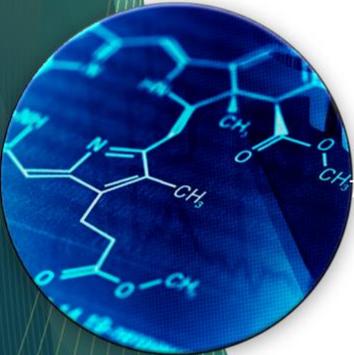
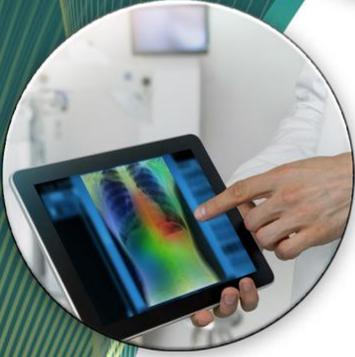


White Paper
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Utilizing DART to Streamline Onboarding and Centralization

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HIGHLIGHTS AND KEY FINDINGS

- Easy and fast access to data is essential in the world of scientific research. Yet, mission-critical research work is often constrained due to delays in the data access approval process. These delays may be the result of complex internal review boards (IRBs) or investigations, manual processing, or the volume of requests relative to staffing.
- Slow approval processes can dramatically affect an organization's ability to foster sound, sustained advances in science and may impact patients' health in the case of applied prevention and treatment research.
- Centralized and streamlined data access request systems, such as the Data Access Request Tracker (DART), can reduce the access request and processing time through customizable and logical workflows by addressing the need for efficient, timely access, as well as any complex investigation requirements.
- Since the initial launch of the DART application at the U.S. Department of Veterans Affairs (VA), the organization has seen a decrease in access request processing and approval times from several months to a few days on average, ultimately improving customer satisfaction levels and data management effectiveness.
- The success of the data access request system has led to further automation and the creation and use of digital resources to enhance researcher collaboration, including the creation of the Project Provisioning Tool (PPT), which improved the VA's ability to manage human capital by automating key workflows.
- The combined use of DART and PPT has reduced provisioning time for new research studies from days to a matter of minutes.
- The use of applications such as DART at the VA have improved workflow efficiency, reduced processing time, enhanced customer satisfaction, and improved human capital time management.



ABSTRACT

The Data Access Request Tracker (DART) application is used for the Institutional Review Board (IRB) Research Data Access request and Preparatory to Research processes. The DART application was created for the U.S. Department of Veterans Affairs (VA) and can be used by any other approved agency. Primary investigators submit one DART request per protocol or proposed protocol and any changes to the request after approval must be accomplished by amending the same request, not by creation of a new request.



DART uses a dashboard landing page with five additional steps for most requests. Each step has a page with an identifying tab: Activity Information, Participants, Data Sources, Documents, and Submit for Requestors or Decision for Approvers.

DART was designed with interaction in mind, knowing that requests are rarely complete on the first attempt. All interactions are captured and permanently stored to ensure a complete history of events is clear and available. Notifications are also automatically generated for all parties when a modification or request is made to ensure there are no lapses in communication.

The DART application exists behind two VA firewalls and all data collected is encrypted at the application and disk level to ensure no identifying information is revealed in the event of an attack. All data in motion is encrypted using Transport Layer Security (TLS) 1.2 or above along with industry-standard, strong cipher protocols. No patient information is ever stored or revealed in DART which also reduces the overall security concerns of the application. All these layers of protection help the VA protect the safety and integrity of their human and digital assets.

PROBLEM STATEMENT

Many researchers have concerns about the time required to obtain approval to access data. These delays have been attributed to multiple issues such as tracking approval, evolving procedures, numerous requirements, and limited resources and staff.

Tracking data access requests can be an extremely difficult task considering the varying workflows and approval processes required for different data sets.

Some requests may require IRB approvals or be informational only, while others may require special approvals from executives or third-party gatekeepers.

Interactions do not stop once a data access request has been approved. Primary investigators may come and go, IRB approvals expire and require additional interactions, and initial requests may not have been complete or accurate.

Manually tracking data access requests can become burdensome or impossible based on differing workflows, changes in organization processes and procedures, and the sheer number of requests that are received yearly. Also, organizational changes may require further training that can be difficult to organize and expensive to conduct.

Another factor to consider is that a slow onboarding process due to poor data tracking practices can decrease an organization's ability to foster sound and sustained advances in science. Researchers who are unable to access data are unable to conduct applied prevention and treatment research that can improve the health and development of countless patients.

In today's fast-paced research world, organizations need to provide scientists and researchers rapid access to datasets to foster sound and sustained advances in science and ensure optimal patient treatment and health.



BACKGROUND

The Data Access Request Tracker (DART) was created to help centralize and streamline data access requests, as well as reduce the time it takes to successfully submit requests. The DART application uses customizable workflows determined by asking the user a series of questions. Based on the answers, a workflow is selected, and the tabs are customized for their request.

The DART application offers organizations a dramatic improvement in access request and approval times—often reducing processing time from several months to just a few days on average.

Each tab must be entirely completed prior to submission and, in nearly all cases, requires all the proper documentation and information necessary for a data manager to make an approval decision. In the rare situation where all the necessary information was not submitted or requires clarification, the data manager can send an additional request back to the submitter via DART. DART then automatically generates an email to the primary investigator with the details of the clarification or request so the primary investigator can take the necessary actions to move the request forward.

Since the initial launch of the DART application, the VA has seen a dramatic decrease in processing and approval times, as well as turnaround time once a request has been approved. Approval times plummeted from several months to the current average of 10 business days for final approval, all while providing transparency, tracking, and document collection and storage. This has improved customer satisfaction levels, as well as improved the effectiveness of the data management team, since their time is now freed up to work on their other responsibilities.

With the help of Initiate Government Solutions (IGS), the VA has taken steps to further automate the provisioning process by creating standalone applications that create file shares, databases, SharePoint collaboration sites, and other resources that once had to be done manually by various teams of people. IGS created the Project Provisioning Tool (PPT) which exposes application programming interfaces (APIs) that DART triggers based on the workflow established for the approved request.



This automation has drastically increased the effectiveness of the entire team by reducing the need for human interaction at each step which has helped the VA manage their human capital more effectively.

Through the DART application and PPT, the VA has been able to decrease the provisioning time for new research studies from days to a matter of minutes, in most cases. The workflows introduced have helped the VA encourage innovation and competition, as well as laying the foundation for several production applications that are based on research initiatives.

TOOL

DART uses a dashboard landing page and has five additional steps for most requests. Each step has a page with an identifying tab. The five pages are Activity Information, Participants, Data Sources, Documents, and Submit for Requestors or Decision for Approvers.

All data in motion is encrypted in DART. No patient information is ever stored or revealed, reducing the overall security concerns of the application.

Dashboard

The DART dashboard is the DART home page where primary investigators can initiate a new DART request, view the To-Do List, and view any previous requests. Once the request is submitted, users access this page to monitor status and initiate changes.

Activity Information

The information page captures the pertinent details of the study and is used to help generate documentation requirements and processes for data access request tracking.

Participants

The Participants page allows the primary investigator to define primary and secondary sites, designate collaborators that are authorized study participants, manage their access authorizations, and specify each participant's role in the study.

Data Sources

The data page allows the primary investigator to select data sources and to specify HIPAA requirements which are used to help generate documentation requirements.



Documents

The documents page displays a list of required documents by site and participant based on inputs and allows for upload of documents. It also displays administrator documents for the user's reference or action.

SUBMIT OR DECISION

The submit page is where the primary investigator submits their completed request. Upon submission, the decision page is where the appropriate parties will review, comment, request changes, deny, or approve.

DART has separate workflows for the various data sets it manages which allows for complete control over the approval process, as well as the documentation and information required for data access approval. See example workflow in Figure 1.

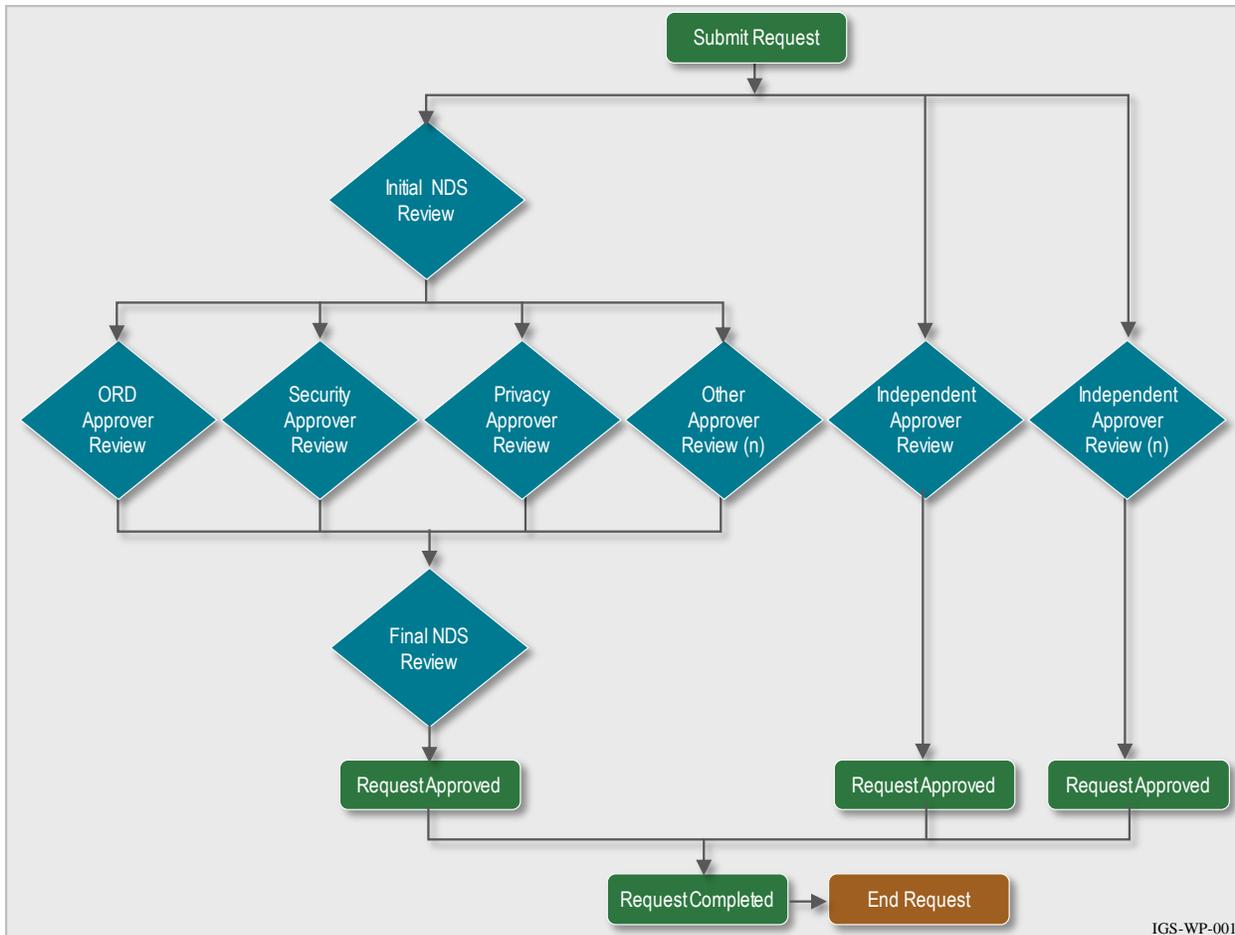


Figure 1: Example of National Data Service (NDS) Workflow

Throughout the entire submission process, tool tips and help dialogs are available to explain what is required for each section or field. In many cases, pre-designed templates are available and preferred.

Templates are made available via a file server that is external to the DART application and should remain static to avoid unnecessary changes to the links DART provides.

Once a request has been submitted and approved, the user or the data management team may continue to make changes to the request. These changes are called amendments and are always tied to the parent request. Amendments are identified with "A####" appended to the end of the request, with each amendment increasing the number appended. This allows for versioning of the request, as well as a complete and accurate history of requests. Amendments occur whenever the primary investigator requires a change either to personnel or to the base request, or when the data managers request additional documentation or information. It is possible to

have multiple amendments prior to an approved request due to this back and forth communication that may be required.

Any time during the process, both the primary investigator and the data managers can see the current status of a request along with any actions that are necessary to move the request forward. It is strongly recommended that primary investigators keep a close watch on their email and the DART application during the approval process because most delays that are experienced are due to the lack of communication or response to requests from the data management team.

KNOWN ISSUES

508 Caveat: If a user is working with the assistive technology tool called ZoomText to navigate the DART Application, an issue may arise where the application starts jumping through the page elements without the user's intervention. If a user encounters this scenario, pressing the CTRL key or hitting the browser's refresh button (F5 in Internet Explorer) will stabilize the application.

CONCLUSION

Ultimately, the DART application provides an extremely flexible platform that can be customized via the use of workflows. Workflows can be created for each individual data source or reused for multiple data sources if the approval process is the same.

The DART application can greatly reduce the overall time from request to approval to provisioning, as well as improve customer satisfaction and reduce the overall costs associated with managing data access requests.

DISCLAIMERS

The DART application does require some changes to be coded into the application which may require a developer familiar with the application. These changes are mostly related to workflows that are outside of the normal or stylistic changes to the application to help seamlessly integrate into the environment or surrounding applications.