The National Academies of
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Mutual Recognition Agreements and Reliance in the Regulation of Medicines

Information Gathering Session

AGENDA

May 3, 2019

4-5pm British Standard Time/11am-12noonEDT/8-9amPDT

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

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4:00pmBST 11amEDT 8amPDT **OPENING REMARKS**
Alastair Wood, Committee Chair

4:05 pm **REMARKS BASED ON GUIDING QUESTIONS**
Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency

4:25 pm **DISCUSSION WITH THE COMMITTEE**

5:00 pm *Adjourn*

GUIDING QUESITONS

• How have MRAs/reliance approaches been developed and utilized at MHRA?
• What has been your experience of such agreements/reliance approaches?
• 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 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.