


Public reporting burden for this collection of information is estimated to average 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 (0925-0753). 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.

**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 submitting)
- Do not include more than 50 files or files with a cumulative size larger than 20 MB in a single 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 Submitted: \_\_\_\_\_  
(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 submitted to the CTSU via the CTSU's Regulatory Submission Portal (use the *Paper CRFs/Queries* option in the first dropdown). Call 1-888-823-5923 if experiencing difficulty.  
Do not fax or mail forms to the CTSU or the EORTC Data Center

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

Item(s) Attached	Number of pages	Visit
<input type="checkbox"/> Adverse Event Form ( <b>Form 8</b> )		<p><u>Baseline, All Arms:</u></p> <input type="checkbox"/> Within 4 weeks before randomization
<input type="checkbox"/> EORTC QLQ-C30 <input type="checkbox"/> EORTC QLQ-BN20		<p><u>During Radiotherapy, All Arms:</u></p> <input type="checkbox"/> Week 1, 2, 3, 4 and 5
<input type="checkbox"/> Neurocognitive Function Forms: * <ul style="list-style-type: none"> <li><input type="checkbox"/> Hopkins Verbal Learning Test-Revised (<b>Hopkins VL</b>): <b>Forms 1 - 6</b></li> <li><input type="checkbox"/> Trail Making Test Part A (<b>TM Part A</b>)</li> <li><input type="checkbox"/> Trail Making Test Part B (<b>TM Part B</b>)</li> <li><input type="checkbox"/> Controlled Oral Word Association (<b>COWA</b>): <b>Forms 1 and 2</b></li> <li><input type="checkbox"/> TMT Data Summary Form</li> <li><input type="checkbox"/> Form CS</li> <li><input type="checkbox"/> Form QP</li> </ul>		<p><u>After the end of Radiotherapy, All Arms:</u></p> <input type="checkbox"/> 4 weeks <u>after</u> the end of Radiotherapy <input type="checkbox"/> <u>AND</u> thereafter for every 6 months until disease progression <input type="checkbox"/> <u>At disease progression</u>
<input type="checkbox"/> Radiotherapy Form ( <b>Form 9</b> )		<p><u>Adjuvant TMZ, Arms 3 &amp; 4:</u></p> <input type="checkbox"/> Additional Assessments
<input type="checkbox"/> Patient Evaluation During RT Form ( <b>Form 10</b> )		<input type="checkbox"/> Within 4 weeks before randomization <input type="checkbox"/> 4 Weeks after Radiotherapy <input type="checkbox"/> Thereafter every 6 months for 5 years
<input type="checkbox"/> Concomitant Temozolomide Form ( <b>Form 11</b> )		<p>* For patients participating in this component</p> <input type="checkbox"/> Baseline <input type="checkbox"/> Thereafter for yearly intervals until tumor progression or death
<input type="checkbox"/> Adjuvant Temozolomide Form ( <b>Form 12</b> )		<input type="checkbox"/> At the end of Radiotherapy
<input type="checkbox"/> Disease Assessment Form ( <b>Form 13</b> )		<input type="checkbox"/> Week 4 during Radiotherapy <input type="checkbox"/> Week 6 during Radiotherapy
<input type="checkbox"/> End of Treatment Form ( <b>Form 14</b> )		<input type="checkbox"/> Arms 2 & 4 only: at the end of concomitant chemotherapy
<input type="checkbox"/> Follow Up Form ( <b>Form 15</b> )		<input type="checkbox"/> Arms 3 & 4 only: After each cycle of Adjuvant Chemotherapy Cycle: _____
<input type="checkbox"/> Disease Assessment Form ( <b>Form 13</b> )		<input type="checkbox"/> 4 Weeks after end of Radiotherapy <input type="checkbox"/> Thereafter every 6 months until disease progression <input type="checkbox"/> At disease progression
<input type="checkbox"/> End of Treatment Form ( <b>Form 14</b> )		<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 ( <b>Form 15</b> )		<input type="checkbox"/> Due every 6 months after disease progression and until patient's death

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