Data Quality Tools: SWOG Expectation Reports and CTSU Data Quality Portal
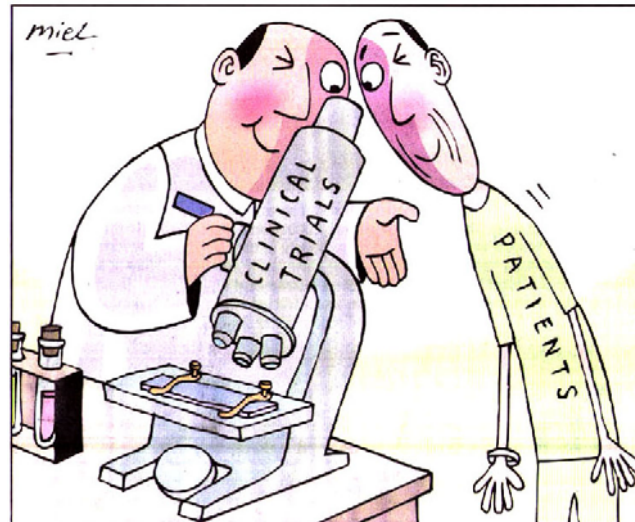
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Coordinating Statistician

Institution Performance

SWOG Statistical Center

Why Do Patients Participate on Clinical Trials?

- Advance medical knowledge
- Access to the latest treatment
- Hope for their own illness
- To make a difference
- Trust

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Why Quality Data are Important

- Clinical trial participants trust us with their lives
- We need to honor their trust and participation through quality data collection
- Ensure that their data are used in the analysis

How does SWOG communicate data needs? Expectations

- Required forms, reports, specimens
- Posted at the time the patient is registered
  - Baseline forms, specimens
  - Others with a defined due date known at the time of patient registration; could be post-baseline
- Posted during protocol treatment and follow-up
  - Based on the follow-up timing for patient
  - Adverse events, treatment given, tumor assessment
- Overdue follow-up (need updated last contact date)

SWOG Reports for Quality

- Query Report
  - Includes queries from data coordinators and study chairs based on their review of the patient chart
  - Across all studies (Rave and legacy)

- Expectation Report
  - Overdue Expectations + upcoming Expectations
  - Patient follow-up reminders
  - Across all studies (Rave and legacy)

How SWOG Measures Data Quality

- Institution Performance Review (IPR)
  - Statistics used to monitor an institution's compliance to data submission requirements
  - Are required forms being submitted?
  - SWOG Policy #33
- Categories of data
  - Baseline (Initial Forms Set)
  - Follow-up
    - On Treatment – required forms, survival status update
    - Off Treatment – survival status update

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Access to SWOG Reports: CRA Workbench on swog.org

What's new in the quality world?

- Data Quality Portal (DQP) on CTSU website
  - Overdue forms
  - Overdue queries

- Status
  - ECOG-ACRIN studies currently deployed
  - SWOG studies coming very soon

DQP – Delinquent Forms

Delinquent Forms Report Summary

Delinquency Aging Report Summary for LPO SWOG

Protocol		Total Delinquencies	< 15 Days	15 - 30 Days	31 - 60 Days	61 - 90 Days	> 90 Days
S0820	●	23	-	-	1	-	22
S1204	●	28	15	-	1	4	8
S1312	●						
S1313	●						
S1314	●						

Rave Delinquencies by Form
Protocol: S1313 | Aging: Total | Last Refresh: 01/20/2017 12:47 AM EST

S1313 ▼ [Go!]

Rave Delinquencies by Form

Site Name	All Forms	Adverse Events: Assessment	Adverse Events: Report	Baseline Tumor: Assessment	Follow-up	Follow-up Tumor: Assessment	Follow-up Tumor: Non-target Disease	Follow-up Tumor: Target Lesions	Onstudy: Laboratory Values
AZ017	7	1	-	-	-	1	1	2	-
CA011	3	-	-	-	3	-	-	-	-
CA043	1	-	-	-	1	-	-	-	-
CA088	5	-	-	-	1	1	-	1	-
CA164	1	-	-	-	1	-	-	-	-
CA243	13	2	-	1	1	1	-	1	1
CT018	39	4	-	-	6	7	6	7	-
CT125	1	-	-	-	1	-	-	-	-
IL097	2	-	-	-	-	-	-	1	-
MI020	6	-	-	-	-	1	1	2	-
MO028	4	-	-	-	-	1	1	1	-
MO046	8	-	-	-	-	2	2	2	-
WA020	27	8	1	-	4	3	3	3	-
TOTAL	117	15	1	1	18	17	14	20	1

Delinquencies and Queries

Rave Delinquencies
Protocol: S1313 | Site: WA020 | Form: All Forms | Aging: Total | Last Refresh: 01/20/2017 12:47 AM EST

All Patients | All Folders | All Forms | Go! | ? Help

1 | 27

Site	Patient	Folder	Form Display Name	Form	Expected Date
WA020	261877	Cycle 14	Adverse Events: Assessment	Adverse Events: Assessment	01/16/17
WA020	254467	Follow-up (1)	Follow-up	Follow-up	01/14/17
WA020	264315	Follow-up Tumor Assessment	Follow-up Tumor: Assessment	Follow-up Tumor: Assessment	01/11/17
WA020	264315	Follow-up Tumor Assessment	Follow-up Tumor: Non-target Disease	Follow-up Tumor: Non-target Disease	01/11/17
WA020	264315	Follow-up Tumor Assessment	Follow-up Tumor: Target Lesions	Follow-up Tumor: Target Lesions	01/11/17
WA020	264315	Follow-up Tumor Assessment	Source Documentation: Follow-up	Source Documentation: Follow-up	01/11/17
WA020	264277	Follow-up Tumor Assessment	Follow-up Tumor: Assessment	Follow-up Tumor: Assessment	01/07/17
WA020	264277	Follow-up Tumor Assessment	Follow-up Tumor: Non-target Disease	Follow-up Tumor: Non-target Disease	01/07/17
WA020	264277	Follow-up Tumor Assessment	Follow-up Tumor: Target Lesions	Follow-up Tumor: Target Lesions	01/07/17
WA020	264277	Follow-up Tumor Assessment	Source Documentation: Follow-up	Source Documentation: Follow-up	01/07/17

Rave Queries
Protocol: S1313 | Site: WA020 | Form: All Forms | Aging: Total | Last Refresh: 01/20/2017 12:47 AM EST

All Patients | All Folders | All Forms | Go! | ? Help

1 | 20

Site	Patient	Folder	Form Display Name	Form	Log Line	Field	Query	Date Query Opened	Marking Group
WA020	258039	Off Treatment (1)	Off Treatment Notice	Off Treatment Notice	N/A	Off treatment reason	Amend off tx reason: pt did not meet progression definition. Change to 'other: elevated tumor marker CA19-9'	01/11/2017	Site from DM
WA020	258039	Cycle 14	Adverse Events: Report	Adverse Events: Report	N/A	Comments	Submit form.	01/11/2017	Site from DM
WA020	258039	Cycle 14	Treatment	Treatment	N/A	Date of last treatment	Tx isn't given every day of the cycle. Amend last date of TX with correct end date.	01/11/2017	Site from DM

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NCI National Clinical Trials Network | NCI Community Oncology Research Program

"Deep Link"

- Brings you right in to Rave
  - Either patient or form depending on where you clicked

Expectation Report vs. DQP Delinquency Report

	Expectation Report	DQP
What's posted?	Overdue and upcoming within defined timeframe.	Overdue only.
What's included	Forms, specimens; anything else for which an expectation has been created (images, uploaded reports).	Forms, source document uploads and anything that has been "calendared" within Rave. Does NOT include specimens.
Overdue definition (Treatment forms)	> 60 days from day expectation is due; doesn't take into treatment delays.	Based on expected date + max treatment delay.
How to access	CRA Workbench; dynamic report updated in real time.	CTSU. Updated nightly.
Which studies	All Rave studies All legacy studies	Rave studies WITH calendaring (10 don't have calendering)

SWOG Query Report vs. DQP Queries

	SWOG Query Report	DQP
What's posted?	Queries from Data Coordinators	Queries from Data Coordinators Queries from Auditors/Monitors Medidata Rave System queries + non-conformant data
Overdue definition	Don't currently measure.	Calculated from date posted. Due within 15 days.
How to access	SWOG CRA Workbench	CTSU
Which studies?	All Rave studies + All legacy studies	All Rave studies

DQP Comments

- Delinquent Forms
  - Complements our Expectation and IPR reports

- Overdue queries
  - One missing lab value ➔ multiple queries (value, units, ULN, LLN, sample collection date)
  - Partially completed forms ➔ missing data queries

- We currently see DQP as a tool; we don't know NCI's long term plan for use

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S1404: Quality Data Goal

- At the time the data are given to Merck for their FDA submission, the number of delinquent forms and overdue queries need to be 0. That's right, 0!

- As of April 16, 2017

	Total	< 15 Days	15-30 Days	31-60 Days	61-90 Days	> 90 Days
Delinquent Forms	1858	566	472	439	151	230
Overdue Queries	2612	902	491	710	163	346

IPR plans

- Restructuring to be more in line with how Rave DQP works
- Revised categories
  - Initial Forms Set
  - Vital Status Update (on and off treatment combined)
    - Calculated from last contact date
  - Form submission (post-baseline) New!
    - Will include all forms (treatment, AE, FUTA, QoL, etc.)
  - Post-baseline specimen submission New!

Planned implementation

- Plan to run the 2 versions concurrently for a few months to assess impact
- Will give sites a few months to resolve newly delinquent cases due to revised definitions
- Revision to SWOG Policy #33
  - Needs to be approved by Board of Governors

Old vs. New: IFS

	Old	New (planned)
Initial Forms Set	Limited forms included in measure; forms necessary to review eligibility	Much expanded list of forms to be included; forms necessary to review eligibility and to assess endpoints
	• Patients registered in ≤ 13 months ago (compliance ≤ 10% overdue) • Patients registered > 13 months ago (compliance = 0 patients overdue)	• Patients registered in ≤ 13 months ago (compliance ≤ 10% overdue) • Patients registered > 13 months ago (compliance = 0 patients overdue)

Old vs. New: Follow-Up and Forms

	Old	New (planned)
Follow-Up (Vital status update)	Two measures • Patients On Treatment (compliance level ≤ 15% overdue) • Patients Off Treatment (compliance level ≤ 20% overdue) • Denominator= Patients with last known status of Alive	One measure • All patients combined (compliance level ≤ 15% overdue) • Denominator= Patients with last known status of Alive
Submission of Forms	None	Overdue post-baseline forms • Denominator = All forms submitted in last 13 months + any currently overdue forms

Thank you!