

Welcome to PhUSE SDE Copenhagen 2019

Chairs:

Pia Hjulskov Kristensen, *H.Lundbeck* & Mikkel Traun, *Novo Nordisk*

Supporting Chairs:

Jean-Marc Ferran, *Qualiance*

Jørgen Mangor Iversen, *Leo Pharma*

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Agenda for this years Copenhagen SDE – ADaM Revisited

Time	Presentation Title	Speaker
8.45 - 9.30	Registration & Welcome Refreshments	
9.30 - 9.40	Welcome	Mikkel Traun, <i>Novo Nordisk</i> Jean-Marc Ferran, <i>Qualiance</i>
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SEND at Novo Nordisk

This presentation describes lessons learned in Non-clinical Data Management while preparing for submission of SEND data in Novo Nordisk A/S. While data management as such has been a function in the clinical area in the last 30+ years, it is a fairly new function in the non-clinical area. It has therefore been very interesting, and at times a bit difficult, to establish the data management processes within the non-clinical area. It has however also been very rewarding, as it has led to reflections about exactly which of the data management processes used in the clinical area are truly required in the non-clinical area.

By now, i.e. about five years after we started this journey, we have IT systems and data management processes in place and we have worked with our systems for a couple of years exposing them to real life studies. We are still adapting both systems and processes and we are still learning about the non-clinical area.

Implementation of SEND was not just another IT project. It certainly led to changes in the non-clinical area – of which some were not foreseen when the project was initiated.

Pia Jellinggaard and
Gitte Koch Ullmann
Novo Nordisk

ADaM @ Lundbeck

Several years ago, CDISC SDTM was implemented in the Biometric Department at Lundbeck. The natural – and necessary – next step was to implement CDISC ADaM. The implementation of this standard was needed to support study reporting by having standardized Analysis Datasets while at the same time being as submission ready as possible.

When creating and specifying ADaM Datasets, the ADaM IG and the ADaM model was followed, always with standardization in mind. To meet our needs, company specific variables have been added, which adhere to the ADaM fundamental principles.

The key document at Lundbeck is our ADaM Specification, which serves many purposes. Many other documents and input/output are related to and used in collaboration with the ADaM Specification. This will be discussed in this presentation along with some of the challenges, we met during the creation of ADaM.

Karin Fleischer Steffensen
H.Lundbeck

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AdaM at Bayer – metadata and automation

One key task in statistical programming is the development of CDISC compliant analysis data sets following ADaM guidelines. Analysis data sets need to be clearly derived and traceable from SDTM data sets and need to consider the study specific analysis specification per SAP.

This task has several challenges, particularly if you want to find elegant reusable ways that work across different studies.

At Bayer we implemented a semi-automated solution called AdaMap that takes a pre-SDTM version as input – which makes it easier to map to ADaM. The next goal is to map directly starting from SDTM. The key concepts of the current ADaM mapping approach and the planned adaptations will be addressed in this presentation.

Elena Glathe
Bayer

One Model to Rule Them All...and in the Trial Bind Them

Multiple operational data model versions and associated implementation guides, frequent updates of controlled terminologies, and the ever-evolving conformance guides and rules, makes it a challenging task to govern and implement a single data standard. To govern both SDTM and ADaM corporate standards and ensure end-to-end implementation is seemingly an unachievable goal to set.

We will share the Novo Nordisk's Master Model approach in data standards governance, how to overcome the hurdles of end-to-end implementation across the organisation, and navigate the conformance requirements for submission.

Karina Stender and Vicky Poulsen
Novo Nordisk

ADSL, Friend or Foe?

When creating a set of ADaMs for a trial or a submission, one commonly used approach is to create the ADSL dataset first, and then pick variables from ADSL when creating other ADaM datasets. While this approach may seem clever at first, only creating each variable once, it may create other problems downstream, particular when performing QC of ADaM.

To avoid costly and lengthy re-QC, it is advocated to create all variables common to more than one ADaM dataset outside the set of ADaMs, either as WORK datasets or separate permanent datasets.

This approach eliminates dependencies between individual datasets, particular dependencies of ADSL, avoiding the need to re-QC all ADaM dataset when a variable in ADSL, but not in other ADaMs needs to be updated.

Jørgen Mangor Iversen
LEO Pharma

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Treatment Allocation in ADaM

For most trial designs the ADaM Implementation Guide provides sufficient guidance on how to allocate treatment related variables across OCCDS and BDS domains. But what about the odd ones out?

This presentation gives a practical approach on how to handle treatment allocation in complex trial design or trials with complex period definitions. Two auxiliary domains are presented, ADTRTEV and ADTRTVIS, to support the allocation of treatment related variables in OCCDS and BDS domains, respectively, and centralise any complex programming efforts.

Ari Knoph

Novo Nordisk

Open Source for Pharma - Solutions, Challenges and Visions

Open Source is famous in almost all working areas. Which solutions are available for clinical study evaluations? Why are there just so few? Do we need this at all?

This presentation will show solutions available in our working area, discuss the challenges and opportunities we have and will envision a bright future full of cooperation and collaboration enabled through open source.

Katja Glass

Katja Glass Consulting

Define Compare: A web-based tool for comparing study metadata

A first step before pooling data for an ISS or ISE is to acknowledge how study metadata compare across studies. Similarly, prior to starting the ADaM programming for a new study, it can be useful to understand how the proposed metadata would differ from previous studies or from company standards. In both cases this can help the programmer answer questions such as 'how do variable derivations differ between studies?' and 'do my codelists contain the same modalities?'. An awareness of these facts can facilitate code re-use, increase standardisation and accelerate the study reporting process.

Define Compare is a free to use, web-based tool from Clinical Metadata. It enables users to compare ADaM Define.xmls helping them to see how their metadata differs across studies.

Andrew Ndikom
Clinical Metadata

Poster Session

► Ask questions

► Network

Company/ Organisation	Poster Title
PhUSE	Best Practices for Submission of Event Adjudication data
CDISC 360	CDISC 360 Use Cases
Novo Nordisk	Challenges in complying with USUBJID requirements
Novo Nordisk	Physical activity tracker
Novo Nordisk	A practical set up of processing big data in ADaM
Ferring	nRAGE – Enhanced Report Appendix Generator
Ferring	NEED FOR SPEED – Accelerating Centralized Monitoring
Katja Glass Consulting	Open Source
StatGroup	After ADAM comes ... Analysis Result (Meta)Data Retrospective view, present and future

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Pair comparison and ranking subjects: The Combined Assessment of Function and Survival (CAFS) case study

This presentation is discussing the scenario of a subject one to one comparison in order to score and rank treated subjects.

The case study disease is called ALS and its very famous since Stephen Hawking was diagnosed with it, while the analysis test is called Combined Assessment of Function and Survival (CAFS) as it is described by Berry et al. 2013. Criteria for ranking the subjects are the combination of time-to-death and ALSFRS-slope, whereas subjects which discontinued early are only compared with others only until their last common day.

The solution implemented tried to tackle the limitations of SAS 'per-row' analysis by implementing a combo of arrays and do i/j loops.

Konstantinos Lymperis

Larix

Three Agencies Tackle Data Sharing: Synergies and Differences

The EMA and then Health Canada have respectively launched separate data transparency policies around sharing of Clinical Study Reports (CSRs). The two regulators are providing additional guidance to help with implementation of their policies and have each formed stakeholder groups. These two stakeholder groups include a variety of professionals and representatives across life sciences and focus on topics around data anonymization, risk of re-identification and data utility while Health Canada's Reference Group also addresses scope and process-related matters. This presentation will elaborate on the approaches, goals and achievements of these two stakeholder groups and reflect on the EMA and Health Canada data sharing processes and requirements and where they overlap and differ from each other. In addition, the recent initiative and pilots from the FDA will be discussed. The author will also reflect on his experience participating in both stakeholder groups and lessons learned that could benefit other industry committees.

Jean-Marc Ferran
Qualiance

PhUSE Update

Yvonne Moores, *PhUSE*



10th–13th November
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The Netherlands

EU 2019

The Clinical Data
Science Conference



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A wide-angle landscape photograph showing a lush green field in the foreground with scattered white wildflowers. A line of trees separates the field from a distant town. On the right, a modern building with a curved facade and a dome sits atop a grassy hill. The sky is bright blue with scattered white clouds.

Thank you for attending Copenhagen SDE 2019

Go-home Cafe