Online Supplement

Brief Report
Using Electronic Health Records to Identify Participants for a Multicenter COPD Clinical Trial

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RELIANCE

Audit of Query Results, Milestone O

Instructions, Mar 20 2018

When: Audit data entry will be accepted by the Clinical Coordinating Center (CCC) until June 15, 2018

Estimated time to complete: We anticipate chart audits will take between 3 minutes and 7 minutes each (total time 1.5-3.5 hours) based on previous audits conducted by the prime.

Purpose: One objective of Phase 1 is to estimate the number of patients at each site eligible for the RELIANCE Trial (Phase 2). The audit requires your site review a random sample of patient records to evaluate the accuracy of the query for identifying potentially eligible patients for the RELIANCE Trial. We expect that not all records identified in the query will meet all eligibility criteria on further inspection. These results will help the RELIANCE Executive Committee customize recruitment strategies for Phase 2.

Completed by: Site Coordinator, site Principal Investigator (PI), or site Co-Investigator (Co-I)

Steps for Audit:

1. Using the list of Audit IDs assigned by the CCC, your site will locate the corresponding patient record in the site survey database, the match should be made based on the records numerical order in the database, e.g., an Audit ID of X0007 corresponds to the 7th record in the database.
2. Your site will complete the Audit of Query Results (AQ) form based on review of all available data in the patients Electronic Health Record (EHR). The site should complete *a new AQ form for each record audited*. The site will keep a local record linking AQ form data to the local patient ID.
3. Each form should be reviewed by your site PI prior to data entry.
4. Each paper form should then be keyed into the Audit database hosted at the CCC using the assigned Audit ID. Your site PI will be provided a password to access the Audit database and complete data entry. Your site can access the Audit database from your RELIANCE landing page. Please contact reliance.team@reliance-study.org if you need your link resent.

What to collect: Please see case report form *Audit of Query Results* (AQ), Milestone O, V1, Mar 20 2018

Definitions for AQ: Please refer to the following definitions during your audit:

Site ID: a number assigned by the CCC to each participating clinical site.

Database ID: a number assigned by the Clinical Coordinating Center (CCC) to each internal (i.e. site-level) database queried as part of the site survey.

Audit ID: a random number that corresponds to the record of a patient report identified as eligible in the data query. For example, if you are assigned Audit ID 007, you will find the 7th record in your site survey database and review that patient's electronic health record (EHR).

Guidelines:

Data audit, *audit of query records* and *chart audit* are used synonymously in Phase 1, they refer to the same process.

Please refer to the eligibility criteria in the *Phase 2 Protocol*, also pasted below for convenience, as the definitive reference as you complete your audit.

Inclusion criteria

- Patient and treating clinician considering treatment intensification options to reduce the risk of COPD exacerbations;
- Age ≥ 40 years;
- Current or past smoker of at least 10 pack years;
- Diagnosis of severe COPD and associated chronic bronchitis;
- Hospitalized with a diagnosis of COPD exacerbation in the past 12 mos.;
- Current medications include inhaled LAMA, LABA/LAMA, or ICS/LABA;
- English or Spanish-speaking.

Exclusion criteria (any of the criteria below)

- Unable or declines to provide informed consent to be randomized to long-term therapy with azithromycin or roflumilast;
- History of intolerance to azithromycin or roflumilast that the patient or patient's treating clinician considers sufficiently serious to avoid either treatment option;
- Current treatment with long –term (more than 30 days) roflumilast or azithromycin; previous treatment with 1 or more doses of azithromycin or roflumilast is not an exclusion criterion, as long as the patient and clinician are seeking treatment intensification options and would be willing to use azithromycin or roflumilast, as per randomized treatment assignment;
- Known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic;
- History of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin;
- Moderate to severe liver impairment (Child-Pugh B or C);
- Current pregnancy;
- Any other clinician-determined exclusion as per their clinical practice. The clinicians will be provided the FDA-approved prescribing information for roflumilast and azithromycin (Appendices 7.1 and 7.2). The prescribing information includes a list of "warnings and precautions" that identifies the potential for adverse effects and is intended to support clinical decision-making that takes into account the risks and benefits of roflumilast and azithromycin for each patient. More information about the Warnings and Precautions are presented in Section 2.3.

Auditors should review the names of maintenance medications for each patient record with their site PI or Co-I to ensure correct documentation.

For any questions, please contact the RELIANCE Team at reliance.team@reliance-study.org

RELIANCE

Audit of Query Results

A. Audit ID

1. Site ID: ___ ___ ___ ___ (*provided by CCC*)
2. Database ID: ___ ___ (*provided by CCC*)
3. This audit was performed on (*check only one*):
   Patient record from Hospital/In-patient database... (1)
   Patient record from Clinic/Outpatient database..... (2)
4. Audit ID: ___ ___ ___ ___ *(provided by CCC)*
5. Audit date:
   ___ ___ - ___ ___ - ___ ___ ___ ___ (ex. 02-18-2018)
   month day year
6. Auditor name (print): _____
7. Auditor signature: _____

B. Eligibility criteria for participant in RELIANCE trial

	Inclusion criteria	Yes	No	Unable to determine
8.	Age at least 40 years	(1)	(2)	(3)
9.	Current smoker with at least 10 pack years of smoking (defined as currently smoking every day or some days; Source: BRFSS) as of the date of the encounter	(1)	(2)	(3)
10.	Former smoker with at least 10 pack years of smoking (defined as having quit smoking); Source: BRFSS) as of the date of the encounter	(1)	(2)	(3)
11.	Diagnosis of chronic obstructive pulmonary disease (COPD) with chronic bronchitis (defined as a physician diagnosis of "COPD" and one of the following: physician diagnosis of "chronic bronchitis" OR documentation of chronic cough and sputum production)	(1)	(2)	(3)
12.	Hospitalized with a diagnosis of COPD exacerbation over the past 12 months	(1)	(2)	(3)
13.	Prescribed one of the following maintenance regimens: inhaled LAMA, LABA/LAMA, or ICS/LABA, ICS/LABA/LAMA (see instruction page for medication names)	(1)	(2)	(3)
14.	Patient speaks English or Spanish	(1)	(2)	(3)
	Exclusion criteria			
15.	Prescribed long-term (>30 days) azithromycin or roflumilast as of the date of the encounter	(1)	(2)	(3)
16.	Pregnant as of the date of the encounter	(1)	(2)	(3)
17.	Physician documentation that azithromycin or roflumilast should not be prescribed; 17s. If "yes", specify: _____	(1)	(2)	(3)
18.	In the assessment of the site PI or Co-I, would this patient be eligible for the RELIANCE Study based on available documentation?	(1)	(2)	(3)

C. Administrative information

19. Name of Principal Investigator (print): _____
20. Signature of Principal Investigator: _____
21. Date of PI signature: ___ ___ - ___ ___ - ___ ___ ___ ___ (ex. 02-18-2018)
    month day year