

Near Real Time Data Flow

Presenter

Kimberley Santing, Industry Consultant – OCS Life Sciences

Co-authors

Stijn Rogiers, argenx

Sandeep Juneja, argenx

Kai Wanke, OCS Life Sciences

Bas van Bakel, OCS Life Sciences

Emmy Pahmer, OCS Life Sciences

- Introduction
- Near Real Time Data Flow
 - Definitions
 - Examples
 - Conclusion
 - Next steps

EXPERTISE

Multiple Client Engagements Since 1998

TRACK RECORD

Successful consultancy and project delivery

FLEXIBILITY

Size, approach and locations - services tailored to clients

INDEPENDENCE

Privately owned offering impartial advice

PEDIGREE

Commitment - 90% repeat business

WELCOME TO OCS LIFE SCIENCES

OCS Life Sciences is a specialist CRO that focuses on bringing high-value expertise and services to our life sciences clients. We're experienced in all phases of clinical trials in a multitude of therapeutic areas. Our services may be delivered as a resourcing solution where our staff provides support for a given period of time either on-site or off-site, or in the form of a project where OCS Life Sciences takes responsibility for delivering the end product. OCS Life Sciences works with a team of more than 30 employees. We're a Gold Partner of [SAS Institute](#) and a [CDISC](#) Gold Member.

Global clients in the Netherlands, Switzerland, Belgium and the UK are engaging in OCS Life Sciences' services.

See how OCS Life Sciences can help you.



Reaching Patients Through Immunology Innovation

The science of co-creation drives our quest to engineer life-changing immunology solutions, the resilient spirit of patients fuels our urgency to deliver them.

The infinity sign symbolizes our commitment to science and patients; it has no bounds.



Patients



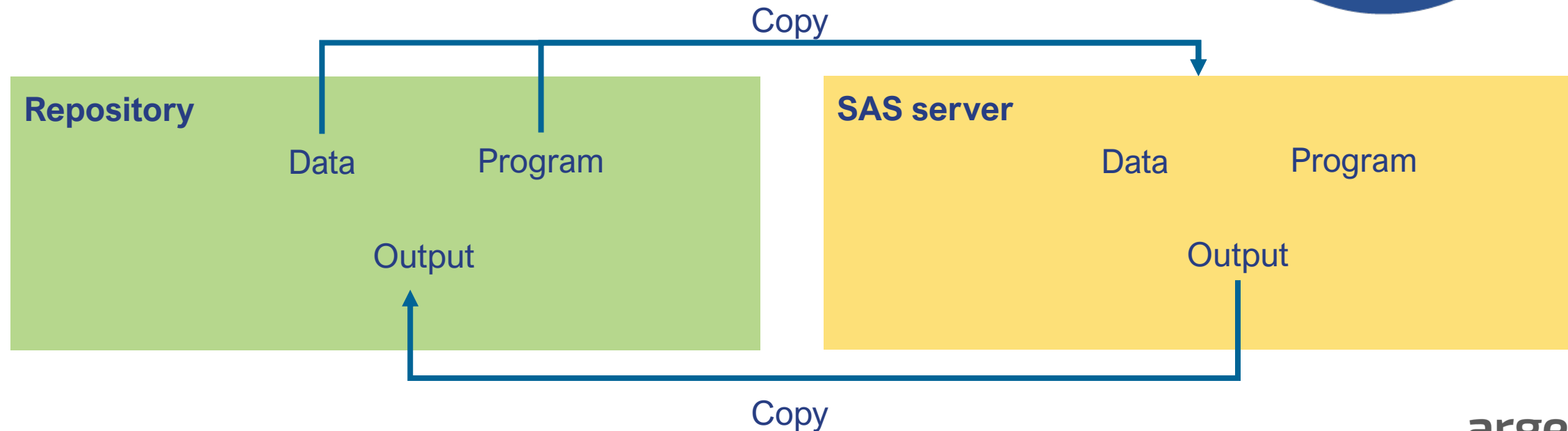
Where we operate



Innovation



- **SAS Life Science Analytics Framework (LSAF)**
- **Structured data repository + Computing environment**
- **Jobs: run SAS code and make output available in repository**



- 2022 - 2024
- Monthly data is no longer sufficient
- Need for near real time data
 - EDC data > internal SDTM data (gSDTM) > internal ADaM data (gADaM)
 - Improved trial oversight & insights
 - Completely automated



Create an LSAF process flow that executes the below steps in an efficient way.

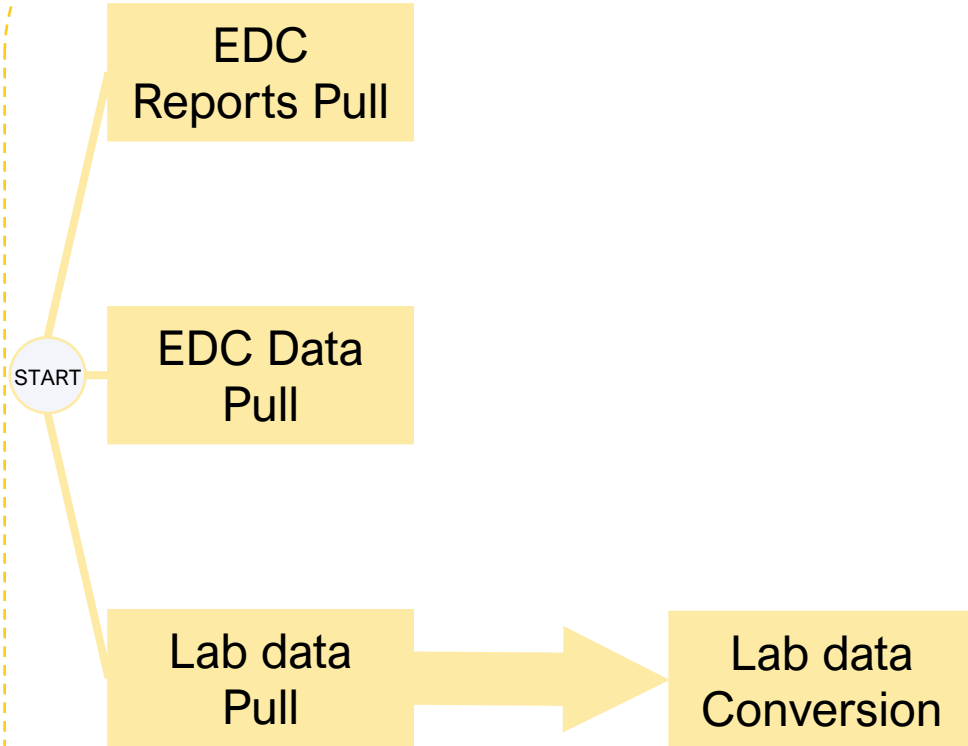
- Pull EDC data from CRO Medidata Rave server
- Create gSDTM
- Push to illuminate platform (eCS)

Additional requirements:

- Pull in custom EDC reports from Medidata Rave
 - Create Adjusted Rave Reports
- Pull in Lab data from lab vendor server
 - Use in gSDTM
 - Create sample tracking reports
- Perform QC checks on the created gSDTM
- Make all output available in eCS
- Process flow error handling and notifications

Near Real Time Data Flow - Overview

Data Ingestion

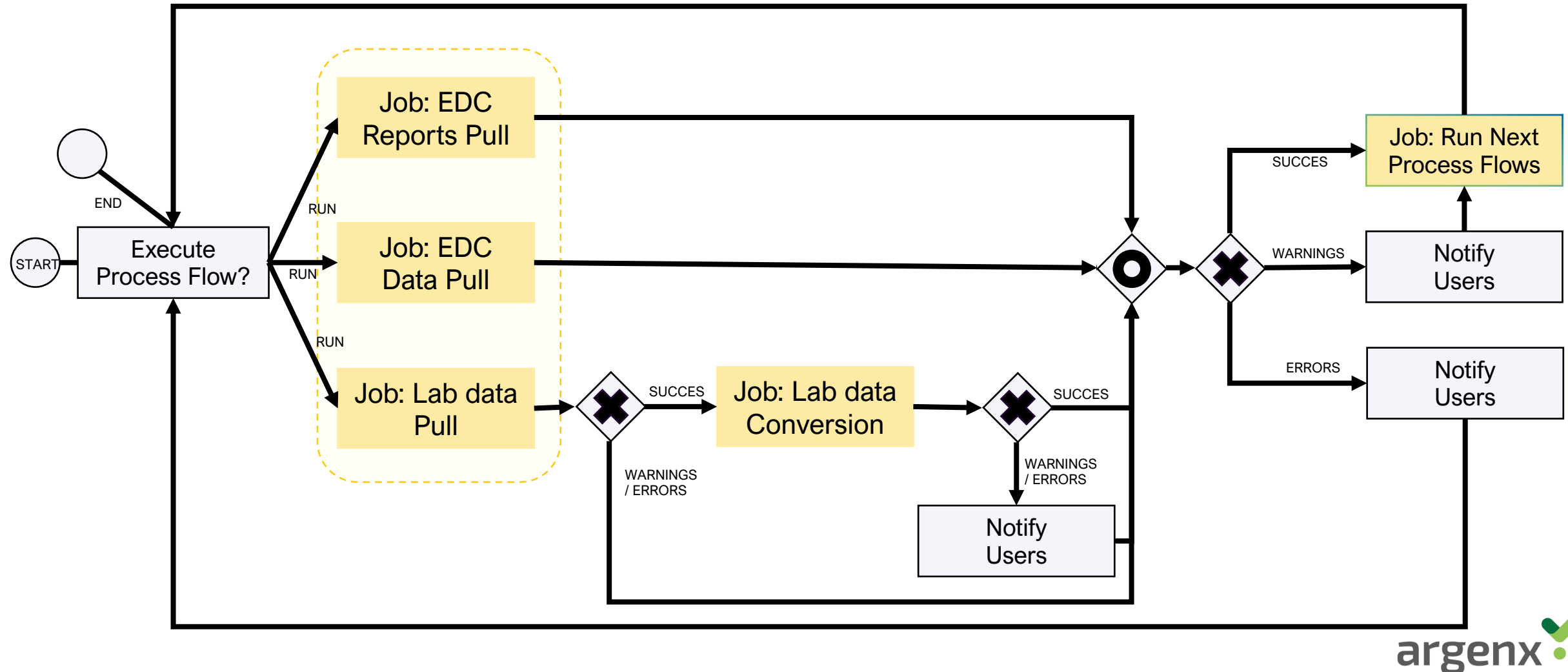


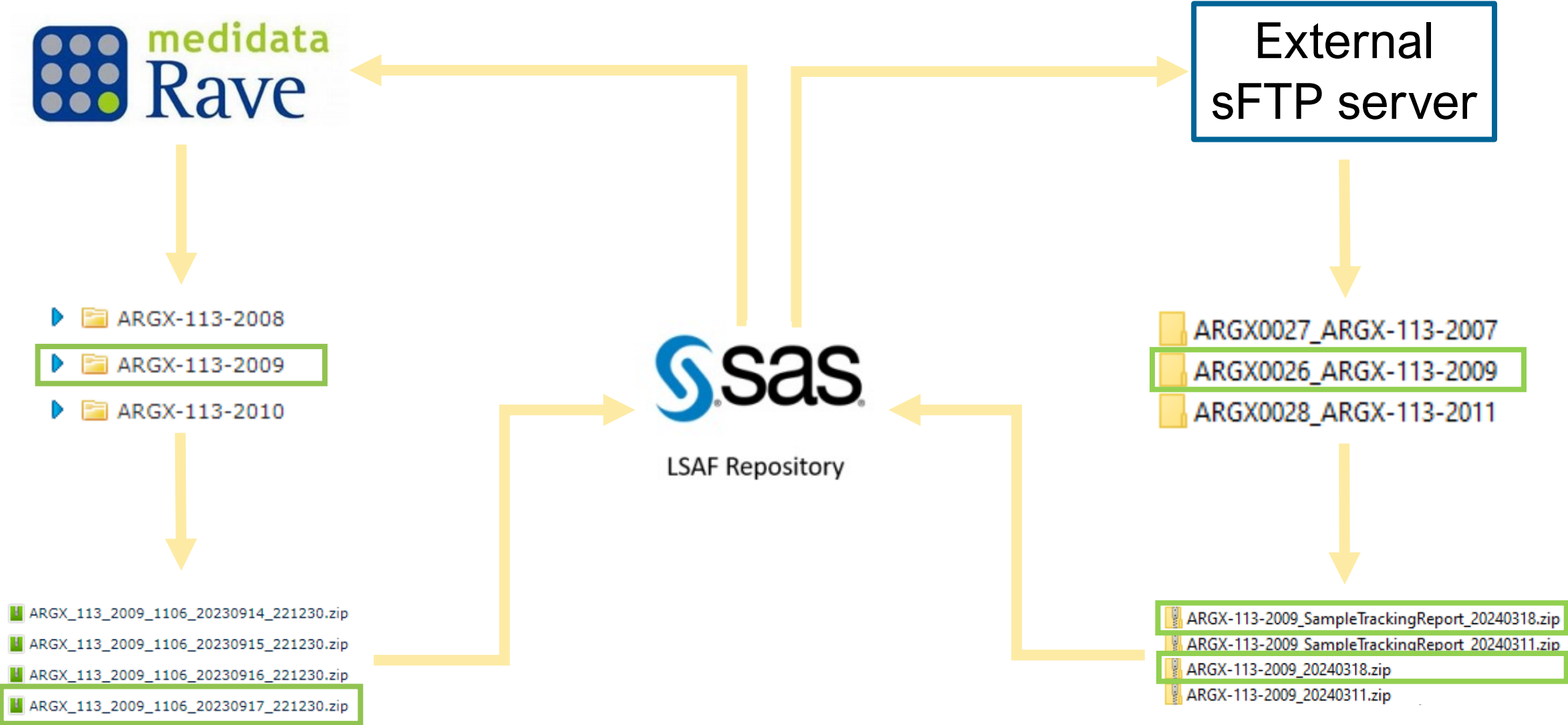
Report

gSDTM

Report

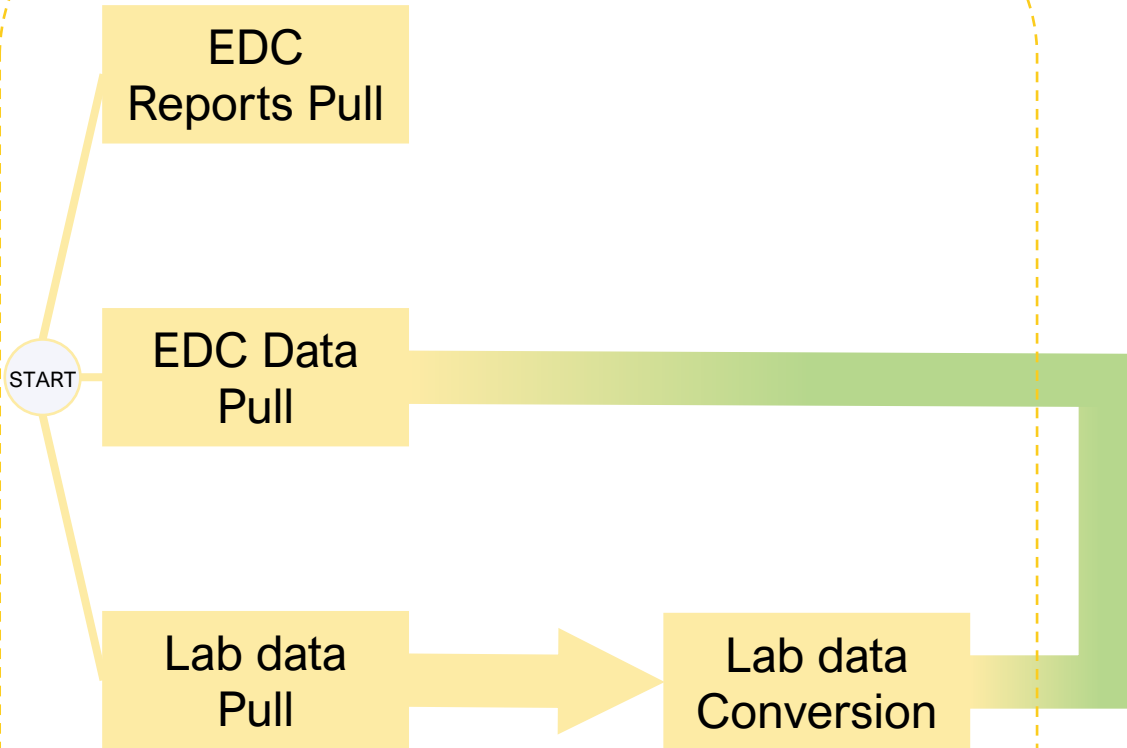
1. Pulls in data from different servers > 2. Converts data where needed > 3. Starts other process flows





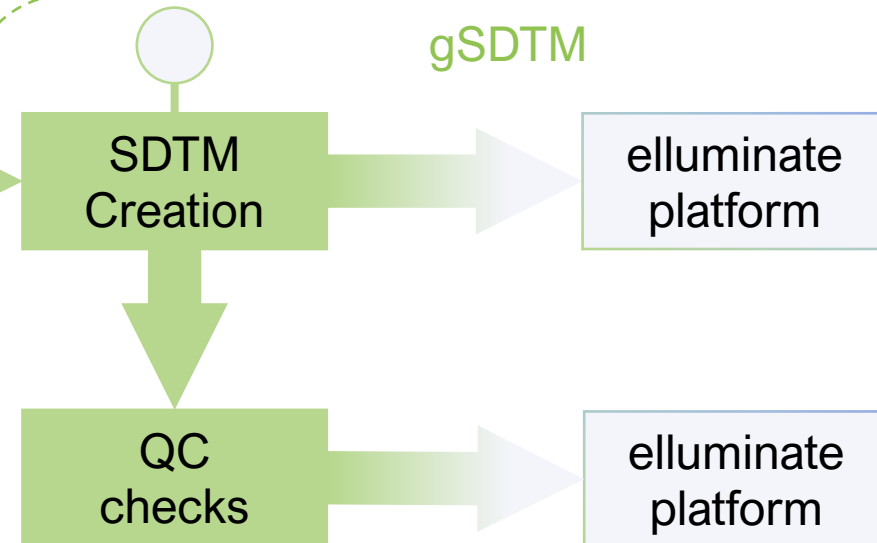
Near Real Time Data Flow - Overview

Data Ingestion



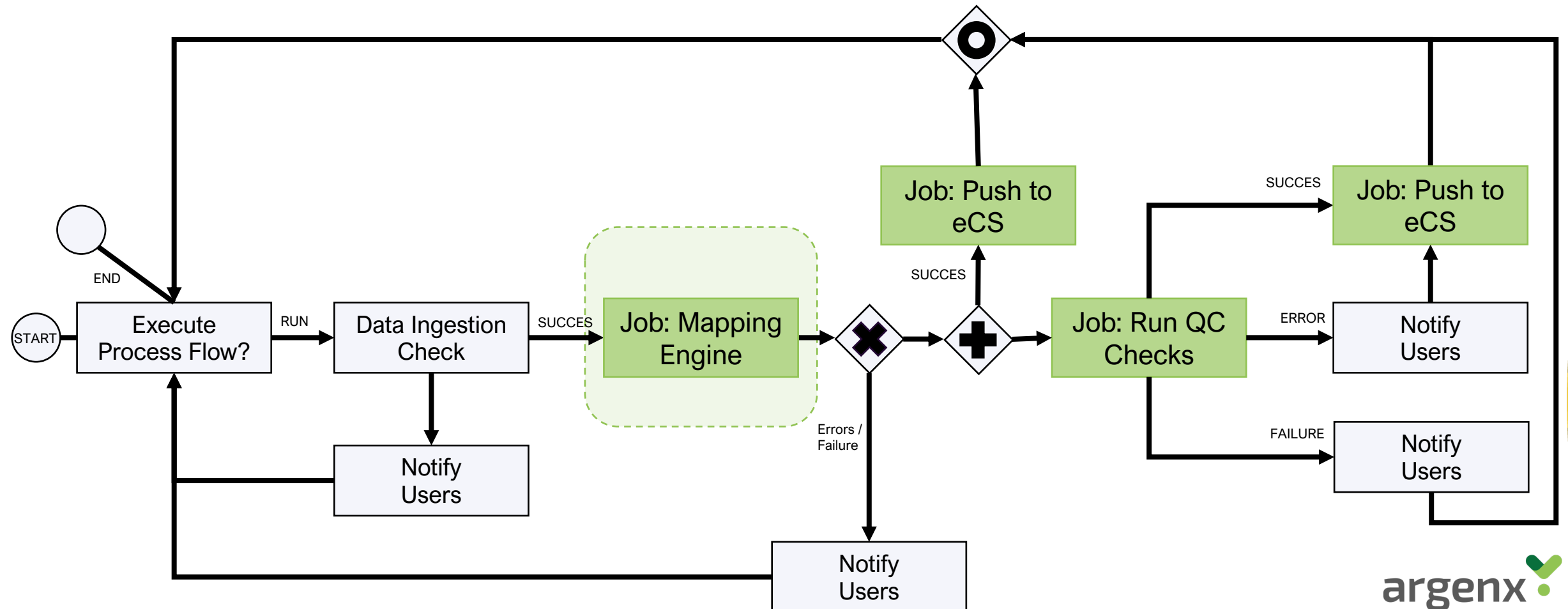
Report

gSDTM



Report

- Triggered by data ingestion flow
- Creates gSDTM & performs QC checks



1961	EDC.DRUGTERM	Subject	DS	SUBJID	Copy from the source	COPY
1985	EDC.DRUGTERM	DS_TERM_TRT	DS	DSDECOD	Recode using EOT recoding	RECODE [EOT]
1986	EDC.DRUGTERM	DS_DECOD_TRT_STD	DS	DSDECOD	When DSDECOD obtained via the EOT recoding is missing, (e.g. if the subject completed the treatment or no reason for discontinuation is specified) the DSDECOD is set to the value of DS_DECOD_TRT_STD ('COMPLETED' or 'DISCONTINUED').	FUNCTION [IF MISSING(#TARGET#) THEN #TARGET# = #SOURCE#;]
	EDC.DRUGTERM	DS_TERM_OTH	DS	DSTERM	DSTERM is set equal to DSDECOD, except when the DS_TERM_OTH is available. In that case DS_TERM_OTH contains the specification of the OTHER reason and it is to be used to overwrite the value 'OTHER' that would otherwise be available.	FUNCTION [#TARGET# = dsdecod; IF NOT(MISSING(#SOURCE#)) THEN DO; IF NOT(dsdecod = 'OTHER') THEN PUT "WAR" "NING: DS_DECOD_TRT_STD and DS_TERM_OTH combination is unexpected: " subjid= ; #TARGET# = STRIP(UPCASE(#SOURCE#)); END;]
1987						
1991	EDC.DRUGTERM	DS_DAT_ST_TRT_YY	DS	DSSTDTC	Generate an ISO date from the available _DD, _MM and _YY variables.	ISODATE [YMD=DS_DAT_ST_TRT_]
1992	EDC.DRUGTERM	DS_DAT_ST_TRT_MM	DS	DSSTDTC	See derivation at the _YY variable.	
1993	EDC.DRUGTERM	DS_DAT_ST_TRT_DD	DS	DSSTDTC	See derivation at the _YY variable.	
1994	EDC.DRUGTERM	DS_DECOD_TRT_STD	DS	DSSTDTC	When the subject completed the treatment the date DSSTDTC should be left blank. (It is not collected)	FUNCTION [IF #SOURCE# = 'COMPLETED' THEN CALL MISSING(#TARGET#);]
1997	EDC.DRUGTERM	DS_DAT_PRE_YY	DS	DSPREDTC	Generate an ISO date from the available _DD, _MM and _YY variables.	ISODATE [YMD=DS_DAT_PRE_]
1998	EDC.DRUGTERM	DS_DAT_PRE_MM	DS	DSPREDTC	See derivation at the _YY variable.	
1999	EDC.DRUGTERM	DS_DAT_PRE_DD	DS	DSPREDTC	See derivation at the _YY variable.	
2002	EDC.DRUGTERM	DS_DAT_CW_YY	DS	DSCWDTC	Generate an ISO date from the available _DD, _MM and _YY variables.	ISODATE [YMD=DS_DAT_CW_]
2003	EDC.DRUGTERM	DS_DAT_CW_MM	DS	DSCWDTC	See derivation at the _YY variable.	
2004	EDC.DRUGTERM	DS_DAT_CW_DD	DS	DSCWDTC	See derivation at the _YY variable.	
2011	EDC.DRUGTERM	RELREC_AE_1_STD	DS		Keep to create RELREC records	KEEP
2015	EDC.DRUGTERM		DS	DOMAIN	Assign DOMAIN to 'DS'	ASSIGN [DS]
2016	EDC.DRUGTERM		DS	DSCAT	Assign DSCAT to 'DISPOSITION EVENT'	ASSIGN [DISPOSITION EVENT]
2017	EDC.DRUGTERM		DS	DSSCAT	Assign DSSCAT to 'TREATMENT'	ASSIGN [TREATMENT]

Source
Dataset and Variable

SDTM
Domain and
Variable

Human-readable
specification

Machine-executable
(pseudo-)code

1961	EDC.DRUGTERM	Subject	DS	SUBJID	Copy from the source	COPY
1985	EDC.DRUGTERM	DS_TERM_TRT	DS	DSDECOD	Recode using EOT recoding	RECODE [EOT]
	EDC.DRUGTERM	DS_DECOD_TRT_STD	DS	DSDECOD	When DSDECOD obtained via the EOT recoding is missing, (e.g. if the subject completed the treatment or no reason for discontinuation is specified) the DSDECOD is set to the value of DS_DECOD_TRT_STD ('COMPLETED' or 'DISCONTINUED').	FUNCTION [IF MISSING(#TARGET#) THEN #TARGET# = #SOURCE#;]
1986	EDC.DRUGTERM	DS_TERM_OTH	DS	DSTERM	DSTERM is set equal to DSDECOD, except when the DS_TERM_OTH is available. In that case DS_TERM_OTH contains the specification of the OTHER reason and it is to be used to overwrite the value 'OTHER' that would otherwise be available.	FUNCTION (#TARGET# = dsdecod; IF NOT(MISSING(#SOURCE#)) THEN DO; IF NOT(dsdecod = 'OTHER') THEN PUT "WAR" "NING: DS_DECOD_TRT_STD and DS_TERM_OTH combination is unexpected: " subjId= ; #TARGET# = STRIP(UPCASE(#SOURCE#)); END;]
1987	EDC.DRUGTERM	DS_TERM_OTH	DS	DSTERM	DSTERM is set equal to DSDECOD, except when the DS_TERM_OTH is available. In that case DS_TERM_OTH contains the specification of the OTHER reason and it is to be used to overwrite the value 'OTHER' that would otherwise be available.	FUNCTION (#TARGET# = dsdecod; IF NOT(MISSING(#SOURCE#)) THEN DO; IF NOT(dsdecod = 'OTHER') THEN PUT "WAR" "NING: DS_DECOD_TRT_STD and DS_TERM_OTH combination is unexpected: " subjId= ; #TARGET# = STRIP(UPCASE(#SOURCE#)); END;]
1991	EDC.DRUGTERM	DS_DAT_ST_TRT_YY	DS	DSSTDTC	Generate an ISO date from the available _DD, _MM and _YY variables.	ISODATE [YMD=DS_DAT_ST_TRT_]
1992	EDC.DRUGTERM	DS_DAT_ST_TRT_MM	DS	DSSTDTC	See derivation at the _YY variable.	
1993	EDC.DRUGTERM	DS_DAT_ST_TRT_DD	DS	DSSTDTC	See derivation at the _YY variable.	
1994	EDC.DRUGTERM	DS_DECOD_TRT_STD	DS	DSSTDTC	When the subject completed the treatment the date DSSTDTC should be left blank. (It is not collected)	FUNCTION [IF #SOURCE# = 'COMPLETED' THEN CALL MISSING(#TARGET#);]
1997	EDC.DRUGTERM	DS_DAT_PRE_YY	DS	DSPREDTC	Generate an ISO date from the available _DD, _MM and _YY variables.	ISODATE [YMD=DS_DAT_PRE_]
1998	EDC.DRUGTERM	DS_DAT_PRE_MM	DS	DSPREDTC	See derivation at the _YY variable.	
1999	EDC.DRUGTERM	DS_DAT_PRE_DD	DS	DSPREDTC	See derivation at the _YY variable.	
2002	EDC.DRUGTERM	DS_DAT_CW_YY	DS	DSCWDTC	Generate an ISO date from the available _DD, _MM and _YY variables.	ISODATE [YMD=DS_DAT_CW_]
2003	EDC.DRUGTERM	DS_DAT_CW_MM	DS	DSCWDTC	See derivation at the _YY variable.	
2004	EDC.DRUGTERM	DS_DAT_CW_DD	DS	DSCWDTC	See derivation at the _YY variable.	
2011	EDC.DRUGTERM	RELREC AE 1 STD	DS		Keep to create RELREC records	KEEP
2015	EDC.DRUGTERM		DS	DOMAIN	Assign DOMAIN to 'DS'	ASSIGN [DS]
2016	EDC.DRUGTERM		DS	DSCAT	Assign DSCAT to 'DISPOSITION EVENT'	ASSIGN [DISPOSITION EVENT]
2017	EDC.DRUGTERM		DS	DSSCAT	Assign DSSCAT to 'TREATMENT'	ASSIGN [TREATMENT]

```

if DSDECOD="-9999.9999" then do;
  put "WARN" "ING: Variable [DS_TERM_TRT] contains value [" DS_TERM_TRT "] not in codelist [EOT]";
  call missing(DSDECOD);
end;

/* #1961: Copy from the source */
SUBJID=strip(SUBJECT);

/* #1986: When DSDECOD obtained via the EOT recoding is missing, (e.g. if the subject completed the treatment or no reason for discontinuation is
IF MISSING(DSDECOD) THEN DSDECOD = DS_DECOD_TRT_STD;
/* #1987: DSTERM is set equal to DSDECOD, except when the DS_TERM_OTH is available. In that case DS_TERM_OTH contains the specification of the OTH
DSTERM = dsdecod;
IF NOT(MISSING(DS_TERM_OTH)) THEN DO;
  IF NOT(dsdecod = 'OTHER') THEN PUT "WAR" "NING: DS_DECOD_TRT_STD and DS_TERM_OTH combination is unexpected: " subjId= ;
  DSTERM = STRIP(UPCASE(DS_TERM_OTH));
END;

/* #1991: Generate an ISO date from the available _DD, _MM and _YY variables. */
%convert_datetime(inday = DS_DAT_ST_TRT_DD, inmonth = DS_DAT_ST_TRT_MM, inyear = DS_DAT_ST_TRT_YY, indatfmt = NUM, outdate = DSSTDTC);
/* #1994: When the subject completed the treatment the date DSSTDTC should be left blank. (It is not collected) */
IF DS_DECOD_TRT_STD = 'COMPLETED' THEN CALL MISSING(DSSTDTC);
/* #1997: Generate an ISO date from the available _DD, _MM and _YY variables. */
%convert_datetime(inday = DS_DAT_PRE_DD, inmonth = DS_DAT_PRE_MM, inyear = DS_DAT_PRE_YY, indatfmt = NUM, outdate = DSPREDTC);
/* #2002: Generate an ISO date from the available _DD, _MM and _YY variables. */
%convert_datetime(inday = DS_DAT_CW_DD, inmonth = DS_DAT_CW_MM, inyear = DS_DAT_CW_YY, indatfmt = NUM, outdate = DSCWDTC);

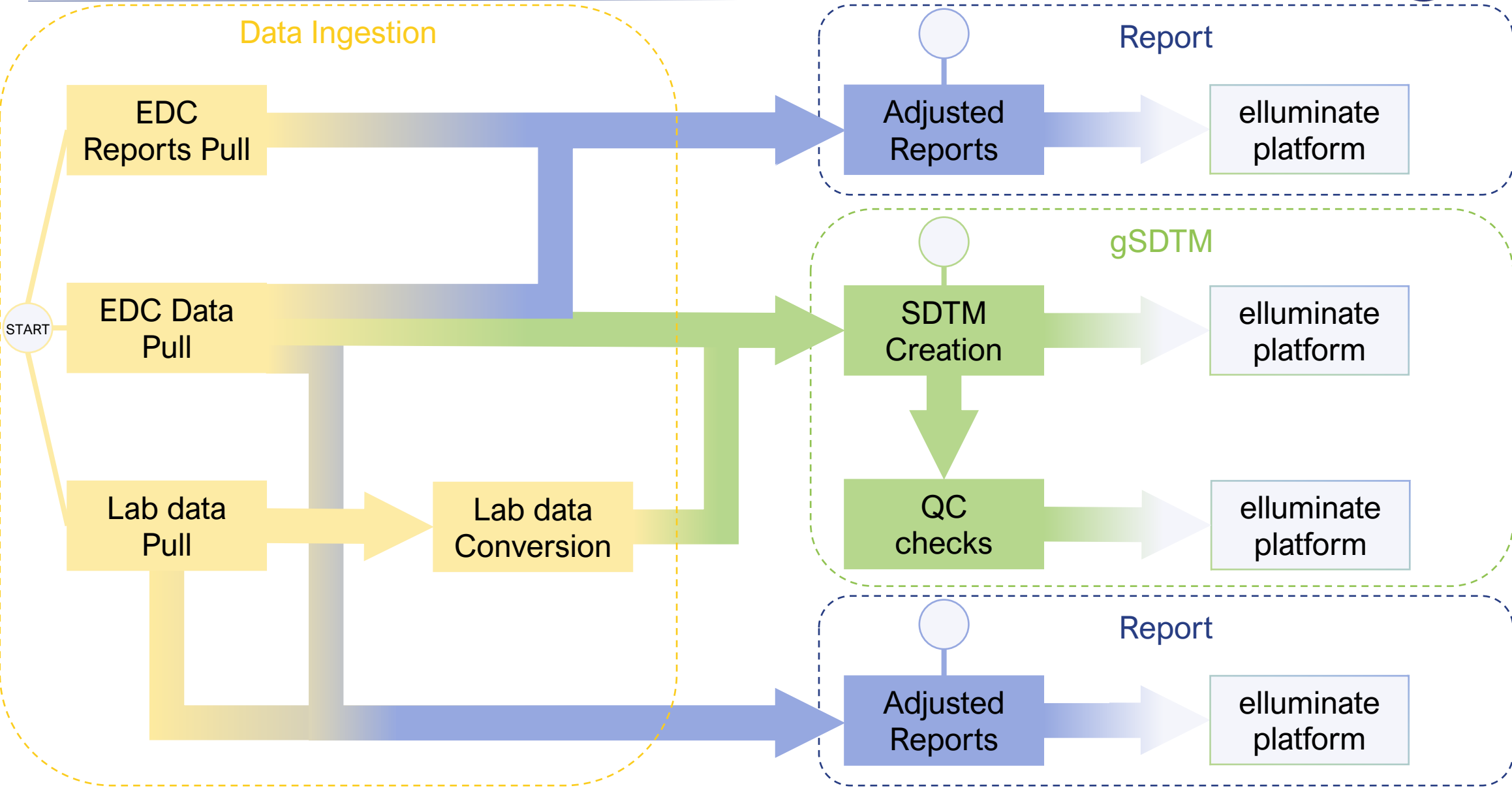
/* #2015: Assign DOMAIN to 'DS' */
DOMAIN="DS";
/* #2016: Assign DSCAT to 'DISPOSITION EVENT' */
DSCAT="DISPOSITION EVENT";
/* #2017: Assign DSSCAT to 'TREATMENT' */
DSSCAT="TREATMENT";

run;

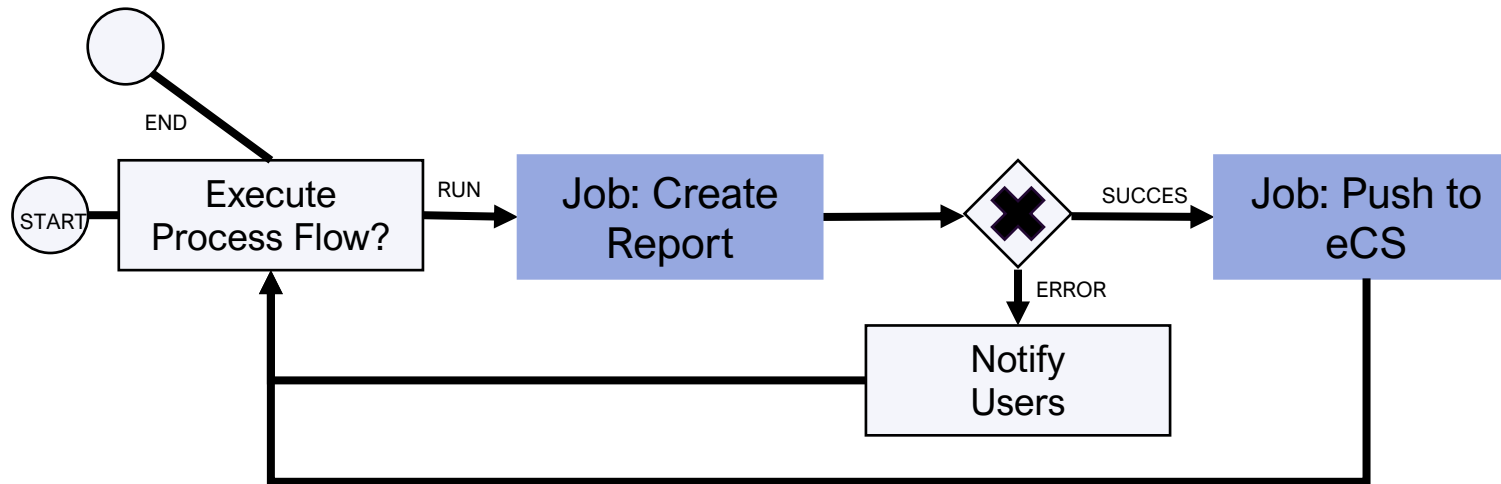
```

Near Real Time Data Flow - Overview

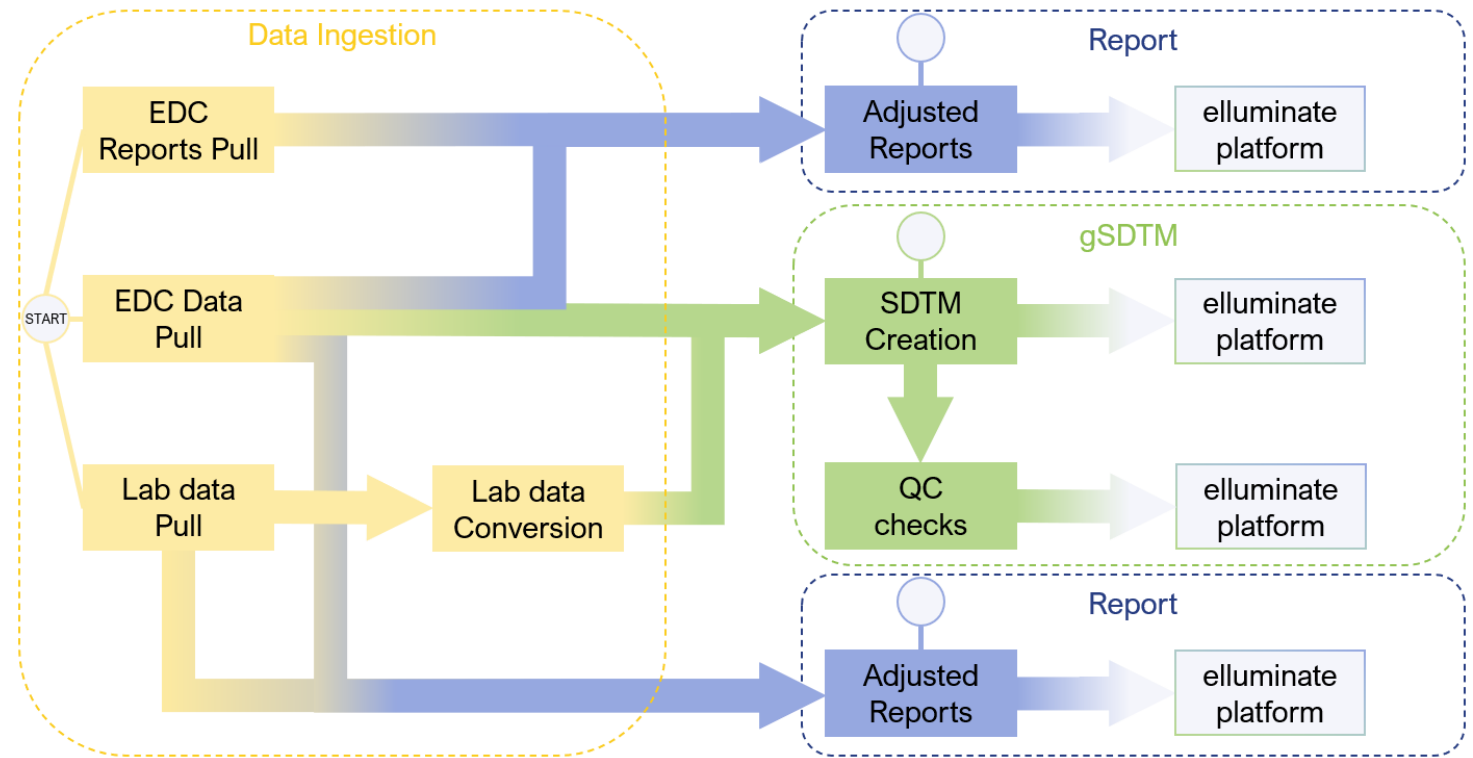
Data Ingestion



- Simple definition: creates report and pushes report
 - 1. Adjusted Rave Reports > Trial oversight
 - 2. Knowledge in Lab Tracking > Sample oversight
- Flexible use for future reports



- Pull raw data + Conversion
- Create gSDTM
- Create (QC) reports
- Push to illuminate Platform (eCS)
- Completely automated



- One schedule per study makes all of this possible
- Start to end takes ~10 min

Near Real Time Data Flow – Next Steps

PF_TASK_ID	PF_TASK_TYPE	TASK_JOB_PATH	TASK_JOB_PARAMETERS	PF_TASK_ID	PF_TASK_TYPE	TASK_JOB_PATH	TASK_JOB_PARAMETERS
_data_ingestion_trigger	USER_TASK			_data_ingestion_trigger	USER_TASK		
_02_rave_reports_pull	SYSTEM_JOB_EXEC	/clinical/argx-113/bp/argx-113-2009/dm/g_sdtm/current/2_jobs/ftp/ftp_rave_run_all_jobs.job	lsaf_path::FOLDER:.../.../.../.../.../; cro::CHARACTER::CRO; jobid::CHARACTER::21895; sasondemand::CHARACTER::Y	_02_rave_reports_pull	SYSTEM_JOB_EXEC	<study_path>/dm/g_sdtm/current/2_jobs/ftp/ftp_rave_run_all_jobs.job	lsaf_path::FOLDER:.../.../.../.../.../; cro::CHARACTER::<cro>; jobid::CHARACTER::<jobid>; sasondemand::CHARACTER::<sod>
_03_rave_pull	SYSTEM_JOB_EXEC	/clinical/argx-113/bp/argx-113-2009/dm/g_sdtm/current/2_jobs/ftp/ftp_rave_run_all_jobs.job	lsaf_path::FOLDER:.../.../.../.../.../; cro::CHARACTER::CRO; jobid::CHARACTER::Reports; sasondemand::CHARACTER::Y	_03_rave_pull	SYSTEM_JOB_EXEC	<study_path>/dm/g_sdtm/current/2_jobs/ftp/ftp_rave_run_all_jobs.job	lsaf_path::FOLDER:.../.../.../.../.../; cro::CHARACTER::<cro>; jobid::CHARACTER::Reports; sasondemand::CHARACTER::<sod>
_04_lab_pull	SYSTEM_JOB_EXEC	/general/dm/jobs/gsdtm_sftp_ext/prod/jobs/sftp_ext_pull.job	lsaf_path::CHARACTER::/clinical/argx-113/bp/argx-113-2009;	_04_lab_pull	SYSTEM_JOB_EXEC	/general/dm/jobs/gsdtm_sftp_ext/prod/jobs/sftp_ext_pull.job	lsaf_path::CHARACTER::<study_path>;
_05_fail_notification	SYSTEM_NOTIFICATION			_05_fail_notification	SYSTEM_NOTIFICATION		

- 1. Fill out placeholders
- 2. Run a job to create the process flow
- 3. Schedule job that starts the process flow
- 4. Enjoy Near Real Time Data

STUDY	PLACEHOLDER	VALUE
argx-113-2009	study_path	/clinical/argx-113/bp/argx-113-2009
argx-113-2009	cro	CRO
argx-113-2009	jobid	21895
argx-113-2009	sod	Y

The argenx logo features the word "argenx" in a white, lowercase, sans-serif font. To the right of the text is a stylized checkmark icon composed of two overlapping shapes: a light blue one on the left and a white one on the right.

argenx

Thank You

The OCS Life Sciences logo consists of a circular icon on the left, which contains a stylized white 'S' shape. To the right of the icon, the text "OCS" is written in a large, bold, white, sans-serif font, and "LIFE SCIENCES" is written below it in a smaller, white, sans-serif font.

OCS
LIFE SCIENCES