

Metrics Champion Consortium (MCC) Clinical Trial Performance Metrics (beta version):

Industry Feedback Process

May 4, 2009



Thank you for your interest in providing feedback to the MCC regarding the MCC Clinical Trial Performance Metrics (beta version). The MCC Clinical Trial Metrics Steering Committee and Working Groups will review all respondents' feedback while they are finalizing the Clinical Trial Performance Metrics (version 1.0), expected to be released by January 2010.

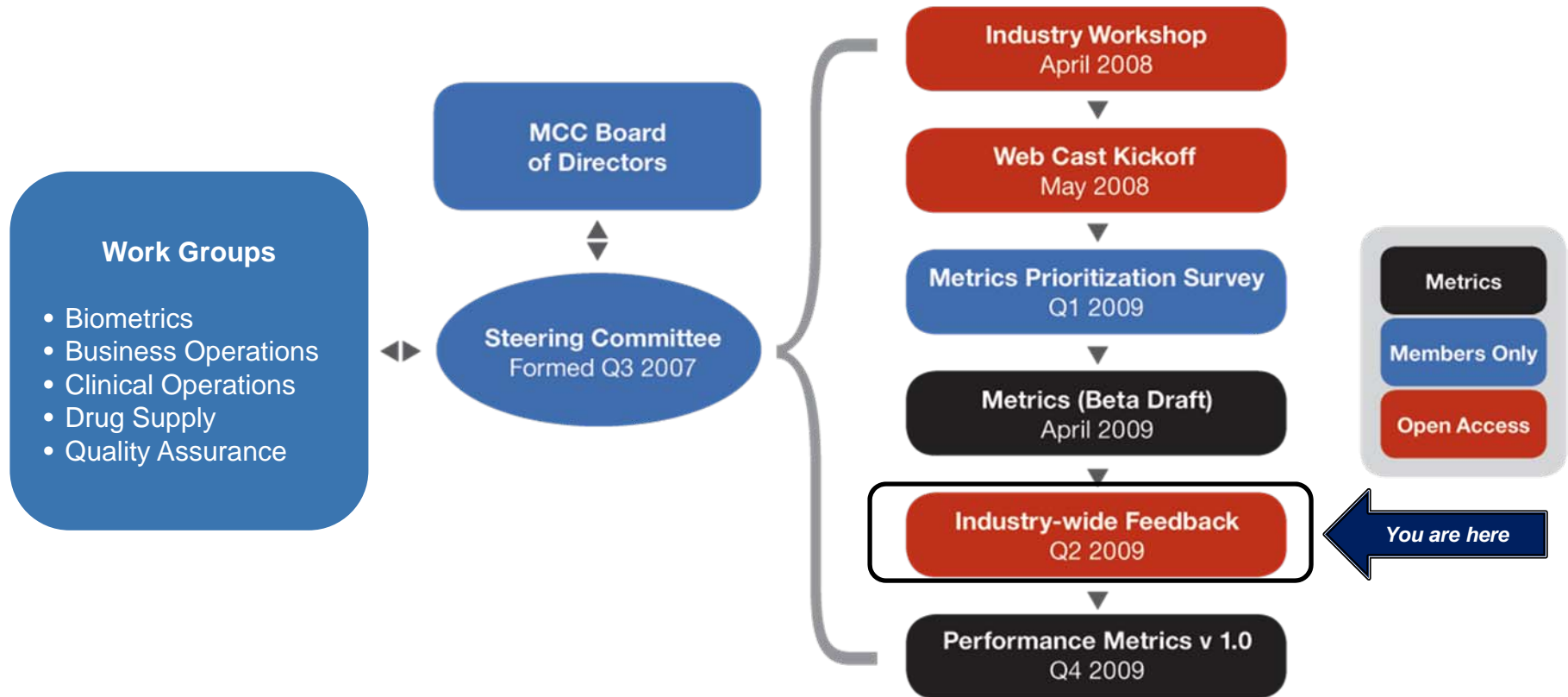
Please review all of the MCC Clinical Trial Performance Metrics (see slides 11-40) prior to starting the online feedback survey - you cannot save a partially completed form if you decide to gather additional input from your colleagues prior to completing the online form.

Please contact Linda Sullivan (lsullivan@metricschampion.org) at (317)848-2908 ext 119, if you have any questions or you wish to learn about joining the MCC to participate in our metrics development initiatives and implementation/shared learning work groups.

[The MCC Clinical Trial Performance Metrics Steering Committee](#)

The mission of MCC is to develop, through a collaborative process, performance metrics within the Biotechnology and Pharmaceutical industry with the intent to ***jointly*** encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls for both Sponsors and Service Providers in support of the drug development process.

Clinical Trial Performance Metrics Development Process



Purpose of MCC Clinical Trial Performance Metrics:

- Create a set of performance metrics that are **key indicators** of performance that are utilized by sponsor/service provider partnerships to manage clinical trial performance
- Constructive conversations are generated between all parties because of metrics
- Sponsors and service providers grow more productive as a direct result of utilizing MCC metrics

Clinical Trial Performance Metrics (Beta version)

Each MCC Clinical Trial Performance Metric has the following components:

Metric #	Metric Type	Metric Title	Category	Definition	Formula / Example	Additional analysis on a "for cause" basis:	Metric Indicator	Reporting Detail	Unit of Measure	Reporting Frequency	Target	Business Driver(s) / Benefit Statement	Comments
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Metrics Type = Cycle Time(CT), Timeliness(T), Quality(Q), Efficiency(E)

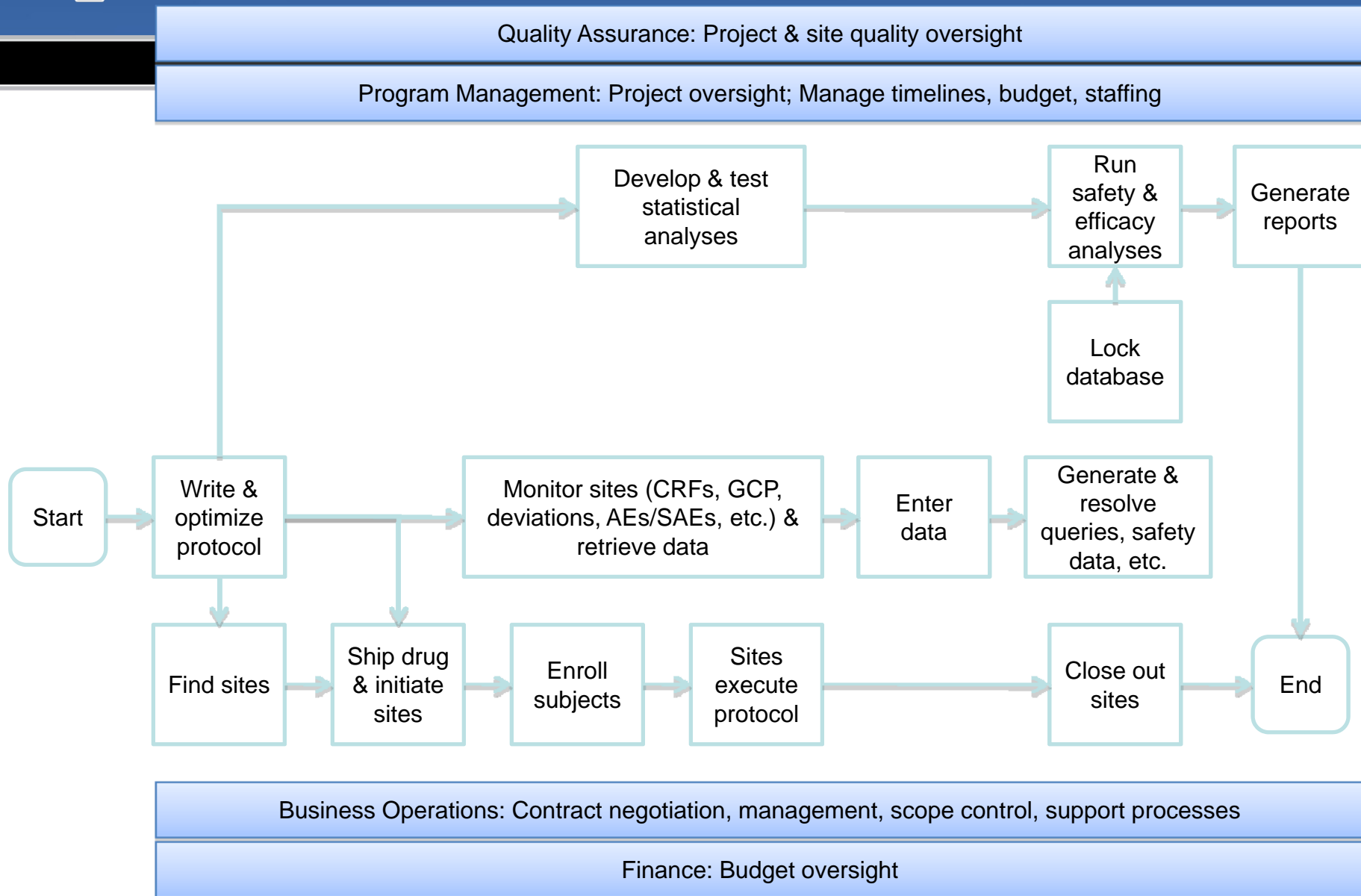
Metrics Indicator

- Leading Indicator = End user will use metric to identify opportunities to affect change in the current trial.
- Lagging Indicator = End user will use metric to identify opportunities to affect change in future study trials.

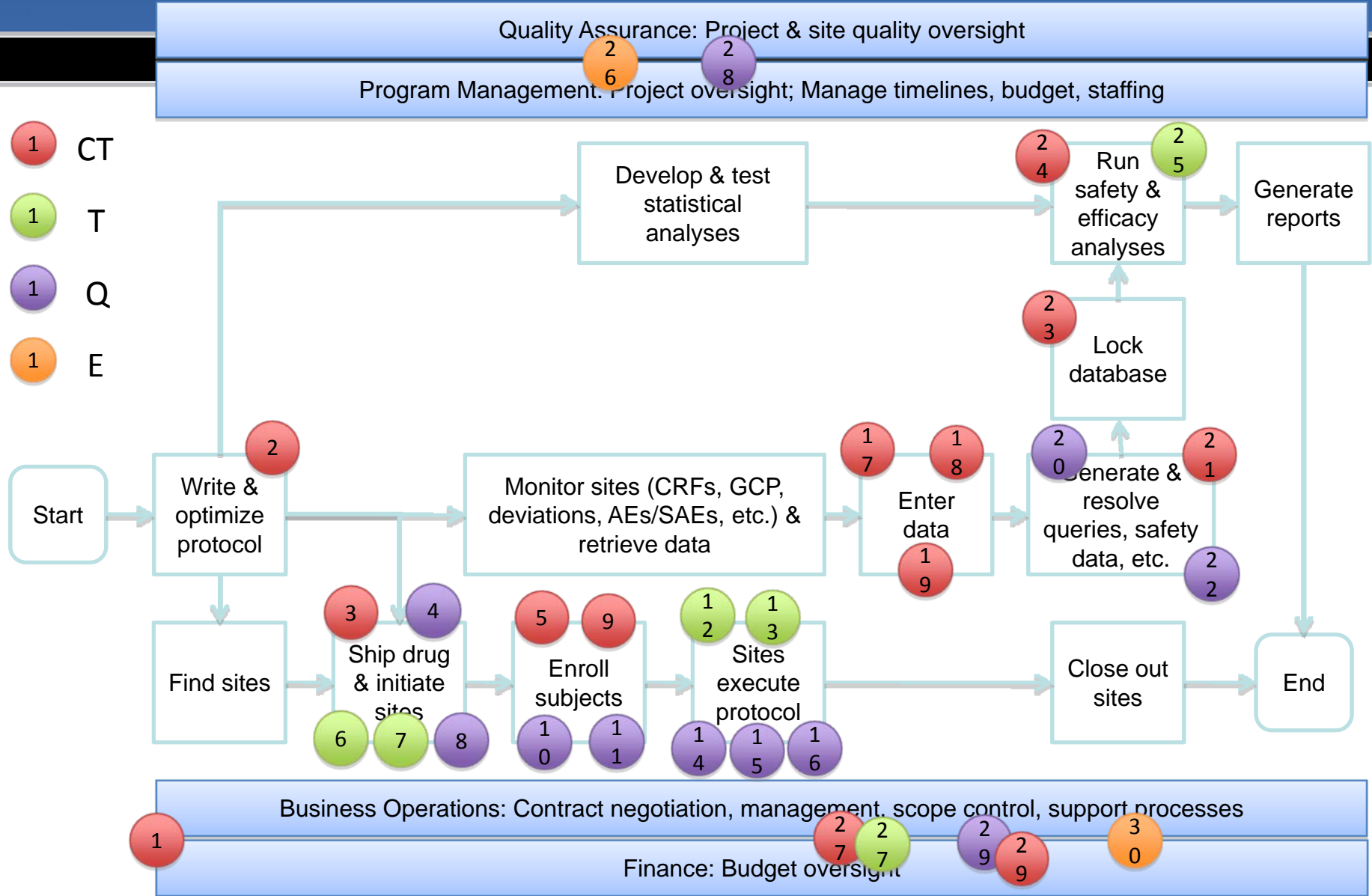
Reporting Detail = Examples of how the data might be reported (i.e. by country, by site, etc.)

Target = Threshold level to prompt further review & discussion

Typical Clinical Trial Process



Metrics Distribution



- Purpose: Provide constructive feedback to the MCC Clinical Trial Metrics Steering Committee and Working Groups about which draft metrics are:
 - most valuable
 - need additional clarification or modification
 - difficult to produce at this time
- Instructions:
 - Review each metric (see slides 11- 40)
 - Score each metric using the feedback form (see sample pdf form)
 - Note general comments on areas for improvement for metrics reviewed
 - Send your feedback to the MCC via the online submission form at <http://www.zoomerang.com/Survey/?p=WEB2295XYBWAGK>

Metrics Feedback Form - Example

For each metric, you will be asked to provide feedback in three areas

Scoring Factor	Scoring Guide (score is 1 - 5)		
	1	3	5
Metric Definition	Definition Not Clear	Neutral	Easy to Understand; Very Clear
Metric Value	Not Valuable	Neutral	Extremely Valuable
Ease of Production	Very Difficult	Neutral	Very Easy; Automated

Please see attached pdf version of the online survey form.



Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
1	CT	Contract finalization and execution timeliness	Contract Execution	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Time from initial written authorization of work/project award to full contract or work order execution. The total number of calendar days from the initial written authorization of work/project award of a project to having the contract or work order fully executed by all parties.	Formula: Total N of calendar days from initial written authorization/project award to last signature on the contract / work order / LOI; # of changes to initial SOW during negotiation process; # of review cycles between the parties; # of days from contract award to first executed agreement (e.g. LOI, LOA, Contract). Specific Example: CRO is notified of project award on November 15, 2007 and the contract is finalized on May 21, 2008. Calendar days = 188 days	Unit of Measure
		Total N days (calendar)

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Business Drivers include: single function, multi-function or full service outsourcing as well as the relationship between the parties; new, repeat or preferred provided. You will be informed of whether there is conceptual agreement on the project requirements by measuring the number of days it takes for a service provider to finalize the work plan and associated costs, obtain legal agreement for contractual terms and by measuring the numbers of days it takes for full contract execution, the number of review cycles throughout negotiation process (contract, SOW and budget) to reach agreement and the number of changes made to the SOW. Lengthy negotiations may be a result of poor scope clarity and/or misunderstanding between the parties regarding work being outsourced. In addition, you can extrapolate that as the relationship matures and the parties agree on the use standard units of measure or milestones, that the number of change orders related to lack of SOW clarity will decrease and the negotiation time will occur in an expedited timely manner.	Additional analysis on a "for cause" basis: Number (N) of sequences/rounds of negotiation/ review of the agreement between the parties.	Once	MSA: 6-8 wks (45-60 days) No MSA: 8 - 12 wks (60 - 120 days)

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
2	CT	Final Approved Protocol to Final Approved CRF	Approved Protocol/CRF Design	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Median number of days that it takes from final approved protocol to final approved CRF.	Formula: Protocol Final date + 36 days= Expected CRF Final Specific Example: Protocol Date= Actual Start/final of 01Jan2008; Expected Finish= 06Feb2008; Actual Finish should be captured	
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
This task is critical in starting the remaining Data Management tasks. For example, once the CRF is approved, the Annotated CRF needs to be completed, the Database needs to be designed and tested, edit checks created, tested etc. Therefore, this is really the starting point for Data Management to begin.	Additional analysis on a "for cause" basis: Because paper and EDC have different approaches, the approach for an EDC would be the median number of days that it takes from final approved protocol to EDC Screens approved for production.	Single	35 days
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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
3	CT	Cycle Time protocol approval to first site activated	Site Selection and Activation	LEADING Indicator

Definition	Formula / Example	Reporting Detail
The total number of calendar days from the date the final approved protocol is released to the CRO to the date of first site activated (trial level, country level) where site activation is defined as site has been approved to begin screening patients.	Formula: X - Y, where X is Date of First Site Activated; and Y is Date of Protocol Approval Specific Example: Protocol Approved April 13 and First Site Activated August 1; [Aug 1 -- Apr 13] = 109 calendar days	By trial level By country
		Unit of Measure
		Days/Weeks

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Leading indicator for protocol issues, site performance, CRO performance, regulatory approvals, etc. Increased understanding of geographical differences in site activation. The adherence to plan for site activation is a leading indicator for patient enrollment performance. Key project management indicator of adherence to project plan.	Analysis of reasons for delay include timelines for ethics approvals/ signed site agreement and regulatory approval. Monitoring resource availability. Protocol amendments.	Bi monthly during site selection phase	Plus or Minus 2 weeks per contract, by geography (G); within 2-4 weeks per contract by geography (Y); >4 weeks per contract by geography (R)

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
4	Q	Investigator Site Reg pack approval rate	Site Selection and Activation	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Percent of investigator site regulatory packets that are approved by the initial approver (e.g. Regulatory Affairs, Site Startup, etc.) after first receipt of complete packet, where complete packet is defined by SOP or Study-specific plan	Formula: X/Y where X is the number of reg packets approved by the initial approver after first receipt of complete packet; and Y is the total number of completed reg packets received Specific Example: A total of 18 completed reg packets are received. Of those, 17 were approved by the initial approver. $17/18 \times 100 = 94.4\%$	% packs approved/ Country/ Trial level
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Investigator Regulatory packets are on critical path to site activation. Poor quality and re-work of packet documents can delay site activation.	Types of quality issues leading to rejection of Site regulatory packages/ Country.	Weekly or monthly, dependent upon planned startup period	>95%

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
5	CT	Cycle time from final Protocol Approval to First Patient-First Visit (all sites)	Patient Screening and Recruitment	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Cycle time from final approved protocol released to CRO to First patient-first visit (as defined by patient has signed Informed Consent--consistent with CMR benchmark definition)	Formula: $[X - Y]/7$ where X is Date of First Patient First Visit ; and Y is Date of Final approved protocol released to CRO Collected on site-by-site basis then averaged across activated sites Specific Example: Final approved protocol released to CRO on February 22. First Patient First Visit occurred June 30. $[June\ 30 - Feb\ 22]/7 = 130\ days = 18.5\ weeks$	By protocol By site By geography
		Unit of Measure
		Weeks

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Provides an early indicator for how project will track to plan. Longer than planned cycle times may indicate a need to initiate risk management plans. Important metric for future planning purposes.		Once, after first patient has consented (protocol level), more frequently at site level	Plus or Minus 2 weeks per contract b/w CRO and sponsor, by geography (G); plus or minus 4 weeks per contract b/w CRO and sponsor by geography (Y); >4 weeks per contract by geography (R)
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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
6	T	% Planned Sites Activated	Site Selection and Activation	LEADING Indicator

Definition	Formula / Example	Reporting Detail
% of planned sites activated at point in time, reported in agreed-upon period (trial level, country level). % of sites activated by CRO vs number per contract, where activated means that site has been approved to begin screening patients	Formula: X/Y where X is the number of sites activated and Y is the total number of sites expected Specific Example: A total of 18 sites are expected (planned) at this point in time. A total of 13 sites have been activated $13/18 \times 100 = 72.2\%$	# sites active/ # expected at time by country/ trial level.
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
The adherence to plan for site activation is a leading indicator for patient enrollment performance.	# of active sites / country. Analysis of reasons for delays include # of ethics approvals/ site and regulatory approvals/ country. Monitoring resource availability.	Bi monthly during site selection phase	>90% (G) >70% but less than 90% (Y) <70% (R) All measures per contract

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
7	T	Drug Onsite at Initiation	Site Initiation	LEADING Indicator

Definition	Formula / Example	Reporting Detail
The number of sites that have drug onsite at Initiation per country.	Formula: % Study Sites with drug onsite at Initiation (by site & country) Specific Example: 56 of 60 sites have drug onsite at initiation. Status is red as this is 93.3% achievement, below 95% target	by country or region
		Unit of Measure
		Total N and %

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Timelines will be met and provide good projections for study drug available at start at country and site levels.	geographic location; manufacturing issues? Delivery issues; contract status	Initiation milestone	>95%

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
8	Q	Drug Supply Planning	Forecasting accuracy	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Total amount of drug needed per patient per country according to forecast.	Formula: IP not used / planned IP x100 Specific Example: 20 unused / 120 total bottles = 16.6% overage, red status as this is >5% target	by country and by site
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Understand planning accuracy and overage at a study level. Reduce waste and cost overruns. Need to consider target - could need to plan for extra in some countries.	improper planning; IVRS; site decisions	Quarterly	<.05

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
9	CT	Cycle time from Site Activation to First Patient First Visit	Patient Screening and Recruitment	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Cycle time from Site Activation, where site activation is defined as site has been approved to begin screening patients, to First patient-first visit (as defined by patient has signed Informed Consent--consistent with CMR benchmark definition)	Formula: $[X - Y]/7$ where X=Date of First Patient First Visit; Y= Date of Site Activation. Collected on site-by-site basis then averaged across activated sites Specific Example: First Patient signed consent May 15; Site was activated April 7 $[(\text{May 15} - \text{April 7})/7] = 3.1$ weeks	By protocol By therapeutic area By geography
		Unit of Measure
		Weeks

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Lagging indicator driven by protocol in/ex criteria, therapeutic area, geography. Adherence to agreed-upon timelines and budget. Timely achievement of contract and project milestones. Driver: Inactive sites tend to lose interest and competing studies may be re-prioritized over trial. Retrospective analysis may also indicate inadequate site selection and/or inadequate site training (especially if long duration is linked to a high screen failure rate)		Quarterly, at project completion, and cumulatively	Within 10% of agreed-upon metric

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
10	Q	Site Productivity	Patient Screening and Recruitment	LEADING Indicator

Definition	Formula / Example	Reporting Detail
<p>Site productivity in tiers:</p> <p>T1) Sites who have not consented any patients;</p> <p>T2) Sites who are below planned enrollment target;</p> <p>T3) Sites who are meeting planned enrollment target;</p> <p>T4) Sites who are exceeding planned enrollment target</p>	<p>Formula: Number of sites in tier/ Total number of sites activated after X days</p> <p>Specific Example:</p> <p>Twenty sites expected to enroll 20 patients each.</p> <p>T1: 3 sites have not enrolled any patients, 3/20=15%</p> <p>T2: 6 sites have enrolled less than planned, 6/20=30%</p> <p>T3: 5 have enrolled equal to planned, 5/20=25%</p> <p>T4: 6 have exceeded.6/20=30%</p> <p>T3 + T4 = 25% + 30% = 55% (R)</p>	<p>Traffic light report ></p> <p>=90% of sites in Tier 3 or 4(G);</p> <p>75%-90% of sites in Tier 3 or 4 (Y);</p> <p>< 75% of sites in Tier 3 or 4 (R)</p>
		<p>Unit of Measure</p> <p>%</p>

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
<p>Sites who are inactive are costly to initiate and monitor. Important metric for future site selection. Root cause analysis should be conducted to understand why site(s) are non-productive. Implement risk mitigation plan</p>	<p># of Competing studies at the site/ country & trial level. Root cause analysis should be conducted to understand why site(s) are non-productive. Implement risk mitigation plan</p>	<p>Frequency dependant on protocol</p>	<p>> =90% of sites in Tier 3 or 4(G);</p> <p>75%-90% of sites in Tier 3 or 4 (Y);</p> <p>< 75% of sites in Tier 3 or 4 (R)</p>
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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
11	Q	Screen Failure Rate	Patient Screening and Recruitment	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Measure of how many subjects are screened (signed consent) vs randomized/ received id number (screen failure rate) vs Planned screen failure rate as determined by the protocol/ TA and specified for the study.	Formula: Total number of screened subjects minus number randomized; that number expressed as %; screen fail rate planned vs screen fail rate actual Specific Example: Number of patients screened 100, patients randomized 75. $(100-75)/100=25\%$ Planned Screen fail rate expected to be 15% - actual is 25%.	By Site, Country, Trial level
		Unit of Measure
		Number

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Projecting enrollment rates at protocol level . Maintaining expectations for screen failure rates will assist with managing the budget allocated for these subjects; the root causes will help determine if a change to protocol is needed. Measurement at site level may indicate need for further root cause analysis and/or mitigation strategy.	# of Protocol violations/ site	Monthly or more frequently during enrollment period.	5% of planned screen failure rate

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
12	T	Correct Drug Inventory & Resupply	Timeliness/Quality of Resupply	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Availability of drug kits on site over time	Formula: Actual # kits onsite/Planned # kits x100 (per site) Specific Example: 110 actual / 100 total planned = 110%, green status	by country and by site
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Measures inventory is correct for planned patient load at site. May be >100% at times when batches received.	improper planning; IVRS; site decisions	Monthly	>95%

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
13	T	% Patients randomized	Patient Screening and Recruitment	LEADING Indicator

Definition	Formula / Example	Reporting Detail
% Patients randomized at point in time vs plan, where randomized is defined per the study protocol.	Formula: X/Y where X is the total # of patients randomized ; and Y is the total # of patients anticipated to be randomized Specific Example: A total of 35 patients are randomized at point time vs an expected 32 randomized patients at point in time. $35/32 \times 100 = 109\%$	By Country By Trial
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Timely enrollment metrics are necessary to ensure trial timelines are met. It may be acceptable for the metric to trend toward the lower end of the target early in the enrollment period. Below target metrics indicate the need for risk management/intervention. A trend toward the upper end of the target may indicate a need to mitigate the risk of over-enrollment.	% of sites activated vs planned. Screen fail rate.	Weekly or monthly, dependent upon planned enrollment period	> =90% (G); 75%-90% (Y); < 75% red

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
14	Q	Patient Retention rate	Patient Screening and Recruitment	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Measure of how many subjects remain in the study vs. randomized/ received id number	Formula: Number randomized/ received id number minus number withdrawn divided by Number randomized/ received id number Specific Example: A total of 70 patients were randomized; of those 4 withdrew from the study. Patient retention rate is $(70-4)/70 = 94\%$	By Site, Trial level
		By Country,
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Projecting retention rates at protocol level . Maintaining expectations for retention rates will assist with managing total number of patients required to meet protocol requirements for completed patients (Implications to Statistical analysis plan): the root causes will help determine if a change to protocol is needed. Measurement at site level may indicate need for further root cause analysis and/or mitigation strategy.	Reasons for withdrawal, if collected	Monthly	2% of planned retention rate

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
15	Q	% Sites Prematurely Terminated	Site Selection and Activation	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
% of Sites Closed after activation and prior to study closeout, either with or without enrolled patients	Formula: X/Y where X is the number of sites closed after activation and prior to study closeout; and Y is the total number of sites activated Specific Example: A total of 27 sites were activated, 3 of which were closed before study end (not planned number) $3/27 \times 100 = 11.1\%$	By trial level By country
		Unit of Measure
		%

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Premature closing of a site is non-productive and leads to increased cost associated with the project. Root cause analysis should be conducted. Were the right sites selected?	Examine site selection strategy	Monthly	

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
16	Q	Audit Findings	Quality Assurance (additional quality metrics in Clin Ops WG metrics)	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Number of site audit findings that are major and critical	Formula: Average # of major/critical findings per final report Specific Example: Of four study sites audited, two are Green (0), one is Yellow (1) and one is Red (4). Average for study is 1.25 findings/site audited. $(0+0+1+4)/4 = 1.25$ Yellow.	by country or region
		Unit of Measure
		N= average number of findings per site

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Provides visibility of areas of concern for delivery, identifies areas of risk and provides basis for potential procedural changes if needed.	Additional analysis on: <ul style="list-style-type: none"> ▪ delegation of responsibilities, ▪ consent issues, ▪ source docs, ▪ % eligible pts, ▪ safety concerns. 	Per Study	0-1=Green, 1-2=Yellow, 2+= Red

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
17	CT	Final CRF/eCFR to Database "Go Live"	Programming/Build	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Median time from sign-off of final CRFs to database "go live". For EDC, time from sign-off of EDC screens to database "go live".	<p>Formula: Median measure for all protocols over set period</p> <p>Specific Example: Protocols A, B and C have a timeline between final CRFs and finalized Database, to produce an average number.</p>	EDC/Paper Database System Data Center (large CROs) Therapeutic Area
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing time to database 'go live' shortens the time to study start and FPI. It improves the chances of meeting end-of-study timelines. By having edit checks final before 'go live', it improves the quality of the data from the beginning.	<p>Additional analysis on a "for cause" basis:</p> <p>Slow database build time could be due to complexity of the study, use of dynamic forms, number of forms, and number of edit checks. Protocol amendments would lead to updates and repeat of setup and validation procedures.</p> <p>High number of errors caught during Sponsor UAT suggests poor QC and requires better in-house procedures or better training.</p>	Single	56 days (40 working days)

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
18	CT	CRFs Received to Data Entry Complete - Paper	Data Entry	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Median number of days from when pages are received and/or scanned to entry complete (2d pass).	Formula: Median measure for all protocols over a set period of time. Specific Example: Protocol A, B, and C have days to complete CRF entry collected, to produce an overall median number.	Phase CDMS Type Therapeutic Area
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing the cycle time for entry of data into the database can improve the overall performance of clinical trials: -Earlier entry of data into the database can reduce delays in query management activities. -Earlier ability to review data allows better trend analysis and decision making. - Less days to complete this task reduces cost in terms of hours coded and staff flexibility. - Reducing the number of days CRFs wait to have this process completed improves accountability.	Additional analysis on a "for cause" basis (Paper only measure, as targets differ by platform): - Determine if delays are technical or process - Level of staff training effect on meeting target - Phase, therapeutic area, customer impact on target.	Quarterly	3 days for CRFs

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
19	CT	Patient Visit Complete to eCRF data entered - EDC	Data Entry	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Median number of days from Patient Visit complete to eCRF started in the system.	Formula: Median measure for all protocols over a set period of time. Specific Example: Protocol A, B, and C have days to complete CRF entry collected, to produce an overall median number.	Phase CDMS Type Therapeutic Area
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing the cycle time for entry of data into the database can improve the overall performance of clinical trials: -Prompt entry of data into the EDC system reduces query management cycles. -Earlier ability to review data allows better trend analysis and decision making. - Less delay improves accuracy of data entered. - Reducing the number of days CRFs, or source documents wait to have this process completed improves accountability.	Additional analysis on a "for cause" basis (EDC only , as targets vary by platform): - Determine if delays are technical or process - Level of training and/or demands on site staff - Phase, therapeutic area, customer impact on target.	Quarterly	5 days for eCRFs

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
20	Q	Data discrepancies generated by automated edit checks	Data Coordination/Cleaning	LAGGING Indicator Could be LEADING Indicator if reported more frequently

Definition	Formula / Example	Reporting Detail
Median number of data discrepancies identified by automated edit checks executed in database.	Formula: Number of discrepancies over number of data fields. Specific Example: Across protocols compare the number of data discrepancies generated per edit check. The rate of discrepancies will be measured.	
		Unit of Measure
		Number/ratio

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing the number of data discrepancies identified is an indication of data and/or collection process quality and can improve overall cycle time and resource use for clinical trials.	Additional analysis on a "for cause" basis: A higher than expected number of discrepancies generated indicates that, 1) the edit checks were not programmed properly, 2) that the questions on the CRF are not clear, or 3) the number of edit checks is too high.	Quarterly	0.5% error rate

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
21	CT	Receipt of Query Response to Database Update Time	Data Coordination/Cleaning	LEADING Indicator

Definition	Formula / Example	Reporting Detail
Median number of days from time DCF response received to time database updated.	Formula: Number of days from DCF receipt to DB updated Specific Example: This measure is the same for paper and EDC studies. Across protocols measure the time in days from when a answered query is received (either in the EDC system, or at the DM site) until the data is updated and the query closed in the system.	
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing the number of data discrepancies identified is an indication of data and/or collection process quality and can improve overall cycle time and resource use for clinical trials.	Additional analysis on a "for cause" basis: Cycle times in excess of target indicate less than optimum processes within the DM organization. Work that is not prioritized, or passed between too many staff members can cause delays.	Quarterly	2 to 3 days

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
22	Q	QC Rounds Required to Meet Target Error Rate	QC/Closeout	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Number of rounds QC required for meet target.	Formula: - Count of required rounds of QC for all studies over a set period averaged. Specific Example: Across protocols, measure the number of times QC has to be accomplished to achieve the contracted DB error rate.	Paper only Target error rate may vary
		Unit of Measure
		Number of rounds % of databases net meeting target

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing the number of rounds of QC required to achieve target error rates: - Reduces time to database lock - Is a clear quality of data indicator - Reduces cost for labor - Provides a higher level of confidence with the customer Reducing the percentage of database transfer delayed: - Assists in meeting DB lock deliverables to the customer. - Reduces cost of DB Lock activities. - Reduces the chances databases need to be reopened.	Additional analysis on a "for cause" basis: - High query rate indicates data issues. - Delay in generating DCFs, and/or receiving responses from sites - Data entry quality. - Level of staff training in Data Cleaning. - Impact of Phase and/or Therapeutic Area.	Quarterly	2 rounds Less than 10%

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
23	CT	LPLV (last patient, last visit) to Database Lock	QC/Closeout	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Median days from last patient, last visit (LPLV) until database is locked by DM ready for SAP.	Formula: Number of days from LPLV to DB Lock (Median). Specific Example: Across protocols measure the number of calendar days to lock each database after the last patient, last visit.	Phase CDMS Type Therapeutic Area
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reduced cycle times for locking a database is more efficient and provides a quality indicator of data collected.	Additional analysis on a "for cause" basis (valid for Paper and EDC). - Extended cycle time contributing factors, including: Delay in receiving CRFs/DCFs from sites, bolus of data at study closeout caused by delays in cleaning, and quality issues.	Quarterly	35 days for paper 21 days for EDC

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
24	CT	SAP Finalization to Final Pre-lock Blinded TLGs	Listings Generation/ Biostatistical Review	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Time from SAP finalization to generation of final draft pre-lock blinded tables, listings, and graphs.	Formula: Difference in dates Specific Example: Across protocols measure the number of calendar days from when the SAP is completed until the TLGs are finalized.	
		Unit of Measure
		Median Days

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Reducing the cycle time for generating draft TLGs will enable much earlier quality reviews and hopefully, result in reduced TLG defects.	Additional analysis on a "for cause" basis: Time from initial draft SAP to initial draft pre-lock blinded TLGs.	per project	TBD

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
25	T	TLGs delivered within target date	Database Delivery/Final	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
<p>Number (%) of TLGs delivered by the original agreed due date.</p> <p>Number of TLG defects due to programming errors (i.e. E1)</p>	<p>Formula: %TLGs delivered on time = $100 * (\text{No. TLGs delivered on time} / \text{total No. of TLGs})$.</p> <p>%TLG E1+E2 defects = $100 * ((\text{no. TLGs with E1 defects} + \text{no. TLGs with E2 defect}) / \text{total no. of TLGs})$</p> <p>Specific Example: Across protocols measure the number of days between the actual TLG delivery dates, compared to the targeted, agreed date. Measure the number that miss the target in terms of a % of total delivered.</p>	<p>Unit of Measure</p> <p>% Defect % Late</p>

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
<p>the defect rate is a surrogate for TLG quality. Evaluating TLG defect rates by key parameters, e.g. therapeutic or project, client name etc., can help the vendor determine areas for improvement and perhaps even their areas of greatest strength.</p>	<p>Additional analysis on a "for cause" basis:</p> <ul style="list-style-type: none"> - Number of revisions of TLG requirements. - Number (%) of TLGs delivered first time right (i.e. with no errors) 	<p>Once for each project.</p>	<p>5% or less for each measure</p>

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
26	E	Determination of project progress versus planned	Earned Value Analysis	LEADING Indicator

Definition	Formula / Example	Reporting Detail
<p>Comparison of the planned amount of work with what has actually been completed to determine if cost, schedule and work accomplished are progressing as planned</p> <p>Schedule Variance is a comparison of the amount of work performed during a given period of time to what was scheduled to be performed and Cost Variance is a comparison of the budgeted cost of work performed with the actual cost. A negative variance means the project is over budget.</p>	<p>Formula: Schedule Variance = BCWP - BCWS Cost Variance = BCWP - ACWP</p>	Unit of Measure
		Percentage

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
<p>EVA provides an early warning signal of variance in cost where a corrective action may be needed. Work is "earned" or credited when it is completed. A key component of this tool is Scope of Work document. The better and more clearly defined the elements of the Scope of Work are, the more value you will get out of the EVA. Work not included in the SOW requires a change order. Scope documents must have well-defined deliverables, a timeframe for delivery that is agreed between the parties, and the proposed (agreed) costs to deliver the product. The EVA will help you to understand not only if things are on schedule, but if both parties are truly gaining value from the work completed and the money spent. You will have some confidence or lack thereof in the FTE allocation based on this metric.</p>	<p>Additional analysis on a "for cause" basis:</p> <p>Schedule Performance Index (SPI): $SPI = BCWP / BCWS$; $SPI < 1$ means project is behind schedule.</p> <p>Cost Performance Index (CPI): $CPI = BCWP / ACWP$; $CPI < 1$ means project is over budget.</p> <p>Cost Schedule Index (CSI): $CSI = CPI \times SPI$; The further CSI is from 1.0, the less likely to have project recovery.</p>	<p>Ongoing throughout contract period; quarterly or when a milestone is completed</p>	<p>>90%</p>

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
27	TBCT	Invoice and payment timeliness	Invoice and Payment	LEADING Indicator

Definition	Formula / Example	Reporting Detail
The percentage of "On Time" payments.	Formula: Total number of invoiced payments received by CRO within the specified contract time / Total number of invoices issued x 100. Cash Collection: average # of days from invoice date to invoice paid / number of invoices compared with contract terms for payments due	
		Unit of Measure
		Invoices

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
You will have a better understanding of your cash flow by being informed of the general quality of the payment process, including the accuracy and timeliness of the invoice, the efficiency of the Sponsor's payment process, and the speed of final payment.	Additional analysis on a "for cause" basis:	Quarterly	Late <10%
	Number of days from event/milestone occurrence to invoice date;		
	Number of days from invoice date to date received by Sponsor;		
	Number of days from invoice date to receipt of payment by CRO		

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
28	Q	Issue identification, management and criticality	Governance/ Issue Escalation Resolution	LAGGING Indicator

Definition	Formula / Example	Reporting Detail	
<p>The identification and management of issues of nonconformity of such actual, potential or perceived severity that their existence would indicate that the nonconformity could compromise the validity and/or integrity of study data or the entire project or put the project at significant risk for cost over-runs or completion.</p> <p>The total number of major/critical issues requiring a party to escalate (beyond the PM) within/between management.</p>	<p>Formula: see EVA; Formula: # of potential major/critical issues escalated for resolution</p>	Unit of Measure	
		Percentage	Number

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
<p>Project governance is the process by which a project is managed and supported at the highest organizational level necessary to ensure its successful completion. Project governance is an active rather than a passive process. Utilizing project governance you will be able to evaluate and monitor the: relationship between the parties involved in the project; project cost and resourcing (planned versus actual) at periodic intervals; flow of information regarding the project; review of potentially critical issues encountered within a project and planned direction for the project through the various project stages.</p>	<p>Additional analysis on a "for cause" basis:</p> <p>Time for critical issue identification and resolution; Total number of Key Staff lost due to removal at Sponsor's/CRO's request; Total number of issues identified; Major deviations from Project Plan</p>	As needed	

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
29	OBJECT	Measure of true change orders and timeliness of execution	Contract Amendments / Change Order (CO) Management	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
The percent of COs that are based on protocol amendments or new Sponsor requests. The percent of COs that are based on protocol amendments or new Sponsor requests.	Formula: # of change orders protocol driven / total # of change orders (= the percentage of change orders that result from a true scope change). Number (#) of days from CO identification to written work authorization; Number (#) of days from CO identification to final CO / contract amendment; # of review cycles; reasons for COs.	
		Unit of Measure
		Percentage

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
You will be informed of the accuracy of the service providers planning and budgeting. You will have some prediction of under resourcing in future bids and proposals. You will determine how well the parties defined the initial scope of work that was agreed upon. A high percentage indicates that the parties were well aligned in the initial work order. You will be informed of the number of days a service provider's ability to finalize the work plan and associated costs and well as obtain legal agreement for a contractual agreement.	Additional analysis on a "for cause" basis: The total number of days from scope change notification to written authorization to start work, to finalization and full execution of the change order/contract amendment. Total number (#) of sequences/rounds of review to achieve finalization. Reasons for change orders.	Per CO	>90%

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Clinical Trial Performance Metrics (beta version)

Metric #	Metric Type	Metric Title	Category	Metric Indicator
30	E	Budget and pricing accuracy	Budget/ Pricing	LAGGING Indicator

Definition	Formula / Example	Reporting Detail
Initial contract value of executed initial agreement plus the "true" change orders to total final cost of trial/contract. Calculate the actual \$\$ and % variance from the budget/total contract value from the initial proposal plus true changes orders submitted to the final actual budget (including all change orders)	Formula: Difference in \$\$ between proposal and final budget and the % variance of that difference Specific Example: Cost of initial proposal plus true changes orders is \$38,000,000 and the total final cost for initial proposal and all changes orders is \$40,000,000, The difference is \$2M or 95%	Unit of Measure
		Total \$\$ difference % variance

Business Driver(s) / Benefit Statement	Additional Analysis on a "for cause" basis	Reporting Frequency	Target
Initial proposal may be used to estimate the total cost of the project and may be used in annual budget planning. The final contract value will show the full cost of the study conduct and if significantly higher can impact the company's overall clinical development budget allocation. Need to be able to predict costs and gain an understanding of how well the project was planned/scoped to avoid "scope creep", unexpected resource demands, inflated cost of trial conduct, etc.	Additional analysis on a "for cause" basis: Quarterly or annual review of actual budget and projected costs to monitor the project budget to determine if the costs are in alignment with the overall budget. EVA below for resource monitoring. Evaluation of projected and actual pass through costs	Ongoing throughout contract period; quarterly or annually	>90%

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