

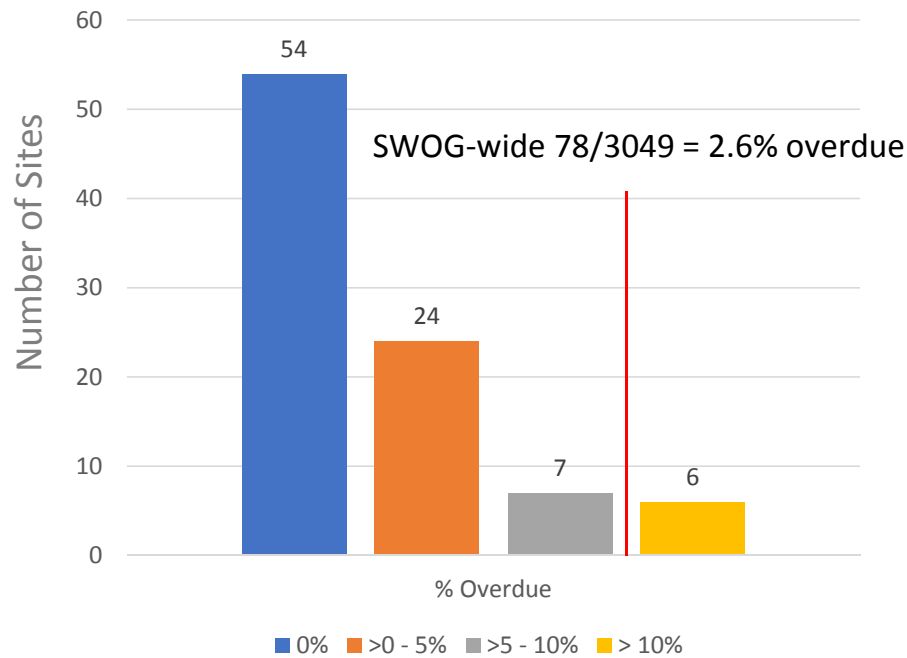
SWOG Statistics and Data Management Center (SDMC) Update

Phyllis Goodman, M.S.

Cathy Rankin, M.S.

Initial Forms Set Submission

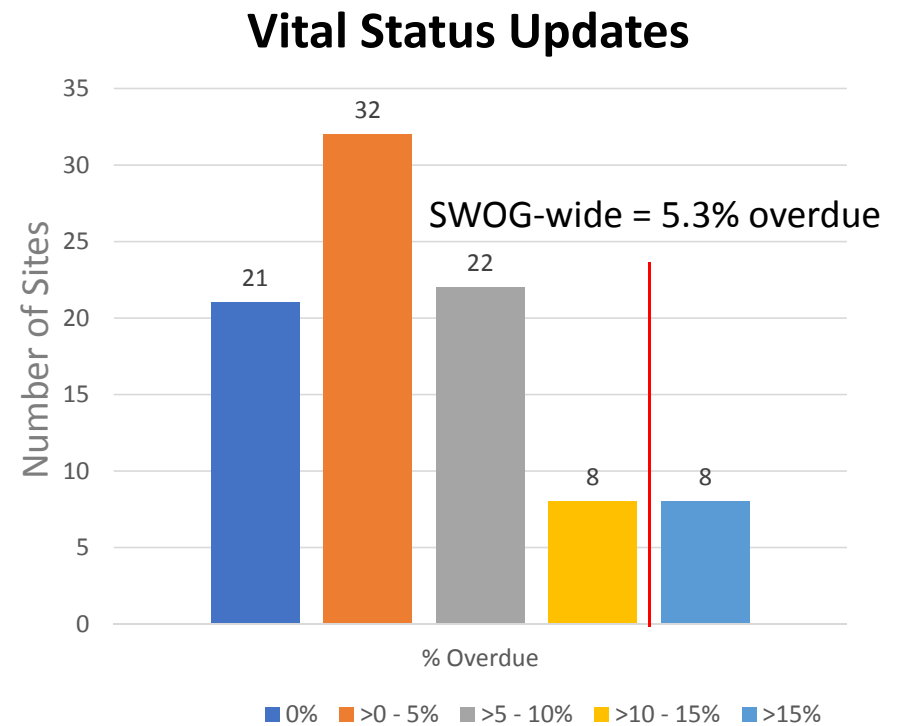
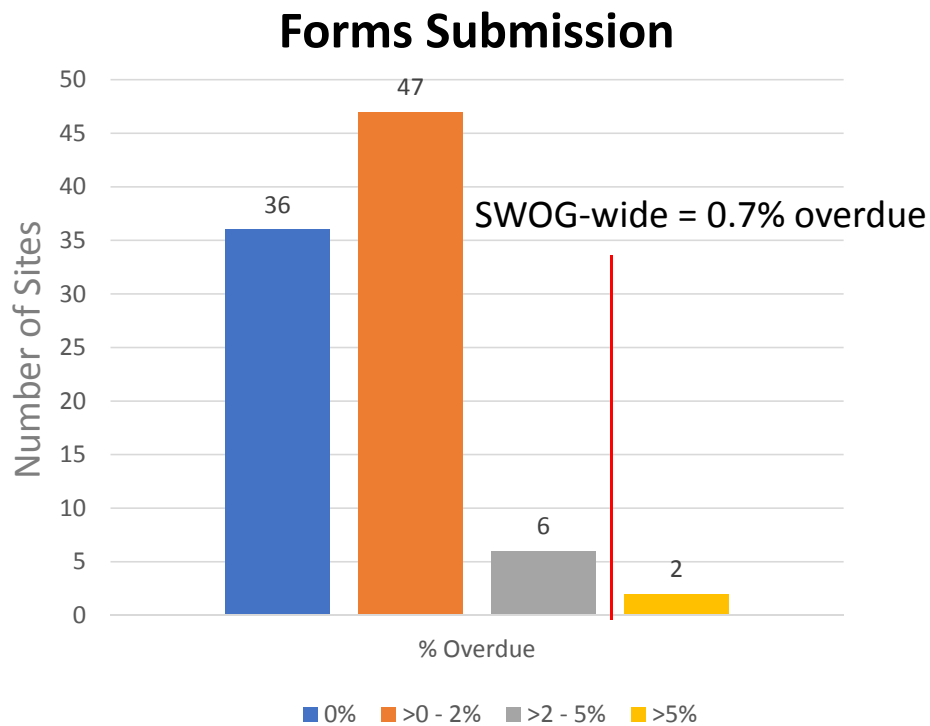
Registrations within the last 13 months



Registrations > 13 months ago

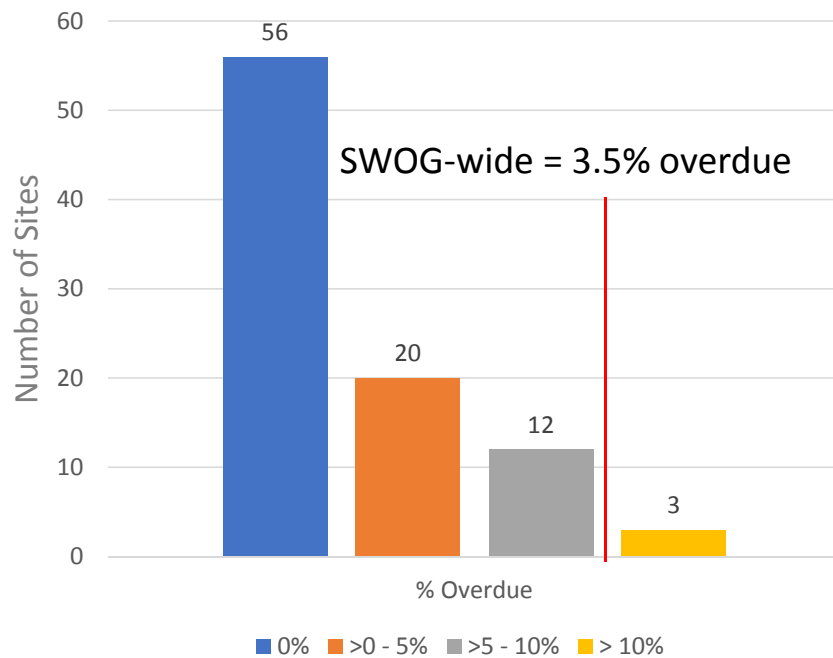
# Patient Registrations	# sites
0 patients registration	87 sites
1 patient registration	3 sites
2 patient registrations	1 site

Forms Submission and Vital Status Updates



Specimen Submission

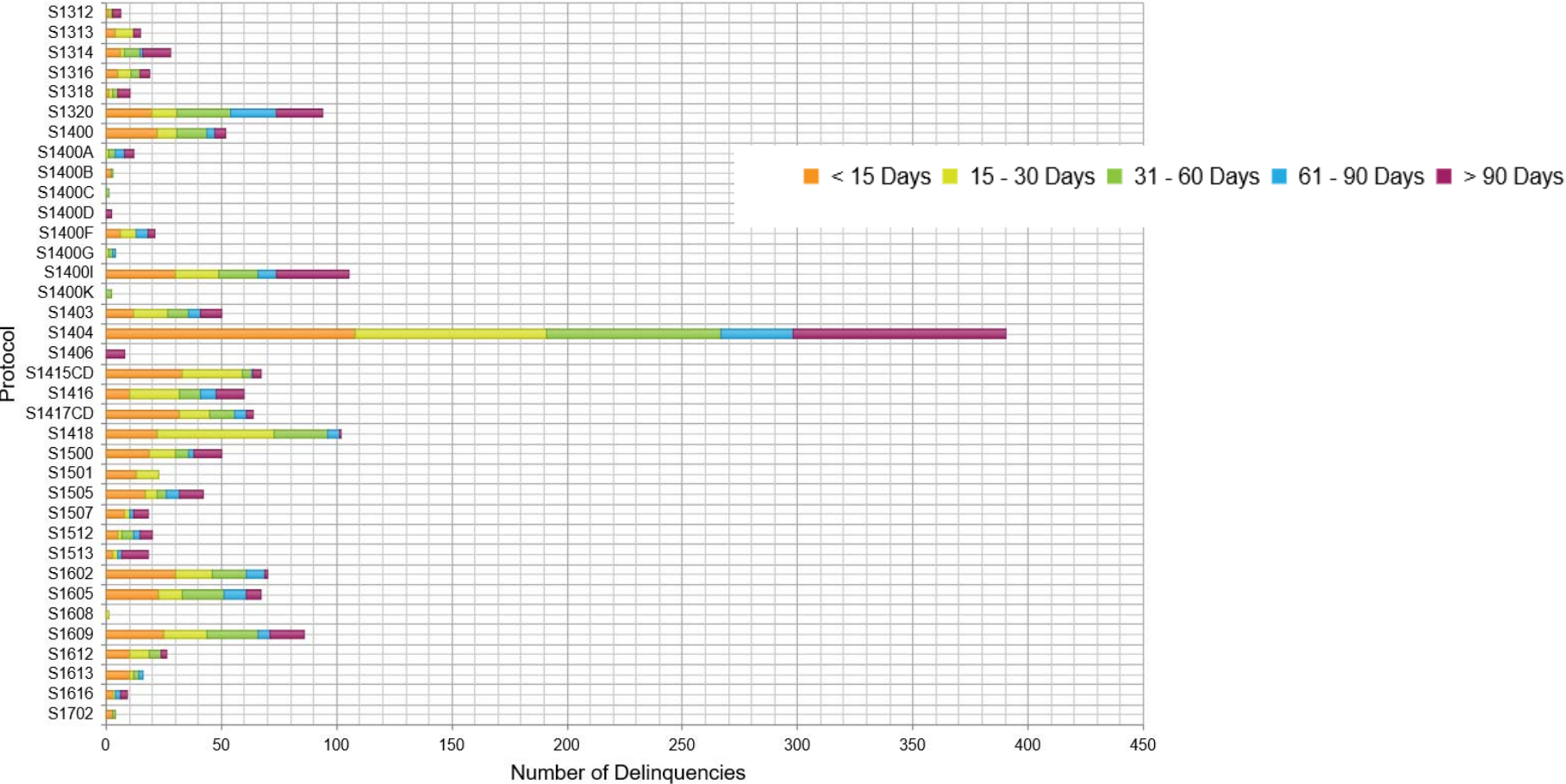
Specimen Due within the last 13 months



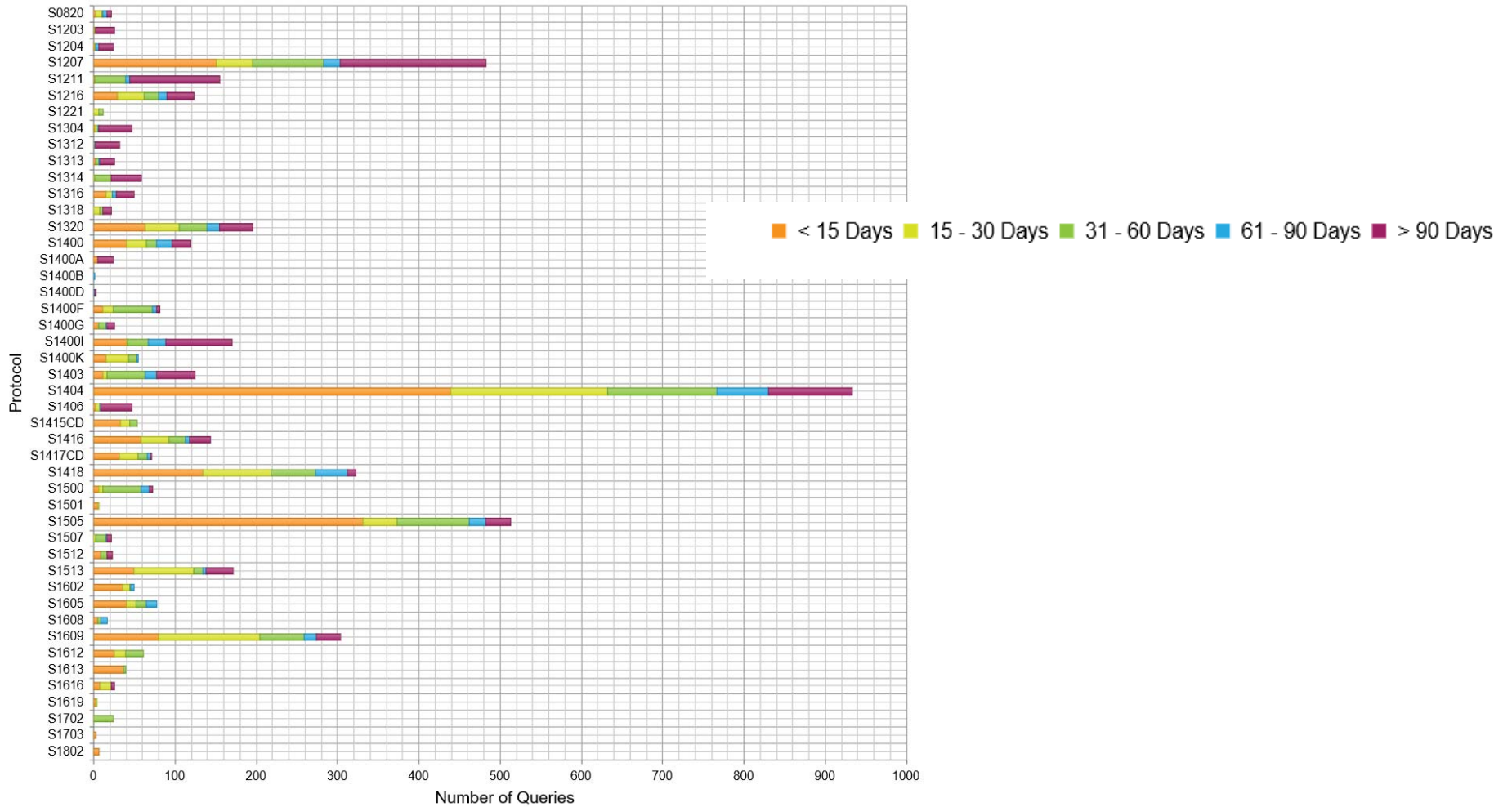
Specimens Due > 13 months ago

# Specimens overdue	# sites
0 specimens	86 sites
1 specimen	3 sites
2 specimens	1 site
3 specimens	1 site

DQP Data Delinquencies



DQP Query Delinquencies



Query 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



Improving Timeliness

NCI/CTSUS seeking feedback on how to improve data and query timeliness

Challenges

- Low resources
- Site turnover
- Increased tasks (e.g., source document upload)

Suggestions from sites?

S1404 - Status

- Interim analysis is imminent
- Data will potentially be sent to FDA
- Submit data, clean-up queries
- Receiving phone calls from SDMC for critical missing data, queries

S1404 - Form Timeliness Metrics

	# Expected Forms (A)	# Forms received on time (B)	# Forms received late	# Forms not received	Cumulative # forms not received (C)	Submission rate (B/A+C)
2017, Q3	9428	5062	3490	876	953	49%
2017, Q4	5736	3605	1486	645	801	55%
2018, Q1	4340	3235	788	317	482	67%
2018, Q2	5560	4721	596	243	398	79%
	25,065					

S1404 - Query Timeliness Metrics

	# Queries Issued (A)	# Queries answered on time (B)	# Queries answered late	# Queries not answered	Cumulative # queries not answered (C)	Submission rate (B/A+C)
2017, Q3	24,064	18,433	2,229	3,402	3,447	67%
2017, Q4	20,051	13,990	2,673	3,388	3,504	59%
2018, Q1	32,133	22,073	3,074	6,986	7,081	56%
2018, Q2	30,008	23,051	6,031	926	1,028	74%
	106,256					

On-Study Form Expectations

- Studies activated since 7/1/2018 → multiple expectations
 - Onstudy: Patient/disease description
 - Onstudy: Lab values
 - Onstudy: Prior treatment
 - Onstudy: Additional data

Vital Status Form

Prospectively capture *Last Date of Contact / Date of Death* and *Vital Status* differently

- Current: capture these data on multiple forms e.g., Treatment Form, Off Treatment Notice, Follow-up Form, Notice of Death
- Future: Collect on a single CRF – the Vital Status Form

Vital Status Form

SWOG VITAL STATUS FORM

Patient Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	S <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Registration Step	<input type="text"/>
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 <i>(If dead, please submit Notice of Death)</i>	<input type="checkbox"/> Alive	<input type="checkbox"/> Dead
Date of last contact <i>(If dead, please enter date of death)</i>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Comments

Vital Status Form

SWOG UAT iMedidata Messages My Profile Help Home Logout
User: Cathy Rankin Biostatistician (Read Only - All Sites)

Patient ID: 272536 S1802 CTSUTST01 272536 Enrollment Date: 05 Sep 2018

Patient Initials (LFM): HMR

Current vital status: Alive
Current date of last contact or death: 05 Sep 2018

Current vital status: Alive
Current date of last contact or death: 05 Sep 2018

Visit	Date
Vital Status (On Treatment)	
Baseline	05 Sep 2018
Patient Reported Outcomes	
Questionnaires: Randomization	05 Sep 2018
Induction Summary	20 Mar 2019
Baseline Step 2	05 Sep 2018
Disease Assessment	05 Sep 2018
Month 03	05 Dec 2018
Standard Systemic Therapy Month 03	05 Dec 2018

Contact SWOG SDMC

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