Updated joint Recommendations for the preparation of a

total services calculation for remuneration related to the conduct of a clinical trial in a trial center

(updated version – as of May 5th, 2025)

Preamble

Carrying out clinical trials is often subject to time constraints. In order to start a clinical trial as soon as possible, it should be possible to finalize the underlying contracts between the parties quickly and easily while addressing all relevant issues. In this context, it is helpful if the potential partners in the contract have (in their respective negotiations) recommendations available that identify examples of recurrent cost items for the accurate determination of the remuneration. In this regard, representatives of the Association of Medical Faculties in Germany (MFT), the German Association of Academic Medical Centers (VUD), the Network of Coordination Centers for Clinical Trials (KKS Network) and the German Association of Research-Based Pharmaceutical Companies (vfa) have drawn up recommendations for the preparation of such a total services calculation for the first time in 2017. In 2025, the following revised version of the common recommendations was published in collaboration with the German Pharmaceutical Industry Association (BPI) and the German Association of Medical Contract Research Organizations (BVMA).

Instructions for use

These recommendations cannot be binding due to antitrust legislation, but they are intended to be a jointly adopted orientation for the negotiation of clinical trial contracts by members of the above-mentioned organizations and other third parties. The recommendations include tasks that may be performed depending on the project in the context of conducting a clinical trial and are not – or only insufficiently – described in relevant service specifications.

If the respective trial protocol and the recommendations are considered, these recommendations should enable comprehensive remuneration of all direct trial-related costs in a total services calculation based on the principle of fee for service. **The recommendations should be regarded as supplementary to the payments / activities listed in the trial protocol.**

General administrative costs and possibly other operational costs are to be considered in the respective total services calculation, provided that they are directly related to the conduct of the clinical trial. General administrative costs specific to the location (e.g. pro rata costs for electricity, room costs, use of equipment, etc.) should be included. In this case, a percentage surcharge (so called “overhead”) would be contrary to the above-mentioned principle of fee for service.

Personnel costs for activities with a specific duration can be calculated by multiplying the time spent on study-related additional work, the individual hourly rate and the corresponding proportion of local costing surcharges. When calculating the individual hourly rate, deductible days such as for holidays, illness, further training, etc. must be taken into account.[1]

Please also note:

- Various members of a trial group may be involved in the various activities listed – even simultaneously.
- Activities BEFORE completion of a written contract are not covered by these recommendations. For these activities, additional remuneration can be agreed in a separate written contract (e.g. in the case of separate screening of the patient population in the context of extensive feasibility activities).
- The activities / tasks listed in the recommendations must be checked in each case for their relevance to the respective clinical trial. Remuneration based on the total services calculation is performed according to the principle of fee for service.
- The total remuneration for a clinical trial project will be proposed based on the total services calculation. This total remuneration also includes the trial-related services of all sub-contracted service providers, e.g. radiology departments or pharmacies. It also includes, for example, the administrative work involved in invoicing patients' travelling expenses or similar. The travel expenses are then to be calculated without local costing surcharge. This proposal forms the basis for contract negotiation.
- Costs that are covered by other benefactors (e.g. statutory health insurance) – such as costs of standard treatment / diagnostic tests – cannot be claimed again with regard to a clinical trial.

[1] Example calculation basis: 163 working days or 1304 hours for 261 working days (5-day week with 40 hours working time) less holidays (30 days), average sick days (20 days), public holidays (10 days), days for further training (8 days) and other (30 days). The figures may vary depending on the applicable pay scale.

ONE-OFF ACTIVITIES IN PREPARATION, INITIATION, AND TRIAL COMPLETION

I. Activities / payments AFTER a written contract of trial participation and BEFORE enrollment of the first patient

- **Project coordination / Organization / Communication / Agreement / Administration**

- **Documents / Certificates**
  - Obtaining essential documents (forms, signatures)

- **Trial-specific training / induction into the clinical trial**
  - Familiarization with the clinical trial (synopsis, protocol, patient information (informed consent), investigator's brochure, other documents; by investigators and members of the trial group / study team, e.g. study nurse, trial coordinator, for pharmacy staff, radiology department);
  - Participation in trial meetings or web meetings (investigators and possibly members of the trial group);
  - Participation in initiation visit (auditor and members of the audit group, if applicable incl. areas involved);
  - Specific CRF and protocol training (e.g. eCRF training, IxRS (IVRS / IWRS = Interactive Voice / Web Response System), ECG samples and assignment, training for assignments with radiographic imaging procedures), usually before enrollment of the first patient;
  - If other trial-specific or general completed training modules (e.g. basic and advanced courses for investigators, refresher and update courses, training with systems, e.g. rater training) are not recognized by the client / sponsor for the specific clinical trial, these should be calculated separately.

- **Implementation**
  - Amendment or creation of specific forms and involvement in the processing of questions by the Ethics Committees, Authorities and other central bodies (e.g. trial center qualifications);
  - Worksheets for trial assistants, or other);
  - Local set up of processes (review boards, validation, tools, etc.);
  - Local trial registration to improve patient recruitment;
  - Preparation of the trial drug handling (preparation, drug accountability, transport);
  - Specific setup for partial service providers (pharmacies, radiology, etc.);
  - Access for monitors to electronic systems in the facilities – calibration of trial-specific medical devices if explicitly requested by the client / sponsor.

II. Activities at the end of the clinical trial

- **Project coordination / Organization / Communication / Agreement / Administration**
  - Return or destruction of non-archival trial-specific material (possibly a separate contract);
  - Participation in close-out visit (auditor and, if applicable, members of the audit group);
  - Archiving incl. preparation of the study documents and the ISF (for clinical trials in accordance with the German Medicinal Products Act, retention period 25 years; commissioning of archive, labelling, organization, transport, etc.; digitization and digital archiving if necessary).

PATIENT-BASED ACTIVITIES FOR PLANNED VISITS RELATED TO THE CLINICAL TRIAL ACCORDING TO THE TRIAL PROTOCOL

Only trial-specific medical services that go beyond regular care (so-called trial-related extra costs) are taken into account in the total services calculation.

- **Project coordination / Organization / Communication / Agreement / Administration**
  - Communication of trial assistants (study nurse) with patients (trial review, appointments, organization);
  - Settlement of patient expenses (e.g. travel expenses).

- **Recruitment/ Study inclusion**
  - Patient information and documentation to an adequate extent with time for queries, follow-up discussions – possibly additional pharmacogenetic informed consent;
  - Assessment and documentation of the current state of health including medical history, physical examination and record of concomitant medication (with indication and allocation to documented diseases or symptoms);
  - Comprehensive process of checking inclusion and exclusion criteria;
  - Randomization.

- **Investigations / Documentation during study**
  - Examination of the patient (e.g. assessment of the trial course, decisions on treatment, dealing with inquiries; investigations);
  - Medical assessment of each adverse event for severity and relationship to the trial;
  - Documentation / reports of serious adverse events;
  - Documentation of changes in concomitant medication with indication and allocation to documented diseases or symptoms;
  - Evaluation of findings of sub-contracted service providers / vendors (e.g. staging, (biopsy), pathology);
  - Documentation of examination results and safety assessments in the patient record;
  - Medical and non-medical consultation of the investigator with other investigators (and treating physicians of the patient) who are not part of the trial group.

- **Training / Instruction of the patient**
  - Training on the use of the trial substance with the patient (instructions on taking the trial substance);
  - Support or explanation of e.g. questionnaires / patient diaries (including electronic diaries or eDiaries or other digital survey tools (e.g. for PROs));
  - Advice / guidance on trial participation (contraception, concomitant medication, food restrictions, etc.).

- **Data management in the trial center**
  - Timely documentation and query management of examination results and safety assessments in the documentation sheet (CRF);
  - If relevant: Importing and checking data from digital recording devices.

- **Review of trial criteria / amendment of trial documents**
  - Changes / amendments by the sponsor that require supplementary documentation or additional

expense during the clinical trial, e.g. explaining ICD changes with protocol amendments and new side effects to the patient

- **Handling of samples (patient-based)**
  - Preparation and dispatch of samples, preparation of the necessary documentation

- **Handling of the investigational drugs (patient-based)**
  - Preparation / delivery of the investigational drugs

ONGOING ACTIVITIES – HIGHER LEVEL (NOT AFFECTING INDIVIDUAL PATIENTS)

Remuneration in the form of regular (e.g. quarterly) payments is recommended.

- **Recruitment**
  - Search for or identification of potential study participants (e.g. reviewing existing data in patient records for compliance with basic selection criteria, compiling queries from the hospital information system (HIS), physician information system (PIS), presenting the trial in departmental discussions or tumor boards);
  - Clarifying the inclusion and exclusion criteria according to the recommendations for inclusion;
  - Sponsor's information on reasons for exclusion (e.g. elevated screening failure rate);
  - Information campaigns, advertisement placement, presentations, e.g. at investigator meetings, etc.

- **Project coordination / Organization / Communication / Agreement / Administration**
  - General tasks of the trial coordinator (e.g. troubleshooting, dealing with protocol violations);
  - Telephone conferences / web meetings, phone monitoring (remote monitoring);
  - Delegation of tasks to the trial center or additional expenses at the sponsor's request (e.g. due to equipment on loan);
  - Coordination of internal subcontracted service providers (e.g. local laboratory, radiology department, pharmacy, pathology, etc.), including storage and forwarding of the information / updating of certificates (e.g. certification by interlaboratory testing) – if this needs to be conducted on a trial-specific basis;
  - Clarification of procedures and finances with external third parties (e.g. patient recruitment etc.);
  - General assessment of side effects / preparation of CIOMS reports / briefing of trial group, registering and filing SUSARs;
  - Local organization (updating information for the trial team, possibly local trial register – if requested by the sponsor, maintenance of the investigator site file);
  - Tasks in the context of patient involvement.

- **Handling of samples (central)**
  - Coordination of sample storage and dispatch (laboratory manual, sample storage, temperature monitoring, etc.)

- **Handling of investigational drugs (central)**
  - Material management (checking expiration dates, reordering, tracking, storage, temperature monitoring, "dry run," etc.) (usually by subcontracted service providers)

- **Monitoring, audits, inspections (exception: due to a compliance violation by the trial center ["for cause"])**
  - Preparation and follow-up of monitoring visits (investigators and members of the trial group and possibly other institutions involved) as well as escorting the monitoring visit (depending on monitoring frequency);
  - Audits2;
  - Fees[1] for trial-specific inspections (dealt with as post-remuneration if necessary).

- **Review of the trial criteria / amendments (difficult to foresee but should be borne in mind)**
  - Procedural amendments (e.g. updating documents, new patient information if applicable);
  - Obtaining essential documents if there is a change in the trial team / extension, if this is requested by the client / sponsor;
  - Review of inclusion and exclusion criteria at the sponsor's request;
  - Changed expenditure on documentation and workload associated with the clinical trial due to amendments[1].

[2] If these costs have not already been taken into account as part of the total services calculation, a separate agreement may be drawn between the individual contracting parties. It is the responsibility of the contracting parties to negotiate the regulation of these costs in individual cases in a legally permissible manner (problem of double payments).