



GSTARs

Global Statistical Analysis & Reporting System

A strategy for Reporting

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Oct 18th 2010

Phuse Berlin

sanofi aventis

Because health matters



GSTARS ? You said GSTARS ?



GSTARS ? You said GSTARS ?

- GStars is the official internal SAS Standard reporting tool
 - for Biostatisticians & Programmers
 - Based on standard lay out discussed and defined by users
 - In the respect of the SA reporting strategy
- To perform
 - In texts and appendices : Tables, listings and Graphs (TLGs)
 - In a standard way
 - Across Therapeutic Area
 - For efficacy and safety result
 - With a limited programming efforts
- To support
 - Official report such as :
 - Key report memory
 - Clinical Study Report
 - Data management committees
 - Exploratory analysis
 - Ad hoc reporting



GSTARS ? You said GSTARS ?

- **Multiple SAS/OS Supported**
 - **SAS V8.12** – SAS9.1.3 – SAS9.2
 - HP UX – **Sun SOLARIS** – Windows **32/64GB**
- **8 related applications**
- **250 Worldwide internal direct users (B&P)**
 - **FRANCE - USA – Japan – China – Germany**
- **200 WW other users**
 - **Medical Affair- Pharmacovigilance – Trial Operation – Medical Writing**
 - **Few external users (CRO)**
- **2.5 Full Time Equivalents (FTEs)**
 - **Administration**
 - **Training**
 - **Enhancement**
 - **Support/maintenance**



You said internal ! why internal Solution ?



Decision with plenty experiences

In_House
Ex-Aventis

Input

• Stalistan

GIDB Lib
(Not limited)

Engine

In house Compiled
Macro Library

User Interface

SAS/AF

Template

Output n

• CDAR Reporting System

ADS
CDISC 3.0
(Not limited)

CR Toolkit™
Compiled
Macro Library

Ex-ay
custo
mizati
on
macro

Web,
Java,
HTML

Generic

Template

Output n

• AdClin

ADS
CDISC 2.6
(Not limited)

AdClin™
Compiled Macro
Library

Project n

Output n

Vender
Customized
Ex-Aventis

Vender
Ex-Sanofi



In house stat reporting strategy

GStars team (WG & DEV) positioned itself as/for:

■ **Close watch and in line with new standards**

- After merge 2 systems : Adclin vs Stalistan
- 2005 Stat Output Standard
- 2006 s-a Good Programming Practice
- 2007 Safety Guideline
- 2009 Standard TLG Template
- 2010 eCSR Standard

■ **Flexible and aggressive to satisfy WW users**

- Adapting legacy programs and output packaging
- Play as a validation tool for non-GStars study reporting
- Take care WW and local eCTD needs

■ **Submission readiness**

- Constantly evolving per inter-department needs
- Produce different output formats (ASCII, RTF, PDF, XML)
- Create RTF in-text tables without re-typing in the CSR



Route to an In-House Reporting System

Persuasive features for the In House Development

■ Manageability

- For the s-a evolving standards
- Cost effectiveness
- Release Stat reporting resources for more challenging work

■ Scalability

- Streamline interdepartmental workflow and needs
- Multiple phases / Module development
- One macro engine / metadata for multi sites deployment
- Adapting new technology

■ Portability

- Across computing platforms, SAS versions, Languages
- Readiness for DMC, FDA and contract CRO
- License and version controls for external usage



GStars

Reporting Modules



GSTARS : Main principles

■ 9 major tablemodules

- %GSCAT
- %GSEVENT
- %GSCONT
- %GSCONTHS

- %GSSUMM
- %GSTTE
- %GSRTF
- %GSLIST

- %GSWPCSA1

■ 2 custom modules

- %GSCUST
- %GSCUSTG

■ 7 Graphic module

- %GTSurv
- %GTForest
- %GTppForest

- %GTLine
- %GTBar
- %GTBox

- %GTScatter

■ A reference macro for metadata %Reflist



GStars LAYOUT: In-Text

title1
 title2 title2
 title3 title3 title3
 title4 title4 title4 title4
 title5 title5 title5 title5 title5
 title6 title6 title6 title6 title6 title6

	ACTIVE 1 (N=123)	ACTIVE 2 (N=125)	ACTIVE 3 (N=126)	Placebo (N=127)
Age (years)				
Number	123	125	126	127
Mean (SD)	35.5 (13.6)	37.0 (15.1)	37.8 (14.8)	36.9 (13.6)
Median	36.0	37.0	37.0	37.0
Min : Max	12 : 65	12 : 72	12 : 72	12 : 67
Race				
White	114 (92.7%)	110 (88.0%)	116 (92.1%)	118 (92.9%)
Black	7 (5.7%)	14 (11.2%)	8 (6.3%)	9 (7.1%)
Asian/Oriental	2 (1.6%)	1 (0.8%)	2 (1.6%)	0

footnote1
 footnote2 footnote2
 footnote3 footnote3 footnote3
 footnote4 footnote4 footnote4 footnote4
 footnote5 footnote5 footnote5 footnote5 footnote5
 footnote6 footnote6 footnote6 footnote6 footnote6 footnote6
 footnote7 footnote7 footnote7 footnote7 footnote7 footnote7 footnote7
 footnote8 footnote8 footnote8 footnote8 footnote8 footnote8 footnote8 footnote8
 PGM=DEVOPS/ZZZ_ADMIN/GSTARS/V0210/REPORT/PGM/gstars_layout.sas OUT=REPORT/OUTPUT/gstars_layout_itrf(27JAN2009 - 12.01)



GStars LAYOUT: End-of-Text

Project Code / Study Number / Analysis: ZZZ_ADMIN / GSTARS / V0210

title1

title2 title2

title3 title3 title3

title4 title4 title4 title4

title5 title5 title5 title5 title5

title6 title6 title6 title6 title6 title6

I

	ACTIVE 1 (N=123)	ACTIVE 2 (N=125)	ACTIVE 3 (N=126)	Placebo (N=127)
Age (years)				
Number	123	125	126	127
Mean (SD)	35.5 (13.6)	37.0 (15.1)	37.8 (14.8)	36.9 (13.6)
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□

footnote1

footnote2 footnote2

footnote3 footnote3 footnote3

footnote4 footnote4 footnote4 footnote4

footnote5 footnote5 footnote5 footnote5 footnote5

footnote6 footnote6 footnote6 footnote6 footnote6 footnote6

footnote7 footnote7 footnote7 footnote7 footnote7 footnote7 footnote7

footnote8 footnote8 footnote8 footnote8 footnote8 footnote8 footnote8 footnote8

PGM=DEVOPS/ZZZ_ADMIN/GSTARS/V0210/REPORT/PGM/gstars_layout.sas OUT=REPORT/OUTPUT/gstars_layout_x.rtf(27JAN2009 - 12:01)



Metadata



■ SAS Metadata are created to manage

■ GSTARS in it environment to define :

- user access to the application
- Compound/Study declaration
- GSTARS Version
- SAS Version
- Computing Environment
 - Study architecture
 - OS (Sun – HP – Windows)
- Language (JP/EN/CH)

■ Setup the study in term of

- Level of security (internal/external)
- Macro usage
- Titles / Footnote
- DMC/CSR/IA/...



GSTARS Companions



Deliverable packaging - GSPACK

- **GSPACK Deliverable packaging - RTF file compilation with**
 - Table of Content (TOC)
 - Section tag insertion
 - Total page counter insertion
 - Bookmark flagging (for PDF)
- **GSFormatter - RTF 2 DOC**
 - An **outside** GStars (SAS) utility (Visual Basic Script)
 - RTF to DOC conversion
 - Storage control on the SAS environment
 - WORD compatibility (for 2000-2003 ASCII output)
 - Graphic resizing and link breaking (x, y proportion re-calc)
 - Conversion acceleration (turn off utility like Spelling Check)
 - Section and total page recount

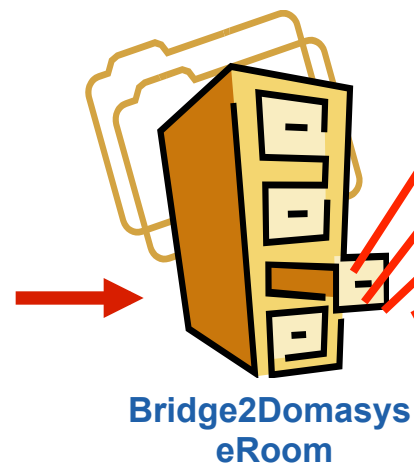
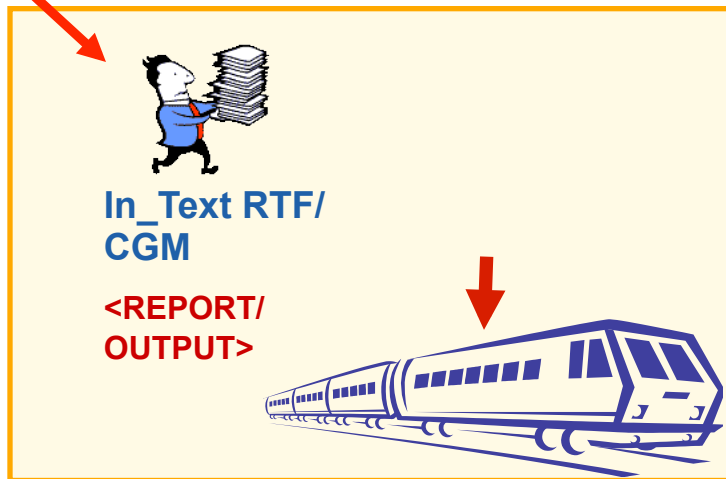


gsformatter - RTF 2 DOC

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In_Text TLGs Auto Insertion



DOMASYS



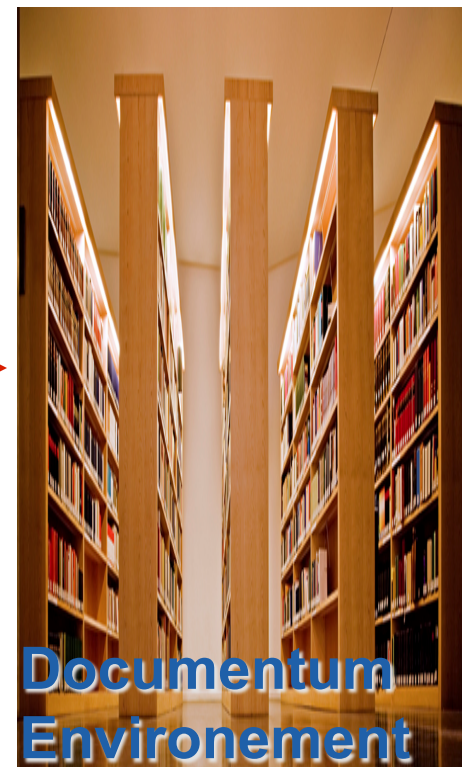


GET – Gstars Exchange Tool

SAS Environment



Appendix PDF
<DOC/APPENDIX>



Documentum
Environnement



Results Upload BY Statistical Reports

 Automatic loading tool to ClinicalTrial.gov (in development)

PRS RESULTS DATA ENTRY TEST SYSTEM



ClinicalTrials.gov
Protocol Registration System





Results: Adverse Event Overview: [Edit Other \(Not Including Serious\) Adverse Event Total](#)

Title: A Trial with dronedarone to prevent Hospitalization or death... NCT00174785 ID: EFC5555

Please enter the number of participants affected and at risk as integers.

	Dronedarone 400mg Bid <i>Dronedarone tablets 400mg twic...</i>	Placebo <i>Matching placebo tablets</i>	
	# Affected *	# at Risk *	
Other Adverse Event(s)			
Total	1584	2291	1527 2313



External Package



DMC External Preparation : Windows version

■ For CRO

■ Complete outsourcing

- Application installation + training
- Save Cost and time at the end....

■ IA: Interim Analysis

- Including training and feasibility assessment
- Installation of Gstars to an external organization

■ DMC : DATA MONITORING COMMITTEE

- Including feasibility assessment, training and installation
- Preparation of the complete analysis program in house
 - Mean that these programs are usable internally for the final analysis (Time and cost saving)



GSTARS Regional Specific Accommodation



Japan - kanji

- Objective filled :
 - Safety Main tables for local submission
 - Local Medical Affair studies
 - Global supportive studies for jp submission
- Shift-JIS encoded dataset and report with MS Gothic font display <JP official standard>
- Double Byte Character Set (DBCS) triggered SAS-J <JASPER>
- Native SAS PROC output in Japanese



Regional Solutions

JP specific version metadata needed p-values extraction

	method	sasver	keyterm
1	CHI		× 2 乗値
2	CMH_GEN		一般連関統計量
3	CMH_NONZ		相関統計量
4	CMH_RM_TABLE		ANOVA 統計量
5	CMH_RM_RIDIT		ANOVA 統計量
6	CMH_RM_RANK		ANOVA 統計量
7	KW		ANOVA 統計量
8	VE		ANOVA 統計量

Table example

Project Code / Study Number / Analysis: TEST / TEST / TEST

Primary System Organ Class Preferred Term	Alfuzosin 10 mg (N=129)
Any class	126 (97.7%)
臨床検査	4 (3.1%)
血中アルカリホスファターゼ増加	2 (1.6%)
尿中蛋白陽性	1 (0.8%)
白血球数減少	1 (0.8%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5 (3.9%)
胃癌	2 (1.6%)
結腸癌	2 (1.6%)
リンパ節転移	1 (0.8%)
肝転移	1 (0.8%)
骨転移	1 (0.8%)
食道癌	1 (0.8%)
前立腺癌	1 (0.8%)
皮膚の新生物	1 (0.8%)
膀胱癌	1 (0.8%)



China

- Objective filled :
 - Safety Main tables for local submission
 - Local Medical Affair studies
 - Global supportive studies for China submission
- EUC_CN encoded dataset and report with Sim-Song font display <CN official standard>
- Double Byte Character Set (DBCS) triggered SAS-CN
- Native SAS PROC output in Chinese

What About Korea ?



NEXT step & Conclusion



NEW version in scopping phase: GSTARS

3

- **Re-foundation with SAS9.2**
 - Integration of reporting and graph new facilities
 - Flexible reporting components for submission package: PP, PN
- **A new companion**
 - **GC-GENERATOR : GStars Code Generator**
 - A executable simple Code maker



Conclusion

A success story

■ Based on user standards

- Without standard development is an adventure

■ 250 daily users (B&P + CDM)

■ 190 active studies (PH 1 to IIIB)

■ Success keys

■ User Involvement

- User Champions network (USN)
- Trainers network
- Permanent working group manage by USN to
 - Prioritize
 - Escalate needs
 - Initiate exchange

■ Dedicated and WW team resources to

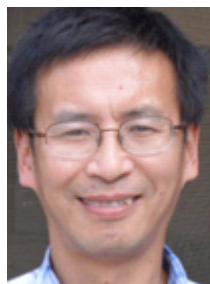
- Administrate
- Support
- Enhance
- Train



A dedicated WW and efficient team...



R. Spearman



J. Yu



C. Anderson

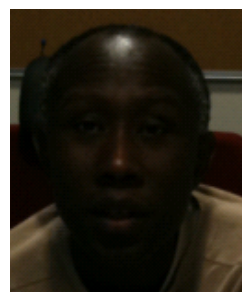


H. Guimard

7 young cannibals



P. Tan



M. Sebai



E. Sun
RL SAS