

Clinical Study Data Processes @ LEO Pharma

LEO[®]



About LEO Pharma A/S

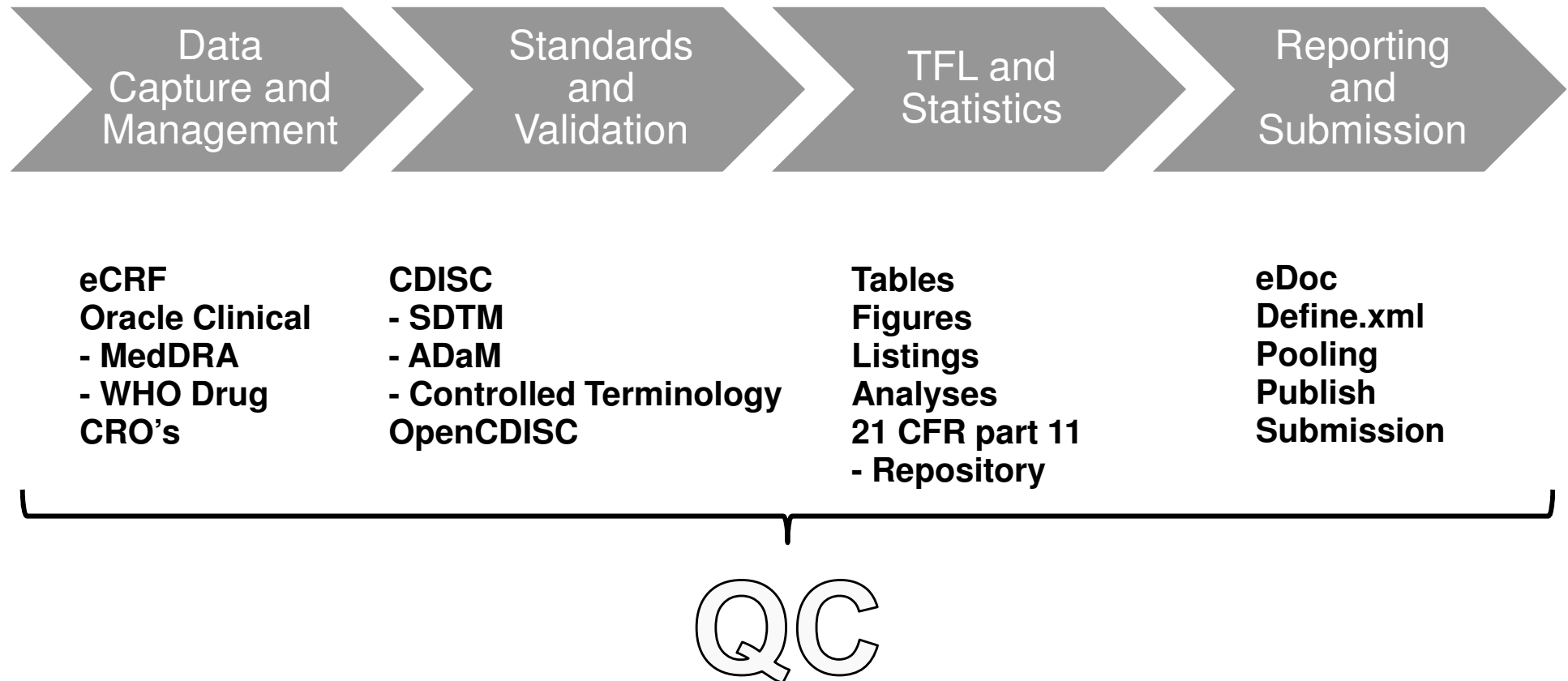
- Independent, research-based pharmaceutical company
- Founded in 1908
- Employs around 5,000 employees worldwide
- Headquartered in Denmark
- Fully owned by the LEO Foundation
- Drugs to dermatologic and thrombotic patients in more than 100 countries
- Vision of becoming the preferred dermatology care partner



Process overview

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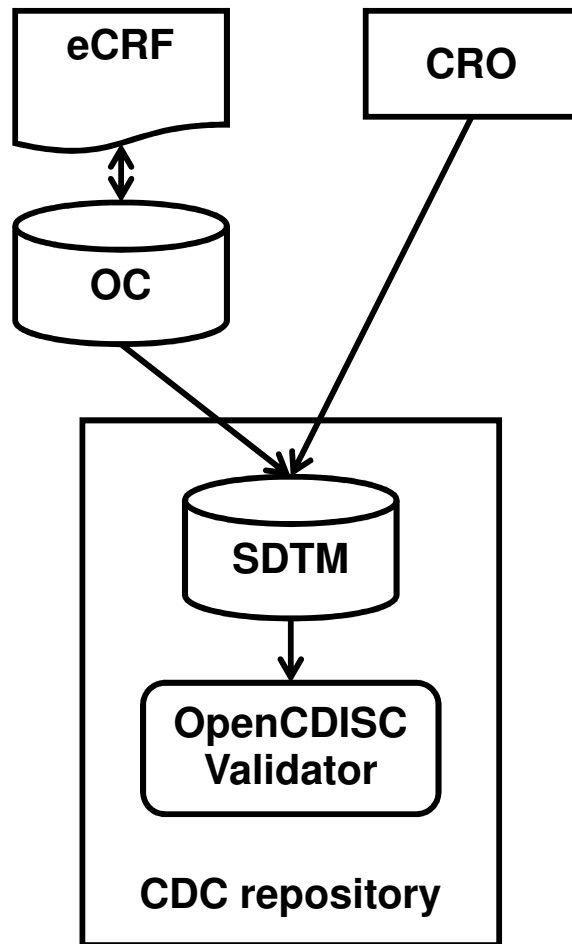
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Data Capture and Management

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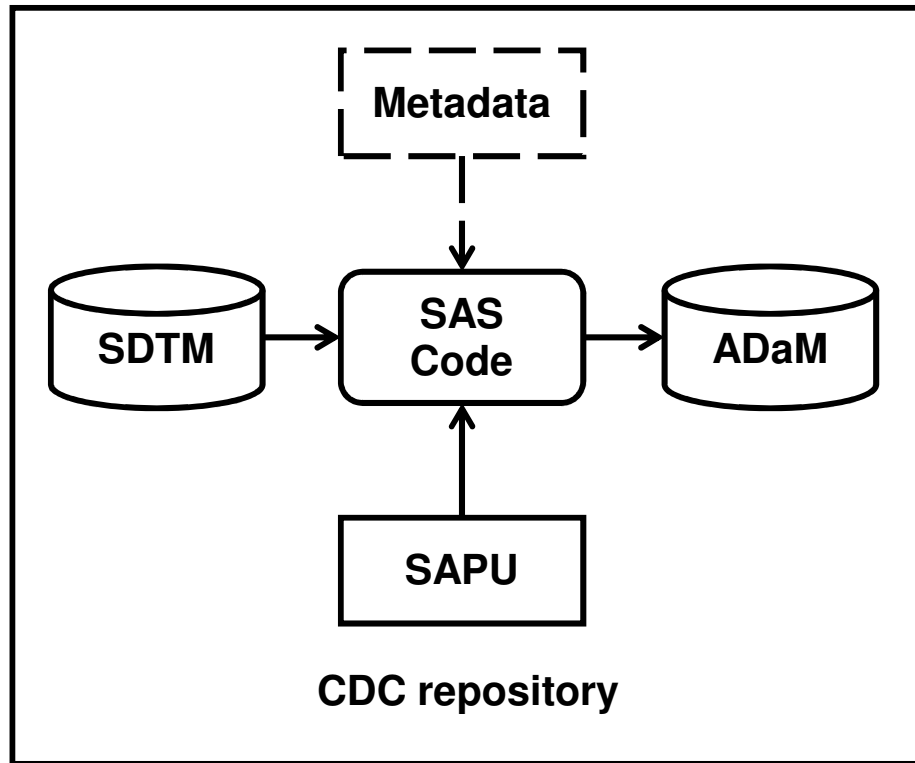


- CRF pages built in OC
 - Standardisation critical
- CRF pages from eCRF
- Data Management in OC
 - MedDRA
 - Who Drug
- CRO outsourcing
 - Standardisation critical
- SDTM
 - From 2004
 - Standardisation benefit & critical
- OpenCDISC Validator
 - Standardisation benefit

Standards and Validation

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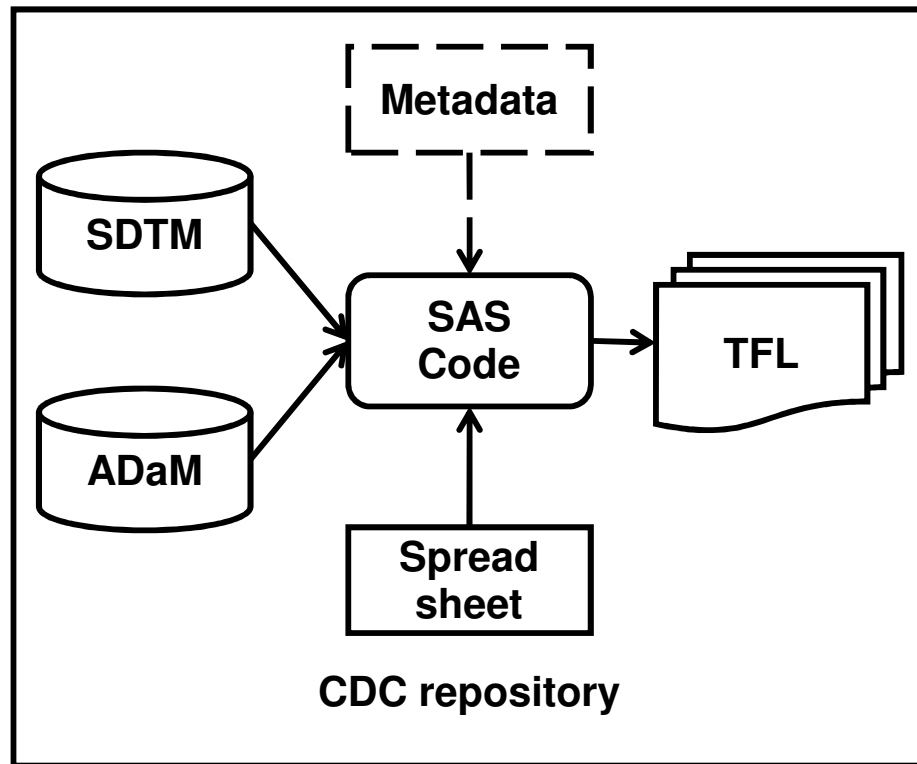


- Depends on standard SDTM
- ADaM since 2006
- Standards allow for study variations
- Standards covers format, not contents
- Complex
- 21 CFR part 11 compliant

TFL and Statistics

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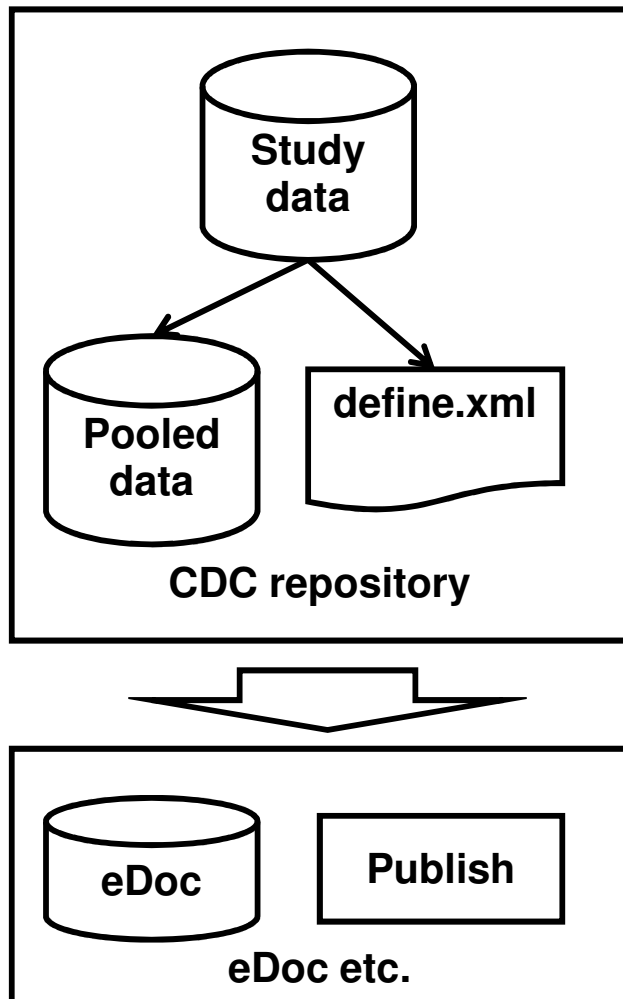


- Standardised/modifiable
- Parameter based
- Partly automated
- Configurable
- Analyses not standardised
- Analyses ad-hoc per study
- 21 CFR part 11 compliant

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

- 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)

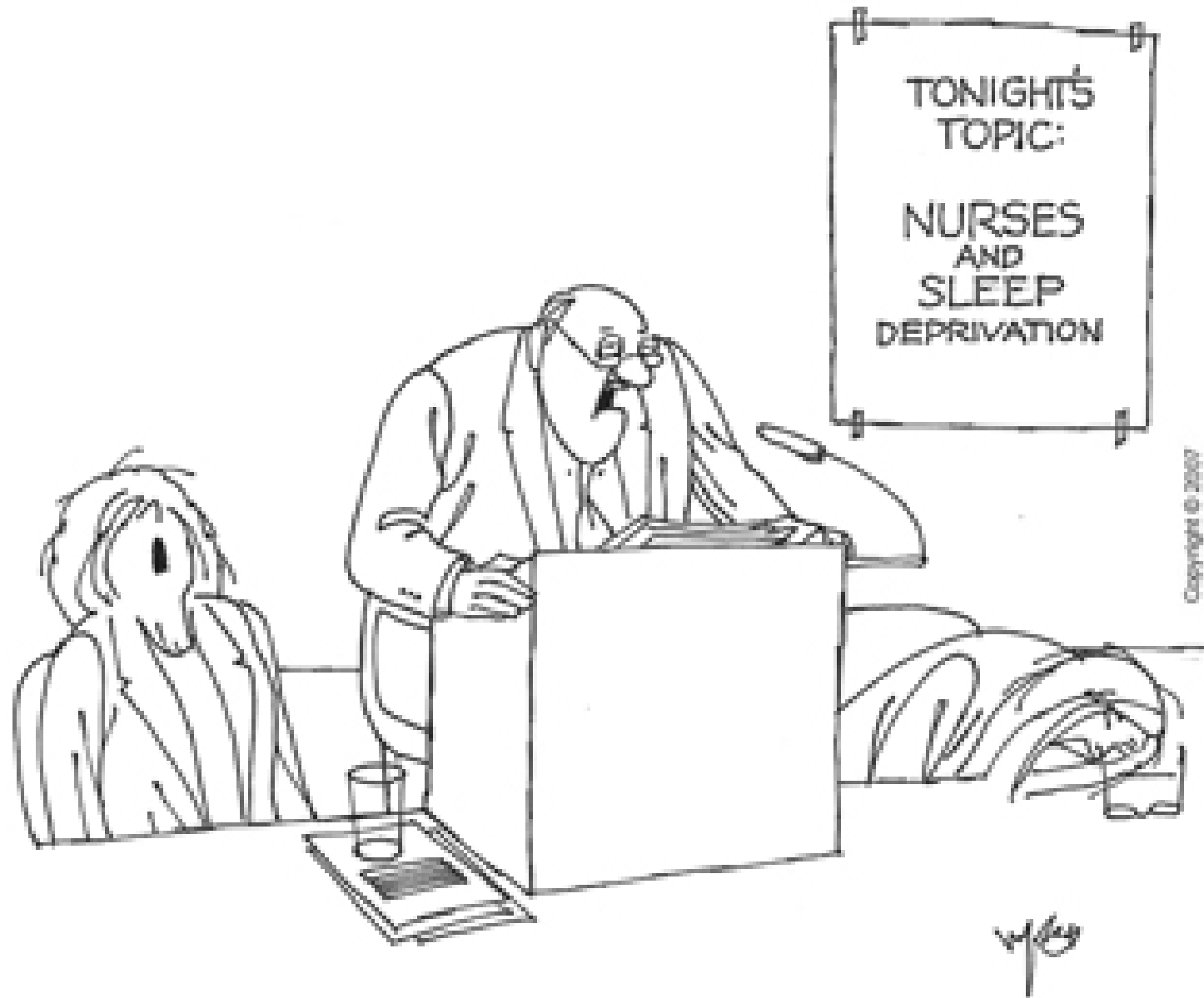
Conclusions

- Clinical Study Data Processes in place
- 10 years of experience in CDSIC standards
- 21 CFR part 11 compliant end-to-end
- Strong focus on standards yields
 - Automatisation
 - 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 ? ..."

