



MRCT and Project Centric Approach

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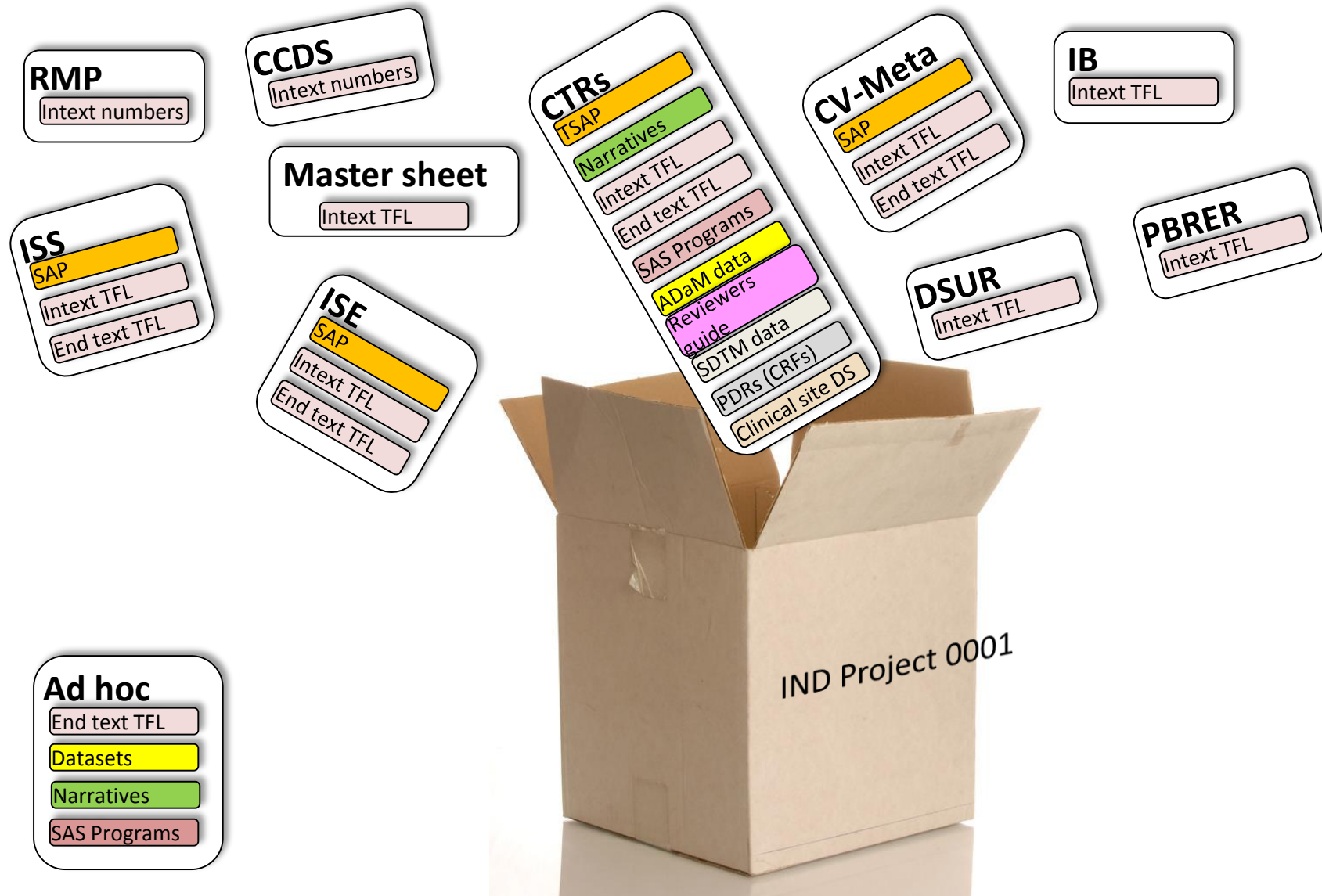
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- ☐ Classic Process
- ☐ Project Centric Approach (PCA) features
- ☐ What to do to meet PCA
- ☐ PCA Benefits
- ☐ MRCT pieces in PCA frame
- ☐ Standards
- ☐ Q&A

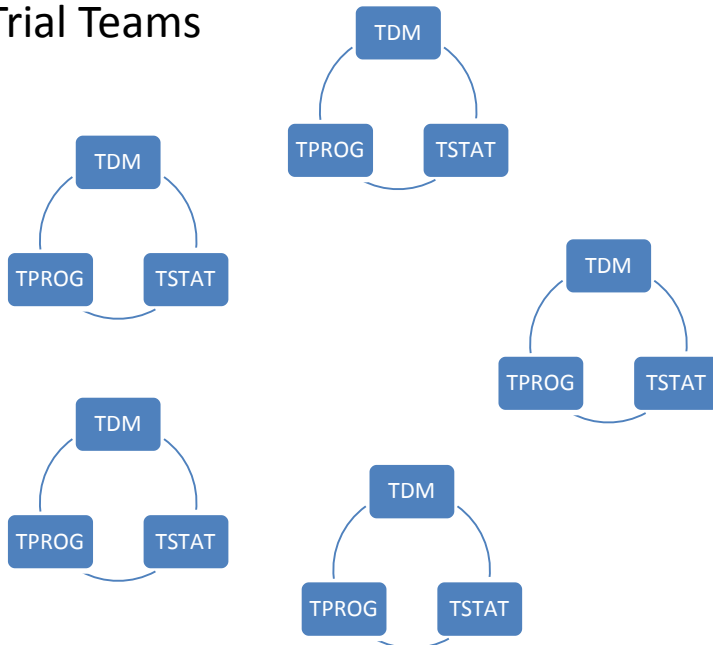
Submission Deliverables



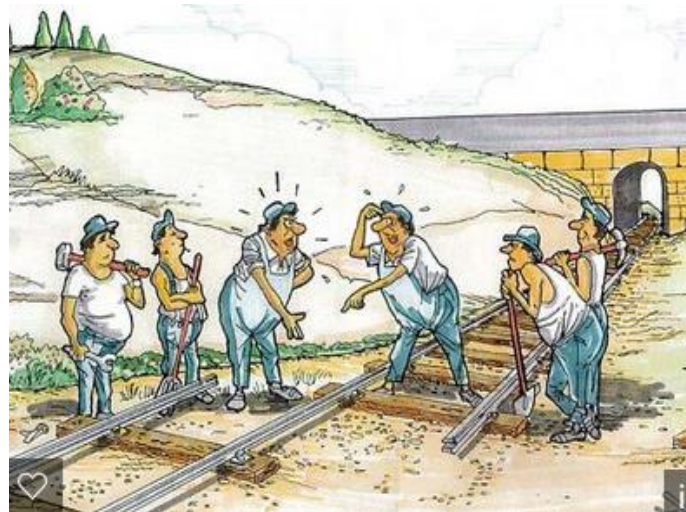
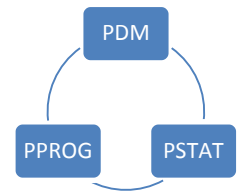
Classic Processes

- ☐ Trial team works in a silo mode
- ☐ No front loading
- ☐ Limited standards
- ☐ Pooling at the end
- ☐ Recourse demanding
- ☐ Tighten timelines at the end
- ☐ Quality control

Trial Teams



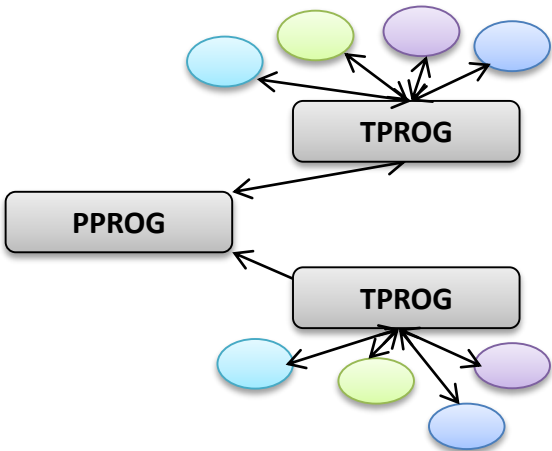
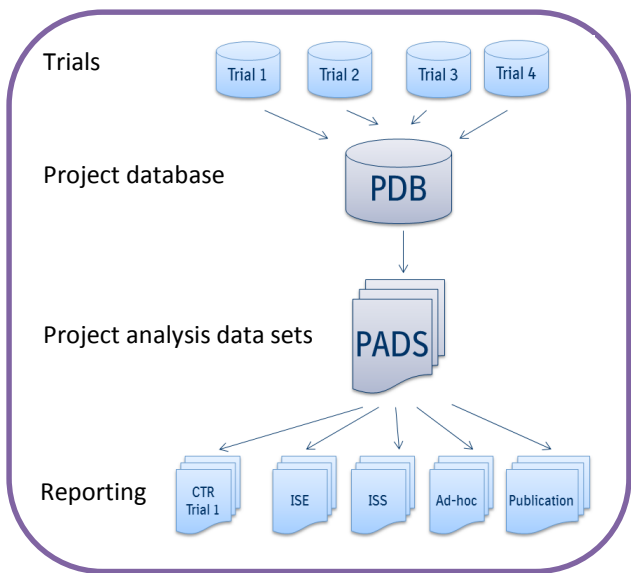
Project Team



Project Centric Approach (PCA) - Features

- ❑ Project teams handle project packages
- ❑ One project source of documents (Core Protocol, Project SAP, Project eCRF etc.)
- ❑ All data in one project database
- ❑ Project library of analysis data set and output programs
- ❑ Early specification of project standards
- ❑ Clear communications and transparent assignment of tasks

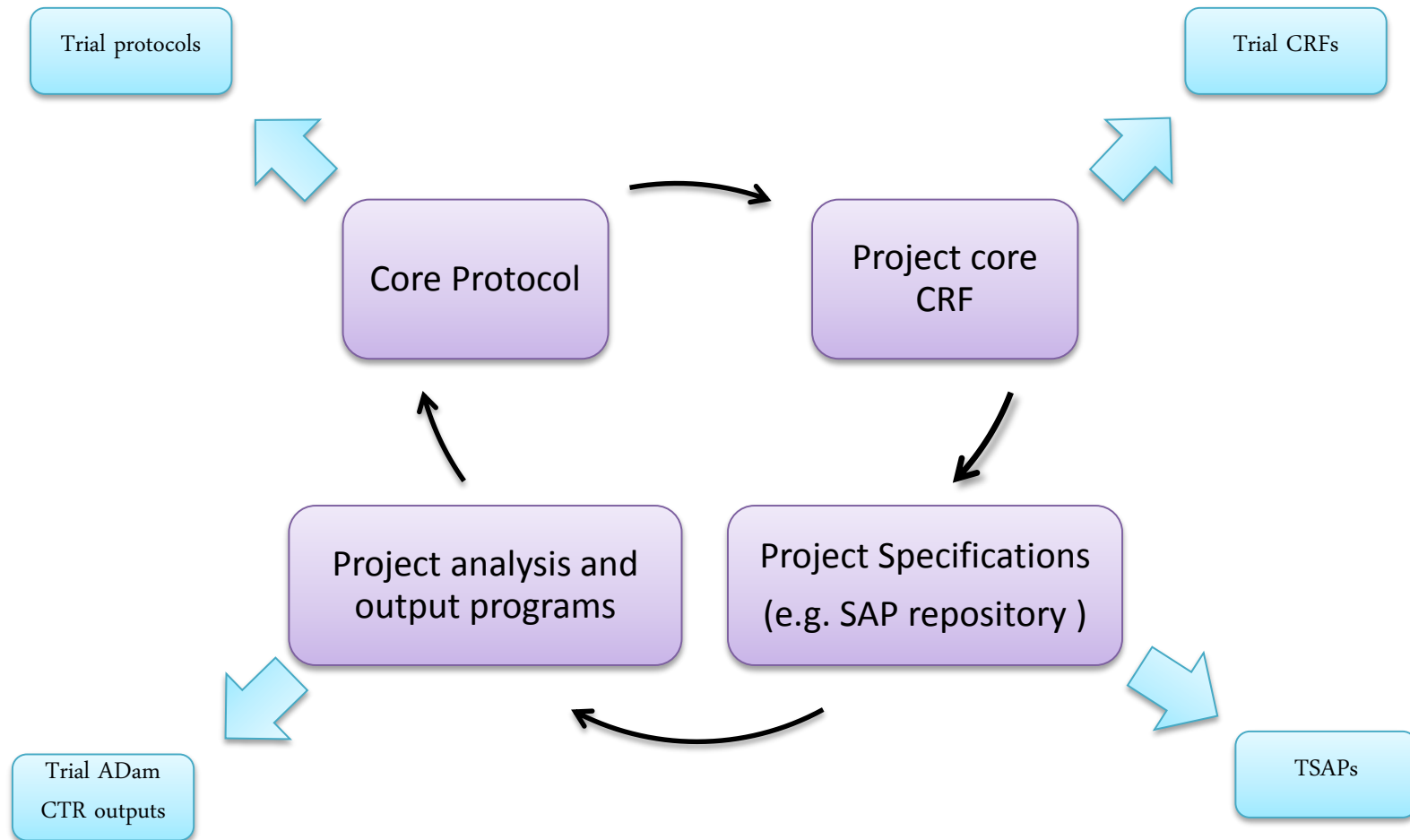
PCA can be implemented for a project or a collection of projects (e.g. substance or indication)



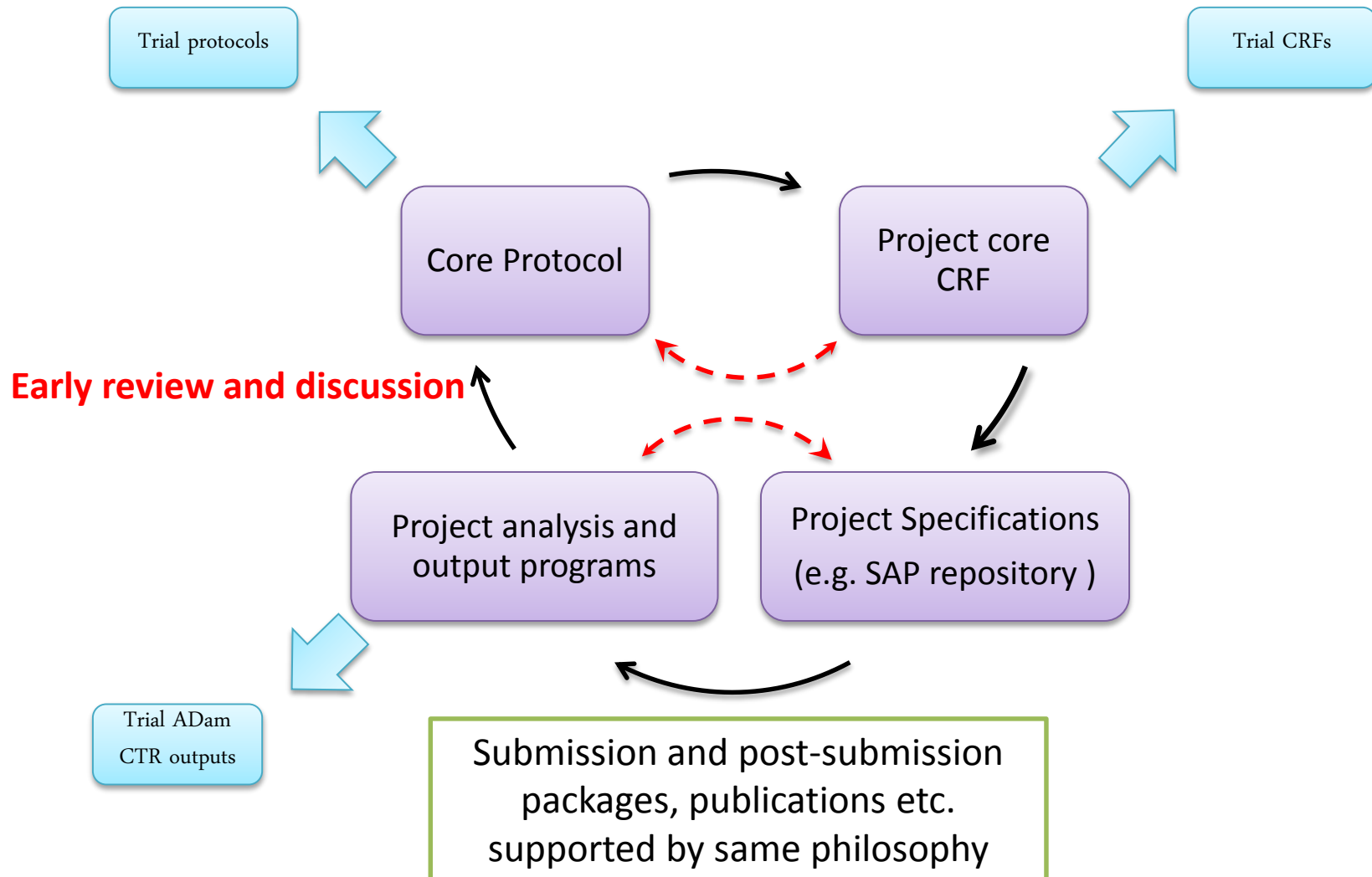
Task assignment matrix

	Name1	Name2	Name ...
Task 1	Responsible	Associate	
Task 2		Responsible	Associate
Task ...			

Project Centric Approach (PCA) - Features



Project Centric Approach (PCA) - Features



What to do to meet PCA

PCA is the same across all DM, Stat and Prog

- ❑ PCA strives for centralisation and harmonisation
- ❑ Early review, agreement and commitment on strategy and specifications
 - PCA starts at beginning of phase II „having the end in mind“
 - Consider starting in phase I when in patients of target indication
- ❑ PCA as a change of mindset with impact on
 - Specification: **Central** project-level specification document covering **all** trial and project deliverables
 - Implementation: Project database and project analysis data sets as source of **all** analyses on trial and project level
 - Operational: **Early** specification of project standards, and shift of tasks, resources and effort **from trial to project level**
- ❑ Late changes are the exception

What to do to meet PCA

Data management

- ❑ Project defined CRF and database standards
 - All common elements will be captured consistently
 - Defined in one place to avoid differences and reinventing the wheel
 - Pages can be added as requirements change throughout the duration of the project
- ❑ Pooling of trials available from start of Phase II, or earlier
 - Greater level of harmonisation across trials
 - Signal detection, quality review and exploratory analyses across the project possible from an earlier time point

What to do to meet PCA

Project level analysis plans

- ❑ SAP repository concept
 - Core PSAP with all trial analysis definitions contained
 - Project display templates used for all work packages
 - Project table of contents
 - Aim to also include all integrated summary and safety work package text in repository
- ❑ “Define once” principle
 - Repository to act as single source of definitions
 - Reduce inconsistencies
- ❑ Goal to increase harmonisation between work packages and remove unnecessary workload from routine analysis

What to do to meet PCA

Project programming concept

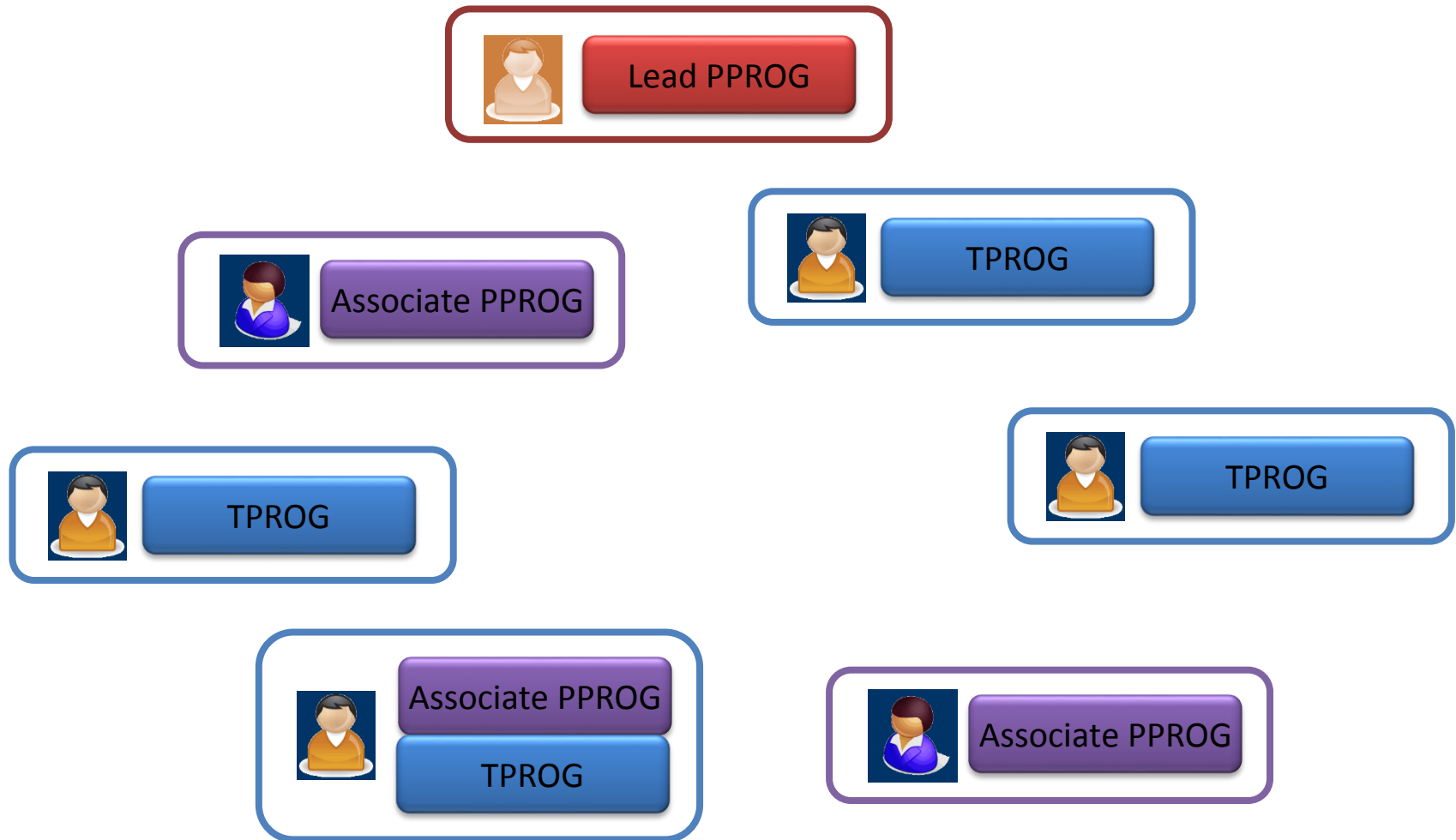
- ❑ Central development of analyses programs supporting:
 - Clinical trial reports
 - Project documents
 - Ad-Hoc requests
- ❑ Central development guarantees:
 - In depth knowledge about analyses
 - Up to date scientific practice
- ❑ Pool of project table shell programs
 - Harmonized look and feel for CTRs and Project documents
 - High quality due to re-usage of existing, previously checked/validated programs
 - Rapid generation and validation of outputs

□ Benefits are

- In-time high quality specifications and outputs
- Free resources for non-standard topics and innovation
- High consistency and quality, simplified trial level activities, reduction of duplication
- Early allocation of sufficient resources

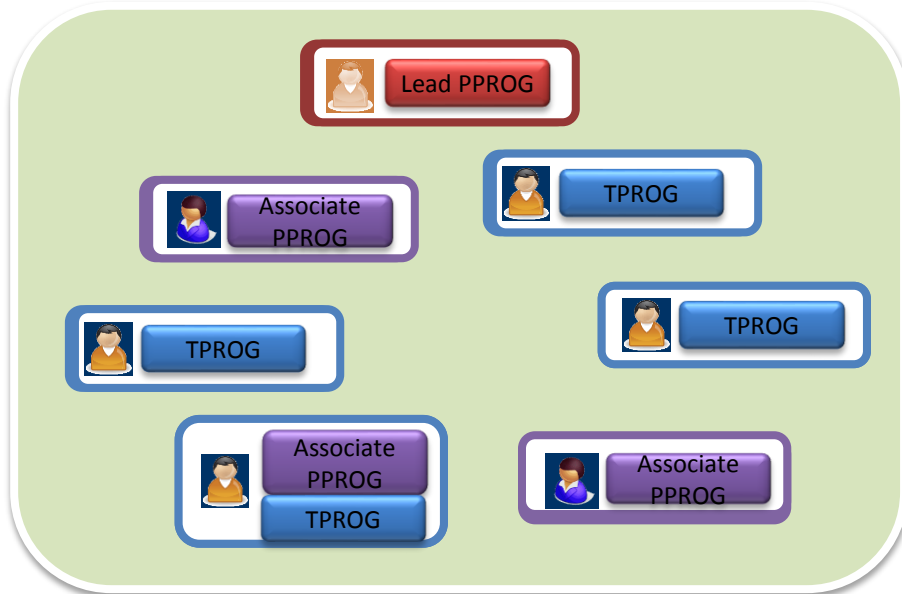
MRCT pieces in PCA frame

Asia in PCA team



PCA team working together

Asia in PCA team



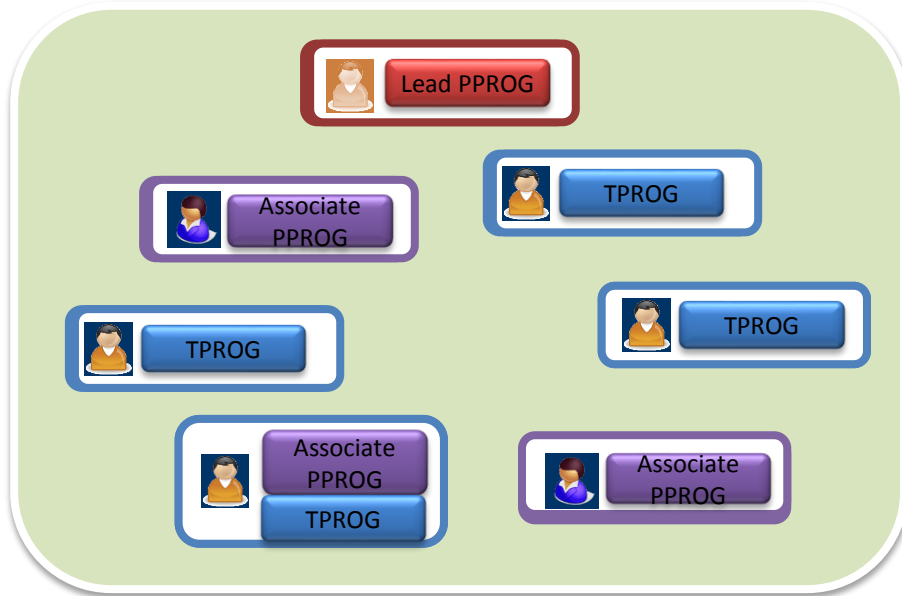
“One project team”

Working together towards standardization and harmonization, leading the project in the right direction

- No independent trial teams

PCA team working together

Asia in PCA team



“One alone cannot get it done”

Lead PPROG:

Main responsibility: oversight of the whole project including trials

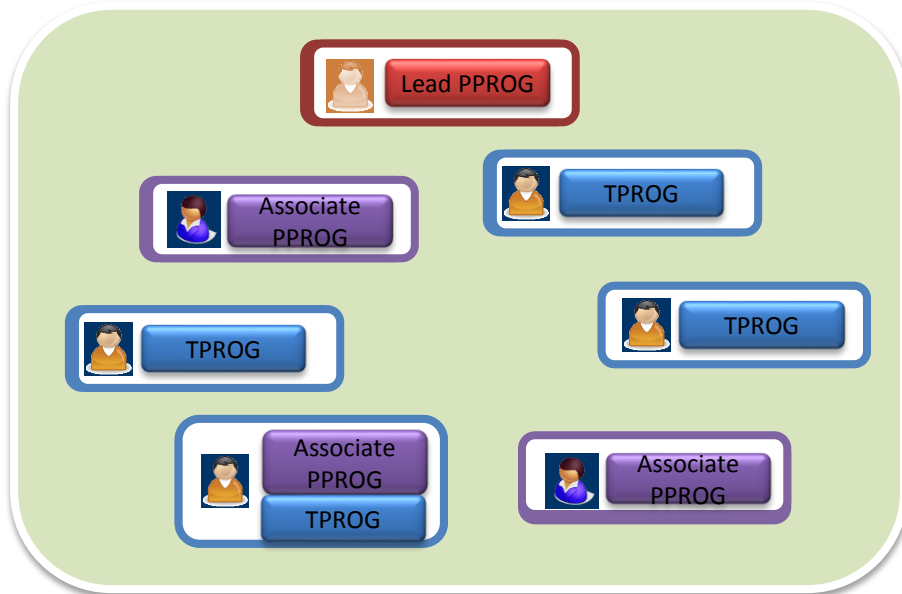
Project team members:

May contribute as:

- Associate PPROGs on project level only
- As TPROGs for one or more trials
OR
- As both at the same or different times

PCA team working together

Asia in PCA team

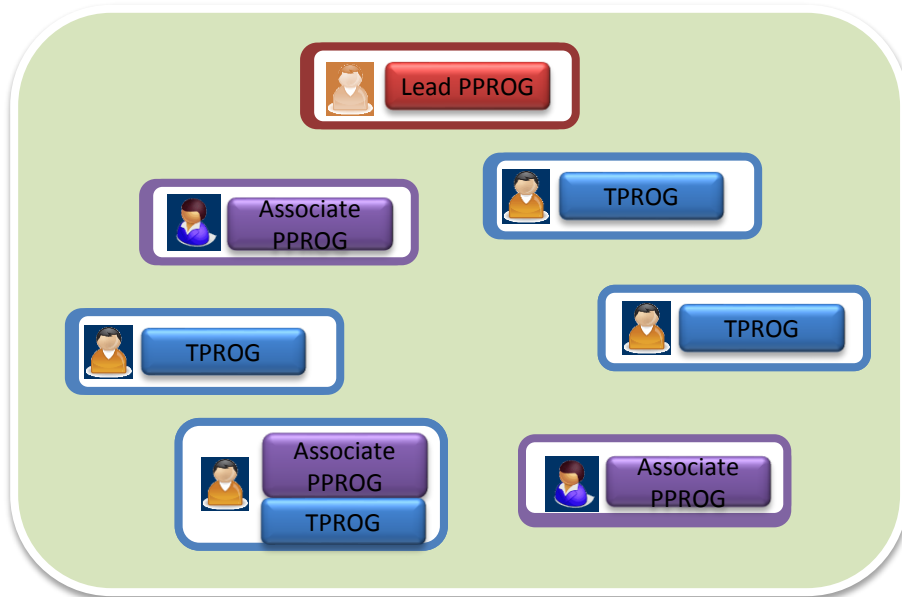


“One alone cannot get it done”

Project team members:

- Contribution depends on available, assigned resources and capabilities
- Core project team is assigned at the start of the project
- Resource allocation and needs are monitored by the lead PPROG and adjustments as needed

PCA team working together

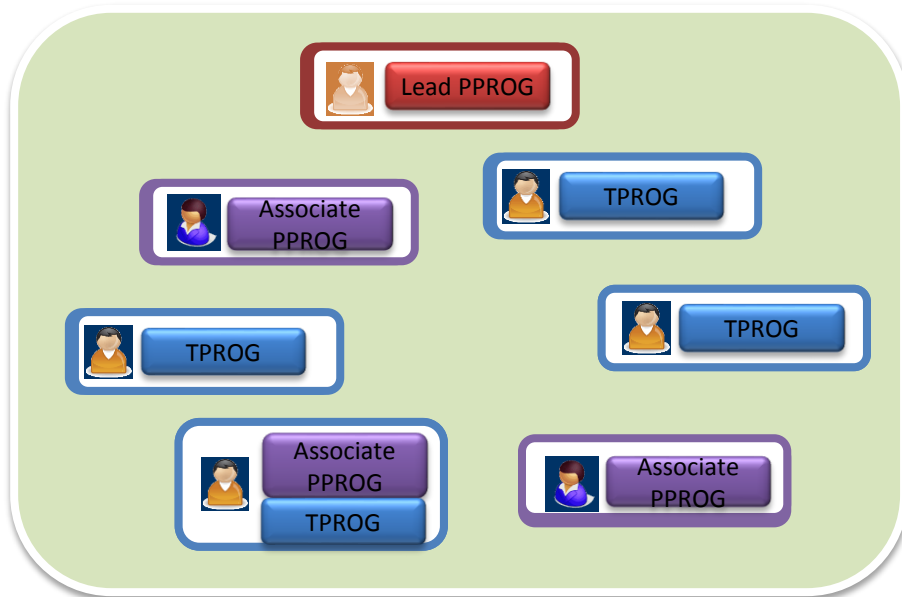


“Define once principle”

Lead & associate PPROGs work together on:

- Providing and maintaining project standards including tools, enable and monitor consistency, provide documentation & guidance
- Providing project deliverables (e.g. PADs, contribution to safety updates, submission etc.)

PCA team working together



“Define once principle”

Close communication and interaction

- Consider and plan interactions in the team from the beginning
- Make sure that all who contribute have a similar understanding/focus
- Benefit from diversity in the team, e.g. each others' contribution & experience

Standardization and consistency for current and future trials is ensured

- No duplication
- No “reinventing the wheel”
- A common objective across functions
- Study processes smoothly

Project Standards

➤ One centralized project specification

A	B	C	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	Z	AA	AB
	Dataset Name	Context (Where condition)	Key Sequence	Variable Name	Variable Label	Variable Type	Variable Length	Variable Format	CT Name	Origin	Source / Derivation	External Document References	External Document Page Numbers	Comment	SAS Programming Statements	Variable Order	CDISC Core	xxxx_01	xxxx_02	xxxx_03
1																				
2	ADxx	*ALL*	1	STUDYID						Predecessor	ADSL.STUDYID					1		X	X	X
3	ADxx	*ALL*	2	USUBJID						Predecessor	ADSL.USUBJID					2		X	X	X
4	ADxx	*ALL*		SUBJID						Predecessor	ADSL.SUBJID					3		X	X	X
12	ADxx	*ALL*		AVISIT	Analysis Visit	text	50			Derived	Nominal time-point based on response assessment schedule (may be trial specific).					8				X
13	ADxx	STUDYID in ("xxxx_01", "xxxx_03")		AVISIT	Analysis Visit	text	50		\$AVISIT1P	Derived	<derivation rule>					8		X		X
14	ADxx	STUDYID eq "xxxx_02"		AVISIT	Analysis Visit	text	50		\$AVISIT2P	Derived	<derivation rule>					8			X	

- Lead PPROG controls
- TPROGs provides details
- Automated trial define.xml
- 2 developers on one domain

Project Standards



- Project ToC repository
- Project Display Templates
- Project TFLs program HUB
- Trials call the project TFLs HUB programs and parameters driven



Project Standards

Task	Recommendation
Source data	PDB (harmonised structure for all trials and all data)
ADS plan	PADS plan on project level for all trials
ADS programming	PADS programs written by PPROGs
ADS generation	Project level, also for trials
ADS validation	Project level, also for trials
Table shell specification	Table shells maintained on project level for all trials
Report programming	Company macros, EOT templates, or project level macros/templates
Report generation	Output generation on trial level
Report validation	Output validation on trial level based on project validation plan

specification shell

Source data

programming plan

generation

**Table
validation**

ADS

Report

