

Budget proposal guidelines for commercial studies

To streamline the review and negotiation process, and to avoid unnecessary delays or pushbacks, please adhere to the following guidelines when preparing your budget proposal.

1. Excel file.

Only Excel files will be accepted. We consider this the most appropriate file type for budgeting, review and negotiation purposes.

2. Unprotected file.

Protected files may prevent us from applying necessary adjustments, which is not acceptable.

3. Currency is euro.

Amounts must be in euro.

4. Protocol date must be specified.

The protocol date on which the budget proposal is based should be specified in the proposal and must match the date of the submitted protocol. This ensures that the correct budget version is reviewed and avoids the need for a repeat review.

5. Complete budget proposal.

Provide an amount for every procedure specified in the submitted budget proposal.

6. Black text only.

We use red text in our initial feedback to indicate our adjustments. Other text colours may be required for the negotiation process as well. We therefore ask you to use black text only in your budget proposal. Use highlighting instead of coloured text to mark items requiring attention.

7. Amounts in number format.

Amounts must be formatted as numbers. Incorrect formatting may cause formula errors.

8. Formulas wherever possible.

Where applicable (e.g., for visit cost totals), formulas should be used to ensure accuracy. The absence of formulas may lead to errors.

9. Overhead percentage is 20%.

Refer to the overhead section on the [CTC website](#) for more information.

10. Visit cost table should include:

- **Procedure names**, using the exact wording from the protocol flowchart for clarity.
- **Unit cost per procedure including overhead**
- **Number of units per procedure per visit**
- **Separate investigator fee and study coordinator fee.** We will primarily use these procedures, more specifically by adjusting the number of units per visit, as a basis for negotiating personnel costs.
- **No procedures that are included in the additional costs.** Including additional cost procedures under the visit costs complicates the review and invoicing process.

- If only per visit totals are provided, we will review them based on our assumptions and will not be able to provide detailed justification during the negotiation process.
- Refer to the budget example for further guidance.

11. No duplication of standard annexes fees.

Fees already specified in the standard annexes should not be repeated in the budget.

12. No Excel comments or notes.

Comments or notes in Excel cells are easily overlooked and will not be read. If remarks or questions are to be included, use a dedicated column instead.

13. No limitations per procedure, subject or study.

Limitations add unnecessary complexity and delay:

- They require separate review with the investigator department.
- They may lead to disagreements between the Sponsor/CRO and the investigator department.
- If additional units are needed during the study and limitations are included in the agreement, a contract amendment may be necessary, resulting in additional administrative workload.

14. The submitted format will be used in the final agreement.

‘Format’ refers to the layout and structure of the budget. If multiple formats containing the same information are submitted, only the most detailed format will be reviewed, at our discretion. This avoids the need to review identical content multiple times. The most detailed format must be included in the final agreement.