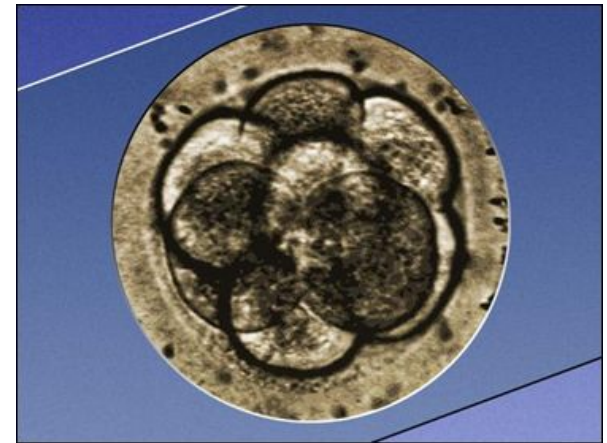


# PAN-EUROPEAN AND INDIVIDUAL NATIONAL PERSPECTIVES ON STEM CELLS: DEVELOPING A UNIFIED EUROPEAN REGULATORY APPROACH?

National Europe Centre, ANU

February 21 2006



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University of York

Director ESRC Stem Cells Initiative

# Outline

- Some background on ESRC SC initiative
- Core social science research questions
- Regulatory response to innovation
- Regulatory diversity: globally and across Europe
- Explaining the differences in regulation
- Areas of convergence?
- Conclusion



# the social science **s**tem **c**ell **i**nitiative

# Current Projects (1)

RES-340-25-0001

***The Global Politics Of Human Embryonic Stem Cell Regulation***

**Prof Brian Salter** University Of East Anglia

RES-340-25-0002

***Forgotten Fetuses - A Sociocultural Analysis Of The Use Of Fetal Stem Cells***

**Dr Julie Kent** University Of The West Of England, Bristol

RES-340-25-0003

***Mapping Stem Cell Innovation In Action***

**Dr Clare Williams** King's College London, University Of London

# Current projects (2)

RES-340-25-0004

***Quality Assured Science: The Role Of Standards In Stem Cell Research***

**Prof Andrew Webster** University Of York

RES-340-25-0007

***Haematopoietic Stem Cells: The Dynamics Of Expectations In Innovation***

**Dr Paul Martin** University Of Nottingham

RES-340-25-0008

***The Social Dynamics Of Public Engagement In Stem Cell Research***

**Dr Sarah Parry** University Of Edinburgh

# Stem Cells – current social science agenda

Analytical sites for interdisciplinary research: I

## The field itself:

- Managing the boundaries – defining the field and its core components
- The role of public procurement in fostering innovation – key in UK (DTI's Intermin.Group)
- From regulatory *science* to regulatory *organisations* – new scientific infrastructures
- Micro analysis of the laboratory/clinic relation

# Stem Cells – current social science agenda

Analytical sites for interdisciplinary research: II

## **Political/public accountability**

- Global research vs. contested political cultures
- Contested lines – cultural *critique* of SC research, and its *advocacy* – (e.g. the role of patient groups/ religio-political groups)
- Meaning and practice of informed consent
- Media representation of SC field

# Stem Cells – current social science agenda

Analytical sites for interdisciplinary research: III

## **Expectations and implementation**

- Knowledge economy/ future expectations
- Socio-Economic evaluation – patterns of corporate investment/role of VK

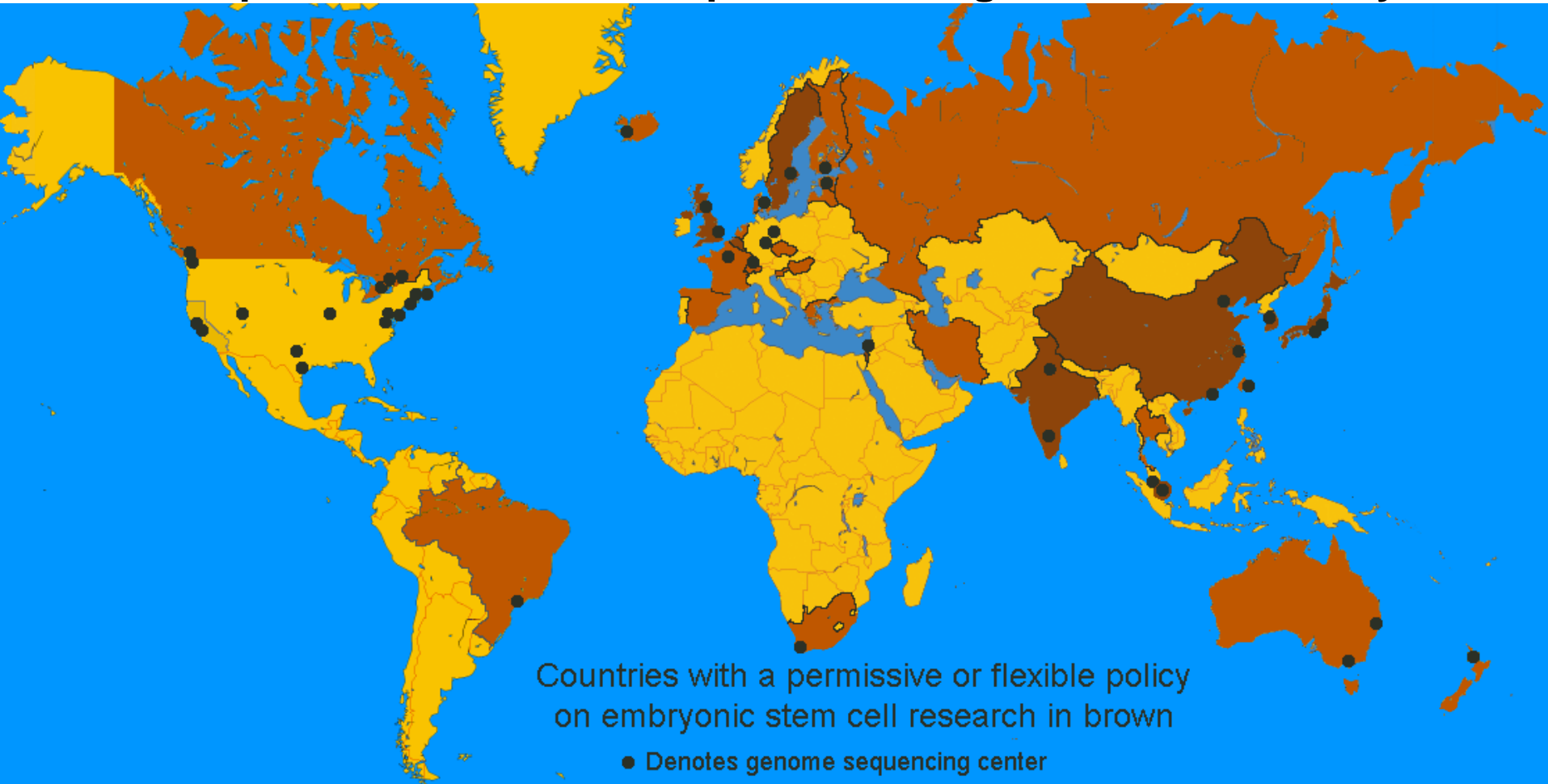
# Risk and regulation

- **Effective regulation not just about risk management but tie-in with wider expectations of civil society: develop socially resilient approach to risk**
- **Governance models need to work with the grain of public sentiment which varies from country to country**
- **Regulation enabling of science and investment (not barrier)**
- **Jasanoff (2005): contrast between US/EU risk management in red and green biotech**
- **Leads to divergent decisions on Stem cells**

# Main questions for social science in regards to regulation of stem cells

- Quality control and sourcing of material across diverse regulatory regimes?
- How might regulatory bodies in different countries interact and learn from each other in managing the new field?
- Will countries modify their regulatory approaches in the future if human stem cell research starts to provide breakthrough therapies?

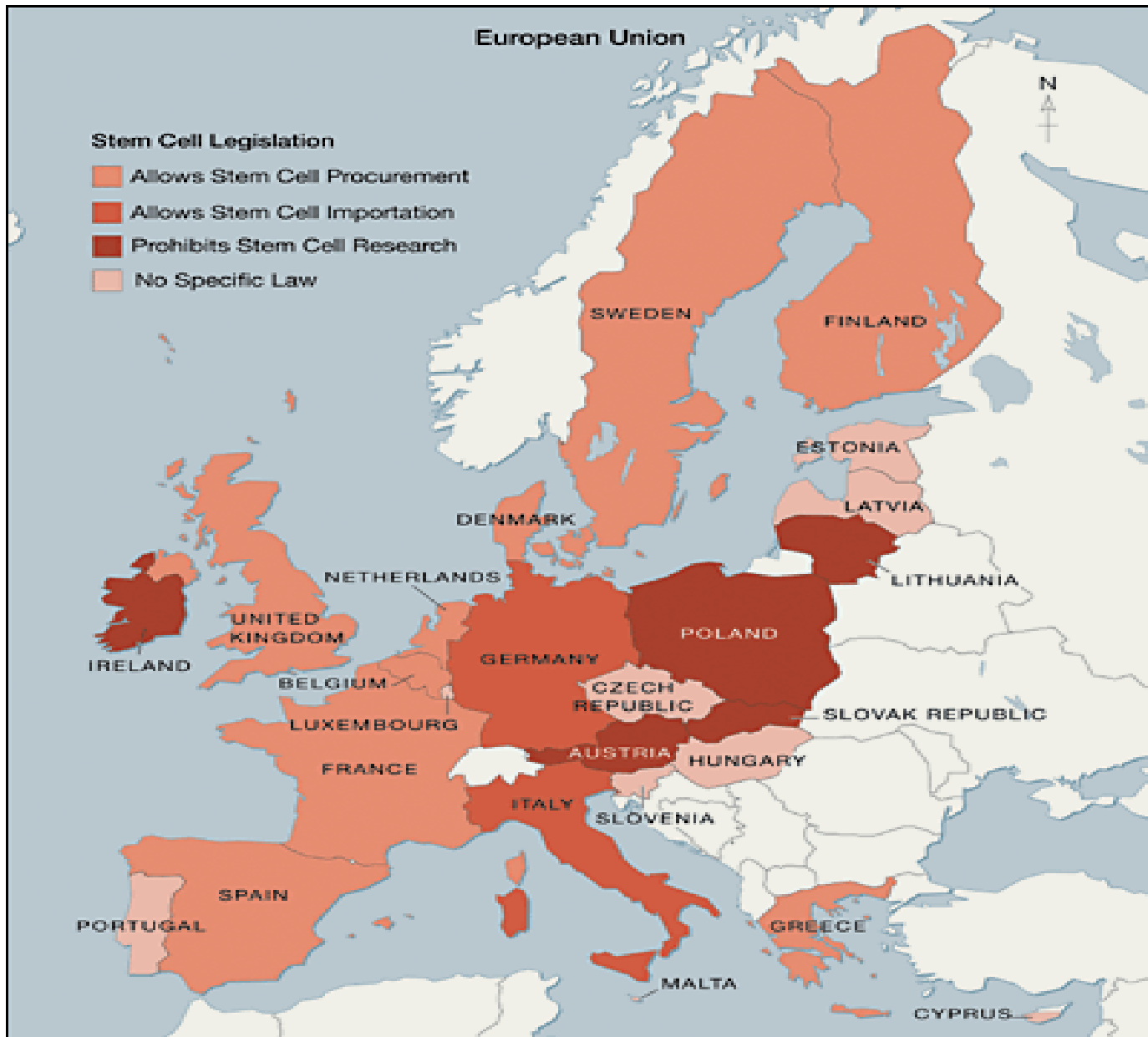
# Global pattern: ESC and therapeutic cloning/or IVF-derived only



© MBBNet

# Focussing down...

Pan-European regulation of stem cells:  
search for some regulatory consensus to  
provide stability



# Regulatory clusters

Three broad groups in Europe:

Ireland, Germany, Austria, Italy and France represent countries in which no ESC derivation is permitted

Netherlands, Sweden, Denmark, Finland, Spain and Greece approve embryonic stem cell derivation from spare embryos but do not permit the production of embryos for research purposes

In the UK and Belgium the creation of embryos for research purposes, via fertilization or cell nuclear replacement (CNR), is permitted

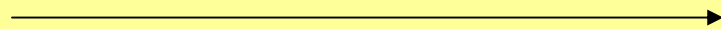
# Bioethics and the 'units' of regulatory/cultural trading

- What moral weight given to different components?

- embryo source
  - aborted
  - IVF supernumerary
  - non-IVF donated
  - cloned
- embryo creation date
- embryo age
- ESC line origin
- ESC line creation date
- ESC line research purpose

<p><b>Option 1</b> Prohibition of procurement of ESCs from human embryos</p>	<p><b>Option 2</b> Prohibition of procurement but allowing importation</p>	<p><b>Option 3</b> Allowing procurement of ESCs from supernumerary human embryos</p>	<p><b>Option 4</b> Prohibition of creation of human embryos for research purposes including cloning</p>	<p><b>Option 5</b> Allowing creation of human embryos for research purposes including cloning</p>
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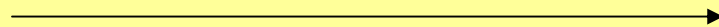
Moral status of embryo declines



18 countries

<b>Option 1</b> Prohibition of procurement of ESCs from human embryos	<b>Option 2</b> Prohibition of procurement but allowing importation	<b>Option 3</b> Allowing procurement of ESCs from supernumerary human embryos	<b>Option 4</b> Prohibition of creation of human embryos for research purposes including cloning	<b>Option 5</b> Allowing creation of human embryos for research purposes including cloning
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Moral status of embryo declines



# Explaining the difference

- Religio-ethical?  
in part only

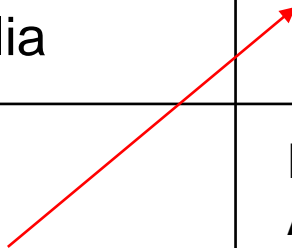


- Political cultural?  
more significant



# Political cultures and policy-making systems

	Pluralistic/ devolved	State led
Open, contested process	USA; Spain; Sweden; Australia	NL; Germany
Closed process	UK; Belgium	France; Accession States? Japan; S Korea



(UK – tends to be expert advisory committees  
closed to public scrutiny)

# Implications for different groups

Because 'national' technological zones 'cut across each other' ...

- Scientists occupy more than one political culture via research networks (engage in regulatory tourism)
- Activist groups may mobilise supranational legislation vs their own country
- Corporate investors: fragmented European market

# Convergences?

- Technical Convergence:

Quality standards relating to **biological identity**:

Developing completely defined culture conditions for stem cell derivation, propagation and differentiation

Defining appropriate cell markers that distinguish stem cell types from one another, and that characterise stem cells, progenitor cells and differentiated cell types ...what counts as a 'true' SC

Quality standards relating to the **biological husbandry** of SC:

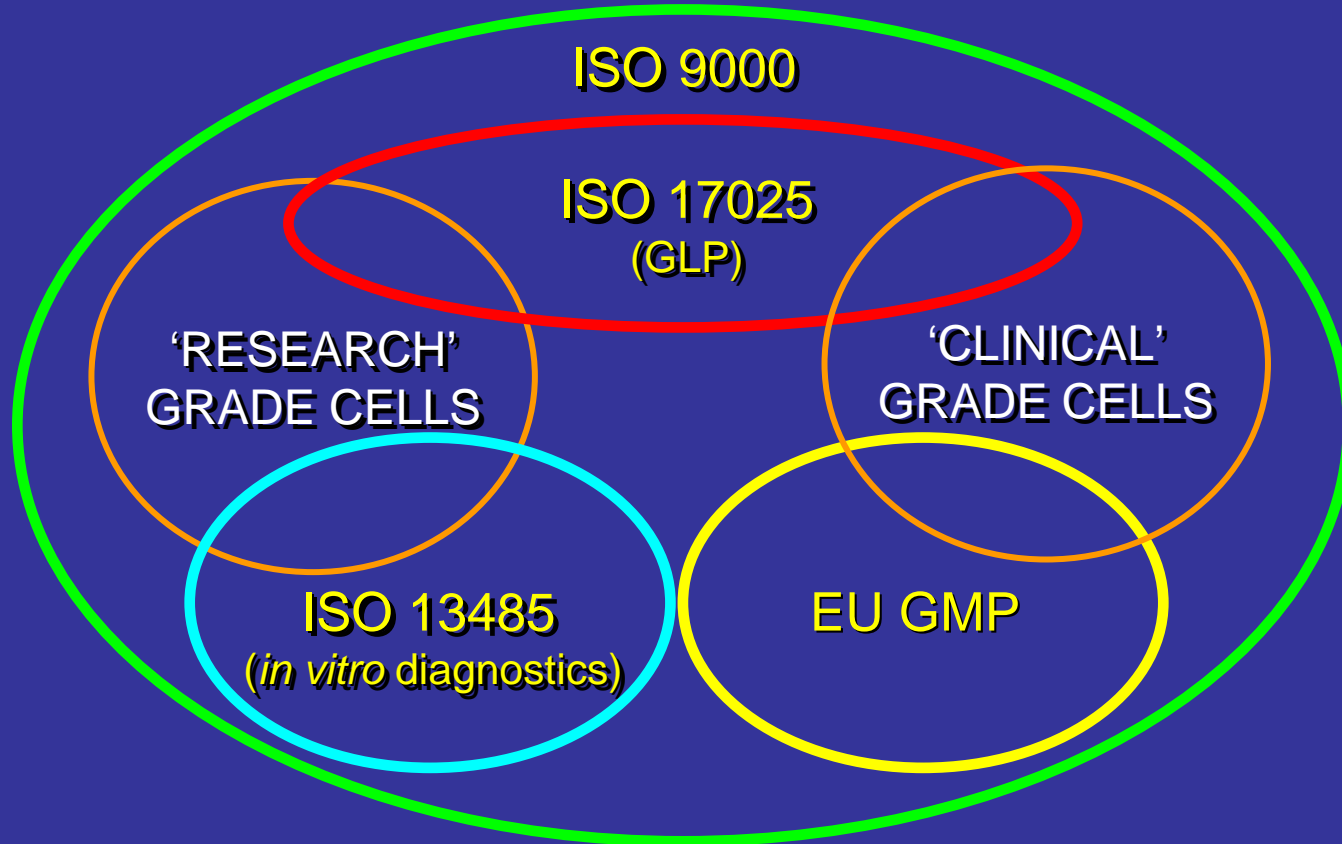
Production, stability, storage and monitoring of lines to be used by third parties: oversight of procurement and access

Quality assurance work of SC Banks (clean rooms/GMP)

Working with local science groups on protocols

# Quality Standards

DH Tissue Banking Code of Practice/UKSCB Code of Practice



Audited by: MHRA; Steering Committee; UKAS

# Regulatory convergence?

- Regulatory consensus is difficult to achieve given the diversity of political cultures prevailing across Europe ...but faster progress when defined in risk-management terms, eg EC Human Tissue Directive: sets 'standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells'. (Feb 8 2006)
- European Commission will make most headway if it continues to devote its attention to the provision of technical standards that harmonise 'identity' criteria and 'husbandry' practices.

But broader role of governance is  
still key

Hwang Case in South Korea – fraudulent  
claims re production of hESCs from cloned  
embryo

# 'Hwang's Stem Cell Achievement Hailed as Revolution'

## 'Cloning pioneer plans to open stem cell bank'



Facility would consolidate all current lines in one location

**AP** Associated Press

June 1, 2005



News

*Nature*

Published online: 22 November  
2005; [Updated](#) online: 24 November 2005

## **Korean stem-cell crisis deepens**

Further claims surface that junior researchers  
donated eggs.

David Cyranoski



The press gather to hear the results of the university investigation.

News

*Nature*

Published online: 20 December 2005; | doi:10.1038/4381056a

## **Korean scandal will have global fallout**

The possibility that Woo Suk Hwang's cloning experiments were faked threatens

## **Hwang scandal hits Korean biotech hard**

Cloning crisis triggers stock collapse.

Ichiko Fuyuno

MACROGEN STOCK



# Implications of SK case

- Local -> global impact (SK, US, UK etc): formal regulatory structures and corporate investment hit
- Re-vitalisation of anti-hESC lobby
- Not just corruption of group/cronyism nor failure of 'peer review' but over-ambitious industrial policy & lack of governance structures in SK
- Scale down hype in future?

# Regulatory ‘work’ ahead for Europe

- New hybrid regulatory institutions (eg to manage chimera and tissue engineering)
- Determining patentability of hESCs: currently prohibited by EPO (firms have to go thru national offices where allowed)
- New ‘centres of excellence’ being established to quicken product approval and authorisation (‘translation science’) will need renewed oversight in light of SK
- Stabilising ethical regime

# Conclusion

- Pan-European regulatory system at political level is emergent but remains uneven and volatile
- More actual convergence been achieved via technical and institutional standards
- Scientists embracing bioethics as way of managing wider political agenda
- Governance and regulation are enabling of S&T