

BTTC Eligibility Checklist

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Purpose



Record the patient's status for each item of the eligibility checklist.

Each activated protocol has a customized eligibility checklist.

Eligibility Checklist eCRF

Inclusion Criteria tab (sample criteria)

Field Name	Description / Instructions	Format
Visit Date ^(m)	Enter the date the form was completed (i.e. the date information was gathered).	DD- MMM- YYYY
Checklist Number	Checklists are numbered sequentially based on NCI approval of amendments that change the eligibility criteria. The eligibility checklist from the original protocol must number 0. Each time the eligibility criteria for a protocol are amended, the checklist number is incremented. (The checklist number may not be the same as the amendment number, since some amendments do not affect the criteria.) The appropriate checklist number is provided by CTMS along with a new customized CRF each time a revised protocol-specific Eligibility Checklist is formulated. <div>  Note: This field cannot be modified by the user. </div>	2 digits
Effective Date	Date of approval of the eligibility criteria by NCI. For the original protocol, the effective date is the date of NCI approval of the study. For revised eligibility criteria, the effective date is the date of NCI approval of the relevant amendment. This date is updated by CTMS at the time the protocol specific checklist is completed or amended by CTMS. <div>  Note: This field cannot be modified by the user. </div>	DD- MMM- YYYY
Waiver Number	The waiver number when the patient is not formally eligible, but is admitted to the study. A reason must be entered in "Eligibility Waiver Reason" field of the Exclusion Criteria tab. Note: Not applicable for NCI-sponsored studies, and therefore, not applicable for BTTC studies.	12 characters

Criterion Response ^(m)	Select the patient's status relative to the eligibility inclusion criterion. Y - Yes N - No X - Not Applicable <div> Note: Do not leave this field empty. Select one of the above responses.</div>	Use pick list.
Sequence	The inclusion criterion sequence number. <div> Note: This field cannot be modified by the user.</div>	2 digits



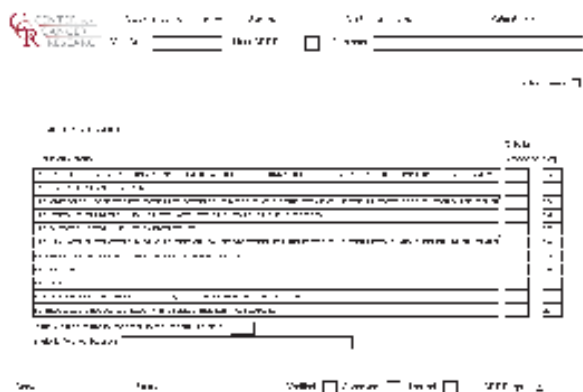
Legend: ^(d) derived field, ^(m) RDC mandatory



Validations

Code	Description	Resolutions
EC01	Waiver Number provided but no Eligibility Waiver Reason has been provided and vice-versa.	An Eligibility Waiver Reason must accompany a Waiver Number.

Eligibility Checklist eCRF

Exclusion Criteria tab (sample)



Field Name	Description / Instructions	Format
Criterion Response ^(m)	Select the patient's status relative to the eligibility exclusion criterion. Y - Yes N - No X - Not Applicable <div> Note: Do not leave this field empty. Select one of the above responses.</div>	Use pick list.
Sequence	The exclusion criterion sequence number. <div> Note: This field cannot be modified by the user.</div>	2 digits
In the opinion of the investigator, is the patient eligible? ^(m)	Select the investigator's decision. Y - Yes N - No X - Not Applicable	Use pick list.

Eligibility Waiver Reason	<p>Patients who are not eligible as per protocol criteria should not be entered on study. If after an appropriate review of the patient's status it is determined that the patient violates one or more of the eligibility criteria, or if no information is available for some of the criteria, the Principal Investigator should state concisely and clearly why the patient has been admitted to the study.</p> <p>Note: since NCI does not issue or approve any waivers, providing this explanation will not make the patient eligible for the study.</p>	64 characters
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Legend: (d) derived field, (m) RDC mandatory

Validations

Code	Description	Resolutions
EC01	Waiver Number provided but no Eligibility Waiver Reason has been provided and vice-versa.	An Eligibility Waiver Reason must accompany a Waiver Number.