



UNDERSTANDING RESEARCH

UNDERSTANDING DEVELOPMENT

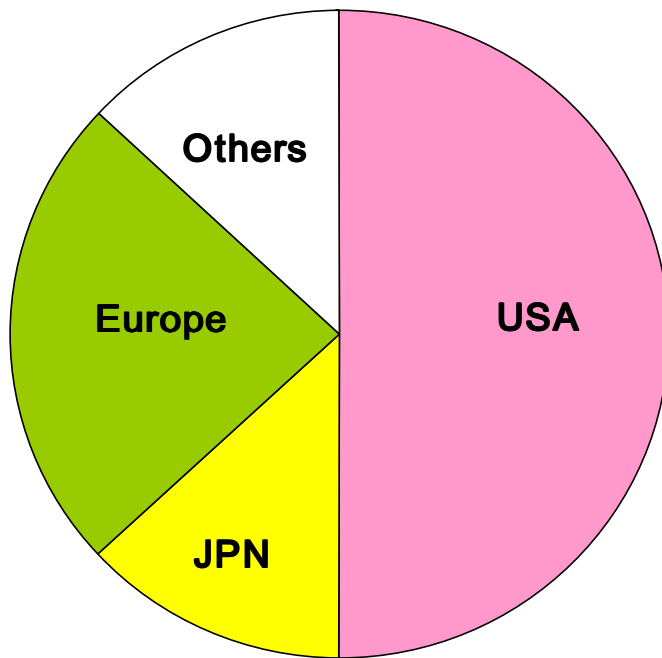
PARTNERSHIP WITH JAPANESE CRO

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Japan – The Land of Opportunity

Global Market (\$600Billion, 2006)



	<u>1995</u> (200)	<u>1997</u> (220)	<u>1999</u> (260)	<u>2003</u> (466)	<u>2004</u> (518)	<u>2006</u> (600)
USA	31% (\$60bn)	35	41	52	54	52 (\$300bn, 500% up in 10years)
JPN	21% (\$40bn)	16	13	12	11	9 (\$60bn, 150%)
Europe	29% (\$60bn)	29	30	23	23	22 (\$120bn, 200%)
Others	19% (\$40bn)	20	16	12	12	17 (\$100bn, 250%)

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Japanese history of Drugs development strategies

1987 → 1998 → 2007

The first decadal change

The second decadal change

Started Japanese GCP process

Approved Bridging Studies Strategies

Guidance and recommendation of Global studies



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Japanese CRO Industry

- o Japanese CRO industry recognized in late 1990s
- o Early 1990s saw predominantly Japanese local studies
- o With revision of GCP Guidelines in 1998, more multi-national trials are conducted in Japan
- o Japanese Pharma companies expanded their clinical research activities – from local to global
- o Phase I – mostly done in Japan / Western Countries
- o Phase II – IV – Japan, USA, Europe, Asia
- o Many global CROs have set up their operations in Japan
- o Few local players having a spread of operations in Asia

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Japanese CRO Industry

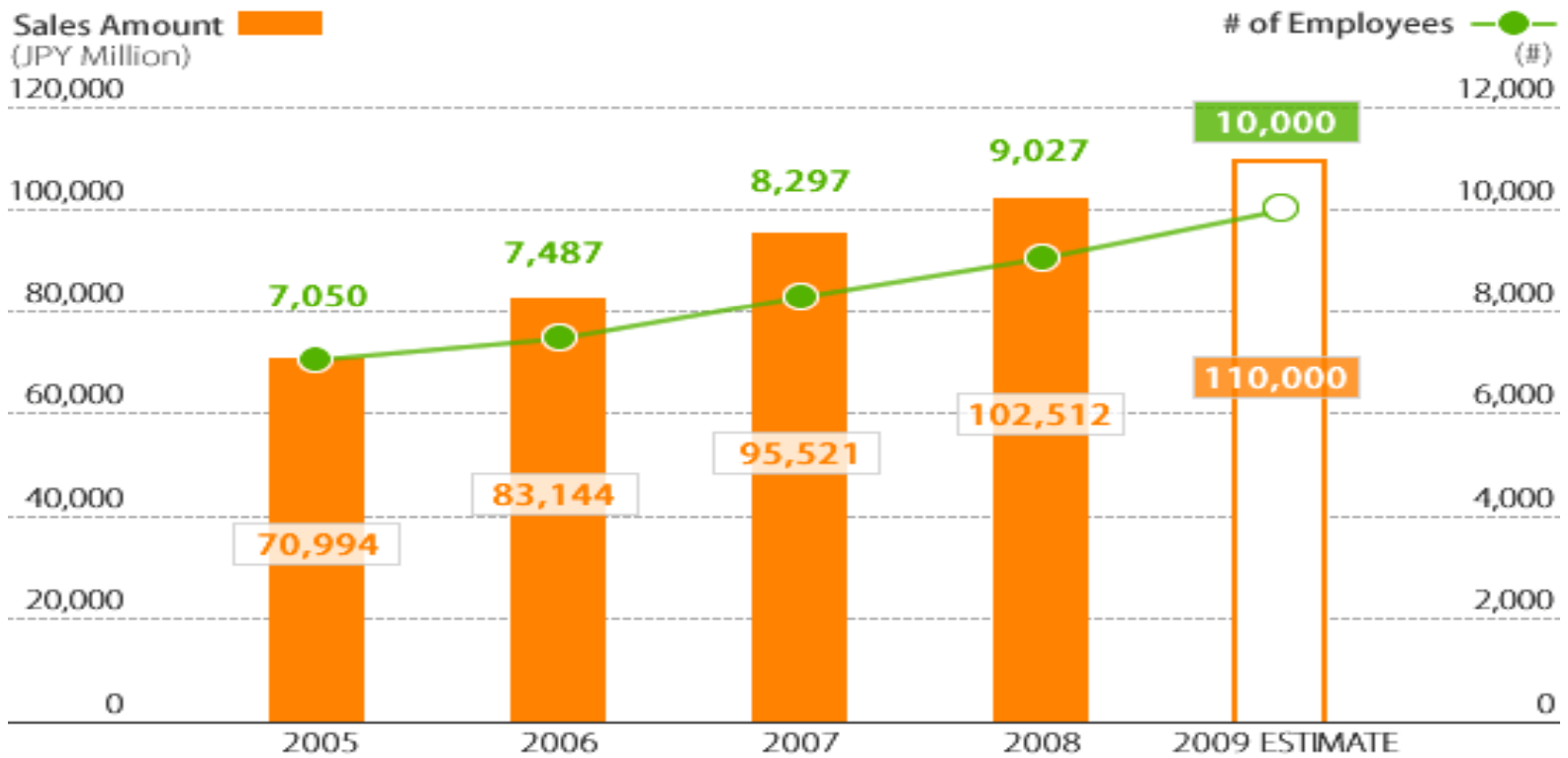
- o Japanese CRO industry revenue in 2008- JPY 102512 mi
- o Break up of the 2008 sales revenue:
 - o 73% from Japanese Sponsors
 - o 27% International Sponsors
- o Break up across functions
 - o Clinical 81%
 - o Medical devices 2%
 - o Food & Supplements 1%
 - o SMO & Site Services 2%
 - o Pre-clinical 2%
 - o BABE, Lab, EDC, QC, Training 12%

Source: JCROA

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Japanese CRO Industry

Movement of Sales Amount and Number of Employees



Source: JCROA

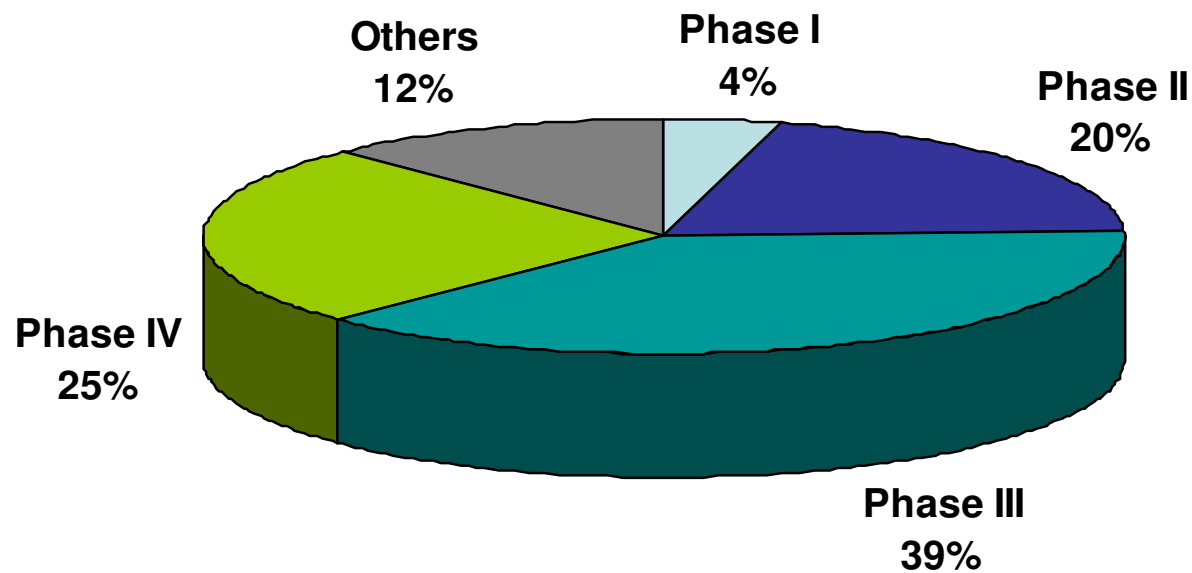
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Break up of Clinical Development Revenue

2008 Clinical Development Revenue 83 K mi JPY



Source: JCROA

Others: BA BE studies, EDC, Training, QC

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Japanese Pharma Sponsoring Asian Studies

No of industry sponsored trials

Japanese Pharma	Korea	Taiwan	China	HongKong	India	Australia
Astell	22	18	9	1	1	15
Daiichi	4	5	8		6	4
Dainippon Sumitomo	1	1	1		3	
Esai	7	7	6	1	8	23
Otsuka	36	5	16	2	5	4
Taiho	1	2	2	1		
Takeda	4	3	1	1	13	17
Kowa					1	
Mitsubishi						1
Total	75	41	43	6	37	64

Source: www.clinicaltrials.gov

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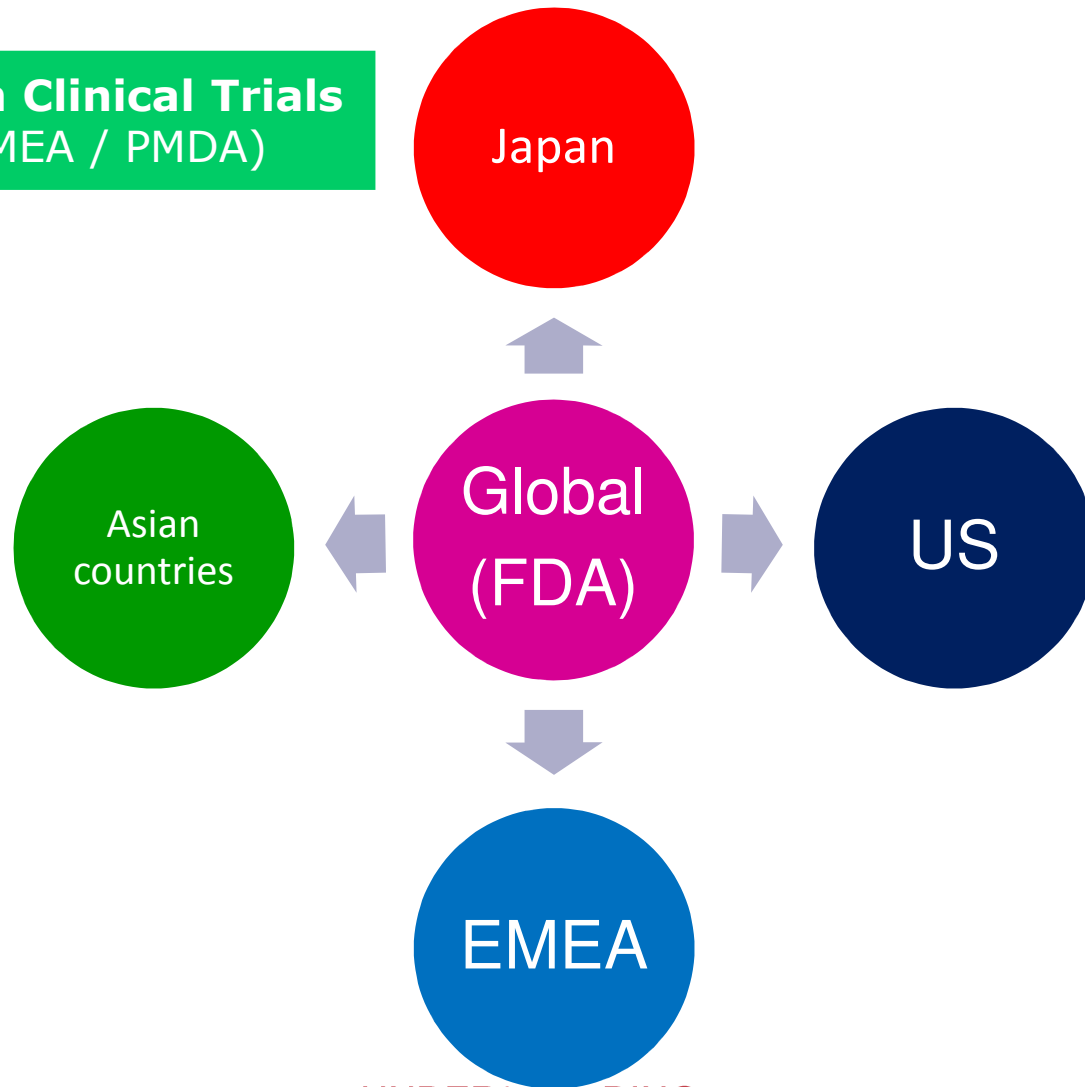
Challenges for Asian Drug Development

- o Regulations and systems in each country are different
- o Regulatory timelines vary
- o Style of working varies – cultural understanding essential – expectation mismatch
- o A great challenge to handle logistics - import / export – local distribution
- o Communication - language barrier– fluency in English
- o EDC – Infrastructure, language, training, connectivity, preference for a specific EDC platform

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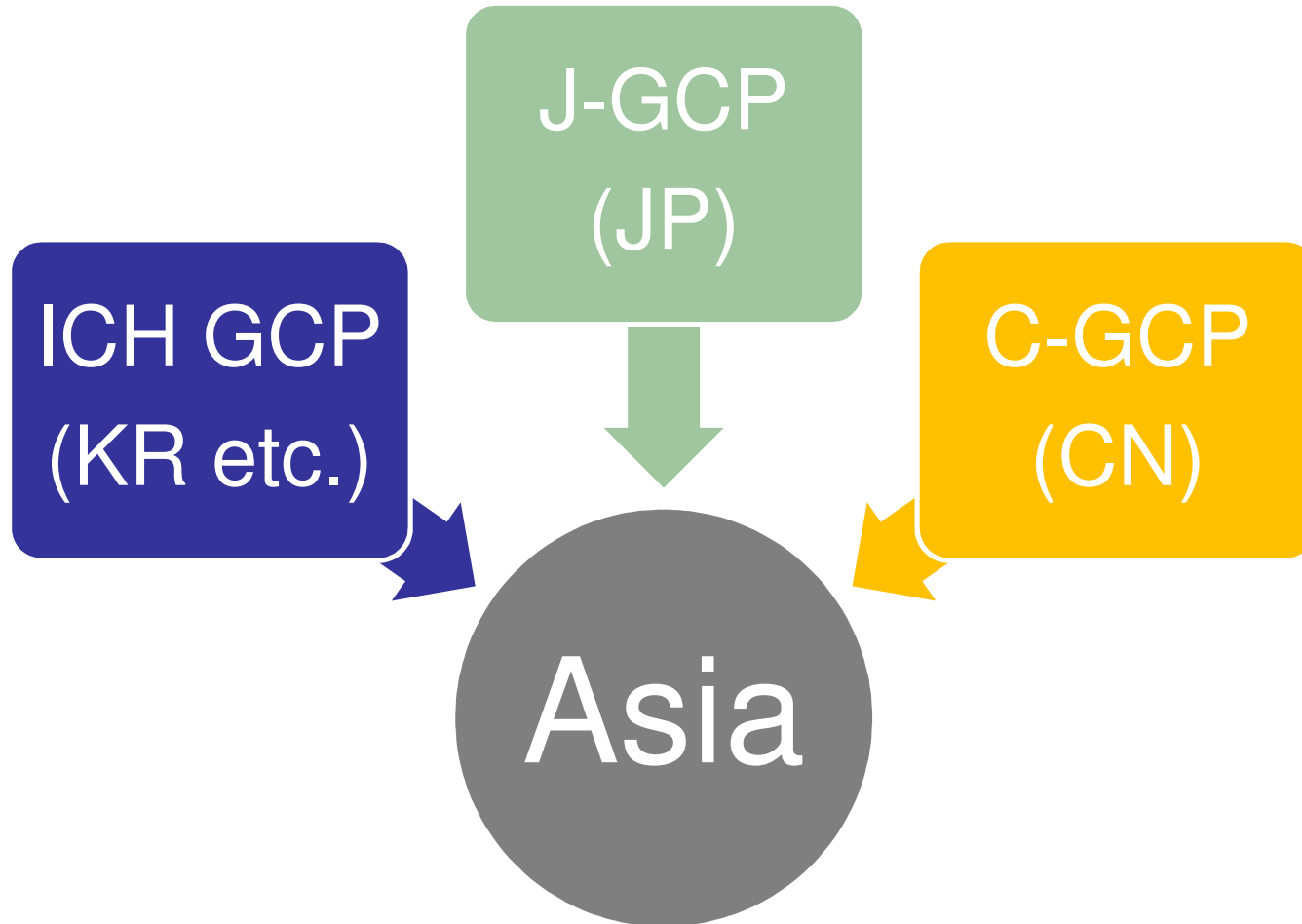
Global Study

Global + Japan Clinical Trials
(US FDA / EMEA / PMDA)



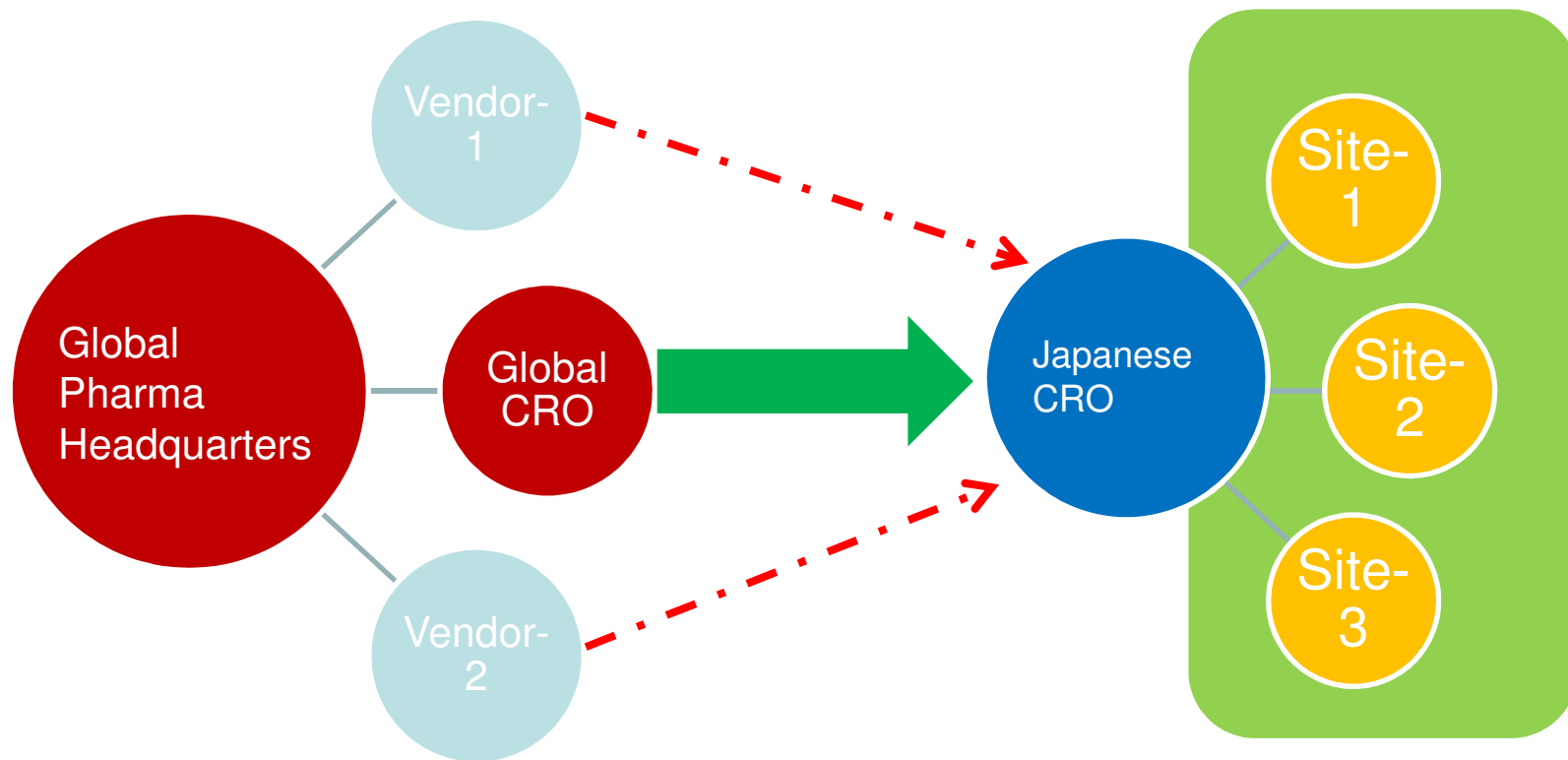
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Asian situation of GCP



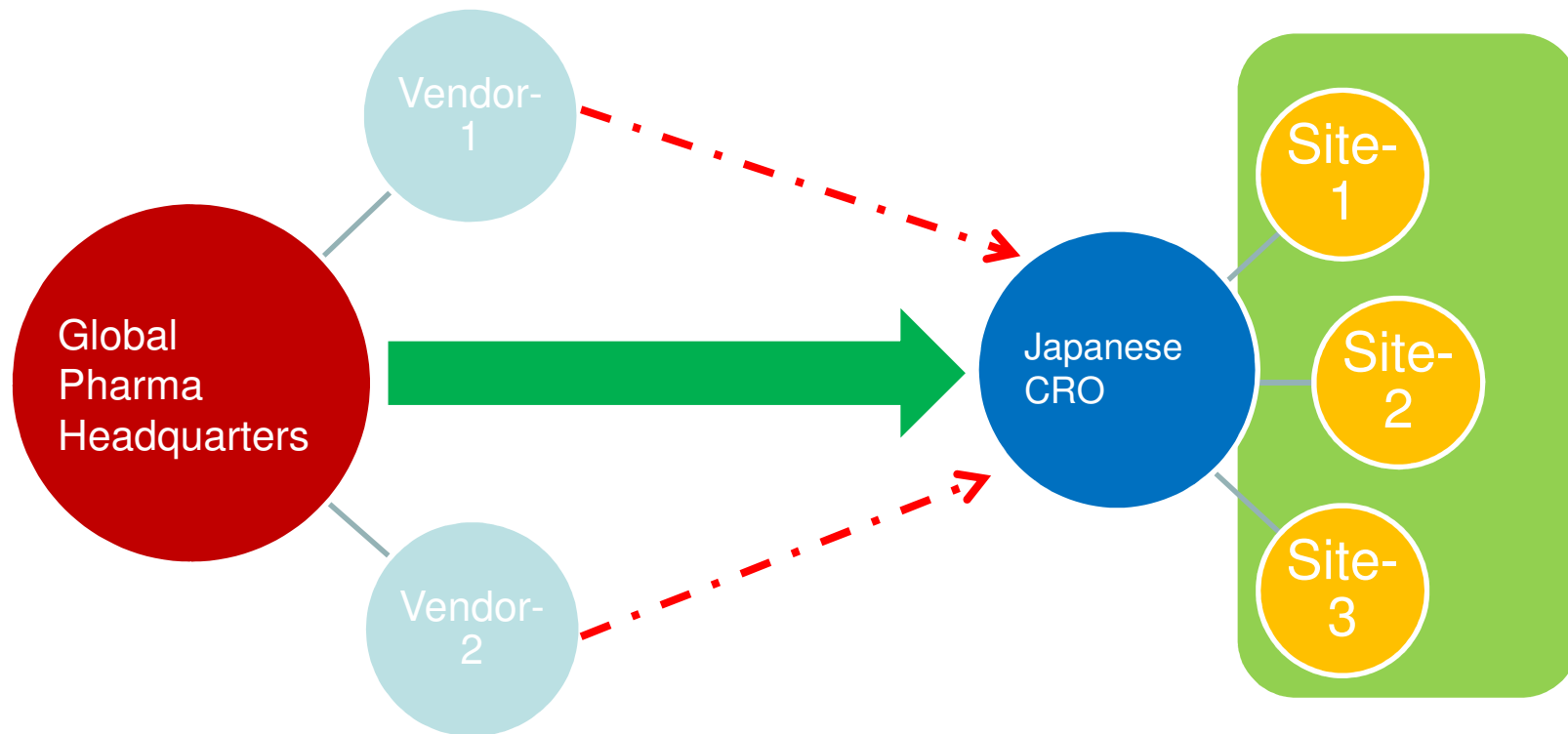
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Global Pharma → Global CRO → Japanese CRO



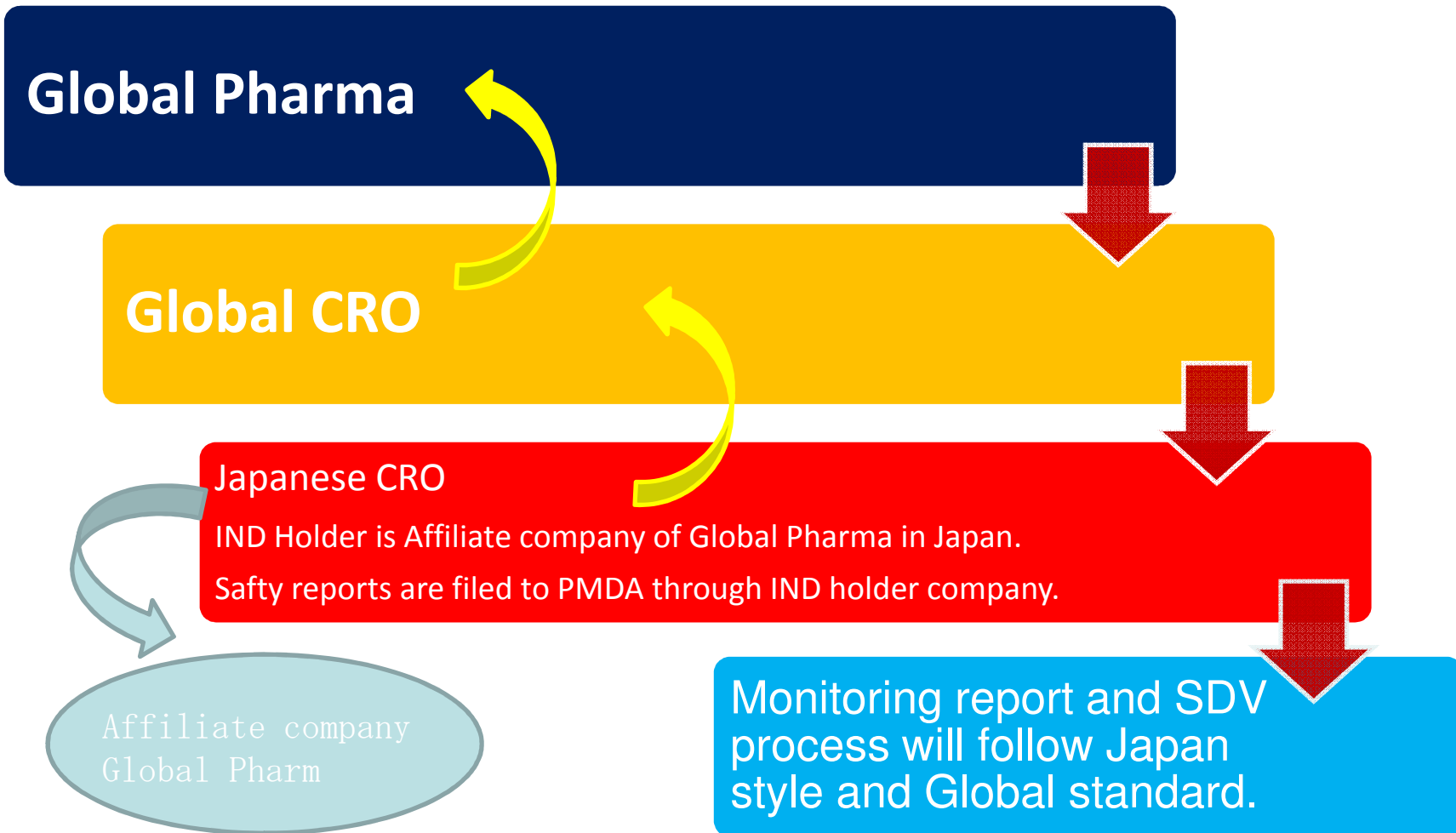
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Global Pharma → Japanese CRO



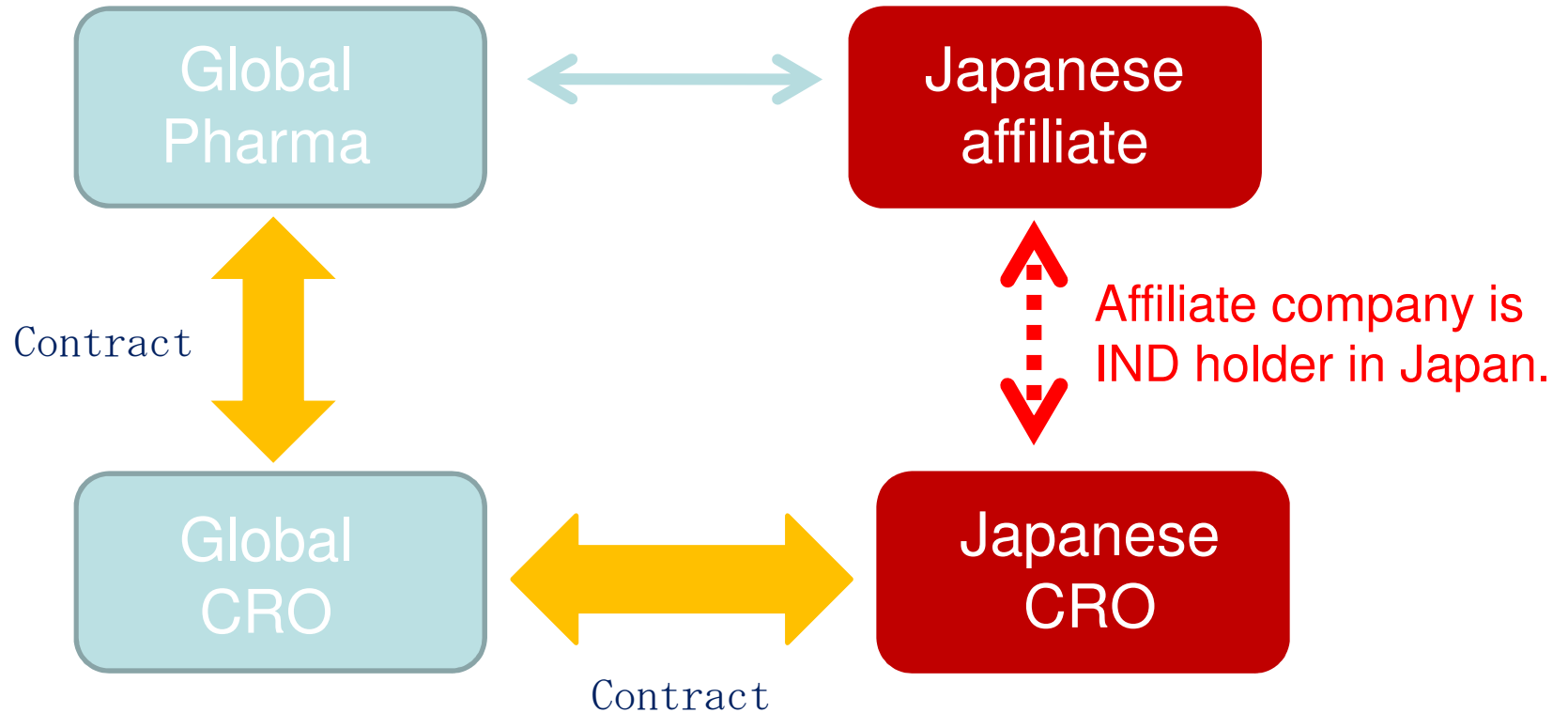
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Global CRO and Japanese CRO co-working process



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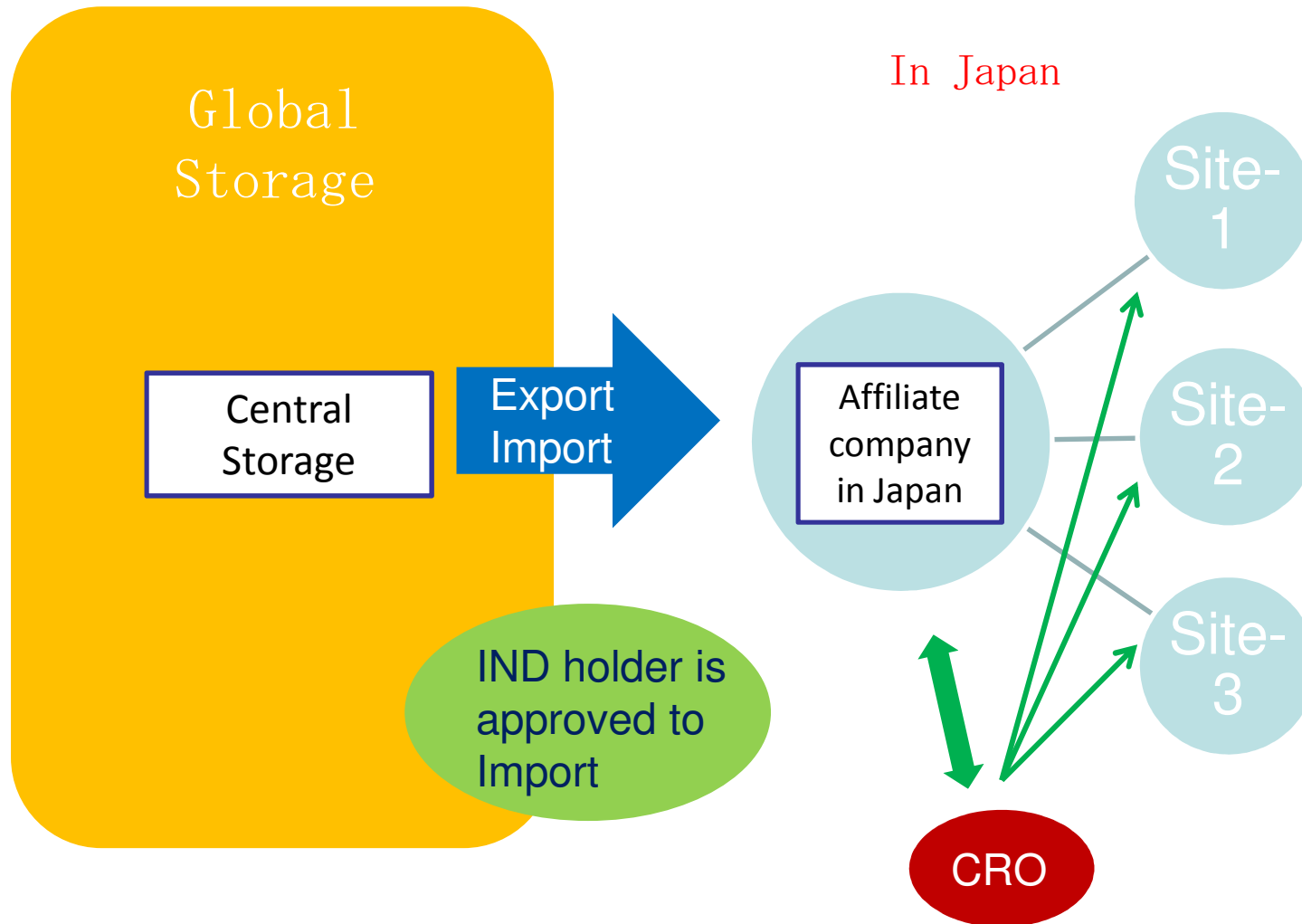
Communication between CRO and Client



In Japan, Japanese affiliate is IND holder, but there is no contracts between Japanese affricate and Japanese CRO.

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Investigational drugs delivery



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Compensation situation

- ◆ In Japan, IND holder should take the insurance to cover all accident during clinical study period.
- ◆ IND holder should show the insurance endorsement to each site's IRB.
- ◆ On the other hand, IND holder should cover all treatments costs of enrolled patients.



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Benefits of Partnering with Japanese CRO

- o Help expand your access to an important hub of research
- o Access to a large pool of patients in Asian region
- o Easily integrate global requirement of scientific research
- o Mitigate risk though cost effectiveness & quality research
- o Provide local regulatory expertise
- o Local logistics support - import / export – local distribution
- o Cross-regional business development support

Japanese standard

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Thank you

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