



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

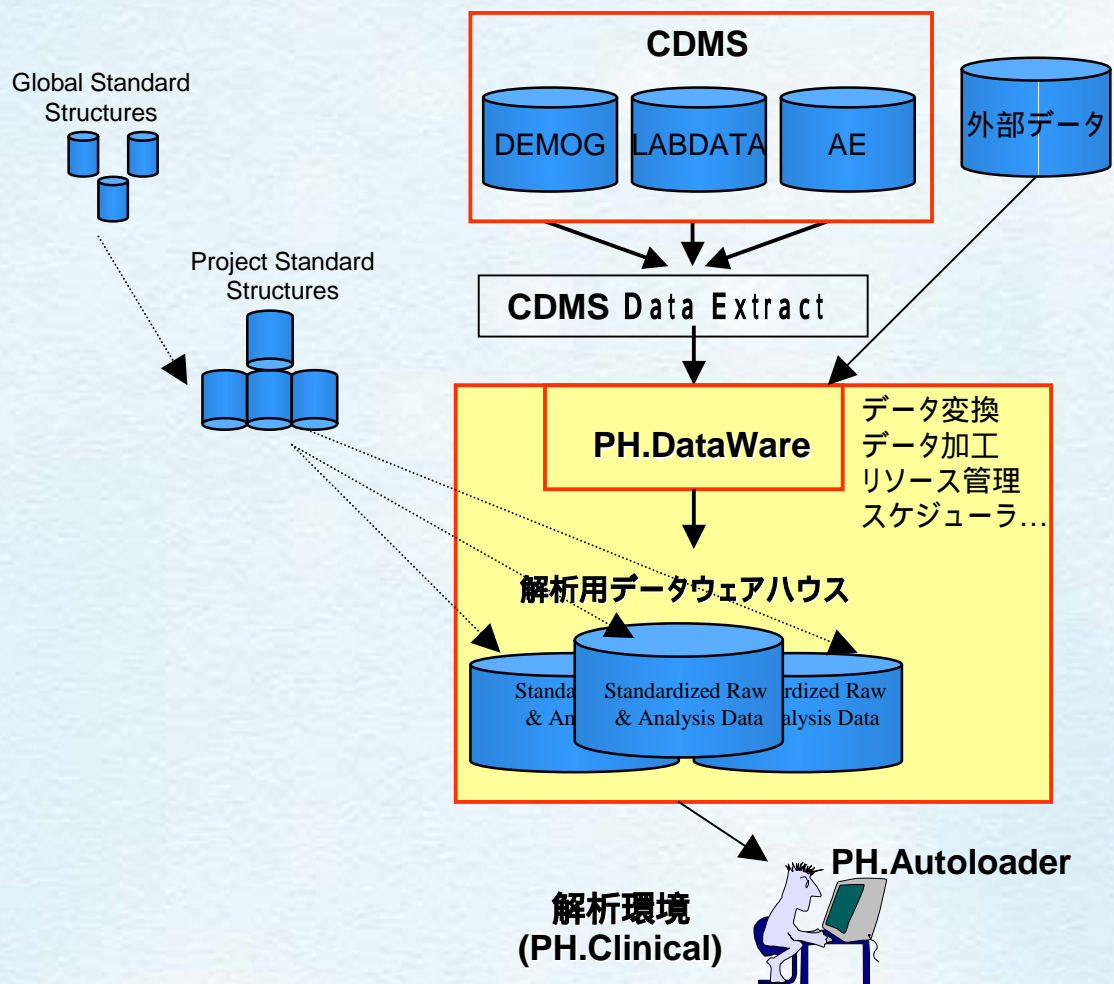
SAS Institute Japan LTD.

PS/インプリメンテーショングループ

平田 明弘

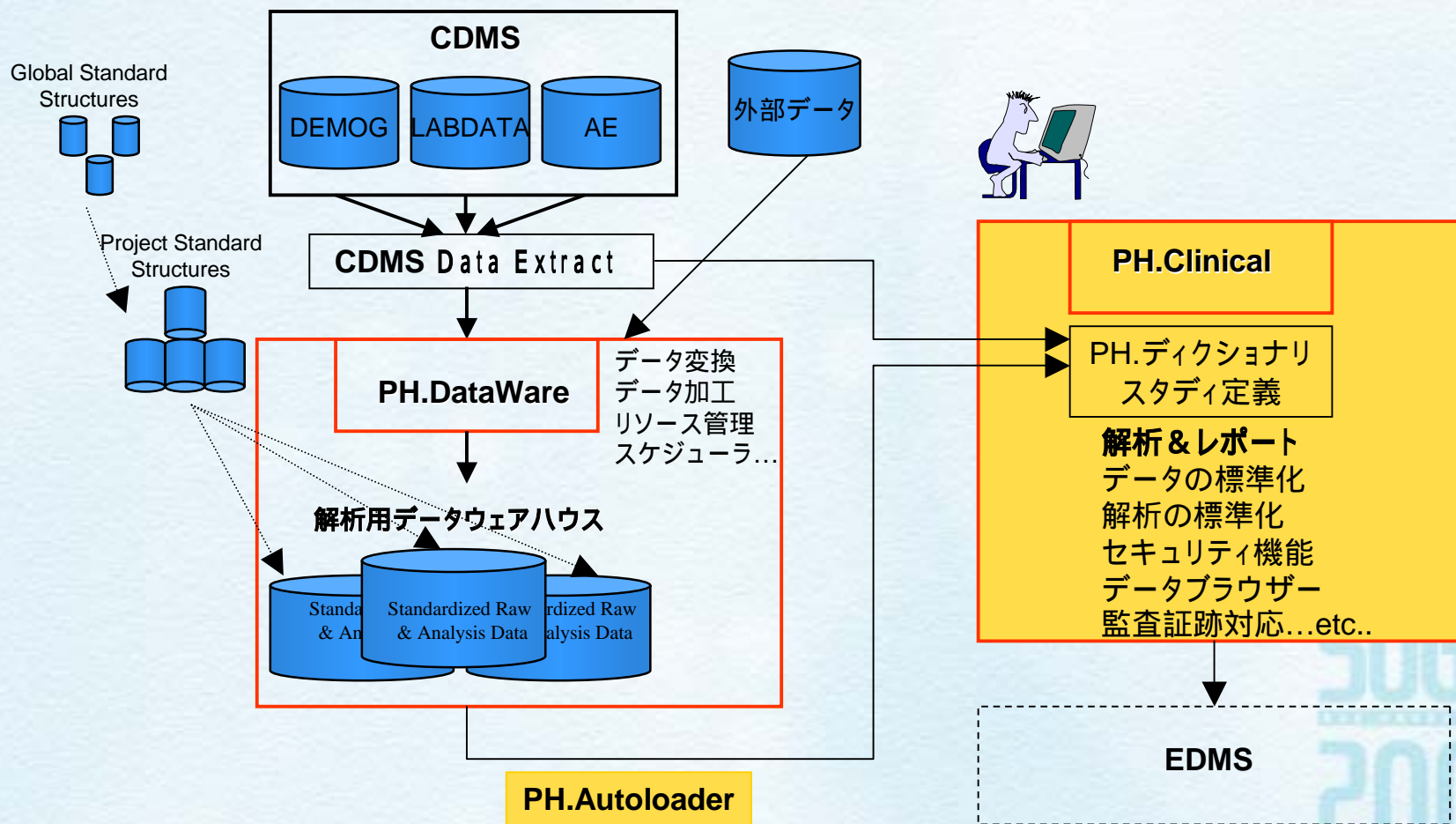
SASによる臨床解析支援ソリューション

解析データ作成・管理(PH.DataWareプロダクト)



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



Experiment of developing the PH.Template using SAS/ODS Part 2

Aug. 2, 2002

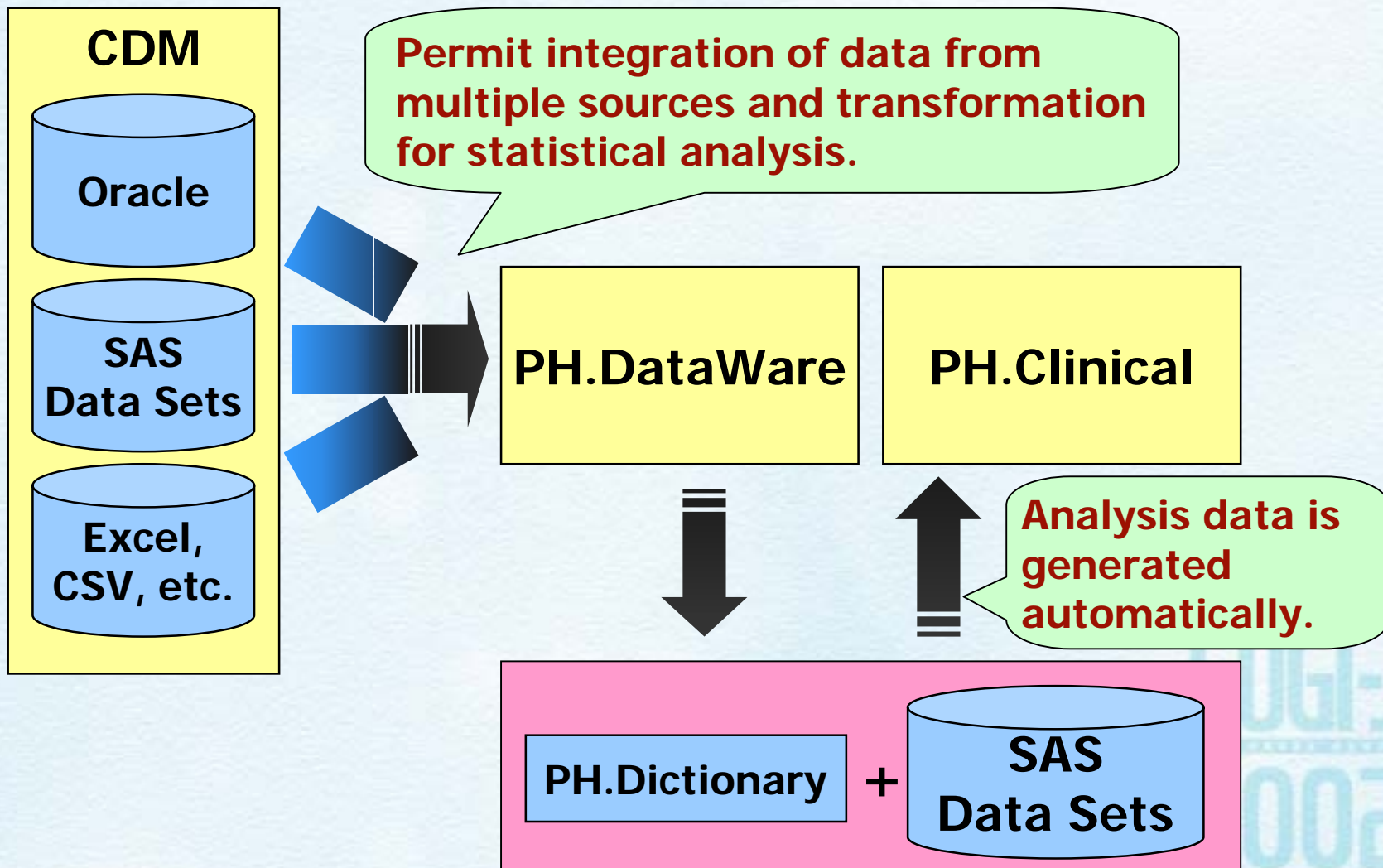
Biometrics, Japan Development Cent.

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



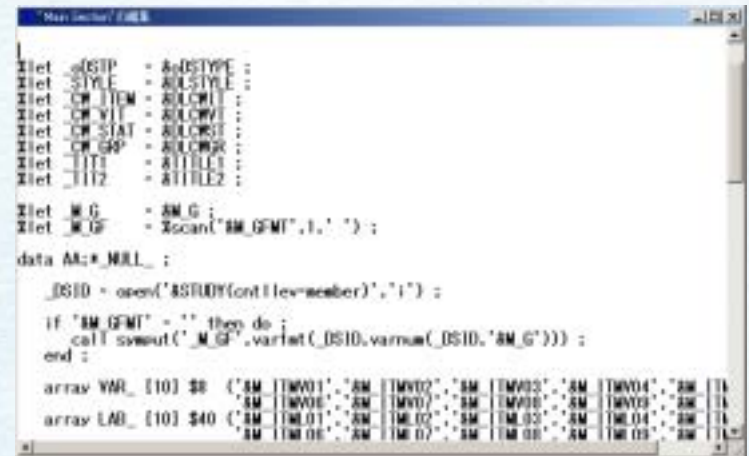
Realized it by using SAS macros

Components of PH.Template

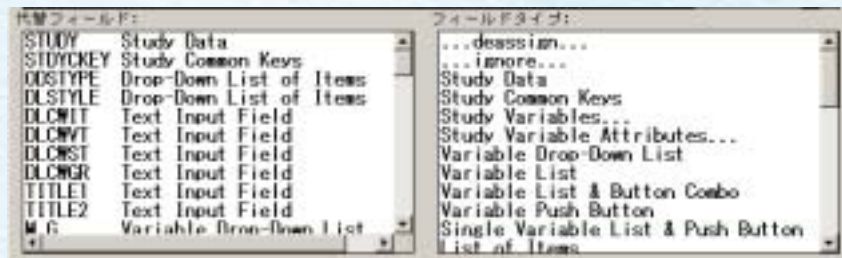
Customized Window



Code Section



Substitution Fields



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_ ;  
    %if &_ODSTP = HTML %then %do ;  
      call symput('_ODSMK', '***||'\R/HTML"<BR>"||'***') ;  
    %end ;  
    %if &_ODSTP = RTF %then %do ;  
      call symput('_ODSMK', '***||'\n'||'***') ;  
    %end ;  
  run ;  
  
  proc format cntlout = work.FORMAT(wher=(FMNAME=compress['*_  
run ;  
  
  proc sql noprint ;  
    select count(FMNAME) into :_M_GC from work.FORMAT ;  
  quit ;  
  
  %do j = 1 %to 10 ;  
  
    %if &&_ITMVA[ 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