



# Consideration in the submission of Holter (EG) Data in an SDTM compliant Format

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# Objective

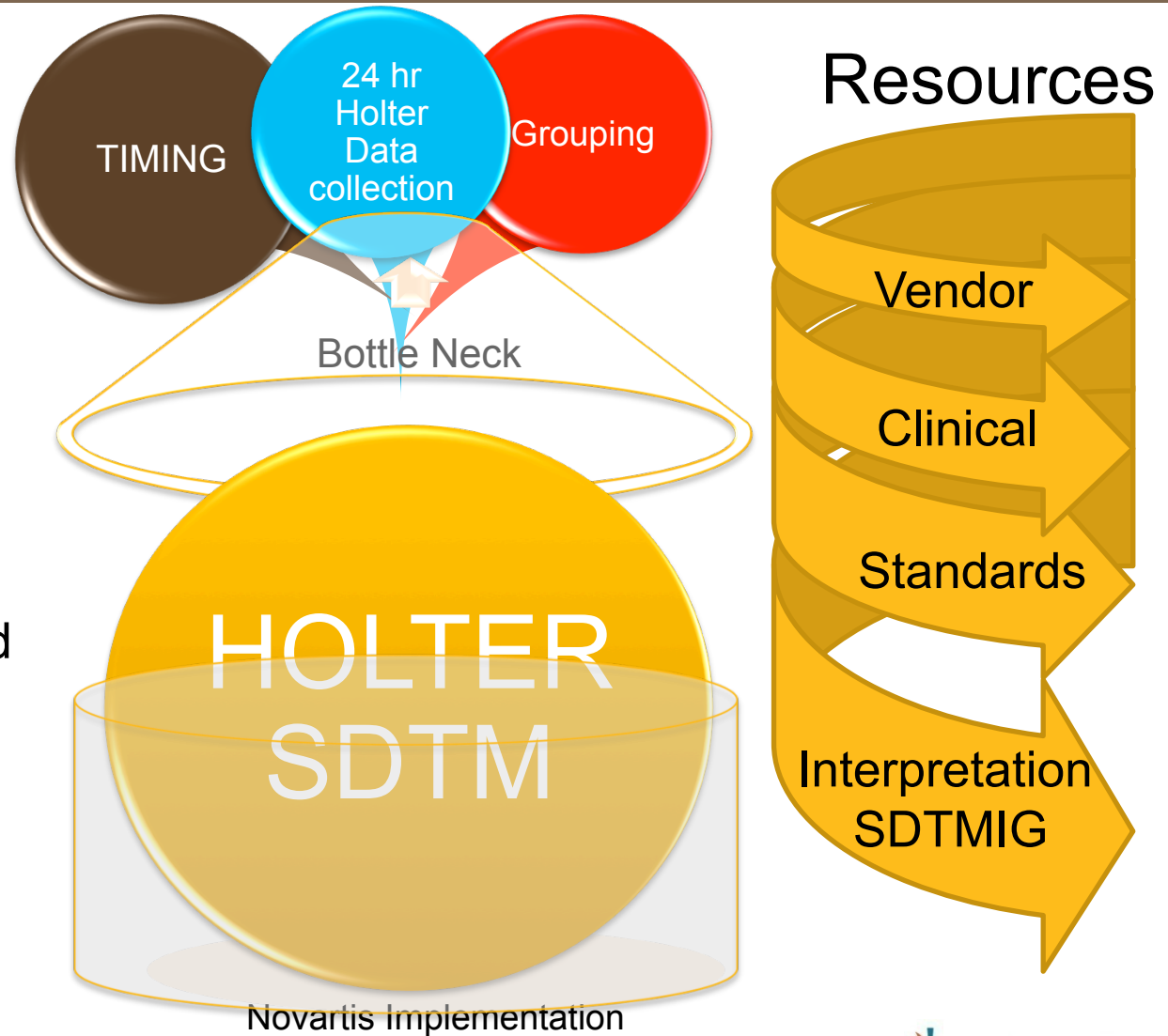
*Insight into the challenges and possible solutions for implementing Holter data*

- Challenges of implementation

- EGTEST
- SDTMIG Interpretation
- Timing
- Grouping

- Solutions adopted

- NCI/CDISC
- EGSCAT
- SUPQUAL

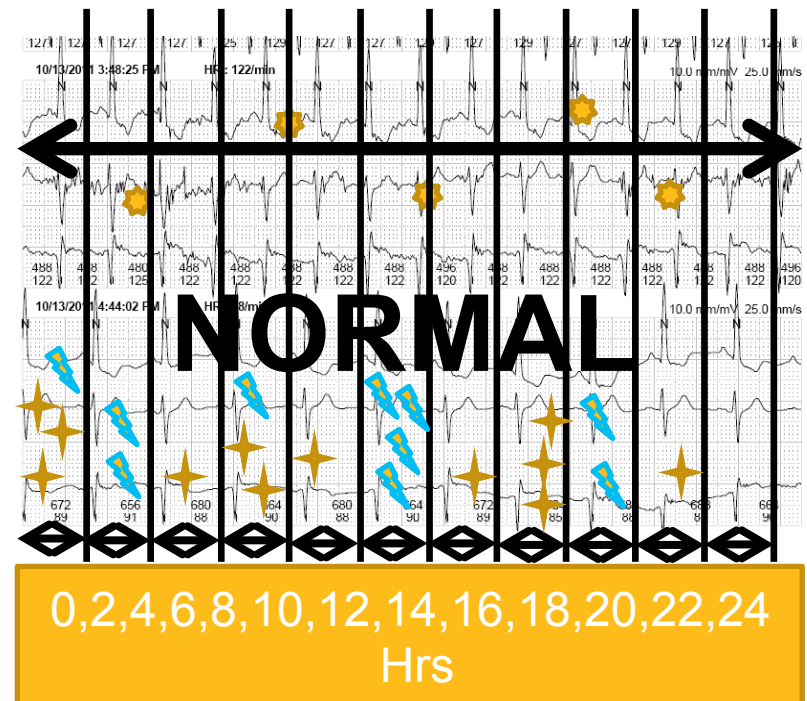


# Holter Data

## Overview Holter

### ■ Electrocardiogram data

- Resting & Ambulatory(Holter) ECG are the same SDTM topic so logic to put in EG domain
- Holter Monitor Strip
  - Overall assessment
    - Assessment interval
    - Max, Mean, Min HR, **Total PACs**
    - Cardiologists unsolicited finding ⚡
    - Overall interpretation
  - Interval measurements and finding
    - Assessment interval
    - Max, Mean, Min HR, **Total PACs** ⚡
    - Solicited findings, **AV 2:1 BLOCK** ⚡
  - Strip findings
    - Representative findings that support overall assessment



# 24 hr Holter vs Resting ECG SDTM Implementation

## *SDTMIG v3.1.2 Key Findings*

- **SDTMIG** – Clear examples for Resting ECG not so clear for Holter
- **EGTEST** – Controlled terminology not complete for parameters to be collected from Holter assessment. E.g. AV Block, Atrial Fibulation, Pause, R on T
- **Groupings** – High level consistency with Resting ECG EGCAT (Measurement and findings) but we have to analyze / report :
  - RESTING ECG
  - **HOLTER ECG STRIP label**
  - **HOLTER ECG Interval**
  - **HOLTER overall**
- **Timing** – Holter over 24hrs, may be subset into hourly intervals (Total number of Pauses > 2 sec) and distinct solicited Findings (2:1 AV Block)

# Implementation challenge

## *Controlled terminology for EG parameters - EGTEST*

- EGTEST codelist is not complete for planned Holter analysis
- Need approximately 50 new EGTEST items
  - Vendor has not approached NCI/CDISC for appraisal discussion
- Data Transfer Spec development time limited
  - Do we work at risk
  - Develop a SUPQUAL “EGTEST” strategy?
  - Is it possible to develop a SUPQUAL Strategy?
- We investigate the “develop a SUPQUAL Strategy”

# Implementation challenge

## Controlled terminology for EG parameters - EGTEST

- In our view it is possible to add the additional Holter data in SUPQUAL using EGGRPID and EGRESCAT
  - EGRESCAT – used to categorize results after the fact
  - EGGRPID – Tie together a block of related records
  - MISSING EGTEST AV 2:1 Mobitz < 3 s and AV 2:1 Mobitz >= 3 s**
  - Use existing codelist EGSTRESC for AV 2:1 Mobitz Finding
  - Categorize the finding “EGRESCAT” based on result
  - Use EGRESCAT to define value of EGGRPID
  - Then use EGGRPID to link to Number of episodes

EG domain  
SUPPEG: supplemental qualifier for EG

VISIT	EGSCAT	EGCAT	EGTPT	EGGRPID	EGRESCAT	EGTEST	EGSTRESC
DAY1	HOLTER ECG - INTERVAL	FINDIN G	1 H O U R P O S T	D A Y 1 _ 1HR_POST _>= 3 SEC	>= 3 SEC	Conduction	AV 2:1 MOBITZ
QNAM	QLABEL		QVAL		IDVAR	IDVAL	
COUNT	Number of episode		52		EGGRPID	DAY1_1HR_POST _>=3sec	

- Solution – NCI / CDISC Approval sought implemented new EGTEST at risk though we think we have a back up if not approved

# Implementation challenge

## Consideration for grouping variables in the EG domain

- EGCAT – Highlevel **‘Interval’**, **‘Measurement’**, **‘Finding’** can be used for Resting and Holter ECG.
- EGMETHOD – ‘12-lead ecg’ (EGMETHOD) applicable to both
- EGSCAT (Sponsor defined)
  - Differentiate between different procedures (RESTING, HOLTER)
  - Differentiate between different modes of data collection

VISIT	EGSCAT	EGCAT	EGTPT	EGGRPID	EG-REFID	EG-SPID	EGTEST	EGSTRESC
DAY1	RESTING ECG	MEASUREMENT	PRE		331PT8		Summary (Mean) Heart Rate	75
DAY1	RESTING ECG	MEASUREMENT	1 HOUR POST		332PT8		Summary (Mean) Heart Rate	65
DAY1	RESTING ECG	MEASUREMENT	6 HOURS POST		336PT89		Summary (Mean) Heart Rate	55
DAY1	HOLTER ECG - OVERALL	MEASUREMENT			55HO81		Summary (Mean) Heart Rate	
DAY1	HOLTER ECG - INTERVAL	MEASUREMENT	PRE	DAY1 - PRE	55HO81	Dev991	Summary (Mean) Heart Rate	72
DAY1	HOLTER ECG - INTERVAL	MEASUREMENT	1 HOUR POST	DAY1 - 1HR_POST	55HO81	Dev991	Summary (Mean) Heart Rate	62
DAY1	HOLTER ECG - INTERVAL		...		...			
DAY1	HOLTER ECG - OVERALL	FINDING					Technical condition	Device replaced 6 hours post-dose after an interruption of about 3 hours.
DAY1	HOLTER ECG - INTERVAL	MEASUREMENT	2 3 HOURS POST	DAY1 - 23HR_POST	55HO81	Dev554	Summary (Mean) Heart Rate	75
DAY1	HOLTER ECG - STRIP LABEL	MEASUREMENT		1	55HO81	Dev554	Summary (Mean) Heart Rate	55
DAY1	HOLTER ECG - STRIP LABEL	FINDING		1	55HO81		Ectopy	PREMATURE ATRIAL COMPLEX
DAY1	HOLTER ECG - STRIP LABEL	FINDING		1	55HO81		Technical problem	ARTIFACT
DAY1	HOLTER ECG - STRIP LABEL	FINDING		1	55HO81		Conduction	AV 2:1 MOBITZ

# Implementation challenge

*Consideration for DATETIME variables in the EG domain*

- Holter data
  - 24 hr continuous recording
  - Assessments
    - Overall, Hourly and event driven findings.
    - All assessments occur within an interval
  
- EG Domain Timing variable
  - EGDTC (Discrete collection and interval start date)
  - EGENDTTC (Interval End date)
  - --STDTC (Start date not applicable for Finding (4.1.4.8 )
  
- How do we record an event that occurs during an interval?



# Implementation challenge

Consideration for DATETIME variables in the EG domain

- EG DOMAIN & SUPPEG for collection
  - EGDTC (Discrete collection and interval start date)
  - EGENDTC (Interval end date)
  - Handling when event date is not the same as collection

EGCAT	EGSCAT	EGSEQ	EGTEST	EGSTRESC	EGTPT	EGDTC	EGENDTC
					Time point Name	Collection start date/time	Collection End date/time
MEASUREMENT	RESTING ECG	1	Summary (Min) Heart rate	55	1 HOUR POST	2013-04-01T8:12	
MEASUREMENT	HOLTER ECG - INTERVAL	3	Summary (Mean) Heart rate	72	1 HOUR POST	2013-04-01T8:02	2013-04-01T9:02
MEASUREMENT	HOLTER ECG - INTERVAL	4	Summary (Min) Heart rate	45	1 HOUR POST	2013-04-01T8:02	2013-04-01T9:02
FINDING	HOLTER ECG - INTERVAL	5	CONDUCTION	AV2:1 BLOCK	1 HOUR POST	2013-04-01T8:02	2013-04-01T9:02

Start and end of Interval for the event

Start and end of finding event

EGDTC	QLABEL	QVAL	IDVAR	IDVAL
EVDTC	Event <b>start</b> date/time	2013-04-01T8:50	EGSEQ	4
EVDTC	Event <b>start</b> date/time	2013-04-01T8:10	EGSEQ	5
EVENDTC	Event <b>end</b> date/time	2013-04-01T8:15	EGSEQ	5

# Conclusions

## *And open questions*

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- Interpretations of STDMIG may differ
  - Many vendors, companies, internal team representatives.
- Are domain forums needed?
- How do we influence domain development?
- Collecting additional information regarding findings is unclear New EGTEST or SUPPEG (EGRESCAT)
- TIMINGs - Are two sets of timing variable needed, event and interval based

# Acknowledgments

## *Contact details*

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