BRIC • BIOPROCESSING RESEARCH INDUSTRY CLUB

BRIC Phase 2
Update on Scope and First Call

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BRIC PHASE 2

- Positive recommendations from BRIC1 Evaluation and Working Group
- Stakeholders (BBSRC, EPSRC, Industrial Club Members) pledge up to £10 million
- At least two funding rounds anticipated in next five years
- Research Programmes relevant to the effective biomanufacture of proteins, nanoplexes & cells

Remit of BRIC2 Scope

- Two overarching themes in the manner of BRIC1:
  - Bioscience understanding to underpin improvement of bioprocesses
  - New enabling tools for implementation of bioprocesses
- Priority areas defined in interactive dialogue with academics and industrial practitioners within/without BRIC

Business Drivers

- Expanding UK position in the global market for biological medicines
- Support of relevant UK Companies developing biological medicines and the underpinning supply chain
- Growth of a vibrant and skilled bioprocess community
- Added value through decreased time, cost and risk of product/process development
- Reduced investment cost and risk by invention of intensive, modular and predictable process characterised by QbD
- Enhanced regulatory confidence through improved process and product integrity/reproducibility

BRIC2 – Five Priority Areas

- Bioprocessing challenges for protein and their host cell producers
- High-throughput bioprocess development
- Effective modelling of whole bioprocesses
- Robust and effective analytics for bioprocessing
- Bioprocessing research for cellular products

I. Bioprocessing challenges for protein and their host cell producers

- Advanced understanding of macromolecular and cellular properties
- Quantitative documentation of bioresponses to process environments
- Subsequent improved design compatible with measured bioproperties
- Reliable and predictive processing tools correlated with molecular structure
- Early demonstrations of manufacturability

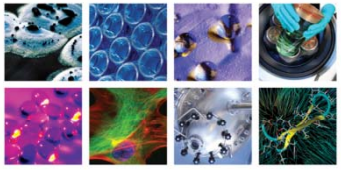
II. High-throughput bioprocess development

- Robust and rapidly achieved procedures to characterise target products or processes
- Early credible evaluation in respect of compatibilities with industrial bioprocessing
- High throughput screeing for multiparallel evaluation
- Credible comparison of analogous unit operations
- Accelerated of intermediate and final products
- Real time bioprocess monitoring

III. Effective modelling of whole bioprocesses

- Robust models to describe bioprocess components
- Processes of *in vivo* cellular assembly
- Integrated unit ops of production, recovery and formulation
- Improved methods for data mining of bioprocessing informatics
- Predictive models based on HTS
- Model-guided decision making for product and process development programmes

IV. Robust and effective analytics for bioprocessing



- Molecular, physiological and biopharmacological descriptions of target products
- Translation of laboratory analytical procedures to robust, near plant ops
- Harness for product and process description in manufacture
- Small-volume, high-throughput analyses to yield credible data suited to product/process definition and predictive modelling

V. Bioprocessing research for cellular products

- Translation of lab-based procedures into bona fide manufacture
- Cell-line and associated bioprocess development
- Underpinning of safe practice in cellular therapies
- Novel culture surfaces, passage technologies, exploitation of environment cues, product recovery, formulation and distribution

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However:

Sufficiently competitive proposals that bridge two or more priorities, or fall outside priority areas, will not be excluded from consideration, provided they fall within the BRIC remit and align with industrial need

BRIC2/1 Application Guidelines

Approximately £3.5M will be made available for two types of opportunities in call for BRIC2/1

- Standard Research Grant (SRG) Application
  - *Collaborative applications encouraged*
  - *Outline application reviewed by BRIC SG*
  - *Invited Full Applications, assessed by Peer Review*
- Enabling Fund (EF) Application
  - *Proposals valued <£100k over 12 months or less*
  - *Bring communities together for collaborative purposes*
  - *Single stage reviewed by SG, other expertise as required*
  - *Successful proposals start < 3 months*

BRIC2/1 Application Guidelines

- More on Enabling Funds…
  - Proposals should explore a specific research theme in BRIC's remit
    - identify and refine the research challenges
    - produce and assess preliminary methods or data to ensure the success of a new approach
  - Activities could include a spectrum from facilitating **cross-disciplinary networking** to the completion of **feasibility studies**, **research groundwork** or **material preparation**
  - Contact the BRIC PM to discuss proposal

BRIC2/1 Application Guidelines

- More on Enabling Funds…
  - Standard Je-S application, but fit case for support to the size of the project
  - £100k limit is the BRIC contribution (80% FEC)
  - Enabling fund grantees may bypass the outline stage for a related project in a future BRIC2 call

Criteria for Assessment

- Scientific Excellence on an International Scale
- Strategic Relevance to BRIC2 Scope
- Economic and Social Impact
- Timeliness and Promise
- Cost Effectiveness
- Staff Training Potential

Enabling Funds and Standard Grants assessed against the same criteria, but EF includes additional aspects to enable the exploration of novel and high-risk approaches.

BRIC2 Special Conditions

In addition to standard RC funding rules, acceptance of BRIC2 Funding recognises additional special conditions

- Offer minimum 28 days notice to BRIC Members of intention publish funded work
- Similar advance notice of IP exploitation opportunities
- Produce Annual Progress Reports
- Attend and present research progress against goals at 6-monthly dissemination meetings
- Present a final close-out report of BRIC funded work to an appropriate dissemination event

Key Dates

March 15th	launch of BRIC2/1 Call
March 30th	open interactive workshop to discuss the call
March – April	BRIC Programme Manager (and others) available for consultation to advance applications
May 5th	deadline for Outline SRG and EF Applications
June 30th	latest date for notification of invitation for Full Applications for SRGs or success of EF Applications
Late August	closing date for Full SRG Applications
September 30th	latest date for commencement of EF Projects
March 31, 2011	latest date for awarding full applications

Key Contacts

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