IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

ISO 3297:2007 Certified ⁜ Impact Factor 7.105 ⁜ Vol. 9, Issue 6, June 2022

DOI: 10.17148/IARJSET.2022.96152

Development of Patient Profile in Clinical Data Management

Vinod Kumar K[1], Prof Saravanan C[2]

Student, Master of Computer Applications, RV College of Engineering, Bengaluru, India[1]

Professor, Master of Computer Applications, RV College of Engineering, Bengaluru, India[2]

Abstract: Healthcare takes more than 10% of the GDP of most developed countries Recent healthcare statistics show that it's one of the largest and fastest-growing industries in the world. Today, approximately 30% of the world's data volume is being generated by the healthcare industry. By 2025, the compound annual growth rate of data for healthcare will reach 36%. Generation of patient profile includes history of patient health visits, tests carried out and such other details are extracted from Medidata Rave. The raw data extraction process is time consuming, several variables are ignored and tedious process. The proposed work "Development of Patient Profile in Clinical data management" helps to solve the issues when extracting the data. The proposed work considers Medidata Rave® clinical data for building patient profile. It consists of modules namely data extraction module, Query Formulation Module and Report Generation Module. In the Data extraction module, the data set retrieved from the Medidata Rave for verification of the specifications stored in the cloud with the specification given to verify for the consistency of the data and identification of the missed variables. In the query formulation module, queries are formulated to fulfil the requirements given in the specification. The report generation module focuses on generating reports for patient profile, missing page report, subject status report and customized EDC report with clinical trial details. The project is implemented using the SAP BO (Business Object) tool is a cloud–based clinical data management system used to capture, manage, and report clinical research data. The outcome of the proposed work helped in developing customized dashboards to provide better visualization. It helped in building clinical data management system pertaining to generation of patient profile, clinical trial details and subject status report. Time taken to process data extraction, query formulation and generating reports was reduced by 70%.

Keywords: Medidata, Patient Profile, Clinical Data Management, Business Object, Dashboards.

I. INTRODUCTION

In United States, before the Food and Drug Administration (FDA) embraces a clinical preparation to begin, specialists perform lab tests and concentrates in animals to test a logical treatment's prosperity and practicality. If these examinations show extraordinary results, the FDA gives underwriting for the mediation to be attempted in individuals. Clinical Data Management (CDM) is a basic cycle in clinical examination, which prompts age of top calibre, solid, and genuinely strong information from clinical preliminaries. The information gathered during a clinical groundwork structure the premise of resulting wellbeing and for effective examination which thus drives dynamic on item advancement or any kind of development in the pharmaceutical industries. The CDM has three types of checks and they are Edit Checks (EDC), Review Listings (RL) and Protocol Deviation (PD).

SAP BO (Business Objects) is a software tool for data report writing and analytics. Business Objects is a gathering of projects which cooperate to recover them and to save information values, change information, assess mind boggling and single dramatic investigations and create reports. BO device is a strong and adaptable factual bundle that sudden spikes in demand for some stages, including Windows and Unix. The Business Objects involves first reading the data sets into the memory and then doing the analysis on this data.

Development of Patient Profile in Clinical Data Management project includes Four major modules i.e.

- Data Fetch
- Query Module
- Data format
- Report Validation

The project is done by following certain hierarchy that starts from

- Interim/Final/ Exploratory dataset specification
- Development of Reports as per Specifications in SAP BO
- EDC, Data listing, Validation log from Medidata

IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

ISO 3297:2007 Certified ⁜ Impact Factor 7.105 ⁜ Vol. 9, Issue 6, June 2022

DOI: 10.17148/IARJSET.2022.96152

- Statistical Reports, Clinical Study Reports(CSR), Publications, Manuscripts

While conducting clinical research trials the data and information of the trials should be recorded and submitted to regulatory body of pharmaceuticals. The trials data will be in the form of Case Record Form or CRF which is collected by hospitals or laboratory. In order to provide those trials data to regulatory body, CRO should maintain standard format of data which is SDTM (Study Data Tabulation Model). The proposed system helps us to convert the raw data (CRF) which is collected during trials to SDTM datasets.

The initial module of this project is creating Annotated Case Report Form(aCRF) from raw CRF. In this module proper variables are assigned to the raw CRF form to understand the variable details to perform BO programming. This Annotated CRF helps the programmer to create the Specification list. Creation of specification list helps to note down details of each and every variable and domain should be created. This includes variable length, method used, type of variable assigned, comments, code list etc.

Creating Report from dataset, in this process a reports supporting a table is almost always produced. One report can support many tables percentages are based on the total number of subjects in each treatment group based on date of collection.

Reporting Environment

This consist of three main interfaces.

- Rave Medidata
- SAP BO tool
- SQL Database

II. EXISTING AND PROPOSED SYSTEM

Existing framework shows that the framework is already in place. The existing system is being used as a point of departure for developing the proposed framework, and it has a few problems that will be addressed in the proposed system. The suggested structure will have examined all of the existing system's weaknesses and will also include a few characteristics that will set it apart from the current framework.

Problem statement

The patient and the history of the patient's data like hospitals visited, tests carried out, lab tests and such other things need to be consolidated in the medical domain that is where the data management comes into picture. The huge amount of unorganized data would be difficult to handle in order to overcome this challenge the clinical data management serves well.

Scope of the project

- The clinical data management for patient report generation is widely used by medical organization
- The generated report reduces the effort of data consolidation when the patient has the history in different health centres across different regions
- The report of a patient is also used by forensic purpose on special consideration
- For proceeding with the medical diagnosis huge number of health centres across the globe rely on the

Methodology adopted in the proposed system

- The focus group includes the health care, hospitals and such other organisations
- The workflow of clinical trial is shown as below in figure 1

IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

ISO 3297:2007 Certified ⁜ Impact Factor 7.105 ⁜ Vol. 9, Issue 6, June 2022

DOI: 10.17148/IARJSET.2022.96152

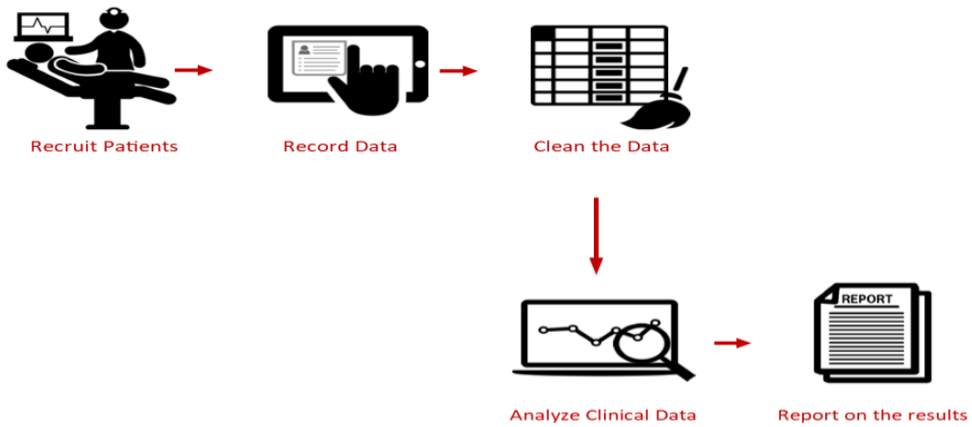

Fig 1: Workflow of Clinical Trial

- The clinical trial data within RAVE provides huge raw data over cloud also enabled with role based access control for security and data integrity
- Data from RAVE is fetched using Business Objects (BO) tool using queries and commands for generating customised reports here, BO tool is a third party tool used by the company for data visualisation report generation and analysis

III. Tools and Technologies

The project is developed using the SAP BO tool and its ODS (output Delivery System) and other technologies which are popular. While the BO tool helps in developing the report in any formats and also be generate varieties of templates.

SAP Business Objects BI: SAP Business Objects BI (SAP BO) is an incorporated set-up of revealing and examination instruments for business insight (BI) stages. SAP BO is focused on business clients. It comprises of various detailing applications that permit clients to find information, perform examination to determine experiences and make reports that envision the bits of knowledge. SAP Business Objects BI utilizes intuitive capabilities and permits clients to look and dissect information from a wide assortment of sources. SAP BO is a front-end BI stage, so the information isn't put away at the application level, however is incorporated from the different back-end sources.

Medidata Rave: Medidata Rave is a cloud-based clinical information the executive's framework used to catch, make due, and report clinical examination information electronically. It empowers the client to record patient data (i.e., visit, lab, and unfriendly occasion information) involving tweaked structures for each exploration study. Clients have quick, straightforward admittance to all reviews, Medidata applications, eLearning proficient instructional classes, online conversations, and more in one spot.

SharePoint: SharePoint is a digital collaboration platform and cloud service that also serves as a document management system, allowing users to exchange and upload work-related documents, videos, and music.

IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

ISO 3297:2007 Certified ⁜ Impact Factor 7.105 ⁜ Vol. 9, Issue 6, June 2022

DOI: 10.17148/IARJSET.2022.96152

IV. SYSTEM DESIGN

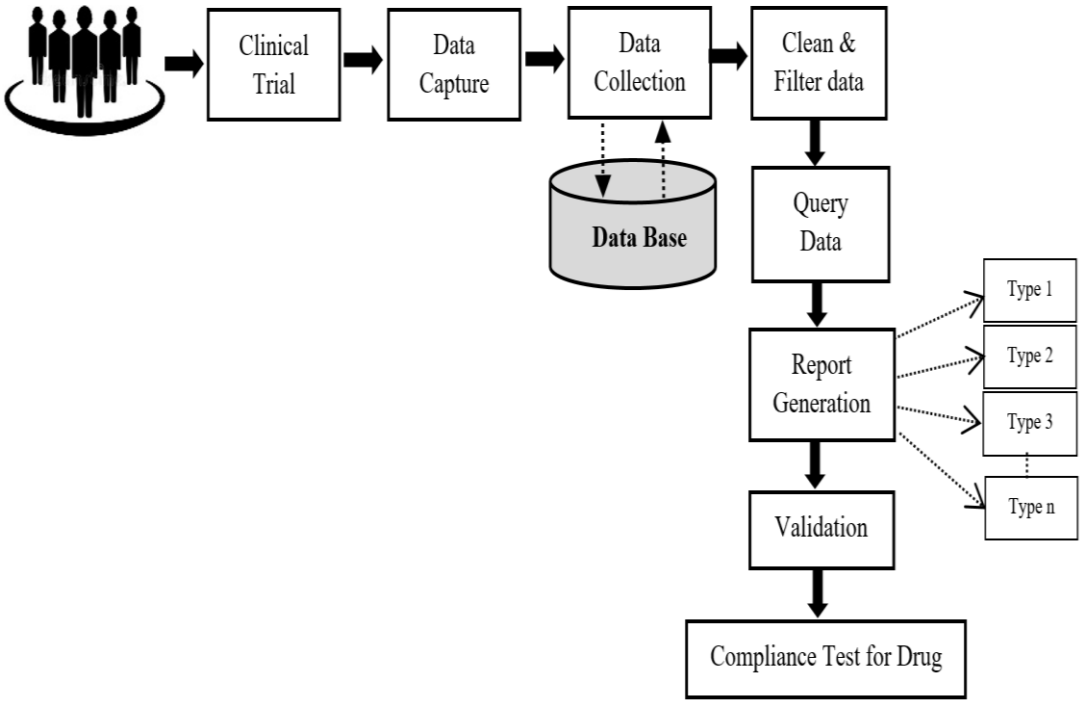

Fig 2: Block Diagram for Report development through clinical trials

The Figure 2 describe the overview of Report development process where the e-CRF datasets according to the SOP's gets classified and then with the help of the BO tools after data cleaning gets converted into the structured and cleaned datasets.

Module Specification

Data Fetch Module
In Data Fetch module the purpose is to fetch the data from the RAVE cloud repository by requesting specified objects as in the specifications. As the object is requested from BO tool then provides the requested object from the cloud repository, which enables the user to drag and drop the required object from the data provider and gives collection of objects according to the specifications.

Query Module
This module is used to filtering the collected object based on the queries. When the queries are applied on the objects on a particular column then the logics are only applied to that column and the entire tables gets changed when the column is attached. Then function is to collect the query and match according to the objects which leads to acknowledgement of the query correctness.

Data format Module
Data format module is the main module for generating the report, because the outlook of the report is based on this module, whatever the logics applied on the reports are visible through this module. This module is used for formatting the templates of the report by applying colours for borders and headers, giving padding, applying style and so on. Also it takes filtered data from the previous stages and then gives the formatted report by enhancing of report view and providing patterns for the report.

Report Validation
Report Validation is the final module, where after all the stages the report need to be validated in this phases. Verifies whether the report meets the requirements. By taking developed report and validation log need to check test cases and apply reports for various scenarios in quality check and match report against the test cases. Once all the validation is done and passes all the cases then release the report for the final production.

IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

ISO 3297:2007 Certified ⁜ Impact Factor 7.105 ⁜ Vol. 9, Issue 6, June 2022

DOI: 10.17148/IARJSET.2022.96152

V. OUTCOME

Table I represents testing Data Fetch for all the variables of specific domain. If any Test Case failed, then need to check the selected variables in data provider with the specification to clarify.

Table I: Data Fetch Testing

TC_Id	Featured Tested	Sample Input	Expected Output	Actual Output	Output Results
TC_01	Accepting Variable	Selecting variables	Variables as in Specification	Variables as in Specification	Pass
TC_02	Accepting Variable	Selecting variables	Variables as in Specification	Variables missed	Fail

The Table II Shows the query testing for the different cases with pass or fail results. If The Test Case got any failure, then check all the filters apply on the site, subject, study.

Table II Query Testing

TC_Id	Featured Tested	Sample Input	Expected Output	Actual Output	Output Results
TC_01	Applying Filters	Specific site id	Display all the subjects in that site	Display all the subjects in that site	Pass
TC_02	Applying Filters	Specific site id	Display all the subjects in that site	Displaying only one subject in the site	Fail
TC_03	Applying Filters	Set site id as 0	Displaying all the subject of all sites	Displaying all the subject of all sites	Pass

The Table III shows Data Format test cases of the system with pass and fail result. If any of the test case fail must change the coding and retry to reduce the errors.

Table III Data Format Testing

TC_Id	Featured Tested	Sample Input	Expected Output	Actual Output	Output Results
TC_01	Header	Providing date	Displaying in DD/MM/YY format	Displaying in DD/MM/YY format	Pass
TC_02	Header	Providing date	Displaying in DD/MM/YY format	Not Display in proper format	Fail

The Table IV shows Report Validation test cases of the system with pass and fail result. If any of the test case fail must reach to the Data Management team to send the data.

IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

ISO 3297:2007 Certified ⁜ Impact Factor 7.105 ⁜ Vol. 9, Issue 6, June 2022

DOI: 10.17148/IARJSET.2022.96152

Table IV Report Validation Testing

TC_Id	Featured Tested	Sample Input	Expected Output	Actual Output	Output Results
TC_01	Validation	Developed Report and Validation log	Matches report against the test cases, also for various scenarios in quality check	Matches report against the test cases, also for various scenarios in quality check	Pass
TC_02	Validation	Developed Report and Validation log	Matches report against the test cases, also for various scenarios in quality check	Miss match in the developed report.	Fail

V. CONCLUSION

The significant task theory gives a rearranged and small form of how an investigational new medication is tried in various clinical preliminary stages to comprehend the security, adequacy and viability on human against a particular illness and how the Business Intelligence(BI) helps puts a job in programming the clinical information from crude information into appropriate satisfactory arrangement and age of tables, Quality data from the clinical trials, postings and figures. In the first place, it strolled through the phases of the new medication improvement measure for an extreme price and drawn-out measures with inspecting the time span and the number of inhabitants in members in each period of clinical preliminary. We at that point moved to our concentrate how clinical information the board and stages accessible for dealing with the clinical information, out of which in LabCorp, we use Medidata which reflect the data changes and updates with in a second.

The clinical information gathered from different destinations primarily in type of electronic Case Report Form (eCRF's), used as raw dataset as an input to work on. The data that is obtained from the e-CRF is saved in EDC and the programmers use it for comparison of report Once it is developed. Then through Data fetch, Querying, formatting report to Report validation the programmer will have the responsibility. The programmer raises the access to that particular study via IT Central which is present in the access pad. After getting access to it, the programmer has to work on the logics for Patient Profiles development that reaches the compliances standard (in some cases, there won't be any output datasets when checked with EDC) which is then sent for the QC (quality check) and after that, the programmer receives the validation log to see whether the programming logic correct or not. After the validation ends, the output is then sent to the Data Management who reviews the output datasets and then take decisions to release the report in production.

In case of report validation, the DM team prepares the manual report and then send it to the site people or the task person, if any kind of discrepancies are found. Whereas in case of updating report according to modified specification, the DM team takes the decision of adding more data to EDC and validation log of the clinical trial. The main benefit of this is Report maintenance post production that the trials are continued without any hindrance which helps in getting new drug to the market and maintain that data without any misconception also by maintaining in post-production.

VI. FUTURE ENHANCEMENT

BO at first intended to finish measurable investigation yet now it is likewise utilized for examination. It is primarily utilized for handling complex crude information into significant data. This significant data assists a foundation with settling on better choices. It is additionally useful to us to accumulate, break down and separate information from different assets. It does the handling, cleaning, burrowing, and bundling for measurable individuals.

The future work mainly depends on how to generate figures which helps to graphical represent the data in forms of charts, bar-graphs, histograms, pie-charts, line graph etc. The requirements of generation of figures include study data and documents, TFL and Protocol. Understanding different forms of listings which include

Coding listings which include mainly three subjects like medical history, adverse events and severity of adverse events and derived in RTF and EXCEL format. Database listings includes huge amount of data with around 50 subjects to be derived in the form of EXCEL sheets. Scientific research listings- mainly is an overview of the clinical research and focuses on adverse event data and the output is derived in RTF and EXCEL format. Apart from these we have other future applications of BO such as Multivariate Analysis, Business Intelligence, Data Science Engineering, Clinical Trials and Drug study, Predictive Analysis.

Multivariate analysis is a bunch of factual methods utilized for investigation of information that contain more than one

DOI: 10.17148/IARJSET.2022.96152

variable. BO tool help with researching the relationship among various factors without classifying them as reliant or free. It takes help of various examinations or preliminaries that mirror the impact of variable components on a solitary outcome. It incorporates examination of factor, bivariate, and numerous relapses.

REFERENCES

[1] Embi, P. J., and P. R. O. Payne. "Clinical Research Informatics: Challenges, Op portunities and Definition for an Emerging Domain." Journal of the American Medical Informatics Association, vol. 16, no. 3, Jan. 2009, pp. 316-327., doi:10.1197/jamia.m3005.

[2] Brigitte Walther, Safayet Hossin, John Townend, Neil Abernethy, David Parker and David Jeffries, “Comparison of Electronic Data Capture (EDC) with the Standard Data Capture Method for Clinical Trial Data”,pp in journal.pone.0025348. Epub 2016 Sep 23.

[3] J. Anderson, L. Caplan, J. Yazdany, M. Robbins, T. Neogi, K. Michaud, et al., "Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice", *Arthritis Care & Research*, vol. 64, no. 5, pp. 640-647, 2012.

[4] Yuanyuan Feng, V. P. Janeja, Y. Yesha, N. Rishe, M. A. Grasso and A. Niskar, "Poster: Classifying primary outcomes in rheumatoid arthritis: Knowledge discovery from clinical trial metadata," 2015 IEEE 5th International Conference on Computational Advances in Bio and Medical Sciences (ICCABS), 2015, pp. 1-2, doi: 10.1109/ICCABS.2015.7344722.

[5] K. Ravvaz and J. Weissert, "An Interactive Tutorial on Simulated Pharmacogenomic Clinical Trials," 2018 IEEE International Conference on Healthcare Informatics (ICHI), 2018, pp. 445-445, doi: 10.1109/ICHI.2018.00093.

