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

International Summit on Human Gene Editing
December 1-3, 2015, Washington D.C.

Thomas Reiss

Fraunhofer Institute for Systems and Innovation Research ISI
Karlsruhe, Germany

thomas.reiss@isi.fraunhofer.de

www.isi.fraunhofer.de/isi-en/
Rational

- 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

© Fraunhofer ISI
Seite 2
Responsibilization

- 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
10 governance principles towards responsibilization

- Quality of interaction:
  - Inclusion
  - Moderation
  - Deliberation

- Positioning, orchestration:
  - Modularity, flexibility
  - Subsidiarity
  - Adaptability

- Supportive environment:
  - Capabilities
  - Capacities
  - Institutional entrepreneurship
  - Transparency, tolerance, law

Responsibilization of human gene editing

1. Inclusion
2. Moderation
3. Deliberation
4. Modularity
5. Subsidiarity
6. Adaptability
7. Capabilities
8. Capacities
9. Institutional entrepreneurship
10. Transparency tolerance law

International rules
- UNESCO
  - USA
  - China
  - European Countries
  - Japan
  - India
  - Others

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

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

- **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
Conclusions

- 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