



MAURIZIO BARDINI  
Italy  
Maurizio has type 1 diabetes

# Challenges in Adapting the Diabetes Therapeutic Area User Guide

Anja Lundgreen & Mikkel Traun  
Novo Nordisk

# The Diabetes TAUG

- Provisional in 2014
- ADaM supplement in March 2016
- Includes drafted new domains
  - Procedure Agents (AG) – previously used in the drafted Asthma TAUG
  - Meal Data (ML)
  - Subject Disease Milestones (SM)
  - Trial Disease Milestone (TM)
- Uses new SDTM v1.5 MIDS variable as a reference concept

# NN SDTM compared with the Diabetes TAUG – Diabetes Complications

## Example from the TAUG

|                                           |                                            |
|-------------------------------------------|--------------------------------------------|
| Example conditions/terms:                 | Pre-specified                              |
| Diabetic Retinopathy <b>MHTERM</b>        | <b>MHPRESP=Y</b>                           |
| Neuropathy                                |                                            |
| Nephropathy                               |                                            |
| Peripheral Vascular Disease               |                                            |
| Atherosclerotic Heart Disease             |                                            |
| Diabetic Ketoacidosis                     |                                            |
| Hyperglycaemic Hyperosmolar Syndrome      |                                            |
| Did the subject have <specific condition> | Yes <b>MHOCCUR</b>                         |
|                                           | No                                         |
| Date of Diagnosis                         | DD-MMM-YYYY <b>MH</b>                      |
| Medical History Category                  | DIABETES (Pre-specified) <b>MH</b>         |
| Medical History Subcategory               | COMPLICATION (Pre-specified) <b>MHSCAT</b> |

## NN SDTM example

Diabetes Complications **MHSCAT** **MH=Medical History**

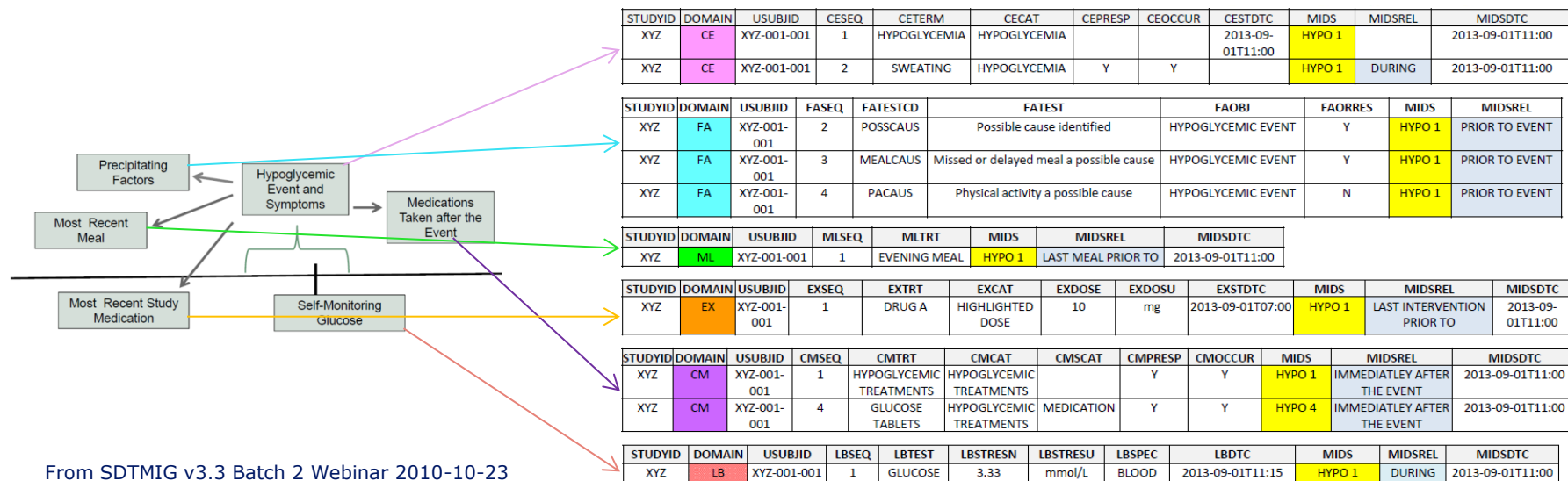
Has the subject been diagnosed with any of the following diabetes complications?

|                                       |                                           |
|---------------------------------------|-------------------------------------------|
| Diabetic Retinopathy <b>MHPRESP=Y</b> | No                                        |
| <b>MHTERM</b>                         | Yes Date of onset <b>MHOCCUR</b>          |
|                                       | DD MMM YYYY <b>MHSTDTC</b>                |
|                                       | Further description <b>DESC in SUPPMH</b> |
| Diabetic Nephropathy <b>MHPRESP=Y</b> | No                                        |
| <b>MHTERM</b>                         | Yes Date of onset <b>MHOCCUR</b>          |
|                                       | DD MMM YYYY <b>MHSTDTC</b>                |
|                                       | Further description <b>DESC in SUPPMH</b> |

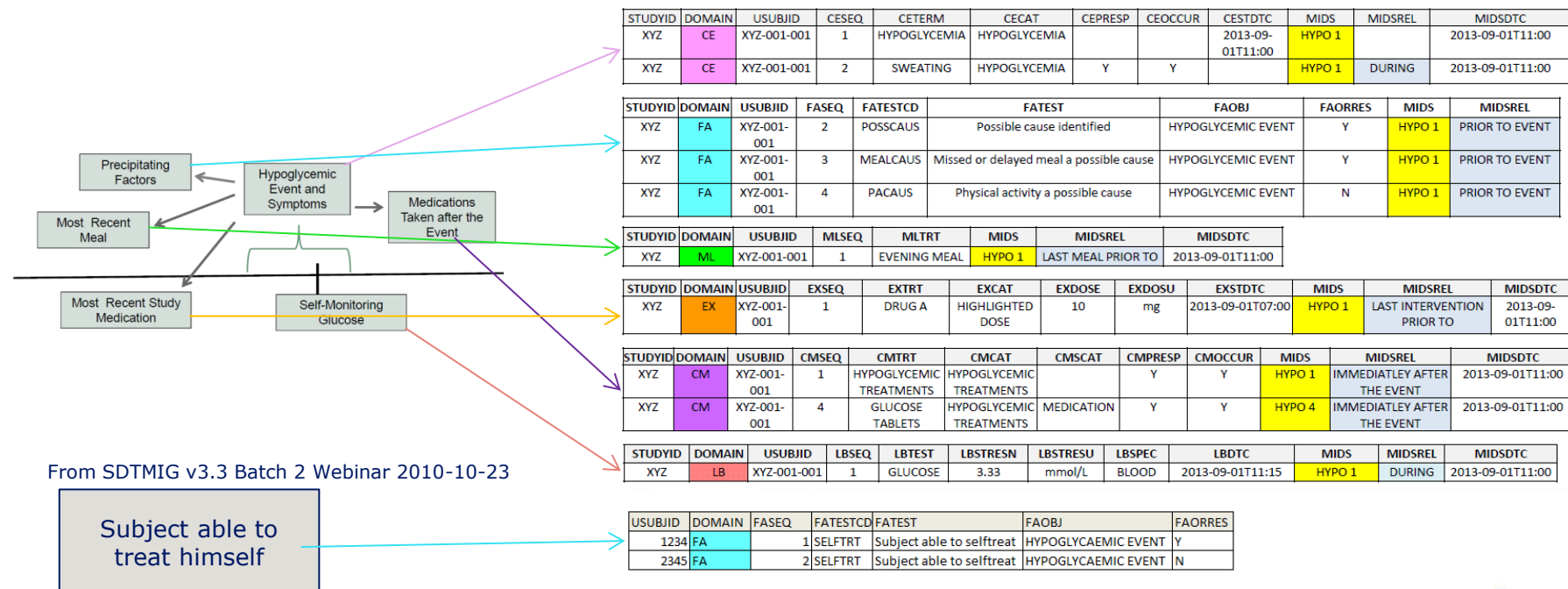
# Hypoglycaemia

- Hypoglycaemic events are of major safety interest in all diabetes trials
  - A hypoglycaemic event is an expected adverse reaction to insulin treatment and one of our safety endpoints is reduction of hypoglycaemic events. In this context it is not meaningful to describe hypoglycaemic events as 'Disease Milestones', it would be more appropriate to regard these as 'Disease Events', and simply see them as clinical events in the CE domain
- The way the diabetes TAUG maps information related to the hypoglycaemic events into many different domains with relationships between them, is different from the current Novo Nordisk practise
- The relationship between the collected information for a hypoglycaemic event is based on the new SDTM v1.5 Disease Milestone reference concepts in the diabetes TAUG
  - Using the MIDS (Disease Milestone Instance Name) variable.

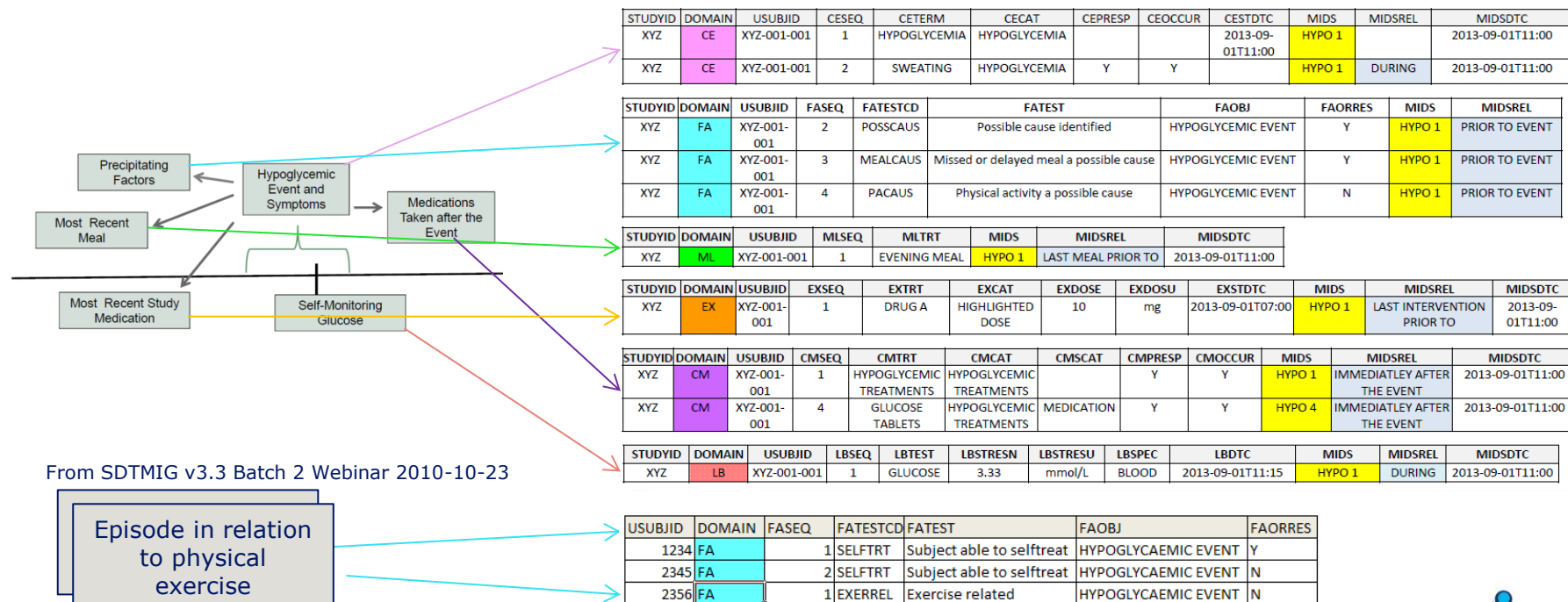
# Hypoglycaemic event – TAUG example



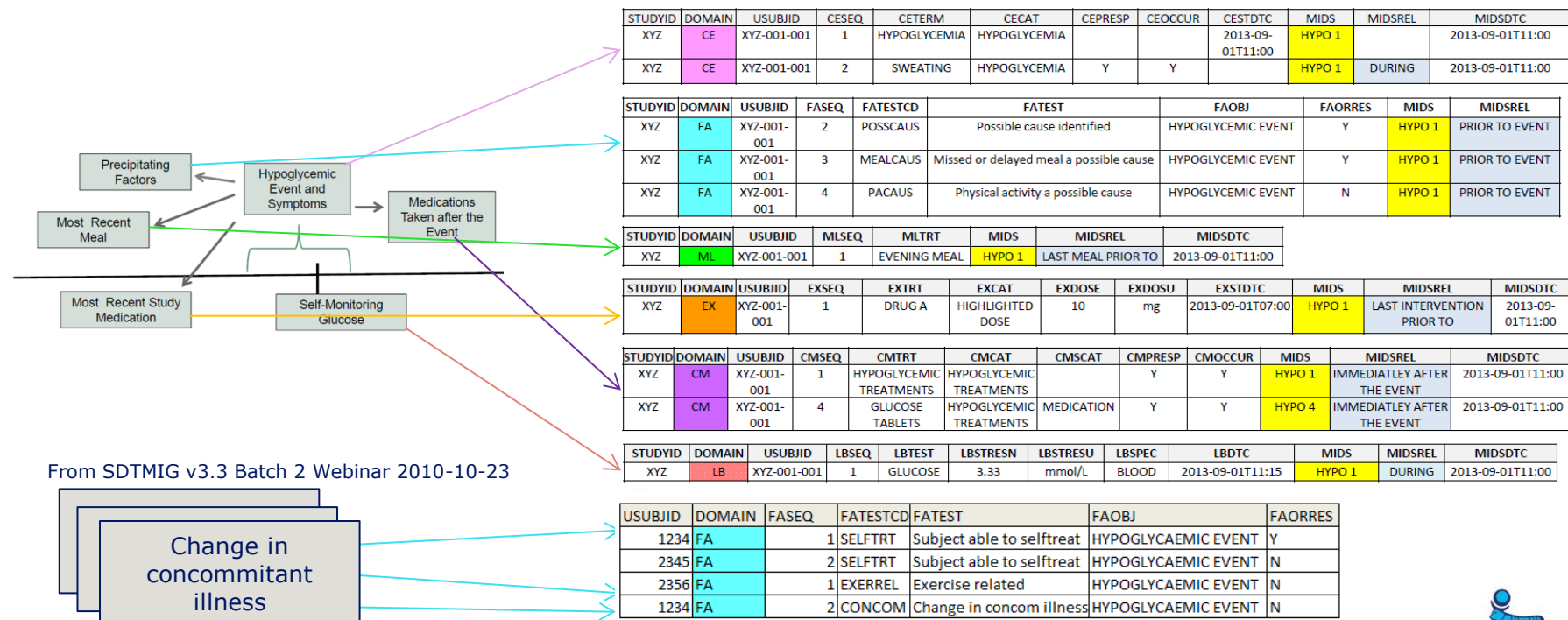
# Hypoglycaemic event – TAUG example



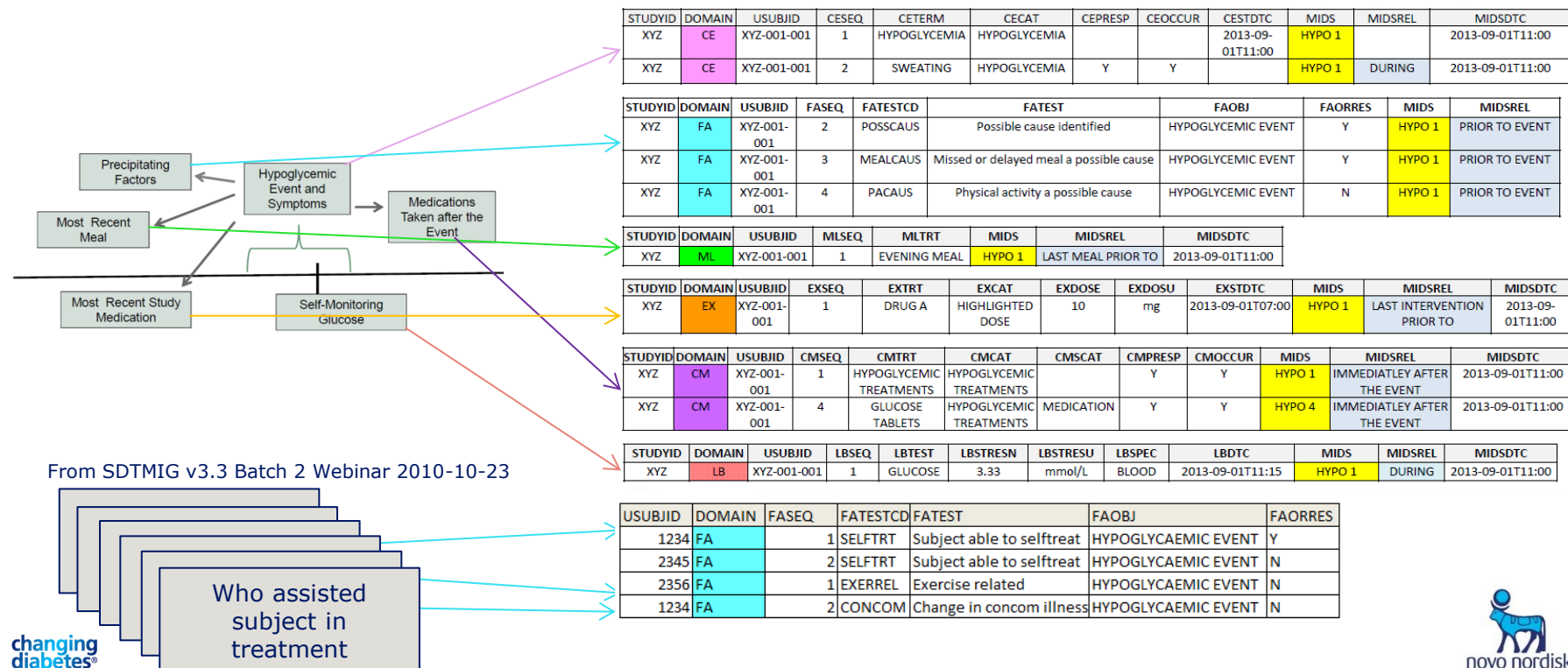
# Hypoglycaemic event – TAUG example



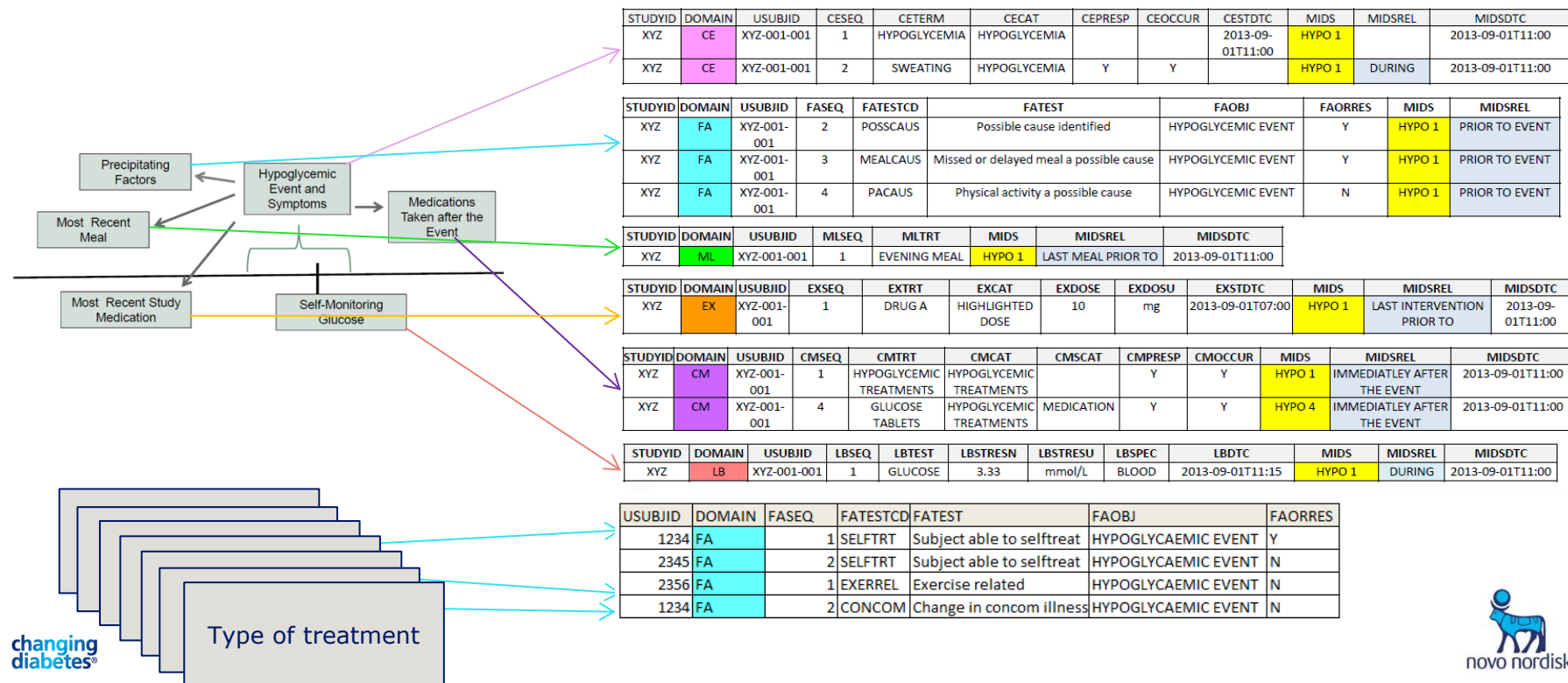
# Hypoglycaemic event – TAUG example



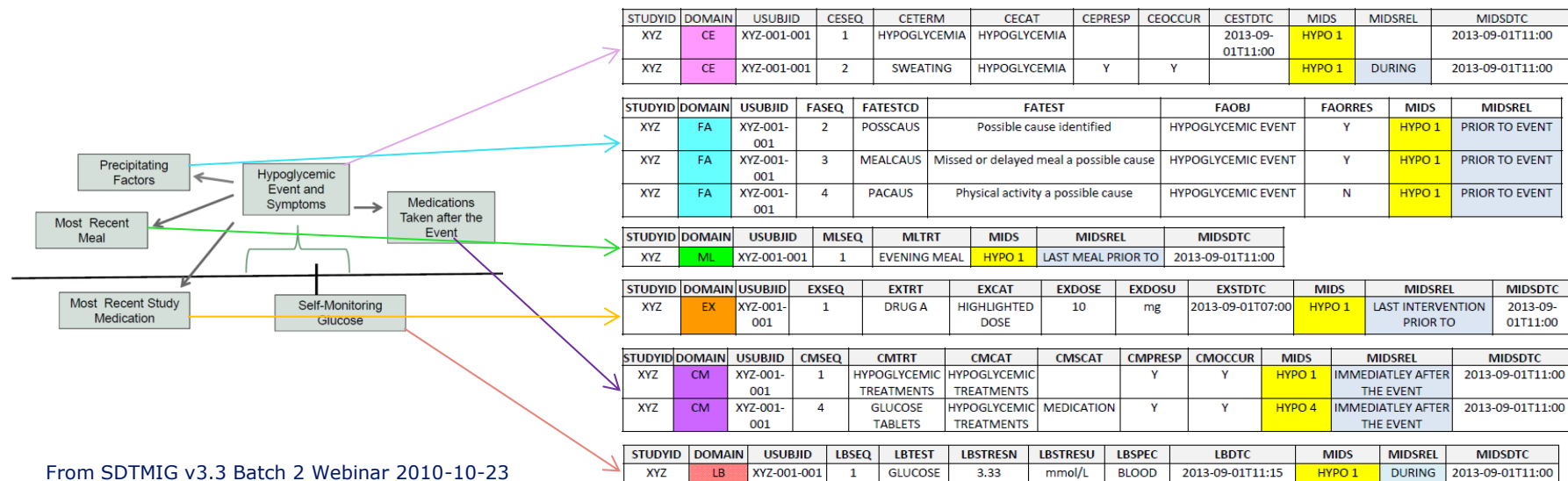
# Hypoglycaemic event – TAUG example



# Hypoglycaemic event – TAUG example

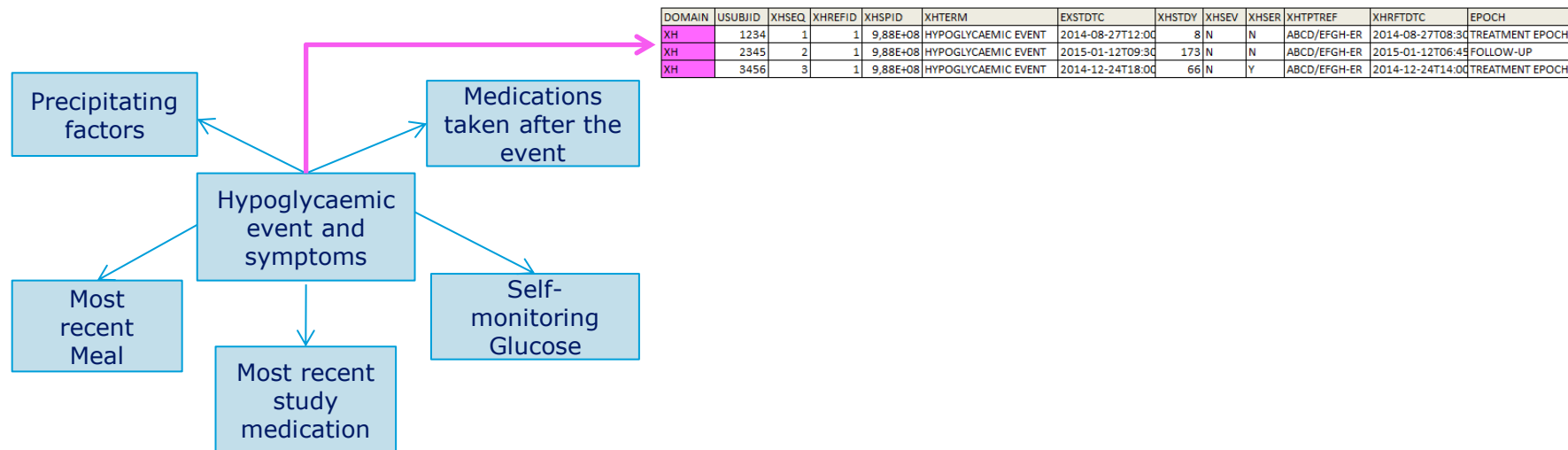


# Hypoglycaemic event – TAUG example

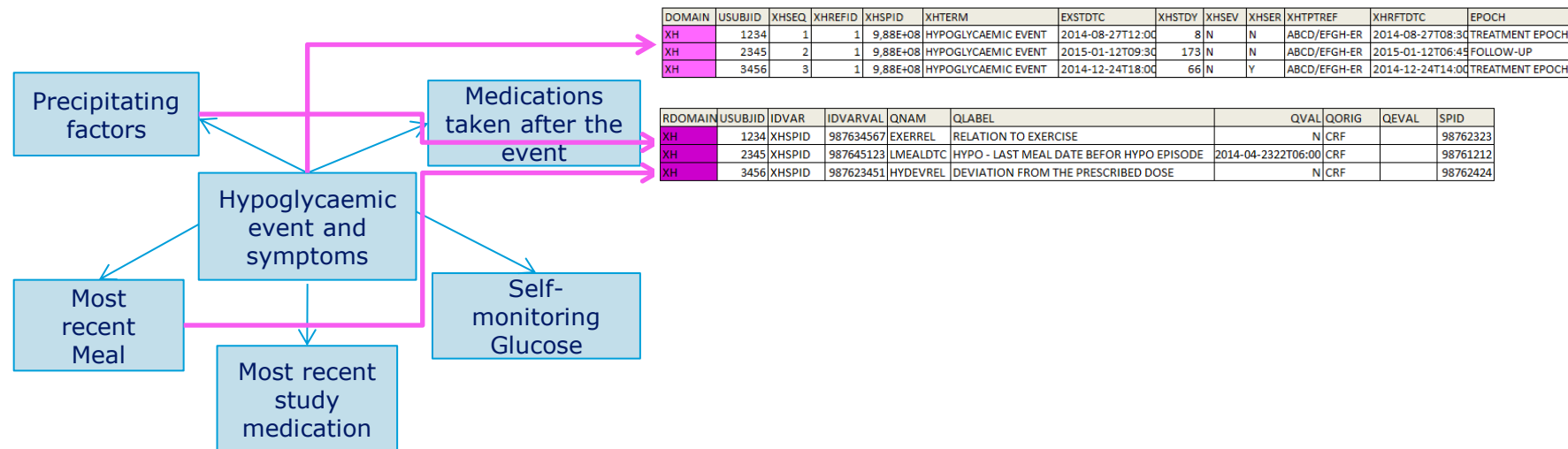


- Juice or Carbohydrates provided by civilian = ML
- Glucose injection provided by medical person = CM

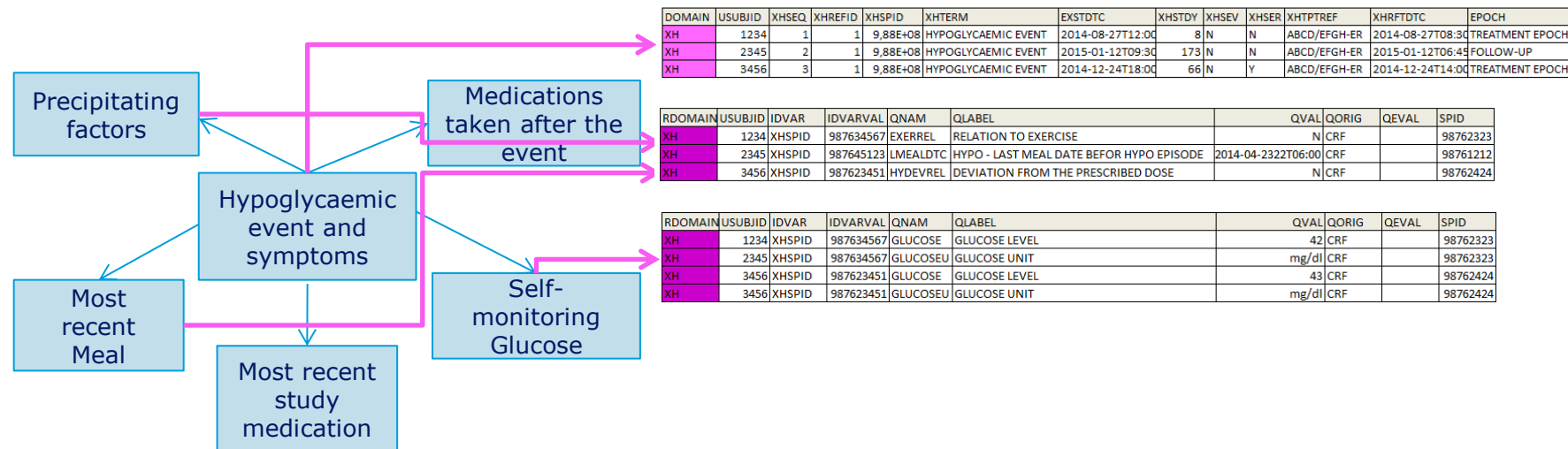
# Hypoglycaemic event – Novo Nordisk example



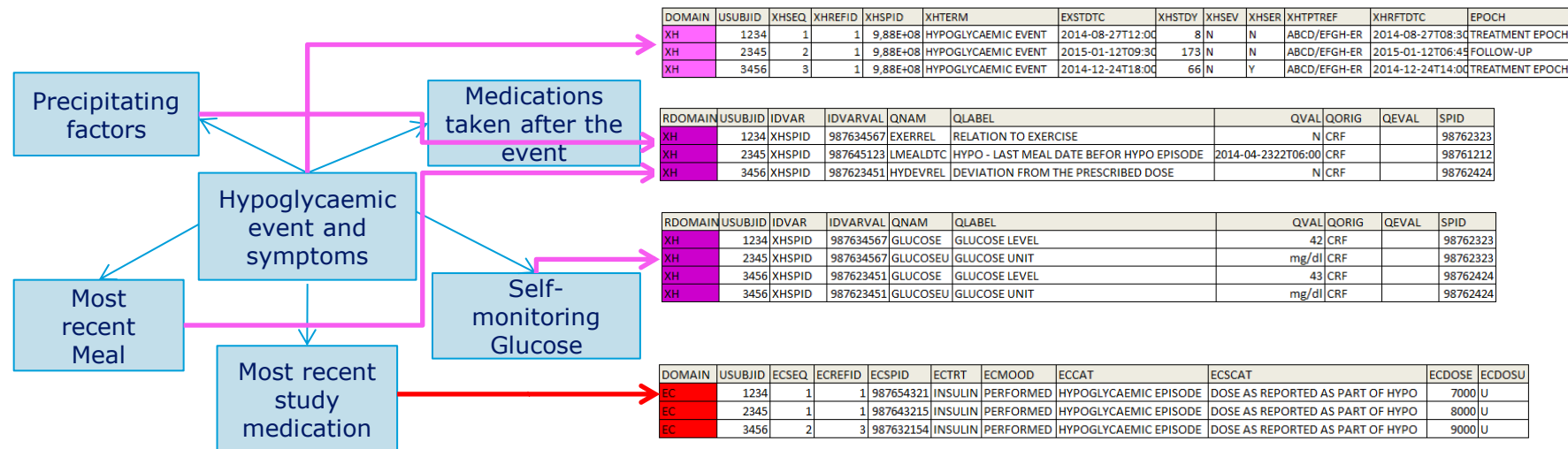
# Hypoglycaemic event – Novo Nordisk example



# Hypoglycaemic event – Novo Nordisk example

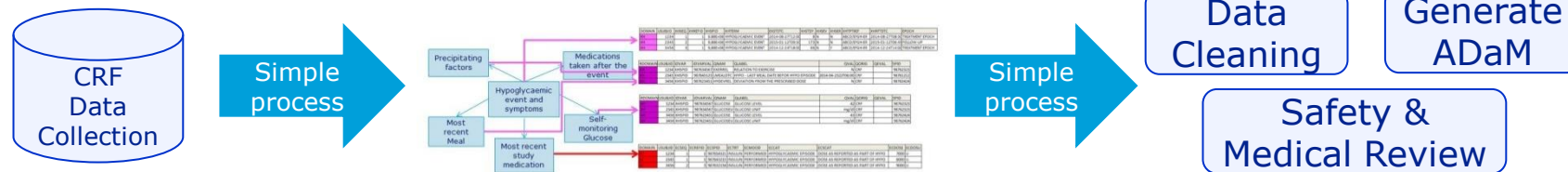


# Hypoglycaemic event – Novo Nordisk example

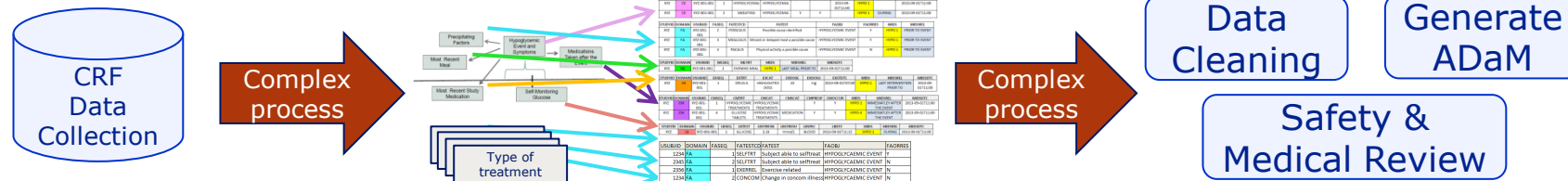


# Challenge

## Current Diabetes TA SDTM implementation at Novo Nordisk



## Diabetes TAUG SDTM model following a detailed topicality and using new SDTM v1.5 variables and reference concepts



# Conclusion

- Adapting the new Diabetes TAUG for our SDTM implementation and corresponding programs for ADaM generation will change our existing clinical data handling and can impact future cross trial data integration
- It is uncertain when the Diabetes TAUG standard will be supported or when it will be required
- It is difficult for sponsors to decide when to apply a new CDISC TAUG standard.

# Presenters

**Anja Lundgreen**

Standards Specialist

Clinical Systems & Data Management

Clinical Data Standards

Novo Nordisk A/S

[ajld@novonordisk.com](mailto:ajld@novonordisk.com)

**Mikkel Traun**

Principal System Developer

Clinical Systems & Data Management

Programming Anchor

Novo Nordisk A/S

[mt@novonordisk.com](mailto:mt@novonordisk.com)



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