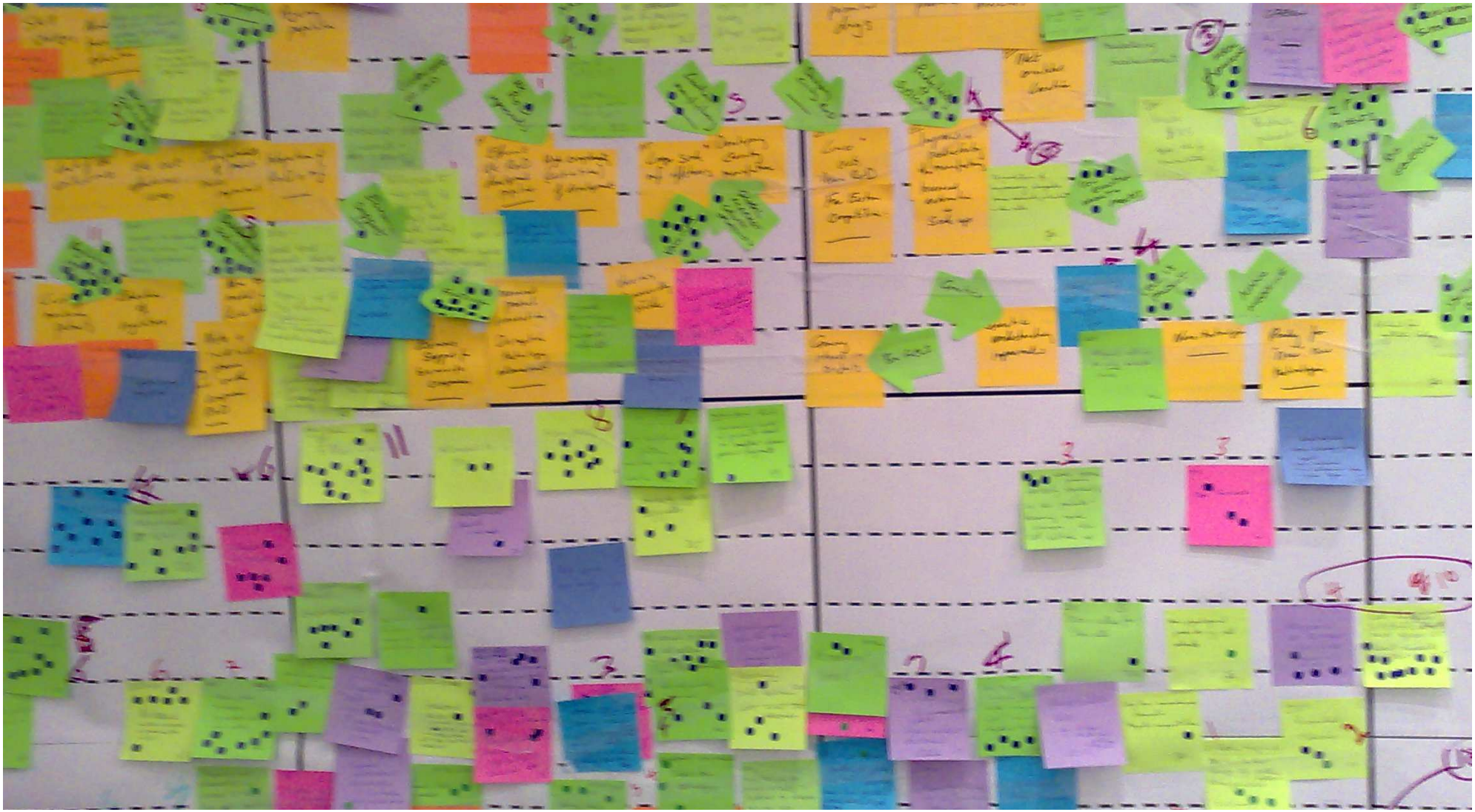
bioProcessUK

Knowledge Transfer Network

bioProcessUK roadmap 30th October 2007



Contents

1.1 Executive Summary Commentary

This report results from a one-day roadmapping workshop to identify priorities for the future programme of bioProcessUK. The workshop took place at the Royal College of Physicians in London, on 30th October 2006. The roadmapping process involved building a layered, forward-looking view of the sector, starting with market trends and drivers, and moving on through key products and technologies, before focusing on the role which bioProcessUK will play in meeting the related challenges. The graphics on the following pages illustrate these priority areas and timescales.

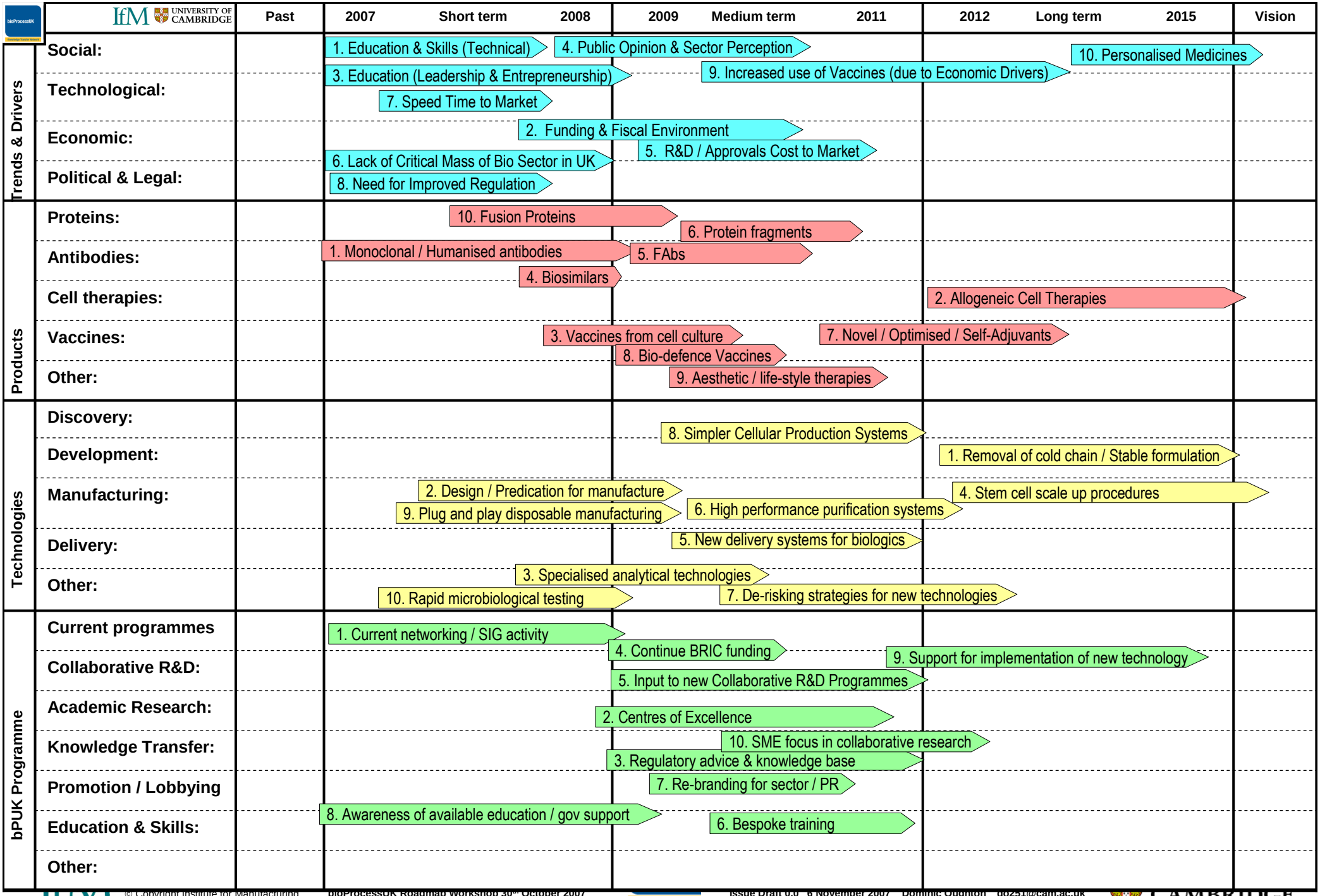
Participants were invited to represent the industrial, academic and public perspectives of the sector, based on their understanding of the market and their insight into the key issues.

In summary, the workshop found that development of education and skills will be critical to the future success of the sector, at a technical level and also in leadership and entrepreneurship, as will the development of the appropriate funding and fiscal environments, if UK is to develop a critical mass of activity. The need to develop a positive perception of bioscience, in the general public and amongst potential recruits, is paramount. Continued rapid technological advances, from the broader application of vaccines to a future vision of personalised medicine will require accelerated time to market and reduced development and approvals costs, which in turn will drive the need for improved regulation.

Priority products will move from derivatives of proteins and antibodies in the short term to new vaccines and allogenic cell therapies in the longer term, with therapies being increasingly targetted at bio-defence and aesthetic / life-style markets. New, non-injection delivery systems will be required to maximise the potential of these new biologics.

The chief technologies required to deliver these products will include temperature-stable formulation to eliminate the cold supply-chain; design for manufacture and analytical techniques; high-performance purification and stem-cell production systems; and associated approaches to de-risking the development of these.

The workshop found that there was a vital role for the continuation of current bioProcessUK activities in networking and special interest groups and funding for BRICs and collaborative R&D. Further programmes which would support the development of the sector would also include knowledge bases for regulatory advice and availability of government support; centres of excellence for academic research and brokering bespoke education and training. bPUK can also play a pivotal role in the re-branding and marketing of the sector in the UK.

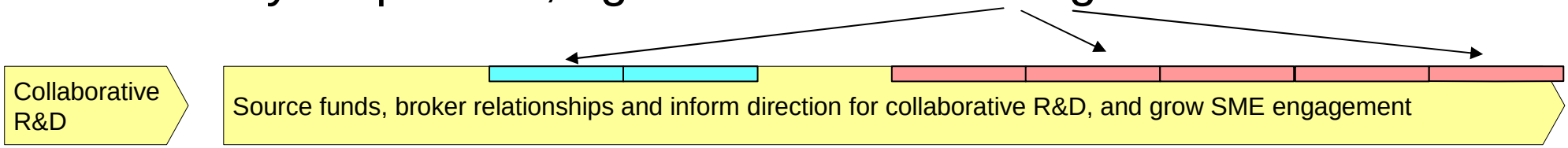

IfM UNIVERSITY OF CAMBRIDGE
Past
2007
Short term
2008
2009
Medium term
2011
2012
Long term
2015
Vision
Trends & Drivers
Social:
Technological:
Economic:
Political & Legal:
1. Education & Skills (Technical)
4. Public Opinion & Sector Perception
10. Personalised Medicines
3. Education (Leadership & Entrepreneurship)
9. Increased use of Vaccines (due to Economic Drivers)
7. Speed Time to Market
2. Funding & Fiscal Environment
5. R&D / Approvals Cost to Market
6. Lack of Critical Mass of Bio Sector in UK
8. Need for Improved Regulation
Products
Proteins:
Antibodies:
Cell therapies:
Vaccines:
Other:
10. Fusion Proteins
6. Protein fragments
1. Monoclonal / Humanised antibodies
5. FAbs
4. Biosimilars
2. Allogeneic Cell Therapies
3. Vaccines from cell culture
7. Novel / Optimised / Self-Adjuvants
8. Bio-defence Vaccines
9. Aesthetic / life-style therapies
Technologies
Discovery:
Development:
Manufacturing:
Delivery:
Other:
8. Simpler Cellular Production Systems
1. Removal of cold chain / Stable formulation
2. Design / Predication for manufacture
4. Stem cell scale up procedures
9. Plug and play disposable manufacturing
6. High performance purification systems
5. New delivery systems for biologics
3. Specialised analytical technologies
10. Rapid microbiological testing
7. De-risking strategies for new technologies
bPUK Programme
Current programmes
Collaborative R&D:
Academic Research:
Knowledge Transfer:
Promotion / Lobbying
Education & Skills:
Other:
1. Current networking / SIG activity
4. Continue BRIC funding
9. Support for implementation of new technology
5. Input to new Collaborative R&D Programmes
2. Centres of Excellence
10. SME focus in collaborative research
3. Regulatory advice & knowledge base
7. Re-branding for sector / PR
8. Awareness of available education / gov support
6. Bespoke training

1.3 Linkages

The graphic on page 6 summarises the key linkages between the challenges identified in the roadmap and the prioritised responses which could be delivered through the future bioProcess UK programme.

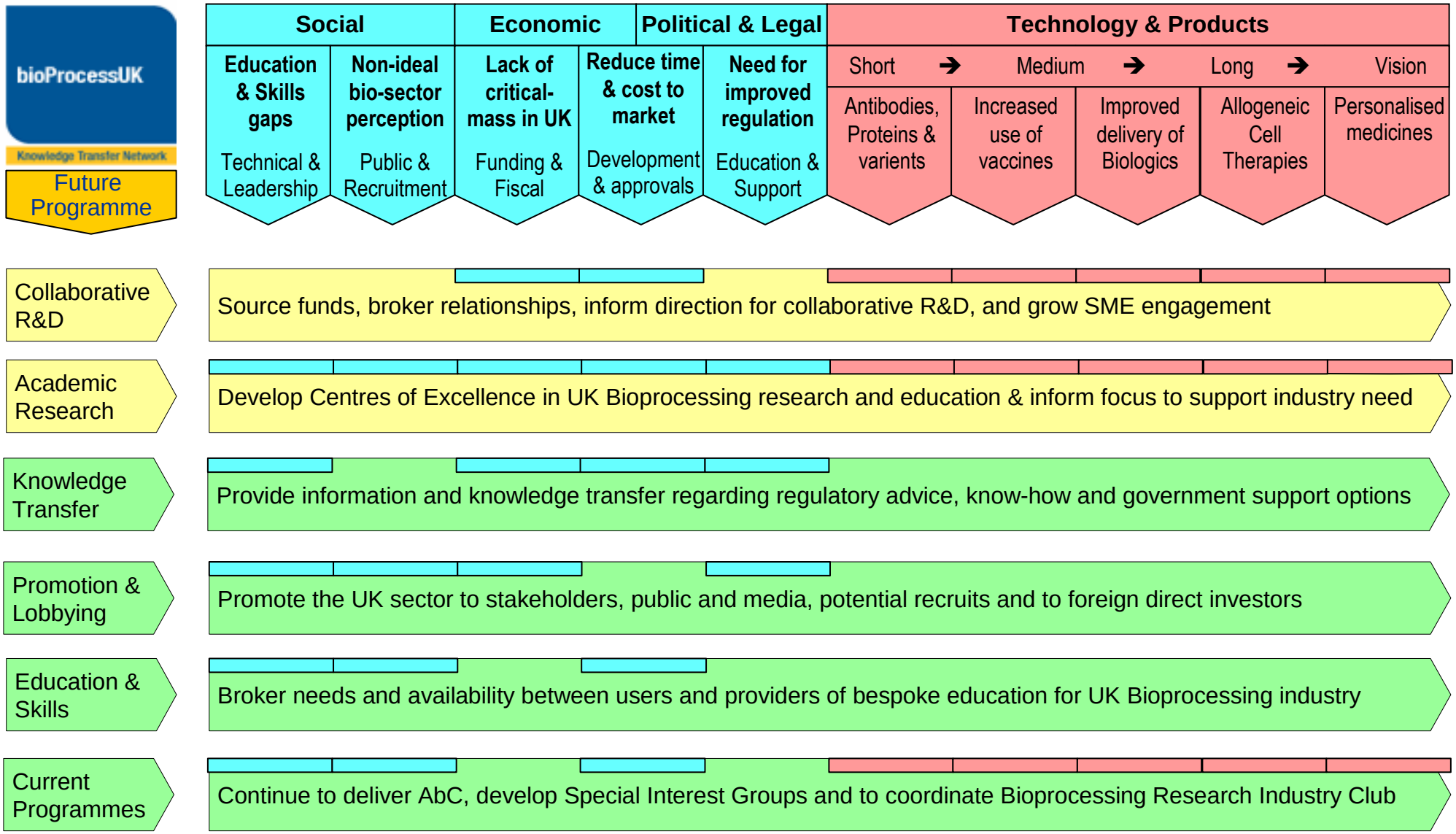
The top layer summarises the most important market trends and drivers ( ) and key product trends ( ).

The bottom layers represent the aspects of the future bPUK programme, with the tags in each box indicating which trends & drivers they respond to, eg:



Page 7 gives more detailed linkages between the key product trends and the necessary technology enablers.

1.4 Executive Summary Linkages

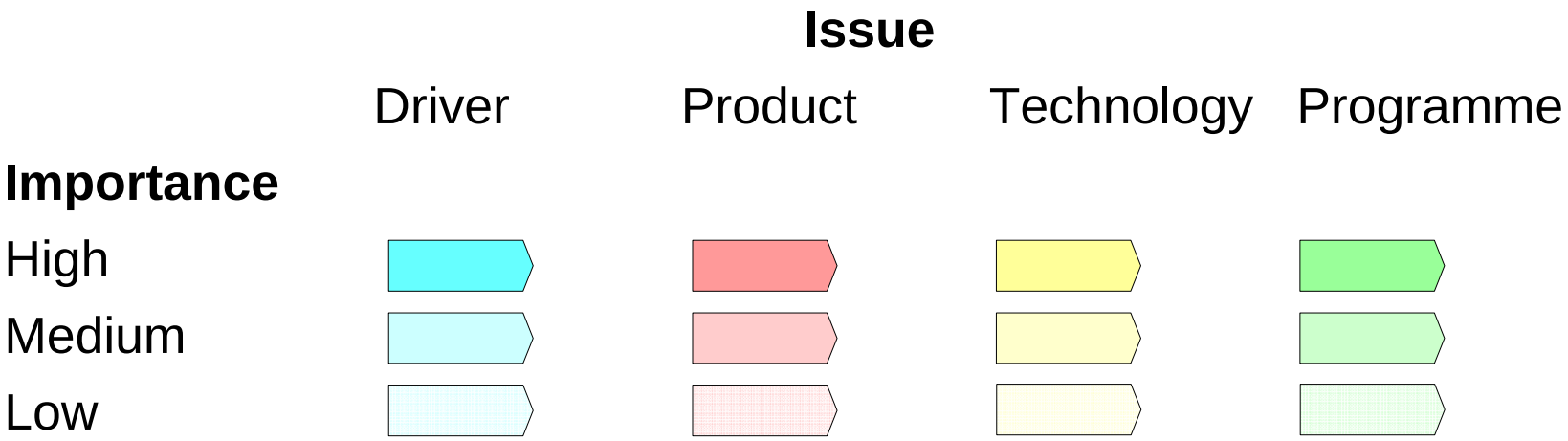


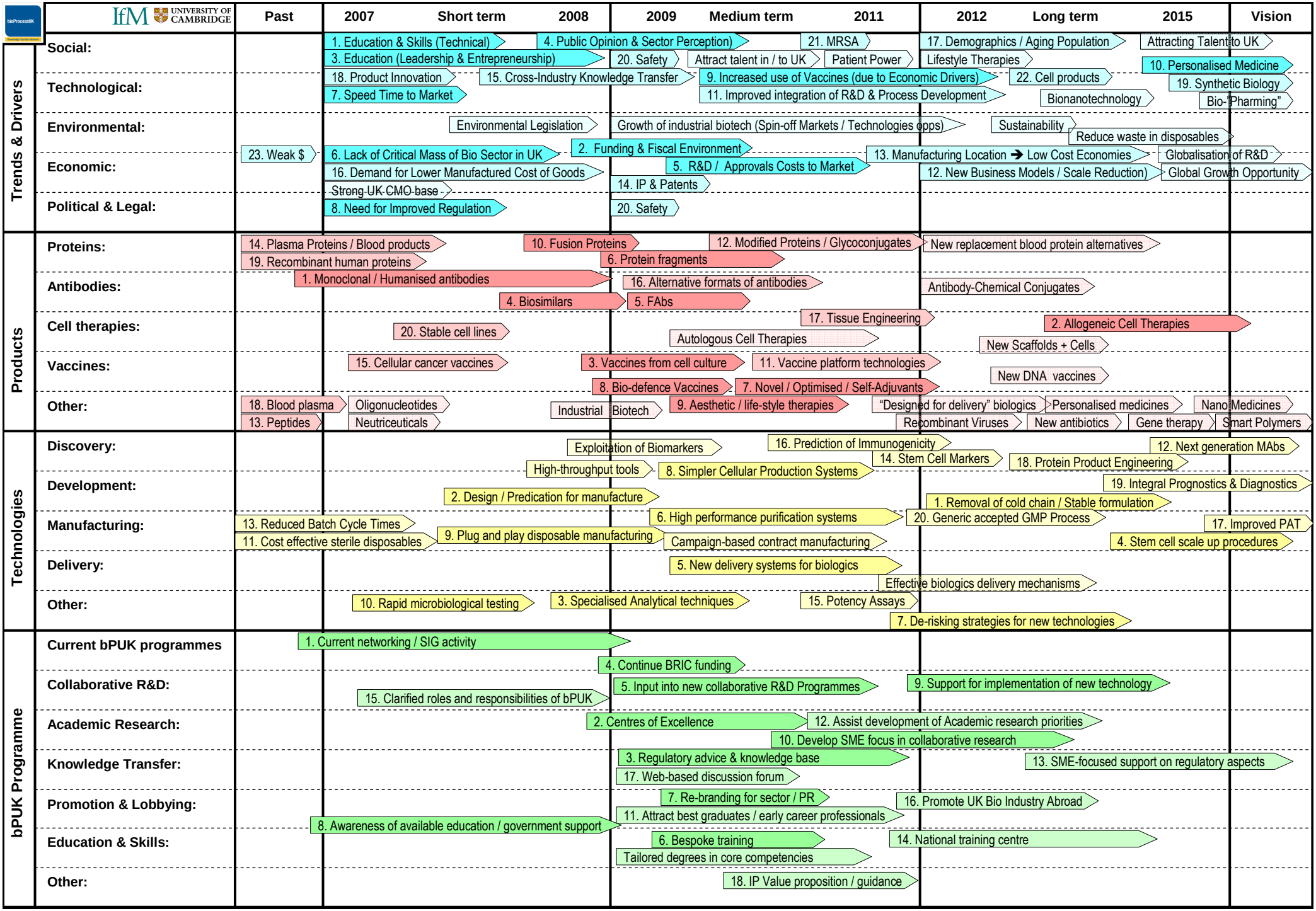
1.4 Product - Technology Linkages

bioProcessUK Knowledge Transfer Network	MAbs / humanised Abs / FAbs biosimilars / fusion proteins	Cell Therapies	Vaccines	Recombinant proteins / protein fragments	Novel / Optimised / Self-Adjuvants	Bio-defence	Aesthetic / life-style therapies	Biologics delivery mechanisms
Formulation / Stabilisation / cold storage								
Design / Predication for manufacture								
Analytical techniques								
Stem cell scale up procedures								
New delivery systems (non-injectable)								
High performance purification systems								
Simpler Cellular Production Systems								
Plug and play disposable manufacturing								

2. Detailed Roadmap landscape

The graphic on the following page, and those on subsequent pages, capture all the key issues identified during the workshop. The relative priorities of these issues are indicated by colour coding – darker colour indicating higher importance.




IfM UNIVERSITY OF CAMBRIDGE
Past
2007
Short term
2008
2009
Medium term
2011
2012
Long term
2015
Vision
Trends & Drivers
Social:
1. Education & Skills (Technical)
4. Public Opinion & Sector Perception)
21. MRSA
17. Demographics / Aging Population
Attracting Talent to UK
3. Education (Leadership & Entrepreneurship)
20. Safety
Attract talent in / to UK
Patient Power
Lifestyle Therapies
10. Personalised Medicine
Technological:
18. Product Innovation
15. Cross-Industry Knowledge Transfer
9. Increased use of Vaccines (due to Economic Drivers)
22. Cell products
19. Synthetic Biology
7. Speed Time to Market
11. Improved integration of R&D & Process Development
Bionanotechnology
Bio-"Pharming"
Environmental:
Environmental Legislation
Growth of industrial biotech (Spin-off Markets / Technologies opps)
Sustainability
Reduce waste in disposables
Economic:
23. Weak $
6. Lack of Critical Mass of Bio Sector in UK
2. Funding & Fiscal Environment
13. Manufacturing Location ➔ Low Cost Economies
Globalisation of R&D
16. Demand for Lower Manufactured Cost of Goods
5. R&D / Approvals Costs to Market
12. New Business Models / Scale Reduction)
Global Growth Opportunity
Strong UK CMO base
14. IP & Patents
Political & Legal:
8. Need for Improved Regulation
20. Safety
Products
Proteins:
14. Plasma Proteins / Blood products
10. Fusion Proteins
12. Modified Proteins / Glycoconjugates
New replacement blood protein alternatives
19. Recombinant human proteins
6. Protein fragments
Antibodies:
1. Monoclonal / Humanised antibodies
16. Alternative formats of antibodies
Antibody-Chemical Conjugates
4. Biosimilars
5. FAbs
Cell therapies:
17. Tissue Engineering
2. Allogeneic Cell Therapies
20. Stable cell lines
Autologous Cell Therapies
New Scaffolds + Cells
Vaccines:
15. Cellular cancer vaccines
3. Vaccines from cell culture
11. Vaccine platform technologies
New DNA vaccines
8. Bio-defence Vaccines
7. Novel / Optimised / Self-Adjuvants
Other:
18. Blood plasma
Oligonucleotides
Industrial Biotech
9. Aesthetic / life-style therapies
"Designed for delivery" biologics
Personalised medicines
Nano Medicines
13. Peptides
Neutriceuticals
Recombinant Viruses
New antibiotics
Gene therapy
Smart Polymers
Technologies
Discovery:
Exploitation of Biomarkers
16. Prediction of Immunogenicity
12. Next generation MAbs
14. Stem Cell Markers
18. Protein Product Engineering
High-throughput tools
8. Simpler Cellular Production Systems
Development:
19. Integral Prognostics & Diagnostics
2. Design / Predication for manufacture
1. Removal of cold chain / Stable formulation
Manufacturing:
13. Reduced Batch Cycle Times
6. High performance purification systems
20. Generic accepted GMP Process
17. Improved PAT
11. Cost effective sterile disposables
9. Plug and play disposable manufacturing
Campaign-based contract manufacturing
4. Stem cell scale up procedures
Delivery:
5. New delivery systems for biologics
Effective biologics delivery mechanisms
Other:
10. Rapid microbiological testing
3. Specialised Analytical techniques
15. Potency Assays
7. De-risking strategies for new technologies
bPUK Programme
Current bPUK programmes
1. Current networking / SIG activity
4. Continue BRIC funding
Collaborative R&D:
5. Input into new collaborative R&D Programmes
9. Support for implementation of new technology
15. Clarified roles and responsibilities of bPUK
Academic Research:
2. Centres of Excellence
12. Assist development of Academic research priorities
10. Develop SME focus in collaborative research
Knowledge Transfer:
3. Regulatory advice & knowledge base
13. SME-focused support on regulatory aspects
17. Web-based discussion forum
Promotion & Lobbying:
7. Re-branding for sector / PR
16. Promote UK Bio Industry Abroad
11. Attract best graduates / early career professionals
8. Awareness of available education / government support
Education & Skills:
6. Bespoke training
14. National training centre
Tailored degrees in core competencies
Other:
18. IP Value proposition / guidance

3. Roadmap detailed content

3.1 Trends & Drivers

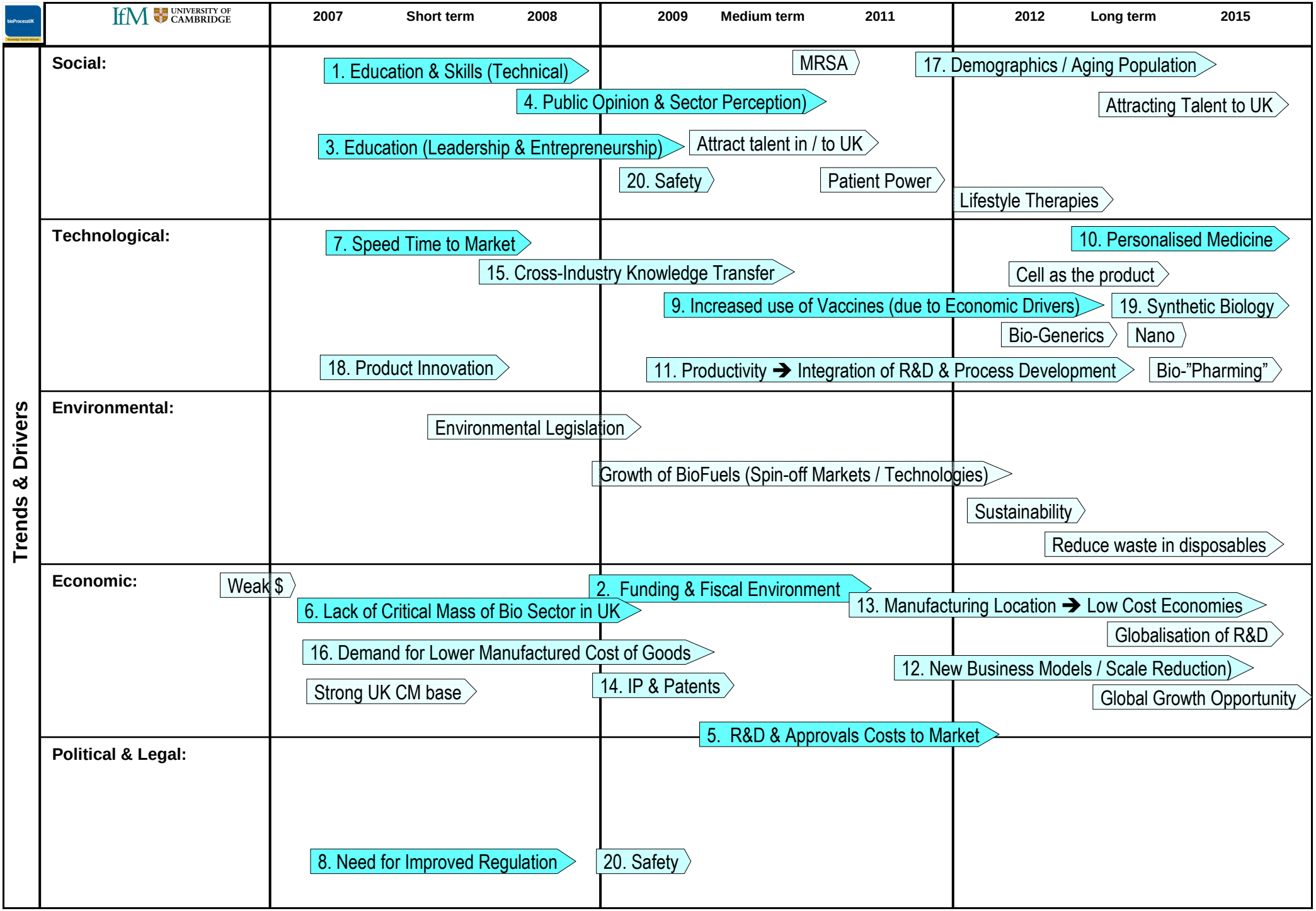
3.2 Products

3.3 Technologies

3.4 bioProcessUK Programme Challenges

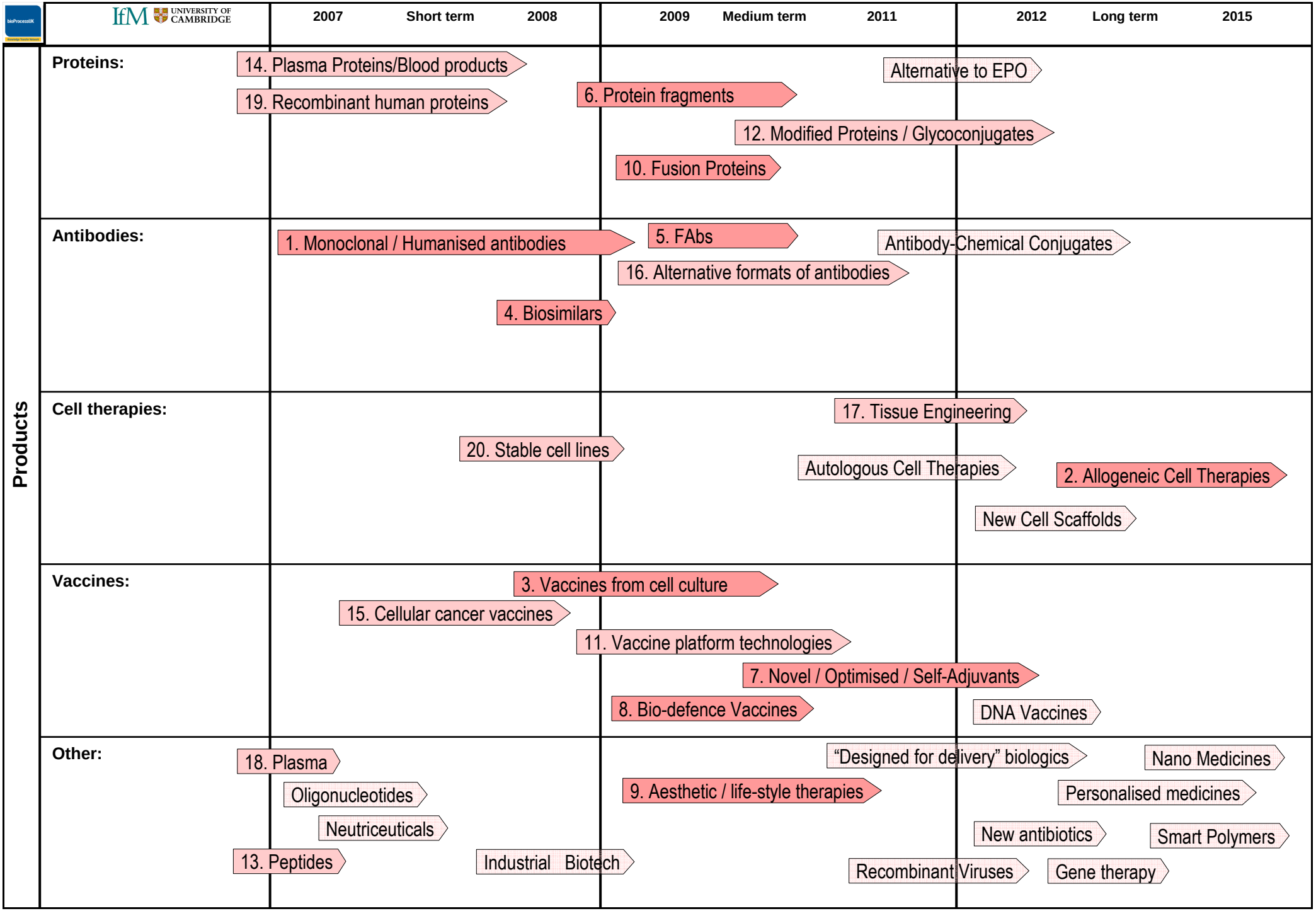
3.1 Top 10 Trends & Drivers

1. Education & Skills (Technical)
2. Funding & financial support / Fiscal environment
3. Leadership and entrepreneurship
4. Public opinion and sector perception
5. Cost of R&D and Approvals to reach market
6. Lack of critical mass of Bio-sector in UK
7. Speed time to Market
8. Need for improved regulation
9. Increased use of vaccines due to economic drivers
10. Personalised medicines


IfM UNIVERSITY OF CAMBRIDGE
2007
Short term
2008
2009
Medium term
2011
2012
Long term
2015
Trends & Drivers
Social:
1. Education & Skills (Technical)
MRSA
17. Demographics / Aging Population
4. Public Opinion & Sector Perception)
Attracting Talent to UK
3. Education (Leadership & Entrepreneurship)
Attract talent in / to UK
20. Safety
Patient Power
Lifestyle Therapies
Technological:
7. Speed Time to Market
10. Personalised Medicine
15. Cross-Industry Knowledge Transfer
Cell as the product
9. Increased use of Vaccines (due to Economic Drivers)
19. Synthetic Biology
Bio-Generics
Nano
18. Product Innovation
11. Productivity ➔ Integration of R&D & Process Development
Bio-"Pharming"
Environmental:
Environmental Legislation
Growth of BioFuels (Spin-off Markets / Technologies)
Sustainability
Reduce waste in disposables
Economic:
Weak $
2. Funding & Fiscal Environment
6. Lack of Critical Mass of Bio Sector in UK
13. Manufacturing Location ➔ Low Cost Economies
Globalisation of R&D
16. Demand for Lower Manufactured Cost of Goods
12. New Business Models / Scale Reduction)
Strong UK CM base
14. IP & Patents
Global Growth Opportunity
5. R&D & Approvals Costs to Market
Political & Legal:
8. Need for Improved Regulation
20. Safety

3.2 Top 10 Products

1. Monoclonal / Humanised antibodies
2. Allogeneic cell therapies
3. Vaccines from cell culture
4. Biosimilars
5. FAbs
6. Protein fragments
7. Novel / Optimised / Self-Adjuvants
8. Bio-defence Vaccines
9. Aesthetic / life-style therapies
10. Fusion Proteins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2007
Short term
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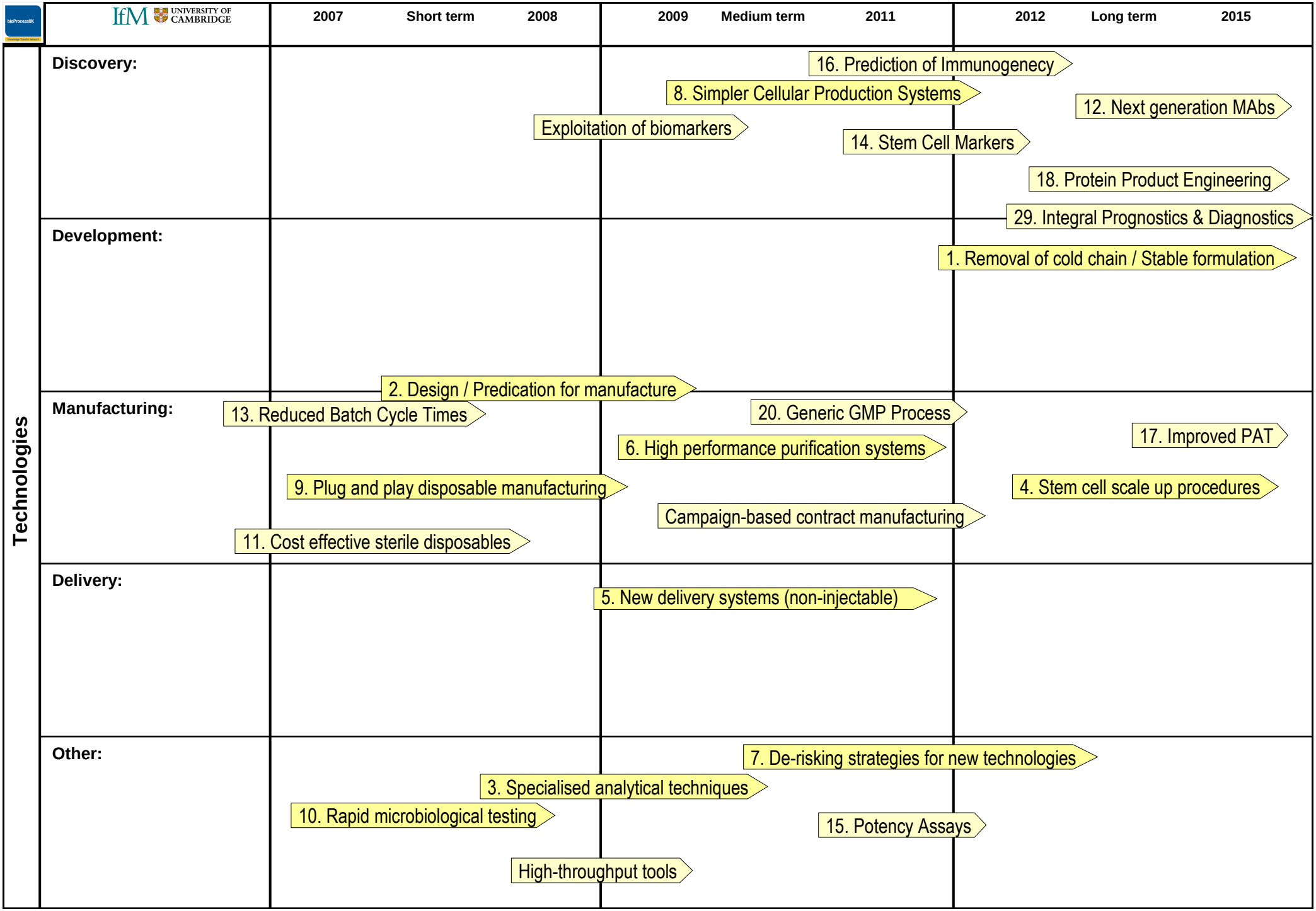
Products
Proteins:
14. Plasma Proteins/Blood products
19. Recombinant human proteins
6. Protein fragments
Alternative to EPO
12. Modified Proteins / Glycoconjugates
10. Fusion Proteins
Antibodies:
1. Monoclonal / Humanised antibodies
5. FAbs
Antibody-Chemical Conjugates
16. Alternative formats of antibodies
4. Biosimilars
Cell therapies:
17. Tissue Engineering
20. Stable cell lines
Autologous Cell Therapies
2. Allogeneic Cell Therapies
New Cell Scaffolds
Vaccines:
3. Vaccines from cell culture
15. Cellular cancer vaccines
11. Vaccine platform technologies
7. Novel / Optimised / Self-Adjuvants
8. Bio-defence Vaccines
DNA Vaccines
Other:
18. Plasma
Oligonucleotides
Neutriceuticals
13. Peptides
Industrial Biotech
"Designed for delivery" biologics
Nano Medicines
9. Aesthetic / life-style therapies
Personalised medicines
New antibiotics
Smart Polymers
Recombinant Viruses
Gene therapy

3.3 Top 10 Technologies

1. Removal of cold chain / Stable formulation
2. Design / Predication for manufacture
3. Specialised analytical techniques
4. Stem cell scale up procedures
5. New delivery systems for biologics (non-injectable)
6. High performance purification systems
7. De-risking new technologies
8. Simpler cellular production systems
9. Plug and play disposable manufacturing
10. Rapid microbiological testing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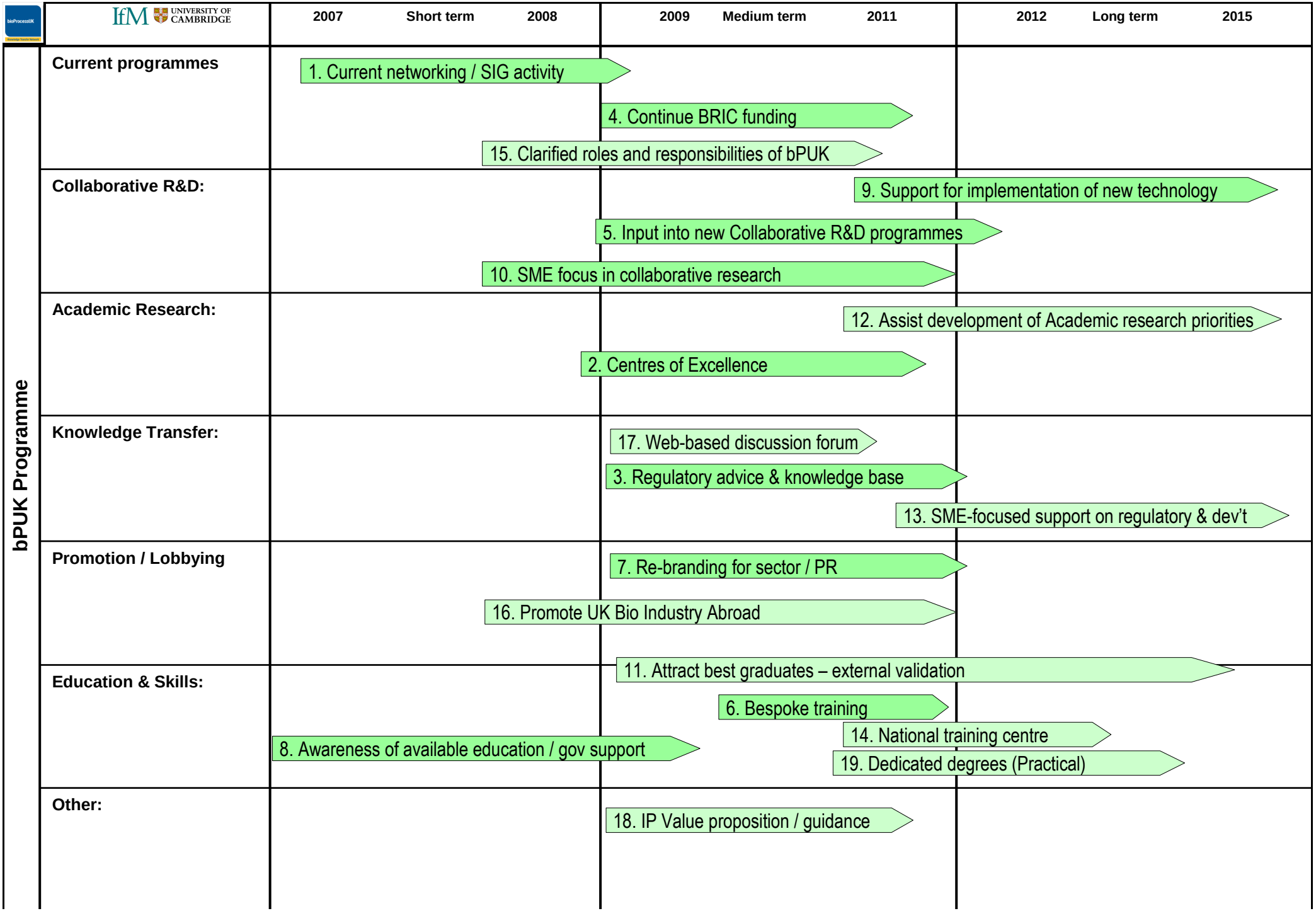
2007
Short term
2008
2009
Medium term
2011
2012
Long term
2015
Technologies
Discovery:
16. Prediction of Immunogenecy
8. Simpler Cellular Production Systems
12. Next generation MAbs
Exploitation of biomarkers
14. Stem Cell Markers
18. Protein Product Engineering
29. Integral Prognostics & Diagnostics
Development:
1. Removal of cold chain / Stable formulation
2. Design / Predication for manufacture
Manufacturing:
13. Reduced Batch Cycle Times
20. Generic GMP Process
17. Improved PAT
6. High performance purification systems
9. Plug and play disposable manufacturing
4. Stem cell scale up procedures
Campaign-based contract manufacturing
11. Cost effective sterile disposables
Delivery:
5. New delivery systems (non-injectable)
Other:
7. De-risking strategies for new technologies
3. Specialised analytical techniques
10. Rapid microbiological testing
15. Potency Assays
High-throughput tools

3.4 Top 10 bioProcessUK Programme Challenges

1. Current networking / SIG activity
2. Centres of excellence
3. Regulatory advice & knowledge base
4. Continue BRIC funding
5. Collaborative R&D (eg vaccines)
6. Bespoke training
7. Re-branding for sector / PR
8. Awareness of available education / Government support
9. Support for implementation of new technology
10. SME focus in collaborative research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Medium term
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2012
Long term
2015
bPUK Programme
Current programmes
1. Current networking / SIG activity
4. Continue BRIC funding
15. Clarified roles and responsibilities of bPUK
Collaborative R&D:
9. Support for implementation of new technology
5. Input into new Collaborative R&D programmes
10. SME focus in collaborative research
Academic Research:
12. Assist development of Academic research priorities
2. Centres of Excellence
Knowledge Transfer:
17. Web-based discussion forum
3. Regulatory advice & knowledge base
13. SME-focused support on regulatory & dev't
Promotion / Lobbying
7. Re-branding for sector / PR
16. Promote UK Bio Industry Abroad
Education & Skills:
11. Attract best graduates – external validation
6. Bespoke training
14. National training centre
8. Awareness of available education / gov support
19. Dedicated degrees (Practical)
Other:
18. IP Value proposition / guidance

4. bioProcessUK Programme Core Challenges

1 Current networking / SIG activity
2 Centres of Excellence
3 Regulatory advice & knowledge base
4 Continue BRIC funding
5 Input into new Collaborative R&D programmes
6 Bespoke training
7 Re-branding for sector / PR
8 Awareness of available education / Government support
9 Support for implementation for new technologies
10 Continued focus on SME's in collaborative research

5. Participants

First name	Last name	Company
Simon	Webster	Avacta
Stephen	Taylor	Avecia Biologics
Ben	Sykes	BBSRC
Mark	Bustard	bioProcessUK
Malcolm	Rhodes	bioProcessUK
Meng	Xu	bioProcessUK
Tony	Bradshaw	bioProcessUK
Narpal	Juttla	bioProcessUK
Andrew	Thompson	bioProcessUK
Philip	Aldridge	CELS
Steve	Hart	Genex Biosystems
Dominic	Oughton	Cambridge IfM
Steve	Mann	Cambridge IfM
Kate	Willsher	Cambridge IfM
Gerhard	Symons	Imperial College London

First name	Last name	Company
John	Lovelady	Intercytex
Nick	Crabb	Intertek
Jonathan	Dempsey	Invitrogen
Mike	Whelan	Iqur
John	Adair	Ithaka
Chris	Jones	NIBSC
Steve	Jones	Novartis Vaccines
Peter	Levison	Pall Life Sciences
Steve	Burton	Prometic Biosciences
David	Winstanley	SEMTA
David	James	Sheffield University
Rosemary	Drake	The Automation Partnership
Zahid	Latif	Technology Strategy Board
Elaine	Martin	University of Newcastle
Andy	Steward	Warwick Effect Polymers

bioProcessUK Roadmap

We welcome your views on this evolving roadmap.

Please make comments and input to:

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