



CodEX[©]

when Excel meets SAS to code clinical data
-DH08-





Business context

- The coding in data management
- Ways to perform clinical coding
- Our constraints

CodEX principles

- A tool that drives the process
- Supported by 2 software

Technical aspects

- CodEX interface
- Communication file
- Run history

Conclusion

Agenda



Business context

- The coding in data management
- Strategies in use for the coding
- Our constraints

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Why do we need to code clinical data ?



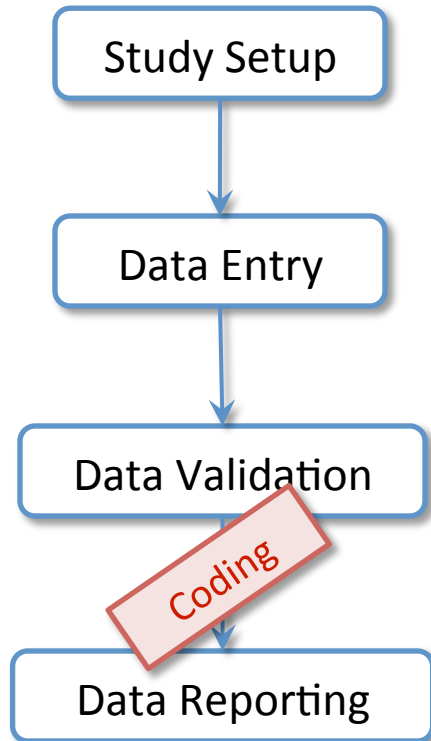
According to the GCDMP October 2013 Edition, chapter “Medical Coding Dictionary Management & Maintenance”, “The use of medical coding dictionaries for medical terms [...] is valuable from the standpoint of **minimizing variability** in the way data are **reported and analyzed**”.

According to FDA Good Review Practices, “Although investigator adverse reaction terms are provided as part of study reports and are listed in case report tabulations, the integrated **analysis** of the ISS requires the applicant to use some way of **grouping** closely related events to obtain an overall rate for a **category of events**.”



Standardization and categorization of the terminologies
for analysis purposes

The coding in Data Management (DM)



DM missions

- Ensure data completion
- Follow the data capture
- Ensure data accuracy
- Ensure data consistency
- Data reporting

DM activities

- (e)CRF / Database set-up
- Set-up controls (*on-line & off-line*)
- Data entry / data loading
- Data review / reconciliations
- Coding
- Data listings

Ways to perform clinical coding



Hard-Coding

- **Manual** (*using browsers*)
- **Queries** (*available*)
- **Medical expertise**
- **Trained people**
- **Consistency**

Automatic

- **Combined with EDC***
- **Real time**
- **Consistency**
- **Medical expertise**
- **Queries**

Hybrid

- **Mix Automatic / Hard**
- **Accuracy / Consistency**
- **Homogeneity**
- **Medical expertise**
- **Queries**

Our constraints



Several Sponsors

- Specific DB structures
- Different EDC* systems

Standardization

CodEX

Multiple Profiles

- Developers
- Data Managers
- Coding officers
- Physicians (*Investigators/Sponsors*)

One common language

Agenda



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Supported by 2 mains software applications



Automatic coding



Hard coding



Quality Control



Consolidation → Append dictionaries



Medical review

Benefits of CodEX: - flexible

Dictionary maintenance



- easy to learn

Drive the process



to use

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An interface easy to use



3- Launch
the action

Click on me to execute
selected action

1.0.6d

2- Choose
the action

1- Complete the
project parameters

Easy means:

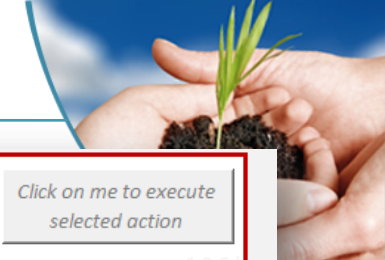
- clear layout
- clear instructions
- clear document history
- clear actions

How to use the tool
([hyperlink for more details](#))

Detailed history of the
tool (*GAMP5 compliance*)

3 distinct blocks

Actions / choices limitation



- CodEX[®] -

when Excel meets SAS to code clinical data

Click on me to execute
selected action

3 main actions
(+ interactive modes)



- CodEX

when Excel meets SAS to c

Action AUTOMATIC coding (generate & execute)

Parameter	
Input dataset name	Coding QC
Dictionary name	RELOAD (generate only)
Dictionary version	RELOAD (generate & execute)
Dictionary key item name	15_1_E
	LLT_NAME

Action AUTOMATIC coding (genera

Parameter	Value
Input dataset name	ae_toCode
Dictionary name	MedDRA
Dictionary version	15_1_E
Dictionary key item name	LLT_NAME
Use of a study specific dictionary	Y
Change primary SOC to display	N
Output file type	XLS
Launch in debugging mode	N

Easy also means:

-limited actions number
-user errors limitation

Instructions

1. Complete all parameters values
2. Choose the action needed
3. Click on button to execute the selected action

Versions

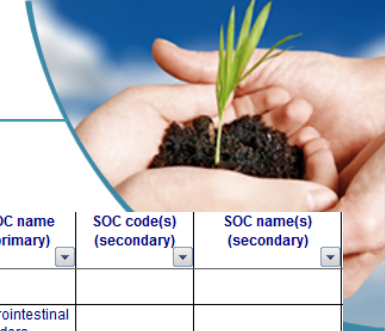
version [date]	reason for change
1.00 [2015-08-06]	Creation of the application

Parameter	Value
Input dataset name	ae_toCode
Dictionary name	MedDRA
Dictionary version	15_1_E
Dictionary key item name	
Use of a study specific dictionary	Y
Change primary SOC to display	Y
Output file type	N
Launch in debugging mode	N

Conditional formatting
for expected answer

Drop-down lists to ensure
validity of the entered data

Communication file



Other item can be added like patient's country, linked medication, ...

Coding status	Coding comments	Change primary SOC code to:	Term to be coded	LLT code	LLT name	PT code	PT name	HLT code	HLT name	HLGT code	HLGT name	SOC code (primary)	SOC name (primary)	SOC code(s) (secondary)	SOC name(s) (secondary)
Manual coding required			ABDOMINAL PAIN CRAMP												
Automatic coding (MedDRA 17.1 E)			ACUTE ABDOMEN	10000647	Acute abdomen	10000647	Acute abdomen	10027678	Gastrointestinal signs and symptoms NEC	10018012	Gastrointestinal signs and symptoms	10017947	Gastrointestinal disorders		
Manual coding required															
Manual coding required															
Manual coding required			LOST OF APPETIT												
Automatic coding (MedDRA 17.1 E)			NERVOUS	10029197	Nervous	10029216	Nervousness	10002869	Anxiety symptoms	10002861	Anxiety disorders and symptoms	10037175	Psychiatric disorders		
Manual coding required			OBSTRUCTION OF SMALL INTESTINE												
Manual coding required															
Manual coding required															
Automatic coding (MedDRA 17.1 E)								10040054	Sepsis, bacteraemia, viraemia and	10021879	Infections - pathogen unspecified	10021881	Infections and infestations	10038359	Renal and urinary disorders
Manual coding required			SKIN RASH (TORSO + ARMS)												
Automatic coding (MedDRA 17.1 E)			NEUROSIS	10029333						2861	Anxiety disorders and symptoms	10037175	Psychiatric disorders		

For coding / medical review

Code update

Comments from Data Management (e.g. query resolution status)

Field to be completed by Coding officer

Flexibility in the output:

- additional information can be reported to support the coding

Easy to use in the output:

- action expected on yellow rows (other are write protected)
- automatic code can be replaced by a manual one

Actions traceability



What have been done ...

- ensure an accurate and consistent coding
- keep connected with SAS to provide successful status

... by **who** and **when**:

- for tracking purpose
- to ensure correct sequence of actions

UserID	Date	Time	Action	Input dataset name	Dictionary name	Dictionary version	Dictionary key item name	Use of a study specific dictionary	Change primary SOC to display	Output file type	Launch in debugging mode	Number of Error
stephane.chollet	27/02/2015	21:06:07	PRE-CODING (generate & execute)	ae_to_code_20feb2015	MedDRA	15_1_E	LLT_NAME	Y	Y	CSV	Y	5
stephane.chollet	27/02/2015	21:07:34	PRE-CODING (generate & execute)	ae_toCode	MedDRA	15_1_E	LLT_NAME	Y				1
stephane.chollet	27/02/2015	21:12:05	PRE-CODING (generate & execute)	ae_toCode	MedDRA	15_1_E	LLT_NAME	Y				0
stephane.chollet	27/02/2015	21:14:27	PRE-CODING (generate & execute)	ae_toCode	MedDRA	15_1_E	LLT_NAME	Y	N	XLS	Y	0
stephane.chollet	27/02/2015	21:35:27	PRE-CODING (generate & execute)	ae_toCode	MedDRA	15_1_E	LLT_NAME	Y	N	XLS	N	3
stephane.chollet	27/02/2015	21:36:13	PRE-CODING (generate & execute)	ae_toCode	MedDRA	15_1_E	LLT_NAME	Y	N	XLS	Y	3
stephane.chollet	27/02/2015	21:41:31	PRE-CODING (generate & execute)	ae_toCode	MedDRA	15_1_E	LLT_NAME	Y			Y	0

QC cannot be done without PRE-CODING

Next step cannot be done is number of error is ≠ 0

Tracking information

Coding is done on same item

SAS error # retrieved from SAS log

Dataset name did not change

In debugging mode, turn on the log options such as MPRINT, MLOGIC, ...

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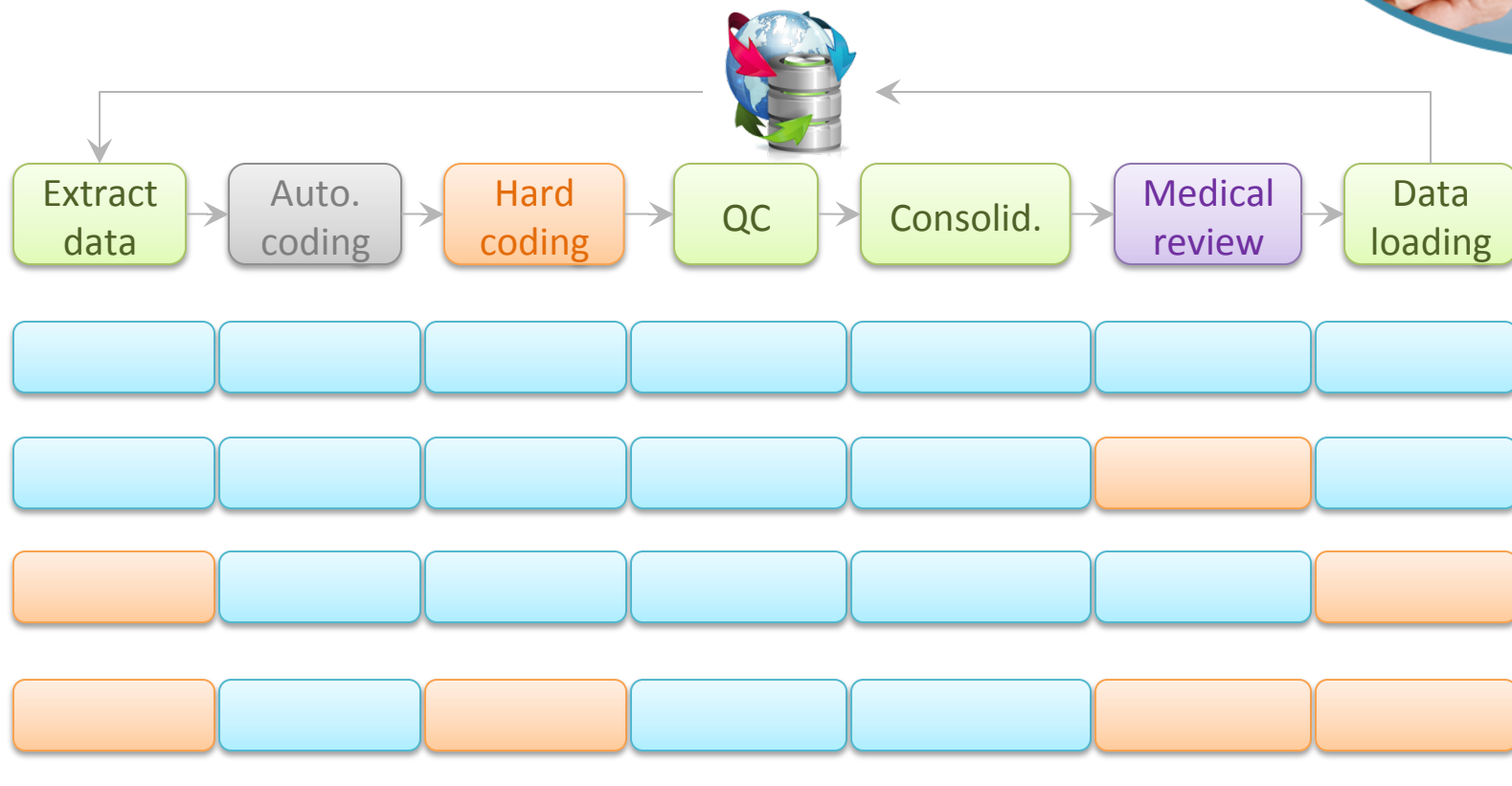


- **CodEX© answers our 2 key challenges**
 - Standardization of SAS programs
 - Common computer communication language

- **CodEX © will also support collaboration between CROs and Sponsors**
 - Share data cleaning activities
 - Split responsibility in the data coding process

Conclusion

- CodEX© as a **collaborative** tool between CRO and Sponsor



And so on ...

- Pre-requisite to CodEX© use is to have coding dictionaries licences

Legend:



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Question

