



OPTIONAL MODULES AND SERVICES

You can mix and match. Or match and mix. It's really up to you.
You have your pick of modules that plug seamlessly into the platform.

In clinical research, confidence comes from clarity.

With eClinicalOS (eCOS) from Merge eClinical, you can choose from a range of options to help you see your study more clearly — and manage it more smartly. Through our exclusive Clinical Configurator™, you simply click-and-pick the capabilities that best fit your research needs. So you get what you need — without having to pay for what you don't.

Capabilities available within the eCOS platform include the following.

THE TOP LINE

-  Pick the capabilities you want
-  Scale eCOS to be just the right size for your team
-  Spark efficiencies with all-in-one platform

AD HOC REPORTING: Ad hoc reporting module helps you create robust ad hoc reports. The data visualization tool allows for the design and build of standard and custom reports that can pull data from any field as well as related metadata.

DATA IMPORTS/API SERVICES: Some data for clinical studies cannot be captured digitally, and some sponsors use multiple vendors to collect all the information they want for a study. The Data Imports option lets you add data to the study EDC without performing data entry (e.g., central lab results that can be provided electronically to the sponsor). The information is imported into eCOS and integrated with the rest of your data. API services provide a way to monitor the study or use imports in an automated fashion, increasing your study team's efficiency. Imports allows you to add data without data entry through SFTP or create web service/API that will upload data directly and map it to CRF. Training program on how to use DI/API available.

DICOM IMAGING: The DiCOM tool lets you upload, store and view medical images directly into the eCOS platform. The module includes a page control for uploading and identifying different types of images such as MRI, CT or PET. A Storage/Data/Retrieve tool is included for image management needs, and you can view any image with iConnectAccess, a zero-download DICOM image and XDS viewer.

DISPENSING: eCOS allows you to define treatment options, to input and track inventory, shipments and site inventory, and to dispense to your subject database. Dispensing details and all relevant shipping information from the shipper to the subject are included in your study's data exports with each subject's record.

ELECTRONIC DATA CAPTURE (EDC): At its core, eCOS offers a fully integrated and comprehensive pathway to capitalize on the robust benefits of an EDC system. Beyond just eliminating wasteful and time-consuming paper records, though, the eCOS EDC function empowers you to track, monitor and improve operational efficiency while ensuring compliance with all necessary regulations. Best of all, the eCOS platform puts every piece of study data at your fingertips through a consistent, integrated interface accessible from virtually any Web-enabled device.

ENDPOINT ADJUDICATION: Unique in the industry, our online adjudication tool saves time and money by enabling you to bring true "paperless workflow" to endpoint adjudication. No more boxes of three-inch-thick notebooks to ship, no more verifying thousands of data points by hand. Instead, you capture source docs and endpoint details as part of a streamlined electronic workflow that facilitates adjudication of endpoints and events, including safety endpoints. You can also collect the information and then provide access to electronic dossiers and forms to sites, coordinators and adjudicators. And you can track progress of the review from a convenient one-stop dashboard.

EPRO: Essentially a digital diary, Electronic Patient-Reported Outcomes (ePRO) lets you collect data directly from patients when studies require them to record compliance with meds, pain levels or other details outside of their clinic visits. Because ePRO is a browser-based system integrated into the overall platform, both patients and researchers can access the data anywhere, anytime.

INVENTORY MANAGEMENT AND DISPENSING: The eCOS Inventory Management and Dispensing module provides an up-to-the-minute status overview of your research inventory and lets you coordinate the entire dispensing and tracking process in a comprehensive and coordinated manner.

LAB NORMALS: With reliance on local laboratories growing, study teams must collect lab-specific normal ranges to use the data provided. But those labs' formats, content and test methods often vary, making it difficult to ensure consistency and accuracy. Lab Normals helps normalize laboratory values to account for data differences between various clinical research sites. This module collects ranges, applies them to subject results for cleaning, and then outputs the data as a regular study export.

MEDICAL CODING: Through this module, you can access MedDRA and WHO Drug dictionaries (based on licensure), capture the text verbatim, and research and assign codes (you can even output the codes in the same export as original study data). Plus, you can select or update your dictionary version to suit your study needs.

RANDOMIZATION: Our Randomization module and Interactive Web Response (IWR) feature let you define the stratification factors used to select and assign subjects to a randomization group. You can also assign randomization records to subjects directly in EDC and have the information included in the same data export.

SAFETY REPORTING: Our Safety Reporting module allows you to generate reports for your study. You can create a readable ICSR report or a MedWatch 3500A v.1.0 report and post it to an eCRF page or use the submission process to transfer it outside of the system. The module outputs AE forms in a standard E2B format.

SOURCE DATA VERIFICATION: With the Source Data Verification function, you can choose any clinical data field to be indicated as “Source Data Verified” when building your study. As a result, you can implement monitoring plans based on a specific target percentage of data to be verified. (Source Data Verification is a native function of eCOS.)

STUDY CONNECT MOBILE APP: Through this easy-to-use mobile application, you have fingertip access to study data such as charts, graphs, reports and key metrics. In addition, the Study Connect mobile app lets you set customized alerts and notifications (e.g., when an adverse event occurs, when a site is activated, when a subject is enrolled, etc.). Even randomization, dispensing and site document capture can be handled on your on iOS®-enabled devices (iPhone® or iPad®) with this app.

STUDY MANAGER: When you find “research” and “the business of research” intersecting (and they always do), you’ll find our Study Manager module to be an ideal ally. Through Study Manager, you can track performance not only in a single trial, but also across your portfolio of trials. It offers an array of valuable functions, including: (1) tracking progress milestones related to site activation; (2) storing site and study-related documents with certain version control capabilities; (3) creating and storing site monitoring visit reports; and (4) tracking financial data (e.g., study budgets and site payments). You already run a great trial; now you can run a great business, too.

STUDY TESTING: Study Testing lets you run full-system scans that automatically generate testing scenarios built on industry-standard templates or fit-for-use delta scenarios you create. You can also manually design and deploy a wide range of custom test cases tailored to your specifications. Full-system data flushes can be done within minutes so you can cycle back and begin again at your convenience.

SUPPORT CENTER: In addition to Level 1 support available around the clock, our Support Center offers ready access to eCOS-Certified Designers who know more than just the ins and outs of the platform. They have experience with every type of trial (pharmaceuticals and medical devices for sponsors, CROs and AROs), at every phase, in all major therapeutic areas, and in more than 50 countries. You can connect with our support specialists in the way that best fits your needs — via phone, email, live chat, Twitter or in person.

TRAINING AND TRACKING: The Training/Tracking module lets you require that users such as clinical trial coordinators and investigators review training material (e.g., study protocol, work instructions, etc.) and pass an online assessment before they’re allowed access to the system. Many clients use this feature to demonstrate FDA-training compliance at research sites. With how easy (and cost-effective) it is to expand your data capture and management capabilities, odds are once you put a single eCOS module to work, others are sure to soon follow. Along the way, you’ll experience what eCOS does best — providing a flexible, powerful and affordable way to manage the data that’s critical to your research.

TRANSLATION SUPPORT: Our translation module allows you with one click to seamlessly include additional language access in your study. Simply design your page. Import non-English translations. And watch the system do the rest, as it automatically provides the appropriate view based on the user’s language choice.



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