Mutual Recognition Agreements and Reliance in the Regulation of Medicines
Information Gathering Session

AGENDA

Monday, 10 June 2019
11am EDT, 9am MDT, 8am PDT, 4pm BST, 5pm CEST

Contact Kelly Choi (KChoi@nas.edu) to register for this event

11 am EDT  OPENING REMARKS
Alastair Wood, Committee Chair

11:05 am  REMARKS BASED ON GUIDING QUESTIONS
Peter Marks, M.D., Ph.D.
Director of the Center for Biologics Evaluation and Research
Food and Drug Administration (FDA)

11:25 am  DISCUSSION WITH THE COMMITTEE

12:00 pm  Adjourn
GUIDING QUESTIONS

- What opportunities do you envisage for greater reliance on information from trusted counterpart regulators in the future?
- What efficiencies could result from such reliance agreements/approaches?
- What are the impediments to such reliance?
  - What changes in law would be required to allow the FDA to share data?
  - How might confidentiality be ensured?
- What specific areas could be subject to such reliance?
  - What are the risks/benefits?
  - How would you prioritize the specific areas that you propose?
- Is it likely that such reliance agreements/approaches could/would accelerate the drug development and market authorization process by reducing inefficiencies and redundant work—tell us how and by how much—specific illustrations would be helpful
- Are you aware of regulatory agencies other than your own, that have such reliance? Please tell us about them