# Template for technical realization of an analyses

Please provide the information below and fill the tables so your study is able to be implemented into the CERTAIN Registry. Please read the information below closely. All yellow marked parts have to be filled.

**Analysis name**:

**Analysis acronym (e.g. BKV 2016)**:

**Contact person (name and email)**:

Parameters from the basic data set are divided into a minimal mandatory and extended optional data set. If you choose parameters from the extended data be aware that it might be not available. However, if the information is fundamentally required for the analysis, list required parameter under study-specific data set. Parameters from the minimal data set are always available.

### Basic data set

1. …
2. …
3. …
4. Etc.

### Study-specific data set

In which visits the study-specific data set has to be shown and how long?

|  |  |
| --- | --- |
| **Visit** | **Required** |
| Initial visit | Yes or No |
| 30-days visit | Yes or No |
| 3-month visit | Yes or No |
| 6-month visit | Yes or No |
| 9-month visit | Yes or No |
| Yearly | Yes or No |
| Half-yearly | Yes or No |
| Last visit | e.g. 1/2/3/… years, unlimited |
| Other (specify) | - |

1. **Section name**: choose a speaking section or group name for a collection of parameters, e.g. creatinine, bilirubin, cholesterol, etc. are all laboratory results, so you could call the section Lab results. Each section name represents a separate tab within the data entry of the CERTAIN Registry, so try to group the parameters in not too much clusters.
2. **Parameter name**: choose a speaking parameter name and avoid abbreviations. In the best case, everyone knows what’s meant with the parameter name and no further explanation is required
3. **Info text**: If the parameter name might be not totally clear for study nurses and you have to specify the parameter name or want to provide more information this information will be shown to the user.
4. **Parameter type**: text, text with multiple choices, number, number with decimal.
5. **Parameter values/suggestion**: List all options which are available to choose. Provide suggestions, if the parameter type is a text.
6. **Validation**: Is specific validation of the parameter required, e.g. specific range in case of numbers or numbers with decimals? Are there warnings or errors?
7. **Visit limitation**: Is the parameter only visible in specific visits? If yes, in which?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Section name** | **Parameter name** | **Info text (optional)** | **Parameter type** | **Parameter values/suggestion  (if type is text)** | **Validation** | **Visit limitation** |
| Lab results | Decoy cells in urine | - | Text | Yes/No | Not empty | No |
|  | Serum creatinine | - | Text | Yes/No | Not empty | No |
| Donor | Age of donor | Age at donation | Number | - | >0 | Initial |

List all your parameters which are monitored **once per visit** in the list below. Following columns are available:

In case you want to monitor parameters with the possibility **multiple times per visit**, like lab results. As section name reuse a given name from above:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Section name** | **Parameter name** | **Info text (optional)** | **Parameter type** | **Parameter values/suggestion  (if type is text)** | **Validation** | **Visit limitation** |
| Lab results | Parameter | - | Text | Decoy cells in urine, Serum creatinine | Not empty | No |
|  | Date | - | Date |  | Not empty | No |
|  | Value | - | Number with Decimal |  | Serum creatinine: WARN: 0.1 < value < 9 mg/dl ERROR: 0.09 < value < 30 mg/dl | No |
|  | Unit | - | Text | Decoy cells in urine: copies/ng, copies/ml;  Serum creatinine: mg/dl, mmol/l | Not empty | No |