



CHALLENGES INVOLVED IN PROJECT MANAGEMENT

Aditi Bose & Khushnoor Dastoor

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 - Humans & Projects – A comparison
 - Healthy vs. Unhealthy project
 - Symptoms of inefficiency
- **Project Management**
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- **Summary**



Vital Signs (Health Indicators)

Humans

Temperature

Heart Rate

Respiratory Rate

Blood Pressure

Projects

Commitment

Communication

Consistency

Proactiveness



Healthy Project

SYNCHRONIZED

Commitment, Communication,
Consistency & Proactiveness

• Clinical
Operations



• Sites



• Data
Management

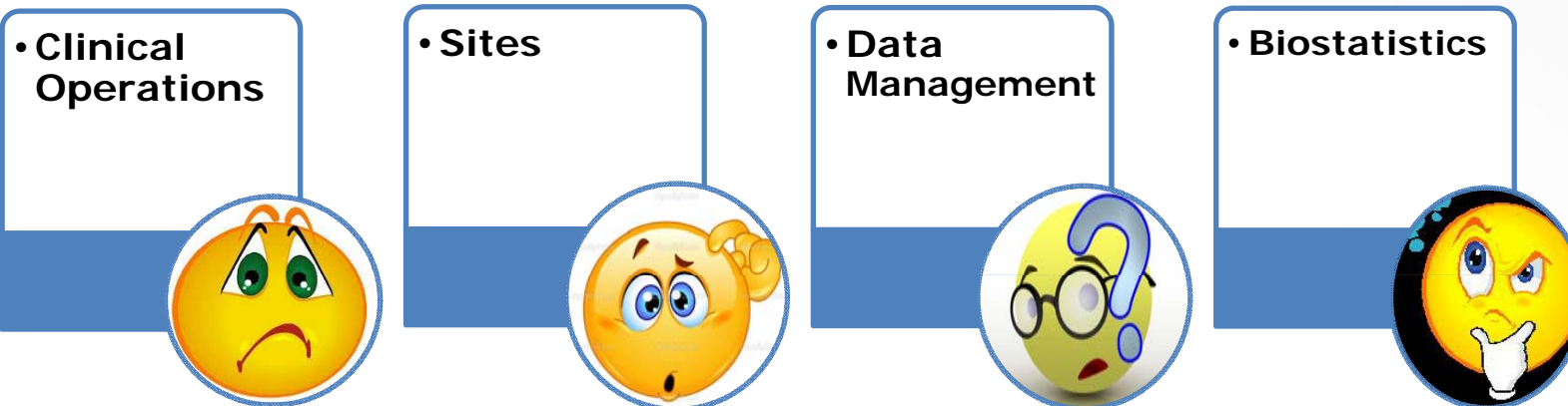


• Biostatistics



Unhealthy Project

UNSYNCHRONIZED
Commitment, Communication,
Consistency & Proactiveness



Symptoms

INEFFICIENCY

- Requirements of a regulation being overlooked
- Ignoring risks
- High employee turnover & resources performing under stress
- Disgruntled customers



Symptoms

INEFFICIENCY

- Shoddy documentation
- Quality checks in haste
- Squeezed timelines
- Unclear priorities

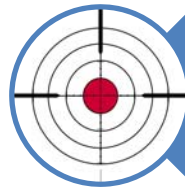


PROJECT MANAGEMENT

Parameters of Project Success, Challenges, Causes & Treatment



Parameters of Project Success



On Scope



On Budget



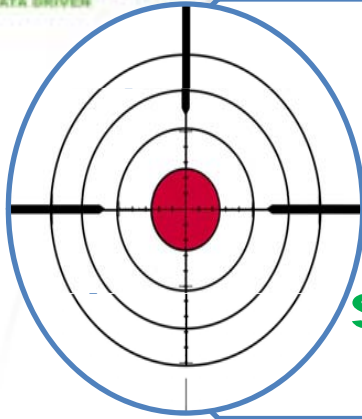
On Time



On Quality



Challenges



Managing frequent small changes
in **Scope**

Negotiating skewed perception of
small changes vis-à-vis actual effort
required



Bridging the gap between scope
and **Budget**

Building a Limo with a Volkswagen
budget





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Challenges



Controlling **Time** when input dependent on others' output

Dealing with procrastination



Ensuring **Quality** with junior resources on the team

Delivering 100% Quality with available competencies



Causes & Treatment

Planning

Conduct

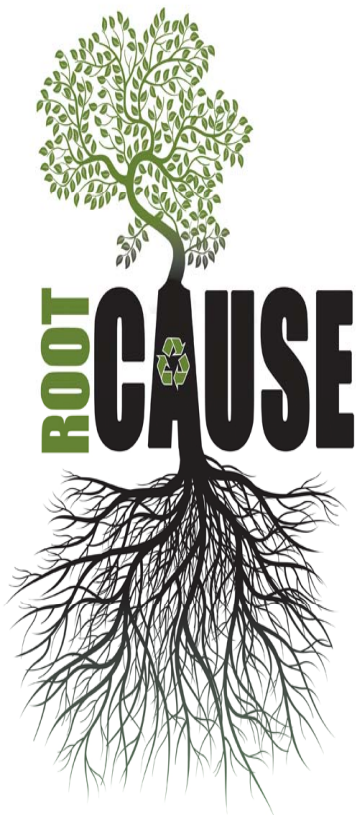
Close-out





PLANNING STAGE





- **Ill-defined** scope of work
- Forecasting **overly optimistic** timelines
- Approvals for important planning documents from **inappropriate** authorities
- **'Head-in-the-sand'** attitude





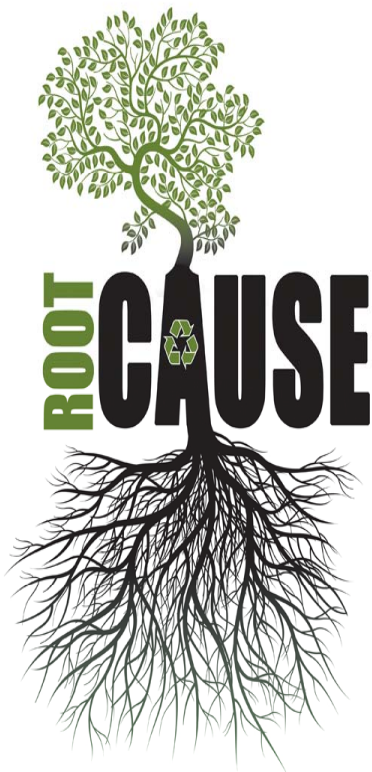
- Involving people with **right expertise** to review and approve planning documents
- Keeping **stakeholders aware** of miniscule changes in scope and its impact on cost and timelines
- Identifying risks and planning for **back-up**
- A robust monitoring process for KRAs with an aggressive focus on **timelines** at this stage





CONDUCT STAGE





- **Unanticipated illogical data** received from sites for which no edit check was planned
- **Unexpected volume** of unclean data from the sites
- **Site-level differences** in completing CRFs leading to consistency issues
- **Delay** in completion of CRFs and DCFs impacting database lock milestone





- Implementing a site-level contingency plan based on **real-time data** pattern
- **Educating sites** about query and inconsistency possibilities by drafting robust CRF Completion Guidelines
- Sharing **site performance reports** and associated project risks with stakeholders
- Focusing on **analyzability** of data and **training** of DM team



Site Performance Indicators

1

- CRF Receipt Frequency

2

- Number of queries/re-queries raised

3

- Query TAT and query aging for each site

4

- Data points for which maximum number of queries raised

5

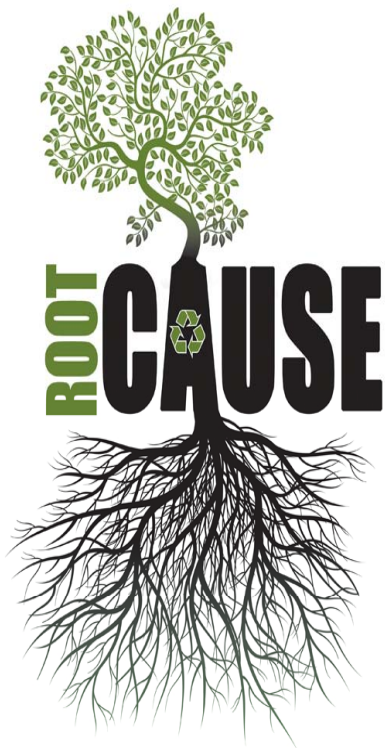
- Illogical application of ND and NA values





CLOSE-OUT STAGE





- **Data** not meeting analysis/regulatory endpoints
- Failure to understand the requirements of the **software** being utilized for analysis





- Obtaining **clarity** on data format requirement for analysis at the planning stage

(ISO 9001 Clause 7.3.2)

- Obtaining Biostats **approval** for key documents that impact data

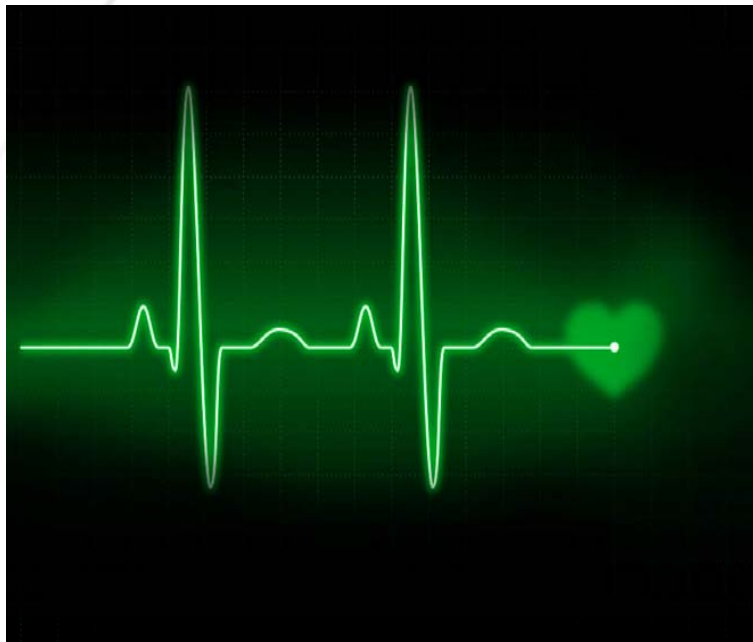
(ISO 9001 Clause 7.3.2)

- **Sharing** data periodically with Biostats to identify systemic data issues early on

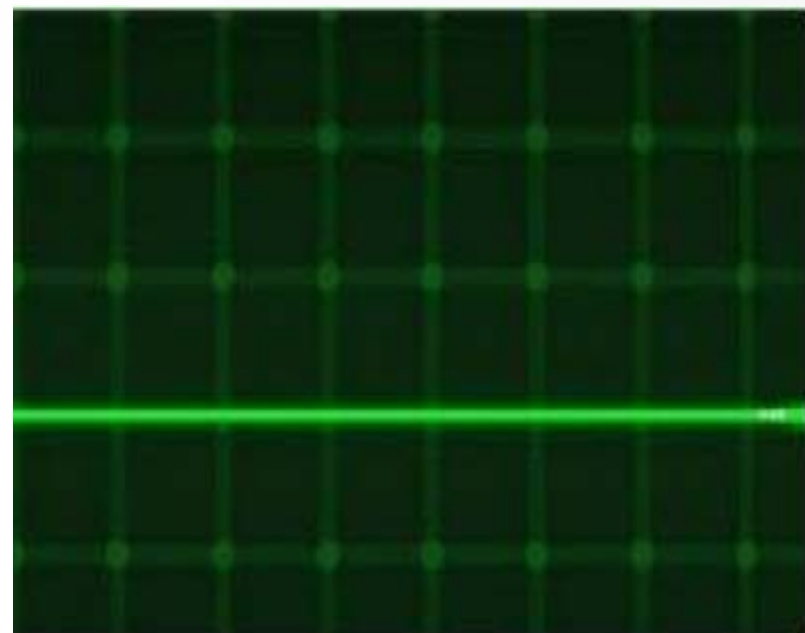
(ISO 9001 Clause 7.3.4)



Summary



**Highs and Lows are part of
Human and Project life!**



**Ignoring warning signs can
be fatal for both!**





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