



Processes to handle CDISC data at IPSEN

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Agenda

01 IPSEN CONTEXT 03 TOOLS/PROCESS

02 IPSEN STANDARDS 04 CHALLENGES / NEXT STEPS

01 IPSEN CONTEXT

Ipsen Context

Outsourcing



All clinical studies are outsourced to CROs under the oversight of IPSEN (full-service and functional CROs)

Management of IPSEN Standards (iSDTM) is outsourced under the oversight of IPSEN

Key actors



DATA MANAGEMENT - DATA SCIENCE
STANDARDS - SYSTEM TEAM
FULL-SERVICE CROs
FUNCTIONAL CROs
STATISTIC

Standards and Tools



Standard model in production :
July. 2015
Clinical DWH in production :
August 2016



80 users (15 DM / 8 STDS)
5 CROs 30 STUDIES



Any interventional study is loaded in IPSEN clinical data warehouse in SDTM format (iSDTM)

02

IPSEN CDISC Standards Library

iSDTM

IPSEN - SDTM IMPLEMENTATION

IPSEN adopted in the past an operational standard model (GIDD) based on CDISC SDTM

- with operational variables (Yes/No leading questions)
- with system variables



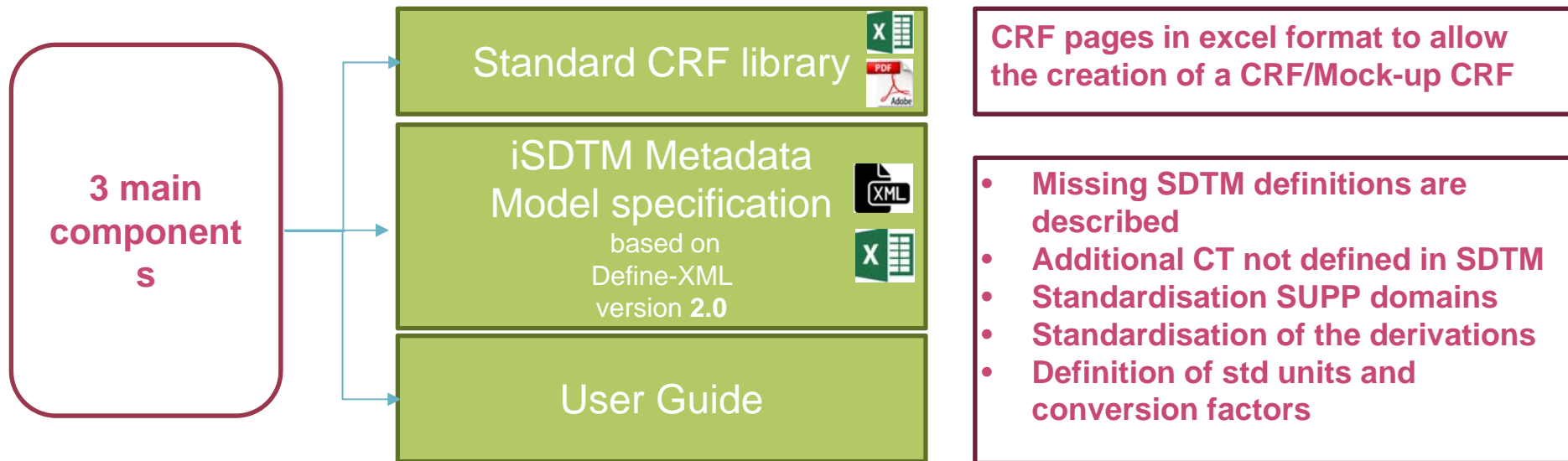
in 2015, IPSEN decided to implement an SDTM model (iSDTM)

- 1 To produce ADAMs from SDTM for traceability
- 2 To avoid rework at the time of data submissions
- 3 To comply to company strategy
With the new outsourcing company strategy no need of operational task internally
- 4 To facilitate interactions with CROs
Most of the CROs should know SDTM (but not your operational model)
CROs have their own operational model (with standard checks, standard reports)
- 5 To use off-the-shelf softwares

IPSEN CDISC Standards Library



iSDTM = IPSEN VISION OF THE CDISC SDTM



03 Tools/Processes



External Ipsen

WHY CTDC (Clinical & Translational Data Center) ?

To have a tool to administrate a standard model (iSDTM)

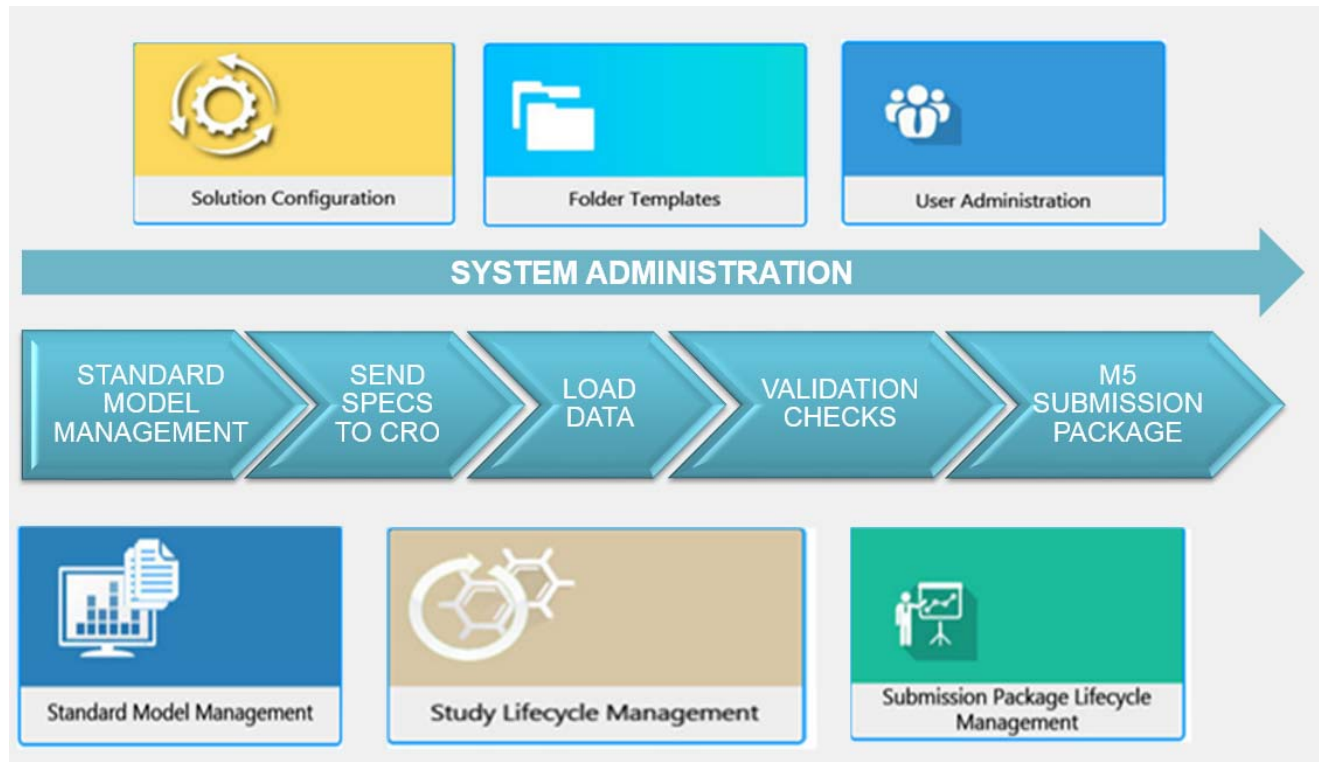
To send clear specifications based on the standard model (iSDTM) to CROs

To check the deliverables from CROs against specifications

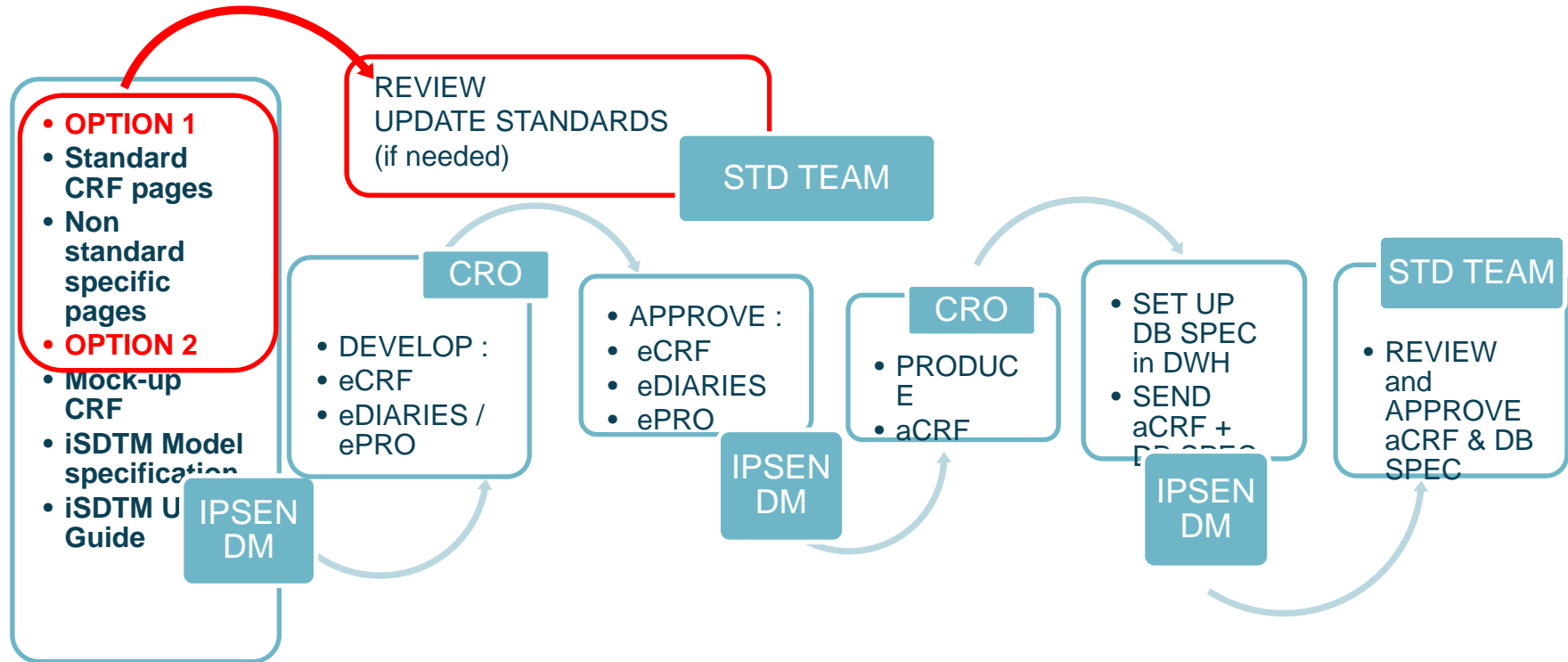
To store and have access to data (SDTM+, ADAMS etc ...)

To load submission packages (structured as M5 folders with ISS, ISE and TFLs)

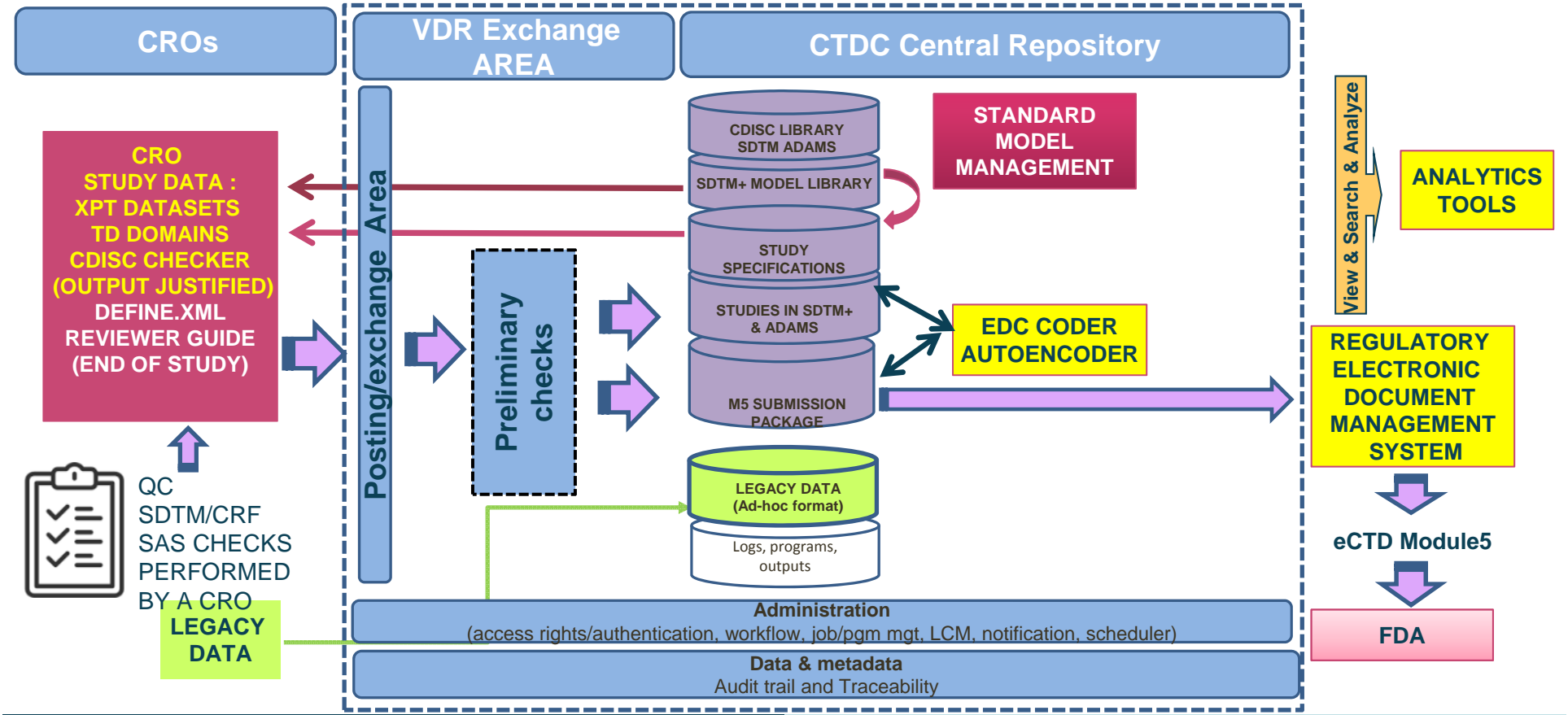
CTDC : HIGH LEVEL OVERVIEW



STUDY SET UP : PROCESS



STUDY LIFE CYCLE : PROCESS



04

Challenges/Next Steps

Challenges



-Processes strongly constrained by company strategy (outsourcing,ressources,.....)

-Processes strongly constrained by CROs procedures

-CROS and Sponsors not at the same technology level (eg : XML, ODM,)

NEXT STEPS

COMING SOON



GOVERNANCE
Implement a data standards governance board

COMING SOON



CDISC SEND
Finalize SEND implementation



PROTOCOL :
Implement the protocol model



eCRF
develop eCRF Standard library (IPSEN URL) model

Thank you