Customized Aggregate Reports

1 INTRODUCTION

Pharmaceutical organizations record and process huge amount of patient safety and clinical data on an ongoing basis. There is a need to analyze this data to support regulatory compliance needs. Additionally, organizations have quality, audit, analytics and management reporting requirements. For these organizations to be able to make informed business decisions, they need to analyze the available patient safety, clinical data and key performance indicators.

Typically, organizations opt for developing customized reports/dashboards as there are no out of the box solutions available to holistically support these requirements. These custom reports query data from the safety or clinical system transactional database or a data mart derived from the safety transactional database and a combination of other data sources like clinical trial database. There is clear need for a solution which provides pre-defined set of reports and assists organizations in meeting analytics requirements.

2 APPROACH

Vitrana team of consultants have vast experience of working globally with customers in developing and deploying custom reports catering to respective regional regulations as well as pharmaceutical organizations' reporting and analytics requirements.

Vitrana customized reports solution capitalizes on this experience for design and development of custom aggregate reports. Vitrana approach for custom aggregate reporting is outlined in the following system context diagram.
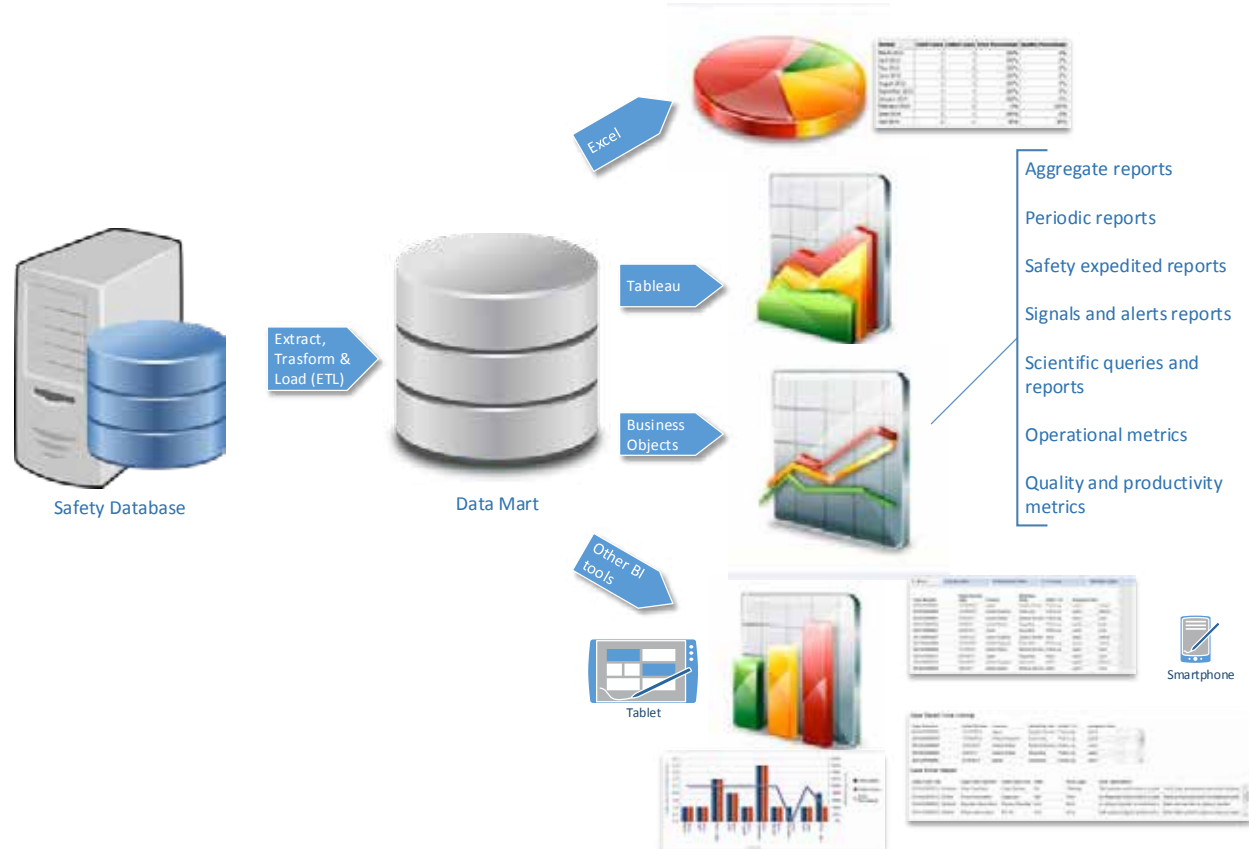

Figure 1: System Context Diagram

The solution uses a custom life sciences data mart decoupled from the safety or clinical system transactional databases. An ETL brings data from the safety database schema and clinical database schema into the data mart at pre-defined frequency. The aggregate reports run on this custom life sciences data mart thereby not impacting the performance of the respective source systems' transactional databases.

3 BENEFITS

Key benefits of the Vitrana approach for a pharmaceutical/contract research organization:

- Greater control and flexibility – flexibility in customizing the data mart as per your specific data and analytics requirements, it also gives you an increased control on size and performance of the mart
- The custom life sciences data mart extracts all key information from the transactional databases for use in querying, reporting and analytics by way of configurable ETL
- No dependency on any proprietary solution/mart, Oracle cloud customers can opt for Argus Safety standard edition rather than the enterprise edition resulting in lower total cost of ownership
- No impact on safety or clinical system performance as the reports use the custom data mart and not the transactional databases
- Utilizes our consultants' exhaustive experience working with multiple customers and with Oracle Argus Insight, Oracle Argus Analytics product strategy and development teams
- Reports can be developed in any of the industry standard reporting/visualization tools such as OBIEE, BI Publisher, Cognos, Business Objects, Tableau, Qlikview, JReports
- Reports can be rendered on portable devices like smartphones and tablets

Vitrana solution has a set of pre-defined report templates based on our consultant's diverse experience in different geographies. Some of the custom aggregate reports for Japan region are:

Safety

- Adverse reaction line list
- Assessment checklist of adverse events (literature and marketed cases)
- PRR signal report
- Adverse drug reaction list (event-case counts)
- JPMA line list
- CSPSR (CSUJ)
- Case line list

Clinical

- Site monitoring (risk based monitoring)
- Data quality
- Trial performance management

Please reach-out to us by email at sales@vitrana.com or by phone at +91 120 463 8700 to know more about Vitrana™ custom aggregate reports solution and have a consultant work with you to discuss your reporting needs and how you can benefit from the Vitrana™ custom aggregate reports approach.