

I-008 Form

Statistical Center Evaluation of CALGB Institutional Data Management Performance

- Purpose
 - To assess institutional data management performance using individual case records
 - To educate institutions about CALGB policies and procedures
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I-008 Form



- Process: Statistical Center
 - Twice annually, the Statistical Center randomly selects up to 12 cases per network on recent CALGB-coordinated treatment studies
 - In summer review cycle, cases come from main members
 - In fall review cycle, cases come from affiliates and at-large members
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I-008 Form

- Process: Statistical Center
 - A data coordinator (DC) in Data Operations reviews the selected case records at the Statistical Center and completes a 13-question I-008 form for each case
 - The DC reviews the data received for
 - Completeness (forms, data items, lab tests)
 - Consistency (within and across forms)
 - Legibility (handwriting, quality of forms)
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I-008 Form

- Process: Statistical Center
 - In the “completeness” review, the DC evaluates data submission compliance based on study-specific requirements
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STATISTICAL CENTER EVALUATION OF CALGB INSTITUTIONAL DATA MANAGEMENT PERFORMANCE


39798

Institutional data management performance is evaluated through review of randomly selected cases on CALGB treatment studies. Case selection is performed twice per year.

Whenever possible, the performance evaluation is conducted by the Data Coordinator assigned to the study from which the case is selected. The performance evaluation is sent to the Institution for review and comment and the results are sent to the Institution Performance Evaluation Committee.

CALGB Form I-008

CALGB Study No.

CALGB Patient ID

Evaluation year

Session (Mark one with an X.) Spring Fall

Are data amended? Yes

Patient Initials Patient Hospital No. _____

Last, First Middle

Institution/Affiliate _____

I. GENERAL INFORMATION

Evaluator roster #

Evaluator name

Is this a re-evaluation? No Yes

Date form completed / /

Most recent mail room date stamp / /

II. COMPLETENESS OF DATA SUBMITTED

1. Have on-study data, including supporting documents required to determine eligibility, been submitted as required by protocol? (Mark one with an X.)

Note → Likert scale: 1=best, 5=worst

1 2 3 4 5 -1
All on-study data submitted All on-study data missing Not Applicable

Specify missing form(s): **Note → Specify must be filled in if score >1**

I-008 Forms

- Process: Statistical Center
 - The Statistical Center sends completed I-008 forms to the Lead CRA of the institutional network (cover letter is sent to the PI)

I-008 Forms

- Process: Institution
 - Institution has one month to review their evaluations and respond to the DC with concerns
 - Institution may send a letter to IPEC if a concern is not resolved
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I-008 Forms

- Process: Institution
 - Institution submits missing or amended data to the Statistical Center
 - Institution retains the I-008 forms
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I-008 Forms

- Process: Institution

Use I-008 forms

- As educational tools for data management staff
 - As performance evaluation tools for data management staff
 - To maintain institutional standard operating procedures for CALGB studies
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I-008 Forms

Compiling reports for IPEC

1. For each **case** evaluated, a mean is calculated for each category (completeness, consistency, legibility)
 2. For each **network**, a mean of case-specific means is calculated for each category
 3. For each **network**, an “overall” mean is calculated as the weighted mean of the three network category means (40% completeness, 40% consistency, 20% legibility)
 4. For the **Group**, a mean of the network “overall” means is calculated
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I-008 Forms

- Statistical Center Reports to IPEC
 - A network is considered substandard if their network overall mean is >2 SD **above** the Group mean (remember, on the 5-level scale, a high score is bad)
 - A summary of network means and substandard performance is sent to IPEC for review at semiannual Group meetings
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Delinquent Data

- The Statistical Center sends periodic **delinquency lists** to institutions
 - The Statistical Center produces **delinquent data reports** for IPEC semiannually
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Delinquent Data

Sample delinquent data list

Cancer and Leukemia Group B

Patients with Delinquent Data

Patients entered on studies opened through 26-SEP-2002
for which follow-up is still required

Main Member : University of X
Affiliate: Hospital Y

Study	Patid	Patient Initials	Hospital Id	Study Entry Date	Clinical Follow-up Date	Clinical Follow-up Status	Patient Survival Date	Survival Status	Patient Data	Delinquent Survival Status**	New Survival Date**
9082	12345	C, AB	656565	02-JAN-1998	15-AUG-2000	In Follow-up	28-NOV-2000	Alive	Both		
9251	23456	D, EF	212121	15-FEB-2001	02-APR-2000	Terminated	20-APR-2001	Alive	Survival	_____	_____
9344	34567	G, HI	424242	05-JAN-1994	02-JAN-2001	In Follow-up	29-DEC-2001	Alive	Clinical		
9661	45678	J, KL	595959	15-FEB-2000	04-APR-2000	Lost	20-JUL-2000	Lost	Both		

** If only survival data are delinquent, survival date and status may be updated by completing these columns and returning this list to CALGB Data Operations. DO NOT complete these columns for patients still in clinical follow-up.

1-aug-2002 CALGB Information Systems

Delinquent Data

- The Statistical Center sends **delinquency lists** 10 times per year to main and at-large members
 - 8 “standard” lists are mailed
 - 2 “flagged” lists are faxed
 - Lists are sent to the Lead CRA who forwards them to affiliates (each affiliate has a separate page)
 - PI receives a copy of the cover letter

Delinquent Data

- All delinquency lists cover patients **entered in all years** who still require follow-up on CALGB-coordinated studies
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Delinquent Data

- Statistical Center creates lists based on the CALGB **minimum data submission requirement**
 - Institution must submit current survival and clinical data every 6 months for 2 years after patient registration
 - Institution must submit current data at least annually thereafter while follow-up is required
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Delinquent Data

- Standard delinquency lists: Responsibilities of the institution
 - Submit protocol-specified required clinical data (forms, supporting documents) to the CALGB Statistical Center
 - Submit updated survival data to the CALGB Statistical Center
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Delinquent Data

- Flagged delinquency lists
 - Twice annually, prior to creating the summary report for IPEC, the Statistical Center faxes to Lead CRAs the delinquency lists in which patients **in the IPEC review window are flagged**
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Delinquent Data IPEC Reports

- IPEC review window:
 - A subset of delinquent patients **entered within the previous 3½ to 4 years**, depending upon the cycle, not including the current year
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Delinquent Data

- Flagged delinquency lists contain **asterisks** next to delinquent cases that will appear on next **IPEC report** if sufficient data are not received by the indicated deadline
 - A cover letter and a **footnote** on the list contain data submission instructions for IPEC cases
 - PIs receive the cover letter and may request the list
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Delinquent Data

Sample list flagged **with IPEC notations**

Cancer and Leukemia Group B

Patients with Delinquent Data

Patients entered on studies opened through 26-SEP-2002
for which follow-up is still required

Main Member : University of X
Affiliate: Hospital Y

Study	Patid	Patient Initials	Hospital Id	Study Entry Date	Clinical Follow-up Date	Clinical Follow-up Status	Patient Survival Date	Patient Survival Status	Patient Data	Delinquent Survival Status**	New Survival Date**	New Survival Date**
9082	12345	C, AB	656555	02-JAN-1998	15-AUG-2000	In Follow-up	28-NOV-2000	Alive	Both		*	
9251	23456	D, EF	212121	15-FEB-2000	02-APR-2000	Terminated	20-JUL-2000	Alive	Survival			*
9344	34567	G, HI	424242	05-JAN-1994	02-JAN-2001	In Follow-up	29-DEC-2001	Alive	Clinical			
9661	45678	J, KL	565656	15-FEB-2000	04-APR-2000	Lost	20-JUL-2000	Lost	Both			*

**IPEC:
footnote**

**IPEC:
asterisk**

*This patient will be considered delinquent in the next IPEC report unless data are received at Data Operations, Statistical Center by 04/26/2003. Send these data marked IPEC, attention Director of Quality Assurance.

** If only survival data are delinquent, survival date and status may be updated by completing these columns and returning this list to CALGB Data Operations. DO NOT complete these columns for patients still in clinical follow-up.

Delinquent Data

- Flagged lists: Responsibilities of the institution
 - Send requested data for **all cases** on the list
 - For **IPEC cases**, follow special data submission instructions in the footnote

IPEC footnote example: "Patient will be considered delinquent in the next IPEC report unless data are received at Data Operations, Statistical Center by **04/26/2005**. Send these data **marked IPEC, attention Director of Quality Assurance.**"

Delinquent Data IPEC Reports

The Statistical Center sends summary **delinquency reports** twice annually to the IPEC for review at the Group meetings

Delinquent Data IPEC Reports

Summary delinquency reports sent to IPEC do not include asterisked patients on the flagged list **if sufficient data are received by the deadline indicated in the footnote**

Delinquent Data IPEC Reports

In the IPEC reports, patients are counted in the year in which they were registered

Delinquent Data IPEC Reports

Performance is substandard if $\geq 10\%$ of cases in a network are delinquent

– for survival or clinical data for the total of all 3½-4 years reported

or

– for survival or clinical data for last full year reported

Delinquent Data

Institutional Performance Evaluation Committee Report
 Table I - Delinquency Status by Institution
 Patients entered on study from 01-JAN-1999 through 30-JUN-2002
 Cut-Off Date: 15-APR-2003

	Institution: Hospital XYZ				Total
	Year Patient Accrued				
	1999	2000	2001	2002	
Number of Patients Entered *	154	163	124	110	551
Number of Patients Dead	68	66	48	20	202
Number of Patients Alive, Follow-up terminated **	1	0	1	1	3
Number of Patients Alive, in Follow-up	85	97	75	89	346
Number in Follow-up for Survival Only	15	25	20	11	71
Number in Follow-up for Survival and Clinical data	70	72	55	78	275
Number delinquent for Survival Data	1	2	2	0	5
Number delinquent for Clinical Data	9	7	8	6	30
Survival Data Delinquency % (alive in follow-up)	1%	2%	3%	0%	1%
Clinical Data Delinquency % (follow-up for survival and clinical)	13%	10%	15%	8%	11%

Substandard

* Less follow-up transfers to another institution; plus follow-up transfers from another institution
 ** Follow-up was terminated for one of the following reasons: the patient was on a study for which all follow-up was discontinued; the patient reached the study-specific follow-up truncation point; the patient was cancelled (never received treatment); the patient withdrew consent for all follow-up.

Delinquent Data

Institutional Performance Evaluation Committee Report
 Table I - Delinquency Status by Institution
 Patients entered on study from 01-JAN-1999 through 30-JUN-2002
 Cut-Off Date: 15-APR-2003

	Institution: Hospital XYZ				Total
	Year Patient Accrued				
	1999	2000	2001	2002	
Number of Patients Entered *	154	163	43	124	484
Number of Patients Dead	68	66	15	48	197
Number of Patients Alive, Follow-up terminated **	1	0	0	1	2
Number of Patients Alive, in Follow-up	85	97	28	75	285
Number in Follow-up for Survival Only	15	25	7	20	67
Number in Follow-up for Survival and Clinical data	70	72	21	55	218
Number delinquent for Survival Data	1	2	0	2	5
Number delinquent for Clinical Data	1	2	1	8	12
Survival Data Delinquency % (alive in follow-up)	1%	2%	0%	3%	2%
Clinical Data Delinquency % (follow-up for survival and clinical)	1%	3%	5%	15%	6%

Substandard

* Less follow-up transfers to another institution; plus follow-up transfers from another institution
 ** Follow-up was terminated for one of the following reasons: the patient was on a study for which all follow-up was discontinued; the patient reached the study-specific follow-up truncation point; the patient was cancelled (never received treatment); the patient withdrew consent for all follow-up.



Delinquency Information Sent by Statistical Center

Statistical Center sends indicated list or report		Jan	Feb	Mar	Apr	Jun	Jul (Grp mtg)	Aug	Oct	Nov (Grp mtg)	Dec
To Lead CRA	<u>Standard Delinquency List (Mailed)</u>	X	X	X		X	X		X	X	X
	<u>Flagged Delinquency List (Faxed)</u>				X			X			
To IPEC	<u>Summary Delinquency Report</u>					X			X		

Presentation Summary and Resources

- Summary
 - IPEC reviews institutional performance semiannually
 - The Statistical Center provides IPEC with data on delinquency and I-008 forms
 - Resources
 - CALGB Policies and Procedures section 2.9 and Appendix B
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