iisra

INVESTIGATOR INITIATED - SPONSORED RESEARCH ASSOCIATION

Position Statement:

Metrics Application Promotes Enhancements to an Investigator Initiated-Sponsored Research (IISR) Program Leading to Higher Scientific and Medical Integrity

Disclaimer: This document should not be construed as providing legal advice. Each company has its own unique program goals and level of risk tolerance. Ultimately, each company should consult their management staff and legal counsel when designing their IISR program.

Purpose

This position statement is designed to list the benefits of metrics analyses, and to provide practical guidance for the incorporation of metrics into an Investigator Initiated-Sponsored Research (IISR) Program.

Definition of Metrics

Business metrics are part of the broad area of business intelligence, which comprises a wide variety of applications and technologies for defining, gathering, storing, analyzing, and utilizing data to help users make more informed business decisions. Measurement of quantifiable components of organization performance can support business strategy decisions and help create more precise organizational goals. Importantly, well-captured metrics also serve as a powerful tool to highlight organizational achievement.

General Overview

This position statement addresses the benefits that can result from systematic utilization of metrics in any IISR program including growth, efficiency, financial, operational, and manpower performance. The value proposition for your IISR program is particularly important to senior management because it can determine a company's decision to support IISR. This position statement will outline steps required for implementation of successful metrics, starting with identification of summary requirements, and continuing with detailed information on design, implementation, analyses, and reports/recommendations for program improvements. Additionally, types of metrics will be identified (growth, efficiency, financial, operational, and manpower) for consideration in measuring and managing your specific IISR program goals.

Introduction to Effective Metrics

Companies supporting IISR programs in the pharmaceutical, biotechnology, and device industries benefit when internal controls are established for IISR proposal submissions, evaluation, funding, and management processes. Use of metrics allows for more accurate program assessment and can identify both strong and weak aspects of the IISR program. Determining project level metrics can be difficult because of the numerous tasks that must be considered in order to produce a single representative productivity measurement that is credible. There are a vast number of different parameters and sub-parameters available for measurement. It is important to identify the most beneficial and meaningful metrics for ongoing assessment and improvement to your IISR program.

Value Proposition to Senior Management

An IISR program should be able to identify, measure, and report value to senior management, particularly in the following areas

1. Data generation and dissemination, including the following
    a. Publication of abstracts, manuscripts, and posters
    b. Oral presentations and educational symposia
    c. Final study reports
2. Product research through Phase I/II pilot studies that
    a. Inspires novel research ideas for further exploration
    b. Provides data for potential future indications
    c. Provides supporting evidence to be used in the creation of Phase III trials
    d. Expands safety information
3. Enhanced communication with industry leaders at advisory panels, speaker events, and community meetings
4. Ongoing IISR program performance improvements for key areas
    a. Efficiency and effectiveness of the proposal evaluation process
    b. Identification and correction of common bottlenecks (eg, budget submissions, legal reviews, contract approvals)
    c. Study milestone monitoring (eg, patient enrollment)
5. Specific and measurable productivity that
    a. Clarifies performance objectives
    b. Identifies successful investigators
    c. Promotes better resource and manpower allocations

Summary Requirements for Effective Performance Metrics

Pre-Planning: Project level metrics requires forethought and planning.

Priority Setting: High numbers of metric evaluations are available for consideration.

Defined IISR Process - Requires standard operating procedures (SOPs) and team training to address the following main components of the IISR process

- Registration
- Submission
- Review/Decision
- Milestone Management
- Reporting
- Administrative Support

Centralized Database (Repository): Useful for providing credible, available, and auditable data source.

Dedicated Manpower: Responsible for timely and accurate data entry of required information.

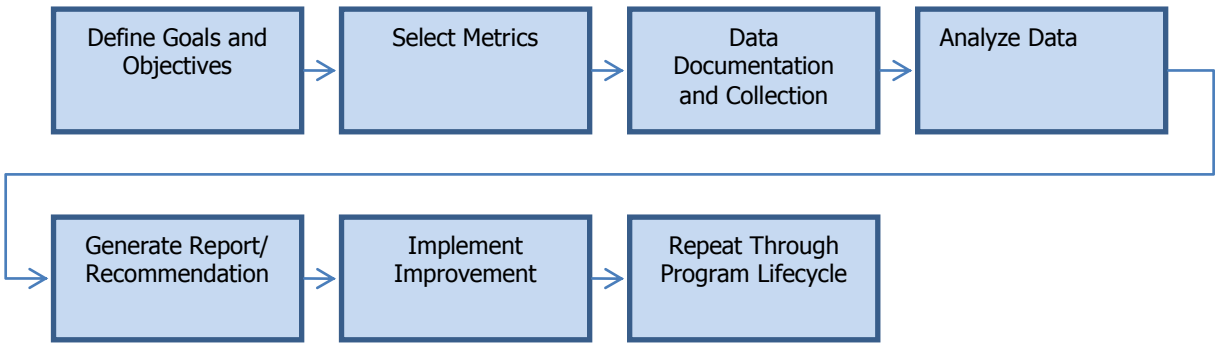
Data Collection: Reliable and consistent collection of information.

Follow Through on Findings: The measure of success is actionable data.

Design, Implementation, Data Analyses, and Reporting

The following steps identify design, implementation, data analyses, and reporting components for metric generation.

Figure 1: Metric Process



1. Define Goals/Objectives
    a. Define desired goals/objectives for continual improvement of the IISR Program. The metric choices to achieve those goals provide greater value if they are
        i. Specific, where you understand exactly what the metric will measure. It is best not to be ambiguous, or to use aggregate variables, which can confuse the data analysis. It is helpful to segment metrics into specific categories, such as registration, submissions, reviews, decisions, monitoring, reporting, and administration support.
        ii. Measurable (quantitative), preferably with a direct measurement rather than a correlative result. (Example: Measuring new investigator registrations may have limited value. Measuring new Investigators that received concept approvals, or met study milestones may have greater value.)
        iii. Clearly understood, where the data collected is supportive of the information desired.
        iv. Utilized with the appropriate perspectives. Design clear metrics with specific and observable criteria, but interpret data within the context of the broader end purpose. (Example: My process is working well because despite fewer grant approvals this year, the approved studies have resulted in a higher number of 1) completed studies and 2) submitted publications.)
    b. Solicit input from operational/functional group managers and staff.
    c. Prioritize specific metrics for initial evaluation (choose initial metrics that are most meaningful and easy to track); progress to more involved metrics later.
    d. Use a reasonable number of metrics (too many or too few measurements may lead to unreliable and unsatisfactory results).
2. Select Metrics
    a. Determine key information upon which important decisions/improvements will be based.
    b. Define metrics clearly and precisely.
    c. Create specific data fields within your data collection system to capture the information of interest.

3. Data Documentation and Collection
    a. Aim to establish a comprehensive and reliable centralized tracking system
        i. Spreadsheets
        ii. Commercial software
        iii. Web-based system (internal or vendor website)
    b. Determine responsibilities
        i. Data collection
        ii. Data entry
        iii. Data analysis
        iv. Report generation and presentation
        v. Implementation
4. Analyze Data – A variety of statistical techniques (alone or in combination) should be considered for metrics analyses including descriptive and inferential statistics.
5. Generate Report and Recommendations
    a. Provide reports identifying 1) strong areas, 2) weak areas, 3) trends, 4) program quantifications, 5) changes over time, and 6) recommendations. Discuss report conclusions and recommendations with invested parties.
    b. Strategize with invested parties to determine new goals and actions items (Note: Key areas for improvement often involve concept/proposal submissions, evaluation timing, and ongoing study tracking).
6. Implement Performance Improvement.
7. Repeat Through Program Lifecycle - Revisit and refine IISR goals/objectives on a regular basis.

Types of Metrics

Metric categories are identified below with a short list of examples per category. Refer to Appendix A "Listing of Potential Measurements" for a more comprehensive list of specific metrics.

1. Growth Metrics
    a. Volume of submissions
    b. Volume of approved protocols/atudies
    c. Volume of publications

2. Efficiency Metrics (time based; cycle times)
    a. Internal efficiency
        i. Time from submission to review decision
        ii. Time from approved proposal to executed contract (expectations linked to local/global, single site vs. cooperative group, etc)
        iii. Reviewer tracking from initiate review date to completion of review
    b. External efficiency
        i. Time from Letter of Intent (LOI) to submission
        ii. Time from approved study to critical study milestones (ie, IRB approval, study initiation, first subject in / last subject out, enrollment, study close out, publication, etc)
3. Financial Metrics
    a. Track individual studies or overall program expenditures against risk/benefits
    b. Financial tracking of specific study milestones against baseline dates to manage forecasting and cash flow
        i. Project initiation
        ii. Enrollment progress
        iii. Study completion
        iv. Publication submission (abstract/manuscript)
4. Operational Metrics
    a. Number of study completions vs. number of studies completed on time
    b. Number of publications vs. number of publications meeting desired timelines
    c. Total annual funding vs. number of resulting publications
5. Manpower Resource Metrics
    a. Total number of FTEs that manage 1) submissions and reviews and 2) active studies (Note: caution should be used if metrics are used to gauge individual performance)
    b. Administrative support – restructure to maximize efficiencies of system administrators, functional support (eg, legal, contracts, regulatory, etc), information technology (IT) support, etc.
    c. Investigator performance tracking (number of approved protocols, efficient enrollment, study conclusions, timely publications)

Conclusion – Capturing, analyzing and reporting on metrics can play an important role in any IISR program. Benefits include

- Demonstrating IISR program value to executive/senior management
- Improving operational effectiveness and efficiencies (process, financial, and manpower)
- Helping achieve overall IISR goals/objectives
- Ultimately, improving patient outcomes

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