

## Metrics Manager: The Workflow Management Solution for Quantitative Imaging Assessment for Clinical Trials

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### Background

Quantitative imaging assessment of tumor response is essential in the management of oncology patients as clinicians use objective response information to determine if a patient should continue clinical trial treatment. However, the current workflow for imaging assessment of tumor response is inefficient and error-prone. In many instances, the clinical team transcribes lesion measurements from the radiology report or the oncologists make the measurements themselves when they are not provided.

This demonstration will focus on the utilization of a quantitative imaging tool that has been integrated with an online workflow management system. The web application (v1) was first developed in 2005 by a Cancer Center Core to manage the imaging review and response assessment for oncology clinical trials for affiliated sites. In 2012, the Core developed a complementary imaging measurement tool as a plugin module to an open source software package framework (ClearCanvas, Toronto, ON). To further promote workflow efficiencies, allow for greater flexibility of system configuration, and modernize the user interface, the website and measurement tool applications were completely overhauled in 2015. Two NCI-Designated Cancer Centers have been using v2.0 since July 2015 and we are currently in the process of migrating approximately 60,000 imaging time points for two Cancer Centers from v1 to v2.0. Data migration verification will be completed by the end of 2015 with target go-lives in early 2016. The Core had future plans to transition the quantitative oncology package from the current thick client platform to an open source, zero footprint web-viewer by 2017 (Open Health Imaging Foundation, Chicago, IL).

### Case Presentation

Metrics Manager V2.0 is an all-in-one quantitative imaging tool and online reporting system (Figure 1). It is a complete workflow solution that streamlines imaging review, quantitative assessment, and reporting for clinical trials. Metrics Manager eliminates paper measurement forms and other outdated, error-prone tools and practices.

Figure 1

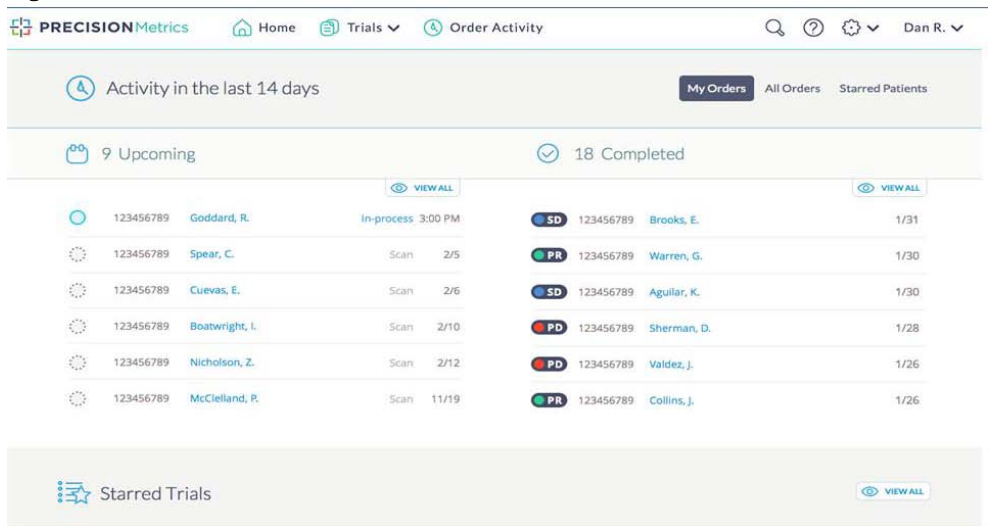


Figure 1: Dashboard view for clinical trial staff after secure login (color coded: PD= progressive disease, SD= stable disease, PR= partial response)

Note: PID used in screenshots are fictitious to comply with HIPAA Regulations.

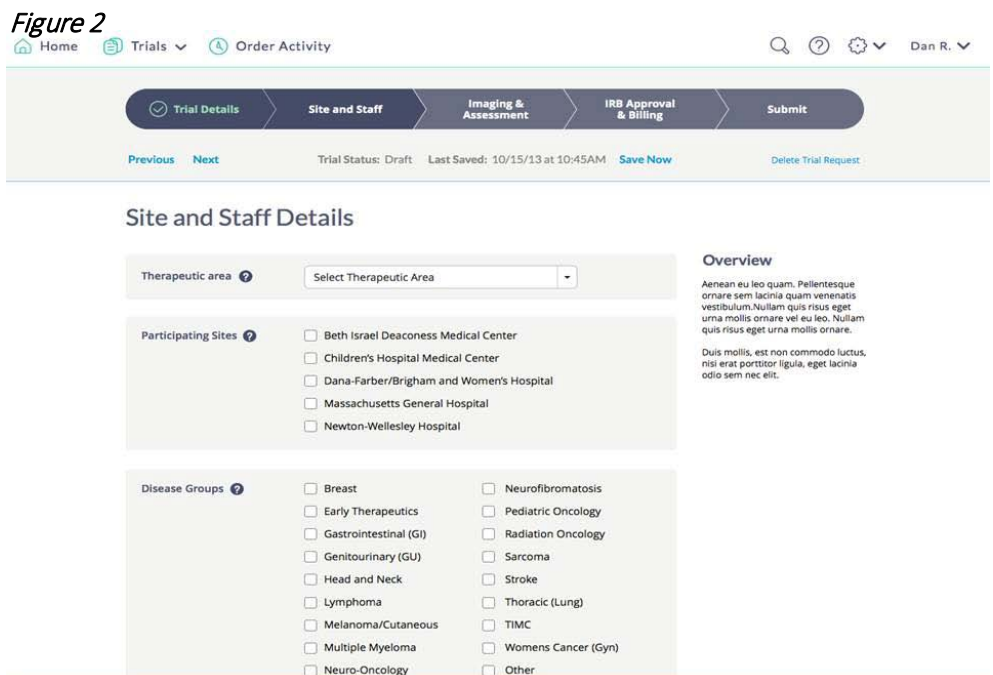
The following goals have been achieved through the implementation of an online workflow management system to manage clinical trials:

- Elimination of paper measurement forms
- Establishment of an image-based longitudinal record
- Improved management of tumor metric requests
- Reduction of incorrect requests (i.e., wrong patient, study, or response criteria)
- Improved results turnaround time and accessibility
- Improved protocol adherence
- Increased reliability and reproducibility of results
- Improved efficiency in preparing for data locks, monitoring visits, and audits
- Improved financial compliance

Adherence to National Cancer Institute vision/requirements for Cancer Center shared resources Metrics Manager offers a complete web-based workflow solution for independent site reviews. The local clinical treatment team can request scan analyses, specify the time when results are needed, and view imaging results through a secure, password-protected website. Online training and certification ensures that the imaging reviewers assess the scan according to the study protocol and specified tumor response criteria with the help of built-in response criteria conformance checks. Upon saving image measurements, quantitative metrics and annotated images are automatically uploaded to the website. After electronic sign-off by the reviewing radiologist, the imaging time point is locked and the clinical team is automatically alerted that the assessment is ready for viewing. Results are provided on-line and on-time, before the patient is seen in the clinic for treatment decisions. The clinical team can access measurement tables, graphs, and annotated images in a single structured report and can print a copy of the report to serve as the source document for trial audits.

Conference attendees will learn how this tool is being used at four NCI-Designated Cancer Centers and how it could be utilized at other cancer centers and hospitals to improve quantitative imaging assessment. Metrics Manager V2.0

presentation will include a demonstration of the measurement tool and integrated online workflow and data management systems developed by our Dana-Farber/Harvard Cancer Center Imaging Core. The demonstration will require the use of a Windows PC and internet access (Figure 2). The attendees will have hands-on experience viewing images, measuring target lesions, annotating non-target lesions, assessing the overall response, and using structured longitudinal



**Figure 2: Trial Request workflow was a customization for YCC, which improved imaging protocol submission, review, and approval**

reporting tools. We will show how Metrics Manager V2.0 can streamline image review and reporting which in turn improves data quality simplifying the auditing process. In support, we will present turnaround time and data quality metrics collected at participating Cancer Centers since the implementation of the system at the sites during 2005-2015.

## Outcome

Prior to implementation of Metrics Manager, over 25% of scans had assessment problems due to errors in percent change calculations, misidentification of baseline/nadir scans, selection of inappropriate overall response, application of incorrect response criteria, or incomplete/conflicting data records. After implementation of Metrics Manager, assessment errors decreased to 3% after response criteria conformance checks were applied (Figure 3).

Figure 3

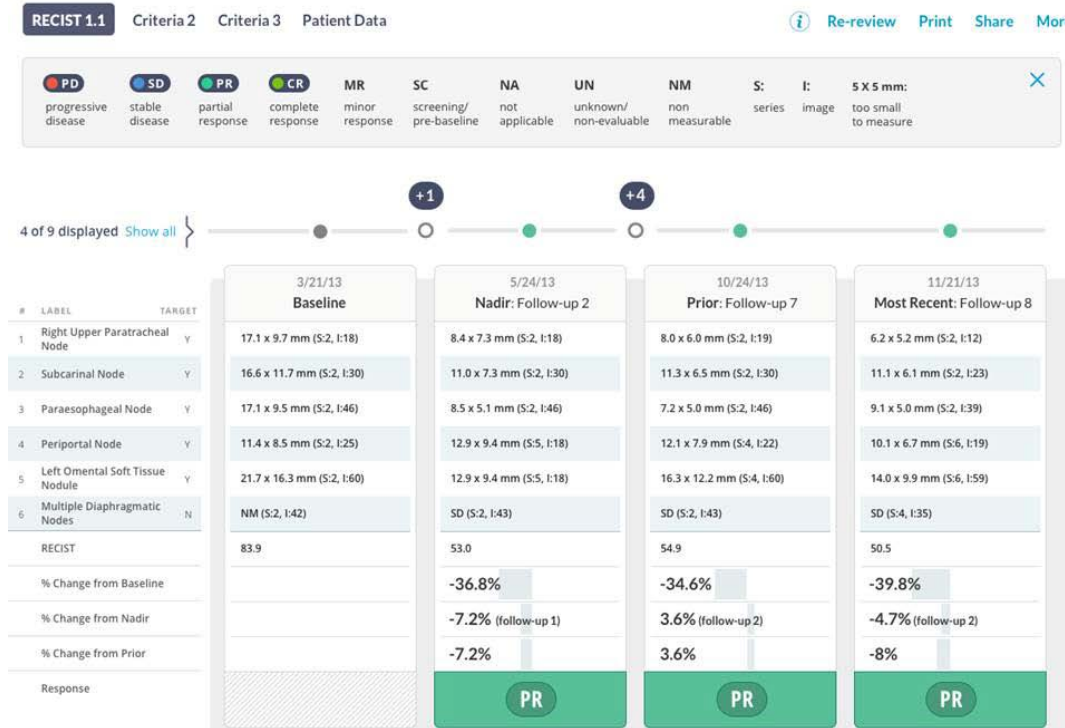


Figure 3: Response assessment results reporting page

Figure 4

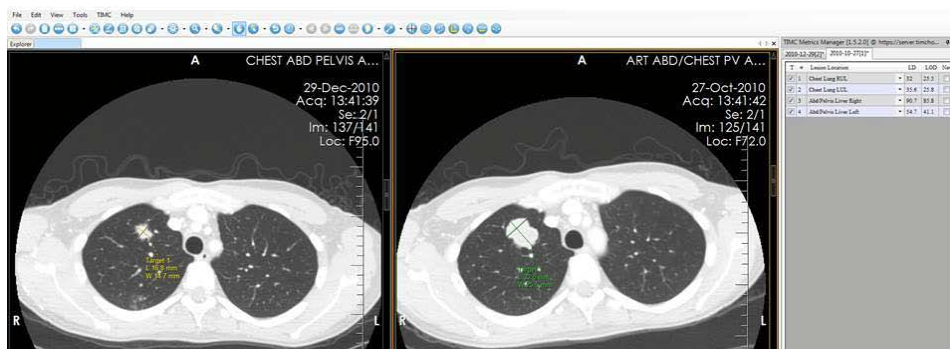


Figure 4: Measurement plugin which communicates with the online workflow management system

## Discussion

As Metrics Manager expanded beyond Dana-Farber/Harvard Cancer Center to include additional NCI-Designated Cancer Centers, there was a need to systematize processes for widespread multi-institutional usage, which was not completely anticipated prior to deployment of v1 at the first external site. Through discussions with user groups at participating Cancer Centers, the Core obtained valuable insight into site specific workflows and needs and has tried to incorporate the knowledge gained into Metrics Manager v2.0 to make the system more flexible and customizable.

## Conclusion

Utilization of Metrics Manager v2.0 at patient accrual sites provides greater standardization, reliability and confidence, which improves the assessment of treatment response or tumor growth, resulting in time and cost savings for sponsors, and improved efficiency and confidence for investigators.

## References

1. Urban T, Harris GJ, Barish MA, Oliveira GR, Zondervan RL, Hanlon WB, Van den Abbeele AD. Benefits of utilizing image analysts for radiological measurements in oncology clinical trials. *Applied Clinical Trials*, November 2010; 19(9):32-36.
2. FDA. Clinical Trial Imaging Endpoint Process Standards Guidance for Industry. Draft Guidance, Revision 1. March 2015.

## Keywords

Open Source, Clinical Trials, Quantitative Imaging Assessment, Workflow Management, Electronic Reporting