DZHK Item Catalogue

The DZHK aims to standardise data collection amongst its clinical studies in order to enable secondary use of the data across studies. Therefore, Standard Operating Procedures (SOPs) as well as acquisition modules for common cardiological assessment procedures are available. This Item Catalogue provides an overview of the existing DZHK-wide standardised acquisition modules. The attached secuTrial® forms contain each module’s items with their respective expressions and intend to serve as a guide to study leaders and coordinators for the preparation of the eCRF. The basic data set contains 42 items, which are mandatory to be collected in every DZHK study. Other modules can be chosen depending on the study protocol. In order to maintain cross-study comparability, we recommend using as many of the harmonised items as possible. In addition, the modules can be extended by study-specific items.

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Harmonised modules with corresponding SOPs

For the following harmonised modules there are SOPs that describe how to perform the examinations. The corresponding SOP for each module can be found on the DZHK website.

**Anamnesis and Clinical Diagnosis (incl. Basic Data Set) (DZHK-SOP-K-02)**

The module Anamnesis and Clinical Diagnosis (incl. Basic Data Set) is used to accurately record known cardiovascular risk factors, previous diagnoses and interventions. The collected findings enable a detailed assessment of a patient’s cardiovascular risk.

The module contains among others the mandatory basic data set with 42 items. In the following, these items are labeled with ** (double asterisk).

The examinations ought to be performed according to DZHK-SOP-K-02.

DZHK-SOP-K-02:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial* form: 13.07.2020
### General information relating to the anamnesis

#### I. Date of examination**

- [ ] tt.mm.jjj
- [ ] unknown
- [ ] not assessed

#### 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

#### 1.2. Date of Birth**

- [ ] mm.jjj

#### 1.3. Height**

- [ ] cm
- [ ] unknown
- [ ] not assessed
- [ ] estimated
- [ ] measured

**Hilfe:** Height is measured in the standing position, without shoes and without head covering. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bedridden patients) should one estimate the values or resort to information provided by the proband.

#### 1.4. Weight**

- [ ] kg
- [ ] unknown
- [ ] not assessed
- [ ] estimated
- [ ] measured

**Hilfe:** Weight is measured in normal street clothing, without a jacket and without shoes. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bedridden patients) should one estimate the values or resort to information provided by the proband.

#### 1.5. Ethnicity: Caucasian**

- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

**Hilfe:** A person’s ethnic origin is defined by their ancestry in relation to a specific ethnic group. This can be determined biologically and/or geographically on the basis of membership of a certain settlement group. Accordingly, a person’s skin colour can also be broadly defined. The colour spectrum can be differentiated from light to dark skin colour.

#### 1.6. Black skin colour***

- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

#### 1.7. Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 55 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 55 (when the myocardial infarction/stroke occurred).

### 2. Cardiovascular risk factors

#### 2.1. Diabetes mellitus**

- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

**Hilfe:** Diabetes mellitus is defined as diabetes which has been diagnosed and/or treated by a doctor. The American Diabetes Association criteria are: haemoglobin A1c ≥ 6.5 % or a fasting blood glucose level of ≥ 126 mg/dl or a 2-hour blood glucose level of ≥ 200 mg/dl in the oral glucose tolerance test.

#### 2.2. Arterial hypertension**

- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed
2.3. Dyslipidaemia**
○ yes ○ no ○ unknown ○ not assessed

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

2.5. Drinks per week*
○ unknown ○ not assessed

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

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

2.8. Current Dialysis Dependency**
○ yes ○ no ○ unknown ○ not assessed

3. Cardiac Diagnoses (Anamnesis and Previous Findings)

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

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

3.4. Heart failure**
   3.4.1. S.p. decompensation*
   3.4.2. Initial diagnosis of heart failure*  
   3.4.3. Current NYHA class*

3.5. Atrial fibrillation/flutter**

3.6. Current or previous diagnosis by a doctor of heart valve disease**

3.7. Diagnosis by a doctor of endocarditis*

3.8. Diagnosis by a doctor of a congenital heart defect**

4. Previous cardiovascular interventions
   4.1. Interventional coronary revascularization**
   4.1.1. If yes, date of last intervention*  

Interventional coronary revascularization is defined as a percutaneously performed intervention on a coronary artery.
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.

<table>
<thead>
<tr>
<th>4.2. Peripheral revascularization*</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, date of last intervention*</td>
</tr>
</tbody>
</table>

- Yes
- No
- Unknown
- Not assessed

**Help:** Peripheral revascularization is defined as a percutaneously performed intervention on a peripheral artery (not including coronary arteries or bypass grafts) e.g. PTA, stent implantation, rotablation et cetera.

<table>
<thead>
<tr>
<th>4.3. Coronary bypass operation**</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, date of last intervention*</td>
</tr>
</tbody>
</table>

- Yes
- No
- Unknown
- Not assessed

**Help:** Coronary bypass operation is defined as operative myocardial revascularization by means of a bypass graft (e.g. from the internal thoracic artery or using arterial/venous grafts). Where applicable, the date of the most recent operation should be entered.

<table>
<thead>
<tr>
<th>4.4. Other vascular operation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, date of last intervention*</td>
</tr>
</tbody>
</table>

- Yes
- No
- Unknown
- Not assessed

**Help:** Other vascular operation is defined as an operation of any kind on non-coronary blood vessels. Where applicable, the date of the most recent operation should be entered.

<table>
<thead>
<tr>
<th>4.5. Heart valve operation**</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, date of last intervention*</td>
</tr>
</tbody>
</table>

- Yes
- No
- Unknown
- Not assessed

**Help:** Heart valve operation 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. dilation, implantation of protheses, heart valve repair).

<table>
<thead>
<tr>
<th>4.5.2. Type of last intervention*</th>
</tr>
</thead>
<tbody>
<tr>
<td>If open surgery*</td>
</tr>
</tbody>
</table>

- Open surgery
- Catheter-based
- Unknown
- Not assessed

- Open replacement
- Open reconstruction
- Unknown
- Not assessed

<table>
<thead>
<tr>
<th>4.5.3. If more than one procedure on one valve was performed, please provide details of the last OP (= current state)*</th>
</tr>
</thead>
</table>

**Help:**

- Aortic valve:
  - Native
  - Reconstruction
  - Mechanical
  - Bioprosthesis
  - TAVI
  - Unknown
  - Not assessed

- Transfemoral
- Transapical
- Transaortic
- Unknown
- Not assessed

- Pulmonic valve:
  - Native
  - Reconstruction
  - Mechanical
  - Bioprosthesis
  - Open
  - Unknown
  - Not assessed

- Mitral valve:
  - Native
  - Reconstruction
  - Mechanical
  - Bioprosthesis
  - Open
  - Unknown
  - Not assessed

- Tricuspid valve:
  - Native
  - Reconstruction
  - Mechanical
  - Bioprosthesis
  - Open
  - Unknown
  - Not assessed

<table>
<thead>
<tr>
<th>4.6. Implanted pacemaker or defibrillator?**</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, what was implanted*</td>
</tr>
<tr>
<td>If yes, date of last event (implantation/exchange)*</td>
</tr>
</tbody>
</table>

- Yes
- No
- Unknown
- Not assessed

- Pacemaker
- Defibrillator
- Unknown
- Not assessed

- Unknown
- Not assessed

- 1-chamber pacemaker (e.g. VVI)
- 2-chamber pacemaker (e.g. DDD)
- Biventricular pacemaker (CRT)
- Unknown
- Not assessed

**Help:** Implantable cardiac pacemaker or defibrillator is defined as status post implantation of a cardiac pacemaker or cardio-verter defibrillator (ICD).
4.7. **Other devices**
   - **Cardiac contractility modulation (CCM)**
   - **Intra-aortic balloon pump (IABP)**
   - **Other devices**

**Hilfe:** Other devices are defined as other implantable devices for cardiac/vascular support. This includes devices for cardiac contractility modulation, 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**
   - **Date of myocardial biopsy**
   - **Biopsy sites**

**Hilfe:** Status post myocardial biopsy is defined as status post biopctic removal of tissue from the heart muscle (e.g., during a right/left catheter examination or operation).

5. **Current secondary diagnoses**

5.1. **PAOD**
   - **Fontaine stage**
   - **Acute ischaemic occlusion**

**Hilfe:** PAOD is defined as a current or previous diagnosis by a doctor of peripheral arterial occlusive disease (in the blood vessels of the pelvis and legs, or from the upper extremity of the subclavian artery to the distal extremity). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Possible symptoms are:
- intermittent claudication,
- pain at rest,
- amputation due to severe arterial vascular insufficiency,
- vascular reconstruction, bypass operation or percutaneous revascularization,
- 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).

5.2. **Stroke/TIA**
   - **Date**
   - **Aetiology**
   - **Diagnosis**
   - **Stroke severity**
   - **Consequences of the stroke**

**Hilfe:** Stroke/TIA is defined as a current or previous diagnosis by a doctor of:
- Ischaemic stroke: Infarction of tissue of the central nervous system, either symptomatic or silent (asymptomatic).
- Transient ischaemic attack (TIA): A transient episode of neurological dysfunction caused by focal brain, 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. in the case of respiratory insufficiency, following a cardiac/circulatory arrest).
- Haemorrhagic stroke: Neurological dysfunction caused by intra-cranial bleeding.
- Stroke where there is uncertainty as to whether the cause was haemorrhagic or ischaemic.

5.3. **Chronic lung disease**

**Hilfe:** Chronic lung disease is defined as a diagnosis by a doctor of a chronic lung disease (e.g., COPD, chronic bronchitis, pulmonary fibrosis) and/or their pharmacological treatment, for example, with inhalable or oral pharmaceuticals.

5.4. **Primary pulmonary Hypertension**
Primary pulmonary hypertension is defined as a diagnosis and/or treatment by a doctor of primary pulmonary hypertension.

5.5. Depression** □ yes □ no □ unknown □ not assessed
   If the response to this question is 'yes', please complete the "Depression" form.

5.6. Cancer more than 5 years ago** □ yes □ no □ unknown □ not assessed
   Cancer more than 5 years ago is defined as a current or previous diagnosis of a malignant cancer. Basal cell carcinoma is not counted as a malignancy.

5.7. Cancer within the last 5 years* □ yes □ no □ unknown □ not assessed
   Cancer within the last 5 years is defined as malignant cancer diagnosed by a doctor 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
   6.2. Diastolic** □ mmHg
   The systolic blood pressure should be measured using a blood pressure monitor that is serviced and calibrated on a regular basis. Where possible, tested devices should be used for epidemiological trials. Blood pressure measurement begins after the patient has been at rest for at least 5 minutes. Three readings are taken at intervals of 2 minutes; the average values of the second and third readings are entered into the CRF.

7. Heart rate after sitting down for 5 minutes
   7.1. Heart rate** □ per minute
   Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after measuring the blood pressure. This should be done manually by counting the radial pulse for 30 seconds; that value multiplied by two should be entered into the CRF (beats/minute).

8. Further diagnoses
   8.1. Dyspnoea on exertion* □ yes □ no □ unknown □ not assessed
   A patient who complains of shortness of breath with physical exertion within the last 14 days and/or at present.
   8.2. Dyspnoea at rest* □ yes □ no □ unknown □ not assessed
   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.
   8.3. Peripheral oedema* □ yes □ no □ unknown □ not assessed
   A patient who complains of bilateral accumulation of fluid in the extremities within the last 14 days and/or at present, whether clinically observed or perceived by the patient.
   8.4. Jugular venous distention* □ yes □ no □ unknown □ not assessed
   The diagnostic test for jugular venous distention is conducted with the upper body of the patient positioned at a 45° angle.
   8.5. Pulmonary rales* □ yes □ no □ unknown □ not assessed
   Pulmonary rales 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 adventitious breath sounds overlying normal breath sounds and indicate a pathological change in the lung.

9. Laboratory diagnostics (blood)
   For clinically stable patients, not more than 1 week old, otherwise up to date!
9.1. Date blood sample was taken**

- [ ] mm/nn

Where applicable, give date for the latest value

- [ ] unknown
- [ ] not assessed

9.2. Haemoglobin**

- [ ] unknown
- [ ] not assessed

Unit**

- [ ] mmol/l
- [ ] g/dl

9.3. Creatinine (serum, heparin plasma)**

- [ ] unknown
- [ ] not assessed

Unit**

- [ ] μmol/l = mmol/l
- [ ] mg/dl

9.4. Total cholesterol**

- [ ] unknown
- [ ] not assessed

Unit**

- [ ] mmol/l
- [ ] 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**

- [ ] mm/nn

- [ ] unknown
- [ ] not assessed

10.2. Day last menstrual period began**

- [ ] mm/nn/nn

- [ ] unknown
- [ ] not assessed

Mögliche Angaben

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

1) 

2) 

3)
Biobanking Basic Set (DZHK-SOP-B-02)

The module Biobanking Basic Set is used to document the quality of samples of the Basic Set. The Basic Set consists of EDTA plasma, serum, citrate plasma, buffy coat and urine.

The processing and storage of the material ought to be performed according to DZHK-SOP-B-02.

DZHK-SOP-B-02:
- Version V1.1
- Valid as of: 15.12.2014
- https://dzhk.de/en/resources/sops/

The corresponding secuTrial® form is only available in German.
State of the attached secuTrial® form: 14.07.2020
# Biomaterial-Begleitschein Basis-Set

## 1. Basis-Set (Allgemeine Informationen)

<table>
<thead>
<tr>
<th>1.1.</th>
<th>Biomaterial-ID Basis Abnahmeset</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>1.2.</th>
<th>Studie</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>1.3.</th>
<th>Einrichtungscode</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## 2. Blut- und Urinprobe

<table>
<thead>
<tr>
<th>2.1.</th>
<th>Blutentnahme durch</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.2.</th>
<th>Zeitpunkt der Blutentnahme tt.mm jjj hh.mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.3.</th>
<th>Blutentnahme ○ venös ○ arteriell ○ unbekannt ○ nicht erhoben</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.4.</th>
<th>Position bei Blutentnahme ○ sitzend ○ liegend ○ unbekannt ○ nicht erhoben</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>min.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.5.</th>
<th>Zeitpunkt der Urinabgabe (Klinik) tt.mm jjj hh.mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.6.</th>
<th>Abstand zur letzten Nahrungsaufnahme Wenn bekannt, bitte die Gesamtstunden angeben ○ &lt; 8 Std. ○ &gt;= 8 Std. ○ unbekannt ○ nicht erhoben</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Std.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.7.</th>
<th>Ernährung parenteral ○ ja ○ nein ○ unbekannt ○ nicht erhoben</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.8.</th>
<th>Menstruation bei Uringewinnung (bei Frauen) ○ ja ○ nein ○ unbekannt ○ nicht erhoben</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Neue DZHK Basis-Sets (bestellt ab Januar 2020) enthalten nur noch je 1 Primärröhrchen.**

<table>
<thead>
<tr>
<th>2.9.</th>
<th>Anzahl gefüllter Primärgefäße</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum</td>
<td>O0 O1 x 10 ml</td>
</tr>
<tr>
<td>EDTA-Plasma</td>
<td>O0 O1 O2 (BD)</td>
</tr>
<tr>
<td>Citrat-Plasma</td>
<td>O0 O1 O2</td>
</tr>
<tr>
<td>Urin</td>
<td>O0 O1</td>
</tr>
</tbody>
</table>

2.10. Zeitpunkt Eingang im Labor
Datum und Uhrzeit
Ansprechpartner
Wenn Urin-Eingang unterschiedlich von Blut:
Ansprechpartner

2.11. Ende der Zentrifugation
Datum und Uhrzeit
Wenn Urin-Eingang unterschiedlich von Blut, hier bitte Zeiten für Urin eintragen:

2.12. Probenbeschaffenheit (Blut)
Ist die Probenbeschaffenheit unauffällig?
Ist die Probenbeschaffenheit lipämisch?
Ist die Probenbeschaffenheit ikterisch?
Ist die Probenbeschaffenheit hämolytisch?

2.13. Probenbeschaffenheit (Urin)
Ist die Probenbeschaffenheit unauffällig?
Ist die Probenbeschaffenheit trüb?
Ist die Probenbeschaffenheit blutig?

2.14. Anzahl gefüllter Aliquotgefäße
Alle 10 Serumgefäße [300µl] gefüllt?
Falls nicht, bitte spezifizieren
Alle 10 EDTA-Gefäße [300µl] gefüllt?
Falls nicht, bitte spezifizieren
Alle 4 Citrat-Gefäße [300µl] gefüllt?
Falls nicht, bitte spezifizieren
Alle 8 Urin-Gefäße [300µl] gefüllt?
Falls nicht, bitte spezifizieren
Alle 2 Buffy Coat-Gefäße [<300µl] gefüllt?
Falls nicht, bitte spezifizieren
Kommentar

2.15a. Zeitpunkt Einfrieren der Aliquot
### 2.15. Zeitpunkt Einfrieren aller Aliquots bei -80°C (Serum, EDTA-Plasma, Citrat-Plasma, Urin, Buffy Coat)

<table>
<thead>
<tr>
<th>Datum und Uhrzeit</th>
<th>tt.mm.jjj hh:mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ansprechpartner</td>
<td></td>
</tr>
</tbody>
</table>

### 3. Besonderheiten

<table>
<thead>
<tr>
<th>Datum und Uhrzeit</th>
<th>tt.mm.jjj hh:mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ansprechpartner</td>
<td></td>
</tr>
</tbody>
</table>
Cardiac Catheter (DZHK-SOP-K-05)

The module Cardiac Catheter is used to document a cardiac catheter examination. This examination enables a better phenotyping of cardiomyopathies, an assessment of the degree of severity and of the prognosis.

The examinations ought to be performed according to DZHK-SOP-K-05 ⁷.

DZHK-SOP-K-05:  
- Version V1.0  
- Valid as of: 01.09.2014  
- https://dzhk.de/en/resources/sops/

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