Innovation, regenerative medicine and redistributed manufacturing: a social science perspective

Targeted Healthcare Production Workshop
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SATSU
Science and Technology Studies Unit

Outline

1. Understanding innovation as a socio-technical process

2. Advanced therapeutics and Cell/Tissue based therapies: innovation spaces/niches

- **knowing your product (the relation between classification and regulation)**
- **understanding biovalue and markets**
- **knowing the UK reimbursement system**
- **understanding the adoption space in creating an effective niche**

3. Implications for Feasibility of Re-distributed manufacturing?

Targeted Healthcare?

Understanding context within which innovation occurs

Innovation and the Scrabble metaphor: ‘ A market is like a Scrabble board: there is no point in wanting to place an innovation that does not correspond to the possibilities it affords…no point in keeping aside the perfect word’ (Callon TCS, 2007)

Distributed (non-linear) model of innovation

Institutional workability

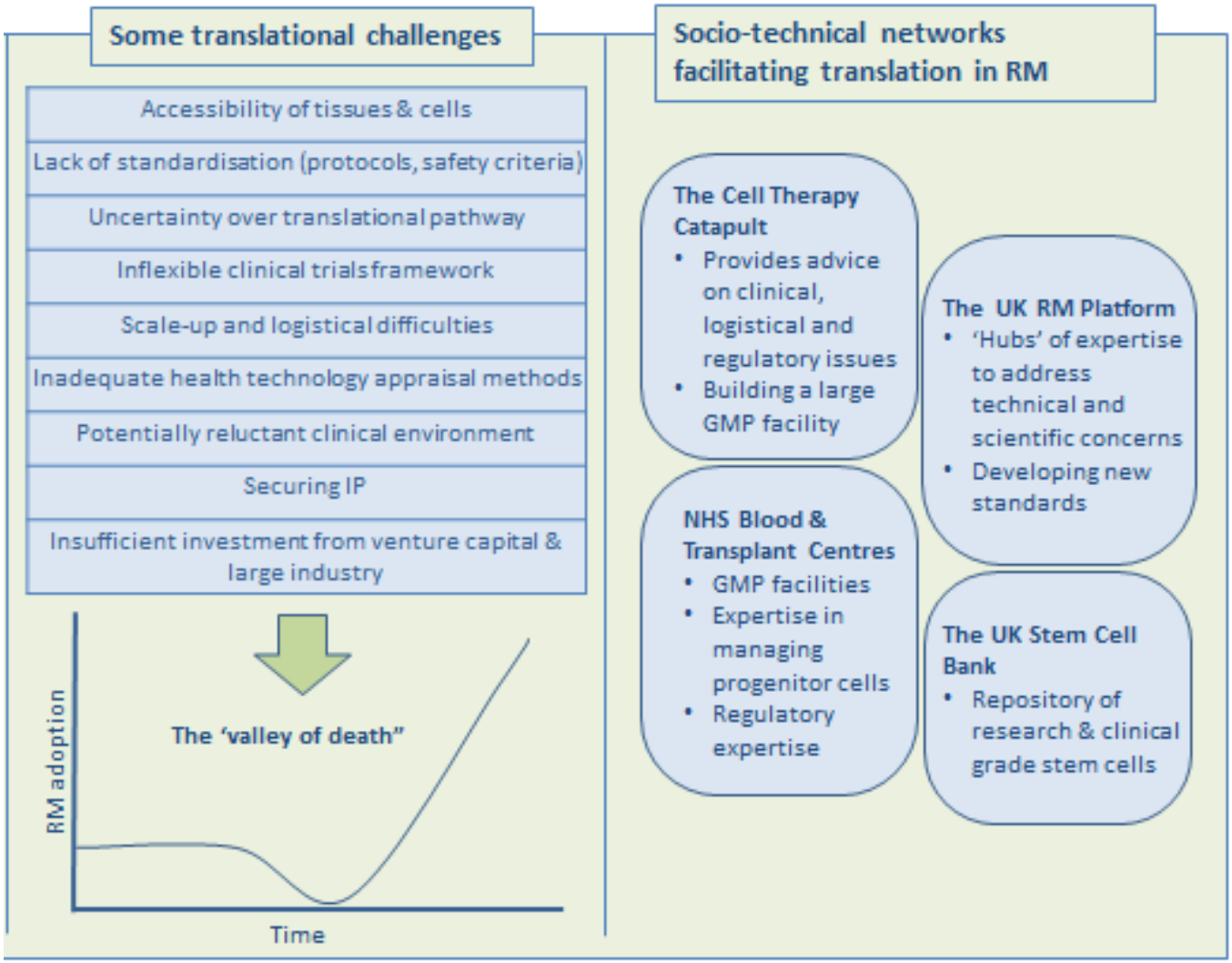
Innovation as a socio-technical process

Organisational – move from 'technological readiness' to 'institutional readiness' in the healthcare system

….from 'technically *working*' to 'institutionally *workable*' technology

(Govt response to HoL inquiry: establish a Regen Medicine Expert Group whose task is to develop 'delivery readiness')

Innovation challenges/ niches *enabling* RM



Source: Gardner and Mahalatchimy, 2015

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Institutional readiness and preparing for regen medicine: establishing *innovation niches* …*opening spaces for novel/radical innovation*

e.g. - biological niche – new clinical trials models
- regulatory niche – ATMP/ and NICE 'mock appraisal'
- institutional niche – CTC and NHSEngland's proposed sites for 'combinatorial innovation'

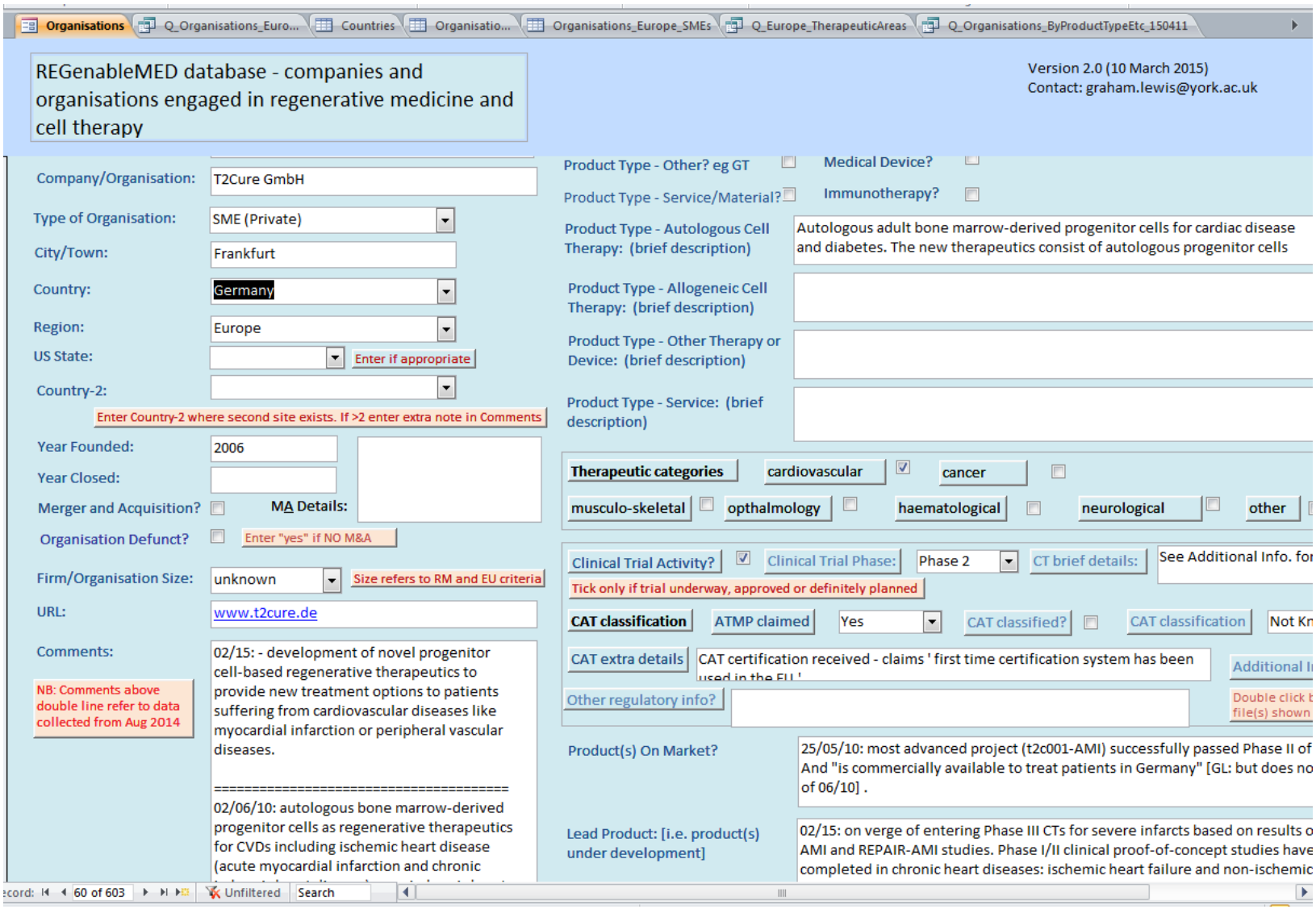
Advanced therapeutics and Cell/Tissue based therapies: what spaces/niches do we need to consider

Know your broad market niche: different possibilities for local, flexible, targeted medicine/healthcare because of different value chains:

- disease modelling
- drug screening and testing
- therapeutics
- services (reagents/materials)

SMEs said to be (have to be?) more flexible: typically one product and need to reconfigure this according to changing circumstances

REGenableMED database of RM organisations



Know the product you are manufacturing

Different classifications of product/different markets:

different product classification leads to different innovation paths and patterns of/possibilities for ‘re-distributed manufacture’

Healthcare products: overview

Medicinal Products

Primary mode of action: chemical

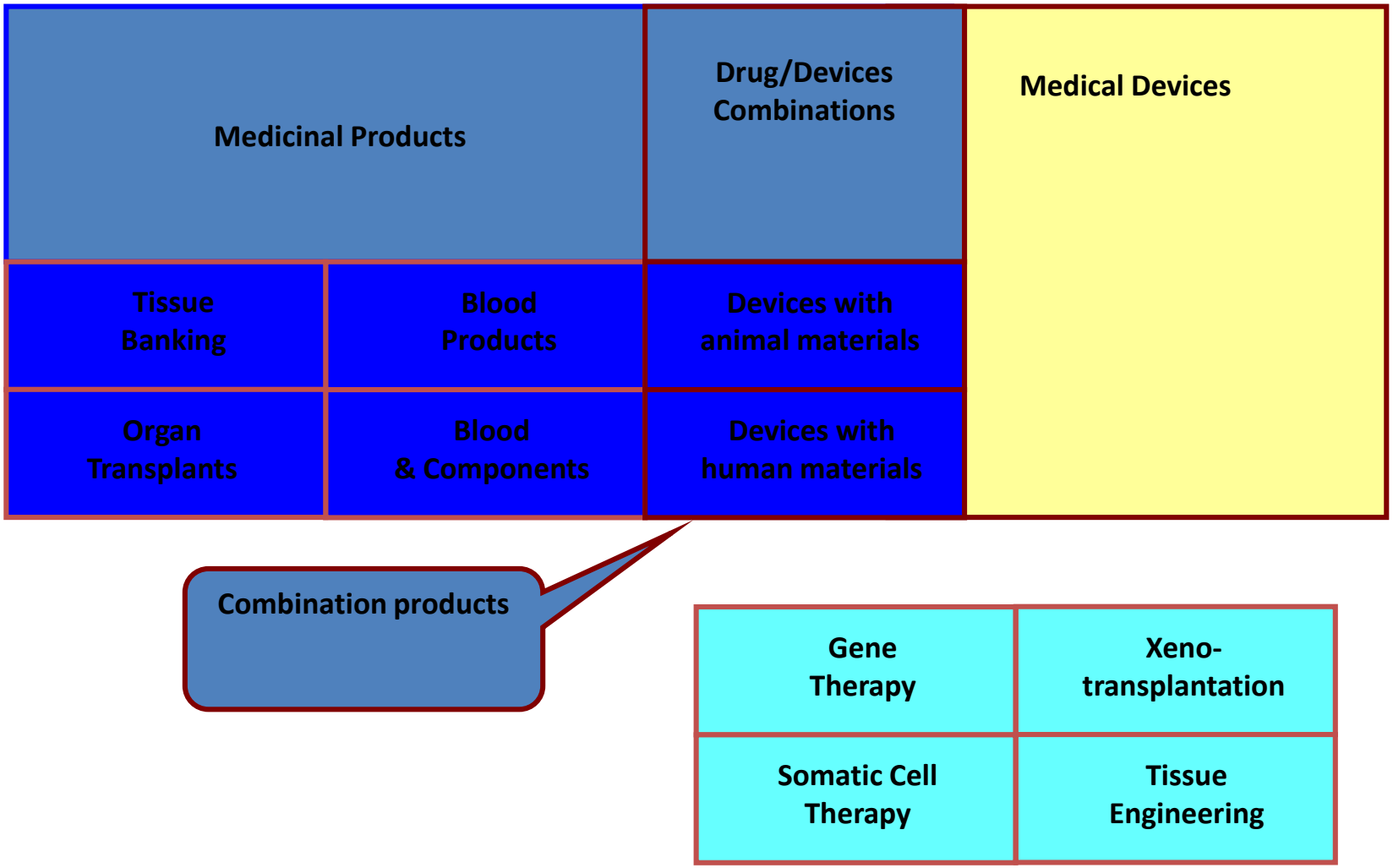
Medical Devices

Primary mode of action: physical

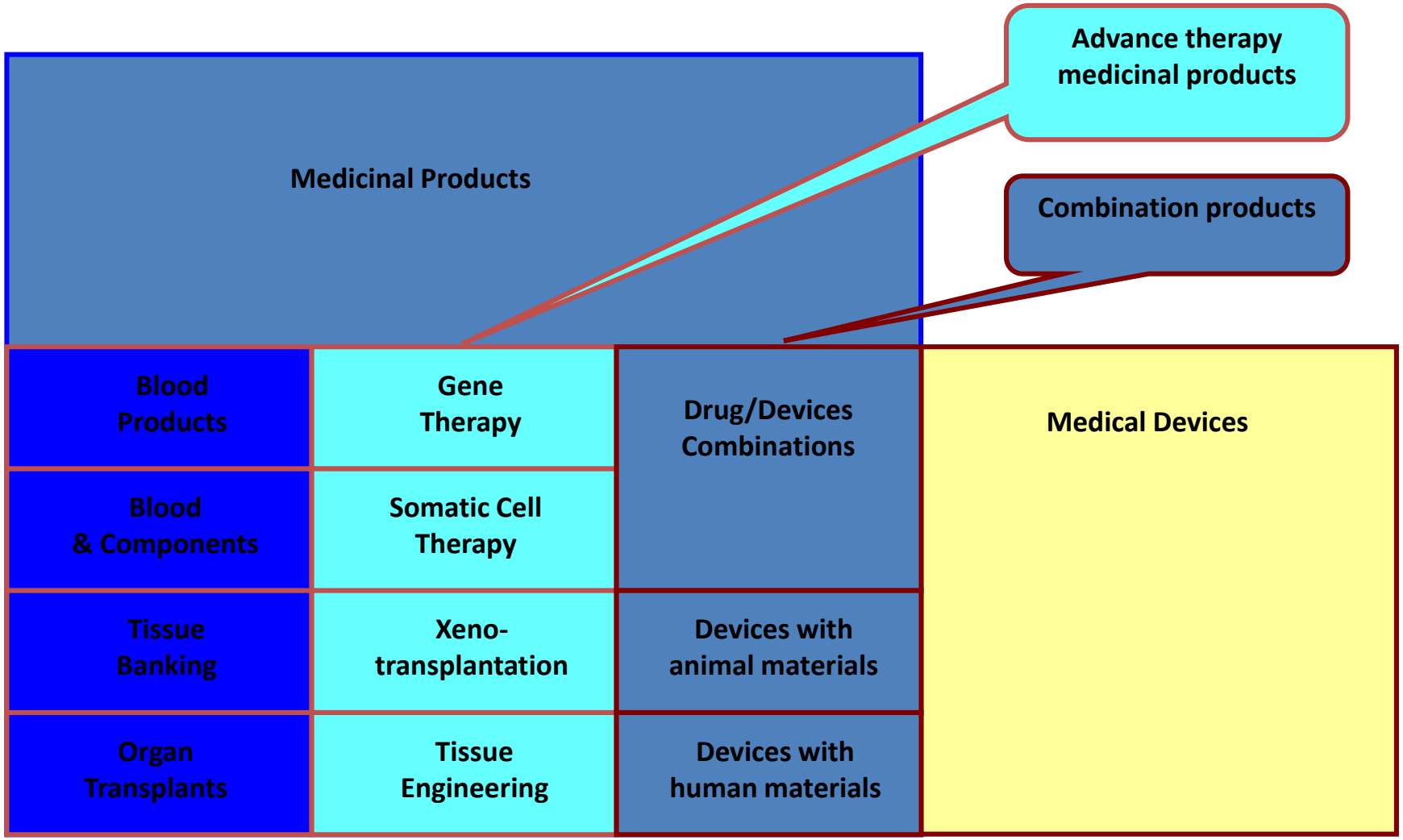
Biological
Primary mode of action: chemical

Tissue-based products
Primary mode of action: physical

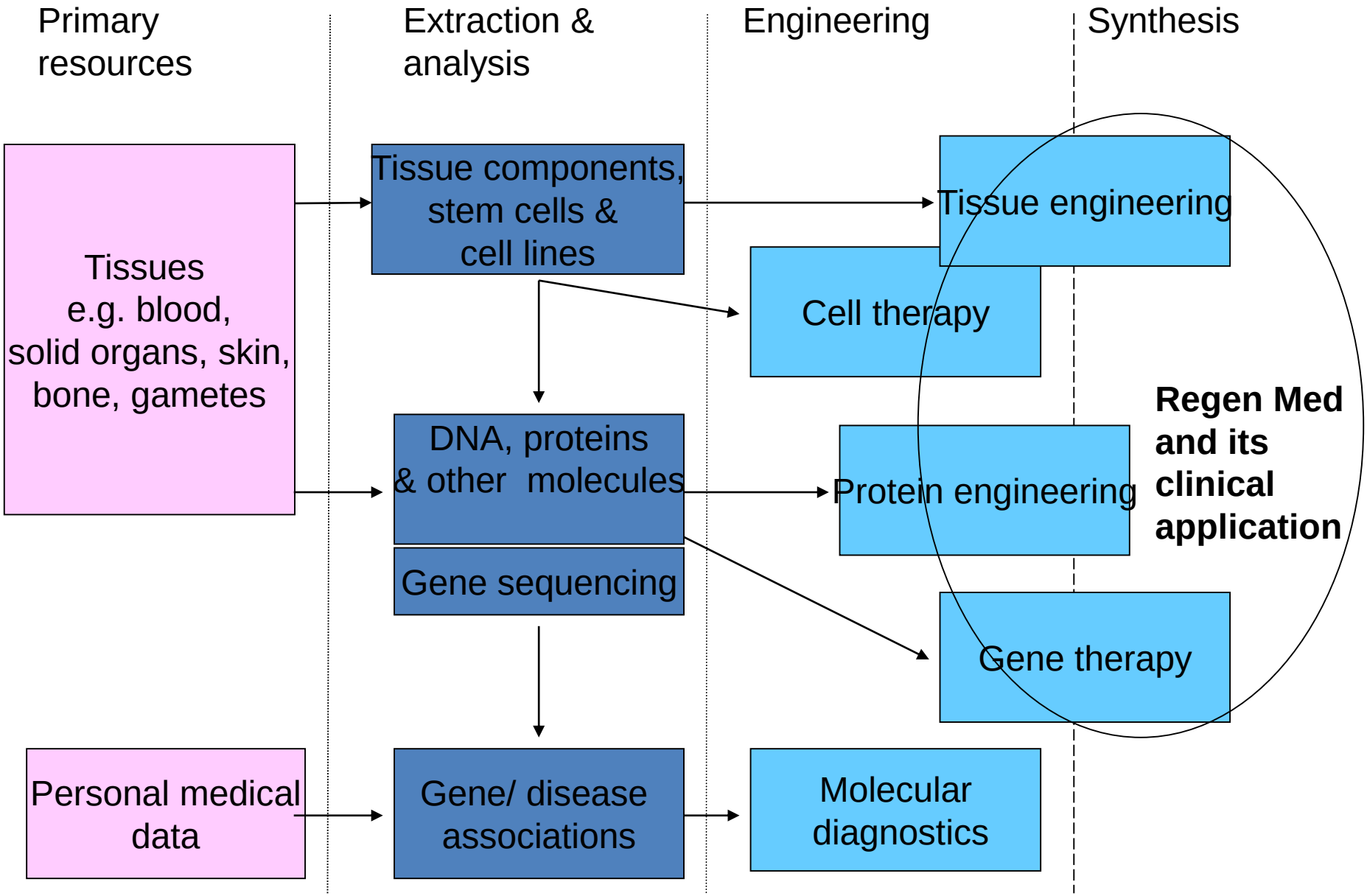
Healthcare products: overview



Healthcare products: overview



Vertical and horizontal chain of economic biovalue creation – bioeconomy market spaces for RM healthcare products



Regulatory spaces in the EU for tissue/cell products

- Centralised ATMP route
- Hospital exemption (national variation)
- 'Unlicensed medicines' ('Specials' in UK)
- Orphan designation
- Compassionate use
- 'Medical device' – decellularised/acellular product/process

The biological identity of Apligraf

-Viable human cells (keratinocytes and fibroblasts) cultured from neonatal foreskin on a bovine-based collagen matrix

The regulatory identity of Apligraf

Regulation

FDA – ‘medical device’

European Medicines Agency - ATMP

Effects of the ATMP Regulation

Hospital exemption route

Hospital-based

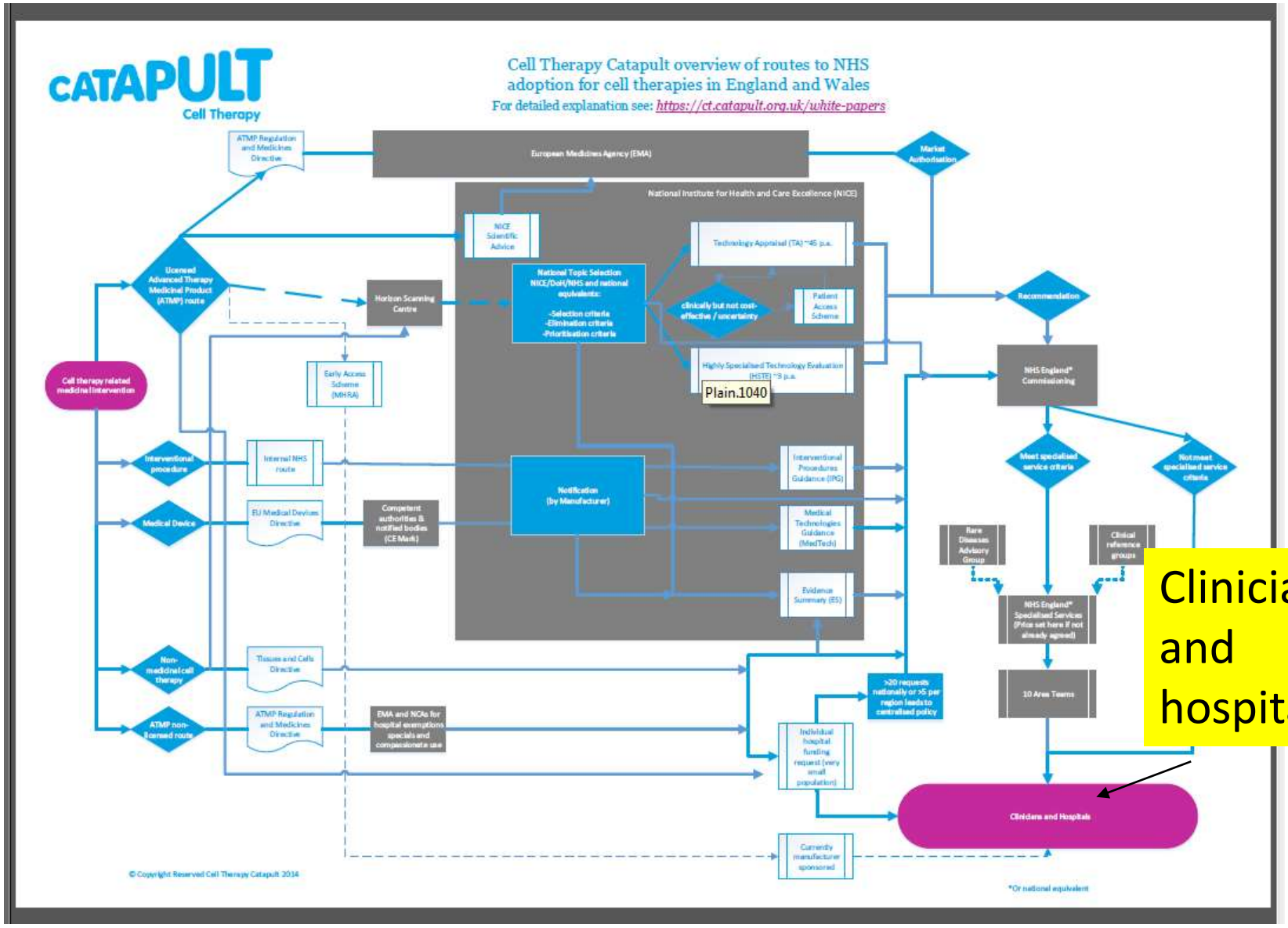
One-off

Individually prescribed

Non-standardised

Non-industrial

Knowing the reimbursement environment



‘Clinicians and hospitals’: Differing ‘adoption spaces’

		Robot	Spinal device	Cells	Coag	Pumps	Ultrs	ECG	CRP
Biography	Plausibility		?						
	Distinc/novelty	+		-			+		
	Visibility	+		-	(SM) -			-	-
	Rationale		-	+		+	?	-	
	Scope	+	-	-		+	?	+	
	Substitute or component	Subst	Comp	Comp	Subst	Comp	?	Comp	Comp
	Future	+			?	+	+		+
Effectiveness	Clinical			?	+	?	?	?	?
	Cost	-							
Utility	Clinical			?		?	?	?	?
	Organisational	+			+	+	?		
	Patient related	+	+		+		+	+	+
Risks	Clinical		-		(SM) -	?			
Requirements	Financial	-	-		(SM) -	-			-
	Use related			-	?		-	-	
	Organisational				(NPT)-	-	?	-	

(+): positive impact; (-): negative impact; (?): uncertain identity/impact; (SM): self-monitoring;(NPT): near-patient testing

Source: S. Ulucanlar , A. Faulkner, S. Peirce, and G. Elwyn, *Social Science & Medicine* 98 (2013) 95e105

Implications for Feasibility of Re-distributed manufacturing? *Distributed into what*?

Determining product classification as AT/CT
Demonstrating its stability (and comparability with approved reference cell line?) and clinical value
What location in the RM value chain?
Understanding regulatory implications (eg safety and efficacy requirements) and classification
Navigating pathway to and adoption space in the clinic

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