Regulation in Practice:

Understanding Regulatory Bodies

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Overview of the paper:

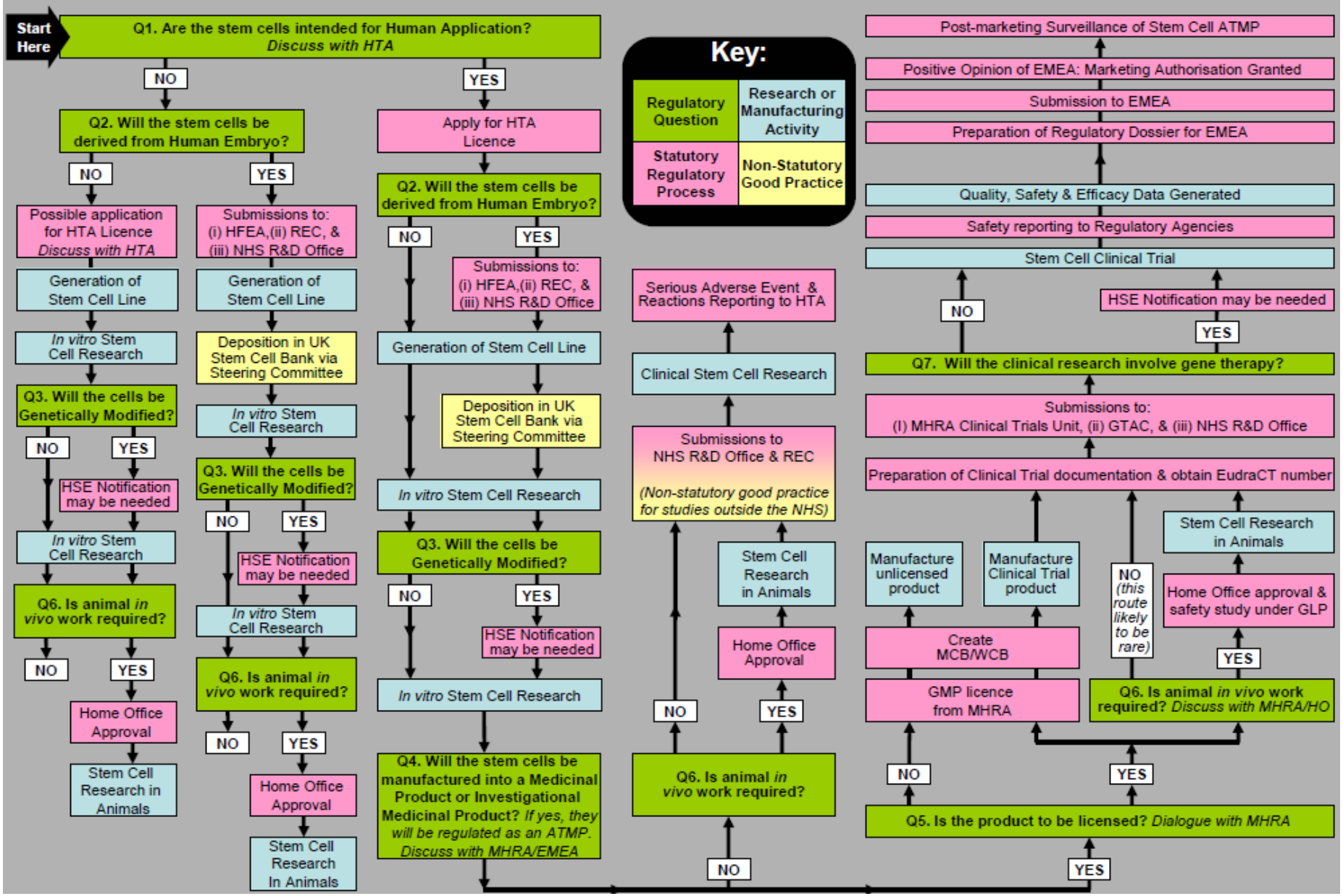
- Introduction: Understanding Regulatory Bodies?
- Two empirical case studies
- Understanding regulatory bodies in practice
- Making sense of uncertainty: Regulatory Regress
- Conclusion

Understanding Regulatory Bodies

- Report on how laboratories make sense of UK stem cell regulation
- Focus upon the uncertainties faced by laboratories
- Make explicit the role of laboratories in *producing*, as well as being subject to, regulatory texts and regulatory practice

Interim UK Regulatory Route Map for Stem Cell Research & Manufacture

Version: 12.03.09



Two empirical case studies

- **The UK Stem Cell Bank:** storage and distribution of hESC lines

  - Interviews and observations conducted 2005-2009, focus upon 2007/2008

Conducted by Neil Stephens

- **'Headlab':** Anonymous UK laboratory working on Huntington's & Parkinson's disease

  - Interviews and observations conducted 2007-2008

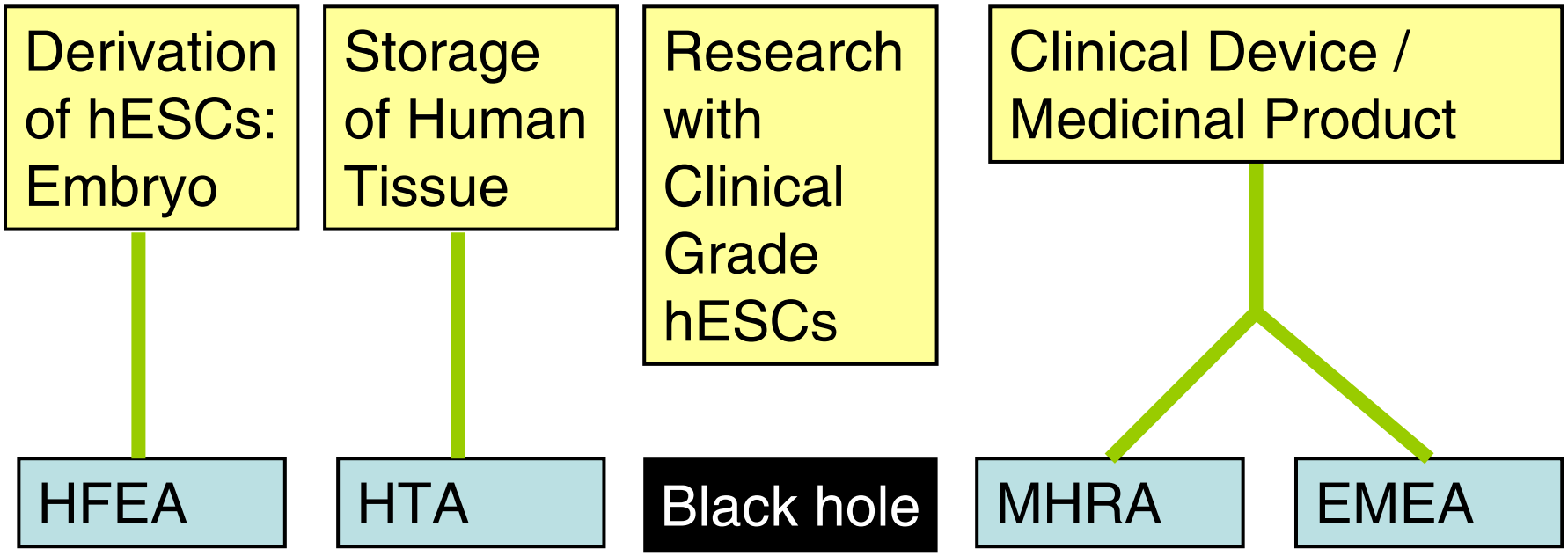
Conducted by Jamie Lewis

Focus on two locations of discussion around these issues:

Quality Forum at the UK Stem Cell Bank, Oct 2007

UK National Stem Cell Network annual meeting, Edinburgh, April 2008

Regulatory bodies present in debates about the UK stem Cell Bank



- Human Fertilization & Embryology Authority
- Human Tissue Authority
- Medicines & Healthcare products Regulatory Agency
- European Medicines Agency

UK Stem Cell Bank Interim Quality Assurance Programme

Ran 2006-2007

Ambiguity & Definitional issues

Medicinal product *or* raw material?

Unclear what the exact definitions of ‘raw material’ and ‘medicinal product’ will be in relation to hESCs.

Furthermore the form eventual therapeutic applications might take is unknown.

Problem of competing imagined futures and multiple expectations.

Hope & promise are important for enrolling resources to a scientific program and framing stakeholder engagement with an emerging technology.

Will hESC lines be used in therapy? Will they be disease models? What form might any of these take? Raw materials of medicinal products?

Imagined futures introduce uncertainties to the present.

Making sense of uncertainty: Regulatory Regress

Starting with Wittgenstein, as interpreted by Winch:

Rules do not include the rules of their own application.

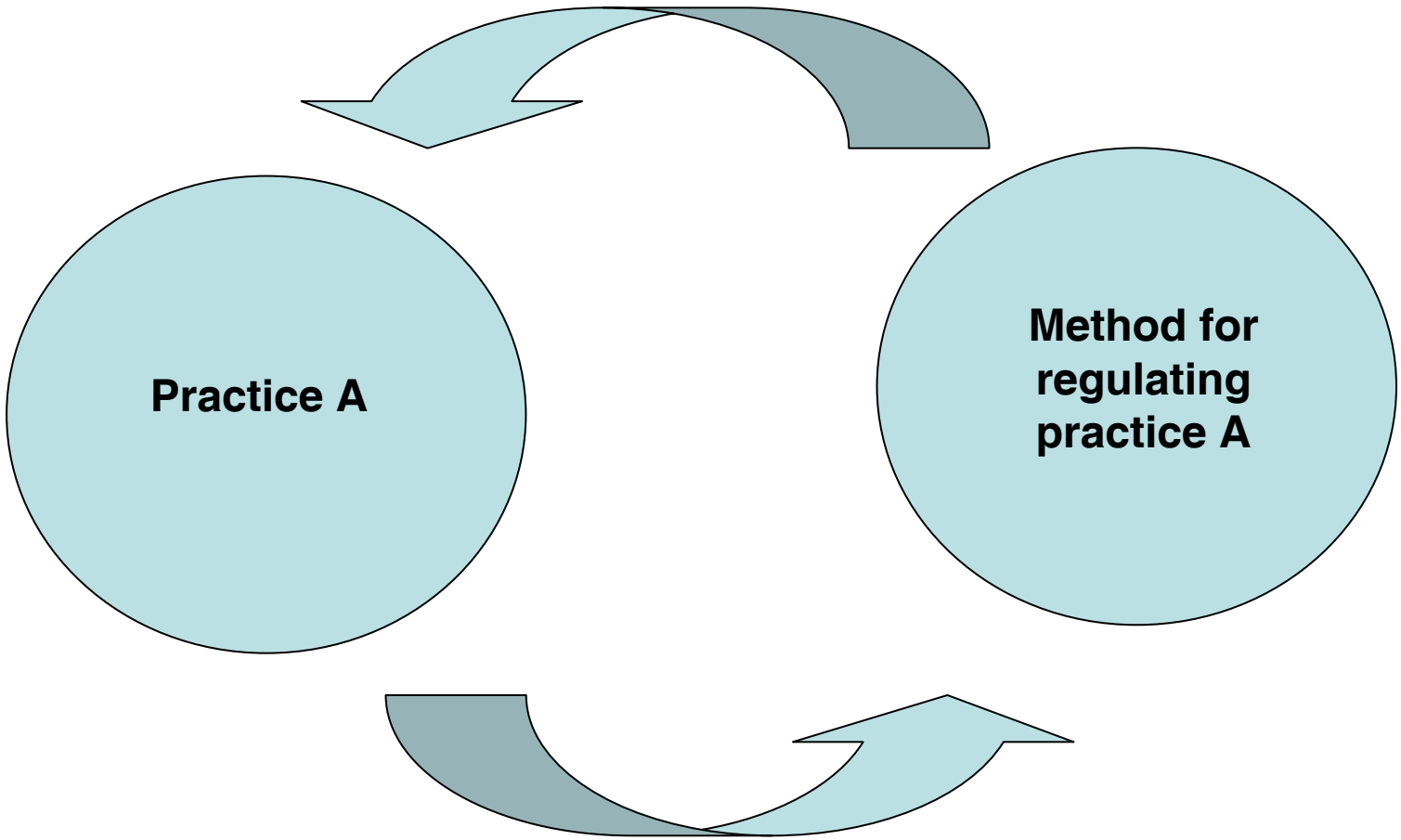
We want to argue that we have empirical evidence to suggest that:

Regulations do not include the rules of their own application.

In the case of the Regulatory Regress, we want to argue that:

Individuals can not know the correct interpretation of a regulation until the wider networks shaping its meaning are settled, yet these wider networks can not be settled until a correct interpretation is agreed.

Regulatory Regress



However, under Regulatory Regress the circularity can be broken; through micro-level social interaction and wider social shaping.

Signs of closing Regulatory Regress: Establishment of the Quality Forum

The UK Stem Cell Bank, working with the laboratories with a HFEA license to derive hESCs, have formed the 'Quality Forum'

Aim to:

- Write a Code of Practice for hESC GMP to be ratified by the HTA & MHRA
- possibility of self-auditing
- possibly introduce the Stem Cell History File

Who makes regulation?

In a traditional concept of regulation there are two clearly defined actors: the ‘regulator’ and the ‘regulated’. The difference between the two is one of power, scrutiny and accountability.

However, our empirical work demonstrates a spreading of autonomy between the two groups at these early stages of regulatory development, before the wider networks are settled.

Subsequently we want to introduce the concept of the ‘regulatory actor’: to encapsulate the shared roles and anxieties of those who are involved in the processes before the role of ‘regulator’ and ‘regulated’ have been settled.

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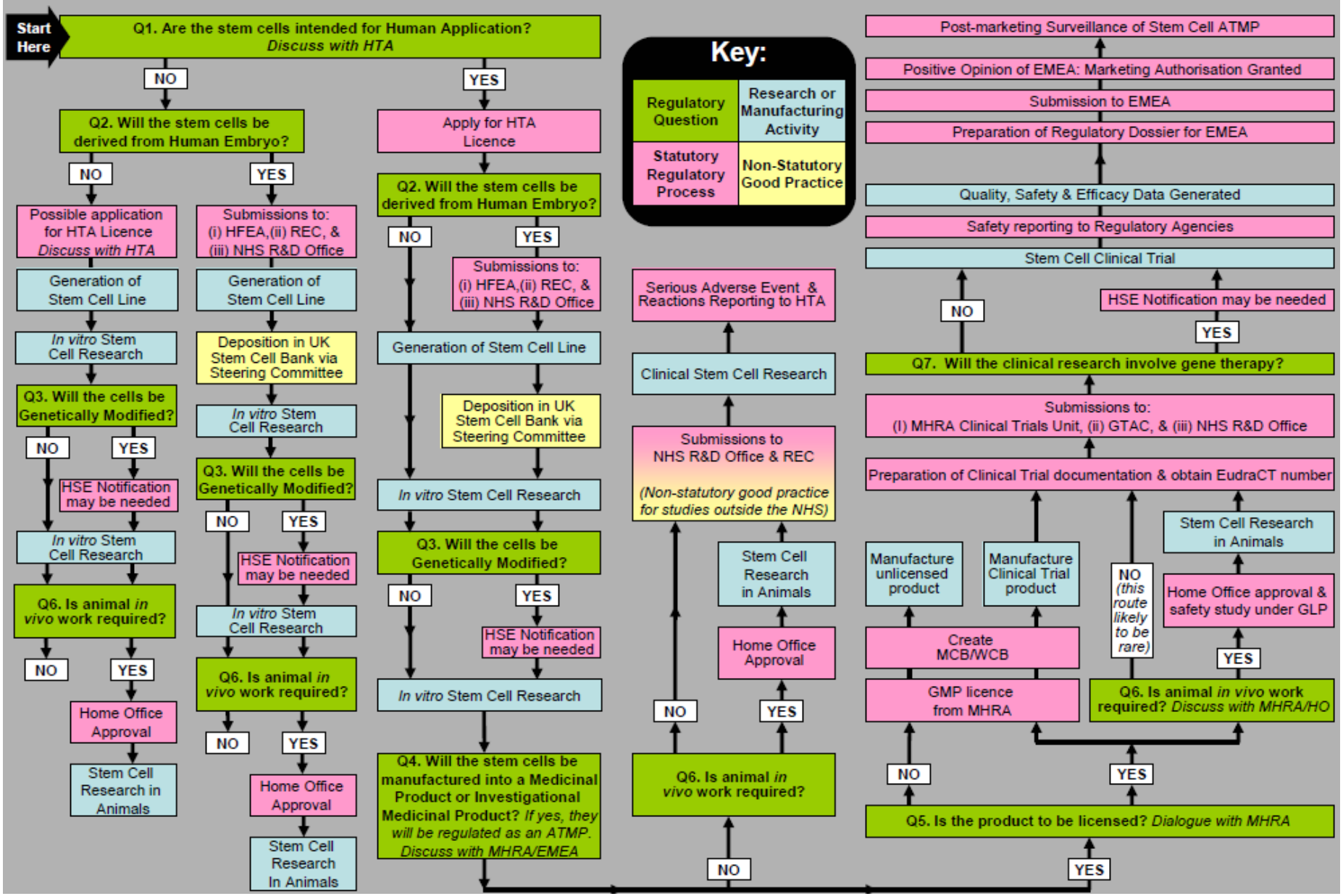

Conclusion

Competing imagined futures introduce uncertainty into the regulatory process

The circularity of needing the regulation before you can produce the science, but need the science before you can produce the regulation, can be termed Regulatory Regress

Under these circumstances of uncertainty the division between regulators and regulated is less distinct as both sets of regulatory actors engage with closing uncertainty.

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