



Implementation of CDISC Standards at Nycomed

PhUSE SDE Basel, 18-MAR-2009



Agenda

- **Background**
- **Clinical data warehouse FACT**
- **CDISC implementation**
- **Current Nycomed CDISC standards**
- **Conclusions and outlook**

Partnering – Together for medicines that matter



Nycomed is actively seeking partnerships

- Co-development from early research on
- In-licensing for marketing by Nycomed
- Out-licensing where Nycomed is not present



The R&D Operating Model – contribution of Data Science



In-house

- **State-of-the-art statistical capabilities**
 - for statistical input into protocol and drug development plans
- **Maintenance of standards**
 - Data acquisition
 - **Data integration**
 - Data quality
- **Ensure availability of integrated clinical trial data for pooled analyses**
(Data Warehouse Development, operation and maintenance)

Outsourced

- **Data cleaning process and database set-up outsourced** (to a large proportion)
Flexible data management capacities available for in-house processing as well as for supervision of Data Management CROs
- **Study specific statistical reporting and generation of analysis data bases**
outsourced with flexible resources for CRO supervision.

Heterogeneous Data Sources

- **CRO databases**
 - standardised SDTM domains based on Nycomed requirements
 - ADaM datasets
- Data from **in-licensing** partners
 - what-ever-they-have structures
- **Legacy** data from two prior companies
 - what-ever-we-have structures

Agenda

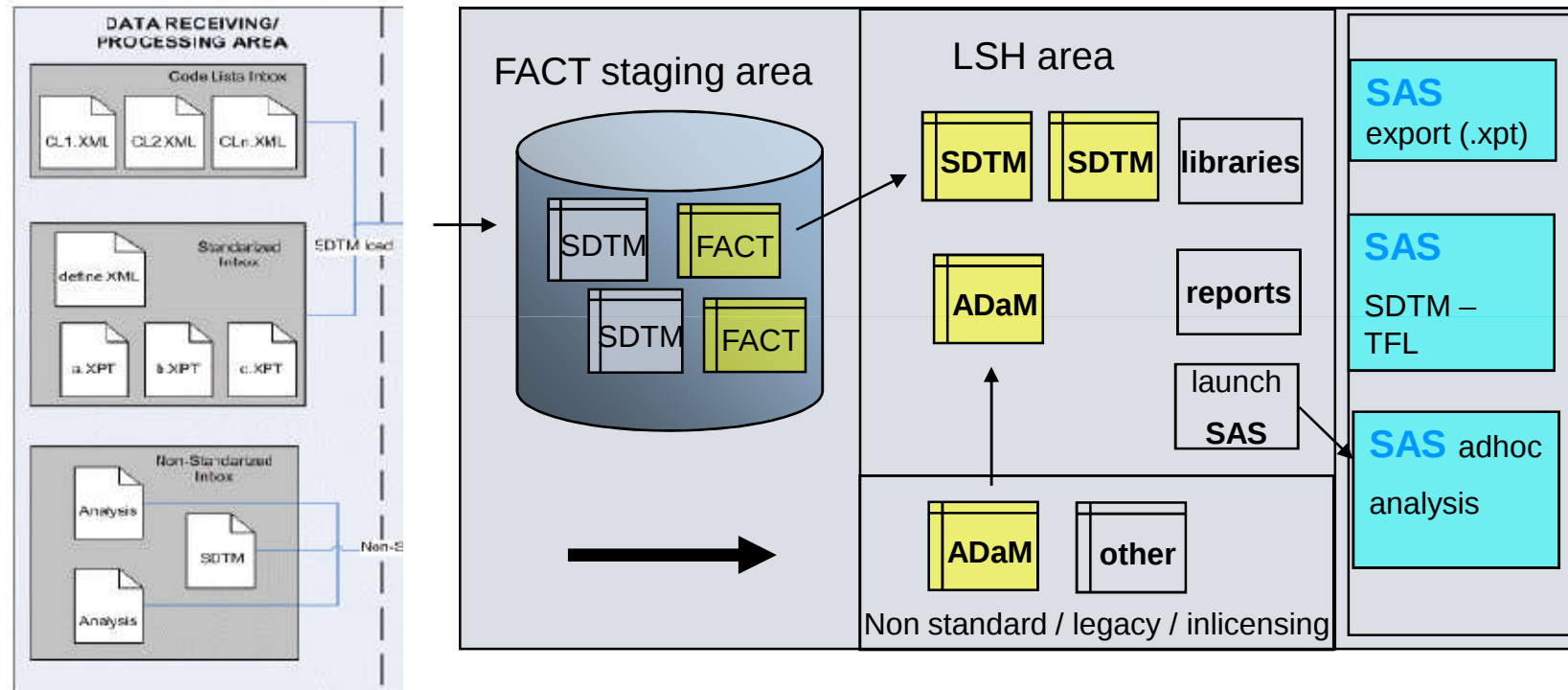
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FACT objectives

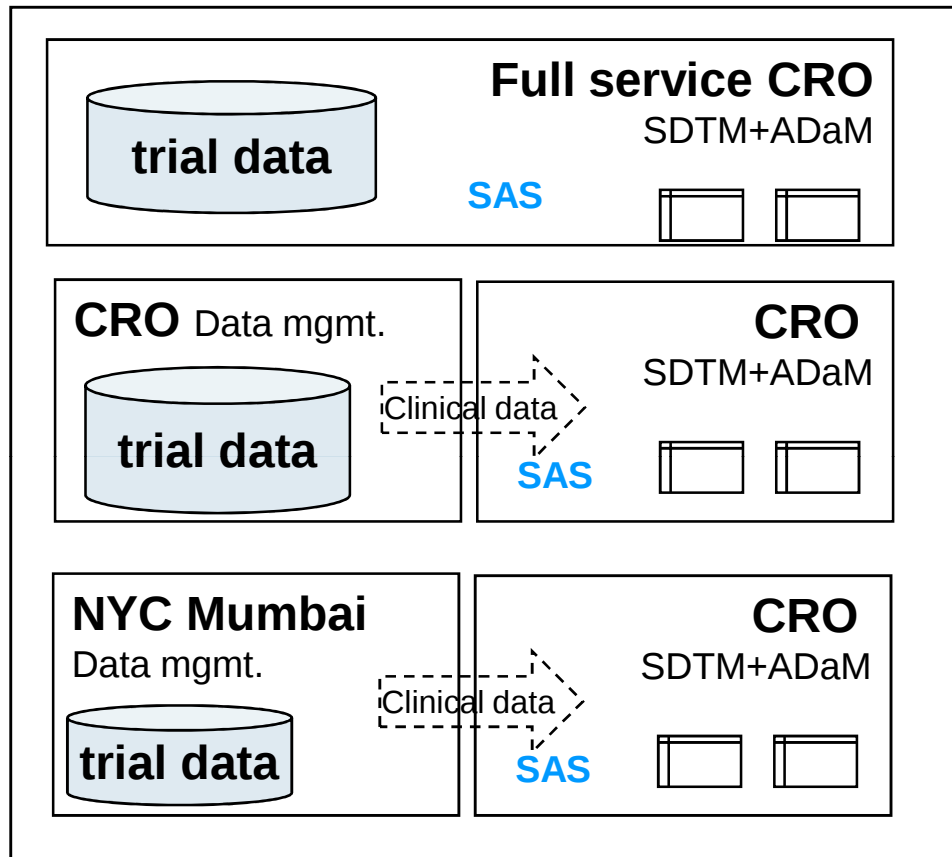


- Ability to **protect** and **explore** one of the main assets of our company: Clinical Trial Data
- **Optimise** procedures for **exchange** of clean clinical trial data with external and internal partners
- Ensure data **integrity**
- **Acquire data** of partners in licensing projects secure and quickly
- Provide a platform for storage of **legacy** data
- Data **availability** for all data-related questions
- Ensure **compliance** with regulations (21 CFR part 11, ICH E9)

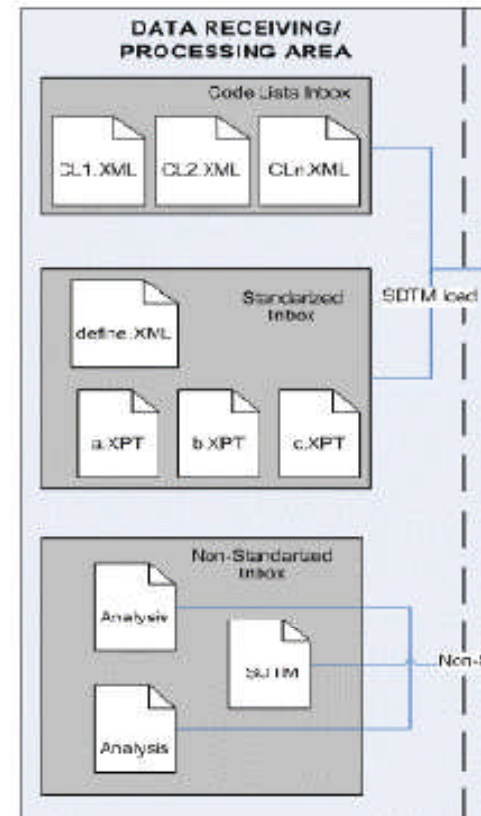
Clinical data warehouse FACT



Data flow and data processing



Full package delivery after TFL finalization



NYCOMED

FACT warehouse

