

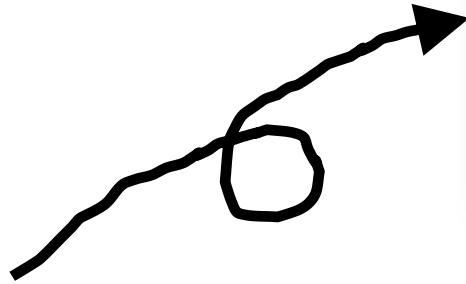


WHAT IS “PhUSE”

CJUG SDTM
LISaS Team
8th March 2012

What is “PhUSE”

- **Ph**armaceutical
- **U**sers
- **S**oftware
- **E**xchange



- In 2004, Stephen Bamford (he headed up Pfizer's Phase I Programming Group) started and The inaugural PhUSE Conference was held in Germany on October 2005.

Homepage

- <http://www.phuse.eu/>

The screenshot displays the PhUSE homepage layout. At the top left is the PhUSE logo. Below it is a 'twitter feed' section with three tweets. To the right is a grid of 12 icons, each with a label: FDA/PhUSE, Annual Conference, Single Day Events, PhUSE Wiki, The Journal, PhUSE Tube, Newsletter, Blog, Forum, Archive, Members, and About. On the far right, a vertical sidebar contains sections for 'PhUSE 12', 'Today Mo 2012', 'Wiki Upda', 'Latest Blo', 'Latest Fo', 'PhUSE Ou Award 20', 'PhUSE co', 'What's be', and 'Events'.

twitter feed

PhUSETwitta Processes – To be or not to be: Processes play a very important part in our job. However ensuring successful imp... bit.ly/WeCcci
10 hours ago · reply · retweet · favorite

PhUSETwitta #FDA/#PhUSE CSS are looking for new projects to advance computational science related to drug development. ow.ly/fSsrw
10 days ago · reply · retweet · favorite

PhUSETwitta @nickdownie The presentations are finally all available. ow.ly/fMNJF #phuse12
13 days ago · reply · retweet · favorite

PhUSETwitta Moving Forward with PDUFA V: Just how standard is standard?: With the recent approval of PDUFA V, there are some... bit.ly/11r0UpP
13 days ago · reply · retweet · favorite

Navigation Grid:

- FDA/PhUSE
- Annual Conference
- Single Day Events
- PhUSE Wiki
- The Journal
- PhUSE Tube
- Newsletter
- Blog
- Forum
- Archive
- Members
- About

Right Sidebar:

- PhUSE 12
- Today Mo 2012
- Wiki Upda
- 1. Code S Updated 10
- A standard every prog header is b
- Latest Blo
- Processe: Anindita Bl Processes our job. Ho implement
- Latest Fo
- PhUSE Ou Award 20 Adrienne E doesnt this
- PhUSE co
- What's be
- 16 days ag
- 2 months a Documents
- 2 months a
- Events
- 2013 Men Details for Tue 01 Jan
- 2013 SDE Indian Sing 2013, Radi
- Get

About



About

- ヨーロッパ在住の解析プログラマーを対象とした Conferenceがルーツ
- 現在は、DM, Stat, Programming, eClinical IT などのTopicを包括的に含んだGlobal platform



PhUSE is an Independent, Not-for-profit organization run by volunteers. Since its inception, PhUSE has expanded from its roots as a conference for European Statistical Programmers, to a global platform for the discussion of topics encompassing the work of Data Managers, Biostatisticians, Statistical Programmers and eClinical IT professionals.

Membership figures as at 19th Aug. 2010

| Country | Membership figures |
|----------------|--------------------|
| United States | 82 |
| United Kingdom | 330 |
| Switzerland | 166 |
| Germany | 69 |
| India | 1 |
| Belgium | 41 |
| Sweden | 64 |
| Denmark | 64 |
| France | 10 |
| China | 0 |
| Poland | 12 |
| Japan | 16 |
| Russia | 2 |

| Country | Membership figures |
|----------------------|--------------------|
| Netherlands | 16 |
| Ireland | 2 |
| Italy | 6 |
| South Africa | 0 |
| Finland | 1 |
| Spain | 2 |
| Hungary | 1 |
| Bangladesh | 0 |
| Canada | 1 |
| Korea | 0 |
| Austria | 1 |
| Total Members | 887 |

Membership figures as at 22nd Nov. 2012

| Country | Membership figures |
|----------------|--------------------|
| United States | 561 |
| United Kingdom | 364 |
| Switzerland | 254 |
| Germany | 133 |
| India | 112 |
| Belgium | 61 |
| Sweden | 52 |
| Denmark | 48 |
| France | 38 |
| China | 27 |
| Poland | 18 |
| Japan | 17 |
| Russia | 0 |

| Country | Membership figures |
|----------------------|--------------------|
| Netherlands | 16 |
| Ireland | 14 |
| Italy | 14 |
| South Africa | 10 |
| Finland | 7 |
| Spain | 5 |
| Hungary | 4 |
| Bangladesh | 3 |
| Canada | 3 |
| Korea | 3 |
| Austria | 2 |
| Total Members | 1766 |

Annual Conference



Annual
Conference

- 年1回、開催場所はヨーロッパ(ドイツ、UKなど)
- 参加者は300-400, Paperは100-150
- 2013年の参加費は通常登録で12万円程度



Patient Centricity

In 2013 the topic of the annual PhUSE conference is Patient Centricity.

Patient Centricity is often abused as a buzzword. Patient Centricity does not have a meaning at all. Patients are not the focus. CROs are far away from patients and have no contact with them. Day out, we work with Patient data that we do not know how much alcohol they drink and if they are taking their medicine and track their disease progressions. We are not patient centric, we are people centric. We are people who work in the pharmaceutical industry, not patients than we do?

| Ticket Class | PhUSE Member |
|--|--------------|
| Full Conference Price | €900 |
| Early Bird Conference Price (Register before 29th June 2013) | €750 |
| Committee / Speaker (Code required - contact PhUSE Office) | €600 |
| Single Day Rate | €300 |

Prices exclude VAT, chargeable at the prevailing rate of Belgium VAT (currently 21%)

Annual Conference (Cont.)



Annual
Conference

- **発表内容はSASに限定されない**
 - SAS, CDISCの発表がほとんどではあるが、Microsoft Tools, Oracle Clinical, Rなどの発表もある
 - For example, Best paper winners;
 - Conference 2005 / RC04: Understanding the Japanese culture and approval process, Richard Harvey, AstraZeneca
<http://www.phusewiki.org/docs/2005/PAPERS/RC04.pdf>
 - Conference 2006 / PD04: Avoiding Mouse Elbow, Malachy Foley, Independent Consultant/Trainer
<http://www.phusewiki.org/docs/2006/PD04.pdf>
 - Conference 2012 / IS04: An Introduction to SDTM, 298 Pages in 20 Minutes?, Jennie McGuirk, ICON
Paper; <http://www.phusewiki.org/docs/2012/PAPERS/IS/IS04.pdf>
Presentation; <http://www.phusewiki.org/docs/2012/PRESENTATIONS/IS/IS04%20-%20An%20Introduction%20to%20SDTM.pdf>

Archive



Archive

- 過去のConferenceのPresentation, Keynoteを閲覧できる (Newsletterはmember only)

PhUSE Archive

Access to all material can be found in this section of the website. In the interest of sharing knowledge, this section is open to everyone.

Newsletters

The Newsletter is the quarterly mailing of PhUSE containing information about upcoming events.

Previous PhUSE Conferences

- [2012](#): Budapest, Hungary
- [2011](#): Brighton, United Kingdom
- [2010](#): Berlin, Germany
- [2009](#): Basel, Switzerland
- [2009](#): Keynote Presentation
- [2008](#): Manchester, England
- [2008](#): Keynote Presentation

2011 Papers / Presentations

Best paper winners are highlighted in bold text and will be featured in the next PhUSE Programming.

Applications and Software Development

AD01: [Development of SAS Standard Macro Systems](#)
Katja Glass, Bayer Pharma AG
[Download Presentation](#)

AD02: [Adoption of Agile in Medidata](#)
Tony Hewer and Andrew Smith, Medidata Solutions Inc
[Download Presentation](#)

AD03: [Translating eClinical Data - The Art and Science of Data](#)
Nikki Dowlman, Perceptive Informatics
[Download Presentation](#)

FDA/PhUSE Annual Computational Science Symposium=CSS Conference



FDA/PhUSE

- 年1回、2013年開催が第4回
- Working Groupの活動報告が主体、FDAが参加しているためアメリカで開催



[Silver Spring Civic Center, Silver Spring Maryland, USA](#)

March 18th - 19th, 2013

The aim of the FDA/PhUSE annual Computational Science Symposium is to provide updates on collaborations with project groups to improve standards, tools and processes across regulatory review and computational science.

The annual Computational Science Symposium will bring FDA, industry and academia together for updates and work on collaborations established at previous symposiums and continued throughout the year. Additional collaborative projects will be created to address additional challenges related to the access and review of data to support product development. The groups will work on possible solutions and practical implementations with the goal of helping the broader community align and share experiences to advance computational science.

PhUSE Wiki



- 臨床試験に関する情報科学技術の知識を共有する場
- 1. FDA CSS Working Groupsのためのオンラインコミュニケーション
- 2. 統計解析ソフト(SAS, R)などのプログラムシェア
- 3. その他、製薬・医療機器・ヘルスケア産業のプログラマの情報交換

Page [Read](#) [View source](#) [View history](#) Search

Navigation trail: [PhUSE Wiki](#)

PhUSE Wiki

Welcome to the  Wiki

Currently 414 users are helping to **Share, Contribute and Advance** clinical informatics.

All content on this wiki is non-binding. All content expresses opinions of users and not necessarily that of their employer nor PhUSE. See our [Disclaimers](#) page.

What is this place?

The PhUSE Wiki is an [PhUSE](#) /FDA/Industry collaboration to provide a medium to share information specifically relating to clinical trial informatics. The wiki has three main goals:

1. To support the FDA Computational Science Center Working Groups by creating an online collaboration environment.
2. To support the sharing of statistical and informatics

Add a new wiki page

News

READ ME MAY 2012 - UPDATES TO WIKI FUNCTIONALITY



FDA Working Groups 2012



- **FDA/PhUSE Computational Science Symposium working groups**
 - WG1: Data Validation and Quality Assessment
 - WG2: Standardizing data within the Inspection Site Selection Process
 - WG3: Challenges of Integrating and Converting Data across Studies
 - WG4: Standards Implementation Issues with the CDISC Data Models
 - WG5: Development of Standard Scripts for Analysis and Programming
 - WG6: Non-Clinical Road-map and Impacts on Implementation

WG 1 : Data Validation and Quality Assessment



• データバリデーション、ルール構築

A) 既存のバリデーションルールの調査と改良

既存のバリデーションルールの有効性評価、チェックカテゴリ・チェック内容の記述・内容の妥当性を見直し、スポンサーによる提出データ準備をサポートする。

B) バリデーションルール作成者向けのガイドライン

現在700以上のバリデーションルールが存在する。さらに領域別標準が作成されており、ルールの数が今後ますます増えていくと予想される。新しいバリデーションルールを作成するための手引き、ベストプラクティス等をまとめる。

C) 変更管理プロセスの策定とサポート

バリデーションルールが増えるにしたがって、その管理が重要になる。問題の提起・改善提案を検討するプロセスを開発する。

WG 2 : Standardizing data within the Inspection Site Selection Process



- **FDA査察 (Risk-based inspection site selection)、Risk-based monitoringなど**

FDA査察が直面する問題

臨床試験の複雑化: サイト数増加・国際臨床試験

リソース問題: 予算カット・PDUFAによるタイムライン設定

効率的に査察を実施すべき

→ リスクベースの査察

Risk-based approachを行うには、どんなデータが必要？

既存のデータ(PR・SDTM)の中にある？

新しいデータが必要？

スポンサーはどんな風にデータを提供すればいい？

FDAはどうやって利用するの？

WG 3 : Challenges of Integrating and Converting Data across Studies



• Legacy data conversion、Integration

データ統合は難しい

統合する目的の不統一: スポンサー vs. 当局

統合前データの不統一: 各者各様の構造化・統合など考えていない

→ CDISCの登場で、統一的なデータが手に入る!

第一段階

Legacy Data Conversion

試験デザインの違いによる影響

データ標準のFlexibilityが与える影響

第二段階

Data Integrationの観点から考えたベストプラクティス(プロトコルの作り方、データ収集ルール)

WG 4 : Standards Implementation Issues with the CDISC Data Models

FDA Working Groups



• Data Reviewer's Guide、SDTM申請での特例ルール作成、社内へのCDISC導入

CDISCを実際に利用する際の問題点について話し合う

A) Study Data Reviewer's Guide
Reviewer向けガイドの内容検討

B) 例外ルールの提案
SDTMに含めなくてもいいデータを提出する事例がある(イニシャルなど)。提出不要のデータを特定し、ガイドラインとしてまとめる。

C) Use Cases
活動内容不明

D) Challenges Industry faces with implementing Standards
活動内容不明

WG 5 : Development of Standard Scripts for Analysis and Programming



• 標準解析プログラム作成(図表)

究極のゴールは、業界で共通の「標準的な解析プロセス」を作ること。以下の8つの活動がある。

- A) 既存のスキプトの収集と保存
- B) 収集したスキプトのバリデーションステップの定義
- C) スキプトの共有プラットフォームの確立
- D) 法律上の所有者・オープンソース化のための問題解決
- E) スキプトのドキュメンテーションのためのテンプレート作成
- F) Google Code上でのスキプト作成・改良のプロセス
- G) Communication Planの作成
- H) 推奨されるTable・List・Figureのホワイトペーパー発行

WG 6 : Non-Clinical Road-map and Impacts on Implementation

FDA Working Groups



PhUSE Wiki

• SEND導入

SENDによるデータ標準化

- データは集まったが、うまく利用できていない
- データをレビュー・抽出・交換する技術が必要
- メタデータ等の付属データを充実させる必要がある

FDA Working Groups 2013



• 2013

- **WG1: Emerging Technologies**
新しいテクノロジーやツールを模索、業界で活用することを検討
- **WG2: Improving Data Quality**
効果的なSDTMデータセットバリデーションの方法。バリデーションチェックの見直し
- **WG3: Optimizing the Use of Data Standards**
何が原因で標準を導入しても効率化しないのか？
- **WG4: Development of Standard Scripts for Analysis and Programming**
データ変換・解析用の標準スクリプトの開発
- **WG5: Non-Clinical Road-map and Impacts on Implementation**
非臨床データの取り扱いに必要な要素・障壁の特定、ならびに解決のためのフレームワークの作成

FDA/PhUSE Annual Conference



PhUSE Wiki

- **TBD for 2013**





Good Programming Practice

• SASプログラミングルールなど

プログラミングには流儀がある。スクリプトの共有には『よいプログラミングルール』が必須。プログラミングのガイドラインを策定する。

見やすいコード vs. スパゲッティコード

沈黙のソース vs. コメントあり

自由きままなインデント vs. 構造化されたインデント

散逸したパラメータ記述 vs. まとめられた記述

拡張性のないアルゴリズム vs. 拡張性が保たれた構造

オブジェクト指向 vs. アスペクト指向

Indications



PhUSE Wiki

• 領域別

領域別にSDTM Implementation等の検討を行う予定らしい(内容はあまりない)

- アルツハイマー
- 心血管系疾患
- てんかん
- 多発性硬化症
- がん
- パーキンソン病
- 疼痛
- 呼吸器系疾患
- リュウマチ

Single Day Events



- Conferenceよりも規模が小さい、1日限りのもの
- US/EU各地で年に数回行われる(2012年は8か所)

PhUSE SDE Belgium 2012

| AGENDA | | | |
|--|--|--------------------------------------|-----------------------|
| Time | Topic | Speaker | Company |
| 8.00 - 9:15 <i>Registration and Coffee</i> | | | |
| 9.15 - 9:30 | Welcome | Wilfried Willems Heidi Curinckx | J&J B&P |
| 9.30 - 10:00 | Legacy Data Conversion - A Practical Example: Oncology | Niels Mathiesen | mathiesen & mathiesen |
| 10.00 - 10.30 | Secure Data Office: Saving time and preserving blinded trial status by utilizing independent programming | Elke Vansnick | SGS |
| 10.30 - 10.45 | 2012 Conference Chairs to promote Budapest Conference | Jean-Marc Ferran Sascha Ahrweiler | PhUSE |
| 10.45 - 11.45 <i>Morning Coffee Break</i> | | | |
| 11.15 - 11.45 | Define.xml for ADaM: Challenges and Innovative Solutions | Dimitri Kutsenko | Entimo AG |

Single Day Events (Cont.)



Single Day
Events

- **PhUSE memberは参加費無料、Non-memberは有料(下記の1st Indian SDEであれば\$35)**



PhUSE Single Day Events (SDE)

[Register Here](#)

SDEs are free to PhUSE members and are generally scheduled between 09.30 and 16.00 including a buffet lunch and refreshments. Agendas will be available on the website 4 weeks prior to each event.

Speakers and presentations **encouraged**, contact the appropriate Chair/Co-Chair

| Location | Date | Theme | Chair/Co-Chair |
|----------------------------------|------------------------------------|---|---|
| Hyderabad, India | Saturday, 23rd February 2013 | India Stats Programming GenNext - PhUSE 1st Indian SDE | Stephen Bamford , Cerafor Ajay Sathe , Cytel |

The Journal



The Journal

- “Pharmaceutical Programming”の発行
- 年に1, 2回、購読は無料

Pharmaceutical Programming

ISSN 1757-0921. Online ISSN: 1757-093X



Maney Publishing
Research • Knowledge • Innovation



Publisher: [Maney Publishing](#) on behalf of [PhUSE](#)

Articles

- F** [SAS code for the estimation and between-group comparison of cumulative incidence functions in competing risks survival analysis](#)
pp. 1-13(13)
Author: *Bond, Simon*

PhUSE Tube



PhUSE Tube

- プレゼンやソフトウェアデモのビデオ（音声あり）
- [e.g., PhUSE FDA CSS Meeting 2012 - Prescription Drug User Fee Act Reauthorization \(PDUFA V\) - Theresa Mulin \(FDA\)](http://play.streamingvideoprovider.com/popplayer.php?it=5dxqiwf2lww8&c1=)

PhUSE Tube - Sharing Knowledge Globally

What is PhUSE Tube?

Welcome to PhUSE Tube the e-sharing repository.

PhUSE Tube offers:

- ability to enhance slide presentations with **audio** in the form of a **video**
- ability to share **software demonstrations**
- ability to share presentations **globally**
- watch and learn from technical videos **when it suits you**
- ability to supplement your professional **development plans**
- potential to become an **international superstar** (well maybe?)



Forum



Forum

- 掲示板
- ほとんど使用されていない

PhUSE Forum

| Forum | Topics | Posts | Last post |
|---|--------|-------|---|
| The technical help room | | | Jan 27 2009 |
| Use this room if you need any help with any of your coding problems. | | 4 21 | 5:17PM by Adrienne Bonwick |
| PhUSE Matters | | | Aug 2 2012 |
| This room can be used to post any thoughts or questions about PhUSE The Society | | 12 61 | 9:32AM by Adrienne Bonwick |
| CDISC Discussions | | | Mar 29 2010 |
| Any thoughts, concerns, ideas or advice about CDISC can be raised here. | | 4 12 | 9:45AM by Stephen Bamford |
| Conference 2010 | | | |

Blog



Blog

- 月に1~2回更新される

The content of this blog expresses opinions solely of the author and not necessarily those of their employer or PhUSE.

[Moving Forward with PDUFA V: Just how standard is standard?](#)

👤 Joanna Koft 📅 03/Dec/2012 10:30

Dec
03

With the recent approval of PDUFA V, there are some key hurdles we must now shift our attention to in order to meet regulations. This blog discusses some of these and opens the door for more discussion and communication on how both the FDA and industry can achieve these requirements.

[continue reading...](#)

📁 Categories: [PhUSE](#), [Standards](#) 🏷️ Tags: None

[Keep your dog on a leash: training your define.xml to behave with the in-laws over the holidays](#)

👤 Greg Fagan 📅 01/Nov/2012 01:00

Nov
01

Working toward a submission is stressful. No doubt about it. There are just so many activities to fit into the timelines and the critical path – including ISS, ISE, database locks, QC, QA, etc. Submitting a product is such a rewarding experience as well – and during this period of scramble, sometimes what seem to be minor issues, are over looked, or over simplified, or even, over complicated. While I will not get into any specifics regarding

Members

- 2013年の会費は£48= 6,000円 (2012年: £72)
- Conference参加で自動的に1年間会員になれる
- 過去のNewsletterやAnnual Reportは会員にならないと見ることができない



Memt

Newsletter

New Membership

Signing up for a membership will automatically enrol you as a member of the Society as shown below.

Please select membership class

£40.00 (exc VAT)

Title

Forename

Surname

Email

Total cost to be billed to you card:

£48.00 (inc VAT)

Members

Login

Email

Password



Remember Me

[Forgotten your password?](#)

Become a member

Access the whole PhUSE web site, [click here to register](#)

Acknowledgments

- **Hajime Shimizu (Takeda)***
- **Miho Hashio (GSK)**
- **Yasutaka Moriguchi (Santen)**
- **Sano Hiroyuki (Tanabe Mitsubishi)**

- **Souma-san's slide deck presented on 2012-04-12 CJUG SDTM meeting**