

**Cross-functional
Standards
Governance for
Pharma**

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PhUSE 2017*

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... and are non-binding recommendations.

Cross-functional Standards Governance for Pharma

Agenda

- The challenge
- Examples
- A modernised approach

Standards Governance for global industry standards

The challenge

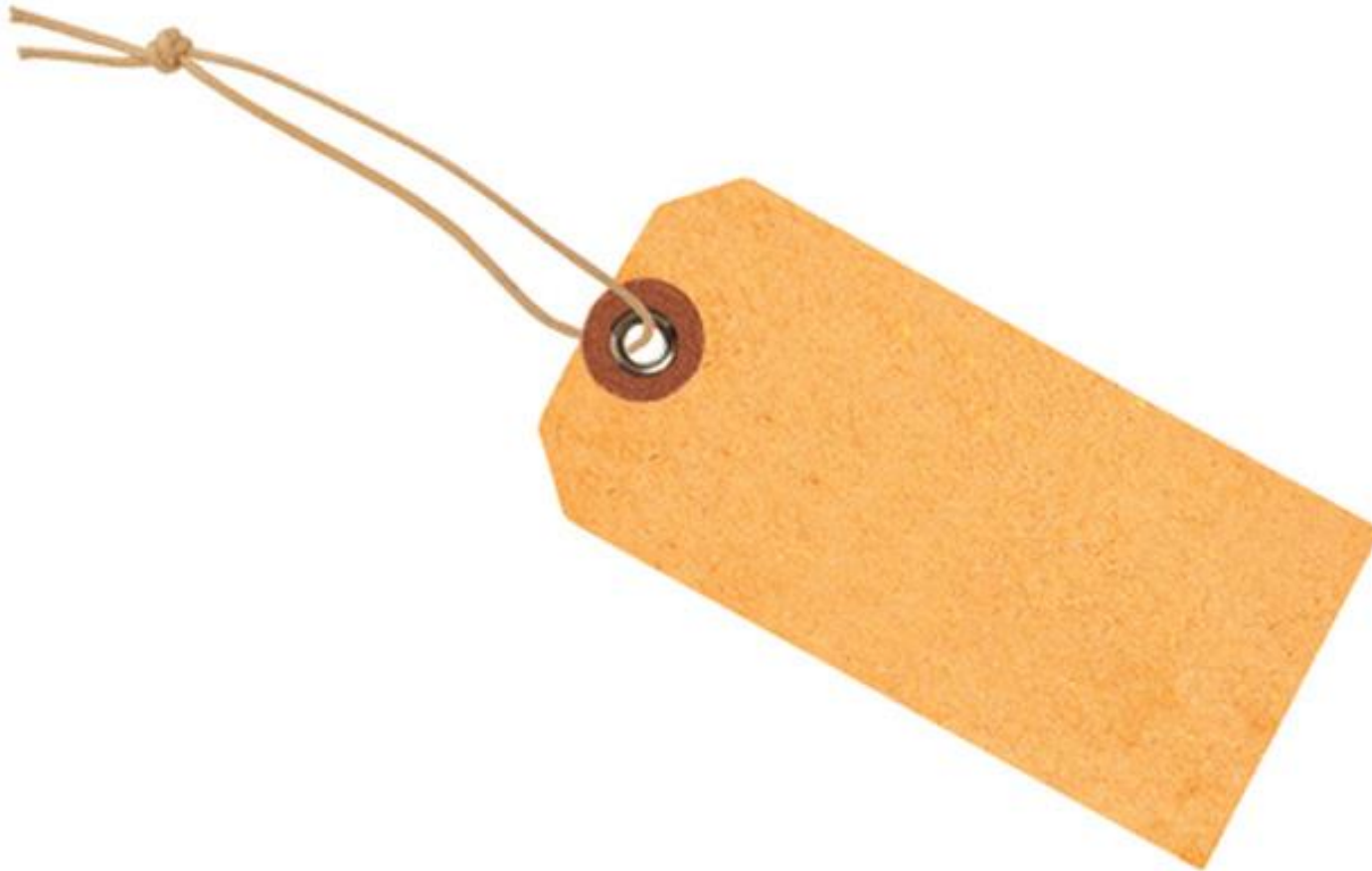
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The challenge



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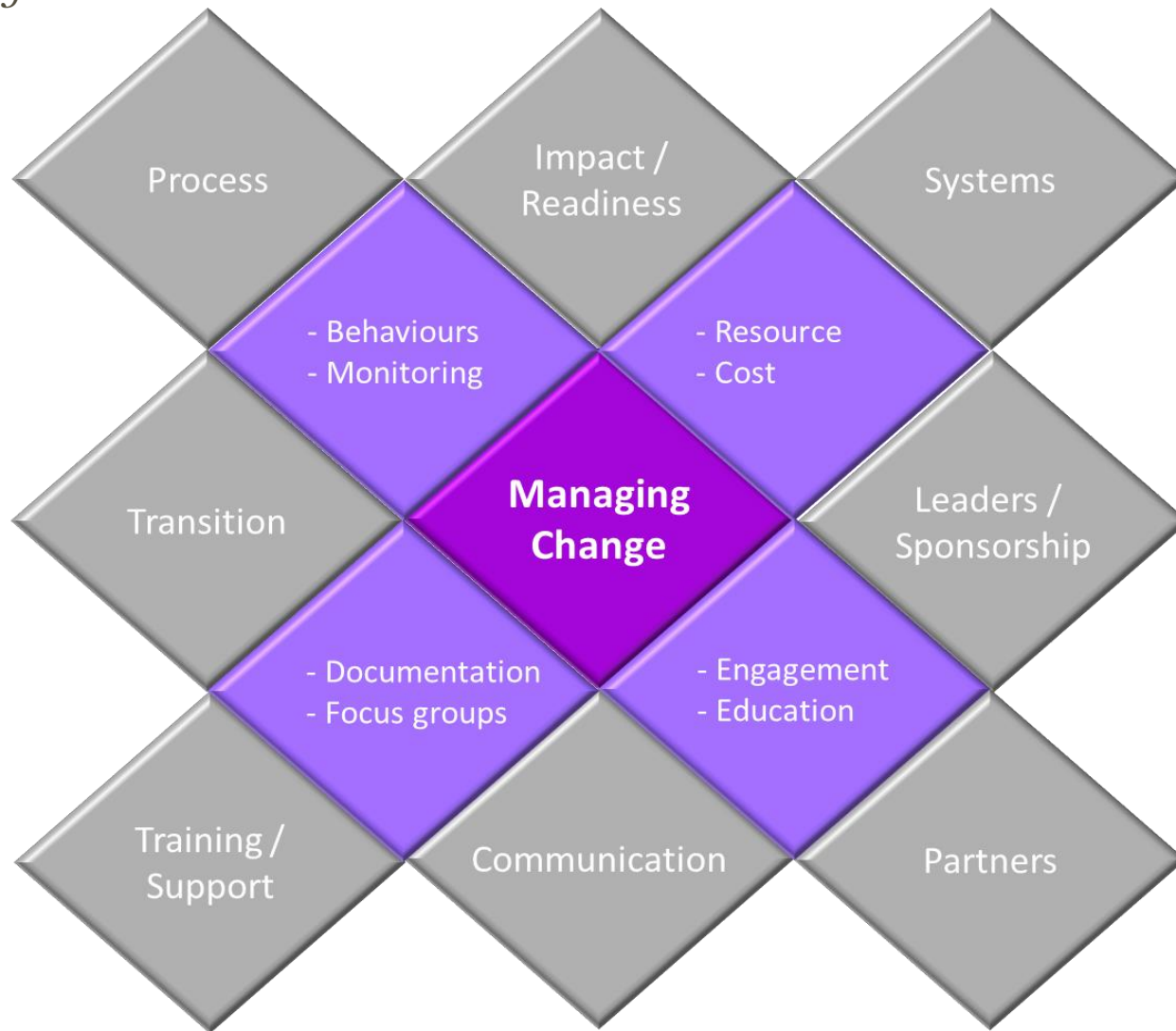
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The challenge



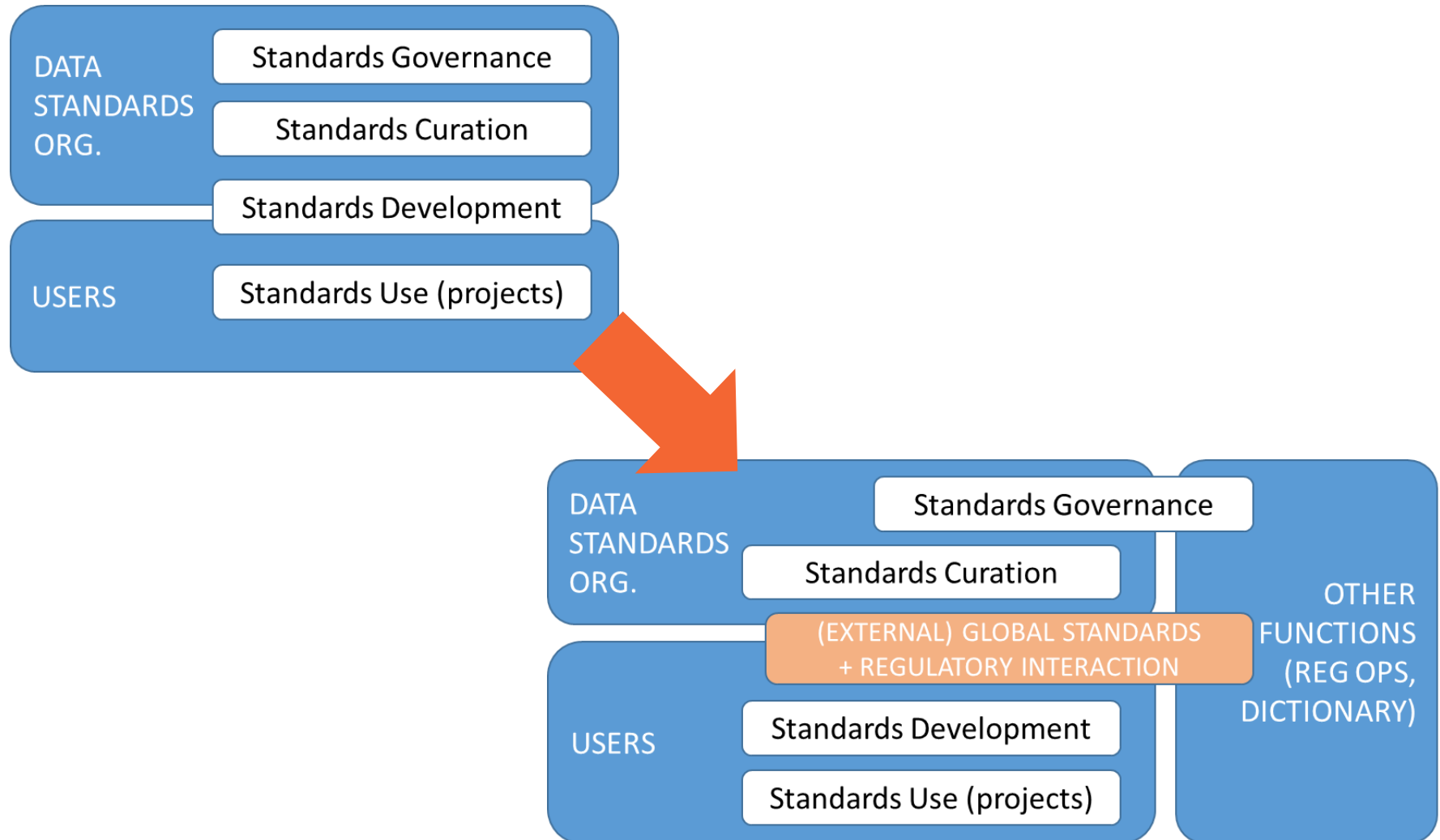
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The challenge



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The challenge

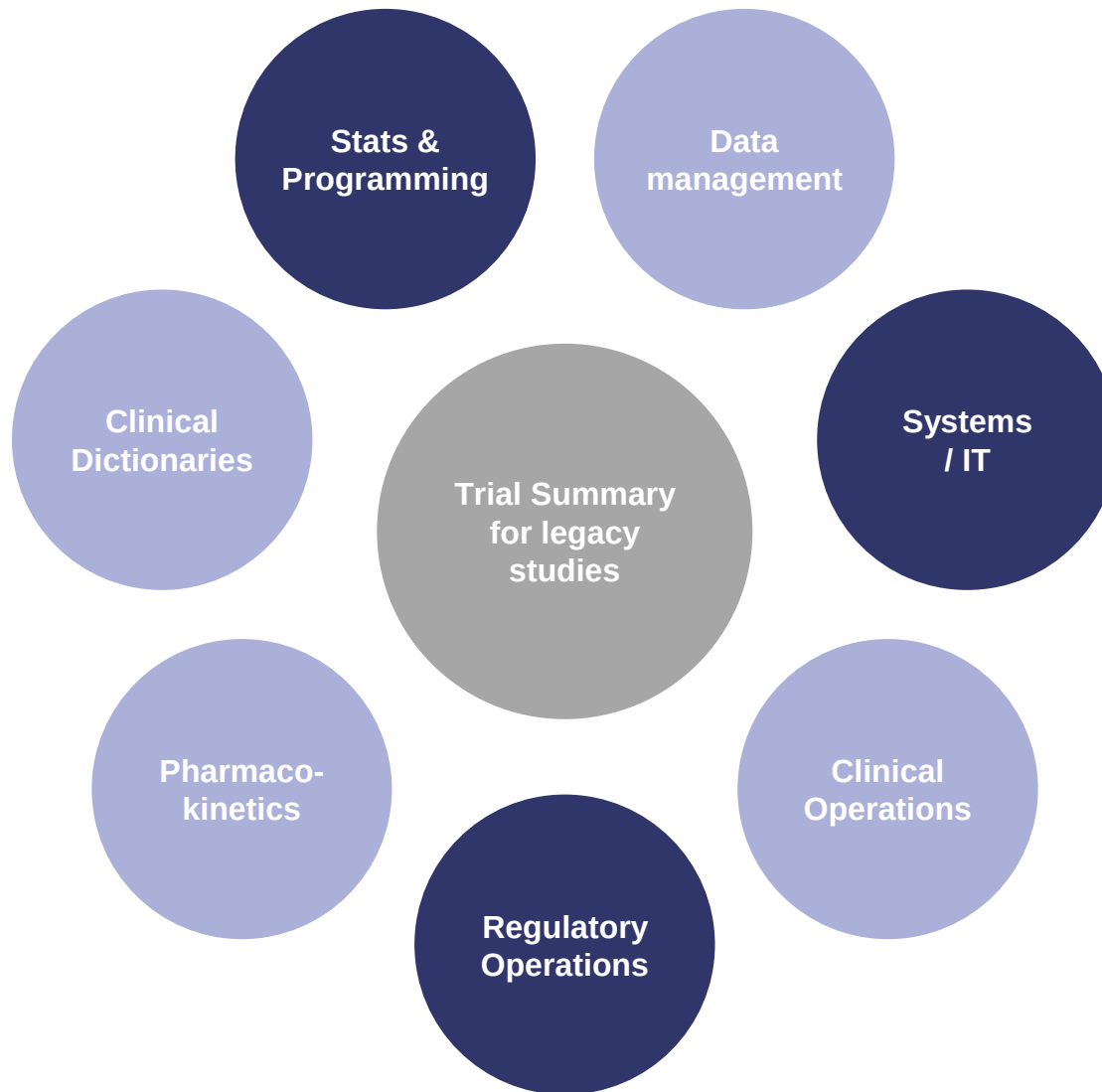


Cross-functional implementation challenges for global standards

Examples

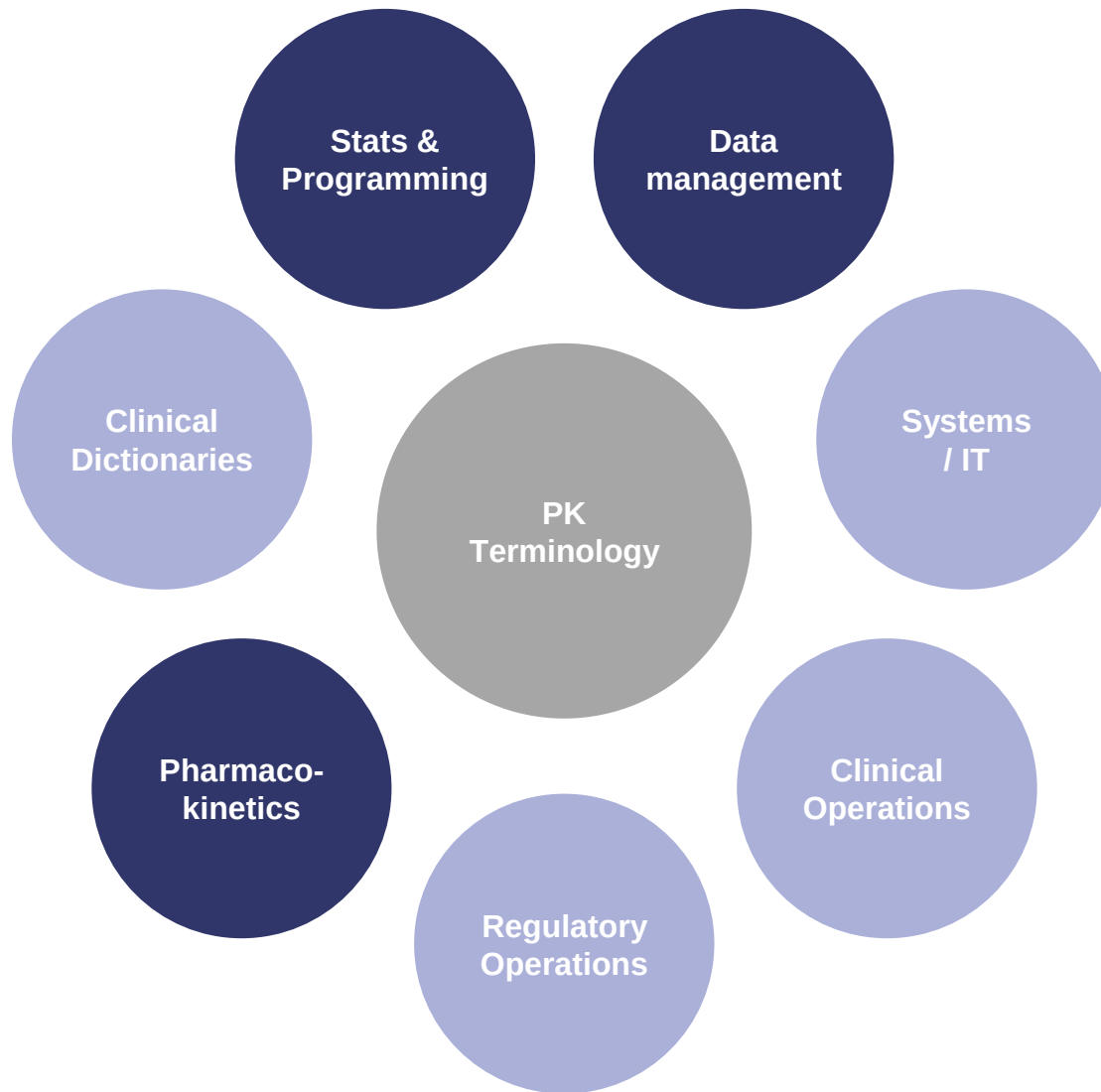
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Examples



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Examples



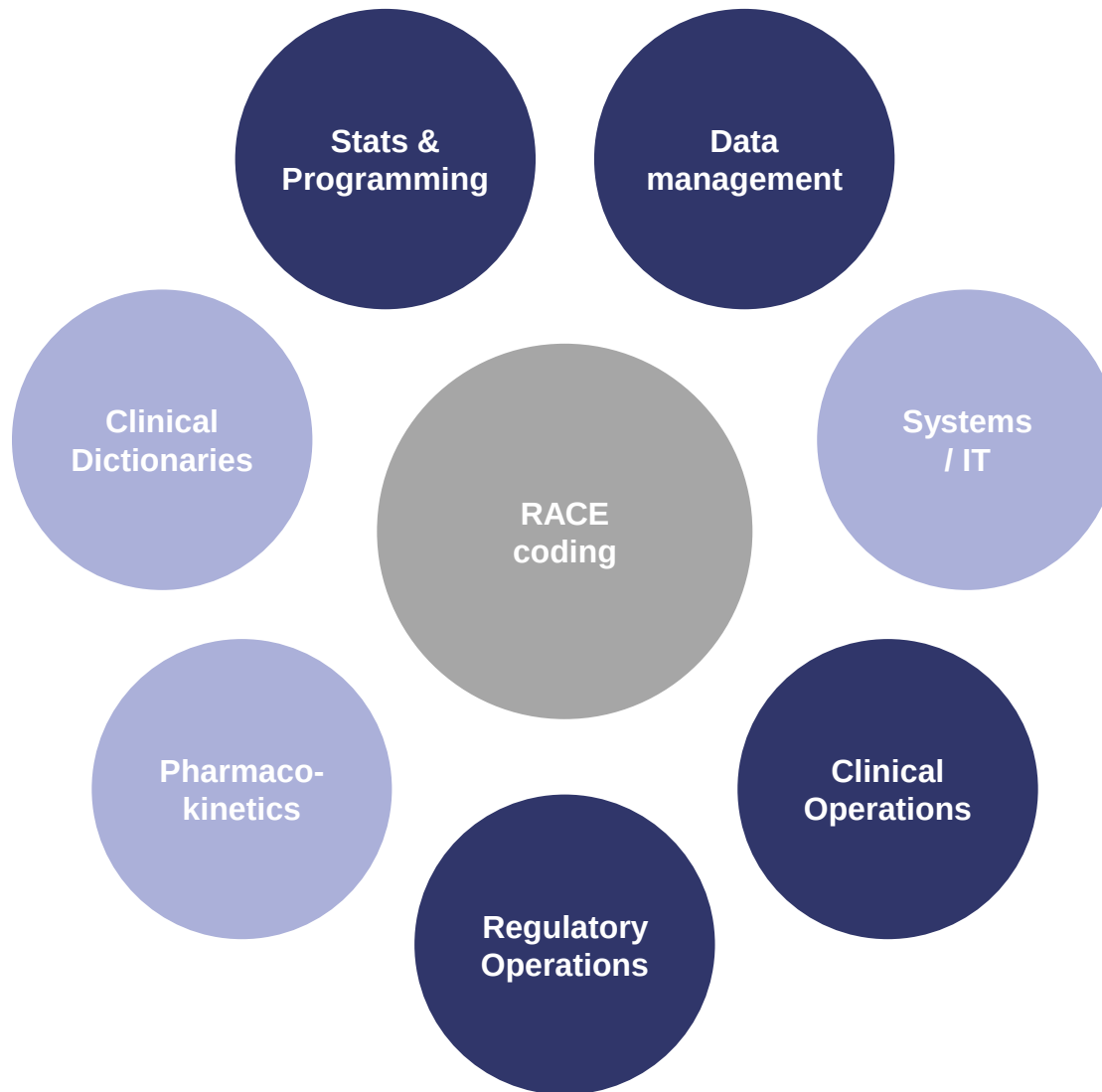
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Examples



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Examples

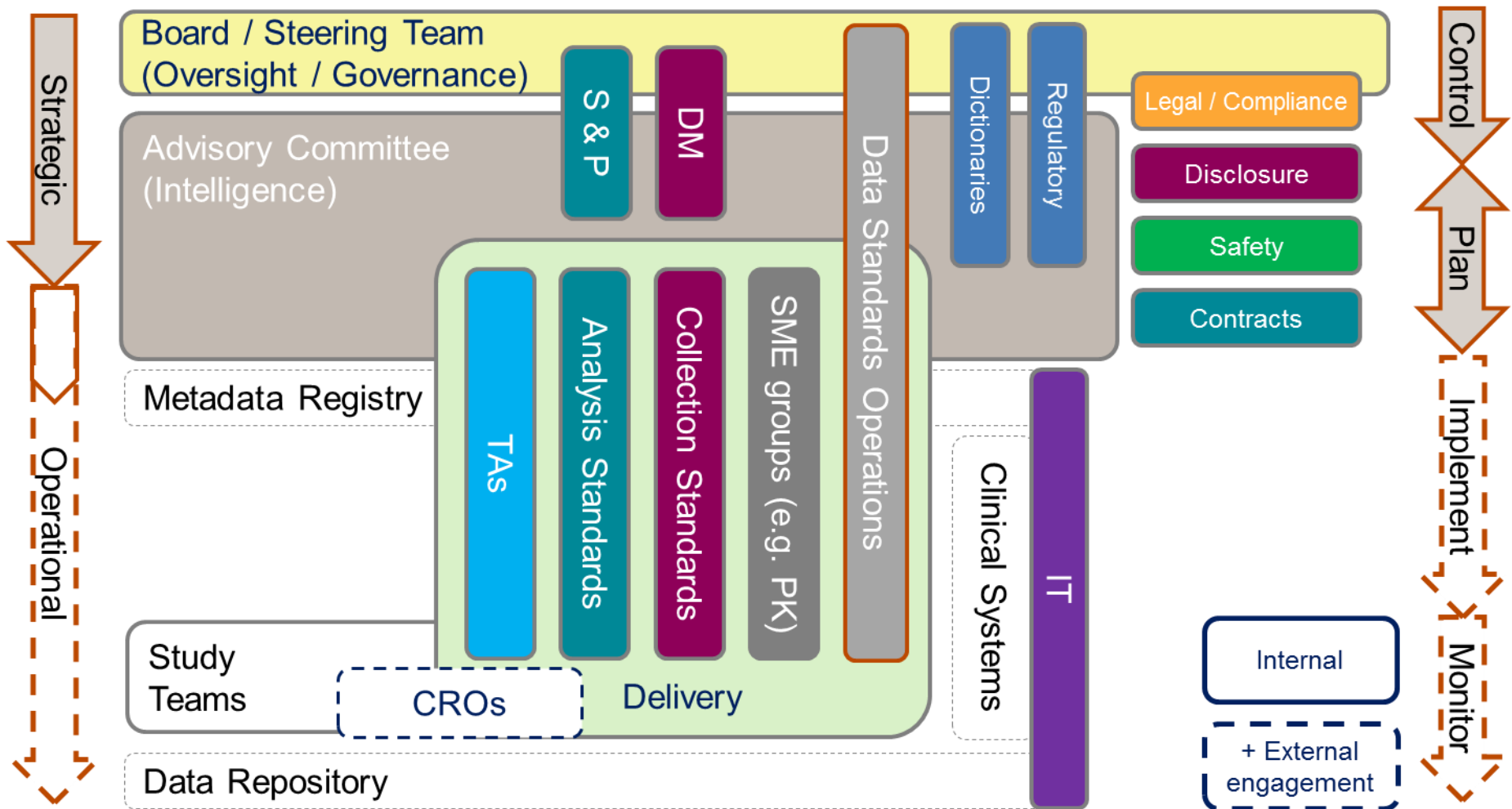


An updated approach to cross-functional standards governance

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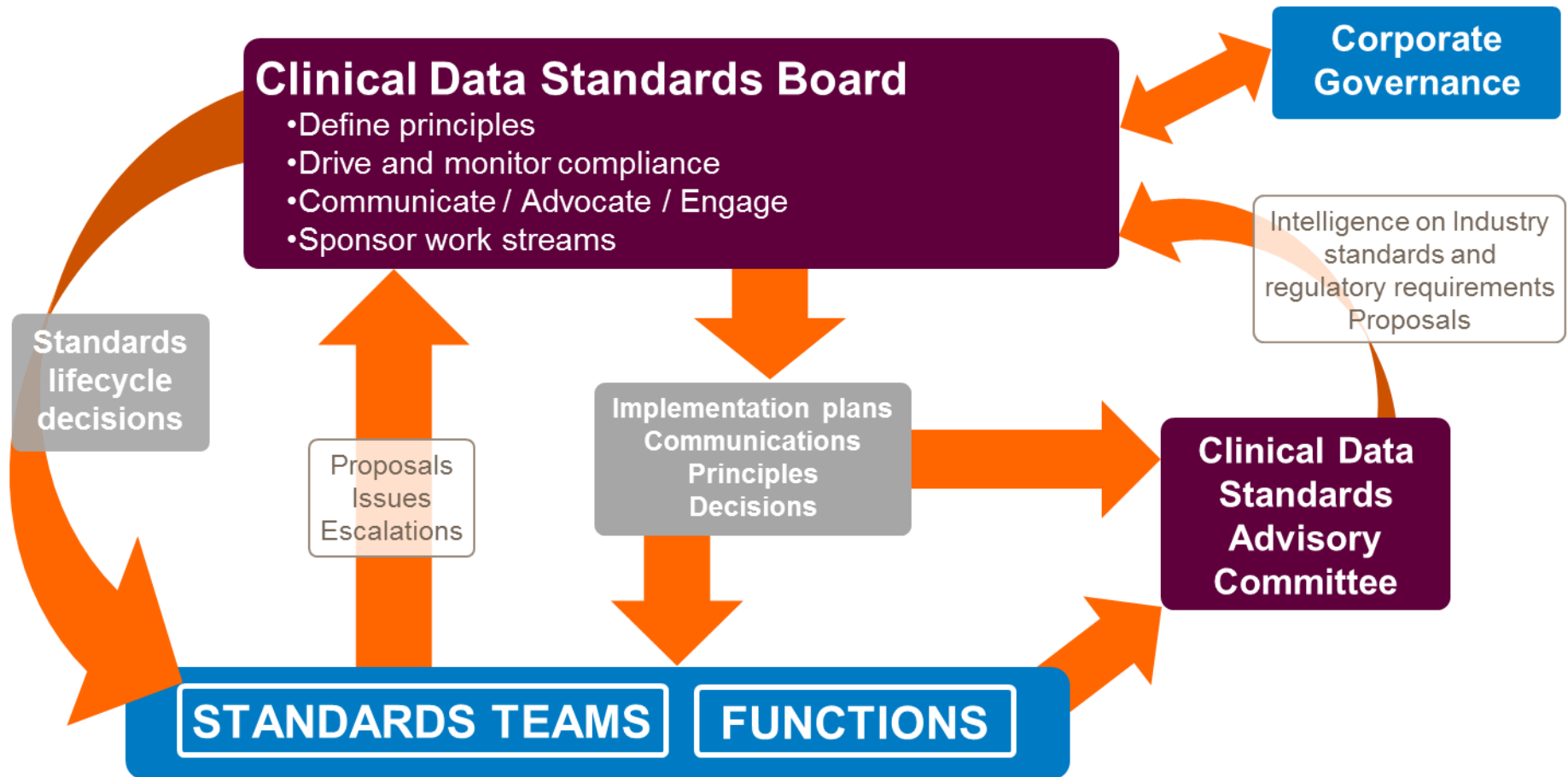
A modernised approach



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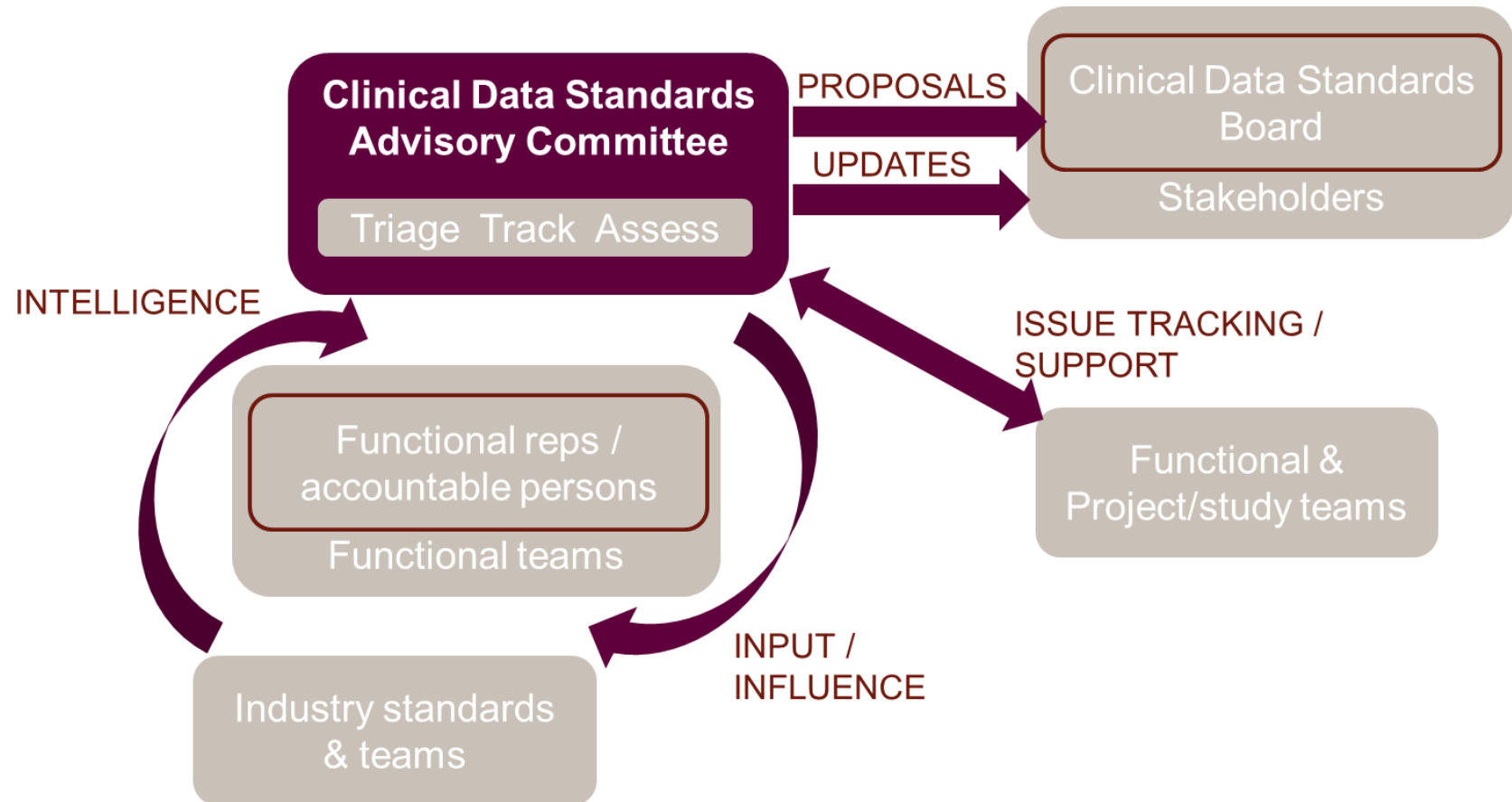
Clinical Data Standards – Board & Advisory Committee



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Clinical Data Standards - Advisory Committee



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Every company should have a standards catalogue

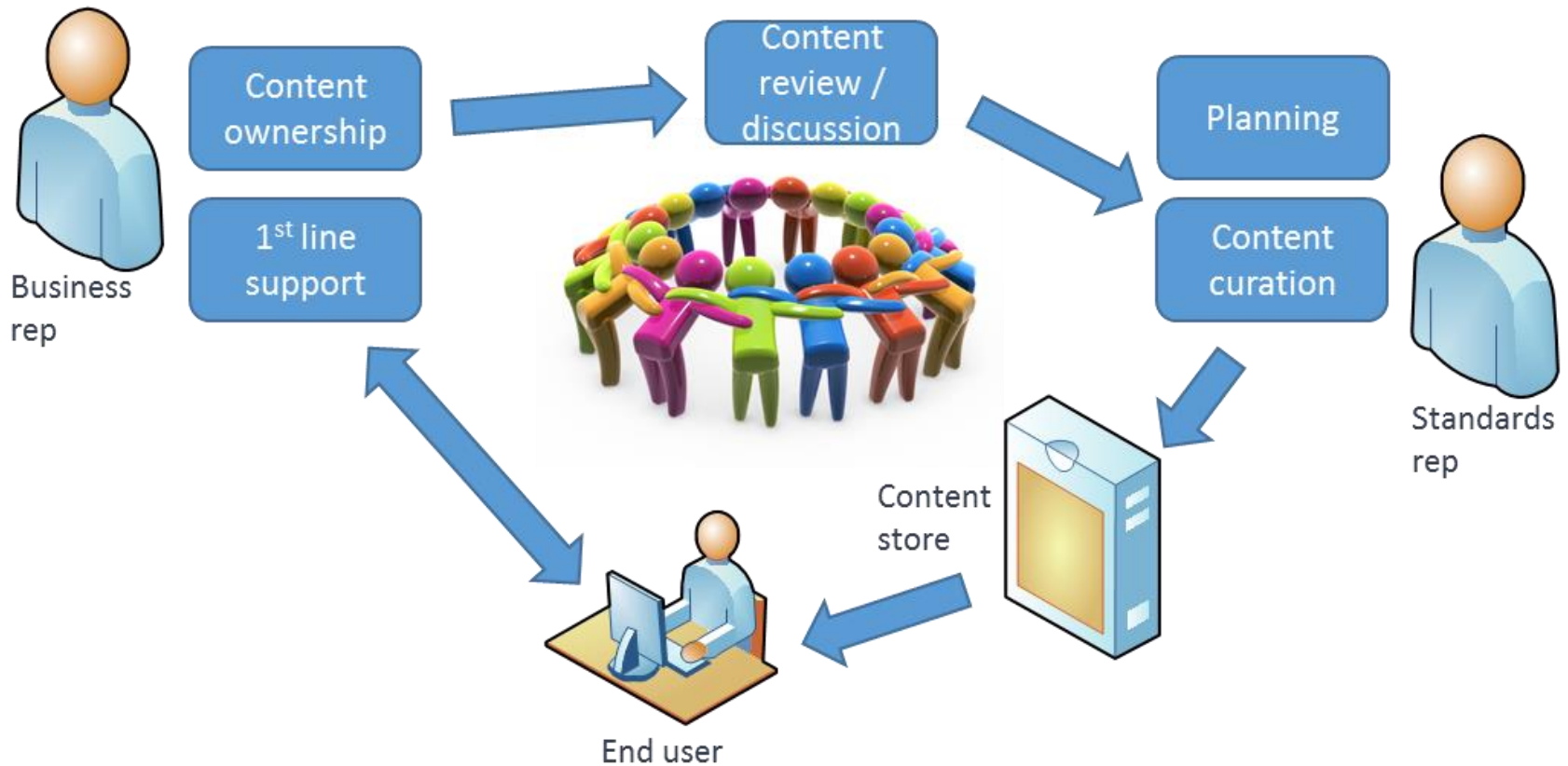


Key information									
Standard	Type	Version	Core standard?	External owner (where applicable)	External status	GSK Status GSK status	FDA Status	FDA Req Date	PMDA Status
ADaM IG	Tabulation	1.2	Y	CDISC	Draft	Monitor	Not yet Active		Not yet Active
ADaM IG	Tabulation	1.1	Y	CDISC	Active	Assessment In Progress	Not yet Active		Not yet Active
ADaM IG	Tabulation	1	Y	CDISC	Active	Active - Preferred	Active - Preferred	17-Dec-16	Active - Preferred
ADaM Model	Tabulation	2.1	Y	CDISC	Active	Active - Preferred	Active - Preferred	17-Dec-16	Active - Preferred
ADaM Terminology	Terminology	P30 (June 2017)	Y	CDISC	Active - Preferred	Active - Preferred	Active		Active
GSK DRUG	Coding Dictionary		Y	N/A	N/A	Active - Preferred	N/A	N/A	N/A
LOINC	Terminology	2.1	N	Regenstrief Institute	Active	Adoption Planned	Active - Preferred	15-Mar-18	Not yet Active
MedDRA	Coding Dictionary	19	Y	ICH	Active	Active - Preferred	Active		Active
NDF-RT	Terminology	-	Y	NCI / VHA	Active	Adoption Planned	Active		
SDTM IG	Tabulation	3.3	Y	CDISC	Draft	Monitor	Not yet Active		Not yet Active
SDTM IG	Tabulation	3.2	Y	CDISC	Active - Preferred	Active - Preferred	Active - Preferred	15-Mar-18	Active - Preferred
SDTM IG	Tabulation	3.1.3	Y	CDISC	Active	Active - Non-preferred	Active - Non-preferred	17-Dec-16	Active - Non-preferred
SDTM IG	Tabulation	3.1.2	Y	CDISC	Active	Inactive	Active - Non-preferred	17-Dec-16	Inactive
SDTM IG	Tabulation	pre 3.1.2	Y	CDISC	Active	Not Adopted	Decommissioned	N/A	Inactive
SDTM Model	Tabulation	1.5	Y	CDISC	Active	Monitor	Not yet Active		Not yet Active
SDTM Model	Tabulation	1.4	Y	CDISC	Active	Active - Preferred	Active - Preferred	15-Mar-18	Active - Preferred
SDTM Model	Tabulation	1.3	Y	CDISC	Active	Active - Non-preferred	Active - Non-preferred	17-Dec-16	Active - Non-preferred
SDTM Model	Tabulation	pre 1.3	Y	CDISC	Active	Not Adopted	Active - Non-preferred	17-Dec-16	Inactive
SDTM Terminology	Terminology	P30 (June 2017)	Y	CDISC	Active - Preferred	Active - Mandated	Active		Active
UCUM	Terminology	1.3	N	ISO	Active	Adoption Planned	Active		Inactive
UNII	Terminology	-	Y	FDA	Active	Active - Preferred	Active		Inactive
WHO-DD	Coding Dictionary	-	N	UMC	Active	Active - Non-preferred	Active		Active - Preferred
SNOMED	Terminology	-		NCI	Active	Active - Preferred	Active - Preferred	15-Mar-18	Inactive

Cross-functional Standards Governance for Pharma



Business users as 1st line support and content developers



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In summary

- The adoption of global industry standards has increased the complexity and impact of change management related to the implementation of new standards, versions and content. In particular, the likelihood of impacts on process and technology, and wider cross-functional organization is increased.

- A more evolved structure for standards curation and governance is recommended, through significantly increased engagement with cross-functional business users which enhances the flow of information between external sources, internal standards teams and end users, and helps drive standards content development.

- The use of a standards catalogue within a company is highly recommended as a mechanism to ensure clear line of sight for all staff.

- Two levels of governance are recommended;
 - a Board which is responsible for approval of general operating principles and new work efforts, and enabling of resource, as well as advocacy and risk management.
 - an Advisory Committee which is responsible for tracking and managing the company standards, identifying the need for remediation, and defining and planning updates to the standards as appropriate.



Thank you. Questions?