



Author: S. LEBEAU – G. NEVEU

## SDTM MAPPING USING ODM - WORKSHOP -

02/02/2016

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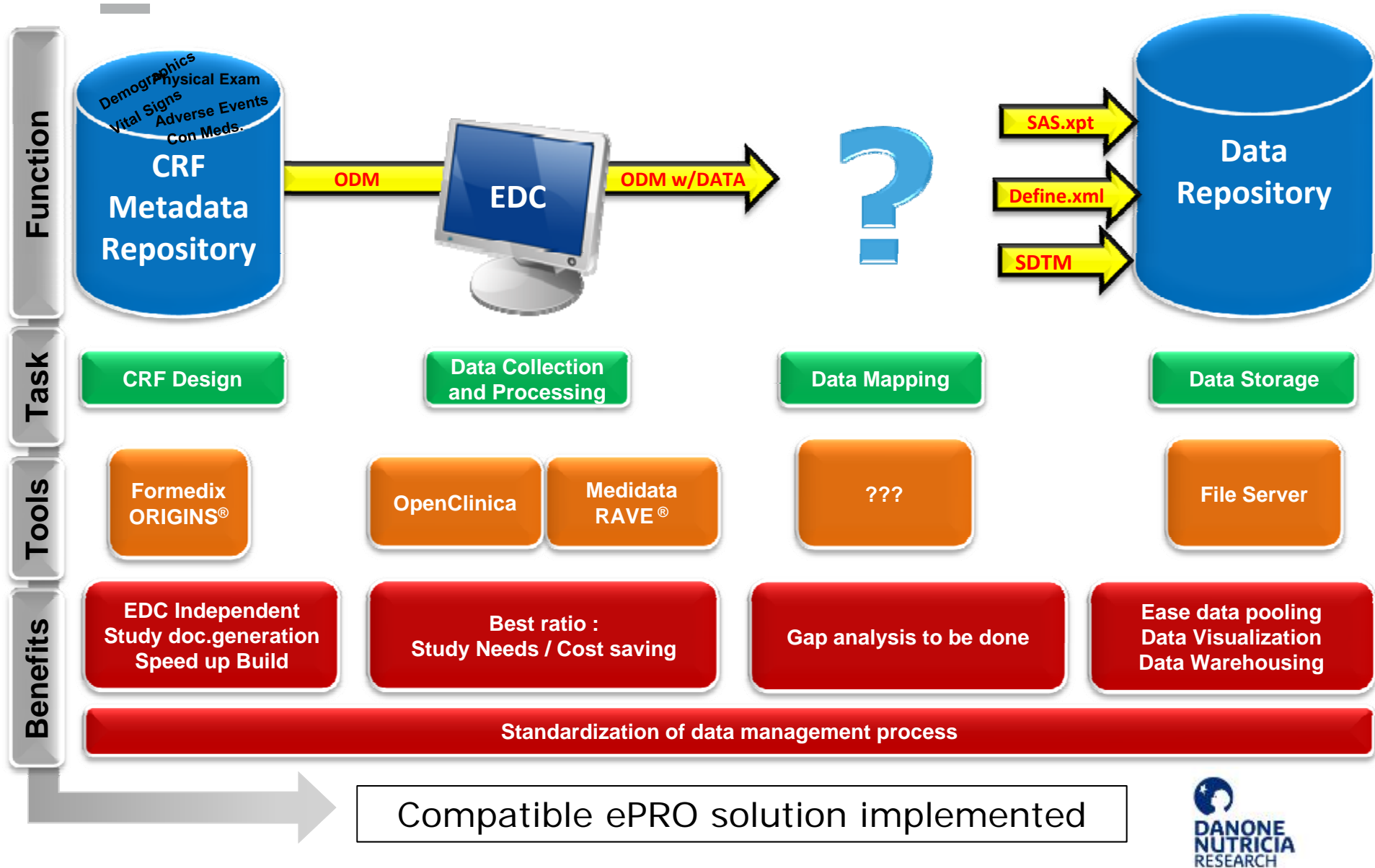




# 01

## INTRODUCTION

# DANONE CLINICAL DATA FLOW (DANFLOW)





# 02

MEDIDATA WEB SERVICES

# ODM ADAPTER

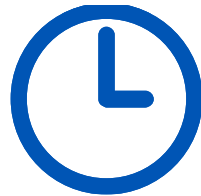
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EASIEST, QUICKEST AND MOST EFFECTIVE WAY TO EXTRACT  
DATA FROM RAVE  
ODM V1.3 FORMAT  
SPECIFICALLY DESIGNED FOR DATAWAREHOUSE INTEGRATION

# MODE INCRÉMENTAL

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Timestamp

*e.g. 2016-02-01T20:34:53*



SourceID

*e.g. 41935664*

# MODE INCRÉMENTAL

```
<ClinicalData StudyOID="PROTOCOL001" MetaDataVersionOID="1214"
mdsol: AuditSubCategoryName="Entered" > <SubjectData SubjectKey="2c05b734-6468-445e-
a50e-9b5042b715f1" mdsol: SubjectKeyType="SubjectUUID" mdsol: SubjectName="SUBJ01" >
<SiteRef LocationOID="SITE01" /> <StudyEventData StudyEventOID="FOLDER1"
StudyEventRepeatKey="FOLDER1[1]" mdsol: InstanceId="1359720" > <FormData
FormOID="DEMOG" FormRepeatKey="1" mdsol: DataPageId="5312700" > <ItemGroupData
ItemGroupOID="DEMOG" mdsol: RecordId="9620263" > <ItemData ItemOID="DEMOG.AGE"
TransactionType="Upsert" Value="32" > <AuditRecord>
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</AuditRecord> </ItemData>
</ItemGroupData>
</FormData>
</StudyEventData> </SubjectData>
</ClinicalData>
```

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<ClinicalData StudyOID="PROTOCOL001" MetaDataVersionOID="1214"
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</AuditRecord> </ItemData>
</ItemGroupData>
</FormData>
</StudyEventData> </SubjectData>
</ClinicalData>
```



# MODE INCRÉMENTAL

---

<SourceID>41935664</SourceID>

<https://medidata.mdsol.com/RaveWebServices/datasets/ClinicalAuditRecords.odm?studyoid=PROTOCOL01&startid=41935665>

## PAGINATION - HEADER

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Cache-Control: private, s-maxage=0

Content-Encoding: gzip

Content-Type: text/xml

Date: Tue, 2 Feb 2016 12:12:09 GMT

Link: <<https://medidata.mdsol.com/RaveWebServices/datasets/ClinicalAuditRecords.odm?studyoid=PROTOCOL01&startid=41935665>>; rel="next"

Server: Microsoft-IIS/7.5

Transfer-Encoding: chunked

Vary: Accept-Encoding

X-AspNet-Version: 4.0.30319

X-AspNetMvc-Version: 3.0

X-Powered-By: ASP.NET



03

HOW DO YOU PRACTISE SDTM  
MAPPING?

# INTERACTIVE WORKSHOP

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- Agenda
  - SDTM mapping level
  - Source of data
  - Methods of mapping
- Share your experience !



## HOW DO YOU MAPPED YOUR DATA?

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- No mapping
- SDTM level ?
  - ➔ Pure (100%)
  - ➔ Like (90-100%)
  - ➔ Other

# HOW DO YOU MAPPED YOUR DATA?

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- Which source of data?
  - SAS® datasets
  - ODM / Define.xml
  - Other

# HOW DO YOU MAPPED YOUR DATA?

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- Which method/tool?
  - Programming language
  - Specific tool
  - Other



# 04 DANONE MAPPING STRATEGY



# GAP ANALYSIS

## Standards

Take advantage of CDISC Standards

- SDTM database structure as Data output
- ODM Compliant as Data input

Ease data pooling  
Data Visualization  
Data Warehousing

## Services

Adopt a tool specifically designed for Clinical data mapping

- Easy to implement and use
- ETL all-in-one tool with no scripting
- Inter-study Reuse fonctionnality
- Independant from an EDC

Reproductibility  
EDC flexibility  
User friendly

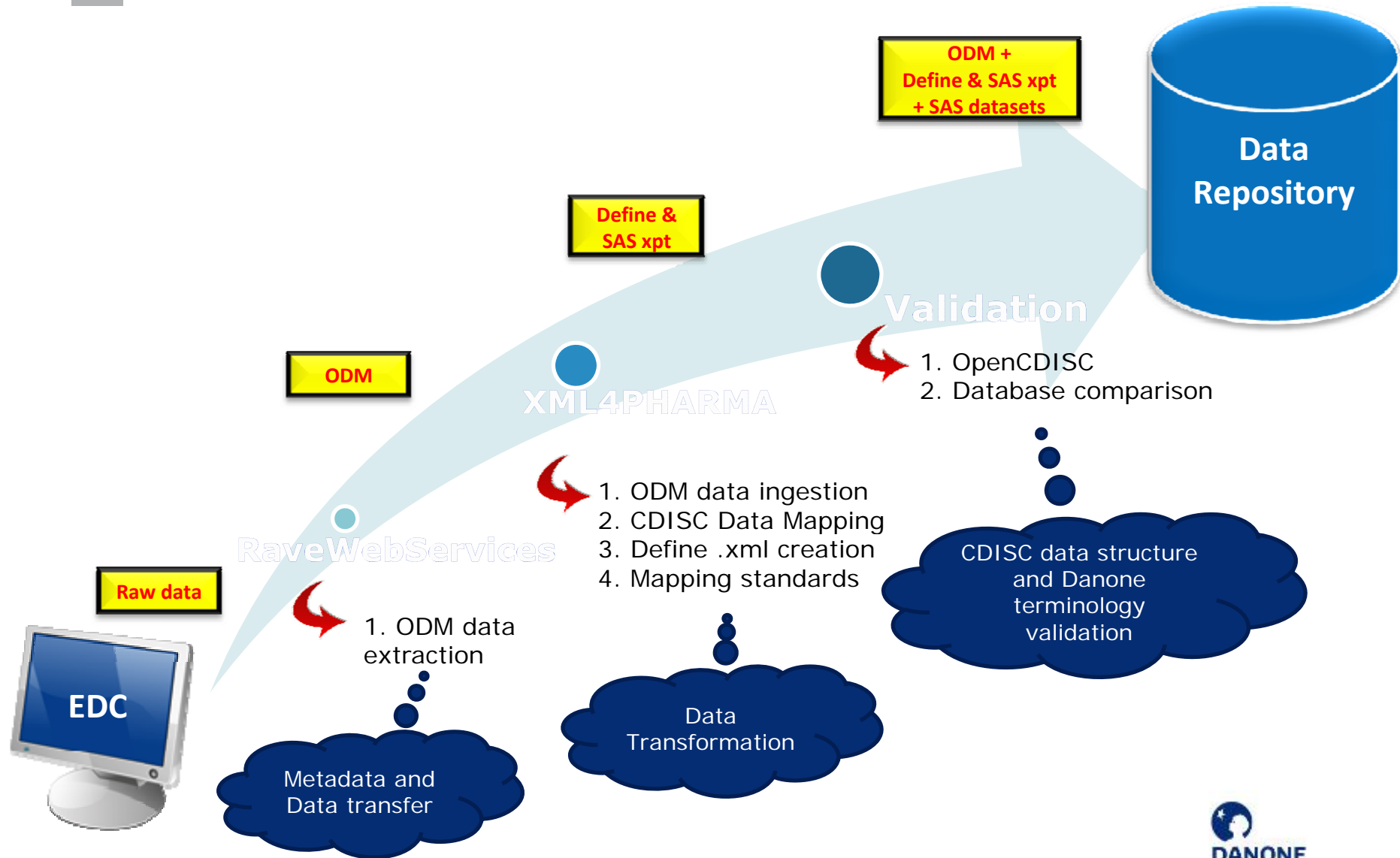
## Ressources

Cost effective & efficient mapping

- User-Friendly and intuitive
- Small FTE investment per study

Improve quality,  
cost and speed ratio

# DANONE DATA MAPPING FLOW





# 05 ODM MAPPING DEMO

# SDTM-ETL™

Domain	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable	Variable
NU999:LB	USUBJID	LB.LBSEQ	LB.LBGRPID	LB.LBREFID	LB.LBSPID	LB.LBTESTCD	LB.LBTEST	LB.LBCAT	LB.LBSCAT
NU999:IE	USUBJID	IE.IESEQ	IE.IESPID	IE.IETESTCD	IE.IETEST	IE.IECAT	IE.IESCAT	IE.IEORRES	IE.IESTRESC
NU999:VS	USUBJID	VS.VSSEQ	VS.VSGRPID	VS.VSSPID	VS.VSTESTCD	VS.VSTEST	VS.VSCAT	VS.VSSCAT	VS.VSPOS
NU999:EG	USUBJID	EG.EGSEQ	EG.EGGRPID	EG.EGREPID	EG.EGSPID	EG.EGTESTCD	EG.EGTEST	EG.EGCAT	EG.EGSCAT
NU999:EX	USUBJID	EX.EXSEQ	EX.EXGRPID	EX.EXSPID	EX.EXTRT	EX.EXCAT	EX.EXSCAT	EX.EXDOSE	EX.EXDOSTXT
NU999:DM	USUBJID	DM.DMSEQ	DM.DMGRPID	DM.DMREFID	DM.DMSPID	DM.DMTESTCD	DM.DMTEST	DM.DMTHDTC	DM.DMTHDTC
NU999:AE	USUBJID	AE.AESEQ	AE.AEGRPID	AE.AEREFID	AE.AESPID	AE.AETESTCD	AE.AETEST	AE.AELLTCD	AE.AELLTCD
NU999:DS	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSPID	DS.DSTESTCD	DS.DSTEST	DS.DSSCAT	DS.DSSCAT
NU999:QS	USUBJID	QS.QSSEQ	QS.QSGRPID	QS.QSREFID	QS.QSPID	QS.QSTESTCD	QS.QSTEST	QS.QSORRES	QS.QSORRES

ODM  
METADATA



EDC System



STUDY  
LINE.XML



SDTM DATASETS



## MAPPING QUICK FEEDBACK

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- Most of variables : Easy drap & drop
- Functions to calculate date difference, create datetime variables, etc...
- Automatic codelists association
- Domains with *-TEST* *-TESTCD* require few scripting adaptation

# MAPPING EXECUTION & RESULT

- Load your ODM clinical data
- Transformation to SAS-XPT
- Visual overview of SDTM tables
- Saved as XPT

Nom	Type
VS.xpt	SAS Xport Transport File
SV.xpt	SAS Xport Transport File
PE.xpt	SAS Xport Transport File
MH.xpt	SAS Xport Transport File
EX.xpt	SAS Xport Transport File
DS.xpt	SAS Xport Transport File
DM.xpt	SAS Xport Transport File
DA.xpt	SAS Xport Transport File
CM.xpt	SAS Xport Transport File
AE.xpt	SAS Xport Transport File

SDTM Tables

NU999:DM	NU999:SV	NU999:DS	NU999:VS	NU999:AE	NU999:MH	NU999:CM	NU999:DA	NU999:EX
STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC			
NU999	DM	NU999-001-001	001	2015-05-27	2015-07-09			
NU999	DM	NU999-001-002	002	2015-08-16	2015-08-18			
NU999	DM	NU999-001-011	011	2015-06-08	2015-07-09			
NU999	DM	NU999-001-007	007	2015-08-08	2015-08-26			



06

LEARNINGS - ISSUES - CHALLENGES

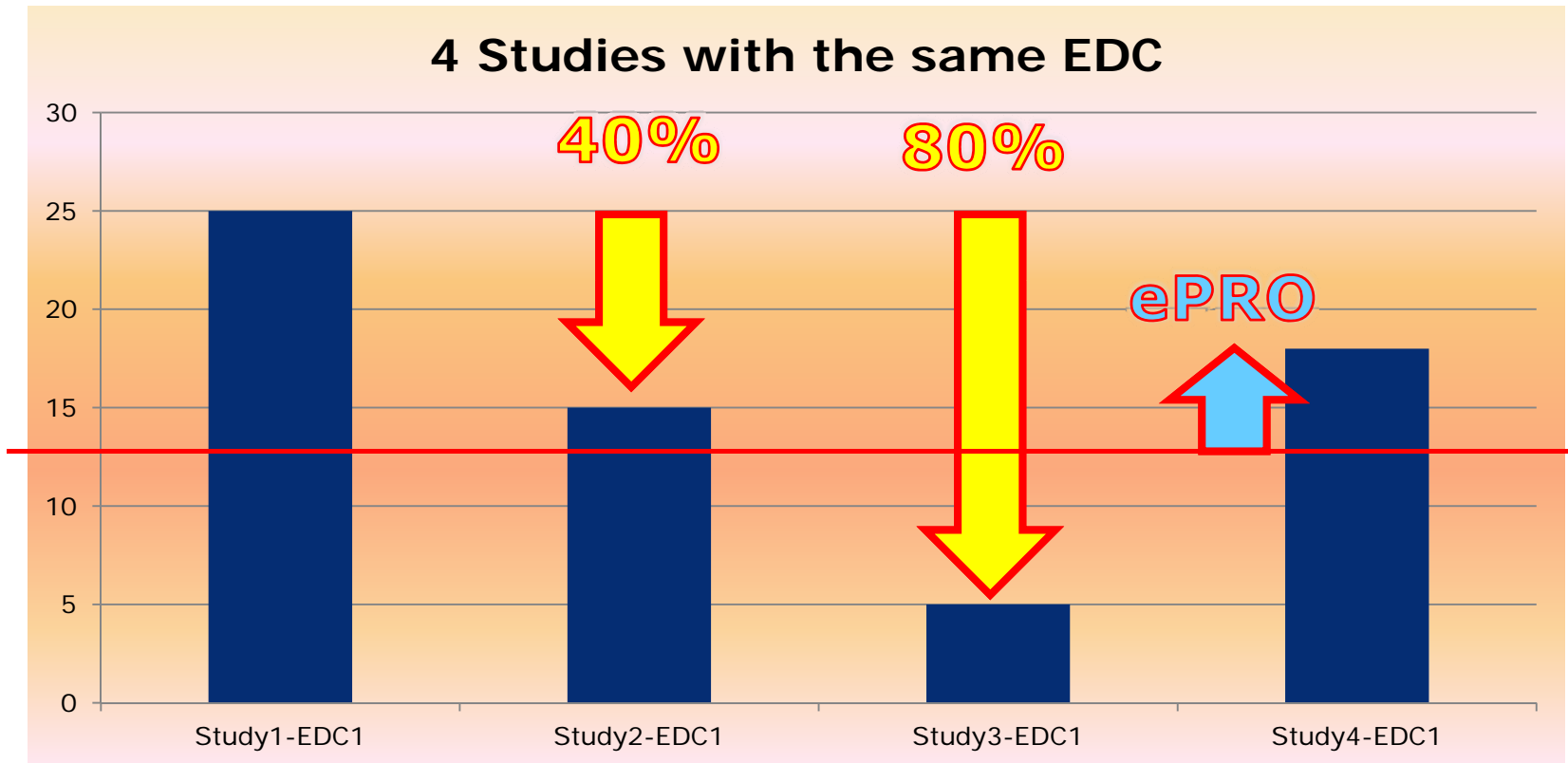
## LEARNINGS & ISSUES

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- Smooth & simple process
- Easy to adopt (including script language)
- Standards CRF forms facilitate mapping
- Previous mappings capitalisation



## STUDY CASES (IMPACT ON MAPPING)



- Global Library for standards mapping scripts
- Standard form ↔ Standard mapping script

## LEARNINGS & ISSUES

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- Less SAS® programming BUT still needed
- ODM structure vs CDISC ODM certification
- Large studies > Tool for ODM data extract





07

ANY QUESTIONS?

THANKS

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# DANONE

*~Origines~*

