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# GOVERNANCE APPROACHES FOR HUMAN GENE EDITING BASED ON RESPONSIBLE RESEARCH AND INNOVATION

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# Rational

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- Human gene editing: simple, rapid, high impact
- Implications for **governance** approaches:
  - **Simple:** in operation asap
  - **Rapid:** anticipatory and adaptive
  - **High impact:** grounded on societal acceptability, considering all relevant stakeholders

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# Responsibilization

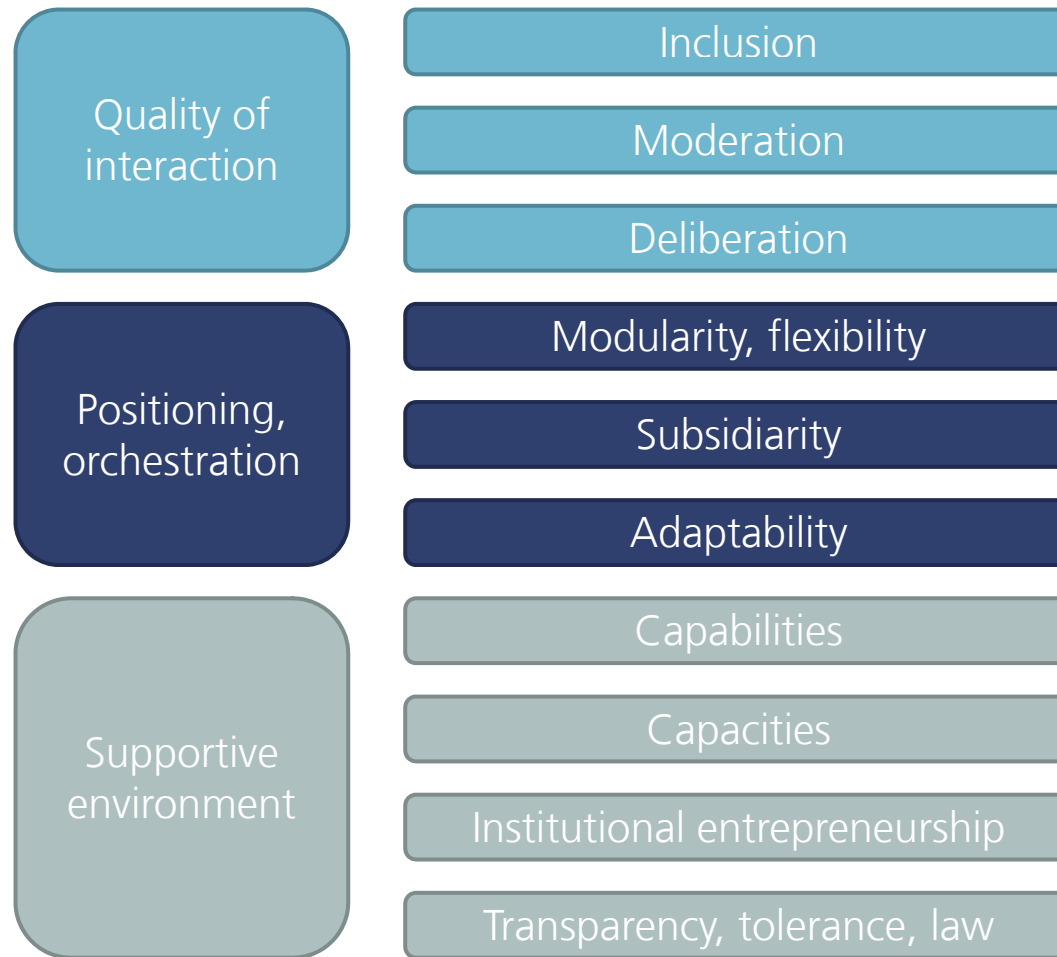
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- Societal stakeholders and innovators share mutual responsibility for innovation with respect to acceptance, sustainability, impact and consequences.
- Innovation becomes embedded deeply into societal structures.
- Reflexive, self-organized and collective design and operation of governance instruments.
- Responsibilization
  - means internalization of issues of concern and represents a fundamental transformation of the innovation system;
  - goes far beyond initiating a public debate or engaging with various stakeholders and discussing gene editing issues.

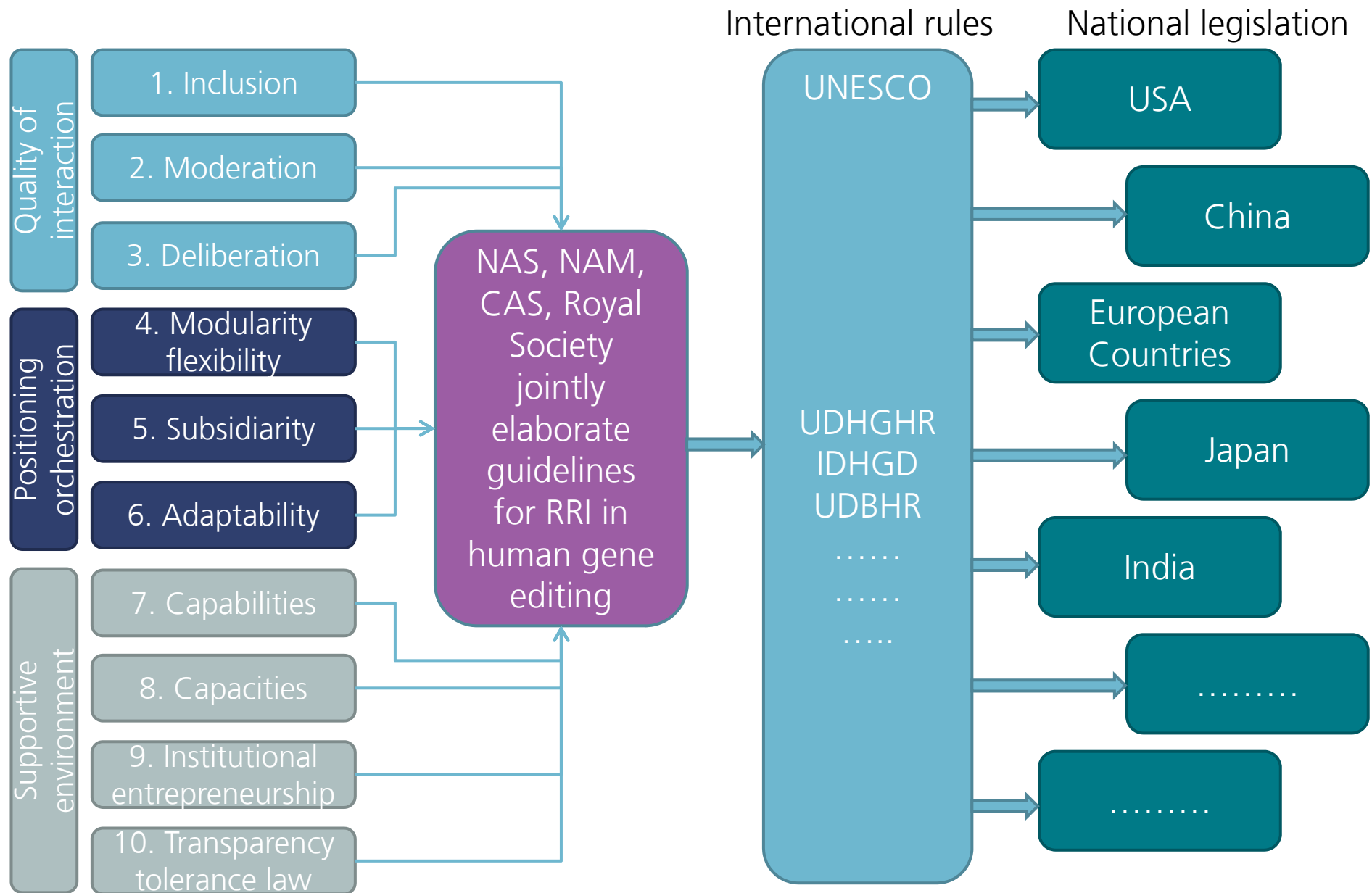
Source: Res-AgorA-project <http://res-agora.eu>

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# 10 governance principles towards responsabilization



# Responsibilization of human gene editing



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# Responsibilization of human gene editing: A first step? (1)

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NAS, NAM, CAS, Royal Society jointly elaborate **guidelines** for RRI in gene editing as a basis for international rules and national legislation

- **Design of process:**

- Establish independent and highly credible moderator, e.g. IBC (p2)
- Assure legitimization of process (p1)
- Involve all relevant stakeholders and double check relevance for the issue (p1)
- Make transparent interest, motives and values of stakeholder (p1)
- Discuss and decide about methods and procedures (p1): workshop series, online consultation, surveys

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# Responsibilization of human gene editing: A first step? (2)

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## ■ **Execution of process**

- Jointly define scope and goals (p1):
  - focus on medical applications of gene editing
  - geographical coverage (US, CN, EU)
- Develop rules to be applied within funding of each organization (p7, p8) (short term) and to form basis for international rules at the UNESCO level (mid term)
- Identify issues and required evidence base (p3)
- Make transparent different knowledge base of involved stakeholders (p10)
- Fact finding: governance settings in place globally, structure into hard and soft and mixed forms, ongoing debates, key insights
- Formulation of guidelines

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# Conclusions

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- Urgent need for governance approaches and instruments
- Governance of human gene editing needs to be
  - Anticipatory and adaptive
  - Broadly grounded on societal acceptability considering all relevant stakeholders
- RRI-framework offers principles and guidelines facilitating the development of such governance instruments
- Joint development of guidelines for RRI in human gene editing by hosts of this summit as first step?
- Shared responsibility between all relevant stakeholders as key issue