

User fee category

|                                                                                                                   |                                                                                                                                                                  | User fees        |                            | Timing of payment                                                                          |                            |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------------|--------------------------------------------------------------------------------------------|----------------------------|
| Consultations                                                                                                     |                                                                                                                                                                  |                  |                            |                                                                                            |                            |
| Drugs/quasi-drugs                                                                                                 | Procedural consultation for drugs                                                                                                                                | Per consultation | 150,900 yen                | Payment by the date of consultation application after arrangement of the consultation date |                            |
|                                                                                                                   | Consultation before the start of expanded clinical trials for drugs                                                                                              | Per consultation | 261,500 yen                |                                                                                            |                            |
|                                                                                                                   | Consultation for electronic study data submission (with recording)                                                                                               | Per consultation | 99,300 yen                 |                                                                                            |                            |
|                                                                                                                   | Consultation for electronic study data submission method                                                                                                         | Per consultation | 249,000 yen                |                                                                                            |                            |
|                                                                                                                   | Consultation for exemption of electronic study data submission (non-orphan drugs)                                                                                | Per consultation | 1,466,600 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation for exemption of electronic study data submission (orphan drugs)                                                                                    | Per consultation | 1,100,000 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on bioequivalence testing, etc. for drugs                                                                                                           | Per consultation | 600,400 yen                |                                                                                            |                            |
|                                                                                                                   | Safety consultation for drugs                                                                                                                                    | Per consultation | 1,925,300 yen              |                                                                                            |                            |
|                                                                                                                   | Safety consultation for drugs (related to ICH S1B [R1])                                                                                                          | Per consultation | 2,500,000 yen              |                                                                                            |                            |
|                                                                                                                   | Quality consultation for drugs                                                                                                                                   | Per consultation | 1,596,500 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on drug BCS                                                                                                                                         | Per consultation | 1,597,900 yen              |                                                                                            |                            |
|                                                                                                                   | Additional consultation on drug BCS                                                                                                                              | Per consultation | 798,500 yen                |                                                                                            |                            |
|                                                                                                                   | Consultation before start of phase I study for drugs (non-orphan drugs)                                                                                          | Per consultation | 4,578,500 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation before start of phase I study for drugs (orphan drugs)                                                                                              | Per consultation | 3,441,000 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation before start of early phase II study for drugs (non-orphan drugs)                                                                                   | Per consultation | 1,752,800 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation before start of early phase II study for drugs (orphan drugs)                                                                                       | Per consultation | 1,320,200 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation before start of late phase II study for drugs (non-orphan drugs)                                                                                    | Per consultation | 4,784,300 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation before start of late phase II study for drugs (orphan drugs)                                                                                        | Per consultation | 3,592,900 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation after completion of phase II study for drugs (non-orphan drugs)                                                                                     | Per consultation | 9,497,400 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation after completion of phase II study for drugs (orphan drugs)                                                                                         | Per consultation | 7,134,300 yen              |                                                                                            |                            |
|                                                                                                                   | Pre-application consultation for drugs (non-orphan drugs)                                                                                                        | Per consultation | 9,497,400 yen              |                                                                                            |                            |
|                                                                                                                   | Pre-application consultation for drugs (orphan drugs)                                                                                                            | Per consultation | 7,130,100 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on application data package for drugs (products developed as recommended by the Study Group on Unapproved and Off-label Drugs of High Medical Need) | Per consultation | 7,134,300 yen              |                                                                                            |                            |
|                                                                                                                   | Drug application data package consultation (products developed through investigator-initiated clinical trials)                                                   | Per consultation | 7,134,300 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on protocols of post-marketing clinical trials of drugs                                                                                             | Per consultation | 2,557,000 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation at completion of post-marketing clinical trials of drugs (preparation of application data, etc.)                                                    | Per consultation | 2,557,000 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation at completion of post-marketing clinical trials of drugs (review of conditions for approval, etc.)                                                  | Per consultation | 1,269,800 yen              |                                                                                            |                            |
|                                                                                                                   | Additional consultation for drugs (non-orphan drugs)                                                                                                             | Per consultation | 2,889,700 yen              |                                                                                            |                            |
|                                                                                                                   | Additional consultation for drugs (orphan drugs)                                                                                                                 | Per consultation | 2,171,200 yen              |                                                                                            |                            |
|                                                                                                                   | Additional consultation for drugs (products developed as recommended by the Study Group on Unapproved and Off-label Drugs of High Medical Need)                  | Per consultation | 2,171,200 yen              |                                                                                            |                            |
|                                                                                                                   | Additional consultation on drugs (products developed through investigator-initiated clinical trials)                                                             | Per consultation | 2,171,200 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on protocols of drug registry use                                                                                                                   | Per consultation | 980,300 yen                |                                                                                            |                            |
|                                                                                                                   | Procedural consultation for drugs                                                                                                                                | Per consultation | 150,900 yen                |                                                                                            |                            |
|                                                                                                                   | Consultation on drug epidemiological study protocol                                                                                                              | Per consultation | 3,007,900 yen              |                                                                                            |                            |
|                                                                                                                   | Additional consultation on drug epidemiological study                                                                                                            | Per consultation | 1,505,900 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation before revision of drug package inserts                                                                                                             | Per consultation | 99,200 yen                 |                                                                                            |                            |
|                                                                                                                   | Consultation on revision of drug package inserts                                                                                                                 | Per consultation | 4,987,400 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on GLP/GCP/GPSP compliance for drugs                                                                                                                | Per consultation | 4,542,900 yen              |                                                                                            |                            |
|                                                                                                                   | Consultation on re-examination compliance for drugs                                                                                                              | Per consultation | 2,300,400 yen              |                                                                                            | + overseas travel expenses |
|                                                                                                                   | Consultation on compliance for supporting documents for revision of drug package inserts                                                                         | Per consultation | 2,300,400 yen              |                                                                                            | + overseas travel expenses |
| Consultation on use of drug registry                                                                              | Per consultation                                                                                                                                                 | 100,000 yen      | + overseas travel expenses |                                                                                            |                            |
| Consultation on data integrity assessment for drug registry (filing of application) (non-orphan drugs)            | Per consultation                                                                                                                                                 | 3,600,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Additional consultation on data integrity assessment for drug registry (filing of application) (non-orphan drugs) | Per consultation                                                                                                                                                 | 1,800,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Consultation on data integrity assessment for drug registry (filing of application) (orphan drugs)                | Per consultation                                                                                                                                                 | 1,800,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Additional consultation on data integrity assessment for drug registry (filing of application) (orphan drugs)     | Per consultation                                                                                                                                                 | 900,000 yen      | + overseas travel expenses |                                                                                            |                            |
| Consultation on data integrity assessment for drug registry (application for re-examination)                      | Per consultation                                                                                                                                                 | 2,112,100 yen    | + overseas travel expenses |                                                                                            |                            |
| Additional consultation on data integrity assessment for drug registry (application for re-examination)           | Per consultation                                                                                                                                                 | 1,056,100 yen    | + overseas travel expenses |                                                                                            |                            |
| Consultation on use of drug database                                                                              | Per consultation                                                                                                                                                 | 1,085,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Consultation on data integrity assessment for drug database (filing of application) (non-orphan drugs)            | Per consultation                                                                                                                                                 | 3,600,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Additional consultation on data integrity assessment for drug database (filing of application) (non-orphan drugs) | Per consultation                                                                                                                                                 | 1,800,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Consultation on data integrity assessment for drug database (filing of application) (orphan drugs)                | Per consultation                                                                                                                                                 | 1,800,000 yen    | + overseas travel expenses |                                                                                            |                            |
| Additional consultation on data integrity assessment for drug database (filing of application) (orphan drugs)     | Per consultation                                                                                                                                                 | 900,000 yen      | + overseas travel expenses |                                                                                            |                            |
| Consultation on data integrity assessment for drug database (application for re-examination)                      | Per consultation                                                                                                                                                 | 2,112,100 yen    | + overseas travel expenses |                                                                                            |                            |

User fee category

|                   |                                                                                                                   | User fees        |                |                            | Timing of payment                                                                          |
|-------------------|-------------------------------------------------------------------------------------------------------------------|------------------|----------------|----------------------------|--------------------------------------------------------------------------------------------|
| Drugs/quasi-drugs | Additional consultation on data integrity assessment for drug database (application for re-examination)           | Per consultation | 1,056,100 yen  | + overseas travel expenses | Payment by the date of consultation application after arrangement of the consultation date |
|                   | Consultation on innovative manufacturing technology for drugs (without on-site inspection)                        | Per consultation | 2,500,000 yen  |                            |                                                                                            |
|                   | Consultation on innovative manufacturing technology for drugs (up to 2 on-site inspectors)                        | Per consultation | 2,900,000 yen  | + overseas travel expenses |                                                                                            |
|                   | Consultation on innovative manufacturing technology for drugs (up to 3 to 4 on-site inspectors)                   | Per consultation | 3,300,000 yen  | + overseas travel expenses |                                                                                            |
|                   | Prior assessment consultation for drugs (quality)                                                                 | Per consultation | 4,817,600 yen  |                            |                                                                                            |
|                   | Prior assessment consultation for drugs (toxicity)                                                                | Per consultation | 3,256,300 yen  |                            |                                                                                            |
|                   | Prior assessment consultation for drugs (non-clinical: toxicity)                                                  | Per consultation | 3,256,300 yen  |                            |                                                                                            |
|                   | Prior assessment consultation for drugs (non-clinical: pharmacokinetics)                                          | Per consultation | 3,256,300 yen  |                            |                                                                                            |
|                   | Prior assessment consultation for drugs (phase I study)                                                           | Per consultation | 5,505,400 yen  |                            |                                                                                            |
|                   | Prior assessment consultation for drugs (phase II study)                                                          | Per consultation | 7,105,200 yen  |                            |                                                                                            |
|                   | Prior assessment consultation for drugs (phase II/III study)                                                      | Per consultation | 11,036,500 yen |                            |                                                                                            |
|                   | Consultation on drug product eligibility for priority review                                                      | Per consultation | 1,300,600 yen  |                            |                                                                                            |
|                   | Consultation on drug product eligibility for priority review (with pre-application consultation for drugs)        | Per consultation | 266,400 yen    |                            |                                                                                            |
|                   | Consultation on orphan drug product eligibility for priority review                                               | Per consultation | 1,300,600 yen  |                            |                                                                                            |
|                   | Consultation on orphan drug product eligibility for priority review (with pre-application consultation for drugs) | Per consultation | 266,400 yen    |                            |                                                                                            |
|                   | Consultation on drug product eligibility for conditional approval                                                 | Per consultation | 1,016,100 yen  |                            |                                                                                            |
|                   | Consultation on drug product eligibility for conditional approval (with pre-application consultation for drugs)   | Per consultation | 208,200 yen    |                            |                                                                                            |
|                   | Consultation on R&D plan for pediatric drugs                                                                      | Per consultation | 1,541,600 yen  |                            |                                                                                            |
|                   | Consultation on drug product eligibility for public knowledge-based application                                   | Per consultation | 1,300,600 yen  |                            |                                                                                            |
|                   | Consultation on pharmacogenomics/biomarkers (qualification)                                                       | Per consultation | 3,270,600 yen  |                            |                                                                                            |
|                   | Consultation on pharmacogenomics/biomarkers (key points of clinical trial protocols)                              | Per consultation | 1,199,900 yen  |                            |                                                                                            |
|                   | Additional consultation on pharmacogenomics/biomarkers (qualification)                                            | Per consultation | 995,700 yen    |                            |                                                                                            |
|                   | Additional consultation on pharmacogenomics/biomarkers (key points of clinical trial protocols)                   | Per consultation | 435,300 yen    |                            |                                                                                            |
|                   | Consultation on bioequivalence of generic drugs                                                                   | Per consultation | 1,077,300 yen  |                            |                                                                                            |
|                   | Quality consultation for generic drugs                                                                            | Per consultation | 531,100 yen    |                            |                                                                                            |
|                   | Consultation on generic drug BCS                                                                                  | Per consultation | 1,597,900 yen  |                            |                                                                                            |
|                   | Additional consultation on generic drug BCS                                                                       | Per consultation | 798,500 yen    |                            |                                                                                            |
|                   | Consultation before minor change notification                                                                     | Per consultation | 319,900 yen    |                            |                                                                                            |
|                   | Consultation before minor change notification for generic drugs                                                   | Per consultation | 320,000 yen    |                            |                                                                                            |
|                   | Consultation on generic drug MF                                                                                   | Per consultation | 320,000 yen    |                            |                                                                                            |
|                   | Consultation on developmental strategy for switch OTC drugs                                                       | Per consultation | 2,500,000 yen  |                            |                                                                                            |
|                   | Additional consultation on developmental strategy for switch OTC drugs                                            | Per consultation | 1,000,000 yen  |                            |                                                                                            |
|                   | Pre-developmental consultation for switch OTC drugs                                                               | Per consultation | 1,800,000 yen  |                            |                                                                                            |
|                   | Consultation on bioequivalence of OTC drugs                                                                       | Per consultation | 1,000,000 yen  |                            |                                                                                            |
|                   | Consultation on post-marketing safety management of switch OTC drugs                                              | Per consultation | 700,000 yen    |                            |                                                                                            |
|                   | Consultation on key points of clinical trial protocols for OTC drugs                                              | Per consultation | 700,000 yen    |                            |                                                                                            |
|                   | Consultation on appropriateness of development of switch OTC drugs                                                | Per consultation | 600,000 yen    |                            |                                                                                            |
|                   | Consultation on appropriateness of development of new OTC drugs                                                   | Per consultation | 300,000 yen    |                            |                                                                                            |
|                   | Quality consultation for OTC drugs                                                                                | Per consultation | 300,000 yen    |                            |                                                                                            |
|                   | Human study plan confirmation consultation for quasi-drugs                                                        | Per consultation | 499,800 yen    |                            |                                                                                            |
|                   | New inactive ingredient development consultation for quasi-drugs                                                  | Per consultation | 249,800 yen    |                            |                                                                                            |
|                   | Prior consultation for quasi-drugs                                                                                | Per consultation | 426,200 yen    |                            |                                                                                            |
|                   | Post-consultation for drugs (with recording)                                                                      | Per consultation | 99,200 yen     |                            |                                                                                            |
|                   | Consultation on drug development pipeline                                                                         | Per consultation | 99,200 yen     |                            |                                                                                            |
|                   | Consultation on GCP/GLP/GPSP for drugs                                                                            | Per consultation | 444,100 yen    |                            |                                                                                            |

User fee category

|                |                                              | User fees                                                                                                                                                      |                  |               | Timing of payment                                                                          |
|----------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------|--------------------------------------------------------------------------------------------|
| Medical device | Consultation on protocol for medical devices | Preparatory interview of consultation for medical devices                                                                                                      | Per consultation | 29,400 yen    | Payment by the date of consultation application after arrangement of the consultation date |
|                |                                              | Consultation before the start of expanded clinical trials for medical devices                                                                                  | Per consultation | 249,000 yen   |                                                                                            |
|                |                                              | Pre-development consultation for medical devices                                                                                                               | Per consultation | 294,100 yen   |                                                                                            |
|                |                                              | Pre-development consultation for medical devices (preliminary consultation completed)                                                                          | Per consultation | 264,700 yen   |                                                                                            |
|                |                                              | Pre-development consultation for medical devices (additional consultation)                                                                                     | Per consultation | 147,000 yen   |                                                                                            |
|                |                                              | Consultation on finalization of application documents for medical devices                                                                                      | Per consultation | 390,100 yen   |                                                                                            |
|                |                                              | Consultation on finalization of application documents for medical devices (additional consultation)                                                            | Per consultation | 196,000 yen   |                                                                                            |
|                |                                              | Consultation on the necessity of clinical trials for medical devices                                                                                           | Per consultation | 980,300 yen   |                                                                                            |
|                |                                              | Consultation on the necessity of clinical trials for medical devices (preliminary consultation completed)                                                      | Per consultation | 950,600 yen   |                                                                                            |
|                |                                              | Consultation on the necessity of clinical trials for medical devices (additional consultation)                                                                 | Per consultation | 490,200 yen   |                                                                                            |
|                |                                              | Consultation on the necessity of clinical trials for medical devices (assessed by referring to clinical literature, etc.)                                      | Per consultation | 1,960,900 yen |                                                                                            |
|                |                                              | Consultation on the necessity of clinical trials for medical devices (assessed by referring to clinical literature, etc.) (preliminary consultation completed) | Per consultation | 1,931,500 yen |                                                                                            |
|                |                                              | Consultation on the necessity of clinical trials for medical devices (assessed by referring to clinical literature, etc.) (additional consultation)            | Per consultation | 980,300 yen   |                                                                                            |
|                |                                              | Safety (1 trial)                                                                                                                                               | Per consultation | 98,000 yen    |                                                                                            |
|                |                                              | Safety (1 trial) (preliminary consultation completed)                                                                                                          | Per consultation | 68,600 yen    |                                                                                            |
|                |                                              | Safety (1 trial) (additional consultation)                                                                                                                     | Per consultation | 46,800 yen    |                                                                                            |
|                |                                              | Safety (2 trials)                                                                                                                                              | Per consultation | 196,000 yen   |                                                                                            |
|                |                                              | Safety (2 trials) (preliminary consultation completed)                                                                                                         | Per consultation | 166,600 yen   |                                                                                            |
|                |                                              | Safety (2 trials) (additional consultation)                                                                                                                    | Per consultation | 98,000 yen    |                                                                                            |
|                |                                              | Safety (3 trials)                                                                                                                                              | Per consultation | 293,800 yen   |                                                                                            |
|                |                                              | Safety (3 trials) (preliminary consultation completed)                                                                                                         | Per consultation | 264,400 yen   |                                                                                            |
|                |                                              | Safety (3 trials) (additional consultation)                                                                                                                    | Per consultation | 147,000 yen   |                                                                                            |
|                |                                              | Safety (4 or more trials)                                                                                                                                      | Per consultation | 390,100 yen   |                                                                                            |
|                |                                              | Safety (4 or more trials) (preliminary consultation completed)                                                                                                 | Per consultation | 360,700 yen   |                                                                                            |
|                |                                              | Safety (4 or more trials) (additional consultation)                                                                                                            | Per consultation | 196,000 yen   |                                                                                            |
|                |                                              | Quality                                                                                                                                                        | Per consultation | 390,100 yen   |                                                                                            |
|                |                                              | Quality (preliminary consultation completed)                                                                                                                   | Per consultation | 360,700 yen   |                                                                                            |
|                |                                              | Quality (additional consultation)                                                                                                                              | Per consultation | 196,000 yen   |                                                                                            |
|                |                                              | Performance (1 trial)                                                                                                                                          | Per consultation | 98,000 yen    |                                                                                            |
|                |                                              | Performance (1 trial) (preliminary consultation completed)                                                                                                     | Per consultation | 68,600 yen    |                                                                                            |
|                |                                              | Performance (1 trials) (additional consultation)                                                                                                               | Per consultation | 46,800 yen    |                                                                                            |
|                |                                              | Performance (2 trials)                                                                                                                                         | Per consultation | 196,000 yen   |                                                                                            |
|                |                                              | Performance (2 trials) (preliminary consultation completed)                                                                                                    | Per consultation | 166,600 yen   |                                                                                            |
|                |                                              | Performance (2 trials) (additional consultation)                                                                                                               | Per consultation | 98,000 yen    |                                                                                            |
|                |                                              | Performance (3 trials)                                                                                                                                         | Per consultation | 293,800 yen   |                                                                                            |
|                |                                              | Performance (3 trials) (preliminary consultation completed)                                                                                                    | Per consultation | 264,400 yen   |                                                                                            |
|                |                                              | Performance (3 trials) (additional consultation)                                                                                                               | Per consultation | 147,000 yen   |                                                                                            |
|                |                                              | Performance (4 or more trials)                                                                                                                                 | Per consultation | 390,100 yen   |                                                                                            |
|                |                                              | Performance (4 or more trials) (preliminary consultation completed)                                                                                            | Per consultation | 360,700 yen   |                                                                                            |
|                |                                              | Performance (4 or more trials) (additional consultation)                                                                                                       | Per consultation | 196,000 yen   |                                                                                            |
|                |                                              | Performance (studies using existing medical records)                                                                                                           | Per consultation | 1,304,700 yen |                                                                                            |
|                |                                              | Performance (studies using existing medical records) (preliminary consultation completed)                                                                      | Per consultation | 1,274,500 yen |                                                                                            |
|                |                                              | Performance (studies using existing medical records) (additional consultation)                                                                                 | Per consultation | 655,100 yen   |                                                                                            |
|                |                                              | Exploratory clinical trial                                                                                                                                     | Per consultation | 1,076,200 yen |                                                                                            |
|                |                                              | Exploratory clinical trial (preliminary consultation completed)                                                                                                | Per consultation | 1,046,800 yen |                                                                                            |
|                |                                              | Exploratory clinical trial (additional consultation)                                                                                                           | Per consultation | 539,100 yen   |                                                                                            |
|                |                                              | Clinical trial                                                                                                                                                 | Per consultation | 2,353,100 yen |                                                                                            |
|                |                                              | Clinical trial (preliminary consultation completed)                                                                                                            | Per consultation | 2,323,700 yen |                                                                                            |
|                |                                              | Clinical trial (additional consultation)                                                                                                                       | Per consultation | 1,176,500 yen |                                                                                            |
|                |                                              | Data sufficiency/application category consultation for medical devices                                                                                         | Per consultation | 134,800 yen   |                                                                                            |
|                |                                              | Data sufficiency/application category consultation for medical devices (additional consultation)                                                               | Per consultation | 39,400 yen    |                                                                                            |
|                |                                              | Consultation on GLP/GCP/GPSP compliance investigation for medical devices                                                                                      | Per consultation | 399,700 yen   |                                                                                            |
|                |                                              | Consultation on GLP/GCP/GPSP compliance investigation for medical devices (preliminary consultation completed)                                                 | Per consultation | 370,300 yen   |                                                                                            |
|                |                                              | Consultation on GLP/GCP/GPSP compliance investigation for medical devices (additional consultation)                                                            | Per consultation | 197,900 yen   |                                                                                            |

User fee category

|                |                                                                                                                    | User fees        |               |  | Timing of payment                                                                          |
|----------------|--------------------------------------------------------------------------------------------------------------------|------------------|---------------|--|--------------------------------------------------------------------------------------------|
| Medical device | Consultation on inspection for use-results evaluation of medical device                                            | Per consultation | 573,800 yen   |  | Payment by the date of consultation application after arrangement of the consultation date |
|                | Safety (1 trial)                                                                                                   | Per consultation | 98,000 yen    |  |                                                                                            |
|                | Safety (1 trial) (preliminary consultation completed)                                                              | Per consultation | 68,600 yen    |  |                                                                                            |
|                | Safety (1 trial) (protocol not evaluated)                                                                          | Per consultation | 147,000 yen   |  |                                                                                            |
|                | Safety (1 trial) (protocol not evaluated) (preliminary consultation completed)                                     | Per consultation | 115,500 yen   |  |                                                                                            |
|                | Safety (1 trial) (additional consultation)                                                                         | Per consultation | 46,800 yen    |  |                                                                                            |
|                | Safety (2 trials)                                                                                                  | Per consultation | 196,000 yen   |  |                                                                                            |
|                | Safety (2 trials) (preliminary consultation completed)                                                             | Per consultation | 166,600 yen   |  |                                                                                            |
|                | Safety (2 trials) (protocol not evaluated)                                                                         | Per consultation | 293,800 yen   |  |                                                                                            |
|                | Safety (2 trials) (protocol not evaluated) (preliminary consultation completed)                                    | Per consultation | 264,400 yen   |  |                                                                                            |
|                | Safety (2 trials) (additional consultation)                                                                        | Per consultation | 98,000 yen    |  |                                                                                            |
|                | Safety (3 trials)                                                                                                  | Per consultation | 293,800 yen   |  |                                                                                            |
|                | Safety (3 trials) (preliminary consultation completed)                                                             | Per consultation | 264,400 yen   |  |                                                                                            |
|                | Safety (3 trials) (protocol not evaluated)                                                                         | Per consultation | 441,200 yen   |  |                                                                                            |
|                | Safety (3 trials) (protocol not evaluated) (preliminary consultation completed)                                    | Per consultation | 411,800 yen   |  |                                                                                            |
|                | Safety (3 trials) (additional consultation)                                                                        | Per consultation | 147,000 yen   |  |                                                                                            |
|                | Safety (4 or more trials)                                                                                          | Per consultation | 390,100 yen   |  |                                                                                            |
|                | Safety (4 or more trials) (preliminary consultation completed)                                                     | Per consultation | 360,700 yen   |  |                                                                                            |
|                | Safety (4 or more trials) (protocol not evaluated)                                                                 | Per consultation | 588,200 yen   |  |                                                                                            |
|                | Safety (4 or more trials) (protocol not evaluated) (preliminary consultation completed)                            | Per consultation | 558,800 yen   |  |                                                                                            |
|                | Safety (4 or more trials) (additional consultation)                                                                | Per consultation | 196,000 yen   |  |                                                                                            |
|                | Quality                                                                                                            | Per consultation | 390,100 yen   |  |                                                                                            |
|                | Quality (preliminary consultation completed)                                                                       | Per consultation | 360,700 yen   |  |                                                                                            |
|                | Quality (protocol not evaluated)                                                                                   | Per consultation | 588,200 yen   |  |                                                                                            |
|                | Quality (protocol not evaluated) (preliminary consultation completed)                                              | Per consultation | 558,800 yen   |  |                                                                                            |
|                | Quality (additional consultation)                                                                                  | Per consultation | 196,000 yen   |  |                                                                                            |
|                | Performance (1 trial)                                                                                              | Per consultation | 98,000 yen    |  |                                                                                            |
|                | Performance (1 trial) (preliminary consultation completed)                                                         | Per consultation | 68,600 yen    |  |                                                                                            |
|                | Performance (1 trials) (protocol not evaluated)                                                                    | Per consultation | 147,000 yen   |  |                                                                                            |
|                | Performance (1 trials) (protocol not evaluated) (preliminary consultation completed)                               | Per consultation | 115,500 yen   |  |                                                                                            |
|                | Performance (1 trials) (additional consultation)                                                                   | Per consultation | 46,800 yen    |  |                                                                                            |
|                | Performance (2 trials)                                                                                             | Per consultation | 196,000 yen   |  |                                                                                            |
|                | Performance (2 trials) (preliminary consultation completed)                                                        | Per consultation | 166,600 yen   |  |                                                                                            |
|                | Performance (2 trials) (protocol not evaluated)                                                                    | Per consultation | 293,800 yen   |  |                                                                                            |
|                | Performance (2 trials) (protocol not evaluated) (preliminary consultation completed)                               | Per consultation | 264,400 yen   |  |                                                                                            |
|                | Performance (2 trials) (additional consultation)                                                                   | Per consultation | 98,000 yen    |  |                                                                                            |
|                | Performance (3 trials)                                                                                             | Per consultation | 293,800 yen   |  |                                                                                            |
|                | Performance (3 trials) (preliminary consultation completed)                                                        | Per consultation | 264,400 yen   |  |                                                                                            |
|                | Performance (3 trials) (protocol not evaluated)                                                                    | Per consultation | 441,200 yen   |  |                                                                                            |
|                | Performance (3 trials) (protocol not evaluated) (preliminary consultation completed)                               | Per consultation | 411,800 yen   |  |                                                                                            |
|                | Performance (3 trials) (additional consultation)                                                                   | Per consultation | 147,000 yen   |  |                                                                                            |
|                | Performance (4 or more trials)                                                                                     | Per consultation | 390,100 yen   |  |                                                                                            |
|                | Performance (4 or more trials) (preliminary consultation completed)                                                | Per consultation | 360,700 yen   |  |                                                                                            |
|                | Performance (4 or more trials) (protocol not evaluated)                                                            | Per consultation | 588,200 yen   |  |                                                                                            |
|                | Performance (4 or more trials) (protocol not evaluated) (preliminary consultation completed)                       | Per consultation | 558,800 yen   |  |                                                                                            |
|                | Performance (4 or more trials) (additional consultation)                                                           | Per consultation | 196,000 yen   |  |                                                                                            |
|                | Performance (studies using existing medical records)                                                               | Per consultation | 1,224,600 yen |  |                                                                                            |
|                | Performance (studies using existing medical records) (preliminary consultation completed)                          | Per consultation | 1,194,700 yen |  |                                                                                            |
|                | Performance (studies using existing medical records) (protocol not evaluated)                                      | Per consultation | 1,746,200 yen |  |                                                                                            |
|                | Performance (studies using existing medical records) (protocol not evaluated) (preliminary consultation completed) | Per consultation | 1,715,200 yen |  |                                                                                            |
|                | Performance (studies using existing medical records) (additional consultation)                                     | Per consultation | 613,400 yen   |  |                                                                                            |
|                | Exploratory clinical trial                                                                                         | Per consultation | 980,300 yen   |  |                                                                                            |

User fee category

|                     |                                                                                                                                          |                                                                                           | User fees        |               |                            | Timing of payment                                                                          |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|------------------|---------------|----------------------------|--------------------------------------------------------------------------------------------|
| Medical device      | Evaluation consultation for medical devices                                                                                              | Exploratory clinical trial (preliminary consultation completed)                           | Per consultation | 950,900 yen   |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                     |                                                                                                                                          | Exploratory clinical trial (protocol not evaluated)                                       | Per consultation | 1,519,700 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Exploratory clinical trial (protocol not evaluated) (preliminary consultation completed)  | Per consultation | 1,488,100 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Exploratory clinical trial (additional consultation)                                      | Per consultation | 490,200 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical trial                                                                            | Per consultation | 1,470,700 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical trial (preliminary consultation completed)                                       | Per consultation | 1,441,300 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical trial (protocol not evaluated)                                                   | Per consultation | 2,647,200 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical trial (protocol not evaluated) (preliminary consultation completed)              | Per consultation | 2,617,700 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical trial (additional consultation)                                                  | Per consultation | 733,000 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Use-results evaluation                                                                    | Per consultation | 2,647,200 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Use-results evaluation (preliminary consultation completed)                               | Per consultation | 2,617,700 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Consultation before IDATEN notification for medical devices                               | Per consultation | 390,100 yen   |                            |                                                                                            |
|                     | Consultation on use of medical device registry                                                                                           |                                                                                           | Per consultation | 100,000 yen   | + overseas travel expenses |                                                                                            |
|                     | Consultation on data integrity assessment for medical device registry (filing of application)                                            |                                                                                           | Per consultation | 580,500 yen   | + overseas travel expenses |                                                                                            |
|                     | Consultation on data integrity assessment for medical device registry (filing of application) (additional consultation)                  |                                                                                           | Per consultation | 290,300 yen   | + overseas travel expenses |                                                                                            |
|                     | Consultation on data integrity assessment for medical device registry (application for use-results evaluation)                           |                                                                                           | Per consultation | 485,100 yen   | + overseas travel expenses |                                                                                            |
|                     | Consultation on data integrity assessment for medical device registry (application for use-results evaluation) (additional consultation) |                                                                                           | Per consultation | 242,600 yen   | + overseas travel expenses |                                                                                            |
|                     | Consultation on GCP/GLP/GPSP for medical devices                                                                                         |                                                                                           | Per consultation | 196,000 yen   |                            |                                                                                            |
|                     | Consultation on GCP/GLP/GPSP for medical devices (preliminary consultation completed)                                                    |                                                                                           | Per consultation | 166,600 yen   |                            |                                                                                            |
|                     | Consultation on GCP/GLP/GPSP for medical devices (additional consultation)                                                               |                                                                                           | Per consultation | 98,000 yen    |                            |                                                                                            |
|                     | Evaluation consultation for re-manufactured single-use medical devices (QMS confirmation)                                                |                                                                                           | Per consultation | 1,498,600 yen | + overseas travel expenses |                                                                                            |
| In vitro diagnostic | Preparatory interview of consultation for in vitro diagnostics                                                                           |                                                                                           | Per consultation | 29,400 yen    |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                     | Pre-development consultation for in vitro diagnostics                                                                                    |                                                                                           | Per consultation | 196,000 yen   |                            |                                                                                            |
|                     | Pre-development consultation for in vitro diagnostics (preliminary consultation completed)                                               |                                                                                           | Per consultation | 166,600 yen   |                            |                                                                                            |
|                     | Pre-development consultation for in vitro diagnostics (additional consultation)                                                          |                                                                                           | Per consultation | 98,000 yen    |                            |                                                                                            |
|                     | Pre-development consultation for companion diagnostics                                                                                   |                                                                                           | Per consultation | 293,800 yen   |                            |                                                                                            |
|                     | Pre-development consultation for companion diagnostics (preliminary consultation completed)                                              |                                                                                           | Per consultation | 264,400 yen   |                            |                                                                                            |
|                     | Pre-development consultation for companion diagnostics (additional consultation)                                                         |                                                                                           | Per consultation | 147,000 yen   |                            |                                                                                            |
|                     | Consultation for development package of companion diagnostics                                                                            |                                                                                           | Per consultation | 1,541,600 yen |                            |                                                                                            |
|                     | Consultation for development package of companion diagnostics (preliminary consultation completed)                                       |                                                                                           | Per consultation | 1,512,200 yen |                            |                                                                                            |
|                     | Consultation on protocol for in vitro diagnostics                                                                                        | Quality                                                                                   | Per consultation | 127,400 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Quality (preliminary consultation completed)                                              | Per consultation | 89,100 yen    |                            |                                                                                            |
|                     |                                                                                                                                          | Quality (additional consultation)                                                         | Per consultation | 60,800 yen    |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (1 trial)                                                | Per consultation | 127,400 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (1 trial) (preliminary consultation completed)           | Per consultation | 89,100 yen    |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (1 trial) (additional consultation)                      | Per consultation | 60,800 yen    |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (2 trials)                                               | Per consultation | 254,800 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (2 trials) (preliminary consultation completed)          | Per consultation | 216,500 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (2 trials) (additional consultation)                     | Per consultation | 127,400 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (3 or more trials)                                       | Per consultation | 381,900 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (3 or more trials) (preliminary consultation completed)  | Per consultation | 343,700 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Performance (other than quality) (3 or more trials) (additional consultation)             | Per consultation | 191,100 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Correlation                                                                               | Per consultation | 254,800 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Correlation (preliminary consultation completed)                                          | Per consultation | 216,500 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Correlation (additional consultation)                                                     | Per consultation | 127,400 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical performance studies                                                              | Per consultation | 735,300 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical performance studies (preliminary consultation completed)                         | Per consultation | 688,000 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical performance studies (additional consultation)                                    | Per consultation | 367,600 yen   |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical performance study for companion diagnostics                                      | Per consultation | 2,353,100 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical performance study for companion diagnostics (preliminary consultation completed) | Per consultation | 2,323,700 yen |                            |                                                                                            |
|                     |                                                                                                                                          | Clinical performance study for companion diagnostics (additional consultation)            | Per consultation | 1,176,500 yen |                            |                                                                                            |

User fee category

|                     |                                                                  |                                                                                                                    | User fees        |               | Timing of payment                                                                          |
|---------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------|---------------|--------------------------------------------------------------------------------------------|
| In vitro diagnostic | Application procedure consultation for in vitro diagnostics      |                                                                                                                    | Per consultation | 78,300 yen    | Payment by the date of consultation application after arrangement of the consultation date |
|                     | Evaluation consultation for in vitro diagnostics                 | Quality                                                                                                            | Per consultation | 127,400 yen   |                                                                                            |
|                     |                                                                  | Quality (preliminary consultation completed)                                                                       | Per consultation | 89,100 yen    |                                                                                            |
|                     |                                                                  | Quality (protocol not evaluated)                                                                                   | Per consultation | 191,100 yen   |                                                                                            |
|                     |                                                                  | Quality (protocol not evaluated) (preliminary consultation completed)                                              | Per consultation | 150,100 yen   |                                                                                            |
|                     |                                                                  | Quality (additional consultation)                                                                                  | Per consultation | 60,800 yen    |                                                                                            |
|                     |                                                                  | Performance (other than quality) (1 trial)                                                                         | Per consultation | 127,400 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (1 trial) (preliminary consultation completed)                                    | Per consultation | 89,100 yen    |                                                                                            |
|                     |                                                                  | Performance (other than quality) (1 trial) (protocol not evaluated)                                                | Per consultation | 191,100 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (1 trial) (protocol not evaluated) (preliminary consultation completed)           | Per consultation | 150,100 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (1 trial) (additional consultation)                                               | Per consultation | 60,800 yen    |                                                                                            |
|                     |                                                                  | Performance (other than quality) (2 trials)                                                                        | Per consultation | 254,800 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (2 trials) (preliminary consultation completed)                                   | Per consultation | 216,500 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (2 trials) (protocol not evaluated)                                               | Per consultation | 381,900 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (2 trials) (protocol not evaluated) (preliminary consultation completed)          | Per consultation | 343,700 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (2 trials) (additional consultation)                                              | Per consultation | 127,400 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (3 or more trials)                                                                | Per consultation | 381,900 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (3 or more trials) (preliminary consultation completed)                           | Per consultation | 343,700 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (3 or more trials) (protocol not evaluated)                                       | Per consultation | 573,500 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (3 or more trials) (protocol not evaluated) (preliminary consultation completed)  | Per consultation | 535,300 yen   |                                                                                            |
|                     |                                                                  | Performance (other than quality) (3 or more trials) (additional consultation)                                      | Per consultation | 191,100 yen   |                                                                                            |
|                     |                                                                  | Correlation                                                                                                        | Per consultation | 254,800 yen   |                                                                                            |
|                     |                                                                  | Correlation (preliminary consultation completed)                                                                   | Per consultation | 216,500 yen   |                                                                                            |
|                     |                                                                  | Correlation (protocol not evaluated)                                                                               | Per consultation | 381,900 yen   |                                                                                            |
|                     |                                                                  | Correlation (protocol not evaluated) (preliminary consultation completed)                                          | Per consultation | 343,700 yen   |                                                                                            |
|                     |                                                                  | Correlation (additional consultation)                                                                              | Per consultation | 127,400 yen   |                                                                                            |
|                     |                                                                  | Clinical performance studies                                                                                       | Per consultation | 440,700 yen   |                                                                                            |
|                     |                                                                  | Clinical performance studies (preliminary consultation completed)                                                  | Per consultation | 396,600 yen   |                                                                                            |
|                     |                                                                  | Clinical performance study (protocol not evaluated)                                                                | Per consultation | 808,600 yen   |                                                                                            |
|                     |                                                                  | Clinical performance study (protocol not evaluated) (preliminary consultation completed)                           | Per consultation | 764,500 yen   |                                                                                            |
|                     |                                                                  | Clinical performance studies (additional consultation)                                                             | Per consultation | 220,500 yen   |                                                                                            |
|                     |                                                                  | Clinical performance study for companion diagnostics                                                               | Per consultation | 1,470,700 yen |                                                                                            |
|                     |                                                                  | Clinical performance study for companion diagnostics (preliminary consultation completed)                          | Per consultation | 1,441,300 yen |                                                                                            |
|                     |                                                                  | Clinical performance study for companion diagnostics (protocol not evaluated)                                      | Per consultation | 2,647,200 yen |                                                                                            |
|                     |                                                                  | Clinical performance study for companion diagnostics (protocol not evaluated) (preliminary consultation completed) | Per consultation | 2,617,700 yen |                                                                                            |
|                     |                                                                  | Clinical performance study for companion diagnostics (additional consultation)                                     | Per consultation | 733,000 yen   |                                                                                            |
|                     | Consultation before IDATEN notification for in vitro diagnostics |                                                                                                                    | Per consultation | 78,300 yen    |                                                                                            |

User fee category

|                              |                                                                                                                                                                                     | User fees        |               |                            | Timing of payment                                                                          |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------|----------------------------|--------------------------------------------------------------------------------------------|
| Regenerative medical product | Procedural consultation for regenerative medical products                                                                                                                           | Per consultation | 141,600 yen   |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                              | Consultation before the start of expanded clinical trials for regenerative medical products                                                                                         | Per consultation | 261,400 yen   |                            |                                                                                            |
|                              | Pre-development consultation for regenerative medical products                                                                                                                      | Per consultation | 314,700 yen   |                            |                                                                                            |
|                              | Pre-development consultation for regenerative medical products (additional consultation)                                                                                            | Per consultation | 157,300 yen   |                            |                                                                                            |
|                              | Non-clinical consultation for regenerative medical products (effectiveness)                                                                                                         | Per consultation | 944,400 yen   |                            |                                                                                            |
|                              | Non-clinical consultation for regenerative medical products (effectiveness) (additional consultation)                                                                               | Per consultation | 472,100 yen   |                            |                                                                                            |
|                              | Non-clinical consultation for regenerative medical products (safety)                                                                                                                | Per consultation | 993,500 yen   |                            |                                                                                            |
|                              | Non-clinical consultation for regenerative medical products (safety) (additional consultation)                                                                                      | Per consultation | 496,800 yen   |                            |                                                                                            |
|                              | Quality consultation for regenerative medical products                                                                                                                              | Per consultation | 993,500 yen   |                            |                                                                                            |
|                              | Quality consultation for regenerative medical products (additional consultation)                                                                                                    | Per consultation | 496,800 yen   |                            |                                                                                            |
|                              | Consultation on qualification of materials for regenerative medical products                                                                                                        | Per consultation | 496,800 yen   |                            |                                                                                            |
|                              | Consultation before therapeutic exploratory study for regenerative medical products                                                                                                 | Per consultation | 1,153,400 yen |                            |                                                                                            |
|                              | Consultation before therapeutic exploratory study for regenerative medical products (additional consultation)                                                                       | Per consultation | 577,100 yen   |                            |                                                                                            |
|                              | Consultation after therapeutic exploratory study for regenerative medical products                                                                                                  | Per consultation | 1,687,200 yen |                            |                                                                                            |
|                              | Consultation after therapeutic exploratory study for regenerative medical products (additional consultation)                                                                        | Per consultation | 844,200 yen   |                            |                                                                                            |
|                              | Prior assessment consultation for regenerative medical products (safety, quality, effectiveness)                                                                                    | Per consultation | 3,684,200 yen |                            |                                                                                            |
|                              | Prior assessment consultation for regenerative medical products (therapeutic exploratory study)                                                                                     | Per consultation | 1,687,200 yen |                            |                                                                                            |
|                              | Prior assessment consultation for regenerative medical products (confirmatory clinical study)                                                                                       | Per consultation | 3,684,200 yen |                            |                                                                                            |
|                              | Pre-application consultation for regenerative medical products                                                                                                                      | Per consultation | 3,684,200 yen |                            |                                                                                            |
|                              | Pre-application consultation for regenerative medical products (additional consultation)                                                                                            | Per consultation | 1,842,000 yen |                            |                                                                                            |
|                              | Consultation on protocols of regenerative medical product registry use                                                                                                              | Per consultation | 294,100 yen   |                            |                                                                                            |
|                              | Consultation on protocols of clinical trials for regenerative medical products after the conditional time-limited authorization (with protocol)                                     | Per consultation | 1,687,200 yen |                            |                                                                                            |
|                              | Consultation on protocols of clinical trials for regenerative medical products after the conditional time-limited authorization (with protocol) (additional consultation)           | Per consultation | 844,200 yen   |                            |                                                                                            |
|                              | Consultation on protocols of clinical trials for regenerative medical products after the conditional time-limited authorization (only for investigation)                            | Per consultation | 1,266,400 yen |                            |                                                                                            |
|                              | Consultation on protocols of clinical trials for regenerative medical products after the conditional time-limited authorization (only for investigation) (additional consultation)  | Per consultation | 633,000 yen   |                            |                                                                                            |
|                              | Consultation at completion of clinical trials for regenerative medical products after the conditional time-limited authorization (with protocol)                                    | Per consultation | 1,687,200 yen |                            |                                                                                            |
|                              | Consultation at completion of clinical trials for regenerative medical products after the conditional time-limited authorization (with protocol) (additional consultation)          | Per consultation | 844,200 yen   |                            |                                                                                            |
|                              | Consultation at completion of clinical trials for regenerative medical products after the conditional time-limited authorization (only for investigation)                           | Per consultation | 1,266,400 yen |                            |                                                                                            |
|                              | Consultation at completion of clinical trials for regenerative medical products after the conditional time-limited authorization (only for investigation) (additional consultation) | Per consultation | 633,000 yen   |                            |                                                                                            |
|                              | Consultation on protocols of post-marketing clinical trials for regenerative medical products (with protocol)                                                                       | Per consultation | 1,687,200 yen |                            |                                                                                            |
|                              | Consultation on protocols of post-marketing clinical trials for regenerative medical products (with protocol) (additional consultation)                                             | Per consultation | 844,200 yen   |                            |                                                                                            |
|                              | Consultation on protocols of post-marketing clinical trials for regenerative medical products (only for investigation)                                                              | Per consultation | 1,266,400 yen |                            |                                                                                            |
|                              | Consultation on protocols of post-marketing clinical trials for regenerative medical products (only for investigation) (additional consultation)                                    | Per consultation | 633,000 yen   |                            |                                                                                            |
|                              | Consultation at completion of post-marketing clinical trials for regenerative medical products (with protocol)                                                                      | Per consultation | 1,687,200 yen |                            |                                                                                            |
|                              | Consultation at completion of post-marketing clinical trials for regenerative medical products (with protocol) (additional consultation)                                            | Per consultation | 844,200 yen   |                            |                                                                                            |
|                              | Consultation at completion of post-marketing clinical trials for regenerative medical products (only for investigation)                                                             | Per consultation | 1,266,400 yen |                            |                                                                                            |
|                              | Consultation at completion of post-marketing clinical trials for regenerative medical products (only for investigation) (additional consultation)                                   | Per consultation | 633,000 yen   |                            |                                                                                            |
|                              | Consultation on GLP/GCP (including GCTP) compliance for regenerative medical products                                                                                               | Per consultation | 613,800 yen   |                            |                                                                                            |
|                              | Consultation on GLP/GCP (including GCTP) compliance for regenerative medical products (additional consultation)                                                                     | Per consultation | 304,000 yen   |                            |                                                                                            |
|                              | Consultation before revision of package inserts of regenerative medical products                                                                                                    | Per consultation | 99,200 yen    |                            |                                                                                            |
|                              | Consultation on revision of package inserts of regenerative medical products                                                                                                        | Per consultation | 4,987,400 yen |                            |                                                                                            |
|                              | Consultation on compliance for supporting documents for revision of package inserts of regenerative medical products                                                                | Per consultation | 2,300,400 yen | + overseas travel expenses |                                                                                            |
|                              | Consultation on use of regenerative medical product registry                                                                                                                        | Per consultation | 100,000 yen   | + overseas travel expenses |                                                                                            |
|                              | Consultation on data integrity assessment for regenerative medical product registry (filing of application)                                                                         | Per consultation | 738,100 yen   | + overseas travel expenses |                                                                                            |
|                              | Additional consultation on data integrity assessment for regenerative medical product registry (filing of application)                                                              | Per consultation | 369,100 yen   | + overseas travel expenses |                                                                                            |
|                              | Consultation on data integrity assessment for regenerative medical product registry (application for re-examination)                                                                | Per consultation | 555,000 yen   | + overseas travel expenses |                                                                                            |
|                              | Additional consultation on data integrity assessment for regenerative medical product registry (application for re-examination)                                                     | Per consultation | 277,500 yen   | + overseas travel expenses |                                                                                            |
|                              | Prior assessment consultation for regenerative medical products (with recording)                                                                                                    | Per consultation | 99,200 yen    |                            |                                                                                            |
|                              | Post-consultation for regenerative medical products (with recording)                                                                                                                | Per consultation | 99,200 yen    |                            |                                                                                            |

User fee category

|                                                |                                                                                                                                                                          | User fees        |               |                            | Timing of payment                                                                          |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------|----------------------------|--------------------------------------------------------------------------------------------|
| Consultation related to the Cartagena Act      | Preliminary reviews under the Cartagena Act (class I)                                                                                                                    | Per consultation | 2,889,700 yen |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                                                | Preliminary reviews under the Cartagena Act (class II)                                                                                                                   | Per consultation | 963,200 yen   |                            |                                                                                            |
|                                                | Consultation on matters related to the Cartagena Act                                                                                                                     | Per consultation | 600,400 yen   |                            |                                                                                            |
|                                                | Pre-consultation related to the Cartagena Act (with recording)                                                                                                           | Per consultation | 99,200 yen    |                            |                                                                                            |
| SAKIGAKE comprehensive evaluation consultation | SAKIGAKE comprehensive evaluation consultation for drugs (quality)                                                                                                       | Per consultation | 4,604,400 yen |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                                                | SAKIGAKE comprehensive evaluation consultation for drugs (non-clinical)                                                                                                  | Per consultation | 7,679,300 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for drugs (clinical)                                                                                                      | Per consultation | 9,208,000 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for drugs (reliability)                                                                                                   | Per consultation | 4,593,900 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for drugs (GMP)                                                                                                           | Per consultation | 4,591,100 yen | + overseas travel expenses |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for medical devices (quality)                                                                                             | Per consultation | 1,499,700 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for medical devices (non-clinical)                                                                                        | Per consultation | 2,497,800 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for medical devices (clinical)                                                                                            | Per consultation | 2,998,800 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for medical devices (reliability)                                                                                         | Per consultation | 1,498,600 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for medical devices (QMS)                                                                                                 | Per consultation | 1,498,600 yen | + overseas travel expenses |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics (quality)                                                                                        | Per consultation | 299,100 yen   |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics (performance)                                                                                    | Per consultation | 999,500 yen   |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics (clinical performance)                                                                           | Per consultation | 1,599,300 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics (QMS)                                                                                            | Per consultation | 599,000 yen   | + overseas travel expenses |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for regenerative medical products (quality)                                                                               | Per consultation | 2,303,400 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for regenerative medical products (non-clinical)                                                                          | Per consultation | 3,836,500 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for regenerative medical products (clinical)                                                                              | Per consultation | 4,606,000 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for regenerative medical products (reliability)                                                                           | Per consultation | 2,301,800 yen |                            |                                                                                            |
|                                                | SAKIGAKE comprehensive evaluation consultation for regenerative medical products (GCTP)                                                                                  | Per consultation | 2,301,800 yen | + overseas travel expenses |                                                                                            |
| Consultation on R&D strategy                   | Consultation on R&D strategy for drugs                                                                                                                                   | Per consultation | 1,541,600 yen |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                                                | Consultation on R&D strategy for drugs (Universities/research institutes and venture companies meeting requirements specified separately*)                               | Per consultation | 154,100 yen   |                            |                                                                                            |
|                                                | Consultation on quality and safety for regenerative medical products                                                                                                     | Per consultation | 1,541,600 yen |                            |                                                                                            |
|                                                | Consultation on quality and safety for regenerative medical products (Universities/research institutes and venture companies meeting requirements specified separately*) | Per consultation | 154,100 yen   |                            |                                                                                            |
|                                                | Additional consultation on quality and safety for regenerative medical products                                                                                          | Per consultation | 496,800 yen   |                            |                                                                                            |
|                                                | Consultation on R&D strategy for medical devices                                                                                                                         | Per consultation | 874,000 yen   |                            |                                                                                            |
|                                                | Consultation on R&D strategy for medical devices (Universities/research institutes and venture companies meeting requirements specified separately*)                     | Per consultation | 87,400 yen    |                            |                                                                                            |
|                                                | Consultation on R&D strategy for regenerative medical products                                                                                                           | Per consultation | 874,000 yen   |                            |                                                                                            |
|                                                | Consultation on R&D strategy for regenerative medical products (Universities/research institutes and venture companies meeting requirements specified separately*)       | Per consultation | 87,400 yen    |                            |                                                                                            |
|                                                | Consultation on R&D strategy for development plans, etc.                                                                                                                 | Per consultation | 73,600 yen    |                            |                                                                                            |
| Simple consultation                            | Simple consultation on new drugs                                                                                                                                         | Per consultation | 22,600 yen    |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                                                | Simple consultation on generic drugs                                                                                                                                     | Per consultation | 22,600 yen    |                            |                                                                                            |
|                                                | Simple consultation on OTC drugs                                                                                                                                         | Per consultation | 22,600 yen    |                            |                                                                                            |
|                                                | Simple consultation on quasi-drugs (including pest control products)                                                                                                     | Per consultation | 22,600 yen    |                            |                                                                                            |
|                                                | Simple consultation on medical devices                                                                                                                                   | Per consultation | 39,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on in vitro diagnostics                                                                                                                              | Per consultation | 39,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on regenerative medical products                                                                                                                     | Per consultation | 22,600 yen    |                            |                                                                                            |
|                                                | Simple consultation on conformance to certification standards for medical devices                                                                                        | Per consultation | 79,800 yen    |                            |                                                                                            |
|                                                | Simple consultation on conformance to certification standards for in vitro diagnostics                                                                                   | Per consultation | 79,800 yen    |                            |                                                                                            |
|                                                | Simple consultation before notification of change for drugs                                                                                                              | Per consultation | 160,000 yen   |                            | Payment by document-based application                                                      |
|                                                | Simple consultation before notification of change for generic drugs                                                                                                      | Per consultation | 160,000 yen   |                            |                                                                                            |
|                                                | Simple consultation before notification of change for OTC drugs                                                                                                          | Per consultation | 160,000 yen   |                            |                                                                                            |
|                                                | Simple consultation after simultaneous inspection of generic drugs                                                                                                       | Per consultation | 22,600 yen    |                            |                                                                                            |
|                                                | Simple consultation before notification of change for medical devices                                                                                                    | Per consultation | 39,400 yen    |                            |                                                                                            |
|                                                | Simple consultation before notification of change for in vitro diagnostics                                                                                               | Per consultation | 39,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on GCP/GLP/GPSP for drugs                                                                                                                            | Per consultation | 20,300 yen    |                            | Payment by the date of consultation application after arrangement of the consultation date |
|                                                | Simple consultation on GCP/GLP/GPSP for medical devices                                                                                                                  | Per consultation | 19,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on GCP/GLP/GPSP for regenerative medical products                                                                                                    | Per consultation | 20,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on GMP inspection                                                                                                                                    | Per consultation | 25,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on QMS inspection                                                                                                                                    | Per consultation | 25,400 yen    |                            |                                                                                            |
|                                                | Simple consultation on GCTP inspection                                                                                                                                   | Per consultation | 26,700 yen    |                            |                                                                                            |

User fee category

|                                   |                                     |                                                               | User fees    |               | Timing of payment                  |
|-----------------------------------|-------------------------------------|---------------------------------------------------------------|--------------|---------------|------------------------------------|
| GLP inspection of test facilities |                                     |                                                               |              |               |                                    |
| All test items                    | Basic fee                           | With animal-rearing facility                                  | Per facility | 1,364,500 yen | Request to the PMDA after payment. |
|                                   |                                     | Without animal-rearing facility                               | Per facility | 839,400 yen   |                                    |
|                                   | Additional fee for target tests     | General toxicity studies                                      | Per study    | 419,600 yen   |                                    |
|                                   |                                     | Reproduction toxicity studies                                 | Per study    | 209,800 yen   |                                    |
|                                   |                                     | Safety pharmacology core battery studies<br>(only for drugs)  | Per study    | 209,800 yen   |                                    |
|                                   |                                     | Hemocompatibility studies<br>(only for medical devices)       | Per study    | 209,800 yen   |                                    |
|                                   |                                     | In vitro studies                                              | Per study    | 209,800 yen   |                                    |
|                                   |                                     | Other studies (dependence, T K, pathology, and other studies) | Per study    | 209,800 yen   |                                    |
|                                   |                                     | Additional fee for target classification                      | Drug         | Per facility  |                                    |
|                                   | Medical device                      |                                                               | Per facility | 209,800 yen   |                                    |
|                                   | Regenerative medical product        |                                                               | Per facility | 209,800 yen   |                                    |
|                                   | Additional compliance accreditation |                                                               | Per facility | 1,007,200 yen |                                    |
| Additional inspection             |                                     | Per inspection from the second inspection onwards             | 416,300 yen  |               |                                    |

|                                                                            |                             |             |                                    |
|----------------------------------------------------------------------------|-----------------------------|-------------|------------------------------------|
| Confirmation of certification on drugs, etc.                               |                             |             |                                    |
| GMP certification on investigational products (with on-site inspection)    | Per product of one facility | 798,900 yen | Request to the PMDA after payment. |
| GMP certification on investigational products (without on-site inspection) | Per product of one facility | 16,200 yen  |                                    |
| Certification of drug products                                             | Per product                 | 16,200 yen  |                                    |
| Other certifications (including GMP/QMS certifications)                    | Per matter of one product   | 9,100 yen   |                                    |

|                            |              |             |                                                                                                                        |
|----------------------------|--------------|-------------|------------------------------------------------------------------------------------------------------------------------|
| Fee for MDSAP report usage |              |             |                                                                                                                        |
|                            | Per facility | 200,000 yen | Payment by the time of application for use of the MDSAP report after instruction from the person in charge at the PMDA |

|                               |                  |           |                                                                         |
|-------------------------------|------------------|-----------|-------------------------------------------------------------------------|
| Use of document storage rooms |                  |           |                                                                         |
|                               | Per day per room | 3,000 yen | Payment upon invoice sent from the PMDA after the end of the use period |

To be eligible, universities/research institutes or venture companies should meet all of the following requirements in principle:

(For universities/research institutes)

- Having not received research expenses exceeding the following amount from the government to proceed with the research on the seed-stage resource:
  - Consultation on R&D strategy for drugs or quality and safety for regenerative medical products: 90 million yen
  - Consultation on R&D strategy for medical devices or regenerative medical products: 50 million yen
- Having not received research expenses from a pharmaceutical company/medical device company under a joint research agreement, etc., toward practical application of the seed-stage resource

(For venture companies)

- Being a small or medium-sized company (with 300 employees or less, or capitalized at 300 million yen or less)
- Any other corporation does not hold 1/2 or more of the total number of shares or investments
- Two or more other corporations do not hold 2/3 or more of the total number of shares or investments
- For the preceding fiscal year, profits of the term have not been reported, or profits of the term have been reported but without operating revenue