



Metrics Champion Consortium (MCC)

Clinical Trial Metrics

Session: D430





Member, Metrics Champion Consortium

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Agenda

Overview of MCC

Liz Wool

Case Study

Marie Hanley

MCC Mission

The Metrics Champion Consortium (MCC) is a not-for-profit organization comprised of biotechnology, pharmaceutical, medical device and service provider organizations who work collaboratively to develop and implement *standardized performance metrics* with the intent of *jointly improving* the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials.

MCC Goals

- Establish **defined sets of standard performance metrics** that facilitate the management of clinical trials
- Encourage the **use of the standard metrics by sponsors and service providers to identify areas for improvement**
- Facilitate the **sharing of metric data among MCC member organizations** (through a blinded database)
- Provide a common basis for constructive discussion between sponsor and service providers that will lead to a **common understanding for the need to improve performance**

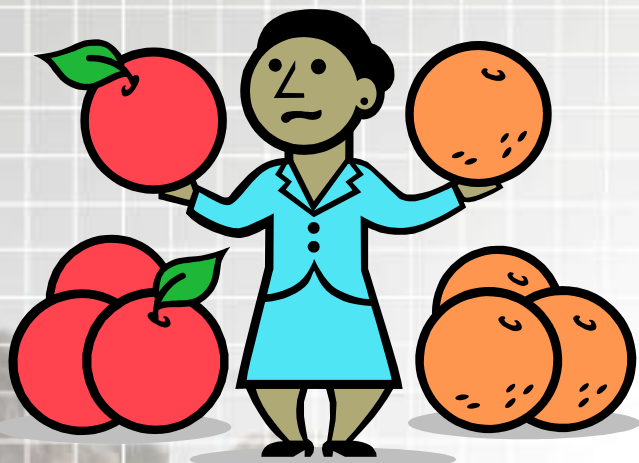
MCC Member Organizations

Abbott Laboratories	Duke Clinical Research Institute	Medtronic
Actelion Pharma	ERT	Merck
Acorda Therapeutics	Esoterix Clinical Trial Services	New England Research Institute
AG Mednet	Eurofins Medinet	Novartis
AstraZeneca	ExecuPharm	Paragon Biomedical
BARC Global Central Lab	GE Healthcare	Parexel / Perceptive Informatics
BioClinica	Genentech	Pfizer
Biogen Idec	Genzyme	PharmaNet
Biomedical Systems	i3	PPD
CardiaBase	iCardiac Technologies	PRA International
Cardio Analytics	ICON	QD-Quality & Training Solutions
Cardiocore	Imaging Endpoints	Quest Diagnostics
Cerexa	INC Research	Quintiles
CHDI	Incyte	RadMD
Clinical Reference Laboratory	Intrinsic Imaging	Regeneron
Clinsys Clinical Research	Ixico	Roche
Cognizant	Lilly	Synarc
CoreLab Partners	M2S	Virtual Scopics
Covance	MacroGenics	WorldCare Clinical
DecisionView	Medidata Solutions	

Lack of Standardized Performance Metrics Creates Challenges

Provider 1

Provider 2

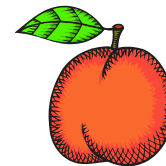
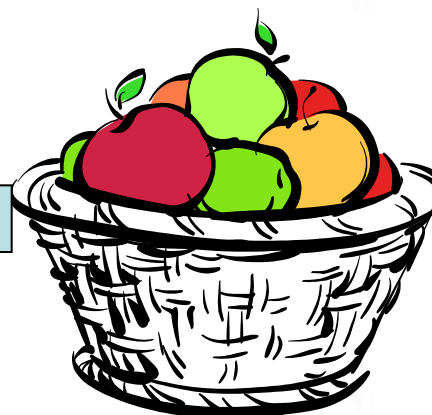
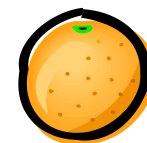


Sponsor

Service Provider

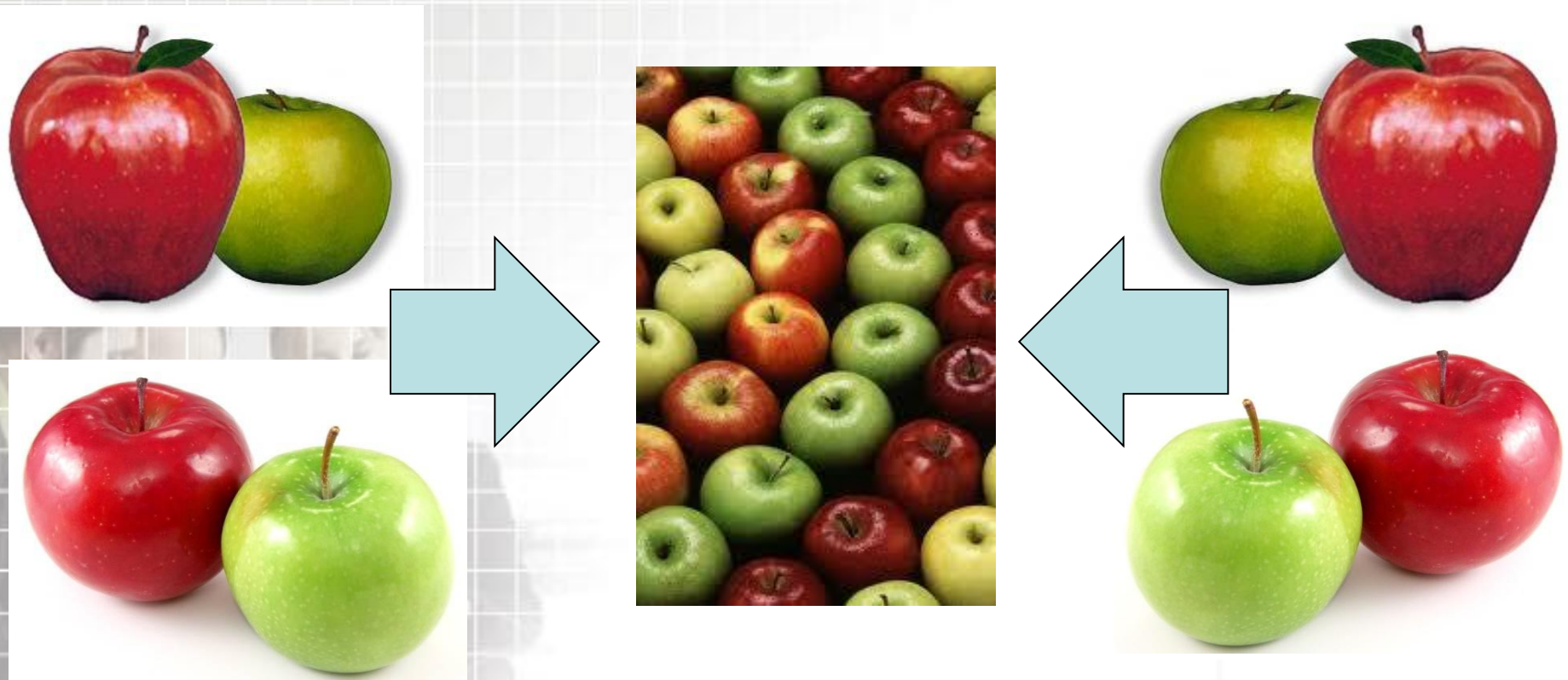
Sponsor A

Sponsor B



Standardized Performance Metric Definitions Creates Opportunities

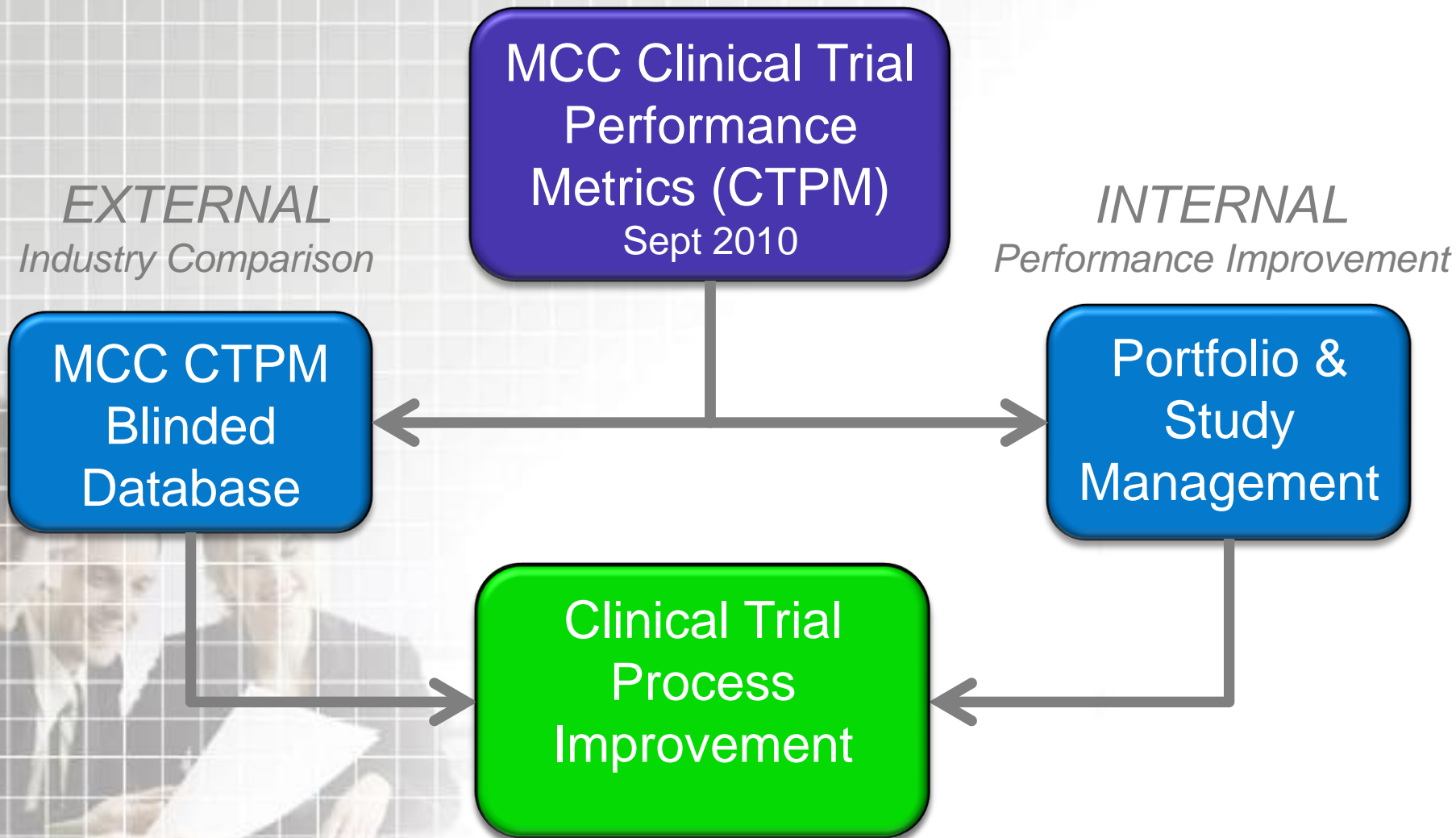
Mutually beneficial standardized performance metrics can be achieved and fruitful for all parties



Clinical Trial Performance Metrics Initiative

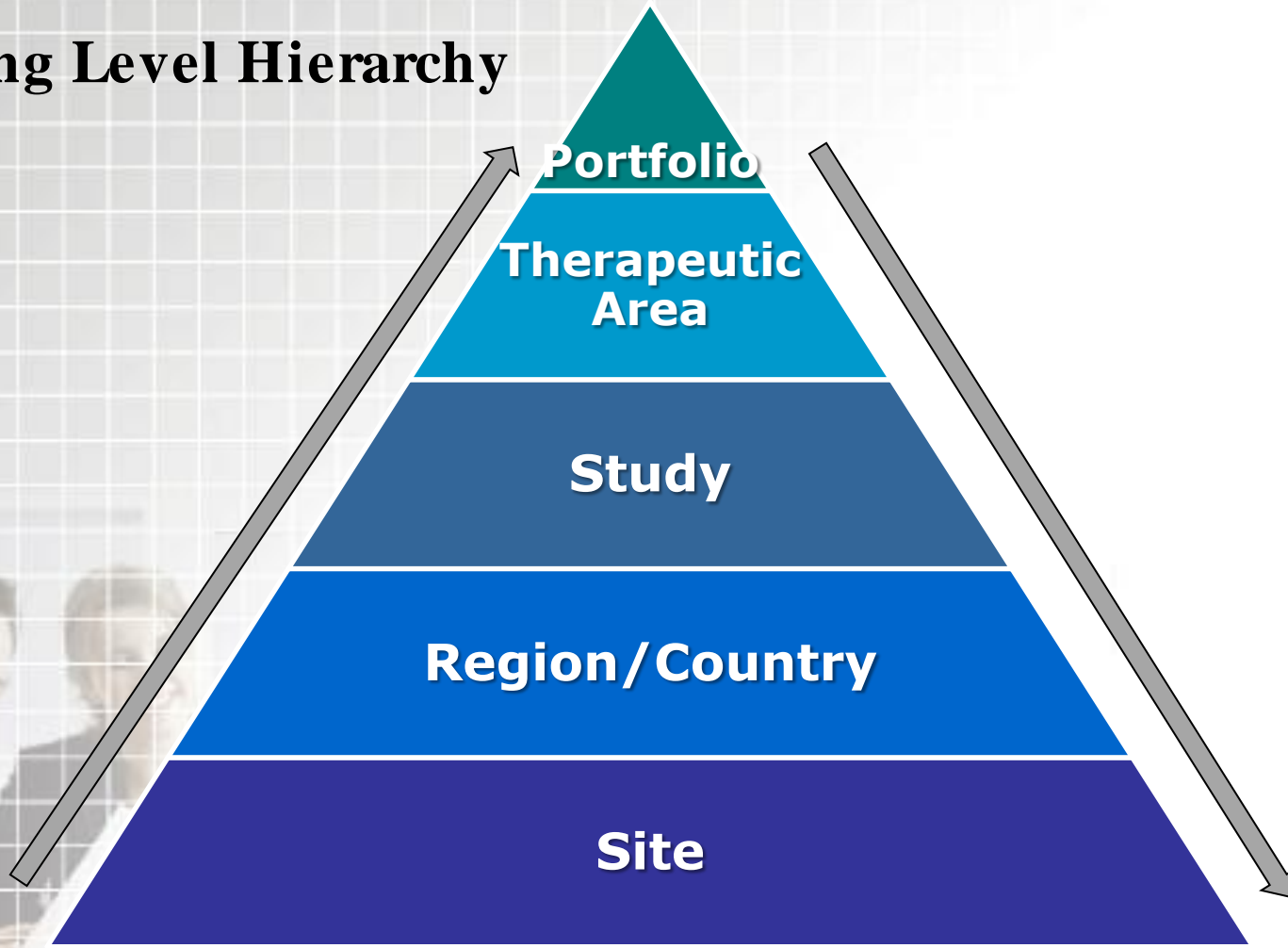


Utilization of Standardized Performance Metric Definitions Will Create Opportunities

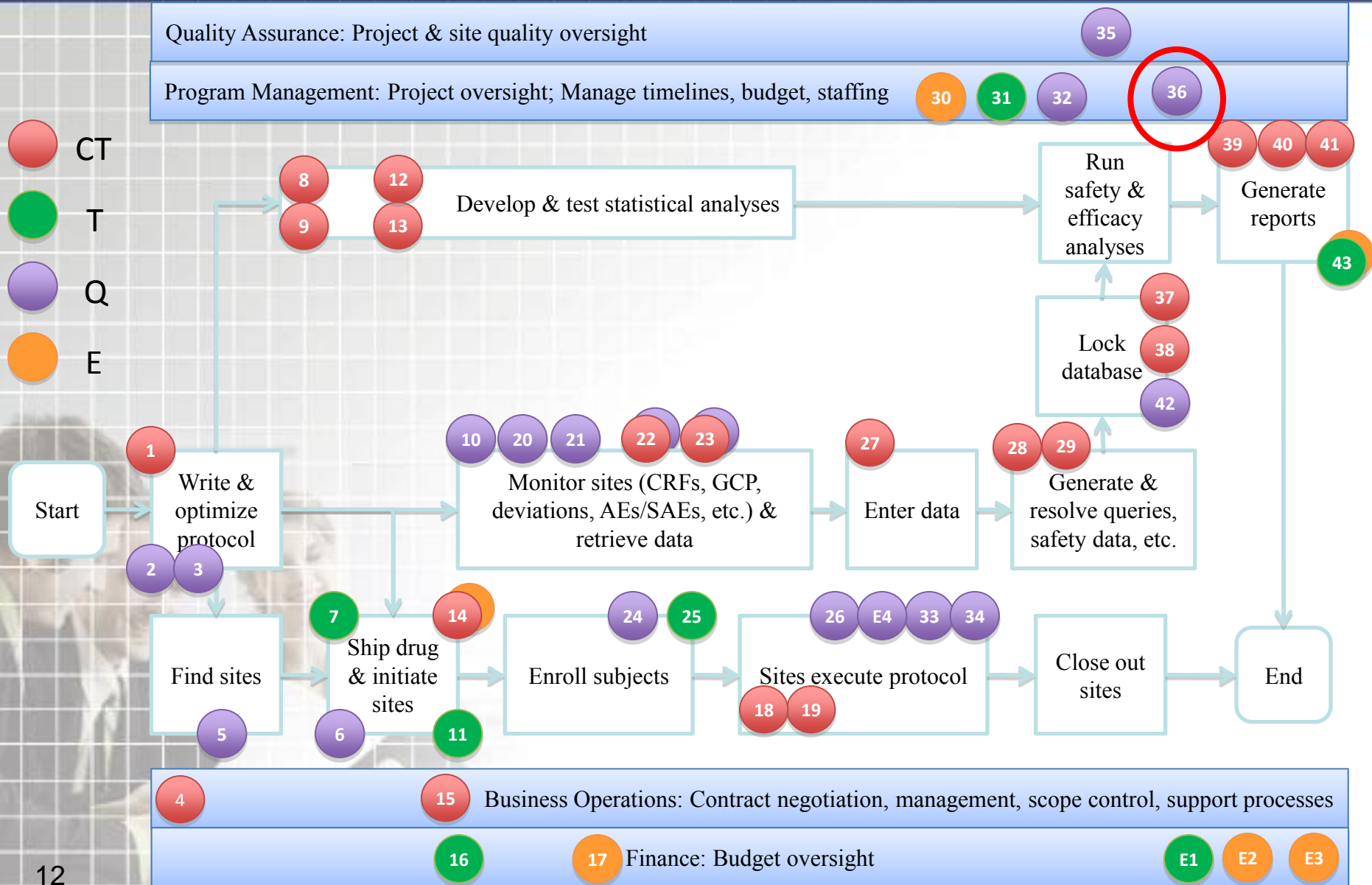


Metric Reporting Levels

Reporting Level Hierarchy



MCC Clinical Trial Performance Metrics v 1.0

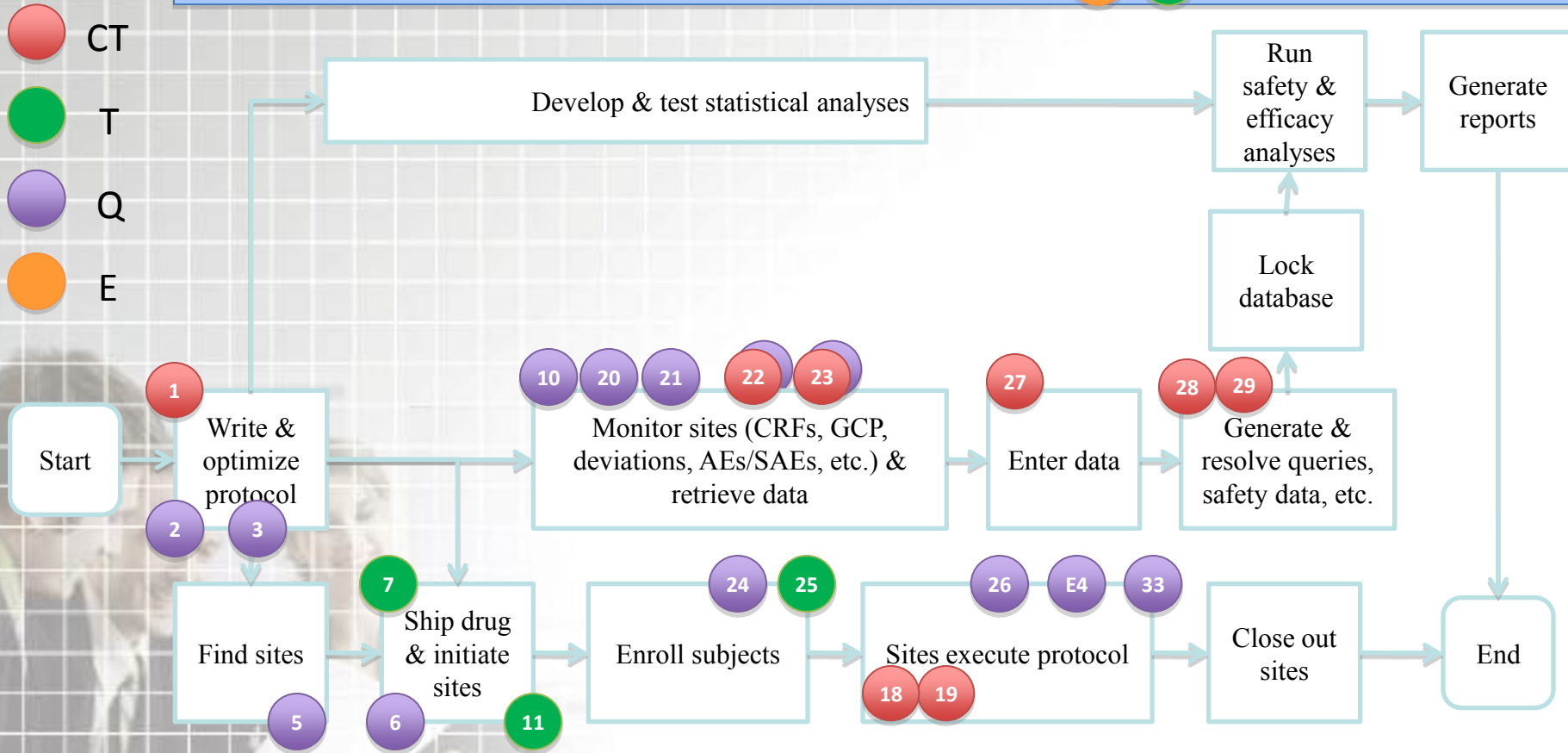


Leading Indicator Metrics

Quality Assurance: Project & site quality oversight

Program Management: Project oversight; Manage timelines, budget, staffing

30 31



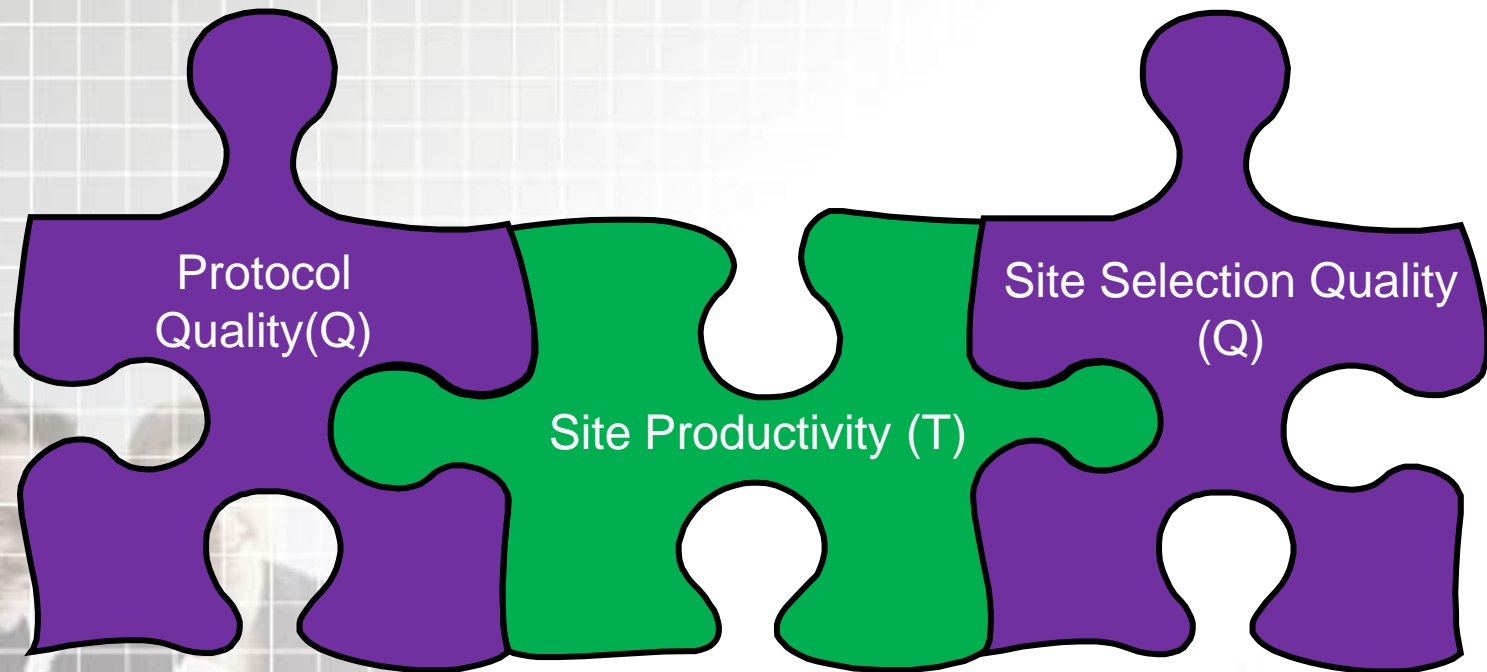
Business Operations: Contract negotiation, management, scope control, support processes

Finance: Budget oversight

E2 E3

MCC Companion Metrics

MCC Companion Metrics show the interrelationship of clinical trial tasks



.... the quality of the protocol and the sites selected for the trial have a direct impact on site productivity

MCC Clinical Trial Performance Metrics v 1.0

Metric #	Metric Type	Metric Title
1	CT	Protocol Feasibility
2	Q	Protocol Versions
3	Q	Protocol Quality Score
4	CT	Contract execution timeliness for non functional outsourcing models
5	Q	Site Selection Quality Score
6	Q	Regulatory Authority Package Approval Rate
7	T	Protocol approval to first site activated
8 - EDC	CT	Final Approved Protocol to Final Approved eCRF - EDC
9 - paper	CT	Final Approved Protocol to Final Approved CRF - paper
10	Q	Monitoring Plan Availability
11	T	% Planned Sites Activated
12 - EDC	CT	Final eCRF to Database "Go Live" - EDC

Metric #	Metric Type	Metric Title
13 - paper	CT	Final CRF to Database "Go Live" - paper
14	CT	Site Activation to First Patient First Visit
	E	
15	CT	Change Order execution
16	T	Timeliness of Invoice payment
17	E	Budget and pricing accuracy
18 - EDC	CT	Patient Visit Complete to eCRF data entered - EDC
19 - paper	CT	Patient Visit Complete to CRF data entered - Paper
20	Q	Monitoring Visit Frequency
21	Q	Monitoring Visit Report Completion
22	CT	Documented Monitoring Visit Report Review
	Q	

MCC Clinical Trial Performance Metrics v 1.0

Metric #	Metric Type	Metric Title
23	CT	Monitoring Follow-Up Letter Completion
	Q	
24	Q	Site Productivity
25	T	% subjects enrolled
26	Q	Patient Retention
27 - paper	CT	CRF Pages Received/ scanned to Data Entry Complete - Paper
28 - EDC	CT	Generation of Query to update of query response - EDC
29 - paper	CT	Generation of Query to update of query response - paper
30	E	Drug Supply Forecasting
31	T	Variance of Drug Inventory & Resupply
32	Q	Protocol Amendments
33	Q	Protocol Deviations

Metric #	Metric Type	Metric Title
34	Q	Sites Prematurely Terminated
35	Q	Audit Findings per Site
36	Q	Issue identification, management and criticality
37 - EDC	CT	LPLV to Database Lock - EDC
38 - paper	CT	LPLV to Database Lock - paper
39	CT	DBL (Database Lock) to final TLG/ TFL (Tables, Listings and Graphs/ Table Figure Listing)
40	CT	Final TLGs to First Draft CSR complete
41	CT	DBL (Data Base Lock) to Final CSR Complete
42 - paper	Q	Final Database Error Rate
43	T	Deviation of final TLGs delivered from final agreed target date.
	E	

MCC Clinical Trial Performance Metrics v 1.0

Exploratory Metrics

Metric #	Metric Type	Metric Title
E1	CT	Timeliness of Invoice generation following contractual milestones
E2	E	Determination of project progress versus planned (original contract value)
E3	E	Determination of project progress versus planned (adjusted contract value)
E4	Q	Site Assessment Quality Tool

Upcoming MCC Activities

MCC Lab Metrics

- Preparation of Version 2.0
- Input to Quality Tools

MCC ECG Metrics

- Preparation of Version 2.0
- Input to Quality Tools

MCC Imaging Metrics

- Implementation Support of Version 1.0
- Input to Quality Tools

MCC Clinical Trial Metrics

- Implementation Support of Version 1.0
- Quality Tool Pilots
- Ongoing Process Improvement WG meetings

MCC Member Blinded Database Project

- Development of database structure
- Database Pilot

Questions for the MCC?

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