



PH.Clinical Templateによる解析帳票作成 に対するシステム化の試み

Part 1

2002/08/02

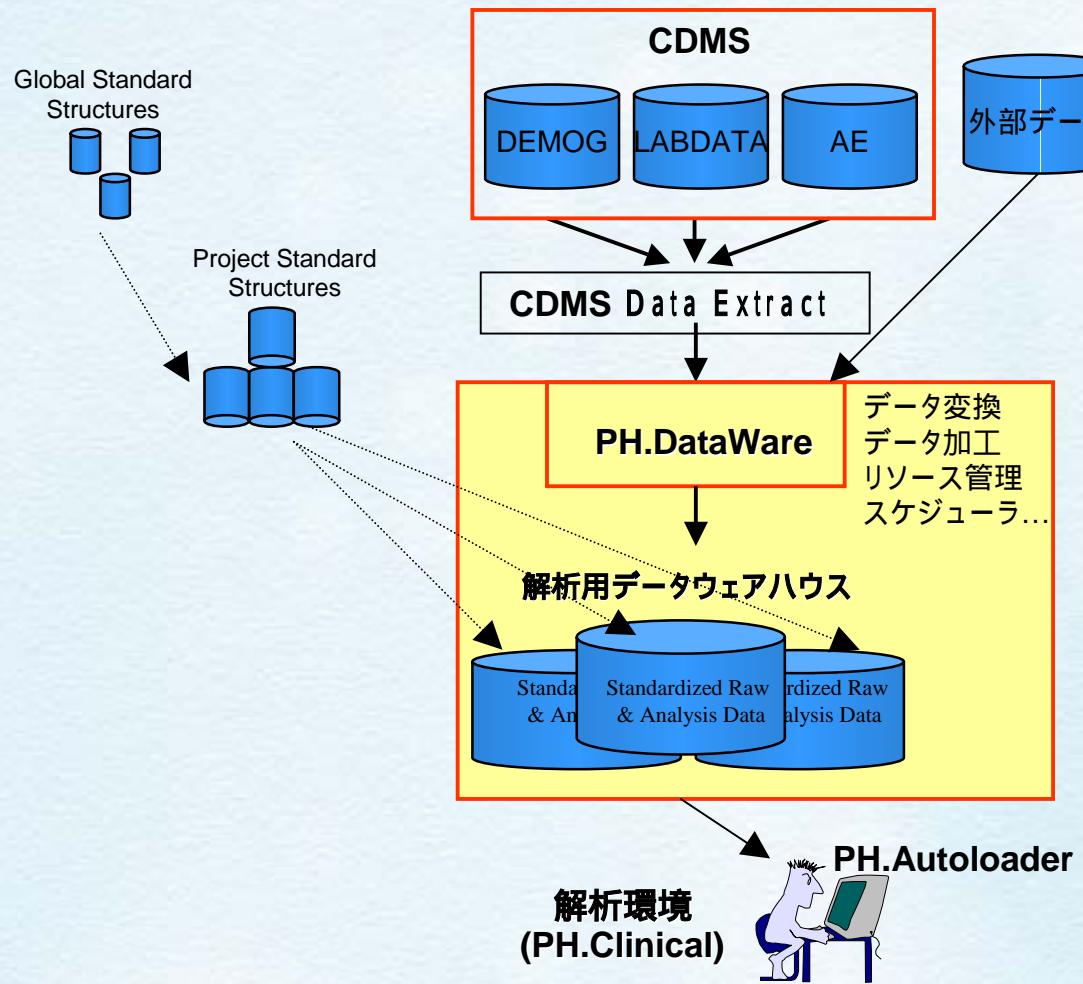
SAS Institute Japan LTD.

PS/インプリメンテーショングループ

平田 明弘

SASによる臨床解析支援ソリューション

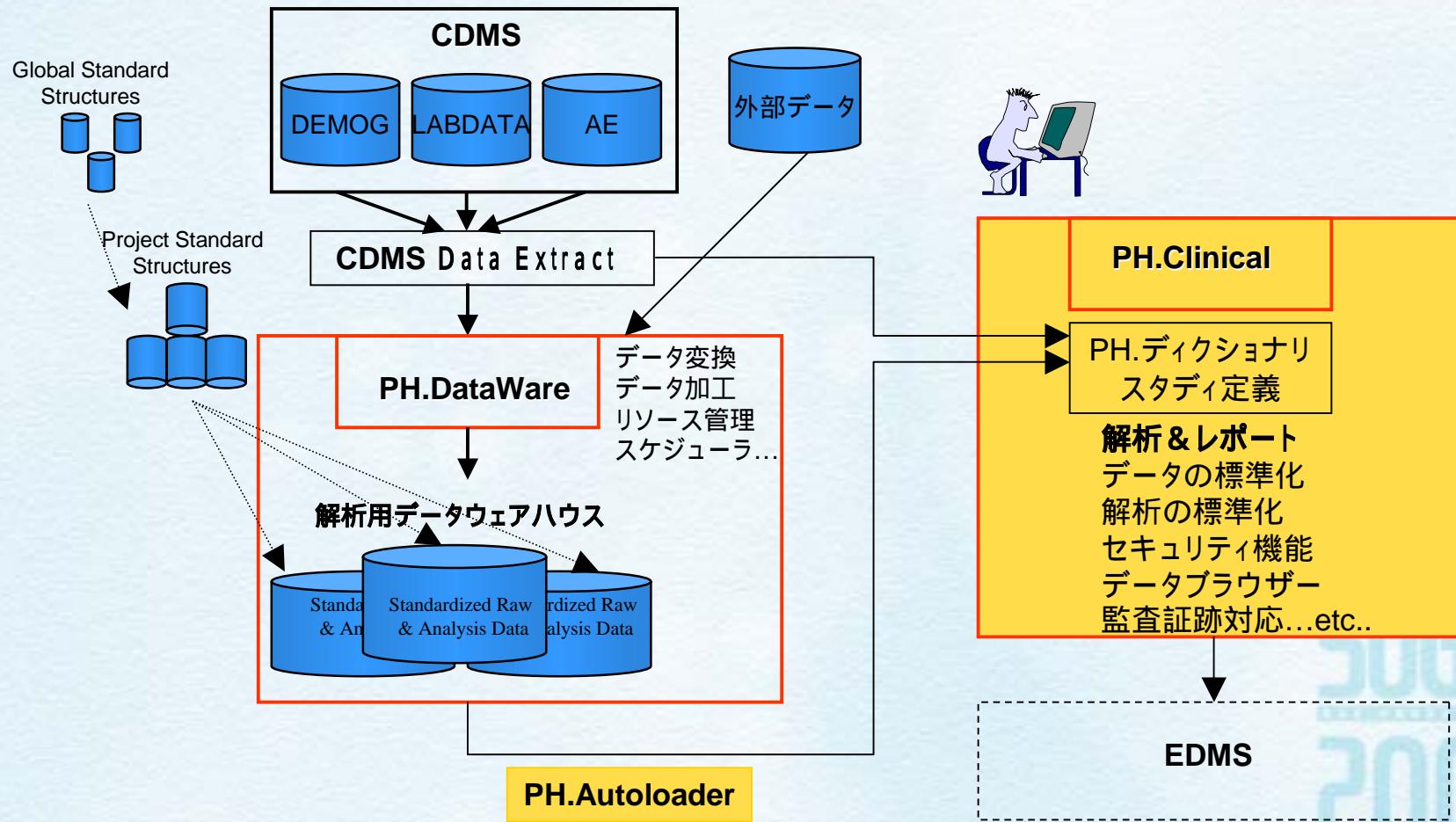
解析データ作成・管理(PH.DataWareプロダクト)



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2002

SASによる臨床解析支援ソリューション

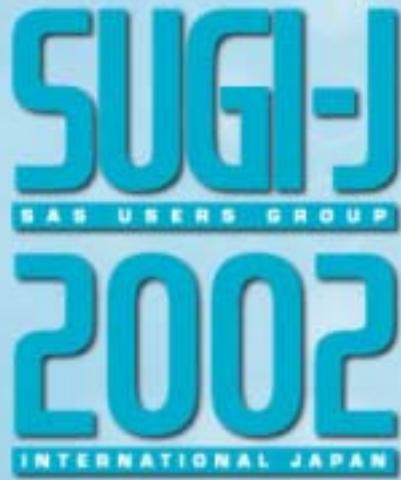
解析帳票作成・管理(PH.Clinicalプロダクト)



PH.DataWare

Demo

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ANNUAL MEETING

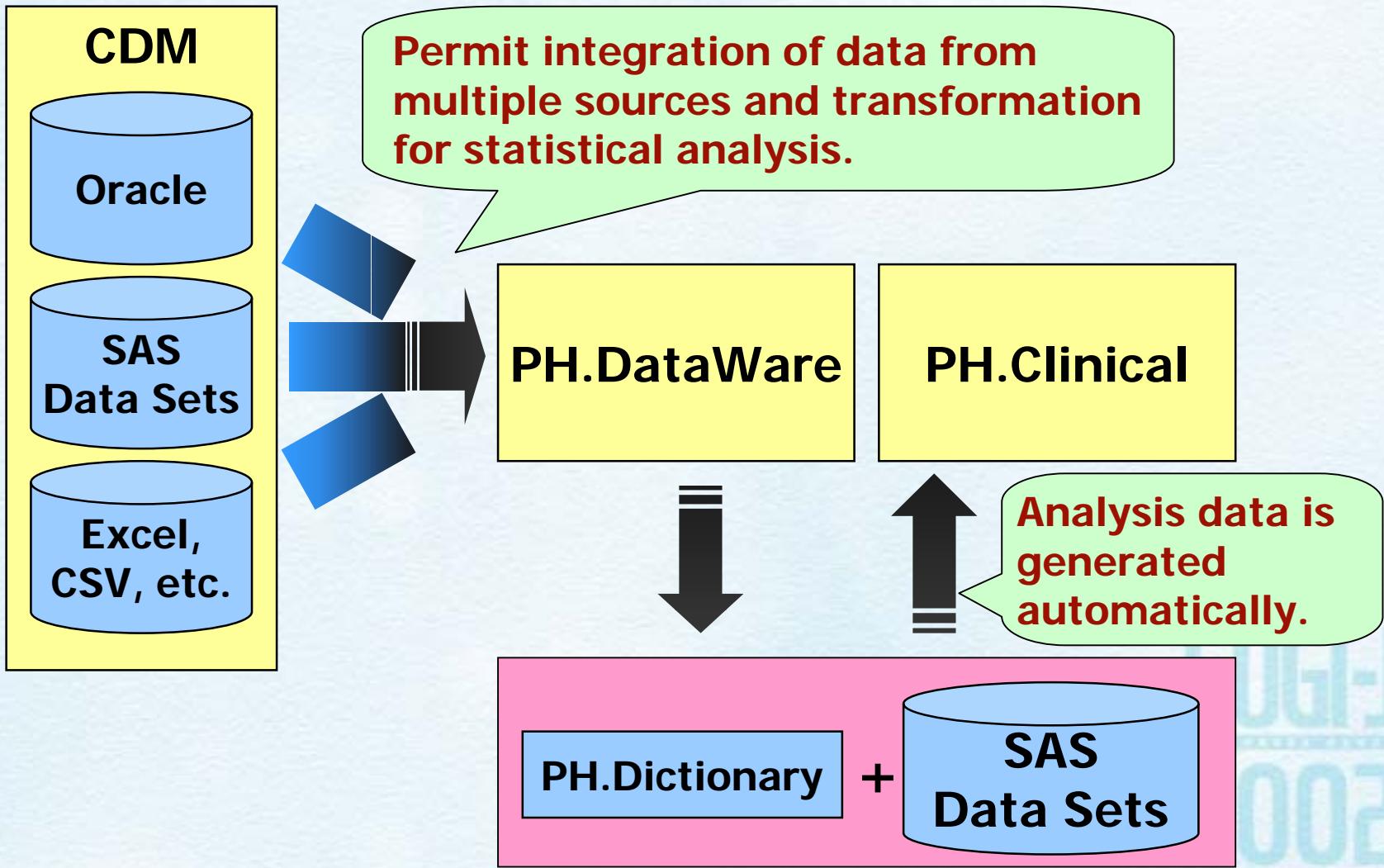


Experiment of developing the PH.Template using SAS/ODS

Part 2

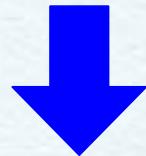
Aug. 2, 2002
Biometrics, Japan Development Cent.
Pharmaceutical Development Div.
TAKEDA CHEMICAL INDUSTRIES, LTD
Koji Iwamoto

Data Flow



Purpose of Analysis System

- ◆ Quality Control and audit trail
- ◆ Eliminate manual SAS program coding
- ◆ Produce outputs in line with ICH-E3 guideline



Reduce workloads and costs!

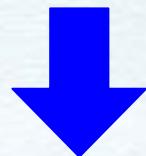
Benefits of PH.Clinical

- ◆ **Quality Control and audit trail**
 - Access Control:
 - User, User Group and Security Role
 - All sessions are recorded in PH.Clinical
 - Outputs are stored with sources and Logs
- ◆ **Eliminate manual SAS program coding**
 - Create Customized PH.Template
 - PH.Template is based on SAS/AF



Lack of PH.Clinical Functionality

- ◆ Eliminate manual SAS program coding
 - PH.Template is based on SAS/AF, however, it does not support V8.2 objects
- ◆ Produce outputs in line with ICH-E3 guideline
 - Cannot manage ODS outputs



Realized it by using SAS macros

Components of PH.Template

Customized Window



Code Section

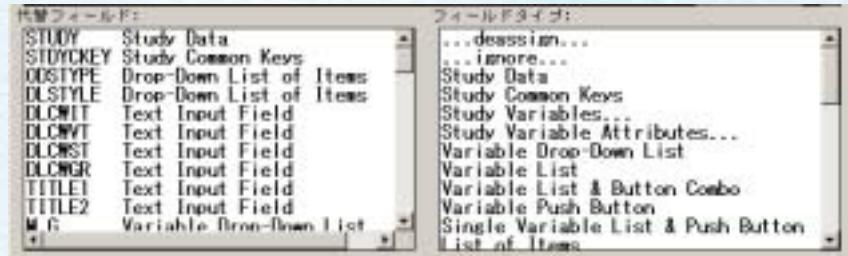
```
/* Main Selection Window */
!let _DSID = &DSIDTYPE;
!let _STYLE = &DSIYSTYLE;
!let _CR_ITEM = &DSICRITEM;
!let _CR_VL = &DSICRVL;
!let _CR_STAT = &DSICRSTAT;
!let _CR_GPT = &DSICRGPT;
!let _TITLE = &DSITITLE;
!let _TIT2 = &DSITITLE2;

!let _M_G = &SM_G;
!let _M_GF = &Scan("SM_GFMT",1," ");

data M=<NULL>;
  _DSID = open('&STUDY(fcn1levmember)',"");
  if "SM_GFMT" = "" then do i;
    call sweat(_M_GF, varname(_DSID, "SM_G"));
  end;
  array VRL_ [10] $8 ('SM_1M01','AM_1M02','SM_1M03','AM_1M04','SM_1M05','AM_1M06','SM_1M07','AM_1M08','SM_1M09','AM_1M10');
  array LAB_ [10] $40 ('SM_1M01','AM_1M02','SM_1M03','AM_1M04','SM_1M05','AM_1M06','SM_1M07','AM_1M08','SM_1M09','AM_1M10');
  
```



Substitution Fields



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PH.Template Output

◆ Output

- Actual text output from the PH.template

◆ Source

- SAS source code used to generate the output

◆ Log

- SAS log generated during run time

◆ Summary

- Summary information such as

- the user, date, and time when the output was created
- overview of the PH.Template, if available
- the study, data sets, and queries used at run time



Components of ODS Model

Customized Window



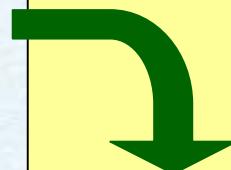
Code Section



Substitution Fields



- Link Substitution fields to Macro Variables
- Invokes SAS macro



SAS macro

```
Macro T11_2A();  
  
data _null_;  
  set &_ODSTP = HTML $then $do ;  
    call symput("_ODSMK",''||"/HTML<BR>"'||"');  
  $end ;  
  set &_ODSTP = RTF $then $do ;  
    call symput("_ODSMK",''||"(n"||"");  
  $end ;  
run ;  
  
proc format outlist = work FORMAT(where=(FMNAME=compress("&_  
run;  
  
proc sql noprint;  
  select count(FMNAME) into :_M_SD from work.FORMAT ;  
quit;  
  
%do J = 1 %to 10;  
  
  set &&_ITM&J ne %str() $then $do;
```

ODS Model Output

◆ Output

- Customized ODS output from the PH.template
- Original SAS text output corresponding with the ODS output
- Listing of data that is used for the ODS output

◆ Source

◆ Log

◆ Summary

PH.Clinical

Demo

SUGI-11
Statistical Graphics
2002
Proceedings