



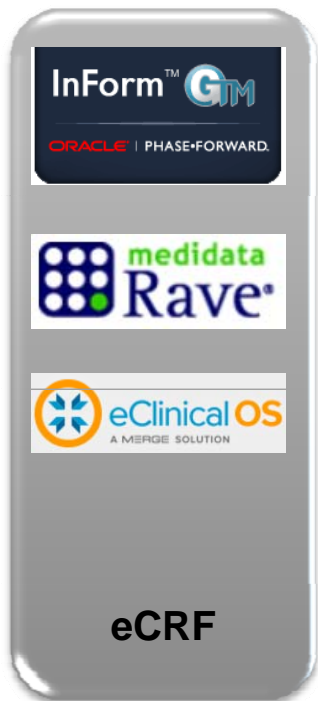
IMPLEMENTATION OF AN IN-
HOUSE DEVELOPED DATA
QUALITY CONTROL (QC) TOOL TO
STREAMLINE SDTM PRODUCTION
RELEASE

WHEN YOU NEED TO BE SURE

SGS

- Setting the Scene
- In the old days
- Consequences
- Why not develop a Tool?
- QC Tool idea
- How was this accomplished?
- Result

SETTING THE SCENE: DATA SOURCES



InForm™ G™
ORACLE | PHASE-FORWARD.

medidata
Rave®

eClinical OS
A MERGE SOLUTION

eCRF



Paper CRF



ORACLE
labpas®

Site specific
systems

eSource



Subject 000002

1	2	3
4	5	6
7	8	9
0	✓	

ePRO



Lab,
imaging, etc.

REQUEST

DOWN
LOAD

INSTALL

CONVERT

META
DATA

QC-TOOL

REPORTS

A2O

SAS

Consequently following steps were performed:

- Programmer set up the conversion of source data towards SDTM data
- Data Reviewer reviews every field of every dataset
- Programmer performs requested updates
- Obligated to work in full cycles until consensus
- Complete paper driven QC process

- Both programmer and data reviewer were always waiting for each other
- Long process of checkmarks for all reviewed items

00000014	1	HAY FEVER	LIVER DISEASE HISTORY	DIAGNOSIS	Y	Y	1.000	SCREENING								
00000017	2	HCV INFECTION	LIVER DISEASE HISTORY	START OF INFECTION	Y	Y	1.000	SCREENING				1980-01-25				
00000018	2	HCV INFECTION	FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	Y	Y	1.000	SCREENING								
00000016	1	HIVES	FAMILY HISTORY	CARDIOVASCULAR	Y	Y	1.000	SCREENING								
00000014	1	HYPERTENSION	FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	Y	Y	1.000	SCREENING								
00000019	1	INHERITED CHILDHOOD ECZEMA / DERMATITIS	FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	Y	Y	1.000	SCREENING								
00000019	4	NONE	MEDICAL HISTORY	ALLERGIC DERMATITIS/ECZEMA	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000023	4	NONE	MEDICAL HISTORY	CARDIOVASCULAR	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000023	4	NONE	MEDICAL HISTORY	ASTHMA	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000021	4	NONE	MEDICAL HISTORY	ATOPIC DERMATITIS/ECZEMA	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000022	4	NONE	MEDICAL HISTORY	ATOPIC DERMATITIS/ECZEMA	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000024	4	NONE	MEDICAL HISTORY	HAY FEVER	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000024	4	NONE	MEDICAL HISTORY	HAY FEVER	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013
00000026	4	NONE	MEDICAL HISTORY	INHERITED CHILDHOOD ECZEMA/DERMATITIS	Y	Y	1.000	SCREENING				2013-07-01			ONGOING	2013

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Conversion validation TEST - MH

MHSEQ	MHGRPID	MHTERM	MHCAT	MHSCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	EPOCH	MHDTCT	MHSTDTCT	MHENRTPT	MHSTDTCT
80	3	PARACETAMOL	MEDICAL HISTORY	DRUG ALLERGY / HYPERSENSITIVITY	Y	Y	1.000	SCREENING					2013-07-01
3	1	PSORIASIS	FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	Y	Y	1.000	SCREENING					
10	1	SEA FOOD	FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	N	Y	1.000	SCREENING					
5	1	SINUSITIS	FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	Y	Y	1.000	SCREENING					
1	1		FAMILY HISTORY	ALLERGIC/IMMUNOLOGIC	Y	Y	1.000	SCREENING					
1	1		FAMILY HISTORY	CARDIOVASCULAR	Y	Y	1.000	SCREENING					
5	2	HCV INFECTION	LIVER DISEASE HISTORY	DIAGNOSIS	Y	Y	1.000	SCREENING					2000

- Manual process prone to human error
- In a new round, always check together with previous round what exactly was changed
- Extensive process to get supplemental qualifiers (SUPPxx) and CO datasets checked
- Heavy documentation and filing
- Not a cost efficient approach

WHY NOT DEVELOP A TOOL?

- Goals of implementing this new tool
 - Decrease waiting time
 - Eliminate rework
 - Shorten timelines
 - Lower cost

QC TOOL IDEA

- Data reviewer and programmer should be able to work simultaneously
- Check everything once
- Automatic indication of what has changed between review rounds
- Extensive Audit Trail
- Clear overview of all identified and solved issues

HOW WAS THIS ACCOMPLISHED

- Data Reviewer and programmer should be able to work simultaneously:
 - QC Tool works with a snapshot of the data, taken by the data reviewer
 - While the programmer is performing updates on the actual database
 - Check gadget or tool to see if they should take action



HOW WAS THIS ACCOMPLISHED

- Check everything only once:
 - Wizard driven system
 - A serie of steps are used in the review process:
 - PARAMS: trial parameters
 - STUDYID: check if the value is correct
 - DOMAIN: domain values
 - VISITMAP: visit/visitnum combination
 - TIMEPOINT: distinct list of timepoints per panel
 - USUBJID: check format of USUBJID
 - DICTION: check the version of dictionaries used
 - VALUES: values used, not available in codelist
 - FINDINGS: --TESTCD/TEST values
 - SDTM: check detailed SDTM values

HOW WAS THIS ACCOMPLISHED

Example: Wizard driven system in steps



What needs to be checked? and Options

PARAMS Next Step >

1 - 5

OKNOKPARAMETERTYPE	PARAMETER_VALUE	MOD_USER	MOD_DATE	HISTORY	FEEDBACK
Baseline Visit Number	1	KARLIEN_KNEVELS	2015-10-07 09:12:09		
Blinding	OPEN	KARLIEN_KNEVELS	2015-10-07 09:12:10		
Database Structure Classification					
Investigational Medication	xxxxx	KARLIEN_KNEVELS	2015-10-07 09:12:11		
STAND Package	STAND_DEF				

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HOW WAS THIS ACCOMPLISHED

- Automatic indication of what has changed between review rounds:
 - After a new snapshot, the tool automatically indicates which changes are made to the data that is already validated, compared to the previous snapshot.
 - Only updates should be checked in a new round.
 - Easy to indicate when a value is not correct

HOW WAS THIS ACCOMPLISHED

Example: Approval and Indication of an error

Studies Patients Steps Columns Issues Listings Codelists Releases Links

What needs to be checked? and Options



SDTM_LB < Previous Step Next Step >

1 - 9

OKNOKFORMREFNAME	STUDYID	DOMAIN	USUBJID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBCAT	LBSCAT
BIOCHEMISTRY	SGS DEMO	LB	SGS_DEMO-01-4002	86	9	ALB	Albumin	CLINICAL CHEMISTRY	GENERA
COAGULATION	SGS DEMO	LB	SGS_DEMO-01-4002	103	9	APTT	Activated Partial Thromboplastin Time	HAEMATOLOGY	HAEMATC
HEMATOLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	108	9	BASO	Basophils	HAEMATOLOGY	HAEMATC
ALCOHOL BREATH TEST	SGS DEMO	LB	SGS_DEMO-01-4002	85	8	ETOHQ	Ethanol Qualitative	CLINICAL CHEMISTRY	GENERA
GLUCOSE	SGS DEMO	LB	SGS_DEMO-01-4002	107	9	GLC	Glucose	CLINICAL CHEMISTRY	LIPIDS AI
SEROLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	123	9	HBSAG	Hepatitis B Surface Antigen	IMMUNOLOGY	VIROLOG
URINE DRUGSCREEN KIT	SGS DEMO	LB	SGS_DEMO-01-4002	77	7	UAMPH	Urine Amphetamines	URINALYSIS	URINE
URINE DRUG SCREEN LAB	SGS DEMO	LB	SGS_DEMO-01-4002	69	6	UAMPH	Urine Amphetamines	URINALYSIS	URINE
URINALYSIS	SGS DEMO	LB	SGS_DEMO-01-4002	56	6	UB	Urine Bilirubin	URINALYSIS	URINE

Text color legend Maximize Go to next round Add Data Record

14 Show All columns Show all records Show all steps Go to step SDTM_LB (1) quicklinks

HOW WAS THIS ACCOMPLISHED

Example: Programmer gets indication action should be taken

```
1 07-10 09:19
SGSDemo_SDS
NOK 1
OK 18
CHANGED 0
-----
SDTM_LB 1
```



```
0 07-10 09:21
SGSDemo_SDS
NOK 0
OK 18
CHANGED 1
-----
```

HOW WAS THIS ACCOMPLISHED

Example: Programmer indicates change is made

Studies Patients Steps Columns Issues Listings Codelists Releases Links

> What needs to be checked? and Options



SDTM_LB

< Previous Step Next Step >

1 - 9

OKNOKFORMREFNAME	STUDYID	DOMAIN	USUBJID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBCAT	LBSCAT
BIOCHEMISTRY	SGS DEMO	LB	SGS_DEMO-01-4002	86	9	ALB	Albumin	CLINICAL CHEMISTRY	GENERAL
COAGULATION	SGS DEMO	LB	SGS_DEMO-01-4002	103	9	APTT	Activated Partial Thromboplastin Time	HAEMATOLOGY	HAEMATO
HEMATOLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	108	9	BASO	Basophils	HAEMATOLOGY	HAEMATO
ALCOHOL BREATH TEST	SGS DEMO	LB	SGS_DEMO-01-4002	85	8	ETOHQ	Ethanol Qualitative	CLINICAL CHEMISTRY	GENERAL
GLUCOSE	SGS DEMO	LB	SGS_DEMO-01-4002	107	9	GLC	Glucose	CLINICAL CHEMISTRY	LIPIDS AN
SEROLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	123	9	HBSAG	Hepatitis B Surface Antigen	IMMUNOLOGY	VIROLOG
URINE DRUGSCREEN KIT	SGS DEMO	LB	SGS_DEMO-01-4002	77	7	UAMPH	Urine Amphetamines	URINALYSIS	URINE
URINE DRUG SCREEN LAB	SGS DEMO	LB	SGS_DEMO-01-4002	69	6	UAMPH	Urine Amphetamines	URINALYSIS	URINE
URINALYSIS	SGS DEMO	LB	SGS_DEMO-01-4002	56	6	UB	Urine Bilirubin	URINALYSIS	URINE

Text color legend

Maximize

Go to next round

Add Data Record

14

Show All columns

Show all records

Show all steps

Go to step

SDTM_LB (1)

quicklinks

HOW WAS THIS ACCOMPLISHED

Example: Update of a record

Studies Patients Steps Columns Issues Listings Codelists Releases Links

> What needs to be checked? and Options



SDTM_LB

< Previous Step

Next Step >

1 - 9

OKNOKFORMREFNAME	STUDYID	DOMAIN	USUBJID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBCAT	LBSCAT
BIOCHEMISTRY	SGS DEMO	LB	SGS_DEMO-01-4002	86	9	ALB	Albumin	CLINICAL CHEMISTRY	GENERAL
COAGULATION	SGS DEMO	LB	SGS_DEMO-01-4002	103	9	APTT	Activated Partial Thromboplastin Time	HAEMATOLOGY	HAEMATO
HEMATOLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	108	9	BASO	Basophils	HAEMATOLOGY	HAEMATO
ALCOHOL BREATH TEST	SGS DEMO	LB	SGS_DEMO-01-4002	85	8	ETOHQ	Ethanol Qualitative	CLINICAL CHEMISTRY	GENERAL
GLUCOSE	SGS DEMO	LB	SGS_DEMO-01-4002	107	9	GLC	Glucose	CLINICAL CHEMISTRY	LIPIDS AN
SEROLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	123	9	HBSAG	Hepatitis B Surface Antigen	IMMUNOLOGY	VIROLOG
URINE DRUGSCREEN KIT	SGS DEMO	LB	SGS_DEMO-01-4002	77	7	UAMPH	Urine Amphetamines	URINALYSIS	URINE
URINE DRUG SCREEN LAB	SGS DEMO	LB	SGS_DEMO-01-4002	69	6	UAMPH	Urine Amphetamines	URINALYSIS	URINE
URINALYSIS	SGS DEMO	LB	SGS_DEMO-01-4002	56	6	UB	Urine Bilirubin	URINALYSIS	URINE

Text color legend

Maximize

Go to next round

Add Data Record

14

Show All columns

Show all records

Show all steps

Go to step

SDTM_LB (1)

quicklinks

HOW WAS THIS ACCOMPLISHED

Example: Unexpected update of a record

- Studies
- Patients
- Steps
- Columns
- Issues
- Listings
- Codelists
- Releases
- Links

> What needs to be checked? and Options



SDTM_LB

< Previous Step Next Step >

1 - 9

OKNOKFORMREFNAME	STUDYID	DOMAIN	USUBJID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBCAT	LBSCAT
BIOCHEMISTRY	SGS DEMO	LB	SGS_DEMO-01-4002	86	9	ALB	Albumin	CLINICAL CHEMISTRY	GENERAL
COAGULATION	SGS DEMO	LB	SGS_DEMO-01-4002	103	9	APTT	Activated Partial Thromboplastin Time	HAEMATOLOGY	HAEMATO
HEMATOLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	108	9	BASO	Basophils	This is not correct	HAEMATO
ALCOHOL BREATH TEST	SGS DEMO	LB	SGS_DEMO-01-4002	85	8	ETOHQ	Ethanol Qualitative	CLINICAL CHEMISTRY	GENERAL
GLUCOSE	SGS DEMO	LB	SGS_DEMO-01-4002	107	9	GLC	Glucose	CLINICAL CHEMISTRY	LIPIDS AN
SEROLOGY	SGS DEMO	LB	SGS_DEMO-01-4002	123	9	HBSAG	Hepatitis B Surface Antigen	IMMUNOLOGY	VIROLOG
URINE DRUGSCREEN KIT	SGS DEMO	LB	SGS_DEMO-01-4002	77	7	UAMPH	Urine Amphetamines	URINALYSIS	URINE
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URINALYSIS	SGS DEMO	LB	SGS_DEMO-01-4002	56	6	UB	Urine Bilirubin	URINALYSIS	URINE

Text color legend

Maximize

Go to next round

Add Data Record

14

Show All columns

Show all records

Show all steps

Go to step

SDTM_LB (1)

quicklinks



HOW WAS THIS ACCOMPLISHED

- Extensive audit trail
 - All changes and updates ever made to data are logged in audit trail.
- Clear overview of all detected and solved issues
 - Possibility to extract a report for filing purpose

Step summary

STEPNR	STEP	ROUND	APPROVED RECORDS	REJECTED RECORDS	CHANGED RECORDS	TOTAL RECORDS	DELETED RECORDS	APPROVED BY USER	APPROVE DATE
1	PARAMS	1/1	4	0	0	4	0	Not applicable	Not applicable
2	STUDYID	1/1	0	0	0	0	0	Not applicable	Not applicable
3	DOMAIN	1/1	0	0	0	0	0	Not applicable	Not applicable
4	VISITMAP	1/1	0	0	0	0	0	Not applicable	Not applicable
5	TIMEPOINT	1/1	0	0	0	0	0	Not applicable	Not applicable
6	USUBJID	1/2	0	0	0	0	0	Not applicable	Not applicable
7	DICTION	1/1	0	0	0	0	0	Not applicable	Not applicable
8	VALUES	1/1	0	0	0	0	0	Not applicable	Not applicable
9	FINDINGS	1/1	0	0	0	0	0	Not applicable	Not applicable
10	NAM	1/1	0	0	0	0	0	Not applicable	Not applicable
11	SPID	1/1	0	0	0	0	0	Not applicable	Not applicable
12	RANGES	1/1	0	0	0	0	0	Not applicable	Not applicable
13	QLABEL	1/1	0	0	0	0	0	Not applicable	Not applicable
14	DYFIELDS	1/1	0	0	0	0	0	Not applicable	Not applicable
15	MIN_FIELDS	1/1	0	0	0	0	0	Not applicable	Not applicable
16	ORDER	1/1	0	0	0	0	0	Not applicable	Not applicable
17	COLUMNS	1/1	0	0	0	0	0	Not applicable	Not applicable
18	TI	1/1	0	0	0	0	0	Not applicable	Not applicable
19	SDTM_AE	3/3	1	0	0	1	0	KARLIEN_KNEVELS	23-SEP-2015
20	SDTM_CM	3/3	0	0	0	0	0	null	null
21	SDTM_DM	1/3	0	0	0	0	0	null	null

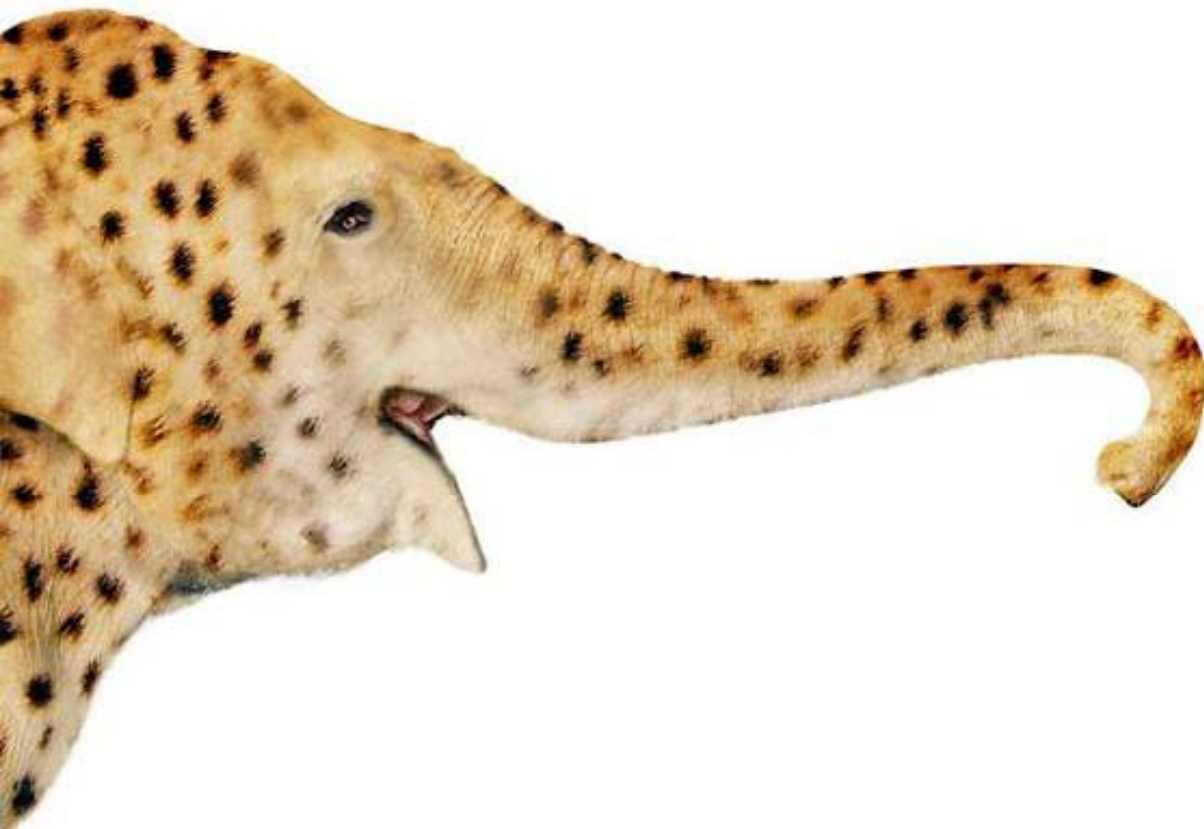
- A tool developed specifically to our needs
- High data quality
- A fully QC'd database before production release
- Less paper = happy trees





SGS

THANK YOU FOR YOUR ATTENTION



**WHERE MEETS EXPERIENCE
MEETS SPEED**

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