	主たる活動										
	Provision/collection/ sharing of information						Strategy/plan				Overall
Contents	Selection of KTLs/KOLs	Provision of latest information on product/therapeutic area (within the scope of approval), medical/scientific exchange	for the assigned therapeutic area/	Feedback on medical/scientific exchange to relevant departments: Identification of UMNs/conversion of information into insight	Collection of latest information at conferences/feedbac k to relevant departments	Planning/holding of Medical Advisory Board Meetings (MABMs)	Support for the development of Medical Plan	Support for LCM Plan (overall)	Support for planning/ management of clinical studies (individual CIS)	Communication with relevant global departments	Collaboration with GVP division
MSL Introductory Education: Medical Affairs (MA)											
Historical Background of MA (Changes in the Environment					_						
1-1 Surrounding Healthcare and Industry Trend)		©	©	0	0	0	0	0	0	0	0
1-2 Functions and Roles of MA, Relationship with Sales and	0	0	0	0	0	0	0	0	0	0	0
1-3 Roles of MSL in MA	0	0	0	0	0	0	0	0	0	0	0
2 MSL Introductory Education: Basic Knowledge About MA 2-1 Mission Vision Value	0	0	0	0	0	0	©	©		0	©
2-2 Medical Plan, Life Cycle Management (LCM)	0	©	0	0	0	0	0	0	0	0	0
2-3 KTL (Key Thought Leader)/KOL (Key Opinion Leader) Engagement	0	0	0	0	0	0	0	0	0	0	0
2-4 Insight/Unmet Medical Needs (UMNs)	0	0	0	0	0	0	0	0	0	0	
3 Related Laws and Regulations/Regulation/Rules 3-1 Pharmaceuticals and Medical Devices Law		©	©			0	0	0	0	©	©
3-2 Code of Practice (IFPMA/JPMA), Code of Fair Competition, etc.		©	©			0	0	0	0	0	0
3-3 MSL Guidelines (PhRMA/EFPIA)		Ö				Ö			Ö	Ö	
3-4 Transparency Guidelines		0	0	_		0		_	0	0	0
3-5 Corporate Code of Conduct/Compliance		0	0	0	0	0	0	0	0	0	
3-6 MSL SOP (JP/US/EU) 3-7 MA Division Rules	© O	© O	© O	© O	© O	© O	© O	© O	© O	© ©	0
3-8 National Public Service Ethics Law, Anti-corruption Act/Bribery	Ŭ	0	0			0	0		0	0	
4 Research Ethics											
4-1 Historical Background of Research Ethics		1					0	0	0	0	
4-2 Integrated Guidelines (Including Difference Between ICH-GCP and Clinical Research Law (Historical Background and Difference in		0		0		0	0	0	0	0	0
4-3 Laws and Regulations Between Japan and Europe/US)		0	0	0		0	0	0	0	0	0
4-4 IIS Support Guidelines (JPMA, PhRMA, EFPIA)		0					0	0	0	0	0
4-5 Compensation and Reparations									0		0
4-6 Act on the Protection of Personal Information Overview of Drug Development	0	0				0			0	0	0
5-1 Flow of Drug Development		©		0	©	0	0	0	©	0	0
5-2 Basics of Non-Clinical Studies		0	0	0	0	0	0	Ö	Ö	0	
5-3 Basics of ICH-GCP/J-GCP		0		_					0	0	0
5-4 Basics of GPSP		© ©		© ©	O		0	0	© ©	© O	<u> </u>
5-5 GVP/RMP 5-6 Basics of Intellectual Properties		0	©	0	0	0	 ⊚	O	0	0	
6 Clinical Research									<u> </u>		
6-1 Basics of Clinical Research (Intervention Study, Observational		0		0	0	0	0	0	0	0	0
Study, Database Study)											
6-2 Basics of Protocol Development 6-3 Basics of Performance of Clinical Research		©		0	0	0	0	0	© ©	0	0
6-4 Basics of Statistical Analysis		0		©	0				Ö		
6-5 Basics of Health Economics		0		Ö	Ö	0	0	0	Ö	0	
7 Publication											
7-1 Guidelines (ICMJE/GPP3) 7-2 Study Registration (UMIN/ClinicalTrials.gov)	0	0			0	0	0	0	0	0	
Study Reporting Guidelines for Paper Preparation/CONSORT											
7-3 Statement, STROBE Statemen)		0		0	0	0	0	0	©	0	0
8 Disease Area/Product Knowledge											
8-1 Disease/Diagnosis/Treatment 8-2 Knowledge on the Assigned/Competitive Product	© ©	© ©	© ©	© ©	© ©	© ©	© ©	0	© ©	© ©	O
8-3 Knowledge on the Assigned/Competitive Product 8-3 Knowledge on Related Drugs for the Assigned Disease	0	0	0	0	0	0	0	© ©	<u> </u>	© ©	0
General Knowledge of Medicine/Pharmaceutical Science/	0	0	0	0	0	0	0	0	0	0	0
Healthcare System		U					U	U	9	9	U
8-5 Company Strategy											
9 Business Skills of MSL 9-1 Communication	©	©	©	©	0	0	0	0	0	0	
9-2 Provision/Collection/Analysis of Information	©	©	©	©	0	0	0	0	0	©	0
9-3 Project Management	0	0	0	0	0	0	Ö	Ö	0	0	0
9-4 Business Manners		0	0	0	0	0			0	0	0
9-5 Presentation]	0	0	0		0	0	0	0	0	0

					Activities of MSL upon Request						
		Re	esults/ communicat	ion							
	Contents	Submission of scientific papers and conference presentations with compliance and GPP3 taken into account	Support for creation of slides	Support for holding of events (e.g. joint seminar) at a conference organized by MA	Support for clinical trials	Company contact point for investigator initiated studies (IISs)		Provision of information on unapproved drugs and off-label use of approved drugs for non-promotional purposes upon request			
1	MSL Introductory Education: Medical Affairs (MA)										
1-1	Historical Background of MA (Changes in the Environment	0	0	0	0	0	©	©	0		
	Surrounding Healthcare and Industry Trend)					•	•		•		
1-2	Functions and Roles of MA, Relationship with Sales and	0	0	0	0	0	0	0	0		
1-3	Roles of MSL in MA	0	0		0	0	0	©	0		
2-1	MSL Introductory Education: Basic Knowledge About MA Mission Vision Value			©	©	©	0	©	©		
2-1	Medical Plan, Life Cycle Management (LCM)			0	0	0	0	<u> </u>	0		
2-3	KTL (Key Thought Leader)/KOL (Key Opinion Leader) Engagement	0		Ö	Ö	0	Ö	0	0		
2-4	Insight/Unmet Medical Needs (UMNs)	0		Ö	0	0		0	0		
3	Related Laws and Regulations/Regulation/Rules										
3-1	Pharmaceuticals and Medical Devices Law	0	0	0	0	0	0	0	0		
3-2	Code of Practice (IFPMA/JPMA), Code of Fair Competition, etc.	0	0	0	0	0	0	0	0		
3-3	MSL Guidelines (PhRMA/EFPIA)							0	0		
3-4	Transparency Guidelines Corporate Code of Conduct/Compliance	0	o	O	© O	© ©	©	© ©	© ©		
3-6	MSL SOP (JP/US/EU)	0	0	0	0	0	0	<u> </u>	0		
3-7	MA Division Rules	 ⊚	0	0	0	0	Ö	0	0		
3-8	National Public Service Ethics Law, Anti-corruption Act/Bribery			Ö		0		©	0		
4	Research Ethics										
4-1	Historical Background of Research Ethics					0	0	0	0		
4-2	Integrated Guidelines (Including Difference Between ICH-GCP and					0	0	0	0		
4-3	Clinical Research Law (Historical Background and Difference in	©		0	0	©	0	0	0		
4.4	Laws and Regulations Between Japan and Europe/US)	0					_				
4-4 4-5	IIS Support Guidelines (JPMA, PhRMA, EFPIA) Compensation and Reparations	0				© ©	0	0	0		
4-6	Act on the Protection of Personal Information	0			0	0	Ö	0	0		
5	Overview of Drug Development				Ŭ	J	Ü	Ü	Ŭ		
5-1	Flow of Drug Development				0	0	0	0	0		
5-2	Basics of Non-Clinical Studies		0	0	0	0		0	0		
5-3	Basics of ICH-GCP/J-GCP				0	0	0	0	0		
5-4	Basics of GPSP				0	0	0	0	0		
5-5 5-6	GVP/RMP Basics of Intellectual Properties	0			0	© O	0	0	0		
6	Clinical Research					0					
	Basics of Clinical Research (Intervention Study, Observational					_					
6-1	Study, Database Study)				0	0	©	0	0		
6-2	Basics of Protocol Development				0			0	0		
6-3	Basics of Performance of Clinical Research				0	0	0	0	0		
6-4	Basics of Statistical Analysis		0		0	0	0	0	0		
6-5	Basics of Health Economics				0	0	0	0	0		
7-1	Publication Guidelines (ICMJE/GPP3)	©	0		0	©	©	0	0		
7-1	Study Registration (UMIN/ClinicalTrials.gov)	<u> </u>	0		0	0	0	0	0		
	Study Reporting Guidelines for Paper Preparation(CONSORT										
7-3	Statement, STROBE Statemen)				0			0	0		
8	Disease Area/Product Knowledge										
8-1	Disease/Diagnosis/Treatment	0	0	0	0	0	0	0	0		
8-2	Knowledge on the Assigned/Competitive Product	0	0	0	0	0	0	0	0		
8-3	Knowledge on Related Drugs for the Assigned Disease	0	0	0	0	0	0	0	0		
8-4	General Knowledge of Medicine/Pharmaceutical Science/							0	0		
8-5	Healthcare System Company Strategy		+			+					
9	Business Skills of MSL										
9-1	Communication	0		0	0	0	0	0	0		
9-2	Provision/Collection/Analysis of Information	0		0	0	0	0	0	0		
9-3	Project Management	0	0	0	0	0	0	0	0		
9-4	Business Manners			0	0	0	0	0	0		
9-5	Presentation			l	0		<u> </u>				