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CDISC STANDARDS USE IN CLINICAL STUDIES: DANONE'S RETURN-ON-EXPERIENCE

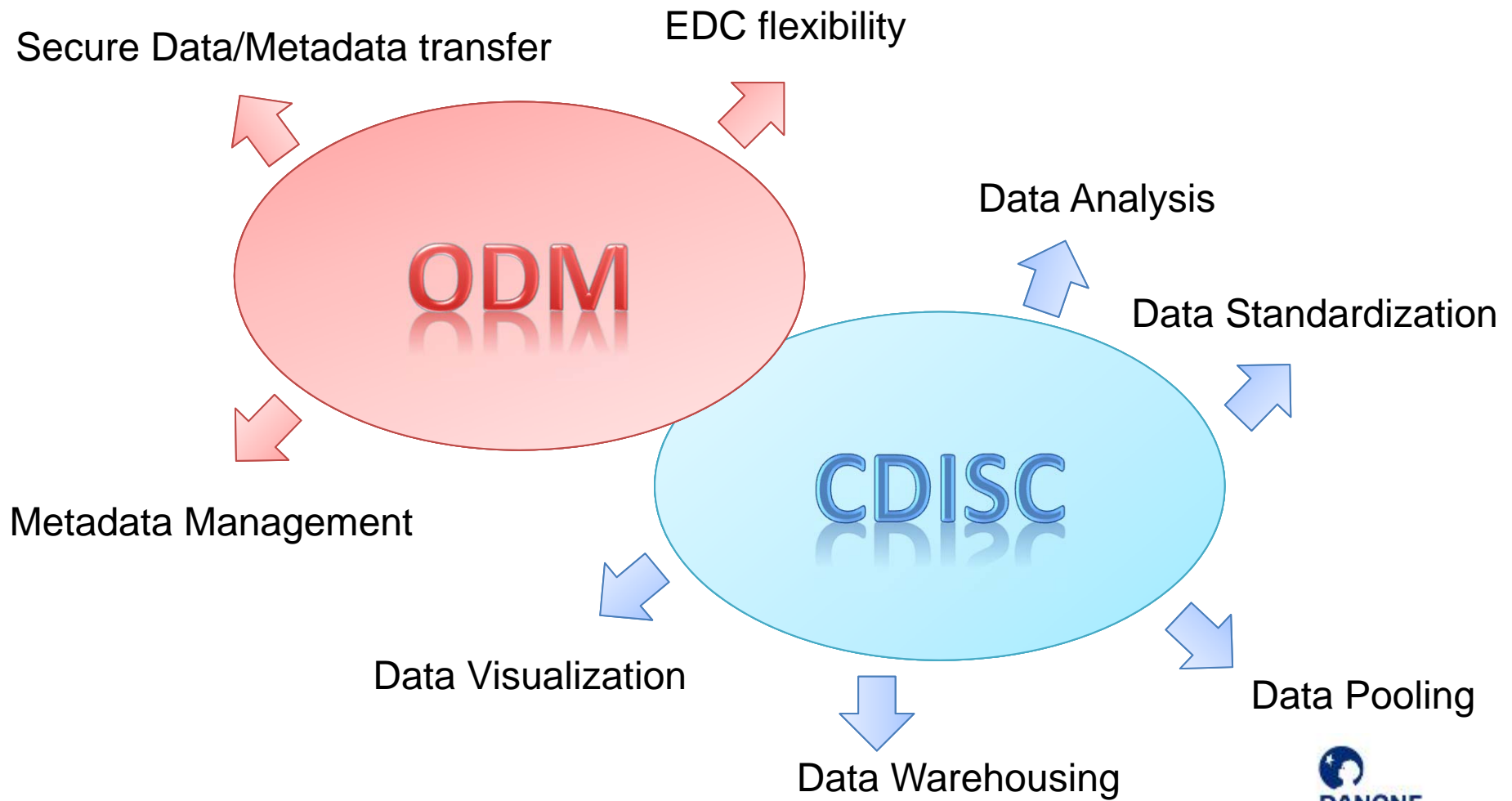Date: 08/12/2014

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AGENDA

1) State of the art

2) eClinical Tools and ODM/CDISC combination

3) Data Flow Overview

4) Feedback on our experience

5) Impact

6) ePRO integration on same workflow

7) Benefits and next steps
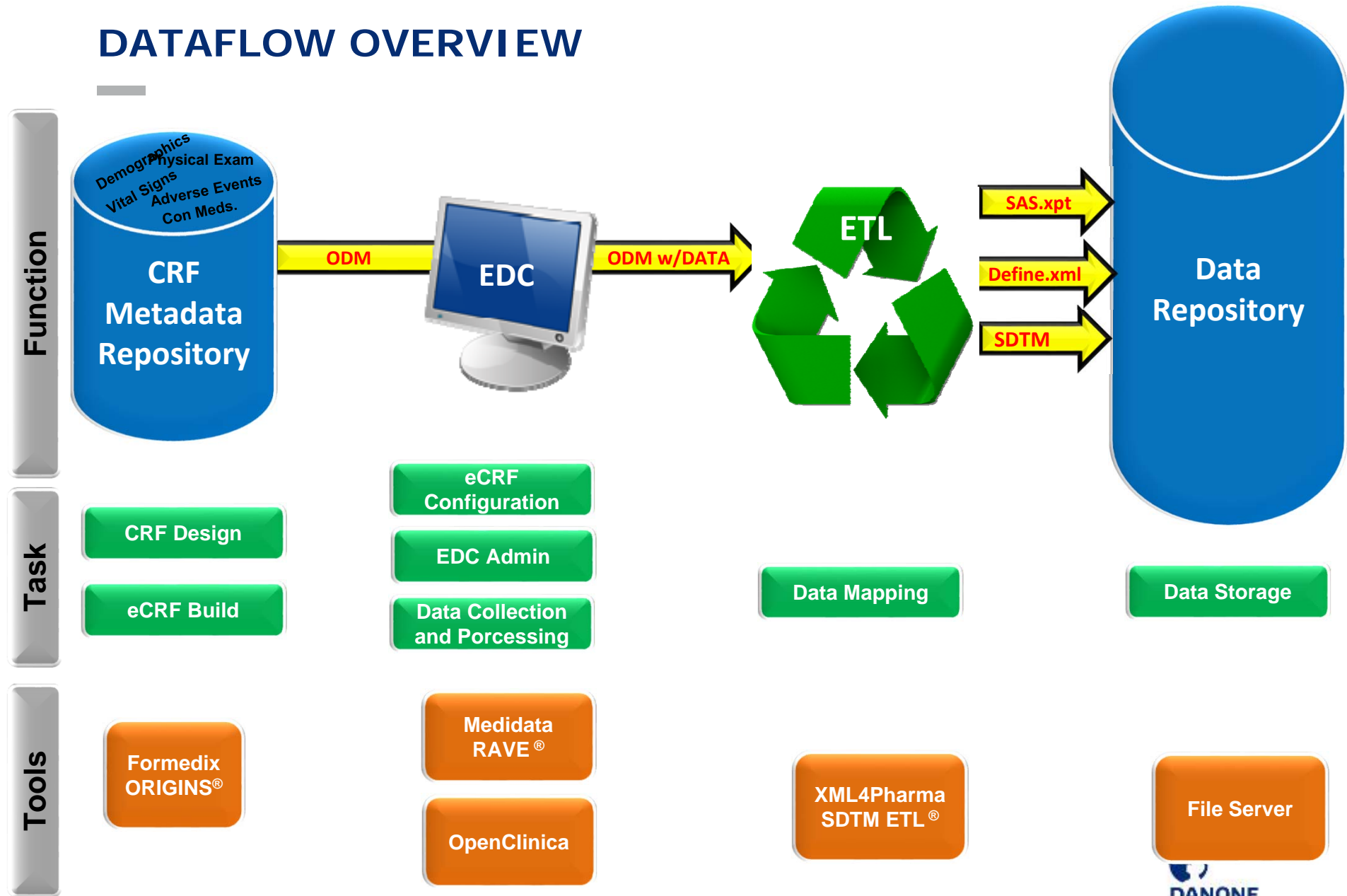
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STATE OF THE ART

➢ Improve the data Governance and Standards

- Metadata Repository library and Study Metadata Modeler implementation

➢ Improve security, control and visibility on data

- Internalize some tasks in-house
- Replace Paper-based by an EDC system
- 4 Danone divisions => large range of study sizes and needs
- Adopt a flexible data management process based on several EDC

➢ Improve the quality, speed and cost ratio for a study

- No impact on FTE, decrease the cost of process and timelines

➢ Facilitate and prepare data for Exploitation

- Ease the data mapping process
- Create a Data Warehouse with CDISC (SEND/SDTM/CDASH) implementation will improve Data Pooling, Analysis and Visualizations

ODM/CDISC APPROACH BENEFITS

Secure Data/Metadata transfer

EDC flexibility

Data Analysis

Data Standardization

ODM

CDISC

Metadata Management

Data Visualization

Data Pooling

Data Warehousing

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DATAFLOW OVERVIEW

Function

Demographics
Physical Exam
Vital Signs
Adverse Events
Con Meds.

CRF Metadata Repository

ODM →

EDC

ODM w/DATA →

ETL

SAS.xpt →
Define.xml →
SDTM →

Data Repository

Task

CRF Design

eCRF Build

eCRF Configuration

EDC Admin

Data Collection and Porcessing

Data Mapping

Data Storage

Tools

Formedix ORIGINS®

Medidata RAVE®

OpenClinica

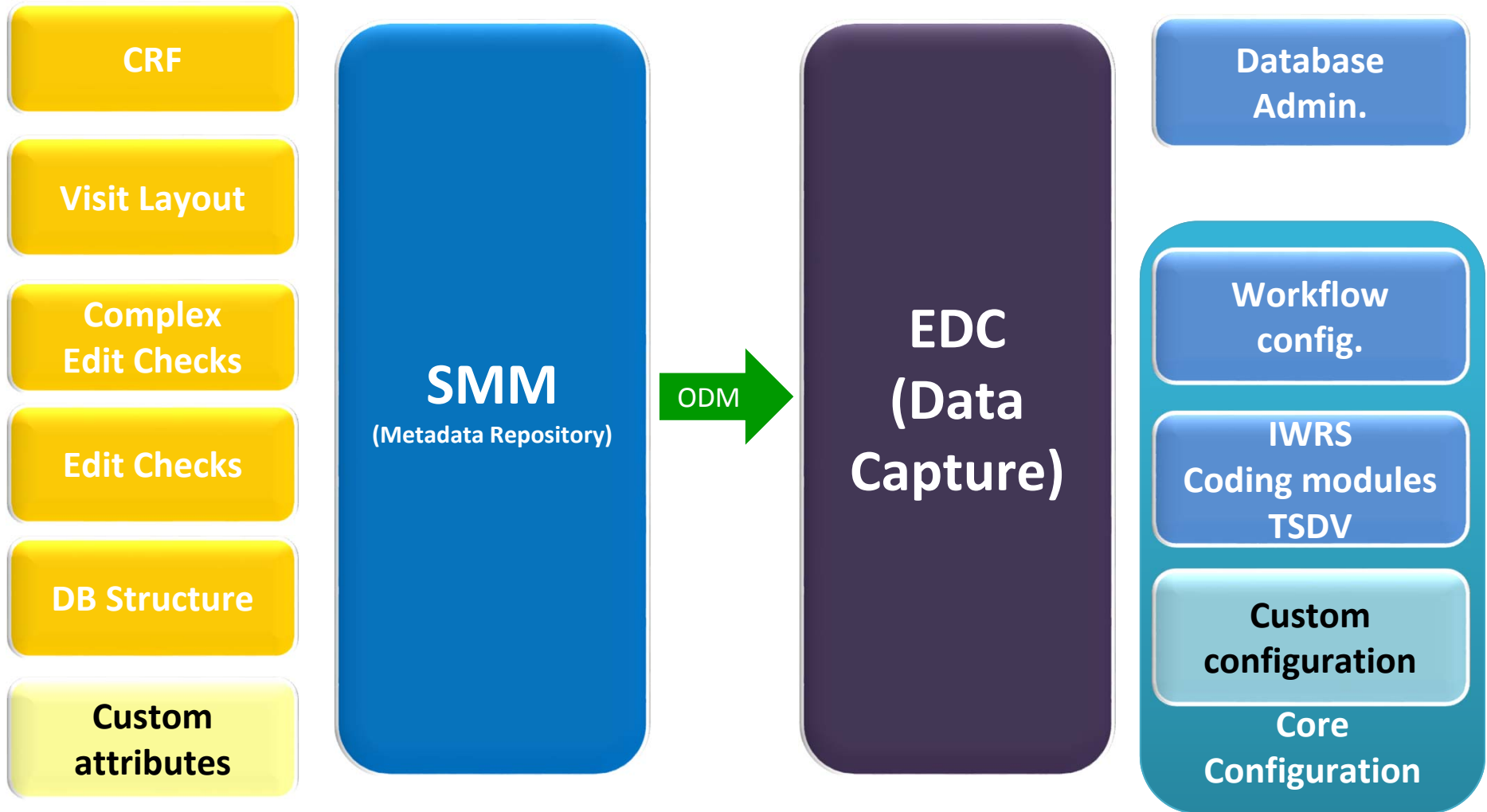XML4Pharma SDTM ETL®

File Server

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SMM APPLICATIONS

- ➢ Metadata Repository creation and management
  - • Standard modules including form, ItemGroups, Items, codelists and measurement units
  - • Simple and complex Edit checks
  - • Custom attributes : CRF completion guidelines, Form design

- ➢ Configure an EDC and provide study documents at the same time
  - • Case Report Form annotated
  - • Database Structure
  - • CRF completion guidelines
  - • Data Validation Plan ?
  - • ODM EDC study configuration file
  - • Previsualize eCRF without EDC system

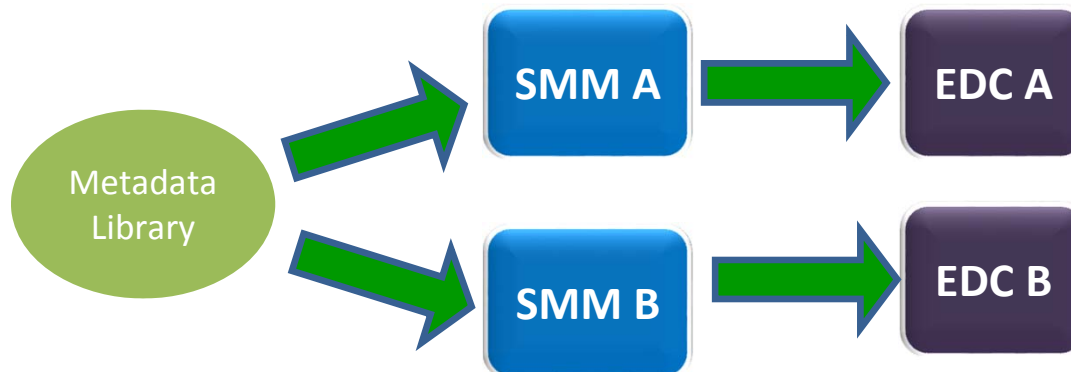DANONE
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SMM-EDC INTERACTION

CRF

Visit Layout

Complex Edit Checks

Edit Checks

DB Structure

Custom attributes

SMM
(Metadata Repository)

ODM →

EDC (Data Capture)

Database Admin.

Workflow config.

IWRS Coding modules TSDV

Custom configuration

Core Configuration

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APPLICATIONS

➢ **Data Management Strategy benefits**

- Ensure a smooth transition between EDC (longitudinal evolution) in avoiding to recreate a Global Library

- Different Data Management Units can use the same Global Library and use different EDC (parallel evolution)

FEEDBACK

> ## Set up of a new WoW

- Creation of standards metadata => Working Group involvement
- Use several EDC => Adapt metadata structure
- SMM implementation done in 3 months
- Discussion with EDC/SMM/Data mapper providers
- Computerized Systems Validation management

> ## Data Mapping

- Different ODM structure from EDC=> Mapping library per EDC
- Adopt CDISC structure homogeneization
- Drag and drop environment can be used at 90%
- Need xsl language knowledges for last 10%
- ODM extracted from EDC missing coding term => SAS and EDC discussion

IMPACT ON FTE/BUDGET

➢ FTE

- ≈50% decrease in study set-up time (Protocol to EDC Go-Live)
- ODM study configuration file imported in EDC
- Automatic study documents generation in human readable format
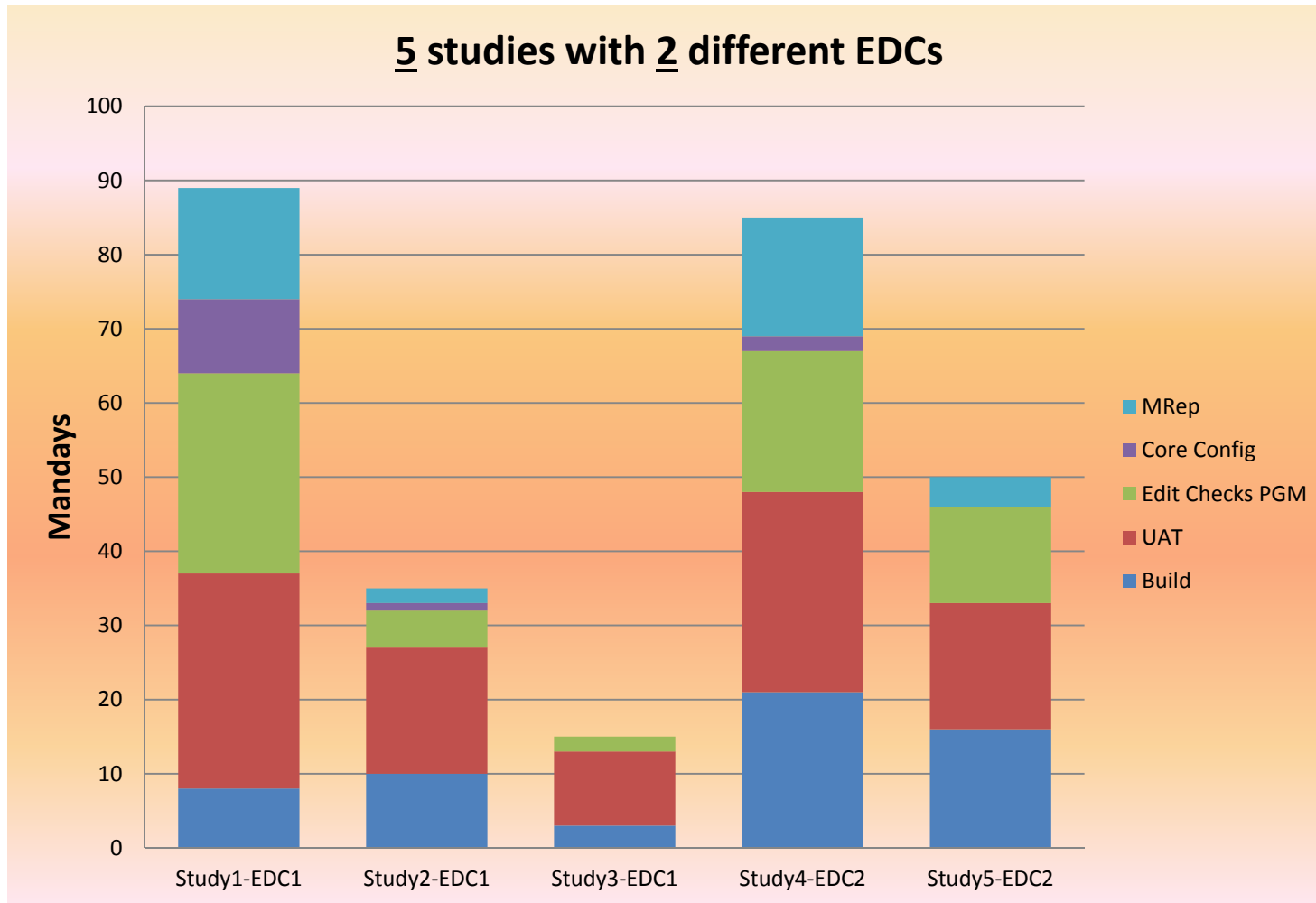- 60-95% study build done in SMM

➢ Budget

- ≈ 20% increase in overall DM study budget (vs. Paper-based)
- Adapt the EDC selection depending on study specification
- Internalize study build activities in-house without FTE increase
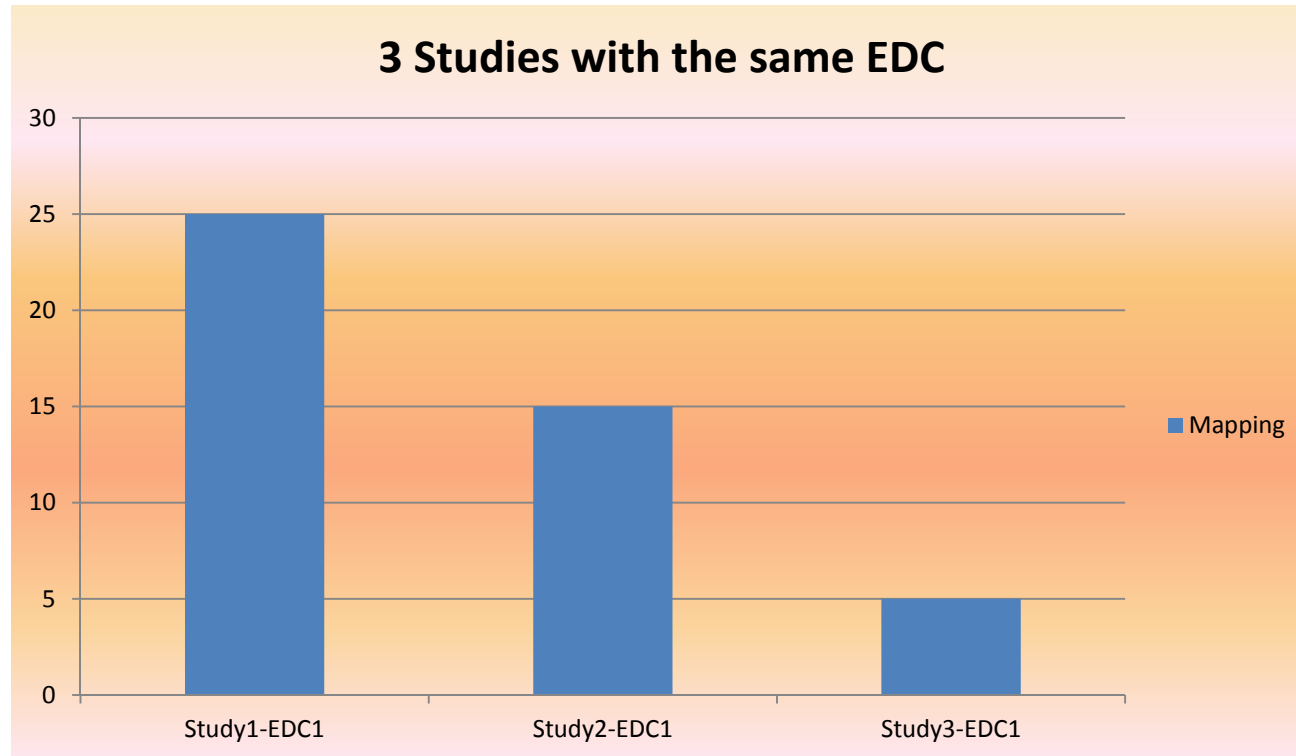- EDC previsualization plug-in in Study Metadata Modeler allows to decrease the EDC rent duration during study build-up phase
- Application Services Provider (Cloud Computing) : No IS, no hardware maintenance, no hotline for end-users, flexibility in term of duration, best fit cost/number of studies.

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STUDY CASES (IMPACT ON STUDY BUILD)

STUDY CASES (IMPACT ON MAPPING)

3 Studies with the same EDC

> Global Library for standards mapping scripts

> Standard form ⇔ Standard mapping script

EPRO INTEGRATION

➢ ePRO fits seamlessly with our WoW
- Same benefits
- Global reduction on mandays
- Cost saving vs standalone solution (50%-230%)
- Same Mrep for ePRO and CRF forms

➢ ePRO CRO vs ePRO (Do it Yourself method)
- No external CRO team to manage
- 2 systems – 2 teams vs 1 system – 1 team
- ePRO and eCRF design with the same designer

➢ Device management
- ePRO based on iOS and Android environment
- Bring Your Own Device (BYOD)
- Device costs included in subject compensation
- Device preconfiguration
- Site/Subject training

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BENEFITS AND NEXT STEPS

➢ Benefits

- Ease data pooling
- Facilitate the creation of standard analyses
- ADAM implementation now possible

➢ Finalized ePRO implementation based on same workflow

- Create standard scripts for ePRO forms

➢ Data Visualization implementation

- JMP Clinical based (CDISC compliant)
- Create standard visualizations
- Data Review Meeting

➢ SEND implementation on preclinical studies

➢ Danone => CDISC Platinum members

- Improve CDISC Nutrition standards

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