Clinical Development Optimisation through Structured and Standardised Study Design

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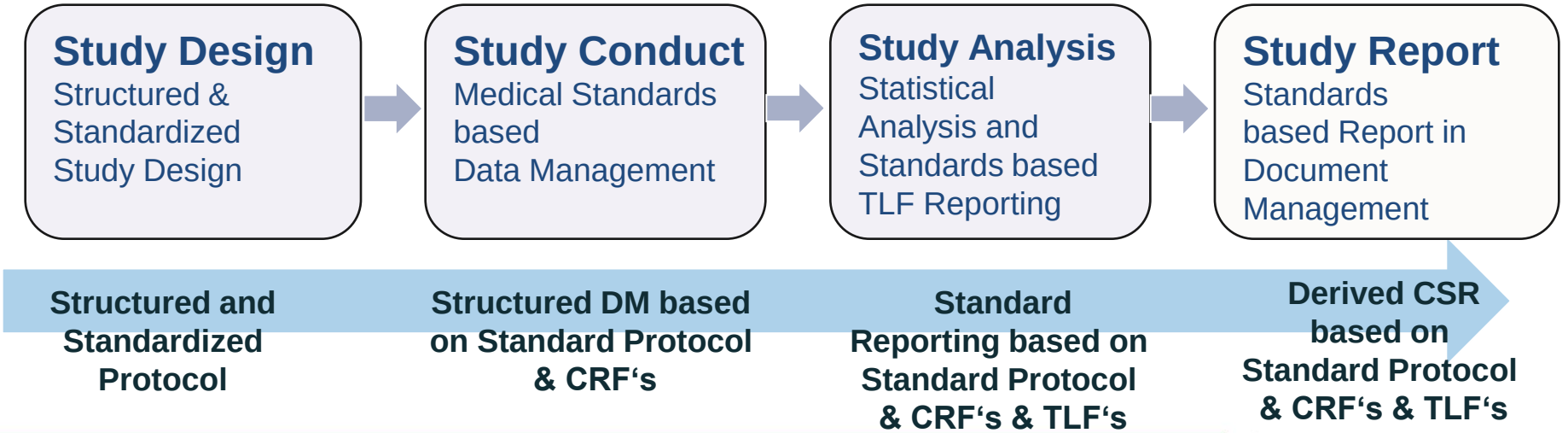
Study design driven by Clinical Standards - overview

- The future role of the study design
- The key success factors
- ESC is enabler of structured study design
- The lifecycle stages of study design
- Study Design Data flow
- Medical Standards Impact on Clinical Trials
- Benefits of Medical Standardization
- Metadata driven Clinical Trials - We are delivering
- Benefits

The future role of the study design

The final study design structure would enable the seamless data flow from design phase to report.

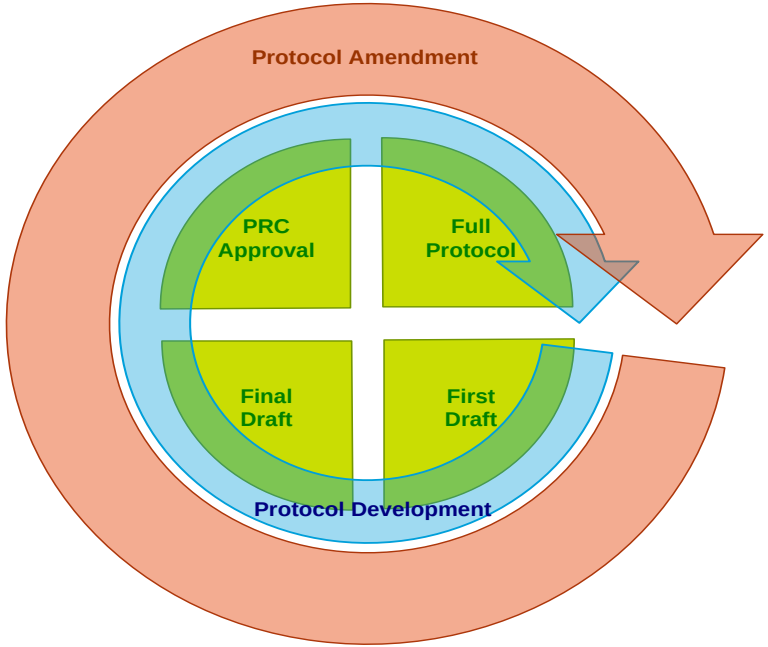
It would require: Structured Study Design | Medical Standardisation | Clinical Project Standards



Enhanced Study Concept

The lifecycle of the Structured Study Design is based on the ESC.

	ESC Lifecycle		
Version	**ESC version 1**	**ESC version 2 (Updated)**	**ESC version 3 (Updated)**
Status *	ESC initial draft	ESC initial draft	ESC initial draft
Status	ESC 1st draft	ESC 1st draft	ESC 1st draft
Status	ESC ready for PRC	ESC ready for PRC	ESC ready for PRC
Status	Final ESC	Final ESC	Final ESC



Each status is validated according to the ESC specification for required ESC elements.

ESC 1st draft – content sample

The ESC is the core component of the Structured Study Design
All subsequent designs are derived from ESC defined in the CPS.

Protocol Area	Corresponding Protocol Elements
Study setup	• Study number • Study Sponsor • Principle Investigator • Primary Objectives • Secondary Objectives • Clinical study phase • Indication • Study design • Primary variable • Secondary variable • Blinding • Randomization

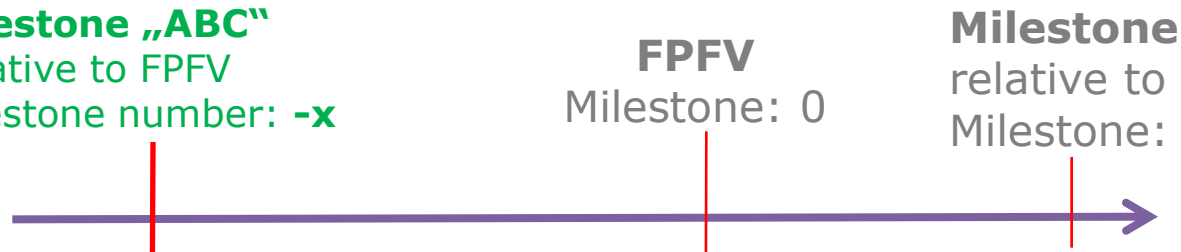
Product	• Test Drug / Reference Drug
	  • Active Ingredient
	  • Dose
	  • Route of administration
	  • Treatment duration

Trial Design	• Trial Arms • Trial Epochs • Assessments

Protocol Area	Corresponding Protocol Elements
Study population	• Inclusion criteria • Exclusion criteria • Withdrawal from treatment
Treatments to be administered	• Treatment administration • Dose modification • Dose Modification criteria • Supportive care • Prior therapy • concomitant therapy
Safety	• AE-Classification • AE-Assessments & documentation • AE-Reporting of SAEs • AE-Expected AE's
Statistics	• Stat. Methods • Sample size • Variables • Demographic characteristics

Metamodel of integration points

The metamodel defines milestones, integration points, templates, connection of templates to milestones



Protocol Design process timelines between CDP and CSR

Downstream processes connected to milestone. Each downstream process relates to the milestone and a sequential process number

-x.1 downstream process 1
Integration point:
Template „**–x.1 process 1**“

-x.2 downstream process 2
Integration point:
Template „**–x.2 process 2**“

The **template** describes

1. the integration point of the downstream process
2. the workflow of execution of the integration point
3. the process deliverables

ESC statuses and related up- or downstream processes

CDP

- 1. Ongoing Study List (CDP)
- 2. Draft Enhanced Study Concept
- 3. Scientific + Clinical Consultation (partners)
- 4. Decision on Outsourcing, CRO Selection
- -26. Appoint Co-ord. Investor
- -26. Planning for Clinical Trial Drug Supplies
- -26. Prefinal List of Countries
- -26 Ordering of Trial Supply

ESC 1st draft

- 9. Evaluation of pre-final countries Strategic Feasibility
- 10. Evaluation of pre-final countries – Operational Feasibility

ESC ready for PRC

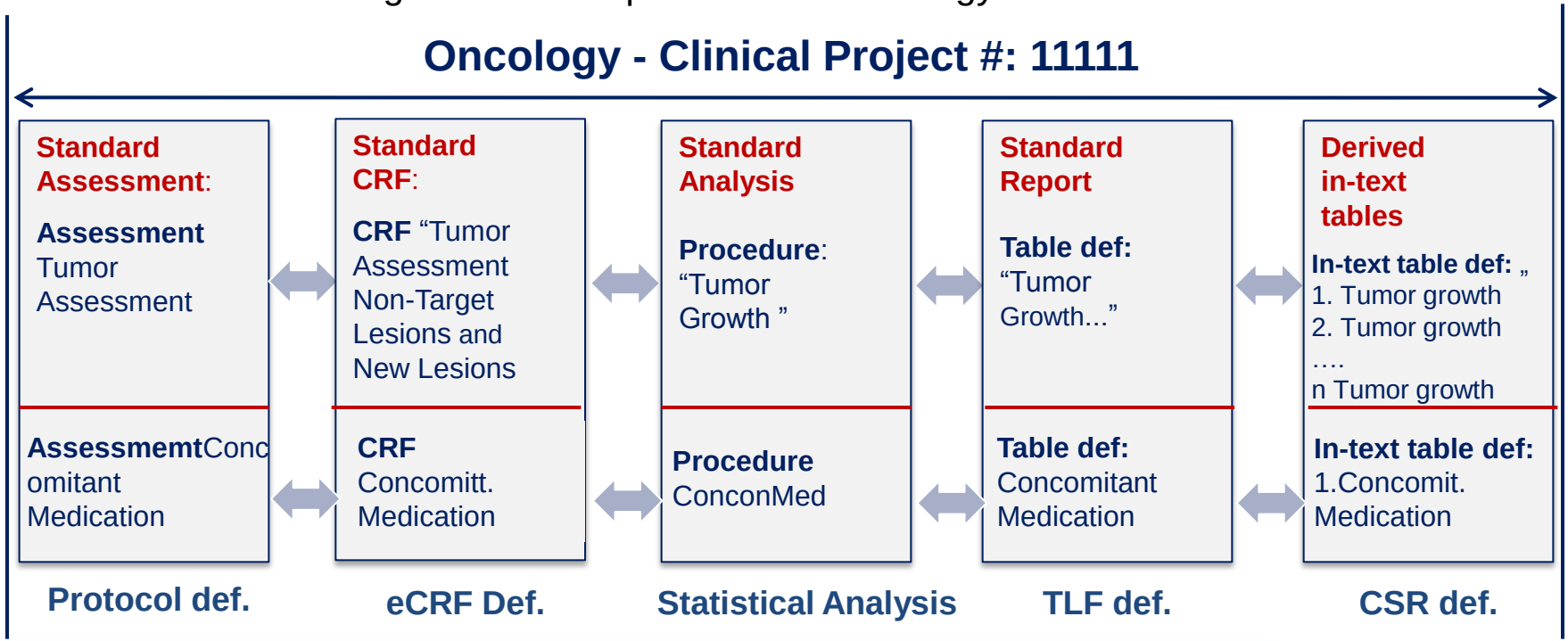
- 11. Randomisation Specs Generation of Candidate Randomisation
- 13. TMF Setup
- 14. Informed Consent
- 15. QC, Translations, CTA
- 16. IMP Planning and Order Specification / Drug Supply
- 17. Data Capture Specs DM
- 18. Final List of Countries
- 19. Qualification Plan
- 20. Selection Visits, Sites

Final ESC

- 8. Final Enhanced Study Concept
- 21. Final Protocol & Translation
- 17. SAP
- 22. eCRF Design DM
- 23. CTMS Setup
- 24. CRA Training

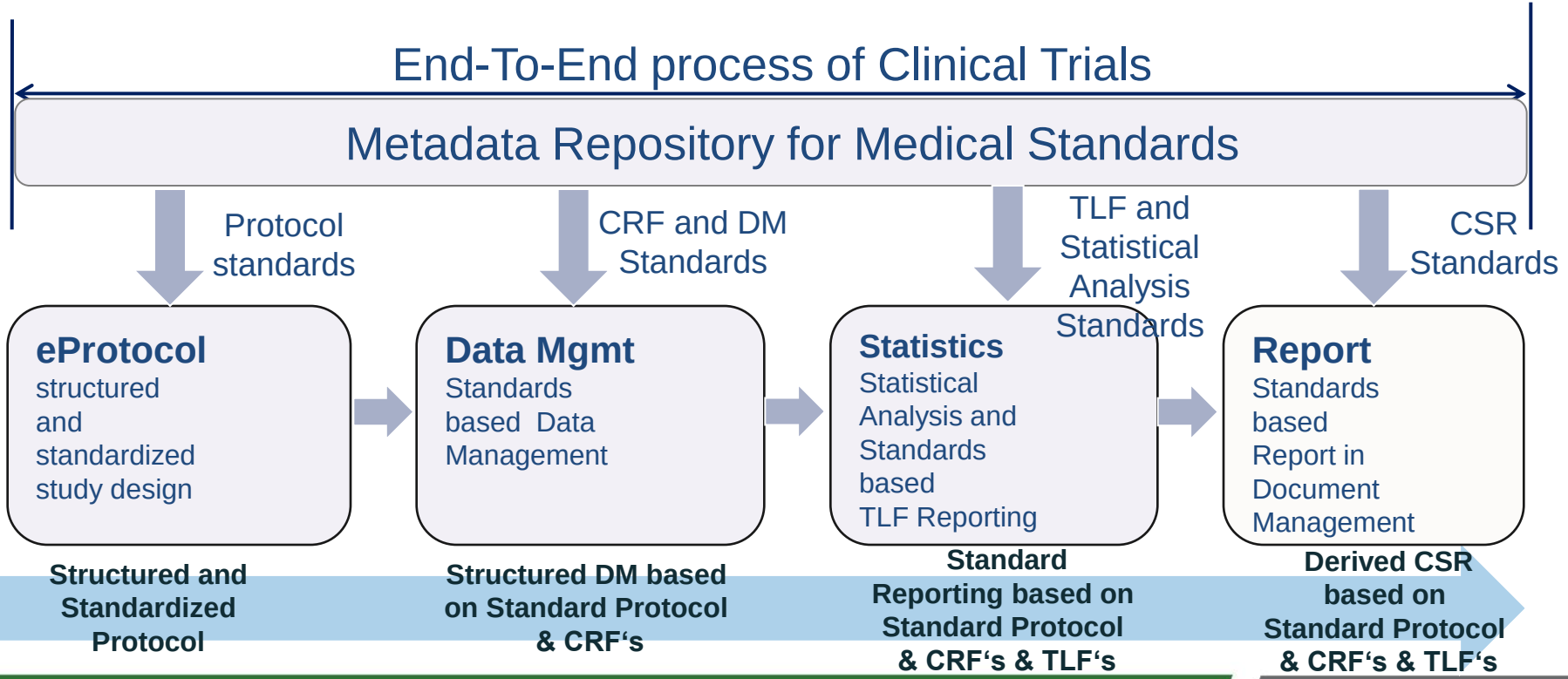
Linked Medical Standards in Repository

- high level concept based on Oncology trial



Metadata driven Clinical Trials

- end-to-end process



Benefits

- estimated benefits of structured Study Design

- **Process of delivering & quantification of benefits**
- **Estimated benefits of structured study design**

  - Higher productivity in R&D
  - IT alignment with Clinical Trial process
  - Reusability of CRF‘s, Statistical procedures, TLF
  - Error prevention rather than error resolution
  - Consistent execution of protocol downstream processes
  - Consistent and efficient set up of data collection
  - Automated data integration
  - Consistent reporting of Clinical Trials
  - Meta-Analysis across Clinical trials and Clinical Projects
  - Safety and efficacy knowledge gain on compound level

Thank you for your interest

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