Document Number:	RCQA-707	Effective Date: 11 Aug 2017
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Title:	Missing and Erroneous NCT Numbers	

1. PURPOSE

The purpose of this document is to outline the process and procedures completed by the Office of Research Compliance and Quality Assurance (RCQA) to review and verify the accuracy of the NCT numbers recorded in Velos.

2. DEFINITIONS

Billing Task Force	A team that consists of representatives from Research, Research Education and Innovative Medicine (RIM) and Office of Research Administration (ORA) that reviews information from a study to determine if there is a possibility of billing to Medicare.
CMS	Centers for Medicaid and Medicare Services
CTD	Clinical Trial Disclosure
CTD Ancillary Committee	Members of the Clinical Trial Disclosure Team or managers within the Office of Research Compliance and Quality Assurance
DOD	Department of Defense
FDAAA	Food and Drug Administration Amendment Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
ICF	Informed Consent Form
ICJME	International Committee of Journal Medical Editors
IRB	Institutional Review Board
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.
NIH	National Institute of Health
Principal Investigator (PI)	An individual who actually conducts a clinical investigation (i.e. under whose immediate direction the test article is administered or dispensed to a subject
PRS	Protocol Registration and Result Reporting System
RCQA	Research Compliance and Quality Assurance

Responsible Party

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 or device 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 or device is being administered, dispensed or used.

Study Team

Principal Investigator, Sponsor-Investigator, Research Coordinator, Study Coordinator, etc.

University of Miami Applicable Clinical Trial (UMACT)

Any study that meets the criteria as defined in the business rules below:

Business Rule #1 – Legal Requirement (FDAAA. FDAMA, and 42 CFR § 11)

Criteria Group 1.1

- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- PI is the Sponsor-Investigator

Criteria Group 1.2

- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- PI is the Responsible Party

Criteria Group 1.3

- Study is interventional and involves a Drug, Device, or Biologic; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND

- Involves at least 1 U.S. Site; AND
- Involves a Serious or Life-Threatening Disease
- PI is the Sponsor-Investigator

Criteria Group 1.4

- Study is interventional and involves a Drug, Device, or Biologic; AND
- Study Start Date is as of September 2007 forward (*not programmed)*; AND
- Involves at least 1 U.S. Site; AND
- Involves a Serious or Life-Threatening Disease
- PI is the Responsible Party

Business Rule #2 – Federal Funding Requirement (NIH Policy on the Dissemination of Clinical Trial Information for Federally Funded Studies)

Criteria Group 2.1

- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; OR
- Study is interventional and involves a Behavioral Interventions, Dietary Changes, Process of Care Changes, Surgical Procedures , or Physical Therapy; AND
- Study Start Date is as of September 2007 forward; AND
- Involves at least 1 U.S. Site; AND
- NIH or DOD Funding; AND
- PI is the Responsible Party;

Business Rule #3 – CMS Mandate Requirement

Criteria Group 3.1

- Study involves a Drug, Device, or Biologic; OR
- Study involves a Behavior, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- PI is the Responsible Party; AND
- Clinical Study/Registry/Clinical Trial; AND
- Medicare Billing

Criteria Group 3.2 (Sponsored Studies)

- Study involves a Drug, Device, or Biologic; OR

- Study involves a Behavior, Dietary Changes, Process of Care Changes, Surgical Procedures, or Physical Therapy; AND
- Sponsor/Collaborative Group/Other Institution is responsible party; AND
- Clinical Study/Registry/Clinical Trial; AND
- Medicare Billing

Business Rule #4 – ICMJE Requirement
Criteria Group 4.1

- PI is the Responsible Party; AND
- Interventional clinical trial wanting to Publish

Business Rule #5 – Requirement for Result Reporting
Criteria Group 5.1

- Study is interventional and involves a Drug, Device, or Biologic; AND
- It is Phase 2-4; AND
- Study Start Date is as of September 2007 forward; AND
- Involves 1 U.S. Site; OR Study is a Federally Funded interventional clinical trial

Velos — An electronic Clinical Trial Management System

3. RESPONSIBILITY

3.1. **CTD Compliance Team Member or Designee**

- Review study for CTD determination
- Make CTD determination
- Create PRS account
- Assist with protocol registration, if applicable
- Review record for consistency and regulatory compliance, if applicable
- Verify protocol registration and entry of NCT number in Velos
- Notify PI/Study Team of missing NCT number

3.2. **PI and/or Study Team**

- Submit study in IRB7
- Register protocol in ClinicalTrials.gov if applicable
- Record NCT number in Velos

3.3. **Billing Task Force**

- Determine if there is a possibility of Medicare billing

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1. Missing NCT Number for Investigator Initiated Trials (IIT)				
4.1.1.	Generate 'CTD Determination Review' Report	The CTD Report is generated from Velos and filtered to review studies that have a CTD Determination of 'required' **OR** 'recommended' **AND** 'Investigator' is the Responsible Party **AND** the NCT Number is Missing	CTD Compliance team member or designee	Monthly
4.1.2.	Save Report	The CTD Determination Review Report is saved in the electronic folders	CTD Compliance team member or designee	Upon generation of report
4.1.3.	Verification of registration for IITs	The PRS is reviewed to ensure that studies that have been identified as 'UMACTs' are registered	CTD Compliance team member or designee	Within 7 business days of report generation from Velos
4.1.4.	Notification of missing NCT number	Study teams associated with studies that are registered and are missing the NCT number in Velos are notified to add the NCT number and that it has the correct 'Unique Protocol ID'	CTD Compliance team member or designee	5 days after Velos report generation
4.1.5.	Study not registered	The study team will work with the Clinical Trial Disclosure Compliance Team or they will proceed on their own to register the protocol on https://register.clinicaltrials.gov *Refer to SOP RCQA-709*	Responsible Party or designee	Prior to enrollment of first participant

ID	Step	Description	Responsible	Timeline
4.1.6.	Notification of registration	The study team will notify the Clinical Trial Disclosure Compliance Team that the protocol has been registered and made public on www.ClinicalTrials.gov	Responsible Party or designee	Upon receipt of NCT number
4.1.7.	Verification of registration	The Clinical Trial Disclosure team will verify that the protocol has been registered and has the correct 'Unique Protocol ID'	CTD Compliance team member or designee	Within 3 days of receiving notification
4.1.8.	Reporting on Non-Compliance	The study team will notify the IRB via deviation report in the annual continuing report that they were non-compliant with policy HSR-P-101 if the study was registered after the first participant was enrolled	Responsible Party or designee.	At time of continuing report

ID	Step	Description	Responsible	Timeline
4.2. Missing NCT Number for Sponsored Trials				
4.2.1.	Generate 'CTD Determination Review' Report	The CTD Report is generated from Velos and filtered to review studies that have a CTD Determination of 'required' **AND** 'Sponsor' is the Responsible Party **AND** the NCT number is missing	CTD Compliance team member or designee	Monthly
4.2.2.	Save Report	The CTD Determination Review Report is saved in the electronic folders	CTD Compliance team member or designee	Upon generation of report
4.2.3.	Verification of registration for sponsored studies	ClinicalTrials.gov is reviewed to verify if the study was registered	CTD Compliance team member or designee	Within 7 business days of report generation from Velos
4.2.4.	Notification of missing NCT number	Study teams associated with studies that are registered and are missing the NCT number in Velos are notified to add the NCT number	CTD Compliance team member or designee	Within 7 business days after Velos report generation
4.2.5.	Unable to verify registration	If unable to verify that study was registered, the most current MCA will be consulted to determine if there is a potential for Medicare Billing	CTD Compliance member or designee	Within 5 business days of verifying that NCT number is missing
4.2.6.	No potential for Medicare billing	If the study does not have the potential for Medicare billing, no further actions are required. Document in report	CTD Compliance member or designee	Upon verification

ID	Step	Description	Responsible	Timeline
4.2.7.	Potential for Medicare billing	Study team is notified to request an NCT number from the sponsoring organization	CTD Compliance member or designee	Within 3 business days of determining if an NCT number is needed for Medicare billing.
4.2.8.	Unable to obtain NCT number	If the Sponsoring organization notifies study team that the study will not be registered, review of contract is completed to verify that sponsoring organization will pick up any costs that the insurer will not pay. See SOP RCQA-705 for next steps	CTD Compliance member or designee	Within 30 days of determining that an NCT number is needed for Medicare billing.

ID	Step	Description	Responsible	Timeline
4.3. Erroneous NCT Number Entered into Velos				
4.3.1.	Generate 'CTD Determination Review' Report	The CTD Report is generated from Velos and filtered to review studies that have an NCT number present and were not previously recorded.	CTD Compliance team member or designee	Monthly
4.3.2.	Save report	The CTD Determination Review Report is saved in the electronic folders	CTD Compliance team member or designee	Upon generation of report
4.3.3.	Check for errors	Each newly recorded NCT number will be reviewed for accuracy	CTD Compliance team member or designee	Within 7 business days of generating the report
4.3.4.	Incorrect NCT number	If the NCT number is incorrect, review of the MCA is completed to determine if there is the potential for Medicare billing	CTD Compliance team member or designee	In parallel with step 4.3.3
4.3.5.	No Medicare billing implications	If the study does not have the potential for Medicare billing, the study team is notified to correct the NCT number in Velos	CTD Compliance team member or designee	Within 3 business days of knowing that the study had Medicare billing.

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.3.6.	Potential for Medicare billing	If the study has the potential for Medicare billing, the following occurs: • Study team is notified to correct the NCT number • Research IT is notified that the NCT number has been corrected • Central Revenue Cycle is notified that the NCT number has been corrected	CTD Compliance team member or designee	In parallel with step 4.3.5
4.3.7.	Potential for Medicare billing and participants enrolled	In addition to completing step 4.3.6, the Office of Billing Compliance is notified for follow-up	CTD Compliance team member or designee	In parallel with step 4.3.5

5. DOCUMENTATION

RCQA will maintain an electronic copy of all reports generated on the shared drive for a minimum of ten years.

For example: S:\RCQA\Clinical Trial Disclosure\CTD Compliance

6. REFERENCES

HSR-P-101 Clinical Trial Disclosure Protocol Registration
Food and Drug Administration Amendment Act Section 801: 2007
Food and Drug Administration Modernization Act Section 113: 1997
42 CFR § 11: Clinical Trial Registration and Result Reporting
NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
Determination of UMACT Workflow
Identifying Responsible Party Workflow
Instructions for completing CTD Ancillary Review in IRB7
Instructions for entering an NCT Number in Velos
Notification of required registration
Notification of recommended registration
Notification NCT number is required

7. TEMPLATES/FORMS/TOOLS

CTD Determination Review Report
University of Miami Clinical Trial Registration and Result Reporting Tool

8. REVISION HISTORY

Effective Date	Revision Date	Author	Description of Changes
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9. SIGNATURES

Prepared by: Signature on file _____ Date: _____
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Approved by: Signature on file _____ Date: _____
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