



Clinical Study Data Processes @ LEO Pharma

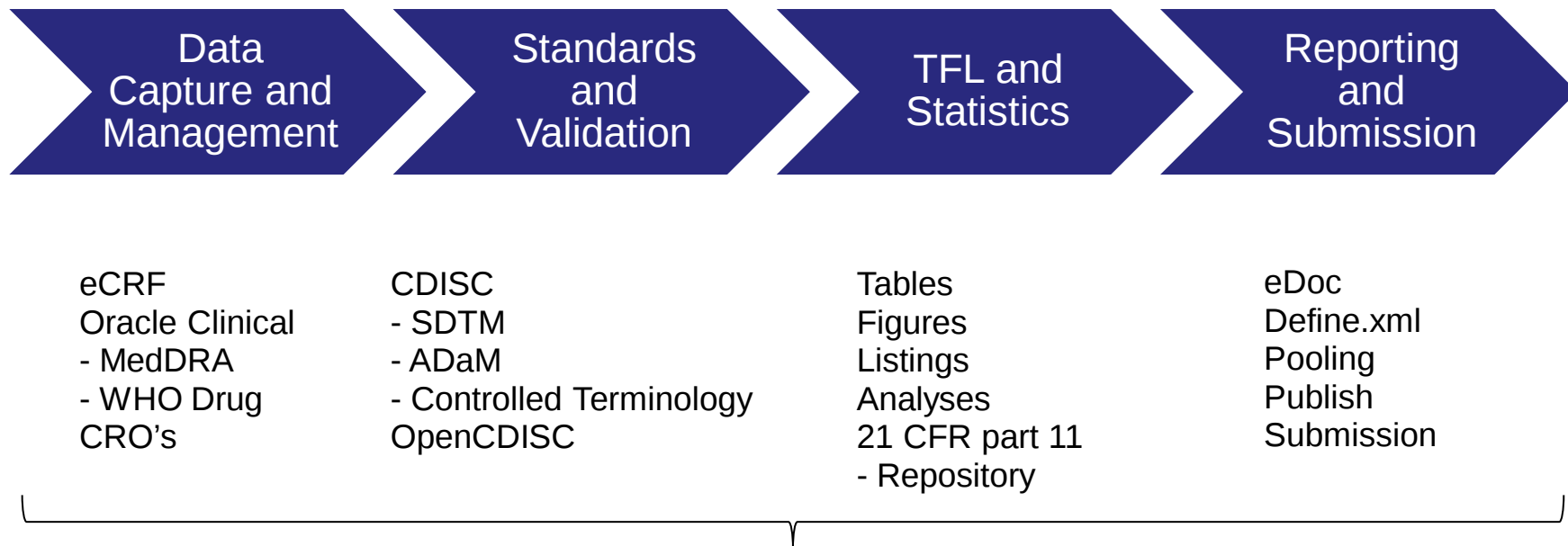
LEO[®]



Process overview

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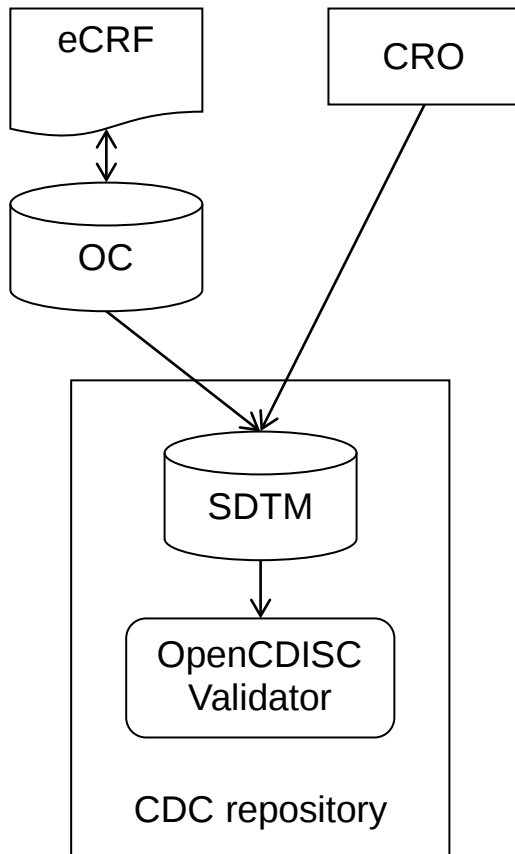
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Data Capture and Management

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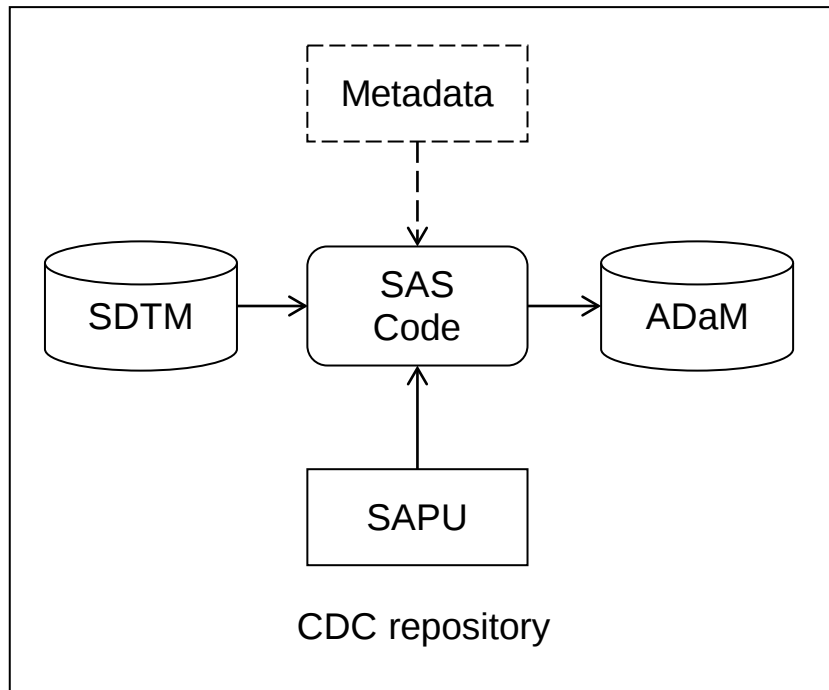


- **CRF pages built in OC**
 - Standardisation critical
- **CRF pages from eCRF**
- **Data Management in OC**
 - MedDRA
 - Who Drug
- **CRO outsourcing**
 - Standardisation critical
- **SDTM**
 - From 2005
 - Standardisation benefit & critical
- **OpenCDISC Validator**
 - Standardisation benefit

Standards and Validation

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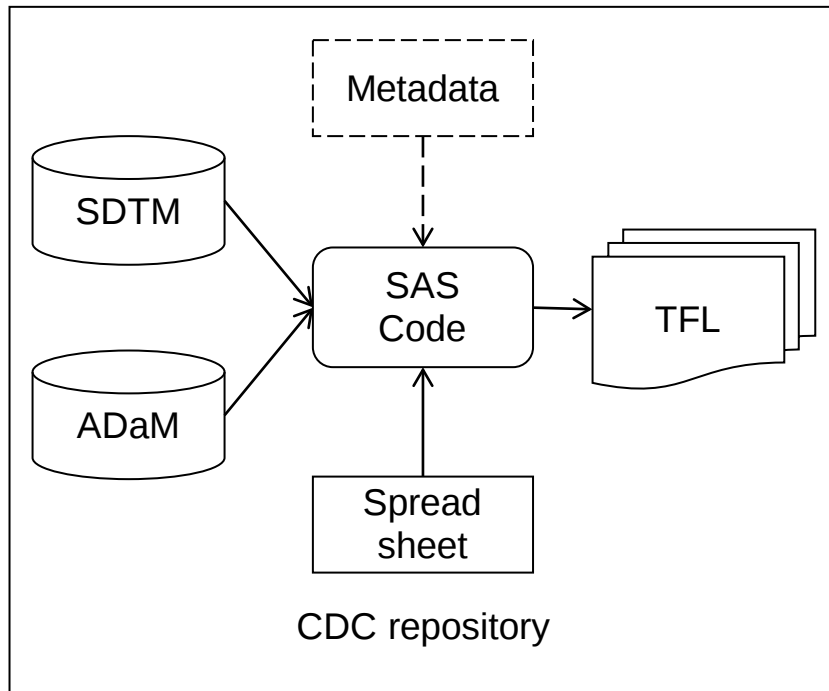


- Depends on standard SDTM
- ADaM since 2006
- Standards allow for study variations
- Standards covers format, not contents
- Complex
- 21 CFR part 11 compliant

TFL and Statistics

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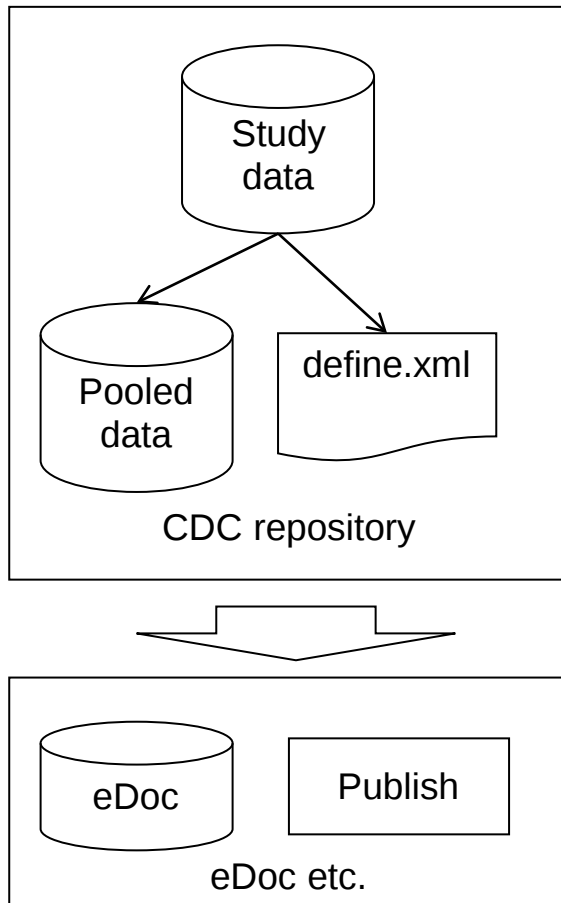


- Standardised/modifiable
- Parameter based
- Partly automated
- Configurable
- Analyses not standardised
- Analyses ad-hoc per study
- 21 CFR part 11 compliant

Reporting and Submission

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- Not always performed
- Pooling dependent of standards
- define.xml ditto (documentation)
- If data standardised, submissions in weeks
- Closed transfer between validated systems
- 21 CFR part 11 compliant

QC processes

- Risk based QC strategy
- The most important and most critical parts
- Primary and secondary end points
- QC of additional parameters if applicable
- Applies to CRF, SDTM, ADaM, Tables, Listings, Figures, Analyses, Poolings, define.xml and everything else relevant
- Any deviation from standards requires additional QC
- Greater adherence to standards yields shorter production time of input to the CSR (months => weeks)

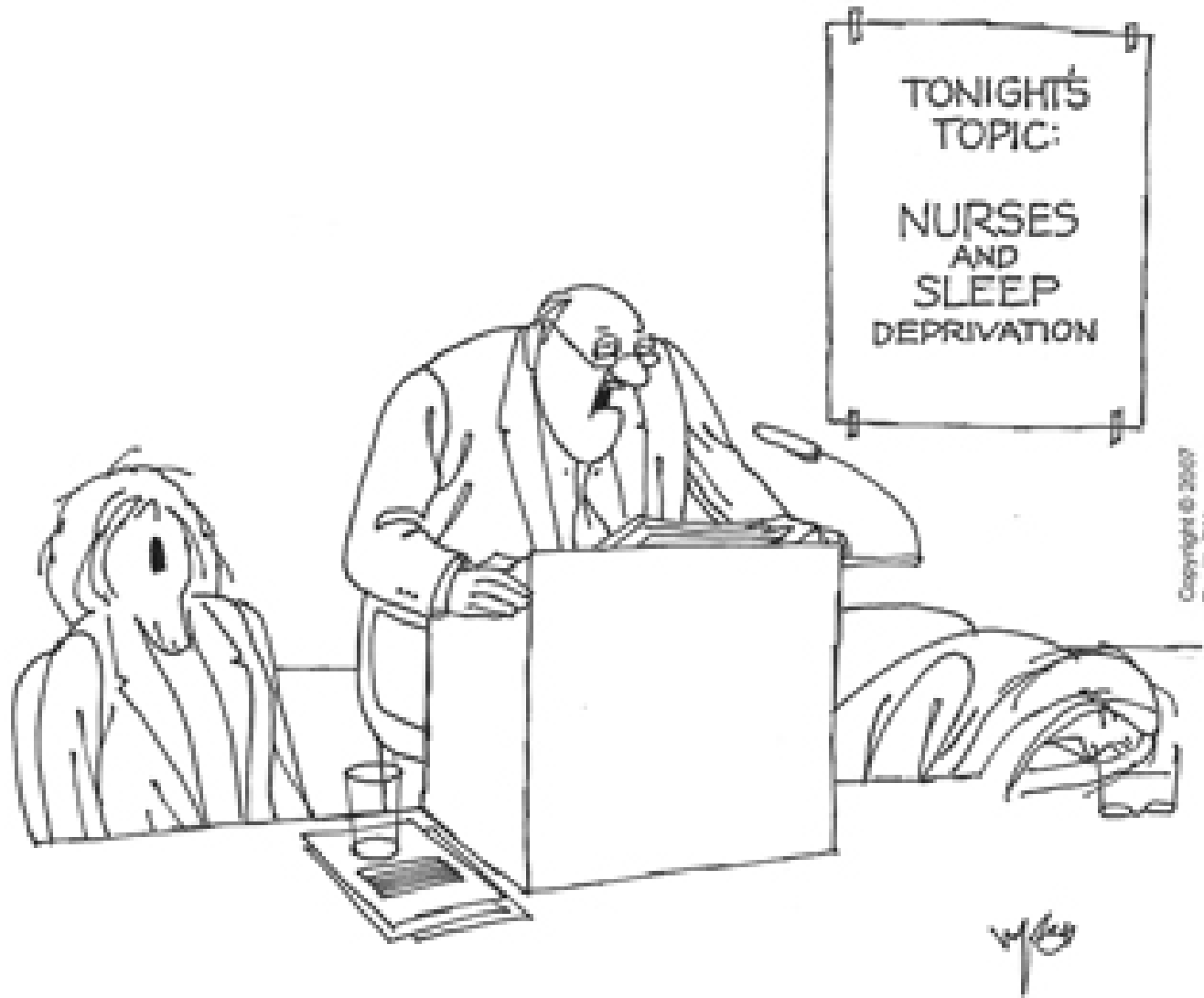
Conclusions

- Clinical Study Data Processes are quite mature
- Years of experience in CDSIC standards
- 21 CFR part 11 compliant end-to-end
- Strong focus on standards yields
 - Automatisatation
 - Flexibility
 - Quick CSR
- More elements needs to be standardised
 - Protocol, CRF, Figures, Analyses, define.xml, Pooling, Submissions, Data standards upgrades

Questions

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"... ANY QUESTIONS P...?"