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Our journey: innovative approach to planning and designing trials in database

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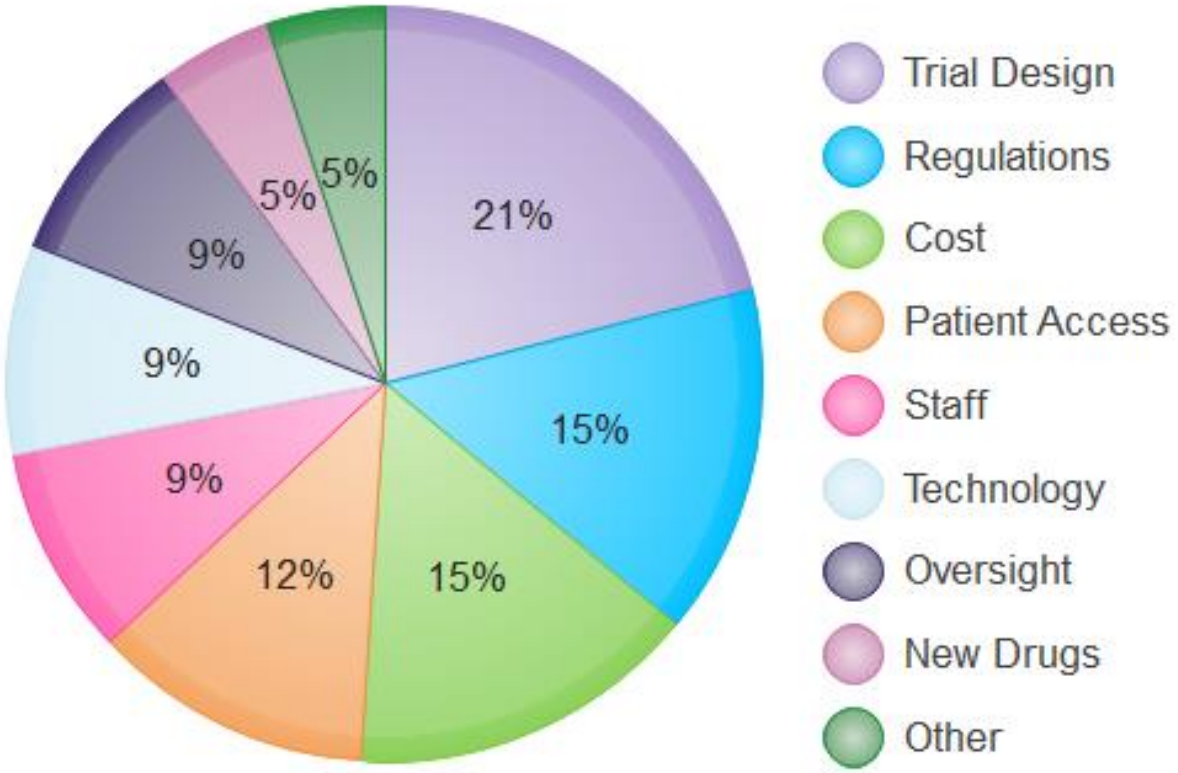
Clinical Operations Challenges



Clinical trials have been growing increasingly complex for years – under pressure to design trials that:

- Give the right answers
- Simple and unobtrusive way for patients
- Acceptable to regulators and payers

knect365.com, Clinical Trials Innovation, Report: Biggest Challenges Clinical Trials

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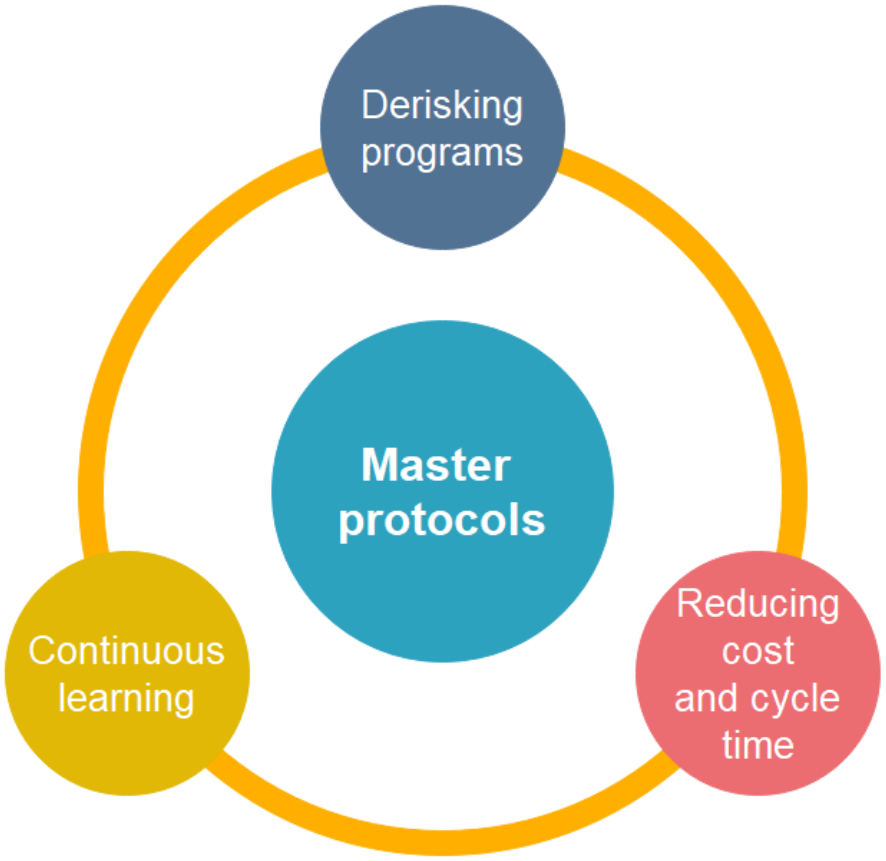
Study Protocol Challenges



Illustrative impact of cost and cycle time savings realized from participating in a phase 2 oncology master protocol

Impact of cycle time savings	Impact of cost savings
Traditional patient enrollment and site-startup time: **117 weeks**	Traditional cost: **$11.2M**
Master protocol patient enrollment and site-startup time: **96–102 weeks**	Master protocol cost: **$9.5–$9.8M**
Savings: 13%–18% (15–21 weeks)	**Savings:** $1.3–$1.6M (12–15%)

Note: Currency amounts in this figure are in US dollars.
Source: Deloitte Center for Health Solutions analysis.

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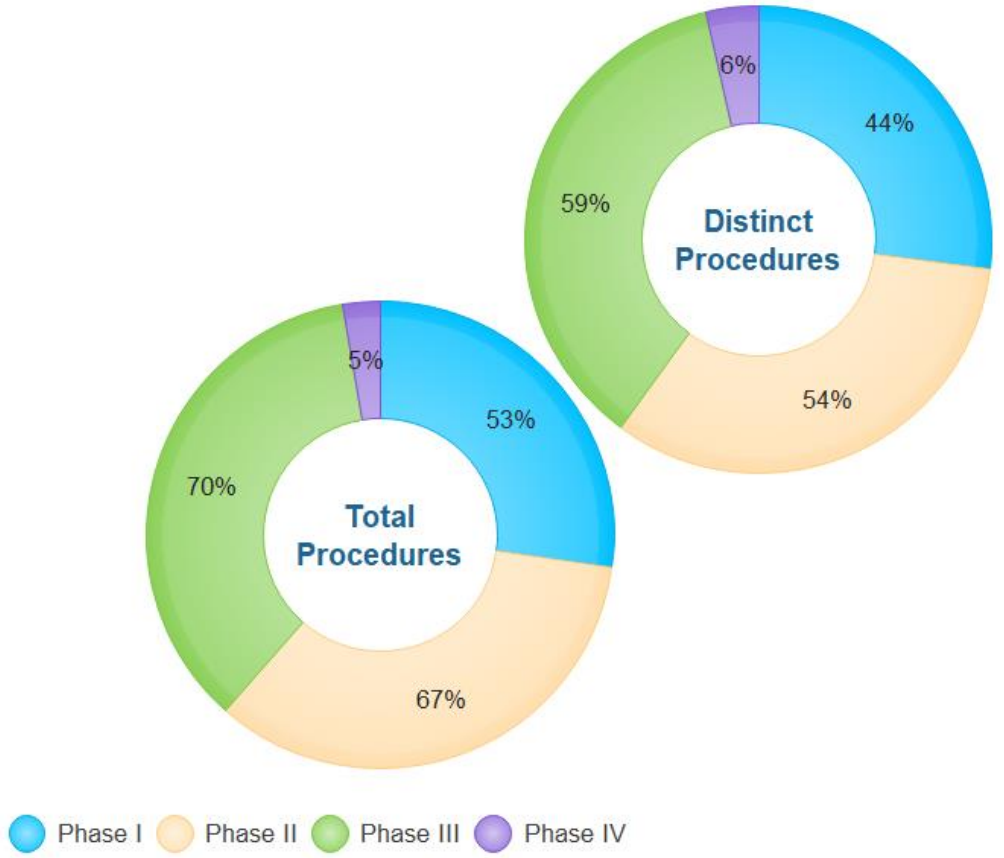
Protocol Design Trends

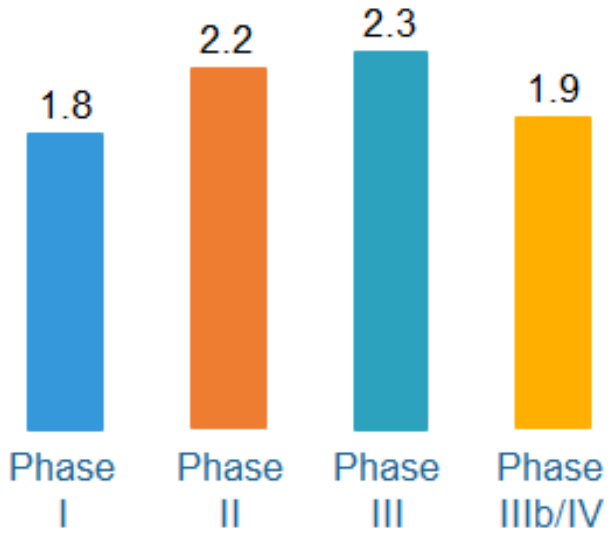
A Typical Phase III Protocol	2001 - 2005	2011-2015
Total Number of Endpoints	7	13
Total Number of Eligibility Criteria	31	50
Total Number of Procedures	110	187
Total Number of Procedures per visit	10	13
Proportion of Procedures that are 'Non Core'	18%	31%
Total number of data points collected*	494,236	929,203



Source: K. Getz, Tufts CSDD; *Medidata Solutions

Protocol Amendments Trends

Mean number of amendments per protocol



Top reason for amendment

Phase I	New and modified safety assessment (15.4% of total)
Phase II	Change in Eligibility Criteria (17.2%)
Phase III	Change in Eligibility Criteria (15.2%)
Phase IIIb/IV	Change in Eligibility Criteria (17.9%)

Implementation cost per amendment:

- On average 3 month of unplanned time
- 141 K$ in direct cost of Phase II protocols
- 535 K$ in direct cost of Phase III protocols

Source: K. Getz, Tufts CSDD

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Why have we started to look to SSD?

01 Reduce number of protocols amendments prior First-Patient-First-Visit (FPFV)

02 Reduce number of CRO contract changes due to late change in design or inconsistent usage of medical standards

03 Reduce number of data points being captured

04 Direct access and use of medical standards in Metadata Repository (MDR)

05 Use structured protocol data to fully realize End to End (E2E) efficiency goals

06 Transforming TPP, CDP and Study Definition into an integrated digital platform to leverage the benefits of having this information available in a machine-readable format

80% of all benefits derived from Standards occur in the study startup phase
(**Gartner:** CDISC standards business case)

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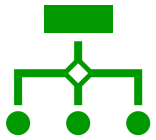
Structured Study Approach



Structured Model

Protocol Standards

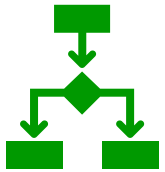
Downstream process support

Clinical Leads and Medical Writing Support

Support Learning Organization

Enhance Study Design

Enforce Medical Standards



Enable Streamlined Clin. Operations

Reduce Protocol Amendments

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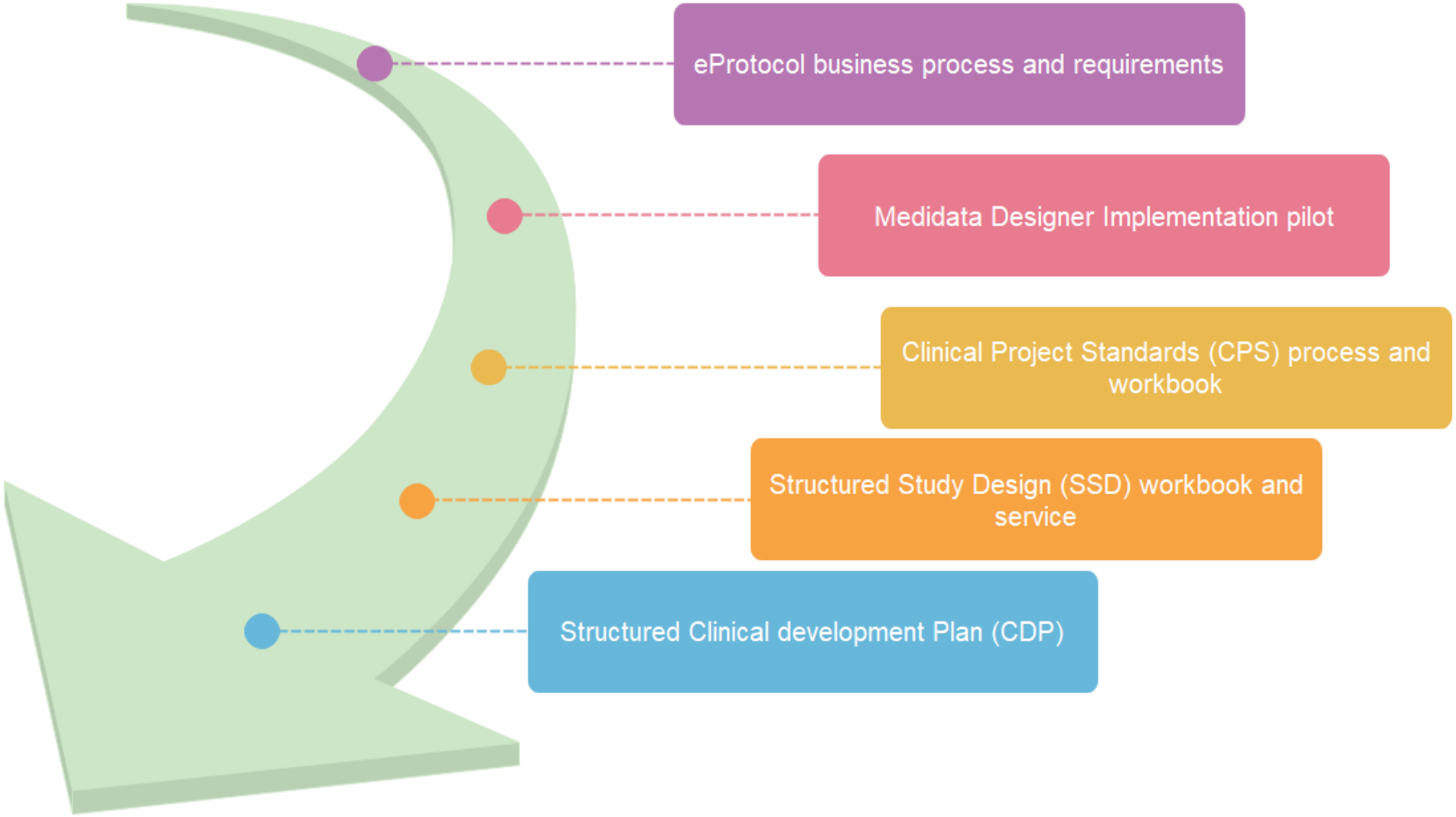
Our Journey



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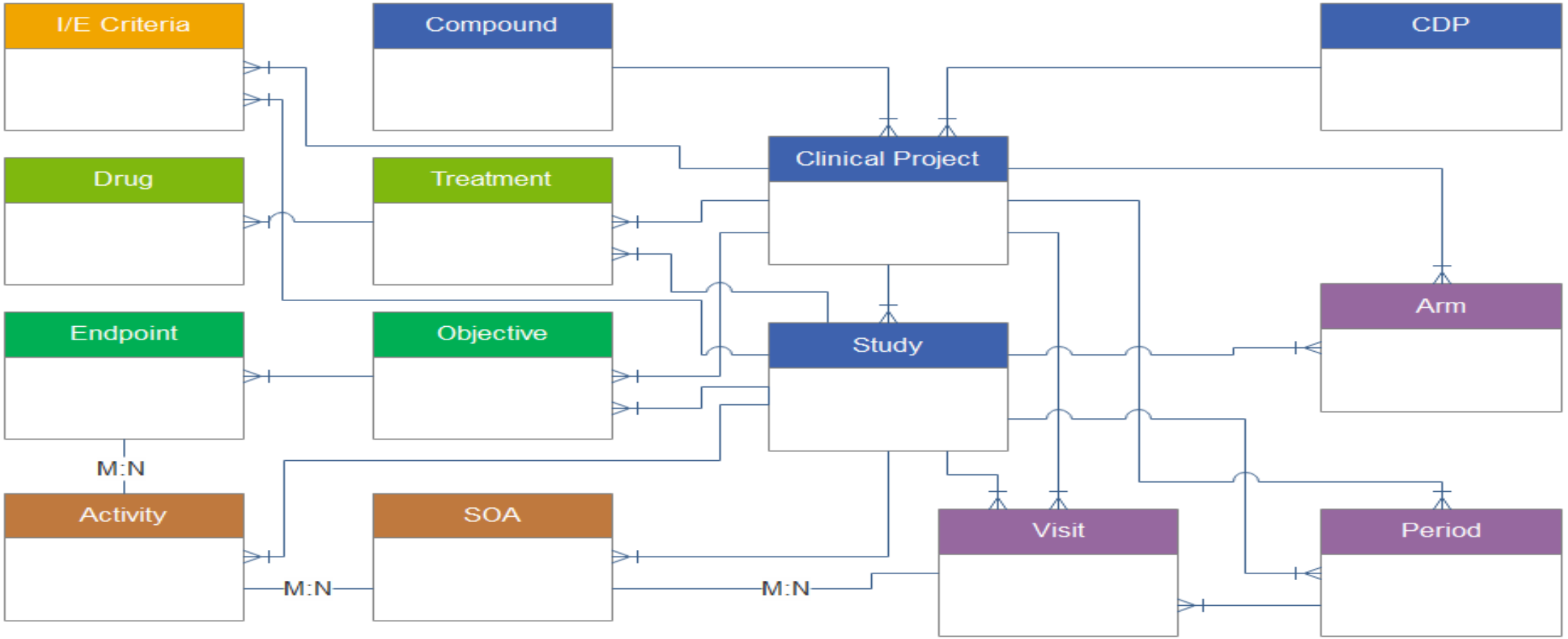
SSD Structure



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Standardization

Project Standardization

Compound

1:n

Clinical Project

1:m

Clinical Trial

Clinical Trial Phase 1

Clinical Trial Phase 2a

Clinical Trial Phase 2b

Clinical Trial Phase 3

Protocol Element Standardization

Protocol Data Elements

- Trial Summary
- Objectives
- Endpoints
- Eligibility
- Treatment
- Protocol Activities
- SOA
- Trial Design
  - Arms
  - Visits
  - Elements

CDO Process Standardization

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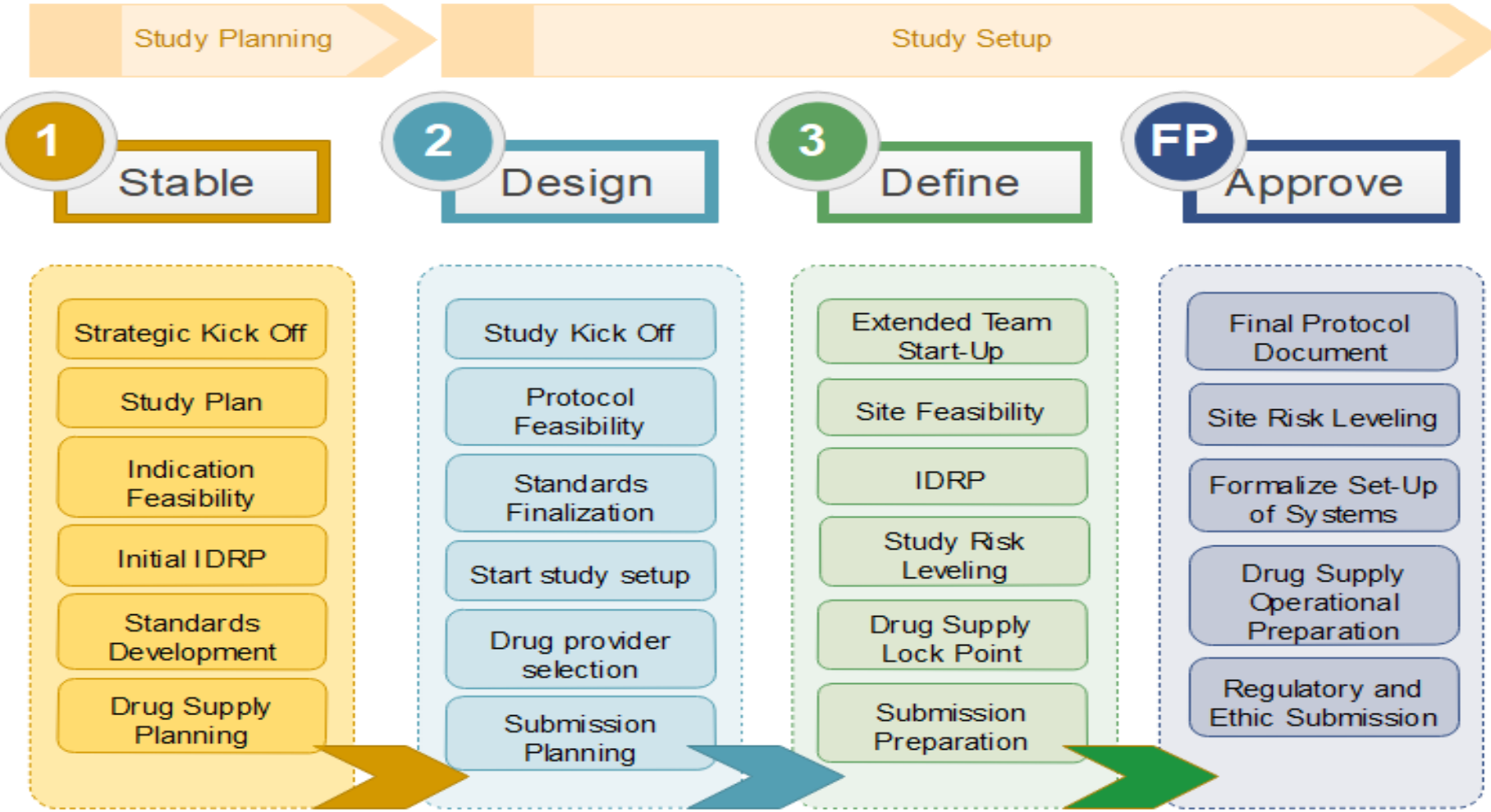
Downstream process support



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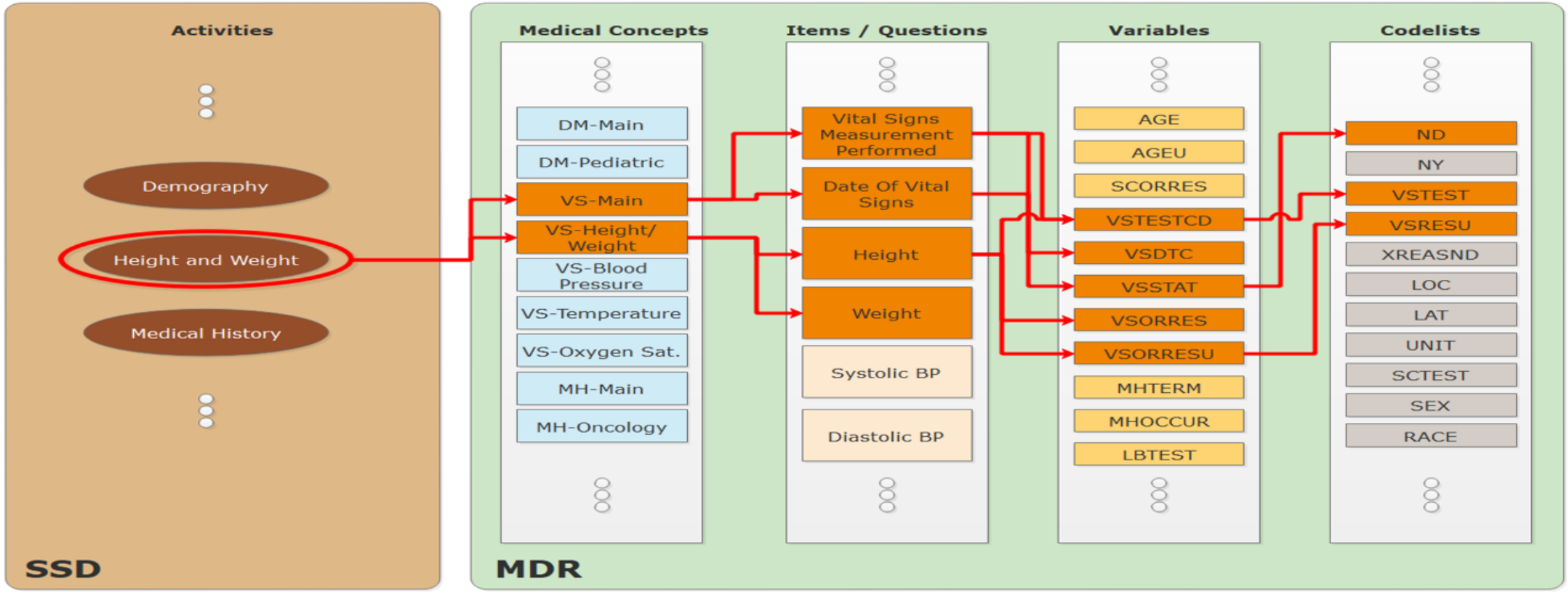
SSD-MDR Integration



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Challenges

Study Complexity

Accounting for an ever increasing Study Complexity

Capturing the increased scope of clinical trials in the past 15 years and the rapidly grown protocol design elements and clinical trial designs in a structured document format.

Standardization

Overcoming resistance against standardization

Study Teams usually want to establish their own individual standard for their project and therefore standards between projects vary. Variability and ambiguity in the terminology of procedures design elements prevent E2E automation.

Template Versions

New Protocol template versions

Making sure that new protocol template versions (as they become available) can seamlessly be implemented without the need to perform changes to the system.

System Introduction

Cross-functional system

System implementation and introduction requires a carefull cross-functional alignment. Process of creating and consuming the information in CDO requires downstream process alignment.

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Learnings

Study Complexity

In order to allow the capturing of novel clinical trial designs, an ongoing analysis of new trends in clinical development have to be performed and continuously applied.

Employ well known trial design specification strategies used by CDISC.

Standardization

Change in mindset and discipline is required to accept company standards (if scientifically justifiable) rather than individual preferences.

Discuss and demonstrate how higher standardization in the trial design enables higher level of automation, so teams can focus on creative work.

Template Versions

New protocol template versions require a certain level of preparation (e.g. defining study design elements, placeholder etc.) before they can be used.

Benefit from and align to TransClerate CPT release process.

System Introduction

Engage all stakeholders and consumers of the protocol information into system design process.

Users still prefer the look and feel of a text editing software such as Microsoft Word so compatibility/ integration with Microsoft Word is integral for adoption.

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Outlook

- Emerging tools to support the SSD concept
- MDR Integration
- CDP/TPP view and alignment
- TransCelerate CPT integration

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