

Pharmaceutical KPI (Interim Version 1.0)
As of May 12, 2010

No.	KPI	Description	KPI formula	Practice Example	Application Date	Relation with Financials	Merit/Need																																														
1	Number of Challenges to "Unmet Needs"	To understand the degree of companies efforts towards to unmet needs	To let companies to define what "unmet needs" are and count the number of unmet needs areas that company engage depending on their own classification methodology	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th>Definition of unmet needs</th> <th>Areas</th> <th>Number of Areas</th> </tr> </thead> <tbody> <tr> <td>Unmet medical needs</td> <td>Thrombosis, cancer, diabetes, autoimmune disease/rheumatoid</td> <td>4</td> </tr> </tbody> </table>	Definition of unmet needs	Areas	Number of Areas	Unmet medical needs	Thrombosis, cancer, diabetes, autoimmune disease/rheumatoid	4	Provided once a year according to the fiscal term.	(Future) sales	We can plan area portfolio strategies and check if they work properly. It is also important from a CSR standpoint.																																								
Definition of unmet needs	Areas	Number of Areas																																																			
Unmet medical needs	Thrombosis, cancer, diabetes, autoimmune disease/rheumatoid	4																																																			
2	Number of Screening	To understand the development capability of new medicine	Breakdown the results of screening for the chemical compounds which entered to preclinical phase by therapeutic categories.	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th>Anatomical Therapeutic Chemical (ATC) Classification System</th> <th>Number of drug candidates</th> <th>Previous 3-year average</th> </tr> </thead> <tbody> <tr> <td>Nervous system & Sensory organ drugs</td> <td></td> <td></td> </tr> <tr> <td>Each organ drugs</td> <td></td> <td></td> </tr> <tr> <td>Metabolic drugs</td> <td></td> <td></td> </tr> <tr> <td>Stem cell drugs</td> <td></td> <td></td> </tr> </tbody> </table> <p>Reference: Wikipedia (Japanese)</p>	Anatomical Therapeutic Chemical (ATC) Classification System	Number of drug candidates	Previous 3-year average	Nervous system & Sensory organ drugs			Each organ drugs			Metabolic drugs			Stem cell drugs			Provided once a year according to the fiscal term.	(Future) sales, Research and development costs	We can understand the development capability and the efficiency of screening test in early stages of the new drug research and development pipeline.																															
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3	Number of Patents & Substance Patents Ratio	To understand the development capability of new medicine	$(\text{Number of substance patents} / \text{Total patents}) \times 100$	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th></th> <th>Substance patents</th> <th>Process patents</th> <th>Usage patents</th> <th>Others</th> <th>Total patents</th> </tr> </thead> <tbody> <tr> <td>Number of patents</td> <td>15</td> <td>28</td> <td>32</td> <td>22</td> <td>97</td> </tr> </tbody> </table> <p>Allowance rate of substance patents = $(15/97) \times 100$</p>		Substance patents	Process patents	Usage patents	Others	Total patents	Number of patents	15	28	32	22	97	Provided once a year according to the fiscal term.	(Future) sales	We can plan for a managerial resource allocation by discovering strong areas of internal research and development according to nature of patents.																																		
	Substance patents	Process patents	Usage patents	Others	Total patents																																																
Number of patents	15	28	32	22	97																																																
4	R&D ratio by Therapeutic Area	To understand the strength of Pipeline, Progress of R&D	Breakdown the R&D expenses for the year by therapeutic areas and the phases (preclinical, clinical, alliance) and divided by total R&D expenditure. Disclose with the accumulated amount for the past 5 years.	<p>Sample Business Case: ABC company</p> <p>(Unit: JPY 100 million)</p> <table border="1"> <thead> <tr> <th rowspan="2">Therapeutic areas</th> <th rowspan="2">Non-clinical practice rate</th> <th colspan="4">Clinical practice rate</th> <th rowspan="2">Rate for alliances</th> <th rowspan="2">Accumulated amount for last 5 years</th> </tr> <tr> <th>I</th> <th>II</th> <th>III</th> <th>IV</th> </tr> </thead> <tbody> <tr> <td>Diabetes</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Therapeutic areas	Non-clinical practice rate	Clinical practice rate				Rate for alliances	Accumulated amount for last 5 years	I	II	III	IV	Diabetes																					Provided once a year according to the fiscal term.	Research and development costs, (Future) sales	We can take early actions for the next reseach and development (R&D) plan by understanding the effect of strategic allignment of area portfolio and the efficiency from R&D project status for each therapeutic area.													
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5	Number of Licensing by Area	To assume the aggressiveness of R&D activities for other geographical areas besides Japan and the result of R&D	Breakdown the licensing expenses for the year by areas and the phases (preclinical, clinical, alliance) and divided by total R&D expenditure. Disclose with the accumulated amount for the past 5 years.	<p>Sample Business Case: ABC company</p> <p>(Unit: JPY 100 million)</p> <table border="1"> <thead> <tr> <th rowspan="2">Locations</th> <th rowspan="2">Non-clinical practice rate</th> <th colspan="4">Clinical practice rate</th> <th rowspan="2">Rate for alliances</th> <th rowspan="2">Accumulated amount for last 5 years</th> </tr> <tr> <th>I</th> <th>II</th> <th>III</th> <th>IV</th> </tr> </thead> <tbody> <tr> <td>U.S.</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Europe</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Locations	Non-clinical practice rate	Clinical practice rate				Rate for alliances	Accumulated amount for last 5 years	I	II	III	IV	U.S.							Europe														Provided once a year according to the fiscal term.	Research and development costs, (Future) sales	We can take early actions for the next reseach and development (R&D) plan by understanding the effect of strategic allignment of area portfolio and the efficiency from R&D project status for each therapeutic area.													
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6	Number of Test Cases by Project	To assume the driving power for clinical test	Number of implemented cases/total cases = implementation ratio for top 10 items	<p>Sample Business Case:</p> <p>ABC company closed 305 contracts with XYZ Contract Research Organization (CRO) and only 246 were executed.</p> <table border="1"> <thead> <tr> <th rowspan="3">Project</th> <th colspan="8">Clinical test rate</th> <th rowspan="3">Contracted number of cases</th> </tr> <tr> <th colspan="2">I</th> <th colspan="2">II</th> <th colspan="2">III</th> <th colspan="2">IV</th> </tr> <tr> <th>R</th> <th>C</th> <th>R</th> <th>C</th> <th>R</th> <th>C</th> <th>R</th> <th>C</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>100%</td> <td></td> <td>100%</td> <td>80%</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> </tr> </tbody> </table> <p>R (Recruiting): participants are currently being recruited C (Completed): the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)</p>	Project	Clinical test rate								Contracted number of cases	I		II		III		IV		R	C	R	C	R	C	R	C			100%		100%	80%															Provided once a year according to the fiscal term. The higher the rate, the better the performance.	(Future) sales	We can sort out the relationship status with Contract Research Organization (CRO) looking at the clinical execution rate.
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7	R&D Success Rate for Therapeutic area and Phase	To understand the R&D success rate by the transition ratio from the previous phase	number of chemical compounds at the stage÷ number of chemical compounds at the previous stage x accumulated successful rate	<p>Sample Business Case: ABC company</p> <p>Area: Diabetes</p> <table border="1"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Clinical phase</th> <th rowspan="2">Number of applications</th> <th rowspan="2">Number of approved</th> </tr> <tr> <th>I</th> <th>II</th> <th>III</th> <th>IV</th> </tr> </thead> <tbody> <tr> <td>Chemical compounds</td> <td>16</td> <td>12</td> <td>10</td> <td>9</td> <td>7</td> <td>6</td> </tr> <tr> <td>Success rate</td> <td></td> <td>0.75</td> <td>0.833</td> <td>0.9</td> <td>0.77</td> <td>0.85</td> </tr> <tr> <td>Cumulative success rate</td> <td></td> <td>0.75</td> <td>0.625</td> <td>0.56</td> <td>0.43</td> <td>0.37</td> </tr> </tbody> </table>		Clinical phase				Number of applications	Number of approved	I	II	III	IV	Chemical compounds	16	12	10	9	7	6	Success rate		0.75	0.833	0.9	0.77	0.85	Cumulative success rate		0.75	0.625	0.56	0.43	0.37	Provided once a year according to the fiscal term. The higher the rate, the better the performance.	(Future) sales	We can plan for a managerial resource allocation by identifying a company's development capacity from the success rate trends in research and development projects.												
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8	Market Shares for Popular Products (by Area)	To know which country or area the Company obtains the market strength and how the company deploy their market in global market.	Revenue of popular items÷Market Share	<p>Sample Business Case: ABC company</p> <p>Note: The off-patent date defers by areas.</p> <table border="1"> <thead> <tr> <th rowspan="2">Preliminary patents</th> <th rowspan="2">Locations</th> <th rowspan="2">Rate in total sales</th> <th colspan="3">Off-patent period</th> </tr> <tr> <th>X < 1</th> <th>1 year < X < 3 years</th> <th>3 years < X < 5 years</th> </tr> </thead> <tbody> <tr> <td rowspan="2">A</td> <td>Japan</td> <td></td> <td>Item BB</td> <td>-</td> <td>-</td> </tr> <tr> <td>U.S.</td> <td></td> <td></td> <td>-</td> <td>Item FF</td> </tr> </tbody> </table>	Preliminary patents	Locations	Rate in total sales	Off-patent period			X < 1	1 year < X < 3 years	3 years < X < 5 years	A	Japan		Item BB	-	-	U.S.			-	Item FF	Provided once a year according to the fiscal term.	(Future) sales Rate of return	We can study the effects on drop in sales by the number of off-patent drugs and plan next strategies as soon as drugs go off patent.																								
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9	Number of Deployment Areas for R&D Basis	To understand the aggressiveness of global Deployment	Number of areas where company deploys laboratories	<p>Sample Business Case: ABC company (sorted by areas)</p> <p>(Unit: JPY 100)</p> <table border="1"> <thead> <tr> <th>Areas</th> <th>Locations</th> <th>Market size</th> <th>Sales</th> <th>Market share</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Nerve</td> <td>U.S.</td> <td>8,000</td> <td>1,500</td> <td>19%</td> </tr> <tr> <td>Europe</td> <td>12,000</td> <td>1,500</td> <td>13%</td> </tr> <tr> <td>Japan</td> <td>5,000</td> <td>2,000</td> <td>40%</td> </tr> <tr> <td>Developing countries</td> <td>12,000</td> <td>1,500</td> <td>13%</td> </tr> </tbody> </table>	Areas	Locations	Market size	Sales	Market share	Nerve	U.S.	8,000	1,500	19%	Europe	12,000	1,500	13%	Japan	5,000	2,000	40%	Developing countries	12,000	1,500	13%	Provided once a year according to the fiscal term.	Sales	We can plan competitive strategies and verify if the past competitive strategies were successful.																						
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10	Project Ratio by Targeted Area	To understand the aggressiveness of global Deployment	Breakdown the projects into local and global areas	<p>Sample Business Case: ABC company</p> <p>(Basic research: 4 areas, clinical research: 3 areas, development research: 3 areas)</p> <table border="1"> <thead> <tr> <th rowspan="3">Locations</th> <th colspan="4">Existence of offices</th> <th rowspan="3">y/y</th> </tr> <tr> <th rowspan="2">Basic research</th> <th rowspan="2">Development Research</th> <th colspan="2">Clinical research</th> </tr> <tr> <th>Internal</th> <th>External (CRO)</th> </tr> </thead> <tbody> <tr> <td>U.S.</td> <td>○</td> <td>○</td> <td>○</td> <td>○</td> <td>-</td> </tr> <tr> <td>Europe</td> <td>x</td> <td>x</td> <td>x</td> <td>x</td> <td>Open two offices</td> </tr> <tr> <td>Japan</td> <td>○</td> <td>○</td> <td>○</td> <td>○</td> <td>Close one office</td> </tr> <tr> <td>Developing countries</td> <td>○</td> <td>○</td> <td>x</td> <td>x</td> <td>-</td> </tr> </tbody> </table>	Locations	Existence of offices				y/y	Basic research	Development Research	Clinical research		Internal	External (CRO)	U.S.	○	○	○	○	-	Europe	x	x	x	x	Open two offices	Japan	○	○	○	○	Close one office	Developing countries	○	○	x	x	-	Provided once a year according to the fiscal term.	(Future) sales, Research and development costs	Figuring out the research and development system such as global drug discovery infrastructure, clinical research infrastructure and so on, we can make an optimized research and development investment plan which is focused on future scenario of global development.								
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11	License Ratio by Area	To understand the aggressiveness of Global Deployment	Breakdown the number of licenses into areas where company has sales rights and divide by total license	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th>Object locations</th> <th>Number of projects</th> </tr> </thead> <tbody> <tr> <td>Global</td> <td>70%</td> </tr> <tr> <td>Local</td> <td>30%</td> </tr> </tbody> </table> <p>Breakouts of local areas can be indicated in the appendix.</p>	Object locations	Number of projects	Global	70%	Local	30%	Provided once a year according to the fiscal term.	(Future) sales, Research and development costs	We can make a managerial resource allocation plan which is focused on future scenario of global development by understanding capability of drug discovery infrastructure, clinical research infrastructure and so on of each area.																																						
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12	License-In Ratio by Therapeutic Area	To specify the pipelines which need to be reinforced and to understand the therapeutic areas which the Company's main focus.	Breakdown the number of license-in items by therapeutic areas into developed products and undeveloped products.	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th rowspan="2">Locations</th> <th rowspan="2">In or Out</th> <th colspan="3">License agreement ratio</th> </tr> <tr> <th>Merchandises</th> <th>Products (unlicensed)</th> <th>y/y</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Global</td> <td>In</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Out</td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="2">U.S.</td> <td>In</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Out</td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="2">Japan</td> <td>In</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Out</td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="2">Developing countries</td> <td>In</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Out</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Locations	In or Out	License agreement ratio			Merchandises	Products (unlicensed)	y/y	Global	In				Out				U.S.	In				Out				Japan	In				Out				Developing countries	In				Out				Provided once a year according to the fiscal term. The contract type must be written.	Sales (in-licensed products sales)	We can plan further sales promotion strategies for corporate/organizational alignment by identifying patent usage in locations where there is no sales channel.
Locations	In or Out	License agreement ratio																																																	
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13	License-Out Ratios by Contract Object	To understand the utilization of in-house patents and the earnings model by intellectual properties	Breakdown the number of license-out items by therapeutic areas into developed products and undeveloped products.	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th rowspan="2">Therapeutic areas</th> <th colspan="2">License agreement ratio</th> <th rowspan="2">Gross interest</th> <th rowspan="2">y/y</th> </tr> <tr> <th>Merchandises</th> <th>Products (unlicensed)</th> </tr> </thead> <tbody> <tr> <td>Diabetes</td> <td>5%</td> <td>40%</td> <td>%/ %</td> <td>-2%/5%</td> </tr> <tr> <td>Nerve</td> <td>13%</td> <td>50%</td> <td>%/ %</td> <td>+3%/-4%</td> </tr> </tbody> </table> <p>Therapeutic areas deffers depending on each company.</p>	Therapeutic areas	License agreement ratio		Gross interest	y/y	Merchandises	Products (unlicensed)	Diabetes	5%	40%	%/ %	-2%/5%	Nerve	13%	50%	%/ %	+3%/-4%	Provided once a year according to the fiscal term. The contract type must be written.	Sales (area license-out fees)	We can design further sales promotion strategies or portfolio strategies to use intellectual assets by recognizing not only product sales but also patent usage.
Therapeutic areas	License agreement ratio		Gross interest	y/y																				
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14	Number of Accepted Literatures by Therapeutic Area	To understand the quality of researcher	Breakdown the number of accepted literatures for major journals by therapeutic areas.	<p>Sample Business Case: ABC company</p> <p>Sales promotion objectives: total number of products and pipelines = 10 (License-out(L.O.) = 4)</p> <table border="1"> <thead> <tr> <th rowspan="2">Contract type</th> <th colspan="3">Number of license agreements</th> </tr> <tr> <th>Merchandises</th> <th>Products (unlicensed)</th> <th>y/y</th> </tr> </thead> <tbody> <tr> <td>Sales promotion</td> <td>10%</td> <td>55%</td> <td>-2%/5%</td> </tr> <tr> <td></td> <td>15%</td> <td>40%</td> <td>+3%/-4%</td> </tr> </tbody> </table>	Contract type	Number of license agreements			Merchandises	Products (unlicensed)	y/y	Sales promotion	10%	55%	-2%/5%		15%	40%	+3%/-4%	Provided once a year according to the fiscal term. The contract type must be written.	Sales (out-licensing revenue)	We can design further sales promotion strategies to use intellectual assets by recognizing not only product sales but also patent usage.		
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15	Number of patents due to expire(within next 1 year, 3 years, and 5 years)	To understand the strength of pipeline	Breakdown the number of patents due to expire(within next 1 year, 3 years, and 5 years)	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th></th> <th>1996-2000</th> <th>2000-2004</th> </tr> </thead> <tbody> <tr> <td>Non-clinical research</td> <td>2</td> <td>1</td> </tr> <tr> <td>Clinical research</td> <td>1</td> <td>3</td> </tr> </tbody> </table>		1996-2000	2000-2004	Non-clinical research	2	1	Clinical research	1	3	Provided data of last five rolling years once a year according to the fiscal term.	None	We can identify good researchers and understand strengths and weaknesses by area.								
	1996-2000	2000-2004																						
Non-clinical research	2	1																						
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16	Ratio of MR (generalist) by Item	To understand the MR's informative ability and sales negotiation	Breakdown the number of MR Generalists by items. (Define MR generalist as MR who is in charge of more than 10 items for this KPI purpose)	<p>Sample Business Case: ABC company</p> <table border="1"> <thead> <tr> <th>Items</th> <th>Rate of MR (G) for the current year</th> <th>3-year average MR (G) rate</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Items	Rate of MR (G) for the current year	3-year average MR (G) rate							Provided once a year according to the fiscal term.	Sales, Labor costs	We can prove the capability of the information provision as the result of shares gain.								
Items	Rate of MR (G) for the current year	3-year average MR (G) rate																						