



Health Science – Clinical Research

DH03: Streaming external data from your lazy work couch

Health Inspired,
Quality Driven.



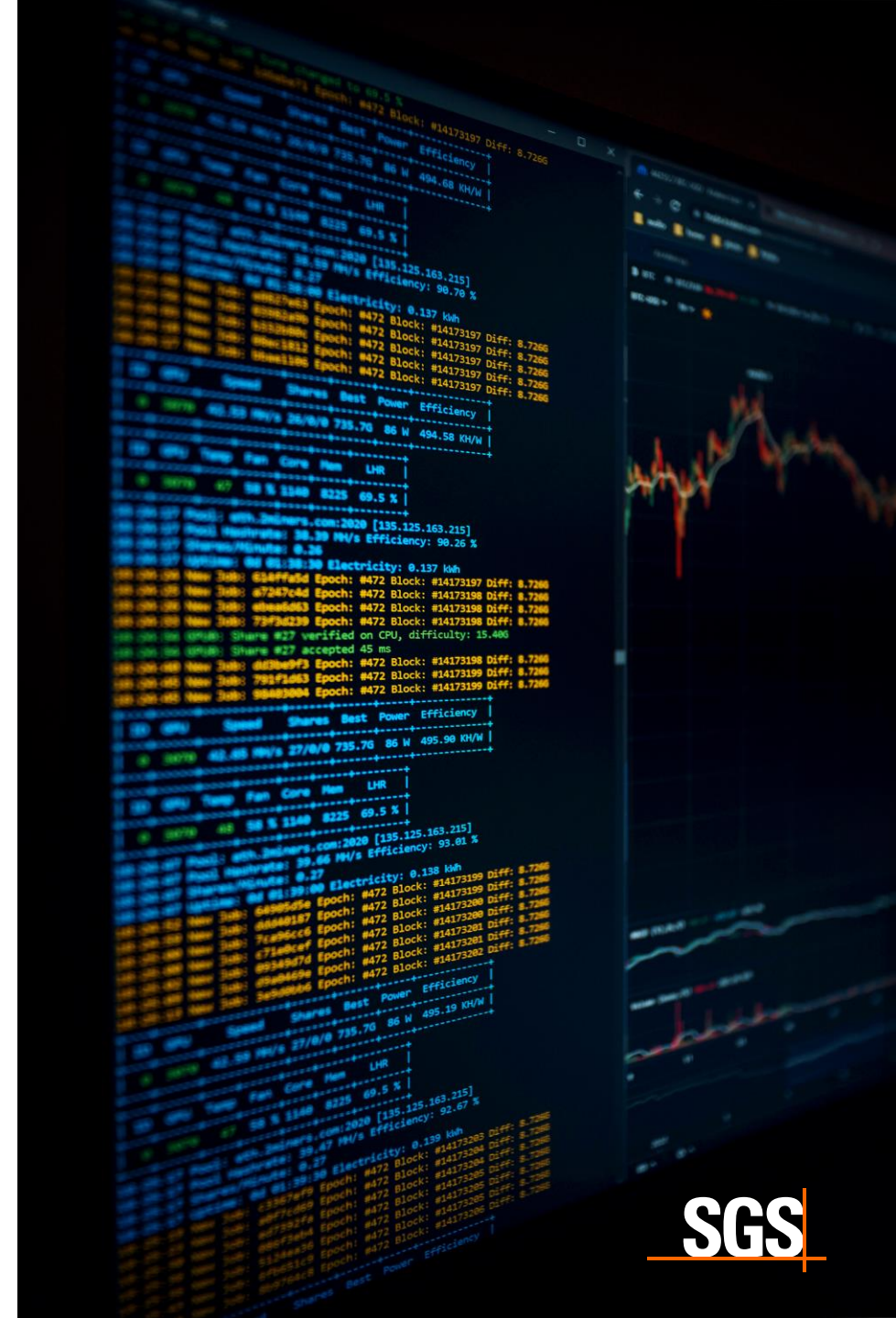
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Agenda

- Introduction to streaming
- Flow
 - First contact with vendor
 - DTA
 - Annotated DTA
 - Load
 - Validation test transfer
 - Production transfer
 - (a)DTA Library
- Conclusions

Introduction to streaming

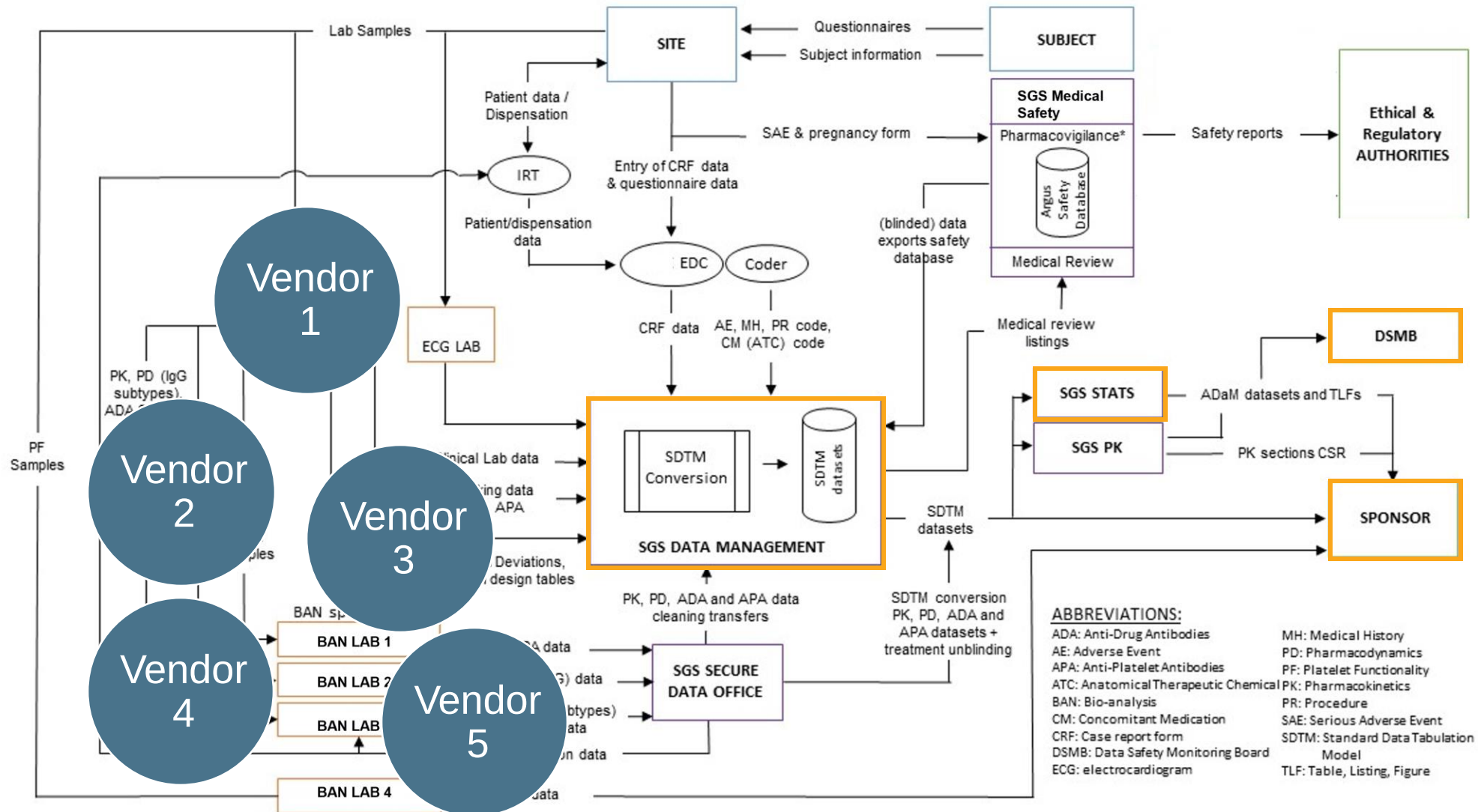


Clinical research today

- Complex study designs
- Complicated data and multiple datastreams
- Numerous stakeholders, vendors
- Strict regulations
- High Quality data
- Time is precious
- Short timelines



Introduction to streaming



Introduction to streaming

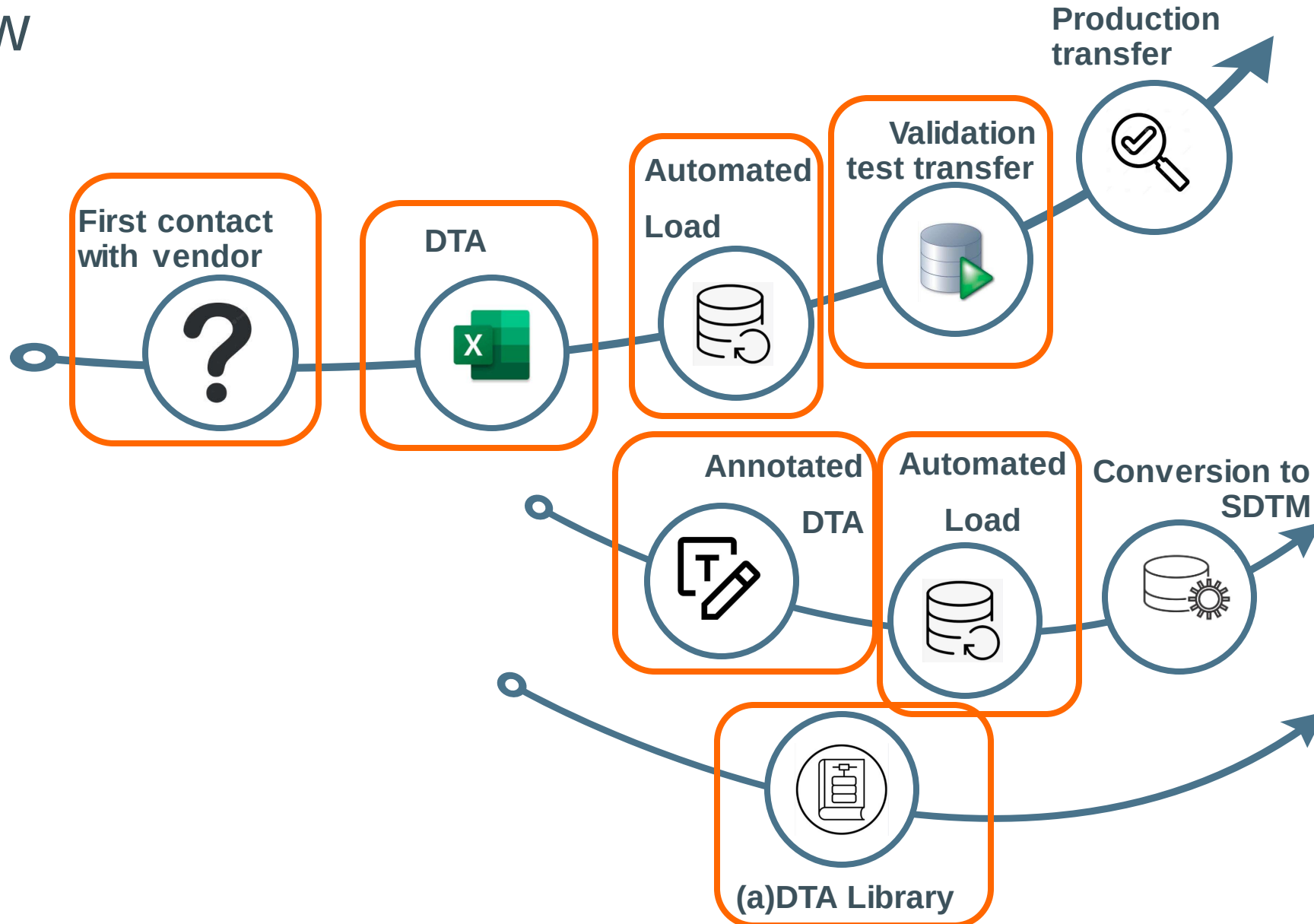


Are you ready to streamline all this data from your lazy work couch?

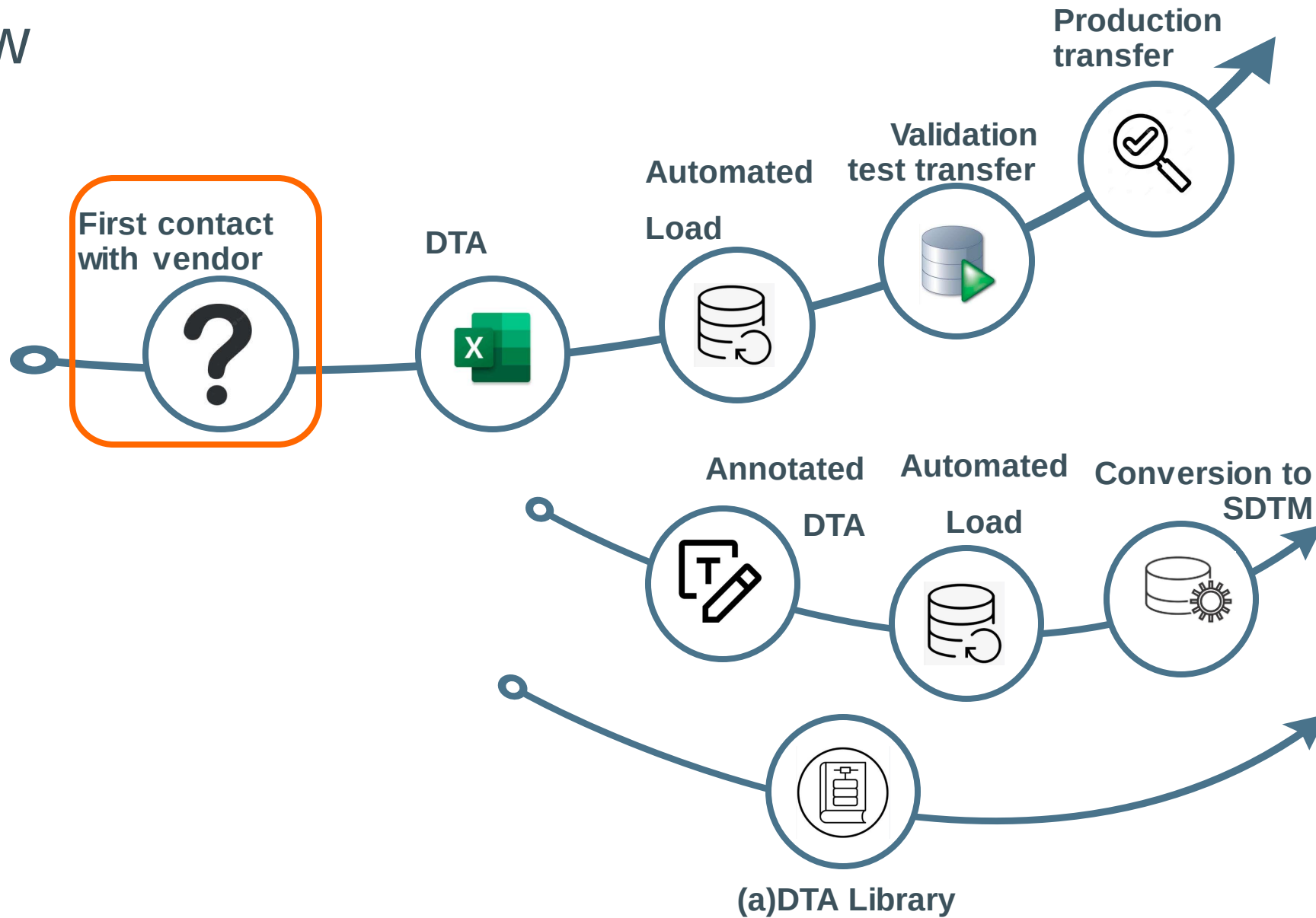




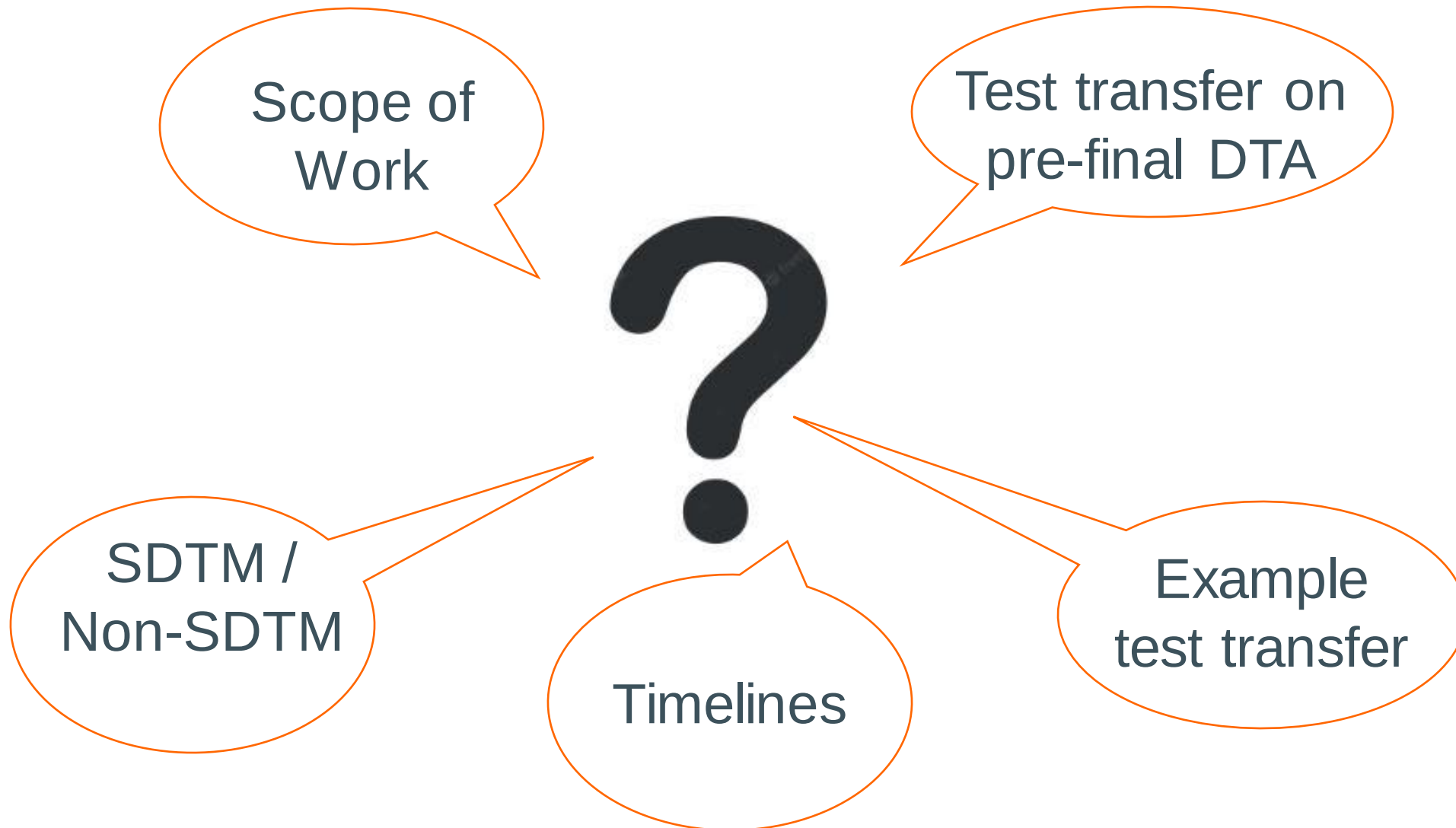
Flow



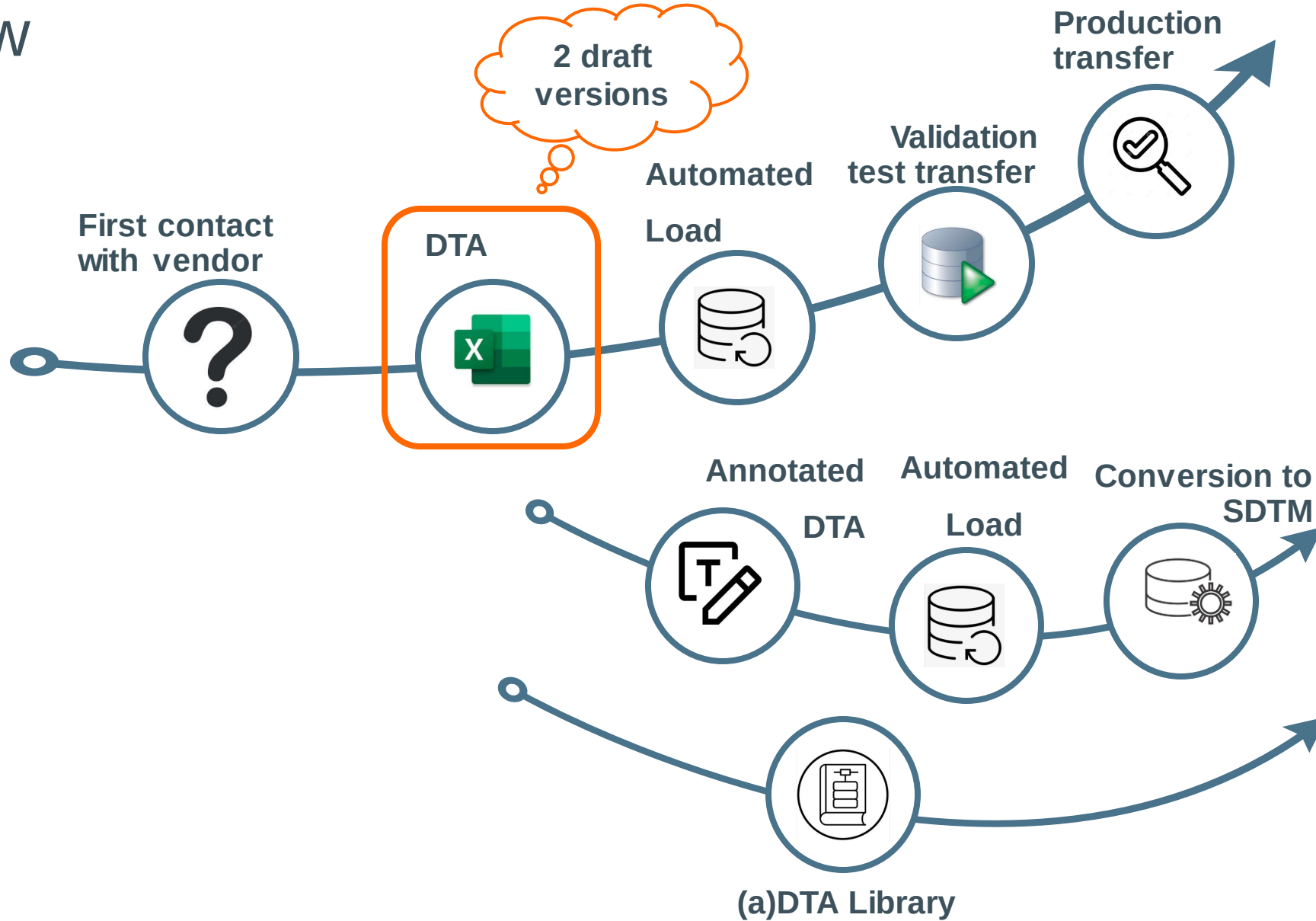
Flow



First contact with vendor



Flow



DTA



Trial Information

Document Version History

General

Transfer Specifications

Test Identifiers

Visit Identifiers

Timepoint Identifiers

PURPOSE

FORMAT OF DATA

MEDIUM OF TRANSFER

FREQUENCY AND TIMING OF TRANSFER

Initial request for a data transfer for a study should be triggered by SGS Clinical Research after the DTA has been finalised/when a (stable) draft version of the DTA is available.

A test data transfer will be received prior to the first transfer of live data. The test transfer may contain live data, if available at that time. SGS Clinical Research will review this as soon as possible and will provide feedback directly to the provider. In case of issues, test transfers will continue until the requirements of the DTA have been met.

The frequency of the live data transfers will be:

- ☐ Once
- ☐ Monthly
- ☐ Other, specify: ...

During the last month before any important interim CDMS lock or the final CDMS lock, transfers may occur more frequently on request of SGS Clinical Research.

FILE STRUCTURE AND CONTENT

UNSCHEDULED VISIT SLOTTING

VISIT AND TIMEPOINT IDENTIFIERS

ANNOTATED DTA



DTA: Transfer Specifications

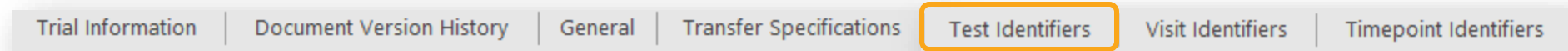
Trial Information | Document Version History | General | **Transfer Specifications** | Test Identifiers | Visit Identifiers | Timepoint Identifiers

<i>Required field</i>	<i>Required field, must be unique</i>	<i>Optional field</i>	<i>'text', 'numeric' or specify exact date format</i>	<i>Specify anticipated maximum variable length. If text, complete by default as 200. If > 200 this variable should be split in more variables.</i>	<i>Optional field Please provide additional explanation on use of variable, if needed. Remove this column if not used.</i>	<i>Please mark the variables (using 'X') that make a unique record in this transfer file.</i>	<i>Please mark the variables (using 'X') if variable should be populated for all records.</i>	<i>List the allowed values separated by a ';' (semicolon sign) If too many possibilities, add an example eg.: xxx If allowed values are specified in a separate sheet, refer to this sheet</i>	<i>Column is only applicable for data transfers that contain secure data. Mark with 'X' if value in variable is potentially unblinding. Remove this column if not used.</i>
Transfer file order	Transfer variable name	Transfer variable label	Format	Anticipated maximum length	Description of transfer variable use	Transfer file key	Populate for all records	Allowed values	Unblinding
2	DOMAIN	Domain Abbreviation	text	200		X	X	LB	
3	USUBJID	Unique Subject Identifier	text	200			X	<Protocol Number-SITEID-SUBJECTID>	
4	LBREFID	Reference ID	text	200			X	eg. T123456	
5	LBTESTCD	Test Short Name	text	200		X	X	see section Test Identifiers	
10	LBSTAT	Completion Status	text	200				NOT DONE	

- Guideline text is available
- ⇒ Consistent approach is used over all trials



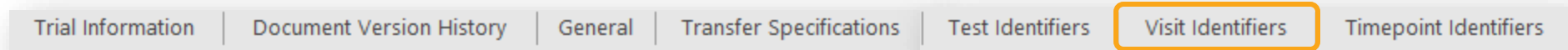
DTA: Test Identifiers



TESTCD	[Test variable_1]	[Test variable_2]	[Test variable_3]	[Test variable_...]
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- Rows with a reference to 'Test Identifiers' sheet
⇒ Column should be present

DTA: Visit Identifiers



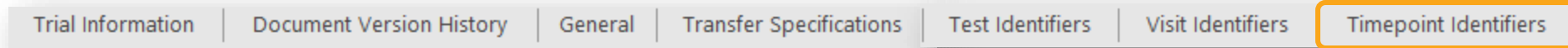
[Visit Variable_1]	[Visit Variable_2]	[Visit Variable_...]
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- Rows with a reference to 'Visit Identifiers' sheet
⇒ Column should be present
- Not all possible visits should be added
 - Add a row for each type of visit (eg. SCREENING, WEEK x, END OF TREATMENT,...)
 - The structure of the visit should be clear



Amendment proof

DTA: Timepoint Identifiers



[Timepoint Variable_1]	[Timepoint Variable_2]	[Timepoint Variable_3]	[Timepoint Variable_4]	[Timepoint Variable_5]	[Timepoint Variable_...]
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- Rows with a reference to 'Timepoint Identifiers' sheet
⇒ Column should be present
- List all possible timepoints

VISIT AND TIMEPOINT IDENTIFIERS

In the Visit and Timepoint identifiers sheet(s), the structure of how the visits and timepoints are built, is specified. When all visits and/or timepoints are listed at the time of the finalization of the DTA, this list will reflect the situation at that moment in time. When after finalization additional visits and/or timepoints are required, an update to the DTA is not necessary if the structure of the visits and/or timepoints is clear.



Amendment proof

DTA: Transfer Specifications

Transfer file order	Transfer variable name	Transfer variable label	Format	Anticipated maximum length	Transfer file key	Populate for all records	Allowed values
1	STUDYID	Study Identifier	text	200		X	<Protocol Number>
2	DOMAIN	Domain Abbreviation	text	200	X	X	LB
3	USUBJID	Unique Subject Identifier	text	200		X	<Protocol Number-SITEID-SUBJECTID>
4	LBREFID	Reference ID	text	200		X	eg. T123456
5	LBTESTCD	Test Short Name	text	200	X	X	see section Test Identifiers
6	LBTEST	Test Name	text	200		X	see section Test Identifiers
7	LBCAT	Category	text	200	X	X	see section Test Identifiers
8	LBORRES	Result	text	200			e.g. 12
9	LBORRESU	Result Unit	text	200			see section Test Identifiers
10	LBSTAT	Completion Status	text	200			NOT DONE
11	LBREASND	Reason Test Not Done	text	200			eg. SAMPLE NOT ANALYZED
12	LBSPEC	Specimen Material Type	text	200		X	see section Test Identifiers
13	LBMETHOD	Method of Test or Examination	text	200		X	see section Test Identifiers
14	VISITNUM	Visit Number	number		X	X	see section Visit Identifiers
15	VISIT	Visit Name	text	200		X	see section Visit Identifiers
16	LBDMTC	Date/Time of Specimen Collection	yyyy-mm-dd			X	eg. 2022-11-01
17	LBTPT	Time Point	text	200		X	see section Timepoint Identifiers
18	LBTPTNUM	Time Point Number	number		X	X	see section Timepoint Identifiers
19	LBELTM	Planned Elapsed Time from Time Point Ref	text	200		X	see section Timepoint Identifiers
20	LBTPTREF	Time Point Reference	text	200	X	X	see section Timepoint Identifiers
21	SQ.LBSPEC1	Specimen Type 1	text	200		X	LYSATE DISTAL S3; LYSATE PROXIMAL S7; LYSATE PROXIMAL R7; LYSATE DISTAL R3
22	COMMENT_1	Comment 1	text	200			e.g. Fold induction lower than 1
23	COMMENT_X	Comment X	text	200			e.g. Fold induction lower than 1

DTA: Test Identifiers



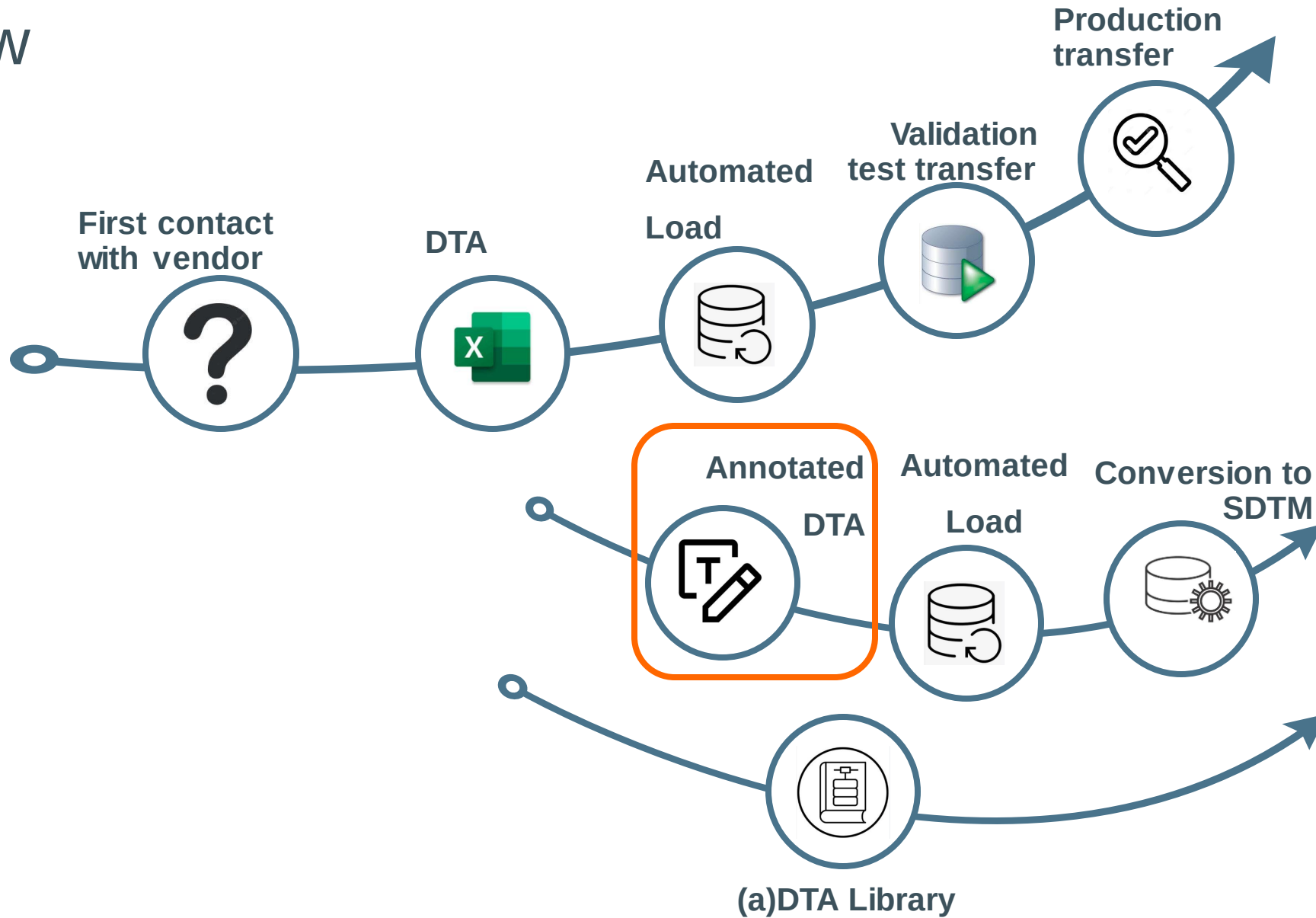
LBTESTCD	LBTEST	LBCAT	LBORRESU	LBSPEC	LBMETHOD
WBCFSSC	Leukocytes/FSC_SSC	IMMUNOLOGY	%	BLOOD	FLOW CYTOMETRY
WBC	Leukocytes	IMMUNOLOGY	EVENTS	BLOOD	FLOW CYTOMETRY
GRANSSC1	Granulocytes/CD3-SSCmed_high	IMMUNOLOGY	%	BLOOD	FLOW CYTOMETRY
GRAN	Granulocytes	IMMUNOLOGY	EVENTS	BLOOD	FLOW CYTOMETRY
GRANLE	Granulocytes/Leukocytes	IMMUNOLOGY	%	BLOOD	FLOW CYTOMETRY
MONOSSC1	Monocytes/CD3-SSCmed_high	IMMUNOLOGY	%	BLOOD	FLOW CYTOMETRY
MONO	Monocytes	IMMUNOLOGY	EVENTS	BLOOD	FLOW CYTOMETRY
MONOLE	Monocytes/Leukocytes	HEMATOLOGY	%	BLOOD	FLOW CYTOMETRY
MOSTAT3P	Monocytes pSTAT3+	IMMUNOLOGY	RATIO	BLOOD	FLOW CYTOMETRY
LYMLE	Lymphocytes/Leukocytes	IMMUNOLOGY	%	BLOOD	FLOW CYTOMETRY
LYM	Lymphocytes	IMMUNOLOGY	EVENTS	BLOOD	FLOW CYTOMETRY
STAT3	STAT3	IMMUNOLOGY		LYSATE	MSD
STAT3P	Phosphorylated STAT3	IMMUNOLOGY		LYSATE	MSD
STAT4P	Phosphorylated STAT4	IMMUNOLOGY		LYSATE	MSD
STAT5P	Phosphorylated STAT5	IMMUNOLOGY		LYSATE	MSD

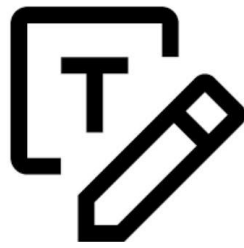
DTA: Visit and Timepoint Identifiers

VISIT	VISITNUM
SCREENING	1000
PERIOD 1 DAY 1	2010
PERIOD xx DAY yy	(xx+1)yy
UNSCHEDULED VISIT xx	99.xx

LBTPT	LBTPTNUM	LBELTM	LBTPTREF
PREDOSE	-0.001		PERIOD xx DAY yy, MORNING DOSE
0H	0	PT0H	PERIOD xx DAY yy, MORNING DOSE
1H	1	PT1H	PERIOD xx DAY yy, MORNING DOSE
2H	2	PT2H	PERIOD xx DAY yy, MORNING DOSE
4H	4	PT4H	PERIOD xx DAY yy, MORNING DOSE
12H	12	PT12H	PERIOD xx DAY yy, MORNING DOSE
PREDOSE	-0.001		PERIOD xx DAY yy, BIOPSY

Flow





Annotated DTA

- Create Annotated DTA for non-SDTM transfers
- DTA between DM and client (vendor not in scope)
- Copy of DTA template +
 - Annotation column(s)

Transfer file order	Transfer variable name	Transfer variable label	Allowed values	Unblinding	Annotation
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- Post Processing sheet

Post-Processing
<i>Completion Guidelines: this section can be used to Include post-processing information. For example, how to map 'not analyzed' or 'not tested' data coming from the Provider.</i>

(a)DTA: Transfer Specifications

Transfer file order	Transfer variable name	Format	Anticipated maximum length	Transfer file key	Populate for all records	Allowed values	Annotation
1	STUDYID	text	200		X	SRP	
2	SUBJID	numeric	4	X	X	eg. 1001	see section Post Processing
3	REFID	text	200		X	eg. T123456	LBREFID
4	SPID	text	200		X	<Protocol Number>	LBSPID
5	VISITID	text	200	X	X	see section Visit Identifiers	
6	TPT	text	200	X	X	see section Timepoint Identifiers	
7	SPECTYPE	text	200		X	BLOOD; LYSATE	
8	ANATOMICALLOCATION	text	200		X	S3; S7; R3; R7	see section Post Processing
9	TEST	text	200	X	X	see section Test Identifiers	
10	TESTPA	text	200		X	see section Test Identifiers	
11	RESULTBIO	text	200		X	e.g. 12	LBORRES
12	RESULTFRU	text	200		X	see section Test Identifiers	
13	METHOD	text	200		X	see section Test Identifiers	
14	COMMENT_1	text	200			e.g. Fold induction lower than 1	
15	COMMENT_X	text	200			e.g. Fold induction lower than 1	
16	EXPNAME	text	200		X	YYMMDD_INI	see section Post Processing

(a)DTA: Test Identifiers

TEST	RESULTFRU	LBTESTCD	LBTEST	LBCAT	LBSPEC	LBMETHOD	LBORRESU	LBSTRESU
BCEBCERA	RATIO	CD19LY	CD19/Lymphocytes	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	%	fraction of 1
BCELYMCO	EVENTS	CDX58O	CD19+ B cells	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	EVENTS	EVENTS
BCELYMFR	%	CDX58OPS	CD19+ B cells pSTAT3+	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	RATIO	RATIO
CD3CD3RA	RATIO	CD3LY	CD3/Lymphocytes	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	%	fraction of 1
CD3LYMCO	EVENTS	CDX008	CD45+CD3+	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	EVENTS	EVENTS
CD3LYMFR	%	CDX009TC	CD45+CD3+CD4+/T Cells	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	%	fraction of 1
CD4CD3CO	EVENTS	CDX27K	CD4+ T cells	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	EVENTS	EVENTS
CD4CD3FR	%	CD4LY	CD4/Lymphocytes	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	%	fraction of 1
CD4CD4RA	RATIO	CDX27KPS	CD4+ T cells pSTAT3+	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	RATIO	RATIO
CD4LYMFR	%	CDX010TC	CD45+CD3+CD8+/T Cells	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	%	fraction of 1
CD8CD3CO	EVENTS	CDX02F	CD8+ T cells	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	EVENTS	EVENTS
CD8CD3FR	%	CDX02FPS	CD8+ T cells pSTAT3+	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	RATIO	RATIO
CD8CD8RA	RATIO	CDX303PS	CD3+ T cells pSTAT3+	IMMUNOLOGY	BLOOD	FLOW CYTOMETRY	RATIO	RATIO
PHOSTAT3		STAT3P	Phosphorylated STAT3	IMMUNOLOGY	LYSATE	ELECTROCHEMILUMINESCENCE		
PHOSTAT4		STAT4P	Phosphorylated STAT4	IMMUNOLOGY	LYSATE	ELECTROCHEMILUMINESCENCE		

(a)DTA: Visit and Timepoint Identifiers

VISITID	VISIT	VISITNUM
SCREEN	SCREENING	1000
P1P1D1	PERIOD 1 DAY 1	2010
PxPyDz	PERIOD xx DAY yy	(xx+1)yy
UNSCHEDULED XX	UNSCHEDULED VISIT xx	99.xx

TPT	LBTPT	LBTPTNUM	LBELTM	LBTPTREF
PREDOSE	PREDOSE	-0.001		PERIOD xx DAY yy, MORNING DOSE
0H	0H	0	PT0H	PERIOD xx DAY yy, MORNING DOSE
1H	1H	1	PT1H	PERIOD xx DAY yy, MORNING DOSE
2H	2H	2	PT2H	PERIOD xx DAY yy, MORNING DOSE
4H	4H	4	PT4H	PERIOD xx DAY yy, MORNING DOSE
12H	12H	12	PT12H	PERIOD xx DAY yy, MORNING DOSE

(a)DTA: Post Processing

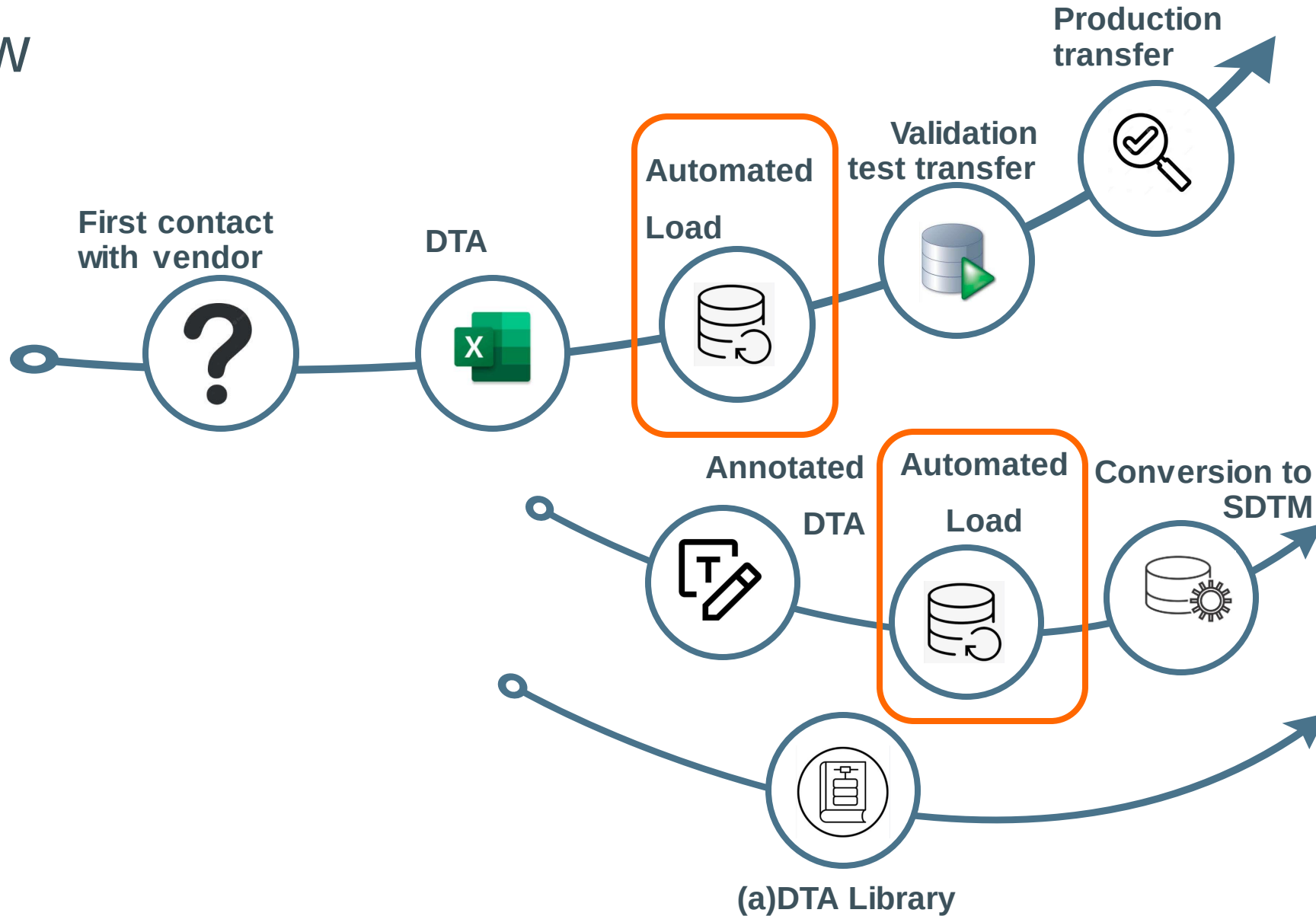
Transfer file order	Transfer variable name	Format	Anticipated maximum length	Transfer file key	Populate for all records	Allowed values	Annotation
7	SPECTYPE	text	200		X	BLOOD; LYSATE	LBSPEC
8	ANATOMICALLOCATION	text	200		X	S3; S7; R3; R7	see section Post Processing

Post-Processing

SUPPLB.LBSPEC1	SPECTYPE decode(ANATOMICAL LOCATION,S3,DISTAL,S7,PROXIMAL,R3,DISTAL,R7,PROXIMAL) ANATOMICAL LOCATION
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QNAM	QLABEL	QVAL
LBSPEC1	Specimen Type 1	LYSATE DISTAL S3
LBSPEC1	Specimen Type 1	LYSATE PROXIMAL S7
LBSPEC1	Specimen Type 1	LYSATE PROXIMAL R7
LBSPEC1	Specimen Type 1	LYSATE DISTAL R3

Flow



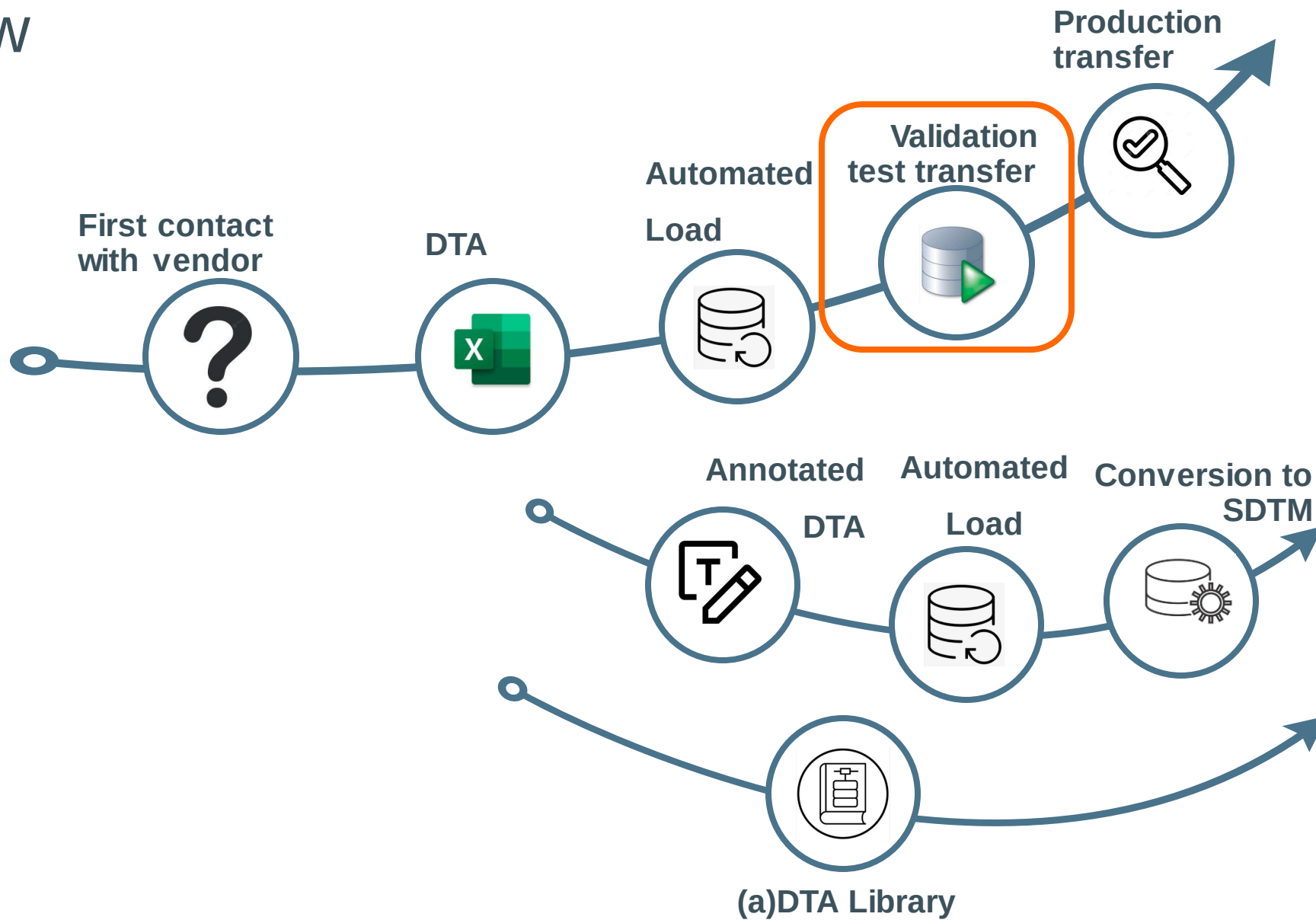
(a)DTA Library

Automated Load

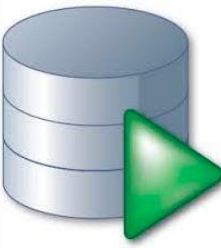
- (a)DTA
 - Transfer Specifications
 - Test Identifiers
 - Visit and Timepoint Identifiers
- Test/Production transfer
 - API: Automated load and conversion



Flow



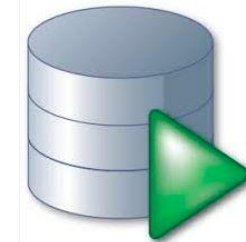
Validation test transfer



- Run library QC rules
- Review output
- Send issues to vendor or approve test transfer



Validation test transfer



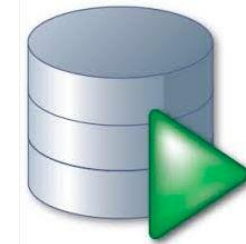
- Example 1:

Check per vendor and per data type that the variables mentioned in the DTA are present in the test transfer

DTA_VARIABLE	TEST_TRANSFER_VARIABLE	IND
STUDYID	STUDYID	
SUBJID	SUBJID	
REFID	REFID	
SPID	SPID	
VISITID	VISITID	
TPT	TPT	
SPECTYPE	SPECTYPE	
ANATOMICALLOCATION		*
TEST	TEST	
TESTPA	TESTPA	
RESULTBIO	RESULTBIO	
RESULTFRU	RESULTFRU	
METHOD	METHOD	
EXPNAME	EXPNAME	

TEST_TRANSFER_VARIABLE	DTA_VARIABLE	IND
STUDYID	STUDYID	
SUBJID	SUBJID	
REFID	REFID	
SPID	SPID	
VISITID	VISITID	
TPT	TPT	
SPECTYPE	SPECTYPE	
LOCATION		*
TEST	TEST	
TESTPA	TESTPA	
RESULTBIO	RESULTBIO	
RESULTFRU	RESULTFRU	
METHOD	METHOD	
EXPNAME	EXPNAME	

Validation test transfer

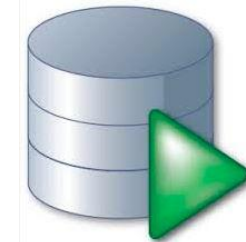


- Example 2:

Check per vendor and data type that the combination of Test Identifiers mentioned in the DTA are present in the test transfer (and vice versa)

DTA_TEST	DTA_TESTPA	DTA_RESULTFRU	TEST_TRANSFER_TEST	TEST_TRANSFER_TESTPA	TEST_TRANSFER_RESULTFRU	IND
CD4LYMFR	CD4 (%)	%				*
CD4CD3FR	Blood CD45+CD3+CD4+/T Cells (%)	%	CD4CD3FR	Blood CD45+CD3+CD4+/T Cells (%)	%	
PHOSTAT4	Lysate Phosphorylated STAT4 (Signal Transducer and Activator of Transcription 4)					*
PHOSTAT3	Lysate Phosphorylated STAT3 (Signal Transducer and Activator of Transcription 3)					*

Validation test transfer



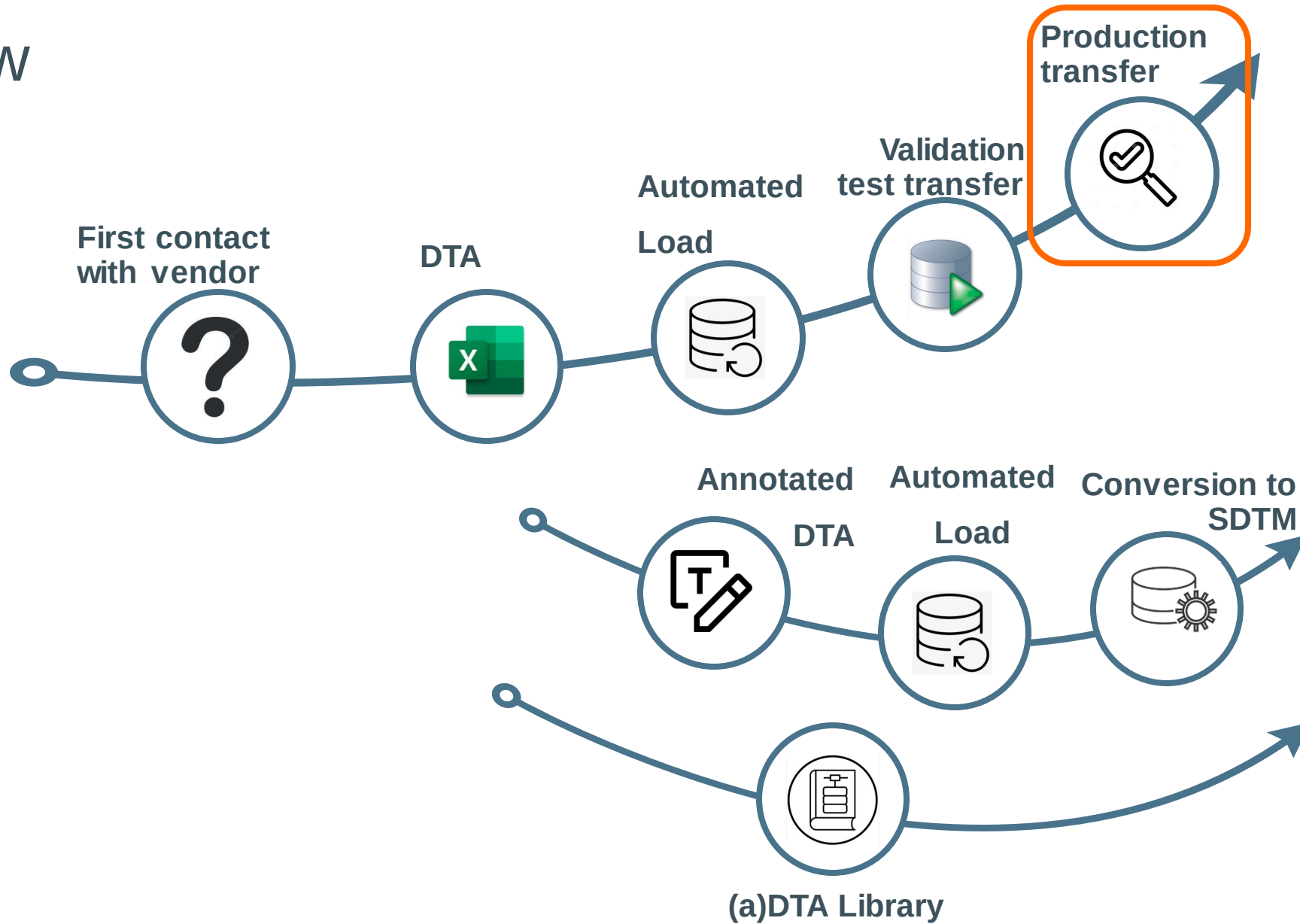
- Example 3:

Check per vendor and per data type that the visits present in the test transfer are present in the visit table

AA_VISITMAP	
VISIT	VISITNUM
SCREENING	1000
PERIOD1_DAY-1	2001
PERIOD1_DAY1	2010
PERIOD1_DAY2	2020
PERIOD1_DAY3	2030
PERIOD1_DAY4	2040
PERIOD1_DAY5	2050
PERIOD1_DAY6	2060
PERIOD2_DAY-1	3001
PERIOD2_DAY1	3010
PERIOD2_DAY2	3020
PERIOD2_DAY3	3030
EARLY_WITHDRAWAL	4000
END_OF_STUDY	5000

TEST_TRANSFER_VISIT	VISIT#VISITMAP	IND
PERIOD1_DAY1	PERIOD1_DAY1	
PERIOD1_DAYS5	PERIOD1_DAYS5	
PERIOD1_DAY6	PERIOD1_DAY6	
P1P1D2		*
SCREENING	SCREENING	

Flow



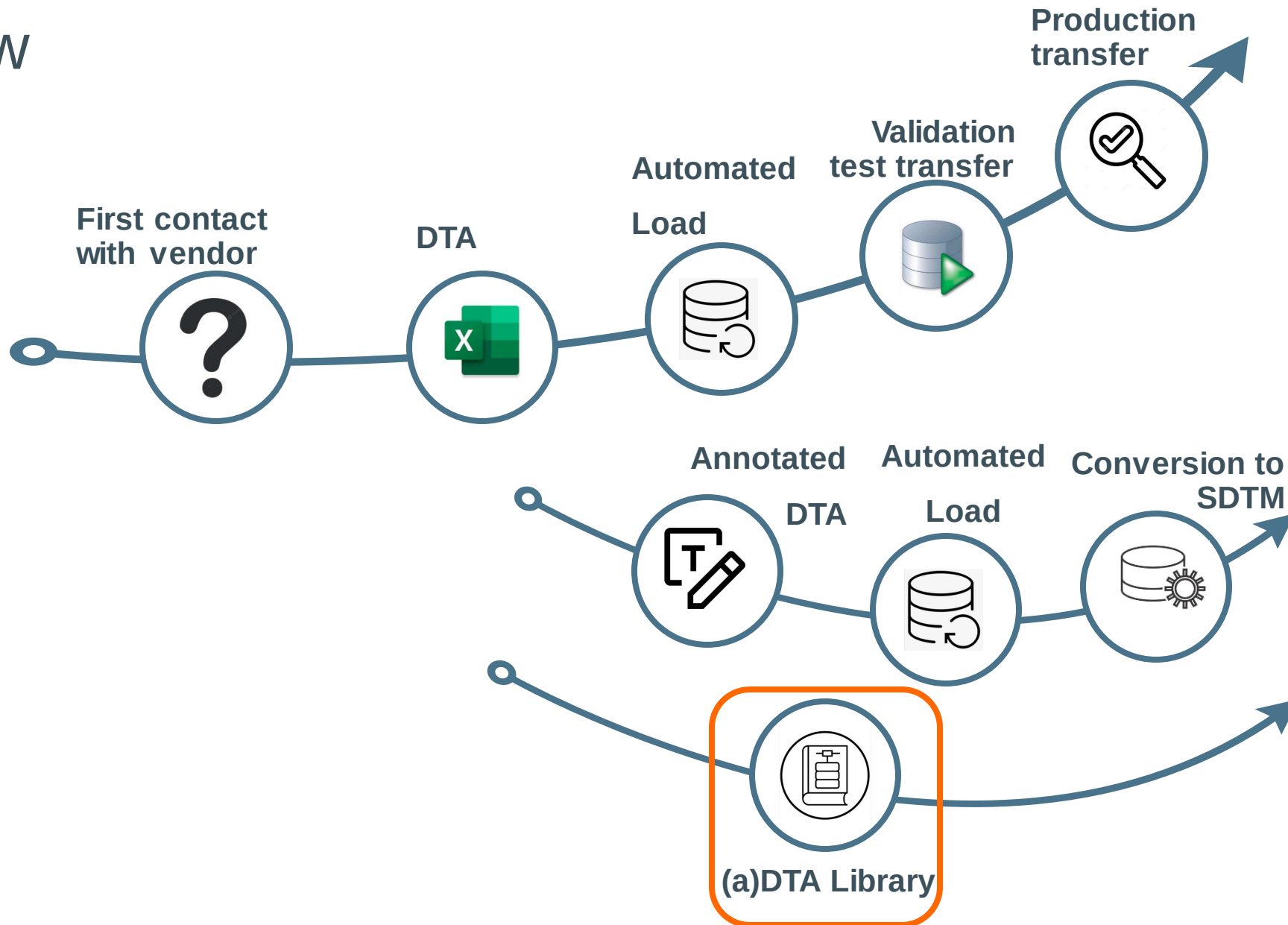
(a)DTA Library

Production transfer

- QC rules will run automatically on production data
 - Ongoing check on structure
 - In time reconciliation

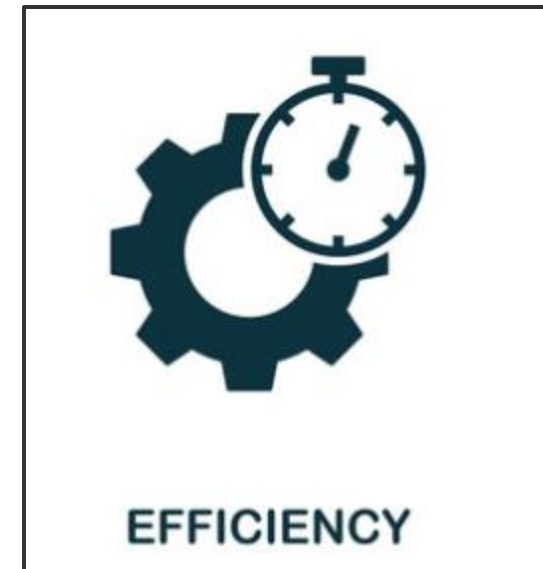


Flow

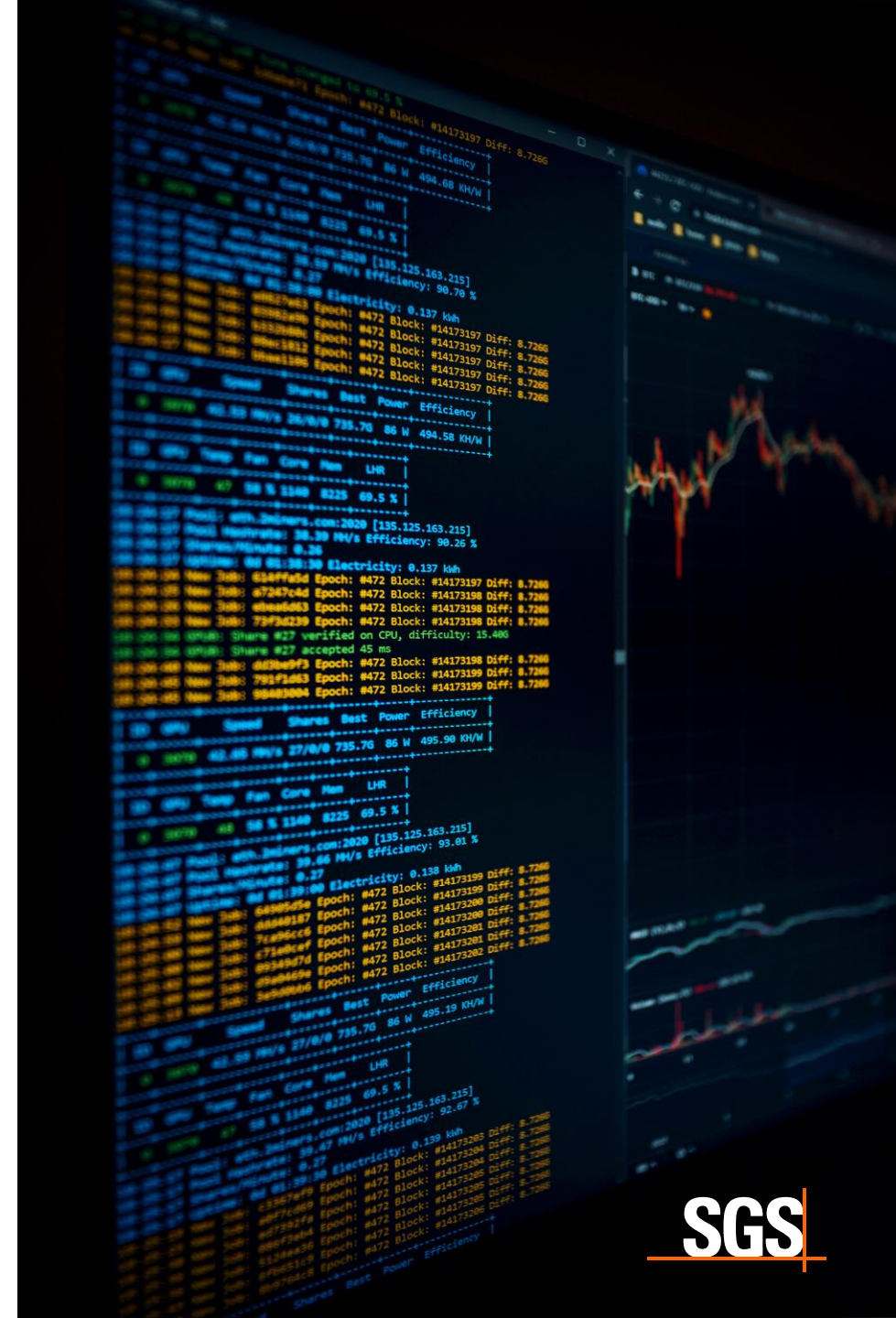


(a)DTA Library

- All DTA sheets from all trials are loaded in the DTA Library
- Search on
 - <Vendor>
 - <Data Type>
- Export library tables to trial specific DTA

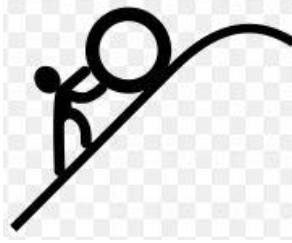


Conclusions



Conclusions

- DTA: amendment proof
 - Automation vendor process
 - (a)DTA library
- ⇒ Time gain
- ⇒ Increase in quality
-
- Challenges:
 - General DTA structure in database





Questions?

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