Reporting & Visualisation : D'un standard maison au format CDISC
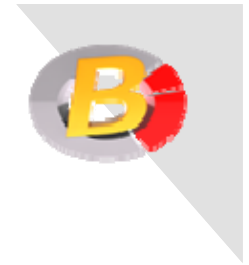
Jérémy MAMBRINI

Florence WAGER

Contents

CDISC Implementation at SERVIER

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Conclusion & Recommendations

CDISC Implementation at SERVIER

Why

> **Regulatory point of view (Electronic Submission)**

> **Standardisation, Interoperability, Transparency, Efficiency, Exchange**

- Cost Saving
- Partners
- Guidelines
- Traceability
- Data Pooling
- Internal Standards

SERVIER

Data collection CRF / e-CRF	Transferred data	Randomisation data

Internal studies (CT)

Patient data
+
**Some derivations
(Validation and Stats)**
+
Operational data

Mapping

I.R.I.S SDTM Referential
Implementation Guide 1.0

Pool SDTM+

Patient data
+
**Some derivations
(SDTM and Stats)**
+
Operational data
+
Trial Data

Regulatory submission

Performed at each exploitation

SDTM « pure »
Patient data
+
**Some derivations
(SDTM and Stats)**
+
(Operational data)
+
Trial Data

ADaM

Patient data
+
All derivations

Filtre

Partnerships

SDTM in an IRIS format
Patient data

Direct

SDTM in a Partner format
Patient data

Mapping

Other format
Patient data

Mapping

Define.xml

SDRG

Define.xml

ADRG

SDTM :

Since 2012 : Standards Implementation
Since 2014 : SDTM for each study before FVFP

ADaM :

Since 2014 : Standards Implementation
Since 2015 : First Study

SDTM

(CDISC)

- CRF data
- Centralized data
- Trial design

SDTM+

(for storage and visualisation)

- CRF data
- Centralized data
- Trial design
- Operational data
  - Derived data
  - Randomisation List
  - Kit Number List
  - Unauthorized Treatments
  - Pharmacovigilance Data
  - …

SDTM « pure »

(for ADaM, data exchange and submission)

Selected Information SUPP--

(e.g. flag CODBREAK in SUPPDM: KITALLOC in SUPPEX)

Formatting submission Rules (Character variables reduced …)

Reporting & Visualisation using CDISC format

What are we talking about ?

Scope

Clinical study

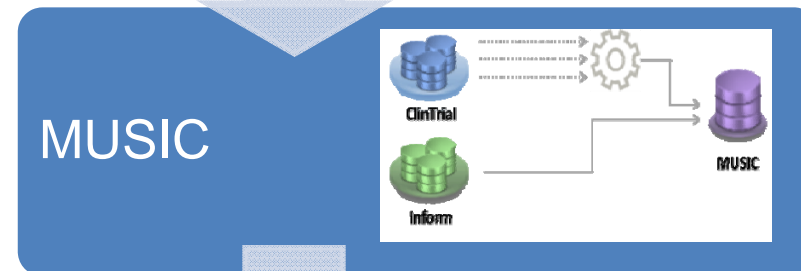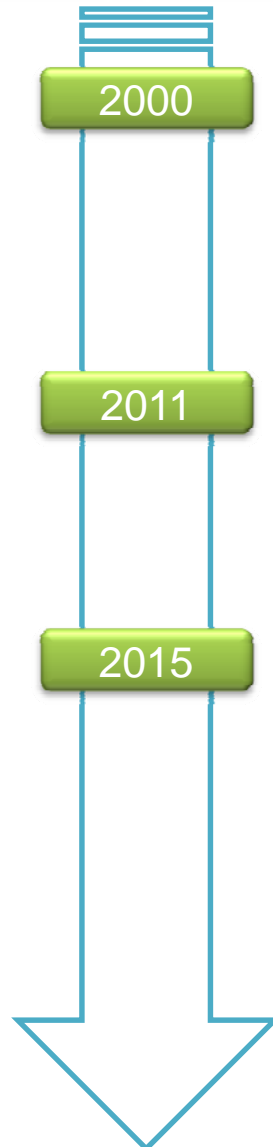*Preparation* > *Conduct* > *Exploitation*

Reporting Visualisation
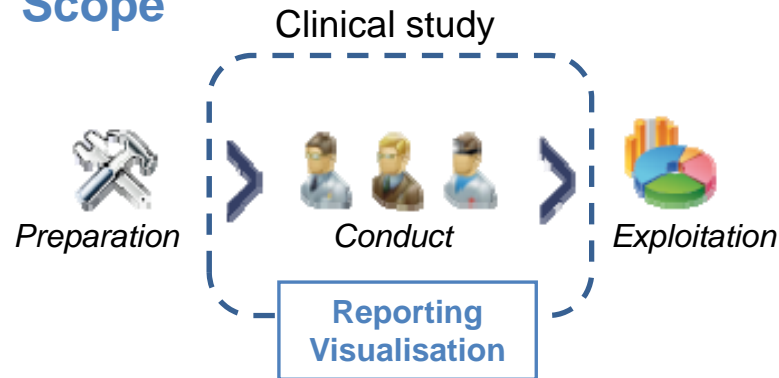
BI Tools

- ➢ **SAP – Business Objects**
- ➢ **SAP suite (Dashboard, Explorer, Lumira…)**
- ➢ **WebI R4**
- ➢ **SAS BI**
- ➢ **Spotfire**

Local standard

CDISC

2000 — BOREAL
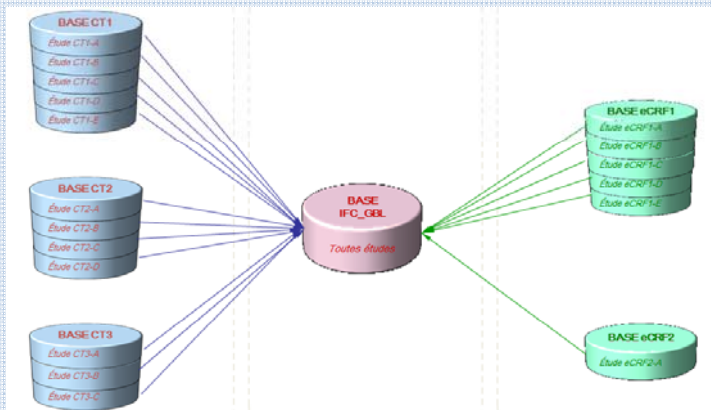
2011 — MUSIC

2015 — MUSICALL
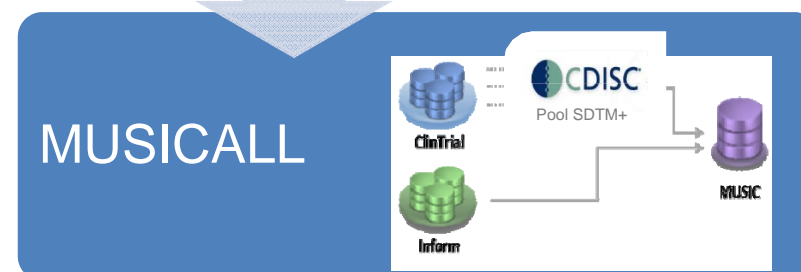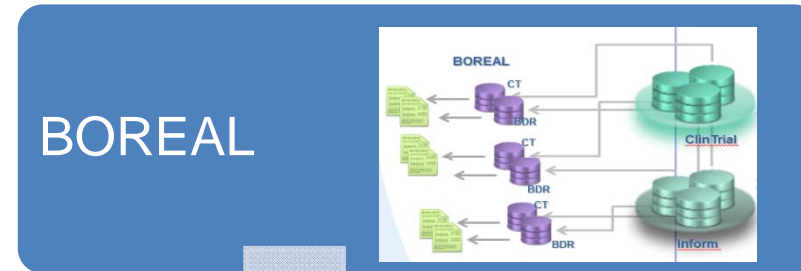
BOREAL
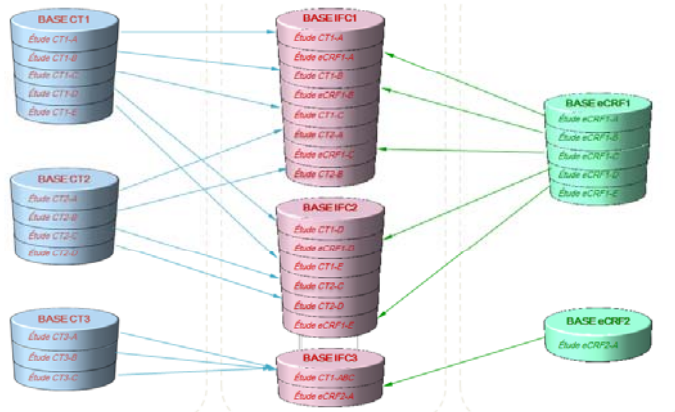
- ➤ 2 Universes/study
- ➤ Efficient
- ➤ Mono study

- ➤ Reporting rework
- ➤ No standardization
- ➤ No link between sources

MUSIC

- ➤ 1 Universe
- ➤ Manual standardisation

- ➤ Multi studies / Multi source documents
- ➤ Standard documents
- ➤ Optimization of processes

MUSIC

- ➤ **Mapping eCRF metadata / clinical data**
- ➤ **All Clinical data normalized in one table**
- ➤ **Duplication of main data for reporting in denormalized tables**

- ➤ **Management of specificities when integrating studies in MUSIC – done item by item - 3 days**

Clinical data	CRF specificities
Operational data and eCRF metadata	Study scheme
	Patches
	Design modification

MUSIC
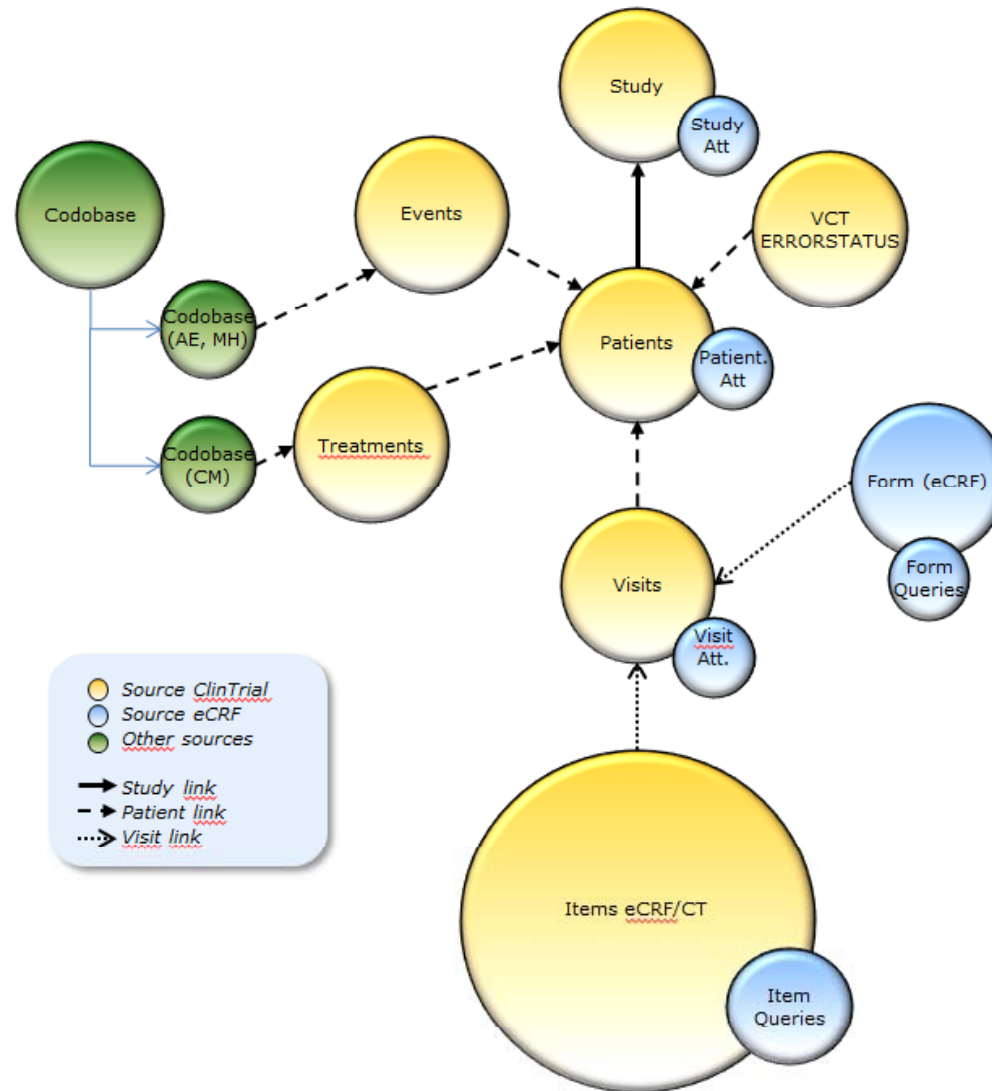
MUSIC
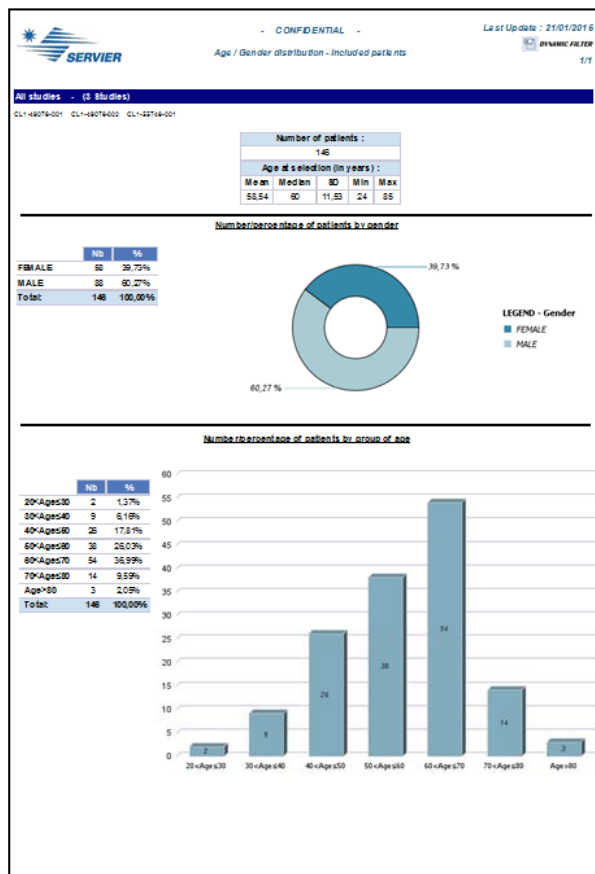
- ➢ **Standard Reports Available10 days after FVFP**

- ➢ **100 standard reports (Webl)**

- ➢ **80 MUSICalised studies**

- ➢ **800 users**

Reporting needs

REX MUSIC

CDISC
SDTM
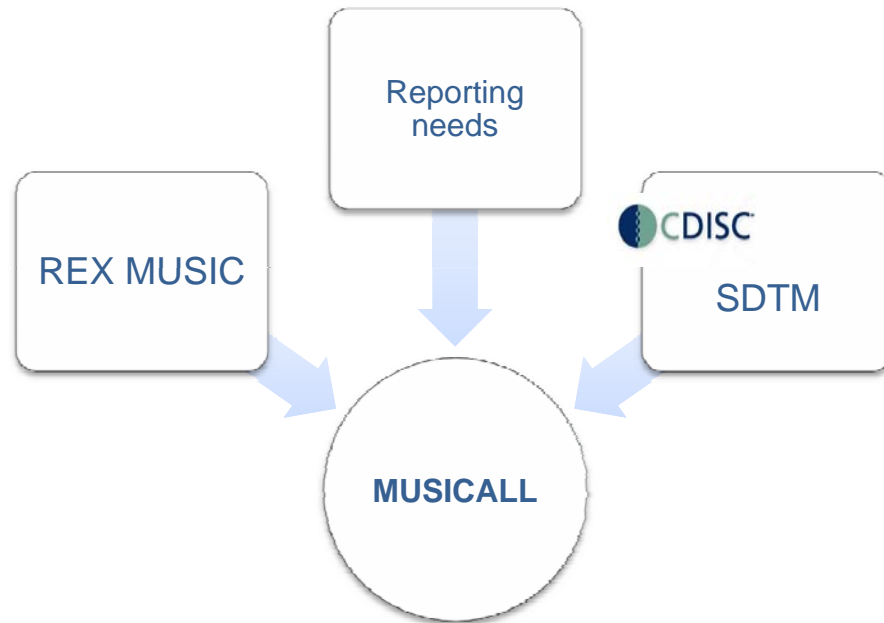
MUSICALL

➢**Increase perimeter (Pool SDTM)**

➢**No manual specifications**

➢**Increased performances**

➢**Structure adapted for programming**

MUSICALL

MUSICALL
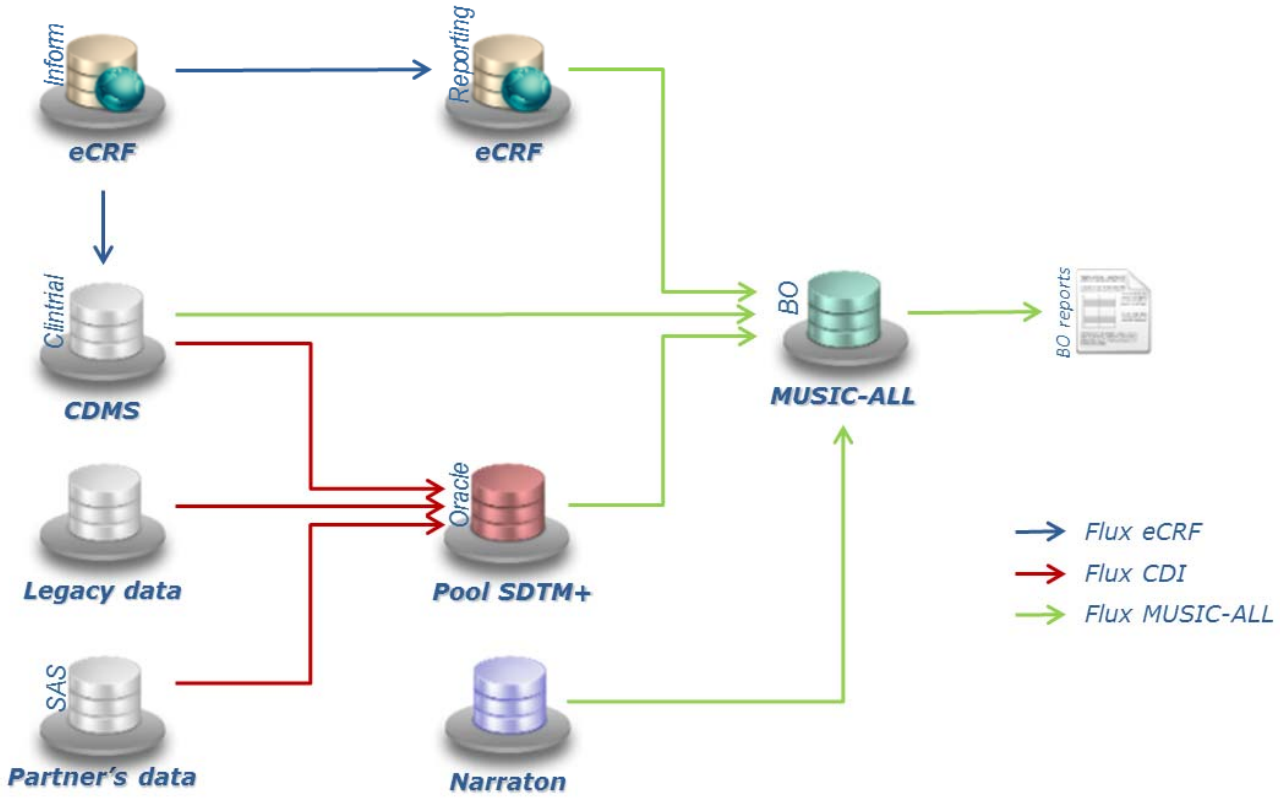
MUSICALL

- ➢ **No duplication of Clinical data**

- ➢ **Domains grouped by classes**

- ➢ **Supp linked to the relevant class**

- ➢ **Some Supp information denormalized in the linked class**

- ➢ **Metadata (eCRF data) linked to visits**

- ➢ **No mapping between metadata and clinical data**

MUSICALL

Conclusion & Recommendations

MUSICALL

- **Prod : dec 2015 – V1**

- **First study february 2016**

- **All standard reports Q2 2016**
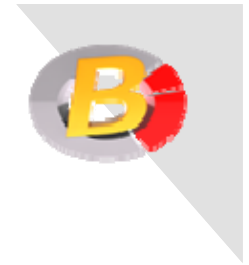
- **V2 (april 2016) : std axes and evolutions**

3 days of manual specificities management	Several clinical data sources (ClinTrial)
Sharing same langage	Rationalisation of mapping to be done
No delay	
Integration of partners data	
Almost centralized calculations	

> ## We use SDTM model to store operational data

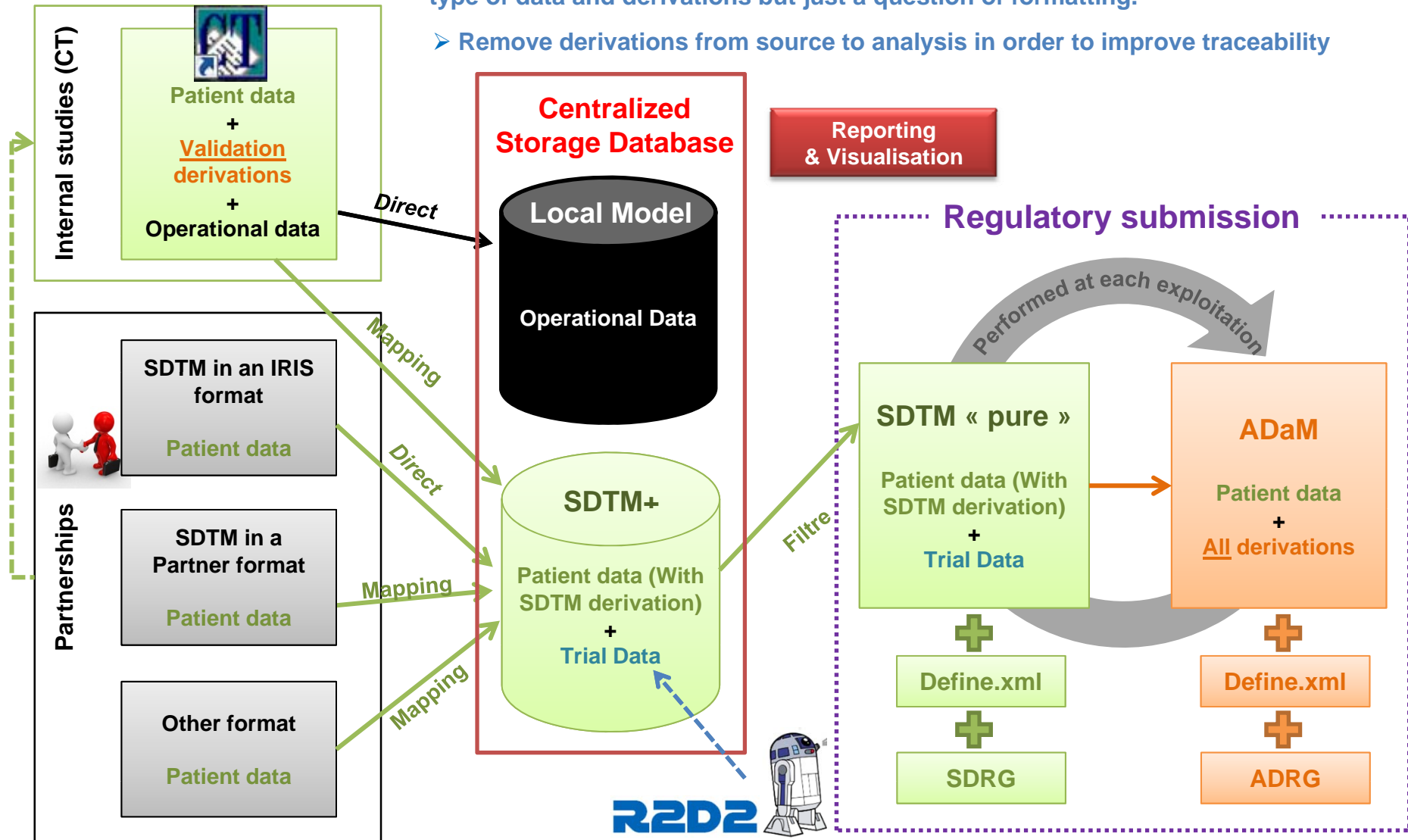| Benefits	Disavantages
Only **one model** in POOL SDTM + : **SDTM**	Only **one model** in POOL SDTM + : **SDTM**
Easier to maintain rather than having different models in the same database	**The SDTM Model was not designed** to store this kind of data and it is **less far comprehensible** than in our source model

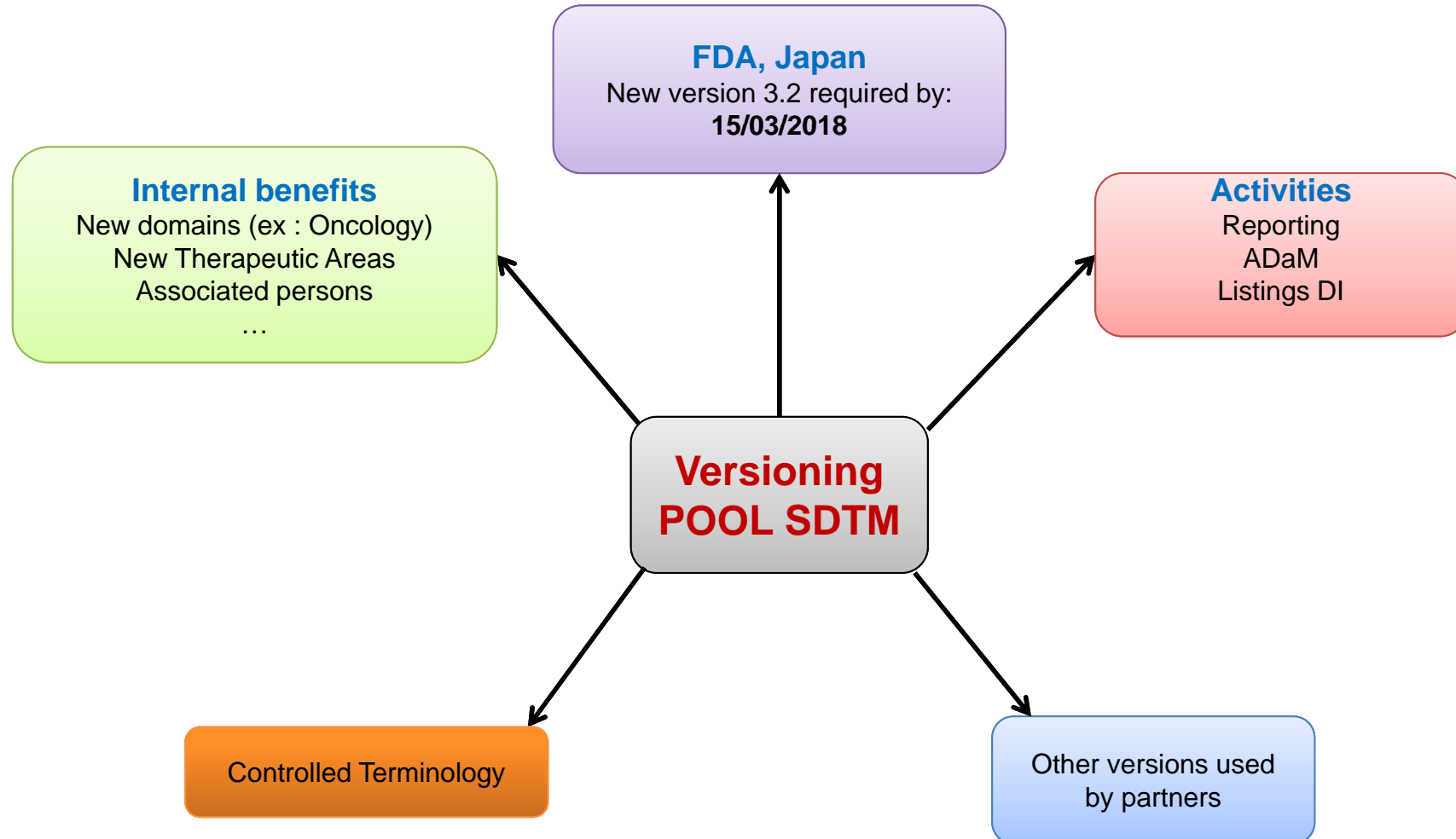> ## We still have some derivations in our SDTM Model

Issues with **traceability**

Issues with **partnership management** and **regulatory submission**

> ## We are still dependent on our data collection tool

Tomorrow

> Move to a new world where « + » from SDTM+ no longer means more type of data and derivations but just a question of formatting.

> Remove derivations from source to analysis in order to improve traceability

Internal studies (CT)

Patient data
+
Validation derivations
+
Operational data

Direct

Centralized Storage Database

Reporting & Visualisation

Local Model

Operational Data

Regulatory submission

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SDTM+

Patient data (With SDTM derivation)
+
Trial Data

Filtre

SDTM « pure »

Patient data (With SDTM derivation)
+
Trial Data

ADaM

Patient data
+
All derivations

Define.xml

SDRG

Define.xml

ADRG

R2D2

SERVIER

FDA, Japan
New version 3.2 required by:
15/03/2018

Internal benefits
New domains (ex : Oncology)
New Therapeutic Areas
Associated persons
…

Activities
Reporting
ADaM
Listings DI

**Versioning
POOL SDTM**

Controlled Terminology

Other versions used
by partners

Questions?

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florence.wager@servier.com (01.55.72.47.07)