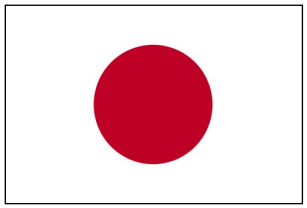


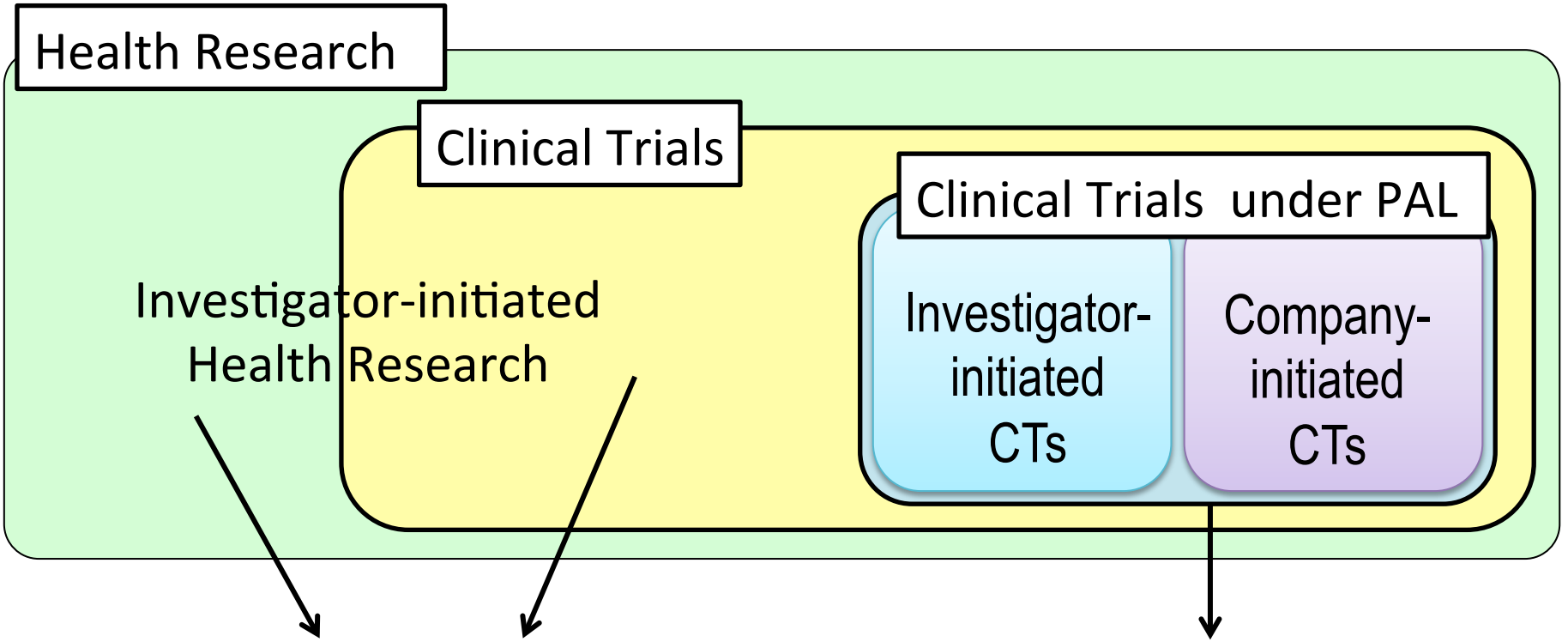
Ministry of Health, Labour and Welfare
For people, for life, for the future

MHLW's Measures to Ensure the Reliability of Investigator-Initiated Clinical Trials

Yasuyuki Sahara (MD, MPH)
Director, Research and Development Division,
Health Policy Bureau
Ministry of Health, Labour and Welfare, JAPAN

28 February -1 March, 2013, Tokyo, Japan

Overview of Japanese Regulations on Health Research



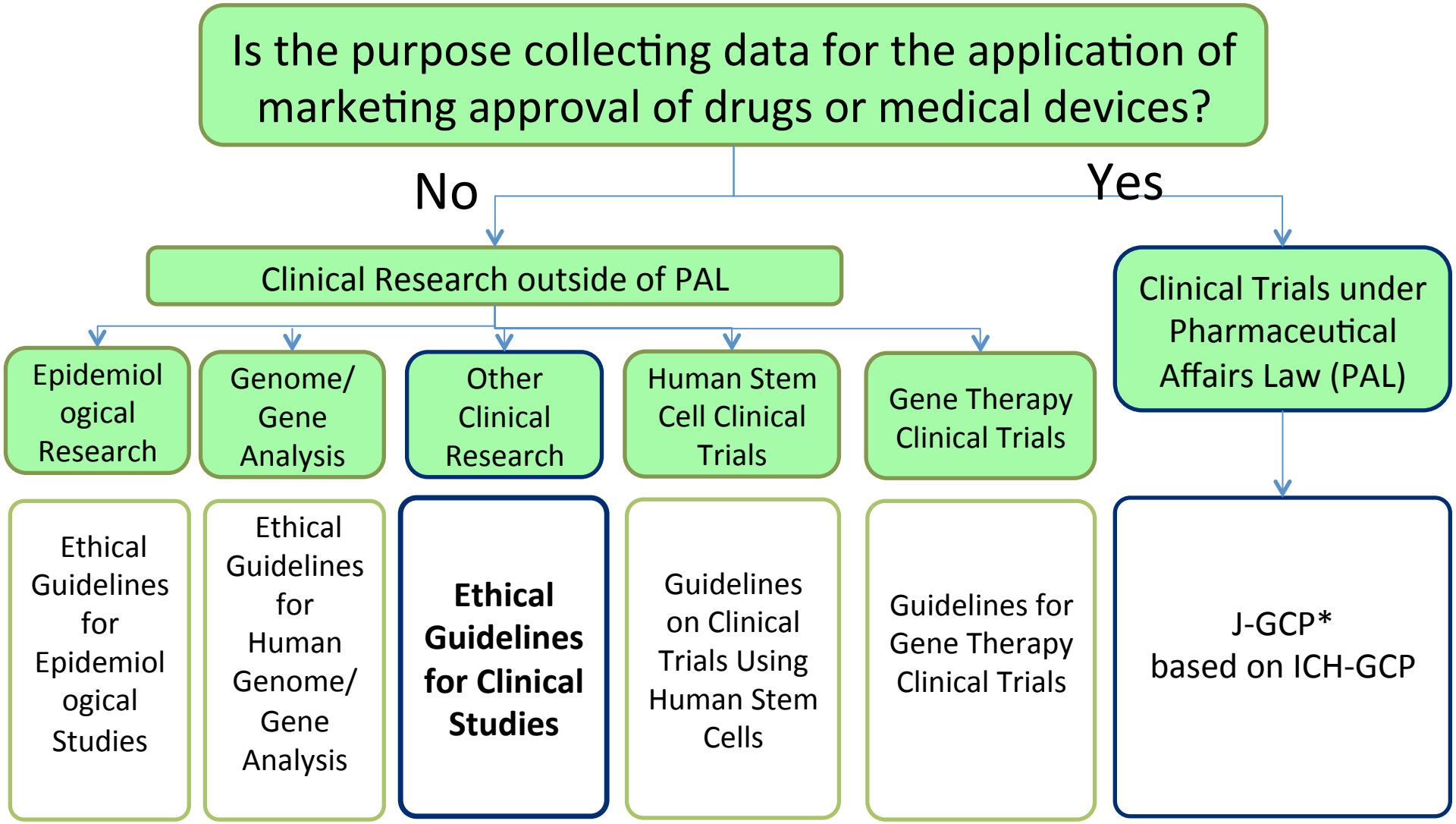
Academic Purpose (other than Registration)

- Interventional studies
- Observational studies
- Human Genome/Gene Analysis

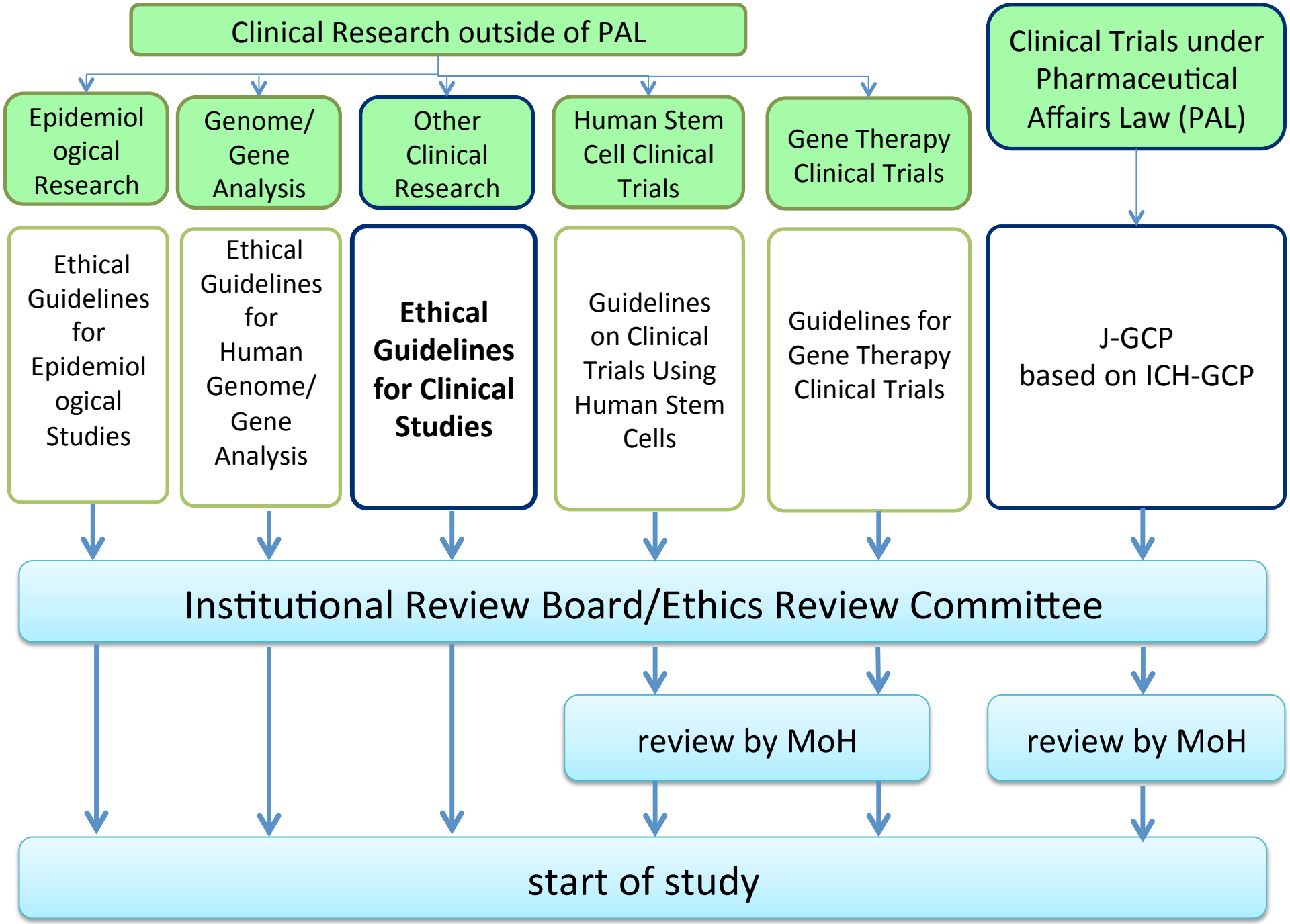
Registration Purpose

Interventional studies intended for application for marketing approval of drugs and medical devices; under Pharmaceutical Affairs Law (PAL)

Major Guidelines for Health Research in Japan



*GCP: Guideline for Good Clinical Practice


Clinical Research outside of PAL
Clinical Trials under Pharmaceutical Affairs Law (PAL)
Epidemiological Research
Genome/ Gene Analysis
Other Clinical Research
Human Stem Cell Clinical Trials
Gene Therapy Clinical Trials
Ethical Guidelines for Epidemiological Studies
Ethical Guidelines for Human Genome/ Gene Analysis
Ethical Guidelines for Clinical Studies
Guidelines on Clinical Trials Using Human Stem Cells
Guidelines for Gene Therapy Clinical Trials
J-GCP based on ICH-GCP
Institutional Review Board/Ethics Review Committee
review by MoH
review by MoH
start of study

Comparison between Japanese GCP and Ethical Guidelines for Clinical Studies

X : no specific provisions in the Ethical Guidelines

Main Provisions in GCP	Main Provisions in Ethical GLs
<u>Standards for Preparing CTs</u>	
● Operating Procedures	● Operating Procedures
● Protocol	● Protocol
● Investigator's Brochure	X
● Compensation to Subjects	● Compensation to Subjects
<u>Standards for CT Management</u>	
● Investigational Product Control	X
● Information on ADRs etc.	● Handling of Adverse Events
● Monitoring	X
● Audit	X
-	● Self-inspection (if necessary)
● Clinical Trial Reports	● Report of result summary
● Record Keeping	X

Comparison between Japanese GCP and Ethical Guidelines for Clinical Studies

X : no specific provisions in the Ethical Guidelines

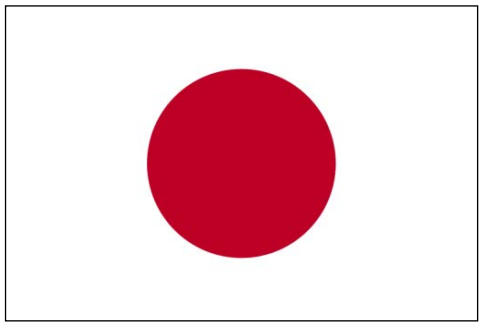
Main Provisions in GCP	Main Provisions in Ethical GLs
<u>Standards for Conducting CTs</u>	
(1) Institutional Review Board	(1) Ethics Committee
● Establishment and Review	● Establishment and Review
● Information Disclosure	● Information Disclosure
● Record Keeping	X
(2) Medical Institution	
● Responsibilities of Head	● Responsibilities of Head
● Clinical Trial Office	X
● Record Keeping	X
(3) Investigator	
● Responsibilities of Investigator	● Responsibilities of Investigator
● Preparation of CRF	X
(4) Informed Consent of Subjects	
● Written Informed Consent	● Written Informed Consent

Improvement in ethics and quality of clinical research

Agenda for Revision of the Ethical Guidelines for Clinical Studies (by summer 2013)

The Issues raised in the Subcommittee for the Ethical Guidelines for Clinical Studies

- System for Improving Quality of the Examination of the Ethics Committee
- Assurance of Quality of the Clinical Research
  - e.g. Confirmation of the Reliability of Data
- Method of the Informed Consent
  - especially for the scope and method of general consent etc.



Thank you for your attention.