

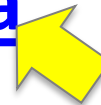


EmPhAsIS

Empowering Pharmacists in Asthma management through Interactive SMS

Baseline Procedures: Consenting and Enrolling Patients

emphasis.core.ubc.ca



Click for more information



EmPhAsIS

Empowering Pharmacists in Asthma management through Interactive SMS

To review how to recruit and screen a potential study participant,
please see the previous mini-webinar on:

“Baseline Procedures: Recruiting and Screening Patients”

Once you have identified a study participant who is willing to participate in the study and fulfills in the inclusion criteria, you are now ready to start obtaining consent and officially enrolling the patient into the study!



For Eligible Patients

INSTRUCTIONS FOR ENROLLMENT
FOR PHARMACY USE ONLY

One Pack per Participant
(If you need more forms, you may download from Website or ask us)

Each Pack Includes: 1 Consent (2 signature pages), 1 Demographics form and 1 Contact Information form

IF ELIGIBLE:

- ☐ Obtain participant consent
 - Review the contents of the Subject Information and Consent Form with the patient.
 - Request participant consent
 - Participant signs two copies of the Subject Information and Consent Form
 - Original signed copy to participant and other signed copy filed in binder
- ☐ Assign Study ID to participant
 - Assign the next unique Study ID
 - Stick label with unique Study ID on all documents pertaining to this Participant
 - Enter information in the study log in Binder
- ☐ Inform Participant of their randomized assignment group (usual)
- ☐ Obtain Participant information
 - Participant completes the Contact Information form
 - Participant completes the Baseline Demographics form
- ☐ Provide Education about asthma
 - Chronic Implication, Technique, Adherence (as per GINA guidelines)
- ☐ Inform Participant about next steps
 - Researchers will contact Participant to complete questionnaires (months 0, 6 and 12)
- ☐ Give Participant their copy of the signed consent, and Participant Guide

Please Fax the following to the Emphasis Researchers at: 604-827-4014

- ☐ Screening Form (Print form if completing online)
- ☐ Contact Information Form
- ☐ Demographics Form
- ☐ Signed page of Consent

☐ Verify if participant is up-dated to study log in Binder

File all these documents in binder provided for this purpose and keep confidential

Instructions for Usual Enrollment FEB 12, 2015

Page 1 of 1

In your binder



- **10 Enrolment Packages (in plastic covers)**

Instructions

Subject Information and Consent Form

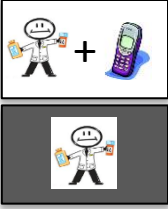
Contact Form

Demographic Form

Participant Guide

[Magnet – Intervention Group only]

- Use 1 package per eligible patient



1. Consent Eligible Patients

- Important part of enrollment process
- Review **Subject Information and Consent Form** with patient
- Have patient sign the 2 copies of page 9
 - 1 copy stapled to form → Patient takes home
 - 1 copy not stapled → Fax to UBC and File in binder
- **AFTER** the patient has signed the consent form, you may inform him/her of the study group assignment



2. Complete Enrolment

Complete Contact and Demographics forms

- Have patient complete
 - **Contact Form**
 - **Demographic Form**



2. Complete Enrolment

Please stick the
Patient **Study ID**
sticker onto the form

Study # 1 3 0 0 5
Site Number Participant #

Contact Information Form

EmPhAsIS: Empowering Pharmacists in Asthma management

Study # [Site Number] - [Participant Number]

Date Completed: dd / mm / yy

Reviewed by: (Please Print name)

Contact information (Pharmacy staff please fax to: 604-827-4014)

For completion by participant

Please answer the following:

Subject Name: Mr./Mrs/Ms Last Name First Name
(please circle one)

Street Address

Town/City Province Postal Code

Telephone Number(s) Home: Area code

Cell: Area code E-mail:

Please choose your preferred Contact Option to answer follow-up questionnaires:

- Phone: ☐ Or Email (link to questionnaire): ☐
- Preferred Contact time: A.M.: ☐ P.M.: ☐ Evening: ☐ Anytime: ☐

Name of Family Physician: Name: Last Name First Name

Phone: Area code

BC Care Card Number (PHN):

Date of Birth (dd/mm/yy):

Will you be away from home over the next 12 months? ☐ Yes ☐ No

If yes, when: Can you still be reached? ☐ Yes ☐ No

Emphasis Contact InfoFeb 11 2015

Patients can complete the
contact form themselves,
but **verify** that **ALL FIELDS**
are completed!



2. Complete Enrolment

Please stick the
Patient **Study ID**
sticker onto the form

Study # 1 3 0 0 5
Site Number Participant #

Demographic Form

EmPhASIS: Empowering Pharmacists in Asthma management through Interactive SMS

Study # [] [] [] - [] []
Site Number Participant Number

For Pharmacy use only

Date Completed: dd / mm / yy

Reviewed by: (Please Print name) Signature: _____

Demographics Form (Pharmacy staff please fax to: 604-827-4014)
For completion by Subject

Please answer the following:

- What is your age?
☐ 14 - 18 ☐ 19 - 29 ☐ 30 - 49
☐ 50 - 69 ☐ 70-89 ☐ 90 years old or older ☐ prefer not to answer
- What is your gender?
☐ Female ☐ Male
- What is your marital status?
☐ Single ☐ Married ☐ Divorced ☐ Widow
- Ethnicity/race (please select which group you most identify yourself with):
☐ Arab ☐ Caucasian/White ☐ Asian/Pacific Islander ☐ Black
☐ First Nations ☐ Hispanic/Latino ☐ Other: _____
- Which of the following best describes the area you live in?
☐ Urban ☐ Suburban ☐ Rural
- What is the highest level of education you have completed?
☐ Elementary/grammar school
☐ High school or equivalent
☐ Vocational/technical school
☐ Some college/university
☐ Undergraduate college/university degree
☐ Graduate or professional degree
☐ Prefer not to answer
☐ other
- Please indicate your annual household income before taxes
☐ Under \$10,000 ☐ \$10,000 - \$29,999
☐ \$30,000 - \$49,999 ☐ \$50,000 - \$74,999
☐ \$75,000 - \$99,999 ☐ \$100,000 - \$150,000
☐ Over \$150,000
☐ Prefer not to answer

Emphasis Demographics form Feb 11 2015

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Patients can complete the
contact form themselves,
but **verify** that **ALL FIELDS**
are completed!



2. Complete Enrolment

Once the patient has completed the **Contact Form** and the **Demographic Form**...

- Fax to UBC **604-827-4014**
- File in your binder (“Completed Forms” tab)
- **Update the Study Log**
 - Found at the front of your binder

Emphasis
Study Log

Research Coordinator: 604-827-1007 FAX: 604-827-4014

Pharmacy:

Enrolment Form ID:

Visit	Event	Visit Date	Event Date	Visit Status	Event Status
Visit 1	Event 1				
Visit 2	Event 2				
Visit 3	Event 3				
Visit 4	Event 4				
Visit 5	Event 5				
Visit 6	Event 6				
Visit 7	Event 7				
Visit 8	Event 8				
Visit 9	Event 9				
Visit 10	Event 10				

2. Complete Enrolment

**Emphasis
Study Log**

Research Coordinator: 604-827-1567 FAX: 604-827-1567

Pharmacy SITE #

Participant STUDY ID #	Name, Phone# and Email	Date DDMMYY	Re-contacted Date DDMMYY	Eligible (Y/N)	Consent (Y/N)	Pharmacist initials Documents Faxed
<div>Study # <input type="text"/> - <input type="text"/> Site Number Participant Number</div> <div>Notes:</div>	<div>Name First: Last:</div> <div>Phone# Cell: Home:</div> <div>Email Name First: Last:</div> <div>Phone# Cell: Home:</div> <div>Email</div>					
<div>Study # <input type="text"/> - <input type="text"/> Site Number Participant Number</div> <div>Notes:</div>	<div>Name First: Last:</div> <div>Phone# Cell: Home:</div> <div>Email</div>					
<div>Study # <input type="text"/> - <input type="text"/> Site Number Participant Number</div> <div>Notes:</div>	<div>Name First: Last:</div> <div>Phone# Cell: Home:</div> <div>Email</div>					

Study Log FEB 17 2015

Fill in your **Site #**
(i.e. 007)

Please stick the
Patient **Study ID**
sticker onto the form

Study # -
Site Number Participant #

Fill in patient name
and relevant contact
information

3. Notify Physician



Fax the **Physician Letter** to physicians in your community

THE UNIVERSITY OF BRITISH COLUMBIA	
 a place of mind THE UNIVERSITY OF BRITISH COLUMBIA Faculty of Pharmaceutical Sciences	 a place of mind THE UNIVERSITY OF BRITISH COLUMBIA Faculty of Medicine Department of Medicine
Investigators: Principal Investigator: Mary De Vera, PhD Faculty of Pharmaceutical Sciences, UBC mdevera@mail.ubc.ca Investigators: Nadatsafavi, MD, PhD Faculty of Medicine, UBC Lynd, BSP, PhD Faculty of Pharmaceutical Sciences, UBC Marra, PharmD, PhD Faculty of Pharmacy Memorial University FitzGerald, MD, FRCPC Faculty of Medicine, UBC Lester, MD Faculty of Medicine, UBC Pe Brasher, PhD Coastal Health Research Institute Tsao, BScPharm, MScPharm, Faculty of Pharmaceutical Sciences, UBC Ragsdale, BScPharm Faculty of Pharmaceutical Sciences, UBC Partners: Collaboration for Outcome Research Evaluation (CORE) at UBC's Faculty of Pharmaceutical Sciences is conducting this study in collaboration with the Faculty of Medicine Research is funded by the Canadian Institutes of Health Research and the College of Pharmacists at the University of British Columbia.	<p>Dear Dr.</p> <p>The purpose of this letter is to inform you of a new study being introduced in your community entitled: EmPhAsIS: Empowering Pharmacists in Asthma management through Interactive SMS. This study is conducted at UBC's Faculty of Pharmaceutical Sciences in collaboration with UBC's Faculty of Medicine.</p> <p>The EmPhAsIS study is designed to assess whether a pharmacist-initiated intervention that includes education and monthly text messages to ask patients how they are managing their asthma medication will help improve adherence to the medication(s) and their outcomes. Pharmacies across BC (which may include your community) will be randomized to provide the EmPhAsIS intervention (education + monthly text messages to assess adherence + follow-up with pharmacists with non-adherent patients) or usual care (education). Patients are eligible for this study if they are: 14 years old or older, diagnosed by a physician as having asthma, fill a prescription for inhaled corticosteroids (ICS), and have access to a cellular phone with texting capabilities. The EmPhAsIS study will take 12 months.</p> <p>As we have partnered with pharmacies/pharmacists in your community, we are taking this courtesy to inform you of this study. If you require additional information regarding this study, you are welcome to contact me at: 604-827-2138 or mdevera@mail.ubc.ca</p> <p>Yours sincerely,</p> <div><div><hr/>Mary De Vera, Ph.D., Principal Investigator</div><div><hr/>Pharmacist Partner</div></div> <div>Please fill in, stamp or affix</div>
Page 1 of 1	
Physician letter July 23, 2014	

Congratulations!

You have now successfully consented and enrolled a patient into the study!

If you are an **Usual Care Pharmacy**, please see next mini-webinar on:

“Baseline Procedures: Usual Care Pharmacy, Next Steps”

If you are an **Intervention Pharmacy**, please see next mini-webinar on:

“Baseline Procedures: Intervention Pharmacy, Next Steps”



EmPhAsIS

Empowering Pharmacists in Asthma management through Interactive SMS

Questions?

Please do not hesitate to contact us

Dr. Mary De Vera at **604-827-2138** (mdevera@mail.ubc.ca)

Research Coordinator (Louise) at **604-827-1567** (louisega@mail.ubc.ca)

Fax: **604-827-4014**

Mailing Address

2405 Wesbrook Mall, Vancouver BC, Canada V6T 1Z3