Key drivers of regulatory change

The four key drivers

- Better patient safety and outcomes based on P4 medicine (predictive, preventative, personalised and participatory)
- New treatments, such as combination therapies, immunotherapies, nutrigenomics, gene editing and digital therapeutics
- Access to real-time information and data
- New technology such as machine learning, RPA, robotic surgery, 3D printing, the Internet of Medical Things and virtual reality

The emerging and evolving regulatory framework

- Data regulation (e.g. GDPR)
- Clinical Trial Regulation (CTR)
- Clinical Trial Data Disclosure
- Pre and Post Market guidelines for Cybersecurity
- Medical Devices Regulation (MDR)
- In Vitro Diagnostics Regulation (IVDR)
- Falsified Medicines Directive
- Good Practices Compliance (e.g. GMP, CVP, GCP, GLP)
- Identification of medicinal products (IDMP)
- Collaboration
- Harmonisation
- Transparency
- Simplification
- Traceability

Impact across the life sciences value chain

- Research
  - Laboratory practices
- Development
  - Clinical practices
- Market Authorisation
  - Vigilance of clinical trials
- Manufacturing
  - Manufacturing practices
- Distribution
  - Distribution Practices
- Commercial
  - Vigilance of products on the market