INTRODUCTION TO MEDIDATA RAVE

ANGELA SMITH
CHRISTINE MCLEOD
SWOG STATISTICAL CENTER
SEATTLE
Background

- SWOG has had online data submission for almost 10 years
  - CRA Workbench website
  - Developed and maintained by the Statistical Center

- Most other Cooperative Groups also have their own online data collection systems
  - Also developed and maintained locally
Background

PRO
- Allows for customization

CON
- Results in disparate systems
- Requires duplicative effort across Groups
Background

- NCI purchased a license from the commercial software company Medidata
- Rave is what Medidata calls their electronic data capture (EDC) system
- All Cooperative Groups are mandated to adopt Medidata Rave for new studies
- Two ways to submit data online:
  - CRA Workbench – studies activated before 4/1/2012
  - Medidata Rave – studies activated after 4/1/2012
Background

- How many of you have heard of Medidata Rave?
- How many of you have used Medidata Rave for industry trials or for NCIC MA.32?
- How many of you are still confused by the picture of people dancing?
Background

• Just in case you don’t remember our every word:
  ◦ Online training videos
    • From Medidata
    • From SWOG
  ◦ Slides available on CRA Workbench
  ◦ Table at Open Forum
Background

- CTSU Help Desk
  - 9:30am – 8:30pm ET
  - 1-888-823-5923
  - ctsucontact@westat.com
Overview

- Accessing Rave
- Navigating to a study
- Navigating within a study
- Form organization
- Form submission
- CRA Workbench changes
- Timeframe
Overview

1. Medidata
   *The Company*

2. iMedidata
   *The Portal*

3. Rave
   *The Application*
Accessing Rave: Activate account

- Look for an email inviting you to activate your new account. Click the link.

Dear User,

Welcome to iMedidata.com -- a faster, simpler way to access all your Medidata Rave® studies, Medidata applications and online discussions in one place. You’ve been invited to activate your new account. Please click on the following link:

http://www.imedidata.com/users/664e717581396196eea6a7b554b9f2a1c0217fd4/activation?locale=eng

If clicking the link above does not work, copy and paste the URL in a new browser window instead.

If you are a current user of Rave and would like a brief tutorial on connecting your Rave account to iMedidata, please click on the following video: http://www.imedidata.com/WebHelpVideos_ENG/init.htm

Thank you for using iMedidata. For more information please visit http://www.imedidata.com. For support with your new account, please email helpdesk@mdsol.com.

This is a post-only mailing. Replies to this message are not monitored or answered.

Medidata Solutions Worldwide
Accessing Rave: Activate account

- Complete the required fields on the iMedidata Account Screen
  - Username: try CTEP IAM username first
  - Password: use CTEP IAM password
  - Security Question, Answer
Accessing Rave: Activate account

- Logon to iMedidata using the username and password you just set
Accessing Rave: Activate account

- “Sign” the iMedidata Terms of Use using your CTEP IAM username and password
Accessing Rave: Logon

- For all subsequent logons, reach this page through
  - CRA Workbench Medidata Rave link or
  - https://login.imedidata.com/selectlogin
Accessing Rave: Logon

- First Logon, select CTEP-IAM IdP link
Accessing Rave: Logon

- Logon using your CTEP IAM username and password
## Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mediflex 56L4 (DEV)</td>
<td>Rave EDC</td>
</tr>
<tr>
<td>S0820 (Dev)</td>
<td>Rave EDC</td>
</tr>
<tr>
<td>S0820 (Tst)</td>
<td>Rave EDC</td>
</tr>
<tr>
<td>S0931 (Dev)</td>
<td>Rave EDC</td>
</tr>
<tr>
<td>SWOG</td>
<td>Rave EDC</td>
</tr>
</tbody>
</table>

## Tasks

- **eLearning (4)**
  - Rave 5.6 EDC Essentials for Clinical Research Coordinators
  - EDC Inspection Readiness for Clinical Sites
  - Rave 5.6 Advanced Rave EDC for Site Users
  - Data Privacy Considerations for Clinical Systems
Accessing Rave

• Accept any pending invitations
  ◦ You will see invitations to studies that your site approves
  ◦ You will also get email notifications that these invitations have been added
  ◦ Just click “accept” to access study

• List of studies
  ◦ Studies for which you have accepted invitations
  ◦ Search tool available
  ◦ Not accessible until eLearnings satisfied
Accessing Rave

- Note eLearning requirements
  - **Required**
    - Rave 5.6 EDC Essentials for Clinical Research Coordinators (45 min)
    - EDC inspection readiness for Clinical Sites (30 min)
    - Data Privacy Considerations for Clinical Systems (50 min)
  - **Optional**
    - Rave 5.6 Advanced Rave EDC for Site Users (20 min)
Questions about Accessing Rave?
Navigating to a Study

- Rave is organized by study
- No cross-study reports or functions
- Select a study
- If multiple sites, select a site
Navigating to a Study

- Study-Site page:
  - Subject List
    - Subjects still enrolled via OPEN
    - Search utility
  - Task Summary (site level): lists subjects with outstanding tasks
  - Link to Icon Key on every page (whew!)
Navigating Within a Study

- Select a subject
- Subject page:
  - Folders and forms
  - Upcoming Visits and Dates
  - Task Summary (Subject level)
<table>
<thead>
<tr>
<th>Visit</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment Forms</td>
<td>04 Apr 2012</td>
</tr>
<tr>
<td>Onstudy</td>
<td>04 Apr 2012</td>
</tr>
<tr>
<td>Month 3</td>
<td>04 Jul 2012</td>
</tr>
</tbody>
</table>

**Task Summary: Subject**

- NonConformant Data: 0 Pages
- Open Queries: 0 Pages
- Sticky Notes: 0 Pages
- Overdue Data: 0 Pages

**Icon Key**

CRF Version 17 - Page Generated: 04 Apr 2012 10:28:45 Pacific Daylight Time
Questions about
Navigating to or within a study?
Form Organization

- Most of the study forms will be organized in study-specific folders
- Paper CRFs will still be part of the protocol, but will be for reference only
- Rave Form Schedule in the protocol can help you find your forms
Form Organization

- Forms in Rave will look different from their paper CRF counterparts
- Question order and content will be the same
- A single paper CRF may become multiple forms in Rave
**SWOG S0820 ONSTUDY FORM**

**Patient Initials:** [Blank]
**SWOG Study No.:** S0820
**Registration Step:** 1

**Institution/Affiliate:** [Blank]
**Physician:** [Blank]

**Participating Group:** [Blank]
**Instructions:** Submit this form within 7 days of registration. All dates are MONTH, DAY, YEAR. Explain any blank fields or blank dates in the Comments section. Place an **[X]** in appropriate boxes.

---

**ELIGIBILITY VERIFICATION:**
Each of the fields below corresponds to a criterion in Section 5 and must be completed for patient to be eligible.

### PATIENT AND DISEASE DESCRIPTION

**Performance status:** [Blank]

**AJCC Clinical Stage:**
- T: T1, T2, T3, T4a, T4b, Tis
- N: N0, N1, N1a, N1b, N1c, N2, N2a, N2b
- M: M0

**Initial diagnosis:**
For each category of disease (colon cancer and rectosigmoid cancer), please select the appropriate stage. Also indicate the date the disease was resected. If patients meet the criteria for more than one disease category, please indicate information for all disease categories.

**Location (select all that apply):**
- Cecum
- Ascending Colon
- Transverse Colon
- Descending Colon
- Left Colon
- Sigmoid Colon
- Rectosigmoid Colon
- Rectum

**Stage (select all that apply):**
- 0
- I
- IIa
- IIb
- IIc
- IIIa
- IIIb
- IIIc

**Primary surgery date (primary resection):** [Blank] / [Blank] / [Blank]

**Has patient had a personal history of colon resection?**
- Yes
- No

**If yes, how many cm have been removed?** [Blank] cm

**Has the patient had ≥ 20 dB of uncorrectable hearing loss for age of any two contiguous frequencies?**
- Yes
- No

*continued on next page*
**SWOG S0820 ONSTUDY FORM**

**Patient ID**

**SWOG Study No.** S0820

**Registration Step 1**

**Patient Initials**

**Risk of cardiovascular events** (select all that apply):
- Age > 75 years
- Hypertension/use of hypertensive medication
- Hyperlipidemia/use of lipid lowering medication
- Current smoker
- Use of low-dose aspirin
- Diabetes mellitus
- Prior history cardiovascular disease
- None of the above applies

**Date of one-year postoperative (pre-registration) colonoscopy**

**Percent of colon surface area visualized**

**Date of one-year postoperative body CT scans**

**LABORATORY VALUES**

**Hematologic:**
- Peripheral platelet count

**WBC** $\times 10^9$/mCL

**Hemoglobin** g/dL

**Hepatic:**
- Total bilirubin mg/dL

**ULN** mg/dL

**SGOT** U/L

**ULN** U/L

**SGPT** U/L

**ULN** U/L

**Renal:**
- Serum creatinine mg/dL

**ULN** mg/dL

**Collection date:**

*continued on next page*

**Date:** 2/3/2012

**Draft**
Prior treatment related to this cancer

Prior chemotherapy: [ ] Yes [ ] No
Type of prior chemotherapy: [ ] [ ] [ ]
(select all that apply):
- [ ] FOLFOX (5-fluorouracil + leucovorin + oxaliplatin)
- [ ] XELOX (CAPOX; capecitabine + oxaliplatin)
- [ ] 5FU + LV (5-fluorouracil + leucovorin)
- [ ] XELODA (capecitabine)
- [ ] Bevacizumab
- [ ] Other, specify:

Date prior chemotherapy started: [ ] [ ] [ ]
Date prior chemotherapy ended: [ ] [ ] [ ]

Prior radiotherapy: [ ] Yes [ ] No

Has the patient ever taken statin medications on a regular basis? [ ] Yes [ ] No
Has the patient taken statin medications on a regular basis in the past 3 years? [ ] Yes [ ] No

*Statin use on a regular basis is defined as daily use for ≥ 1 month.

Comments:
### ELIGIBILITY VERIFICATION
Each of the fields below corresponds to a criterion in Section 5 and must be completed for the patient to be eligible

#### Performance Status

#### AJCC Clinical Stage

<table>
<thead>
<tr>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>M</td>
</tr>
</tbody>
</table>

#### Initial diagnosis location (select all that apply)

<table>
<thead>
<tr>
<th>Cecum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascending colon</td>
</tr>
<tr>
<td>Transverse colon</td>
</tr>
<tr>
<td>Descending colon</td>
</tr>
<tr>
<td>Left colon</td>
</tr>
</tbody>
</table>
Form Organization

- Rave allows us to only show you the parts of the form that apply to your patient
- Some Rave forms may not appear unless certain questions are answered a certain way
SWOG
S0820 COLONOSCOPY REPORT FORM

SWOG Patient ID [ ] [ ] [ ] SWOG Study No. S0820 Registration Step 1

Patient Initials __________ F M

Institution / Affiliate ___________ Physician ___________

Participating Group: Group Name/Study No./Patient ID ___________ / ___________ / ___________

Instructions: Please submit this form within 7 days of registration, after 36 month colonoscopy, after year 8 post-registration colonoscopy, and at any other clinically indicated colonoscopy during treatment. All dates are MONTH, DAY, YEAR. Explain any blank fields or blank dates in the Comments section. Place an X in appropriate boxes.

Was a colonoscopy performed? [ ] Yes [ ] No

Reason for colonoscopy: [ ] Pre-registration (one-year post-operative) [ ] Year 8 post-registration Month 36 [ ] Other, as clinically indicated

COLONOSCOPY REPORT

Date of colonoscopy: ___________ / ___________ / ___________

Percent of colon surface area visualized: ___________ %

Quality Indicators

Photo documentation available? [ ] Yes [ ] No

Documentation of the ileocolic anastomosis (for right-sided hemicolectomies) OR colonic anastomosis with cecal landmarks? [ ] Yes [ ] No

Colonoscope withdrawal time indicated? [ ] Yes [ ] No

Total withdrawal time: ___________ minutes

Cancer

Evidence of recurrence of primary colorectal cancer? [ ] Yes [ ] No

Evidence of new (2nd) primary colorectal cancer? [ ] Yes [ ] No

If Yes, describe location (select all that apply):
- Cecum
- Ascending colon
- Transverse colon
- Descending colon
- Left colon
- Sigmoid colon
- Rectosigmoid
- Rectum

Evidence of metastasis of colorectal cancer? [ ] Yes [ ] No

If Yes, please indicate site(s) (select all that apply):
- Regional nodes
- Lung/pleura
- Bone
- Other, specify:
- Liver
- CNS/brain

continued on next page
## SWOG S0820 COLONOSCOPY REPORT FORM

**SWOG Patient ID**: [Redacted]

**SWOG Study No.**: S0820

**Registration Step**: 1

**Patient Initials**:

**ADENOMAS**

Evidence of occurrence of adenoma? [ ] Yes [ ] No

If Yes, describe all adenomas found during this colonoscopy using the codes below for location, histology, and percent villous. Record adenoma size according to the greatest transverse diameter:

<table>
<thead>
<tr>
<th>Size (cm)</th>
<th>Location</th>
<th>Histology</th>
<th>Excised?</th>
<th>% Villous</th>
<th>High-Grade Dysplasia</th>
<th>%</th>
<th>Landmark</th>
<th>Distance From Anatomical Landmark (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>2.</td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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</tr>
<tr>
<td>5.</td>
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<tr>
<td>6.</td>
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<tr>
<td>7.</td>
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<td></td>
</tr>
<tr>
<td>8.</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Location codes**

- C: Cecum
- A: Ascending colon
- T: Transverse colon
- D: Descending colon
- L: Left colon
- S: Sigmoid colon
- R: Rectosigmoid
- RM: Rectum

**Histology codes**

- T: Tubular
- TV: Tubulo-villous
- V: Villous
- F: Flat
- PJ: Peutz-Jegher
- J: Juvenile
- H: Hyperplastic
- S: Serrated

**% Villous codes**

- 0-25%
- 26-67.5%
- 78-100%

**Landmark codes**

- A: Anus
- S: Splenic flexure
- H: Hepatic flexure
- C: Cecum
- AO: Appendix orifice
- IC: Ileo-cecal valve

**Other (If Other, indicate in Comments)**

**Comments**

**Draft**

2/8/2012
<table>
<thead>
<tr>
<th>CRF History</th>
</tr>
</thead>
<tbody>
<tr>
<td>100107 - Colonoscopy Assessment</td>
</tr>
<tr>
<td>200106 - Colonoscopy Assessment [Pre-Registration (one-year post-operative)]</td>
</tr>
<tr>
<td>200114 - Colonoscopy Assessment [Month 36]</td>
</tr>
<tr>
<td>200106 - Onstudy: Patient and Disease Description</td>
</tr>
</tbody>
</table>

**Subject:** 100107

**Page:** Colonoscopy Assessment - Colonoscopy

1. **Was a colonoscopy performed?**
   - [ ] Yes
   - [x] No

2. **Reason for colonoscopy**
   - Month 36

3. **Date of colonoscopy**

4. **Comments**

---

**Printable Version**  **View PDF**  **Icon Key**

CRF Version 8 - Page Generated: 26 Mar 2012 09:36:00 Pacific Daylight Time
<table>
<thead>
<tr>
<th>CRF History</th>
<th>Quality Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>100107 - Colonoscopy Report [Month 36]</td>
<td>Photo documentation available?</td>
</tr>
<tr>
<td>100107 - Colonoscopy Assessment [Month 36]</td>
<td>No</td>
</tr>
<tr>
<td>200106 - Colonoscopy Assessment [Pre-Registration (one-year post-operative)]</td>
<td>Documentation of the ileocolic anastomosis (for right-sided hemicolecctomies) <strong>OR</strong> colonic anastomosis with cecal landmarks?</td>
</tr>
<tr>
<td>200114 - Colonoscopy Assessment [Month 36]</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Colonscope withdrawal time indicated?</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Total withdrawal time</td>
</tr>
<tr>
<td></td>
<td>minutes</td>
</tr>
</tbody>
</table>
Form Organization

- Some forms are available as needed by using “Add Event” feature
  - S0820 Audiometry
  - S0820 Colonoscopy
  - Off-Treatment Notice
  - Follow-up Form
  - Notice of Death
### New Subject

<table>
<thead>
<tr>
<th>Visit</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment Forms</td>
<td>04 Apr 2012</td>
</tr>
<tr>
<td>Onstudy</td>
<td>04 Apr 2012</td>
</tr>
<tr>
<td>Month 3</td>
<td>04 Jul 2012</td>
</tr>
</tbody>
</table>

#### Task Summary: Subject

- **NonConformant Data**: 0
- **Open Queries**: 0
- **Sticky Notes**: 0
- **Overdue Data**: 0

#### Add Event

- **Icon Key**: Follow-up
- **Audiometry (Other timepoint)**
- **Colonoscopy (Other timepoint)**
- **Death**
- **Off Treatment**

---

Questions about Form Organization?
Form Submission

- Parts of a Form
- System Queries
- Manual Queries
- Sticky Notes
- Logline Fields
- Submitting source documentation
- Save without submitting
Form Submission: Parts of a Form

- Parts of a Form
  - Question
  - Entry field
  - Status icon
    - Click to see audit trail
  - Edit icon
  - Query icon
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was an Audiometry evaluation performed?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Planned assessment</td>
<td></td>
</tr>
<tr>
<td>Date of pure tone audiometry</td>
<td></td>
</tr>
<tr>
<td>If Other, specify</td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>
Form Submission: System Queries

- System queries generated by Rave
  - NonConformant data
  - Required fields left blank
  - Bad dates
  - Values out of expected range
- If response box present, may type response, rather than changing data
- All system queries must be resolved before the data are sent to SWOG
Subject: 200115
Page: Audiometry Assessment - Audiometry

Was an Audiometry evaluation performed?

- Planned assessment
- Date of pure tone audiometry: 51 Mar 2012

If Other, specify

Comments

Printable Version  View PDF  Icon Key
This form is saved. The data are sent to SWOG when all system queries are resolved.

Subject: 200113
Page: Audiometry Assessment - Audiometry

Was an Audiometry evaluation performed? Yes

Planned assessment
- This field is required. Please complete.
  Opened To Site from System (26 Mar 2012)

Date of pure tone audiometry
  Entry Error
  51
  Mar
  2012

If Other, specify

Comments

Printable Version  View PDF  Icon Key

Leading cancer research. Together.
### Audiometry Assessment - Audiometry

**Subject:** 200115  
**Page:** Audiometry Assessment - Audiometry

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
</table>
| Planned assessment                         | **?** This field is required. Please complete.  
Opened To Site from System (26 Mar 2012) |
| Date of pure tone audiometry               | Entry Error            |
| If Other, specify                          | Month 36               |
| Comments                                   | Entry Error            |
|                                            | New Information        |
|                                            | Per Query              |

---

**Printable Version**  
**View PDF**  
**Icon Key**

Subject: 200113
Page: Audiometry Assessment [Month 36] - Audiometry

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was an Audiometry evaluation performed?</td>
<td>Yes</td>
</tr>
<tr>
<td>Planned assessment</td>
<td>Month 36</td>
</tr>
<tr>
<td>Date of pure tone audiometry</td>
<td>15 MAR 2012</td>
</tr>
<tr>
<td>If Other, specify</td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

Printable Version  View PDF  Icon Key
Form Submission: Manual Queries

- Manual queries generated by Data Coordinator
  - If response box present, must be filled in, with or without changing data
  - If response box not present, data must be changed
Subject: 200113
Page: Audiometry Assessment [Month 36] - Audiometry

Was an Audiometry evaluation performed? Yes

Planned assessment
   Month 36

Date of pure tone audiometry

This date does not correspond to Month 36 for this patient. Please check.
Opened To Site from DM (26 Mar 2012)

If Other, specify

Comments

Entry Error 15 Mar 2012

Printable Version View PDF Icon Key

Save Cancel
Subject: 200113
Page: Audiometry Assessment [Month 36] - Audiometry

Was an Audiometry evaluation performed?
Yes

Planned assessment
Month 36

Date of pure tone audiometry
Per Query: 15
Jan: 2012

Fixed typo

If Other, specify

Comments

Printable Version  View PDF  Icon Key
Was an Audiometry evaluation performed?  
Yes

Planned assessment  
Month 36

Date of pure tone audiometry  
15 JAN 2012

This date does not correspond to Month 36 for this patient. Please check.
Opened To Site from DM (26 Mar 2012)

Fixed typo

If Other, specify

Comments

Printable Version  View PDF  Icon Key

Form Submission: Sticky Notes

- Sticky notes
  - Will appear as reminders after saving form
  - Do not need response or data changes
  - Must acknowledge
  - Appear in task list
<table>
<thead>
<tr>
<th>Reporting period start date</th>
<th>01 MAR 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting period end date</td>
<td>10 MAR 2012</td>
</tr>
</tbody>
</table>

Were adverse events assessed during this time period?
- Please complete AE Reporting form. [Open To Site from System (26 Mar 2012)] [Acknowledge]
- Yes, and events

Date of most recent adverse event assessment: 10 MAR 2012
Questions about Parts of a Form, System Queries, Manual Queries, or Sticky Notes?
Form Submission: Logline fields

- Logline fields
  - Used to capture data about an unknown number of events
# SWOG S0820 COLONOSCOPY REPORT FORM

## Patient Information
- **SWOG Patient ID**: [Enter ID]
- **SWOG Study No.**: S0820
- **Registration Step**: 1
- **Patient Initials**: [L, F, M]

## Adenomas
- **Evidence of occurrence of adenoma?**
  - [ ] Yes
  - [ ] No

If Yes, describe all adenomas found during this colonoscopy using the codes below for location, histology, and percent villous. Record adenoma size according to the greatest transverse diameter:

<table>
<thead>
<tr>
<th>Size (cm)</th>
<th>Location</th>
<th>Histology</th>
<th>Excised?</th>
<th>% Villous</th>
<th>High-Grade Dysplasia</th>
<th>%</th>
<th>Landmark</th>
<th>Distance From Anatomical Landmark (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

- **Location codes**
  - C: Cecum
  - A: Ascending colon
  - T: Transverse colon
  - D: Descending colon
  - L: Left colon
  - S: Sigmoid colon
  - R: Rectosigmoid
  - RM: Rectum

- **Histology codes**
  - T: Tubular
  - TV: Tubulo-villous
  - V: Villous
  - F: Flat
  - PJ: Peutz-Jeghers
  - J: Juvenile
  - H: Hyperplastic
  - S: Serrated

- **% Villous codes**
  - 0-0.25%
  - 0.25-26%
  - 26-26.75%
  - 26.75-76%
  - 76-76.75%
  - 76.75-100%

- **Landmark codes**
  - A: Anus
  - S: Splenic flexure
  - H: Hepatic flexure
  - O: Other (If Other, indicate in Comments)

## Comments:

---

2/8/2012

Draft
Describe all adenomas found during this colonoscopy using the codes below for location, histology, and percent villous. Record adenoma size according to the greatest transverse diameter:

<table>
<thead>
<tr>
<th>#</th>
<th>Size</th>
<th>Location</th>
<th>Histology</th>
<th>Excised?</th>
<th>% Villous</th>
<th>High-grade dysplasia</th>
<th>%</th>
<th>Landmark</th>
<th>Distance from landmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>cm</td>
<td>...</td>
<td>...</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

Add a new Log line Inactivate
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<td>Yes</td>
<td>0 - 25%</td>
<td>No</td>
<td>50%</td>
<td>Cecum</td>
<td>2 cm</td>
</tr>
<tr>
<td>2</td>
<td>1.5 cm</td>
<td>Left colon</td>
<td>Flat</td>
<td>Yes</td>
<td>0 - 25%</td>
<td>No</td>
<td>40%</td>
<td>Other</td>
<td>2.5 cm</td>
</tr>
<tr>
<td>3</td>
<td>2 cm</td>
<td>Rectum</td>
<td>Villous</td>
<td>No</td>
<td>26 - 75%</td>
<td>Yes</td>
<td>30%</td>
<td>Anus</td>
<td>3 cm</td>
</tr>
<tr>
<td>4</td>
<td>2 cm</td>
<td>Rectum</td>
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Inactivate
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4 ▼ INACT_L - Log line not required ▼ Inactivate ▼ Cancel
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Add a new Log line  Inactivate  Reactivate
Form Submission: Source documentation

- Submitting source documentation
  - FAX not an option for Rave studies
  - Rave has a special kind of field that allows the upload of electronic documents
  - Document MUST have any instances of patient name, SSN and geographic information redacted first
This form is saved. The data are sent to SWOG when all system queries are resolved.

Subject: 200118
Page: Upload source documentation - Source documents

<table>
<thead>
<tr>
<th>#</th>
<th>Document Type</th>
<th>Date of Procedure</th>
<th>23 FEB 2012</th>
<th>Upload redacted document</th>
<th>200118-Op-Resection.docx</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Operative report</td>
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<td></td>
<td></td>
<td>200118-Op-Resection.docx</td>
</tr>
</tbody>
</table>

Add a new Log line  Inactivate

Printable Version  View PDF  Icon Key

CRF Version 17 - Page Generated: 03 Apr 2012 12:54:18 Pacific Daylight Time
This form is saved. The data are sent to SWOG when all system queries are resolved.

**Subject:** 200118

**Page:** Upload source documentation - Source documents

<table>
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<tr>
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<tr>
<td>2</td>
<td>Pathology report</td>
</tr>
</tbody>
</table>

Add a new Log line  Inactivate

Printable Version  View PDF  Icon Key

CRF Version 17 - Page Generated: 03 Apr 2012 12:56:20 Pacific Daylight Time
Form Submission: Save without submitting

- CRA Workbench forms have “Submit” and “Save without submitting” buttons
  - Submit runs edit checks and sends the data to SWOG if they pass
  - Save without submitting simply saves the data without running edit checks
- Rave only offers a “Save” button on its forms
Form Submission: Save without submitting

- We added a “Save without submitting” checkbox to the bottom of every form.
- To save your data without sending to SWOG, check the box and click Save.
- A system query for the checked box will prevent the data from being sent to SWOG.
- Edit checks will run on other fields as well.
- Be sure to use this option if you’re in danger of session timeout. Rave will log you off after 75 minutes of inactivity and you will lose any unsaved changes.
Percent of colon surface area visualized

Date of one-year postoperative body CT scans

If you’re not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don’t submit to SWOG yet.
| **Percent of colon surface area visualized** | 40 % |
| **Date of one-year postoperative body CT scans** | 28 FEB 2012 |

*If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.*

| ? This box must be unchecked for submission of this form to SWOG. Opened To Site from System (26 Mar 2012) | Entry Error |

**Printable Version  View PDF  Icon Key**

Questions about Loglines, Submitting Source Documentation, or Save Without Submitting?
CRA Workbench Changes

- Many CRA Workbench tools and utilities still available for Rave studies
- NOT:
  - Data Submission
  - Queries
CRA Workbench Changes

- **Rave Studies YES**
  - Link to OPEN
  - Link to Rave
  - Link to Specimen Tracking
  - Expectation report
  - IPR report
  - Ineligible patients report
  - Other SWOG tools, resources

- **Rave Studies NO**
  - Data/Form Submission
  - Queries
Timeframe

- So how soon do I have to care?
- First studies this summer
  - Phase II GI S1115
  - Phase II GU S1107
- All studies activated from this point on will be in Rave!
- No studies activated earlier will be converted to Rave
More Questions??