



Statistical Center Institutional Performance Evaluation Tools

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Objectives

- Describe CALGB Statistical Center institutional evaluation (I-008) forms
- Describe delinquency lists and tables sent by the Statistical Center to institutions
- Describe delinquency reports and I-008 summaries sent to IPEC by the Statistical Center

Institutional Performance Evaluation Committee (IPEC)

- Functions of the IPEC:
 - Develops and implements standards for the performance of CALGB institutions
 - Reviews the performance of CALGB institutional members (semiannually)
 - Reports findings to the Membership Committee, Board of Directors, Principal Investigators (their own network's results)

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Institutional Performance Evaluation Committee (IPEC)

- IPEC uses data from the following in its performance reviews:
 - Statistical Center (I-008 forms, delinquency information)
 - Data Audit Committee, Surgical Quality Assurance Committee (SQAC), Quality Assurance Review Center (QARC), and the PET Committee

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I-008 Forms

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 Forms

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

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I-008 Forms


- 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*

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I-008 Forms

- Process: Statistical Center
 - The DC reviews the data received for
 - Completeness (forms, data items, lab tests)
 - Consistency (within and across forms)
 - Legibility (handwriting, quality of forms)
 - The DC codes each item using a 5-point Likert scale and provides comments in “specify” areas

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STATISTICAL CENTER EVALUATION OF CALGB INSTITUTIONAL DATA MANAGEMENT PERFORMANCE

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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 Last, First Middle Patient Hospital No. _____

Institution/Affiliate _____

I. GENERAL INFORMATION

Evaluator roster #
 Evaluator name
 Date form completed / /
 Is this a re-evaluation? No Yes
 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
 - In the “completeness” review, the DC evaluates data submission compliance based on protocol-specific requirements

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I-008 Forms

- Some comments frequently made on I-008 forms:
 - On-study data: missing supporting pathology or lab reports
 - Follow-up forms: not sent at protocol-specified frequency; dates covered by AE forms not consistent with those on follow-up forms; supporting lab reports or flow sheets missing
 - Legibility: decimal added to existing boxes

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I-008 Forms

- Process: Statistical Center
 - The I-008 forms are entered into the CALGB database
 - The Statistical Center sends electronic versions of the completed I-008 forms to the Lead CRA and PI of the institutional network, using Secure Mail

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I-008 Forms

- Process: Institution
 - Institution has one month to review their evaluations and respond with concerns to the DC who completed the form; forms can be amended
 - Institution may send a letter to IPEC (via QA Director) 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
 - Institution uses 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

The Statistical Center compiles 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 sends reports to IPEC
 - A network is considered substandard if their network overall mean is >2 SD **above** the Group mean (remember, the lower the score, the better the performance)
 - A summary of network means and substandard performance is sent to IPEC for review semiannually

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Delinquent Data

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

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Delinquent Data

- The Statistical Center sends **delinquency lists** 10 times per year by Secure Mail to main and at-large members
 - 8 mailings contain “standard” lists
 - 2 mailings contain “flagged” lists
 - Lists are sent to the Lead CRA who forwards them to affiliates (each affiliate has a separate page)
 - PI also receives the lists

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Delinquent Data

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

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Delinquent Data

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

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Delinquent Data

Sample standard delinquent data list

Cancer and Leukemia Group B Patients with Delinquent Data
 Patients for whom follow-up is still required and who are delinquent as of run date

University of X (Main or At-large Member)
 Hospital Y (Affiliate)

Study	Patient ID	Patient Initials	Hospital ID	Study Entry Date	Clinical Follow-up Date	Clinical Follow-up Status	Patient Survival Date	Patient Survival Status	Delinquent Data	New Survival Status**	New Survival Date**
10002	12345	C,AB	656565	01/02/2004	08/15/2004	In Follow-up	11/28/2004	Alive	Both		
10102	23456	D,EF	212121	02/15/2005	04/02/2005	Terminated	04/20/2005	Alive	Survival		
9682	34567	G,HI	424242	01/05/1998	01/02/2005	In Follow-up	12/29/2005	Alive	Clinical		
19808	45678	J,KL	565656	02/15/2004	04/04/2004	Lost	07/29/2004	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.

Run Date: September 19, 2006

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Sample Standard Delinquent Data List: Explanation 1 Of 5

(See slide 22 for Sample Standard Delinquent Data List.)

- **Clinical Follow-up Date** and **Clinical Follow-up Status** reflect the most recent complete data the Statistical Center has received about the patient with respect to the endpoints of the study. Usually study endpoints involve disease response, progression, and adverse events.

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Sample Standard Delinquent Data List: Explanation 2 Of 5

(See slide 22 for Sample Standard Delinquent Data List.)

- For the first patient in this list (patient 12345), the Statistical Center has received clinical data indicating that the patient has not reached an endpoint as of the last evaluation (on 8/15/04). The patient is still in follow-up. The **Delinquent Data** column indicates that both clinical and survival follow-up are now required, since clinical and survival follow-up dates are not recent enough to meet the minimum data submission requirements.

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Sample Standard Delinquent Data List: Explanation 3 Of 5

(See slide 22 for Sample Standard Delinquent Data List.)

- Patient 23456 reached a study endpoint on 4/2/05, and no further clinical follow-up is required (Clinical Follow-up Status is “Terminated”). Survival data, however, are still required and are delinquent according to this report.

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Sample Standard Delinquent Data List: Explanation 4 Of 5

(See slide 22 for Sample Standard Delinquent Data List.)

- Patient 34567 is still in follow-up for clinical and survival data. Survival data are current enough, but this list indicates clinical data are delinquent (that is, insufficient or incomplete clinical data have been provided).

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Sample Standard Delinquent Data List: Explanation 5 Of 5

(See slide 22 for Sample Standard Delinquent Data List.)

- Patient 45678 has been declared lost by the institution. However, CALGB policy requires that lost patients appear on delinquency lists and in delinquency statistics.

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Delinquent Data

- Standard delinquency lists: Responsibilities of the institution
 - Submit protocol-specified required clinical data (forms, supporting documents) to the Statistical Center
 - Submit updated survival data to the Statistical Center; if clinical status is “terminated”, you may provide survival data on the lines on the right side of the page, and return the page to Data Operations.

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Delinquent Data

- Flagged delinquency lists
 - Twice annually, 2 months prior to creating the summary report for IPEC, the Statistical Center sends delinquency lists in which **cases in the IPEC review window are flagged**

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Delinquent Data

Cases in the IPEC review window:

- Are a subset of all delinquent cases; were **entered within the previous 3½ or 4 years**, depending upon the cycle, not including the current year
- Will appear in the delinquency reports to IPEC unless **sufficient** protocol-required data are received by the deadline indicated on the flagged delinquent data list

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Delinquent Data

- Flagged delinquency lists contain **asterisks** next to delinquent cases in the IPEC window
- A cover letter and a **footnote** on the list contain data submission instructions for IPEC cases
- PIs also receive the cover letter and the list

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Delinquent Data

Sample list flagged with IPEC notations

IPEC:
asterisk

Cancer and Leukemia Group B Patients with Delinquent Data
Patients for whom follow-up is still required and who are delinquent as of run date

University of X (Main or At-large Member)
Hospital Y (Affiliate)

Study	Patient ID	Patient Initials	Hospital ID	Study Entry Date	Clinical Follow-up Date	Clinical Follow-up Status	Patient Survival Date	Patient Survival Status	Delinquent Data	New Survival Status**	New Survival Date**	
*	10002	12345	C,AB	656565	01/02/2004	08/15/2004	In Follow-up	11/28/2004	Alive	Both		
*	10102	23456	D,EF	212121	02/15/2005	04/02/2005	Terminated	05/20/2005	Alive	Survival		
	9682	34567	G,HI	424242	01/05/1998	01/02/2005	In Follow-up	12/29/2005	Alive	Clinical		
*	19808	45678	J,KL	565656	02/15/2004	04/04/2004	Lost	07/29/2004	Lost	Both		

IPEC:
footnote

*This patient will be considered delinquent in the next IPEC report unless data are received at Data Operations, Statistical Center by 10/20/2006. 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.
Run Date: September 19, 2006

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 **10/20/2006**. Send these data **marked IPEC, attention Director of Quality Assurance.**”

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Delinquent Data IPEC Reports

- The Statistical Center sends summary **delinquency reports** twice annually to the IPEC for review

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Delinquent Data IPEC Reports

- In the IPEC reports, patients are counted in the year in which they were registered when computing delinquency.

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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

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Delinquent Data Report

IPEC window

Institutional Performance Evaluation Committee Report - Table II

Patients entered on study from 01/01/1980 through 12/31/2005 on CALGB-coordinated treatment and non-treatment studies requiring follow-up
Delinquency Cut Off Date: 9/19/2006

Member Network: University A

	Total 1980-2001	Year Patient Accrued				Total 2002-2005	Total 1980-2005
		2002	2003	2004	2005		
Number of Patients Entered *	292	34	56	98	96	284	576
Number of Patients Dead	202	22	28	47	18	115	317
Number of Patients Alive, Follow-up terminated **	11	2	5	2	12	21	32
Number of Patients Alive, in Follow-up	79	10	23	49	66	148	227
Number in Follow-up for Survival Only	20	1	6	27	11	45	65
Number in Follow-up for Survival and Clinical Data	59	9	17	22	55	103	162
Number delinquent for Survival Data	8	0	3	1	6	10	18
Number delinquent for Clinical Data	9	0	2	0	9	11	20
Survival Data Delinquency % (Patients Entered)	3%	0%	5%	1%	6%	3%	3%
Survival Data Delinquency % (Alive in Follow-up)	10%	0%	13%	2%	9%	7%	8%
Clinical Data Delinquency % (Fol-up for Surv & Clin)	15%	0%	12%	0%	16%	11%	12%

* 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 canceled (never received treatment); the patient withdrew consent for all follow-up.

Both percentages are substandard

Delinquent Data: Recent Change

- As of September 2006, the delinquency list sent to a network is accompanied by a version of the IPEC delinquency report run at the same time as the list.
- This report gives the network a snapshot of its current delinquency statistics.
- Reports that accompany delinquency lists are not sent to IPEC.

Delinquent Data: Important Changes Coming

- At the December 2006 administrative committee meetings, IPEC, Membership Committee and the Board of Directors will discuss how to incorporate long-term delinquencies into review of network performance. Delinquent data for patients registered *prior* to the current IPEC review window will soon impact your evaluation.
- Changes to policy will be announced Group-wide once approved.

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Delinquency Information Sent by the Statistical Center: Usual Schedule

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

Frequently asked questions

- Q: I've sent the data. Why is the patient still on the delinquency list?
- A: It may take a month or more between the time you receive the delinquency list and the time all data are entered. Also, you may have sent incomplete data (data not sufficient to update our database, particularly with regard to disease status). If the patient is on the list 2 months after you have sent the data, check with the data coordinator for the study.

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Frequently asked questions

- Q: Why does a lost patient keep appearing on my delinquency list? I've tried everything to find the patient. Will lost patients affect my network's evaluation?
- A: CALGB policy requires lost patients to stay on the delinquency list. After lost patients move out of the IPEC review window, they no longer impact your delinquency rate and performance evaluation. This may change once IPEC begins to evaluate long-term delinquency.

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Frequently asked questions

- Q: If a patient withdraws consent to be followed, how do I get them off the delinquency list?
- A: The patient should sign a letter indicating they withdraw consent for follow-up for clinical *and* survival data. If they refuse to sign, but their intent has been clearly stated, the treating physician may sign a letter in the patient's stead. Once the Statistical Center receives the letter, the patient will come off the delinquency list.

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Frequently asked questions

- Q: Will I-008 patients also be on the delinquency list?
- A: Possibly, but not necessarily. The delinquency list is a snapshot of all patients who are delinquent, according to CALGB minimum data submission requirements, at the time the list is run. I-008 patients are a limited number of patients chosen randomly, irrespective of their delinquency status at time of selection. If data were submitted late according to protocol-specific requirements, the I-008 completeness score reflects that delinquency, even if the data are in hand at the time of the I-008 review.

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Frequently asked questions

- Q: How is the evaluation of institutional performance by the Statistical Center for IPEC different from the patient case review performed by the CALGB Data Audit Committee (DAC)?

(continued)

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Frequently asked questions

- A: There are three primary differences between these evaluation processes:
 1. Number of patients reviewed: The Statistical Center creates reports for IPEC that reflect delinquency of data submitted for all of the institution's patients in the IPEC review window. The DAC reviews data for only those patients that are selected for the audit.

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Frequently asked questions

- A: There are three primary differences between these evaluation processes:
 2. Method of data review: The Statistical Center staff check submitted data for consistency and completeness based on protocol requirements. The DAC compares submitted data to the patient's institutional primary medical record and to the protocol in order to assure the submitted data are accurate and complete.

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Frequently asked questions

- A: There are three primary differences between these evaluation processes:
 3. Frequency of data review: The Statistical Center evaluates networks for IPEC twice annually (I-008s, delinquency reports). The DAC audits institutions with acceptable performance about every 3 years.

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Presentation Summary

- The CALGB Statistical Center sends Lead CRAs and PIs delinquency information and I-008 forms.
- The CALGB Statistical Center provides IPEC with summary information about delinquency and I-008 forms.
- IPEC uses information from the Statistical Center, Data Audit Committee and other sources to evaluate institutional performance semiannually.

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Resources

CALGB Policies and Procedures section 2.9 and Appendix B, found at www.calgb.org

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