CodEX©

when Excel meets SAS to code clinical data

-DH08-

phuse

Keyrus

14 October 2015
Agenda

14 October 2015

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

CodEX principles

Technical aspects

Conclusion
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

*EDC: Electronic Data Capture*
Our constraints

Several Sponsors
- Specific DB structures
- Different EDC* systems

Standardization

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

CodEX

One common language

* EDC: Electronic Data Capture
Agenda

1. Business context
2. CodEX principles
   - CodEX drives the process
   - Supported by 2 software applications
3. Technical aspects
4. Conclusion
CodEX drives the process

- Extract data
- Data loading

- Automatic coding
- Hard coding
- Quality Control
- Consolidation
- Medical review

Legend:
- Data Manager
- non specific profile
- Coding officer
- Physician

Standard part = standard programs
consult

findings

consult
append

execute

manage

manage
Supported by 2 mains software applications

- Automatic coding
- Hard coding
- Quality Control
- Consolidation → Append dictionaries
- Medical review

**Benefits of CodEX:**
- flexible
- easy to learn and to use

[Diagram showing process flow and benefits]
Agenda

1. Business context
2. CodEX principles
3. Technical aspects
   - CodEX interface
   - Output
   - Run history
4. Conclusion
An interface easy to use

1- Complete the project parameters

2- Choose the action

3- Launch the action

Easy means:
- clear layout
- clear instructions
- clear document history
- clear actions

How to use the tool:
1. Complete all parameters values
2. Choose the action needed
3. Click on button to execute the selected action with the parameters

Detailed history of the tool (GAMP5 compliance)

3 distinct blocks

Keep in mind ideas: easy to use and be trained on
### Actions / choices limitation

#### Keyrus - CodEX°
- when Excel meets SAS to code clinical data

#### 3 main actions (+ interactive modes)

#### Easy also means:
- **Limited actions number**
- **User errors limitation**

#### Drop-down lists to ensure validity of the entered data

#### Conditional formatting for expected answer

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**Keep in mind ideas:** easy to use and be trained on
### 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**

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**Communication file**

<table>
<thead>
<tr>
<th>Coding status</th>
<th>Coding comments</th>
<th>Change primary SOC code to</th>
<th>Term to be coded</th>
<th>LLT code</th>
<th>LLT name</th>
<th>PT code</th>
<th>PT name</th>
<th>HLT code</th>
<th>HLT name</th>
<th>HLGT name</th>
<th>SOC code (primary)</th>
<th>SOC name (primary)</th>
<th>SOC code(s) (secondary)</th>
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</table>
### 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

<table>
<thead>
<tr>
<th>UserID</th>
<th>Action</th>
<th>Dataset name</th>
<th>Dictionary name</th>
<th>Dictionary version</th>
<th>Dictionary key item name</th>
<th>Use of a study specific dictionary</th>
<th>Change primary SOC to display</th>
<th>Output file type</th>
<th>Launch in debugging mode</th>
<th>Number of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>stephan.chollot</td>
<td>PRE-CODING (generate &amp; execute)</td>
<td>ae_to_code</td>
<td>MedDRA</td>
<td>15_1_E</td>
<td>LLT_NAME</td>
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<td>Y</td>
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- QC cannot be done without PRE-CODING
- Coding is done on same item
- Dataset name did not change
- SAS error # retrieved from SAS log
- In debugging mode, turn on the log options such as MPRINT, MLOGIC, …
Agenda

1. Business context
2. CodEX principles
3. Technical aspects
4. Conclusion
Conclusion

- **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

Legend:

- **CRO**
- **Sponsor**

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