

## Unified Adjudication Workflow

Recent years have seen an increasing regulatory interest in establishing centralized, objective, and reliable methods of managing and reporting safety and efficacy results. In an effort to break down the data silos that have characterized the space of end-point adjudication Datatrak has developed a powerful and flexible end-point adjudication module that lives within the EDC itself.

By eliminating the barrier between adjudication processes managed by paper or independent adjudication systems, we can provide powerful workflow management, improved operational quality, and process oversight alongside the cost savings and quality of life improvements that come from simplifying your technology burden.

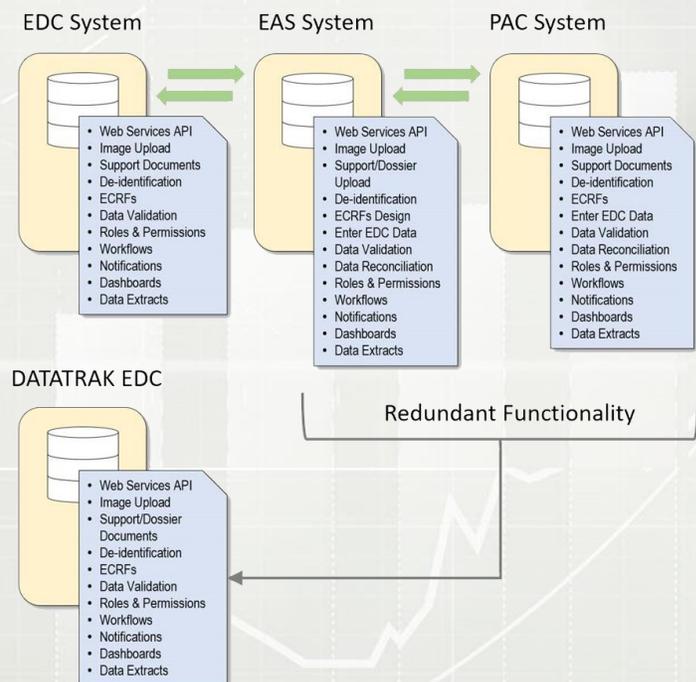
## Flexible Workflow Design

Our Adjudication module is centered around the implementation of a few very powerful and easy to use trial design tools. Using the same utilities that are used to build your trials and your patient casebooks, our users can now wrap any end-point collected in the EDC in a controlled approval workflow.

## Image Data Capture and Review

- Upload images directly to eCRFs for reference
- Automatically extract DICOM data into eCRFs
- Pin other essential documents to tasks
- Assigned adjudicators are blinded to the results of the assessments of other adjudicators, preserving objectivity

## Datatrak's Adjudication Process



## Adjudicate Safety Endpoints

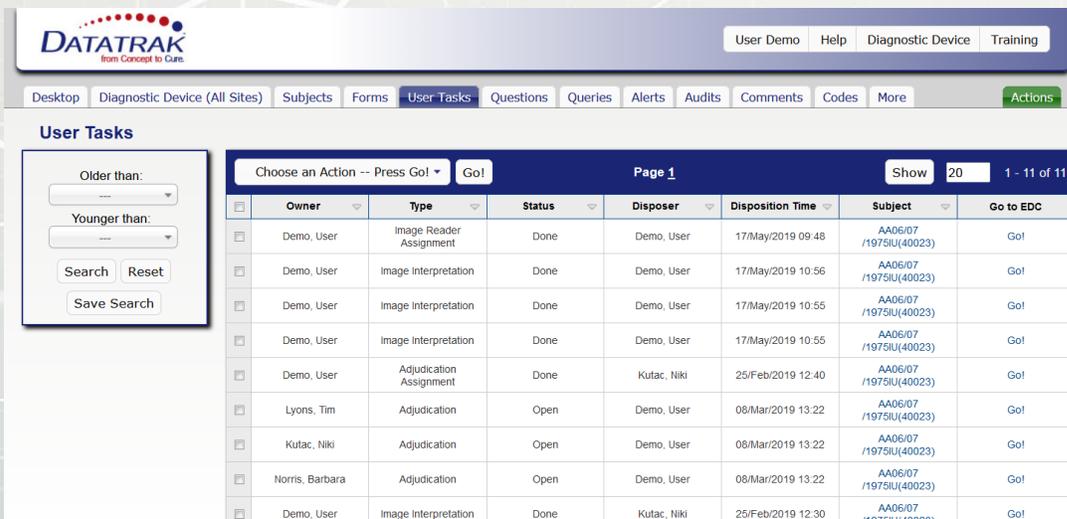
- Approval workflows do not have to be used on every event
- When a safety event is escalated to a Serious Adverse Event, after review the event can be optionally sent into adjudication when necessary
- User task notifications ensure the safety event will be handled quickly without the delay of communicating across systems
- On demand workflow approvals like this can be extended to any critical endpoints

## Work with Real-time Data and Centralized Tools

The most current versions of important documentation housed in our Files Manager can be shared with adjudicators, in addition to select eSource data chosen from the patient casebook. We have the ability to share specific data points with adjudicators in a manner that preserves their blinding to the patient. This means they can safely work with real time data without having to engage in a complicated process of exchanging information across systems. Similarly when responding to the questions issued by adjudicators, the source data is immediately at hand.

## Convenient Task and Query Management

- Tasks issued to users can be tracked on user dashboards and can be paired with email notifications
- Improve oversight with our Notifications Manager, a central repository for viewing and reporting on active and completed user tasks
- Adjudicators can issue queries and requests for information inline on their assessment forms
- Queries can be reviewed, reported on, and responded to using the same centralized tools used in the EDC



The screenshot shows the Datatrak User Tasks dashboard. At the top, there is a navigation bar with the Datatrak logo and the tagline "From Concept to Care". To the right of the logo are links for "User Demo", "Help", "Diagnostic Device", and "Training". Below this is a secondary navigation bar with tabs for "Desktop", "Diagnostic Device (All Sites)", "Subjects", "Forms", "User Tasks" (which is active), "Questions", "Queries", "Alerts", "Audits", "Comments", "Codes", "More", and an "Actions" button.

The main content area is titled "User Tasks". On the left, there is a search filter panel with "Older than:" and "Younger than:" dropdown menus, and "Search", "Reset", and "Save Search" buttons. The main part of the dashboard is a table with the following columns: Owner, Type, Status, Disposer, Disposition Time, Subject, and Go to EDC. The table is on "Page 1" and shows 11 rows of data. The "Status" column contains values like "Done", "Open", and "Done". The "Go to EDC" column contains "Go!" links for each row.

Owner	Type	Status	Disposer	Disposition Time	Subject	Go to EDC
Demo, User	Image Reader Assignment	Done	Demo, User	17/May/2019 09:48	AA06/07 /1975U(40023)	Go!
Demo, User	image interpretation	Done	Demo, User	17/May/2019 10:56	AA06/07 /1975U(40023)	Go!
Demo, User	Image interpretation	Done	Demo, User	17/May/2019 10:55	AA06/07 /1975U(40023)	Go!
Demo, User	Image Interpretation	Done	Demo, User	17/May/2019 10:55	AA06/07 /1975U(40023)	Go!
Demo, User	Adjudication Assignment	Done	Kutac, Niki	25/Feb/2019 12:40	AA06/07 /1975U(40023)	Go!
Lyons, Tim	Adjudication	Open	Demo, User	08/Mar/2019 13:22	AA06/07 /1975U(40023)	Go!
Kutac, Niki	Adjudication	Open	Demo, User	08/Mar/2019 13:22	AA06/07 /1975U(40023)	Go!
Norris, Barbara	Adjudication	Open	Demo, User	08/Mar/2019 13:22	AA06/07 /1975U(40023)	Go!
Demo, User	Image Interpretation	Done	Kutac, Niki	25/Feb/2019 12:30	AA06/07 /1975U(40023)	Go!

## Improve Operational Reporting and Quality Metrics

- Eliminate the imprecision of pulling data across multiple systems to assemble reports
- Our EDC's ad-hoc reporting tools and powerful Business Intelligence capabilities allow you to analyze and characterize your endpoints and adjudication process within and across studies
- More easily focus in on particular types of studies or circumstances
- Gain more visibility into the agreement rate of adjudicators or quality metrics regarding the handling of adjudicator queries



## Adjudication

### Datatrak Image Data Capture

Datatrak's Medical Imaging Capture allows for the analysis and annotation of image data, including the versioned images, processed into Datatrak's EDC platform. Whether you are utilizing CORE lab services, or conducting internal scientific research, Datatrak will enhance your information needs with our sophisticated enterprise platform.

### Reduce Cost and Simplify your Tech Burden

With every additional technology system your organization is using come a variety of direct and subtle costs. Multiple contracts, integration and validation difficulties, more complicated training procedures; these are all difficulties that can be eased or eliminated by reducing the number of supporting technologies you interface with as a company.

Unified technologies like our EDC aim to provide you with the greatest possible level of functionality in a single, streamlined product. If you're interested in discussing with us how we can simplify your lives, please reach out to us to schedule a [demo](#) today.

### Datatrak Enterprise Cloud

*Enterprise Platform*  
*Business Intelligence*  
*Clinical Trial Management*  
*Electronic Data Capture*  
*Image Data Capture*  
*ECG Data Capture*  
*Adjudication*  
*RTSM*  
*Clinical Trial Design*  
*ePRO*  
*eCOA*  
*eConsent*