

# 日中SAS友好活用：マルチランゲージ機能を活用した医薬品開発におけるプログラム開発

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## A case of Japan/China collaboration : SAS programming using Multi-language function in drug development

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## 要旨：

社内開発した全世界共通の解析環境を基に、日本と中国でローカル言語に対応したSAS環境を整えてきた。この2つの環境を活用し中国と日本が協力してCTD用の日本語の安全性帳票の作成を実現した事例を報告する。

キーワード：マルチランゲージ機能、中国語、CTD、安全性帳票

# AGENDA

- **BACKGROUND**
- *TECHNOROLOGY FOR REPORTING*
- *COLLABOLATION OF JAPAN/CHINA*
- *SUMMARY*

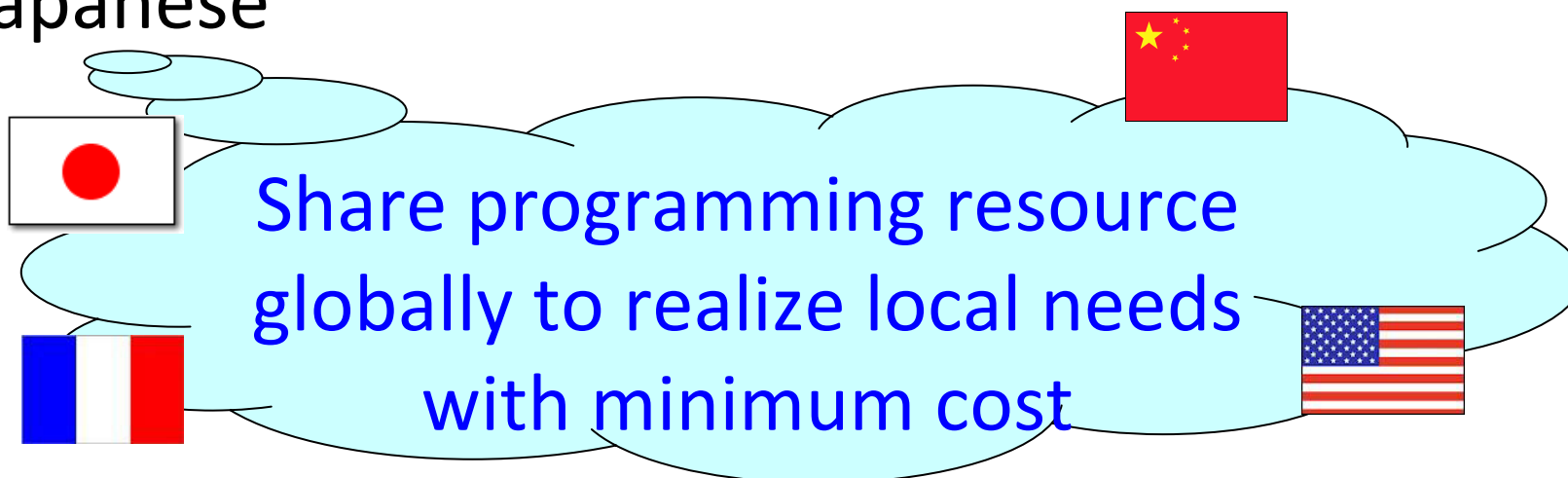
## Circumstances of pharmaceutical industry

- Pressure to decrease development cost
  - Loosing market due to expansion of generics
  - Need more investments to in-licensed products
  - Outsourcing, Offshore ( reduce fixed cost)

**Need to seek an efficient cost model for drug development**

## Our needs

- The number of studies conducted in Japan decrease, but submission task is increasing
- Most of the work for study level has been globalize, but for CTD preparation local language is mandatory for Module 2 in Japanese



## China site

- From 2009
- Members
  - Biostatistics & Programming organization in size of 30 – 40
  - 80% is SAS Programmer
- Beijing

## Solid business with China

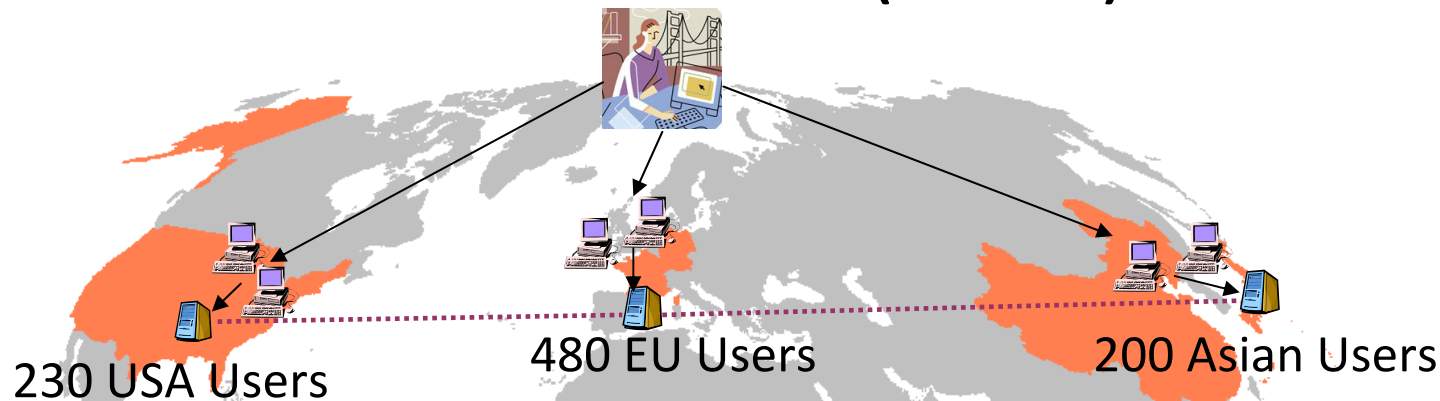
- Programming activity in Japan has been supported by China site colleagues over past two years.
- But still limited to produce the study outputs in English.

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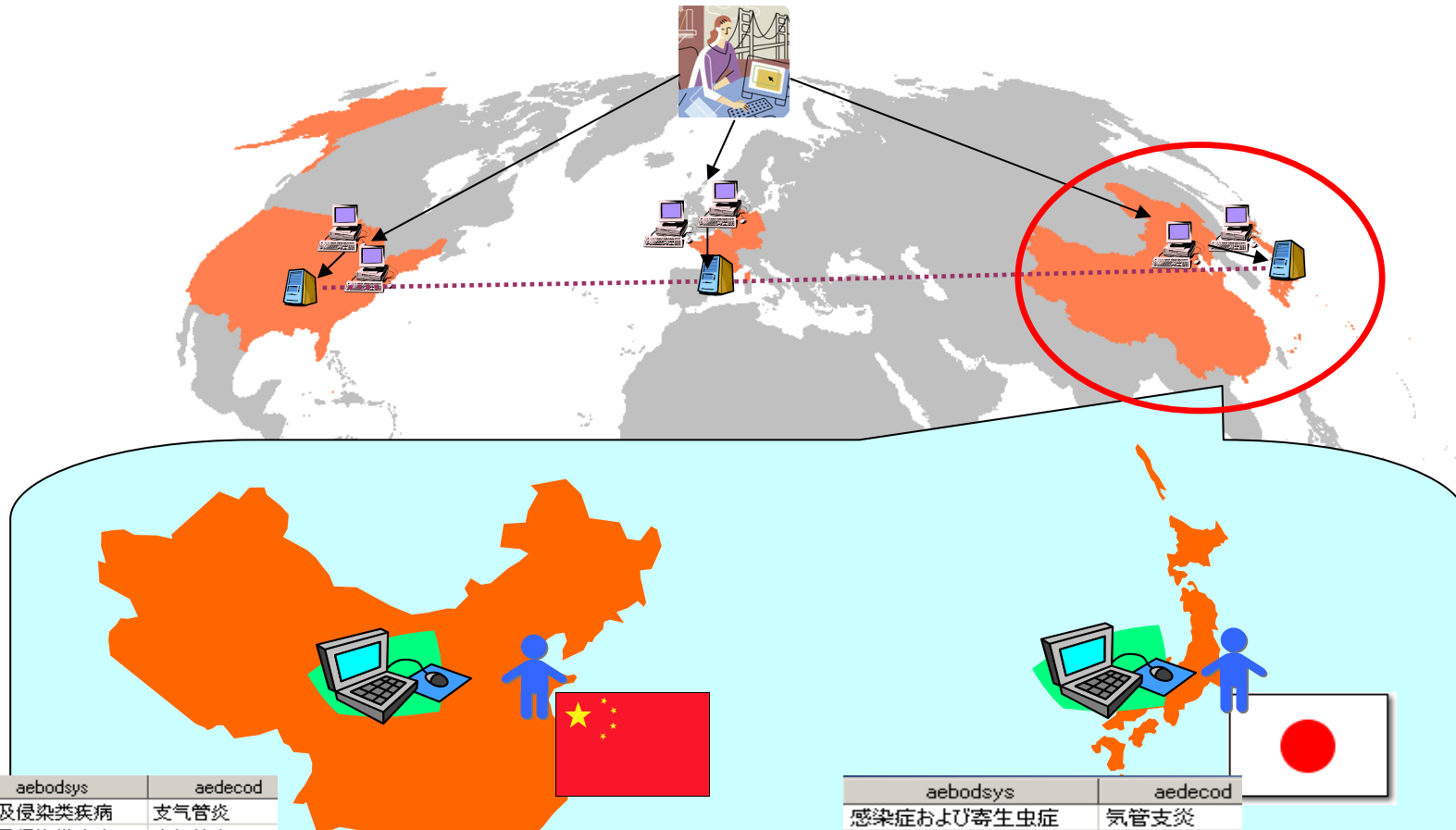


# WORLDWIDE INTEGRATED SAS Environment (WISE)



- deployed in July, 2008
- 1 UNIX server by continent (TK/Asia-GV/US-MP/EU) 
- Access through local citrix server 
- SAS9E

# How to handle "local needs"?



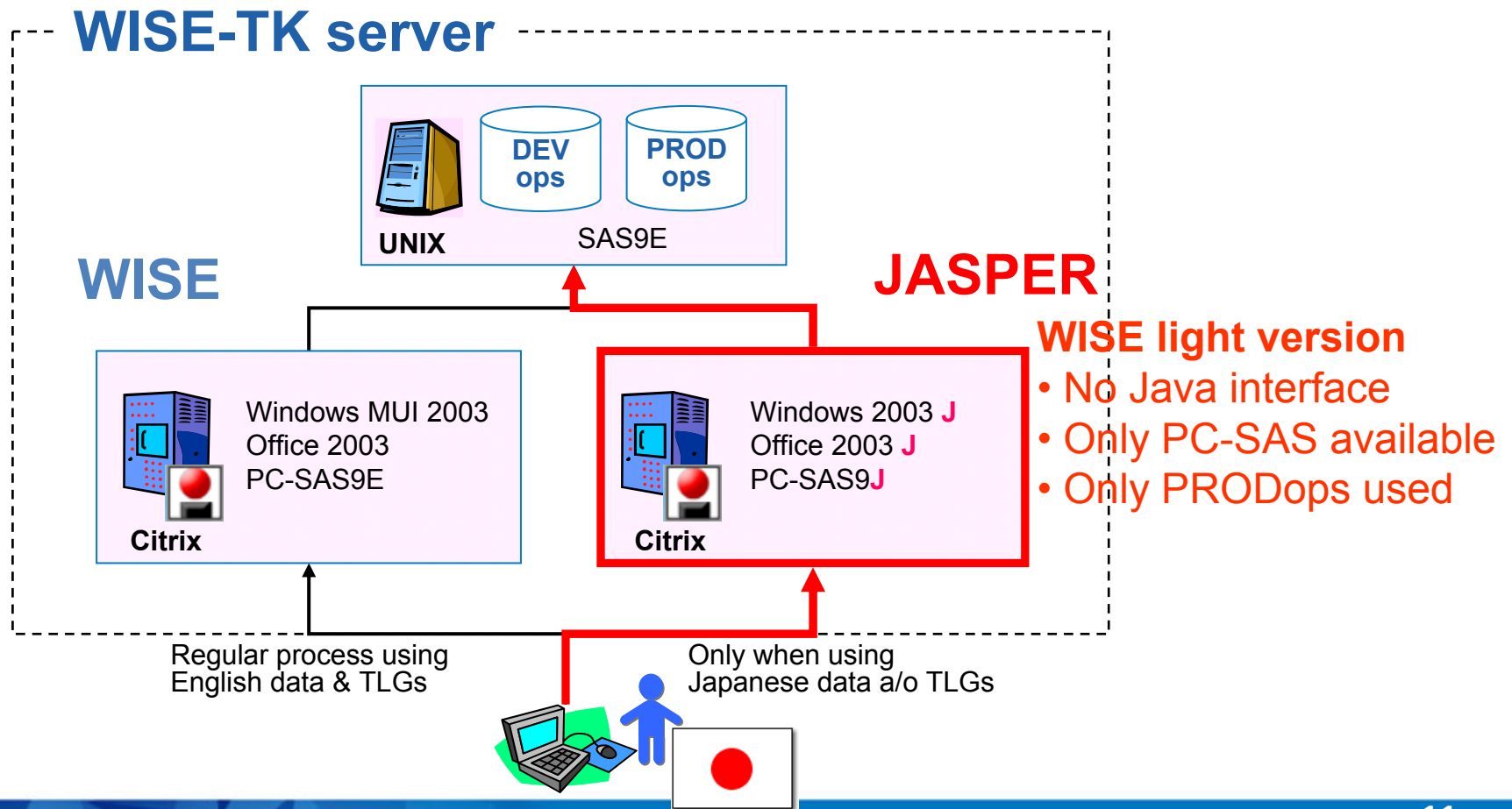
aebodsys	aedecod	Primary System Organ Class	
		Trt A (N=166)	Trt B (N=330)
	Preferred Term n(%)		
感染及侵染类疾病	支气管炎		
感染及侵染类疾病	支气管炎		
感染及侵染类疾病	鼻咽炎		
感染及侵染类疾病	鼻咽炎	144 (86.7%)	290 (87.9%)
感染及侵染类疾病	鼻咽炎		
感染及侵染类疾病	尿路感染		
	感染及侵染类疾病	62 (37.3%)	119 (36.1%)
	细菌性腹膜炎	19 (11.4%)	35 (10.6%)
	尿路感染	13 (7.8%)	17 (5.2%)
	鼻咽炎	5 (3.0%)	12 (3.6%)
	感染性肺炎	2 (1.2%)	12 (3.6%)
	支气管炎	4 (2.4%)	11 (3.3%)

aebodsys	aedecod	Primary System Organ Class	
		Trt A (N=166)	Trt B (N=330)
	Preferred Term n(%)		
感染症および寄生虫症	気管支炎		
感染症および寄生虫症	気管支炎		
感染症および寄生虫症	鼻咽炎		
感染症および寄生虫症	鼻咽炎	144 (86.7%)	290 (87.9%)
感染症および寄生虫症	鼻咽炎		
感染症および寄生虫症	尿路感染		
	感染症および寄生虫症	62 (37.3%)	119 (36.1%)
	細菌性腹膜炎	19 (11.4%)	35 (10.6%)
	尿路感染	13 (7.8%)	17 (5.2%)
	鼻咽炎	5 (3.0%)	12 (3.6%)
	肺炎	2 (1.2%)	12 (3.6%)
	気管支炎	4 (2.4%)	11 (3.3%)

# Japanese SAS Processing Environment for specific Reporting (JASPER)

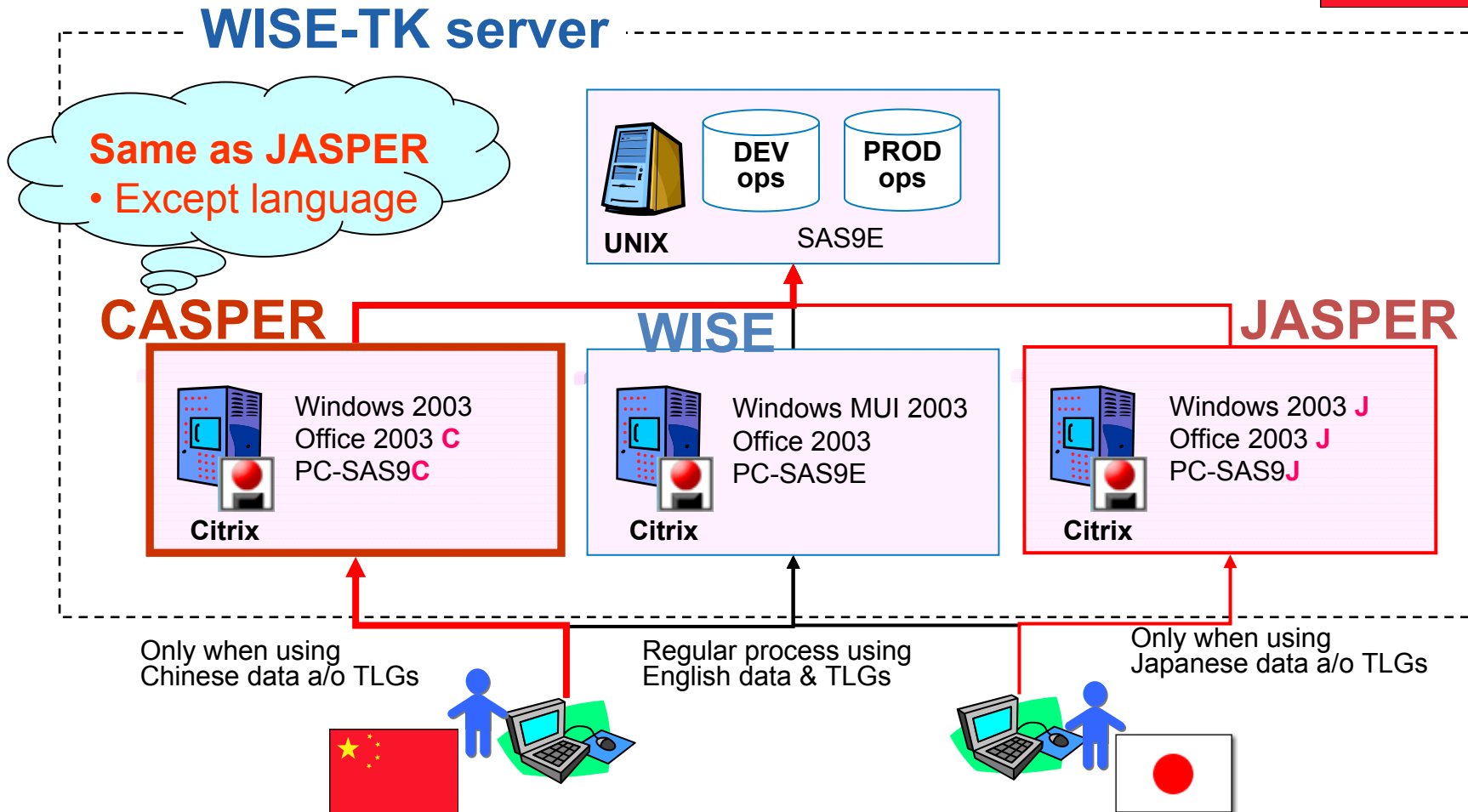
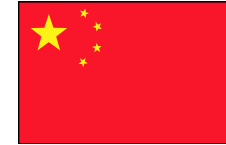


- deployed in January, 2009



# Chinese version of JASPER (**CASPER**)

- deployed in March, 2011



# *Fantastic* Reporting Tool: GStars

Global **S**tatistical **A**nalysis and **R**eporting **S**ystem

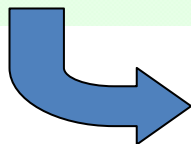
- to produce Table/Listing/Graphs (TLGs)
  - following sanofi-aventis standards
- *Industrial Revolution* in TLG creation
  - Before : Expensive custom-made TLGs
  - After: TLGs with global standard/quality at a minimum workload



# Fantastic Reporting Tool: GStars

- SAS macro compilation

```
%gsevent(filename = &pgmname
,pgmname = &pgmname
,dataset = adsd.adae (keep=usubjid aetrtefl aebodsys aedecod aesoc1fl aeorder aeptord)
,refds = adsd.addm
,recid = usubjid
,selpop = %str(safet
,withcond = %str(aetr
,varcol = %str(armar
,varlingrp = %str(aebo
,varlin = %str(aedec
,options = dest=app
dispfmt=npct
);
```



Adverse events data		
Treatment emergent adverse events (TEAEs)		
Number (%) of patients with TEAE(s) by Primary SOC and PT		
Safety population		
Primary System Organ Class	Trt A	Trt B
Preferred Term n(%)	(N=166)	(N=330)
Any class	144 (86.7%)	290 (87.9%)
Infections and infestations	62 (37.3%)	119 (36.1%)
Peritonitis bacterial	19 (11.4%)	35 (10.6%)
Urinary tract infection	13 (7.8%)	17 (5.2%)
Nasopharyngitis	5 (3.0%)	12 (3.6%)
Pneumonia	2 (1.2%)	12 (3.6%)
Bronchitis	4 (2.4%)	11 (3.3%)
Sepsis	2 (1.2%)	10 (3.0%)
Septic shock	4 (2.4%)	7 (2.1%)
Influenza	3 (1.8%)	6 (1.8%)
Erysipelae	2 (1.2%)	5 (1.5%)



# GStars in everywhere

## multi-language & compatibility



### English

aebodsys	aedecod
Infection and infestations	Gastroenteritis
Infection and infestations	Bronchitis
Infection and infestations	Viral infection
Infection and infestations	Exanthema subitum



```
%gsevent(filename = &pgmname
,pgmname = &pgmname
,dataset = adsd.adae (keep=usubjid aetrte
,refds = adsd.addm (keep=usubjid safety
,recid = usubjid
,selpop = %str(safety eq 'Y')
,withcond = %str(aetrtefl eq 'E' and aesoc1
,varcol = %str(armanffmt=aman. &coltrf
,va1inarp = %str(ae
```

### Chinese

aebodsys	aedecod
感染及侵染类疾病	胃肠炎
感染及侵染类疾病	支气管炎
感染及侵染类疾病	病毒感染
感染及侵染类疾病	幼儿急疹



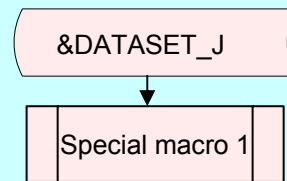
### Japanese

aebodsys	aedecod
感染症および寄生虫症	胃腸炎
感染症および寄生虫症	気管支炎
感染症および寄生虫症	ウイルス感染
感染症および寄生虫症	突発性発疹



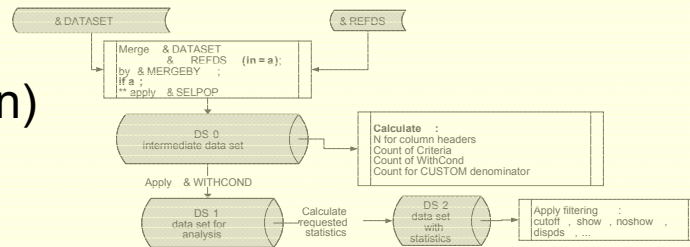
# Multi-language & Compatibility

Language control

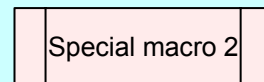


To manage some problematic 2-byte characters' code

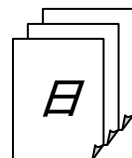
GStars  
(English version)



Language control



To display 2-byte characters' code correctly in a table





## 日本語出力

Primary System Organ Class Preferred Term n(%)	Drug A (N=xxx)
Any class	xxx (xx.x%)
感染症および寄生虫症	xxx (xx.x%)
上気道感染	xx (xx.x%)
胃腸炎	xx (xx.x%)
気管支炎	xx (xx.x%)
肺炎	xx (xx.x%)
突発性発疹	xx (xx.x%)
ウイルス感染	xx (xx.x%)
中耳炎	xx (xx.x%)
ウイルス性発疹	xx (xx.x%)
膿痂疹	xx (xx.x%)
口腔カンジダ症	xx (xx.x%)
せつ	xx (xx.x%)

## 中国語出力

Primary System Organ Class Preferred Term n(%)	Drug A (N=xxx)
Any class	xxx (xx.x%)
感染及侵染类疾病	xxx (xx.x%)
上呼吸道感染	xx (xx.x%)
胃肠炎	xx (xx.x%)
支气管炎	xx (xx.x%)
感染性肺炎	xx (xx.x%)
幼儿急疹	xx (xx.x%)
病毒感染	xx (xx.x%)
中耳炎	xx (xx.x%)
病毒性皮疹	xx (xx.x%)
脓疱病	xx (xx.x%)
口腔念珠菌病	xx (xx.x%)
疔	xx (xx.x%)

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## What's challenge to do the submission task in offshore site?

- Language
  - Japanese administration needs Japanese outputs for safety tables in submission documents
- Strategy
  - People of many departments have to discuss the strategy of submission, so usually recognized submission task need to be done by Japanese members

## Idea for new collaboration


- Would it be possible to develop programs for Japanese tables in Chinese environment?
  - Can be handle different language under the Multi-language environment
  - Many of the tables especially safety tables can be defined regardless of the submission strategy

# CASPER to JASPER (1)

- Step 1: Create and validate programs for AE tables using GStars in CASPER. The outputs (tables) are in Chinese in CASPER

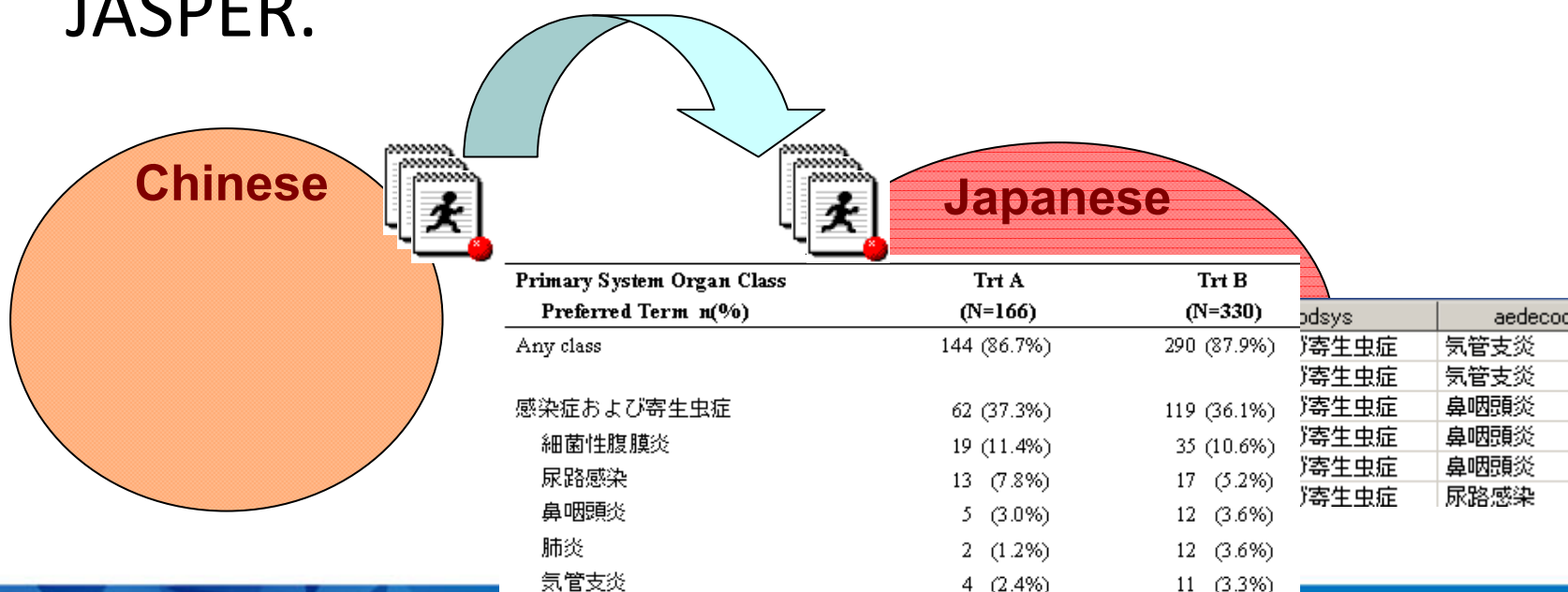
**Chinese**

aebodsys	aedecod		Trt A (N=166)	Trt B (N=330)
感染及侵染类疾病	支气管炎	<b>Primary System Organ Class</b> <b>Preferred Term n(%)</b>		
感染及侵染类疾病	支气管炎			
感染及侵染类疾病	鼻咽炎			
感染及侵染类疾病	鼻咽炎			
感染及侵染类疾病	鼻咽炎			
感染及侵染类疾病	尿路感染		Any class	144 (86.7%)
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		支气管炎	4 (2.4%)	11 (3.3%)



# CASPER to JASPER (2)

- Step 2: Transfer the validated programs into JASPER
- Step 3: Do the final execution and check in JASPER. The outputs are in Japanese in JASPER.



## Road of development

- A Chinese programmer who has been responsible for Japan support for past two years in China, visited Japan for 6 weeks
- She developed about 20 programs during her stay

## Communication with offshore site

- Many Japanese/Chinese staffs communicated between the sites in past 2 years
- Working under the same environment
  - SOP, Standards, Systems, Tools, Organization
- Easier to arrange staying the staff for some duration

Relation between the sites  
made it possible this great  
work-share!!



# Know-how during development (1)

- Sort order of the term of Adverse event
  - Avoid to use the variable as a sort base which includes local language

aedecod	aeptord
胃肠炎	3
支气管炎	1
病毒感染	4
幼儿急疹	2

Create variable for order to be consistent with English version

order by AEPTORD

Primary System Organ Class	Drug A
Preferred Term n(%)	(N=xxx)
Any class	xxx (xx.x%)
感染及侵染类疾病	xxx (xx.x%)
	(xx.x%)
	(xx.x%)
	(xx.x%)
	△△ (xx.x%)

Provide the same order with the English version

## Know-how during development (2)

- Validation
  - Visual, spot check in case there are garbled characters (文字化け).
- How to keep consistency of the program version
  - Made rules for transferring the programs
  - See the time stamp of the programs to confirm the consistency of them between the sites

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# Summary

## Standard/Tools

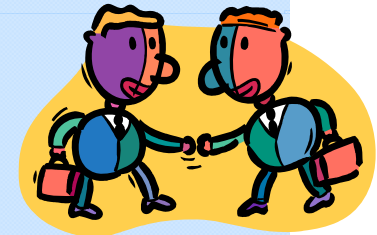
SOP, Template programs,  
WISE, GStars etc



Know-How  
High skills

## Site collaboration

Japan, China



High commitment  
Full assurance  
Respect

## Realize the mixture of Globalization & Localization

Produce Japanese outputs on Chinese  
environment!!

## 参考文献

- 2010年SASユーザー総会発表  
「“Standard Template Programs”の開発」