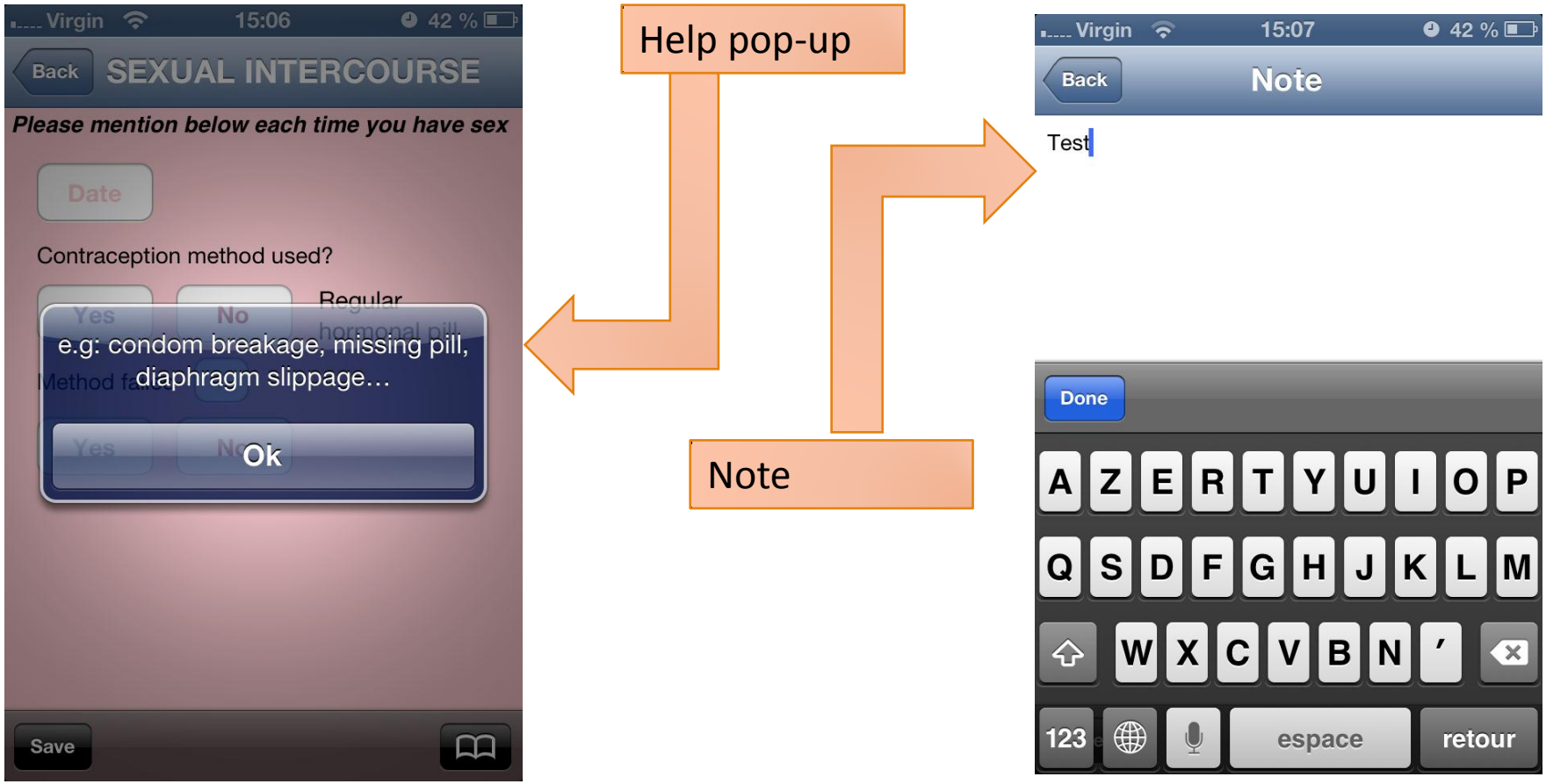
- First option was to use a paper questionnaire but it soon appeared inefficient (target population, sensitive questionnaire…). It was decided to replace the paper version by a smartphone application

- The application
  - Developped 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



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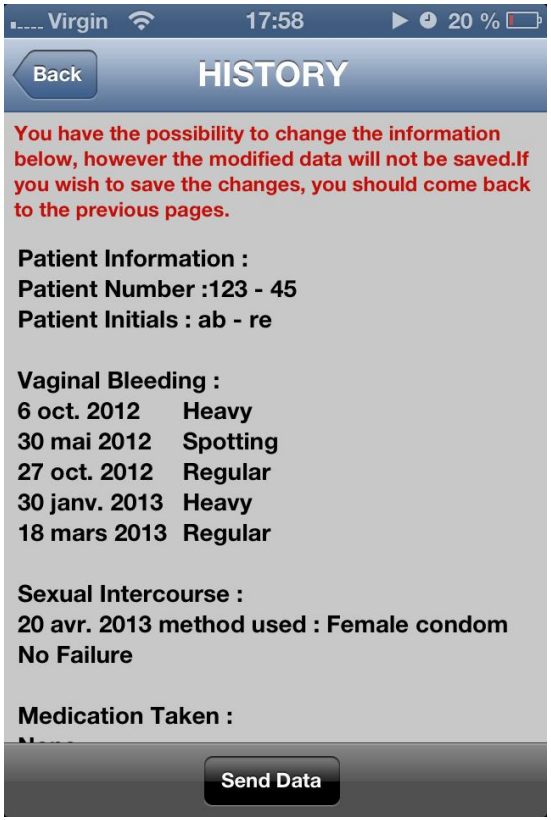

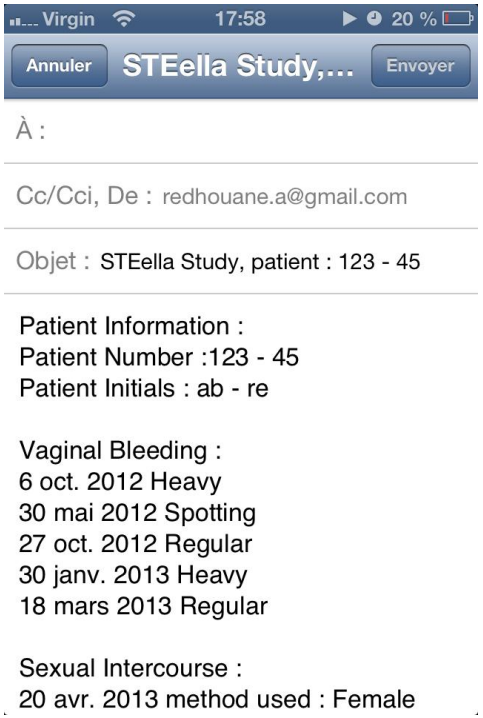

Questions for the immediate future

- Better compliance with etools?
- 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?