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

	Contents	Results/ communication			Activities of MSL upon Request				
		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)	Support for post-marketing clinical trials	Provision of information on unapproved drugs and off-label use of approved drugs for non-promotional purposes upon request	Explanation about scientific information that MRs cannot deal with
1	MSL Introductory Education: Medical Affairs (MA)								
1-1	Historical Background of MA (Changes in the Environment Surrounding Healthcare and Industry Trend)	○	○	○	○	◎	◎	◎	◎
1-2	Functions and Roles of MA, Relationship with Sales and	○	○	◎	◎	◎	◎	◎	◎
1-3	Roles of MSL in MA	○	○		○	◎	◎	◎	◎
2	MSL Introductory Education: Basic Knowledge About MA								
2-1	Mission Vision Value			◎	◎	◎	○	◎	◎
2-2	Medical Plan, Life Cycle Management（LCM）			◎	◎	○	○	◎	◎
2-3	KTL (Key Thought Leader)/KOL（Key Opinion Leader） Engagement	○		○	○	◎	○	◎	◎
2-4	Insight/Unmet Medical Needs (UMNs)	○		○	◎	◎		◎	◎
3	Related Laws and Regulations/Regulation/Rules								
3-1	Pharmaceuticals and Medical Devices Law	○	○	◎	◎	◎	◎	◎	◎
3-2	Code of Practice (IFPMA/JPMA), Code of Fair Competition, etc.	◎	◎	◎	◎	◎	◎	◎	◎
3-3	MSL Guidelines (PhRMA/EFPIA)							◎	◎
3-4	Transparency Guidelines			○	◎	◎		◎	◎
3-5	Corporate Code of Conduct/Compliance	◎	◎	◎	○	◎	◎	◎	◎
3-6	MSL SOP（JP/US/EU）	○	◎	◎	○	◎	○	◎	◎
3-7	MA Division Rules	◎	◎	◎	◎	◎	○	◎	◎
3-8	National Public Service Ethics Law, Anti-corruption Act/Bribery			○		◎		◎	◎
4	Research Ethics								
4-1	Historical Background of Research Ethics					◎	○	○	○
4-2	Integrated Guidelines (Including Difference Between ICH-GCP and					◎	○	○	○
4-3	Clinical Research Law (Historical Background and Difference in Laws and Regulations Between Japan and Europe/US)	◎		○	○	◎	○	○	○
4-4	IIS Support Guidelines (JPMA, PhRMA, EFPIA)	○				◎		○	○
4-5	Compensation and Reparations					◎	○	○	○
4-6	Act on the Protection of Personal Information	○			◎	◎	○	◎	◎
5	Overview of Drug Development								
5-1	Flow of Drug Development				◎	◎	○	○	○
5-2	Basics of Non-Clinical Studies		○	○	○	◎		◎	◎
5-3	Basics of ICH-GCP/J-GCP				◎	◎	◎	○	○
5-4	Basics of GPSP				◎	◎	◎	○	○
5-5	GVP/RMP	○			◎	◎	◎	○	○
5-6	Basics of Intellectual Properties					○			
6	Clinical Research								
6-1	Basics of Clinical Research (Intervention Study, Observational Study, Database Study)				◎	◎	◎	○	○
6-2	Basics of Protocol Development				◎			○	○
6-3	Basics of Performance of Clinical Research				◎	◎	◎	○	○
6-4	Basics of Statistical Analysis		○		◎	◎	◎	○	○
6-5	Basics of Health Economics				◎	◎	◎	○	○
7	Publication								
7-1	Guidelines (ICMJE/GPP3)	◎	◎		○	◎	◎	○	○
7-2	Study Registration (UMIN/ClinicalTrials.gov)	◎	○		◎	◎	◎	○	○
7-3	Study Reporting Guidelines for Paper Preparation(CONSORT Statement, STROBE Statemen)				◎			○	○
8	Disease Area/Product Knowledge								
8-1	Disease/Diagnosis/Treatment	○	○	○	○	○	○	○	○
8-2	Knowledge on the Assigned/Competitive Product	○	○	○	◎	○	○	○	○
8-3	Knowledge on Related Drugs for the Assigned Disease	○	○	○	○	○	○	○	○
8-4	General Knowledge of Medicine/Pharmaceutical Science/ Healthcare System							○	○
8-5	Company Strategy								
9	Business Skills of MSL								
9-1	Communication	○		○	○	○	○	○	○
9-2	Provision/Collection/Analysis of Information	○		○	○	○	○	○	○
9-3	Project Management	○	○	○	○	○	○	○	○
9-4	Business Manners			○	○	○	○	○	○
9-5	Presentation				○				