In Closing:

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An Invitation: Generic Parallel Scientific Advice

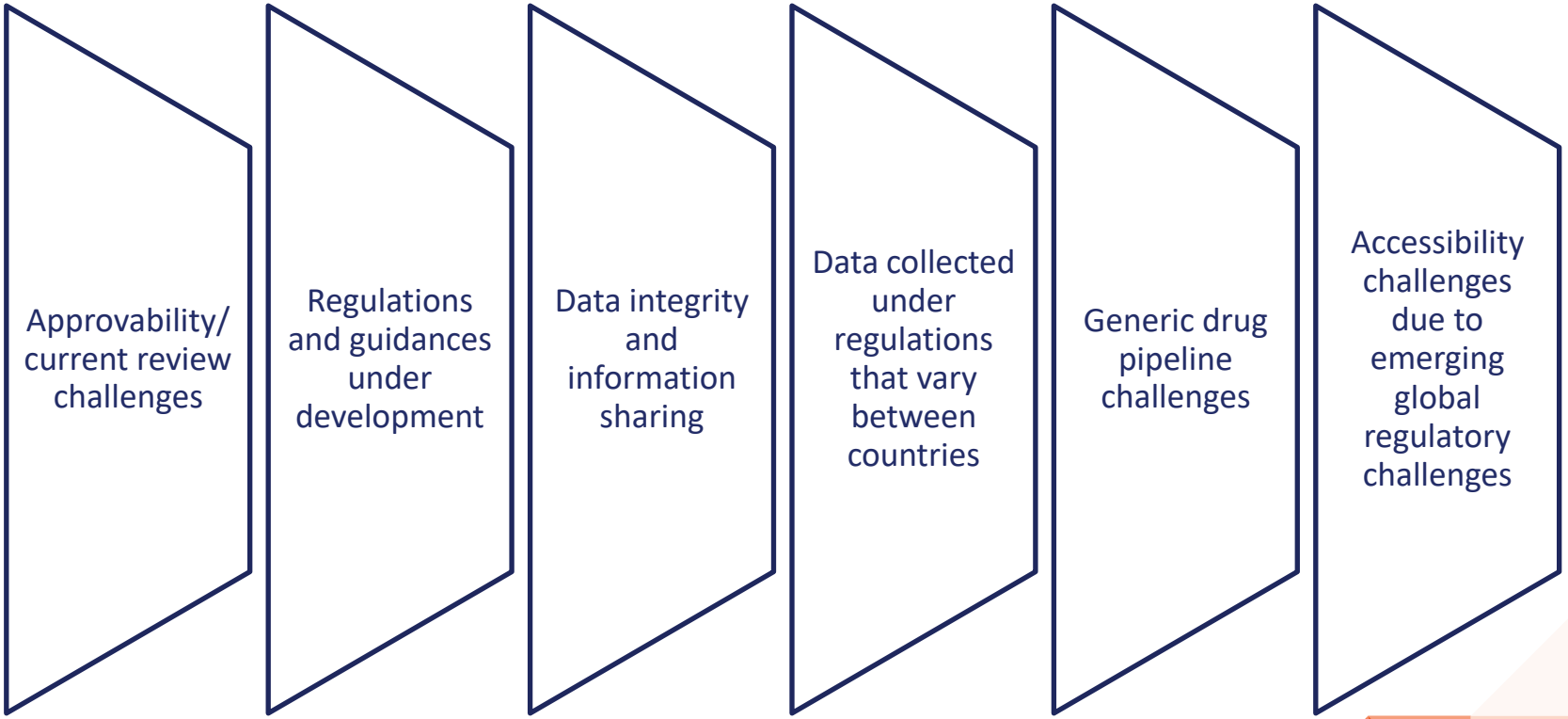
What: A voluntary pilot program to facilitate discussions between generic drug developers, FDA, and the European Medicines Agency

Why: Prospective generic drug applicants can engage in concurrent scientific conversation with both agencies on key issues

How: Request a meeting to address specific scientific inquiries around the development of complex generic drug products by emailing a "Request for Parallel Scientific Advice" justification to

EMAinternational@EMA.Europa.EU **and** preANDAhelp@FDA.HHS.gov

FDA Generic Drug Cluster



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https://www.fda.gov/drugs/generic-drugs/global-generic-drug-affairs

Generic International Harmonization Efforts

December 2022

First draft bioequivalence (BE) guideline under ICH (M13A) on BE for immediate-release solid oral dosage forms

January 2023

FDA draft guidance for industry and Federal Register notice to solicit public comments

May 2023

FDA webinar to help industry with the M13A guidance

June 2023

ICH Assembly endorsement of a second topic to harmonize BE for modified-release products


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