



MCC Update: Implementing Standardized Clinical Trial Performance Metrics to Manage Risk and Drive Quality in Clinical Trials

Jeanne Green, RN, MS, CCRA
Director, Clinical Operations
ExecuPharm, Inc.

Dr. Brian B. O'Neill
External Alliances/Enterprise Systems QRM
Registered QMS 2008 Principal Auditor,
IRCA
F-Hoffmann-La Roche Ltd.

Linda Sullivan
VP Operations
Metrics Champion Consortium

3rd Annual Effective Business Development Outsourcing Relationships (Philadelphia, PA) July 20, 2011



<http://www.metricschampion.org>

- MCC Clinical Trial Performance Metrics
- MCC Quality Scoring Tools
- Roche Case Study: Sponsor/Service Provider Collaborative Development and Implementation of Quality Metrics
- Q&A

The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical, medical device and service provider organizations.

Our mission is to help sponsor and service provider organizations involved in the pharmaceutical, biotechnology and medical device industries improve their overall clinical trial development processes through the utilization of MCC standardized clinical trial performance metrics (time, cost & quality) by:

- ❖ Supporting the ongoing collaborative development of standardized performance metrics and process improvement tools
- ❖ Encouraging the continuous implementation of the metrics and tools among MCC members
- ❖ Providing a collaborative learning environment for members to share best practices, discuss challenges and industry trends
- ❖ Offering live and online educational opportunities to support the use of performance metrics and tools in member organizations



MCC Member Organizations

Abbott Laboratories

Actelion Pharma

Acorda Therapeutics

AG Mednet

AstraZeneca*

BARC Global Central Lab

Beaufort CRO

BioClinica

Biogen Idec

Biomedical Systems

CardiaBase

Cardio Analytics

Cardiocre

Celgene

Cerexa

CHDI

Clinical Reference Laboratory

Clinsys Clinical Research

Cognizant

CoreLab Partners

Covance

Covidien

Customized Improvement Strategies

DecisionView

Duke Clinical Research Institute

ERT*

Esoterix Clinical Trial Services

Eurofins Medinet

ExecuPharm

Forte Research Systems

GE Healthcare

Genentech

Genzyme

Halloran Consulting Group

i3

iCardiac Technologies

ICON

Imaging Endpoints

INC Research

Incyte

Intrinsic Imaging

Ixico

Lilly*

M2S

MEDIDATA GmbH

Medidata Solutions

Medtronic

Merck

MLM Labs

New England Research Institute

Novartis

Novella Clinical

Paragon Biomedical

Parexel / Perceptive Informatics

Pfizer*

PharmaNet*

PPD*

PRA International

QD-Quality & Training Solutions

Quest Diagnostics

Quintiles*

RadMD

Regeneron

Roche*

Sunovion Pharmaceuticals

Synarc

Virtual Scopics

WorldCare Clinical

* MCC Board of Directors

Lack of Standardized Performance Metric Definitions Creates Challenges

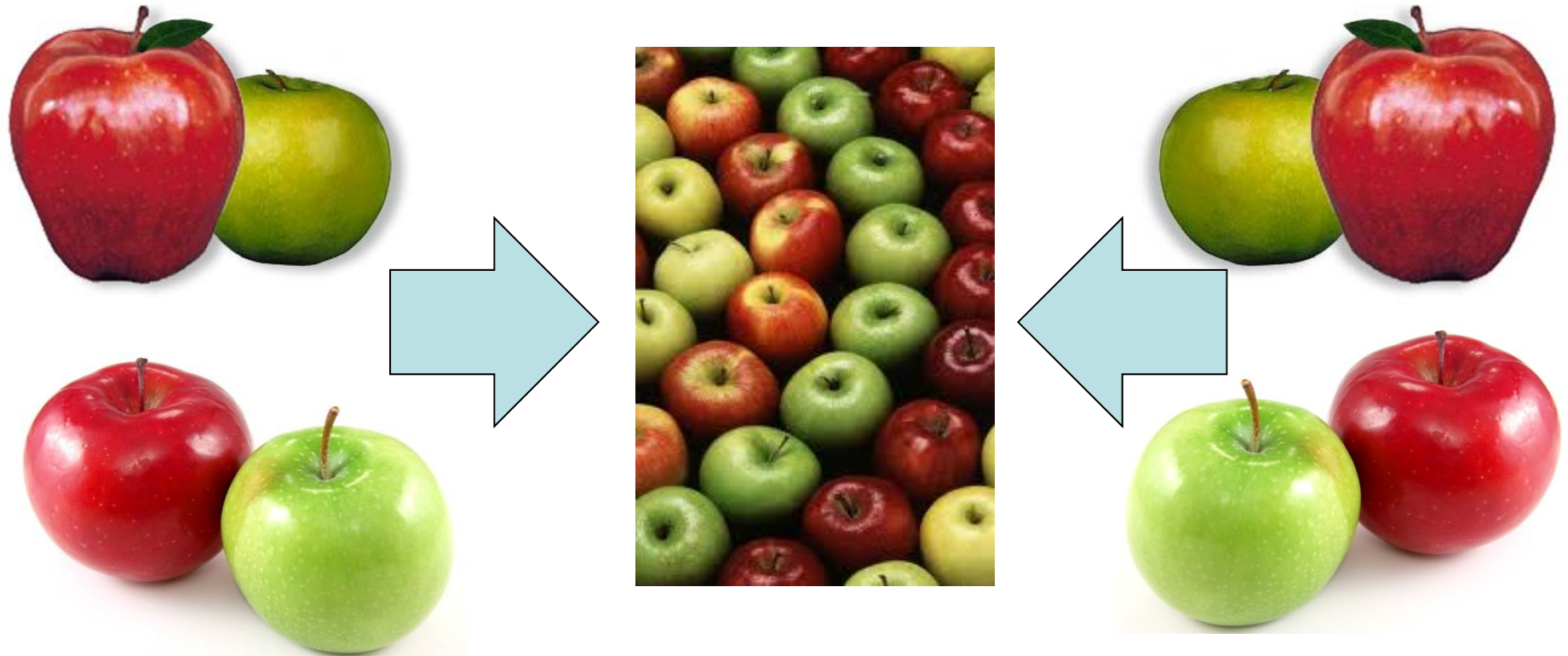


- Sponsors use different service providers
 - Managing metrics across portfolios across service providers is a challenge

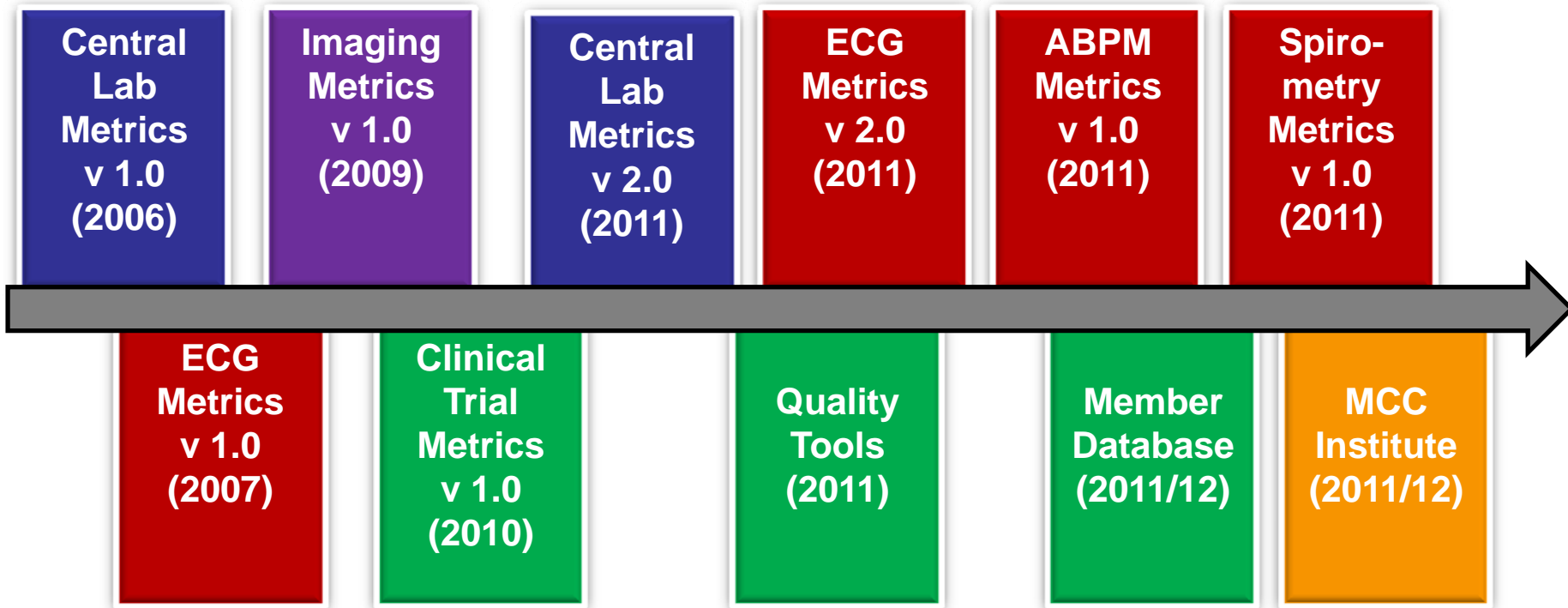
- Service providers are faced with managing varying performance based metrics from Sponsors

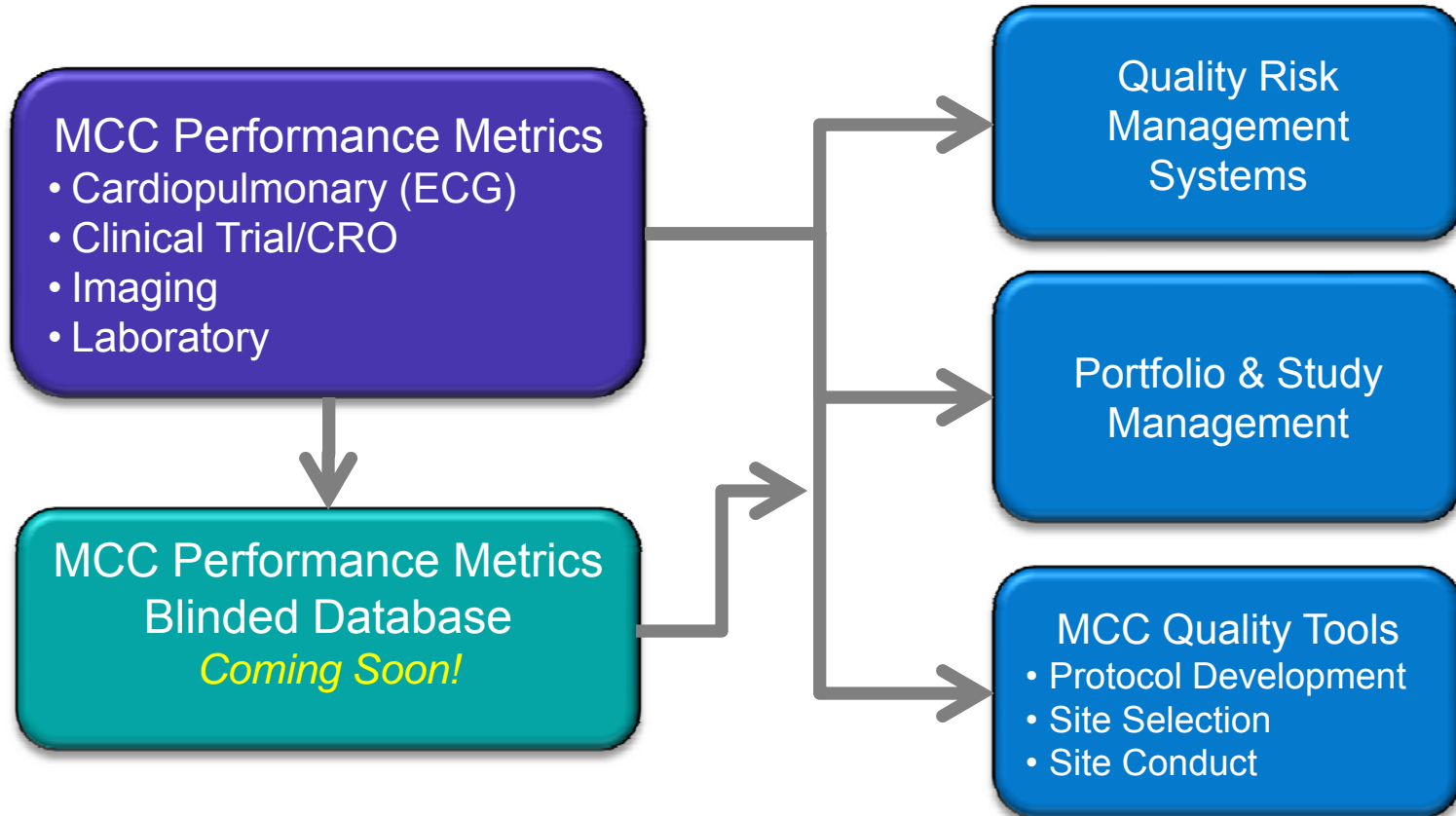


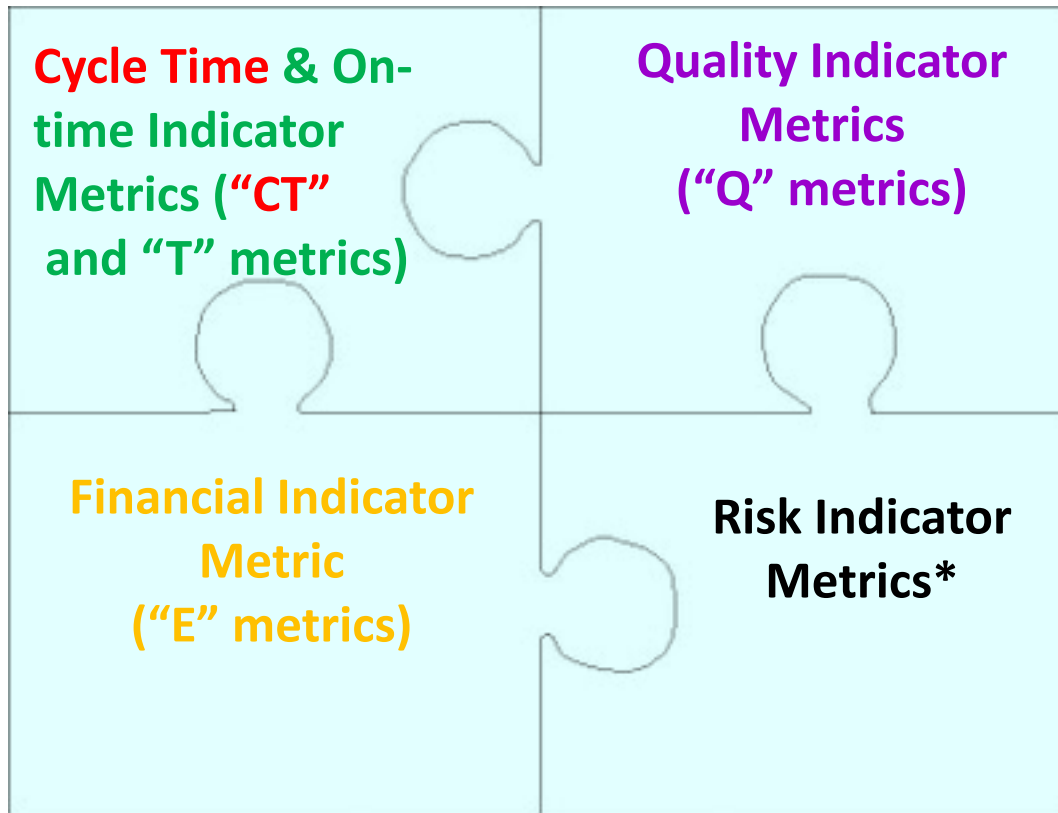
Mutually beneficial standardized performance metrics can be achieved and fruitful for all parties



MCC Program Timeline



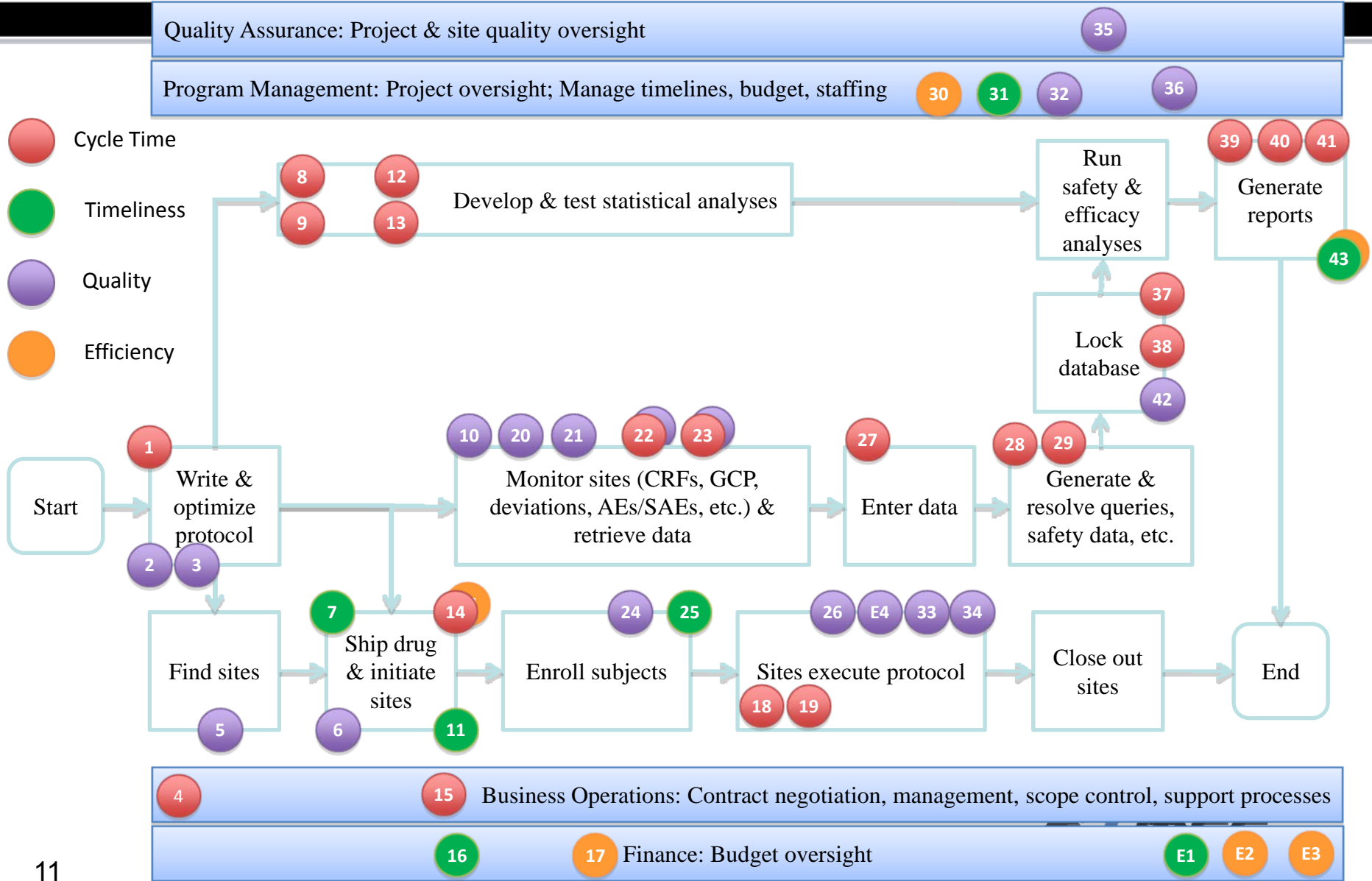




* Some MCC metrics can be used as Risk Indicator Metrics – this designation is determined by an organization.

Anatomy of a MCC Clinical Trial Performance Metric

Metric #	Metric Type	Metric Title	Category	Metric Indicator	Part of Study
	CT, T, Q or E		Business Operations, Clinical Operations, Data Management, etc.	LEADING or LAGGING Indicator	Study Startup, Conduct and Close-Out
Definition (see Wiki for detailed definitions)		Formula / Example		Reporting Detail	
		Formula:		Site / Country / Study / Therapeutic Area / Portfolio levels	
		Example:		Unit of Measure	
				Calendar days, % etc.	
Business Driver(s) / Benefit Statement		Additional Analysis on a "for cause" basis		Reporting Frequency	Threshold Target
Statement about why this metric is important /the reason for utilizing metric. Who / what / why...		List of "drill down" metrics that should be reviewed when the metric is not within established target		Monthly, Quarterly, etc.	Threshold target or acceptable range. Exceeding target triggers additional analysis on a "for cause" basis
Companion Metrics		The term "companion metrics" refers to the concept that many MCC metrics should be examined in combination with other MCC metrics ... together they give you a more complete picture of performance			



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

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

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

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

Exploratory Metrics

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

- Database Key Features:
 - Able to track and compare your organization's metrics to other members (blinded manner)
 - Hosted in computing cloud environment
 - Online metric analytic reporting tool will allow users to “drill down & roll up” to different reporting levels
- Database program requirements:
 - MCC members will have the option to participate in the database
 - Must contribute MCC metrics to the database to be able to view reports

New program to provide MCC Members the opportunity to participate in ***MCC only*** workshops and online courses taught by leading industry consultants.

- Metric Basics (100 level)
 - Which MCC metrics should I use & how do I get started?
 - Displaying MCC metrics and communicating with your management
- Advanced Topics (200 - 400 levels)
 - Creating a Balanced Scorecard for your company using MCC metrics
 - Improving your company's performance using MCC metrics
 - Measuring & improving quality using MCC metrics
 - Measuring & reducing risk in your company using MCC metrics
 - Strategies for addressing issues that emerge during the implementation of a large-scale organization change



MCC Quality Tools



Beginning in Q4 2009, a group of Sponsor and CRO Process Improvement & QM specialists began working together to:

- Encourage the use of the metrics for process improvement
- Help MCC members avoid pitfalls such as sub-optimization
- Develop new approaches to assessing Quality

MCC Process Improvement WG expressed frustrations that many organizations focus on whether clinical trials are being executing in a **timely** manner ...



... but do not measure how **well** tasks are being completed.



The *quality* of something can be determined by comparing a set of inherent characteristics with a set of requirements.

- If those inherent characteristics meet all requirements, high or excellent quality is achieved.
- If those characteristics do not meet all requirements, a low or poor level of quality is achieved

Source: <http://www.praxiom.com/iso-definition.htm>

A successful clinical trial is dependent on many factors:

- Robust, scientifically and ethically sound protocol
- Selection of high-performing, GCP compliant sites that contribute timely, accurate and complete data
- Keen oversight of quality execution throughout the life of the trial

Recent regulatory agency warning letters highlight deficiencies in GCP compliance and sponsor oversight, both which have the potential to compromise high-quality agency submissions.

Lack of quality in clinical trials can lead to:

- Increased risk to subject's health, safety and welfare
- Poor data quality
- Higher regulatory risk
- Increased costs
- Longer time to approval
- Reputational impact
- Poor decisions
- Rejected applications
- Rework

*Ultimately this impacts those our industry is trying to serve -
patients who need new drugs and medical devices*

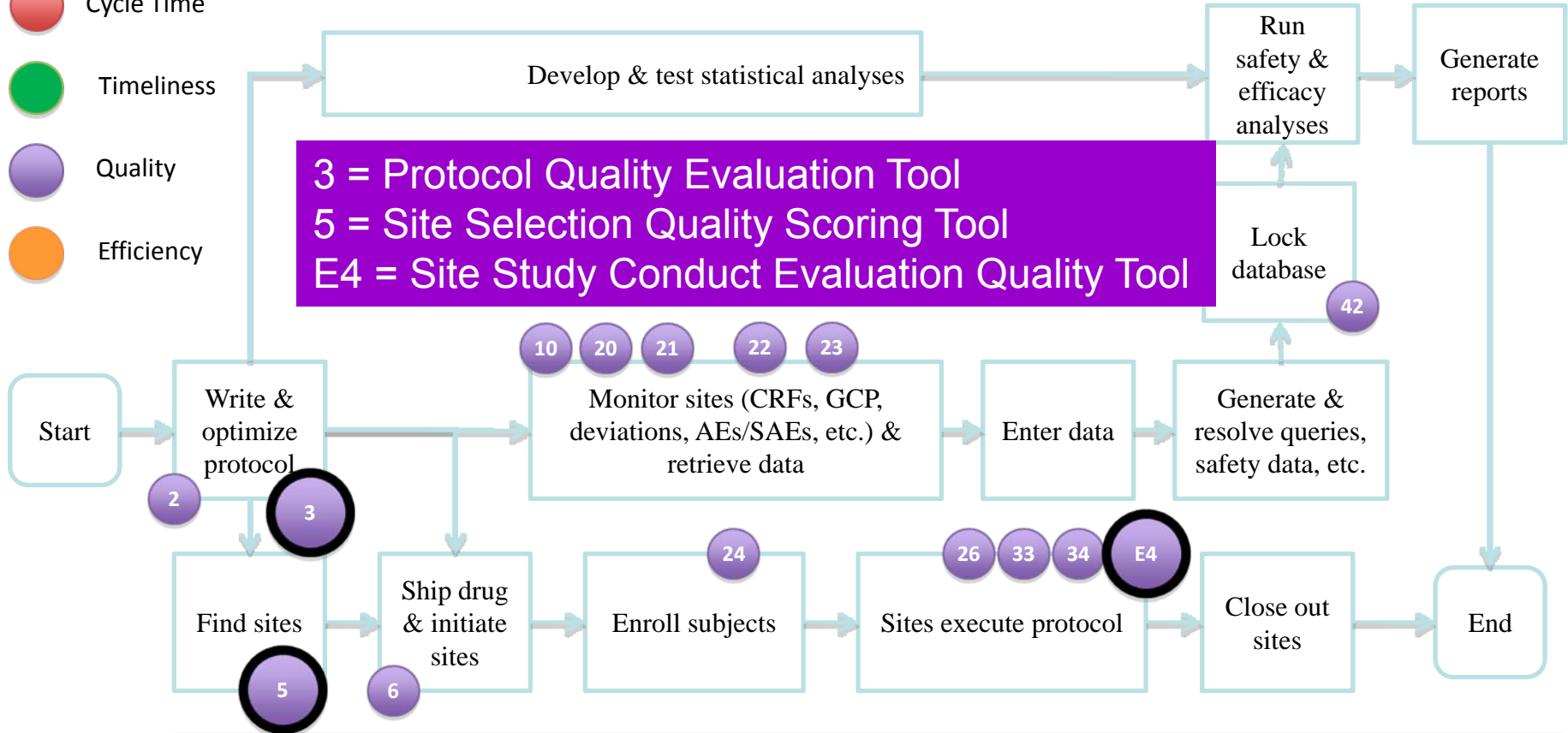
MCC Clinical Trial Performance Metrics Quality Focus

Quality Assurance: Project & site quality oversight 35

Program Management: Project oversight; Manage timelines, budget, staffing 32 36

- Cycle Time
- Timeliness
- Quality
- Efficiency

3 = Protocol Quality Evaluation Tool
 5 = Site Selection Quality Scoring Tool
 E4 = Site Study Conduct Evaluation Quality Tool



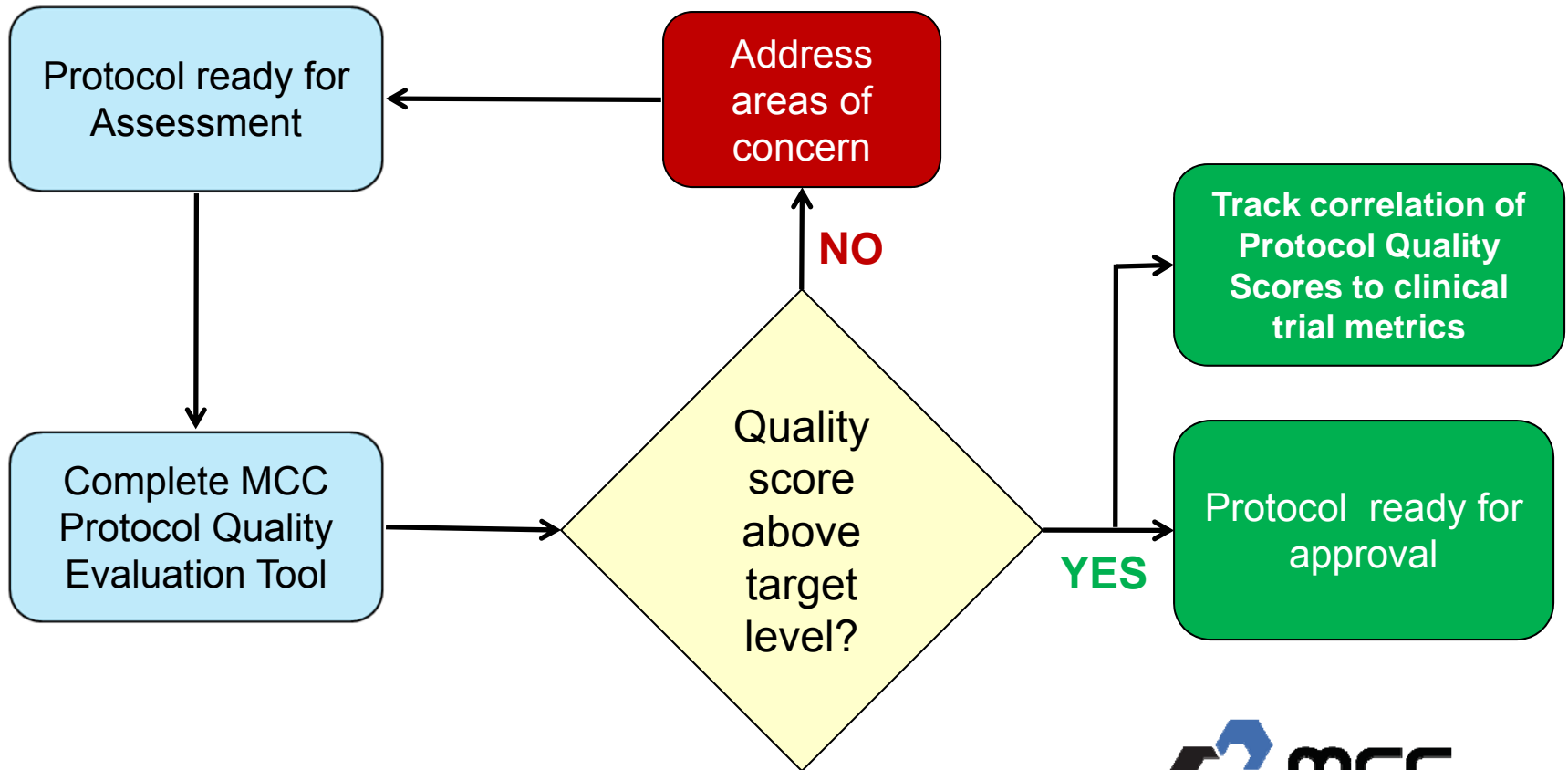
Business Operations: Contract negotiation, management, scope control, support processes

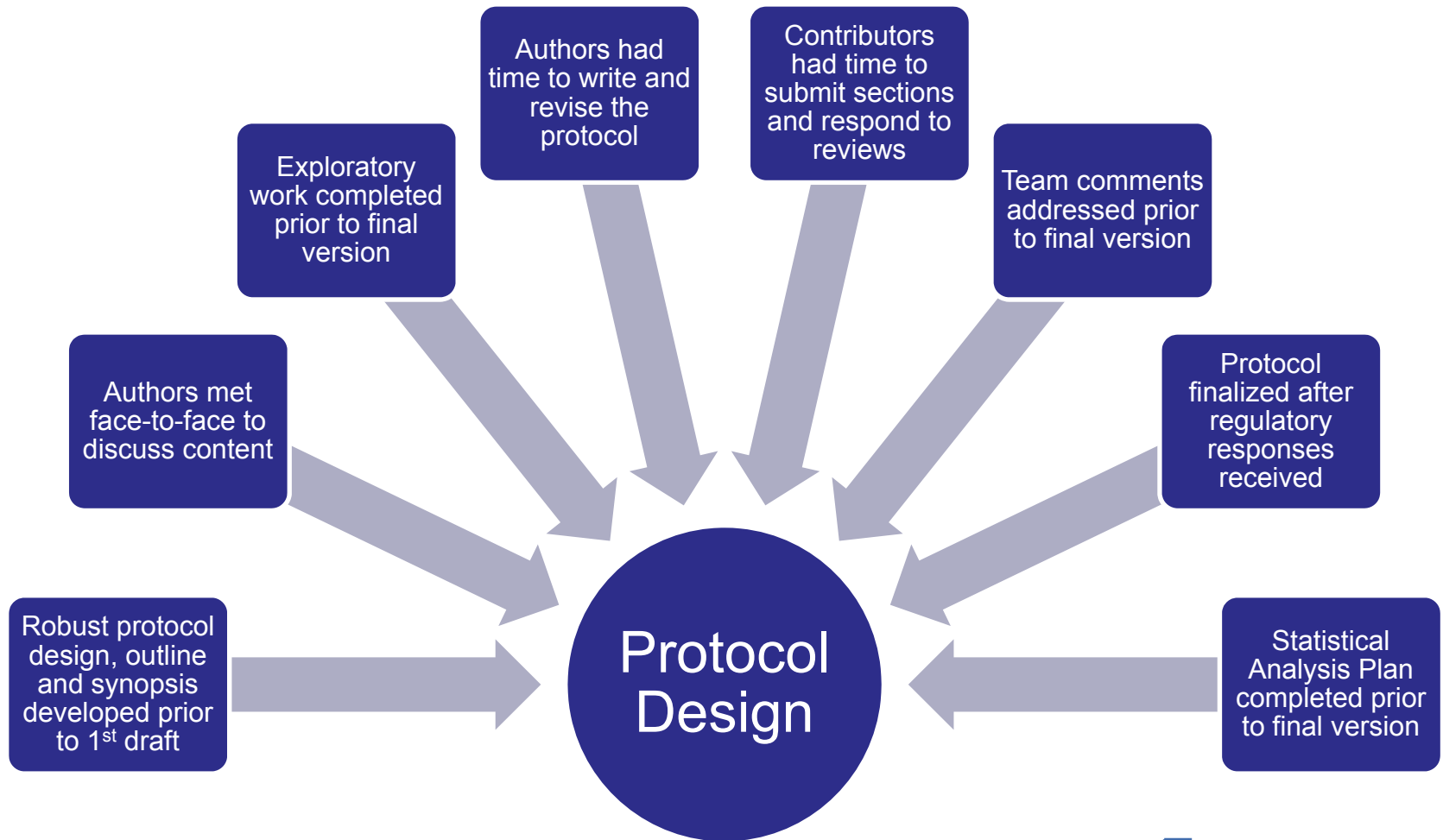
Finance: Budget oversight

The new suite of MCC Quality Scoring Tools utilizes a standard approach to identifying potential risk and measuring quality in clinical trials – providing clear direction and ease of execution and analysis.

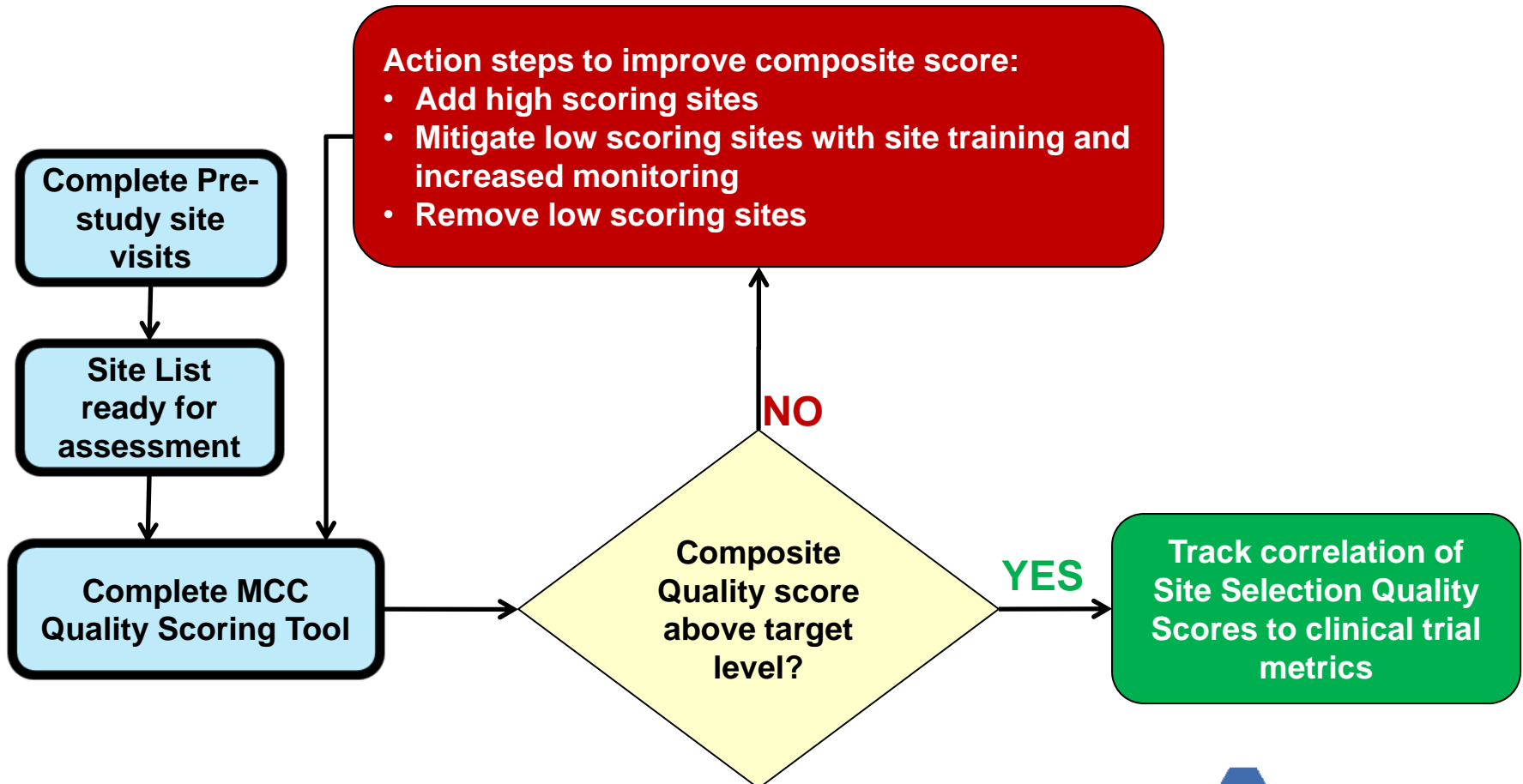
MCC Quality Scoring Tools will help organizations raise the quality standards of protocol writing, site selection, and site quality during study conduct.

Protocol Development (self assessment)





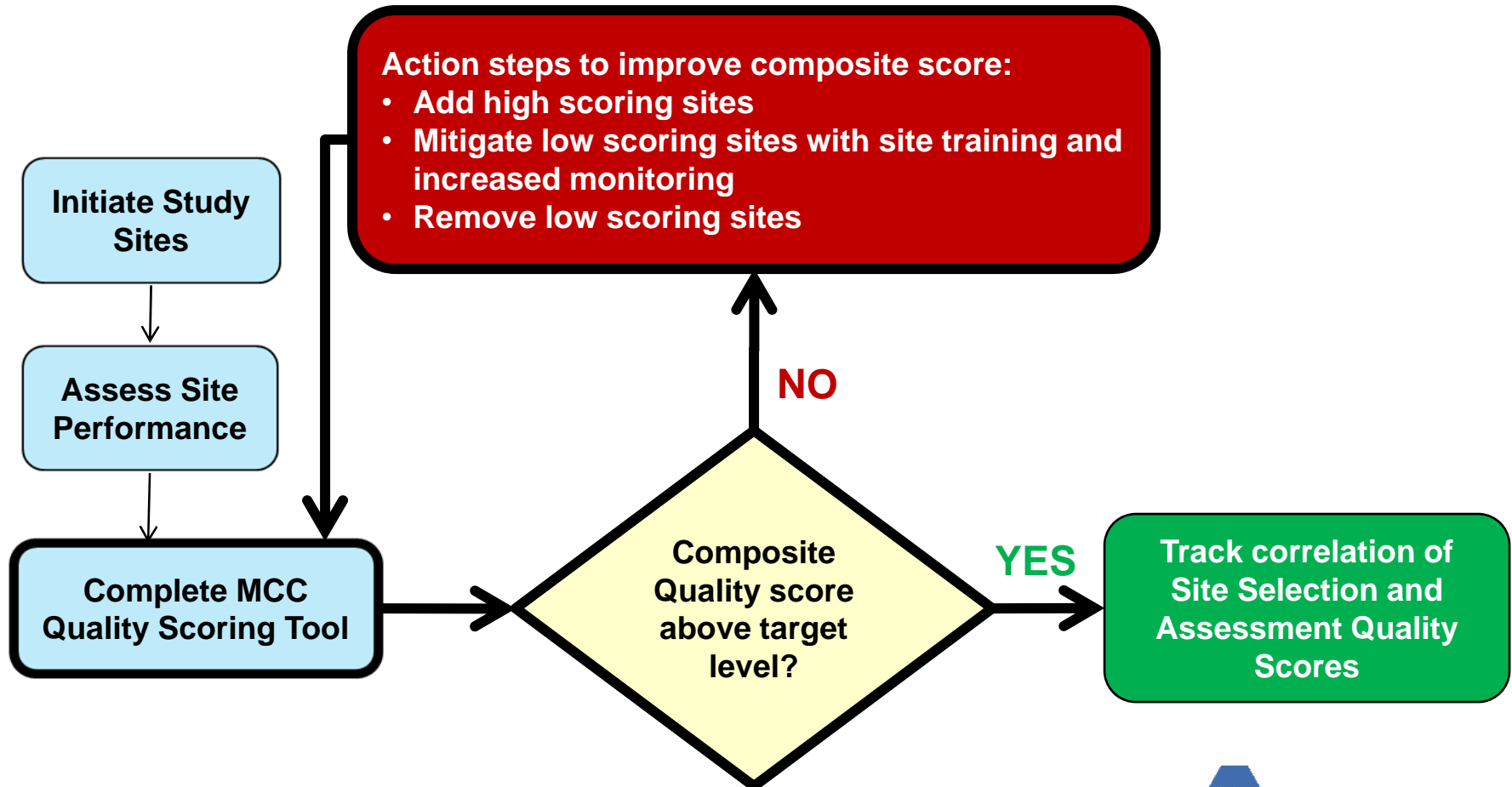
Site Selection Quality Scoring Tool



- Each site is rated on a standard set of eight site quality criteria
- Criteria are weighted as to relevance per protocol
- Each site score is automatically calculated from responses to these quality criteria

- Sites can be marked as included or excluded in final site selection list
- A total score is derived for individual countries for all sites scored as well as selected sites only
- Final result should be used as a guide in determining final site selection list

Site Study Conduct Evaluation Quality Scoring Tool

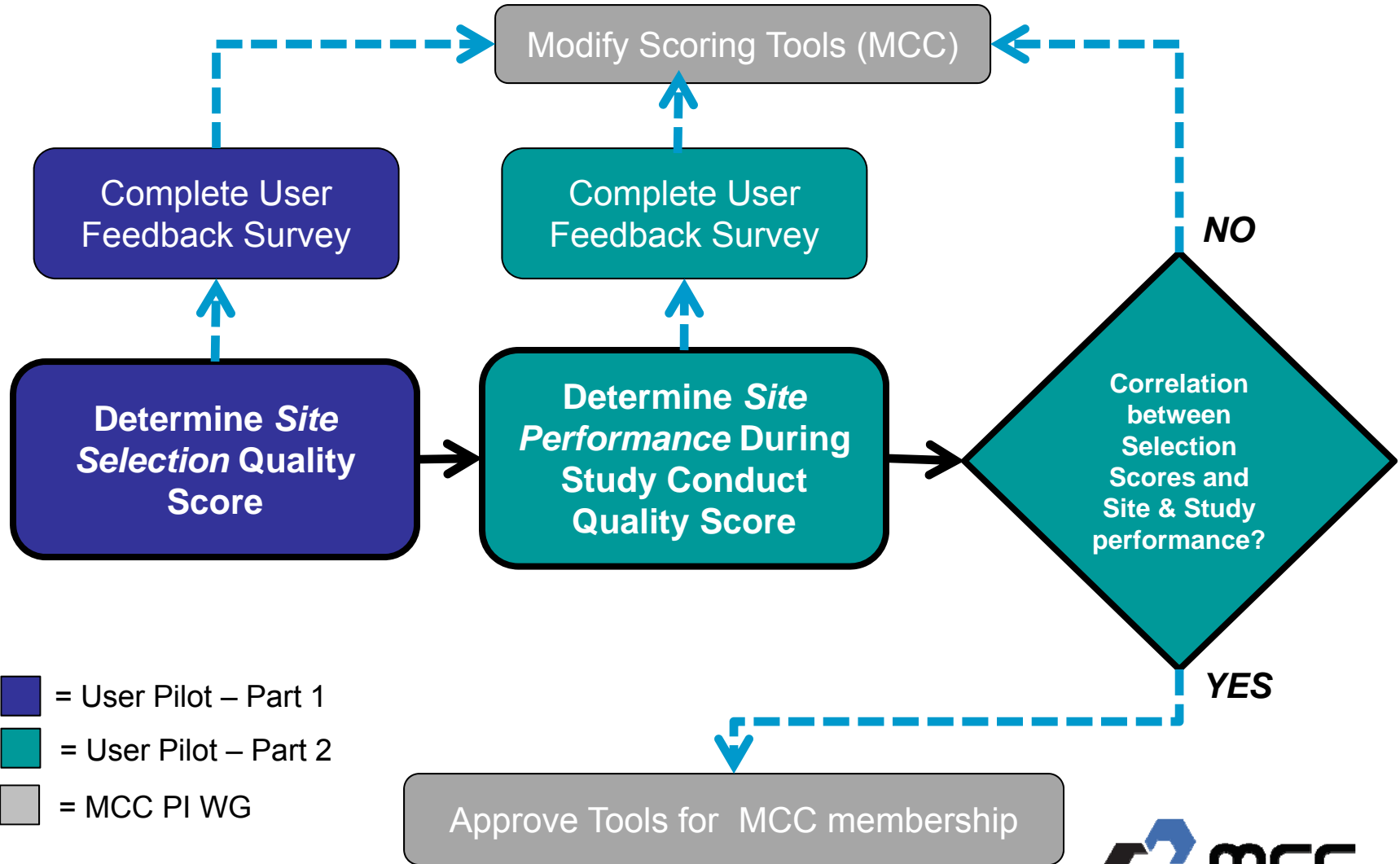


- Each active site is rated on a standard set of thirteen site quality criteria
- Criteria are weighted as to relevance per protocol
- Each site score is automatically calculated from responses to these quality criteria

- A total score is derived for individual countries for all sites scored as well as selected sites only
- Final result should be used as a guide in determining final site performance during study conduct

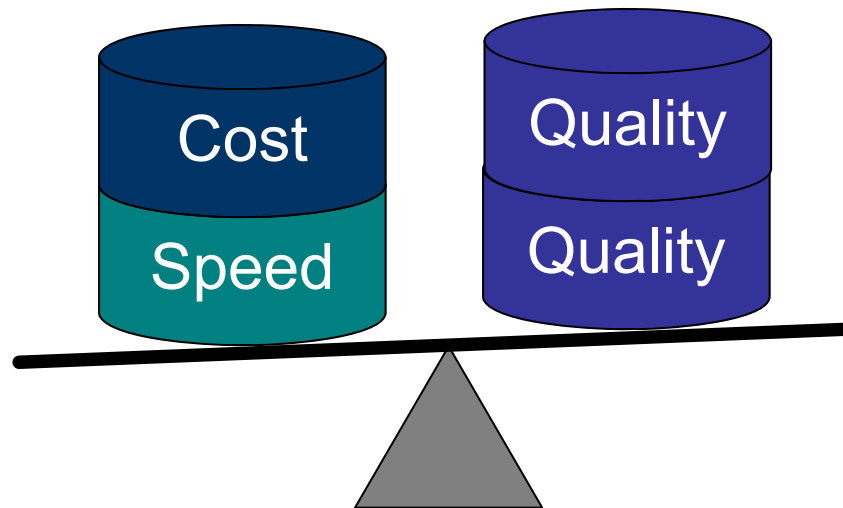
- Goal is to establish a reasonable threshold which all sites surpass as a measure of quality
- Focus should not just be on the score - but rather using the tool to assist in rational discussion amongst the team selecting and evaluating sites
- The act of measuring should modify behavior and highlight sites at risk for poor performance:
 - Does a site lack skills and need specific training?
 - Are there enough high quality sites selected in country X?

By maximizing the overall score for selected sites, organizations maximize your chances of on-time enrollment and successful completion of a trial!



- = User Pilot – Part 1
- = User Pilot – Part 2
- = MCC PI WG

Reducing the time and cost of a task should be balanced with maintaining/improving quality



MCC Performance Metrics and Quality Tools provide sponsors and service providers with the ability to achieve the right balance

Sponsor/Service Provider Collaborative Development and Implementation of Quality Metrics

Brian O'Neill, F. Hoffmann-La Roche Ltd.

3rd annual conference on Effective Business Development
Outsourcing Relationships

Philadelphia, July 19-21, 2011

Topics

- ▶ Metrics used routinely to identify/manage risk to quality of our clinical studies
- ▶ Collaborative development of metrics with sponsor and service provider
- ▶ Routine implementation of quality metrics - a collaborative success story

Continuous Risk Evaluation consists of three steps – Base Risk Profile, Key Risk Indicators, and a resulting Risk Priority Number

Basic QRM Calculation Logic

Roche Value-to-the-Company List

1,000	1	20,000	2,400
1,000	1	10,000	1,200
1,000	1	5,000	600
1,100	1	20,000	2,640
1,100	1	10,000	1,320
1,100	1	5,000	660
1,200	1	20,000	2,880
1,200	1	10,000	1,440
1,200	1	5,000	720
1,300	1	20,000	3,120
1,300	1	10,000	1,560
1,300	1	5,000	780
1,400	1	20,000	3,360
1,400	1	10,000	1,680
1,400	1	5,000	840
1,500	1	20,000	3,600
1,500	1	10,000	1,800
1,500	1	5,000	900
1,600	1	20,000	3,840
1,600	1	10,000	1,920
1,600	1	5,000	960
1,700	1	20,000	4,080
1,700	1	10,000	2,040
1,700	1	5,000	1,020
1,800	1	20,000	4,320
1,800	1	10,000	2,160
1,800	1	5,000	1,080
1,900	1	20,000	4,560
1,900	1	10,000	2,280
1,900	1	5,000	1,140
2,000	1	20,000	4,800
2,000	1	10,000	2,400
2,000	1	5,000	1,200

2) BRP Questionnaire for QRM

Q1: Do you have a confidentiality agreement with Roche? Global or Regional Location

Confidentiality agreement based on Roche standard template signed and available

Confidentiality agreement signed and available for use based on Roche standard template

Confidentiality agreement in progress

Not applicable

Q2: Do you have a master services agreement with Roche? Global

Master services agreement based on Roche standard template signed and available

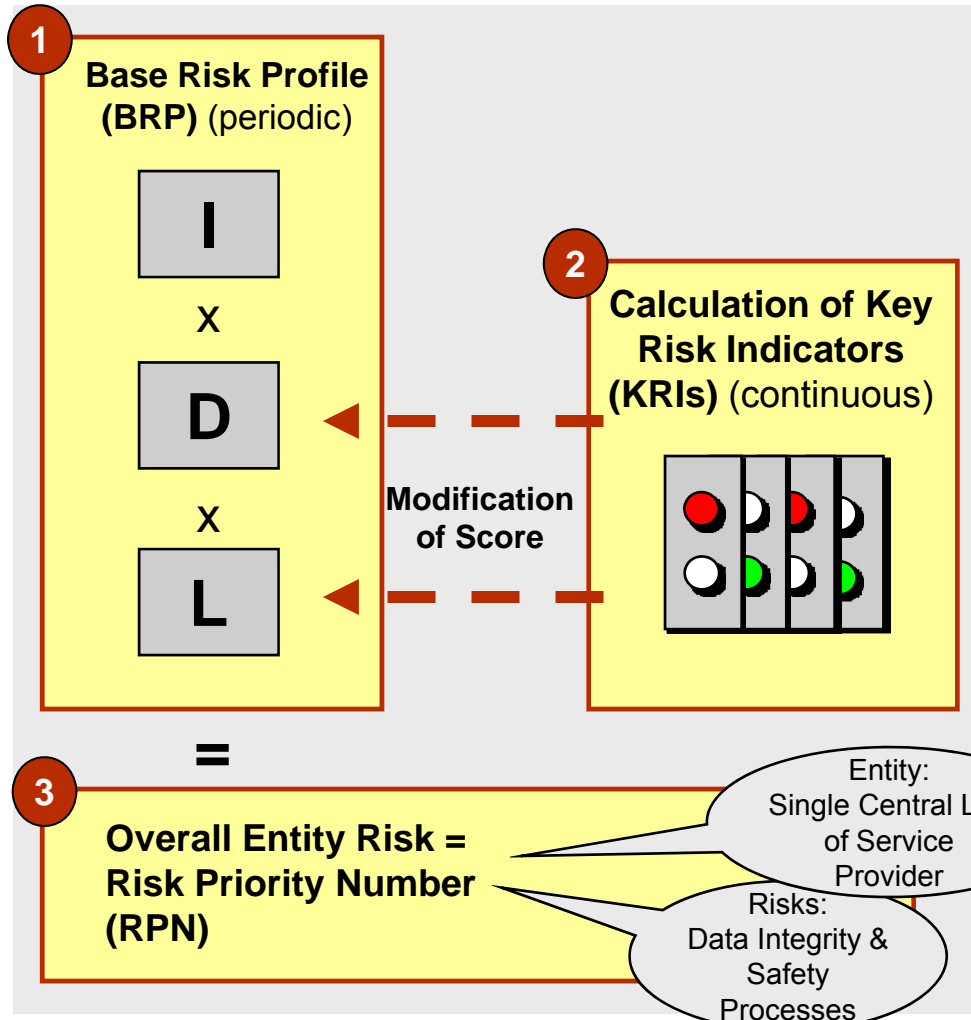
Master services agreement signed and available for use based on Roche standard template

Master services agreement in progress

Not applicable

BRP Questionnaire

Filled out by Service Provider



KRI Data Sheets

SPA001: On-time kit delivery to sites
23 data (July - September 2008)

Regional Split		Total Q3	
Region	CLab Location	# of kits shipped	the # of kits shipped on-time
OVERALL			
Region 1	City 1		
Region 2	City 2		
Region 3	City 3		
Region 4	City 4		
Region 5	City 5		
Region 4	City 4		
Region 5	City 5		

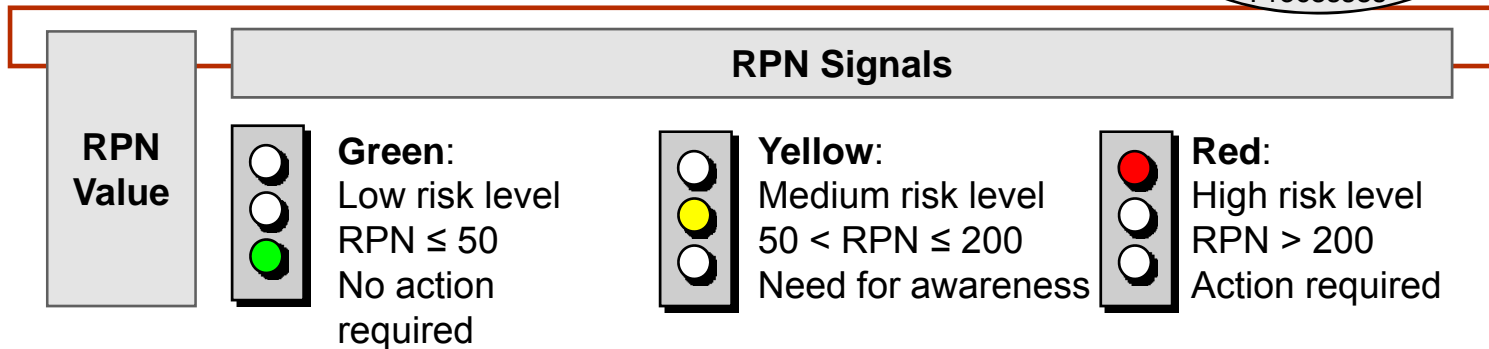
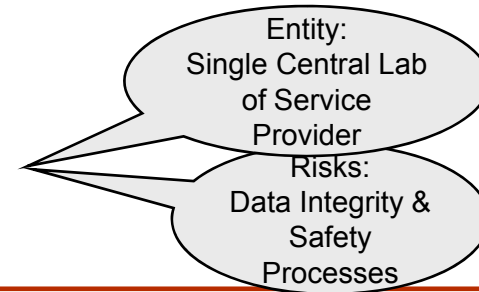
Filled out by Service Provider

The resulting Risk Priority Numbers are the ultimate 'QRM risk currency' - they indicate the overall risk level of the entity

Basic QRM Calculation Logic

3 Overall Entity Risk = Risk Priority Number (RPN)

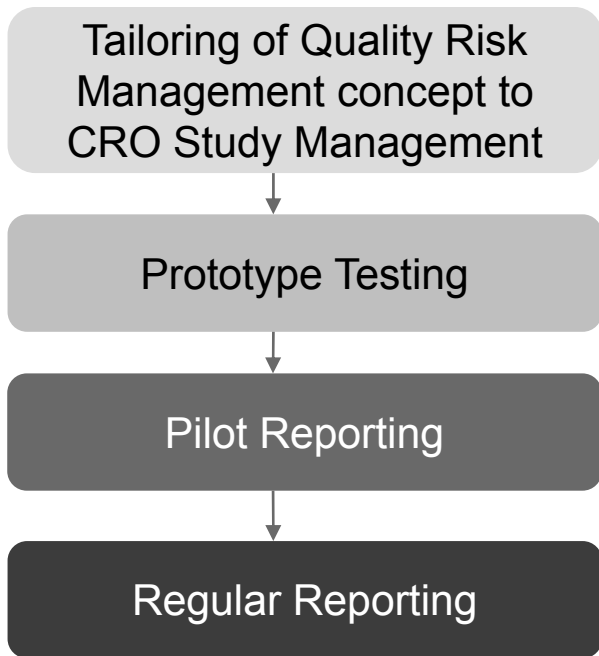
- ▶ RPN value = BRP modified by KRIs
- ▶ RPN value translates into RPN signal
- ▶ RPN signal (red/yellow/green) indicates risk status



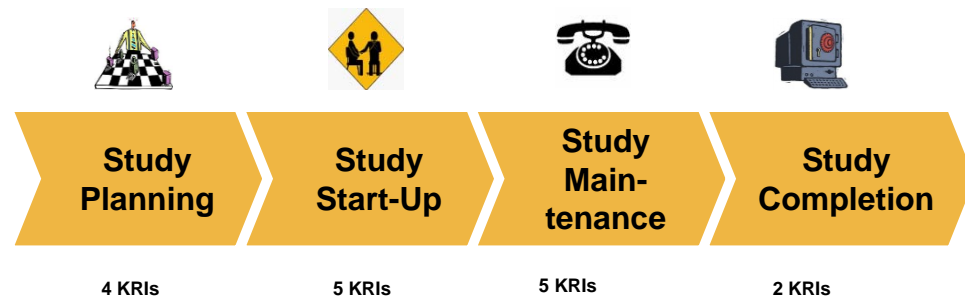
	Data Integrity		Safety Processes	
	BRP	RPN	BRP	RPN
Service Provider	18.0	216.0	12.0	144.0

KRI development along CRO Study Management Operations

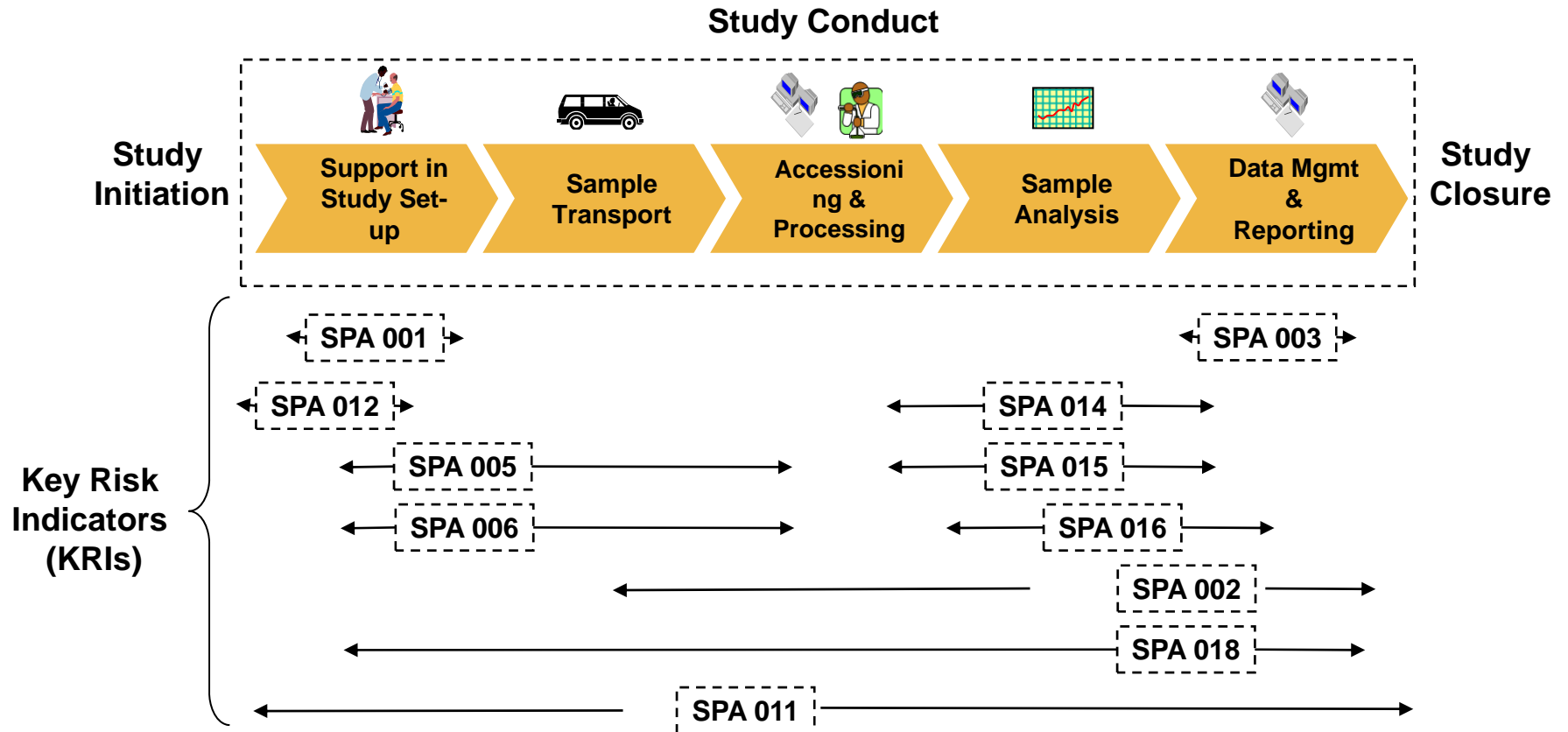
Status of QRM Project Development & Implementation for CROs



CRO Study Management Tasks in Scope for Prototype



KRIs along Central Lab Service Provider Operations



KRI Tool Input & Resulting Risk Reports

KRI Tool Input

Base Risk Profile Questionnaire

1

Q52 Do you have standardised global processes for reporting of alarm values?

Yes
No
Not applicable (e.g. because centre not provided)

Q53 Is empty data for specimen sampling kits tracked and available?

Yes
No
Not applicable (e.g. because centre not provided)

+

Key Risk Indicator Data

2

Local Lab/Protocol Site	Total (1/5/2008)	Number of events within stability of received samples	Value	Threshold	KRI Signal	Explanatory Note, if applicable *
Overall	17795	17100	96.04%	95.0%	Green	
X	85x1	825x	96.84%	95.0%	Green	
MF13621	3	1	33.33%	95.0%	Green	
MAZ1573	146	145	99.32%	95.0%	Green	
MVZ1571	25	11	44.00%	95.0%	Red	
NB10781	401	354	88.28%	95.0%	Green	
NC10971	141	136	96.46%	95.0%	Green	
NP1444	112	111	99.11%	95.0%	Green	

KRI Tool Output

Risk Reports

3

Detailed Risk Assessment for XXX

Overview: Detailed Risk Assessment for XXX

Risk Safety Processes: Risk Data Integrity

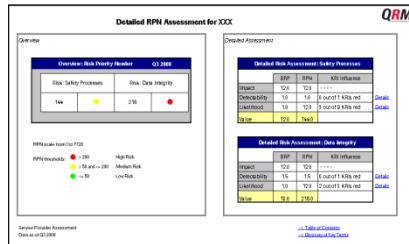
QRM

Indicator	Q4 2006	Q1 2007	Q2 2007	Q3 2007	Q4 2007	Q1 2008	Q2 2008	Q3 2008
SP1001 On-Time Kit Delivery to Sites	1	1	1	1	1	1	1	1
SP1002 Kit Label/Information on Kit	1	1	1	1	1	1	1	1
SP1003 Kit Kit/Kit/Kit/Kit/Kit/Kit	1	1	1	1	1	1	1	1
SP1004 Sample/Specimen/Kit/Kit/Kit	1	1	1	1	1	1	1	1
SP1005 Specimen/Kit/Kit/Kit/Kit	1	1	1	1	1	1	1	1
SP1006 Kit/Kit/Kit/Kit/Kit	1	1	1	1	1	1	1	1
SP1007 Lab/Kit/Kit/Kit/Kit	1	1	1	1	1	1	1	1
SP1008 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1009 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1010 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1011 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1012 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1013 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1014 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1015 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1016 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1017 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1018 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1019 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1
SP1020 Specimen/Specimen/Kit/Kit	1	1	1	1	1	1	1	1

Service Problem Assessment Date: 01/03/2008

Composition of a Risk Report

Part 1 RPN Assessment



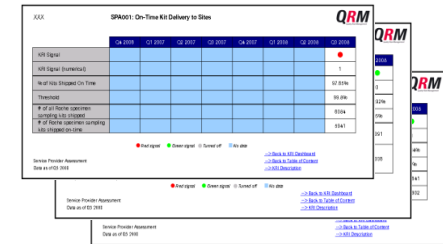
- ▶ **RPN Assessment** - over-view on Risk Priority Numbers for 'Safety Processes' and 'Data Integrity'

Part 2 Key Risk Indicator Dashboard



- ▶ **KRI Dashboard** - overview on all KRI signals

Part 3 Details per Key Risk Indicator



- ▶ **KRI Details** including details on input data and thresholds

Risk Report Extract



Detailed KRI Assessment Summary Report

Data as of Q1 2011

	SP	DI	D	L	PV	Overall	Location 1	Location 2	Location 3	Location 4
SPA001	x	x		x	H	●	●	●	●	●
SPA002	x			x	H	●	●	●	●	●
SPA003		x		x	L	●	●	●	●	●
SPA005	x			x	H	●	●	●	●	●
SPA006	x	x		x	L	●	●	●	●	●
SPA011	x			x	L	●	●	●	●	●
SPA012	x			x	L	●	●	●	●	●
SPA014	x			x	M	●	●	●	●	●
SPA015	x	x	x		H	●	●	●	●	●
SPA016	x			x	M	●	●	●	●	●
SPA018	x			x	M	●	●	●	●	●

● Red signal ● Green signal
● Turned off ■ No data

SP: KRI linked to the risk 'Safety Processes'

DI: KRI linked to the risk 'Data Integrity'

D: KRI linked to 'Detectability'

L: KRI linked to 'Likelihood'


PV: Predictive Value (Strength of the KRI): H = High, M = Moderate, L = Low

[--> Risk Assessment](#)
[--> Table of Contents](#)
[--> KRI Description](#)

Service Provider Assessment

Data as of Q1 2011

Risk Report Extract



Detailed KRI Assessment for Location 1

	SP	DI	D	L	PV	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	
SPA001	x	x		x	H	●	●	●	●	●	●	●	●	Details
SPA002	x			x	H	●	●	●	●	●	●	●	●	Details
SPA003		x		x	L	●	●	●	●	●	●	●	●	Details
SPA005	x			x	H	●	●	●	●	●	●	●	●	Details
SPA006	x	x		x	L	●	●	●	●	●	●	●	●	Details
SPA011	x			x	L	●	●	●	●	●	●	●	●	Details
SPA012	x			x	L	●	●	●	●	●	●	●	●	Details
SPA014	x			x	M	●	●	●	●	●	●	●	●	Details
SPA015	x	x	x		H	●	●	●	●	●	●	●	●	Details
SPA016	x			x	M	●	●	●	●	●	●	●	●	Details
SPA018	x			x	M	●	●	●	●	●	●	●	●	Details

● Red signal ● Green signal [--> Risk Assessment](#)

● Turned off ■ No data [--> Table of Contents](#)

[--> KRI Description](#)

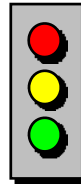
SP: KRI linked to the risk 'Safety Processes'
DI: KRI linked to the risk 'Data Integrity'
D: KRI linked to 'Detectability'
L: KRI linked to 'Likelihood'
PV: Predictive Value (Strength of the KRI): H = High, M = Moderate, L = Low

Service Provider Assessment
 Data as of Q1 2011

Risk Report Signaling and Risk Response Forms

Risk Report Signaling

- ▶ The overall risk level, indicated by the value of the RPN (Risk Priority Number), can be either
 - high (=red signal)
 - medium (=yellow signal)
 - low (green signal)



- ▶ RPN is calculated for “Safety Processes”

and

The image shows three overlapping screenshots of the QRM (Quality Risk Management) system. The top screenshot is titled 'Detailed RPN Assessment for XXX' and shows a table with columns for 'Risk Priority Number' and 'Detailed Risk Assessment Safety Process'. The middle screenshot is titled 'Detailed RPN Assessment for XXX' and shows a table with columns for 'Risk Priority Number' and 'Detailed Risk Assessment Safety Process'. The bottom screenshot is titled 'SPR001: On-Time Kit Delivery to Sites' and shows a table with columns for 'Risk Priority Number' and 'Detailed Risk Assessment Safety Process'.

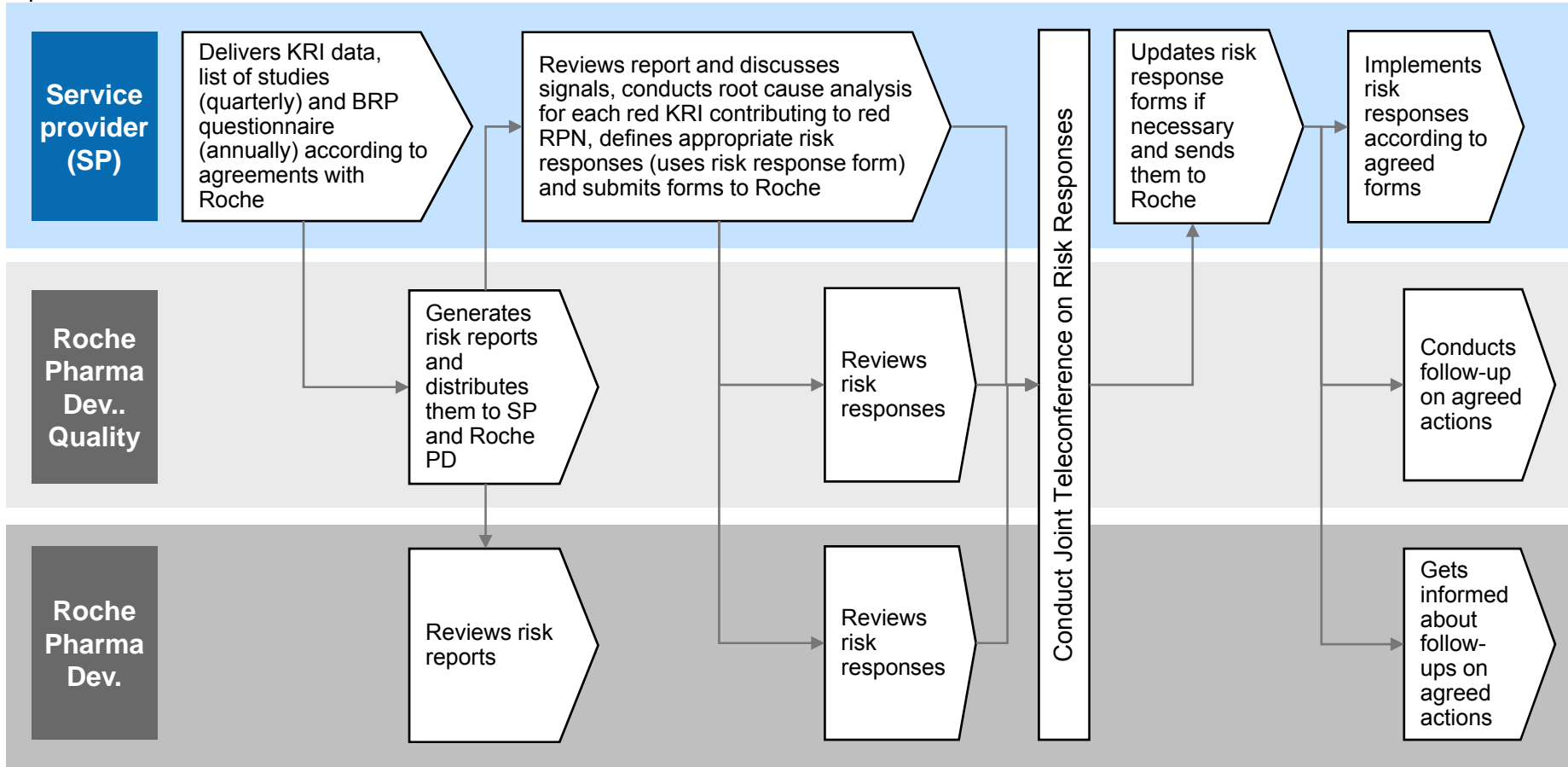
Risk Response Forms

- ▶ Risk response forms, which ask for mitigating actions, need to be completed for all red KRIs of an entity that has a red Risk Priority Number, implying high risk level

The image shows a screenshot of a Risk Response Form. The form is titled 'KRI ID' and 'Signal' (red). It contains a table with columns for 'KRI ID', 'Signal', 'Report ID', and 'Complies Response'. The table has one row with a red signal. Below the table, there is a section for 'Mitigating Actions' with columns for 'ID', 'Description of Mitigating Action', 'Responsible', and 'Timeline'. There are three rows of mitigating actions listed.

The signal management process ensures coordination of all involved parties during each QRM risk reporting cycle





Signal Management Process during QRM Risk Reporting Cycle



Note: If requested, ad hoc teleconferences can be held directly after data submission and/ or report distribution.

In addition to the benefit of direct risk management information, QRM creates additional essential advantage for Service Providers

QRM Key Benefits for Service Providers

Key Benefit	Detailed Explanation
1 Improved Working Relationship	 <ul style="list-style-type: none"> ▶ Advance to a truly collaborative and proactive <i>risk mitigation approach</i> jointly with Roche rather than remain with a reactive, ad-hoc and less interactive <i>audit approach</i> only
2 Prioritized Improvement Activities	 <ul style="list-style-type: none"> ▶ Identify key areas for improvement and resource allocation ▶ Focus audits on risk areas highlighted by QRM
3 Fact-based Competitive Advantage	 <ul style="list-style-type: none"> ▶ Take the opportunity to <ul style="list-style-type: none"> – Leverage existing QRM data for other clients (benchmarking) – Customize QRM system and implement at other clients
4 Reassured Health Authorities	 <ul style="list-style-type: none"> ▶ Demonstrate a proactive attitude towards risk management to health authorities

Contact information:

Jeanne Green jgreen@execupharm.com

Brian O'Neill brian.oneill@roche.com

Linda Sullivan lsullivan@metricschampion.org