GCP WG Activity Report

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2nd Joint Conference of Taiwan and Japan on Medical Products Regulation

GCP WG members

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Agenda

1. Findings from GCP WG

2. Details of Findings

Findings from GCP WG (similarities)

1. Equivalent Standards of GCP
2. Clinical data utilization
3. Consultation service to prepare a protocol

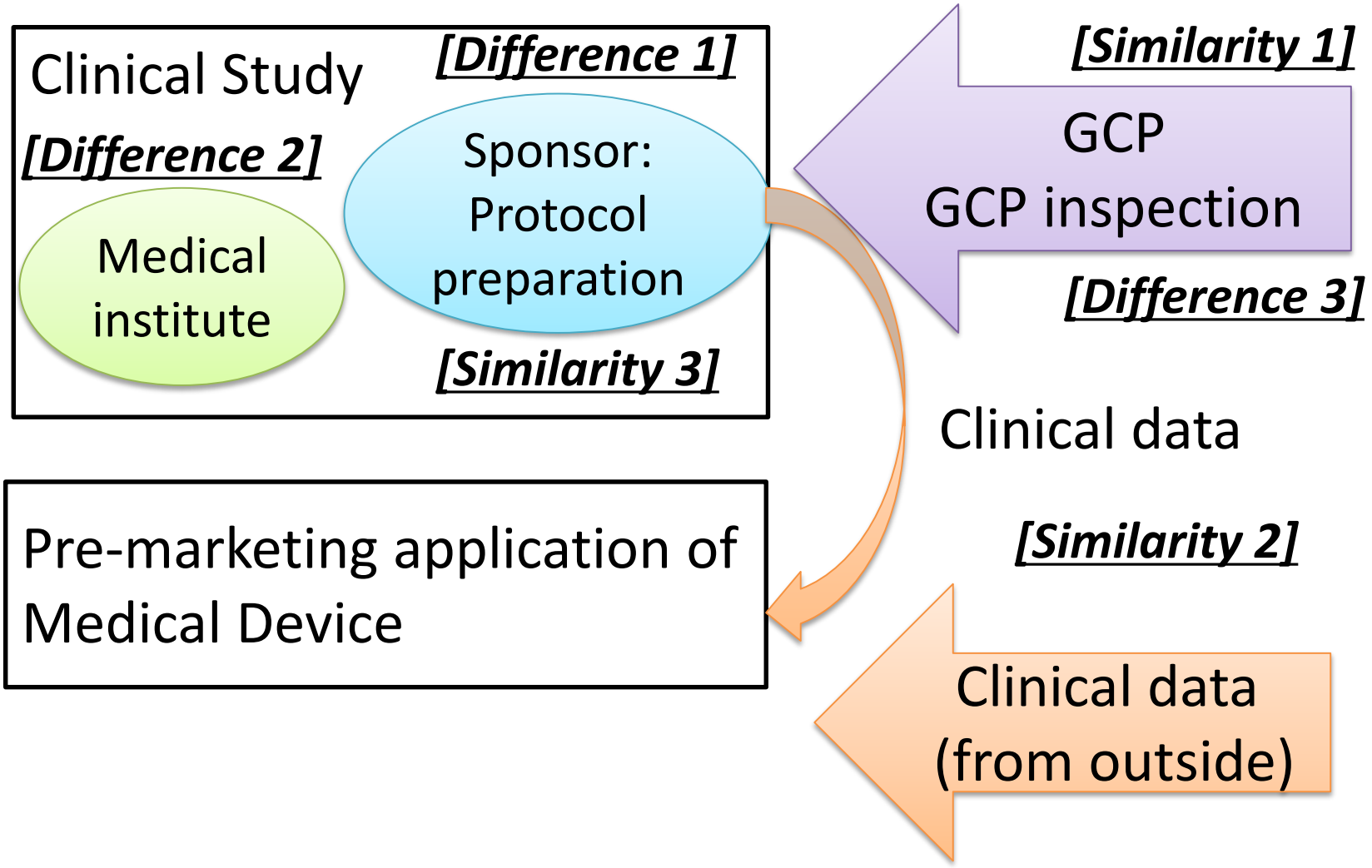
Findings from GCP WG (differences)

1. Scope of clinical study checked by Regulatory Authority in advance

2. Requirements for medical institutes and physicians to conduct clinical study

3. GCP inspection by Regulatory Authority

Overview of discussion points in GCP WG



Agenda

1. Findings from GCP WG

2. Details of Findings

Similarities - 1/3

1. Equivalent Standards of GCP
   a. Japan: ICH-Based GCP, confirmation for the equivalence to ISO 14155: 2011
   b. Taiwan: ICH-Based GCP, harmonization with ISO 14155: 2003, under consideration for ISO 14155: 2011
2. Clinical data utilization
3. Consultation service to prepare a protocol

Similarities - 2/3

1. Equivalent Standards of GCP
2. Clinical data utilization
   a. Both Regulatory Authorities utilize clinical data obtained in the world, if appropriate.
   b. Note: Domestic clinical data are required for some contact lenses in Taiwan.
3. Consultation service to prepare a protocol

Similarities - 3/3

1. Equivalent Standards of GCP
2. Clinical data utilization
3. Consultation service to prepare a protocol
   a. Both Regulatory Authorities provide consultation service for sponsor to prepare a protocol before starting the clinical study.
   b. Note: Charge in Japan, Free in Taiwan.

Differences – 1/3

1. Scope of clinical study checked by Regulatory Authority in advance
   a. Japan: Clinical study for MD pre-marketing approval should be notified.
   b. Taiwan: Clinical study for new MD research in addition to for MD registration should be approved.
2. Requirements for medical institutes and physicians to conduct clinical study
3. GCP inspection by Regulatory Authority

Differences – 2/3

1. Scope of clinical study checked by Regulatory Authority in advance
2. Requirements for medical institutes and physicians to conduct clinical study
   a. Japan: No requirements for them
   b. Taiwan: 5 years of clinical experiences and specific training hours for physician; teaching hospital for medical institute
3. GCP inspection by Regulatory Authority

Differences – 3/3

1. Scope of clinical study checked by Regulatory Authority in advance
2. Requirements for medical institutes and physicians to conduct clinical study
3. GCP inspection by Regulatory Authority
   a. Timing: After pre-marketing application in Japan; after completion of clinical study in Taiwan
   b. Inspection site: Sponsor and medical institute in Japan; medical institute in Taiwan
   c. On-site inspection: Sampling in Japan; all in Taiwan
   d. Oversea inspection: Yes in Japan; no in Taiwan
   e. Note: Inspection is conducted for clinical study for MD application/registration in both side.

Thank you for your attention