Managing a Research Trial Using PROC REPORT Dashboards

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Agenda

- **Brief overview of clinical trial**

- **Dashboard tool for monitoring investigator data submissions**

- **PROC REPORT code for creating your own dashboard**

Background

- **Data Manager for a large cancer clinical trial that accrued patients between 2003 and 2011**
  - **Involved 40+ hospitals around the world with over 1000 patients included in the study**
  - **Data analysis depended on the <u>voluntary</u> submission of approximately 20 case record forms by 40+ investigators (surgeons) from around the world**
    - Clinical details around preoperative, intraoperative, and postoperative surgery measurements and outcomes
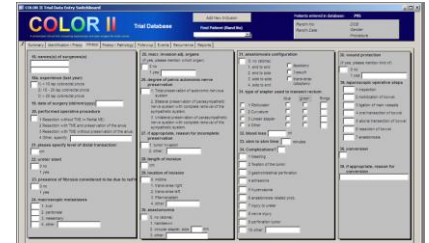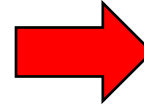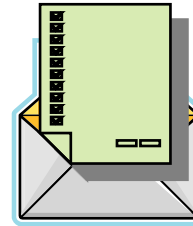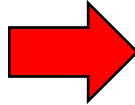- **Trial Objective**
  - **Compare patient outcomes between <u>laparoscopic surgery</u> and <u>open surgery</u> techniques for resection**

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Sites Participating in Clinical Trial

Europe
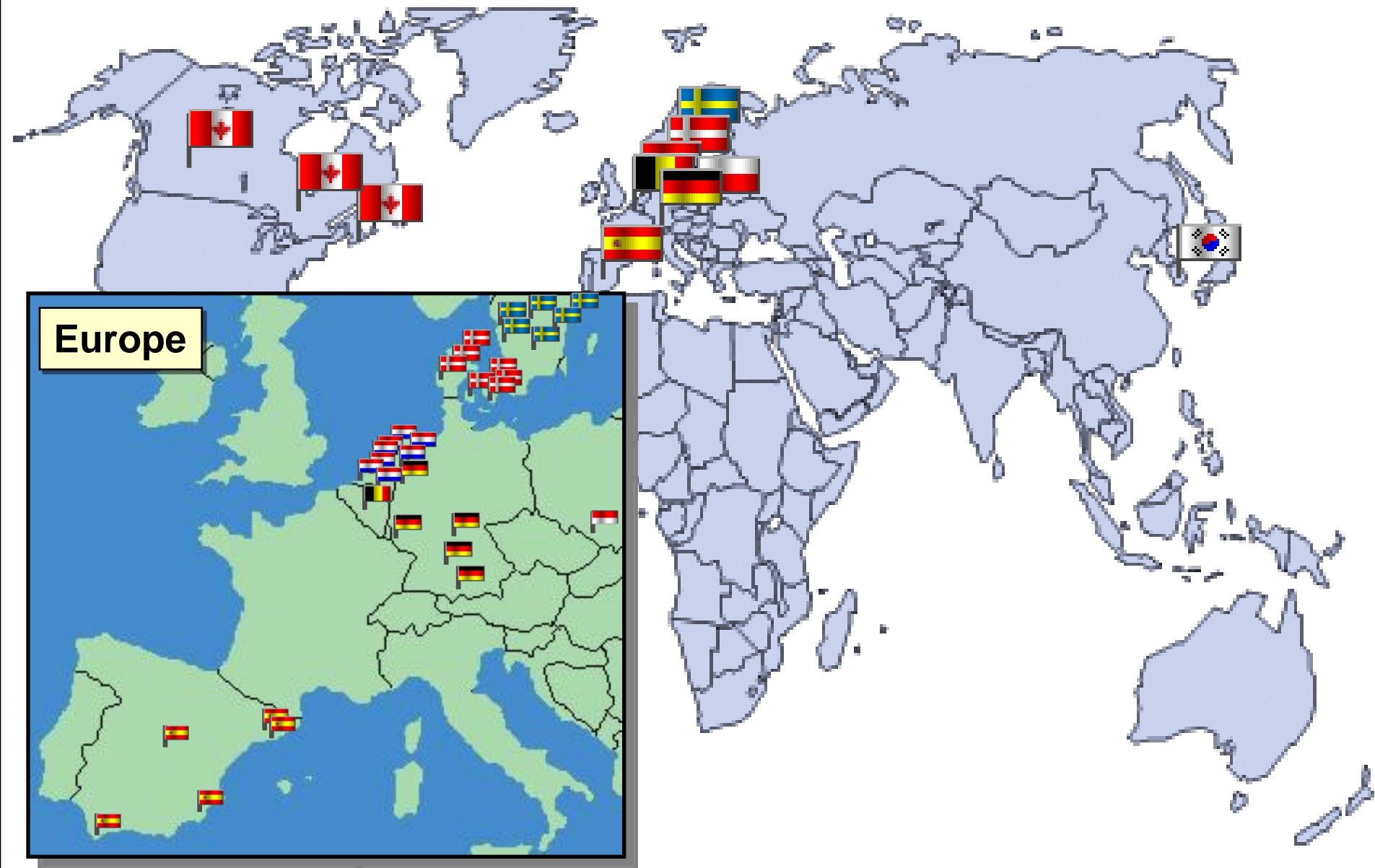
Trial Data Management Process
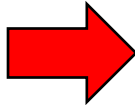
Investigator performs surgery

Investigator completes required <u>Case Record Forms</u>

Case Record Forms sent to Trial Coordinating Centre

Data entered in Access database

Report provided to Investigator

'Case Record Forms Received' Dashboard report produced periodically

The Challenge

- ## <u>The Problem</u>
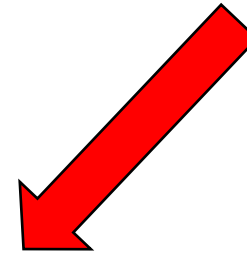 - ▶ **For many hospital sites, data submission to the Trial Coordinating Centre in Halifax was initially very poor**
  - ▶ **By 2009, <u>only about 50% of the required Case Record Forms had been received at the Trial Coordinating Centre.</u>**

- ## <u>The SAS Solution</u>
  - ▶ **Wanted to provide <u>better feedback to investigators</u> on the status of each of their patient's Case Record Forms**
  - ▶ **Developed a SAS 'Dashboard' for each site that shows at a glance <u>which case record forms are outstanding for each patient</u> at that site, and disseminated report quarterly.**

Part of 'Case Record Forms Received' Report

country=▮▮▮▮ site=▮▮▮▮▮▮

Rand'n Number	Rand Date	Surg Date	Excluded?	Death?	Patient Withdrew?	Lost to FU?	ID Form	Pre-Op Form	Intra-Op Form	Post-Op Form	Pathology Form
▮▮▮	▮▮▮	▮▮▮	Included	No	No	No	Yes	Yes	Yes	Yes	Yes
▮▮▮	▮▮▮	▮▮▮	Included	No	No	No	Yes	Yes	Yes	Yes	Yes
▮▮▮	▮▮▮		Included	No	Yes	No	Yes	Yes	N/A	N/A	N/A
▮▮▮	▮▮▮	▮▮▮	Included	No	No	Yes	Yes	Yes	Yes	Yes	Yes
▮▮▮	▮▮▮		Included	No	Yes	No	Yes	Yes	N/A	N/A	N/A
▮▮▮	▮▮▮	▮▮▮	Included	No	No	No	Yes	Yes	Yes	Yes	Yes
▮▮▮	▮▮▮	▮▮▮	Included	No	No	No	Yes	Yes	Yes	Yes	Yes
▮▮▮	▮▮▮	▮▮▮	Included	No	No	No	Yes	Yes	Yes	Yes	Yes
▮▮▮	▮▮▮		Included	No	No	No	No	No	No	No	No
▮▮▮	▮▮▮		Included	No	No	No	No	No	No	No	No

Yes -> Data was received at the trial coordinating center
No -> Data was NOT received at the trial coordinating center
N/A -> Data is not available, not required, or data cannot be collected (patient died, lost to follow-up, etc)

Investigator can <u>quickly</u> review report and identify which Case Record Forms are outstanding for each patient
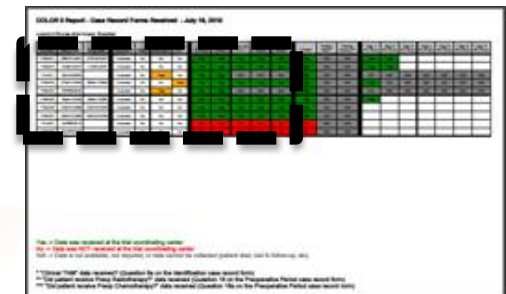
Data Submissions After Implementing Dashboard

Case Record Forms Received
1. Identification, 2. Preop, 3. Intraop, 4. Postop and 5. Pathology

Legend:
- ■ All 5 Case Record Forms Not Received
- ■ All 5 Case Record Forms Received

Category	Received	Not Received
Before Dashboard	53%	47%
After 12 Months	81%	19%
After 14 Months	93%	7%
After 16 Months	95%	5%
After 18 Months	99%	
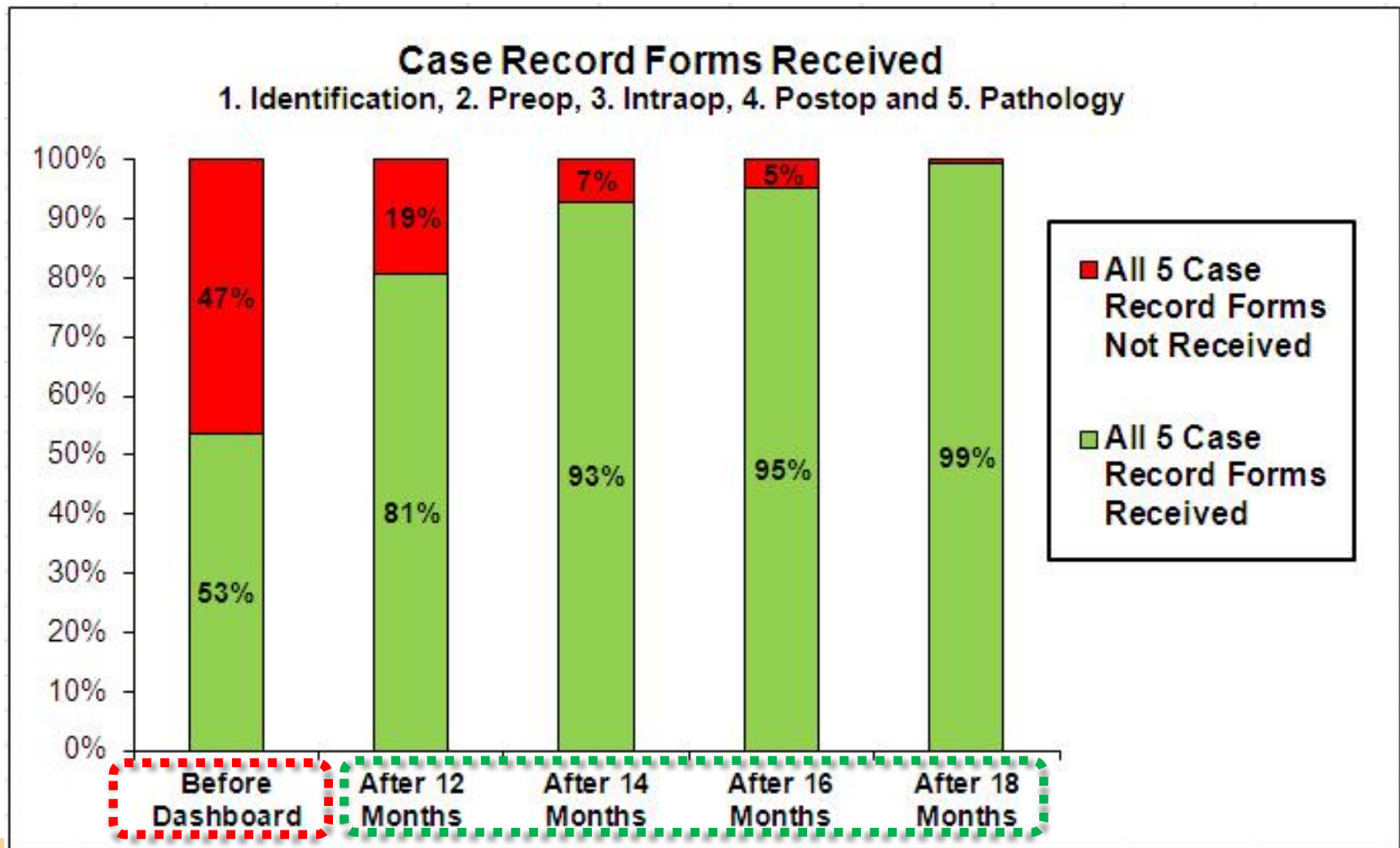
Almost 50% of Case Record Forms were missing prior to Dashboard implementation

Within 18 months, 99.4% of required data had been submitted by investigators!

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SAS Code…Easy as 1, 2, 3!
Step 1 – Create formats

```
proc format;

    /* ----- Formatting for the 'Patient Withdrew' field ----- */
    value withdrew
        1 = "Yes"         /* Text you want to see displayed */
        0 = "No";         /* on the dashboard */


    value trafwd
        1 = "orange"      /* Color you want the cell background */
        0 = "white";      /* to be for these values on the dashboard*/


    /* ----- Formatting for the 'Case Record Form Received' fields ----- */
    value crf
        1 = "Yes"         /* Text you want to see displayed */
        2 = "No"          /* on the dashboard */
        8 = "N/A"
        9 = "N/A";


    value trafcrf
        1 = "green"       /* Note: You can also use the hex RGB code - cx006600 */
        2 = "red"         /* Note: You can also use the hex RGB code - cxFF9900 */
        8 = "grey"        /* Color you want the cell background */
        9 = "grey";       /* to be for these values on the dashboard*/
run;
```

Step 2 – Prepare dataset

```
/*******************************************************************
  Prepare your data file at this point, prior to running
  PROC REPORT (ie. sort dataset, recode values etc as necessary)

  You also need to format any variables that will appear in the
  dashboard.
 ********************************************************************/

data final;
    set trialdata;

    /* Format any fields that will appear in the dashboard */
    format  surgdat randdat date9.
            excl excl. death death. withdrawal withdrew. losttofollowup lostfu.
            idform preform okform postform patform crf.;
run;

proc sort data=final;
   by site country;
run;
```

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Step 3 – Generate PROC REPORT output

```
ODS PDF file='C:\Missing Case Record Forms Dashboard.pdf';

proc report data=final nofs
    column randno randdat surgdat
           blank1
           excl death withdrawal losttofollowup
           blank1
           idform preform okform postform patform;

    define randno /'Rand`n Number' style = {cellwidth=.60in just=center font=('arial',8pt)};
    define randdat /'Rand Date' style = {cellwidth=.75in font=('arial',8pt)};
    define surgdat /'Surg Date' style = {cellwidth=.75in font=('arial',8pt)};
    define excl /'Excluded?' style = {background = trafexcl. just=center cellwidth=.63in font=('arial',8pt)};
    define death /'Death?' style = {background = trafdeth. just=center cellwidth=.45in font=('arial',8pt)};
    define losttofollowup /'Lost to FU?' style = {background = traflost. just=center cellwidth=.45in font=('arial',8pt)};
    define withdrawal /'Patient Withdrew?' style = {background = trafwd. just=center cellwidth=.63in font=('arial',8pt)};
    define idform /'ID Form' style = {background = trafcrf. just=center cellwidth=.55in font=('arial',8pt)};
    define preform /'Pre-Op Form' style = {background = trafcrf. just=center cellwidth=.58in font=('arial',8pt)};
    define okform /'Intra-Op Form' style = {background = trafcrf. just=center cellwidth=.58in font=('arial',8pt)};
    define postform /'Post-Op Form' style = {background = trafcrf. just=center cellwidth=.58in font=('arial',8pt)};
    define patform /'Pathology Form' style = {background = trafcrf. just=center cellwidth=.61in font=('arial',8pt)};
    define blank1 /'.' style = {background = black cellwidth=.002 in font=('arial',2pt)}; /* creates a black line */

    by country site;
run;

ODS PDF close;
```

Other applications

▶ **Early success with the Dashboard approach encouraged adaptation for other regular reports to investigators**

1. **Data quality dashboards**
    - **Does the data submitted make sense? If data is outside of a specified range, Highlight the field in red.**
    - **Are there missing values on the original Case Record Form? If so, Highlight the field in red.**

2. **Other types of Missing Case Record Form dashboards**
    - **Follow-up, Cancer Recurrence reports**

3. **Missing Data reports for the Quality of Life substudy**

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Conclusion

- Data management for a large clinical trial with 50+ investigators around the world is a very challenging task!

- Providing regular feedback to researchers around their data submissions <u>promotes accountability</u> and <u>facilitates improvement of data quality</u>

- PROC REPORT provides an easy tool for creating a click-and-run dashboard that is easy to interpret, and can be distributed to researchers as often as necessary to support improvement of data quality