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Title:	CTD and Billing Implications	

1. PURPOSE

The purpose of this document is to outline processes and procedures and to describe templates, supporting documents and reports issued by the Office of Research Compliance and Quality Assurance (RCQA) for billing issues related to Clinical Trial Disclosure.

2. DEFINITIONS

CMS	Centers for Medicaid and Medicare Services
CMS Change Request 8401	The purpose of this change request (CR) is to inform providers and suppliers that effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items/services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1.
CTD	Clinical Trial Disclosure
IIT	Investigator Initiated Trials
MCA	Medicare Coverage Analysis
NCT #	National Clinical Trial (NCT) number, another term for the ClinicalTrials.gov registry number unique to each record. The format for the ClinicalTrials.gov registry number is "NCT" followed by an 8-digit number, e.g.: NCT00000419
Principal Investigator (PI)	An individual, who actually conducts a clinical investigation under whose immediate direction the test article is administered, dispensed or used.
RCQA	Office of Research Compliance and Quality Assurance
RCQA ED	Executive Director of the Office of Research Compliance and Quality Assurance
Responsible Party (RP)	The term used by FDAAA to designate the entity or individual responsible for the clinical trial and for the submission of clinical trial information. This can mean: • The sponsor of the clinical trial, or • The principal investigator if so designated
Sponsor	A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug device or biologic is administered, dispensed or used under the immediate direction of another individual.

Sponsor-Investigator	An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug, device or biologic is being administered, dispensed or used.
Study Team	Principal Investigator, Sponsor-Investigator, Research Coordinator, Study Coordinator, etc.

3. RESPONSIBILITY

3.1. **CTD Compliance Officer or Designee**

- Review study
- Notify study team of required registration
- Notify study team of non-compliance

3.2. **Billing Office**

- Notify RCQA if bill is on hold for missing NCT number

3.3. **Responsible Party or designee**

- Obtain NCT number for sponsored studies
- Register study on ClinicalTrials.gov for Investigator Initiated Trials (IITs)
- Request review/revision of current Medicare Coverage Analysis (MCA) as applicable

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1. Review of Studies with Billing Compliance Implication				
4.1.1.	Notification that NCT number is missing	Notification is received from billing department that bills are on hold for a study that is missing the NCT number in Velos.	Billing Office	At time of submitting claim
4.1.2.	Review of study	Study is reviewed to determine if NCT number is available and has not been entered into Velos.	CTD Compliance Officer or designee	Within 5 business days of notification

ID	Step	Description	Responsible	Timeline
4.1.3.	Notification of study team to record NCT number	If study is externally sponsored and has an NCT number, or study is an IIT that has been registered, the study team is notified to record the NCT number in Velos.	CTD Compliance Officer or designee	Within 3 business days of step 4.1.2
4.1.4.	NCT number not available for IIT	For IIT studies, the study team is notified that bills are on hold due to the CMS Change Request 8401, requiring that NCT numbers are included on bills submitted to Medicare for services associated with a Clinical Trial/Study.	CTD Compliance Officer or designee	Within 3 business days of step 4.1.4
4.1.5.	Obtain NCT Number	IIT study team must obtain an NCT number by registering their protocol. *Refer to SOP RCQA-710 for steps to follow to Obtain NCT number.*	Responsible Party or designee	Within 30 calendar days of notification
4.1.6.	Notification of non-compliance	For studies that have bills on hold for more than 60 calendar days due to missing NCT numbers, RP, Department Chair, Chief Privacy and Data Integrity Officer, and Chief Compliance Officer will receive notification about non-compliance.	CTD Compliance Officer or designee	Within 60 calendar days of continued non-compliance
4.1.7.	Removal of study from CTD non-compliant list	Upon review of applicable systems and determination that an NCT number has been obtained, the study will be removed from the CTD non-compliant list.	CTD Compliance Officer	Within 3 business days of NCT number being recorded in Velos
4.1.8.	Disagreement with MCA	If the study team disagrees with the MCA, the Office of Research Administration is contacted and a review and/or revision of current MCA is requested.	Responsible Party or designee	Within 30 calendar days of notification that NCT number is missing

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1.9.	Issue Unresolved	If study remains non-compliant after 4.1.6 has been completed, the Institutional Official and Chief Compliance Officer are notified.	CTD Compliance Officer or designee	Within 90 calendar days of continued non-compliance

5. DOCUMENTATION

RCQA will maintain an electronic copy

6. REFERENCES

CMS Change Request 8401
RCQA-710 Missing and Erroneous NCT Numbers in Velos

7. TEMPLATES/FORMS/TOOLS

N/A

8. REVISION HISTORY

N/A

9. SIGNATURES

Prepared by: Signature on File Date: 18 Apr 2017
Yolanda P. Davis, BS, CCRP
Clinical Trial Disclosure Manager, RCQA

Approved by: Signature on File Date: 18 Apr 2017
Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director, RCQA