

National Cancer Institute (NCI)  
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

## Operational Efficiency Working Group (OEWG) Timelines and Tracking Website

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### Introduction

All ETCTN studies are assigned an OEWG target activation date and an absolute deadline for opening the trial to national patient enrollment. The timeline starts when the Letter of Intent (LOI) is reviewed by the NCI Cancer Therapy Evaluation Program (CTEP). **If a study is not activated with CTEP by the absolute deadline, it is terminated by CTEP** and a new LOI is required should the investigator still wish to pursue the research.

**The target timeline for ETCTN studies is 210 days and the absolute deadline is 450 days.** The target timeline is broken-down into three major stages with suggested timeframes:

Review Stage	Timeframe
LOI Review and Approval	60 days
Protocol Authoring	60 days
Protocol Review and Approval (CTEP & NCI CIRB*) and Pre-Activation Activities	90-150 days
<b>Total Timeline</b>	<b>210 -270 days</b>

\* Local DF/HCC review and activation procedures are not included in the OEWG timeline. For ETCTN studies, NCI Central Institutional Review Board (CIRB) approval satisfies the OEWG pre-activation IRB approval requirement.

The OEWG clock does not stop for any hold issues (pharmaceutical collaborator review and drug commitment, FDA review for IND filing protocols, NCI Biomarker Review Committee (BRC) approval, NCI

CIRB approval, etc.). To ensure CTEP study activation prior to the OEWG deadline, study teams should respond to all CTEP and NCI CIRB requests in a full and timely manner.

## Procedure

- 1) Beginning at the time of initial LOI submission, the Protocol Chair can follow the progress of their study using the [OEWG Timeline Report Website](#). The page can also be accessed via the Secure Access Login located at the top of the [CTEP homepage](#).
  - a) The website provides the target and absolute deadlines in addition to key milestone dates throughout the entire review process.
- 2) Refer to the [CTEP Timeline Report Website Quick Reference Guide](#) & [CTEP Timeline Report Website Video Tutorial](#) for instructions on using the site.
- 3) The progress of a study can be viewed and exported either as a basic Tracker Report ([Appendix A](#)), Sequential Report ([Appendix B](#)), or a Gantt Report ([Appendix C](#))
- 4) Once a study progresses to the protocol stage, individuals listed as study coordinators on the protocol title page or Protocol Submission Worksheet (PSW) will be able to view the study within the OEWG Timeline Report Website.

Notes about the OEWG Timeline Report Website:

- A CTEP-IAM account is required to access the site. Refer to the [DF/HCC ETCTN CTEP-IAM Registration Guide](#) for instructions on obtaining an account.
- A Protocol Chair can only view those LOIs and Protocols for which he or she is the overall protocol chair.
- It generally takes 2-3 days from LOI submission for the study to be fully processed by the CTEP Protocol and Information Office (PIO) and therefore be available for viewing on the OEWG Timeline Report Website.

## Links

CTEP OEWG Information Page: <http://ctep.cancer.gov/protocolDevelopment/OEWG.htm>

OEWG Timeline Report Website: <https://eapps-ctep.nci.nih.gov/sw-web/login.action>

CTEP Timeline Report Website Quick Reference Guide: <https://eapps-ctep.nci.nih.gov/sw-web/nodecorate/qrg.jsp>

CTEP Timeline Report Website Video Tutorial: [https://eapps-ctep.nci.nih.gov/sw-web/Tutorial/Final\\_Reports/Timeline.html](https://eapps-ctep.nci.nih.gov/sw-web/Tutorial/Final_Reports/Timeline.html)

## Appendix A: Sample OEWG Tracker Report

### OEWG Document Tracker Report

<b>Document Number:</b>	####	<b>Pathway:</b>	Unsolicited LOIs
<b>Phase:</b>	I	<b>Latest Activity (Date):</b>	Protocol Active (03/31/2016)
<b>Principal Investigator:</b>	Study Chair Name	<b>Target Date:</b>	08/19/2015
<b>Associated INDs:</b>	123456	<b>Absolute Deadline:</b>	04/15/2016
<b>Lead Organization:</b>	Dana-Farber - Harvard Cancer Center LAO	<b>Planned:</b>	210
		<b>Actual:</b>	435
<b>Current Status:</b>	Active		
<b>Associated Agents:</b>	Agent Name(s)		
<b>Associated Diseases:</b>	Cancer, NOS		
<b>Document Title:</b>	Protocol Title		

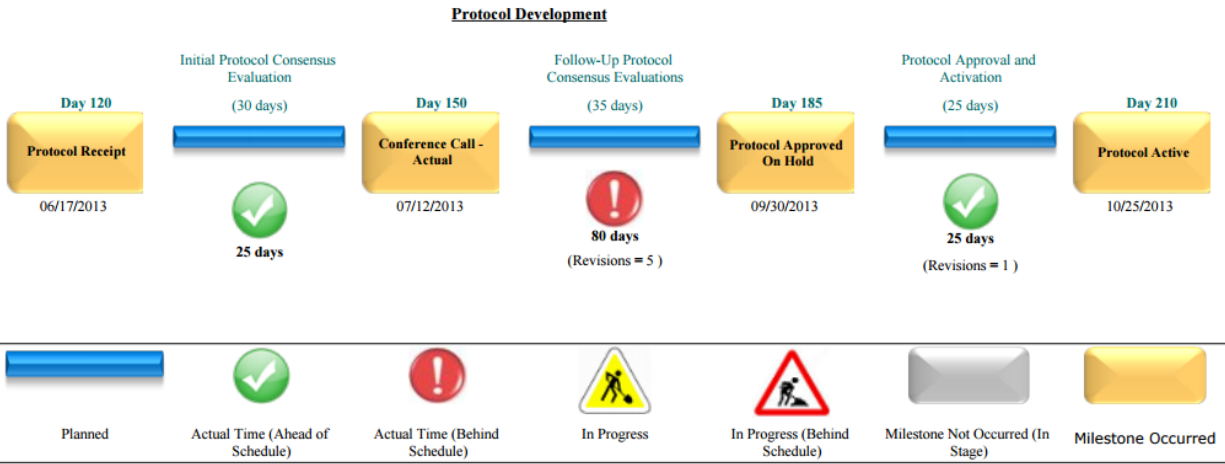
  

Document Milestones	Change Type	Milestone Date
<b>LOI Approval</b>		
<b>Initial LOI Consensus Evaluation</b>		
OEWG Start Date	Original (0)	01/21/2015
IDB Review	Original (0)	01/21/2015
PRC Review	Original (0)	01/22/2015
Conference Call - Planned	Original (0)	02/02/2015
Consensus Review Received in PIO	Original (0)	02/05/2015
Consensus Review Sent to PI	Original (0)	02/05/2015
Conference Call - Actual	Original (0)	02/06/2015
Drug Commitment/Industry Approval Received	Original (0)	02/17/2015
Consensus Review Received in PIO	Original (0)	05/12/2015
Drug Commitment/Industry Approval Received	Original (0)	05/12/2015
Consensus Review Sent to PI	Original (0)	05/14/2015
LOI Approved	Original (0)	05/14/2015
Consensus Review Received in PIO	Original (0)	06/10/2015
Consensus Review Sent to PI	Original (0)	06/11/2015
<b>Protocol Authoring</b>		
<b>Protocol Development</b>		
Protocol Receipt	Original (0)	07/02/2015
<b>Protocol Development</b>		
<b>Initial Protocol Consensus Evaluation</b>		
PRC Review	Original (0)	07/23/2015
Consensus Review Received in PIO	Original (0)	07/27/2015
Consensus Review Completed	Original (0)	07/29/2015
Consensus Review Sent to PI	Original (0)	07/29/2015
Conference Call - Planned	Original (0)	08/07/2015
Conference Call - Actual	Original (0)	08/07/2015
<b>Follow-Up Protocol Consensus Evaluations</b>		
Revised Protocol Submitted	Revision (1)	08/28/2015
Consensus Review Received in PIO	Revision (1)	09/09/2015
Consensus Review Completed	Revision (1)	09/10/2015
Consensus Review Sent to PI	Revision (1)	09/10/2015

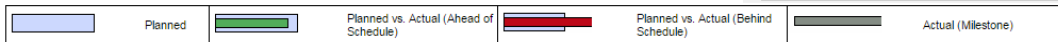
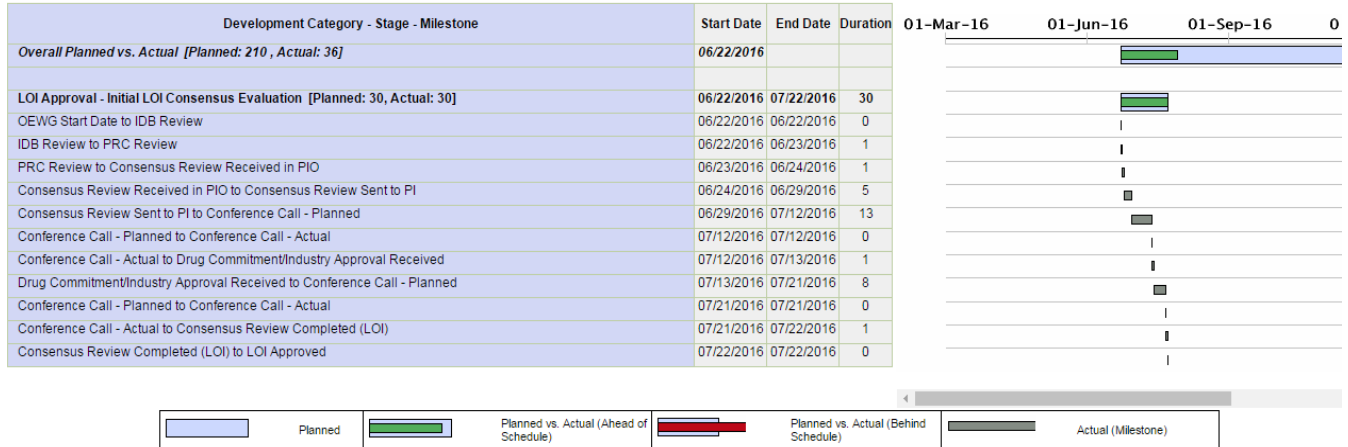
## OEWG Document Tracker Report

Document Milestones	Change Type	Milestone Date
<b>Protocol Development</b>		
<b>Follow-Up Protocol Consensus Evaluations</b>		
Revised Protocol Submitted	Revision (2)	09/22/2015
Protocol Approved On Hold	Revision (2)	09/30/2015
Protocol Approved On Hold	Revision (2)	11/09/2015
Revised Protocol Submitted	Revision (3)	12/02/2015
Protocol Approved On Hold	Revision (3)	12/10/2015
Revised Protocol Submitted	Revision (4)	02/08/2016
Protocol Approved On Hold	Revision (4)	02/10/2016
<b>Protocol Approval and Activation</b>		
Protocol Approved	Revision (4)	03/10/2016
Protocol Active		03/31/2016

## Appendix B: Sample OEWG Sequential Report



## Appendix C: Sample OEWG Gantt Report



Notes: The total Actual Days for a category may not equal the sum of the actual days for each stage due to non-sequential occurrences of milestones within stages i.e. stage begin and end dates overlapping, subsequent stages ending prior to the previous one beginning, etc.