PhUSE Single Day Events

Copenhagen, Denmark

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SDTM Panel Discussion

PhUSE Single Day Event
Copenhagen 2018

Mikkel Traun
Novo Nordisk

SDTM Panel Discussion

Ferring	Leo Pharma	Lundbeck	Novo Nordisk	Bayer
Jens Langendorf Systems Development Manager	**Niels Højsgaard Jørgensen** Manager, Statistical Programming	**Karin Gembert** Senior Director, Data Management & Programming	**Trine Næstoft** Director, Clinical Data Standards	**Elena Glathe** Head of Statistical Analytics, Germany

SDTM Panel Discussion

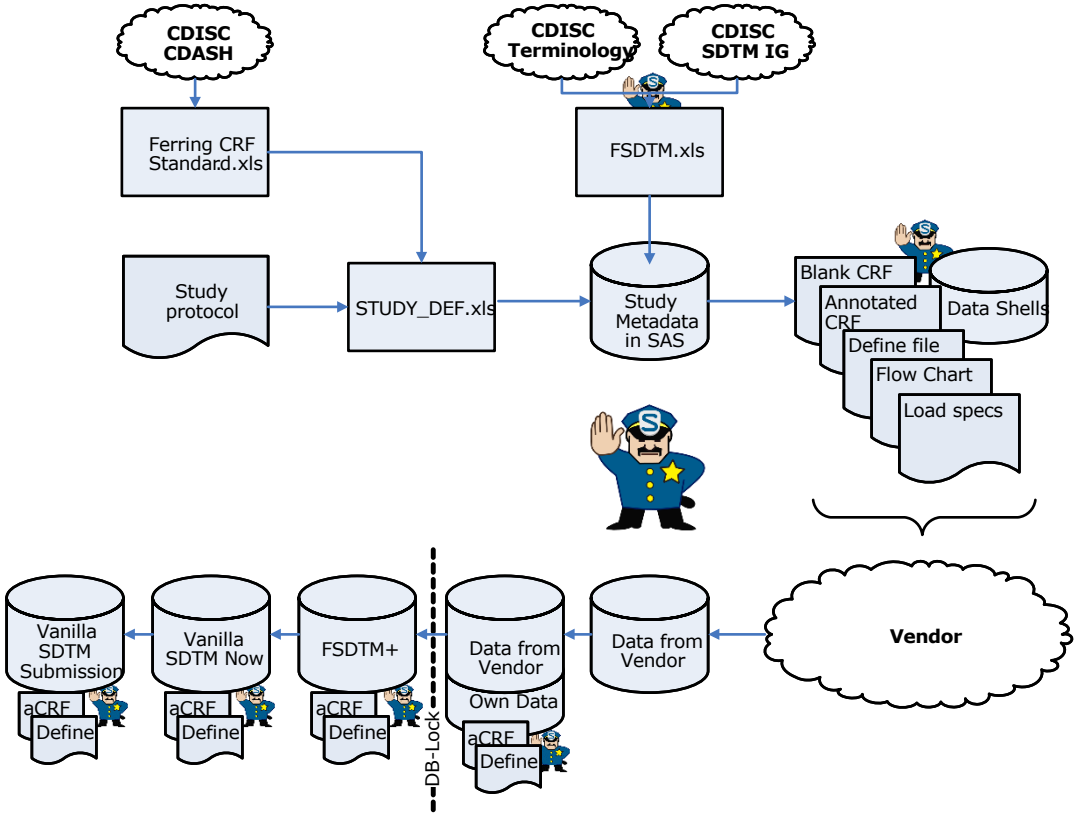
How has implementation of SDTM changed over time in the pharma companies in our region

- When, by whom and how was SDTM made initially?
- How has the SDTM generation changed over the recent years, and what has been the drivers for the change?
- How will the SDTM generation be in the future and why?

SDTM at Ferring

Jens Langendorf
Systems Development Manager

SDTM @Ferring



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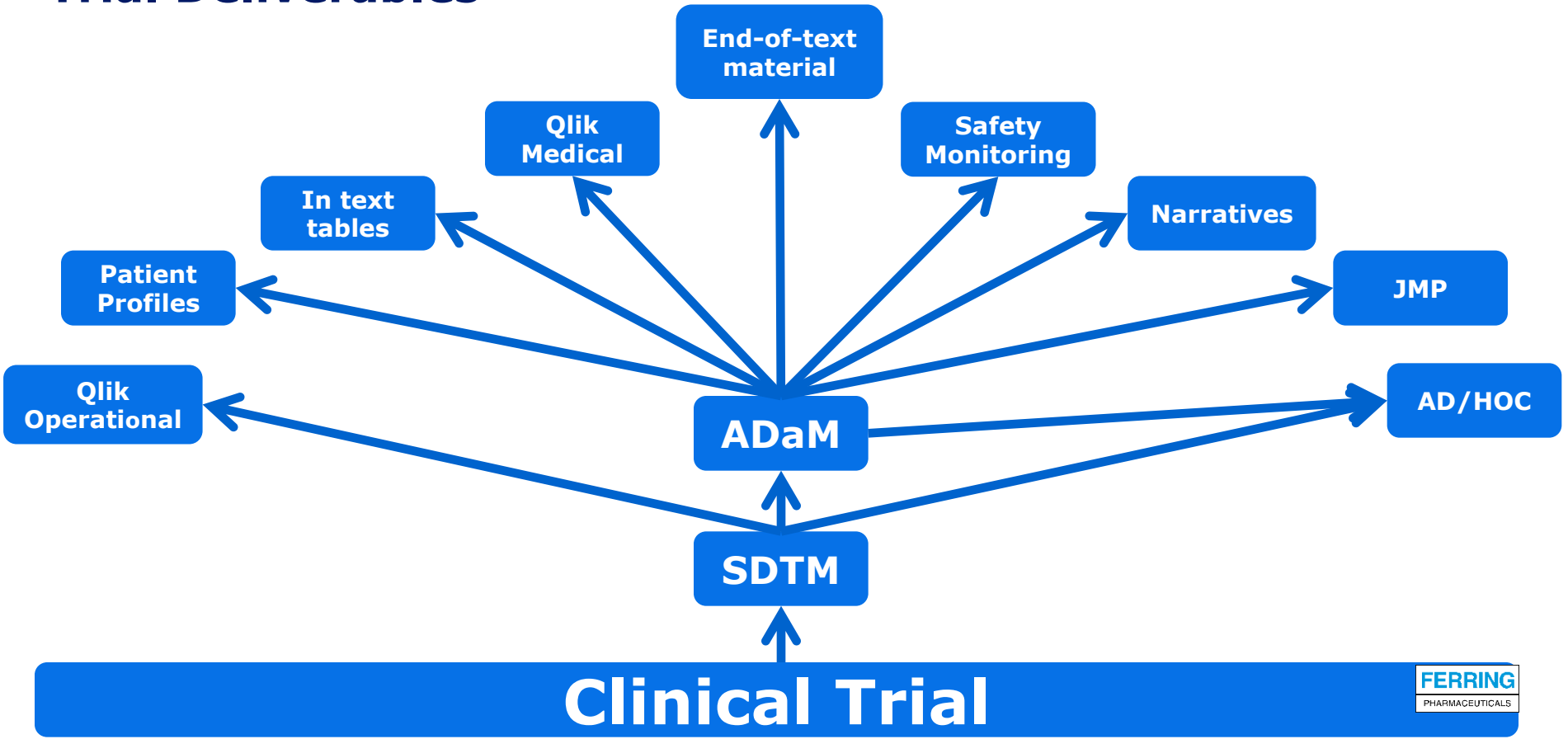
Trial Deliverables



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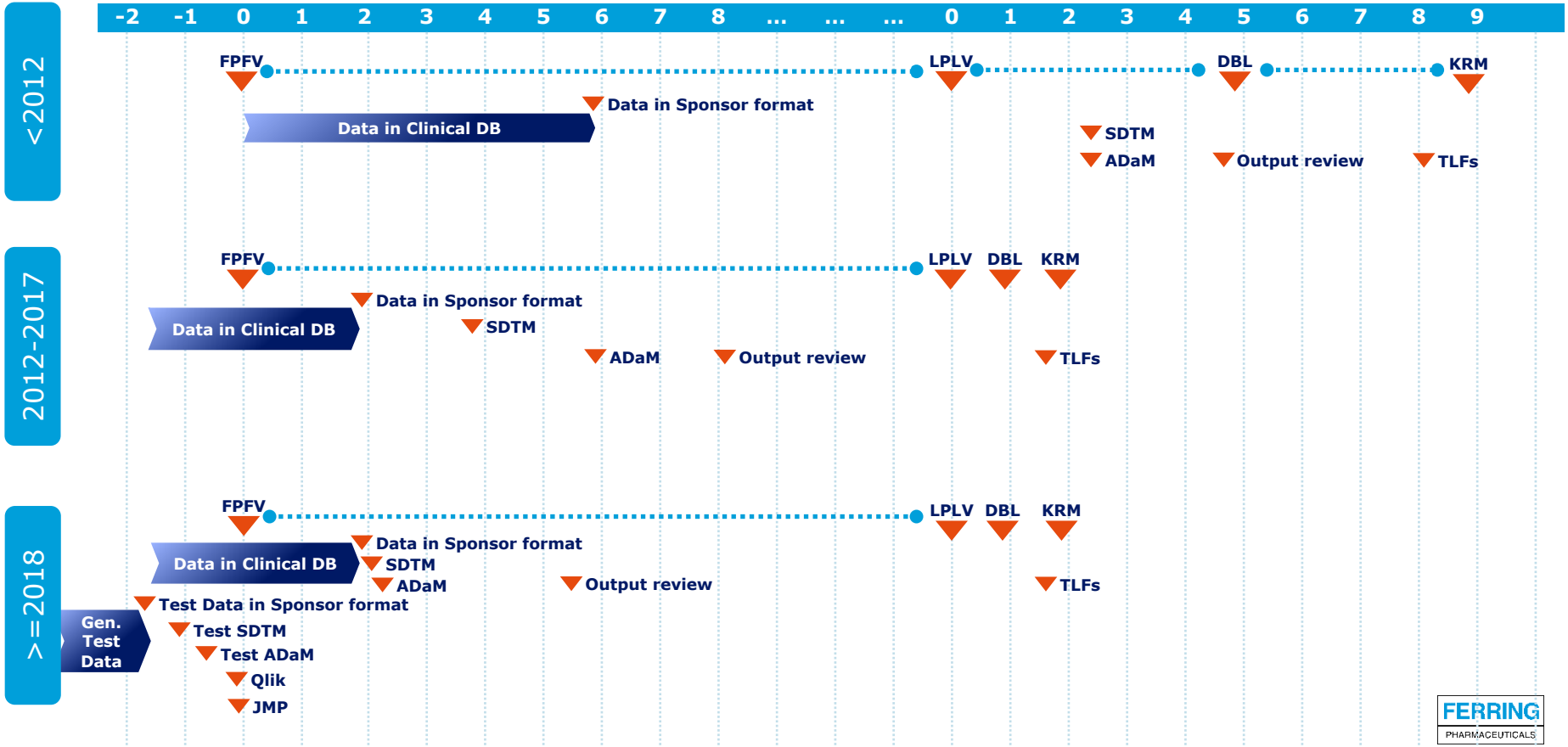
When is SDTM made ?



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When, by whom and how was SDTM originally made ?

When

- SDTM+/- since 2007
- Metadata driven/Tool based since 2009
- SDTM since 2010
- Down-stream based on SDTM since 2012

By Whom

- 95% Data Management (Metadata maintenance, Study definition, system development)
- 3% Stat. pgm. (~EX)
- 2% Stat. (Trial Design)

How

- Highly metadata driven (Excel)
- Think SDTM in CRF build
- Homemade SAS standard programs
- 5% study specific code (EX, Rand.lists)

Ferring DM: 9 permanent, 10 TCS consultant. CPH, US, Japan, India, (China)

FERRING PHARMACEUTICALS

How has the SDTM generation changed over the recent years, and what has been the drivers for the change?

Originally

It hasn’t changed

Now

Drivers

- Happy with the overall flow and study workload
- Lag of resources to improve
- No vendor has presented a full solution

How will the SDTM generation be in the future and why?

Current Challenges	*Solutions*	*Drivers*
• Version Control	• SHARE+Omar 	• Adherence to changing standards
• Timelines	• Test data generator	• SDTM+ADaM based deliveries expected just after FPFV
• Resources for improving tools	• Use vendor tools more (SAS CST, LSAF, Pinnacle 21, …)	• Less internal system development

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SDTM at LEO Pharma

Niels Højsgaard Jørgensen
Manager, Statistical Programming

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When, by whom and how was SDTM made initially?

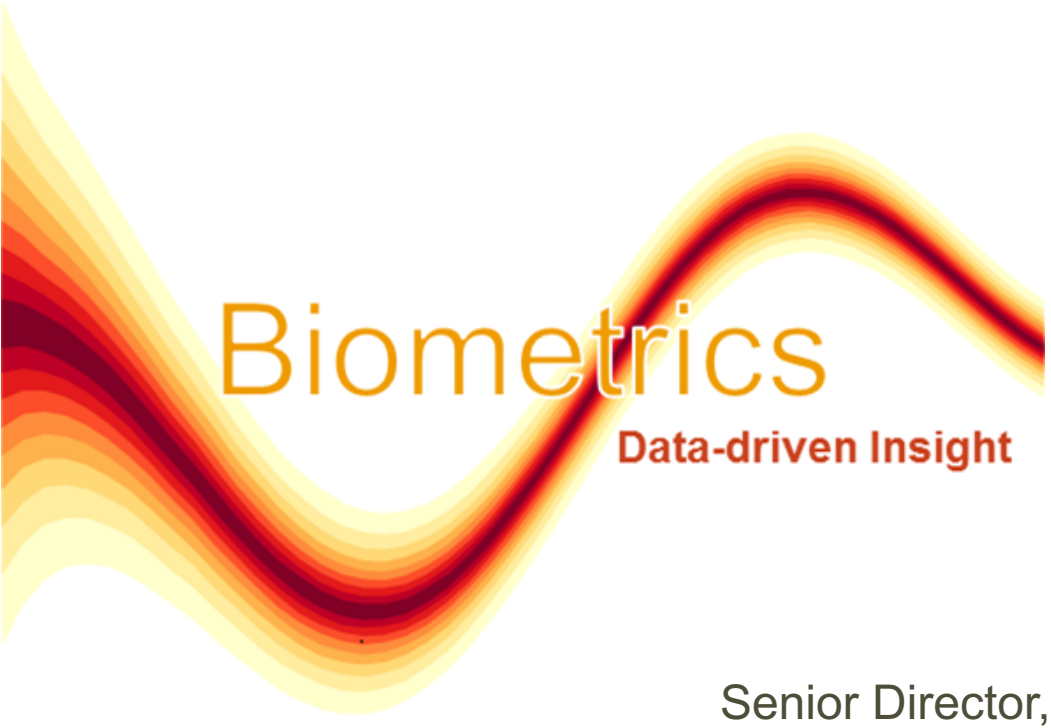
When	Whom	How
• SDTM since 2004. • First SDTM submission in 2006. • All submissions in SDTM and ADaM since then.	• Initially a programmer in Data Management. • Always many trials outsourced to CRO's. • Still CRO's. SDTM oversight in Statistical Programming.	• Ad-hoc SAS code from Oracle Clinical. • Ad-hoc SAS code creating SDTM from CRO 'raw' data.

How has the SDTM generation changed over the recent years, and what have been the drivers for the change?

Originally	Now	Drivers
• Ad-hoc SAS programs. • Programmer in Data Management made SDTM. • CROs asked to make “SDTM”.	• Detailed LEO SDTM specifications. • CRO’s deliver regular and submission ready SDTM. • SDTM responsibility in Statistical Programing. • Pride in high CDISC knowledge and first movers.	• Higher consistency and quality in SDTM. • Adherence to LEO SDTM standards. • Medical / data monitoring. • SAS / CDISC competencies in Statistical Programing. • EDC system outsourced and resource limitations.

How will the SDTM generation be in the future and why?

Current challenges	Solutions	Drivers
• SDTM not always submission ready. • Lack of adherence to LEO standards. • Lack of SDTM consistency. • Overdue deliverables.	• Regular SDTM deliverables from before FPFV. • MDR implementation. • Stronger defined LEO standards and Study Composer. • More automatization.	• Higher SDTM quality and consistency. • Less (no) post processing of SDTM. • Much greater throughput (more trials). • More time to focus on relevant deliverables (ADaM and TFLs).



SDTM at Lundbeck

Karin Gembert
Senior Director, Data Management and Programming

When, by whom and how was SDTM made initially?

When

- Since 2008
- First SDTM Submission 2013

By Whom

- Initially Database programmers in Biometric Programming
- Later Statistical Programmers

How

- Initially SAS Data Integration Studio
- Later Lundbeck SDTM Library

How has the SDTM generation changed over the recent years, and what has been the drivers for the change?

Originally

- Initially Created by mapping tool SAS DI
- Then, an in-house SDTM creation tool, built solely using SAS and Excel
- Complex with a steep learning curve
- High level of standardization possible

Now

- Mapping templates in EntimICE
- Template programs for post-processing
- Split responsibility CDM and SP
- Supported by Standards Manager
- Less Lundbeck specific

Drivers

- Make mapping easier
- CDM involvement
- Adherence to CDISC
- Less ridged and easier to maintain
- Flexibility to update as needed by study requirements

How will the SDTM generation be in the future and why?

Current Challenges

- Steep learning curve for the CDMs
- Responsibility split CDM and SP
- SDTM consistency
- Implementation ongoing – all is new

Solutions

- Build skills and competencies
- Efficient governance
- Templates

Drivers

- Consistency throughout the whole data chain
- Faster
- Adherence to changing standards
- Less ridged and less Lundbeck specific

SDTM at Novo Nordisk

Trine Næstoft
Director, Clinical Data Standards

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When, by whom and how was SDTM made initially?

When

- First SDTM submission in 2013
- From 2016 all trials will be generated in SDTM

By Whom

- Initially Statistical Programmers from Biostatistics
- Recent years insourced SAS programmer consultants anchored in Clinical Data Standards, CSD&TM

How

- SAS custom programs, partly metadata driven
- Metadata maintained in MDR as well as Excel

CSD&TM: Clinical Systems, Data & Trial Management

MDR: Metadata Repository

How has the SDTM generation changed over the recent years, and what has been the drivers for the change?

Originally

- Custom SAS programming
- Partly metadata driven
- Statistical Programmer in Biostatistics
- SAS Programming Consultants

Now

- High use of standard programs
- High use of metadata
- New SDTM Programmer role in DM, GSC
- Supported by Clinical Data Standards department in HQ

Drivers

- Version control of standards
- Need for consistency in adherence to standards
- Need for alignment & scalability
- Need for efficiency: Less effort per trial by use of metadata driven standard programs supplemented with custom programs
- Leveraging existing global DM roles

GSC: Global Service Centre, Novo Nordisk India

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How will the SDTM generation be in the future and why?

Current Challenges

- Prepare standards for use in MDR
- Integration between multiple systems and semi-automated and manual steps
- End-to-end mind-set and culture in organisation
- Complexity

Solutions

- Skills and competencies
- End-to-end governance of standards
- High use of standard programs
- High use of metadata
- Improved systems integration

Drivers

- Efficiency
- Consistency
- Quality
- Adherence to changing standards and regulatory requirements

MDR: Metadata Repository

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SDTM at Bayer

Elena Glathe
Head of Statistical Analytics, Germany

When, by whom and how was SDTM made initially?

When

- Since 2010 operationally SDTM+ is generated.

  Submissions in SDTM for submissions

By Whom

- SDTM+ done by DM programming (clinical data center)
  SDTM done externally

- 2018: SDTM+/SDTM creation is transferred to statistical programming

How

- SAS program templates and macros,
  partly Excel metadata mapping
- Metadata in SAS data sets,
  Mapping specs partly in Excel

How has the SDTM generation changed over the recent years, and what has been the drivers for the change?

Originally

- Program templates

Now

- Generated mapping programs using Excel mapping specs
- Updated mapping macros for specifics tasks (relative days, treatment emergent flag)
- Metadata available as sas datasets → machine readable

Drivers

- Easier maintenance
- Flexible adjustments of mappings in Excel.
- Complex derivations are better covered in macros to reduce errors

How will the SDTM generation be in the future and why?

Current Challenges

- Clean implementation over all studies
- One standard for all
- CDASH planned
- Streamline of template scripts
- Move from SDTM+ to pure SDTM (mid term)
- Implementation of new Systems (LSH)

Solutions

- One strategy over the whole company

Drivers

- MDR implementation for all standards elements

SDTM Panel Discussion

Questions to the Panel

- When, by whom and how was SDTM made initially?
- How has the SDTM generation changed over the recent years, and what has been the drivers for the change?
- How will the SDTM generation be in the future and why?

When, by whom and how was SDTM made initially?

	When	By Whom	How	Trend
FERRING PHARMACEUTICALS	2007	• 95% DM • 5% Stat Prog	• SAS std pgms	• Originate from DM or Stat Prog • SAS based • Mainly custom • Some use of metadata
LEO	2004	• DM & CROs • Oversight by Stat Prog	• Ad-hoc SAS code	
Lundbeck	2008	• Biometric / Statistical Programming	• SAS DI Studio • SAS std pgms partly metadata driven	
novo nordisk	2013	• Stat Prog + • In-house Consult	• SAS custom pgms & macros, partly metadata driven	
BAYER	2010	• DM Prog + • CRO	• SAS custom pgms & macros, partly metadata driven	

How has the SDTM generation changed over the recent years?

	Originally	*Now*	Drivers	Trend

FERRING PHARMACEUTICALS	It hasn't changed		• Happy
			• Lack resources
			• No vendor solution
				• More consistent and correct SDTM
				• Ease of use and maintenance
				• Version Control
				• Roles:
				  • DM versus Stat
				  • In-house versus CRO

LEO	• DM • AD-hoc Pgms	• CRO • Stat Prog specify and responsible	• Higher consistency • Adherence to standard	
Lundbeck	• Biometric Programming • SAS + Excel	• CDM + Stat Prog • EntimICE • Template Pgms	• Easy mapping • CDM role • Less ridged/Maintn	
novo nordisk	• Consultants • Custom Pgm • Partly metad	• DM role • Std Pgm and metadata	• Versions Control • Consistency • Scalability	
BAYER	• DM Prog and CRO • P Templates	• Stat Prog • Std Pgm and metadata	• Easy Maintenance • Flexible • Use SAS macros	

How will the SDTM generation be in the future and why?

	Challenge	Solution	Drivers	Trend
FERRING PHARMACEUTICALS	• Versioning • Timelines • Resources	• Omar solution • Test data • Vendor tools	• Changing standards • SDTM during conduct • Less internal systems	• Consistency • Changing standards • Control of standards • Metadata & MDR • Systems • Competencies
LEO	• Quality • Timelines	• SDTM early • MDR tools • Leo Standards	• Consistent Quality • Less post process • Efficiency & Capacity	
Lundbeck	• Complexity • DM–Stat Prog • Consistency	• Competencies • Governance • Templates	• Consistency & speed • Changing standards • Less Lundbeck-ridged	
novo nordisk	• Prepare use • Integration • End-to-end	• Competencies • Governance • Metadata use	• Efficiency • Consistency, Quality • Changing standards	
BAYER	• Consistency • Efficiency • New systems	• One strategy over the whole company	• MDR implementation for all standards elements	

Thank you to our SDTM Panel

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