

Innovative Imaging Platform Technology’s Impact on Reading Center Workflow Efficiencies in Global Oncology Clinical Trials: EXCELSIOR™ and the STAR Project

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ABSTRACT

Title: Innovative Imaging Platform Technology’s Impact on Reading Center Workflow Efficiencies in Global Oncology Clinical Trials: EXCELSIOR™ and the STAR Project

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Objective: To examine how an integrated, comprehensive, cloud-based imaging platform can address challenges in oncology clinical trials, including lack of visibility and transparency, limited access to data and images, and missing statuses of subjects and timepoints.

Design: The System Test and Review (STAR) pilot study was implemented in MERIT’s EXCELSIOR imaging platform to enable a randomized solid tumor trial using mRECIST HCC reading criteria. A pool of radiologists in three regions (U.S., Europe, China) read sample scans according to a blinded, two-reader, sequential locked timepoint read paradigm. This 2+1 paradigm automatically randomized each independent reader (Reader 1, Reader 2, and Adjudicator) so reads were allocated evenly. The reader pool was chosen to reflect common international study designs and to test the system from multiple locations as well as accessing different network servers.

Results: The EXCELSIOR platform enhanced real-time tracking of image workflow, processing and read status; increased visibility and transparency across reader locations; and kept study milestones on track. It enabled readers and team members to work collaboratively from multiple global locations and provided 100% access to data and images on-demand. Utilizing geo-dispersed servers and backup systems ensured 99.9% uptime and helped overcome the challenge of keeping patient data within country as required for China and as per data privacy regulations.

Conclusion: EXCELSIOR resulted in reader workflow efficiencies in the STAR project by increasing data transparency, maintaining study milestones, and providing greater access to images and data. It also supported and improved worldwide collaboration among readers and other stakeholders.

Disclosures: Dr. Kim and Ms. Chintala are both employed at MERIT CRO, Inc. No other disclosures.

OBJECTIVES

To examine how an integrated, comprehensive, cloud-based imaging platform can address challenges in oncology clinical trials, including lack of visibility and transparency, limited access to data and images, and missing statuses of subjects and timepoints. The project also examined how the reading platform may address potential issues of any reading criteria to enhance data quality and increase efficiency of reads.

DESIGN

The System Test and Review (STAR) pilot study was implemented in MERIT’s EXCELSIOR imaging platform to enable a randomized solid tumor trial using mRECIST HCC reading criteria. A pool of radiologists in three regions (U.S., Europe, China) read sample scans according to a blinded, two-reader, sequential locked timepoint read paradigm. This 2+1 paradigm automatically randomized each independent reader (Reader 1, Reader 2, and Adjudicator) so reads were allocated evenly. The reader pool was chosen to reflect common international study designs and to test the system from multiple locations as well as accessing different network servers. The international reader pool was also chosen to test a variety of workstations with reads from different radiologists, with a goal of continually improving EXCELSIOR and enhancing the radiologists’ reading experience.

RESULTS AND DISCUSSION

The EXCELSIOR platform:

- Enhanced real-time tracking of image workflow, processing, and read status
- Increased visibility and transparency through built-in query functionality that enhanced communications
- Kept study milestones on track
- Enabled readers and team members to work collaboratively from multiple global locations with 100% access to data and images on-demand

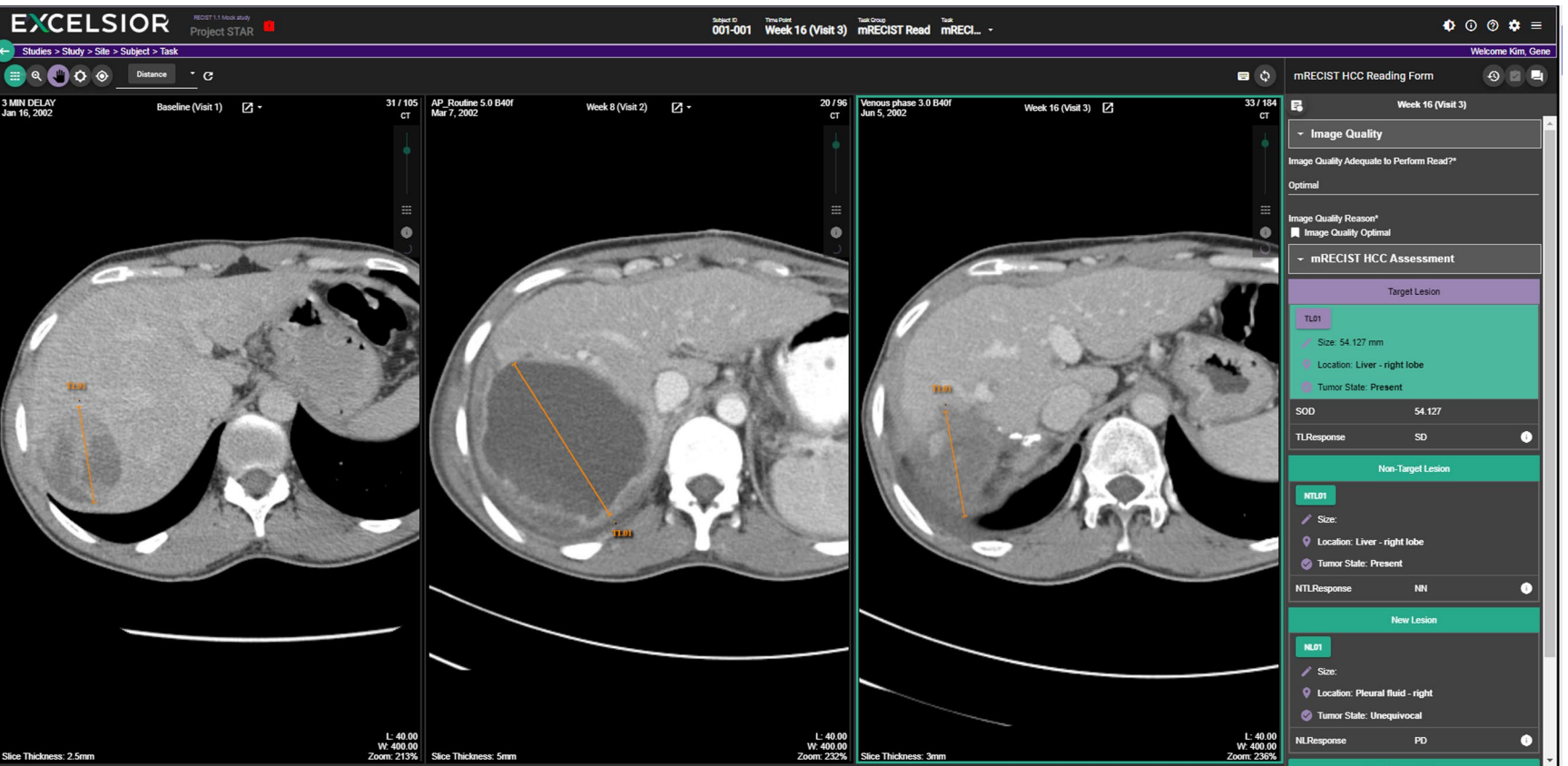


Image 1. EXCELSIOR Reading Form showing Target Lesion at Follow-up

Project management team members were easily able to monitor reader worklists and track the completion of reads in real-time. MERIT’s geo-dispersed servers and backup systems ensured 99.9% uptime and helped overcome the challenge of keeping patient data within country as required for China and as per data privacy regulations.

The ongoing collaboration of the readers, the project team, and system developers helped to promote continuous feedback and improvement in EXCELSIOR’s features, including annotation tools, automatic lesion calculations, and sophisticated response criteria algorithms.

Many of these features help to address the potential challenges of reading criteria and increase the efficiency of reads. Abramson et al. grouped the potential pitfalls of RECIST into the following categories which is applicable to various response criteria :

- Baseline selection of lesions
- Reassessment of target lesions
- Reassessment of nontarget lesions
- Identification of new lesions
- Assigning overall response

The authors also suggested following best practices may be further improved by imaging platforms that offer calculation of measurement totals and prevent inappropriate entries.



Baseline Selection of Lesions

Potential Issue: Selection of too many target lesions

- The fully-configurable system in the STAR study allowed only the correct number of lesions to be selected at baseline. The system also supports modification of published response criteria if required per protocol and imaging charter.

Reassessment of Nontarget Lesions

Potential Issue: Assessment of new disease

- The STAR reading platform provided readers with a simple way to differentiate between equivocal and unequivocal new lesions, therefore ensuring that progression is captured at the appropriate timepoint.

Assigning Overall Response

Potential Issue: Failure to observe the requirement that a 5 mm absolute increase in sum of target lesion diameters is needed (in addition to a 20% increase) to assign Progressive Disease.

- The automatic calculation of the sum of target lesion diameters generated by the STAR system allowed readers to focus on assessment of disease rather than response calculation.

CONCLUSIONS

EXCELSIOR resulted in reader workflow efficiencies by increasing data transparency, maintaining study milestones, and providing greater access to images and data. It also supported and improved worldwide collaboration among readers and other stakeholders. EXCELSIOR is configurable and can support a variety of response criteria, such as RANO, iRECIST, Lugano and others for greater analytical flexibility. Ensuring that the read system contains features that enhance the reader’s efficiency is critical, not only to increase productivity, but also to maintain a high quality of read data.

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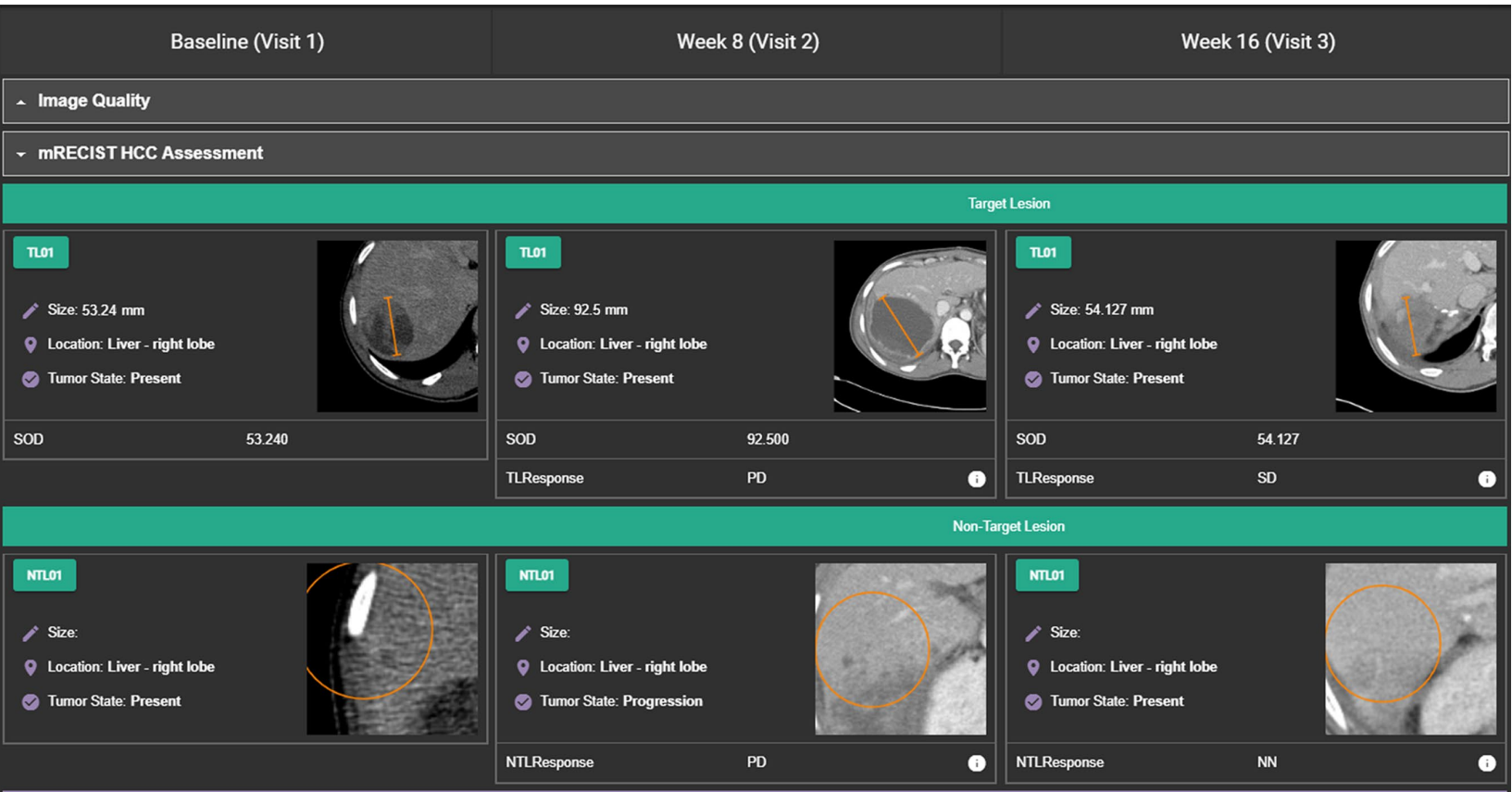


Image 2. EXCELSIOR historic view of baseline and subsequent timepoints