

Stress-Free Database Lock – SASsy Tools to Save Your Sanity

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LEO Pharma
– leading
in medical
dermatology

Agenda

• Dermatology
beyond the skin

- Introduction
- LEO Statistical Computing Environment
- Stressful DBL
- DBL assist toolbox
- Summary
- Questions



Introduction

- Critical milestone.
- Several functions involved.
- Multitude of programming and documentation activities (Pre and Post DBL).
- Time pressure.
 - From LSLV to KR (Goal: 4 weeks)
 - From LSLV to submission (Goal: 4 months)
- API based tools to support statistical programmers.

Statistical computing environment (SCE)

Life science analytics framework (LSAF)

- Stores Clinical data and SAS Programs.
- Code development and output creation.
- Workspace vs Repository

Workspace	Repository
Individual work area	Shared work area
Not Access controlled or Audit trailed	Access controlled and audit trailed
Items can be updated in interactive SAS session	Items can only be updated with LSAF Jobs

LSAF Job and Manifest file

- Job is an XML wrapper around the SAS code
- Manifest file is an XML file that is created after a job run.
- Source of key information about the latest job run.

Job Manifests

adae.mnf x

Details

Programs

Parameters

Inputs

Outputs

Logs

SAS Results

SAS Internal SAS External All

All files transferred from the repository that were referenced by SAS programs

Number of files: 16

Size of files: 2.81 MB

Time taken to transfer files: 0:0:30 (h:m:s:ms)

Text to filter 16 files

Name	Location	Version ↓	Size	Referenced SAS Program
fa.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.45	256 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
relrec.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.45	256 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
ae.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.44	192 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
dm.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.44	128 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
ex.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.44	256 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
suppae.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.44	128 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
suppds.sas7bdat	/leo/clinical/lp0162/1338/sdtm/data	1.44	128 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
trial_setup_adam.sas	/leo/clinical/lp0162/1338/setup	1.2	10.74 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas
mk_adam.sas	/leo/clinical/lp0162/1338/adam/macros	1.1	13.52 KB	/leo/clinical/lp0162/1338/adam/programs/adae.sas

LSAF APIs

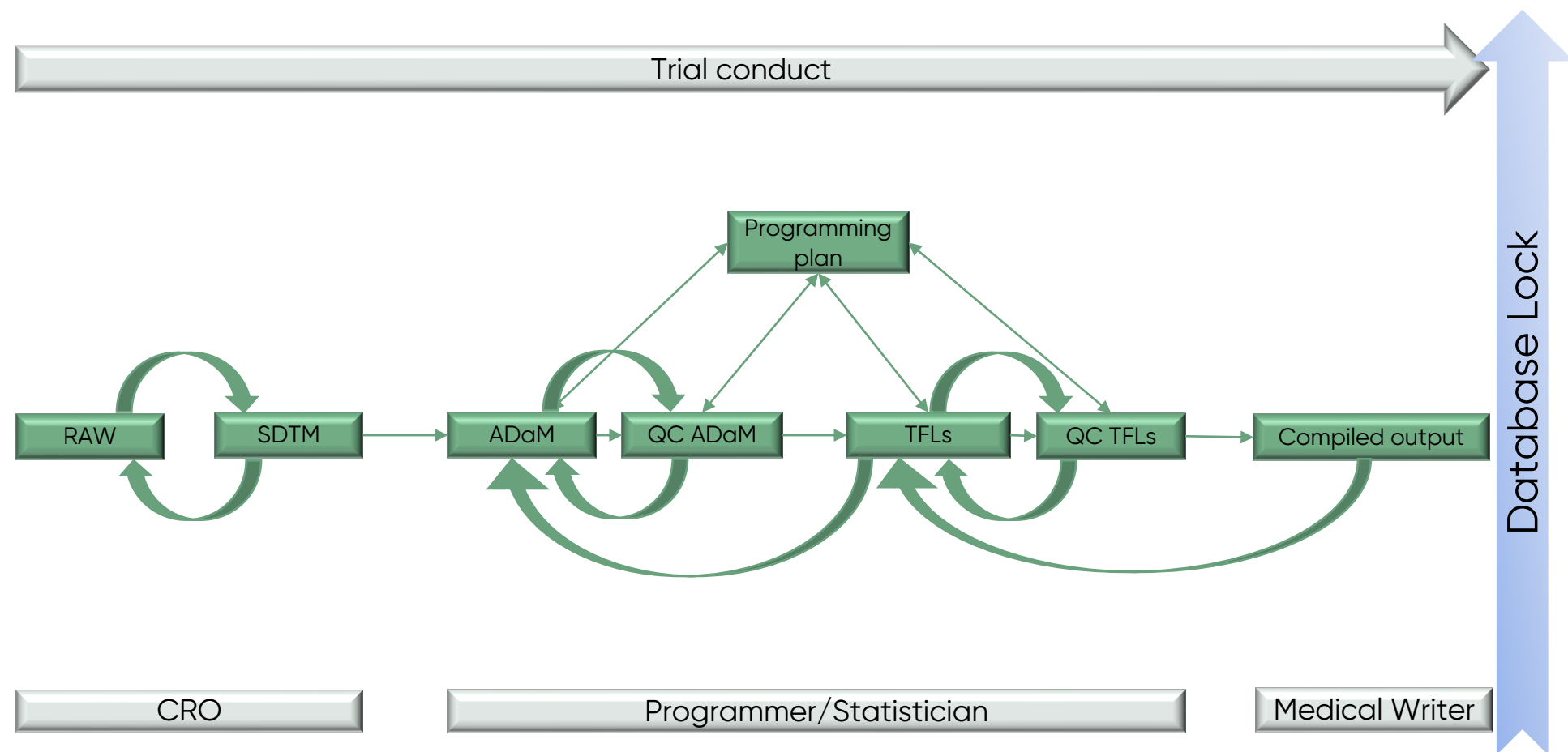
LSAF comes with a large set of APIs.

- Interact with the system metadata
- For most of the functionality in the SCE interface, there is an API. Eg:
 - Check In/Check Out files
 - Copy/delete files
 - Version/Sign files etc
- LEO has used these APIs to develop a bunch of tools which we are going to look at next

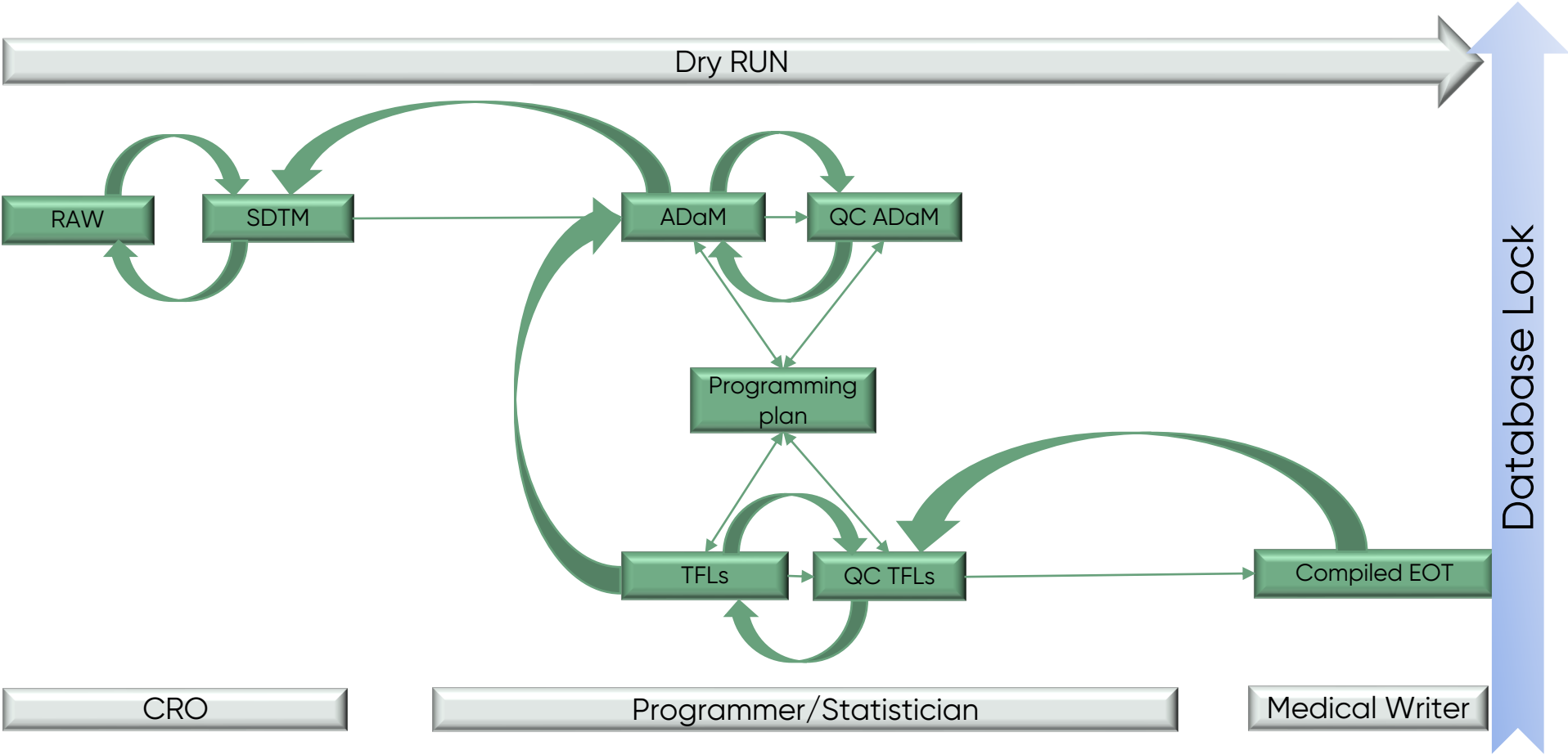


API Parameters	
▸ Alphabetical Module List	SAS Macro API Reference Guide
▸ Alphabetical Macro List	RepositoryService Module
Clinical Macros	Overview
▸ DictionaryService Module	Macro Summary Table
▸ ExternalDictionaryService Module	Dictionary
▸ StandardsService Module	%LSAF_CHECKIN Macro
▸ StudyService Module	%LSAF_CHECKOUT Macro
▸ StudyTlfService Module	%LSAF_COPY Macro
▸ TLFTemplateService Module	%LSAF_CREATECONTEXT Macro
Content Macros	%LSAF_CREATEFILE Macro
▸ BatchRepositoryService Module	%LSAF_CREATEFOLDER Macro
▸ BatchWorkspaceService Module	%LSAF_DELETE Macro
▸ RecycleBinService Module	%LSAF_DELETEVERSION Macro
▸ RepositoryService Module	%LSAF_DISABLEVERSIONING Macro
Overview	%LSAF_DOWNLOADFILE Macro
Macro Summary Table	%LSAF_ENABLEVERSIONING Macro
%LSAF_CHECKIN Macro	%LSAF_EXISTS Macro
%LSAF_CHECKOUT Macro	%LSAF_GETCHECKEDOUTFILES Macro
%LSAF_COPY Macro	%LSAF_GETCHILDREN Macro
%LSAF_CREATECONTEXT Macro	%LSAF_GETCONTEXTSTATE Macro
%LSAF_CREATEFILE Macro	%LSAF_GETCOPYTOWORKSPACESTATUS Macro
%LSAF_CREATEFOLDER Macro	%LSAF_GETITEMID Macro
%LSAF_DELETE Macro	%LSAF_GETPARENTMEMBERSHIPCONTEXT Macro
%LSAF_DELETEVERSION Macro	%LSAF_GETPROPERTIES Macro
%LSAF_DISABLEVERSIONING Macro	%LSAF_GETSYNCINFO Macro
%LSAF_DOWNLOADFILE Macro	%LSAF_GETTOPOLEVELCONTEXTS Macro
%LSAF_ENABLEVERSIONING Macro	%LSAF_GETTYPE Macro
%LSAF_EXISTS Macro	%LSAF_GETVERSIONS Macro
%LSAF_GETCHECKEDOUTFILES Macro	%LSAF_ISCHECKEDOUT Macro
%LSAF_GETCHILDREN Macro	%LSAF_ISCONTAINER Macro
%LSAF_GETCONTEXTSTATE	%LSAF_ISFILELOCKED Macro
	%LSAF_ISVERSIONED Macro
	%LSAF_LOCKFILE Macro
	%LSAF_MOVE Macro
	%LSAF_PERMANENTLYDELETE Macro
	%LSAF_RENAME Macro
	%LSAF_SEARCH Macro
	%LSAF_SYNCFILETOWORKSPACE Macro
	%LSAF_UNDOCHECKOUT Macro
	%LSAF_UNLOCKFILE Macro

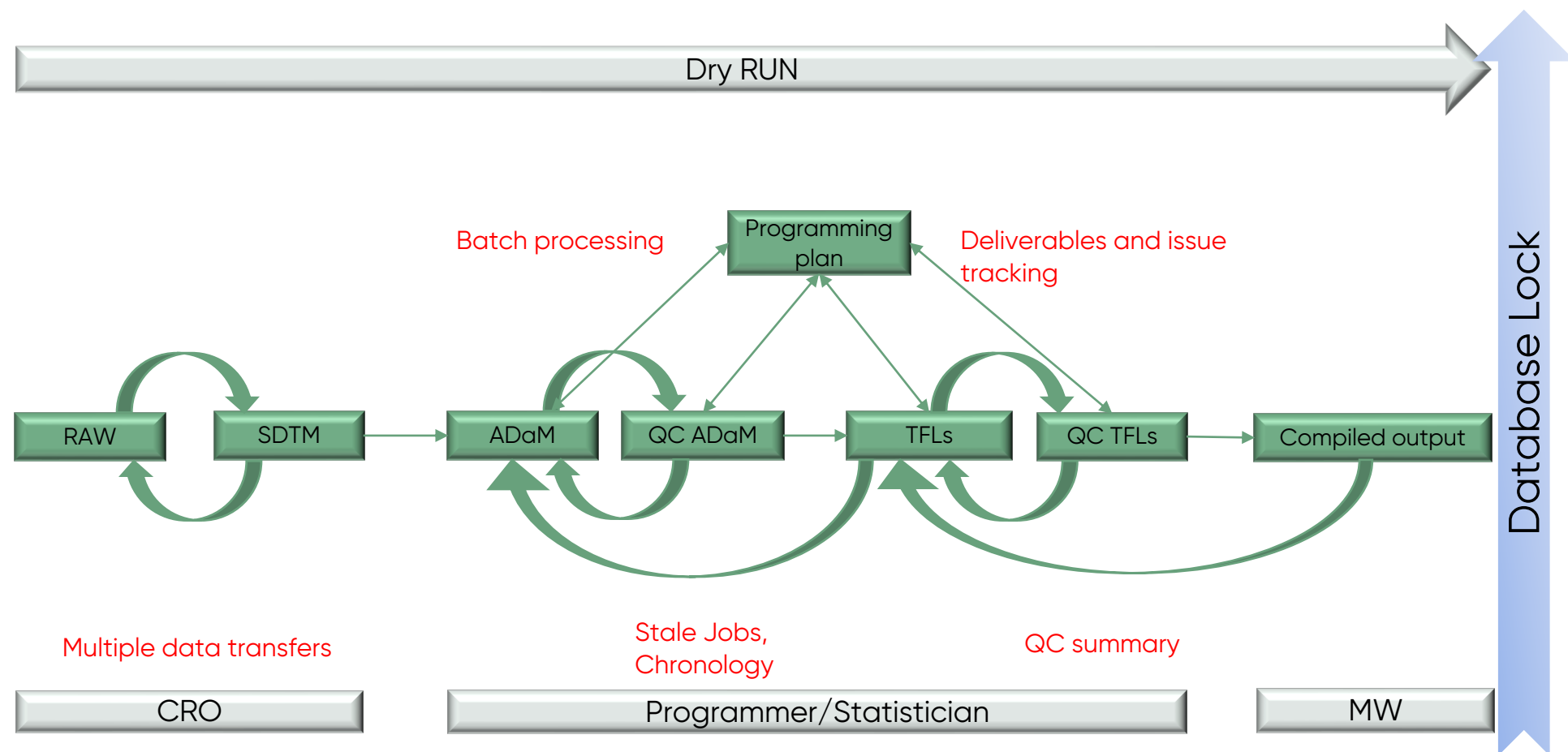
Database Lock



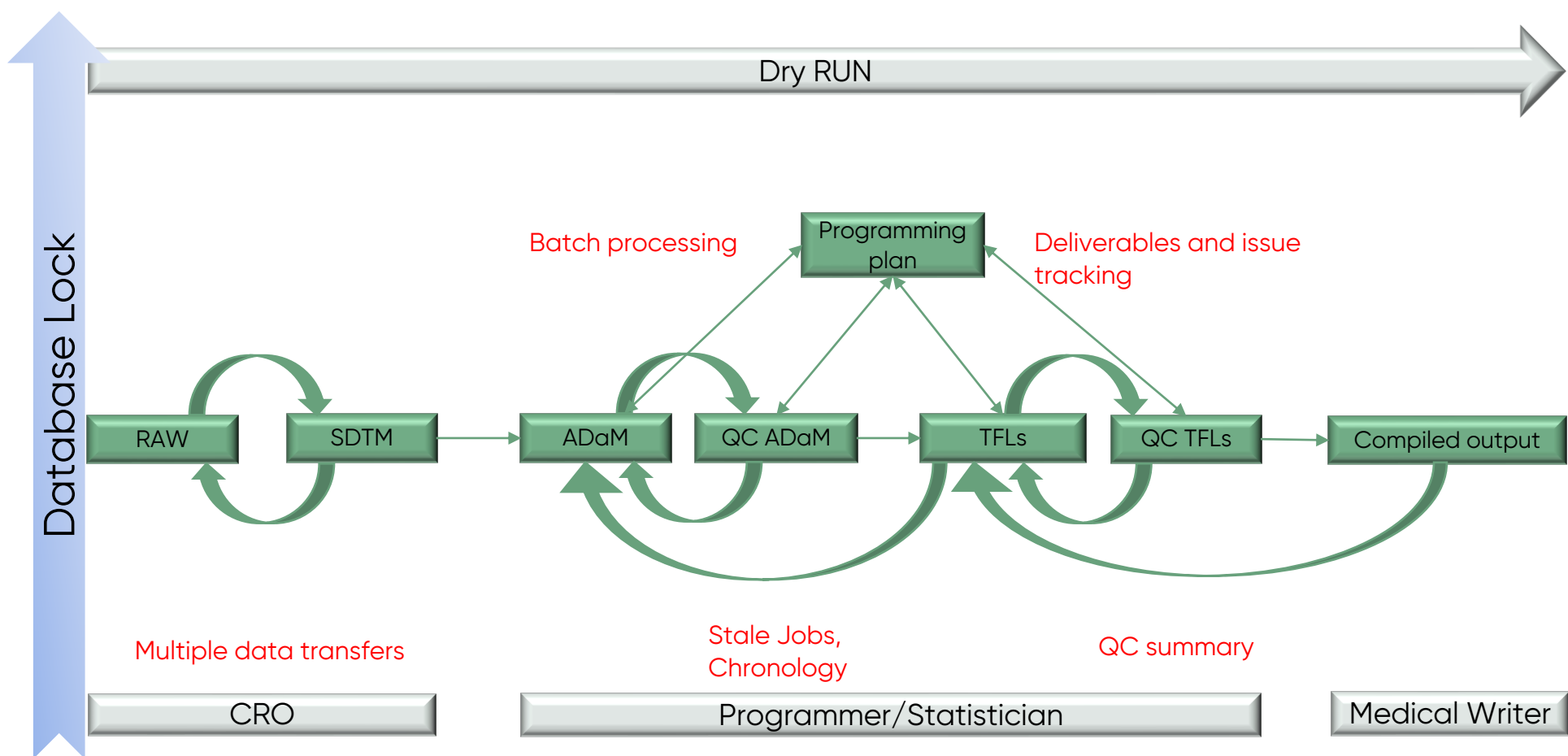
Parallel Activities



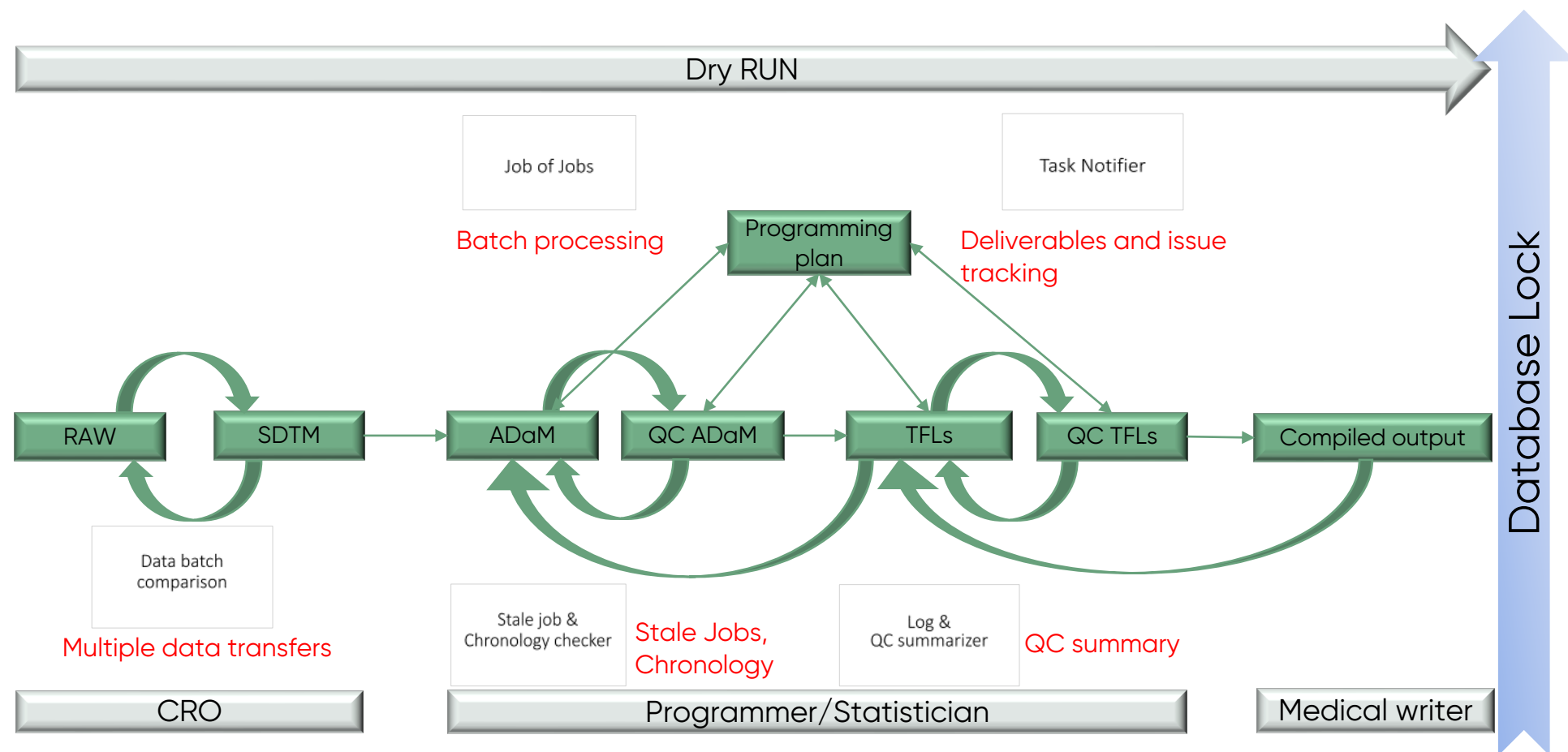
Pre-DBL challenges



Post-DBL challenges



DBL assist toolbox



Job of Jobs

Job of Jobs

- API based tool for executing the Jobs in a batch where the grouping and the ordering is controlled with the Programming plan. The tool allows for :
 - Parallel or sequential execution of jobs/qc_jobs in batches.
 - Scheduling job batches.
 - Dynamic Job selection from ProgPlan for execution.
 - Running jobs as batch in both repository and workspace.

ID	Type	Program	Title	Programmer	QCer	Level of QC	Batch Name	Batch Order
10	Table	t_subj_disp_scr.sas	Subject disposition - screened subjects	Allan	Parag	P-O-L	Batch 1	1
20	Figure	f_tt_disc.sas	Time to permanent discontinuation of IMP - Kaplan-Meier - FAS	Allan	Sune	P-O-L	Batch 1	2
30	Figure	f_tt_disc_by_reas.sas	Time to permanent discontinuation of IMP by reason - cumulative incidences - FAS	Parag	Sune	P-O-L	Batch 2	1
40	Table	t_subj_disp_scr.sas	Subject disposition - randomized subjects	Parag	Allan	P-O-L	Batch 2	2
50	Table	t_tt_disc.sas	Time to permanent discontinuation of IMP - Kaplan-Meier - FAS	Sune	Parag	C-O-L	Batch 1	3

Execution status reports

➤ Individual job runs.

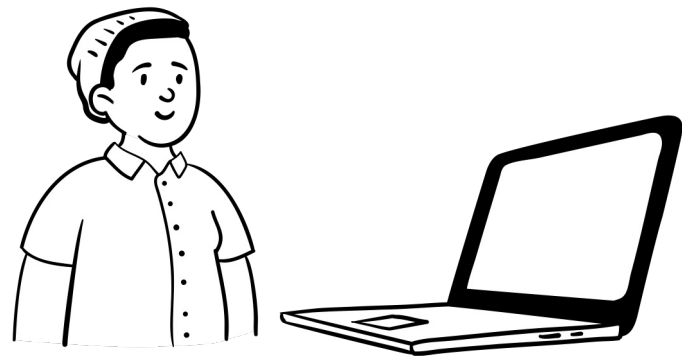
Program	ID	Status
/leo/clinical/lp0162/1342/tfl/baseline/jobs/t_subj_disp_scr.job	1c7d1d50-09c2-472f-8523-8c18f8a106b0	COMPLETED_SUCCESSFUL
/leo/clinical/lp0162/1342/tfl/baseline/jobs/f_tt_disc.Job	df35c81a-46f7-462e-ad59-86b1123f7181	COMPLETED_SUCCESSFUL
/leo/clinical/lp0162/1342/tfl/baseline/jobs/f_tt_disc_by_reas.job	994d99de-33a5-4b63-a5bd-535450c03635	COMPLETED_ERRORS
/leo/clinical/lp0162/1342/tfl/baseline/jobs/t_subj_disp_scr.job	b7a25157-1111-4294-8605-b5fd97fa72fe	COMPLETED_WARNINGS
/leo/clinical/lp0162/1342/tfl/baseline/jobs/t_tt_disc.job	046643fa-5f3a-400a-a8f3-63041471a026	COMPLETED_SUCCESSFUL

➤ Notify users of any discrepancies between list of programs in the programming plan and the programs in the SCE.

```
⚠ WARNING:Program exists in the programming plan, but no such program exists in LSAF: qc_t_resc_treat.sas
⚠ WARNING:Program exists in the programming plan, but no such program exists in LSAF: qc_t_disp_screenfail.sas
⚠ WARNING:Program exists in the programming plan, but no such program exists in LSAF: qc_t_baseline_ods_mh.sas
```

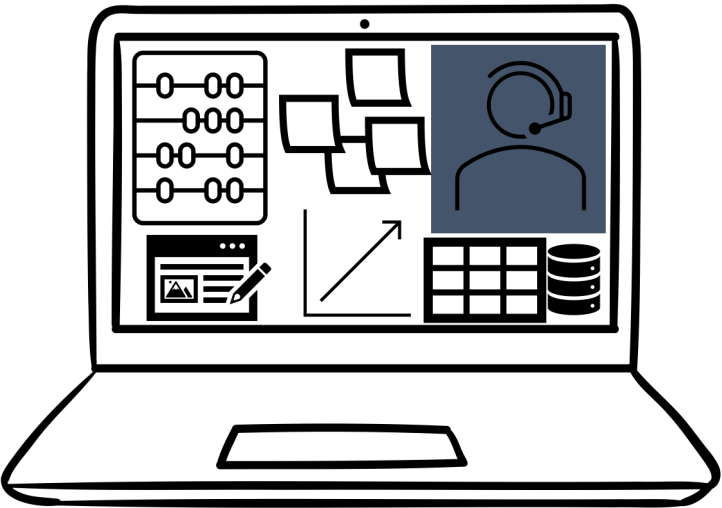
Task Notifier

TFL/ADaM programmers

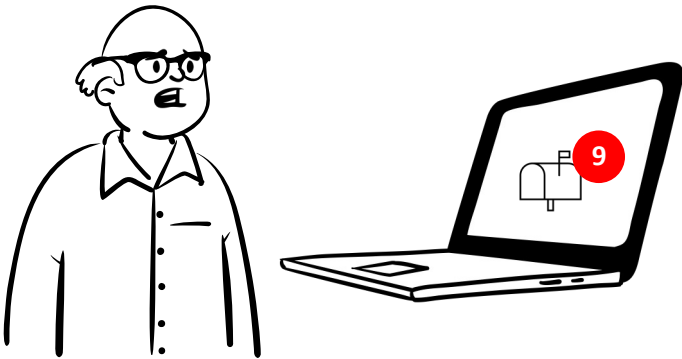
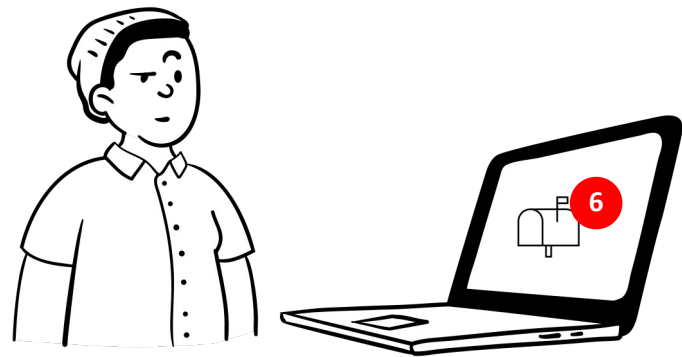


ID	Title	Program	Programmer	QCer	Issues	Status
10	AE summary	aes.sas	ABCDK	XYZDK	1,2	In progress
20	ConMeds	cm.sas	DEFDK	XYZDK		Final

TFL/ADaM QC programmers

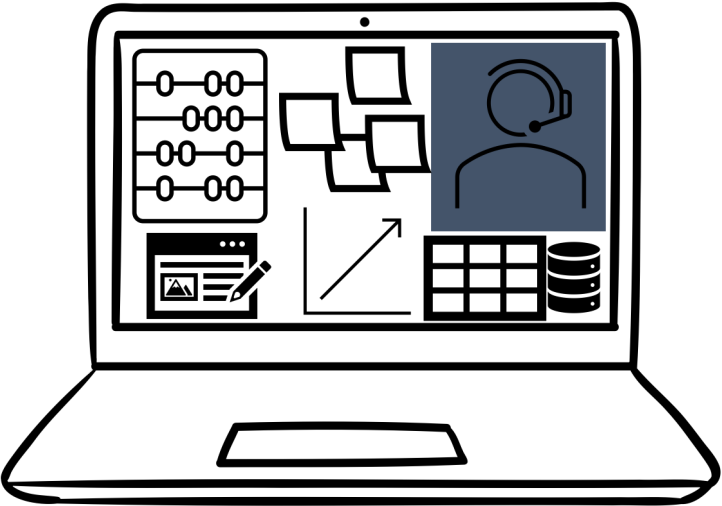


TFL/ADaM programmers



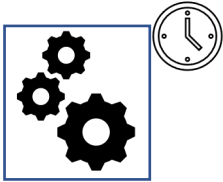
ID	Title	Program	Programmer	QCer	Issues	Status
10	AE summary	aes.sas	ABCDK	XYZDK	1,2	In progress
20	ConMeds	cm.sas	DEFDK	XYZDK		Final

TFL/ADaM QC programmers



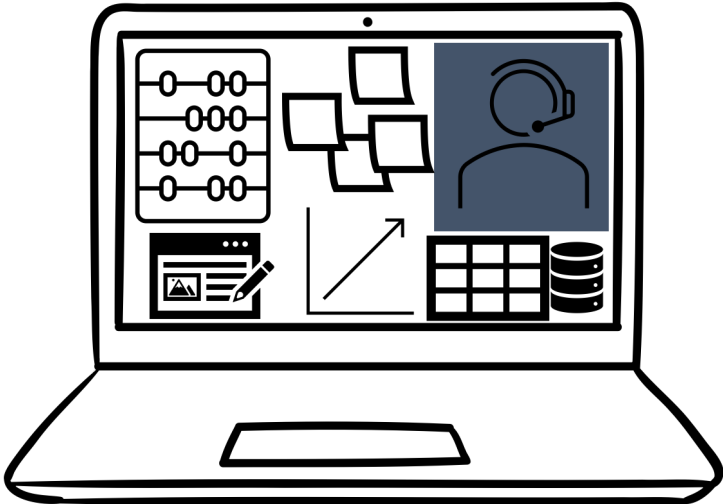
TFL/ADaM programmers

ID	Title	Program	Programmer	QCer	Issues	Status
10	AE summary	ae.sas	ABCDK	XYZDK	1,2	In progress
20	ConMeds	cm.Sas	DEFDK	XYZDK		Final



ID	Title	Program	Programmer	QCer	Issues	Status
10	AE summary	ae.sas	ABCDK	XYZDK	1,2,3	In progress
20	ConMeds	cm.sas	DEFDK	XYZDK		In Progress
30	MedHist	mh.sas	ABCDK	UVWDK		In Progress

TFL/ADaM QC programmers



Task Notifier

- Simple SAS programs to detect differences between two versions of the prog plan
- Job will run at fixed intervals (frequency is up to the team)
- Only people with changes will be notified – and only one mail per time interval

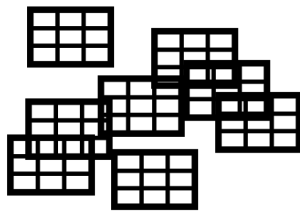
Prog plan change	Who will be notified
New issue	Programmer
New TFL	Programmer/QCer (when present)
Status change	Programmer/QCer
Change of responsible person	Programmer/QCer

Data batch
comparison

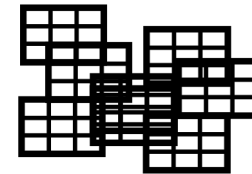
Data batch comparison

- LEO outsources the SDTM generation
- Last minute data cleaning activities are ongoing
- Quick overview of changes in the data batches is desired
- Examples of differences :
 - Added/removed datasets or variables
 - Differences in dataset level/variable level metadata
 - Differences in values for observations with same key

SDTM batch 1



SDTM batch 2

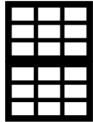


Step 1: Identify old vs new datasets

SDTM batch 1

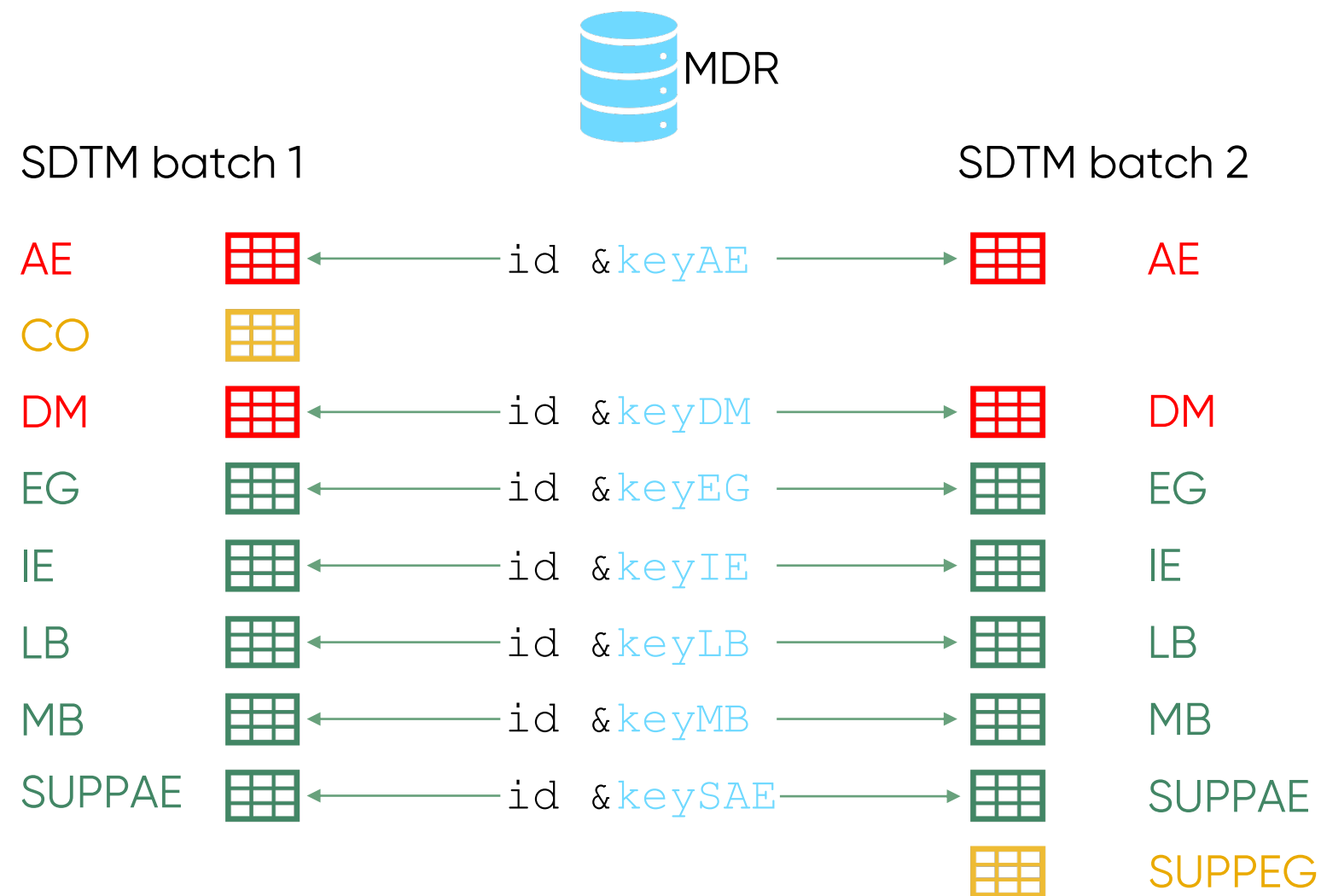
AE	
CO	
DM	
EG	
IE	
LB	
MB	
SUPPAE	

SDTM batch 2

	AE
	DM
	EG
	IE
	LB
	MB
	SUPPAE
	SUPPEG



Step 1: Identify old vs new datasets



Step 2: Dataset level difference overview

- Helicopter view of the differences

DATASET	SYSINFO	Types of mismatches
ae	33	Data set labels differ Variable has different label
ce	0	NO DIFFERENCE BETWEEN OLD & NEW
cm	0	NO DIFFERENCE BETWEEN OLD & NEW
co	0	NO DIFFERENCE BETWEEN OLD & NEW
da	0	NO DIFFERENCE BETWEEN OLD & NEW
dm	4096	A value comparison was unequal

Step 3: All variable level differences

- SAS dataset with all the distinct differences across the domains

DS	_OBS_	VAR	BASE	COMPARE	DIF
DM	1	ACTARM	ARM1	Placebo	XXXXXXXXXX
DM	2	ACTARM	ARM1	WonderDrug	XXXXXXXXXX
DM	5	ACTARM	ARM2	Placebo	XXXXXXXXXX
DM	9	ACTARM	ARM2	WonderDrug	XXXXXXXXXX
EX	1	EXTRT	ARM1	Placebo	XXXXXXXXXX
EX	3	EXTRT	ARM1	WonderDrug	XXXXXXXXXX
EX	4	EXTRT	ARM2	Placebo	XXXXXXXXXX
EX	7	EXTRT	ARM2	WonderDrug	XXXXXXXXXX
...					

Step 4: Extensive Dataset level differences

- SAS dataset per domain showing only variables with differences

DS	_TYPE_	_OBS_	ACTARM	ACTARMCD
DM	BASE	1	ARM1	ARM1
DM	COMPARE	1	WonderDrug	LEO
DM	DIF	1	XXXXXXXXXX	XXXX
DM	BASE	2	ARM2	ARM2
DM	COMPARE	2	Placebo	PLB
DM	DIF	2	XXXXXXX	XXXX
DM	BASE	3	ARM1	ARM1
DM	COMPARE	3	Placebo	PLB
...				

DS	_TYPE_	_OBS_	EXTRT
EX	BASE	1	ARM1
EX	COMPARE	1	WonderDrug
EX	DIF	1	XXXXXXXXXX
EX	BASE	2	ARM2
EX	COMPARE	2	Placebo
EX	DIF	2	XXXXXXX
EX	BASE	3	ARM1
EX	COMPARE	3	Placebo
...			

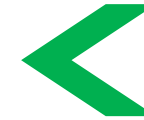
Stale job & Chronology checker

Stale job checker

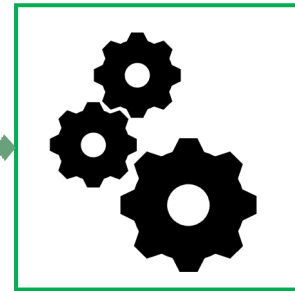
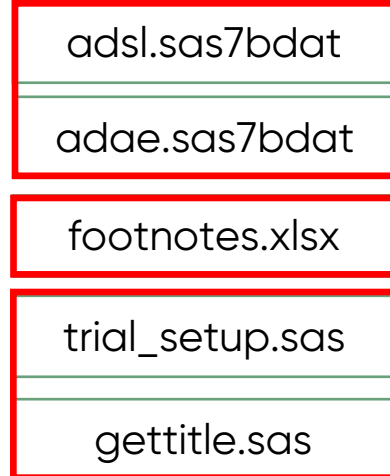
Input Modification
datetime



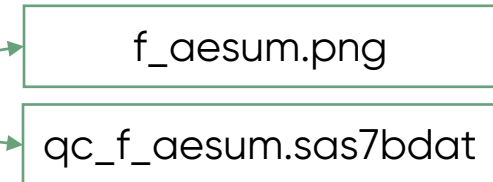
Job Execution
datetime



Output Modification
datetime

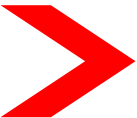


Job



Stale job checker

Input Modification
datetime



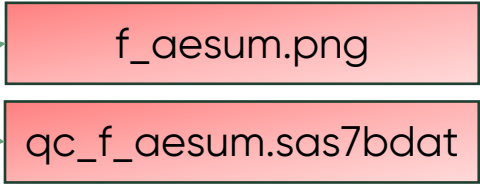
Job Execution
datetime



Output Modification
datetime



Stale Job



Stale job checker

Input Modification
datetime

Job Execution
datetime

Output Modification
datetime

adsl.sas7bdat
adae.sas7bdat
footnotes.xlsx
trial_setup.sas
gettitle.sas

adsl.sas7bdat
adae.sas7bdat
footnotes.xlsx
trial_setup.sas
gettitle.sas

adsl.sas7bdat
adae.sas7bdat
footnotes.xlsx
trial_setup.sas
gettitle.sas

adsl.sas7bdat
adae.sas7bdat
footnotes.xlsx
trial_setup.sas
impute.sas



f_aesum.png
qc_f_aesum.sas7bdat

f_aesum.png
qc_f_aesum.sas7bdat

f_aesum.png
qc_f_aesum.sas7bdat

f_aesum.png
qc_f_aesum.sas7bdat



Stale job checker

- API based utility to identify and list stale jobs
- Identifies the inputs leading to the job becoming stale

Program	Input file	Input file version	Status
/leo/clinical/lp0162/1342/tfl/baseline/jobs/t_subj_disp_scr.job	/leo/clinical/lp0162/1342/adam/data/adsl.sas7bdat	12.0	Stale
/leo/clinical/lp0162/1342/tfl/baseline/jobs/t_subj_disp_scr.job	/leo/clinical/lp0162/1342/tfl/macro/gettitle.sas	11.0	Stale
/leo/clinical/lp0162/1342/tfl/baseline/jobs/f_tt_disc_by_reas.job	/leo/clinical/lp0162/1342/adam/data/adsl.sas7bdat	1.3	Stale
/leo/clinical/lp0162/1342/tfl/baseline/jobs/f_tt_disc_by_reas.job	/leo/clinical/lp0162/1342/tfl/macro/trial_setup.sas	1.3	Stale

Stale job checker

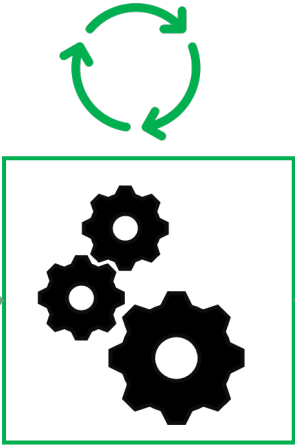
Input Modification
datetime



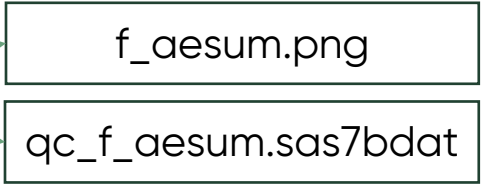
Job Execution
datetime



Output Modification
datetime



Job



Chronology checker

TFL generation

ADaM

ADaM QC

TFL program

TFL

TFL QC

ADSL.sas7bdat

qc_adsl.sas

t_demog.sas

t_demog.txt

qc_t_demog.sas

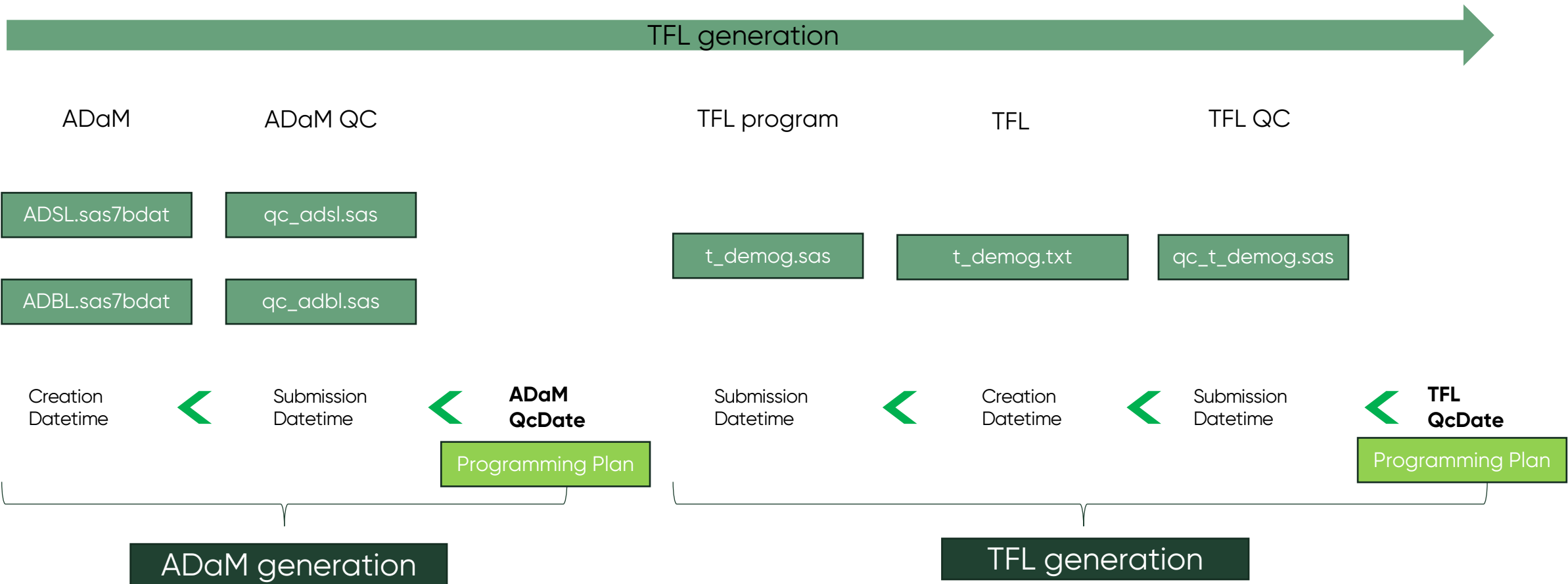
ADBL.sas7bdat

qc_adbl.sas

- **API based utility identifies the jobs that do not follow the expected sequence of execution.**

Chronology checker

Dermatology
beyond the skin



Log & QC summarizer

Log Summarizer

- API based utility that scans through the Log files in the Repository
- Lists the Errors, Warnings and Special Notes in a report

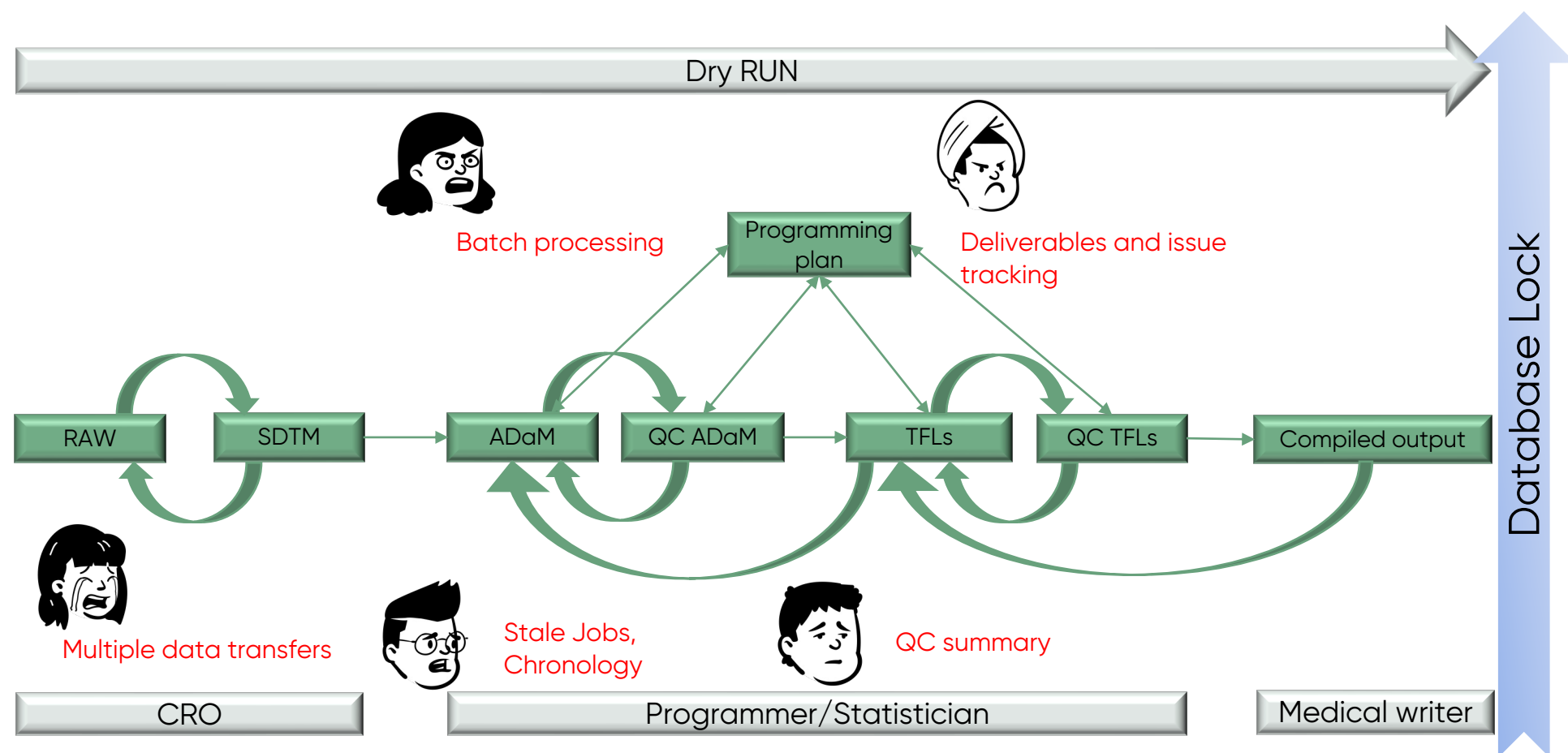
Type	Filename	Line #	Original log message
ERROR	adsl		No ERROR found
WARNING	adsl		No WARNING found
Special NOTES	adsl	140	Missing values were generated from performing operations on missing values.
		487	Variable RANDFL is uninitialized.
		543	Invalid argument to function INPUT. Missing values may be generated.

QC Summarizer

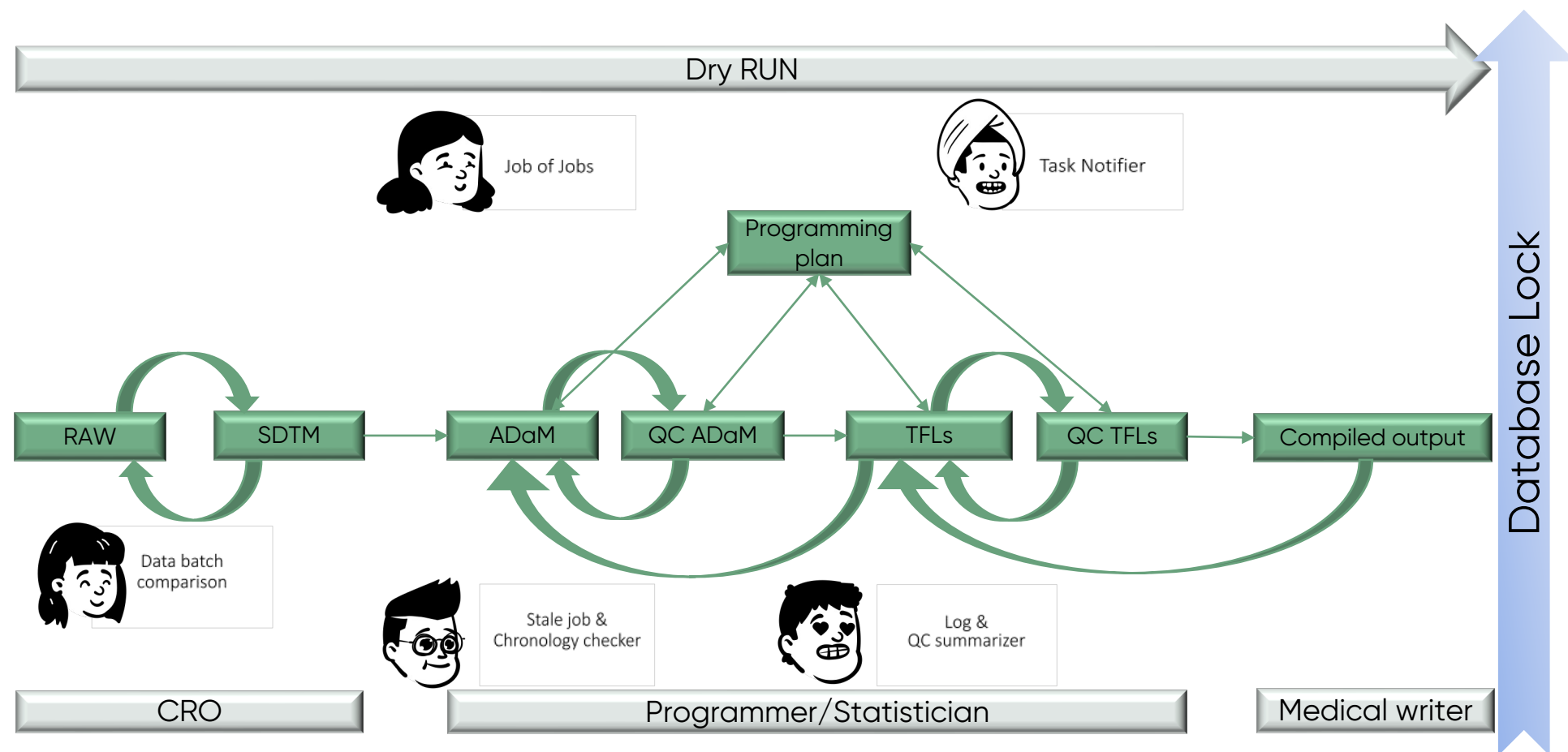
This utility looks for all proc compare results (txt files) created by the qc programs in a folder. It then scans the txt files for any detected differences and generates a report. The report lists all the programs with the information if they have unequal records or not.

Compare report	Line #	Report message
qc_adsl	57	NOTE: No unequal values were found. All values compared are exactly equal.
qc_adsv	215	Total Number of Values which Compare Unequal: 0. Max Diff: 4.2857E-07
qc_adtte	35	NOTE: No unequal values were found. All values compared are exactly equal.
...		

DBL: Hair - raising



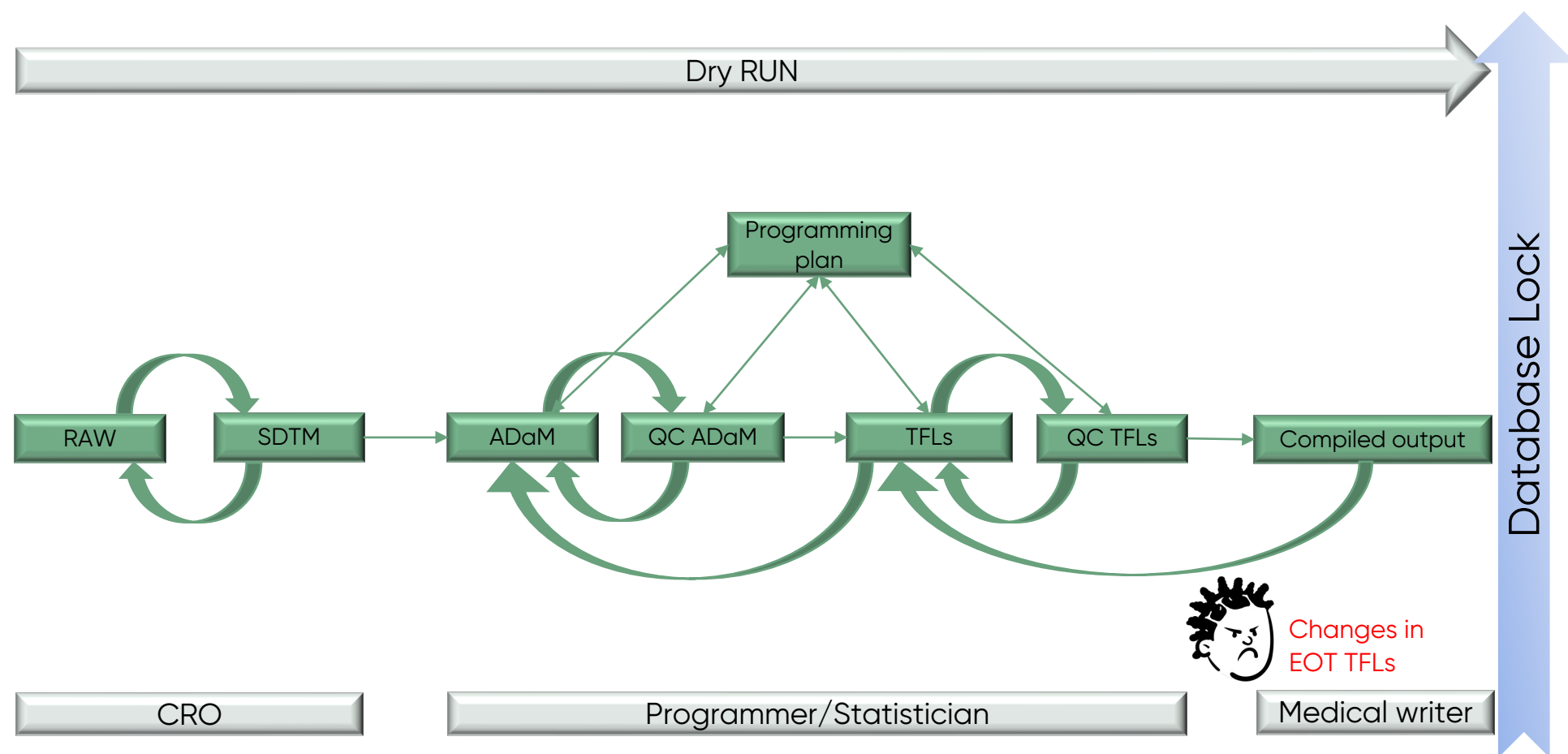
DBL: Zen-tastic



Questions?



Bonus Material: Changes in TFLs



Bonus Material: Changes in TFLs

