A Rapidly Changing Regulatory Landscape: What Medical Affairs Should Do

WEBINAR COMPANION WORKSHEET

Monitor and adapt to a rapidly evolving landscape

- [ ] Leverage AI, digital tools and internal experts to monitor and communicate regulatory and policy changes
- [ ] Keep SOPs, training, and cross-functional playbooks current
- [ ] Cross functionally prioritize and implement solid strategies to withstand the effects of shifting policy

Medical Affairs as guardians of truth

- [ ] Maintain scientific integrity in research and decision-making
- [ ] Proactively communicate trial results, funding sources, and relationships
- [ ] Expand Medical Affairs' role in scientific education for HCPs, payers, and the public
- [ ] Frame value in terms of both clinical outcomes and economic impact

Enhance and evolve research capabilities and priorities

- [ ] Align Medical, Regulatory, Legal, and Commercial teams on strategic research priorities
- [ ] Build HEOR/RWE capabilities to strengthen access and evidence generation
- [ ] Strengthen partnerships with academia and institutions facing reduced funding

Think in Global Market Access terms

- [ ] Develop medicines and strategies for global approval and pricing
- [ ] Mitigate risks in manufacturing due to high tariffs