Denmark
Fast Track to Approval: Speed and Efficiency
15th June 2016
Lundbeck Offices, Copenhagen
Dear Single Day Event Attendee,

It is our great pleasure to welcome you to this event. For the eighth year, we are running a series of Single Day Events across Europe: Frankfurt (Germany), Copenhagen (Denmark), Utrecht (Netherlands), Basel (Switzerland) and Cambridge (UK) are our destinations this year. We hope that you will find these events beneficial in both their content and structure. They give a great opportunity to network and meet colleagues from other companies during the year while waiting for the main Conference, which will take place in Barcelona (8th-12th October) this year.

In addition to our EU Single Day Events, additional SDEs will be organised in the US, India and Japan. It would be highly appreciated if you could let your colleagues in other regions know about the upcoming events. More details are available on the PhUSE website.

Kath and I have been very fortunate this year to work with a very experienced sub-committee who have brought a lot of motivation and energy to our small team. We would like to thank the various companies that support these events and provide us with high-standard locations and catering facilities to fully enjoy them.

Again, this year, we have chosen to continue to provide the SDE brochure in both paper and electronic format at the events. This provides consistency between the events in both quality and format. The electronic option allows you to get the agenda ahead of the event to better plan your day and also helps us to promote the event. Also, you will notice that once again a vast majority of presentations will be ‘never seen before’ presentations. This not only demonstrates the energy of our community but also ensures that you receive new information. A big ‘thank you’ to all our presenters for dedicating time and effort to the success of these events.

As usual your feedback is key to us. We want to deliver the best events possible and we will review any comments or suggestions you make with great interest and will try to action them for future events.

Many thanks for your participation.

Best regards,

Adie & Kathryn
PhUSE EU Single Day Event Chair Organisers 2016

Why do more than 70% of people living with psychiatric and neurological disorders experience discrimination?

All over the world psychiatric and neurological disorders are a growing burden, not only for individuals but for families and societies as well.

An estimated 700 million people worldwide are living with these disorders and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences.

Lundbeck is a specialized pharmaceutical company focused on depression, schizophrenia, Parkinson’s disease and Alzheimer’s disease. For more than 70 years, we have been at the forefront of research within neuroscience and our development and distribution of pioneering treatments continues to make a difference to patients worldwide.

We are recognized for having helped hundreds of millions of people living with psychiatric and neurological disorders. However, there is still a massive need for further help.

Every day, we strive for improved treatment and a better life for people living with psychiatric and neurological disorders – we call this Progress in Mind.

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Best regards,

Adie & Kathryn
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Dear Single Day Event Attendee,

We are pleased to welcome you to the PhUSE Single Day Event (SDE) Scandinavia 2016. The Event will be hosted at the Lundbeck A/S facilities in Valby, Copenhagen. This gives you the opportunity to see where many of your colleagues at Lundbeck carry out their daily work, and it will also give you the unique opportunity of hearing presentations and networking with colleagues from both local and international companies.

This year’s SDE has the theme “Fast Track to Approval: Speed and Efficiency”. We have prepared an agenda where we look into many parts of the clinical data management, analysis and preparation of submission deliverables, covering:

- applying Therapeutic Area Standards
- centralised monitoring of data
- data de-identification
- new EMA requirements on public disclosure
- aCRF tool
- metadata & ADaM
- CDISC implementation trends.

We have invited a broad spectrum of presenters from both local and international companies, who will share their thoughts and ideas on how to approach the challenges in preparing submission with speed and efficiency in mind.

During lunch, you will have time to network with your colleagues in the café area. The Event will close with news from PhUSE.

We would like to thank our sponsors Lundbeck A/S, SAS Institute A/S, S-cubed ApS, Qualiance, NNIT A/S, HERAX and Entimo for their support for this Single Day Event in Copenhagen.

The SDE intends to stimulate discussion and knowledge-sharing. Your contribution in terms of questions and comments throughout the day will be the key to success. We hope you will enjoy the day, learn from each other and get to know some new people.

Let us all share our experiences and get inspiration from others who can give a new flavour to our daily work!

Best regards,

Pia & Mikkel

Copenhagen Single Day Event Chairs 2016

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**Agenda**

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**Introduction**

Pia Hjulskov Kristensen
H. Lundbeck A/S

Mikkel Traun
Novo Nordisk A/S

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Your guide to the day
Abstract
Haemophilia is an inherited condition that affects the blood’s ability to clot. Worldwide, it is estimated that 1 boy in every 5,000 will be born with haemophilia A and 1 boy in every 30,000 will be born with haemophilia B. The data mainly deals with general haemophilia disease related data such as FIX infusions, plasma FIX activity level, FIX replacement therapy, bleeding history, bleeding episodes, Hemophilia Joint Health Score, Target Joint Status, FIX inhibitors, FIX gene sequencing, etc.

This presentation will focus on the approach of how CDISC CDASH and SDTM models have been implemented on this data, and challenges and important considerations around data structure/mapping. There are many new laboratory parameters which are not present in the latest standards-controlled terminology. We have succeeded to a far extent with our approach. We believe this could be considered a candidate for a Therapeutic Area Standards User Guide development.

Biography
Malathi Hari works as a senior programmer for the Nordic CRO Larix A/S. With more than five years’ experience in the pharmaceutical industry, her main areas of expertise are SDTM and ADaM programming, creating TLGs, standardisation of SAS programs, submission package and compliance check. She has worked with several intervention and therapeutic trials such as vaccination and immunogenicity, atopic dermatitis, haemophilia, alpha-mannosidases and Crohn’s disease. Malathi constantly strives to maintain up-to-date knowledge of CDISC standards and participates in CDISC ADaM team meetings and webinars. Her hobbies and leisure pursuits include singing traditional Indian songs, dancing, origami crafts and cultural event management.
Centralised Monitoring of Data

Abstract
With the publication of the final ICH E6(R2) guideline scheduled for November 2016, there is increasing focus on centralised monitoring of data to identify issues such as missing data, inconsistent data, data outliers or unexpected lack of variability, and data trends such as the range and consistency of data within and across sites. This presentation will cover Lundbeck’s approach to identifying the issues mentioned, and detail the usage of Oracle, SAS, R and Spotfire for analysing and visualising eCRF data, SDTM data, analysis data sets, and related operational data.

Biography
Inge Thøger Christensen holds a PhD in Pharmaceutical Science from the University of Copenhagen. She is a Senior Clinical Data Analyst at Lundbeck, working with the exciting challenge of getting more insights out of clinical data. She works with integrating data from different sources and developing reporting dashboards for clinical trials.

Data De-identification Made Simple

Abstract
This presentation will cover a small collection of macros to de-identify a complete set of well-formed SDTM data using the de-identification specification itself as metadata. The macros will handle any set of domains and variables, as long as they comply with SDTM in any version compatible with the specification. The macros demonstrate a robust way of handling metadata, variations of SDTM data, SAS code generation and dynamic execution, macro parameter validation, and reporting of any findings. The presentation is, though, focused on interpretation and implementation of various de-identification requirements, as they are presented in the specification.

Biography
Jørgen Mangor Iversen has worked in the IT industry since 1987 and in the pharma industry since 2005 as a programmer. Since 1991 the primary tool he has been SAS. During this time he has developed a number of large and complex solutions for a variety of industries. Apart from this extensive experience in programming, he holds a BSc in Computer Science from Aalborg University and a Master of IT in Software Construction from the IT University of Copenhagen.

Integrating the New EMA Requirements on Public Disclosure in the Study Conduct Process

Abstract
The EMA has been a strong advocate for data transparency and public disclosure of study results. It is now compulsory to disclose safety and efficacy results from studies conducted in Europe in the EudraCT database 6 to 12 months after LPLV and to disclose anonymised CSRs for studies, as part of a centralised marketing authorisation procedure.

While sponsors are presently dealing with these new requirements to comply with the new regulatory framework, a number of initiatives to provide standards to optimise these processes are emerging from CDISC, TransCelerate and PhUSE in particular. The implementation of such standards will impact the end-to-end process from protocol definition all the way to analysis results metadata and hopefully bring benefits down the line to the study conduct process. This presentation will describe the current process and provide some insight into what the future data flow could be.

Biography
Jean-Marc Ferran is an independent consultant based in Copenhagen with 14 years’ experience in the life sciences industry. Prior to starting his company Qualiance, he worked as a statistician, standards manager and as Director of Statistical Programming at Novo Nordisk and Ferring Pharmaceuticals. Jean-Marc has worked 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 and has recently been representing the group at the stakeholder meetings held at the EMA as part of the consultations on the Policy 0070 CSR anonymisation guidance. Prior to joining the PhUSE Board of Directors in 2014 as Special Projects Director and, since 2016, as Strategic Partnerships Director, Jean-Marc was a member of the PhUSE Annual Conference Committee and chaired the Annual Conference in 2012 in Budapest.
13:25–13:50

Experience of Implementing an aCRF Tool

Abstract
During the CDISC implementation at Novo Nordisk, we have developed a semi-automated SDTM annotated CRF (aCRF) tool to ease the process of generating an aCRF. As the process for generating the aCRF manually includes many routine tasks, the benefits of the tool are to automate some of these. The tool can copy annotations from already annotated forms in a pre-loaded and controlled aCRF library.

Challenges and considerations when implementing a tool for creation of SDTM annotated CRFs: Now the first version of an aCRF tool is available we need to continuously evaluate optimisation opportunities based on the benefits and challenges we discover going forward.

Biographies
Hanne van Kints has more than 20 years’ experience within the pharmaceutical industry and data management and has been at Novo Nordisk A/S for the past eight years. She has worked across all areas within data management and has participated in several IT and business improvement projects. She is currently heavily involved in the major CDISC project at Novo Nordisk, implementing changes and new functionality to the Clinical Data Warehouse (CDW) system for it to be CDISC-compliant, as well as in validation, testing, documentation and training.

Mike Abel Korsgaard is an IT project manager currently working on the CDISC project at Novo Nordisk A/S. In the CDISC project he has, among other things, been responsible for implementing a semi-automatic annotated Case Report Form (CRF) tool with the aim of supporting the business in the creation of annotated CRF’s. Mike has worked at Novo Nordisk for eight years as a member of the Corporate IT department. He began his career at Novo Nordisk as a service manager responsible for several IT infrastructure services such as the BlackBerry service, the email service and the email retention solution, a central mail storage system for employees under legal hold. Mike holds a master’s degree in finance and accounting from Copenhagen Business School.

13:50–14:15

Metadata & ADaM Implementation/STREAMing Deliverables @ Ferring

Abstract
The time from database lock to delivery of high-quality output supporting the decision-making and clinical trial reporting is the classic key performance indicator for our group. However, the increasing focus on centralised monitoring is changing the scene as we are now also expected to deliver weekly if not daily updates during the conduct of a clinical trial.

Despite ADaM still maturing, the core of the data structures is sufficiently stable to facilitate an efficient approach based on the ADaM metadata and the actual ADaM implementation. At last year’s PhUSE SDE Scandinavia, we presented and demonstrated our standardised reporting using the ADaM (STREAM) concept in the context of production of summary tables. Based on a short recap of the STREAM concept for summary tables, this presentation will demonstrate how the concept can be applied throughout the conduct of a trial and further extended beyond production of summary tables for trial reporting. Anchoring of all deliverables in the ADaM data ensures consistency and quality of the deliverables and enables efficiency gains by reusability of applications across trials. During the presentation it will also be discussed how supporting centralised monitoring activities based on ADaM data impacts the way we work at Ferring.

Biography
Bjarke Klein is Associate Director of Statistical Operations at Global Biometrics, Ferring Pharmaceuticals A/S. In this role he is responsible for optimising the processes surrounding the deliverables based on ADaM data sets. Prior to heading the Statistical Operations group he was a project statistician at Ferring for 10 years. During this period he was involved in submissions to the FDA, EMA and PMDA. Before he joined Ferring he worked at Statens Serum Institut for three years as a biostatistician.

Bjarke holds a Candidate of Sciences in Mathematics and Computer Science from Aalborg University and a PhD in Statistics from the University of Southern Denmark.
Abstract
At Novo Nordisk we have produced CDISC ADaM data sets for FDA submissions, including the associated ADaM metadata in Define.xml. Since the process of creating ADaM analysis data sets is iterative and complex, it is an inherent task to keep the metadata definitions aligned with the ADaM data sets.

We have tried various approaches for ensuring that the ADaM metadata are correct and aligned. We will share our experiences, best practices and visions of how ADaM metadata can be kept in sync with the ADaM data sets during the trial analysis and reporting phase as well as supporting the submission requirements.

Biography
Morten Hasselstrøm Jensen has worked at Novo Nordisk for three years and has a background within biomedical engineering and informatics including a PhD in Diabetes Technology. During his time at Novo Nordisk, he has worked with implementation of CDISC ADaM in several clinical trials across insulin and growth hormone projects and in Novo Nordisk in general. Furthermore, he has been driving one of the first deliverables of CDISC ADaM data sets and documentation at Novo Nordisk to regulatory authorities.

14:15–14:40
Keeping your ADaM Metadata in Sync

HERAX supports our clients in realizing the benefits of data standardization through process optimization by delivering
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- New processes
- IT architecture
- Data flows

HERAX ensures that new processes and standards are implemented as planned by providing
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- Project Management
- SOP/WI creation/updates
- Validation
- Vendor Management

HERAX delivers a robust solution and vendor selection process, unbiased of any technology and service vendor, covering
- URS
- Use cases
- Request for Information
- Request for Proposal
- Vendor selection

HERAX applies our best practices to projects for clients around the world, delivering selection and implementation services for e.g.
- EDC
- Clinical Data Warehouse
- Metadata Repository
- Risk Based Monitoring
- CTMS

HERAX is a consultancy specializing within Clinical Development, Pharmacovigilance and Regulatory Affairs, bridging the business and IT. HERAX services clients around the world, optimizing business processes, finding and implementing IT solutions, unbiased of any technology vendor.
Abstract
SAS JMP Clinical is a natural choice for implementing Risk-based Monitoring (RBM), including Central Statistical Monitoring (CSM), for a number of reasons: it builds on SAS, is fully based on CDISC (SDTM and/or Adam), is interactive, allows tailor-made applications, and permits advanced statistical inferential methods for site performance evaluations, among others.

With CDISC standards fully being implemented at Ferring Pharmaceuticals, we have built a SAS JMP Clinical template for Central Statistical Monitoring (CSM) that is easy to adapt to the specific trial at hand. Its main focus is on poor, if not fraudulent, site performance using statistical inference, as well as overall trial performance (e.g. in terms of recruitment quality as opposed to recruitment speed and hitting the right target population). Site performance is assessed from various angles by looking at primary, key secondary and key safety endpoints as these may be most sensitive to data anomalies. The idea is to look for unnatural small variations, unnatural high or low incidences and unanticipated correlation structures.

The first part of this presentation will be on the functionality of SAS JMP Clinical for RBM in general, whereas the second part will be a demo of the SAS JMP Clinical template used at Ferring for CSM specifically.

Biographies
Valérie Nedbal, PhD, serves as Senior JMP System Engineer for Northern Europe at SAS Institute GmbH in Heidelberg, working closely with customers for software implementation. Prior to this, she was Product Manager for Bioinformatics for SAS EMEA and supported life sciences sales activities. Before joining SAS, Valérie was Senior Field Marketing Manager for LION Bioscience AG, a software company offering solutions in the life sciences market. Valérie holds a PhD in Biology from the German Cancer Research Center in Heidelberg, and has done post-docs at the Max-Delbrück Center, Berlin-Buch and at the European Molecular Biology Laboratory, Heidelberg.

Egbert van der Meulen has been Senior Director, Biostatistics at Ferring Pharmaceuticals since 2007 and has been working in the pharma industry for over 20 years. He holds a PhD in Mathematical Statistics from the University of Groningen in the Netherlands, and has interest in innovative methods and designs such as response-adaptive top-down dose-finding designs but also in harvesting the fruits of global standardisation and automation, and, last but not least, in central statistical monitoring.

Why Modern CDISC Data Visualisation Matters in Clinical Trials

Speakers and abstracts
15:50–16:15
CDISC Implementation Trends

Abstract
This presentation will give an overview of CDISC implementation trends in pharma. How do different pharma companies prepare for the regulatory requirements of CDISC standards? Which IT solutions and process designs support the CDISC requirements and what are the benefit areas?

Biography
Jacob Jensen is a project manager at HERAX. He specialises in CDISC, application and technical architecture work, process optimisation, system validation, business case development and project management. Jacob has worked with Clinical Data Warehouse, Statistical Computing Environment, eTMF and CDISC implementations and integrations. He also works as a trainer at the HERAX Training Academy, responsible for the Pharma CDISC Approach and Use training courses.
Qualiance, founded in 2010, has gained customers in Denmark, Sweden, Switzerland, Germany, Belgium, France, the UK and the USA as well as a strong network of partners. We have an 87% repeat-business rate and we are proud of our track record of high-profile projects. Qualiance has helped 5 of the top-10 pharmaceutical companies in the world and a number of medium-sized and large organizations.

Please get in touch to find out how we can support your projects

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Denmark

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www.twitter.com/QualianceTwitta
Looking Forward

June
- India SDE, Hyderabad: 18th June
- EU CSS, Basel, Switzerland: 21st-22nd June

July
- USA SDE, Deerfield, IL: 21st July
- India SDE, Trivandrum: 30th July

August
- USA SDE, Frenchtown, NJ: 4th August
- Japan SDE, Tokyo: 4th August

October
- PhUSE Annual Conference, Barcelona, Spain: 9th-12th October

November
- China SDE, Shanghai: 4th November
- USA SDE, Durham, NC: 10th November

December
- Japan SDE, Osaka: 1st December
- India SDE, Mumbai: 3rd December
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Barcelona 2016
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Princesa Sofia Gran Hotel, Barcelona