



## Closing - PhUSE Single Day Events, Tokyo, 31<sup>st</sup> Oct 2014

Why today?  
What & why PhUSE?  
What's next?

Link to Prezi



[http://prezi.com/p77zfstdrzs/present/?auth\\_key=4d37wvn&follow=cdxkkg\\_3ylu&kw=present-p77zfstdrzs&rc=ref-102376387](http://prezi.com/p77zfstdrzs/present/?auth_key=4d37wvn&follow=cdxkkg_3ylu&kw=present-p77zfstdrzs&rc=ref-102376387)

# Why today?



Let's come out of the shadows while fortune smiles

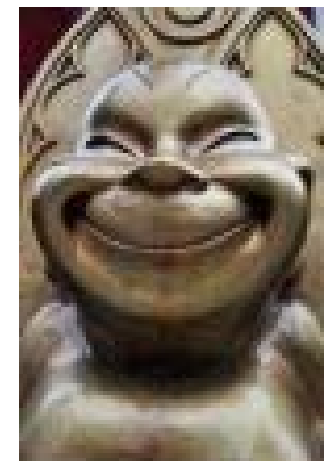
- プログラムする人って, もっと評価されて, いいのでは?
- 今がチャンス・・・2つのチャンスを活かしましょう

Chance 1 :

NDA Submission team

Chance 2 :

Paradigm Shift



# e.g. Statistical Programmer(SP)

## - a little-known amazing person



- High-skilled in SAS **programming**
- Develop, Review and Check Spec. of **SDTM & ADaM** in an actual study
- Follow and Apply **Global** standards, Regulations and Rules
- Understand what is **Clinical Trials**
- Understand clinical meaning of **TLG** in **CSR**
- Have a general knowledge of **Biostatistics**
- **Lead and Cultivate** junior programmers
- Embody a Spirit of **Teamwork**
- Never overlook even a small **mistake**
- Strong **Communications Skills** (Biostatistician, Project Leader: PL, Data Management and etc.)
- Precisely Management of **Time and Resources** for CSR Development under big pressure of PL
- Overcome a hard schedule of NDA submission with **never complaining**



Let's come out of the shadows

- **Amazing skilful/knowledgeable person,**
- but a little-known in almost of all offices especially in Japan**
- **Same as other attendees today?**

凄いんだけど地味

# Why today?



Let's come out of the shadows while fortune smiles

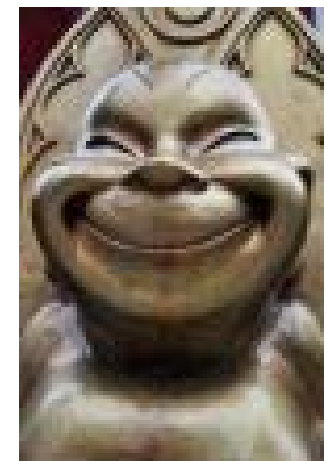
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Chance 1:  
Let's jump into **NDA Submission team**



- NDA Submission – **Crucial Event** for Pharma Company

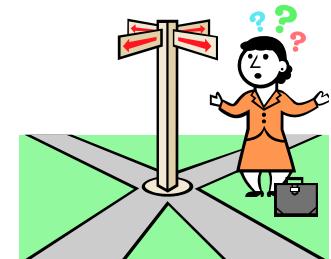


申請は極めて大事なイベント

- Rare Opportunity – **eData NDA Submission** is starting
  - we can be indispensable person, indispensable CRO, indispensable Vendor

- Your Choice

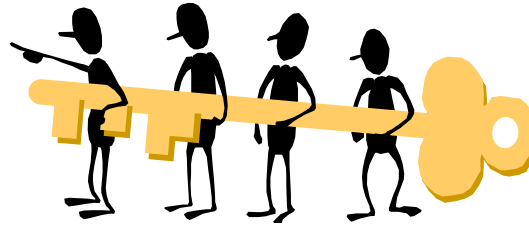
- **Mission-Critical Person or Lose your Status**
- Fork in the road in your life



人生の分かれ道

- Welcome Specialists
  - **Let's come out of the shadows**

## Chance 2: Paradigm Shift



Increasing “No one makes it **alone**”

We need **you** because “No one makes it **alone**”

**Consider a lot of Alone** ... 脚下照顧 → **Alone**をどう捉えるか？

only Pharma, only CRO, only PMDA, only Academia, only Vendor

only Biostatistics, only DM, only CRA, only Physician,

only Japan, only Asia, only EU, only US...

Welcome Specialists

— **Let's come out of the shadows**

パラダイムシフト: 世の中の変化を敏感に捉え・・・  
「一人じゃ何も出来ない」って気付けるか否か？  
特に、ソフトウェアが絡む世界では重要

# What is PhUSE?



Pharmaceutical Users Software Exchange [www.phuse.eu](http://www.phuse.eu)

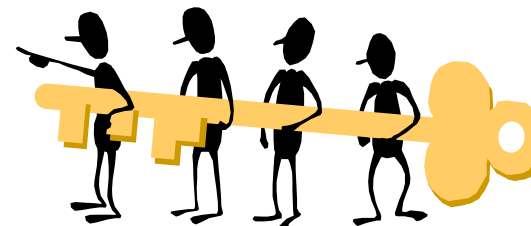
Welcome to  
our website

- Global Group of Programmers, Statisticians, Data Scientists
  - Vendor Neutral, Inclusive and Open
- 
- PhUSEはプログラマの意見交換会から発展したNPO
  - プログラマ, 生物統計家, データ・サイエンティストの国際グループ
  - ベンダーに対し中立的で, 包括的かつオープン

## Mission:

### Provide Platform for

- Creating & Sharing Ideas
- Implementing Tools & Standards around Data
- Exploring Innovative Methods and Technologies



「一人じゃ何も出来ない」って気付いた人の  
意見交換&活動の場



# Why PhUSE?



## Aims and Scope:

Topics include but are **not limited to**:

- Statistical programming
- Representation of clinical data
- Fundamental programming techniques and macros
- Publishing of results
- Electronic submission of clinical data
- Statistical Routines
- Laboratory data
- Pharmacokinetic and Pharmacodynamic programming
- Program and Application development
- Software development lifecycle
- Validation and quality management
- Development, implementation and use of clinical data management, remote data capture and Pharmacovigilance systems
- Regulatory environment and regulations
- Development of standards
- **CDISC Implementation** ←今回
- Use and implementation of medical dictionaries
- Project and resource planning
- Working with consultants/ CROs
- Off-shoring and working in global teams
- Metrics
- Training and education programs
- Infrastructure and IT support

今回はCDISCをテーマにしましたが、PhUSEは上記のように何でもありで、最新のトピックスを中立的なユーザーの観点で意見交換できる点が強み



## Members Benefit

### Benefit to attend

- Annual Conference
- Annual Computational Science Symposium(CSS)
- Single Day Events (SDE)

### News & Training

- PhUSE News
- One day training courses
- Various e-learning courses

### PhUSE Archives

- keynotes presentation (videos)
- papers and presentations from past conferences

### PhUSE Wiki and PhUSE Discussion Forum

- Learn from the industry experts and expand your skill sets
- Get an opportunity to connect with people through PhUSE conferences networking and volunteering opportunities various other knowledge resources such as

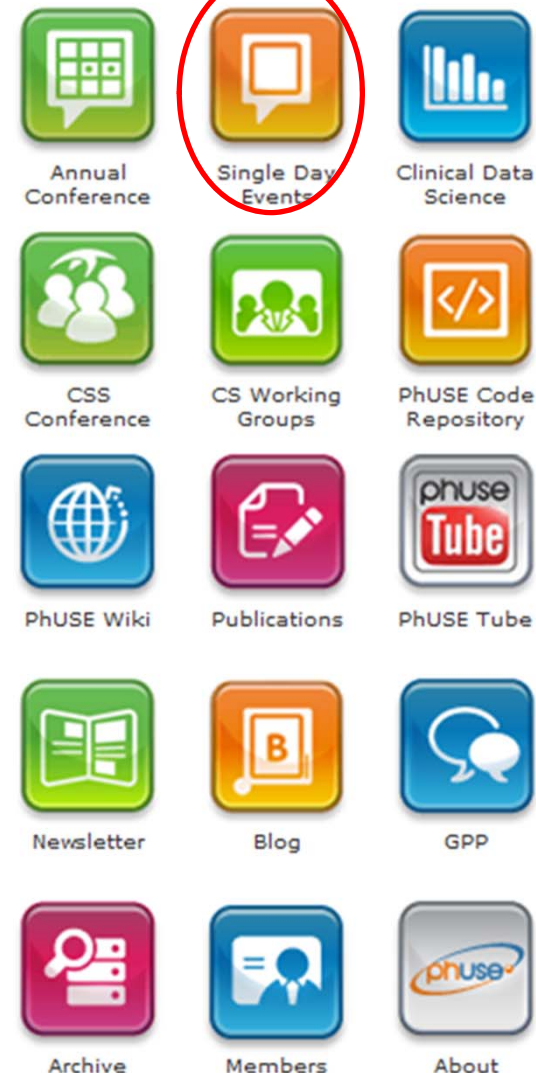
# Why PhUSE?

会員でなくても, ほとんどの資料に  
アクセス&ダウンロード可です。

太っ腹というか, ミッションの通り



是非, 覗いてみて!



# PhUSE Events in FY2014



| Location           | Date             | Theme                                                       |
|--------------------|------------------|-------------------------------------------------------------|
| Frankfurt Germany  | 6-May            | Implementing Standards & Custom-Tailored Solutions          |
| Boston USA         | 7-May            | Dataset Submissions: Documentation & Strategy               |
| London UK          | 22-May           | Clinical Trial Disclosure & Transparency                    |
| Copenhagen Denmark | 22-Jun           | Data Transparency & Traceability                            |
| Basel Switzerland  | 3-Jul            | Data Visualisation                                          |
| Indianapolis USA   | 15-Jul           | Transparency in Clinical Research                           |
| Chennai/Pune India | 19-Jul           | Graphs Programming and Visualisation using Varied Platforms |
| Durham USA         | 5-Aug            | Outsourcing                                                 |
| Bridgewater USA    | 20-Aug           | Standards Implementation                                    |
| Brussels Belgium   | 18-Sep           | Happy ADaM-ing                                              |
| San Francisco USA  | 26-Sep           | Data Visualization                                          |
| London UK          | 12 to 15 - Oct   | <b>Annual Conference:</b> Data Transparency                 |
| <b>Tokyo Japan</b> | <b>31-Oct</b>    | <b>Standard Data Implementation and Validation</b>          |
| Shanghai China     | 28-Nov           | Focus on ADaM and TFL Standardization                       |
| Silver Spring USA  | 15 to 17 - March | Annual <b>Computational Science Symposium</b>               |

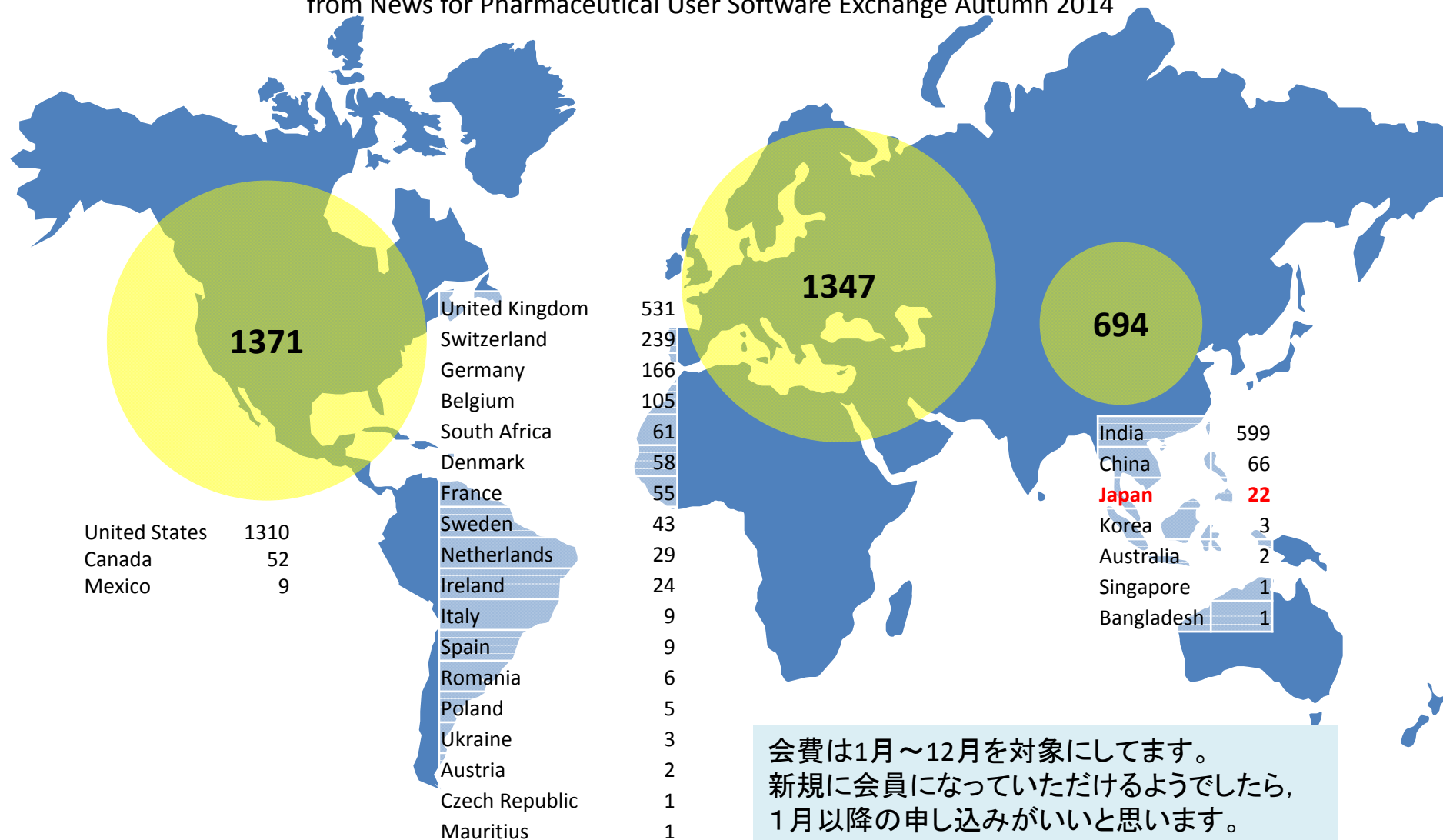
今年度は13 のSDE(CDISC 6, Disclosure 3, other 4), カンファレンス&シンポジウムを終了または準備中。  
本日のものを含め, 地域対抗意識を利用した「頑張った資料」が保存されてます。しかも誰でもダウンロード可。

# Membership Figures



Total Members 3412

from News for Pharmaceutical User Software Exchange Autumn 2014



# What's next?



Two – Single Day Events Planned in FY 2015

(来年はSDEを最低2回はやります！)

SDE 1:

Topic – Clinical Trial Disclosure & Transparency (仮題)」

Where – TBD

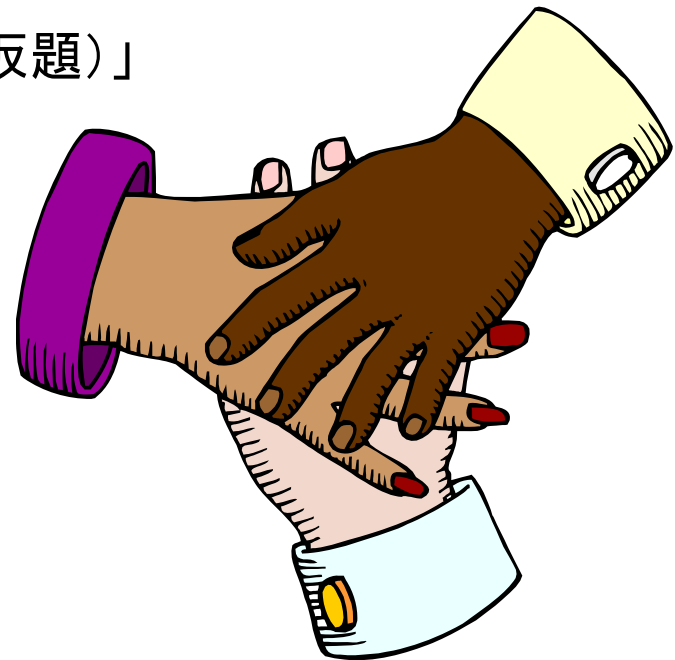
When – Around June 2015

SDE 2:

Topic – TBD

Where – TBD

When – TBD (Around Autumn to Winter 2015)



お疲れさま  
参加いただいたみなさん・・・主役はあなた  
Speakers & Japan working Group

| Speakers Today | Japan Working Group |
|----------------|---------------------|
| Ippei Akiya    | Yoshiteru CHIBA     |
| Kunihito Ebi   | Akira Soma          |
| Masami Ohchi   | Ippei Akiya         |
| Max Kanevsky   | Kazuo Shinozu       |
| Yohei Takanami | Koichi Yamaguchi    |
| Yuki Ando      | Yoshiko Kitagawa    |
| Yumiko Asami   | Yoichi Higashibeppu |

ありがとう , Thanks  
Sponsors & Global Supporters

Sponsors:

|                  |                                                                                                                                                                                                                                                                   |
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Ajay, Nand, Trudy, Adie, Steve, Frank, Yuguang