Knowledge transfer and exploitation of stem cell research

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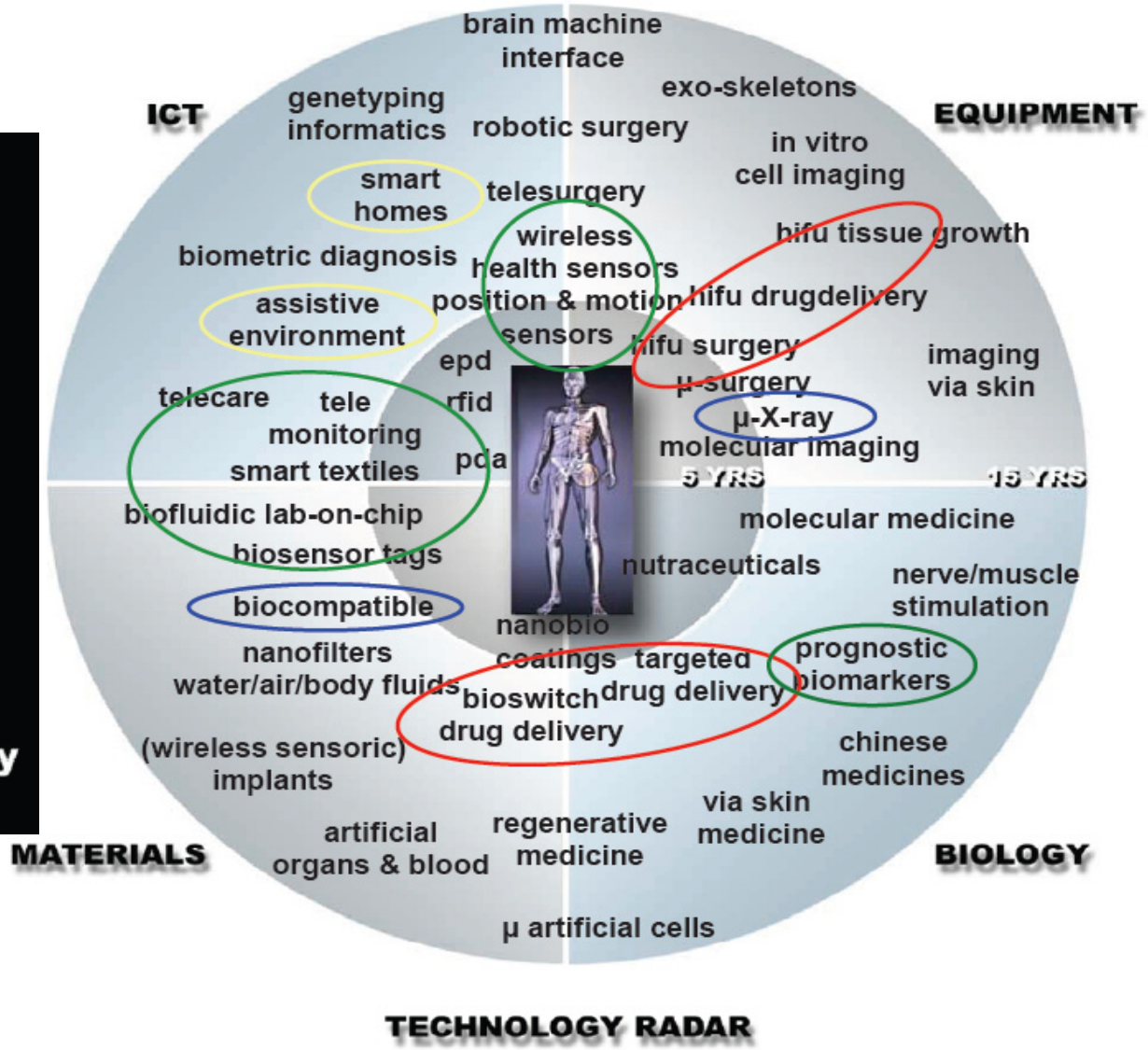
Business opportunities

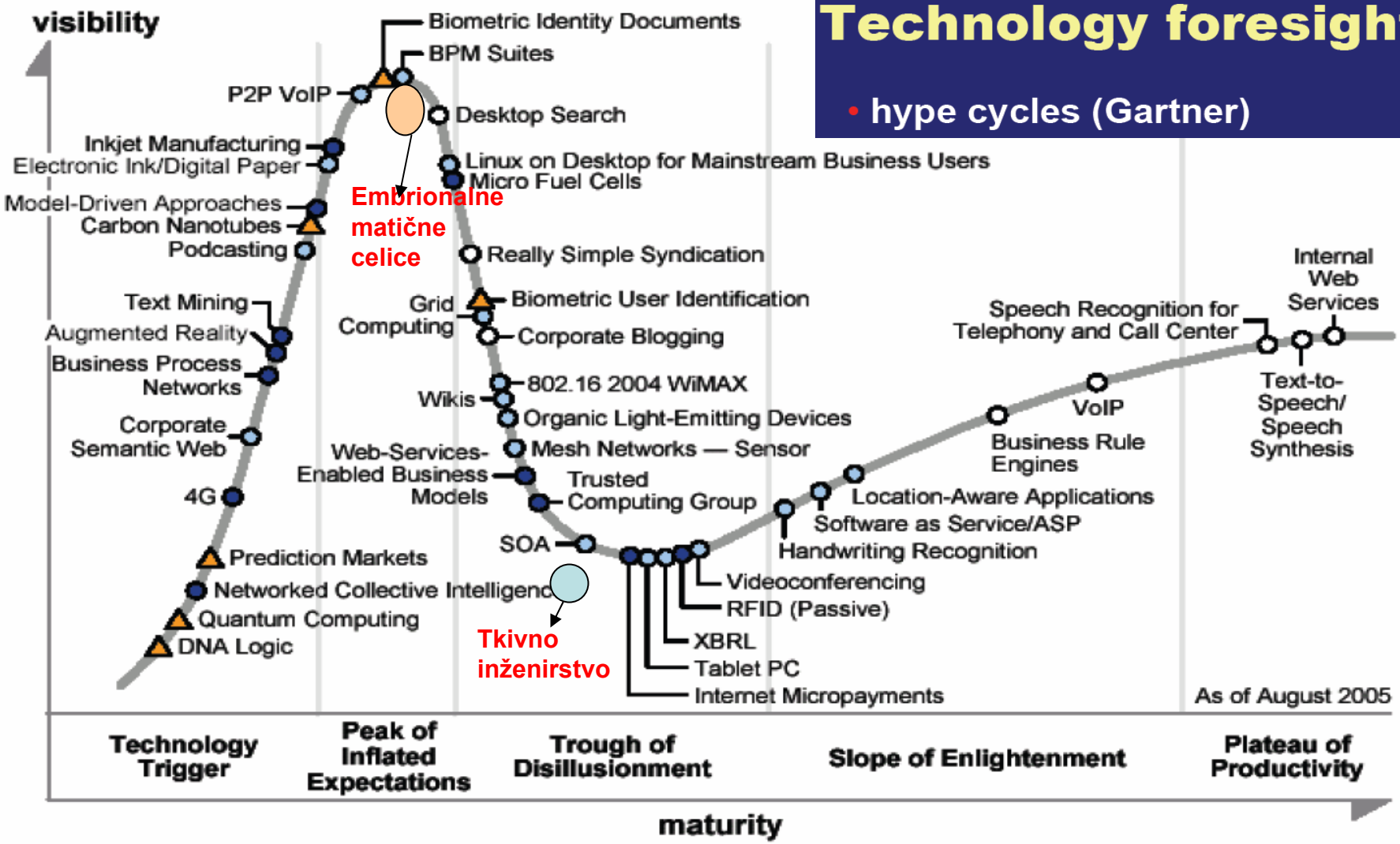
HEALTH CARE

- Less hospitalisation
- Homecare
- Elderly population
- Health IT
- Telemedicine
- Early diagnosis
- Drugs on target
- Minimal invasive
- Body repair & beauty
- Nanobio fusion



Technology foresight

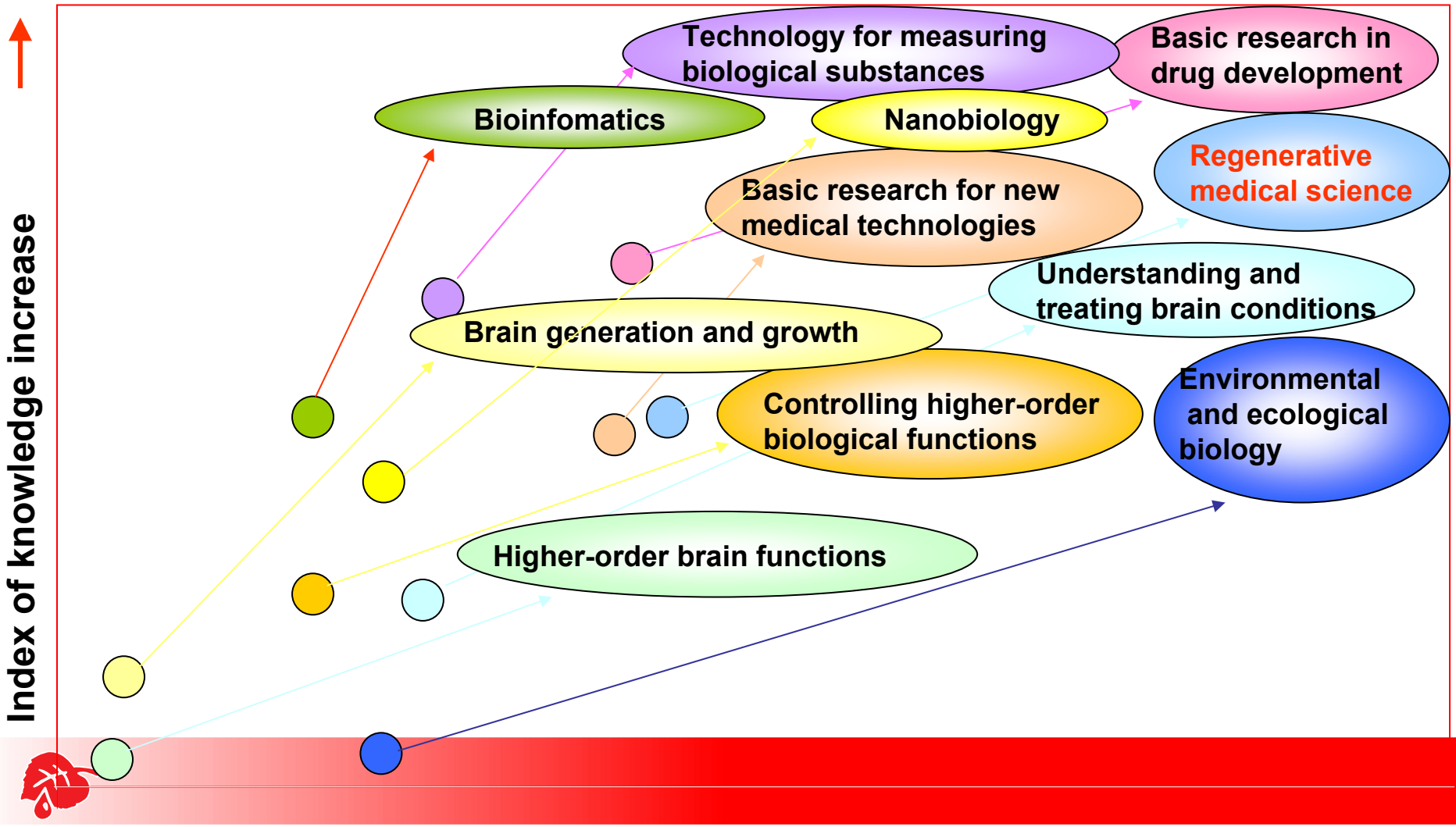
- hype cycles (Gartner)



Changing influence of Life science

before 2015

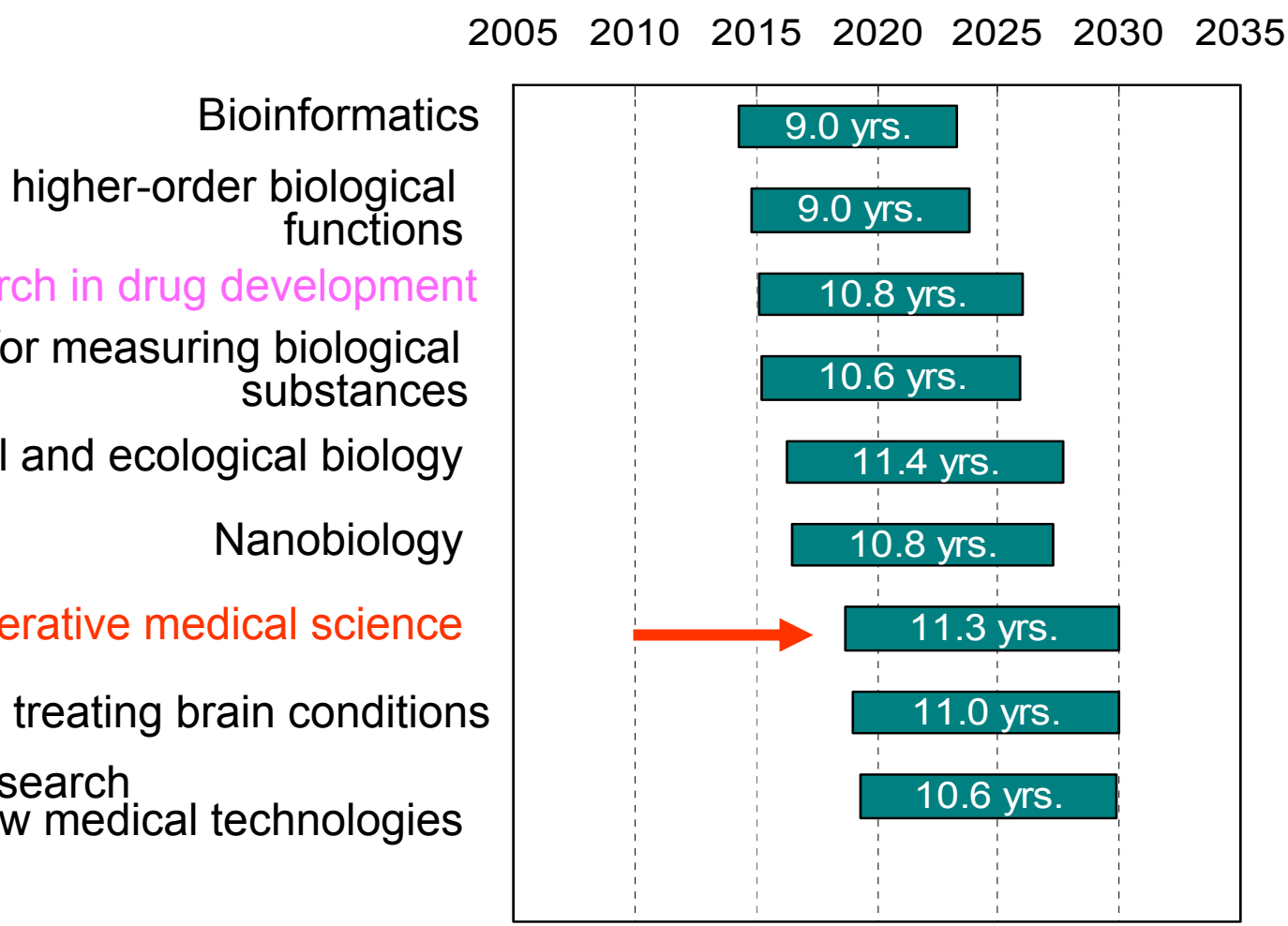
after 2015



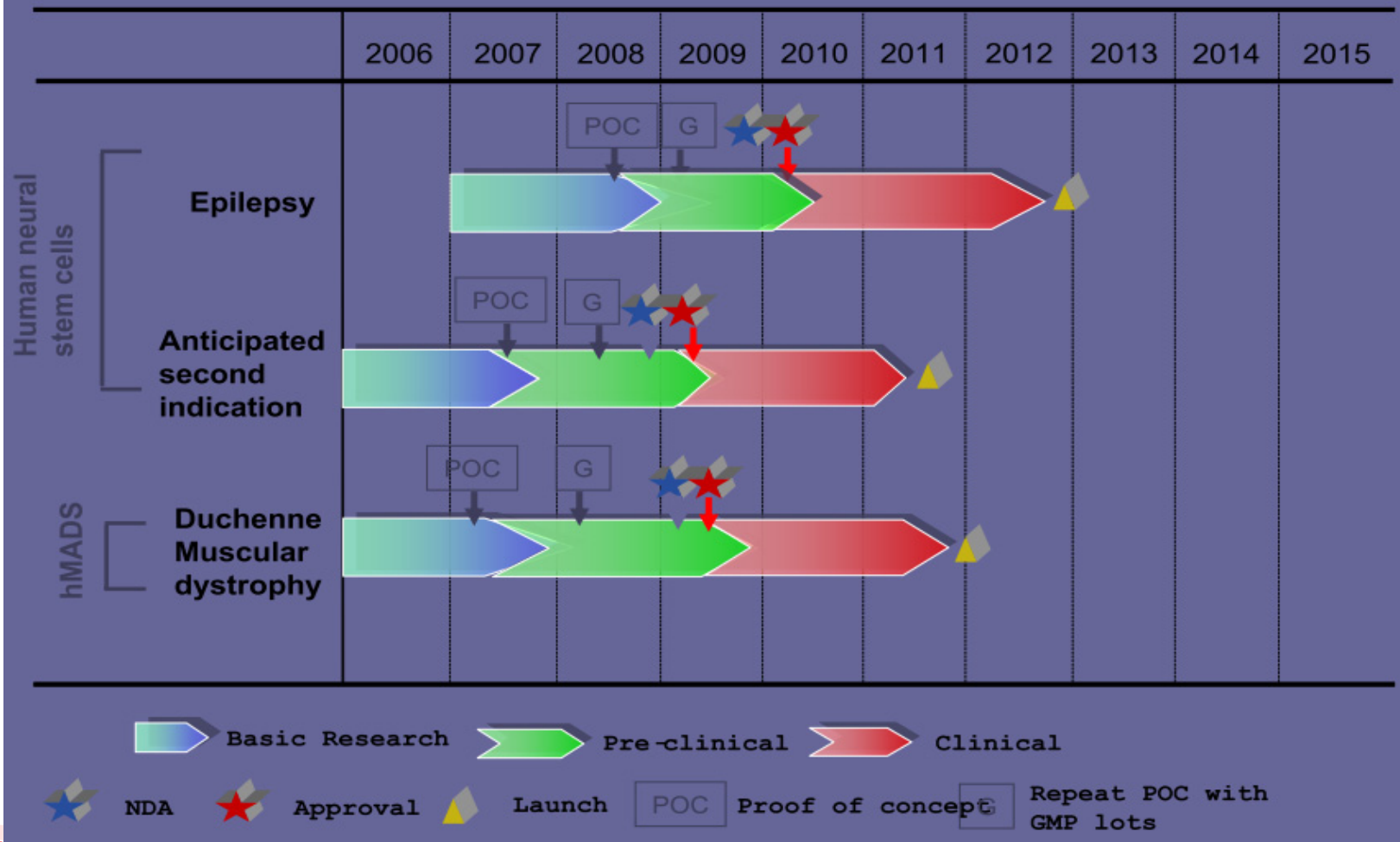
Expected time to realisation – Life sciences

Time of technology realisation

Used in real life



Stem Cell Therapy



Stem cells in medical use

Fundamental Ethical Principles at Stake.

(Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Nov. 2000)

"In the context of European pluralism, it is up to each Member State to forbid or authorise embryo research. In the latter case, respect for human dignity requires regulation of embryo research and the provision of guarantees against risks of arbitrary experimentation and instrumentalisation of human embryos."

The situation in EU

:

Legislation in individual countries incomplete, different.

The Oviedo Convention of the Council of Europe on human rights and biomedicine (1997)

Article 18: The creation of human embryos solely for research is prohibited.

About 30 states signed, 20 ratified

Protocol on prohibition of human cloning, 1998.

Second thoughts: have we overregulated?

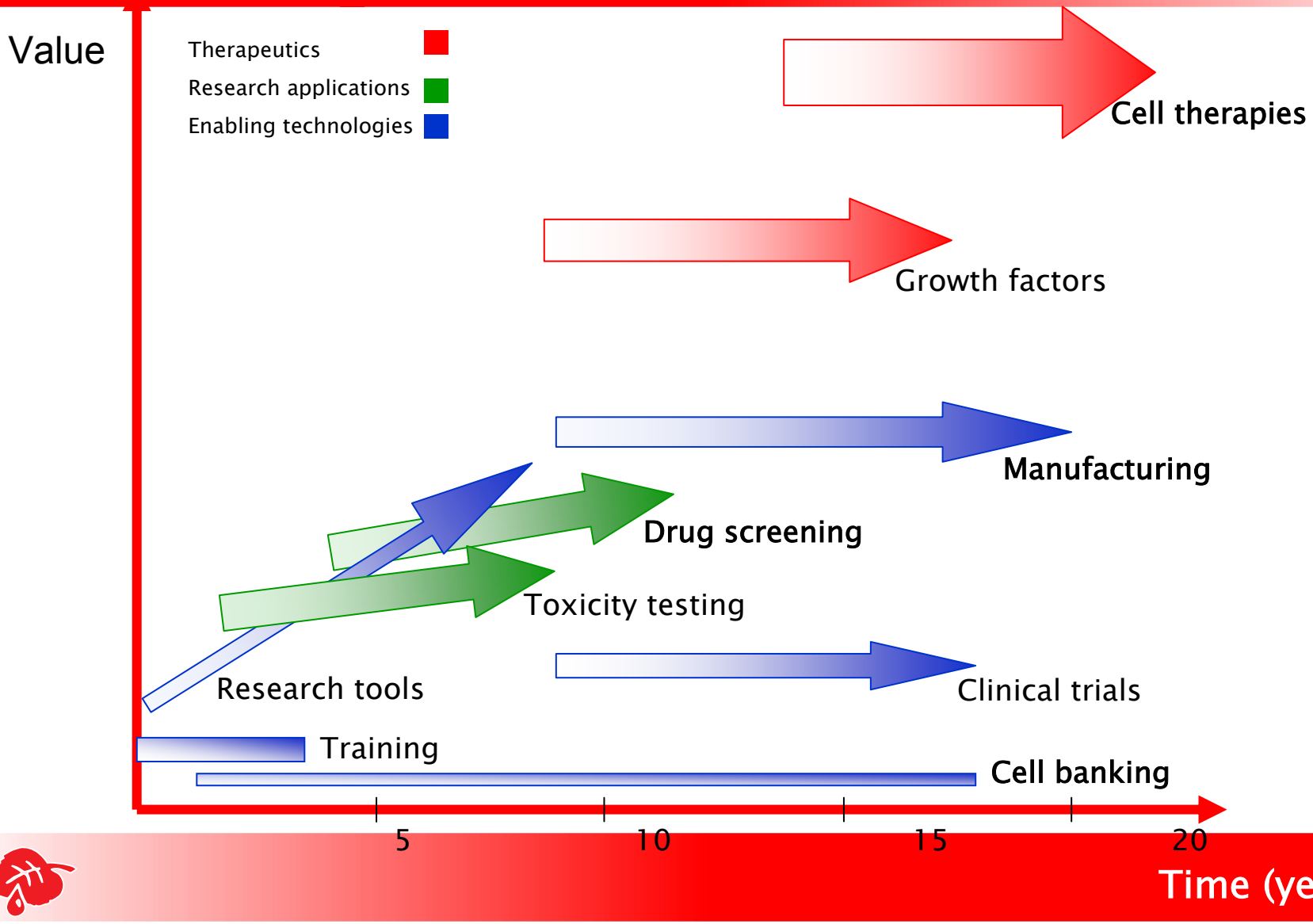
Pressures of the science lobby, industry, patients..

Regulation in EU member states re. embryonic stem cell (ESC) research (2003)

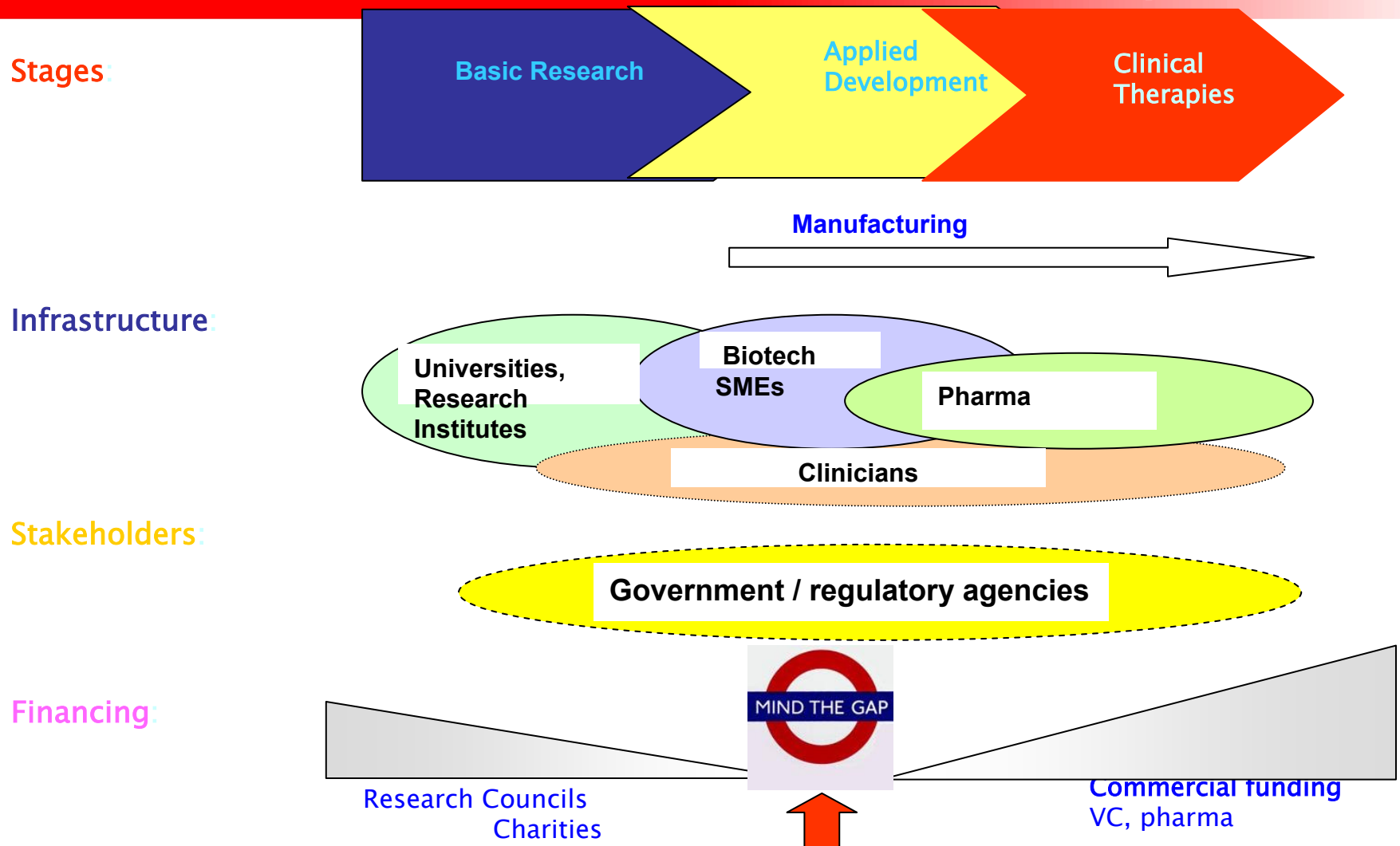
REGULATIONS IN EU MEMBER STATES REGARDING HUMAN EMBRYONIC STEM CELL RESEARCH

	AT	BE	DK	DE	ES	FI	FR	GR	IE	IT	LU	NL	PT	SE	UK
Allowing for the procurement of human embryonic stem cells from supernumerary embryos by law						X		X				X		X	X
Prohibition of the procurement of embryonic stem cells from human embryos but allowing by law for the importation of human embryonic stem cell lines	X		X	X											
Prohibition of the procurement of embryonic stem cells from human embryos					X		X		X						
No specific legislation regarding human embryo research		X								X	X		X		
Allowing for the creation of human embryos for stem cell procurement by law															X
Prohibition of the creation of human embryos for research purposes and for the procurement of stem cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on 4 April 1997	X		X	X	X	X	X	X	X			X	X	X	

Timescale for commercial opportunities



Translation of stem cell research into commercial products



Bench to bed side – work flow

- Isolate individual stem cell populations
- Ensure that cells retain their functionality and potential to differentiate

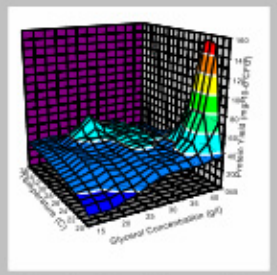
- Characterize & track stem cell populations
- Ensure that cells are "transplant" ready

- Culture stem cell lines in a stable, multi- or pluri-potent state, free from mutations & to sufficient quantity
- Enable Economical expansion to make cell-therapy a reality

- Control & activate stem cell differentiation to desired lineages
- Functionally active differentiated cells

Enabling technologies for Stem cell therapies

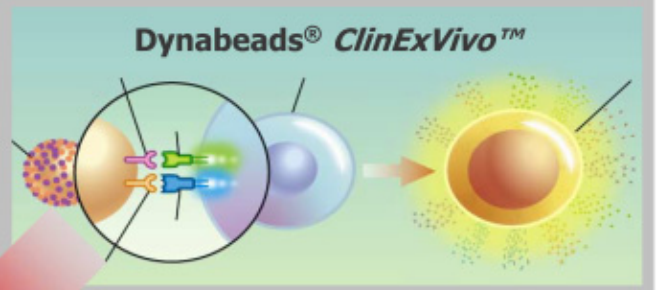
Economic Production of Large Quantities of Cells



Optimized media

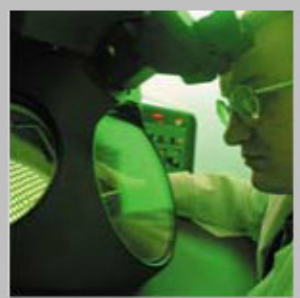
Process development

Isolation of Differentiated/ Desired Cell Types



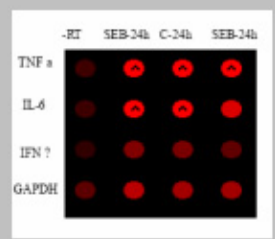
Research tools

Batch Release Testing



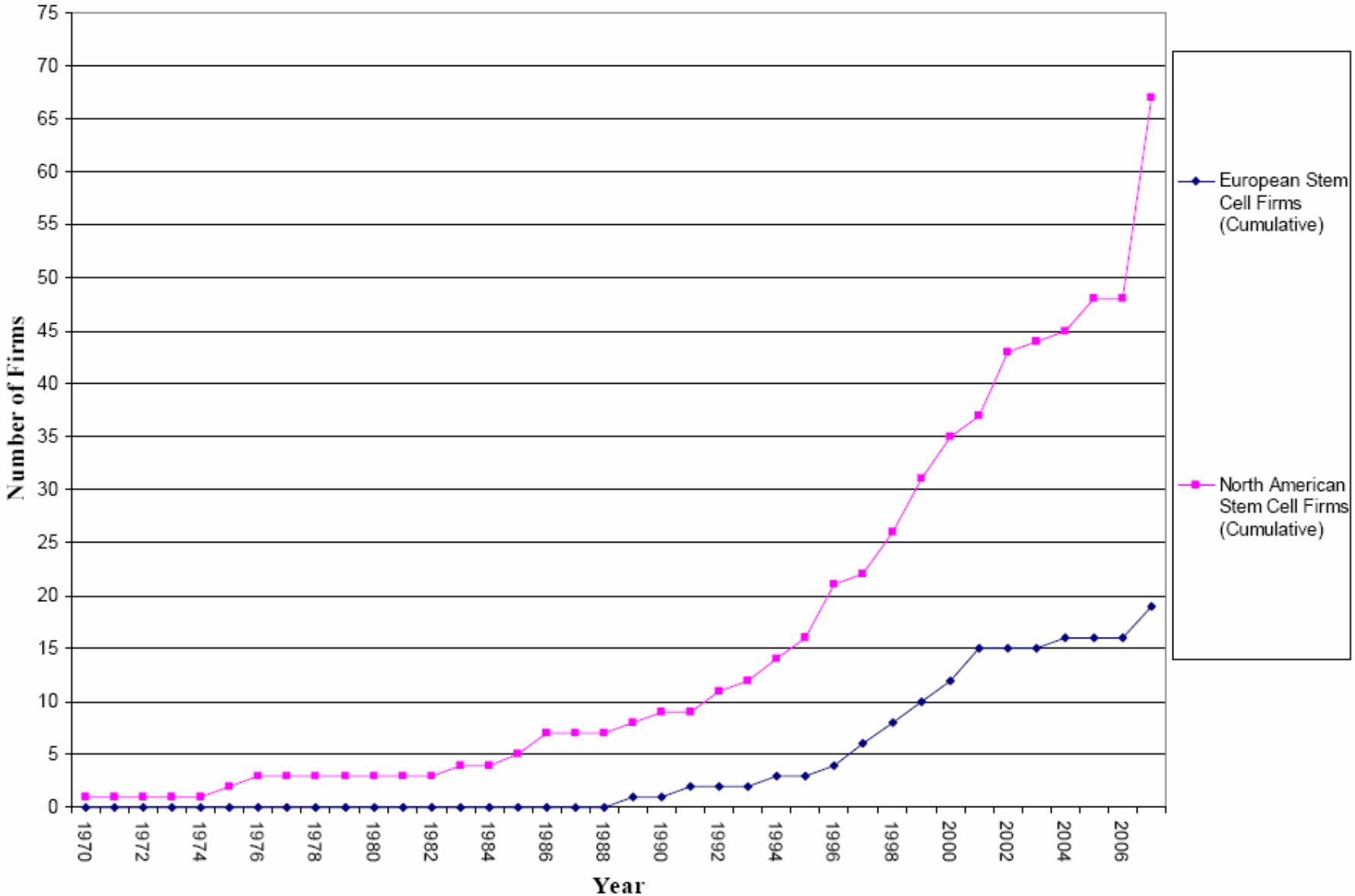
- Sterility/mycoplasma
- General safety
- Tumorogenicity
- Adventitious agents
- Novel cell-based test

Cell Banking / Characterization

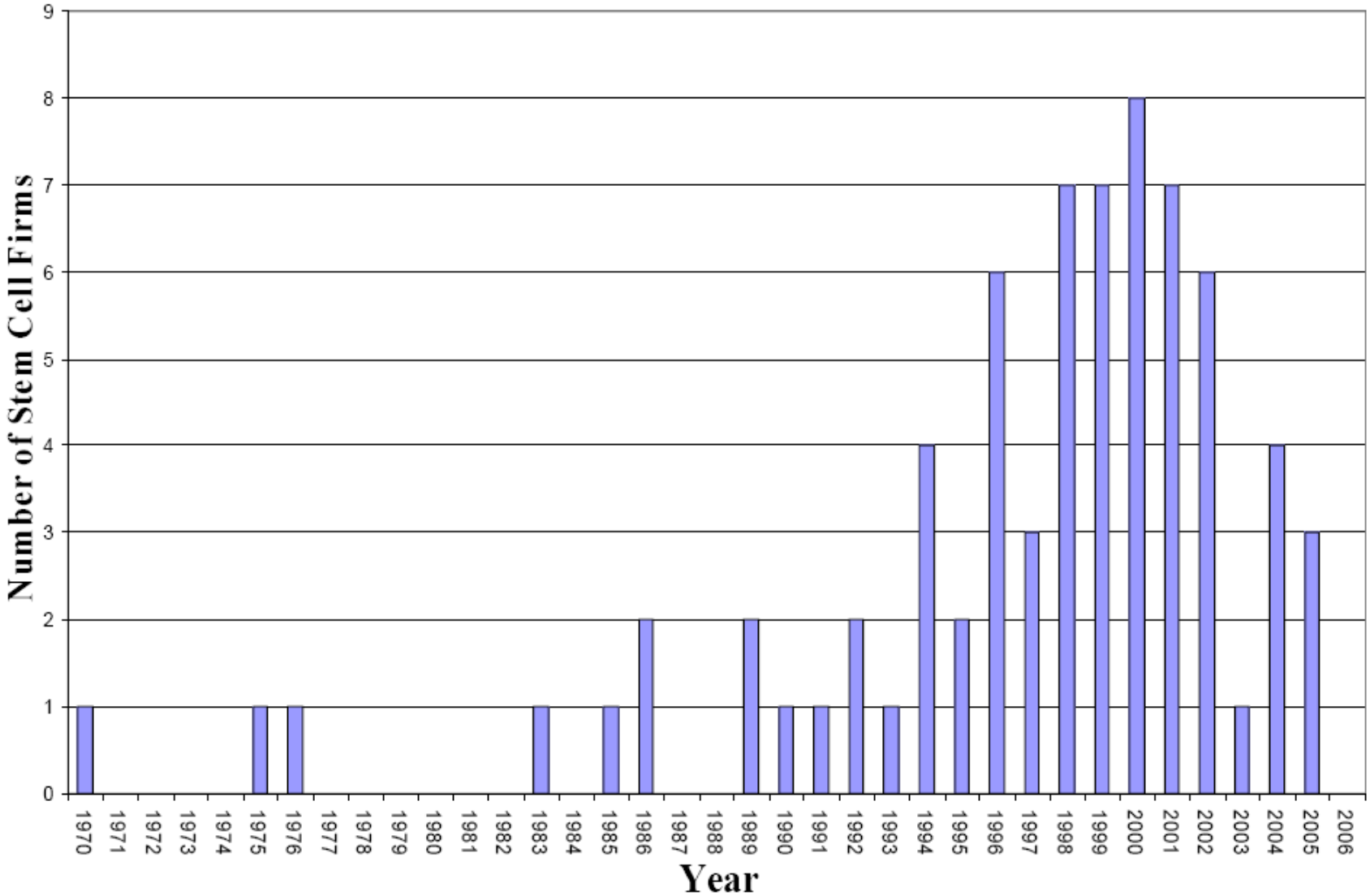


invitrogen™

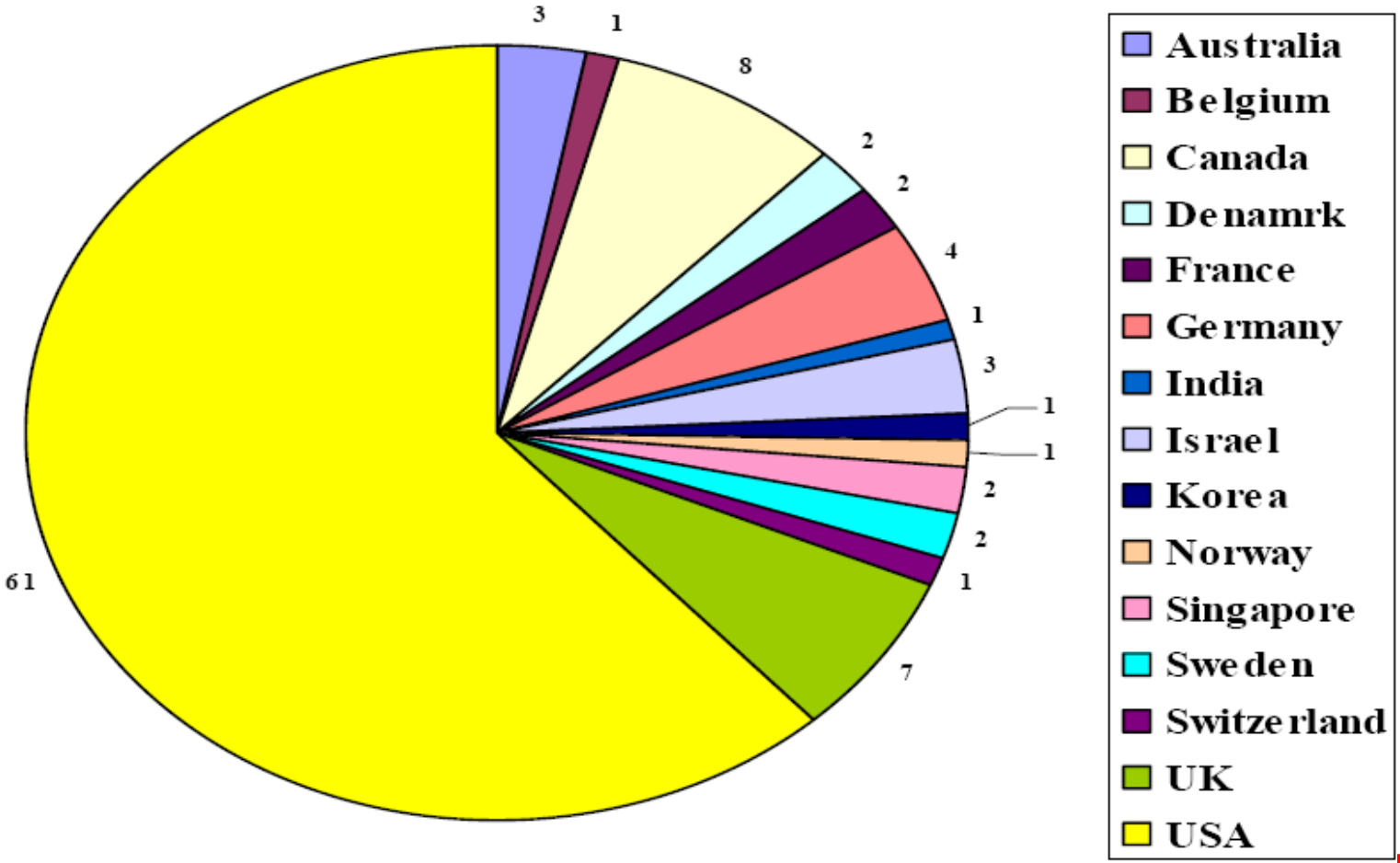
Growth of European & North American Stem Cell Firms



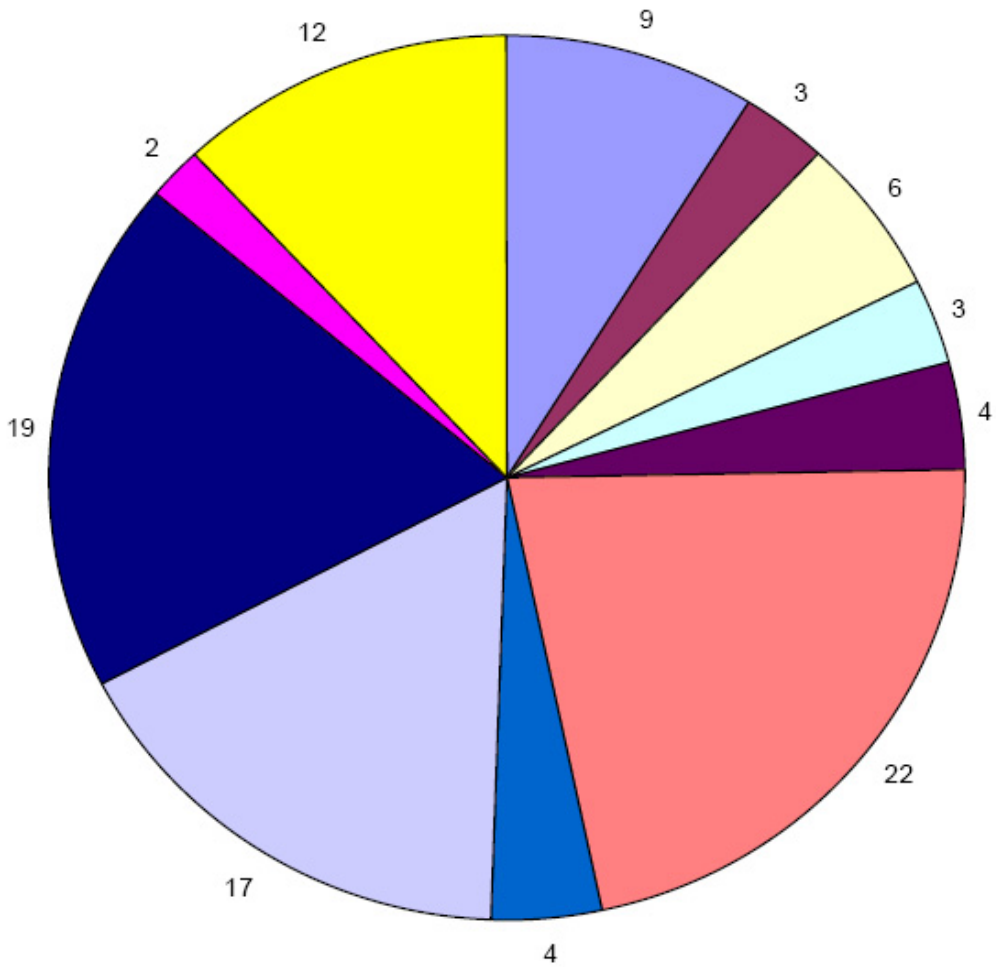
Number of Stem Cell Firms Founded 1970-2006



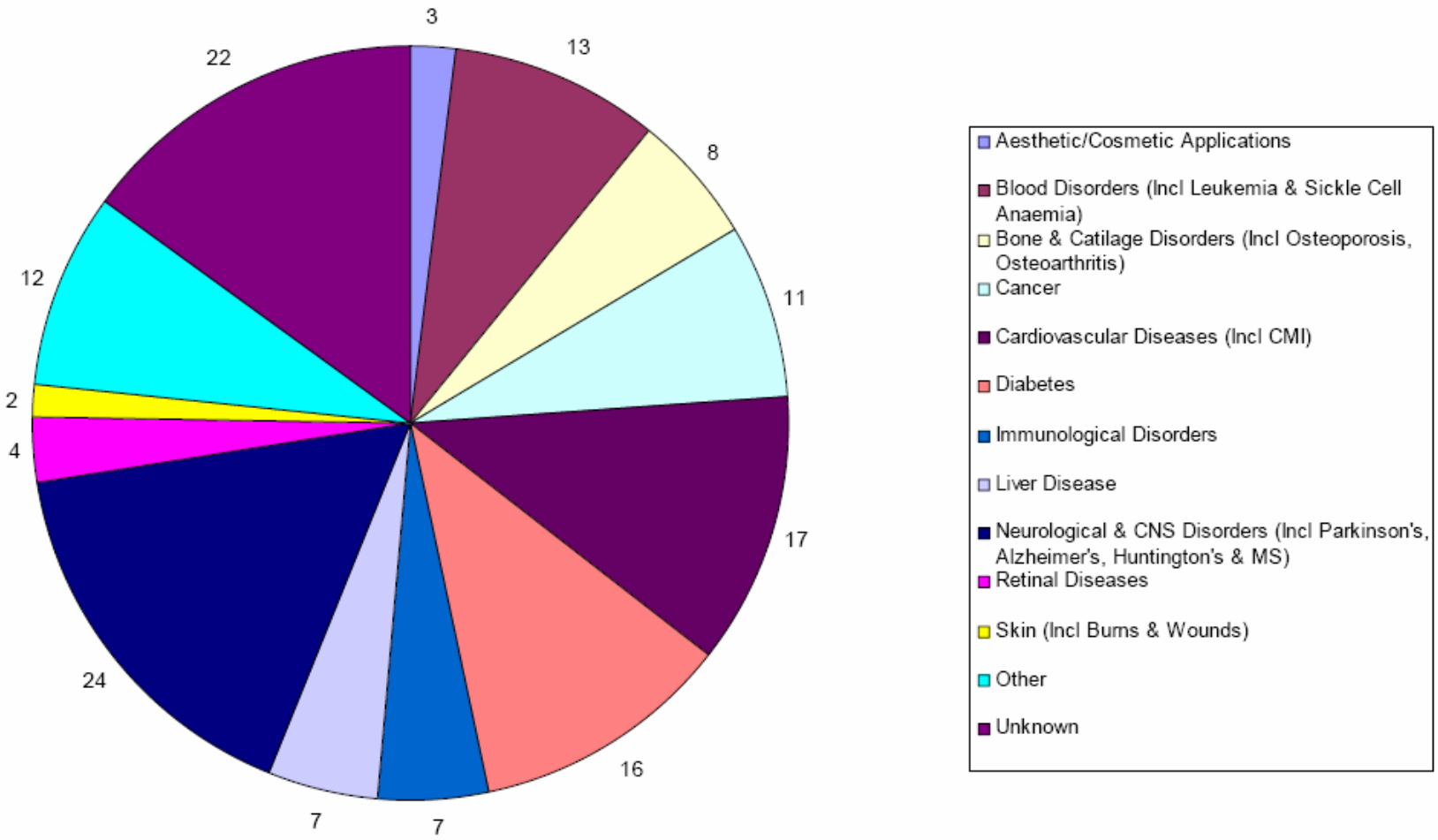
Distribution of Firms by Country



Stem Cell Types Being Developed by Firms



Disease Focus of Stem Cell Firms



Organisation types of stem cell legal entities

ORGANIZATION TYPE

- Enabling Service (407)
- Enabling Technology (641)
- Therapeutic (264)
- Consultant (109)
- Academic / Research Center (342)
- Network (29)
- Society (49)
- Investor/Venture Capitalist (25)
- Regulatory Body (99)
- Publication (52)

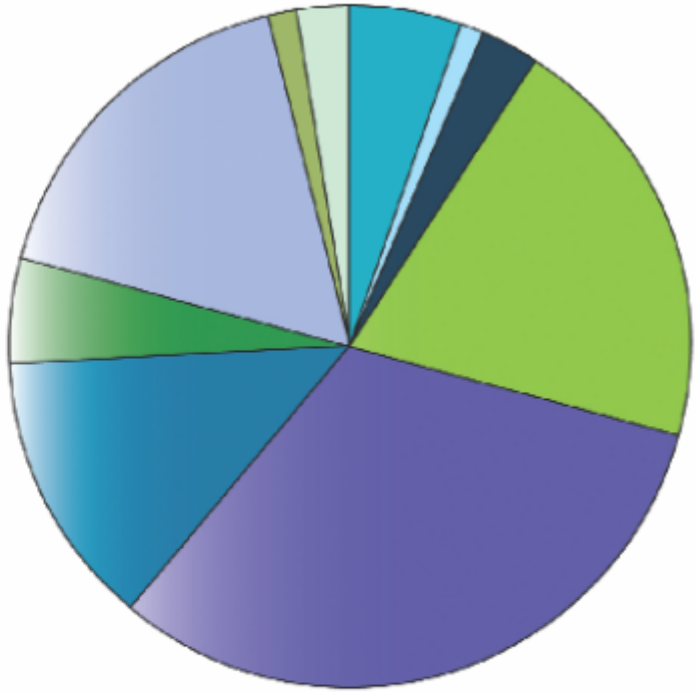


FIGURE 1

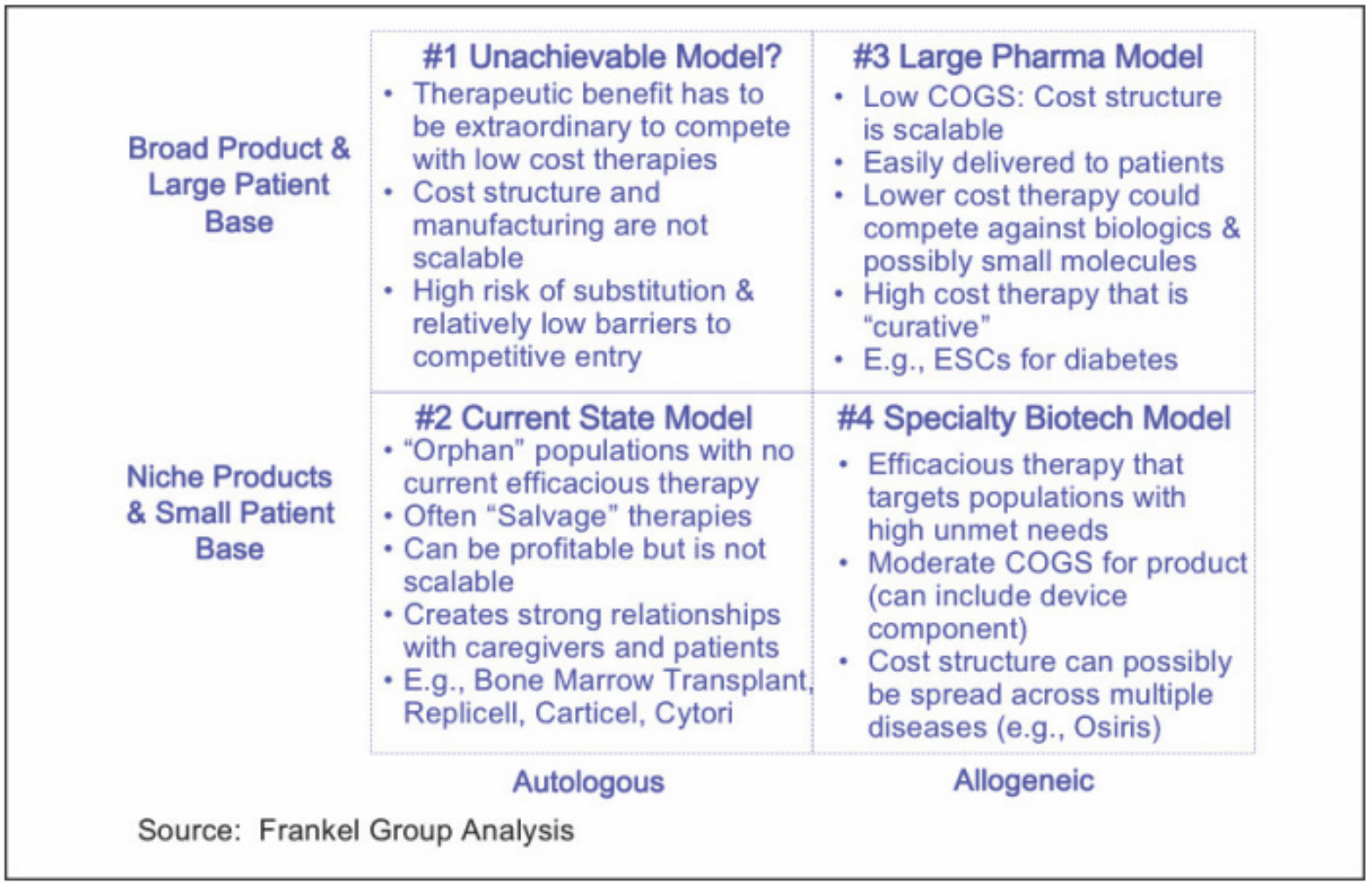
Top Ten Regenerative Medicine Products

Company	Product	Product Type	Therapeutic Area	Indication	Launch	2007 WW Revenue	'06-'07 Rev Growth
Medtronic	**Infuse**	Growth factor w/matrix	Bone	Spinal fractures, orofacial fractures, open tibial fractures	2002	~$700ME	18%
LifeCell	**Alloderm**	Allogeneic acellular matrix	Skin	Skin replacement / hernia repair	1994	$167.1M	40%
Genzyme	**Carticel**	Autologous cell based	Cartilage	Knee repair	1995	~$88ME	~30%
Stryker	**OP-1**	Growth factor w/matrix	Bone	Humanitarian Device Exemption for spine fusion & long bone fractures	2005	~$80ME	60%
RTI	**Spinal Implants**	Allogeneic Acellular matrix	Bone	Spinal fractures	1991	$41.1M	17%
Organogenesis	**Apligraf**	Allogeneic Neonatal cells w/matrix	Skin	Diabetic skin ulcers	1998	~$30ME	10%+
Advanced Biohealing	**Dermagraft**	Allogeneic Neonatal cells w/matrix	Skin	Diabetic skin ulcers	1997	~$20ME	10%+
Integra Lifesciences	**Various**	Allogeneic acellular matrix	Skin	Skin repair / replacement	2001	~$20ME each	25%
Osiris/ Nuvasive	**Osteocell**	Allogeneic cell based	Bone	Fracture repair	2005	$15.2M	83%
Cytori	**Celution**	Autologous cell based	Soft Tissue (adipose)	Reconstructive Breast Surgery	2008 (ex-US)	~$10-12M*	N/A

E=estimated from various sources
*=company projections for 208
Source: Company 10K Information, Frankel Group Analysis

FIGURE 2

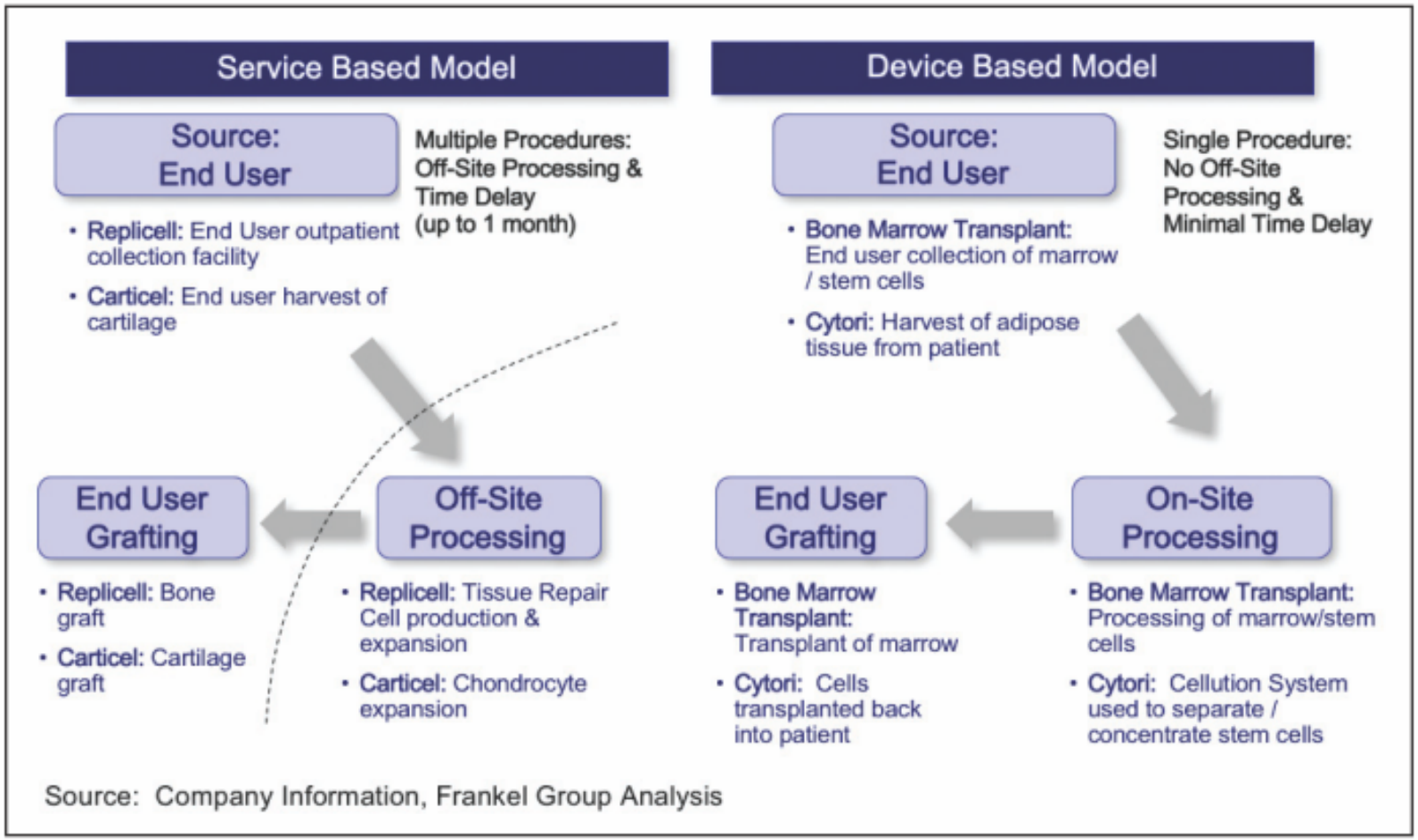
Cell Based Business Models



Source: Frankel Group Analysis

FIGURE 3

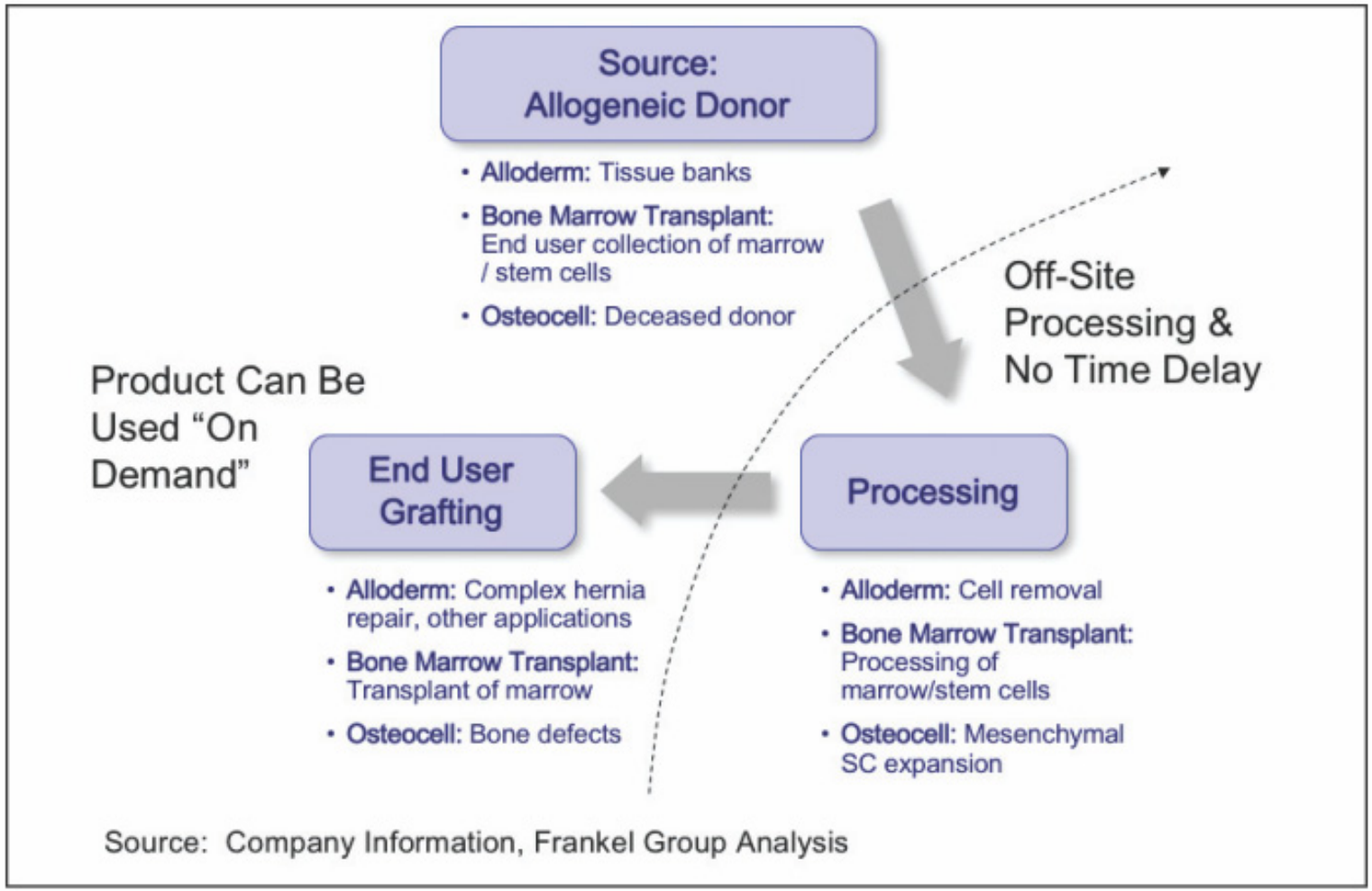
Today's Autologous Business Models



Source: Company Information, Frankel Group Analysis

FIGURE 4

Today's Allogeneic Business Model – Speciality Pharma Model



Source: Company Information, Frankel Group Analysis

Success is not final, failure is not fatal: it is the courage to continue that counts.

Winston Churchill