Why You Need a *Validated Imaging* Data Management Solution

> To ensure the safety and efficacy of new therapies, rigorous regulation has been put in place to ensure their development has been documented properly.

Research entities such as pharmaceutical and biotech organizations, academic medical centers (AMCs) and contract research organizations (CROs) must adhere to these regulations before a new treatment is approved for general use.

In the case of new drug-based therapies, the United States Food and Drug Administration (FDA) requires the conduct and results of a clinical trial to follow a regulation commonly referred to as 21 CFR Part 11. This regulation also applies to creating approvable, usable artificial intelligence (AI) for use in clinical workflows. This is crucial for pharmaceutical and healthcare organizations, as AI models have the power to accelerate clinical trials and improve patient care by intelligently interpreting data and feeding downstream systems, helping researchers save time and money.

What is 21 CFR Part 11?

Part 11 of Title 21 of the Code of Federal Regulations requires anyone submitting electronic records to the FDA to ensure those records are trustworthy and equivalent to paper records. To do this, they must prove that all electronic records:

- *Are authentic, confidential and retrievable*
- *Come from a validated, well-defined and testable system*
- *Include time-stamped audit trails of changes to data, who made them and why they were made*
- *Use operational system checks to ensure correct workflows*
- *Document who has access and editing rights within your system*
- *Use e-signatures that include the printed name of the signers, the date and time of signatures, and the intention of each signature*

What is a medical imaging platform?

A medical imaging platform is a way to easily access, analyze and manage medical images. It should enable the storage of medical images in DICOM® and other formats and allow images to be translated between these formats.

A medical imaging platform should allow for more visibility into valuable imaging data by helping you discover, manage and curate data cohorts. It should allow for algorithms to be unleashed on your data to enable greater accuracy and efficiency. And it should allow for greater access and collaboration, within your organization or with collaborators across the world, alleviating the gaps in current CTMS platforms and picture archiving and communication systems (PACS) while still integrating with them.

While an imaging platform cannot replace the work done by a CTMS or CRO, it can work in conjunction with them, and allow more control over and visibility into your data so you can more easily test hypotheses before contracting one, as well as give you the ability to reuse this data more easily.

For AMCs, having imaging data be auditable is important for several reasons. In addition to the clinical trial work they may be doing with pharmaceutical organizations, having auditable records is crucial for maintaining the integrity of imaging data used in patient care and research. Academic medical organizations may also want to do exploratory and secondary research in addition to clinical trials, and the data they've collected should be validated.

In addition to clinical trials, pharmaceutical organizations may also have initiatives to train models and develop AI or possibly even manage smaller-scale trials in-house. This requires an infrastructure to access and manage all of your data, wherever it may live, while establishing an audit trail so the results of these efforts can be validated and therefore usable.

Working with clinical trials management systems

A clinical trials management system (CTMS) can help pharma organizations manage and track their research activities in one centralized location. These are useful for managing information such as training records and participants. However, a CTMS may lack certain features that make them inadequate alone. These limitations include:

- Difficulty accessing data across locations
- Insufficient data management capabilities to store current and historical data for analysis
- Inadequate data reuse capabilities
- Absence of data standardization across different CTMS platforms
- Inconsistency around imaging data, which consists of large files that may differ in quality, file type and available metadata

In addition, CTMS platforms may lack features for comprehensive regulatory reporting and auditing. Validating a CTMS for FDA approval requires multiple resources and a large amount of documentation. Changing even one form within the system can take weeks to properly document.

Benefits of working with a validated system

Working with a system that has been designed with validation in mind can help researchers achieve peace of mind and save time and resources. With a system in place that automatically tracks changes, creates audit logs and correctly sets user permissions, researchers will have everything in place for FDA approval or in the event of an audit. Time savings can be substantial, given that researchers won't have to backtrack and document changes manually every time a change is made to data, including who made the change and why.

Flywheel activates phase 3 clinical trial

A research laboratory needed a way to conduct a complex phase 3 clinical trial in accordance with the FDA. The multicenter trial to assess the efficacy and safety of a new treatment in participants with moderately severe to severe non-proliferative diabetic retinopathy (NPDR) needed to be randomized, double-masked, sham-controlled and two-arm, while staying in compliance.

With Flywheel Validated Core, researchers in dispersed clinical sites can upload ophthalmic images and data from multiple sites into one, centralized location, where it can undergo comprehensive reader review. This work is completed with audit trail logging to help researchers ensure changes to their data are retraceable and re-constructible per 21 CFR Part 11 regulations.

Introducing Flywheel Validated Core

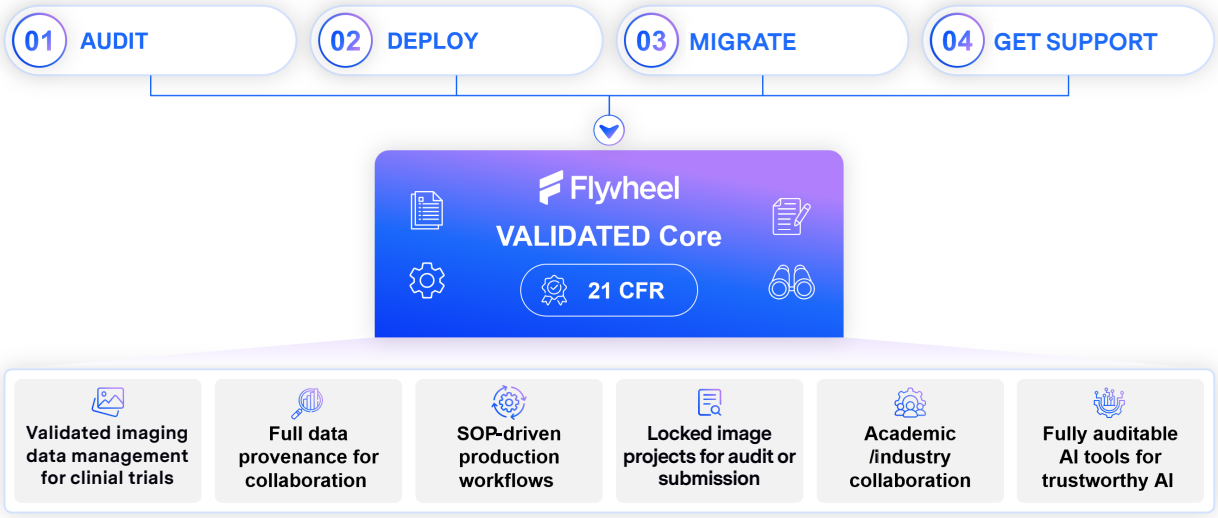
Flywheel, the leading medical imaging AI platform, has been helping pharmaceutical organizations such as Roche and Genentech, Telix Pharmaceuticals and more develop the next great drug-based treatments more efficiently by automating their imaging data processing pipelines. As a result, they've saved significant time and minimized the potential for human error in the drug development process.

Now, Flywheel has unveiled the Flywheel Validated Core. It provides the same features of the standard Flywheel platform in a fully documented 21 CFR Part 11 compliant environment that allows you to document standard operating procedures (SOPs) for imaging workflows, create fully provenanced data sets and lock data that will be subject to an audit or submitted to a regulatory body.

In addition, Flywheel Validated Core provides:

- Compliant deployment of your instance in your chosen cloud
- Validated features for fully traceable data management with documented audit trails
- Logging of each change made in the system, including what type of change occurred, the reason for deletion, the value at the time of saving and the user who initiated this change
- The ability to export a full audit trail report at the project level
- Two-factor authentication to create locked, fully provenanced data sets for trustworthy AI development
- A secure environment that can be used for secure and compliant collaboration and quality control
- Integration with existing CTMS and PACS platforms

A Validated Instance for Compliant Production



How it works

Flywheel's Validated Core is a version of the Flywheel Core platform that offers the same functionality, ingesting data from multiple sources and curating it to common standards, but with a range of compliance features turned on. This means the platform prompts you to log any changes made, as well as who made the changes and why the changes were made, and then tracks all of that information automatically for audit purposes. Not only are changes to data documented, but the deployment of Flywheel is documented as well.

To launch your Flywheel instance, our team of expert solution engineers can migrate your current SOP-driven workflows. The end goal is that Validated Core gives you visibility into your imaging data all within a stable, traceable and reproducible environment.

Access to added benefits

In addition to the functionality associated with the Validated Core, Flywheel also provides:

Managed audit services: Flywheel clients can audit Flywheel and our deployment of your instance to ensure they are within regulatory compliance.

Professional services: Get access to experienced data scientists to train your team, consult on your Flywheel instance, and develop algorithms and containerized pipelines specific to your workflow needs.

Flywheel compliance documentation and data management: This allows for more efficient submission of data products or AI tools to regulatory bodies such as the FDA.

Putting you in control of your imaging data

Ultimately, Flywheel aims to give pharmaceutical organizations and AMCs more control over their imaging data so clinical trials can be audited, AI tools can be approved and valuable data can be reused, licensed and stored properly. By achieving compliance with a validated imaging platform, you can accelerate new discoveries and improve drug development, generating more revenue and improving the lives of people the world over.

If you'd like to learn more about Flywheel Validated Core, ***schedule a demo*** *to get started.*

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