University of New Mexico Comprehensive Cancer Center/New Mexico Cancer Care Alliance

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: Velos Case Report Form development and Completion Monitoring

SOP No.: 5.3	Version No.: 4	Effective Date: 02/28/2011

Owner: Clinical Research Operations Manager

Name: Ebany Martinez-Finley, PhD

Signature

12/19/2017
Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature

3/28/2018
Date

INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at New Mexico Cancer Care Alliance (NMCCA) sites, including UNM Comprehensive Cancer Center (UNMCCC) for the identification of Case Report Form (CRF) requirements and monitoring the completion of Velos Case Report Forms.

Identification of specific CRFs to be completed for each protocol.

Assess adherence to timelines for completion of Velos CRFs.

SCOPE

This SOP applies to the procedures for assigning and monitoring of Velos CRF completion per department timelines. Completion of CRFs per timeline is essential to maintain data quality and integrity.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator's records and reports
January 1988	FDA Guidelines for the Monitoring of Clinical Investigations
ICH E6 (R2)	Section 1.1,

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in arranging clinical research chart and completion of Velos CRFs. This includes (but not limited to) the following:

Principal investigator (PI)

Sub-investigator (Sub-I)

UNMCCC Clinical Research Operations Manager (CROM)

NMCCA Clinical Research Manager (CRM)

Clinical Research Nurse (RN)

Clinical Research Coordinator (RC)

Data Coordinator (DC)

NMCCA Clinical Research Supervisor (NMCCA CRS)

UNMCCC Clinical Research Supervisor (UNMCCC CRS)

Velos Database Manager (DM)

UNMCCC QA Team (QA)

Scientific Writer (Writer)

PROCEDURES

Identification of CRF assignment

Owner	Criteria / Steps
PI QA / Writer DM	QA/Writer will work with the PI to identify which CRFs are to be completed for the study using the Velos Case Report Form Check List. The Velos CRF Check List will be uploaded in Velos in the Versions tab for the study for future reference. PI will identify any special data that will need to be completed for their study. A study specific Velos CRF will be designed for this purpose by QA/Writer and built by the Velos Data Manager.

Monitoring of Velos CRF Completion

RN/RC DC UNMCCC CRS	Each time a patient on an Investigator Initiated trial is enrolled, Velos will send a notification to the UNMCCC Clinical Research Supervisor. UNMCCC Clinical Research Supervisor will audit CRFs for completeness for 5% of patient's enrolled on Investigator Initiated Trials, beginning in March 2014.
UNMCCC CRS DC	Velos CRF Timelines Baseline CRFs completed by Cycle 1 Day 1 Cycle CRFs completed by Day 1 of next cycle Patient Status changes completed within 48 hours of change. Patient DOB, Physician, ethnicity, race, and diagnosis completed within 48 hours of Informed Consent. Patient SAEs or reportable protocol deviations to be entered into Velos within 48 hours of report being filed.
RN/RC DC UNMCCC CROM/ NMCCA CRS	When CRFs are not completed per department timelines, the clinical research supervisor will send out an email identifying a timeline for completion. If CRFs are still not complete by deadline, the CROM/CRM will be notified.

Quality Management of CRF Completion

UNM CCC Clinical Research Supervisor UNM CCC QA Team	Research supervisor will keep a monthly report of the percentage of CRF completion and report as a quality indicator and utilize for discussion with employee.