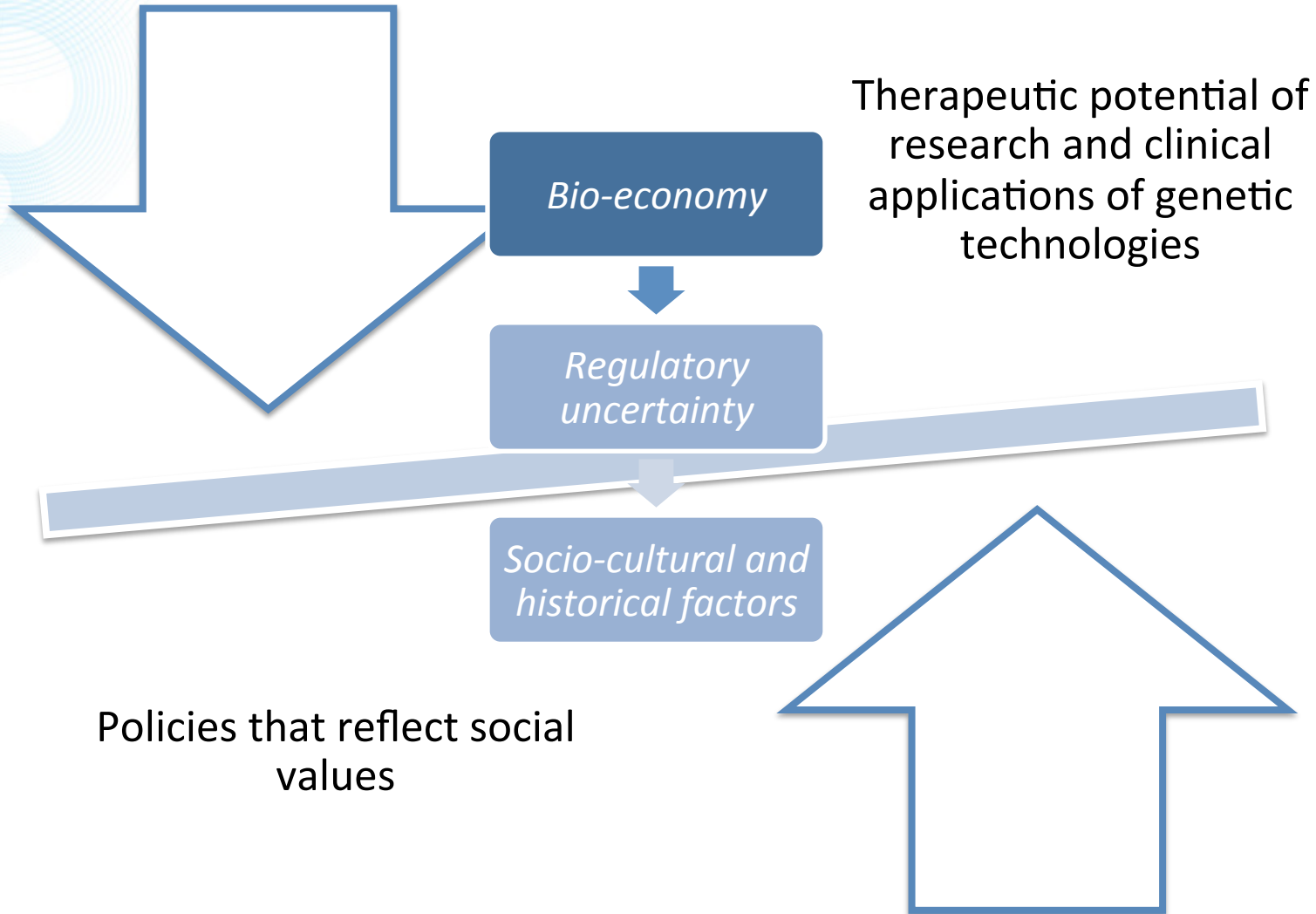


More than regulatory challenges for genomic medicine in Latin America: Gaps, Barriers and Challenges

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Therapeutic potential of research and clinical applications of genetic technologies

Bio-economy

Regulatory uncertainty

Socio-cultural and historical factors

Policies that reflect social values

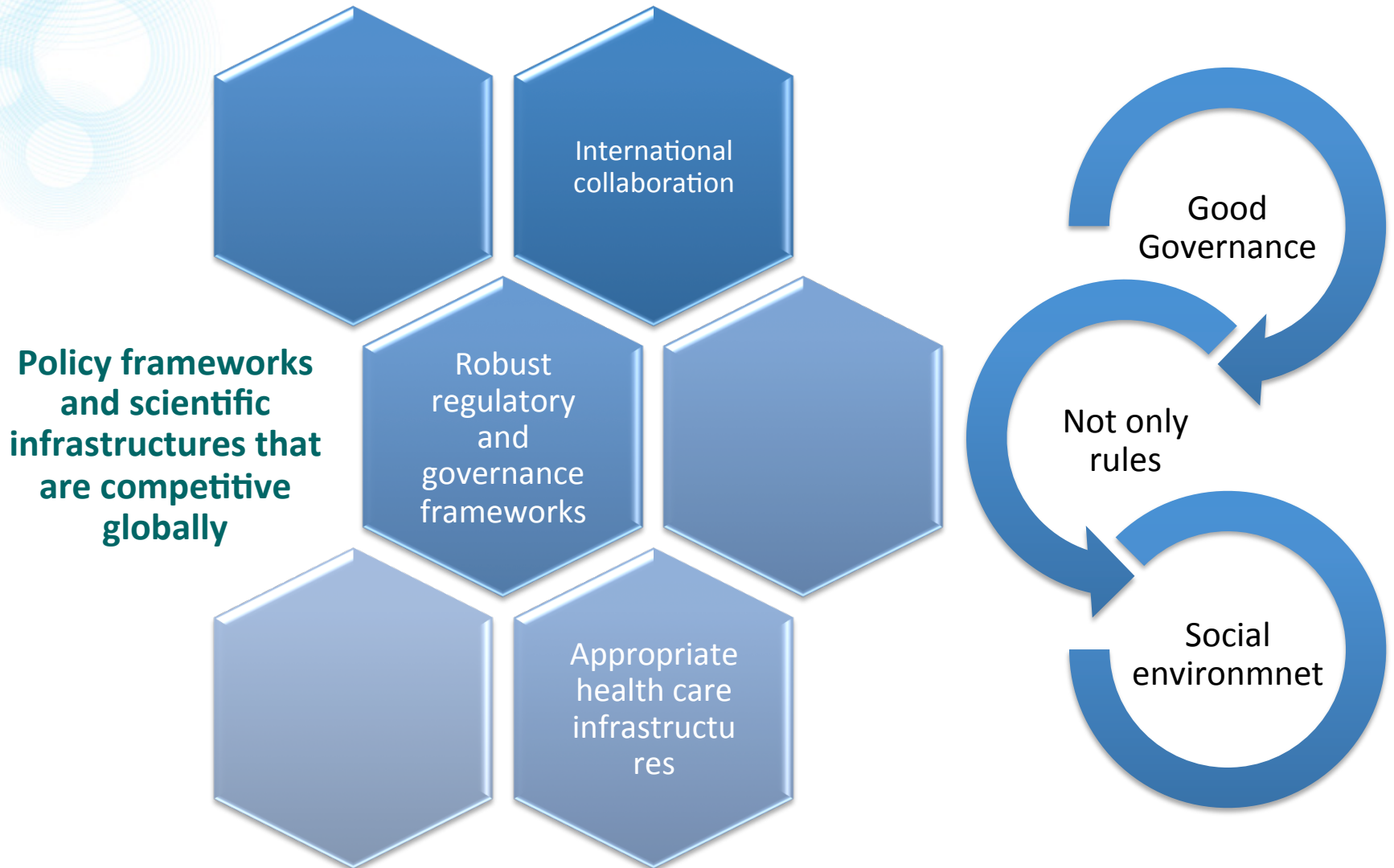
National home-keeping policies

At the intersection of the international and local governance of Genetic Medicine

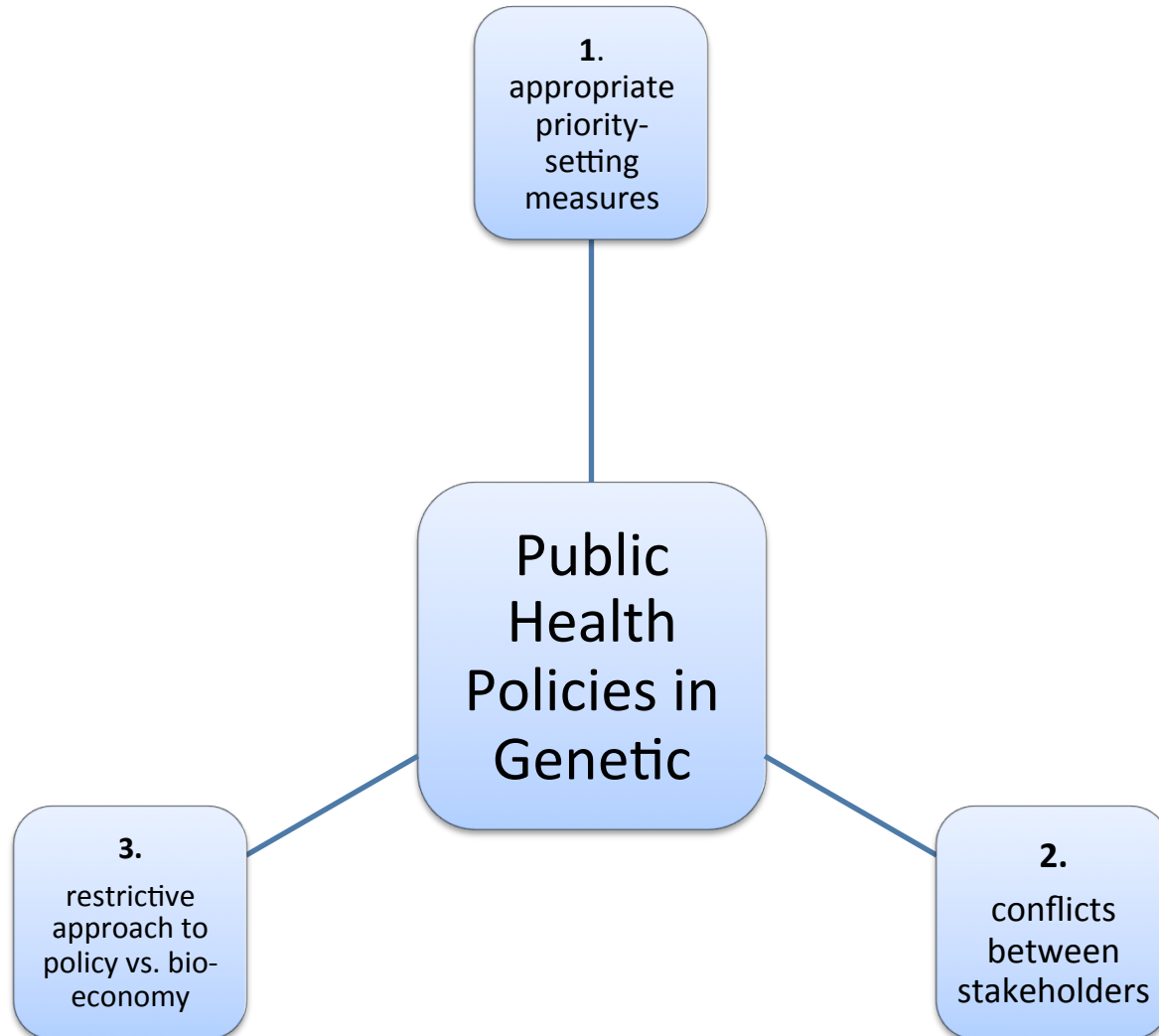
Absence of robust policy frameworks.
Risk of abuse

International standards
¿policy convergence or policy transfer?

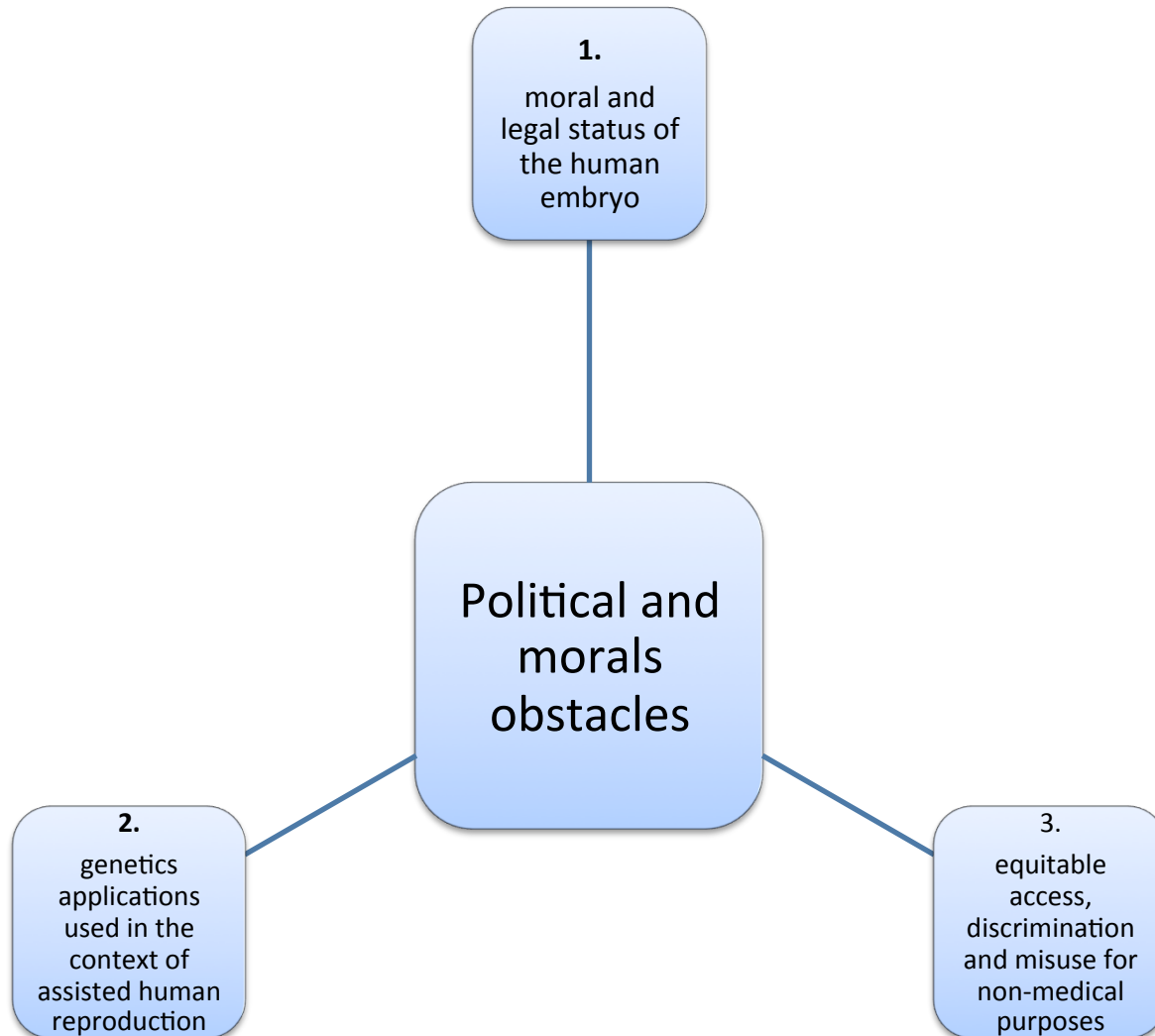
More than regulatory challenges for genomic medicine



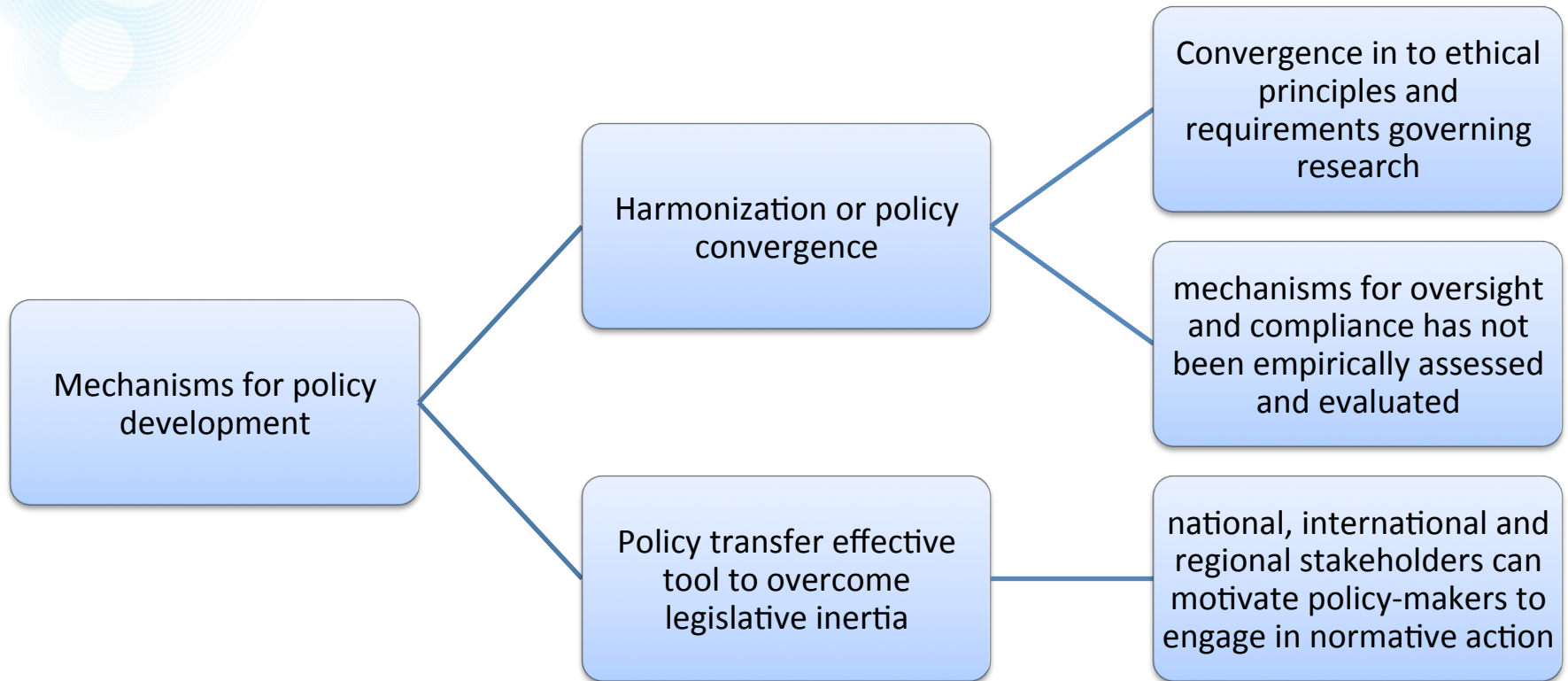
Policy approaches in LA: Gaps



Policy approaches in LA: Barriers



In this context, how should policy be developed?



What is the state of the art of regulation in LA

- Barriers → Biomedical research and clinical translation
- Gaps → There is no specific regulation for genetic research and medicine
- Challenges → Transition to an efficient regulatory model.

Challenges: how to overcome the barriers

In the absence of governments' normative action, laissez faire approaches will prevail. Promote a market model.
“Ethical arbitrage”

By regulations, governments would be able to demonstrate that they are capable of making ethical assessments, encouraging regulatory consistency and establishing priorities

Regulatory vacuums and the lack of adequate procedural and substantive safeguards undeniably lead to abuse –that much we have learned from history

Challenges

Transition to an efficient regulatory model

- First step → Improve regulatory space
- Second step → Design and implement flexible, efficient and clear regulation with the participation of stakeholders
(Scientists, Professional Societies, Patients' Organization, Academic Organizations, Regulatory Agencies)

Between the first and second step it is necessary to create a regulatory culture

The rights and health of patients and improve health care system are the keys

Regulators need to work more closely with scientists

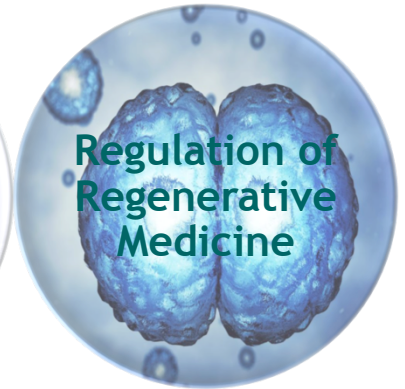
Interactive discussions

Accelerating regulatory science initiatives



Gaps to effective transfer

Strengthening good regulatory practices







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