

California's Comparative Effectiveness Research (CER) Study Tracking Database

Scott Riddle

System Support Manager



List of Terms

- **Case Report:** also referred to as “Admission” in our DBMS
- **Tumor:** Tumor information consolidated from associated Case Reports
- **Source:** Hospital and/or Physician reported in the Case Report
- **Tracker:** CER Tracking Database

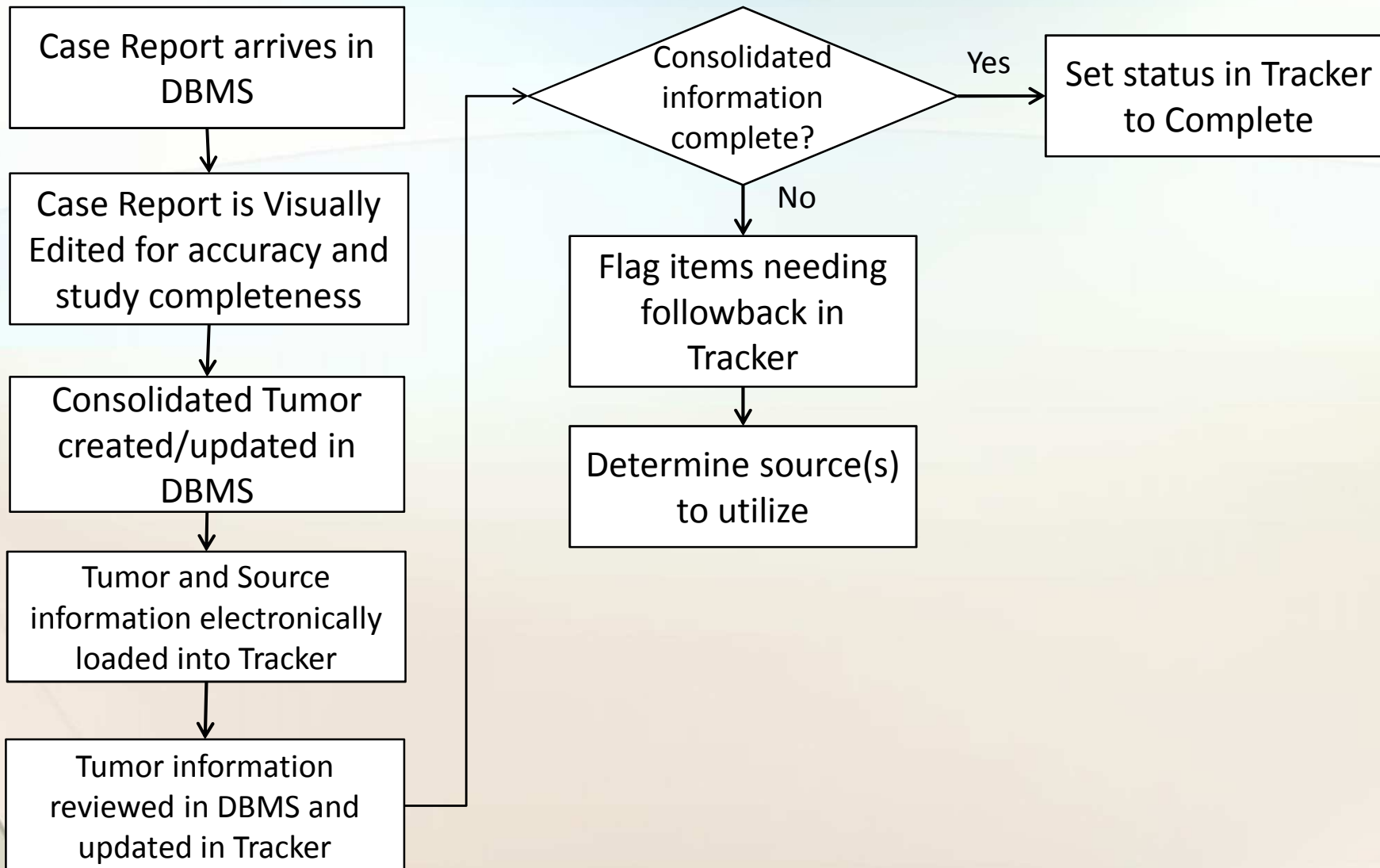
Overview of the California CER Study

- Funded as part of American Recovery and Reinvestment Act (ARRA) Comparative Effectiveness Research activities through the Office of the Secretary Contract Number 200-2008-27957.
- Study criteria
 - Breast, Colorectal, and Chronic Myeloid Lymphoma Sites
 - 16 items common to each site
 - 1 to 3 Site specific items
- Geographic area – 13 counties (Region 3 of California)
- Estimated 5,000 Consolidated Tumors (7,500 case reports)
- Every Case Report is Visually Edited
- Followback will be performed on missing information

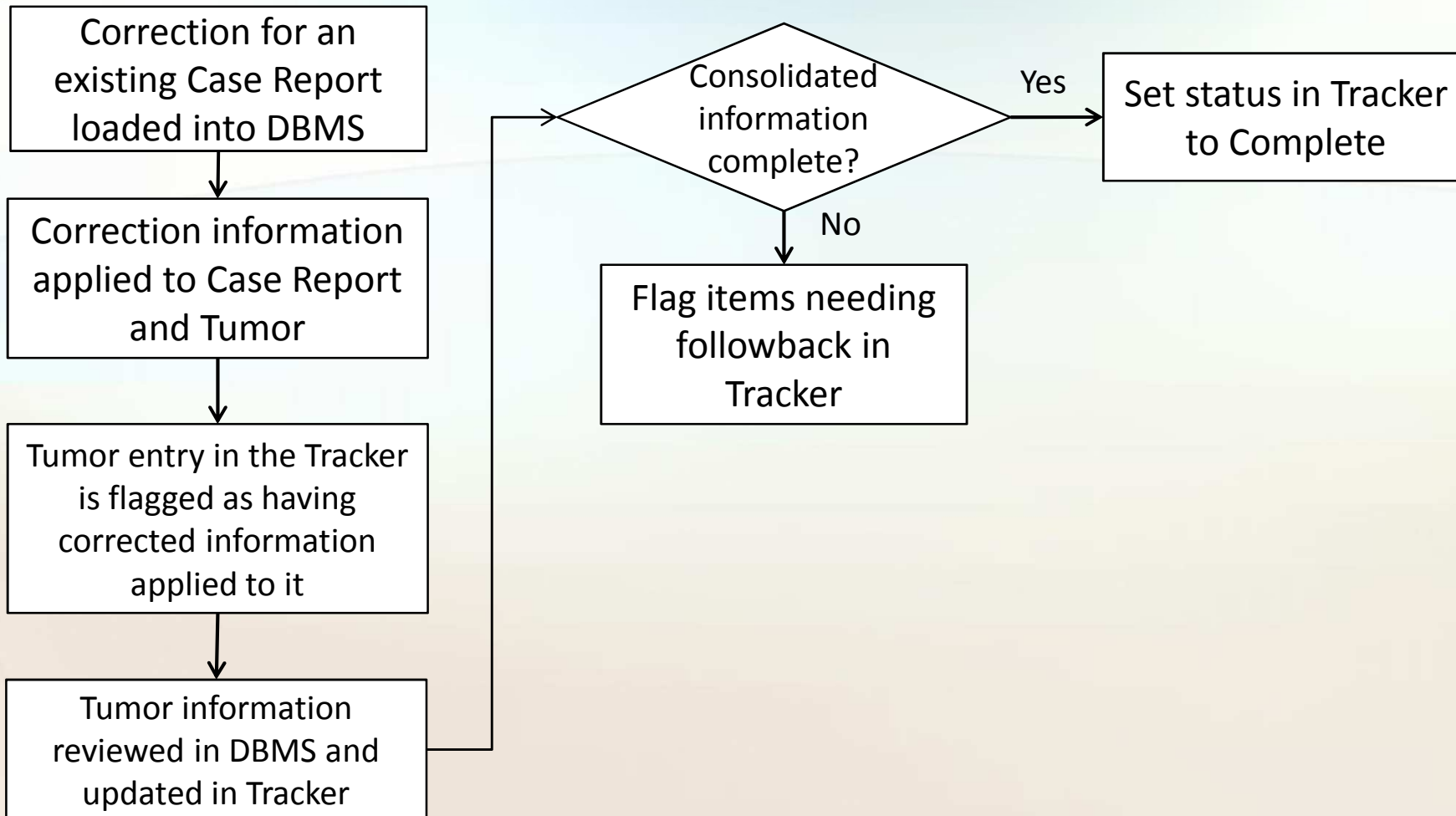
Tracking Database Specifications

- Initial Specifications
 - Use a modified version of our customized SEER Patterns Of Care Tracker as a template
 - Track whether a Tumor needed follow back (regardless of what was missing)
 - Multiple users needed to use the Tracker at the same time
- After we got started...
 - Added tracking of each missing item
 - Incorporated item tracking in Worksheet generation

Initial Workflow



Secondary Workflow



Master Form

2011 CER Study Tumor ID: 4894801 Show New Exit

Master ID: 2012 Patient ID: 4333638 Case Status: Pending - Data review Complete

SSN: Last Name: First Name: DOB: Date Last FU: Vital Status: Alive

Site: C186 Histology: 81403 Tumor Text: Colon Invasive Date DX: TNM: 410 120 000 CS Stage Group: 630

NOTE: The Case Status will reset if the Source Status codes are not set to a Complete status.

FacID	Source	Source Status	Med Rec No	Comments
0000311015	Kaiser Roseville	Source Reviewed, Arranging Visit (Sol: 110002817313)		
A0075460		No Need To Contact (Complete)		
*		Source Not Reviewed (Not Started)		

Source Detail Set to No Contact

Have Need, N/A, Collected

Smoking
 Height
 Weight
 RX Text Fields
 cTNM Staging
 Subsequent RX
 Correction Reviewed

Chemo
 Agent
 Dose Planned
 RX Dates
 Completion
 Rad Sum
 Hormone
 BRM

Supportive Agents
 G-CSF
 EGF
 TGF
Breast
 ER
 PR
 HER2

Colorectal
 KRAS
 JAK2
 BCR-Abl

Treatment OK
 Everything OK
 Need All
Reset All

Comments about the case (explain ineligibility here):
 TV: 7/2/11 CEA: 17.6 (H); 9/23/2011 5FU/LEUCOVORIN- DISCONTINUED DUE TO NEUTROPENIC SEPSIS; pT4aN1b;

Automated History

FacName	ChangeDate	PreviousStatus	NewStatus

Record: 2012 of 4818 No Filter Search

Worksheet Examples

Comparative Effectiveness Research Study Master ID: 2824

Tumor: Breast Invasive

TNM: 200 310 000
CS Stage: 540

Smoking: Never Used Current User Quit w/in 1 Year of DX
 Quit > 1 Year of DX Former user, Unknown when Quit Unknown

Height: _____
Weight: _____

Agent Name	NSC #	Start Date	End Date	Planned / Received	Dose	Units	# Doses
				Planned			
				Received			
				Planned			
				Received			
				Planned			
				Received			
				Planned			
				Received			
				Planned			
				Received			
				Planned			
				Received			

Check box if the following tests were run:

HER2
 ER
 PR

Prescribed GCSF Given Prescribed/Refused Prescribed/Unknown Unknown

Prescribed EGF Given Prescribed/Refused Prescribed/Unknown Unknown

Prescribed TGF Given Prescribed/Refused Prescribed/Unknown Unknown

Radiation: Yes No Radiation Notes: _____

Comments: 18-11 ER IHC neg, PR IHC neg, Her-2 IHC neg @ 1+; 4/12-Chemo NOS w/NR MD(4/29/13-complete no to additional info-ah). is surgeon. No med-onc listed. Report: TREATED
MEMO BUT FAILED.TRANSFER FROM . ER ADMIT W/EPILEPSY DUE TO MENINGITIS. UNKNOWN AT DX. DOES HAVE ACTIVE DISEASE.

Comparative Effectiveness Research Study Master ID: 4707

Physician: _____ Tumor: Colon Invasive

Patient Name: _____ SSN: _____ TNM: 300 220 000
Date of Birth: _____ CS Stage: 540

Smoking: Never Used Current User Quit w/in 1 Year of DX
 Quit > 1 Year of DX Former user, Unknown when Quit Unknown

Height: _____
Weight: _____

Treatment	Agent Name	NSC #	Start Date	End Date	Planned / Received	Dose	Units	# Doses
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			

Hormone 1
Hormone 2
BRM 1
BRM 2

Check box if the following tests were run:

KRAS

GCSF Not Prescribed GCSF Given Prescribed/Refused Prescribed/Unknown Unknown

EGF Not Prescribed EGF Given Prescribed/Refused Prescribed/Unknown Unknown

TGF Not Prescribed TGF Given Prescribed/Refused Prescribed/Unknown Unknown

Radiation: Yes No Radiation Notes: _____

Comments: ah; CHEMO NOS

Comparative Effectiveness Research Study Master ID: 4707

Patient Name: _____ Med Rec No: 500928 Tumor: CML
SSN: _____ TNM: 888 888 888
Date of Birth: _____ CS Stage: 888

Smoking: Never Used Current User Quit w/in 1 Year of DX
 Quit > 1 Year of DX Former user, Unknown when Quit Unknown

Height: _____
Weight: _____

Treatment	Agent Name	NSC #	Start Date	End Date	Planned / Received	Dose	Units	# Doses
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			
					Planned			
					Received			

Hormone 1
Hormone 2
BRM 1
BRM 2

Check box if the following tests were run:

BCR-ABL2
 JAK2

GCSF Not Prescribed GCSF Given Prescribed/Refused Prescribed/Unknown Unknown

EGF Not Prescribed EGF Given Prescribed/Refused Prescribed/Unknown Unknown

TGF Not Prescribed TGF Given Prescribed/Refused Prescribed/Unknown Unknown

Radiation: Yes No Radiation Notes: _____

Comments: Pt receiving Gleevec, need details; S/W/H info coded. Co-morbid NR;

Disposition Report

5/30/2013
1:05 PM

CER Study Tracking Disposition Report

Case Counts	
Tumor	Number of Cases
Appendix	2
Appendix Carcinoid	7
Appendix Invasive	25
Appendix NET	3
Breast In Situ	673
Breast Invasive	2,625
Breast NET	1
CML	41
Colon Carcinoid	3
Colon In Situ	26
Colon Invasive	1,019
Colon NET	9
Not applicable	33
Rectosigmoid Carcinoid	2
Rectosigmoid In Situ	4
Rectosigmoid Invasive	94
Rectum Carcinoid	21
Rectum In Situ	11
Rectum Invasive	291
Rectum Malignant Melanoma	1
Rectum NET	6
Total Cases:	4,897

Case Status		
Category	Status	Number of Cases
Pending	Pending - Data review Incomplete	210
	Pending - Data review Complete	810
Started	Pending - Source Contact Made	2
	Pending - Completion Data to be Entered	215
Complete	Complete	3,623
Ineligible	Ineligible	37
Total Cases:		4,897

5/30/2013
1:05 PM

CER Study Tracking Disposition Report

Source Counts		
Source Type	Category	Number of Sources
Hospital	Not Started	135
	Source Reviewed	733
	Pending Visit	1
	Pending Fax	2
	Pending Call	1
	Complete	5,518
Physician	Not Started	127
	Source Reviewed	133
	Pending Fax	1
	Complete	7,368
Total Sources:		14,019

Completeness Report

CER Completeness Report

Tumor	Total Cases	Completed Cases	Percent Complete
Appendix	2	0	0.0%
Appendix Carcinoid	7	3	42.9%
Appendix Invasive	25	21	84.0%
Appendix NET	3	3	100.0%
Breast In Situ	672	537	79.9%
Breast Invasive	2,624	1,906	72.6%
Breast NET	1	1	100.0%
CML	41	32	78.0%
Colon Carcinoid	3	3	100.0%
Colon In Situ	26	26	100.0%
Colon Invasive	1,019	793	77.8%
Colon NET	8	5	62.5%
Rectosigmoid Carcinoid	2	2	100.0%
Rectosigmoid In Situ	4	4	100.0%
Rectosigmoid Invasive	94	62	66.0%
Rectum Carcinoid	21	15	71.4%
Rectum In Situ	10	9	90.0%
Rectum Invasive	291	196	67.4%
Rectum Malignant Melanoma	1	1	100.0%
Rectum NET	6	4	66.7%
Total:	4,860	3,623	74.5%



Questions?