



Advancing Research. Improving Lives.™



NRG Oncology and VisionTree Optimal Care™ (VTOC) Frequently Asked Questions

Overview

VisionTree Optimal Care™ (VTOC) v4.1 is a secure, encrypted cloud-based platform to collect/report patient reported outcomes measures (PROMs) data for NRG Oncology studies. VTOC is currently offered for RTOG 0920, RTOG 0938 RTOG 0924, NRG-HN001, NRG-HN002, NRG-CC003 and NRG-CC004 as a web-based option for collecting PRO forms at all study protocol time points, providing corresponding email reminders to patients and NRG Oncology Research Associates (RAs). PRO data can be completed by the patient from any computer with internet access, including their home, as well as on-site with the assistance of the RA.

VTOC v4.1, designed and manufactured by VisionTree® Software, Inc., is compliant with the Health Insurance Portability and Accountability Act of 1996 ('HIPAA') and ARRA HITECH Act of 2009. All HIPAA requirements and standards have been met for the sources and uses of data promulgated under the U.S. Department of Health and Human Services regulations (the 'HIPAA Regulations').

VTOC is fully compliant with 21 CFR Part 11 Statistical Process Control System for de-identified research data collection, as well as the Personal Health Information Protection Act ('PHIPA') established in Ontario in 2004.

Frequently Asked Questions & Answers

Why would our site consider using VTOC for an NRG Oncology study?

Collecting quality of life data on paper at specified time points can be challenging, particularly at 6 months and beyond. VTOC has been used successfully to improve the collection of missing quality of life data (see: ASTRO Abstract presented October 5, 2011: Electronic Web-Based Technology Significantly Improves Quality of Life (QOL) Data Collection: Analysis of RTOG 0828). This system is a tool to assist the patient in completing these questionnaires in private. It does require the RA to maintain the contact with the patient until the time point is completed.

Are there any Technical Requirements?

The only requirement to use VTOC is to access the internet on a computer/device with one of the following browsers: Internet Explorer 7+, Chrome, FireFox or Safari.

How is VTOC Data Security Managed?

VTOC is 256-bit SSL encrypted for all https traffic and encrypts all patient and medical team passwords, as well as tracks all activity with a user audit log. Servers employ power-on and user passwords, virus protection, and battery backup systems in an SAS-70 compliant data center with restricted access to authorized maintenance through 24/7 biometric security measures.

All VisionTree support personnel have passed HIPAA compliance standards tests and the system is continually upgraded to ensure secure data exchange. The VisionTree Optimal Care™ system meets the highest research standards for human subject data and is very sensitive to participant confidentiality and consent. Security is always a high priority, not only to protect from data or hardware loss, but also to ensure confidentiality.

How do I introduce VTOC to the patient?

When introducing VTOC to the patient, please make sure to go over the following:

- Give the patient the VisionTree FAQs for the Patient.
- Remind the patient that the emails will be sent from newreminder@optimalcare.com and will contain the RTOG logo.
- Walk through VTOC with the patient so they become familiar with the system.

Can a patient login to complete the QoL assessments from home or the waiting room?

Yes, anywhere there is internet access. VTOC also has a mobile-responsive application for smart phones and tablets.

What should I do to prepare for a patient visit in which QoL is due?

For an upcoming patient visit, please review the Rave folder to see what assessments need to be completed. If the QoL assessments are still listed, that means they have not been completed yet. Please make sure to have the patient complete the assessments during the visit. If the patient has a smart phone or your site has a computer or tablet available for patient use, please recommend the patient completes the assessment in the waiting room. VTOC is launching Kiosk Mode and FastTrack that will allow for an easier and improved experience if completing in the office or at home (please see questions below). A paper form can also be given to the patient. If the patient prefers to use VTOC after being offered paper, please remind them to go into the system to complete his/her QoL assessments.

Of note, whether a patient opts to use VTOC or paper forms to complete QoL, what really matters for the study is that the QoL forms be completed on time. As for any study endpoint, we need your help to ensure that this happens consistently. Please do not assume that if a patient is using VTOC that the QoL forms are automatically being completed. Please check the QoL completion for each patient (using the Rave folder or VTOC software) on a regular basis to ensure that we do not miss collection time points. This is essential for the study, as QoL is a key endpoint in interpreting the results of the study. We very much appreciate your help.

What is Kiosk Mode?

Kiosk Mode is a secure option for patients to fill out forms without having to log into their VTOC patient portal. The RA simply logs into their VTOC portal, finds the patient, selects the form(s) a patient should complete and hands them a tablet (or computer), so the patient can complete the forms right then and there. The forms are presented to the user in a wizard-driven sequence, meaning they will automatically be taken to the next form instead of having to click and open each form.

To launch Kiosk Mode:

- Step 1: Log into the VTOC portal
- Step 2: Find the patient
- Step 3: Under the “Patient To Dos” tab, check the forms you would like the patient to complete
- Step 4: Click “Kiosk Mode”
- Step 5: You will then be redirected to the Kiosk Mode page and can safely hand the computer or tablet to the patient to complete the forms you have selected.



Active	Assigned	Template	Active Start - Active End	Status	Modified On	Action
		RTOG 3510 - Breast Q Radiation Module - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>
		RTOG 3510 - FACT-B - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>
		RTOG 3510 - FACT-TS-G v1 - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>
		RTOG 3510 - Financial Burden - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>
✓		RTOG 3510 - PRO-CTCAE Shortness of Breath & Chest Pain - End of RT	RTOG 3510 03/31/2017 - 03/30/2018	Not Started		View Edit History <input checked="" type="checkbox"/>
		RTOG 3510 - PROMIS Ability to Participate in Social Roles and Activities - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>
		RTOG 3510 - PROMIS Emotional Distress-Anxiety - Short Form 4a - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>
✓		RTOG 3510 - PROMIS Fatigue - Short Form 4a - End of RT	RTOG 3510 03/31/2017 - 03/30/2018	Not Started		View Edit History <input checked="" type="checkbox"/>
		RTOG 3510 - Productivity - End of RT	RTOG 3510 03/31/2017 - 04/30/2017	Not Started		View Edit History <input type="checkbox"/>

What is FastTrack Mode?

Similar to Kiosk Mode, an RA is able to select forms for a patient to complete, but instead, an email would be sent to the patient with a link that opens the form(s), and submits it to VTOC when complete. The patient never has to enter a password or username.

To launch FastTrack:

- Step 1: Log into the VTOC portal
- Step 2: Find the patient
- Step 3: Under the “Patient To Dos” tab, check the forms you would like the patient to complete
- Step 4: Click “Fast Track”
- Step 5: A link will be sent to the patient’s email

Can patient accounts be created from existing clinical systems?

Yes, VisionTree provides the ability for import via CSV, Excel, HL7 or Web service format.

Who has access to the NRG Oncology PRO data and patient email addresses?

VTOC is roles and rules based with access only provided to authorized NRG Oncology study sites. A system audit log is accessible and managed by NRG Oncology for user login activity (date, time, action taken, IP address). The RA should review the system with the patient prior to the patient using the VTOC system.

How long is the data maintained by VisionTree?

Data including patient email address is maintained for the duration of the study. Data retention is consistent with commitments made to subjects, IRB and NRG Oncology, as the sponsor.

Can a patient begin using VTOC if they have begun the study on paper?

Yes, the patient may switch to electronic copies.

How can I start using VTOC for my NRG Oncology study?

If you are participating in one of the approved studies offering VTOC:

- Submit the NRG Oncology protocol to your IRB noting the use of VTOC –.
- NRG Oncology receives notification that your site has enrolled a patient who has consented to VTOC and notifies VisionTree to create a VTOC site user account. VisionTree creates an account for an RA based on the information provided on the enrollment form (i.e. name of person who registered the patient will receive an account).
- If a site contacts VisionTree directly to create an account, VisionTree will confirm access with NRG Oncology prior to creating an account.
- A temporary login (username/password) is emailed to you, which requires you to change your password. You can then begin entering patients. If you have a VTOC account from a previous study, a drop down filter will appear on your patient lookup page to manage all NRG Oncology and RTOG Foundation studies within VTOC with one login.
- VTOC process for patient study account creation and data collection/management:
 - Step 1: Create VTOC patient Account and apply study.
 - Step 2: You may confirm what forms/reminders have been applied to the patient portal and the time points by clicking the 'Patient To Dos' tab in the patient record. The 'check mark' (√) indicates an active PRO, along with its completion status (not complete, in progress or complete).
 - Step 3: The patient will receive up to three (3) email notifications 3 weeks prior to the active duration of the PRO form time point coming to a close for eligible completion. You can receive the same email reminders for any given patient by logging into your VTOC portal, find and select your patient(s), click the "Perform Actions" tab and click the "Update Calendar" link. Add your email to the "Additionally send reminders to email" field and click "Apply".
 - Step 4: The completed PRO data is auto-exported in monthly batch export to NRG Oncology headquarters on the first of every month.
 - Step 5: Your site will receive credit for this patient by case number for PRO form completion.

Can VTOC be used in the day to day clinical radiation oncology workflow?

Yes, VTOC is implemented in over 400 sites throughout the United States and Europe with 2.5M+ using the VTOC platform. With a modular, subscription based model, all clinical and patient facilities can implement VTOC into their daily clinical, research and paperless Meaningful Use compliant radiation oncology workflow.

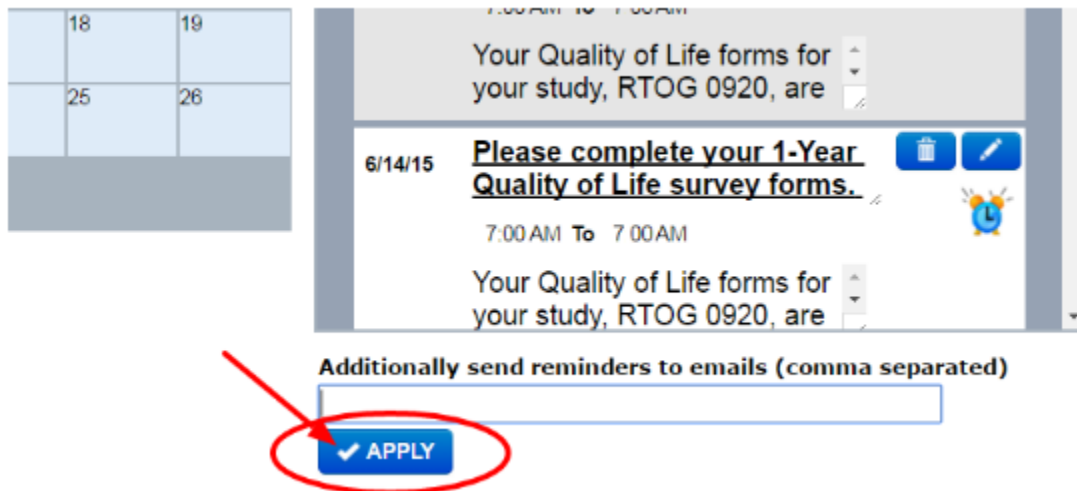
Is VTOC ‘Meaningful Use’ Certified?

Yes, VTOC v4.1 is 2014 ARRA Meaningful Use certified by an ONC-ATCB (Certificate # 04072014-2538-9:) as an modular EHR which includes meeting Foundational Security and Privacy criteria for: Access Control, Emergency Access, Automatic Log-off, Audit Log, Integrity, Authentication, General Encryption and Encryption when exchanging electronic health information.

How can I add my email to receive the same email reminders that the patient receives?

The patient will receive up to three (3) email notifications per PRO timepoint. You can configure your email to receive the same email reminders for any given patient:

1. Find the patient and click on the patient’s record.
2. Select the “Perform Actions” tab
3. Click the “Update Calendar” link.
4. Scroll to the bottom of the page and add your email to the “Additionally send reminders to email” field and click “Apply”.



Who do I contact for technical support?

Any questions regarding these steps, please contact your VisionTree support team, anytime at: support@visiontree.com / (619) 295-2800 x3. VisionTree will also provide a monthly refresher/intro webinar. A training link can be found on the RTOG website and VisionTree websites, see: <http://visiontree.com/assets/files/rtog/slides/index.html>

