PharmaSUG China 2023 - Paper BR-179

BeiGene CSM Platform – an interactive visualization dashboard for implementing Risk-Based Quality Management

Xiaoxuan Li, BeiGene

ABSTRACT

The effective management of risks in clinical trials is crucial to ensure the reliability and integrity of the study results. Traditional quality management approaches often fall short in proactively identifying and monitoring potential risks that may impact the outcome of clinical trials. In this paper, we present a novel data visualization tool developed using Power BI, which aims to enable risk-based quality management and facilitate the identification and monitoring of risks in clinical trials.

The visualization tool encompasses various components to provide a comprehensive overview of the study's overall information, key risk indicator, data quality evaluation, and quality tolerance limit. By integrating these elements, our tool offers a holistic approach to risk management, allowing researchers and stakeholders to gain valuable insights into potential risks throughout the trial process.

The core objective of our tool is to enable proactive risk identification. It achieves this by aggregating and visualizing data from multiple sources, such as electronic data capture systems and clinical trial management systems. Through interactive dashboards and intuitive visual representations, the tool empowers users to identify patterns, trends, and outliers that may indicate risks and deviations from quality standards.

INTRODUCTION

In response to the requirement of implementing risk-based quality management (RBQM) set forth by the International Conference on Harmonization Good Clinical Practice Guideline E6 (ICH GCP E6), BEIGENE has taken proactive measures to implement RBQM into its numerous studies. Against this background, BeiGene developed the Central Statistical Monitoring (CSM) Platform. It mainly consists of three important parts, which are Key Risk Indicator, Data Quality Evaluation, and Quality Tolerance Limit.

To facilitate the display and communication of analysis results, the CSM platform built with POWER BI has greatly improved efficiency. Unlike static spreadsheets in Excel or Traditional TFL, the CSM platform offers a dynamic and interactive interface that enhances the user experience. With its visually appealing and intuitive design, the platform enables teams to grasp complex analysis outcomes more easily and quickly. The interactive nature of the CSM platform empowers users to explore data, apply filters, and drill down into specific details, facilitating a deeper understanding of the risk landscape. This enhanced interactivity fosters better collaboration and decision-making within the team, as stakeholders can actively engage with the data and contribute valuable insights.

Moreover, the CSM platform can quickly find at-risk sites or patient details. Through its intuitive visualizations and advanced filtering capabilities, the platform allows teams to swiftly identify sites or patients that require immediate attention. This efficiency is crucial in time-sensitive situations, enabling prompt actions to mitigate risks and ensure the delivery of high-quality outcomes.

DATABASE OF CSM PLATFORM

In the area of clinical research, the ICH GCP E6 guidelines have set the stage for the implementation of risk-based quality management (RBQM) practices. Recognizing the significance of adhering to these requirements, BeiGene has developed a validated system, the CSM platform. To ensure the reliability and credibility of this platform, the validated database, Azure Blob, is used. It is a component of Microsoft Azure's cloud computing services, has many advantages as a database for the CSM platform. First and foremost, Azure Blob provides secure and reliable data storage, ensuring the integrity and confidentiality of sensitive clinical information. It utilizes robust encryption protocols, safeguarding against unauthorized access and data breaches. Furthermore, Azure Blob boasts high scalability, enabling accommodate growing data volumes without compromising performance.

KEY RISK INDICATOR

The purpose of Key Risk Indicators is to identify specific risks of interest across sites to focus on clinical operational quality.

Figure 1. Relative Score by Site

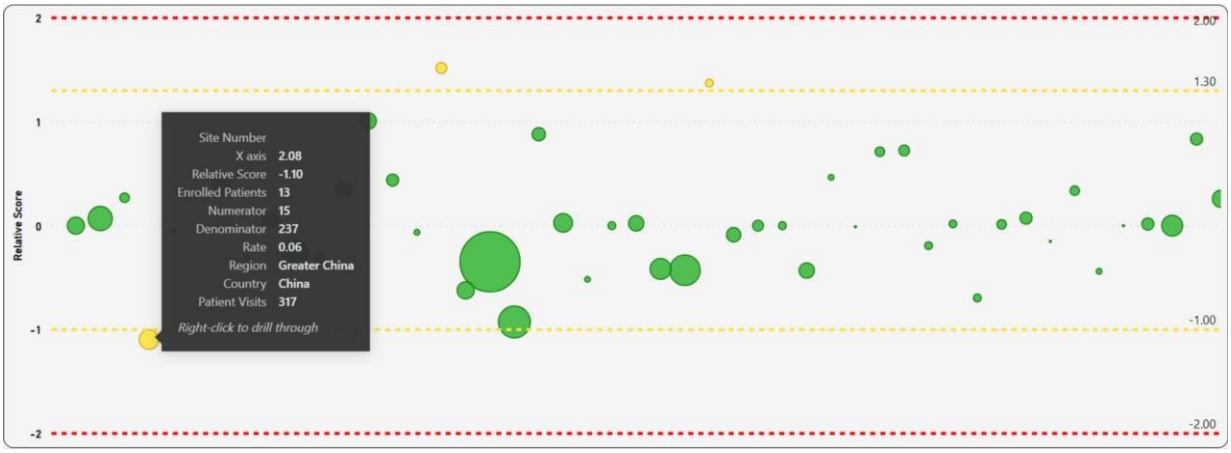


Figure 2. Observed and Expected Value Trends Over Time

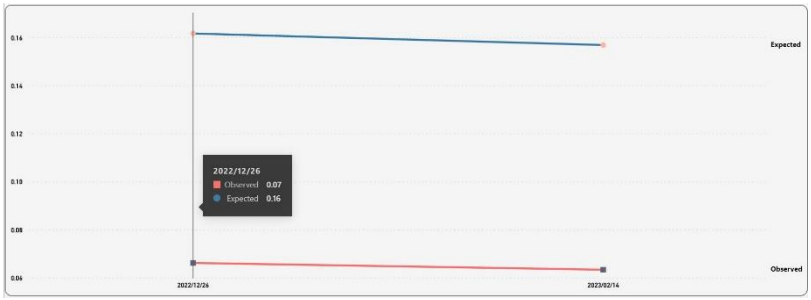


Figure 3. Listing of Protocol Deviations

Country	PD ID	PD Type	PD Category	PD Category Subtype	PD Occurrence Date	PD Sponsor Classification	PD Status
China	1-100CIL	Subject Deviation	Safety	Safety Reporting (Sponsor, IRB/IEC)	2021-11-30	Important PD	Active
China	1-1BLTJK	Subject Deviation	Protocol Compliance	Visit Compliance	2022-01-12	PD	Active
China	1-NW6EL	Subject Deviation	Protocol Compliance	Study Assessments & Procedures	2021-05-03	PD	Active
China	1-NW6EM	Subject Deviation	Protocol Compliance	Study Assessments & Procedures	2021-05-10	PD	Active
China	1-NW6EN	Subject Deviation	Protocol Compliance	Study Assessments & Procedures	2021-05-31	PD	Active
China	1-2RLDMU	Subject Deviation	Protocol Compliance	Study Assessments & Procedures	2022-02-17	PD	Active
China	1-2RLDMY	Subject Deviation	Protocol Compliance	Study Assessments & Procedures	2022-05-12	PD	Active
China	1-2RLDS2	Subject Deviation	Protocol Compliance	Visit Compliance	2022-05-06	PD	Active
China	1-2RLD7F	Subject Deviation	Protocol Compliance	Visit Compliance	2022-06-17	PD	Active
China	1-2RMGG8	Subject Deviation	Protocol Compliance	Visit Compliance	2022-06-17	PD	Active

Figure 4. Deviation Count (All Sites)

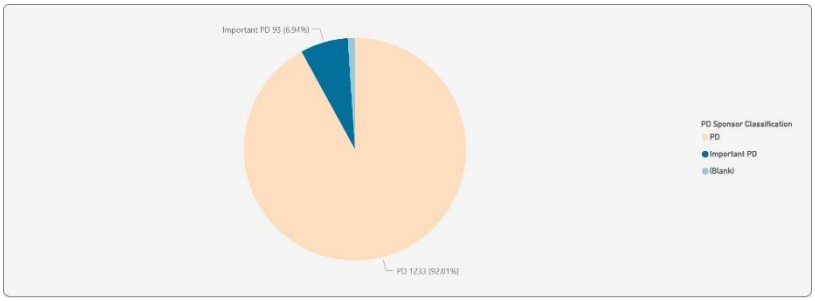


Figure 5. Deviation Count (Corresponding Site)

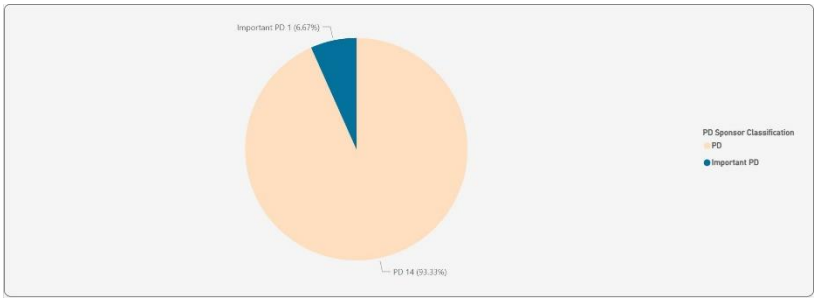


Figure 6. Deviation Count by Category (All Sites)

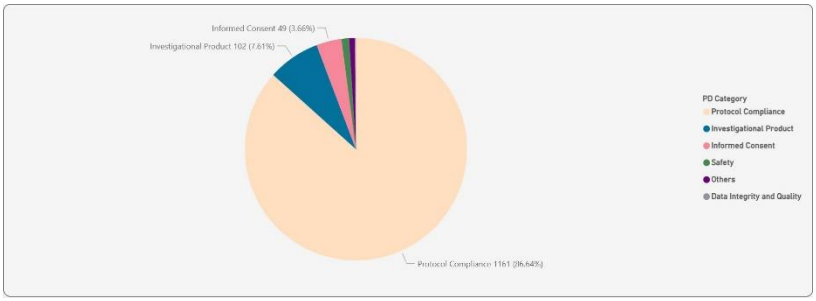


Figure 7. Deviation Count by Category (Corresponding Site)

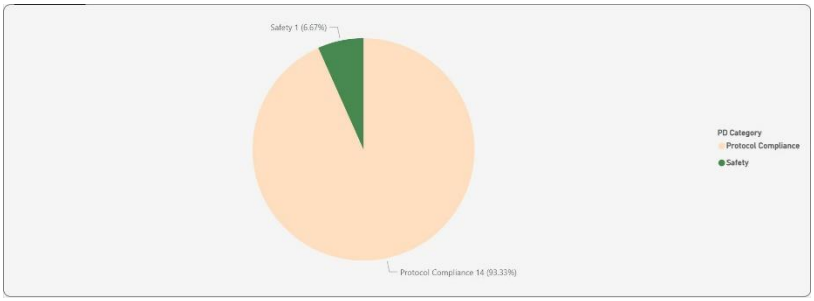


Figure 8. Deviation Count by Subcategory (All Sites)

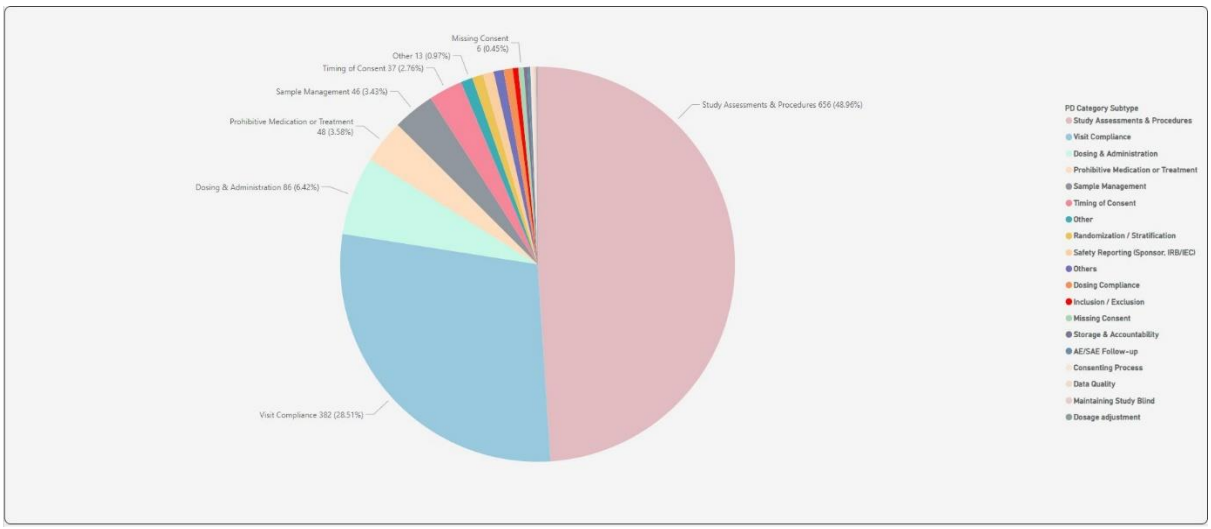
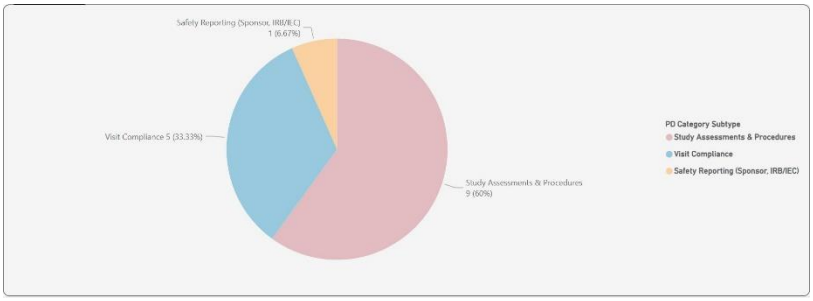


Figure 9. Deviation Count by Subcategory (Corresponding Site)



DATA QUALITY EVALUATION

The purpose of Data Quality Evaluation is to perform a comprehensive statistical analysis on all data and variables, to identify sites that differ from the others. Which focus on clinical data quality.

Figure 10. Risk Score by Site

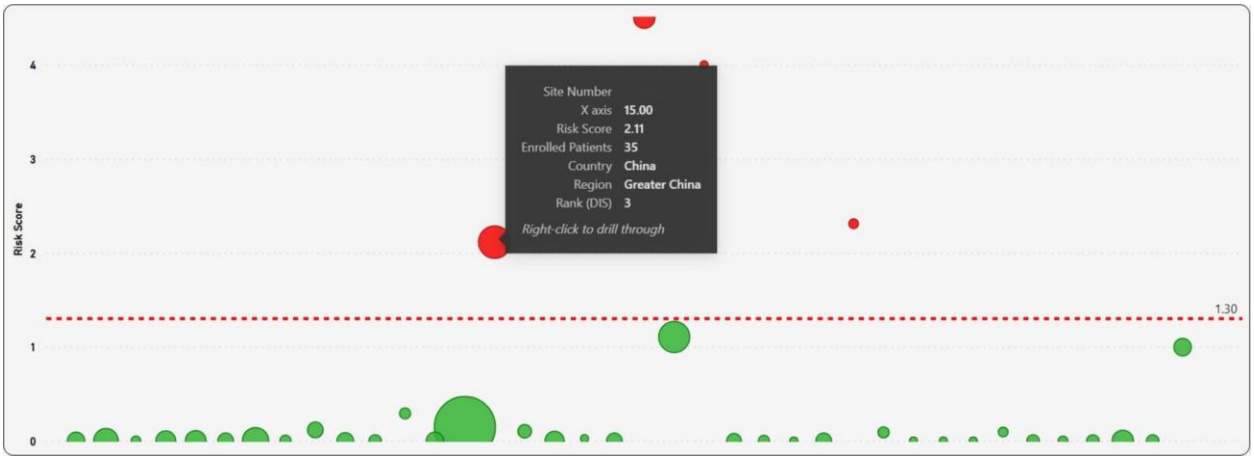


Figure 11. Risk Score Trends Over Time

Figure 12. Ranks (Risk Score) Trends Over Time

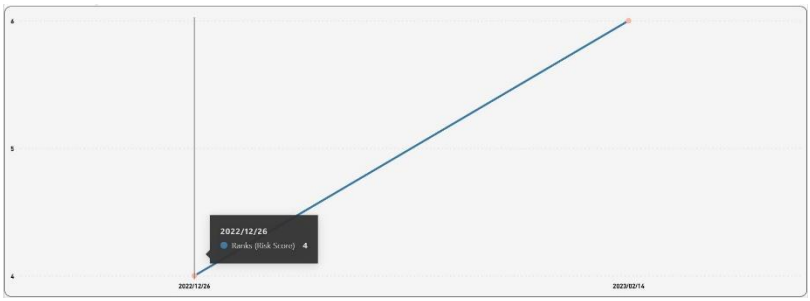


Figure 13. Enrolled Patients Trends Over Time

Figure 14. Enrolled Patients Trends Over Time

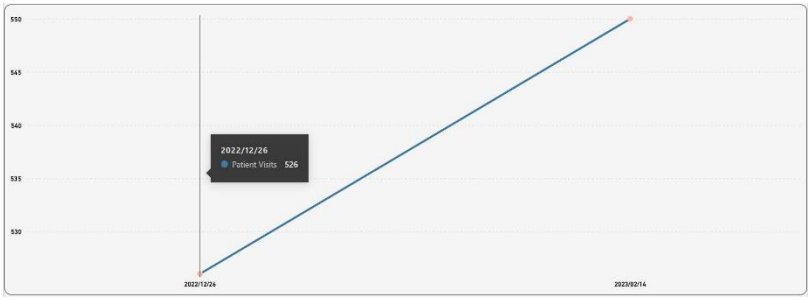


Figure 15. Outlier Test by Domain

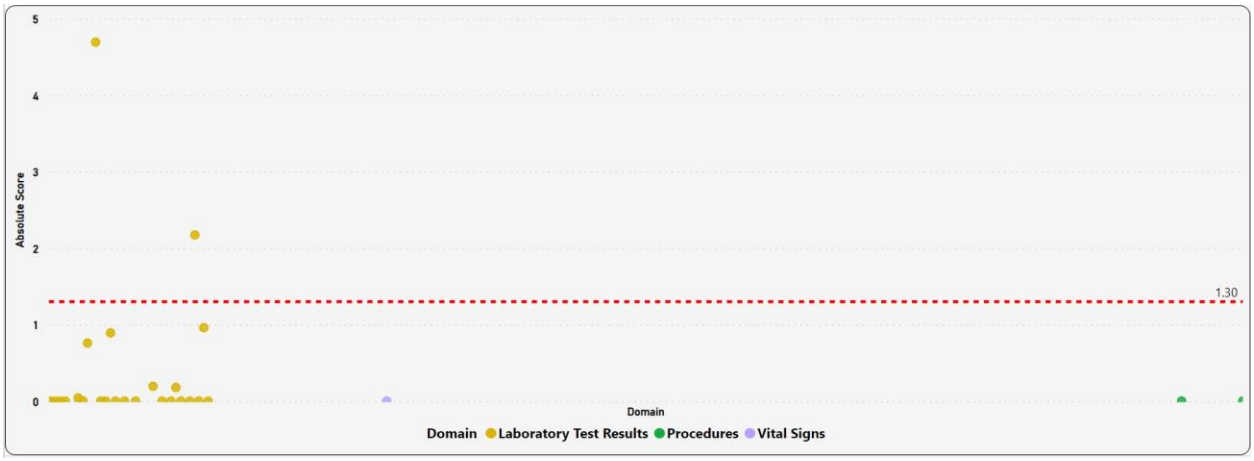
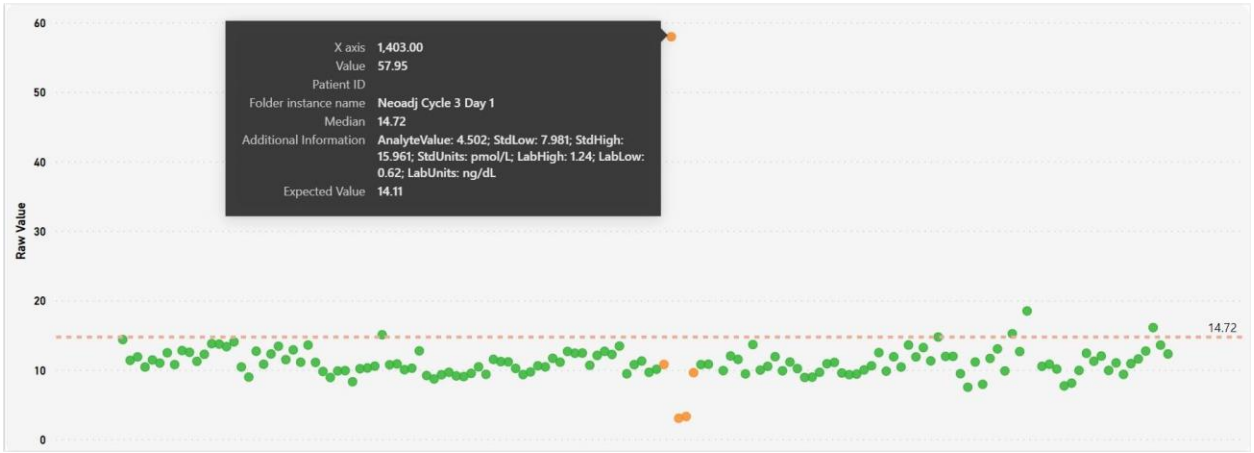


Figure 16. Details of Outlier Test



QUALITY TOLERANCE LIMIT

The purpose of Quality Tolerance Limit is to identify study-wide systematic issues that can impact subject safety or reliability of trial results.

Figure 17. QTL Performance

Figure 18. Details of QTL

Date of Randomization	Date of Last Dose	Sanpshot Date	Start Date and Time of Study Drug	Primary Reason for Treatment Discontinuation	If Other, Specify	Type of Progression	Related to COVD-19?	If Physician Desicion, Specify
19 OCT 2020	20 OCT 2020	2023/02/14	20 OCT 2020 10:35	Adverse Event			No	
10 NOV 2021	29 DEC 2021	2023/02/14	11 NOV 2021 11:11	Adverse Event			No	
30 NOV 2020	1 DEC 2020	2023/02/14	1 DEC 2020 10:45	Adverse Event			No	
08 MAR 2021	21 APR 2021	2023/02/14	9 MAR 2021 12:40	Withdrawal by subject			No	
27 APR 2021	9 JUN 2021	2023/02/14	28 APR 2021 13:35	Withdrawal by subject			No	
12 OCT 2020	12 OCT 2020	2023/02/14	12 OCT 2020 11:26	Adverse Event			No	
17 MAR 2021	7 APR 2021	2023/02/14	17 MAR 2021 15:55	Progressive disease		Radiographic	No	
26 JAN 2021	11 MAR 2021	2023/02/14	27 JAN 2021 11:12	Withdrawal by subject			No	
23 FEB 2021	5 APR 2021	2023/02/14	24 FEB 2021 10:45	Adverse Event			No	
7 SEP 2021	19 OCT 2021	2023/02/14	7 SEP 2021 15:00	Withdrawal by subject			No	
20 JUN 2022	3 AUG 2022	2023/02/14	21 JUN 2022 10:44	Physician decision			No	THE RESEARCHERS CONSIDERED THE BENEFIT OF THE PATIENTS AND ASKED THEM TO LEAVE THE GROUP FOR OTHER TREATMENTS.
19 OCT 2021	19 OCT 2021	2023/02/14	19 OCT 2021 21:03	Adverse Event			No	
20 MAY 2021	1 JUL 2021	2023/02/14	20 MAY 2021 10:31	Progressive disease		Radiographic	No	
15 JUL 2022	05 AUG 2022	2023/02/14	15 JUL 2022 14:50	Progressive disease		Radiographic	No	
13 AUG 2020	25 SEP 2020	2023/02/14	14 AUG 2020 11:38	Adverse Event			No	
13 AUG 2020	25 SEP 2020	2023/02/14	14 AUG 2020 11:10	Withdrawal by subject			No	

CONCLUSION

One of the key advantages of the CSM platform built with POWER BI is its interactivity. Unlike Excel and traditional TFL, which provides static tables and charts, the CSM platform allows the team to interact with the data dynamically. This interactivity enables them to drill down into specific details, and explore different perspectives, leading to a deeper understanding of the analysis results. The team can actively engage with the data, uncovering insights and making informed decisions based on timely information.

In addition to interactivity, the CSM platform provides a more intuitive user experience. The visualizations and dashboards are designed with clarity and simplicity in mind, ensuring that the analysis results are easily comprehensible to the entire team, regardless of their technical expertise. The platform's user-friendly interface facilitates seamless navigation and interaction, eliminating the barriers to understanding and fostering better collaboration among team members.

ACKNOWLEDGMENTS

I am very grateful to the whole Data Science and Digital Innovations (DSDI) - Central Statistical Monitoring team for their continuous valuable suggestions and greatly support in developing the CSM platform.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Xiaoxuan Li
BeiGene
15826795190
xiaoxuan.li@beigene.com