SWOG Site Operations

SDMC Update

Cathy Rankin, MS

S0777 Update

March 29, 2019 SWOG Myeloma Committee leadership heard from Celgene

We are excited to announce that the EMA Committee for Medical Products for Human Use (CHMP) has reached a positive opinion regarding the approval of the Revlimid triplet (RVd) in Europe The indication statement granted is:

> *Revlimid as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone (see section 4.2) is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.*

S0777 Update

Prospective Regulatory Trials

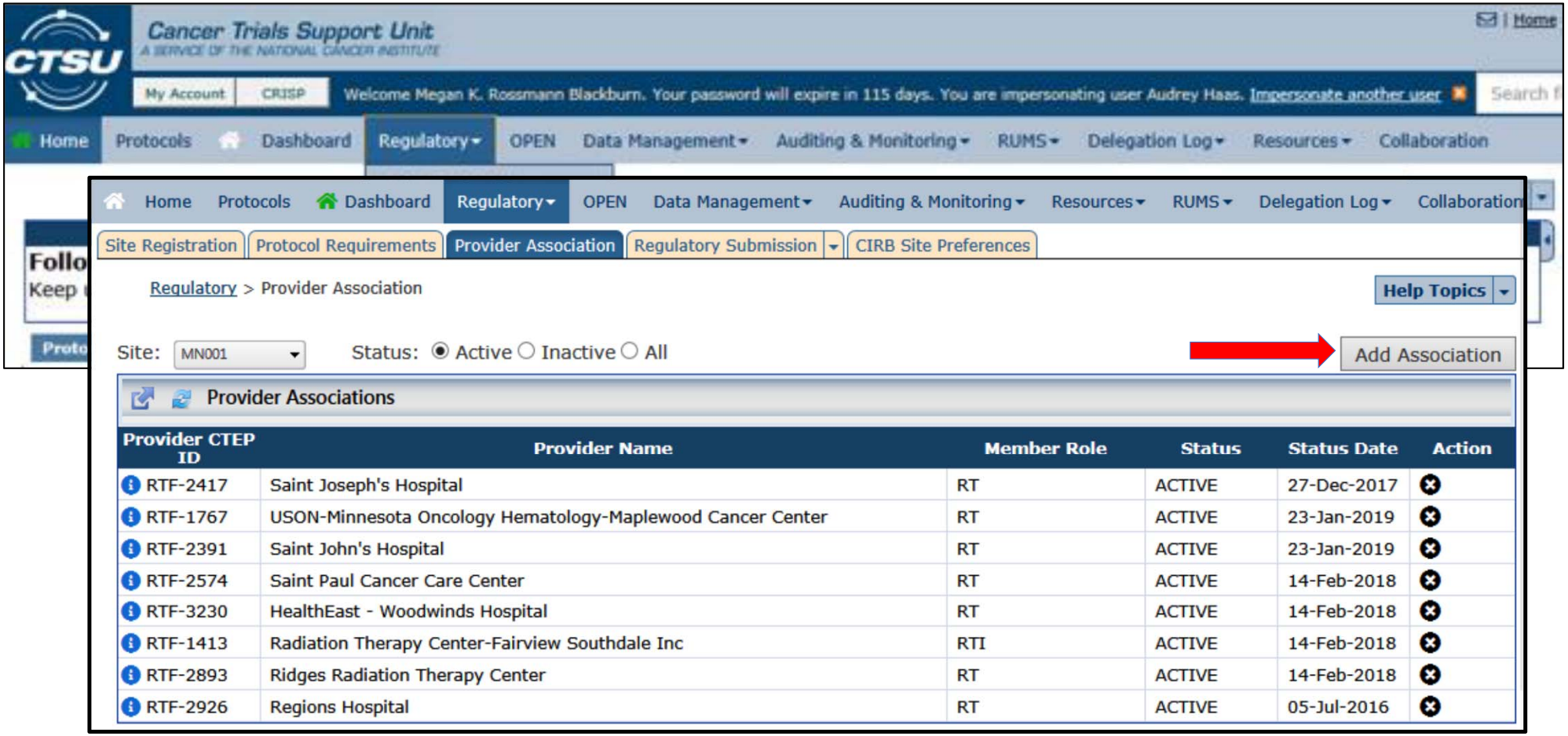
Committee	Study ID	Accruing patients
Breast	S1418	Yes
GU	S1605 - bladder S1806 - bladder	Yes Yes
Lung	S1400 (and sub-studies) LUNGMAP S1800A S1900A S1900B S1900C S1914	(S1400F) Yes Spring 2019 Yes Summer 2019 Fall 2019 Fall 2019
Melanoma	S1404	No

Provider Associations for S1806

This study uses the IROC integration suite to document that the enrolling sites are associated with a radiation provider credentialed for the study modalities.

Enrolling sites must link to the patient's associated radiation provider using the Provider Association page on the CTSU member's website. This is a one-time link for each site/modality provider combination. THIS MUST BE DONE PRIOR TO REGISTRATION!!

Any individual associated with the site may view association. Those with a primary role may update associations. The enrolling site is responsible for ensuring all approvals are in place.


Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
CTSU
Home
My Account
CRISP
Welcome Megan K. Rossmann Blackburn. Your password will expire in 115 days. You are impersonating user Audrey Haas. Impersonate another user
Search
Home
Protocols
Dashboard
Regulatory
OPEN
Data Management
Auditing & Monitoring
RUMS
Delegation Log
Resources
Collaboration
Site Registration
Protocol Requirements
Provider Association
Regulatory Submission
CIRB Site Preferences
Regulatory > Provider Association
Help Topics
Site: MN001
Status: Active Inactive All
Add Association
Provider Associations
Provider CTEP ID
Provider Name
Member Role
Status
Status Date
Action
RTF-2417 Saint Joseph's Hospital RT ACTIVE 27-Dec-2017
RTF-1767 USON-Minnesota Oncology Hematology-Maplewood Cancer Center RT ACTIVE 23-Jan-2019
RTF-2391 Saint John's Hospital RT ACTIVE 23-Jan-2019
RTF-2574 Saint Paul Cancer Care Center RT ACTIVE 14-Feb-2018
RTF-3230 HealthEast - Woodwinds Hospital RT ACTIVE 14-Feb-2018
RTF-1413 Radiation Therapy Center-Fairview Southdale Inc RTI ACTIVE 14-Feb-2018
RTF-2893 Ridges Radiation Therapy Center RT ACTIVE 14-Feb-2018
RTF-2926 Regions Hospital RT ACTIVE 05-Jul-2016

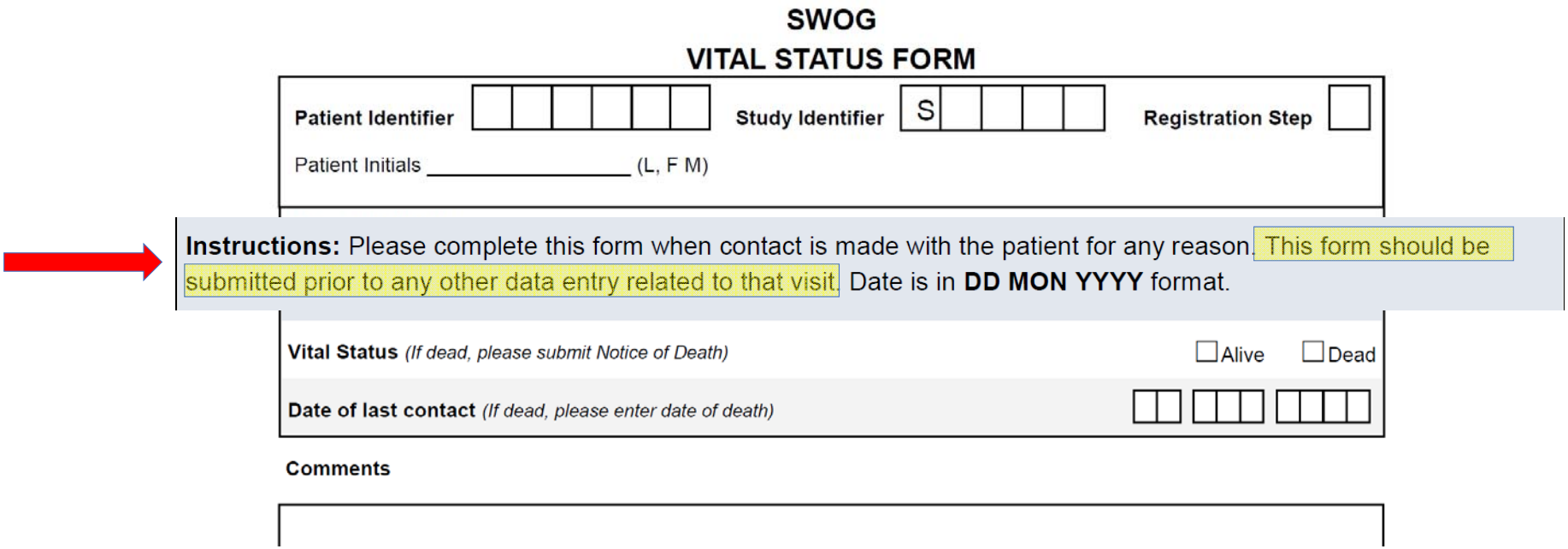
Vital Status Form

A way to capture *Last Date of Contact / Date of Death* and *Vital Status* differently than we have in the past.

Collection on a single CRF – the Vital Status Form – for studies newly activating.

Historically vital status data were captured on multiple forms e.g., Treatment Form, Off Treatment Notice, Follow-up Form, Notice of Death.

Vital Status Form



SWOG

VITAL STATUS FORM

Patient Identifier ☐☐☐☐☐☐ **Study Identifier** S☐☐☐☐ **Registration Step** ☐

Patient Initials _____ (L, F M)

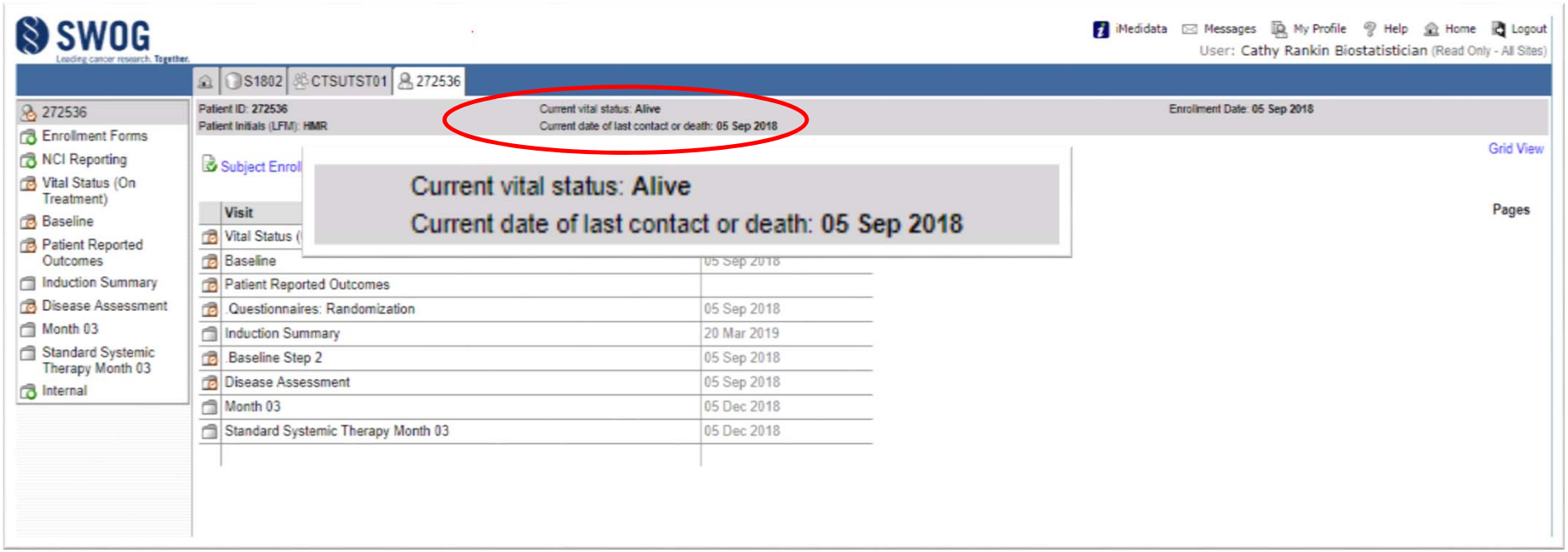
Instructions: Please complete this form when contact is made with the patient for any reason. This form should be submitted prior to any other data entry related to that visit. Date is in **DD MON YYYY** format.

Vital Status *(If dead, please submit Notice of Death)* ☐Alive ☐Dead

Date of last contact *(If dead, please enter date of death)* ☐☐ ☐☐☐ ☐☐☐☐

Comments

Vital Status Form




COMING
Soon

New Standard Case Report Forms

SDMC will incorporate global standards (CDASH) for data acquisition in CRFs per NCTN mandate.

CDASH standards improve the common understanding across the clinical trial stakeholders and yield better quality data, reduce data queries and facilitate efficient mapping for regulatory submissions forth by FDA

You will notice changes on SWOG standard forms:

New question text or

Re-ordering of CRFs or information on CRFs

New Studies: Don't Wait, Participate! (1)

- **S1600** - *Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes*
  - **Primary cell carcinoma of the bladder; planned cystectomy within 28 days after reg**
  - **Sites must meet five requirements** (see protocol) before first patient registration
  - **Study Chair:** Jill Hamilton-Reeves, PhD, RD, CSO

- **S1614** - *Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors*
  - **Stage I-III solid tumor malignancy, planned systemic anti-cancer therapy, HBsAG or anti-HBc positive**
  - **Slide Set:** For Staff and Investigators available on SWOG.org and CTSU.org
  - **Study Chair:** Jessica Hwang, MD, MPH

These Symptom Control Quality of Life Committee studies activated in February and March and are open to SWOG and NCTN sites.

New Studies: Don't Wait, Participate! (2)

- **S1703** - *Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) vs. Usual Care in Metastatic Hormone Receptor Positive Breast Cancer Patients*
  - **ER+ and/or PR+, HER-2 negative metastatic breast cancer**
  - **Study Chair:** Melissa Accordino, MD
  - Open to SWOG and NCTN sites
  - Activated July 2018, Cancer Care Delivery Committee

- **S1714** – *Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients*
  - **Stage I-III primary non-small cell lung, breast or ovarian cancer, planning to start taxane-based chemotherapy**
  - **Study Chair:** Meghna Trivedi, MD • Open to SWOG sites
  - **Training required!** Attend Session on **Thursday, Noon to 1:30 pm**
  - Activated March 1, 2019, Symptom Control and Quality of Life Committee

5th Annual

NCORP Research Base Clinical Trials Workshop

- For Clinical Research Professionals and Investigators at NCORP, Member and LAPS Institutions and Affiliates
- Studies in the following SWOG research areas will be discussed:
  - Cancer Care Delivery Research
  - Cancer Survivorship
  - End of Life and Palliative Care
  - Prevention & Epidemiology
  - Symptom Control and Quality of Life
- New agenda and topics at each annual workshop
- The workshop consists of didactic presentations and breakout sessions for information sharing.

WEDNESDAY, OCTOBER 2

Fall 2019 SWOG Group Meeting

Chicago