Considerations for GCP inspections
- Industry view -

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COI Disclosure

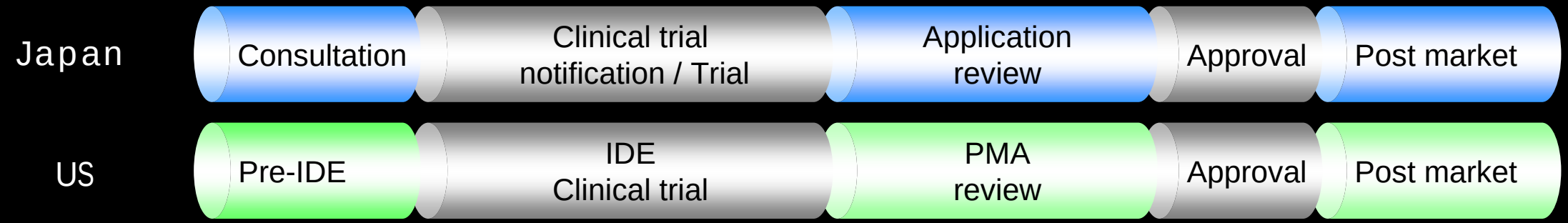
- The authors have no financial conflicts of interest to disclose concerning the presentation.

Notification

- This presentation includes the content of the individual's opinion and is not representative of the company.

Development process

- No difference b/w Japan and US on regulation (text)



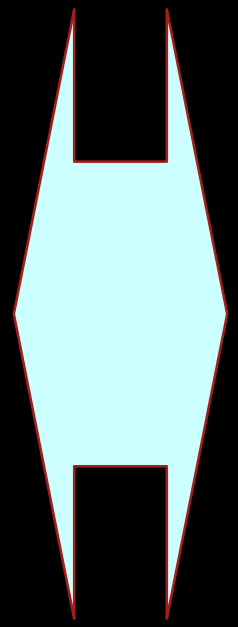
What's "actual" difference?→actual process/operation

what industries really feel

US

Class III products (PMA)	Bimo audit
Class II products (510(k)	*Pick up audit for class II?*

- Mainly focus on system integrity
- Accuracy may not be important if there is no big impact on endpoints
- May accept even if there are some limitation at audit



Japan

Class IV products	Same level of GCP audit
Class III products	

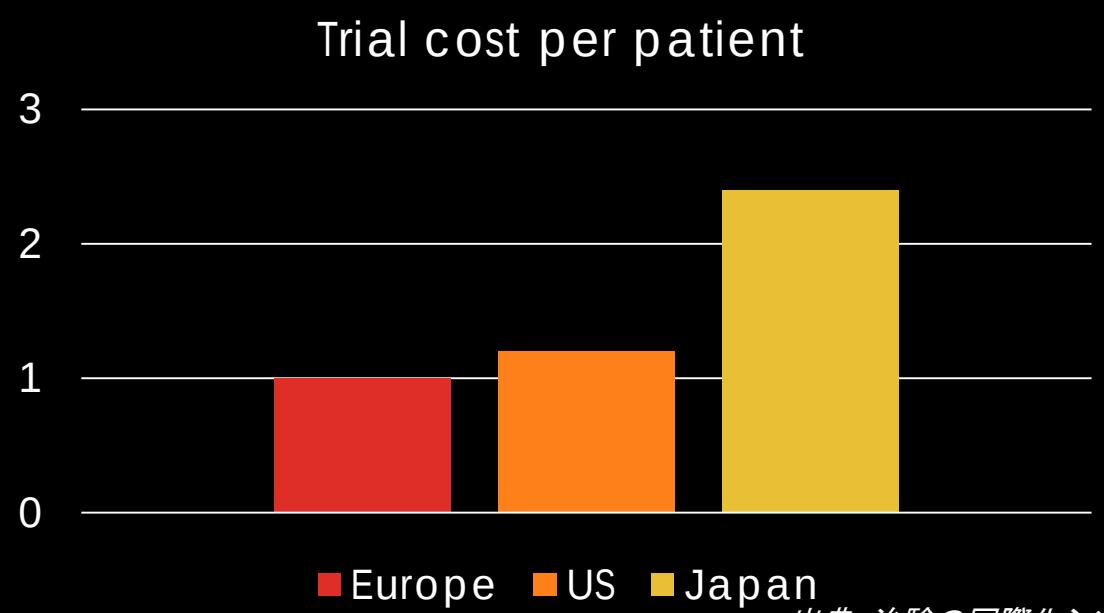
- Mainly focus on accuracy (requires strict accuracy)
- Confirm the system based on precedent principle
- Requires free-access to all original documents at all sites

Actual quality level b/w Japan and US

Deviation rate

- US: 0.5～5% on items
- Japan: 0.01～0.1% on items
  - Based on our experience

Cost of clinical trials



出典：治験の国際化シンポジウム

Japanese culture may cause for activation of clinical trials in Japan....

Basic and cultural difference

US

- GCP compliance should be cared by each parties
- It's important how handle according to SOPs

Japan

- GCP compliance should be cared by each parties, but primary responsibility should be cased by sponsor (Industries)
- It's important how handle accurate (not only according to SOPs, but also data itself)

Consideration about error/deviations

US

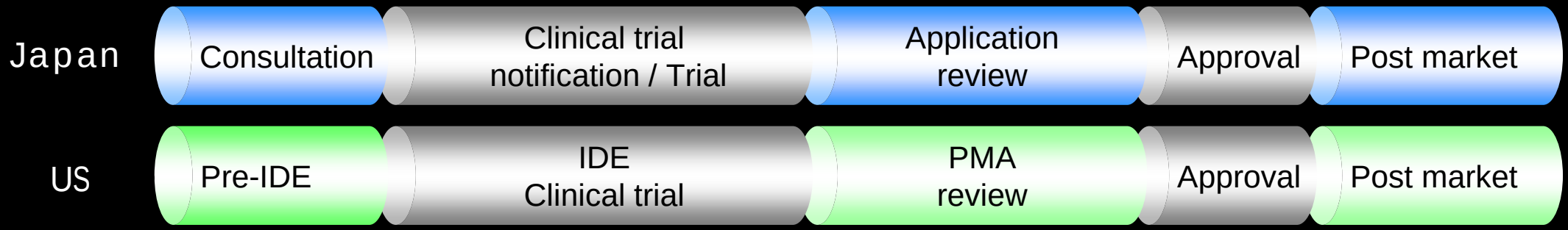
- Deviations found are human error.
- Number of deviation may not be most important. CAPA (and resulting improvement) after deviation is most important. (process is most important)

Japan

- Number of deviation is most important factor.
  - Number of deviation should be included in IRB annual report template.
- If “one” error is observed, doubt system itself, and try to avoid “any” minor error.

timing difference

GCP conformity audit (Shomen-Chosa)
- After submission (during review of submission package)
- Document audit first (if any issue, on-site audit will be happened)
- Process document and CSR



Bimo inspection
- During clinical trial
- on-site audit
- Process documents

Timing issue: Pros. and Cons

Audit timing	Proc.	Cons.
During trial	● To be able to check process integrity ● Once find any issues on process, may find solutions before trial completion.	● Data accuracy will not be included.
After submission	● To be able to check process integrity and Data accuracy	● Once find any critical issues on process, may not find solutions

- **Key point is what's most important on quality of clinical trial**
- **This may directly relate to cost of clinical trials**

For next step/Future

- To activate global trial (in Japan and US), minimization of cost and requirement is important (but should keep quality as minimum)
- Let's learn from difference Japan and US, and improve the circumstance of clinical trials
  - what's essential factor on quality of clinical trial
- MDSAP for GCP audit will be good idea for future.

Conclusion

- No difference b/w Japan and US on regulation (text), but we found difference on management of audit (actual process/operation).
- Cultural background may cause for actual management.
- Let's learn from difference Japan and US and consider what's essential factor on quality of clinical trial
- MDSAP for GCP audit will be good idea for future.

Thank you for your attention!