



# *METADATA REPOSITORY CONCEPT*

20<sup>th</sup> February 2018, German CDSIC User Network  
Christian Geretzki

**PAREXEL**<sup>®</sup>  
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# AGENDA

- **WHY AND HOW TO USE STANDARDS**
- **HIERACHY IN THE REPOSITORY**
- **STANDARDS IN MDR**
- **CDASH AS OVERLAY IN MDR**



## About Me:

Christian Geretzki  
Principal Data Standards Analyst

Member of Data Standards Governance Team  
responsible for seamless integration between MDR  
Standards and EDC systems

# WHY DO WE NEED STANDARDS

Database Programmer:

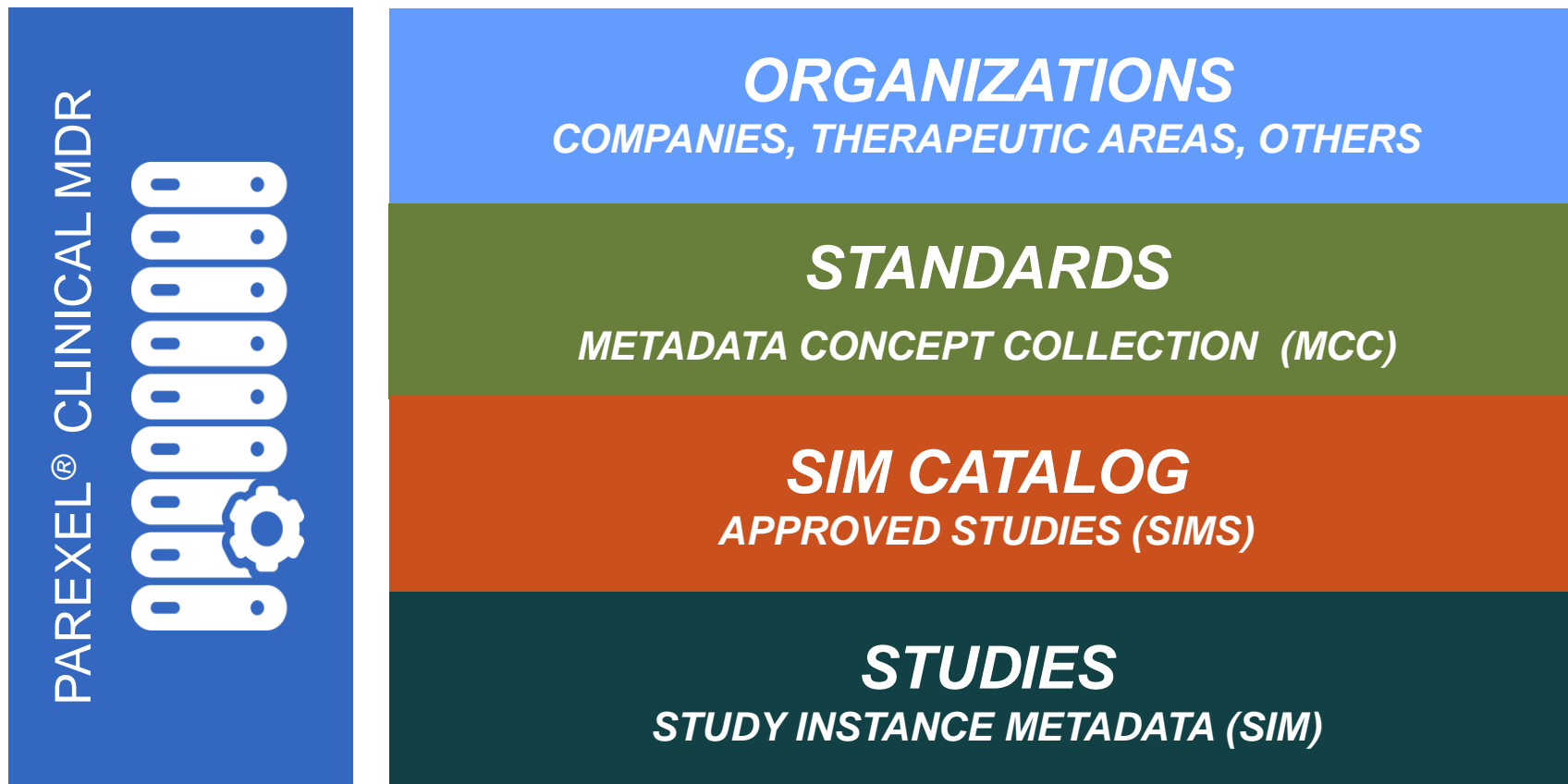
- It's working fine as it is.
- We are all experts and know how to setup studies.



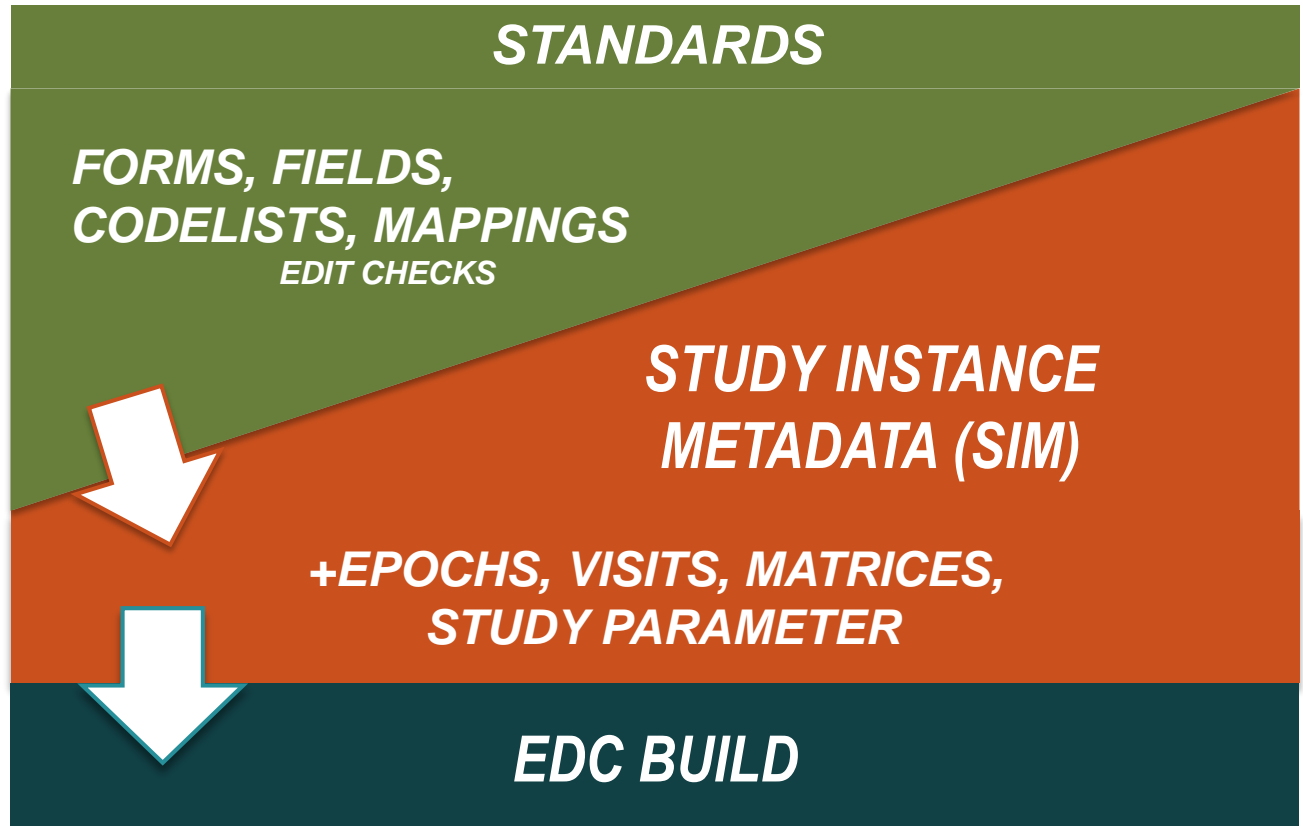
**Working with Standards leads to:**

- **Additional departments are involved.**
- **They never fit what we need.**
- **We need to work around restrictions.**
- **So is a time consuming job.**

# METADATA STANDARDS HIERARCHY



# METADATA STANDARDS CONTENT



# METADATA STANDARDS MANAGEMENT – CORE METADATA AND EXTENDED METADATA

PAREXEL® CLINICAL MDR



## STANDARDS (MCC)

CORE PARAMETER

OVERLAY AREA

CDASH /GLOBAL

SAS LABEL / QUESTION TEXT / DOMAIN

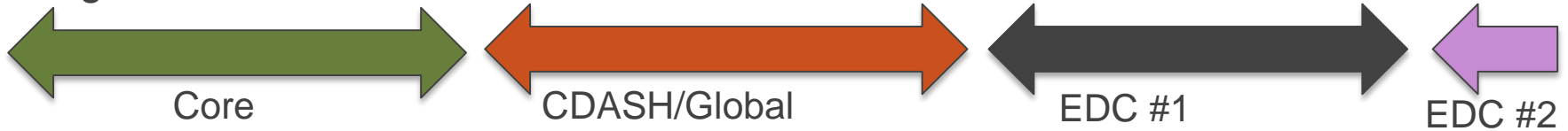
- SAS LABEL
- QUESTION TEXT
- DOMAIN
- DISPLAY OPTION

- SAS LABEL
- QUESTION TEXT
- DOMAIN
- DATASOURCE

- SAS LABEL
- QUESTION TEXT
- DOMAIN
- COLLAPSIBLE

# MANAGING CORE AND OVERLAY METADATA

Manage Core and Overlay metadata in one spreadsheet with each item as a single record.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	
	Name*	Form (Name), Item Group (Name)*	Length	Value Set (OID)	Description	Question	Required	CDASH	CDASH Question Text	CDASH Short Prompt	Sponsor Text	SAS Label	CDASH IIG Core	CDASH Definition	CRF Completion Instruction	DataL abs->	Item Name	Display Option	Short Prompt	Source	MaxLen	MinLen	MaxPre	MinPre	DataGroup Name	Reverse	FieldOID	
1	AEYN	Adverse Event_Non	1	C66742_C_NY	An indication whet	Were any advers	N		Were any adverse event	Any Adverse E	Did the subject ex	Any Adv	O	An indic	Indicate if the subject experienced any adverse events. If yes, include the appropriate details where indicated on the CRF.													
3	AETERM	Adverse Event_Adv	200		Verbatim (i.e., inve	Adverse Event	Y		What is the adverse eve	Adverse Event	Adverse Event Tel	Adverse	HR	Verbatim	Record only one diagnosis, sign or symptom per line tel	Encoding												
4																												
5																												
6																												
7																												
8																												
9																												
10																												



Once imported,

the core and overlay metadata become part of the standard MCC

and

are copied into each SIM along with the standard.

ORGANIZATION: PAREXEL  
9 FORMS, 9 DOMAINS, 126 VARIABLES

**INFORMATION** COLLABORATE REQUESTS

**Item Properties**  
Name: LBDAT  
Oid: 1afebdb8-a133-46a6-ab5f-8f146e8ea27e  
Data Type: date  
CDASH Variable:  
SDTM Variable:  
Description:  
The date of specimen collection represented in an unambiguous date format (e.g., DD-MON-YYYY).  
Question: Sample Collection Date (DDMMYYYY)  
Length: 11  
Mandatory: false  
Required: false

**CDASH**  
CDASH Question Text:  
What was the date of the lab specimen collection?  
CDASH Short Prompt: Collection Date  
PXL Text: Sample Collection Date (DDMMYYYY)  
PXL SAS Label: Actual Collection Date  
CDASH IG Core: R/C  
CDASH Definition:  
The date of specimen collection represented in an unambiguous date format (e.g., DD-MON-YYYY).  
PXL Justification:  
CRF Completion Instructions:  
Record the date when the specimen collection was done using this format (DD-MON-YYYY).  
PXL Completion Instructions:  
Notes:

**DataLabs**  
Item Name:  
Display Option: date (calendar picker)  
Short Prompt:  
Source: EDC  
MaxLen: 11  
MinLen: 11  
MaxPrec:  
MinPrec:  
DataGroup Name:  
Tablecolumn Label:  
PDE Verify: false  
Hidden: false  
Condition:  
Derivation Name:  
Dictionary:  
Check IsRequired: false  
Check NonConformant: true  
Check MinLength: true  
Check MaxLength: true  
Check MinPrecision:  
Check MaxPrecision:  
Check NotAnswered:  
Check NormalRange:  
NormalLow:  
NormalHigh:



# CDASH/GLOBAL OVERLAYS

## On Forms:

**CDASH**  
Domain Class: Findings  
Domain: LB  
Data Collection Scenario: LB-Local Processing

## Domain Class options:

to DSA  
Events  
FA  
Findings  
Interventions  
Special Purpose

## On Itemgroups:

**CDASH**  
Category  
Hematology  
Sub Category

# CDASH/GLOBAL OVERLAY

## On Items:

» LBTESTCD\_CHEM  
K | Potassium Measurement  
SODIUM | Sodium Measurement  
UREAN | Urea Nitrogen Measurement  
PROT | Total Protein Measurement  
ALB | Albumin Measurement  
CREAT | Creatinine Measurement  
BILDIR | Direct Bilirubin Measurement  
BILI | Total Bilirubin Measurement  
ALT | Alanine Aminotransferase Measurement  
AST | Aspartate Aminotransferase Measurement  
GLUC | Glucose Measurement  
PHOS | Phosphate Measurement  
ALP | Alkaline Phosphatase Measurement  
UREA | Urea Measurement  
CA | Calcium Measurement  
MG | Magnesium Measurement  
CL | Chloride Measurement  
BICARB | Bicarbonate Measurement  
LDH | Lactate Dehydrogenase Measurement  
CRP | C-Reactive Protein Measurement  
T3 | Triiodothyronine Measurement  
T4FR | Free Thyroxine Measurement  
TSH | Thyrotropin Measurement

{ Laboratory Test Code }

### CDASH

CDASH Question Text: What was the lab test code?

CDASH Short Prompt: Lab Test Code

PXL Text: Parameter

PXL SAS Label: Lab Test Code

CDASH IG Core: Req (SDTM)

CDASH Definition:

Terminology used for laboratory test codes of the CDISC Study Data Tabulation Model.

PXL Justification:

CRF Completion Instructions:

Record the name of the Lab measurement or finding, if not pre-printed on the CRF. If collected on the CRF, the sponsor may provide additional instructions to ensure the data is entered as intended.

PXL Completion Instructions:

Notes:

# CDASH/GLOBAL OVERLAY

## On Codelists / ValueSets:

Laboratory Test  
Code\_C\_LB\_Chem

- K | Potassium Measurement
- SODIUM | Sodium Measurement
- UREAN | Urea Nitrogen Measurement
- PROT | Total Protein Measurement
- ALB | Albumin Measurement
- CREAT | Creatinine Measurement
- BILDIR | Direct Bilirubin Measurement
- BILI | Total Bilirubin Measurement
- ALT | Alanine Aminotransferase Measurement
- AST | Aspartate Aminotransferase Measurement
- GLUC | Glucose Measurement
- PHOS | Phosphate Measurement
- ALP | Alkaline Phosphatase Measurement
- UREA | Urea Measurement
- CA | Calcium Measurement
- MG | Magnesium Measurement
- CL | Chloride Measurement
- BICARB | Bicarbonate Measurement
- LDH | Lactate Dehydrogenase Measurement
- CRP | C-Reactive Protein Measurement
- T3 | Triiodothyronine Measurement
- T4FR | Free Thyroxine Measurement
- TSH | Thyrotropin Measurement

### Value Set Properties

Items: 23

Name: Laboratory Test Code\_C\_LB\_Chem

Synonym: Laboratory Test Code

Extensible: true

Submission value: LBTESTCD\_LB\_CHEM

Description:  
Terminology used for laboratory test codes  
CDISC Study Data Tabulation Model.

Preferred Term:  
CDISC SDTM Laboratory Test Code Terminology

OID:  
C65047\_C\_LB\_CHEM:9285f042-aa68-4914-4c6e5e90aab2

Global Unique ID (C Code): C65047

Required: true

### Value Set Item Properties

Code / Submission Value: CREAT

Decode / Synonym: Creatinine Measurement

Description:  
A measurement of the creatinine in a biological specimen.

Preferred Term: Creatinine Measurement

Global Unique ID (C Code): C64547

OID:  
CLI.6.C65047\_C\_LB\_CHEM:9285f042-aa68-4914-8eec-4c6e5e90aab2.C64547

Required: false

**DataLabs**

Data Entry Prefix:

**CDASH**

Display Text: Creatinine

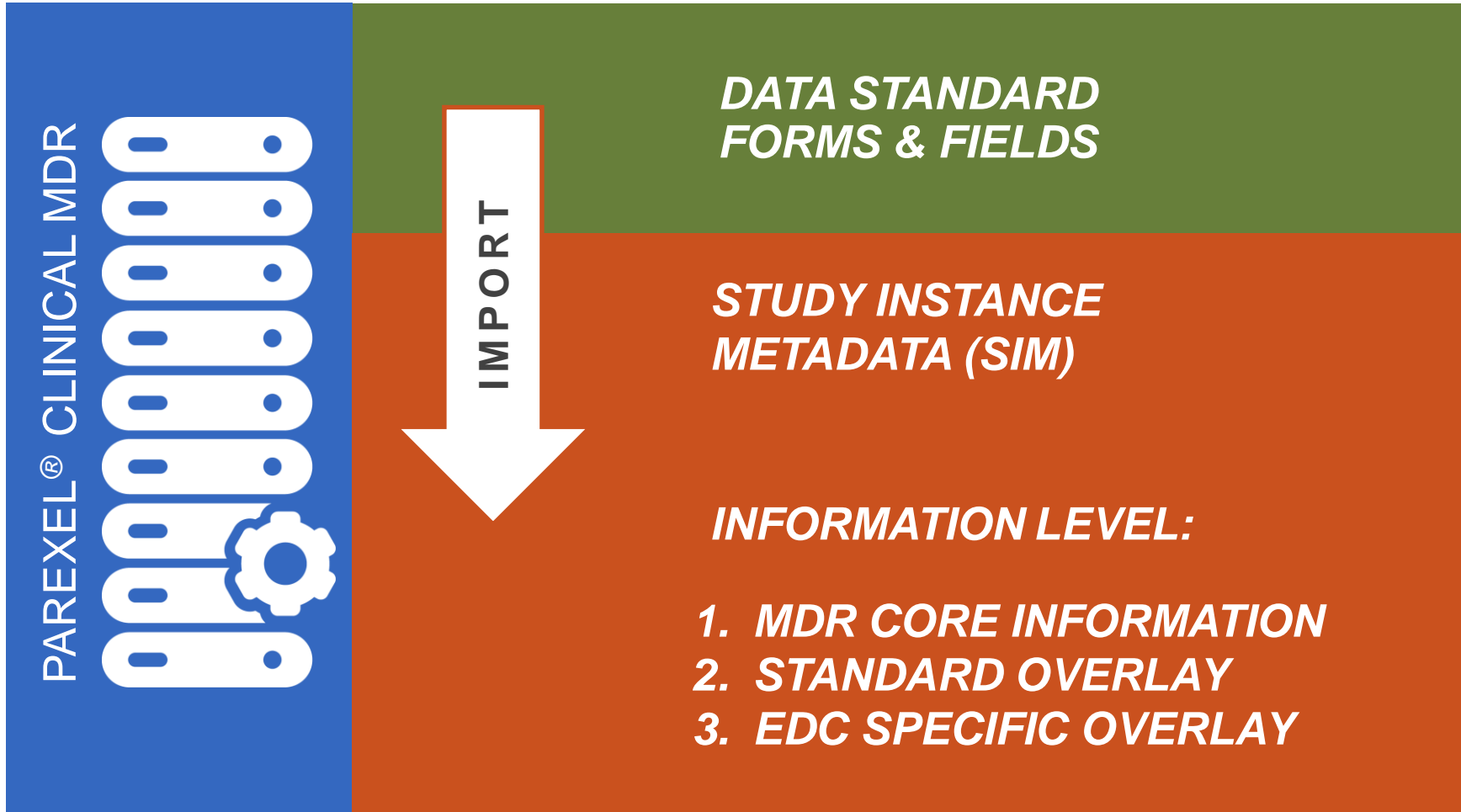
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*THANK YOU*



*BRINGING STANDARDS  
TO LIFE*

# OVERLAY WAKE UP

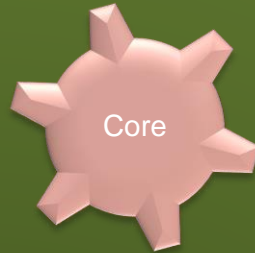


# OVERLAY WAKE UP

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## STUDY INSTANCE METADATA (SIM)



- **NAME**
- **DATA TYPE**
- **LENGTH**
- **DISPLAY TEXT**

**FIXED IN THE MDR  
DATABASE STRUCTURE**

### Item Properties

Name: COMPDATE

Oid:

4136e0d2-2491-4449-9562-da31b75e102c:a790347  
e-9fb8-45ad-a0c0-47f5162f6ea5

Data Type: date

Description:

Completion Date (This Item is intended for EDC purp  
ose only)

Question: Completed Date:

Length: 11

Mandatory: false

Required: false

# OVERLAY WAKE UP

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## STANDARD OVERLAY = CDASH



- **DOMAIN**
- **DATA COLLECTION SCENARIO**
- **CDASH DEFINITION**
- **SAS LABEL**
- **PXL TEXT (JUSTIFICATION)**

### CDASH

Domain Class: Events

Domain: AE

Data Collection Scenario: DENORMALIZED

**CDASH INFORMATION  
NOT RELATED TO A SPECIFIC EDC-SYSTEM**



# OVERLAY WAKE UP

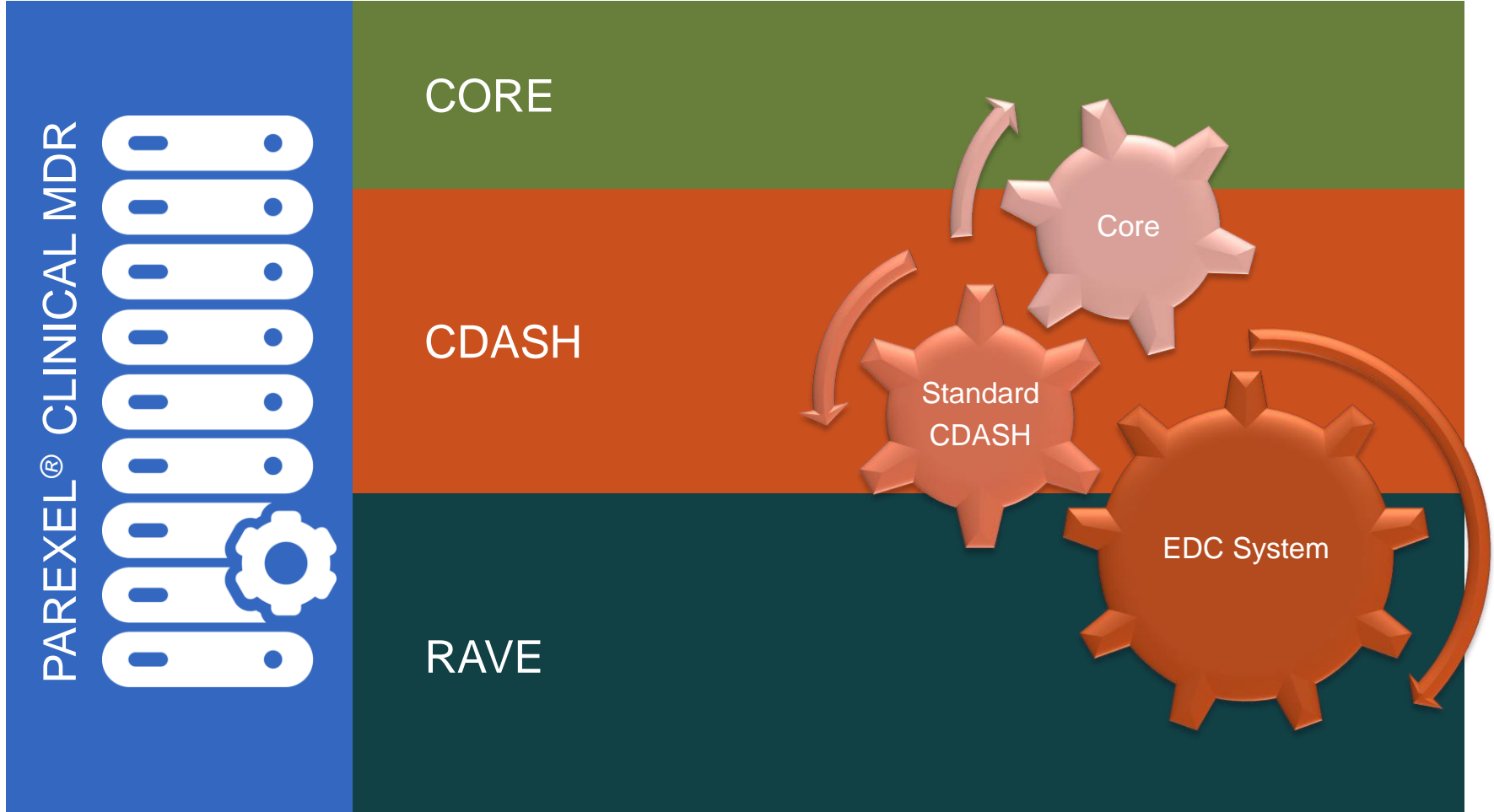
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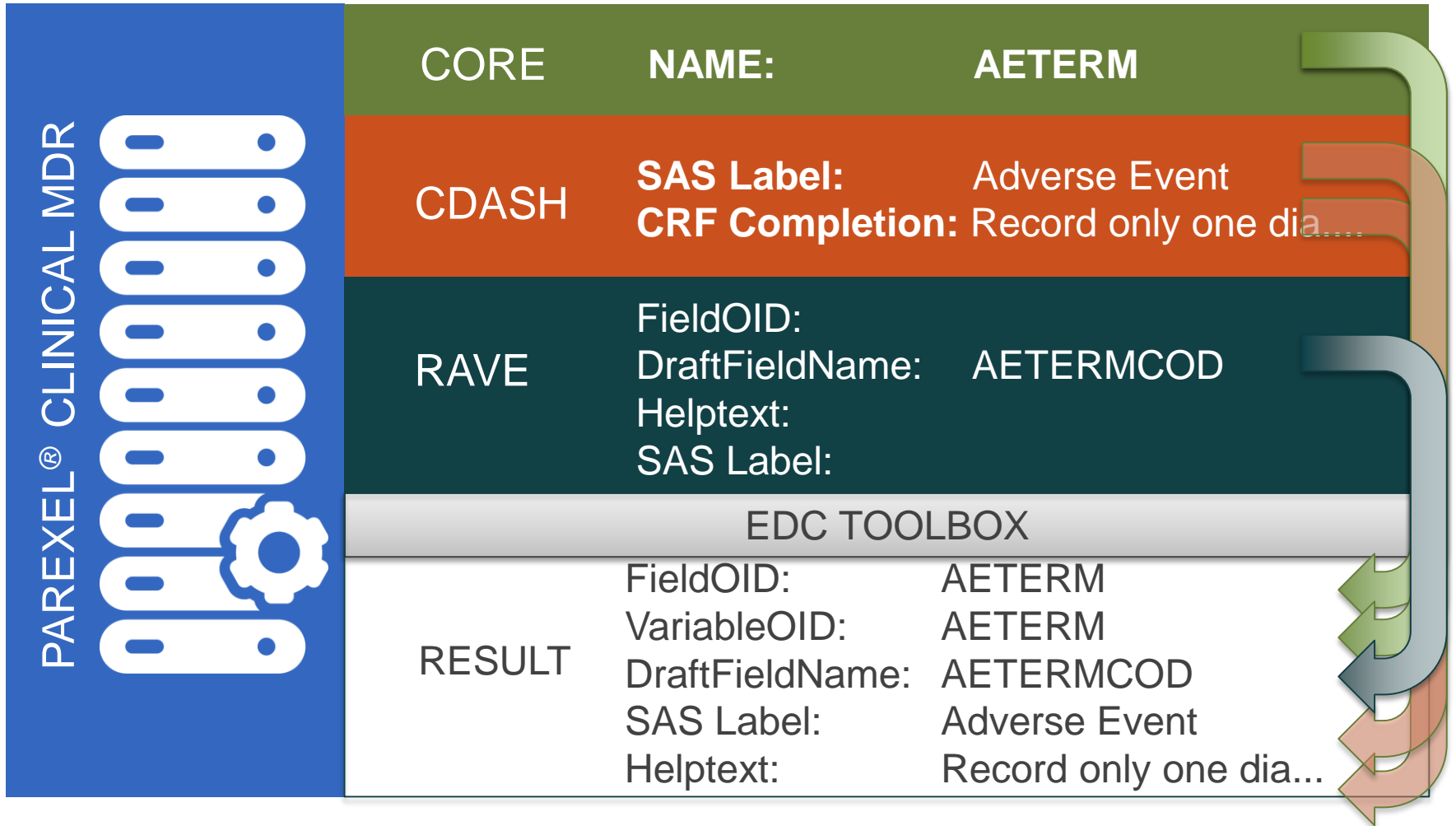
## ***EDC SPECIFIC OVERLAYS***

- Control Type
- Form/Field Identifier
- Double Data Entry
- Ident level
- Headertext
- Helptext / Links
- Default Value
- Is Required?
- Field Edit Checks
- Security Settings (e.g. Blinded-Unblinded)

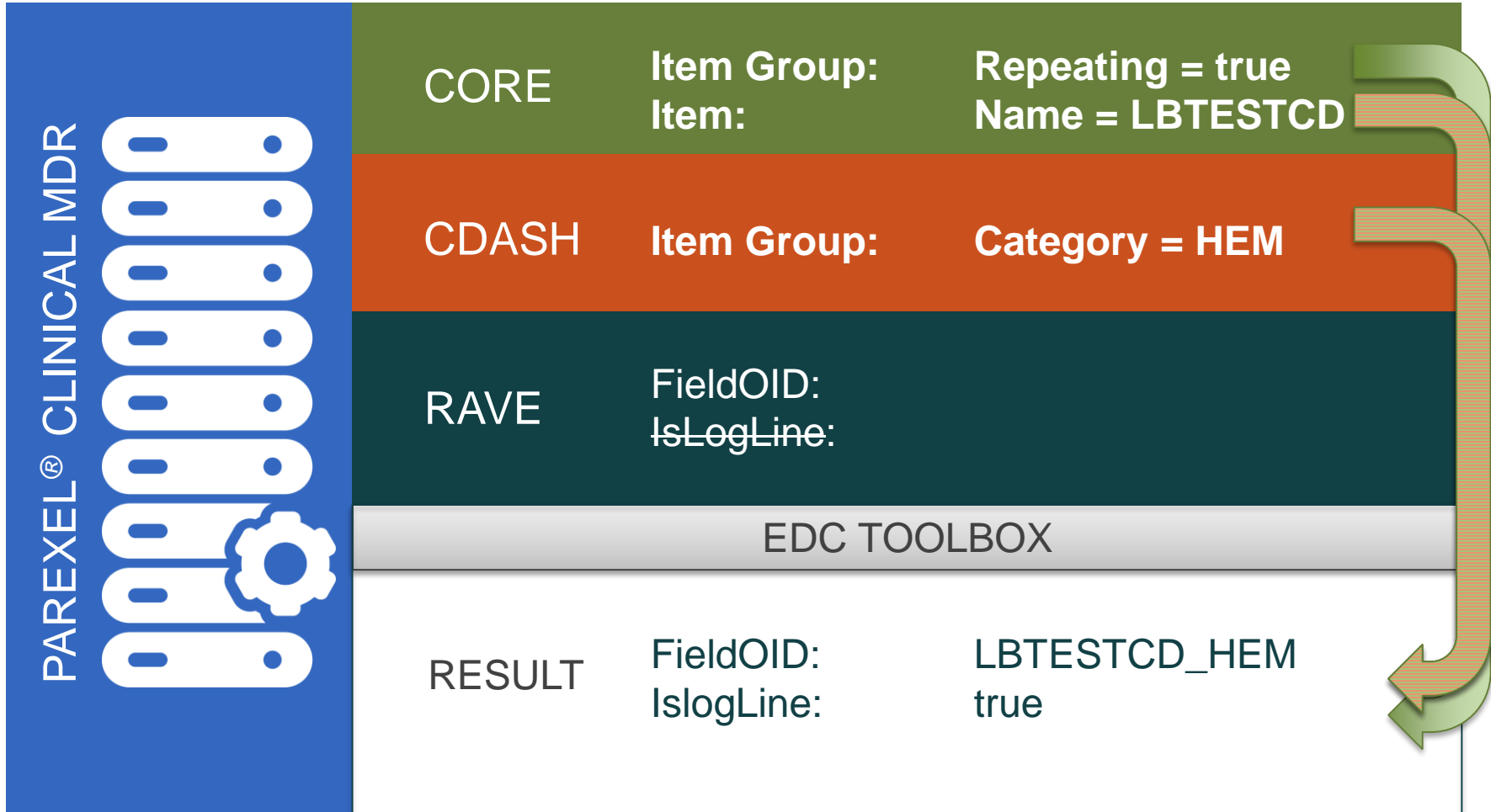
# OVERLAY DRESS UP



# OVERLAY DRESS UP



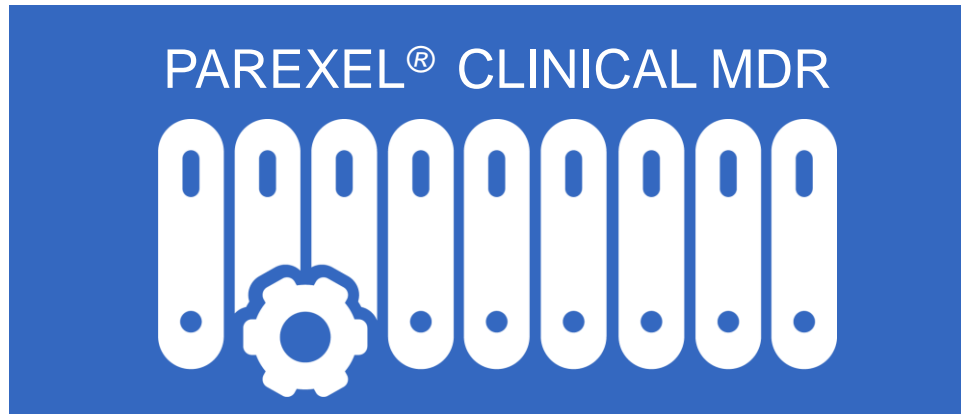
# OVERLAY DRESS UP



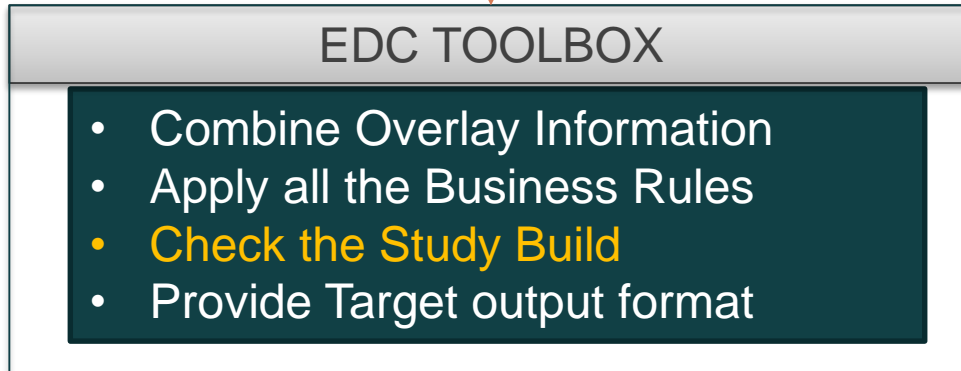
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# CHECK OUTFIT



Using WEB-API



## SANITY CHECKS

*Dataformat and Datatype doesn't match*

*Form not assigned to any visit*

*Controltype doesn't fit*

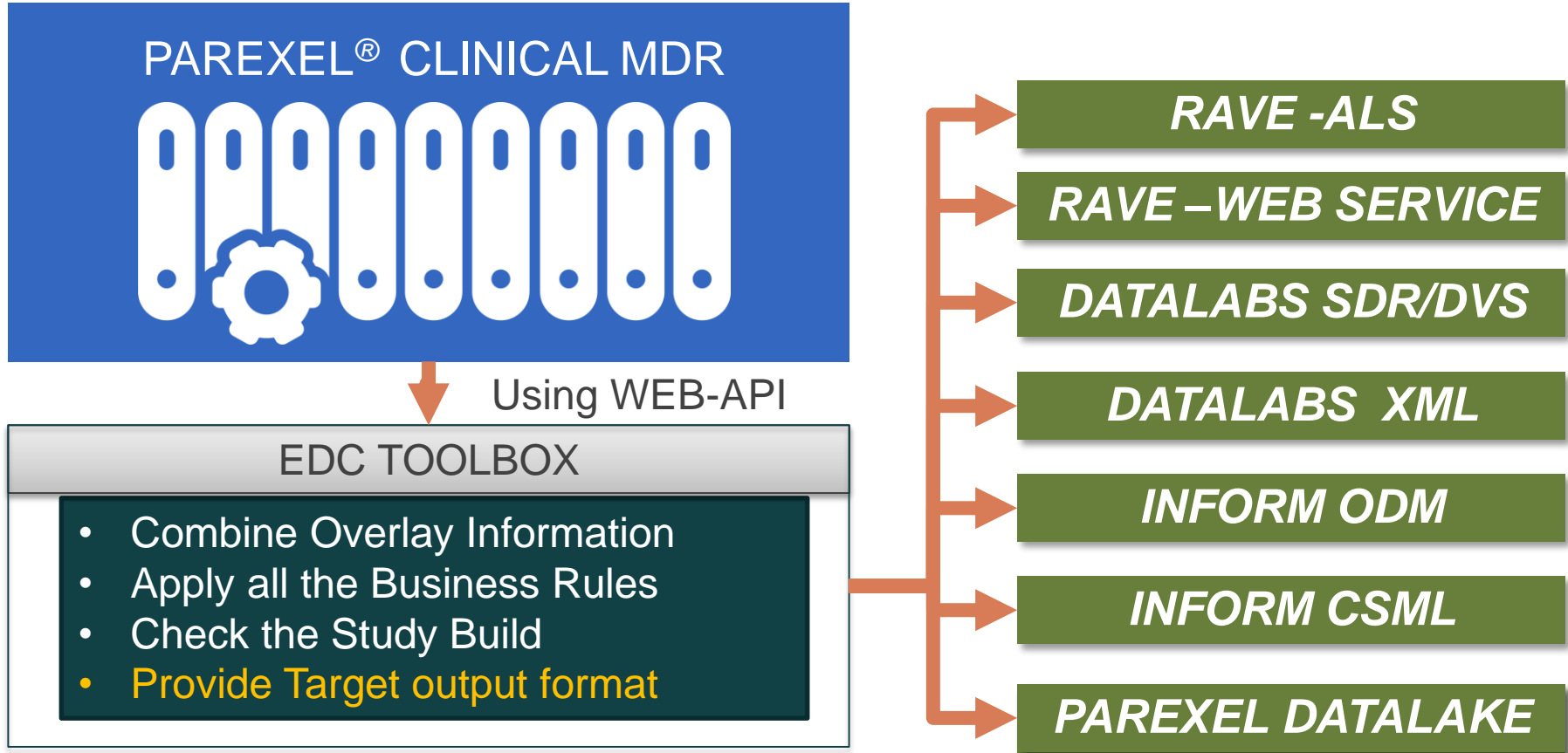
*SAS Label exceed 40char*

*Fieldlength doesn't match ValueSet Items*

*Same Fieldname but different Datatype*

*Field hidden without any default value*

# STUDY TO GO



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*THANK YOU*

again