



# Project Standard Implementation

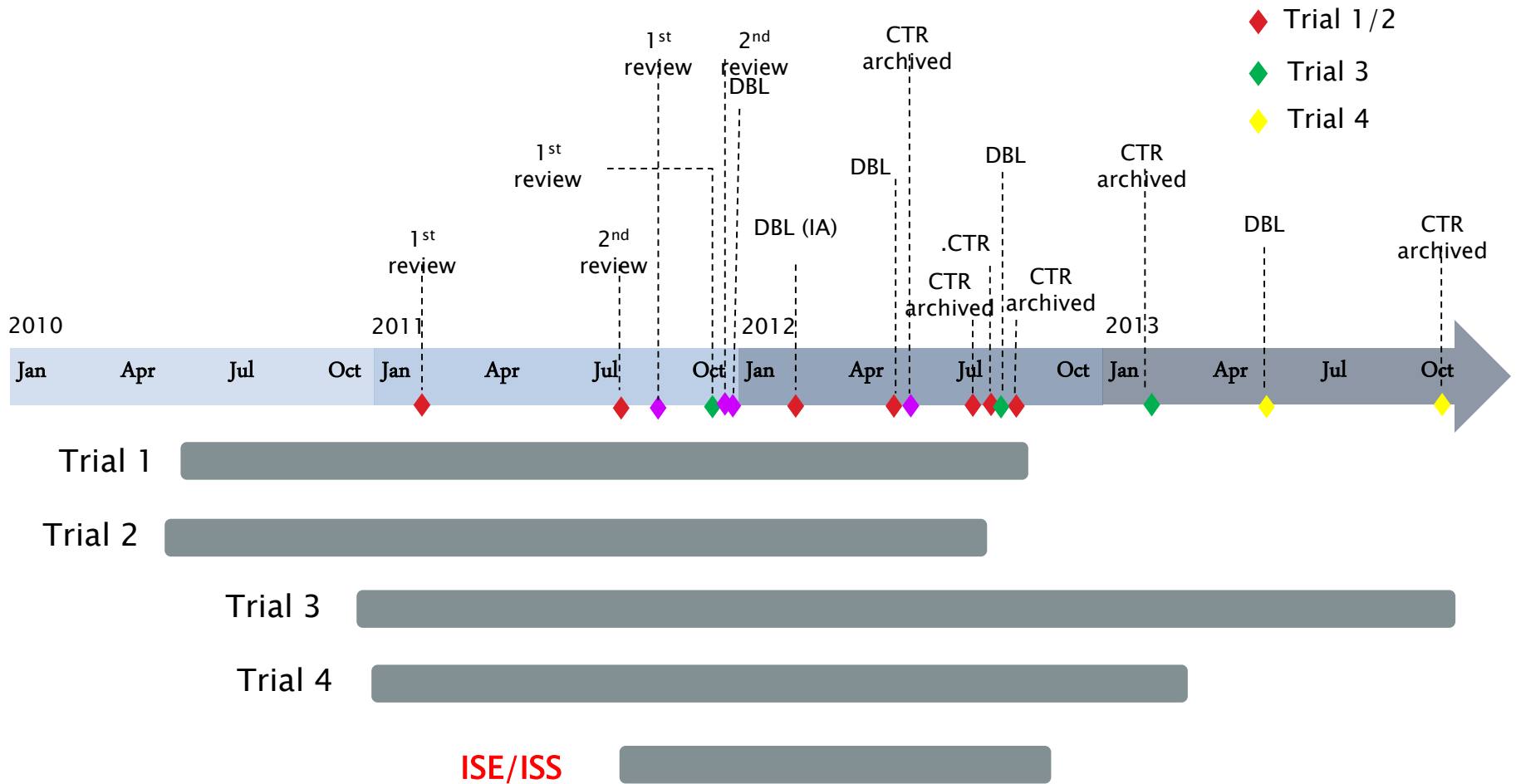
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concept
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workflow

# Section 1: PCA concept

# Historic Pathway of Project Timelines



# Challenge at Project Peak Time

Multi-critical timeline  
Multi-tasking with all team members  
Data integration process  
ISS/ISE SAP preparation  
Medra/whodra dictionary alignment



# Art of Programming Work





# Project Centric Approach

- ▶ Working concept implemented by project team

1. Centralisation and harmonisation of project- standard covering all trial and project deliverables and used for implementation with the end in mind

2. Shift of tasks, resources and effort from trial to project level



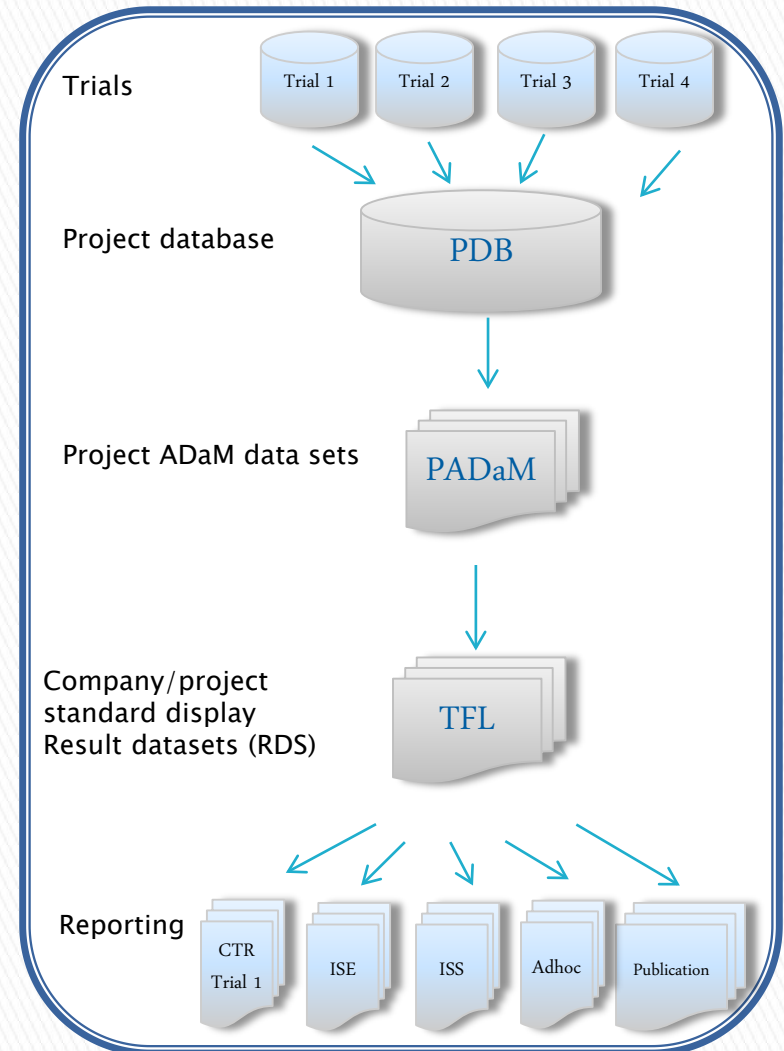




# Section 2: PCA Process Flow

# Programming Flow Chart

- **Central ADS**
  - ADS are maintained by the same programmers with high expertise;
- **Central TFL templates**
  - Company standard display plus project/trial specific TFL programs is standardized and easy to re-use;
- **Standardized Result Datasets**
  - Reduce efforts in validation and review of results



# Interaction and communication

## Issue - Strategy - Implementation considering example of Statistics

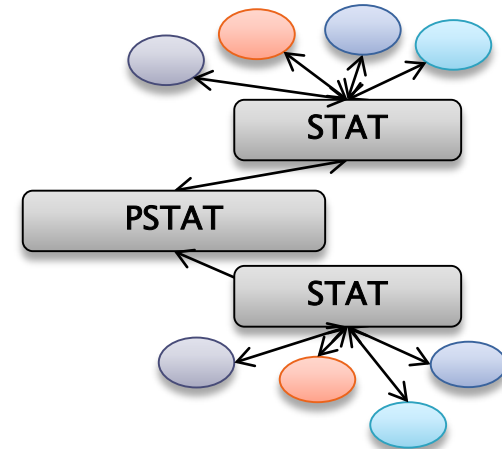
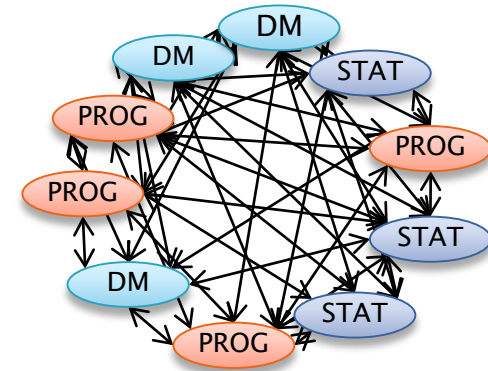
- Many **people** might work on project level



- Unclear responsibilities
- Complex communication

- PSTAT: Statistical project accountability and oversight
- Task responsibility assigned to STAT
- PSTAT confirms decisions

- Clear and transparent assignment of tasks
- Task assignment matrix
- Specialists for certain types of tasks



Task assignment matrix

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

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