



Patient Benefit by Scientific Collaboration

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CMC Regulatory Affairs

AstraZeneca

September 2023

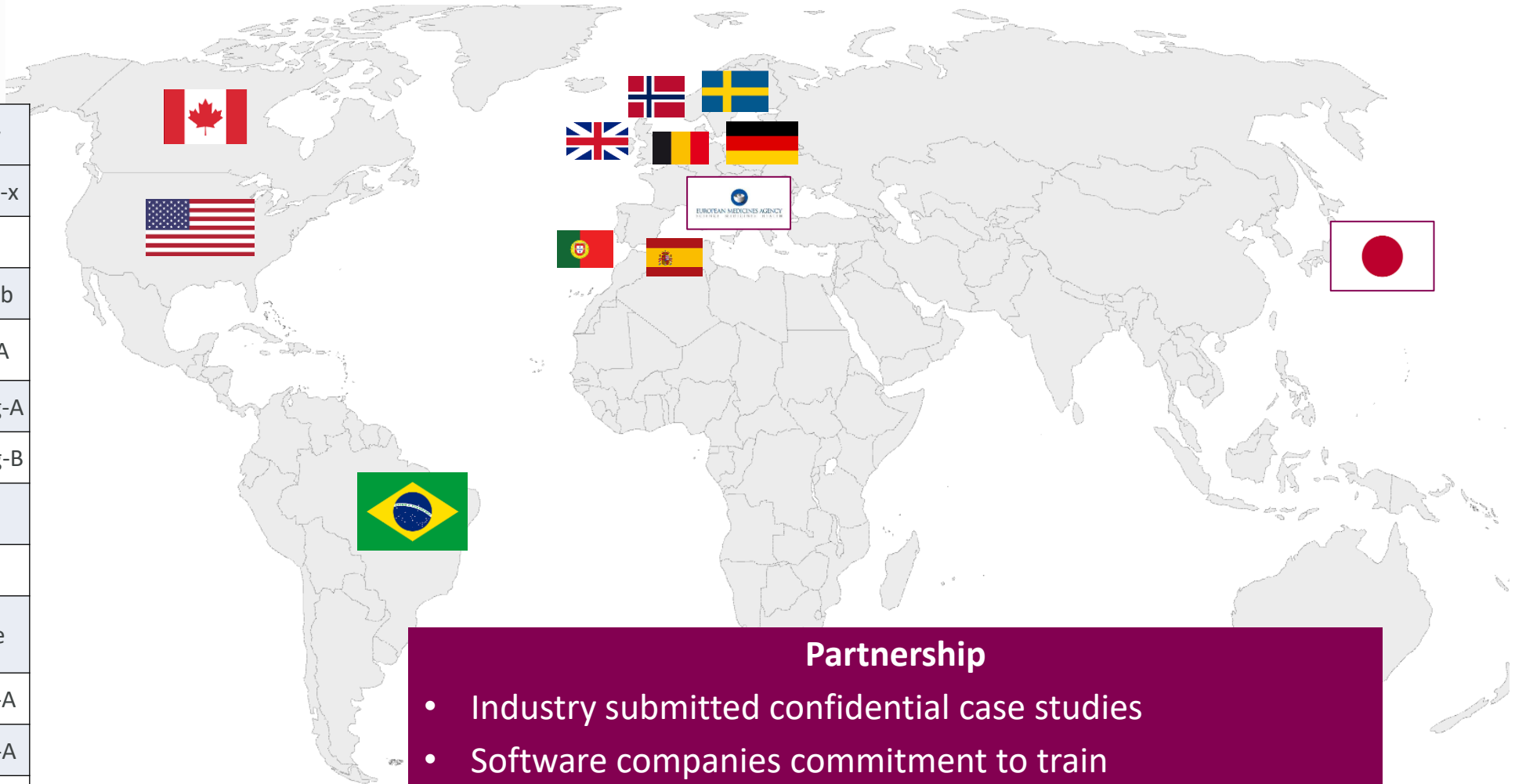


Scientific collaboration to advance quality medicines to patients

2 year path from September of 2021 to M-CERSI workshop



Case study	Company	Case study
1	Amgen	Amgen-Drug-x
2	Astrazeneca	Lesinurad
3	Astrazeneca	Acalabrutinib
4	EMD (Merck KGaA)	EMD-Drug-A
5	Janssen	Janssen-Drug-A
6	Janssen	Janssen-Drug-B
7	Merck & Co (MSD)	Etoricoxib
8	Novartis	Ribociclib
9	Pfizer	Fluconazole
10	Roche	Roche-Drug-A
11	Sanofi	Sanofi-Drug-A
12	Vertex	Vertex-Drug-A



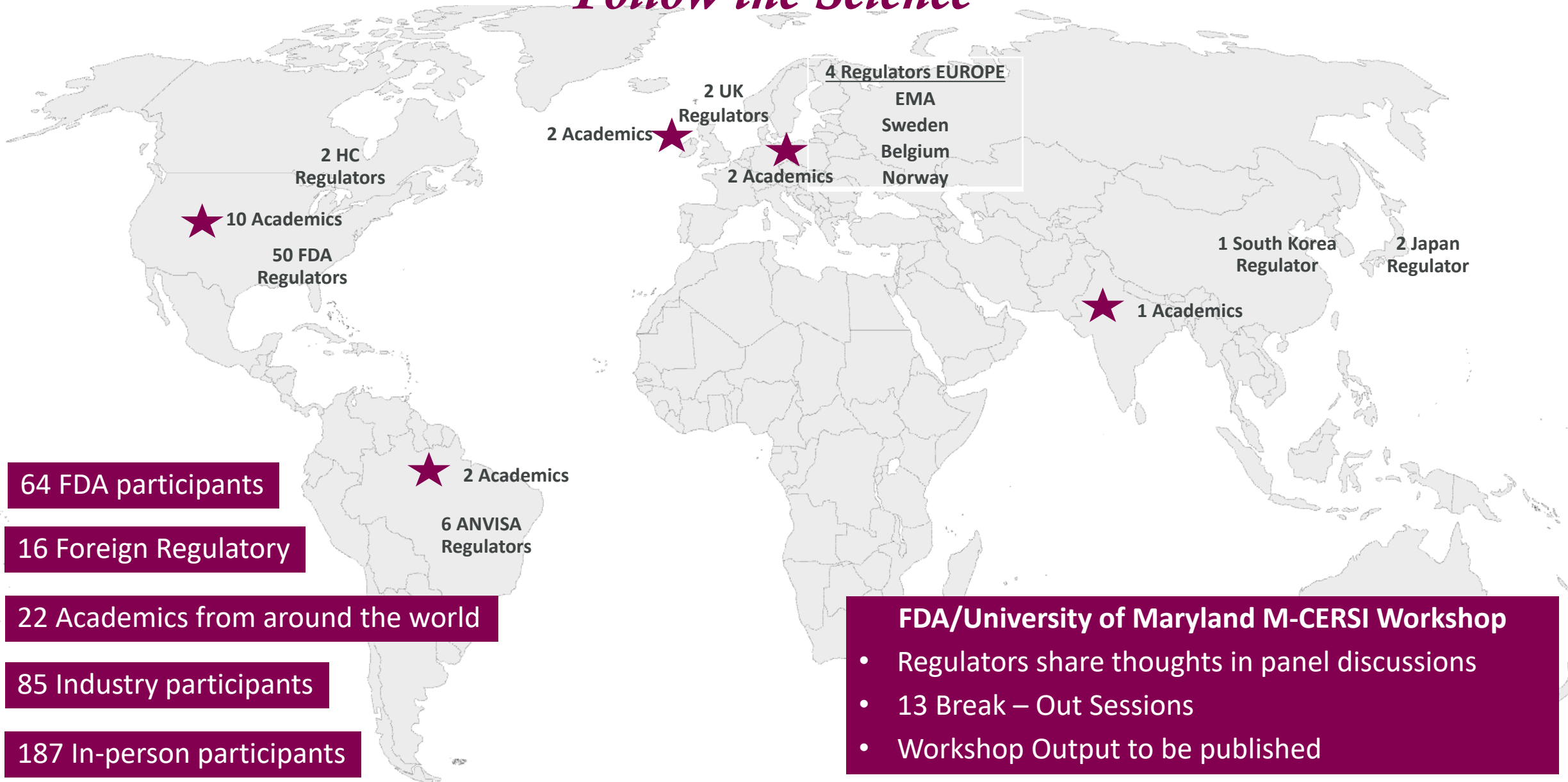
Partnership

- Industry submitted confidential case studies
- Software companies commitment to train
- Agreement to involve academics
- Independently & collaboratively reviewed by regulators



Workshop Scientific Collaboration: Industry-Regulators- Academics

Follow the Science



Choices, Chances and Change

Make a Choice to take a Chance for us to see Change

- Workshops: European based, Brazil, Canada and Japan?
- Publications:
 - 3 day workshop – 3 publications + 1 summary publication
 - White paper – best practice on for PBBM reports
- ICH Guideline:
 - ICH M15 General Principles for Model Informed Drug Development
 - Provides a framework for model development and validation
 - ICH M12 Drug Interaction Studies (M12 - applications of PBPK)
 - ICH Mx Physiological Based Biopharmaceutic Models



Acknowledgements



UNIVERSITY OF
MARYLAND

Jim Polli



U.S. FOOD & DRUG
ADMINISTRATION

Bhagwant Rege, Rebecca Moody, Paul Seo



EUROPEAN
MEDICINES
AGENCY

Evangelos Kotzagiorgis



Health
Canada



MHRA
Regulating Medicines and Medical Devices



独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency



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Claire Mackie Tyco Heimbach Christer Tannergren|
Sumit Arora Anamitro Banerjee Mitra Amitava
Xavier Pepin Sandra Suarez-Sharp Jamei Masoud

Sponsors

AstraZeneca

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Tycho Heimbach

Certara

All Moderators, Speakers, Scribes and all
Workshop Participants



Thank You

