Clinical Trial Data Sharing and Safeguarding the Privacy of Patients
Tokyo, Japan
30th June 2015
Welcome

Dear Single Day Event Attendee,

It is our great pleasure to welcome you to the second Japan Single Day Event in Tokyo.

PhUSE is an independent, not-for-profit organisation run by volunteers. Since its inception in 2005, 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 e-clinical IT professionals. Since 2014, the PhUSE working group has focused on organising events in Japan.

The theme of today’s PhUSE Single Day Event is “Clinical Trial Data Sharing and Safeguarding the Privacy of Patients”. Data sharing could advance scientific discovery and improve clinical care by maximising the knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials.

The second Japan SDE will introduce an outline of these activities and welcome constructive discussion among participants. Our goal is that you leave today’s event feeling that you have had ideas challenged and been inspired to think of new concepts of cooperation between industry and academia.

We would like to thank our sponsors – SAS Institute Japan, Bell Medical Solutions and Takumi Information Technology – for their support. This event would not have been possible without the effort of the working group, and we would like to thank them as well for all their contributions.

We wish to extend our gratitude and welcome to all organisers, participants and sponsors of the event. We hope you will all enjoy this event and will learn a lot about the concept and implementation of data sharing. This event will also provide you a great networking opportunity as you will get the chance to meet many people from different organisations.

Many thanks for your participation.

Best regards,

Michiko Watanabe
PhUSE Japan Single Day Event 2015 Chair

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Speakers and Abstracts

09:05 - 09:35
Yoshiyuki Kobayashi, Statistical Research & Training Institute, Ministry of Internal Affairs & Communications

Abstract
This presentation will provide a brief explanation on the legal systems governing the secondary use of official statistical data. The 2007 Statistics Act includes the provision of entrusted tabulation, anonymized data and questionnaire information. The presentation will focus on and explain the following points of anonymized data:
- Procedures for production
- Conditions for provision
- Obligations and penalties.

Biography
Yoshiyuki Kobayashi is a professor of the Statistical Research and Training Institute, Ministry of Internal Affairs and Communications. His work focuses on the following fields:
- Empirical study on statistical disclosure controls from both the legal and technical perspectives
- Methodological and empirical study on the production of pseudomicrodata for educational use
- Study on the structure of statistical data and statistical metadata.

Yoshiyuki also has extensive experience of teaching statistics to employees of administrative organisations and graduate students at Hitotsubashi University and Rikkyo University.

09:35 - 10:05
Global Trends in Clinical Trial Data Sharing (CTDS)
Atsushi Hyogo, Daiichi-Sankyo

Abstract
Clinical trial (data) transparency includes multiple-aspect, registration of clinical trials (registry, protocol publication), disclosure of clinical study results (disclosure of summary, study results publication, CSR synopsis and full CSR) and sharing clinical study data (individual patient data: IPD). In the past few years, there has been a marked increase in public demand for sharing clinical trial data, and this is regarded as one of the most significant global trends not only in the healthcare industry but also in the medical world. This trend is based on regulatory requirements, policies from industry groups/third parties and public expectation. Consequently, by early 2015, many pharmaceutical companies announced their policy for clinical trial transparency and implementation of clinical trial data sharing. This presentation will cover background, history, current situation and global trends in clinical trial data sharing (CTDS).

Biography
Atsushi Hyogo is Senior Director, New Drug Regulatory Affairs Department at Daiichi Sankyo. Since April 2012, he has held the following responsibilities: Leader for Global Regulatory Management Group, Global Regulatory Office Lead, and Member of Clinical Trial Data Transparency Discussion Team.

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10:20 - 11:50
Privacy-Enhancing Technologies for Personal Data Analysis
Jun Sakuma, University of Tsukuba

Abstract
Data analytics has been studied extensively, with the aim of discovering valuable knowledge from large-scale datasets. When a dataset contains private or sensitive information, maintaining confidentiality and preserving its privacy is critical. This talk explains the fundamental techniques for maintaining anonymity of personal data. As an advanced technology, the concept of secure computation and its application to personalised medication is also introduced.

Biography
Jun Sakuma received a PhD in Engineering from the Tokyo Institute of Technology, Tokyo in 2003. He has been an associate professor in the Department of Computer Science, School of Systems and Information Engineering, University of Tsukuba, Tsukuba, Japan since 2009. Prior to that, he worked as an assistant professor in the Department of Computational Intelligence and Systems Science, Interdisciplinary Graduate School of Science and Engineering, Tokyo Institute of Technology, Tokyo (2004 - 2009). He also worked as a researcher at Tokyo Research Laboratory, IBM, Tokyo (2003 - 2004). His research interests include data mining, machine learning, data privacy and security.
Speakers and Abstracts

11:50 - 12:30

**Challenge Examples: Public Institution**
Kiyomi Shirakawa, National Statistics Center, Hitotsubashi University

**Abstract**
Following the revision of the Statistics Act in 2009, Japan authorised creating anonymised microdata based on official statistics. To date, six types of anonymized official statistics microdata, compiled by the National Statistics Center, have been released by the Statistics Bureau. These statistics come from, for example, the ‘Survey on Time Use and Leisure Activities’, the ‘Employment Status Survey’ and the ‘Population Census’. Methods for creating anonymised microdata are perturbative and non-perturbative.

Until now, surveys other than the Population Census have used non-perturbative methods. Non-perturbative methods, in particular, include sampling, re-coding, top-coding and bottom-coding as well as deletion of direct identifiers such as individual names or addresses.

The Population Census, on the other hand, has always used perturbative methods, which include microaggregation, random swapping and noise addition. This presentation introduces creating anonymised microdata for the Population Census based on perturbative methods.

**Biography**
Kiyomi Shirakawa is an associate professor at the Institute of Economic Research, Hitotsubashi University and a senior researcher at the National Statistics Center of Japan. He has been working on three themes based on statistical analytical methods:
1) Project team formation for software development based on multivariate analysis
2) The detection of outliers in hierarchical enterprise sales
3) The measurement of disclosure risk and amount of information loss in a multi-dimensional cross-tabulation table.

Future studies will include the creation of anonymised data and synthetic data. The study of synthetic data focuses on the approach of optimal random number generation based on fundamental statistics.

13:30 - 14:00

**IT Environments for CTDS**
Toru Tsunoda, SAS

**Abstract**
De-identification is not the only means for sharing clinical trial data with external parties and safeguarding the privacy of patients. Following the approval of external party research proposals by independent review panels, IT environments for research activities such as data management and statistical analysis by external parties have been introduced by many sponsors. In this presentation, environments including utilisation process, and major functions, are briefly explained.

**Biography**
Toru Tsunoda works for SAS Institute Japan and is in charge of business development and sales support for Japanese healthcare and life sciences markets.

Before joining SAS Institute Japan in 2009, he provided management consultancy services including strategy planning and business process re-engineering to pharmaceutical and IT industries in global and domestic consultancy firms.

He received a bachelor’s degree in physics from Tokyo University of Science, completed a Master of Business Administration and is a Ministry of Economy, Trade and Industry Registered Management Consultant.
Speakers and Abstracts

14:00 - 14:30
PhUSE De-Identification Working Group: Providing De-identification Standards to CDISC Data Models
Jean-Marc Ferran, PhUSE Board & Koichi Yamaguchi, Eli Lilly Japan

Abstract
In this era of data transparency and sharing data with researchers, companies are defining their processes and de-identification guidance in order to comply with data privacy regulations. In particular, it is possible for researchers to request access to data across sponsors, and both the difference of data models and de-identification techniques may make the analyses cumbersome and error-prone.

While CDISC data models are now adopted into the industry, PhUSE launched in July 2014 a dedicated Working Group to define de-identification standards for CDISC data models starting with SDTM. Participants from pharmaceuticals, CROs, software vendors, CDISC specialists, data privacy specialists and academia have joined forces to define a set of rules against SDTM to provide the industry with a consistent approach to data de-identification and increase consistency across anonymised datasets.

Every domain and variable holding potentially Personally Identifiable Information (PII) has been rated in terms of impact on data privacy. Based on that rating, the variables are allocated standard rules of de-identification and the rationale and the impact on data utility is documented.

This presentation will elaborate on the Working Group’s main findings, the current deliverables and on the perspective of taking this first initiative to the next stage.

Biographies
Jean-Marc Ferran is an independent consultant based in Copenhagen with 12 years’ experience in the life sciences industry. Prior to starting his company, Qualiance, he worked as a statistician, programmer and director at Novo Nordisk and Ferr ing Pharmaceuticals. Jean-Marc has recently been working on a data transparency implementation for a top-20 pharmaceutical company as Data De-identification Track Lead and advises companies on how to implement data transparency initiatives. He also leads the PhUSE De-Identification Working Group focusing on CDISC standards in his capacity of Special Projects Director at PhUSE. Prior to joining the PhUSE Board of Directors, Jean-Marc was a member of the PhUSE Annual Conference Committee and chaired the 2012 Annual Conference in Budapest.

Koichi Yamaguchi received an MSc in Genetics from Hiroshima University in 2002. Prior to joining Eli Lilly Japan in 2012 as Senior Statistical Analyst, he worked for several companies including ACRONET, Novartis and, most recently, Jansen, mainly as a statistical programmer/analyst. He has also been an active member of the CDISC Japan User Group ADaM Team and Sub-Lead since 2013.

14:30 - 15:00
Quiz – Are You Still With Me?
Maiko Akutagawa, Takumi Information Technology

Biography
Maiko Akutagawa received a master’s degree in science in health management from Keio University in 2014. She has worked both as a statistician and as a senior SAS programmer in clinical studies at Takumi Information Technology. She is also a visiting researcher at the University of Shizuoka (Department of Drug Evaluation and Informatics).

15:00 - 15:30
JPMA DS-TF8: Clinical Trial Data Sharing
Hisao Takeuchi, Sumitomo Dainippon, Katsuhiko Sawada, Taiho, Mina Izuchi, Pfizer, Shin Aoki, Astellas, Tomoko Kato, Sanofi, Wataru Ohtsuka, Chugai and Yoichi Higashibeppu, Eisai

Abstract
Clinical trial data sharing has not yet been broadly implemented in Japan despite awareness of its importance. JPMA DS-TF8 examines the readiness for “Principles For Responsible Clinical Trial Data Sharing (EFPIA/PhRMA)” via a questionnaire survey.

This presentation will cover a summary of the questionnaire survey, a challenge example in “3. Sharing Results with Patients Who Participate in Clinical Trials”, which is relatively behind in comparison to other actions for the EFPIA/PhRMA principles in Japan, and an introduction to multi-sponsor request website clinicalstudydatarequest.com, which domestic pharma companies have just joined.

Biography
JPMA DS-TF8: Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary association comprising 71 research-oriented pharmaceutical companies (as of May 2015). As a member of the IFPMA, the JPMA is engaged with various global issues in the pharmaceutical and healthcare sector.

FY2015 Task Force 8 of the Data Science Expert Committee focuses on “Clinical Trial Data Sharing” and addresses CTDS from a data science standpoint.

15:30 - 16:30
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Throughout the presentations, the speakers will provide a comprehensive explanation of the early stages of CTDS in Japan to programmers and other pharmaceutical industry players.

Biography
JPMA DS-TF8: Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary association comprising 71 research-oriented pharmaceutical companies (as of May 2015). As a member of the IFPMA, the JPMA is engaged with various global issues in the pharmaceutical and healthcare sector.

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・ADaM Validation, Metadata & Define-XML
・ADRG

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Parkinson’s Sufferer

John Sall
Co-Founder and Executive Vice President of SAS

Simon Weston OBE
Falklands War Veteran

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さあ、体感してください。あなたの手で。
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