

 OVERSIGHT[™]
TRIAL DATA INTEGRITY MONITORING SYSTEM

See the full picture
through the lens of OVERSIGHT[™]

It's critical to be able to see trends and anomalies in your data and take necessary action, but audit trail reports are not easy to read. Add OVERSIGHT[™] IRT booster to your IXRS[®]3 to view organized, on-demand data history of Kits, Subjects, and Sites.

OVERSIGHT™ automatically organizes your data to help identify anomalies such as sites making high risk data edits, making too many data adjustments, or unexpected system transactions.



Events View

Provides a count by location for each IXRS event, data change type (if applicable) and reason for change.



Summary View

Provides the same data as the Events view, but breaks out events, data change and reasons separately. This allows the user to identify trends by location, high / low performers or any outliers.



Transaction Details

Provides a detailed view of all IXRS events. Providing details such as: who performed the transaction, on what date/time, before and after values.

Filter and drill into the transaction data to see what's really going on

While raw Site, Kit, and Subject data is always recorded in the IRT, can you get any actionable insights from it?

Not without extra steps like exporting the data and manually processing it.



Figure 1: Transaction details recorded in IXRS

Subject Audit Trail

Events

Transaction Details

Summary

Transaction Date (UTC)

Start

End

Event Type

Data Change Type

12/1/2024

→ 4/3/2025

Edit Date of Birth, Edit Informed Cons...

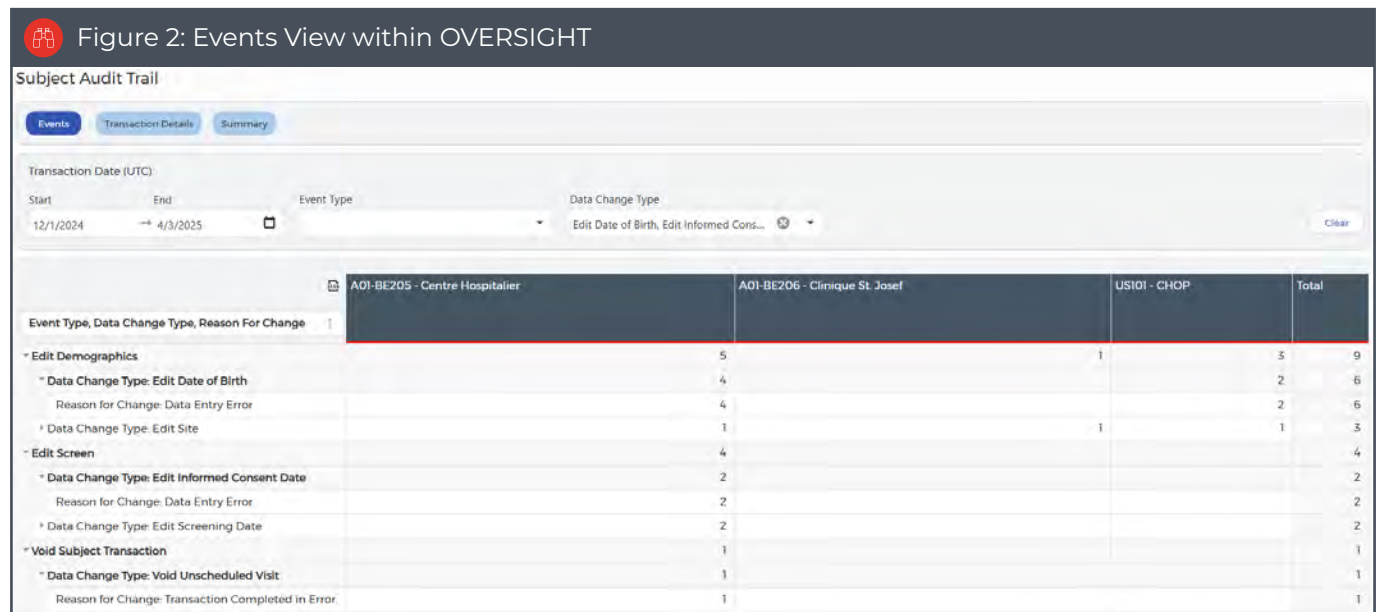
Clear

Export

Subject ID	Record Type	Event Type	Event Name	Event Attribute	Attribute Value	Data Change Type	Changed From	Changed To
Q								
A01-BE2050002	VOID	Void Subject Transaction	Unscheduled Visit	N/A	N/A	Void Unscheduled Visit	Registered	VOID
A01-BE2050006	Update	Edit Demographics	Edit Demographics	Date of Birth	Sep-1991	Edit Date of Birth	Sep-1990	Sep-1991
A01-BE2050007	Update	Edit Demographics	Edit Demographics	Date of Birth	May-1979	Edit Date of Birth	May-1982	May-1979
A01-BE2050007	Update	Edit Demographics	Edit Demographics	Date of Birth	May-1980	Edit Date of Birth	May-1979	May-1980
A01-BE2050008	Update	Edit Demographics	Edit Demographics	Date of Birth	01-Jul-1989	Edit Date of Birth	Jul-1989	01-Jul-1989
A01-BE2050008	Update	Edit Demographics	Edit Demographics	Site Code	A01-BE205	Edit Site	US101 - CHOP	A01-BE205 -
A01-BE2050010	Update	Edit Screen	Screen	Screening Date	09-Mar-2025	Edit Screening Date	03-Mar-2025	09-Mar-2025
A01-BE2050010	Update	Edit Screen	Screen	Informed Consent Date	09-Mar-2025	Edit Informed Consent Date	03-Mar-2025	09-Mar-2025
A01-BE2050010	Update	Edit Screen	Screen	Informed Consent Date	08-Mar-2025	Edit Informed Consent Date	09-Mar-2025	08-Mar-2025
A01-BE2050010	Update	Edit Screen	Screen	Screening Date	08-Mar-2025	Edit Screening Date	09-Mar-2025	08-Mar-2025

OVERSIGHT™ gives you the ability to filter and organize this data on-demand directly in the IXRS®3 platform

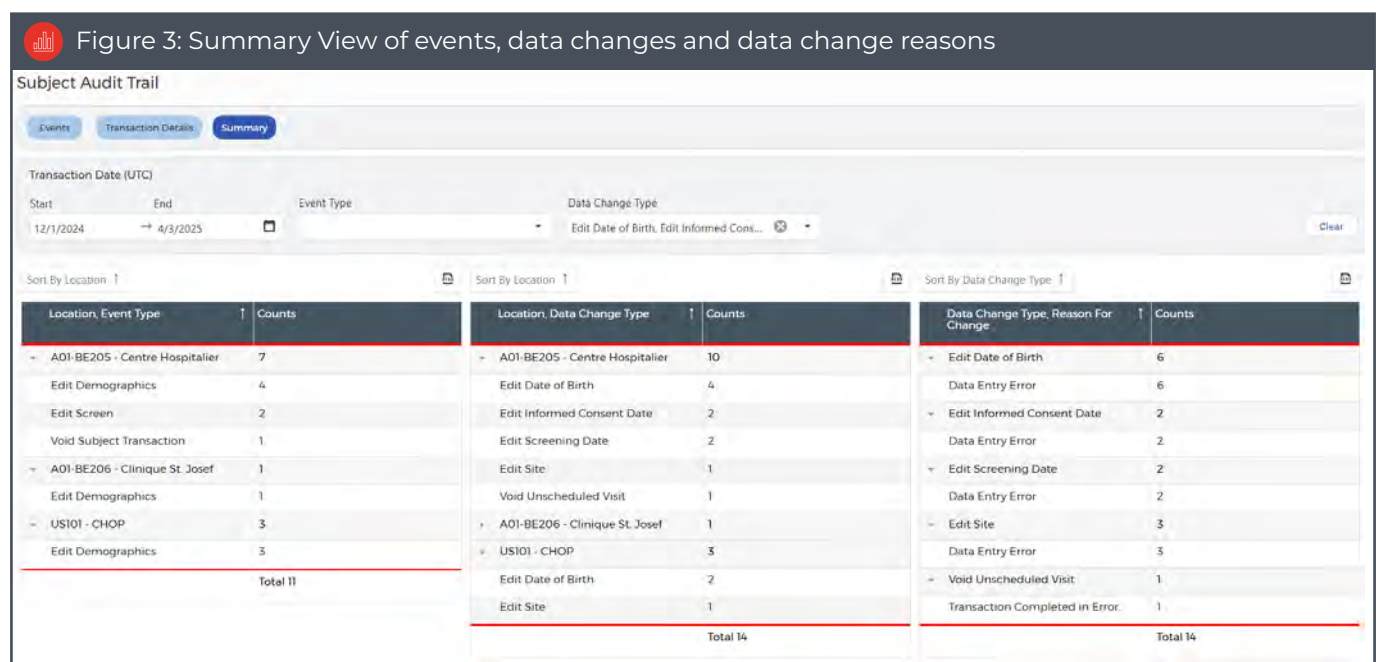
Now, you can clearly see how many events occurred in the study and by site, as well as data changes to easily identify irregularities.



When you can see the outliers – you can investigate and take timely action

Through the lens of OVERSIGHT™, you can easily notice and flag anomalies in the data entered by sites and take the necessary steps to correct the issues before they become a much bigger problem.

The summary view provides visibility into all the changes and adjustments, allowing you to make informed decisions: is this data anomaly acceptable or is it time to pick up the phone and contact the site?



Providing effective data OVERSIGHT™ is critical to maintaining regulatory compliance

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) revised guidance requires documented evidence on how the sponsor performed surveillance of the study.

The Data Integrity guidance put out by the MHRA, FDA, and the EMA aimed to not only assure data integrity but to enhance and take a more proactive approach.

We developed the OVERSIGHT™ tool for IXRS®3 so you don't have to wait for the discrepancies to reveal themselves when it's already too late.

Ask us about adding this IRT booster to your IXRS platform today—and always stay on top of the data guidelines and regulations.

“OVERSIGHT™ identifies if critical control points in your trial have changed, who changed them, and why.”



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