
The monitoring plan for this study requires you to conduct 100% Source Data Review (SDR) of a subject's medical history and concomitant medications that are current entering the study. The subject does not have any medical history or concomitant medications that would exclude him from the study.

Subject LRH became a patient of Dr. Srinivasan in March 2011. He had previously been diagnosed with allergic rhinitis in 1998, obesity in 2004, and hypertension in 2007 that were active when he became a patient of Dr. Srinivasan in March 2011. The following is a list of the subject's current medical history and concomitant medications:

Current Medical History:

- Allergic Rhinitis, diagnosed 1998
- Obesity, diagnosed 2004
- Hypertension, diagnosed 2007
- Diabetes Mellitus - Type II, diagnosed Jan-2013
- Osteoarthritis - right hip, diagnosed Mar-2014
- Hyperlipidemia, diagnosed Sep-2014
- Gastroesophageal Reflux Disease (GERD), diagnosed Jan-2015
- Lower Extremity Edema, diagnosed Feb-2018
- Asthma, diagnosed May-2018
- Diabetic Retinopathy, diagnosed Nov-2018
- Depression, diagnosed Mar-2020
- Fatigue, diagnosed May-2020

Current Medications:

* The start date of the current medications may start at the same time as the medical history item or after the medical history item if there has been a change in treatment or a new dose of a previously used medication.

Fexofenadine HCL, 180 mg, QD, started 2003, to treat allergic rhinitis

Enalapril Maleate, 5 mg, PO, BID, started 2013, to treat hypertension

Ertugliflozin/Sitagliptin, 5/100, PO, QD, started Jan-2016, to treat diabetes mellitus type II

Paracetamol, 1000 mg, PO, BID started Jul-2016, to treat osteoarthritis of the right hip

Famotidine, 20 mg, PO, QD, started Jan-2015, to treat gastroesophageal reflux disease (GERD)

Hydrochlorothiazide, 25 mg, PO, QD, started Mar-2018, to treat lower extremity edema

Budesonide, 180 mcg, INH, BID, started May-2018, to treat asthma

Albuterol, 90 mcg, INH, PRN, started May-2018, to treat asthma

Diltiazem, 300 mg, PO, QD, started Sep-2018, to treat atrial fibrillation

Aflibercept, .05 ml, IVA, Q2M, started Dec-2018, to treat diabetic retinopathy

Escitalopram, 10 mg, PO, QD, started Mar-2020, to treat depression

- 1) Issue #1 – Diltiazem is listed to treat atrial fibrillation, but there is no medical history of atrial fibrillation
- 2) Issue #2 – Subject has obesity, hypertension and DM Type II. The subject is treated for hypertension and DM Type II but does not have any treatment for hyperlipidemia. Should the CRA ask about that? Identify something that would have to be treated.