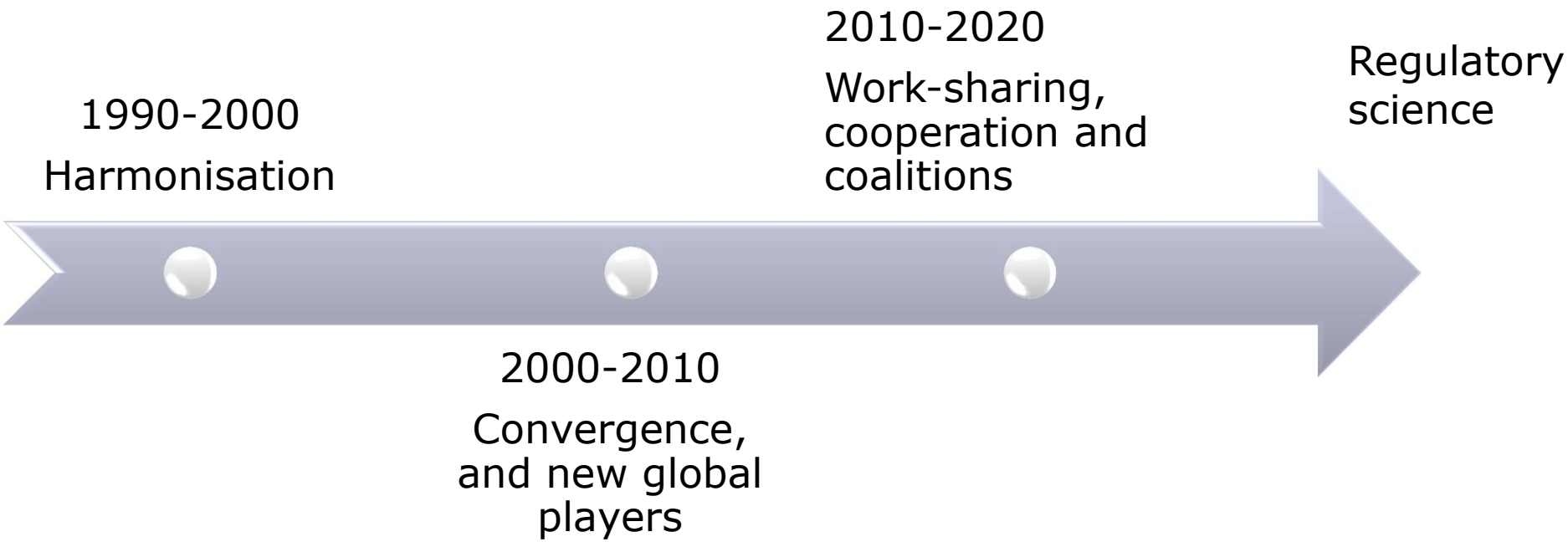
Why do we need to converge globally and collaboratively?

- Changing pharmaceutical environment due to **global** nature of medicine development and research (India becoming a key player):
  - Global movement of **clinical trials**
  - Increasing complexity of **supply chains** and manufacture outside of the EU – increasing risks of falsification, counterfeits, and concerns over data integrity
- Increasing needs for international **collaboration**, information/**knowledge** sharing and work sharing to achieve a global vision
- Emerging Science and new **opportunities** for patients
- New **challenges** for Health Systems

Changing face of international collaboration



Regulatory Science is the evolution of convergence

Challenges:

- Stimulating innovation in clinical evaluation
- Supporting new approaches to improve product manufacturing and quality
- Ensuring Regulatory readiness to evaluate innovative emerging technologies

Building together creates an easier framework for convergence!

Possible Evolution

- A new assessment approach is needed addressing an evolving business model
- Harnessing new methods of generating evidence including real world data (big data!) to improve health outcomes