



IMDRF

International Medical Device
Regulators Forum | 26th Session

Scene Setting: Industry Perspective

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Developing Regulatory Systems

Varied Paths &
Approaches Globally

Challenges and
Considerations

Themes and
Considerations for
Developing a
Regulatory
Framework

Opportunities for the
Future



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Varied Paths & Approaches Globally

- Pharmaceutical-based models (current or evolved from)
- Central/state/local/provincial
- Use of third parties
- Single regulator vs. multi-regulator
- Reference jurisdictions/GHTF model
- Post-market surveillance focus

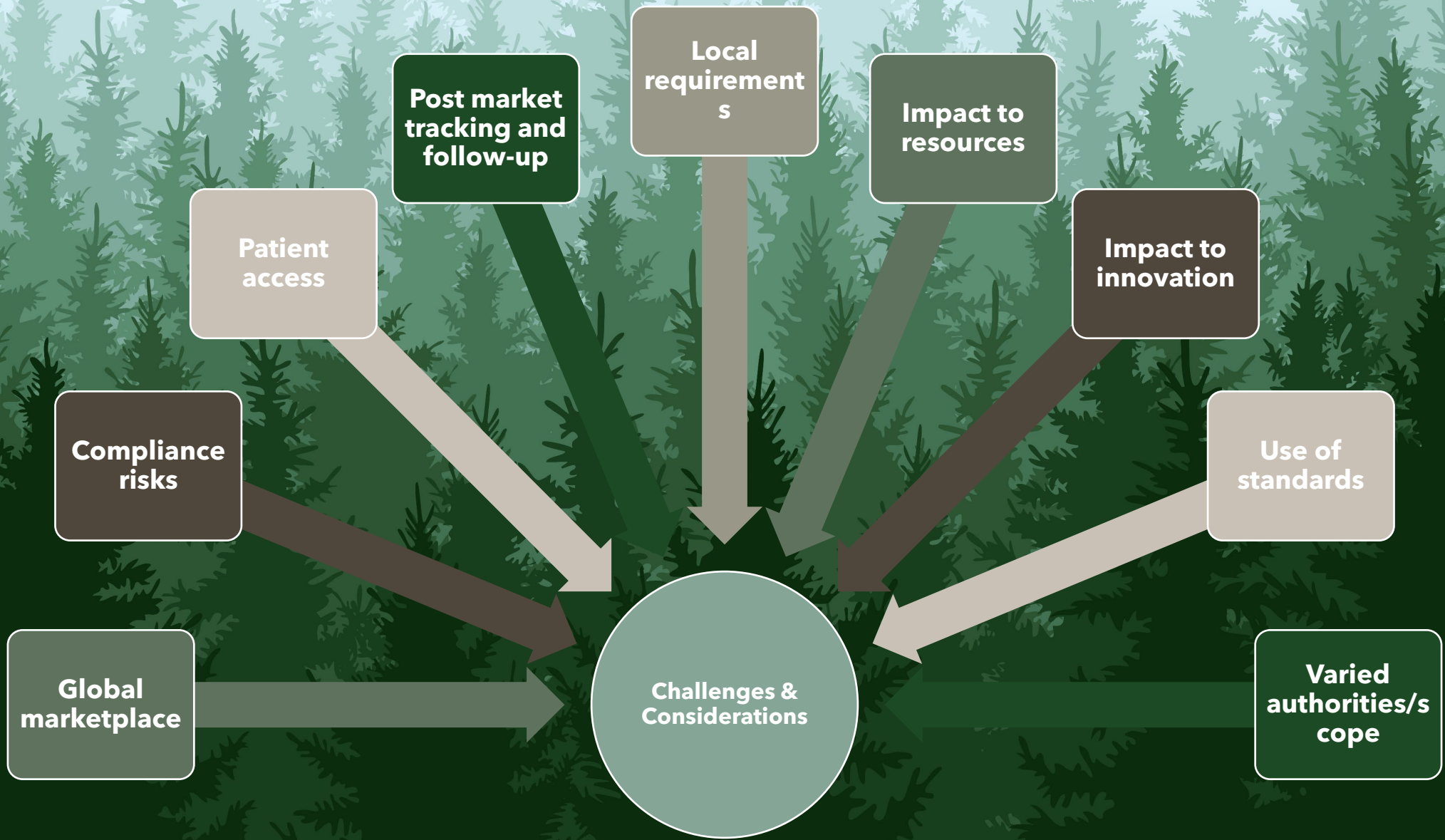


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Themes and Considerations for Developing a Regulatory Framework

- Varied authorities/scope
- Workforce considerations and resource constraints
- Access to technical expertise
- Local requirements
- Legal framework available for reliance/recognition
- Step-wise approach
- Use of global standards



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Opportunities for the Future

- IMDRF as the glue and catalyst
- Partner where possible
- Leverage and learn from other experiences
- Capacity building
- Movement to common frameworks and reliance in whole or part
- Utilize global standards
- Incremental steps



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