Appendix (related to Article 4)

User fee category

Revised on May 8, 2025

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

Appendix (related to Article 4) Revised on May 8, 2025 User fee category

			User fees		Timing of payment
	Additional consultation on data interwity accompant for drug database		User rees	L average travel	Tilling of payment
	Additional consultation on data integrity assessment for drug database (application for re-examination)	Per consultation	1,056,100 yen	+ overseas travel expenses	
	Consultation on innovative manufacturing technology for drugs (without onsite inspection)	Per consultation	2,500,000 yen		
	Consultation on innovative manufacturing technology for drugs (up to 2 onsite 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	ехрепзез	_
	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 preapplication 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	Per consultation	1,300,600 yen		_
	application Consultation on pharmacogenomics/biomarkers (qualification)	Per consultation	3,270,600 yen		Payment by the date of consultation application a arrangement of the consultation date
' -	Consultation on pharmacogenomics/biomarkers	Per consultation	1,199,900 yen		
	(key points of clinical trial protocols) Additional consultation on pharmacogenomics/biomarkers				
. –	(qualification) Additional consultation on pharmacogenomics/biomarkers	Per consultation	995,700 yen		
-	(key points of clinical trial protocols)	Per consultation	435,300 yen		- Consultation date
-	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 Consultation on key points of clinical trial protocols for OTC drugs	Per consultation Per consultation	700,000 yen 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		1
	Human study plan confirmation consultation for quasi-drugs	Per consultation	499,800 yen		1
	New inactive ingredient development consultation for quasi-drugs	Per consultation	249,800 yen		1
	Prior consultation for quasi-drugs	Per consultation	426,200 yen		1
	Post-consultation for drugs (with recording)	Per consultation	99,200 yen		1
-	Consultation on drug development pipeline	Per consultation	99,200 yen		1
<u> </u>	Consultation on GCP/GLP/GPSP for drugs	Per consultation	444,100 yen		-

Appendix (related to Article 4) Revised on May 8, 2025 User fee category

			User fees	Timing of payment
Preparator	ry interview of consultation for medical devices	Per consultation	29,400 yen	
Consultation	on before the start of expanded clinical trials for medical devices	Per consultation	249,000 yen	
	opment consultation for medical devices	Per consultation	294,100 yen	
Pre-development consultation for medical devices (preliminary consultation completed) Pre-development consultation for medical devices (additional consultation)		Per consultation	264,700 yen	
		Per consultation	147,000 yen	
	on on finalization of application documents for medical devices	Per consultation	390,100 yen	
	on on finalization of application documents for medical devices consultation)	Per consultation	196,000 yen	
,		Per consultation	980,300 yen	
Consultation	on on the necessity of clinical trials for medical devices ry consultation completed)	Per consultation	950,600 yen	
Consultation	Consultation on the necessity of clinical trials for medical devices (additional consultation)		490,200 yen	
Consultation	on on the necessity of clinical trials for medical devices by referring to clinical literature, etc.)	Per consultation Per consultation	1,960,900 yen	
Consultation	on on the necessity of clinical trials for medical devices by referring to clinical literature, etc.)	Per consultation	1,931,500 yen	
(preliminar Consultation	ry consultation completed) on on the necessity of clinical trials for medical devices		•	
	by referring to clinical literature, etc.)	Per consultation	980,300 yen	
	Safety (1 trial)	Per consultation	98,000 yen	
I	Safety (1 trial) (preliminary consultation completed)	Per consultation	68,600 yen	
1	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	Payment by the date consultation application
Cons	Quality (preliminary consultation completed)	Per consultation	360,700 yen	arrangement of th
ultat	Quality (additional consultation)	Per consultation	196,000 yen	oonoanation date
ion	Performance (1 trial)	Per consultation	98,000 yen	
Consultation on protocol for medical devices	Performance (1 trial) (preliminary consultation completed)	Per consultation	68,600 yen	
otoc	Performance (1 trials) (additional consultation)	Per consultation	46,800 yen	
Ö fo	Performance (2 trials)	Per consultation	196,000 yen	
ir me	Performance (2 trials) (preliminary consultation completed)		166,600 yen	
edica	Performance (2 trials) (additional consultation)		98,000 yen	
al de	Performance (3 trials)	Per consultation	293,800 yen	
vices	Performance (3 trials) (preliminary consultation completed)	Per consultation	264,400 yen	
U)	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 suffic	ciency/application category consultation for medical devices	Per consultation	134,800 yen	
Data suffic	ciency/application category consultation for medical devices	Per consultation	39,400 yen	
(additional Consultation	consultation) on on GLP/GCP/GPSP compliance investigation for medical		-	
devices Consultation	on on GLP/GCP/GPSP compliance investigation for medical	Per consultation Per consultation	399,700 yen 370,300 yen	
	reliminary consultation completed)	i di donadilalidh	310,300 yen	I

				User fees	Timing of payment
	Consultation	n on inspection for use-results evaluation of medical device	Per consultation	573,800 yen	
		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	Per consultation	360,700 yen	
		completed) Safety (4 or more trials) (protocol not evaluated)	Per consultation	588,200 yen	
		Safety (4 or more trials) (protocol not evaluated)	Per consultation	558,800 yen	
		(preliminary consultation completed)		-	
		Safety (4 or more trials) (additional consultation)	Per consultation	196,000 yen	
		Quality Outlike (preliminant consultation completed)	Per consultation	390,100 yen	
	Evalua	Quality (preliminary consultation completed)	Per consultation	360,700 yen	
	uation	Quality (protocol not evaluated) Quality (protocol not evaluated) (preliminary consultation	Per consultation	588,200 yen	
		completed)	Per consultation 558,800 yen		
	nsul	Quality (additional consultation)	Per consultation	196,000 yen	Payment by the date
	consultation for medical devices	Performance (1 trial)		consultation application arrangement of the	
	n for	Performance (1 trial) (preliminary consultation completed)	Per consultation	68,600 yen	consultation date
	mec	Performance (1 trials) (protocol not evaluated) Performance (1 trials) (protocol not evaluated)	Per consultation	147,000 yen	
	lical	(preliminary consultation completed)	Per consultation	115,500 yen	
	devi	Performance (1 trials) (additional consultation)	Per consultation	46,800 yen	
	ces	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) Performance (2 trials) (protocol not evaluated)	Per consultation	293,800 yen	
		(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)	Per consultation	558,800 yen	
		(preliminary consultation completed) 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)	Per consultation	1,194,700 yen	
		(preliminary consultation completed) 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	
1		Exploratory clinical trial	Per consultation	980,300 yen	

				User fees		Timing of payment
	ш	Exploratory clinical trial (preliminary consultation completed)	Per consultation	950,900 yen		
	Evaluation consultation for medical devices	Exploratory clinical trial (protocol not evaluated)	Per consultation	1,519,700 yen		
	latio	Exploratory clinical trial (protocol not evaluated) (preliminary	Per consultation	1,488,100 yen		
	n co	consultation completed) Exploratory clinical trial (additional consultation)	Per consultation	490,200 yen		
	nsult	Clinical trial	Per consultation	1,470,700 yen		_
	tatio	Clinical trial (preliminary consultation completed)	Per consultation	1,441,300 yen		_
	n for	Clinical trial (protocol not evaluated)	Per consultation	2,647,200 yen		
	mec	Clinical trial (protocol not evaluated) (preliminary consultation	Per consultation	2,617,700 yen		_
	dical	completed)				
	dev	Clinical trial (additional consultation)	Per consultation	733,000 yen		
	ices	Use-results evaluation	Per consultation	2,647,200 yen		Payment by the date of
	0 11 11	Use-results evaluation (preliminary consultation completed)	Per consultation	2,617,700 yen		consultation application
		on before IDATEN notification for medical devices	Per consultation	390,100 yen	+ overseas travel	arrangement of the consultation date
		on on use of medical device registry	Per consultation	100,000 yen	expenses	
	of applicat	on on data integrity assessment for medical device registry (filing tion)	Per consultation	580,500 yen	+ overseas travel expenses	
	Consultati	on on data integrity assessment for medical device registry (filing tion) (additional consultation)	Per consultation	290,300 yen	+ overseas travel expenses	
	Consultati	on on data integrity assessment for medical device registry	Per consultation	485,100 yen	+ overseas travel	_
		on for use-results evaluation) on on data integrity assessment for medical device registry			expenses + overseas travel	_
-	(application	on for use-results evaluation) (additional consultation)	Per consultation	242,600 yen	expenses	
	_	on on GCP/GLP/GPSP for medical devices	Per consultation	196,000 yen		_
		on on GCP/GLP/GPSP for medical devices (preliminary on completed)	Per consultation	166,600 yen		
	Consultati	on on GCP/GLP/GPSP for medical devices (additional	Per consultation	98,000 yen		
		consultation for re-manufactured single-use medical devices	Per consultation	1,498,600 yen	+ overseas travel expenses	_
		ry interview of consultation for in vitro diagnostics	Per consultation	29,400 yen		
	Pre-develo	opment consultation for in vitro diagnostics	Per consultation	196,000 yen		_
		opment consultation for in vitro diagnostics (preliminary	Per consultation	166,600 yen		
		on completed) opment consultation for in vitro diagnostics (additional	Per consultation	•		-
-	consultation	,		98,000 yen		
		opment consultation for companion diagnostics opment consultation for companion diagnostics (preliminary	Per consultation	293,800 yen		
	consultation	on completed)	Per consultation	264,400 yen		
	Pre-develo	opment consultation for companion diagnostics (additional	Per consultation	147,000 yen		
		on for development package of companion diagnostics	Per consultation	1,541,600 yen		
		on for development package of companion diagnostics	Per consultation	1,512,200 yen		
H	(prelimina	ry consultation completed) 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	Per consultation	89,100 yen		1
		consultation completed) Performance (other than quality) (1 trial) (additional				Payment by the date o
	ဂ္ဂ	consultation)	Per consultation	60,800 yen		consultation application a
	nsu	Performance (other than quality) (2 trials)	Per consultation	254,800 yen		arrangement of the consultation date
	Itatic	Performance (other than quality) (2 trials) (preliminary consultation completed)	Per consultation	216,500 yen		
	on or	Performance (other than quality) (2 trials) (additional	Per consultation	127,400 yen		
	n pro	consultation) Performance (other than quality) (3 or more trials)	Per consultation	381,900 yen		_
	tocc	Performance (other than quality) (3 or more trials) (preliminary	Per consultation	343,700 yen		_
) for	consultation completed) Performance (other than quality) (3 or more trials) (additional				_
	Consultation on protocol for in vitro diagnostics	consultation)	Per consultation	191,100 yen		_
	itro c	Correlation	Per consultation	254,800 yen		_
	liagr	Correlation (preliminary consultation completed)	Per consultation	216,500 yen		_
	nosti	Correlation (additional consultation)	Per consultation	127,400 yen		_
	S	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		_

			User fees	Timing of payment
Applicati	ion procedure consultation for in vitro diagnostics	Per consultation	78,300 yen	
	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)	onsultation) Per consultation 60,800 yen		
	Performance (other than quality) (1 trial)	Per consultation	127,400 yen	
	Performance (other than quality) (1 trial) (preliminary	Per consultation	89,100 yen	
	consultation completed) Performance (other than quality) (1 trial) (protocol not evaluated)	Per consultation	191,100 yen	
	Performance (other than quality) (1 trial) (protocol not evaluated)	Per consultation	150,100 yen	
	(preliminary consultation completed) 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	
Evalu	Performance (other than quality) (2 trials) (additional consultation)	Per consultation	127,400 yen	
atior	Performance (other than quality) (2 trials) (additional consultation) Performance (other than quality) (3 or more trials) Performance (other than quality) (3 or more trials) (preliminary consultation completed) Performance (other than quality) (3 or more trials) (protocol not evaluated) Performance (other than quality) (3 or more trials) (protocol not evaluated) (preliminary consultation completed)	Per consultation	381,900 yen	
n cons		Per consultation	343,700 yen	
ultatic	Performance (other than quality) (3 or more trials) (protocol not evaluated)	Per consultation	573,500 yen	Payment by the date
on for in	Performance (other than quality) (3 or more trials) (protocol not evaluated) (preliminary consultation completed)	Per consultation	535,300 yen	consultation application arrangement of the consultation date
vitro	Performance (other than quality) (3 or more trials) (additional consultation)	Per consultation	191,100 yen	
vitro diagnostics	Correlation	Per consultation	254,800 yen	
gnos	Correlation (preliminary consultation completed)	Per consultation	216,500 yen	
stics	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	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)	Per consultation	764,500 yen	
	(preliminary consultation completed) 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	
Conculto	ation before IDATEN notification for in vitro diagnostics	Per consultation	78,300 yen	

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			User fees		Timing of payment
	Procedural consultation for regenerative medical products	Per consultation	141,600 yen		
	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 Consultation before therapeutic exploratory study for regenerative medical	Per consultation	496,800 yen		
-	products Consultation before therapeutic exploratory study for regenerative medical	Per consultation	1,153,400 yen		
	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	Per consultation	844,200 yen		
H	products (additional consultation) Prior assessment consultation for regenerative medical products (safety,	Per consultation	3,684,200 yen		
-	quality, effectiveness) 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		
L	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	Per consultation	1,687,200 yen		
-	(with protocol) Consultation on protocols of clinical trials for regenerative				
	medical products after the conditional time-limited authorization	Per consultation	844,200 yen		
-	(with protocol) (additional consultation) 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		
t	Consultation on protocols of clinical trials for regenerative	5			
	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	Per consultation	1,687,200 yen		
	(with protocol)	r ei consultation	1,007,200 yell		
	Consultation at completion of clinical trials for regenerative medical products after the conditional time-limited authorization	Per consultation	844,200 yen		Payment by the date
-	(with protocol) (additional consultation) Consultation at completion of clinical trials for regenerative				consultation application
	medical products after the conditional time-limited authorization	Per consultation	1,266,400 yen		arrangement of the consultation date
H	(only for investigation) 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		
İ	Consultation on protocols of post-marketing clinical trials for regenerative	Danasassikatian	4.007.000		
	medical products (with protocol)	Per consultation	1,687,200 yen		
	Consultation on protocols of post-marketing clinical trials for regenerative medical products	Per consultation	844,200 yen		
	(with protocol) (additional consultation)	1 of concuration	011,200 yen		
	Consultation on protocols of post-marketing clinical trials for regenerative medical products	Per consultation	1,266,400 yen		
\perp	(only for investigation) Consultation on protocols of post-marketing clinical trials for regenerative		, , ,		
	medical products	Per consultation	633,000 yen		
+	(only for investigation) (additional consultation) Consultation at completion of post-marketing clinical trials for regenerative				
	medical products (with protocol)	Per consultation	1,687,200 yen		
T	Consultation at completion of post-marketing clinical trials for regenerative	D-1	044.000		1
	medical products (with protocol) (additional consultation)	Per consultation	844,200 yen		
	Consultation at completion of post-marketing clinical trials for regenerative medical products	Per consultation	1,266,400 yen		
L	(only for investigation)	1 el consultation	1,200,400 yen		
	Consultation at completion of post-marketing clinical trials for regenerative medical products	Per consultation	633,000 yen		
╆	(only for investigation) (additional consultation) 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	Per consultation	304,000 yen		
-	(additional consultation) Consultation before revision of package inserts of regenerative medical				
L	products	Per consultation	99,200 yen		
-	Consultation on revision of package inserts of regenerative medical products Consultation on compliance for supporting documents for revision of package	Per consultation	4,987,400 yen	+ overseas travel	
	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	
T	Consultation on data integrity assessment for regenerative medical product registry (filing of application)	Per consultation	738,100 yen	+ overseas travel	
+	Additional consultation on data integrity assessment for regenerative medical	Per consultation	369,100 yen	expenses + overseas travel	
-	product registry (filing of application) Consultation on data integrity assessment for regenerative medical product			expenses + overseas travel	-
\perp	registry (application for re-examination) Additional consultation on data integrity assessment for regenerative medical	Per consultation	555,000 yen	expenses	
	product registry (application for re-examination)	Per consultation	277,500 yen	+ overseas travel expenses	
1	Prior assessment consultation for regenerative medical products (with	Per consultation	99,200 yen		
	recording)				

Appendix (related to Article 4) Revised on May 8, 2025 User fee category

			User fees		Timing of payment
τ _α ς,	Preliminary reviews under the Cartagena Act (class I)	Per consultation	2,889,700 yen		
Consultation related to the Cartagena Act	Preliminary reviews under the Cartagena Act (class II)	Per consultation	963,200 yen		Payment by the date of consultation application after
ation r artage	Consultation on matters related to the Cartagena Act	Per consultation	600,400 yen		arrangement of the
elated na Ac	Pre-consultation related to the Cartagena Act (with recording)	Per consultation	99,200 yen		consultation date
4 -	SAKIGAKE comprehensive evaluation consultation for drugs (quality)	Per consultation	4,604,400 yen		
	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	
SA	SAKIGAKE comprehensive evaluation consultation for medical devices	Per consultation	1,499,700 yen	expenses	_
SAKIGAKE	(quality) SAKIGAKE comprehensive evaluation consultation for medical devices		-		_
	(non-clinical) SAKIGAKE comprehensive evaluation consultation for medical devices	Per consultation	2,497,800 yen		_
com	(clinical)	Per consultation	2,998,800 yen		_
preh	SAKIGAKE comprehensive evaluation consultation for medical devices (reliability)	Per consultation	1,498,600 yen		
comprehensive	SAKIGAKE comprehensive evaluation consultation for medical devices (QMS)	Per consultation	1,498,600 yen	+ overseas travel expenses	Payment by the date of consultation application after
	SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics	Per consultation	299,100 yen	SAPS.11333	arrangement of the consultation date
evaluation consultation	(quality) SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics	Per consultation	999,500 yen		Consultation date
ation	(performance) SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics		-		_
con	(clinical performance)	Per consultation	1,599,300 yen		
sulta	SAKIGAKE comprehensive evaluation consultation for in vitro diagnostics (QMS)	Per consultation	599,000 yen	+ overseas travel expenses	
tion	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	Per consultation	4,606,000 yen		-
ļ.	medical products (clinical) SAKIGAKE comprehensive evaluation consultation for regenerative		•		_
l l	medical products (reliability) SAKIGAKE comprehensive evaluation consultation for regenerative	Per consultation	2,301,800 yen	L average travel	
	medical products (GCTP)	Per consultation	2,301,800 yen	+ overseas travel expenses	
	Consultation on R&D strategy for drugs	Per consultation	1,541,600 yen		
	Consultation on R&D strategy for drugs (Universities/research institutes and venture companies meeting	Per consultation	154,100 yen		
	requirements specified separately*)	5 " "			_
Con	Consultation on quality and safety for regenerative medical products Consultation on quality and safety for regenerative medical products	Per consultation	1,541,600 yen		
Consultation	(Universities/research institutes and venture companies meeting	Per consultation	154,100 yen		
ation	requirements specified separately*) Additional consultation on quality and safety for regenerative medical	Per consultation	496,800 yen		Payment by the date of
on R	Consultation on R&D strategy for modical devices	Per consultation			consultation application after arrangement of the
R&D	Consultation on R&D strategy for medical devices Consultation on R&D strategy for medical devices	Per consultation	874,000 yen		consultation date
strategy	(Universities/research institutes and venture companies meeting requirements specified separately*)	Per consultation	87,400 yen		
еду	Consultation on R&D strategy for regenerative medical products	Per consultation	874,000 yen		
1	Consultation on R&D strategy for regenerative medical products	Dan ann ailte tion	07.400		
	(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 on new drugs	Per consultation	22,600 yen		
	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		Payment by the date of
1	Simple consultation on medical devices	Per consultation	39,400 yen		consultation application after arrangement of the
1	Simple consultation on in vitro diagnostics	Per consultation	39,400 yen		consultation date
-	Simple consultation on regenerative medical products Simple consultation on conformance to certification standards for medical	Per consultation	22,600 yen		_
	devices	Per consultation	79,800 yen		
Simple	Simple consultation on conformance to certification standards for in vitro diagnostics	Per consultation	79,800 yen		
ole c	Simple consultation before notification of change for drugs	Per consultation	160,000 yen		
onsu	Simple consultation before notification of change for generic drugs	Per consultation	160,000 yen		
consultation	Simple consultation before notification of change for OTC drugs	Per consultation	160,000 yen		Payment by document-
ъn	Simple consultation after simultaneous inspection of generic drugs	Per consultation	22,600 yen		based application
	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		ļ
	Simple consultation on GCP/GLP/GPSP for drugs	Per consultation	20,300 yen		_
	Simple consultation on GCP/GLP/GPSP for medical devices	Per consultation	19,400 yen		Payment by the date of
	Simple consultation on GCP/GLP/GPSP for regenerative medical products	Per consultation	20,400 yen		consultation application after arrangement of the
	Simple consultation on GMP inspection	Per consultation	25,400 yen		- consultation date
	Simple consultation on QMS inspection	Per consultation	25,400 yen		-
1 1	Simple consultation on GCTP inspection	Per consultation	26,700 yen		

Appendix (related to Article 4) Revised on May 8, 2025

User fee category

				User fees	Timing of payment
GLP inspection	n of test facilities		•		<u> </u>
	Basic fee	With animal-rearing facility	Per facility	1,364,500 yen	
	Dasic lee	Without animal-rearing facility	Per facility	839,400 yen	
		General toxicity studies	Per study	419,600 yen	
		Reproduction toxicity studies	Per study	209,800 yen	
All test items	Additional fee for	Safety pharmacology core battery studies (only for drugs)	Per study	209,800 yen	
st ite	target tests	Hemocompatibility studies (only for medical devices)	Per study	209,800 yen	
ms		In vitro studies	Per study	209,800 yen	Request to the PMDA afte payment.
		Other studies (dependence, T K, pathology, and other studies)	Per study	209,800 yen	payment.
		Drug	Per facility	209,800 yen	
	Additional fee for target classification	Medical device	Per facility	209,800 yen	
		Regenerative medical product	Per facility	209,800 yen	
Additional com	npliance accreditation		Per facility	1,007,200 yen	
Additional insp	pection		Per inspection from the second inspection onward	ds 416,300 yen	
Confirmation	of certification on drugs, etc.				
		ucts (with on-site inspection)	Per product of one facility	798,900 yen	
GMP certific	ation on investigational prod	ucts (without on-site inspection)	Per product of one facility	16,200 yen	Request to the PMDA
Certification	of drug products		Per product	16,200 yen	after payment.
Other certific	cations (including GMP/QMS	certifications)	Per matter of one product	9,100 yen	
			•		•
Fee for MDSA	P report usage				
			Per facility	200,000 yen	Payment by the time o application for use of th MDSAP report after instruction from the person in charge at the PMDA

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

(For universities/research institutes)

Use of document storage rooms

- •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

Per day per room

3,000 yen

Payment upon invoice sent from the PMDA after

the end of the use period

- •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