DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

DZHK-SOP-C-01

Basic data

Version: V2.0 Valid as of: 23.03.2023

Replaces version: V 1.0 dated: 01.09.2014

Modification notice: Ethnicity and skin color not applicable

NEW: Vital status recording (end of study)

This SOP is a translation from the original German SOP and valid without signatures.

	Expert Author*	**Expert Review**	**Endorsed by Section Head**	**Approved by DZHK**
Name	Rolf Wachter (Göttingen)	Sebastian Kufner (Munich)	Stefan Kääb	Steffen Massberg

CONTENTS

1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Full form
ASD	atrial septal defect
COPD	chronic obstructive pulmonary disease
CT	computer tomography
HDL-cholesterol	High density lipoprotein cholesterol
LDL-cholesterol	Low density lipoprotein cholesterol
MRT	magnetic resonance tomography
pAVK	peripheral arterial occlusive disease
SOP	standard operating procedure
VSD	ventricular septal defect
TIA	Transitory ischemic attacks

1.2 OBJECTIVE

Uniform definitions are proposed in the context of this SOP when a corresponding risk factor/clinical diagnosis is considered to be present.

1.3 TARGET GROUP

This SOP is intended for individuals who make entries into the basic data module ‚Anamnesis'. These may be e.g. physicians or study assistants.

1.3.1 Inclusion Criteria

Included are all patients who meet the respective inclusion/exclusion criteria of the respective study.

1.3.2 Exclusion Criteria

None. If information cannot be collected in full, it should be collected to the greatest extent possible.

1.4 APPLICATION AND TASKS

The purpose of the anamnesis/clinical diagnoses is to accurately record known cardiovascular risk factors. The anamnesis is a core element of medical diagnostics. The findings obtained allow a detailed estimation of a person's cardiovascular risk.

Collection of the anamnesis/clinical diagnoses is an integral part of all observational and clinical studies of the DZHK. The exact implementation of the DZHK basic data set is described in the item catalog. There, as well as in all eCRFs, all mandatory basic items are marked with **.

1.5 TERMS AND DEFINITIONS

Date of examination

- is defined as the date on which the examination takes place.

Sex and date of birth

- are defined as the data which appear on the person's identity card.

Height and weight

- height: Measured standing, without socks and without headgear. Weight: Measured in usual street clothes, without jacket and without shoes. Preferably, measurements should be taken; only if this is not possible (e.g. bedridden persons) should the data be estimated or based on anamnestic information from the participant.

Ethnicity: Caucasian

- ethnic origin is defined by a person's ancestry with respect to a particular population group. This can be determined biologically and or geographically by a certain settlement affiliation. The classification Caucasian means here light-skinned people of European origin.

Familial predisposition of myocardial infarction or stroke

- is defined as a medically diagnosed myocardial infarction or stroke in one or both biological parents, biological siblings (including half-siblings) or biological children, provided the female relative was under age 65, or the male relative under age 60 (at the time of the myocardial infarction/stroke).

Diabetes mellitus

- is defined as diabetes which has been diagnosed and/or treated by a physician.
  - American Diabetes Association criteria include:
    - hemoglobin A1c ≥ 6.5 % (48 mmol/mol Hb) or a fasting blood glucose level of ≥ 126 mg/dl (7.0 mmol/l) or a 2-hour blood glucose level of ≥ 200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test.

Arterial hypertension

- is defined as a current or previous medical diagnosis of arterial hypertension, treated with diet, exercise, and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90mmHg measured by a physician on at least two separate days after a 5-minute resting phase qualify for a diagnosis of arterial hypertension.

Dyslipidemia

- is defined as a current or previous diagnosis of dyslipidemia which was diagnosed and/or is being treated by a physician.
- one or more of the following criteria:
  - total cholesterol ≥ 190 mg/dl (5mmol/l),
  - LDL cholesterol ≥ 115 mg/dl (3mmol/l),
  - HDL cholesterol < 40 mg/dl (men) (1mmol/l) and < 45 mg/dl (1,2 mmol/l) (women).

Smoker

- is defined as current or previous use of cigarettes, cigars, pipes, hookah, e-cigarette or smokeless tobacco.
  ‚Yes' for daily or occasional smoking (≥ 1x/month) even with abstinence of less than 6 months;
  ‚Ex-smoker' if abstinent for more than 6 months; ex-smoker since …;
  ‚No' for ‚never smoked'.

Current dialysis requirement

- is defined as current regular, at least weekly, renal replacement therapy (including hemodialysis and peritoneal dialysis) within the last 30 days.

Coronary heart disease

- is defined as a current or previous medical diagnosis with one or more of the following criteria:
  - coronary artery stenosis of ≥ 50 % (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
  - previous coronary artery bypass operation,
  - previous percutaneous coronary intervention,
  - arteriosclerosis-induced myocardial infarction.

Condition post myocardial infarction

- is a physician's diagnosis of the disease. Rationale: Acute myocardial infarction is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial infarction.

  One or more of the following criteria must apply:

  - evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99 % percentile of the upper reference limit and, additionally, at least one of the following factors:
    - Ischemic symptoms, ECG changes indicative of new ischemia, e.g. ST segment-changes or a new left bundle branch block, development of pathological Q waves in the ECG,
    - imaging studies show a loss of viable myocardial tissue or new regional kinetic abnormalities,
    - angiographic evidence of stenosis/vascular occlusion.

Cardiomyopathy

- is defined as a physician's diagnosis of a primary heart muscle disease.

Heart failure

- is defined as a current or previous physician-documented diagnosis of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, jugular venous congestion, pulmonary edema on physical examination or pulmonary edema on chest x-rays. Documentation of reduced left ventricular function alone without clinical signs of heart failure does not meet the criteria for heart failure.

Atrial fibrillation/flutter

- is defined as a current or previous physician's diagnosis of atrial fibrillation or atrial flutter. It is defined as persisting for at least 30 seconds or evidence on surface ECG.

Current or previous medical diagnosis of heart valve disease

- is defined as heart valve disease (insufficiency or stenosis), which has been diagnosed and/or treated by a physician.

Physician-diagnosed congenital heart defect

- if a patient has a known congenital heart defect, this is coded here. Congenital heart defects include shunt vitia (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life.

Interventional coronary revascularization

- is defined as an intervention performed transcutaneously on a coronary vessel. on a coronary artery, e.g. PTCA, stent implantation, rotablation et cetera.

Coronary bypass surgery

- is defined as a surgical placement of bypass vessels (e.g., from the mammary artery or by use of arterial/venous grafts). If applicable, enter the date of the last operation.

Heart valve intervention

is defined as an intervention on a heart valve performed transcutaneously or by surgical procedure under vision.

Implantable cardiac pacemaker or defibrillator

- is defined as condition post implantation of a cardiac pacemaker or defibrillator.

CURRENT SECONDARY DIAGNOSES

PAD

- is defined as a current or previous physician's diagnosis of peripheral arterial occlusive disease (pelvic-leg vessels or upper extremity from the subclavian artery to distal). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Symptoms may include:
  - claudication,
  - amputation due to severe arterial vascular insufficiency,
  - vascular reconstruction, bypass surgery or percutaneous revascularization,
  - a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological $TCPO_2$ measurement, evidence of at least 50 % or greater stenosis of a peripheral artery by ultrasound, CT, MRT, or angiography).

Stroke/TIA

- is defined as a current or previous diagnosis by a physician.

Chronic lung disease

- is defined as a physician's diagnosis of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) or current long-term therapy with inhaled or oral pharmaceuticals.

Depression

- is defined as a current or previous diagnosis by a physician. The administration of antidepressants alone does not qualify for a diagnosis of depression.

Cancer

- is defined as a current or previous medical diagnosis of malignant cancer. Basal cell carcinoma does not count as a malignancy. A distinction is made between more than 5 years ago and less than 5 years ago.

Blood pressure

- systolic blood pressure should be determines using a regularly maintained and calibrated blood pressure monitor. If possible, devices tested for epidemiological studies (e.g. Omron 705 IT) should be used. Blood pressure measurement begins after the patient has been sitting for at least 5 minutes.

Heart rate

- heart rate measurement starts after the participant has been sitting for at least five minutes. It can be performed simultaneously with the blood pressure measurement.

Vital status

- vital status (alive/deceased) must be recorded for each participating subject at the end of a study. If a person dies before the end of the study, the time of death, as well as the cause of death (cardiovascular/non-cardiovascular) must be documented. This is usually recorded on a separate eCRF form, as it is not collected at the same time as the other items of the basic dataset.

RELATIONS TO OTHER INVESTIGATIONS

Here, the interrelationships from the individual SOP to other procedures are described.

Mandatory pretest (SOP …):	*None specified*
Recommended pretest (SOP …):	*None specified*
Pretest (SOP) to be excluded	*None specified*
Interference with other parts of the study:	*None specified*

Mandatory follow-up (SOP …):	*None specified*
Recommended follow-up(SOP …):	*None specified*
Follow-up (SOP) to be excluded:	*None specified*

The contents of the DZHK-SOP-C-01 Basic Data Set are also part of the DZHK-SOP-C-02 Anamnesis/Clinical Diagnoses/Physical Examination. If DZHK-SOP-C-02 is performed, the DZHK basic data set is thus collected.

1.6 QUALITY LEVEL

Quality data collection

This SOP describes a data collection of quality level 2 of the DZHK. A higher quality level could possibly be achieved if, for example, standardized interviews such as those used in the German National Cohort were used. Because the studies planned so far in the DZHK do not require a quality level higher than 2, initially only SOPs for that level have been written.

DZHK Quality Levels	
Realisation	
Level 1	The examination is performed in accordance with the guidelines of the scientific societies.
Level 2	The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the investigators are defined in the SOP.

Level 3	The examination is performed according to the specifications of the DZHK SOP and certification of the investigators: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

2 PREREQUISITE OF THE INVESTIGATION

All circumstances are considered in order to ensure that the examination is conducted under suitable conditions.

2.1 REQUIREMENTS FOR ROOMS/EQUIPMENT

The examination room should have a room temperature of 22-26 °C. Generally, the room should have a table at which the proband and the interviewer can sit in a comfortable atmosphere in order to conduct the interview.

2.2 DEVICES/HARDWARE

PC with a monitor, keyboard, mouse, printer and printer paper. Depending on the respective study, the forms for standardized documentation of the proband's responses should be available as source files, if needed.

2.3 DOCUMENTS REQUIRED

- Docket
- Barcode for scanning

2.4 INFORMATION REQUIRED

- Examiner number
- Survey number (label)
- Beginning of examination
- Proband number

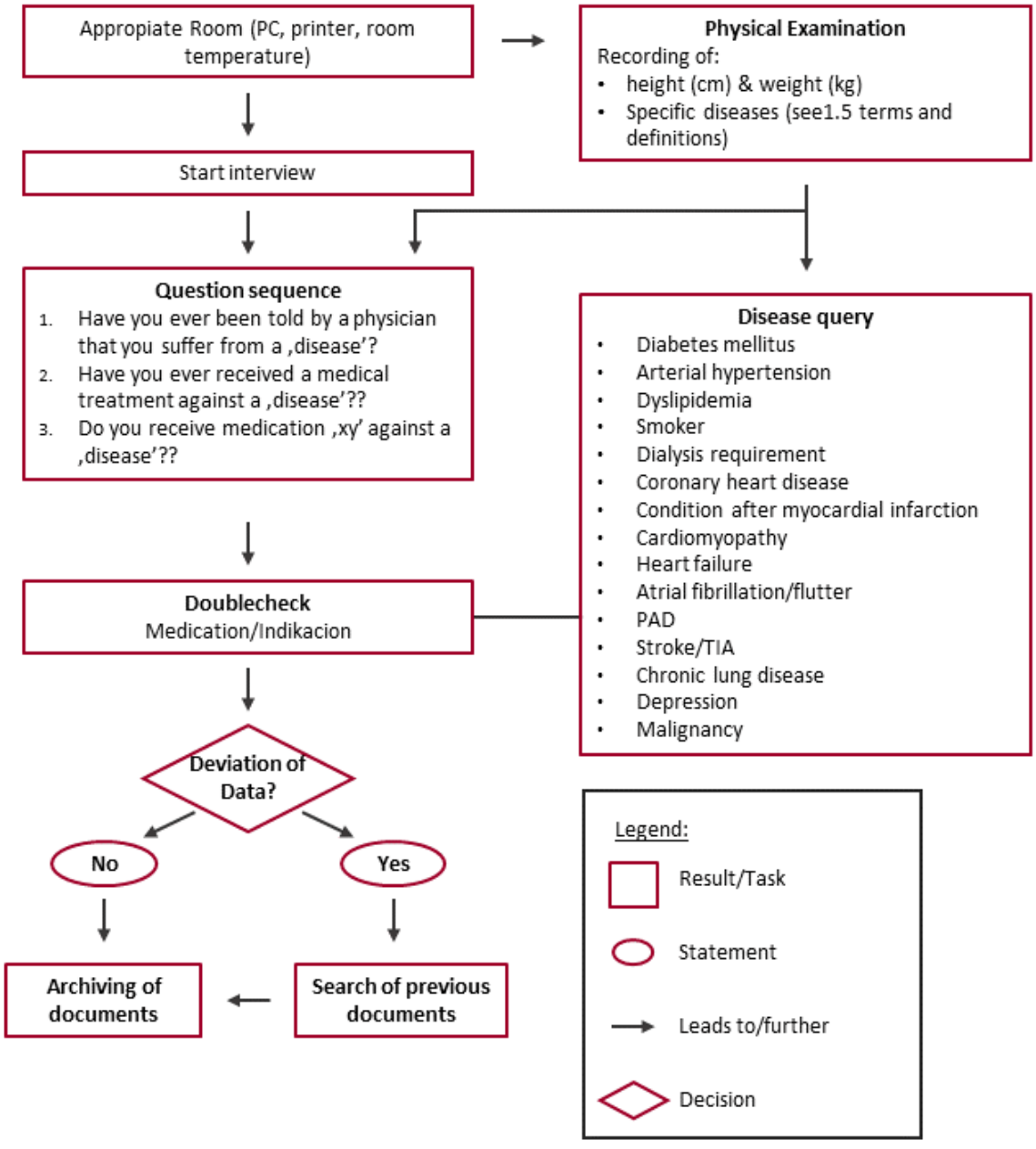
2.5 STAFF

Persons using this SOP must have completed their training in the medical field (e.g. medical assistant, nurse, licensed physician). Students of medicine may use this SOP after they have successfully passed their first medical examination (German *Physikum)*.

All users must have completed a prior course of instruction/certification for this SOP or DZHK-SOP-C-02 Anamnesis/Clinical Diagnoses, respectively.

3 IMPLEMENTATION PROCESS/WORK PROCESS/WORK STEPS

3.1 PROCESS FLOW CHART



3.2 PREPARING FOR THE EXAMINATION

3.2.1 Preparing the Work Space

Find a suitable room with a table. Bring the room to a temperature between 22 and 26 °C.

3.2.2 Preparing the Equipment

All equipment (PC/laptop/printer) should be switched on and must be ready for operation. A form (source data documentation) should be at hand.

3.3 CARRYING OUT THE EXAMINATION

Physical examination – anthropometry

- height (in cm) and weight (in kg) are given either as self-reported values (level 1) or as measured values (level 2). In the eCRF, a mark is made to whether the values given are based on anamnestic information or measured values.

Anamnesis

A medical diagnosis is considered to be given if it has been diagnosed by a physician and/or therapy is being administered which is considered to specifically target a certain disease. All documentation in medical documents (e.g. doctor‘s letters) justifies accepting the diagnosis as given.

When carrying out the examination, for each clinical diagnosis, the following questions should be asked in the interview:

1. Have you ever been told by a physician that you suffer from a “disease”?
2. Have you ever received a medical treatment against a “disease”?
3. Do you receive medication “xy” against a “disease”?

As a “cross-check”, the indication should be requested and documented for each medication the patient receives. A checking rule is stored in the database, which produces a corresponding message in the event of discrepancies (e.g. negative answers to 1-3, but taking corresponding medication).

In case of ambiguities (e.g. whether relevant diagnoses have been made, but the subject has consulted doctors for clarification), when and where those consultations took place should be noted as precisely as possible in the comments field. After the interview, documents of the respective consultancies shall be inquired.

Inquiry about specific diseases, see section 1.5.

FOLLOW-UP AND RECORDING OF DATAA special debriefing session is not planned. The data should be entered without delay (usually within 7 days).

3.4 DEALING WITH DEVIATIONS

If a clear answer cannot be obtained for certain questions, this should be documented.

General particularities should always be noted in the commentary/notes field.

4 LITERATURE AND REFERENCES

ACCF/AHA Guidelines Circulation 2011;124:103-123

5 MODIFICATIONS

Modifications compared with the previous version.

Section	Description of the modification compared with the previous version
1.5	Ethnicity: Skin colour not applicable
	Vital status (end of study)

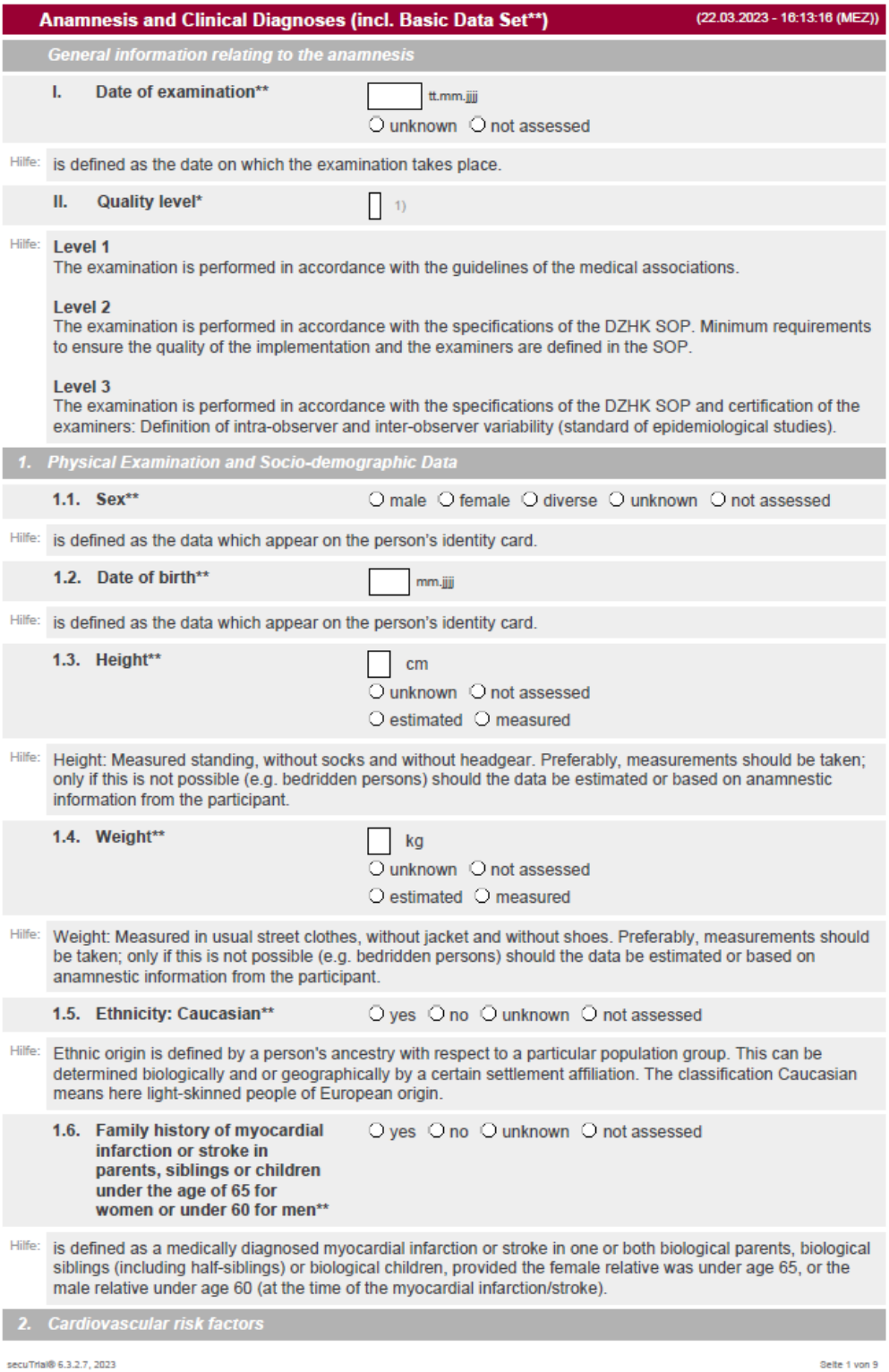
6 LIST OF CONTRIBUTORS

Name	Function	Contribution
PD Dr. Rolf Wachter	Author	Drafted the SOP
Dr. Sebastian Kufner	Reviewer	Expert review
Dr. Natalie Arnold	WG Data standardization	Scientific review
Prof. Marcus Dörr	WG Data standardization	Scientific review
Prof. Frank Edelmann	WG Data standardization	Scientific review
Dr. Christoph Gertler	WG Data standardization	Scientific review
Prof. Stefan Kääb	WG Data standardization	Scientific review
Prof. Till Keller	WG Data standardization	Scientific review
Dr. Monika Kraus	WG Data standardization	Scientific review
Dr. Kristin Lehnert	WG Data standardization	Scientific review
Prof. Benjamin Meder	WG Data standardization	Scientific review
Prof. Eike Nagel	WG Data standardization	Scientific review
Prof. Matthias Nauck	WG Data standardization	Scientific review
Dr. Jürgen Prochaska	WG Data standardization	Scientific review
PD Dr. Anja Sandek	WG Data standardization	Scientific review
Christian Schäfer	WG Data standardization	Scientific review

Dipl.-Ing. Jens Schaller	WG Data standardization	Scientific review
Tabea Scharfe	WG Data standardization	Scientific review
Prof. Renate Schnabel	WG Data standardization	Scientific review
Dr. Farbod Sedaghat-Hamedani	WG Data standardization	Scientific review
Dana Stahl	WG Data standardization	Scientific review
Dr. Johannis Trebing	WG Data standardization	Scientific review
Prof. Philipp Wild	WG Data standardization	Scientific review
Prof. Tanja Zeller	WG Data standardization	Scientific review
Mahsa Lee	WG Data standardization	IT implementation
Dipl.-Inf. Sabine Hanß	WG Data standardization	IT implementation
Dr. Julia Hoffmann, Dr. Ilka Wilhelmi	WG Data standardization	Coordination

7 APPENDIX

7.1 eCRF Module



Anamnesis and Clinical Diagnoses (incl. Basic Data Set)** (22.03.2023 - 16:13:16 (MEZ))

General information relating to the anamnesis

I. **Date of examination**** ☐ tt.mm.jjjj
○ unknown ○ not assessed

Hilfe: is defined as the date on which the examination takes place.

II. **Quality level*** ☐ 1)

Hilfe:
Level 1
The examination is performed in accordance with the guidelines of the medical associations.

Level 2
The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the examiners are defined in the SOP.

Level 3
The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

1. Physical Examination and Socio-demographic Data

1.1. **Sex**** ○ male ○ female ○ diverse ○ unknown ○ not assessed

Hilfe: is defined as the data which appear on the person's identity card.

1.2. **Date of birth**** ☐ mm.jjjj

Hilfe: is defined as the data which appear on the person's identity card.

1.3. **Height**** ☐ cm
○ unknown ○ not assessed
○ estimated ○ measured

Hilfe: Height: Measured standing, without socks and without headgear. Preferably, measurements should be taken; only if this is not possible (e.g. bedridden persons) should the data be estimated or based on anamnestic information from the participant.

1.4. **Weight**** ☐ kg
○ unknown ○ not assessed
○ estimated ○ measured

Hilfe: Weight: Measured in usual street clothes, without jacket and without shoes. Preferably, measurements should be taken; only if this is not possible (e.g. bedridden persons) should the data be estimated or based on anamnestic information from the participant.

1.5. **Ethnicity: Caucasian**** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Ethnic origin is defined by a person's ancestry with respect to a particular population group. This can be determined biologically and or geographically by a certain settlement affiliation. The classification Caucasian means here light-skinned people of European origin.

1.6. **Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 60 for men**** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a medically diagnosed myocardial infarction or stroke in one or both biological parents, biological siblings (including half-siblings) or biological children, provided the female relative was under age 65, or the male relative under age 60 (at the time of the myocardial infarction/stroke).

2. Cardiovascular risk factors

secuTrial® 6.3.2.7, 2023 Seite 1 von 9

2.1. Diabetes mellitus** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as diabetes which has been diagnosed and/or treated by a physician.
1. American Diabetes Association criteria include:
   - hemoglobin A1c ≥ 6.5 % (48 mmol/mol Hb) or a fasting blood glucose level of ≥ 126 mg/dl (7.0 mmol/l) **or** a 2-hour blood glucose level of ≥ 200 mg/dl dl (11.1 mmol/l) during an oral glucose tolerance test.

2.2. Arterial hypertension** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous medical diagnosis of arterial hypertension, treated with diet, exercise, and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90mmHg measured by a physician on at least two separate days after a 5-minute resting phase qualify for a diagnosis of arterial hypertension.

2.3. Dyslipidemia** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous diagnosis of dyslipidemia which was diagnosed and/or is being treated by a physician.
One or more of the following criteria:
1. total cholesterol ≥ 190 mg/dl (5mmol/l),
2. LDL cholesterol ≥ 115 mg/dl (3mmol/l),
3. HDL cholesterol < 40 mg/dl (1mmol/l) (men) and < 45 mg/dl (1,2 mmol/l) (women).

2.4. Smoker** ○ yes ○ no ○ ex-smoker (stopped ≥ 6 mth. ago) ○ unknown ○ not assessed

Ex-smoker since** ☐ jjjj
○ unknown ○ not assessed

Pack years* ☐
○ unknown ○ not assessed

Hilfe: is defined as current or previous use of cigarettes, cigars, pipes, hookah, e-cigarette or smokeless tobacco.
1. ‚Yes' for daily or occasional smoking (≥ 1x/month) even with abstinence of less than 6 months;
2. ‚Ex-smoker' if abstinent for more than 6 months; ex-smoker since ...;
3. ‚No' for ‚never smoked'.
4. Pack year is the product of the number of years of cigarette smoking multiplied by the average number of packs smoked per day.
   Example: A patient who has smoked 2 packets of cigarettes per day for 20 years has 40 pack years

2.5. Drinks per week* ☐
○ unknown ○ not assessed

Hilfe: the number of alcoholic drinks consumed per week. One drink is defined as e.g. 0.25 l of beer, 0.1 l of wine or 0.02 l of spirits.
Example: A person who drinks 0.5 l beer twice a week on average has 4 drinks per week.

2.6. Medically diagnosed alcoholism** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous physician's diagnosis of alcoholism.

2.7. Renal failure* ○ yes ○ no ○ unknown ○ not assessed

2.7.1. Degree of renal dysfunction*
○ 1 – eGFR 90 ml/min or higher
○ 2 – eGFR 60–89 ml/min
○ 3 – eGFR 30-59 ml/min
○ 4 – eGFR 15-29 ml/min
○ 5 – eGFR < 15 ml/min or current dialysis dependency
○ unknown
○ not assessed

Hilfe: any participating individual who has a renal function impairment as diagnosed by a physician.

Degree of renal dysfunction:
If known, the degree of renal dysfunction should be quantified using the estimated glomerular filtration rate

(eGFR). There are different methods for estimation, but if available, the MDRD formula should be used (s. SOP).
Based on the results, the following grade classification is made:
1 – eGFR 90 ml/min or higher
2 - eGFR 60-89 ml/min
3 - eGFR 30-59 ml/min
4 - eGFR 15-29 ml/min
5 - eGFR < 15 ml/min or current dialysis requirement
unknown
not assessed

2.8. Current dialysis dependency** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as current regular, at least weekly, renal replacement therapy (including hemodialysis and peritoneal dialysis) within the last 30 days.

3. *Cardiac Diagnoses (Anamnesis and Previous Findings)*

3.1. Coronary heart disease** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous medical diagnosis with one or more of the following criteria:
1. coronary artery stenosis of ≥ 50 % (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
2. previous coronary artery bypass operation,
3. previous percutaneous coronary intervention,
4. arteriosclerosis-induced myocardial infarction.

3.2. Condition post myocardial infarction** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is a physician's diagnosis of the disease. Rationale: Acute myocardial infarction is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial infarction.
One or more of the following criteria must apply:

1. Evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99 % percentile of the upper reference limit and, additionally, at least one of the following factors:
   - Ischemic symptoms,
   - ECG changes indicative of new ischemia, e.g. ST segment changes or a new left bundle branch block, development of pathological Q waves in the ECG,
   - imaging studies show a loss of viable myocardial tissue or new regional kinetic abnormalities,
   - angiographic evidence of stenosis/vascular occlusion.

3.3. Cardiomyopathy**
If the response to this question is "yes", please complete the "Cardiomyopathy Diagnostics" form. ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a physician's diagnosis of a primary heart muscle disease. If the response to this question is "yes", further data is collected in the "Cardiomyopathy Diagnostics" form.

3.4. Heart failure** ○ yes ○ no ○ unknown ○ not assessed

3.4.1. S.p. decompensation* ○ yes ○ no ○ unknown ○ not assessed

3.4.2. Initial diagnosis of heart failure* ☐ jjjj
○ unknown ○ not assessed

3.4.3. Current NYHA class* ○ I ○ II ○ III ○ IV ○ unknown ○ not assessed

Hilfe: is defined as a current or previous physician-documented diagnosis of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, jugular venous congestion, pulmonary edema on physical examination or pulmonary edema on chest x-rays. Documentation of reduced left ventricular function alone in the absence of clinical signs of heart failure does not meet the criteria for heart failure.
Status post decompensation is defined as any previous admission to a hospital with symptoms of heart failure (see above).

Initial diagnosis of heart failure is defined as the time point when heart failure was diagnosed for the first time by a physician. Hence, it does not refer to the time point of first onset of symptoms, which is often much earlier.
NYHA class: Classification of the patient's symptoms based on the New York Heart Association classification of heart failure:

1. NYHA I: No complaints
2. NYHA II: Complaints with greater exertion
3. NYHA III: Complaints during light exertion
4. NYHA IV: Complaints at rest

3.5. Atrial fibrillation/flutter** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous physician's diagnosis of atrial fibrillation or atrial flutter. It is determined as persisting for at least 30 seconds or evidence on surface ECG.

3.6. Current or previous medical diagnosis of heart valve disease** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as heart valve disease (insufficiency or stenosis), which has been diagnosed and/or treated by a physician. A more precise differentiation and severity classification of valvular heart disease will be made on the echocardiography form if an echocardiogram is documented as part of the study.

3.7. Medically diagnosed endocarditis* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: if at any time, currently or in their previous medical history, a person has been diagnosed with endocarditis (heart valve inflammation), it will be documented here.

3.8. Physician diagnosed congenital heart defect** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: if a patient has a known congenital heart defect, this is coded here. Congenital heart defects include shunt vitia defects (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life. Patent foramen ovale does not belong to the class of congenital heart defects.

4. Previous cardiovascular interventions

4.1. Interventional coronary revascularization** ○ yes ○ no ○ unknown ○ not assessed

4.1.1. If yes, date of last intervention* ☐ mm.jjjj

○ unknown ○ not assessed

Hilfe: is defined as an intervention performed transcutaneously on a coronary vessel, e.g. PTCA, stent implantation, rotablation et cetera. Purely diagnostic measures (intravascular ultrasound (IVUS), optical coherence tomography (OCT)) as well as functional measurements (e.g. fractional flow reserve (FFR) measurements) are not interventional coronary revascularization procedures. Where applicable, the date of the last intervention should be entered.

4.2. Peripheral revascularization* ○ yes ○ no ○ unknown ○ not assessed

4.2.1. If yes, date of last intervention* ☐ mm.jjjj

○ unknown ○ not assessed

Hilfe: is defined as an intervention performed transcutaneously on a peripheral vessel (excluding coronary vessels or bypass grafts), e.g., PTA, stent implantation, rotablation, etc. If applicable, enter the date of the last intervention. Ablation procedures (e.g., renal denervation) are not peripheral revascularization. Where applicable, the date of the last intervention should be entered.

4.3. Coronary bypass operation** ○ yes ○ no ○ unknown ○ not assessed

4.3.1. If yes, date of last intervention* ☐ mm.jjjj

○ unknown ○ not assessed

Hilfe: is defined as surgical myocardial revascularization using bypass graft (e.g. from the mammary artery or using arterial/venous grafts). Where applicable, the date of the most recent surgery should be entered.

4.4. Other vascular operation* ○ yes ○ no ○ unknown ○ not assessed

4.4.1. If yes, date of last intervention* [ ] mm.jjjj

○ unknown ○ not assessed

Hilfe: is defined as surgery of any kind on non-coronary vessels. Where applicable, the date of the most recent surgery should be entered.

4.5. Heart valve operation** ○ yes ○ no ○ unknown ○ not assessed

4.5.1. If yes, date of last intervention* [ ] mm.jjjj

○ unknown ○ not assessed

Hilfe: is defined as a minimally invasive percutaneous (catheter-based) or open surgical procedure on a heart valve. This includes the surgical reconstruction/replacement of heart valves, valvuloplasty procedures as well as interventional treatment of heart valve diseases (e.g. blasting, implantation of prostheses, repair of heart valves). Where applicable, the date of the most recent surgery should be entered. The most recent event is to be coded according to type, whereby any transapical aortic valve replacements are to be coded as "catheter-based". In addition, details of the surgical procedure should be given.

4.5.2. Type of last intervention* ○ open surgery ○ catheter-based ○ unknown ○ not assessed

If open surgery* ○ replacement ○ reconstruction ○ unknown ○ not assessed

4.5.3. If more than one procedure on one valve was performed, please provide details of the last OP (= current state)*

Aortic valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ TAVI ○ unknown ○ not assessed

○ transfemoral ○ transapical ○ transaortal ○ unknown ○ not assessed

Pulmonic valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ unknown ○ not assessed

Mitral valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ clipping ○ unknown ○ not assessed

Triscuspid valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ unknown ○ not assessed

4.6. Implantable pacemaker or defibrillator** ○ yes ○ no ○ unknown ○ not assessed

4.6.1. If yes, what was implanted?* ○ pacemaker ○ defibrillator ○ unknown ○ not assessed

4.6.2. If yes, date of last event (implantation/exchange)* [ ] mm.jjjj

○ unknown ○ not assessed

4.6.3. If pacemaker, please give pacemaker type* ○ 1-chamber pacemaker (e.g. VVI) ○ 2-chamber pacemaker (e.g. DDD) ○ biventricular pacemaker (CRT) ○ unknown ○ not assessed

Hilfe: is defined as condition after implantation of a pacemaker or intracardiac defibrillator (ICD). Where applicable, the date of the most recent operation (implantation/exchange) is toshould be entered. The number of probes currently connected to the pacemaker device is also coded. A device with only one probe is to be coded as a 1-chamber pacemaker, a device with atrial and ventricular probes as a 2-chamber pacemaker. Devices for cardiac resynchronization therapy, with two ventricular probes, are to be coded as a biventricular pacemaker (CRT).

4.7. Other devices* ○ yes ○ no ○ unknown ○ not assessed

4.7.1. Cardiac contractility modulation (CCM)* ○ yes ○ no ○ unknown ○ not assessed

4.7.2.	**Intra-aortic balloon pump (IABP)***	○ yes ○ no ○ unknown ○ not assessed
4.7.3.	**Other devices***	

Hilfe: are defined as other implantable devices for cardiac/vascular support. This includes devices for cardiac contractility management, for neuromodulation (e.g. vagus nerve stimulator, baroreceptor stimulator), intra-aortic balloon pumps and left ventricular cardiac assist devices.

4.8.	**S.p. myocardial biopsy***	○ yes ○ no ○ unknown ○ not assessed
4.8.1.	**Date of myocardial biopsy***	☐ mm.jjjj ○ unknown ○ not assessed
4.8.2.	**Biopsy sites***	○ left ventricle ○ right ventricle ○ left and right ventricle ○ unknown ○ not assessed

Hilfe: is defined as status post bioptic removal of tissue from the myocardium (e.g. during a right/left catheter examination or surgery). Where applicable, the sampling site as well as the date of the most recent myocardial biopsy should be coded.

5. *Current secondary diagnoses*

5.1.	**PAOD****	○ yes ○ no ○ unknown ○ not assessed
5.1.1.	**Fontaine stage***	○ I ○ IIa ○ IIb ○ III ○ IV ○ unknown ○ not assessed
5.1.2.	**Acute ischaemic occlusion***	○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous diagnosis by a physician of peripheral arterial occlusive disease (pelvic-leg vessels or upper extremity from the subclavian artery to distal). Renal, coronary, cerebral and mesenteric vessels and aneurysms are excluded. Possible symptoms are:

1. intermittent claudication,
2. pain at rest,
3. amputation due to severe arterial vascular insufficiency,
4. vascular reconstruction, bypass surgery or percutaneous revascularization,
5. a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological TCPO2 measurement, evidence of 50 % or greater stenosis of a peripheral artery by Doppler/duplex sonography, CT, MRT, or angiography).

Classification of the degree of severity is done according to the Fontaine classification:

Stage and Clinical Picture	
I.	Asymptomatic PAOD
II.	Intermittent claudication 1. with walking distances > 200 metres (Stage IIa) 2. with walking distances < 200 metres (Stage IIb)
III.	Pain at rest
IV.	Necrosis, gangrene

Acute ischemic occlusion refers to a currently (in the last 30 days) occurring proven acute ischemic occlusion of a peripheral arterial vessel.

5.2.	**Stroke/TIA****	○ yes ○ no ○ unknown ○ not assessed
5.2.1.	**Date***	☐ mm.jjjj ○ unknown ○ not assessed
5.2.2.	**Aetiology***	○ ischaemic ○ haemorrhagic ○ unknown ○ not assessed
5.2.3.	**Diagnosis***	○ TIA ○ stroke ○ unknown ○ not assessed
5.2.4.	**Stroke severity***	○ minor ○ major ○ unknown ○ not assessed
5.2.5.	**Consequences of the stroke***	○ disabling ○ non-disabling ○ unknown ○ not assessed

Hilfe: is defined as a current or previous diagnosis by a physician of:

1. Ischaemic stroke: Infarction of tissue of the central nervous system, either symptomatic or silent (asymptomatic).
2. Transient ischaemic attack (TIA): A transient episode of neurological dysfunction caused by focal cerebral, spinal cord or retinal ischaemia without acute infarction, which resolves completely within 24 hours. This definition is not met by chronic (non-vascular) neurological diseases or other acute neurological diseases such as metabolic or ischaemic encephalopathy resulting from general hypoxia (e.g. respiratory failure, post cardiovascular arrest).
3. Haemorrhagic stroke: Neurological dysfunction caused by intra-cranial bleeding.
4. Stroke where there is uncertainty as to whether the cause was haemorrhagic or ischaemic.

Severity of the stroke: A stroke is considered "minor" if neurological symptoms can be completely reversed within 30 days or the change in the NIH Stroke Scale (see Appendix 7.3 NIH Stroke Scale) is less than 3 points compared to the NIH Stroke Scale before the stroke. A stroke is considered "major" if neurological deficits are still detectable 30 days after the event or the NIH Stroke Scale is at least 3 points higher than prior to the stroke.

Consequences of the stroke: A stroke is considered "disabling" if the modified Ranking Scale score is greater than 2 90 days after the stroke. If the modified Rankin Scale score is 2 points or less 90 days after the stroke, the stroke is coinsidered "non-disabling".

The modified Rankin Scale of 0 to 6 describes the range from complete health to death.

5. 0 - No symptoms.
6. 1 - No significant impairment. Can perform daily activities despite some symptoms.
7. 2 - Slight impairment. Is able to care for him or herself without assistance, but is limited in daily activities.
8. 3 - Moderate impairment. Requires assistance in daily life, but is able to walk without assistance.
9. 4 - More severe impairment. Requires assistance with personal hygiene; is not able to walk without assistance.
10. 5 - Severe impairment. Bedridden, incontinent, requires constant nursing assistance.
11. 6 – Death caused by apoplexy.

5.3. Chronic lung disease** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a diagnosis by a physician of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) and/or their pharmacological treatment, for example, with inhalable or oral pharmaceuticals (e.g. betamimetics, anti-inflam¬matory drugs, leukotriene receptor antagonists, or steroids).

5.4. Primary pulmonary Hypertension* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as physician-diagnosed and/or treated primary pulmonary hypertension.

5.5. Depression** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous medical diagnosis of depression. The administration of antidepressants alone does not qualify for a diagnosis of depression.

5.6. Cancer more than 5 years ago** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as a current or previous medical diagnosis of malignant cancer. Basal cell carcinoma is not counted as a malignancy.

5.7. Cancer within the last 5 years* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: is defined as malignant cancer diagnosed by a physician less than 5 years ago. Basal cell carcinoma is not counted as a malignancy.

6. Blood pressure after 5 minutes at rest

6.1. Systolic** ☐ mmHg
○ unknown ○ not assessed

6.2. Diastolic** ☐ mmHg
○ unknown ○ not assessed

Hilfe: The systolic blood pressure should be measured using a blood pressure monitor that is serviced and calibrated on a regular basis. Where possible, devices tested for epidemiological studies (e.g. Omron 705 IT) should be

used. Blood pressure measurement begins after the patient has been sitting for at least 5 minutes. 3Three measurements are taken at intervals of 2 minutes; the mean values of the second and third measurements are entered into the CRF.

7. Heart rate after sitting down for 5 minutes

7.1. Heart rate**

☐ per minute

○ unknown ○ not assessed

Hilfe: Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after blood pressure measurement. A manual count of the radial pulse over 30 seconds is performed; this value multiplied by two should be entered into the CRF (beats/minute).

8. Other diagnosis

8.1. Exertional Dyspnea*

○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of dyspnea on exertion within the last 14 days and/or at present. In cases of known heart failure, for patients within NYHA stages II-IV, dyspnea on exertion should be coded.

8.2. Dyspnea at rest*

○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of shortness of breath even when at rest (e.g. when talking) within the last 14 days and/or at present. In cases of known heart failure, for patients in NYHA stage IV, dyspnea at rest should be coded.

8.3. Peripheral edema*

○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of bilateral clinically or self-perceived water retention in the extremities within the last 14 days and/or at present.

8.4. Jugular venous distention*

○ yes ○ no ○ unknown ○ not assessed

Hilfe: The diagnostic test for jugular vein congestion is conducted with the upper body of the patient positioned at a 45° angle. The height at which the jugular vein collapses is then determined. on-pathological collapse is no later than the level of the jugular, which usually corresponds to an 8 cm water column or 5-6 mmHg anterior to the right atrium. If the jugular vein collapses above the jugulum, jugular venous congestion must be coded.

8.5. Pulmonary rales*

○ yes ○ no ○ unknown ○ not assessed

Hilfe: are defined as sounds heard over the lung during auscultation which are created by the movement of fluids and/or secretions during inspiration and expiration. They belong to the category of respiratory sounds that are superimposed on normal breath sounds and indicate a pathological change in the lung.

9. Laboratory diagnostics (blood)

In clinically stable individuals, these values may be no more than one week old, and must be determined again thereafter.

9.1. Date blood sample was taken**

☐ tt.mm.jjjj Where applicable, give date for the latest value

○ unknown ○ not assessed

Hilfe: if known, the date of the last value should be given here.

9.2. Hemoglobin**

☐

○ unknown ○ not assessed

Unit**

○ mmol/l

○ g/dl

Hilfe: if the value is known, it must be given in mmol/l or g/dl.

9.3. Creatinine (serum, heparin plasma)**

☐

○ unknown ○ not assessed

Unit**

○ µmol/l=nmol/ml

○ mg/dl

Hilfe: this value can be determined from serum and heparin plasma and expressed in µmol/l, nmol/ml or mg/dl.

9.4. Total cholesterol**

☐

○ unknown ○ not assessed

Unit**

○ mmol/l
○ mg/dl

Hilfe: if the value is known, it must be given in mmol/l or mg/dl.

10. The next three anamnestic questions are for women only

10.1. Menopause?**

○ yes ○ no ○ unknown ○ not assessed

10.1.1 Year of menopause**

☐ jjjj

○ unknown ○ not assessed

10.2. Day last menstrual period began**

☐ tt.mm.jjjj

○ unknown ○ not assessed

Hilfe: is defined as the time of the last spontaneous menstrual period in the life of a woman that is not followed by ovarian triggered bleeding from the uterus for at least 12 months.. The year in which the menopause began is to be coded. The day on which the last menstrual period began is required only for perimenopausal women.

Mögliche Angaben

Bitte wählen Sie bei den oben mit Anmerkungen versehenen Feldern eine der hier aufgelisteten Angaben.

1)

1
2
3

Vital status		(22.03.2023 - 16:13:16 (MEZ))
1.	Was the vital status recorded?**	○ yes ○ no ○ unkown ○ not assessed
2.	Date of last contact**	tt.mm.jjjj
3.	Status of the patient**	○ is alive ○ is dead
4.	Date of death**	tt.mm.jjjj
5.	Cause of death**	○ cardiovascular ○ non-cardiovascular ○ unknown ○ not assessed