Discussion points

① Pros and cons of CEA systems. how to leverage on pros and avoiding the cons.

② How to handle with the applications without confirmatory P3 clinical data?

Innovative medicines approved through CEA Pathways?
Medical products for rare / orphan diseases?

③ How have been handling with the applications for the diseases where the conduction of comparative Phase-3 studies is difficult (such as rare / orphan diseases)?
How to accelerate the access to the medical products for this kind of diseases?

④ Potential of the usage of foreign clinical data and/or Multi-Regional Post-Marketing Studies/Surveys for CEA approvals.

etc.,

RA Part-2 Consensus

Part-2; Conditional Early Approval (CEA) System

- In the 7th APAC meeting, we have reached a consensus that CEA is an effective and efficient way to promote early access to highly necessary medicines for patients in Asia, and that -multi-regional drug development and entry of medicines to different countries may face challenges without convergence of CEA approaches.
- RA-EWG will continue exploring the possibility of further convergence of early approval systems in Asia.

Final comment

- CEA seems to be a new approval pathway, but actually the similar approval pathway has been used in Japan in the area of rare / orphan diseases.
- It would be helpful for achieving the early access of innovative medicines (and medical products for rare/orphan diseases) if Asian economies consider the adaptation of CEA pathways.