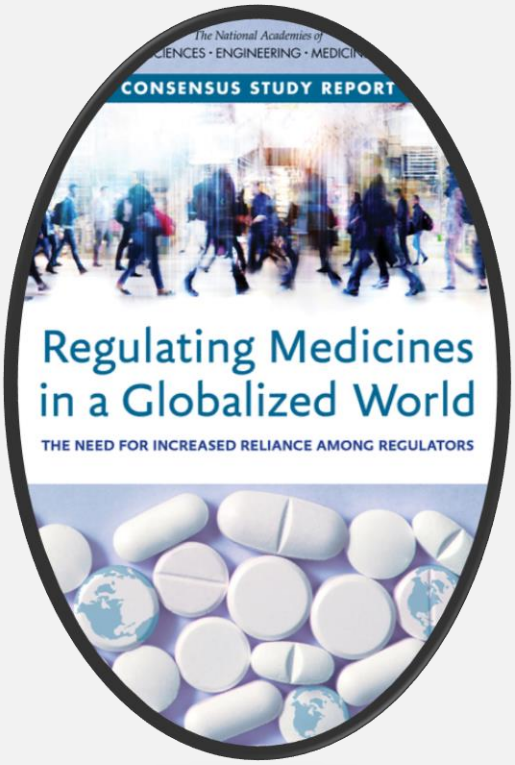
Regulatory Reliance – If not now, when? What are the current barriers?

Friday, September 4

10:30am-12noonEDT /4:30-6pmCEST

Objective: To identify current barriers to greater use of regulatory reliance and to explore potential solutions

Background: This Webinar will focus on the barriers to greater use of regulatory reliance during the pandemic by drawing upon messages from the recently released NASEM report on regulatory reliance that was funded by FDA's Office of Global Policy and Strategy.



DRAFT Agenda

10:30am **Welcome & Background**
Alastair Wood, Fmr Study Chair

Focusing on regulatory reliance as a 21st century best practice, especially during a pandemic when time is of the essence, panelists are asked to respond to the question:

- What do you see as current barriers to greater use of reliance-based regulatory pathways and how might they be overcome?

Webinar Facilitator: Alastair Wood
10:40am **Moderator: Murray Lumpkin**

Guido Rasi, Chair of ICMRA and current Executive Director, EMA

Emer Cooke, Director, Regulation of Medicines and other Health Technologies, WHO, and imminent Executive Director, EMA

Janis Bernat, Director of Biotherapeutics & Scientific Affairs, IFPMA

Mikel Arriola, Fmr Federal Commissioner, COFEPRIS, Mexico

Margaret Hamburg, Fmr Commissioner of Food and Drugs, US FDA

Panel Discussion Questions to Consider

- How can we best remove current barriers to and advocate for greater use of reliance-based regulatory pathways during the current pandemic?
- What needs to change to make this happen?
- Should/could someone/some organization coordinate this? For example, can someone/organization coordinate data on PPE quality-just as a relatively simple example?

Panel Discussion
Moderators: Alastair Wood & Murray Lumpkin
11:20am

- Jeffrey Drazen, Fmr Editor-in-Chief of The New England Journal of Medicine
- Margaret Hamburg, Fmr FDA
- Guido Rasi, ICMRA & EMA
- Emer Cooke, WHO & EMA
- Janis Bernat, IFPMA
- Mikel Arriola, Fmr COFEPRIS, Mexico

12noon Adjourn