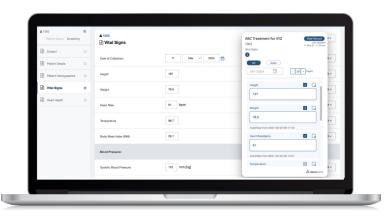


Rave Companion Bridging the gap between EHR and EDC

For years, site personnel have manually re-entered data from other systems or documents into electronic data capture (EDC) software. They open a form in the EDC system, minimize it, and then hunt for the data in another system (e.g., Electronic Health Record (EHR)) or document (e.g., lab data in a spreadsheet). Then, they return to the EDC system and manually enter the data into the form. There's too much back and forth, typing, and errors in this approach, resulting in more queries.



Sites are overburdened with data entry

Clinical trial sites spend too much time re-entering data, which introduces transcription errors, resulting in more raised queries to be resolved.

70%

of EDC data is duplicated from other sources¹ 20%

of the cost of a trial is spent on data duplication and verification¹

Over Half

of Principal Investigators are 'one and done' with clinical trials, citing data entry and time commitments as key reasons²

Rave Companion, a simple-to-use browser plugin, reduces data entry efforts for clinical trial sites by making it easier and faster to populate Rave EDC forms with source data from other systems (e.g., EHR, CTMS, eSource) and documents (e.g., lab values in a spreadsheet). Medidata Health Record Connect is a healthcare data interoperability engine for securely and compliantly acquiring, transforming, and exchanging electronic health record (EHR) data. Combined, this solution accelerates data entry, eliminates transcription errors, and reduces queries, enabling sites to spend more time on higher-value research activities and with their patients.

When a Clinical Research Coordinator (CRC) at the site opens a Rave EDC form, Companion automatically pops up a compact replica of the form. If the site is connected to Health Record Connect, they can link the patient in Rave EDC to their healthcare record by providing one-time patient identification information. Once linked, Companion queries Health Record Connect to find and present matching data for the form, enabling the form to be completed over 90% faster than with manual data entry.

Unlike other EHR-to-EDC solutions that can take months to implement on each study, Health Record Connect doesn't require site-by-site EHR system integrations and data transfer agreements or complex study- and system-specific EHR-to-protocol mappings, so it's up and running immediately.

^{1.} Innovations in Data Capture Transforming Trial Delivery, Applied Clinical Trials, 2021

^{2.} One and done: Reasons principal investigators conduct only one FDA-regulated drug trial, Contemporary Clinical Trials Communications, Volume 6, 2017 Pages 31-38.



If the site isn't connected to EHR data or there's data that's in another system or document, the CRC can still use Companion's always-on-top, floating form to take it alongside the other window and complete the form without having to switch back and forth. And the CRC always has eyes on the data. Nothing is saved until the CRC clicks 'Save' on the form in Rave EDC. All Rave Companion actions are audited so that traceability is maintained.

Benefits

Make data entry easier and faster for your sites

Sites replace time-consuming, error-prone data transcribing with populating forms with connected EHR data in a single click, completing forms over 90% faster than manual data entry.

Improve data quality

Because manual data entry is reduced, there are fewer errors and fewer queries raised by CRAs and Data Managers.

Reduce monitoring efforts

If directly sourced EHR data populates a form, sponsors and CROs can decide to reduce their source data verification (SDV) efforts because the data is electronically sourced.

Features

Populate with EHR data

Rave Companion, enabled with Medidata Health Record Connect, presents structured EHR data that assists sites in quickly finding and selecting data for Rave EDC forms. The site maintains full control over what EHR data goes where. Rave Companion further accelerates data entry by auto-populating multiple fields with values in the same date range.

Stay 'in sync'

Rave Companion automatically stays in sync with the Rave EDC form. The Companion form is free-floating, meaning users can have it alongside any source application or document. There's no need to switch back and forth between windows. Data entered or captured into Companion is automatically reflected in Rave EDC.

Capture source data from any application

With Rave Companion, any site can simply pointand-click or drag to capture data from any source system/ document.

The Medidata Advantage

Streamlining clinical trial workflows doesn't have to be difficult if you have the vision to look at things differently. Rather than taking the same approach as EHR-to-EDC solutions that rely on complex mappings between EHR and EDC systems, take months to implement, and are not scalable, Medidata developed Rave Companion enabled with Medidata Health Record Connect. Companion provides automated assistance to help the CRC complete data entry much faster, easier, and more accurately using information already in the site's EHR or other systems/documents. Companion is very simple for sites to install and use, and the CRC always controls what data is saved into Rave EDC. Medidata is transforming how data is captured and managed in clinical studies with Rave Companion enabled with Medidata Health Record Connect.