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## Using DataFax and SAS® to Implement an Automated Clinical Trial Contract Payment System

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### Administering Reimbursements

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- 61 Investigator sites
- 5500 Subjects
- 5 years from start to finish of study
- Subjects can transfer between sites
- 16 visits per subject over 3 years

## Needs

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- Assign payment values
- Make summary reports
- Create letters
- Track payments

## Reimbursement to Investigators

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- Should be prompt
- Fair
- Objective
  
- Helps staff run a better site
- Encourages subject retention

## Prerequisites

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- Have a means of tracking CRFs
- Identify CRFs required for flagging a visit as completed.
- Agree on pay rate for completed subject visits.
- Agree on pay rate for any other investigator tasks.

## Pay-for-performance Model

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- Use DataFax to track CRFs
- A completed visit consists of having a set of completed CRFs with no outstanding queries.
- Payment to investigator each quarter based on number of subject visits completed

## Each Quarter

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- Extract data
- Tally CRFs for each subject
- Calculate completed visits
- Calculate payment for each site based on visits x pay-rate
- Calculate total due site for entire study minus amount already paid

## Reports

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- Provide each site with summary of completed visits, payments to date, and payments due.
- Create a letter for each site from a template and insert macro variables into the letter.

## Form Tracking Report

VaxGen, Inc.  
Study VAX004

Accumulative Case Report Forms (CRFs) Received By Subject  
(DataFax validation level >=1, As of 30sep02)

Site #	Sub No	Init	Visit Number											
			1 Screening	2 0	3 0.5	4 1	5 1.5	6 6	7 6.5	8 12	9 12.5	10 18	11 18.5	
1	2427	GJC										1	1	1
	2775	BRB	1	1	1	1	1	1	1	1	1	1	1	1
	2777	FBW	1	1	1	1	1	1	1	1	1	1	1	1
	2778	CWS	1	1	1	1	1	1	1	1	1	1	1	1
	2779	RDC	1	1	1	1	1	1	1	1	1	1	1	1
	2780	MSB	1	1	1	1	1	1	1	1	1	1	1	1
	2781	HFO	1	1	1	1	1	1	1	1	1	1	1	1
	2782	JTS	1	1	1	1	1	1	1	1	1	1	1	1
	2783	MTA	1	1	1	1	1	1	1	1	1	1	1	1
	2784	SLD	1	1	1	1	1	1	1	1	1	1	1	1
	2785	WTD	1	1	1	1	1	1	1	1	1	1	1	1
	2796	JWR	1	1	1	1	1	1	1	1	1	1	1	1

## SAS code for letter

```
*Loop through the sites to output two letters per site.;
%macro rpt;
%do i=1 %to &nobs;
  data _null_;
    set r&cutdt;
    if _n_=&i;
    call symput('pifirst',trim(left(right(pifirst))));
    call symput('pilast',compress(pilast));
    call symput('degree',compress(degree));
    call symput('piaddr1',piaddr1);
    call symput('piaddr2',piaddr2);
    call symput('picity',left(trim(picity)));
    call symput('pistate',compress(pistate));
    call symput('pizip',pizip);
  . . .
%end;

```

## A SAS generated letter

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- October 14, 2003
- 
- George Granola, M.D.
- Saint Paul University Health Sciences Center
- 3336 Spruce Avenue
- Kansas City, KA 63111
- 
- Re: CLS 033:
- \* Payment for third quarter of 2002
- 
- Dear Dr. Granola:
- 
- Enclosed you will find a copy of the payment summary and accumulative case report form (CRF) received by subject reports for your review.
- 
- The enclosed information indicates a total of 108 subjects enrolled and 1608 completed
- Subject visits (including screening enrollments) for your center . At a reimbursement rate
- Of \$140.25 per subject visit, and including the 15% withhold, your site is due reimbursement
- Of \$262,005.23. Since total reimbursement due is more than Drugco's accumulative
- Payments of \$313,739.71, Drugco's check in the amount of \$4,165.31 will be sent to the
- Payment address listed in our clinical trial agreement. Please note that we included the 30.5
- Month visit in total reimbursement for clinical trial services at the agreed rate of \$120.00;
- 
- If you have any questions or concerns, please contact me at your earliest convenience.
- Thank you for your efforts in this important clinical trial.
- 
- Sincerely,
- 
- 
- John Adams
- Associate director, administration
- 
- Enclosures

## A SAS letter – macro vars highlighted

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-

## Automate

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- Use crontab  
30 05 1 6 \* /vae/be/vax003/contracts/prog/autojob
- The autojob script will:
  - Execute DF2sas to extract latest data
  - Run SAS to create SAS datasets
  - Run SAS jobs to generate special datasets, reports, and letters
  - Backup output files
  - Mail letters in .rtf format to the program administrator

## Cautions

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- Have firm agreement as to what constitutes a completed visit

## Summary

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- Take advantage of DataFax's rapid and accurate CRF processing.
- Use Base SAS to maintain accounting, generate reports and letters.
- Pay for performance.
- Automate.