“Your bits will be ready Tuesday” - Building a UK Manufacturing Industry in Regenerative Medicine

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www.cir-strategy.com/events

“Cellmate” – c.1993

Robotic Cell Culture – History and Context

- 1988 First four Cellmates built by TTP for EPO production for J+J at Celltech
- 1991 Eleven Cellmates for chicken pox/shingles vaccine for Merck
- Launched as a product in 1993 and TAP formed in 1998 as a TTP spin-out to exploit
- Now over 200 TAP robot systems around world producing biologic therapies, and cells for drug research
- Turned an art into a process and removed the witchcraft (but not the prejudice!)
- Showed production science had a place in cell culture

Stem Cells and Regenerative Medicine

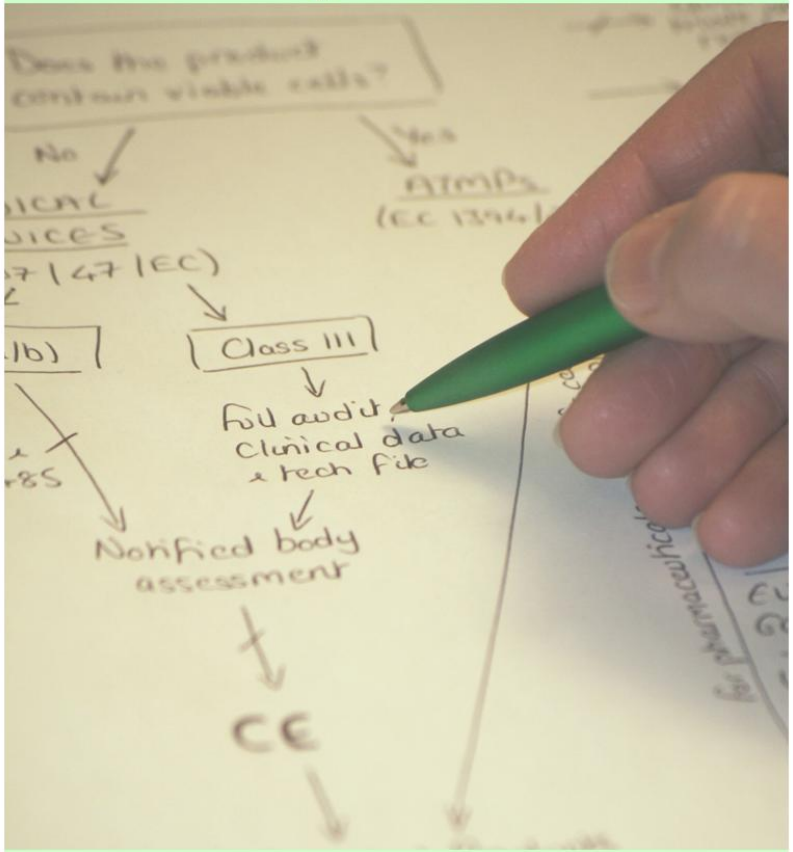
- 1990's science shows ability to isolate and propagate stem cells
- Capability to differentiate stem cells into many/all cell types
- Yamanaka showed that differentiation was reversible (iPSCs)
- Potential for both autologous and allogeneic therapies as one time "cures" (essentially spare parts as cells/tissue/organs)
- BUT
- Instability of culture processes and lack of scale
- Lack of relevant process and characterisation tools
- Complex regulatory and ethical issues
- High investment in basic science research, but little in exploitation and supporting technologies

remedi project – How to build a UK Industry in Regenerative Medicine

- 2004 EPSRC funded Grand Challenge Project (£8m)
- Soft and hard issues – policy, regulatory, process development, clinical adoption, health economics, analytical tools
- 11 academic centres, led by Loughborough University
- Important papers showing that stem cell production and scale up is tractable and capable of optimisation
- IfM policy paper for *remedi* mapped out key steps for Government and the potential for the UK to take a lead and secure a significant industry

building a viable regenerative medicine industry

a guide for stakeholders

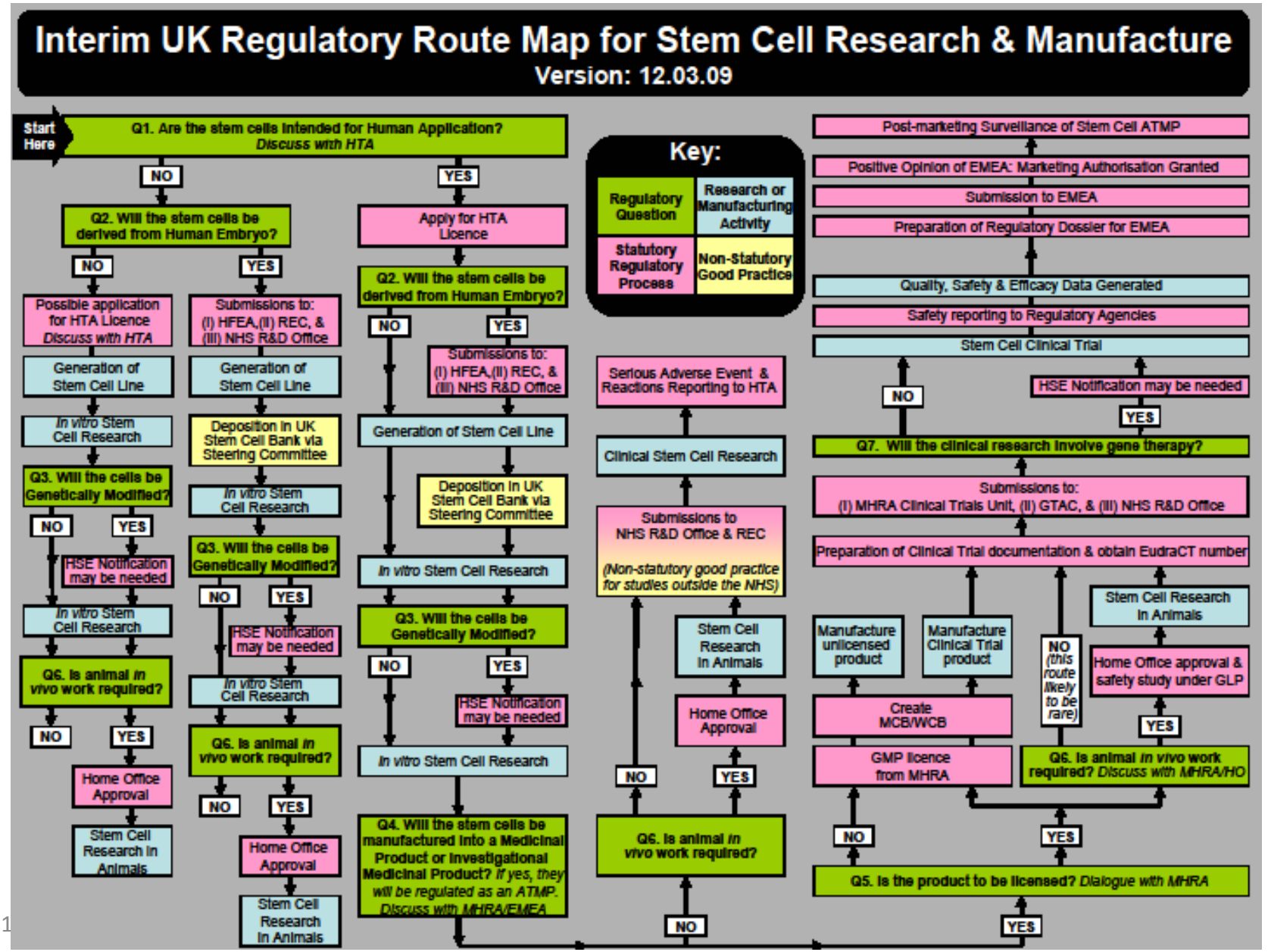


edited by David Williams, Richard Archer and Adrian Dent

Parallel Developments

- East of England Stem Cell Network explores opportunities to create a RM industrial base around Cambridge (2009)
- BIA forms trade association for RM (2008)
- Doctoral Training Centres for PhDs in RM manufacturing (2008)
- TSB encouraged to support RM, especially grants for clinical studies (2009 - £22m)
- Geron start first SC clinical trial in US for spinal trauma (2010)
- ReNeuron start first clinical trial in UK for stroke (2011)
- EPSRC Centre for Innovative Manufacturing in RM established as follow on to *remedi* – Loughborough/Keele/Nottingham (2010)
- Regulatory road map published by DoH (2009)

A Crystal Maze?



".....and though I walk through the valley of the shadow of death, I shall fear no evil..... venture capitalists

- Hermann Hauser produces report on Technology and Innovation Centres for Lord Mandelson/BIS, citing RM as example of a new industry candidate (March 2010)
- Hauser criteria for creating a TIC:
  - Strong, existing UK science base leading to a new industry
  - Absorptive capacity in UK ("capture the value stack")
  - "Grow and stick"
  - Multi £bn pa potential revenues for UK in 10 year horizon
  - Creation of "investable propositions" by TICs

Catapults

- David Cameron announces Government's support for TIC programme, through BIS, under TSB management (~ £200m, Dec 2010)
- HVM and Cell Therapy TICs announced in March 2011 Budget and further five "Catapults" later in year
- Inconclusive consortium bid process (UCL v Cambridge v Edinburgh) for Cell Therapy Catapult ("CTC") through 2011, so TSB initiate internally instead.
- Cameron announces London location for CTC as part of Autumn Statement on Healthcare (Dec 2011)

Creating the CTC

- Small team of consultants at TSB, overseen by Interim Advisory Group (January to May 2012)
- Recognition of need to create a new CT industry in UK, not just helping the small number of existing UK players
- £10m pa evergreen core funding, gearing to £30m pa
- Key need to show that the UK, as an integrated innovation system, can take RM from early academic/clinical science all way to routine adoption – demonstrate via pilot projects
- David Nicholson 2011 paper on NHS innovation policy a critical factor in feasibility
- Key need for manufacturing expertise and resources

Manufacturing Matters in RM

- RM products are difficult to manufacture
- RM services need strong logistics
- COGs are potentially high, cf drugs and biologics, but labour costs are not critical
- Little standard process equipment and instrumentation
- Limited contractor capability
- Regulations are unclear and untested
- Production tools also needed for earlier stages of research and clinical trial development
- A licensed production facility is difficult to move offshore
- The money is in the making

Cell Therapy Catapult Capability

- Located at Guy's Hospital, adjacent to parallel academic and clinical facilities
- World class expertise in new team to undertake all stages of projects, from early evaluation of basic academic and clinical research ideas, through to Phase 2 clinical studies on the best
- Around 80 – 100 permanent staff, when complete
- Key expertise in programme selection, design and management
- Initial focus on Pilot Projects to demonstrate UK capability and build resources, all essentially foc to originator.
- Staged pipeline, with typically two projects pa completing clinical studies
- In-house pilot facilities for process and characterisation development work
- Commercial expertise to place successful investable propositions with conventional finance or acquisition partners in exchange for commitment to stick in UK.

Facilities:	Location
BRC Faculty of Translational Medicine, School of Translational & Experimental Medicine, GSTFT R&D, JCTO, NIHR L(S)CLRN, NIHR PCRN, NIHR RDS (London), Scientific Cafe, Seminar rooms	16th Floor
Clinical Research Facility , GMP Cell Therapy Suite, Immune Monitoring Core	15th Floor
Quintiles Phase I Clinical Trials Unit	14th Floor
GMP Pharmacy	13th Floor
Assisted Conception Unit (with GMP ES suite)	11th Floor
Genomics Core	5th - 8th Floor

The CTC Mission

- The Cell Therapy Catapult will grow the industry in the UK to substantial and sustainable levels by providing:
  - Skills and finance to take products into successful clinical trial, de-risking them for further investment
  - Clinical expertise and access to NHS clinical partners
  - Technical expertise and infrastructure to ensure products can be made to GMP and delivered cost effectively
  - Regulatory expertise to ensure that products can get to the clinic safely and in the shortest time
  - Opportunities for collaboration, nationally and globally
  - Access to business expertise, grants and investment finance so that commercially viable products are progressed and investable propositions generated