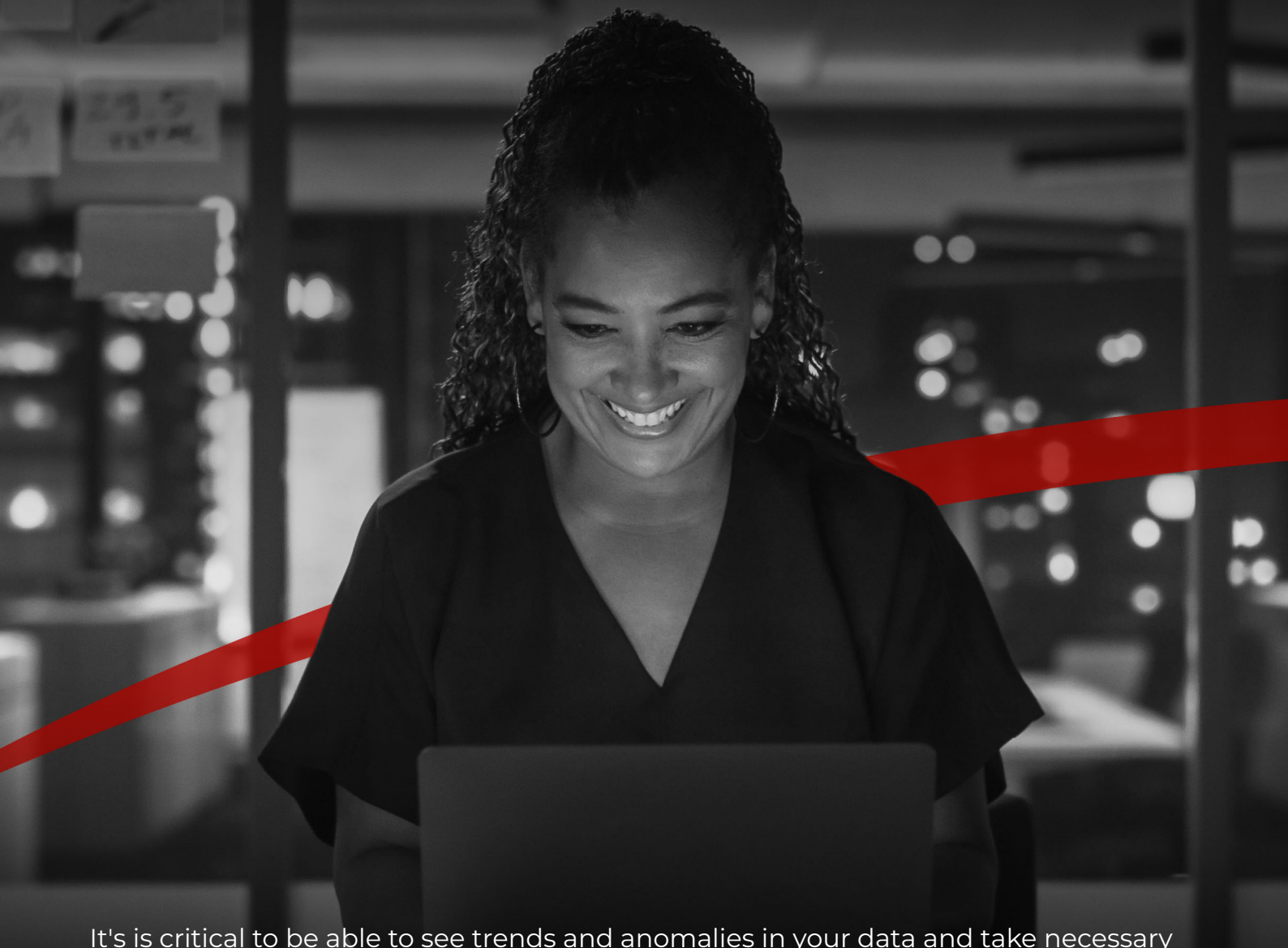




See the full picture
through the lens of OVERSIGHTTM



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 OVERSIGHTTM IRT booster to your IXRS³ 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 Report

Events | **Transaction Details** | Summary

Transaction Date (UTC): Last 7 Months | Subject ID: All | Country: All | Site Code: All | Site Name: All | Investigator: All

Record Type: All | Event Type: Multiple selections | Event Name: All | Event Attribute: All

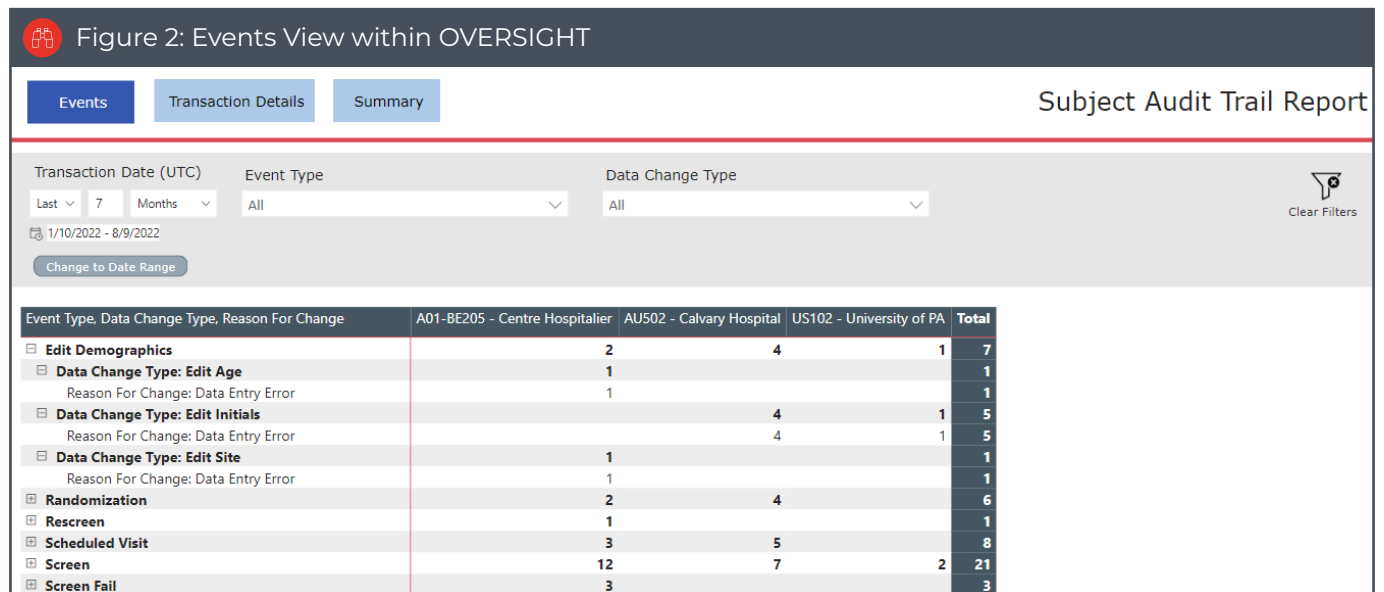
Data Change Type: All | Reference Number: All | Reason For Change: All | Transaction Completed By: All

Returning 194 records

Country	Site Code	Site Name	Investigator	Subject ID	Record Type	Event Type	Event Name	Event Attribute	Attribute Value	Data Change Type	Changed From	Change
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	A01-BE2050005	Update	Edit Demographics	Edit Demographics	Age	68	Edit Age	66	68
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	US1020002	Update	Edit Demographics	Edit Demographics	Site Code	A01-BE205	Edit Site	US102 - University of PA	A01-BE205
Australia	AU502	Calvary Hospital	James Robinson	AU5020002	Update	Edit Demographics	Edit Demographics	Initials	SEW	Edit Initials	SEE	SEW
Australia	AU502	Calvary Hospital	James Robinson	AU5020002	Update	Edit Demographics	Edit Demographics	Initials	SEE	Edit Initials	SET	SEE
Australia	AU502	Calvary Hospital	James Robinson	AU5020005	Update	Edit Demographics	Edit Demographics	Initials	SSB	Edit Initials	SSS	SSB
Australia	AU502	Calvary Hospital	James Robinson	AU5020007	Update	Edit Demographics	Edit Demographics	Initials	DDT	Edit Initials	DDD	DDT
United States	US102	University of PA	Louise Jones	US1020002	Update	Edit Demographics	Edit Demographics	Initials	ABG	Edit Initials	ABC	ABG
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	A01-BE2050010	Insert	Rescreen	Rescreen	Rescreening Date	05-Aug-2022	N/A	N/A	N/A
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	A01-BE2050010	Insert	Rescreen	Rescreen	Subject Status	Rescreened	N/A	N/A	N/A
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	A01-BE2050001	Insert	Scheduled Visit	Assignment Visit 4	Baseline Body Surface Area	1.00 m ²	N/A	N/A	N/A
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	A01-BE2050001	Insert	Scheduled Visit	Assignment Visit 4	Body Surface Area at Visit	1.00 m ²	N/A	N/A	N/A
Belgium	A01-BE205	Centre Hospitalier	Emma Thys	A01-BE2050001	Insert	Scheduled Visit	Assignment Visit 4	Calculated	A: Active 200	N/A	N/A	N/A

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

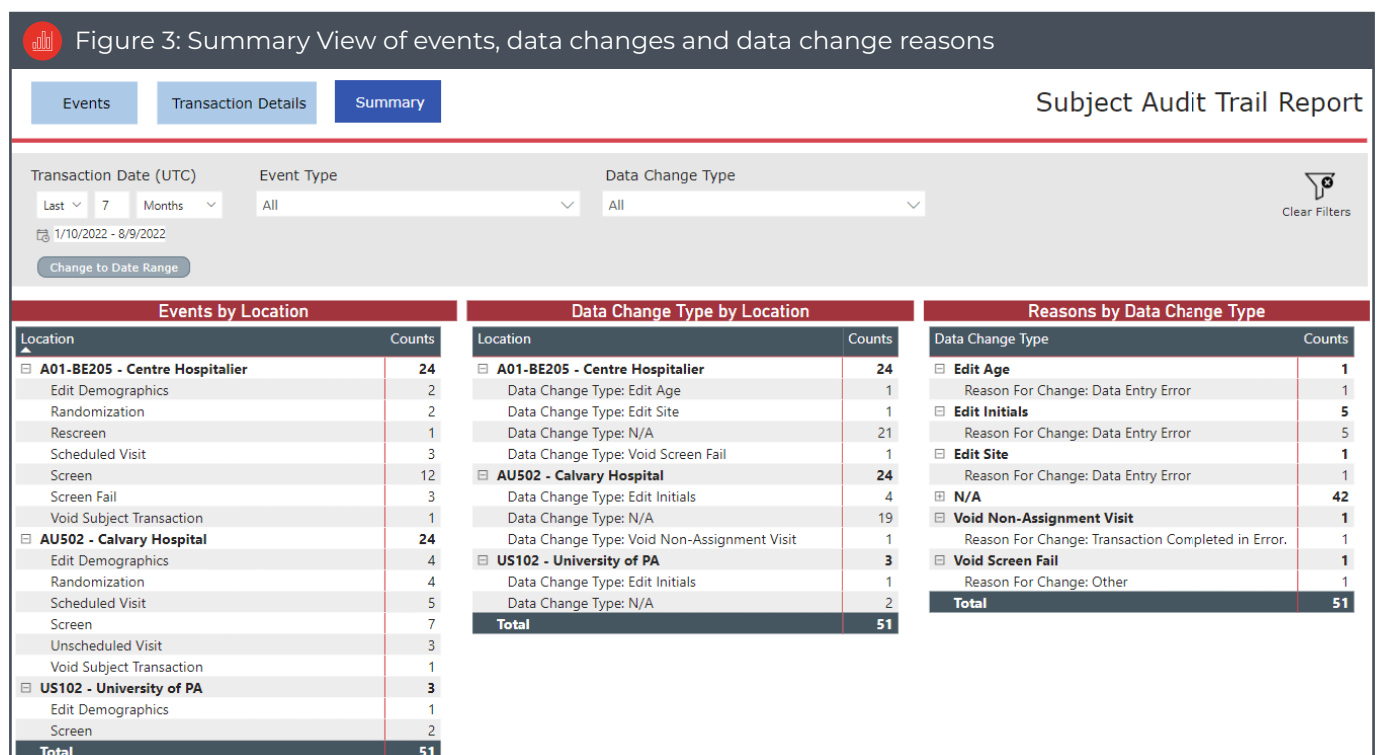
Now, you can clearly see how many events occurred in the study and by site, as well as data changes to easily identify irregularities.



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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