

# VaultConnections

Vault Safety ↔ Vault EDC



## Streamline Clinical Serious Adverse Event (SAE) Reporting and Management

Automatically exchange comprehensive information on reported events, including serious adverse events (SAEs), and streamline reconciliation between data management and pharmacovigilance teams with the Safety-EDC Connection. There is flexibility to choose and transfer information from over 200 casebook and custom data fields (100% more than E2B), including relevant subject data. Easily sharing applicable information reduces queries for clinical sites and enables pharmacovigilance teams to more rapidly process cases and improve quality of safety outputs.

Clinical and data teams have visibility into receipt of SAEs and case ID if an adverse event is promoted to a case in Vault Safety. If a site(s) makes a change to a SAE, new data is automatically sent to Vault Safety and linked as a follow-up. Follow-ups may also be flagged as 'significant' to ensure timely processing for in-flight cases. Linking SAEs and case follow-ups back to clinical source data, reduces risk of inconsistent data and case processing review time as well as streamlines reconciliation processes.



## Benefits

Veeva's purpose-built Safety-EDC Connection automates data sharing between Vault EDC and Vault Safety.

### Safety Team

- **Automate intake of comprehensive data:** Transfer 200+ clinical subject reportable event data fields
- **Accelerate case processing:** View and add relevant subject data
- **Improve safety outputs:** View the SAE with totality of subject information
- **Streamline reconciliation:** SAE, subject data, and follow-ups are linked back to clinical source

### Clinical and Data Teams

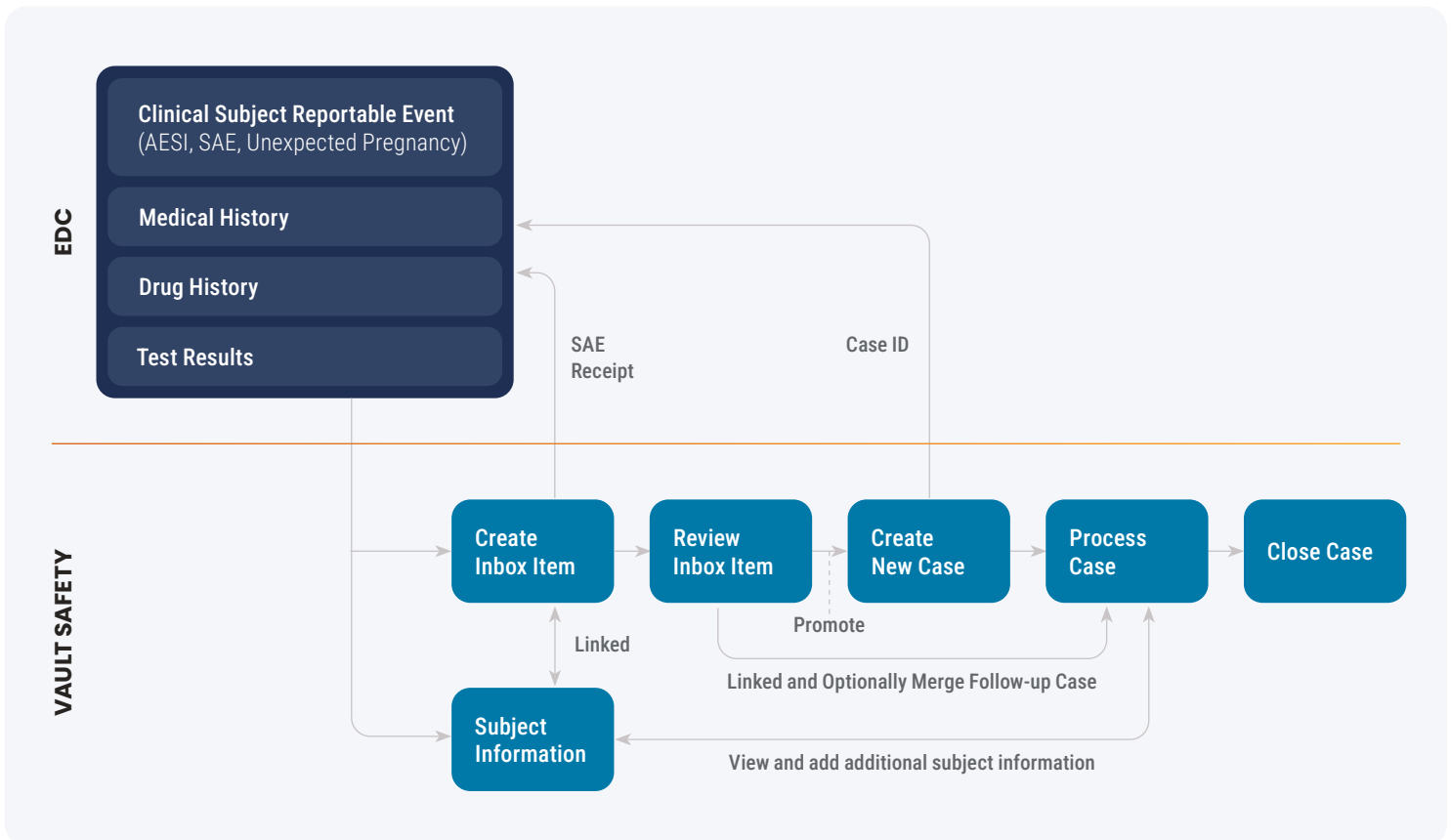
- **Significantly reduce manual reconciliation:** Data consistency between EDC and safety applications with automated data flow
- **Reduce site burden:** PV teams independently access and add relevant subject data, reducing queries for sites and clinical teams
- **Efficient communication:** Visibility into SAE receipt and safety case ID



## How it Works

When a clinical site enters a SAE in Vault EDC, the Safety-EDC connection automatically creates an inbox item in Vault Safety and transfers relevant subject data. A case processor reviews the new safety inbox item, and if it meets the criteria, promotes the SAE to an initial case and shares the Vault Safety Case ID with Vault EDC. During case processing in Vault Safety, if medical reviewers need more data, they can view and include additional subject information in Vault EDC such as medical and drug history, test results, and other adverse events. If a site user later updates the SAE in Vault EDC, the Safety-EDC connection automatically creates a new follow-up inbox item, links it to the safety case, and may flag as significant based on pre-defined criteria. The case processor can review and optionally merge the follow-up data with the existing case.

Synchronization of data between Vault EDC and Vault Safety is managed and maintained with mapped data fields. Organizations can easily add, modify, or disable default fields, simplifying setup and configuration.



*For more information on the Safety-EDC Connection, reach out to your account partner.*