

# Event Adjudication end-2-end traceability

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## Introduction

Event adjudication is a review done by two independent medical specialists who assesses events for fulfilment of pre-defined clinical criteria.

Adjudication data do not replace or otherwise modify investigator reported data.

In Novo Nordisk adjudication data is used to assess key efficacy and safety variables in primary and secondary analyses, in addition to the investigator reported data.

The poster presents Novo Nordisk's approach to a data standard for adjudication data, and how it supports **end-to-end traceability**.

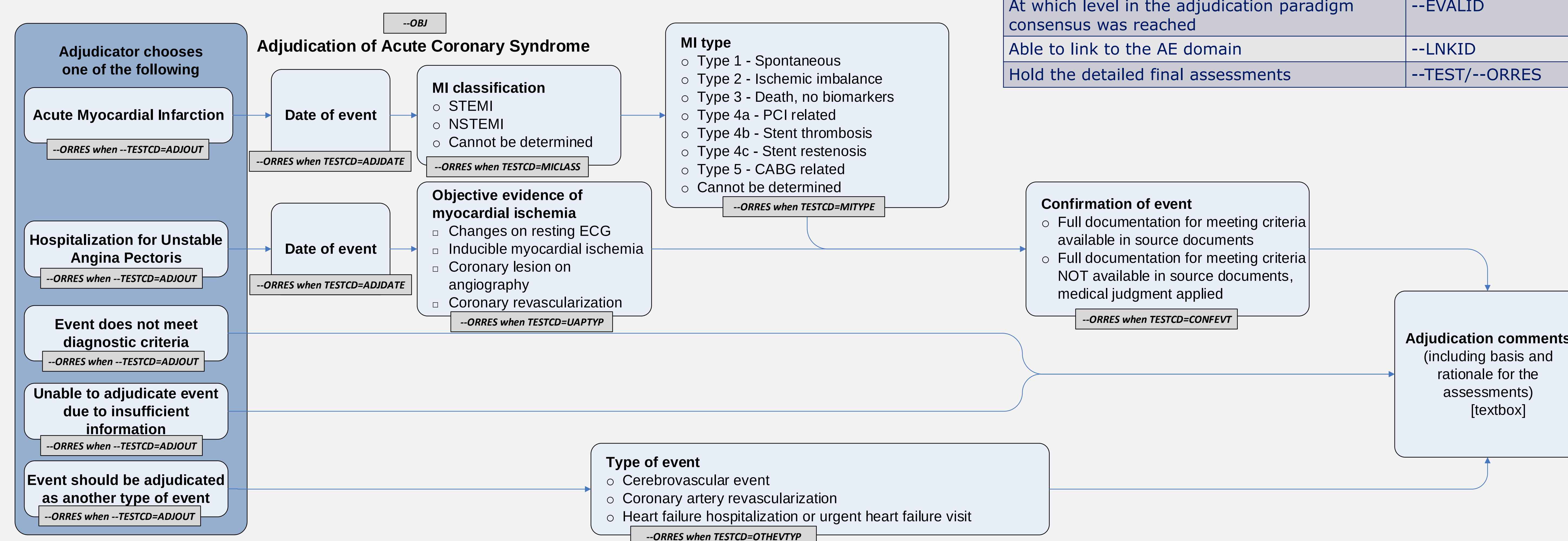
## Requirements

- **Technical Conformance Guide:** 'Whenever adjudication data is provided it should be clearly identified so that the reviewer can distinguish the results of adjudication from data as originally collected'.
- Assessments from different types of events in different clinical settings are to be captured and reported.

## SDTM considerations

- Novo Nordisk has implemented a sponsor defined stand-alone domain with the Findings About concept.
- Only the final agreed assessments from the two independent adjudicators are submitted in our SDTM data set.

## Standardised data collection design



| --LNKID | --REFID | --TESTCD | --TEST                                  | --OBJ | --ORRES                            | --EVAL                 | --EVALID             | --DTC |
|---------|---------|----------|-----------------------------------------|-------|------------------------------------|------------------------|----------------------|-------|
| 14      | 1       | SOURADEV | Source of adjudicated event             | ACS   | INVESTIGATOR REPORTED              | ADJUDICATION COMMITTEE | PRIMARY ADJUDICATION |       |
| 14      | 1       | ADJOUT   | Adjudication outcome                    | ACS   | ACUTE MYOCARDIAL INFARCTION        | ADJUDICATION COMMITTEE | PRIMARY ADJUDICATION |       |
| 14      | 1       | ADJDATE  | Evaluated Event Onset date              | ACS   | 2017-01-01                         | ADJUDICATION COMMITTEE | PRIMARY ADJUDICATION |       |
| 14      | 1       | MICLASS  | Classification of Myocardial Infarction | ACS   | ST ELEVATION MYOCARDIAL INFARCTION | ADJUDICATION COMMITTEE | PRIMARY ADJUDICATION |       |
| 14      | 1       | MITYPE   | Type of Myocardial Infarction           | ACS   | TYPE 1 MYOCARDIAL INFARCTION       | ADJUDICATION COMMITTEE | PRIMARY ADJUDICATION |       |
| 14      | 1       | CONF EVT | Confirmation of event                   | ACS   | FULL DOCUMENTATION AVAILABLE       | ADJUDICATION COMMITTEE | PRIMARY ADJUDICATION |       |

## Conclusions

Currently the SDTMIG does not offer explicit guidance on how adjudication results are to be represented in SDTM.

We would all benefit from standardised data collection and more guidance in SDTM standards within this area.

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