

# NEW DOMAINS FOR IG 3.3 FROM REVIEW BATCH 1

## CV

### *CARDIOVASCULAR PHYSIOLOGY*

03-MAR-2015, 20<sup>th</sup> German CDISC User Network Meeting

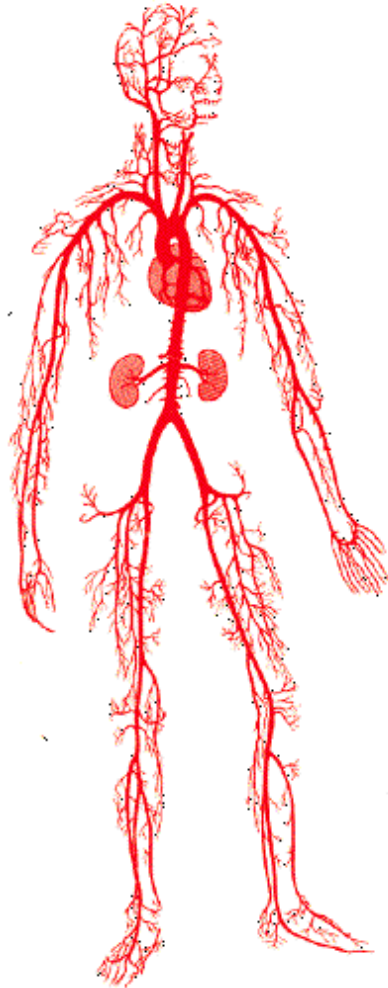
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# CARDIOVASCULAR PHYSIOLOGY – CV DOMAIN



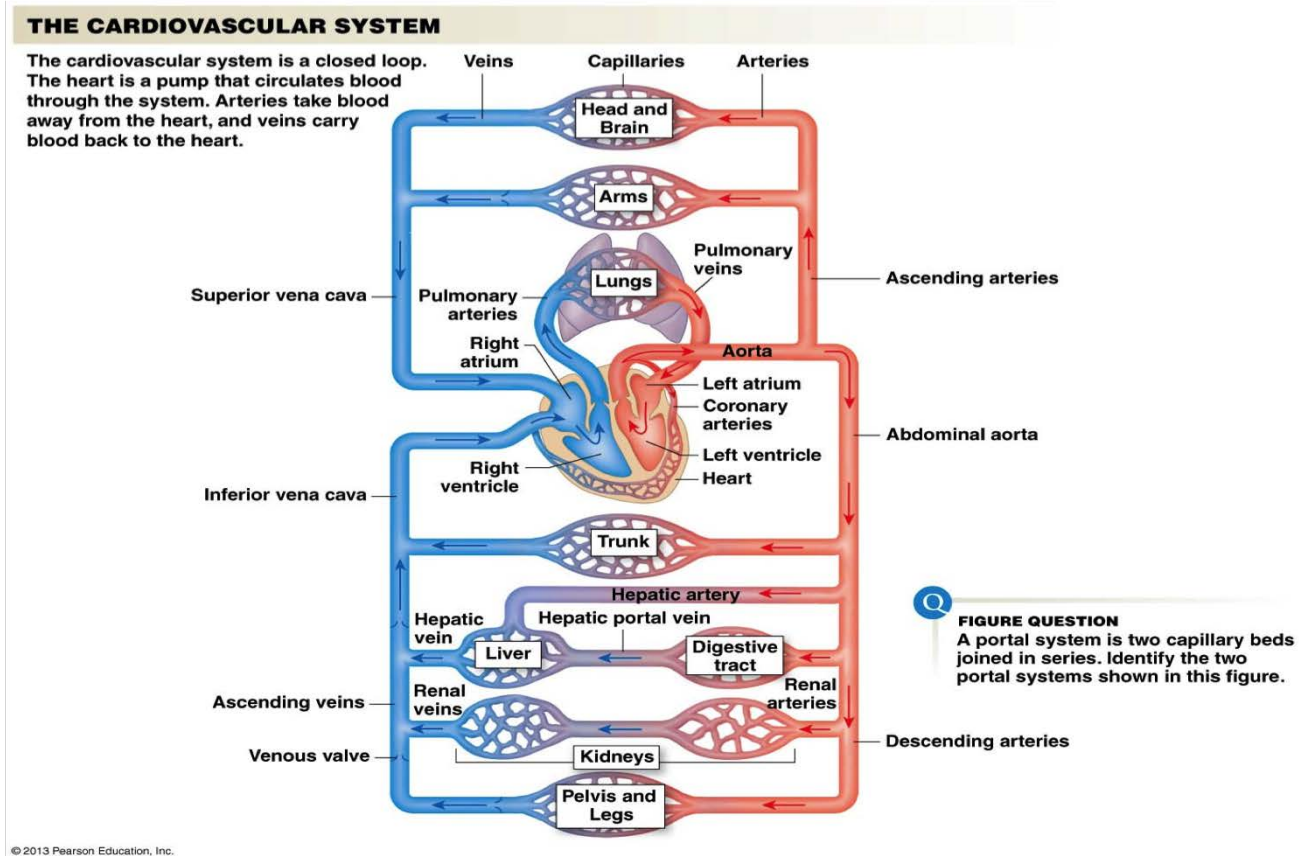
- Introduction to the Cardiovascular Physiology
- Disorders and Diseases
- CV Domain + Example

# INTRODUCTION

## CARDIOVASCULAR PHYSIOLOGY

### Cardiovascular System

- Cardio = Heart, vascular = blood vessels
- Essential components: Heart, Blood, Blood Vessels



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## Disorders/Diseases of the cardiovascular system

- Pericarditis
- Hypertension
- Heart Valve Disease
- Aorta Disease
  - i.e. Arteriosclerosis
- Coronary Heart Disease (CHD): Plaque building up inside the coronary (heart) arteries
  - May lead to myocardial infarction, angina, sudden death
- Cardiac Arrhythmias
  - Tachycardia, Bradycardia, Sinus Arrhythmia

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# *CV = CARDIOVASCULAR PHYSIOLOGY*

## *WHY DO WE NEED IT?*

- **Part of TAUG CV (v1.0 Draft) , Findings Domain**
- **Designed to report data on cardiovascular physiology findings including information relating to heart, blood vessels, and circulation**
  - Stenosis – narrowing bloodvessels and valves
  - New York Heart Association Class (NYHA) – Classifies the extent of heart failure
  - Ischemic myocardium percentage
- **Holds results/findings of a cardiovascular diagnostic procedure**
  - Conduct of procedures go into Procedure Domain (PR) – Bypass Surgeries, Heart Transplants, etc.
  - Data describing structural measurements of the heart go into Morphology Domain (MO): macroscopic results (size, shape, color, other abnormalities)

# CV – WHAT IS NEW?

- New/Updated CT for CVTESTCD and CVTEST

|          |                                |      |            |       |   |     |
|----------|--------------------------------|------|------------|-------|---|-----|
| CVTESTCD | Test or Examination Short Name | Char | (CVTESTCD) | Topic | Short name of the measurement, test, or examination described in CVTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in CVTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). CVTESTCD cannot contain characters other than letters, numbers, or underscores.<br>Examples: NYHACLS, KILLIPCL | Req |
|----------|--------------------------------|------|------------|-------|---|-----|

|        |                          |      |          |                   |   |     |
|--------|--------------------------|------|----------|-------------------|---|-----|
| CVTEST | Test or Examination Name | Char | (CVTEST) | Synonym Qualifier | Verbatim name of the test or examination used to obtain the measurement or finding. The value in CVTEST cannot be longer than 40 characters. Examples: New York Heart Association Class, Killip Class | Req |
|--------|--------------------------|------|----------|-------------------|---|-----|

# CV – WHAT IS NEW?

## SDTM CT 2013-06-28

| CVEXAMCD | Cardiovascular Test Code                                    |
|----------|---|
| COARTDOM | Coronary Artery Dominance;<br>Coronary Anatomy<br>Dominance |
| CVLREGTS | Cardiac Valvular<br>Regurgitation Severity                  |
| CVLSTNS  | Cardiac Valvular Stenosis<br>Severity                       |
| ISHMYOP  | Ischemic Myocardium<br>Percentage                           |
| LADMN    | Left Atrium Dimension                                       |
| LVDMNED  | Left Ventricle Dimension,<br>End-Diastole                   |
| LVDMNES  | Left Ventricular Dimension,<br>End-Systole                  |
| LVEF     | Left Ventricular Ejection<br>Fraction                       |
| NUMDCAV  | Number of Diseased<br>Coronary Vessels                      |

## SDTM CT 2014-12-19

| CVTESTCD | Cardiovascular Test Code                |
|----------|---|
| CARDIDX  | Cardiac Index                           |
| CARDOUT  | Cardiac Output                          |
| COARTDOM | Coronary Artery Dominance               |
| CVLREGTS | Cardiac Valvular Regurgitation Severity |
| CVLSTNS  | Cardiac Valvular Stenosis Severity      |
| ISHMYOP  | Ischemic Myocardium Percentage          |
| LADMN    | Left Atrium Dimension                   |
| LVDMNED  | Left Ventricle Dimension, End-Diastole  |
| LVDMNES  | Left Ventricular Dimension, End-Systole |
| LVEF     | Left Ventricular Ejection Fraction      |
| NUMDCAV  | Number of Diseased Coronary Vessels     |
| PVR      | Pulmonary Vascular Resistance           |
| SVR      | Systemic Vascular Resistance            |

# CV – MAPPING EXAMPLE

- **CV Physiology findings – example**

– CVTESTCD = NYHACLS, KILLIPCL, CCSGRDS are not yet in CT, but CT is extensible

| Row | STUDYID | DOMAIN | USUBJID | CVSEQ | CVTESTCD | CVTEST                            | CVORRES | CVSTRESC | CVDTC      |
|-----|---------|--------|---------|-------|----------|-----------------------------------|---------|----------|------------|
| 1   | ABC     | CV     | ABC-123 | 1     | NYHACLS  | New York Heart Association Class  | I       | I        | 2010-05-16 |
| 2   | ABC     | CV     | ABC-123 | 2     | NYHACLS  | New York Heart Association Class  | II      | II       | 2010-05-31 |
| 3   | ABC     | CV     | ABC-123 | 3     | KILLIPCL | Killip Class                      | II      | II       | 2010-06-12 |
| 4   | ABC     | CV     | ABC-123 | 4     | NYHACLS  | New York Heart Association Class  | II      | II       | 2010-06-22 |
| 5   | ABC     | CV     | ABC-123 | 5     | KILLIPCL | Killip Class                      | II      | II       | 2010-06-24 |
| 6   | ABC     | CV     | ABC-123 | 6     | NYHACLS  | New York Heart Association Class  | I       | I        | 2010-07-06 |
| 7   | ABC     | CV     | ABC-123 | 7     | KILLIPCL | Killip Class                      | II      | II       | 2010-08-03 |
| 8   | ABC     | CV     | ABC-124 | 1     | CCSGRDS  | Canadian CV Society Grading Scale | 1       | 1        | 2011-01-02 |
| 9   | ABC     | CV     | ABC-125 | 1     | CCSGRDS  | Canadian CV Society Grading Scale | 2       | 2        | 2011-03-03 |



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*THANK YOU*