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KRI and KPI Prioritization for Life Sciences Industry from Business Intelligence

Mrudula M. Pardeshi
Management Student, Prin. L. N. Welingkar Institute of Management and Development Research, Matunga, Mumbai, Maharashtra, India

Abstract:
Life Sciences industry today faces a critical challenge when it comes to risk tacking and risk prioritization in the Phase 3 of clinical trials. Pharmaceutical companies have huge volumes of data that is gathered over the span of the trial, and even more detailed data during the human drug testing phase. The data collected is huge in volume, the analysis of this humungous data and finding the pain points ID of the biggest challenges this industry faces.

Keywords: *Pharmaceutical trials, phase 4, phase iv, QLIK view introduction*

1. Introduction

The Clinical Trial Industry which forms a very crucial part of the Life Sciences industry is expected to grow $64 B by 2020, up from $38.4 B at present, representing a CAGR of 9% between 2015 and 2020. [1] The research and development arm of the company forms a major pillar of the company. A huge sum is invested by the company every year to maintain the flow of the clinical trial.

Observations about study subjects are normally collected for all subjects in a series of domains. A domain is defined as a collection of logically related observations with a common topic. The logic of the relationship may pertain to the scientific subject matter of the data or to its role in the trial. Each domain is represented by a single dataset. Each domain dataset is distinguished by a unique, two-character code that should be used consistently throughout the submission. This code, which is stored in the SDTM variable named DOMAIN, is used in four ways: as the dataset name, the value of the DOMAIN variable in that dataset, as a prefix for most variable names in that dataset, and as a value in the RDOMAIN variable in relationship tables. All datasets are structured as flat files with rows representing observations and columns representing variables. Each dataset is described by metadata definitions that provide information about the variables used in the dataset. The metadata are described in a data definition document named ―define‖ that is submitted with the data to regulatory authorities [3].

The clinical trial is spread over various phases namely:

- Phase I
- Phase I
- Phase III
- Phase IV

The phase III and phase IV are the most important in this process involves the human drug testing and the FDA approval for commercial purpose. The company invests a huge financial amount in this clinical trial process. The span where the trial ranges is 8 to 12 years.

The pharmaceutical company after investing such huge amount expects to find milestones with the data that is collected over the years. Any key finding that is hidden under such huge amount of data and goes unnoticed will cost the company a fortune.

The major problems that the pharmaceutical company faces are as:

- Data collection in the orderly manner
- Data analysis
- Deduction of meaningful inferences
- Monitoring over the risk areas

2. Analysis of the PAIN PONTS

2.1. Data Collection in the Orderly Manner

The data that is collected is not in the same format. The fundamental unit of any trial is the availability of a patient who fits the inclusion exclusion criteria of any clinical trial [2]. The data that is being collected for this patient is sometimes not in the standard format due to technical or human error, e.g. the age of a certain person needs to be recorded and is recorded numeric instead of character i.e. 37 instead of thirty-seven. This leads to a difference in the actual and expected results. This captured data is then stored in tabular format which is referred to as domains.

2.2. Data Analysis

The above problem if persists over a large volume of data that is collected over the time period gives rise to the problem of incorrect data analysis. Due to the discrepancy in the collected data, the computational system that is being used for analysis creates a wrong result.

A wrong result may over shadow the key finding that could lead to a breakthrough in the research and development process. The analysis of the data that is collected at the patient level then aggregated to the race, ethnicity or gender on after the analysis of the effects of the drug. This generalization is then reflects as a side effect warning at times or the aggregated analysis may lead to a change in composition of the compound being used in the drug.

2.3. Deduction of Meaningful Inferences

The analysis of the data leads rock solid findings. These findings then form the base of the inferences that are later derived. A misinformation can lead to gaps in the efficacy and efficiency of the drug.

2.4. Monitoring Over the Risk Areas

The fundamental unit for the data collection is a Clinical trial Site. The site as it is usually referred to be abstract, the physical aspect of it is the medical center i.e. the hospital. A hospital can have various patients undergoing treatment for various illnesses. These areas where patients with common illness in the same medical center undergo treatment is referred to as Site. Hence the absence of a physical nature to Site.

Every site has a site monitor who monitors over the periodic reporting of the patients, their timely dosage and exposure tracking. The site monitor reports to the principal investigator. The principal investigator (PI) if often a doctor who specializes in the illness under treatment. The PI then reports the finding to the Clinical trial Research and Development team. These findings along with the data analysis are used to increase the drug efficiency leading to a better cure.

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- Fraudulent data entries
- Analysis of dataset with these fraudulent entries
- Monitoring the behavior of the site
- Tracking the performance of the site
- Tracking patient consistency
- Tracking patient adverse reactions
- Tracking the adverse reactions related to the Drug

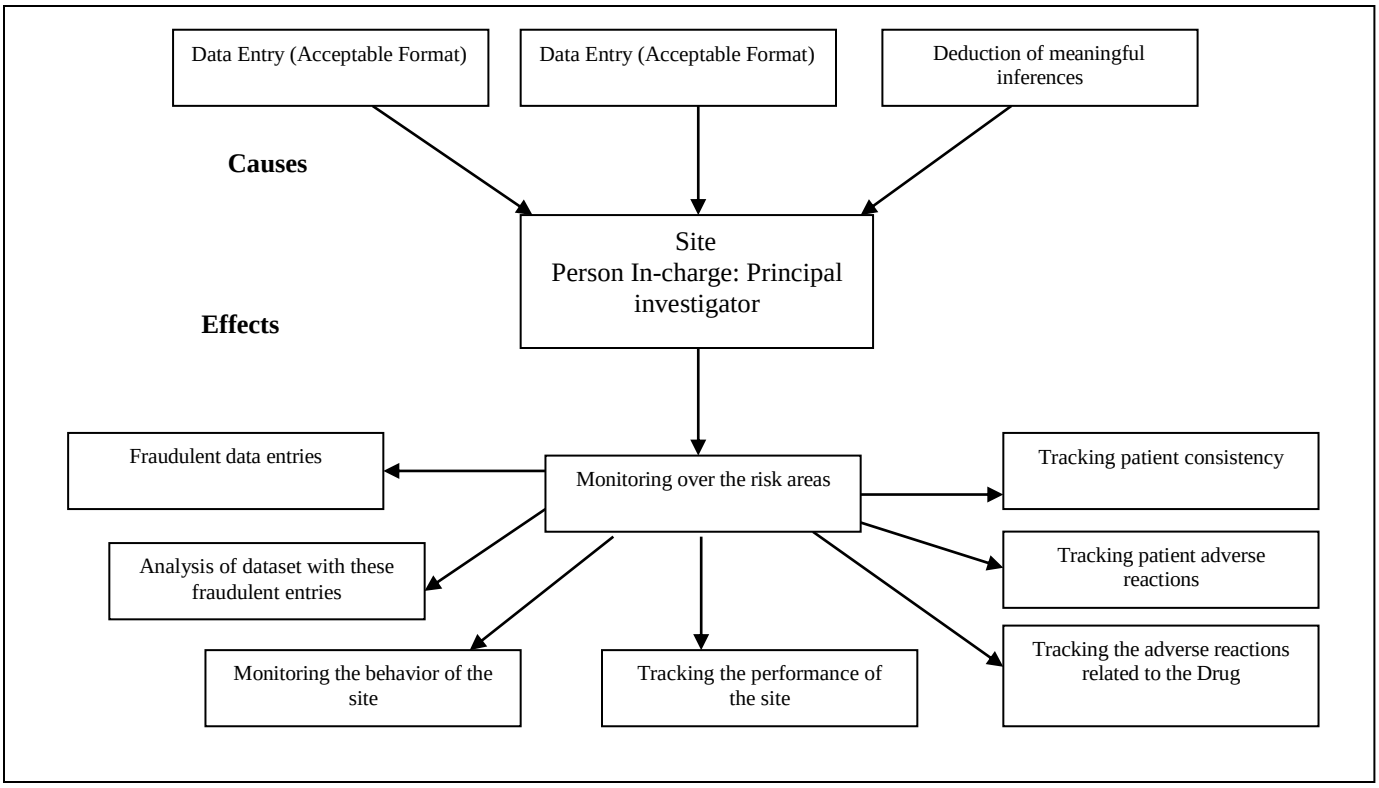

Figure 1: Block diagram representing the cause effect analysis of a Site Deduction of meaningful inferences

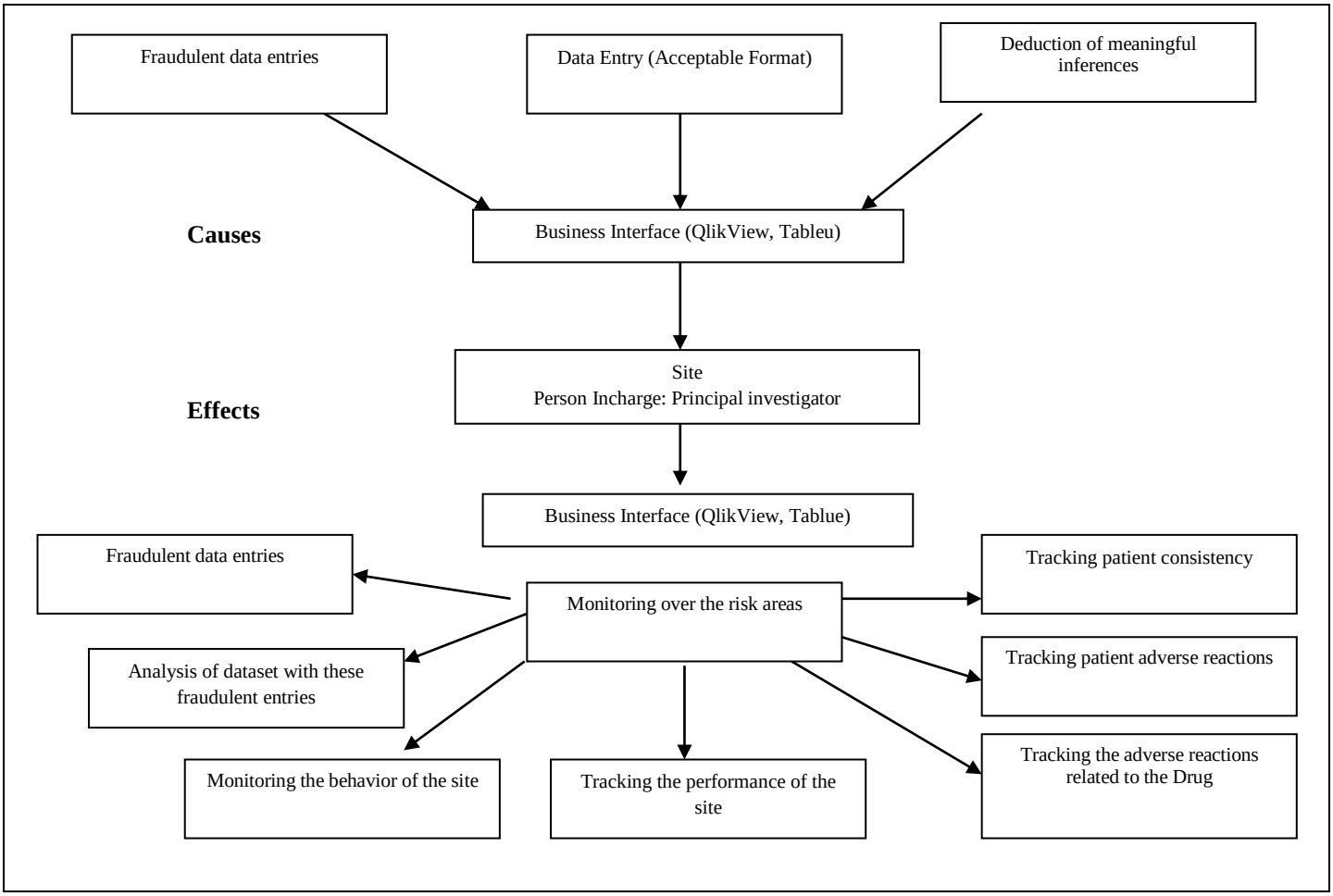

Figure 2: Block diagram representing the cause effect analysis of a Site and the intended solution

3. Proposed Solution

The addition of a Business Intelligence tool such as QlikView or Tableu will lessen the troublesome data capture. As the first step is rectified the errors further down are reduced thus increasing the efficiency of the overall process. The above approach is based on the Poka yoke Japanese approach where the input is corrected at the start. The in memory analytics provided by the BI platform can be further used to analyze the KPI and KRI. The in-built functionality of the BI tool can be leveraged to identify the risk parameters. There is ease in data handling. The Due to the introduction of the BI platform at 2 stages there is initial cost that the pharmaceutical company will incur, however the final cost is reduced as the various corrective measures that are required for the correction of the problems arising in the cause state.

4. Conclusion

Leveraging the in-built algorithms provided by the BI platform the data entry and analysis problems are taken care of here. Due to an acceptable amount of data flowing in the BI tool we can perform the data analysis giving more accurate results and thereby increasing the chances of finding the key findings. Due to a better analysis a greater control is exerted on the monitoring. The pain points or the KRI's can be easily prioritized using the in -built Rank algorithm. Once these KRI's are ranked we can introduce the KPI's and re-rank the KRI's. This will lead to a more efficient ranking as other factors are also being considered for ranking the KRI's.

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