

Dispositions regarding data quality

Data documentation period

Before the audit indicators of the previous year (= calendar year) will be analyzed. Namely, regardless of whether an audit takes place in January 2018 or December 2018, in both cases the evaluation basis will be built from the data of the previous year (2017).

Exceptional cases

Initial certification	In initial certifications the indicators for at least 3 consecutive months will be presented. On the audit date, this period must not be older than 3 months. These exceptional regulations do not apply for the imposed number of primary cases respectively for resections. It is generally recommended to record the patients data from the beginning of the year.
First surveillance audit	Through the "Initial certification" process, it is possible not to be able to indicate the full annual calendar period even in the first surveillance audit. In this case, besides the incomplete period of the last calendar year, further additional assessments of the current calendar year indicators may be necessary. Other observations can be found in the "Special evaluations" chapter.
Flexibility of audit deadline establishment	By the flexibility of audit deadline establishment it is possible that no audit takes place in one year. This situation occurs, for example, when the first surveillance audit took place in December 2016, and the second surveillance audit is planned for February 2018. In this case, the second surveillance audit will analyze both the 2016 and 2017 data. The data of 2016 will be sent to OnkoZert in advance, until 30.09.2017 (identical terms according to "Audit period in 4th quarter").
Reduced audit cycle	If according to the submitted application no audit takes place, the data sheet will be sent to OnkoZert, updated to 31.03 with the data of the previous year.
Special assessments	The presentation of the indicators usually refers to the documentation period of a calendar year defined above. In addition to this presentation, other assessments can be analyzed in the certification process (some or all indicators). This will be made especially when data are missing, for example in case of non-fulfillment of the specified terms, their fulfillment to the limit; implausibilities and high oscillations compared to previously sent data. If there is a data deficit, the period of the data analysis may be extended to the current calendar year (e.g. additional evaluation starting from the beginning of the year). The evaluation period is usually considered to be the last 12 months. These special evaluations can be both in the advantage of the Centre (for example non-fulfillment of the imposed limits for a calendar year/12 months), and in disadvantage. In principle, the forecast analysis does not represent the evaluation basis.

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Audit period in 4th quarter

The Centres that have an audit in the 4th quarter, respectively in those that skipped an annual audit for flexibility reasons, irrespective of the date of the audit, the data sheet (including the results quality matrix) will be sent at the latest on 30.09 of the respective year.

Formal evaluation of indicators before the audit

Only the formal quality of data operation and the fulfillment degree are analyzed in the evaluation. The accuracy of the presented data as well as the functionality of the indicators (the functionality of the tumor documentation) will be checked during the audit and will be documented in the audit report.

Analysis of deficiencies in the presented data

In the data quality assessment performed by OnkoZert, implausibilities, failure to comply with the imposed terms or incomplete information may be noted. In this respect, an analysis reported to indicators will be performed. Depending on this analysis of indicators, improvement actions will be established. The outcome of this analysis can show, for example, the fact that no actions are required as a result of the individual analysis of implausible values. For the presentation of the indicators analysis, the OnkoZert form "Protocol for analysis of the deficiencies in the documented data" is available.

Evaluation of indicators in the on-site audit

The failure to comply with the imposed terms and the implausible character of the data are the main theme of the indicators analysis during the on-site audit (the evaluation basis is, for example, the "Analysis protocol" document). Other explanations resp. proof regarding deficiencies in the presented data will be prepared, as appropriate, to be presented by the Centre during the on-site audit.

The auditor will analyze the complete situation in the audit based on the analysis of the indicators and of other audit information. Depending on this overall complete analysis, the decision regarding the audit will be taken. If the general perception of the audit is positive and the analysis that refers to non-fulfillment of indicators by the Centre is adequate, then the non-fulfillment of an indicator does not necessarily represent a deviation.

In the case of non-deficient indicators, the registration and documentation of the data will be randomly assessed.

In the event of conflict or inconsistency between the terms of the German version of this document and the English translation, the German version shall prevail.