


Public reporting burden for this collection of information is estimated to vary from 5 to 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.

Filling out PDF Forms

This PDF form contains “**roll-over** or **double-click**” help functionality.

This form allows you to enter data directly onto the screen. After completing the form, you are able to print the document so that you can fax/mail the document.

To fill out a form:

1. Select the hand tool. 
2. Position the pointer inside a field, and click to type text.
3. After entering text or selecting a check box, do one of the following:
 - Press tab to accept the form field change and go to the next form field.
 - Press Shift+Tab to accept the form field change and go to the previous form field.
 - Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.
4. Once completed, print the form.

* STY - RTOG - 0834 *

RTOG-0834 CTSU DATA TRANSMITTAL FORM

For Post-Enrollment Data Submissions

- Use this form for post-enrollment data submissions; do not use this form to submit site registration/patient enrollment documents
- Record only one patient and protocol per transmittal form
- Ensure Patient ID and Protocol ID are recorded on each page of each item included
- Ensure pages are in proper sequence (2-sided forms must be copied by site before faxing)
- Do not fax more than 50 pages in one submission
- **Changes to data initiated by the site must be reported on the Data Correction Form**

- Submit updated data with a new CTSU Data Transmittal Form and new date

Date: ____ - ____ - ____ (dd-mm-yyyy)	Total # Pages Faxed: _____ (Including Transmittal)	Patient ID#: ____ (EORTC Sequential IDENT. No.)
Site Name: _____ (Institution)	NCI CTEP Code: _____ (Internal ID)	
Site Address: _____	INST. No: _____	
Transmittal Completed By: _____	Phone #: _____	
Email address: _____		

The item(s) listed below should be faxed to CTSU at 1-301-545-0406. Call 1-888-823-5923 if experiencing difficulty faxing. Do not mail forms to CTSU. Do not fax or mail forms to the EORTC Data Center

Item(s) Attached	Number of pages	Visit
<input type="checkbox"/> Query Form (Query)		
<input type="checkbox"/> Data Correction Form (DCF)		
<input type="checkbox"/> Local Pathology / Genetic Testing (Form 2)		<input type="checkbox"/> Before Randomization
<input type="checkbox"/> On Study Form (Form 5)		<input type="checkbox"/> Before 1 st treatment administration (Send this with other baseline forms)
<input type="checkbox"/> Hematology Form (Form 6)		<u>Baseline, All Arms:</u> <input type="checkbox"/> Within 4 weeks before randomization <u>During Radiotherapy, Arms 2 & 4:</u> <input type="checkbox"/> Week 1, 2, 3, 4, and 5 for TMZ administration <u>End of Radiotherapy, Arms 2 & 4:</u> <input type="checkbox"/> Week 6 <u>After the end of Radiotherapy, All Arms:</u> <input type="checkbox"/> 4 weeks <u>after</u> the end of Radiotherapy <u>Adjuvant TMZ, Arms 3 & 4:</u> <input type="checkbox"/> Additional Assessments
<input type="checkbox"/> Biochemistry Form (Form 7)		<u>Baseline, All Arms:</u> <input type="checkbox"/> Within 4 weeks before randomization <u>During Radiotherapy, Arms 2 & 4:</u> <input type="checkbox"/> Week 4 <u>End of Radiotherapy, Arms 2 & 4:</u> <input type="checkbox"/> Week 6 <u>After the end of Radiotherapy, All Arms:</u> <input type="checkbox"/> 4 weeks <u>after</u> the end of Radiotherapy <u>Adjuvant TMZ, Arms 3 & 4:</u> <input type="checkbox"/> Additional Assessments

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Item(s) Attached	Number of pages	Visit
<input type="checkbox"/> Adverse Event Form (Form 8)		<u>Baseline, All Arms:</u> <input type="checkbox"/> Within 4 weeks before randomization <u>During Radiotherapy, All Arms:</u> <input type="checkbox"/> Week 1, 2, 3, 4 and 5 <u>End of Radiotherapy:</u> <input type="checkbox"/> Week 6 <u>After the end of Radiotherapy, All Arms:</u> <input type="checkbox"/> 4 weeks <u>after</u> the end of Radiotherapy <input type="checkbox"/> <u>AND</u> thereafter for every 3 months until disease progression <input type="checkbox"/> <u>At disease progression</u> <u>Adjuvant TMZ, Arms 3 & 4:</u> <input type="checkbox"/> Additional Assessments
<input type="checkbox"/> EORTC QLQ-C30 <input type="checkbox"/> EORTC QLQ-BN20		<input type="checkbox"/> Within 4 weeks before randomization <input type="checkbox"/> 4 Weeks after Radiotherapy <input type="checkbox"/> Thereafter every 3 months until disease progression or death <input type="checkbox"/> At disease progression <input type="checkbox"/> Follow up
<input type="checkbox"/> Neurocognitive Function Forms: * <input type="checkbox"/> Hopkins Verbal Learning Test-Revised (Hopkins VL): Forms 1 - 6 <input type="checkbox"/> Trail Making Test Part A (TM Part A) <input type="checkbox"/> Trail Making Test Part B (TM Part B) <input type="checkbox"/> Controlled Oral Word Association (COWA): Forms 1 and 2 <input type="checkbox"/> TMT Data Summary Form <input type="checkbox"/> Form CS <input type="checkbox"/> Form QP		* For patients participating in this component <input type="checkbox"/> Baseline <input type="checkbox"/> Thereafter for yearly intervals until tumor progression or death
<input type="checkbox"/> Radiotherapy Form (Form 9)		<input type="checkbox"/> At the end of Radiotherapy
<input type="checkbox"/> Patient Evaluation During RT Form (Form 10)		<input type="checkbox"/> Week 4 during Radiotherapy <input type="checkbox"/> Week 6 during Radiotherapy
<input type="checkbox"/> Concomitant Temozolomide Form (Form 11)		<input type="checkbox"/> Arms 2 & 4 only: at the end of concomitant chemotherapy
<input type="checkbox"/> Adjuvant Temozolomide Form (Form 12)		<input type="checkbox"/> Arms 3 & 4 only: After each cycle of Adjuvant Chemotherapy Cycle: _____
<input type="checkbox"/> Disease Assessment Form (Form 13)		<input type="checkbox"/> 4 Weeks after end of Radiotherapy <input type="checkbox"/> Thereafter every 3 months until disease progression <input type="checkbox"/> At disease progression
<input type="checkbox"/> End of Treatment Form (Form 14)		<input type="checkbox"/> End of Protocol Treatment (or in case patient is not randomized) Arms 3 & 4 only <input type="checkbox"/> At disease progression
<input type="checkbox"/> Follow Up Form (Form 15)		<input type="checkbox"/> Due every 3 months after disease progression and until patient's death

For CTSU use only: Short Name shown in (brackets)