
SCDM 2017
ANNUAL CONFERENCE
September 24-27 I Orlando
SCDM
Society for Clinical Data Management
DATA DRIVEN
SDV – What Is It Good For?
Absolutely Nothing!
Khushnoor Dastoor
Executive Director & Head QA
PPCE

SDV- What is good for? Absolutely nothing!

Considering the cultural aspect of SDV
to provide a more balanced approach for increased trial efficiency

TABLE OF CONTENTS

AN INTRODUCTION OF THE FACTS AS THEY STAND

1.1% of changes are a direct result of SDV.

RBM: an industry buzz word. Processes evolving around dynamic risk analysis.

Shiny new technology allows us to investigate, forecast and predict like never before.

Sites do not generally form an integral part of the communication chain when it comes to technological upgrades and strengthening of a sponsor's processes and Standard Operating Procedures.

WHAT SPONSORS WANT

Economics

- To use resources more intelligently

Integrity

- To let automation do what it does best

Efficiency

- To improve clinical trial success rates

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"I'd like to meet you halfway, but I'm terrible with fractions."

WHAT SITES WANT (AN SCRS PERSECTIVE)

Integration
- When disruptive methods/technology implemented

FEEDBACK!
- When they get it right, when they get it wrong

Interaction
- Continued CRA contact

Don't add to the burden
- Scanning and faxing documents offsite is not efficient

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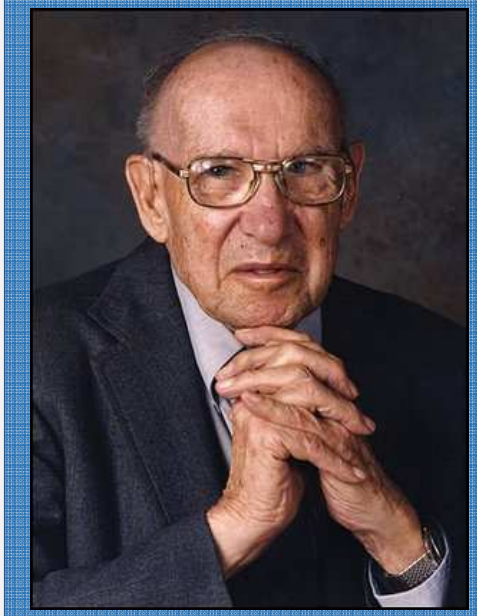
THE SPONSOR PERSPECTIVE



"There is nothing so useless as doing efficiently that which should not be done at all."

Peter F. Drucker

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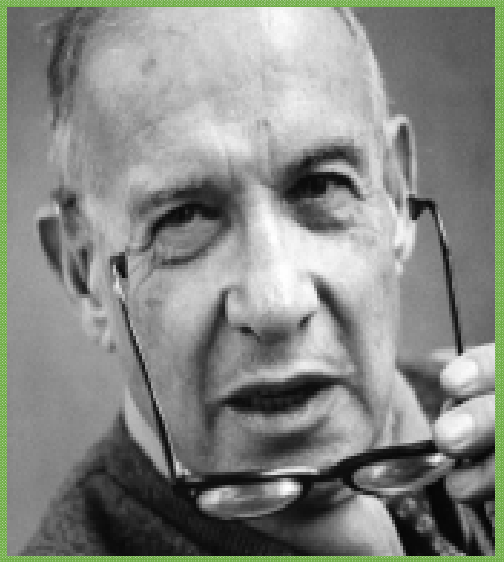
WHAT THE SITE THINKS OF THAT PERSPECTIVE

"Culture Eats Strategy for Breakfast"



Peter F. Drucker

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AN INTRODUCTION TO DANIEL GOLEMAN

"In a very real sense we have two minds:

One that thinks,

and one that feels"

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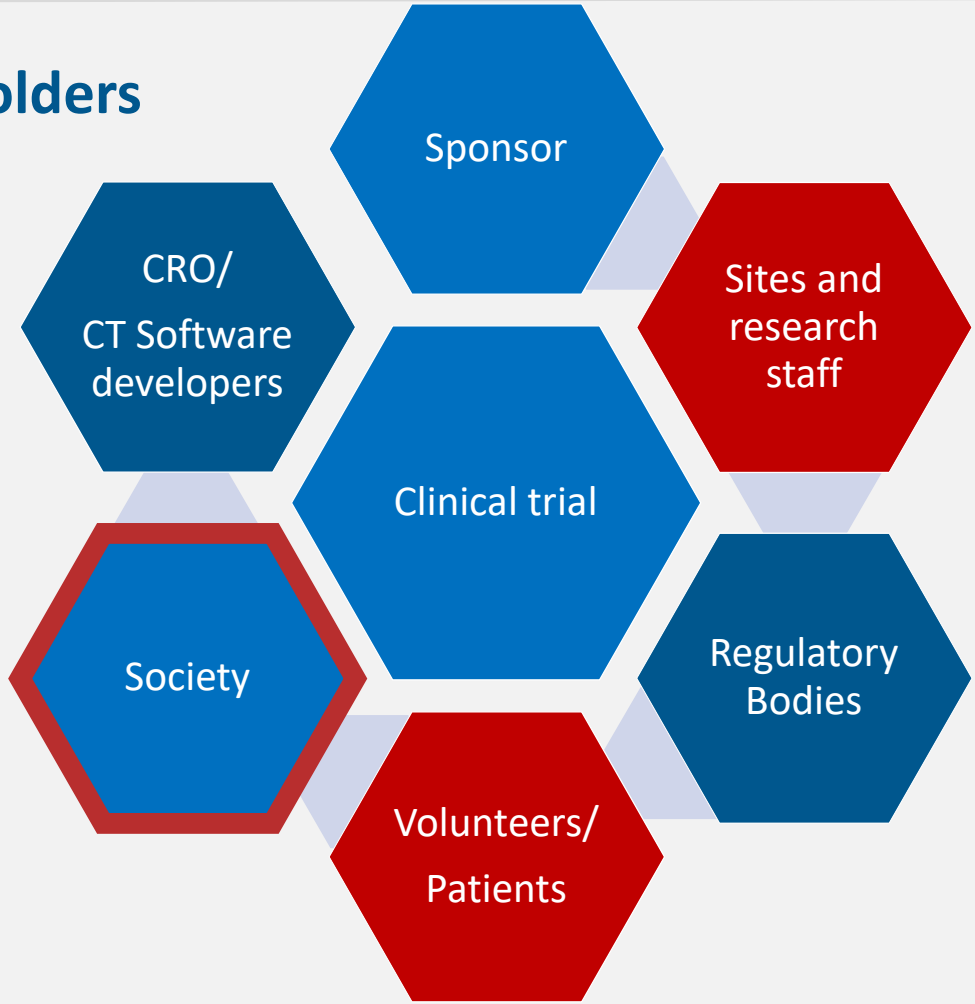
OF MINDS THAT THINK AND MINDS THAT FEEL…

Key Stakeholders



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CASE STUDY: BACKGROUND

- Oncology trial
- Other trials for several indications based on the same IP
- 2 sites in Eastern Europe have been involved in several other trials for the same IP
- Some sites are less technologically adept and are still involved in mostly paper trials
- The CRA is a trusted ally and the bridge between the sites and the sponsor
- Rank as the Top 2 for the largest number of queries and open queries on an ongoing study
- Rank as the Top 2 for average re-query rates on the previous study on an ongoing study

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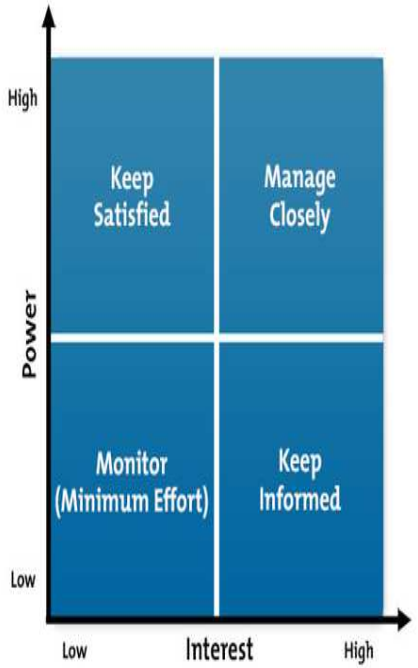
CASE STUDY: STAKEHOLDER ANALYSIS

QF-71-01-1 Risk Assessment and Control Plan

Power/Interest Grid for Stakeholder Prioritization



SWOT Analysis

Sr. No	Key Stakeholder	Interaction	Power of Influence	Interest	Prioritization	Strengths	Weaknesses	Opportunities	Threat

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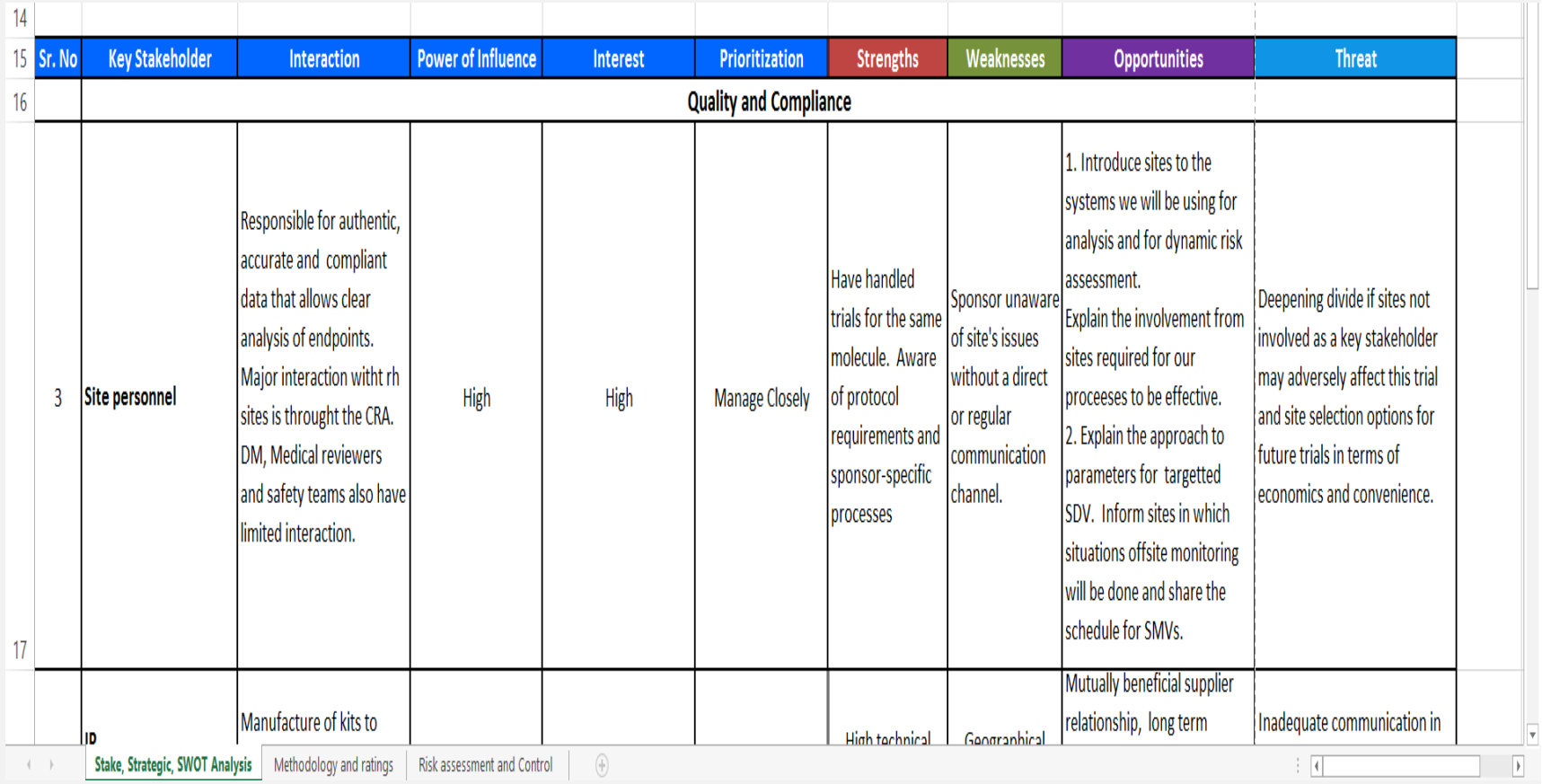
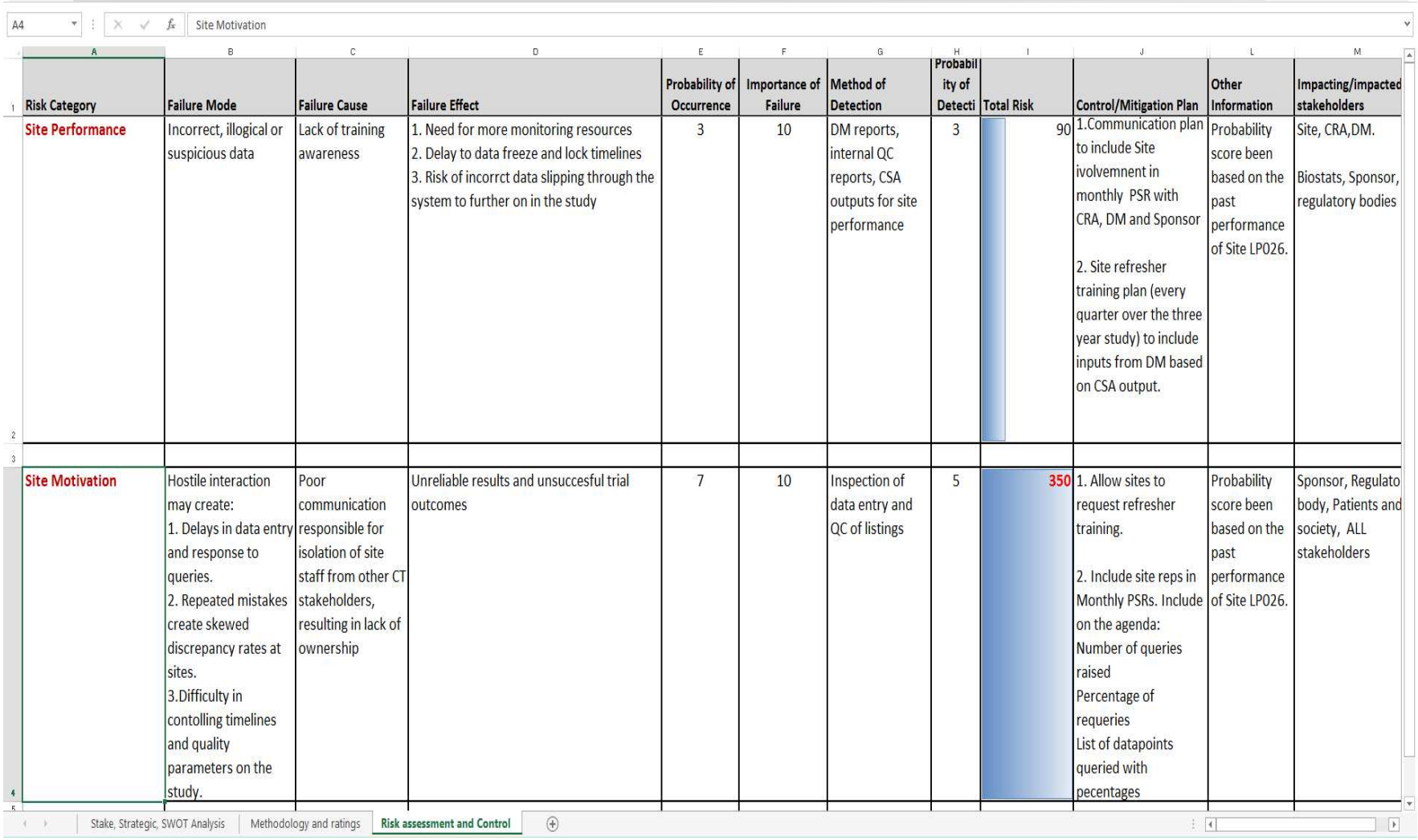
CASE STUDY: RISK INDICATORS



Sr. No	Key Stakeholder	Interaction	Power of Influence	Interest	Prioritization	Strengths	Weaknesses	Opportunities	Threat
	Quality and Compliance								
3	Site personnel	Responsible for authentic, accurate and compliant data that allows clear analysis of endpoints. Major interaction witht rh sites is throught the CRA. DM, Medical reviewers and safety teams also have limited interaction.	High	High	Manage Closely	Have handled trials for the same molecule. Aware of protocol requirements and sponsor-specific processes	Sponsor unaware of site's issues without a direct or regular communication channel.	1. Introduce sites to the systems we will be using for analysis and for dynamic risk assessment. Explain the involvement from sites required for our proceeses to be effective. 2. Explain the approach to parameters for targetted SDV. Inform sites in which situations offsite monitoring will be done and share the schedule for SMVs.	Deepening divide if sites not involved as a key stakeholder may adversely affect this trial and site selection options for future trials in terms of economics and convenience.
	ID	Manufacture of kits to				High technical	Geographical	Mutually beneficial supplier relationship, long term	Inadequate communication in

Stake, Strategic, SWOT Analysis | Methodology and ratings | Risk assessment and Control

CASE STUDY: EXTRACT FROM THE RISK ASSESSMENT PLAN FOR THE STUDY



A4 | Site Motivation

Risk Category	Failure Mode	Failure Cause	Failure Effect	Probability of Occurrence	Importance of Failure	Method of Detection	Probability of Detecti	Total Risk	Control/Mitigation Plan	Other Information	Impacting/impacted stakeholders
Site Performance	Incorrect, illogical or suspicious data	Lack of training awareness	1. Need for more monitoring resources 2. Delay to data freeze and lock timelines 3. Risk of incorrct data slipping through the system to further on in the study	3	10	DM reports, internal QC reports, CSA outputs for site performance	3	90	1.Communication plan to include Site ivolvemnent in monthly PSR with CRA, DM and Sponsor 2. Site refresher training plan (every quarter over the three year study) to include inputs from DM based on CSA output.	Probability score been based on the past performance of Site LP026.	Site, CRA,DM. Biostats, Sponsor, regulatory bodies
Site Motivation	Hostile interaction may create: 1. Delays in data entry and response to queries. 2. Repeated mistakes create skewed discrepancy rates at sites. 3.Difficulty in contolling timelines and quality parameters on the study.	Poor communication responsible for isolation of site staff from other CT stakeholders, resulting in lack of ownership	Unreliable results and unsuccesful trial outcomes	7	10	Inspection of data entry and QC of listings	5	350	1. Allow sites to request refresher training. 2. Include site reps in Monthly PSRs. Include on the agenda: Number of queries raised Percentage of requeries List of datapoints queried with pecentages	Probability score been based on the past performance of Site LP026.	Sponsor, Regulato body, Patients and society, ALL stakeholders

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CASE STUDY: SITE INPUT TO THE RISK ASSESSMENT PLAN

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	Risk Category	Failure Mode	Failure Cause	Failure Effect	Occurrence	Failure	Detection	Detecti	Total Risk	Control/Mitigation Plan	Information	stakeholders
5												
6	Site Timelines	Review of site action (CRA, DM, Medical Review) is often delayed, creating pressure on sites to complete subsequent actions under compressed timelines.	Timelines not adhered to by other stakeholders	Delays to key milestones	7	7	Study Metrics for Data capture, SDV and DM Review, Query Aging Report	1	49	Incude metrics for all stakeholders in monthly PSRs for greater accountability.	Risk identified by site based on previous studies	Site, Biostatistics, Regulatory Body

HARNESSING TECHNOLOGY TO IMPROVE HUMAN RELIABILITY

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- **Can Site Performance dashboards help:**
  - Provide feedback for when sites get it right? ☑
  - Provide feedback for when sites get it wrong? ☑
- **Can statistical models help:**
  - Alert CRAs by flagging inauthentic data? ☑
  - Shine a light for sites on the probability of meeting site freeze timelines? ☑
  - Forecast the probability of an AE based on lab value trends? ☑

(AN AMICABLE) CONCLUSION

- Broaden the perspective on Centralized Monitoring
- Involve sites in the creation of the Risk Assessment plan.
  Communicate regarding technologies like eSource.
- Decide on the control centre for monitoring and communication
- Decide on a site monitoring mix based on Compliance, Complexity, Competence and Communication
  tSDV, rSDV, metrics and dashboard reviews, refresher training
- Create ownership and make sure all stakeholders are on the same side to exploit current technology to its fullest potential.