Mobile App Development

Pharmacovigilance – Report on safety and adverse events

02 June 2016

Introduction

- Thank you for sharing your interest!
- This document contains the full form that needs to be transformed into a mobile app (Addendum)
- We've been asked to leave the client's name out of this document
- Please send Jan (jan.demey@hict.com) your proposal before Wednesday 8 June, 2016, 12:00 CEST (noon)

Content

- Your proposal
- Context
- Functional requirements (update!)
- Technical requirements
- Addendum (update!)

Your proposal – 1/2

- How you see the app, and the deliverables
- The design and development of the app
  - Approach and methodology
  - Data
    - Security
    - Encryption
  - PDF
    - Generation, with anonymised patient data
    - Emailing the PDF (sending, changing email address)
- Timeline (milestones, interactions, testing, delivery, etc.)
- Deployment
  - How will the app be hosted? Where? Cost?
  - Provide information on the type and cost of data storage
- Preconditions

Your proposal – 2/2

- Maintenance
  - Support for the app after delivery
  - Procedure for change requests (How? Price structure?)
- Budget
- Financial proposition to hict as an intermediary
- Reference cases
  - Apps
  - Apps in pharmaceuticals and healthcare

Context - Who

- We are **hict**
  - A consulting agency in Belgium
  - Market: Healthcare
    - Providers
    - Suppliers
    - Public services
- Our customer for this project:
  - Pharmaceutical company
    - Looking to deploy a **mobile app** in the **Middle East**
- You
  - Have a solid experience in app development
    - Preferably (not necessarily) with medical/patient data
  - Have an interest in international projects
  - Can take on a project with a mid-September (2016) deadline

Context - What

- Mobile App
  - Replace a paper and web form with a simple app
    - The form currently exists as a website, but it is not being used. Our client has therefore decided to have a mobile app so that physicians can complete form while they're with the patient
  - See the addenda for the form (8 sections)

- Purpose
  - Report safety and adverse event topics concerning pharmaceutical products

- Concerns
  - Security
  - Usability
  - Maintenance

Functional Requirements

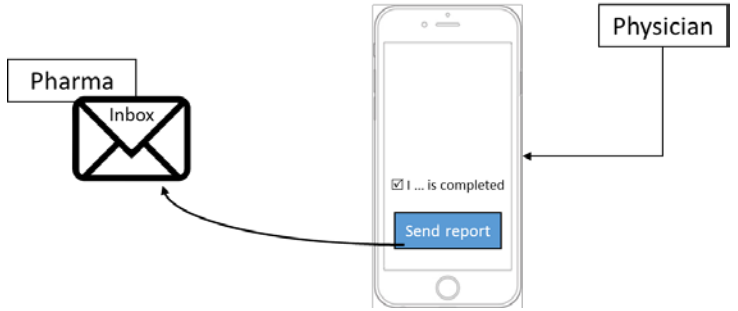
- Users – non-technical profiles
  - Pharmaceutical company
  - Physicians
- Location: Middle East
  - Hospitals
  - Private clinics
  - Over the counter business (OTC)
- Language: English
- Look and feel
  - The app should have the style / colours of the client (pharmaceutical company)

Functional Requirements

- Access
  - User permissions:
    - Pharmaceutical company:
      - Update list of products
    - Physicians / nurses / pharmacists:
      - Register safety and adverse events
  - A third party should provide access to the app
    - Could be the same party that hosts the data server (see Technical Requirements – Data storage)
    - The pharmaceutical company finances the hosting, but is not allowed access to the database without explicit consent
      - The users are only allowed to use the app, either to update the product list (pharma), or to report an adverse event (physician)

- Logging
  - When the pharmaceutical company updates the product list

- Data registration
  - Select a product from a predefined list of pharmaceutical products
  - Generate a PDF of the completed report
    - Automatically anonymise the patient data
    - Email the PDF report to the pharmaceutical company
      - The email address is a generic address of the pharmaceutical company



Technical Requirements

- Platforms (*Trusted source*)
  - iOS
  - Android

- Data storage
  - According to legal requirements
    - Location: public – private – hybrid cloud?
    - Encryption
  - Data storage is hosted by a third party
    - Could be the same party that manages accounts (see Functional Requirements – Access)

Timeline

- In production by mid-September 2016

Addendum - 1

Global: Adverse Event and Special Situation Reporting Form

Instructions:

This form is to be used for reporting Adverse Events (AEs) and Special Situations originating from a spontaneous source, a Non-Interventional Study (NIS), a Market Research and Patient Support Program (MAP) and a Compassionate Use Program (CUP).

AEs and Special Situations will be collectively referred to as "adverse events" hereafter.

For AEs and Special Situations originating from

- Spontaneous sources: Omit section A, B and C and start to complete the form with Section 1 – Reporter Details.
- NIS: Complete section A first in addition to the other sections.
- MAP: Complete section B first in addition to the other sections.
- CUP: Complete section C first in addition to the other sections.

The four essential elements for AE/Special Situations reporting are marked with * of which at least one subfield needs to be populated in each section.

Once completed, forward the form to your Roche Local Safety Unit (LSU) or to Roche Safety Operations as applicable.

For dates, spell out the first three letters of the month, DD/MMM/YYYY, e.g., 07/APR/2015.

A. NIS REPORTS ONLY

NIS Protocol Number:	
Site Number:	
Patient Number:	

Did the patient receive a studied medicinal product as per the NIS protocol? ☐ Yes ☐ No

Are any of the adverse events reported on this form exempted from collection as per the NIS protocol? ☐ Yes ☐ No

B. MAP REPORTS ONLY

Note: Even if there is no identifiable patient, complete as many details as possible.

MAP ID:		Project Title:	
MAP Service Provider:		Respondent ID:	
Address:		E-mail Address:	
		Telephone Number:	
Country:		Fax Number:	

Addendum - 2

C. CUP REPORTS ONLY	
CUP Number:	
Patient Number:	

1. REPORTER DETAILS *		
Reporter First Name:		Occupation:
Reporter Surname:		☐ Physician (specify speciality):
Address:		
		☐ Pharmacist
Postal/Zip Code:		☐ Nurse
Country:		☐ Consumer/Patient
E-mail Address:		☐ Legal
Telephone Number:		☐ Company Representative
Fax Number:		☐ Other (specify):
Has the Regulatory Authority been notified of this report? ☐ Yes ☐ No ☐ Unknown		

2. PERMISSION TO CONTACT HEALTHCARE PROFESSIONAL (HCP)	
If the reporter is a consumer/patient, permission to contact HCP regarding adverse event(s)? ☐ Yes ☐ No	HCP Contact Details:

Addendum - 3

3. PATIENT DETAILS *

Name/Initials:		Weight:	☐ kg ☐ lb
Gender:	☐ Male ☐ Female ☐ Unknown	Height:	☐ cm ☐ inch
Date of Birth:		Ethnic Origin:	☐ Asian ☐ Black ☐ Caucasian ☐ Hispanic
or age at time of event:	☐ Year(s) ☐ Month(s) ☐ Day(s)		☐ Other (specify):

4. SUSPECT PRODUCT * - If more than 4, continue in Additional Relevant Information, Section 8

	Product Name (report brand name if available)	**Indication/ condition** for which the product has been prescribed	**Dose and Unit**	**Route**	**Frequency**	**Start Date**	**Stop Date** (or ongoing)	**Batch/ Lot Number**
A								
	Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown				Was the suspect product reintroduced? ☐ Yes ☐ No If so, did the event recur? ☐ Yes ☐ No ☐ Unknown			
B								
	Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown				Was the suspect product reintroduced? ☐ Yes ☐ No If so, did the event recur? ☐ Yes ☐ No ☐ Unknown			
C								
	Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown				Was the suspect product reintroduced? ☐ Yes ☐ No If so, did the event recur? ☐ Yes ☐ No ☐ Unknown			
D								
	Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown				Was the suspect product reintroduced? ☐ Yes ☐ No If so, did the event recur? ☐ Yes ☐ No ☐ Unknown			

Addendum – 4

5. ADVERSE EVENT(S)/SPECIAL SITUATION(S) * - If required, continue in Additional Relevant Information, Section 8

Adverse Event (AE) (list primary first)	**Onset Date**	**Outcome** (enter number as per the key below) If outcome is unknown, use key 6 and add further details in Section 8	**Resolved/ Improved Date**	**Seriousness** (enter one or more numbers as per the key below)	**Causality** **Y=Yes, N=No, U=Unknown, NP=Not Provided** (specify all suspect products that may have caused the adverse event). If causality is unknown, specify "unknown" and add further details in Section 8			
					Suspect Product			
					A	**B**	**C**	**D**

Key for outcomes:

1. Fatal, 2. Not Recovered/Not Resolved, 3. Recovered/Resolved, 4. Recovered/Resolved with sequelae, 5. Recovering/Resolving, 6. Unknown

Key for seriousness:

1. Death (if yes, provide date): **2. Life-Threatening** (use only if patient was at immediate risk of death due to adverse event) **3. Initial/Prolonged Hospital Admission** **4.Congenital Anomaly/Birth Defect** **5. Persistent or Significant Disability** **6. Medically Significant** (important medical event that may jeopardize the patient and may require medical/surgical intervention to prevent the other outcomes) **7. Non-serious Adverse Events of Special Interest (AESI)** as per NIS protocol **8. Non-serious**

Addendum - 5

6. CONCOMITANT MEDICATIONS

Also include herbal, homeopathic medications and supplements as well as OTC products. If more than 6, continue in Additional Relevant Information, Section 8

Product Name (report brand name if available)	Indication	Dose and Unit	Route	Frequency	Start Date	Stop Date (or ongoing)

7. TEST(S) PERFORMED TO EVALUATE ADVERSE EVENT(S) E.g., baseline results prior to product. If required, continue in Additional Relevant Information, Section 8

Test	Date of Test	Test Result (include units if applicable)	Reference Range	Result Pending?
				☐
				☐
				☐
				☐
				☐
				☐

Addendum - 8

8. ADDITIONAL RELEVANT INFORMATION

Provide a description of the adverse event(s), concurrent conditions and relevant medical history (including start and end date if applicable), clinical course, causality (if unknown), treatment for adverse event(s) and outcome.

[redacted] **USE ONLY OR VENDORS ACTING ON BEHALF OF** [redacted]

LRN: AER: Local Received Date: Company Received Date:

Report Type ☐ Initial ☐ Follow-Up

☐ Spontaneous ☐ Literature ☐ Other (specify):

NIS Protocol Number: MAP ID: CUP Number:

Ancillary Documentation? ☐ Yes ☐ No

Supplementary Form attached? ☐ Yes ☐ No

Contact

Please send Jan your proposal before Wednesday 8 June, 2016, 12:00 CEST (noon)

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