

Instructions: Generating and Using “Report 1”

COPD Severity and Adherence to GOLD Guidelines in the Community Pharmacy Setting

September 30, 2016

Purpose of “Report 1”:

“Report 1” serves two critically important purposes:

1. This report will be the official, comprehensive list of potential research participants. ONLY patients listed on “Report 1” will be eligible to participate in the study. The information in this report, when combined with other “Report 1s” from all study sites, will be used to describe the sample population used in this study in all publications and presentations.
2. The Community Pharmacist Investigator (CPI) will use “Report 1” to 1) document basic information **for all patients on the list**, and 2) track the recruitment and/or enrollment progress of all patients.

Generating “Report 1”:

- Please generate “Report 1” **within the first week following the date that the CPI from your pharmacy is approved**. Our Project Manager, Cheryl Hoffer, will notify you of that official approval date. **“Report 1” should contain 12 full months of data**. For example, if the date that the report is run is September 15, 2016, then the date range must be 9/15/15 through 9/14/16. **NOTE:** We have been granted a waiver of consent, by the STLCOP IRB, for this initial phase of participant recruitment only—in other words, you do not need to obtain the consent of your patients before generating this report.
- Please generate “Report 1” from the data in your pharmacy’s dispensing system, **with the fields marked with an asterisk (*) in the field descriptions below**. You must export your report an Excel spreadsheet format in the template provided. The fields that are **marked with a small cross (†)** must be entered **manually** for each patient.
- An inclusion criterion for the study participants mandates that they be 40 years old or older. Therefore, please apply a filter to include ONLY patients who are ≥40 years of age.
- “Report 1” must only contain fills for medications defined as a “COPD medication” for this study. For each medication, please capture fills for **all strengths of all inhaled (lung) dosage forms**. The only **oral** medications will be theophylline and roflumilast. The table below lists the specific medications, with brand name(s) and product NDC, which should be included in your database query. IMPORTANT: “Report 1” should only capture **unique patients**—i.e. patients should only be listed ONCE in the report. **For example, a patient who has filled 3 different COPD medications, with multiple refills for each drug, must only be listed ONCE in “Report 1”.**

Drug	Brand(s)	Product NDC
ALBUTEROL SULFATE	AccuNeb	Various
SALMETEROL XINAFOATE AND FLUTICASONE PROPIONATE	Advair	0173-0695
VILANTEROL TRIFENATATE AND UMECLIDINIUM BROMIDE	Anoro	0173-0869
INDACATEROL MALEATE	Arcapta	0078-0619
IPRATROPIUM BROMIDE	Atrovent	Various
FORMOTEROL FUMARATE AND GLYCOPYRROLATE	Bevespi	
VILANTEROL TRIFENATATE AND FLUTICASONE FUROATE	Breo	0173-0859
ARFORMOTEROL TARTRATE	Brovana	63402-911
ALBUTEROL SULFATE AND IPATROPIUM BROMIDE	Combivent	0597-0024
ROFLUMILAST (ORAL)	Daliresp	0310-0095

FORMOTEROL FUMARATE AND MOMETASONE FUROATE	Dulera	0085-7206
FORMOTEROL FUMARATE	Foradil	Various
	Perforomist	
UMECLIDINIUM	Incruse	0173-0873
ALBUTEROL	ProAir	
	Proventil	
SALMETEROL XINAFOATE	Serevent	0173-0520
TIOTROPIUM BROMIDE	Spiriva	0597-0075
TIOTROPIUM BROMIDE MONOHYDRATE AND OLODATEROL HYDROCHLORIDE	Stiolto	0597-0155
FORMOTEROL FUMARATE DIHYDRATE AND BUDESONIDE	Symbicort	Various
THEOPHYLLINE (ORAL ER)	Theo-24	Various
	Theochron	
ACLIDINIUM BROMIDE	Tudorza Pressair	0310-0800
ALBUTEROL	Ventolin	
LEVALBUTEROL HYDROCHLORIDE	Xopenex	Various

- Strongly consider **PRINTING** a hard copy of this report to use for tracking purposes on a daily basis after it is initially generated. If you do, please store the hard copy in a locked and secure location within the pharmacy. Then, **after** you have entered all of the data in an electronic Excel file, please destroy the hard copy by shredding it.
- **IMPORTANT! After you have enrolled your FINAL research participant:**
 1. Ensure that all mandatory fields have been completed for research PARTICIPANTS. **ALL data in all fields collected for research PARTICIPANTS will be included in your pharmacy's final version of "Report 1".**
 2. Ensure that all mandatory fields have been complete for NON-PARTICIPANTS. **For NON-PARTICIPANTS, only SOME of the data collected will be included in your pharmacy's final version of "Report 1".**
 3. Prepare the report for sending to the STLCOP investigators **by modifying the ROWS containing NON-PARTICIPANTS to INCLUDE ONLY the following data:**
 - COPD_Drug_Name
 - NDC
 - Date_Filled
 - Patient_Contacted
 - Reason_NON_Participant
 - Age_Decade
 - Sex
 - Number_COPD_Meds
 4. **For NON-PARTICIPANTS, the data in the following cells MUST BE DELETED** (i.e. the cells MUST be NULL or BLANK) before sending to the STLCOP investigators:
 - ALL Name fields (last, first, middle initial, and other)
 - DOB
 - Date_Study_Visit
 5. SEND your FINAL (edited) "Report 1" to the STLCOP investigators **ONLY as an attachment VIA MHC CareMail.**

"Report 1" Field Descriptions:

*Name_Last

Please populate this field from the “last name” field in the pharmacy’s dispensing system. This should contain the “last name” of the patient that is printed on a label for a prescription filled at your pharmacy. This field is formatted for TEXT and is mandatory only for PARTICIPANTS. For NON-PARTICIPANTS, this cell must be blank/null.

***Name_First**

Please populate this field from the “first name” field in the pharmacy’s dispensing system. This should contain the “first name” of the patient that is printed on a label for a prescription filled at your pharmacy. This field is formatted for TEXT and is mandatory only for PARTICIPANTS. For NON-PARTICIPANTS, this cell must be blank/null.

***Initial_Middle**

Please populate this field from the “middle name” OR “middle initial” field in the pharmacy’s dispensing system. This should contain the “middle initial” of the patient that is printed on a label for a prescription (IF applicable) filled at your pharmacy. This is an OPTIONAL FIELD for all patients and is formatted for TEXT. For NON-PARTICIPANTS, this cell must be blank/null.

***Name_Other**

Please populate this field from any field in the pharmacy’s dispensing system that might contain an “alias” for the patient. This is an OPTIONAL FIELD for all patients and is formatted for TEXT. For NON-PARTICIPANTS, this cell must be blank/null.

***DOB**

Please populate this field from the “date of birth” field in the pharmacy’s dispensing system. This field is formatted for DATE in the “14-Mar-12” format and is mandatory for PARTICIPANTS. For NON-PARTICIPANTS, this cell must be blank/null.

***COPD_Drug_Name**

Please populate this field from the most-commonly-used “drug name” field in the pharmacy’s dispensing system. This is a **MANDATORY FIELD** for ALL patients and the cell is formatted for TEXT. **The ONLY drugs defined as a COPD medication are listed in the table above.**

***NDC**

Please populate this field from the “NDC” field in the pharmacy’s dispensing system. This is a MANDATORY FIELD for ALL patients and the cell is formatted for NUMBER, with no decimal places.

***Date_Filled**

Please populate this field from the “date filled” field in the pharmacy’s dispensing system. This is a MANDATORY FIELD for all patients and the cell is formatted for DATE in the “14-Mar-12” format.

†Patient_Contacted

The CPI must manually enter data in this field for each patient individually. Please only use the drop-down options. The only allowable data are:

“0” = Patient was NOT contacted, or no attempts were made to contact the patient

“1” = Patient was contacted, regardless of the patient agreed to participate in the study

This is a MANDATORY FIELD for ALL patients and the cell is formatted for NUMBER, with no decimal places.

†Date_Study_Visit

The CPI must manually enter data in this field and will **ONLY** be entered for research PARTICIPANTS who complete all study materials (Participant Questionnaire, Informed Consent, and Authorization for Release of Medical Records). The field the cell is formatted for DATE in the “14-Mar-12” format, but must be null (blank) for NON-PARTICIPANTS.

†Reason_NON_Participant

The CPI must manually enter data in this field and will only be entered for NON-PARTICIPANTS. Please only use the drop-down options. The **ONLY** possible entries include:

- “0” = Unable to contact OR did not attempt to contact
- “1” = Patient contacted, but declined to participate
- “2” = Patient is deceased
- “3” = Patient no longer obtains prescriptions from this pharmacy
- “4” = Patient denies having COPD
- “5” = Patient no longer takes any medication for COPD
- “6” = Patient is not English-speaking
- “7” = Patient is unable to participate (e.g., cognitive impairment)
- “8” = Previous participant in study at a different pharmacy
- “9” = Other

The field the cell is formatted for NUMBER, with no decimal places, but must be null (blank) for PARTICIPANTS.

†Age_Decade

The CPI must manually enter data in this field. For HIPAA reasons, the exact age of the patient may be defined as “protected health information” and will not be allowed for THIS PHASE of the study (exact age is allowed for participants because they will sign an informed consent document). Please only use the drop-down options. The only allowable entries are:

- “1” = 40-49 years
- “2” = 50-59 years
- “3” = 60-69 years
- “4” = 70-79 years
- “5” = 80-89 years
- “6” = >/= 90 years

This is a MANDATORY field for ALL patients and it is formatted for NUMBER, with no decimal places.

†Sex

The CPI must manually enter data in this field. This is a MANDATORY field for ALL patients and it is formatted for NUMBER, with no decimal places. Please only use the drop-down options. The only allowable entries are:

- “0” = Female
- “1” = Male

This field is formatted for NUMBER, with no decimal places.

†Number_COPD_Meds

The CPI must manually enter data in this field. Simply count the number of distinct COPD medications (**NOT** total number of fills) for the patient. For example, enter “3” for a patient who has filled prescriptions for albuterol, Flovent, and Stiolto during the past 12 months. This is a MANDATORY field for ALL patients and it is formatted for NUMBER, with no decimal places.

**For ANY QUESTIONS about generating or using “Report 1”,
please contact the Project Manager, Cheryl Hoffer.**