

AR05

Enhancing Data Integrity in Double-Blind Clinical Trials Using a Shiny App for Kit ID Checks

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About the Authors

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Ling Zhang

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- Ling is a Senior Principal Data Scientist at Roche, specializing in the Oncology portfolio. Before joining Roche, she worked as a statistical programmer consultant in the pharmaceutical industry. Ling holds an M.Sc. in Biostatistics from the University of Western Ontario, Canada.

Agenda

- Overview of Kit IDs in Clinical Trial
- Challenges in Cleaning Kit IDs in Clinical Database
- Design and Features of Kit IDs Shiny App
- Implementation and Impact
- Conclusion
- Q&A

Overview of Kit IDs in Clinical Trial

- **Double-Blinded Clinical Trial** is gold standard for evaluating the efficacy and safety of interventions, as they minimize bias in data collection and analysis
- To Maintain the integrity of the trial, it is essential to ensure the treatment assignments are concealed
- **Kit IDs in Double-Blinded Clinical Trial** are unique identifiers to link patients to actual treatment assignments

The Role of Kit IDs

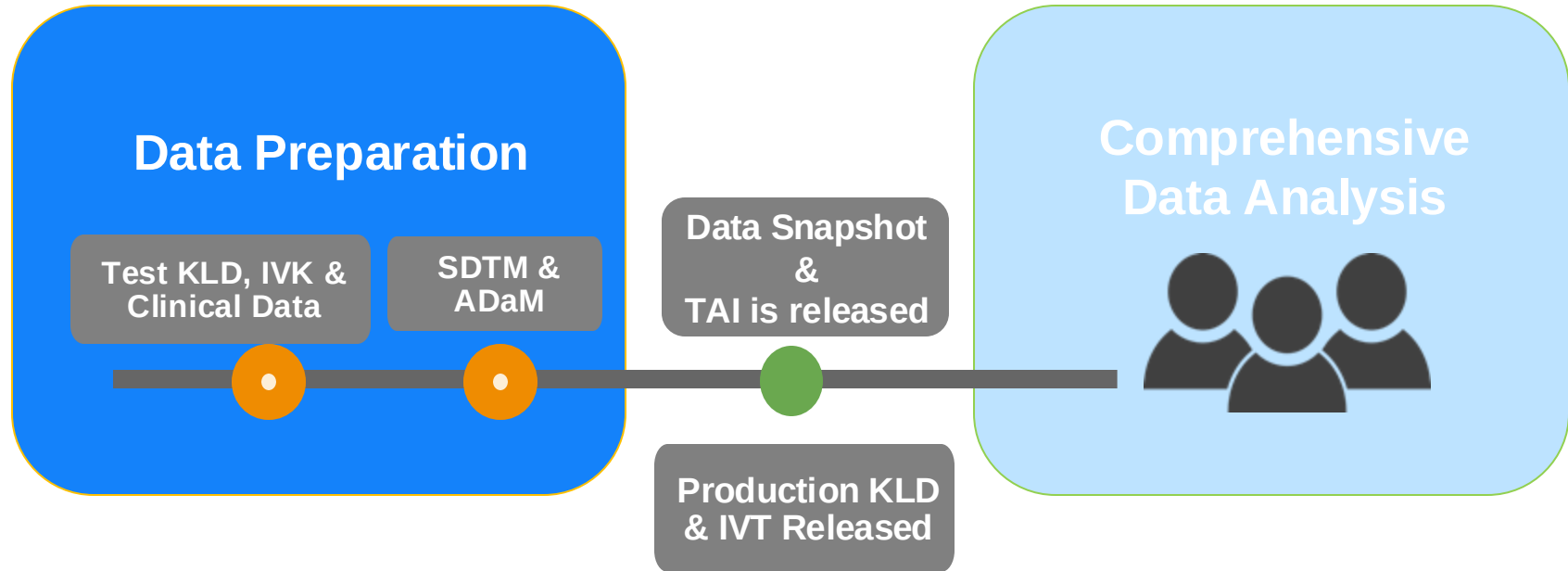
Importance of Kit ID Data Quality

- Accurate kit ID management is essential for ensuring proper unblinding and data analysis.

Impact of Kit ID Errors

- Inaccurate or unclear kit ID data can result in incomplete unblinding, misinterpretation of treatment outcomes, and potential regulatory non-compliance.
- These errors can undermine the credibility of the trial and delay or disrupt the approval process

Key Data Types in Clinical Trial



Challenges in Cleaning Kit IDs in Clinical Database

Investigational sites manually enter kit IDs into the clinical database:

Data Entry Errors

- Mistyped, incomplete, or missing kit IDs.

Mismatches with Kit Label Database (KLD)

- Differences between kit IDs recorded in the clinical database and those in the KLD.

Timing Constraints

- Data must be cleaned and verified quickly before Treatment Assignment Information is released, which is time-sensitive and prone to mistakes.

Design and Features of Kit IDs Shiny App

The purpose of Shiny App is designed to improve the accuracy of kit ID data before the Treatment Assignment Information (TAI) is released, ensures a clean, error-free unblinding process.

Core Functionality

- Compares kit IDs from clinical database with Test KLD in real-time.
- Flags discrepancies for further investigation.

User-Friendly Interface

- Filters and search features for data review.
- Suggestions for resolving mismatched kit IDs

Interactive Visualizations

- Interactive dashboard for clear visual representation of data discrepancies

Example 1 - Kit ID Errors

Patient 30453 was dosed on 2024-07-11 and 2024-08-09, Kit ID XXX61895 contains an extra X, which does not match the corresponding Kit ID in the test KLD file. Kit ID XX32465 is missing from the test KLD file, indicating error.

Patients	Treatment	Treatment Administration Date	Kit IDs
30453	Tecentriq/Placebo	2024-07-11	XXX61895
30453	Tecentriq/Placebo	2024-08-09	XX32465

Example 2 - Kit ID Errors

Patient 30448 was dosed on 2024-05-29 and 2024-06-19 using the same Kit ID (XX32824). This indicates that Kit IDs may not have been entered correctly.

Patients	Treatment	Treatment Administration Date	Kit IDs
30448	Tecentriq/Placebo	2024-05-29	XX32824
30448	Tecentriq/Placebo	2024-06-19	XX32824

Example 3 - Kit IDs vs Test KLD

Patient 30595 was dosed on 2023-04-29 and 2023-05-19. However, the Kit IDs (XX13684 and XX48394) entered into the clinical database are not listed in the test KLD dataset, suggesting potential discrepancies or errors.

Patients	Treatment	Treatment Administration Date	Kit IDs from Clinical Database	Test KLD
30595	Tecentriq/Placebo	2023-04-29	XX13684	None
30595	Tecentriq/Placebo	2023-05-19	XX48394	None

Example 4 - Kit IDs vs IVKs

- The check compares date a kit identification was assigned to a patient with the date treatment was administered, and flags cases where the date difference exceeds the protocol-defined window.
- The check identifies a Kit ID mismatch between the IVK system and the clinical database.

Patients	Treatment	Kit IDs from Clinical Database	Treatment Administration Date from Clinical Database	Date Assigned from IVK	Date Difference	Comments
30123	Tecentriq/Placebo	XX43724	2024-05-26	2024-06-17	22 days	
30125	Tecentriq/Placebo	XX43745	2024-05-26	Not found in IVK		

LIVE DEMO

Implementation and Impact

Successful Integration

- The Shiny App has been integrated into the data quality check workflow of multiple clinical trials.

Key Benefits

- **Reduction in Errors:** Minimizes errors during the TAI unblinding process, ensuring data integrity.
- **Early Issue Detection:** Proactively identified discrepancies and resolved them early.
- **Enhanced Efficiency:** Improved operational efficiency through automated checks.

Conclusion

Key Takeaways

- The Shiny App enhances data integrity by proactively resolving discrepancies.
- Facilitates a seamless and error-free unblinding process, ensuring reliable clinical trial outcomes.

Future Developments

- Extend functionality to include other critical data elements.

Questions?

Contact Info

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Backup Slides

KIT ID Checks



- IVK vs. RAVE Check
- Test KLD vs. RAVE Check
- RAVE Kit ID Duplicate Check
- Date Discrepancy Check
- Dummy TAI Creation

RAVE vs.IVK Kit ID Check

This check detects Kit ID mismatch between IVK and RAVE by Patient

Path to RAVE exposure data

Expecting entimICE path to RAVE exposure data e.g. root/clinical_studies/ROXXXX/CDTXXXX/G0XXXX/data_processing/SDTMv/data/prod/bxinf1.sas7bdat.

Path to the IVK data

Expecting entimICE path to IVK data e.g.root/clinical_studies/ROXXXX/CDTXXXX/G0XXXX/data_processing/SDTMv/data/prod/ivk_nc.sas7bdat.

Kit variables to be checked

Search:

Rave Kit IDs without a match value in IVK

	PATNUM	Trt	Kit_in_RAVE	Date_in_RAVE	Comment
	All	All	All	All	All
1	30005	BLINDED TIRAGOLUMAB	GUU12952	2022-03-15	Not found in IVK because it's after IVK snapshot date
2	30126	BLINDED TIRAGOLUMAB	GUU38061	2022-03-15	Not found in IVK because it's after IVK snapshot date
3	30158	BLINDED TIRAGOLUMAB	GUU01452	2022-03-16	Not found in IVK because it's after IVK snapshot date
4	30162	BLINDED TIRAGOLUMAB	GUU79572	2022-03-17	Not found in IVK because it's after IVK snapshot date
5	30178	BLINDED TIRAGOLUMAB	GUU01452	2022-03-08	
6	30239	BLINDED TIRAGOLUMAB	GUU01416	2022-03-16	Not found in IVK because it's after IVK snapshot date

IVK vs. RAVE Check

Test KLD vs. RAVE Check

RAVE Kit ID Duplicate Check

Date Discrepancy Check

Dummy TAI Creation

RAVE vs. Test KLD Kit ID Check

This check detects Kit ID mismatch between test KLD and RAVE exposure data

Path to RAVE exposure data

Expecting entimICE path to RAVE exposure data e.g.

root/clinical_studies/ROXXXX/

CDTXXXX/GOXXXX/data_processing/SDTMv/data/prod/txinf1.sas7bdat

Path to the test KLD data

Expecting entimICE path to test KLD data e.g. root/clinical_studies/ROXXXX/

CDTXXXX/GOXXXX/data_processing/SDTMv/data/test/kld_nc.sas7bdat

Import Data

Kit variables in RAVE exposure data to be checked

Check test KLD and Rave

No data issue found in the data.

- IVK vs. RAVE Check
- Test KLD vs. RAVE Check
- RAVE Kit ID Duplicate Check**
- Date Discrepancy Check
- Dummy TAI Creation

RAVE Kit ID Duplicate Check

Note:

This check detects duplicated kit IDs in RAVE exposure data. It applies to studies where kit ID can only be used once per dosing interval per study treatment per patient. Please check how your study kit is dispensed before using this check.

Path to RAVE exposure data

root/clinical_studies/RO7092284/CDT30301/GO41767/data_analysis/CSRInte

Expecting entimICE path to RAVE exposure data e.g.
root/clinical_studies/ROXXXX/
CDTXXXX/GOXXXX/data_processing/SDTMv/data/prod/txinf1.sas7bdat.

Import Data

Kit variables in RAVE exposure data to be checked

KIT1

Check Duplicated Kit IDs in Rave

Copy

CSV

Excel

PDF

Print

Search:

	PATNUM	treatment	administered_date	kit_in_rave
	All	All	All	All
1	30178	BLINDED TIRAGOLUMAB	2022-03-08	GUU01452
2	30158	BLINDED TIRAGOLUMAB	2022-03-16	GUU01452
3	30326	BLINDED TIRAGOLUMAB	2022-02-24	GUU06319
4	30326	BLINDED TIRAGOLUMAB	2022-03-17	GUU06319
5	30336	BLINDED TIRAGOLUMAB	2022-02-22	GUU17837
6	30336	BLINDED TIRAGOLUMAB	2022-03-15	GUU17837

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- IVK vs. RAVE Check
- Test KLD vs. RAVE Check
- RAVE Kit ID Duplicate Check
- Date Discrepancy Check
- Dummy TAI Creation

RAVE vs.IVK Date Check

Note:

This check compares kit assigned date in IVK with treatment administered date in RAVE and flags the data which has more than 3 days date difference between the IVK and RAVE. Issues detected here won't impact unblinding but may alert study team of possible deviations. Please discuss with your study team about if this check is useful for your study or not.

Path to RAVE exposure data

```
root/clinical_studies/RO7092284/CDT30301/GO41767/data_analysis/CSRInt
```

Expecting entimICE path to RAVE exposure data e.g.
 root/clinical_studies/ROXXXX/
 CDTXXXX/GOXXXX/data_processing/SDTMv/data/prod/txin1.sas7bdat.

Path to the IVK data

```
root/clinical_studies/RO7092284/CDT30301/GO41767/data_analysis/CSRInt
```

Expecting entimICE path to IVK data e.g.root/clinical_studies/ROXXXX/CDTXXXX/
 GOXXXX/data_processing/SDTMv/data/prod/ivk_nc.sas7bdat.

Kit variables to be checked

 Search:

Date Discrepancy between IVK and Rave by Patient and Kit ID

	PATNUM	KITID	date_in_ivk	date_in_rave	diff
	All	All	All	All	All
1	30001	GUU91305	2020-02-28	2020-03-31	32 days
2	30004	GUU11429	2021-01-19	2021-01-26	7 days
3	30021	GUU00121	2021-06-29	2021-07-07	8 days
4	30021	GUU00716	2021-05-18	2021-05-26	8 days
5	30021	GUU03542	2021-06-01	2021-06-16	15 days
6	30021	GUU10375	2021-11-05	2021-11-10	5 days
7	30021	GUU11119	2020-07-28	2020-08-05	8 days
8	30021	GUU17073	2020-12-01	2020-12-09	8 days
9	30021	GUU27162	2021-01-12	2021-01-20	8 days
10	30021	GUU27492	2021-02-02	2021-02-10	8 days

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