

The Biogen Raw Metadata Access(BRaMA) Library is a collection of metadata consisting of select fields from several legacy and ongoing study database specifications integrated with information from Program/Clinical Trial Metadata equipped with a robust search functionality.

Purpose

A Raw Metadata Library is a useful resource for multiple stakeholders in Biometrics at various stages of the clinical trial process; from assisting Data Management with the design of the database to referencing prior assessments and SDTM mappings, to helping Biostatisticians and ADaM teams determine what forms of analysis methods were carried out on similar assessments. The alternative involves relying on individuals past experience/asking colleagues which is unreliable and inefficient. A Library reflecting a collection of metadata consisting of select fields from several legacy and ongoing study database specifications integrated with study operational information equipped with a robust search functionality has been successfully implemented at the company wide level with minimal cost. The Library called BRaMA (Biogen’s Raw Metadata Access) is now integrated with the EDC specification process and it is referenced by the SDTM team leading to fewer governance requests. Methodology used to create such a library has been discussed.

Process Flow

Clinical Trial Metadata

ViewSearchEditSDTMConnectBiogenDashboardsSDVOther ResourcesLogout (username)Biometrics Pipeline

Study Details

Product

Ocrelizumab Fumarate

BBB Number

BBB095

Product Code

02797

Study #

272MS303

Last Edited

2021-10-19 00:27:49

Therapeutic Area

Neurology

Indication

Multiple Sclerosis

Global Medical

Non-Interventional

Study Status

Concept Approved

State

Active

Used Biogen Data Collection Standards

Trial Stage

Concept Approved

Phase

P3

Study Status Description

Active

SMT Formed

2020-11-24

Study Design / Short Title

APAC study

Sites

50

Subjects

100

Blinded

FormOID

FieldOID

DraftFieldName

VariableOID

DataDictionaryName

ControlType

DM

DM_RACEOTH

DM_RACEOTH

DM_RACEOTH

Asian Subclassification

Text

DM

DM_RACEOR

DM_RACEOR

DM_RACEOR

DropDownList

DM

DM_RACEOROT

DM_RACEOROT

DM_RACEOROT

Text

Form: Anti-Aducanumab Antibody

Generated On: 02 Jun 2021 03:55:59

Specimen Type

Blood

Urine

Plasma

Serum

Specimen Category

Chemistry

Hematology

Urinalysis

HIV/HBV/HCV

Drug Screen

FSH

PK

Anti-aducanumab antibody

Was the sample collected?

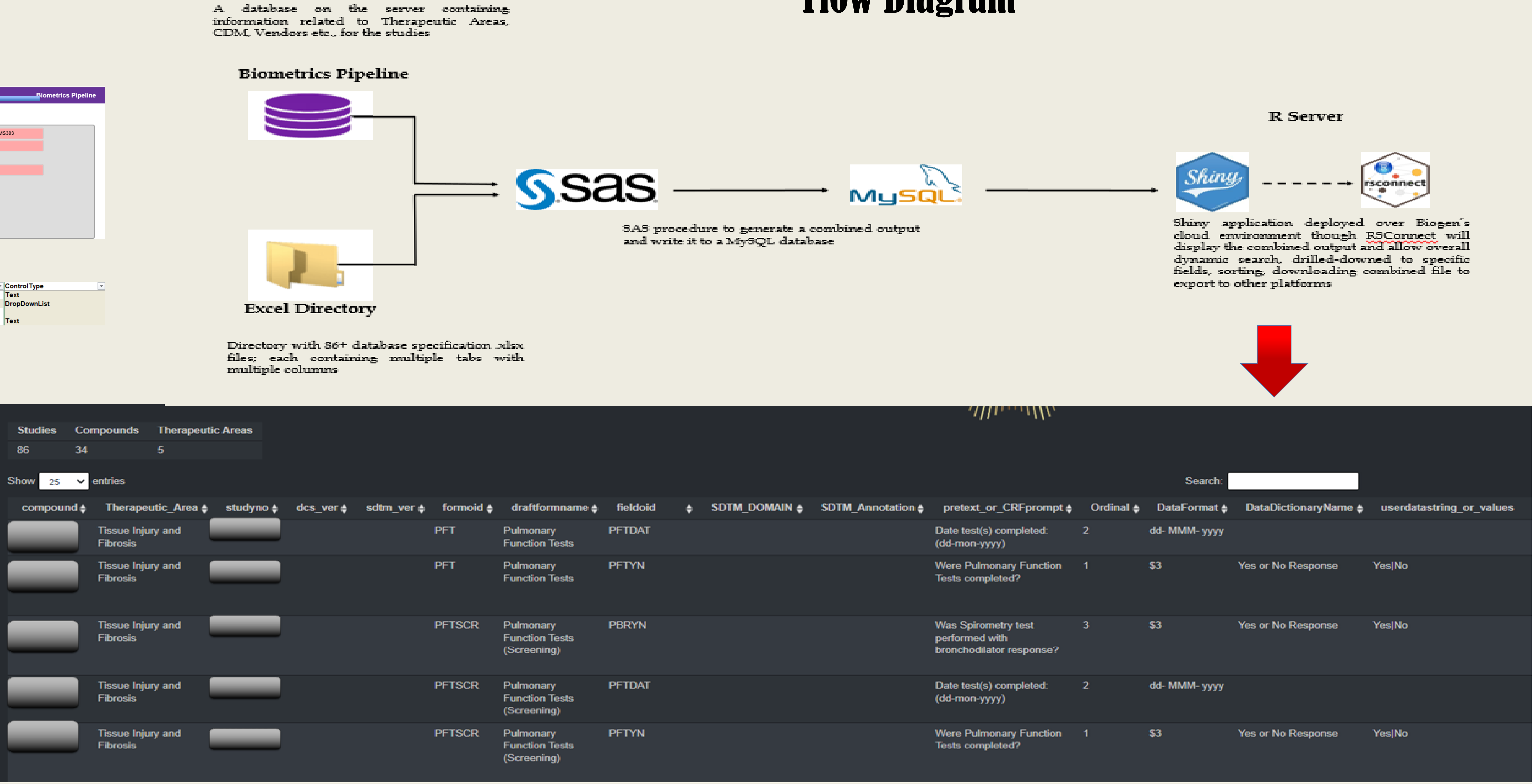
Yes

No

Collection Date (dd-mon-yyyy)

Collection Time (24-hour clock)

Flow Diagram



- ❖ Login using company network credentials
- ❖ Process exists to maintain content and include upcoming studies
- ❖ Includes target SDTM Domain and annotations

