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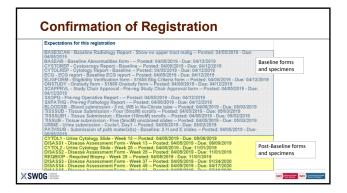
Reports and Tools to Support Quality Data Phyllis Goodman, M.S. Coordinating Statistician Institution Performance SWOG Statistical Center

What defines quality? • NCTN Grant Submission required data on • Timeliness • Were the required data forms submitted? • Were the required data forms submitted on time? • Accuracy • We don't compare submitted data to source documents (other than audited and monitored charts) so... • Is the submitted data free of queries?

How does SWOG facilitate data submission? • Expectation System: Created to identify the submission requirements for forms, reports, specimens, patient completed forms • Expectation = Anything that is "expected" to be submitted to the Statistical Center • Protocol-specific data requirements • May be posted conditionally based on treatment arm, stratification factor, form disease status, consent answers, etc.

When are expectations posted? 1. At the time the patient is registered 2. During protocol treatment and follow-up

At patient registration • Baseline requirements (Initial Forms Set) • Forms (e.g. On-study, Baseline abnormalities, Baseline tumor assessment) • Pathology/Operative reports • Specimens • Other study-specific items (e.g. Quality of Life questionnaires, imaging) • Defined time point post registration (e.g. Week 4) • Quality of Life questionnaires, other study-specific forms • Specimens • Appear on the Confirmation of Registration

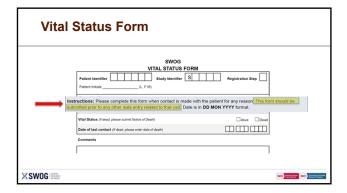


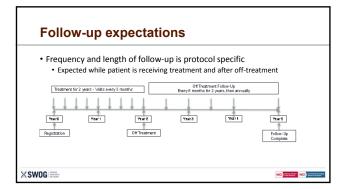
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During protocol treatment and follow-up Dynamic, time-period specific Looks at next form due based on treatment schedule "Period beginning" is determined from patient's previous visit Submission schedule based on data stored in the SWOG database regarding expected patient assessment times Forms for most treatment studies include Adverse event, treatment, follow-up tumor assessment Newer forms and specimens are now being added e.g., S1802 prostate study with cycle-specific PSA, testosterone forms, S1614 cycle-specific lab values

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Follow-up expectations Follow-up time Calculated as days between the day the report is run and the patient's last contact date (date last known to be alive) Last contact date Studies prior to 2019 - updated from any one of a number of forms: treatment, adverse event, follow-up tumor assessment forms or SWOG Follow-Up Form New! Vital Status Update form First introduced in 2 GU studies, S1802 and S1806 Wave of the future – now on all studies going forward





Purpose of Long-Term Follow-up Continued medical surveillance Treatment toxicity resolution Meaningful end-results reporting Accurate survival data Reporting of long-term adverse events and treatment related malignancies

Specimen Expectations • Specimens can be for determining eligibility, translational medicine studies, future use (banking) • Some specimens can be opted out of by the participant per the Informed Consent and recorded during the registration process; expectations for patients who opt out will not be posted • Baseline specimens are part of the Initial Forms Set • Post-baseline specimens • Increasingly, specimens are required per protocol • If a post-baseline specimen expectation is posted for a patient who did not consent to specimen collection, notify the SDMC → we'll fix it!

Due dates

- New guidelines from CTSU = 15/15/30 for Baseline/On treatment/Off treatment data
 - Baseline data due within 15 days of registration
 - On treatment data due within 15 days of visit/event
 - Off treatment data due within 30 days of visit/event
- Always check Section 14 for data submission timelines as older studies will be different
- Specimens (baseline and post-baseline) Per Section 15. Typically...

 - Blood products, urine due within 15 days
 Tissue due within 28 days of...but check protocol for actual time frame

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SWOG Reports for Quality

- Expectation Report
- Institution Performance Review (IPR) Report
- Query Report
- Ineligible Patients Report
- SWOG Patients in Follow-Up

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Data: Modes of Entry

- Pre-Rave: Data entered via the CRA Workbench and are applied to the SWOG database immediately
- Rave: Data are applied to the SWOG database overnight and appear on reports the next day

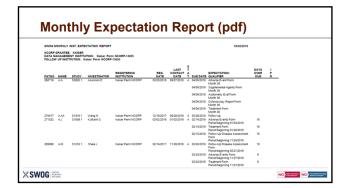


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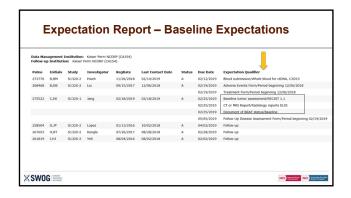


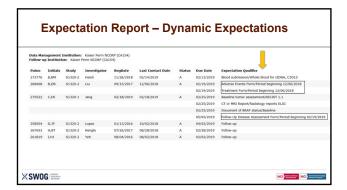


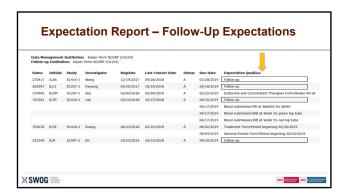
Expectation Report: 2 Versions Monthly Reports Static report generated at the beginning of the month Current Reports Dynamic report that reflects up-to-the-minute database status Both Downloadable to Excel Identify overdue expectations which affect IPR statistics with a code as to which category it belongs

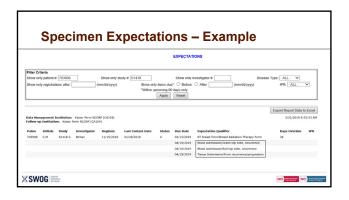


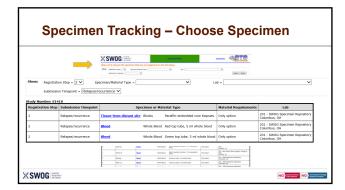


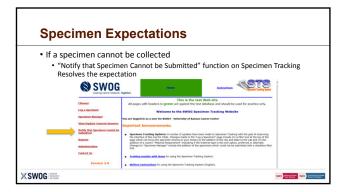












Institution Performance Review (IPR) • Statistics used to monitor and measure an institution's compliance with data submission requirements • Are required forms being submitted? • SWOG Policy #33: Compliance guidelines • Updated in October 2017 • The IPR report is run monthly and contains the compliance rates (percentages) for each category

Tracking Compliance: IPR Report Four categories Initial Forms Set (baseline data) Post-baseline forms submission Vital status updates Specimen submission Overdue items contributing to the IPR categories are identified on the Expectation Report IFS, IFS13, FORM, FUP, FORM/FUP, SPEC, SPEC13 Definitions on "Expectation and IPR Reports" page

• Posted on the SWOG CRA Workbench and mailed to the PI and Head

CRA of the LAPS/Member/NCORP

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Initial Forms Set (IFS) Compliance Level • Expectations "associated with" patient registration • Registrations within the last 13 months: Patient has any IFS expectation more than 30 days overdue • Out of compliance: If >10% of patient REGISTRATIONS are overdue • Registrations greater than 13 months ago: Patient has any unresolved IFS expectation • Out of compliance: If any patient REGISTRATION in this category

Post Baseline Forms Compliance Level • Any post-baseline expectation (except specimens) that are more than 60 days overdue • Denominator is all forms due within the last 13 months + any overdue forms from • Out of compliance if >5% of FORMS are overdue

Vital Status Update Compliance Level

- Update to patient's last contact date is more than **60 days** overdue
 - Out of compliance if >15% of PATIENTS being followed are overdue

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Specimen Submission Compliance Level

- Specimens due within the last 13 months: Patient has any specimen expectation more than **30 days** overdue
 - Out of compliance: If >10% of patient SPECIMENS are overdue
- Specimens due greater than 13 months ago: Patient has any unresolved specimen expectation
 - Out of compliance: If any patient SPECIMEN in this category

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IPR Statistics and Report SWOG Institution Performance Review Statistics Data as of 0300/2/2019 Principal Investigator: Data as of 0300/2/2019 Principal Investigator: Data as of 0300/2/2019 Principal Investigator: A Registration steps lacking submission of Intital Forms Set A1 Registration more than 13 more than 15 more th

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Two Consecutive Months If an institution remains out of compliance on any measure for two consecutive months, a warning email is sent to the PI and Head CRA Three Consecutive Months The institution is at risk of suspension with loss of registration privileges. If not corrected within 1 month, the institution may be suspended

Ouery Report Not tied to Expectations or IPR Will be a future component of site performance Just as important Located in the Reports link on CRA Workbench; future plans to push out to sites in a monthly report Reports Reports

