Medical Research Council

MRC Translational Funding Opportunities

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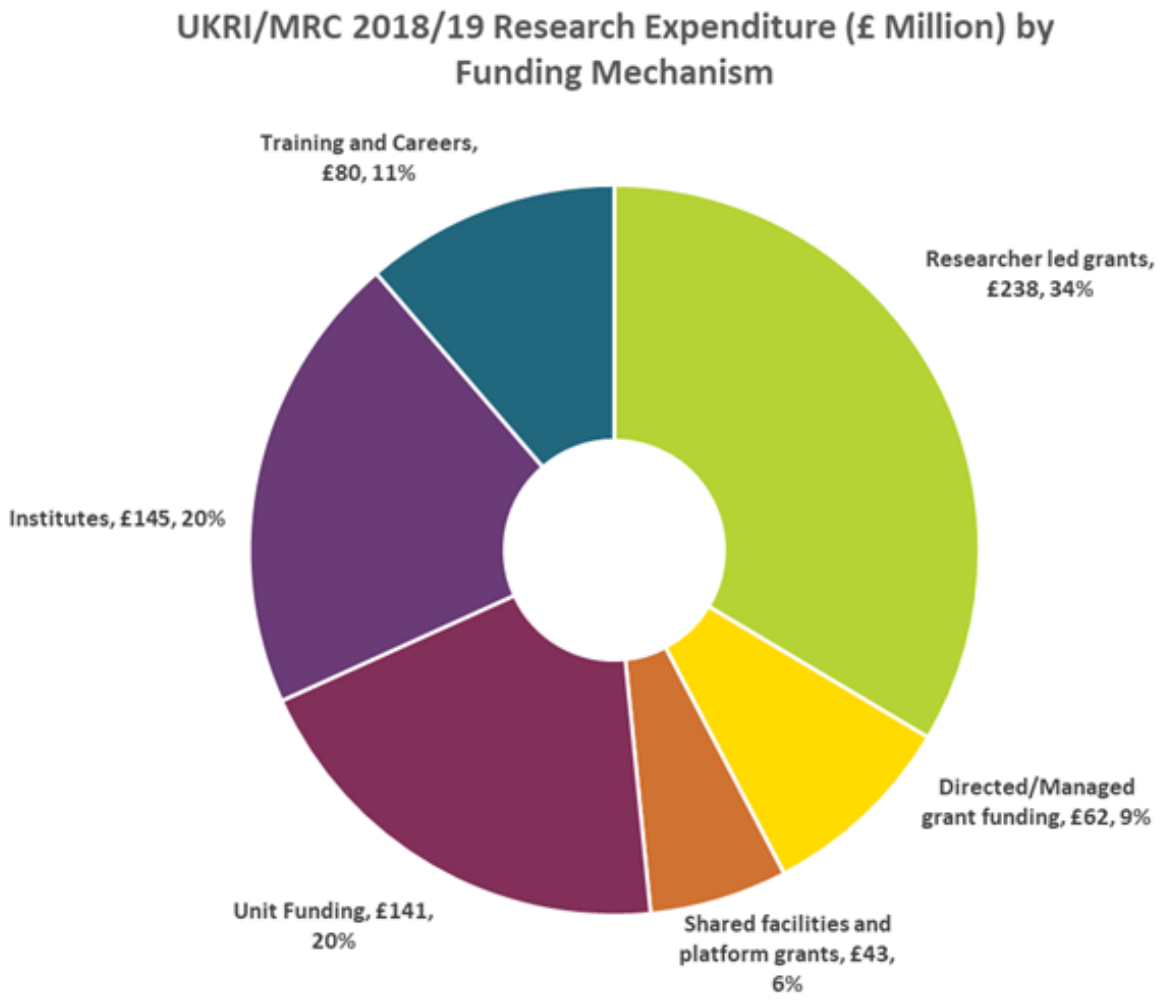
Programme manager, Translation
3 April 2020

2018/19 MRC Research Programme Expenditure



- C. **£700m** of expenditure by funding mechanism across the MRC portfolio
- These different mechanisms allow for a balance between strategic direction, open funding streams and an agile response to new opportunities

- Researcher led grants
- Directed/Managed funding
- Shared facilities and platforms
- Units
- Institutes
- Training and Careers

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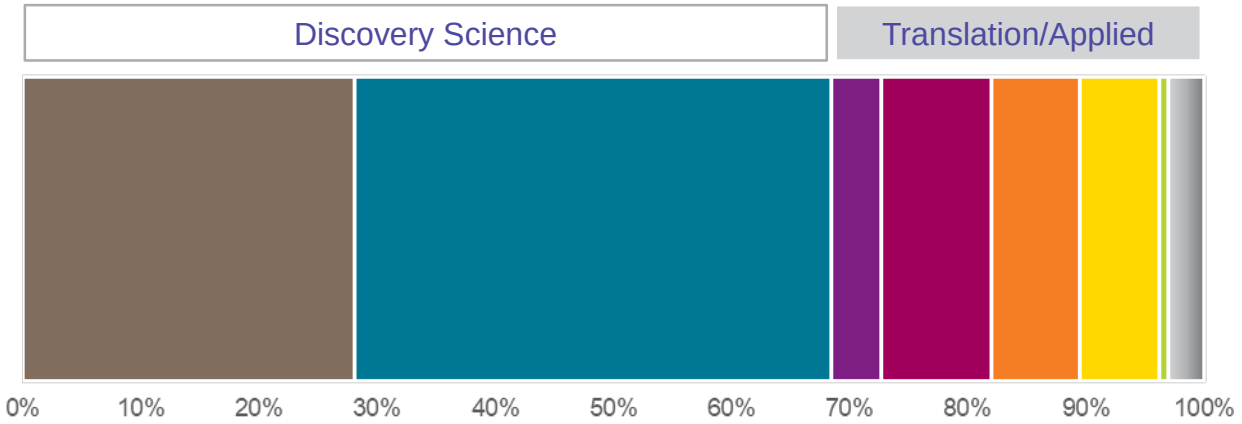
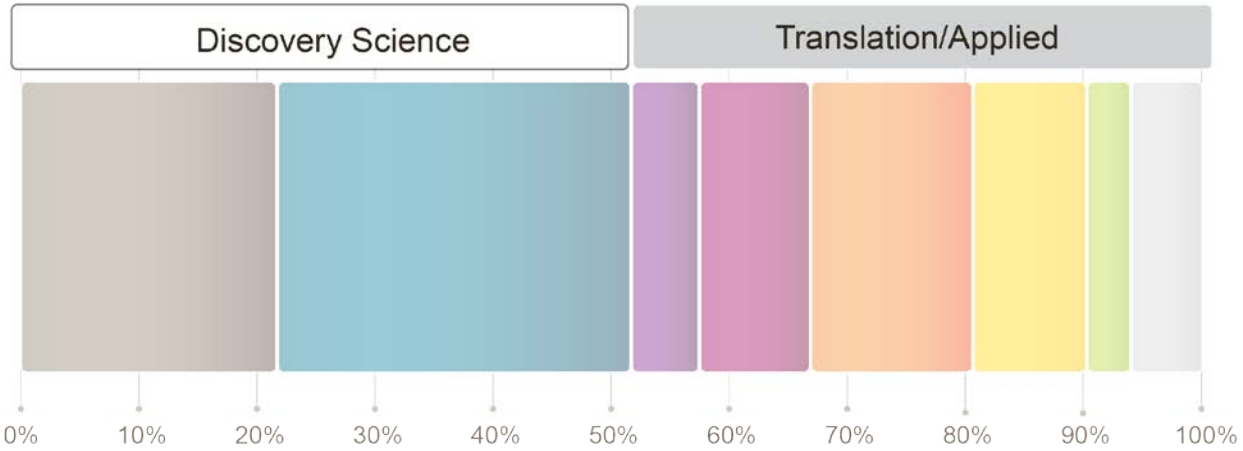
Discovery Science and Applied Research Portfolio

MRC 5 year Average 14/15 – 18/19



Public Sector and Research Charity 2014



- Underpinning
- Mechanisms of Disease (aetiology)
- Detection, Screening and Diagnosis
- Evaluations of Treatments and Therapeutic Interventions
- Health and Social Care Services Research
- Prevention of Disease and Conditions, and Promotion of Well-Being
- Development of Treatments and Therapeutic Interventions
- Management of Diseases and Conditions

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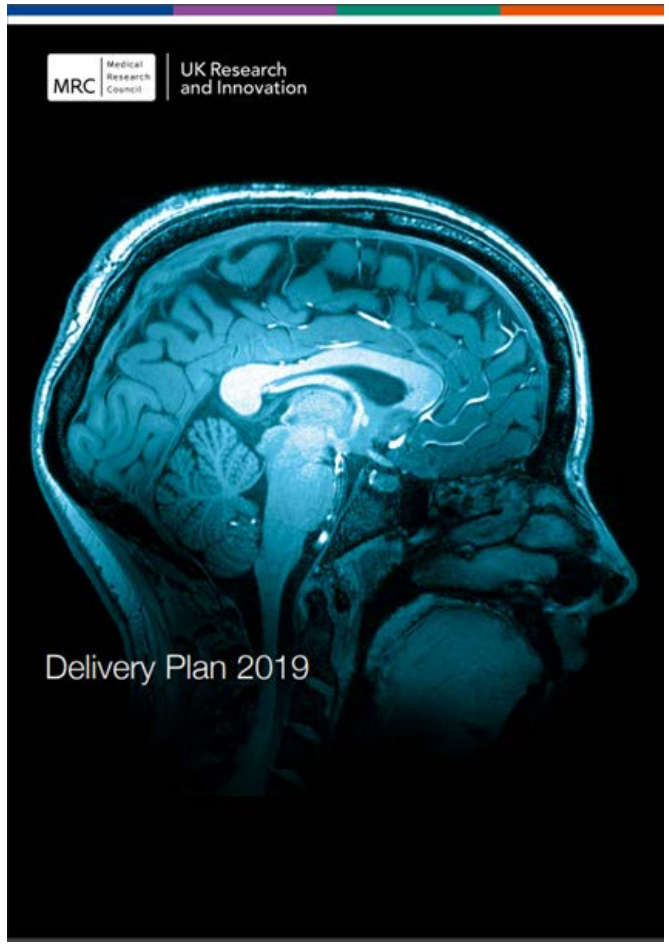
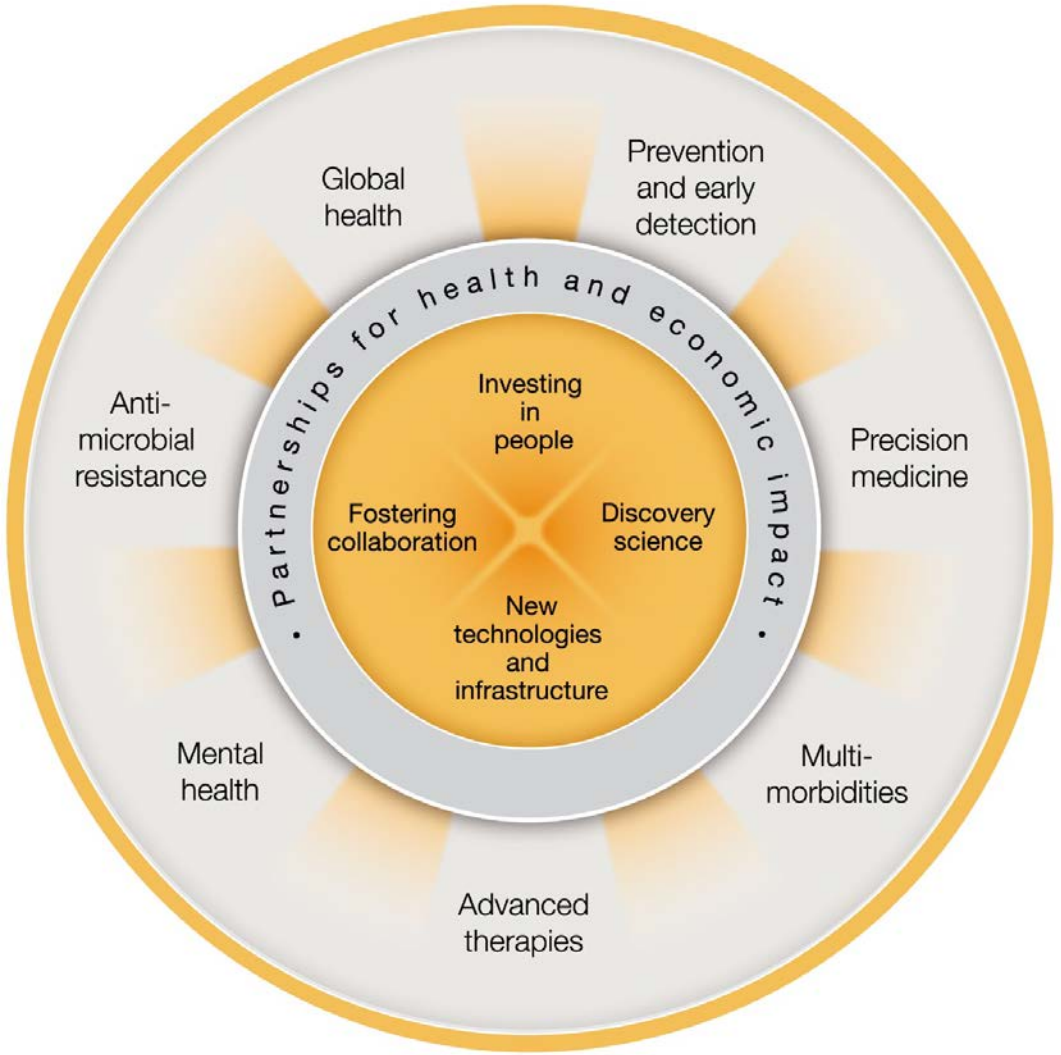
MRC Delivery Plan 2019: Priorities





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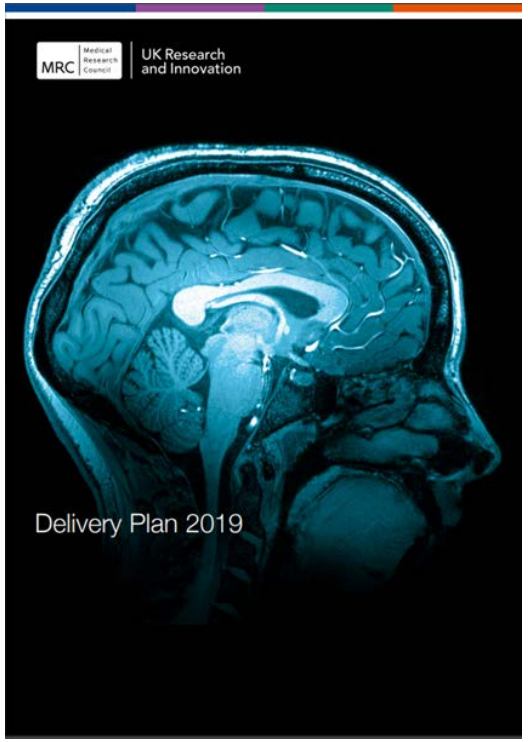
MRC Delivery Plan 2019: New Developments



Key themes under development, subject to funding:

- Review our current portfolio of centres & units with increased investment in new **Centres of Excellence**
- Pursue ways to connect & boost the **precision medicine** landscape
- Become a more active investor in **infrastructure and technology development**
- **Training**: create more capacity in priority areas e.g. precision and experimental medicine, diagnostics & data analytics
- More consistent investigator-led mode funding for **applied global health** work
- Complementing translational funding with support for centres to address key areas for **industry/academic collaboration**
- MRC will take advantage of increased opportunities for **cross-council working** in areas such as multi-scale biology, digital technologies for AI & health, environment/health interactions & the Physics of Life initiative

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Global Health

- MRC spends approx**. £100m** per year on global health research
- Global infections remains a priority, but portfolio covers all areas including mental health, cancer, maternal, child and adolescent health
- Multidisciplinary work is key: e.g. for topics such as urbanisation, environmental threats
- MRC has a broad global health remit: we fund fundamental science through clinical trials to health systems research
- New programmes likely to feature a major focus on research capacities and skills in developing countries
- A **new Applied Global Health Research Board** for stable, sustained response mode opportunities which will also be open to investigators from LMICs **has launched in early January 2020:**

  https://mrc.ukri.org/funding/science-areas/global-health-and-international-partnerships/applied-global-health-research-board/

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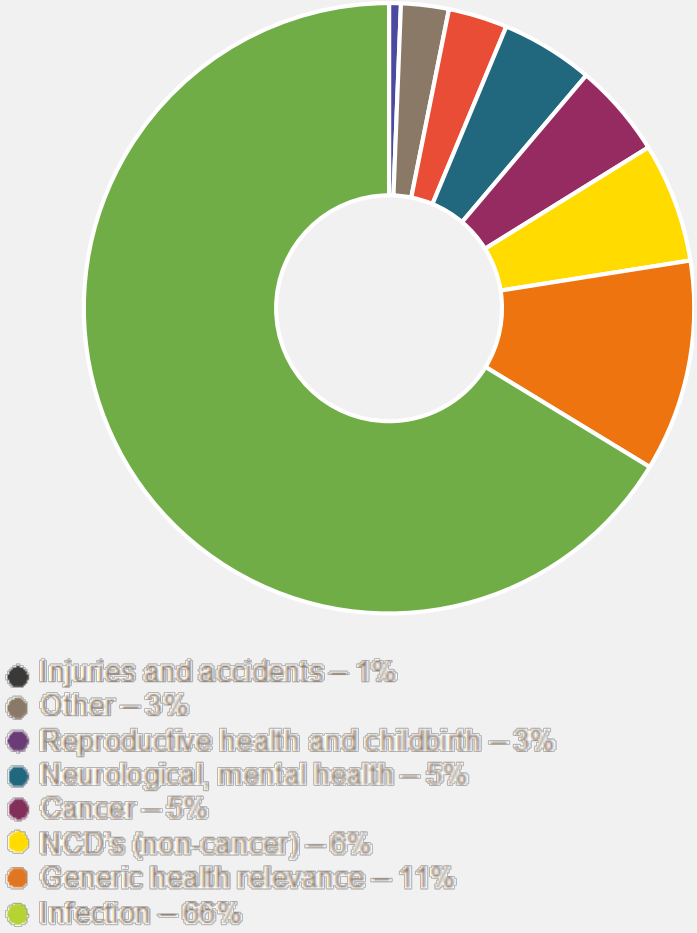
2016/17 Global Health Spend by Health Area



MRC Industry Charter

Integrity • Clarity of purpose • Independence • Openness

- Engendering a permeable cross-sector culture through collaboration and people exchange remains a priority
- Open innovation and precompetitive collaboration, with access to industry expertise, facilities and equipment, offers enormous benefits to UK academia
- Biological insight and novel thinking from academia is highly valued by business
- Aim is to position the UK as an attractive target for R&D investment

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Major initiatives in partnership with industry

Translational Funding

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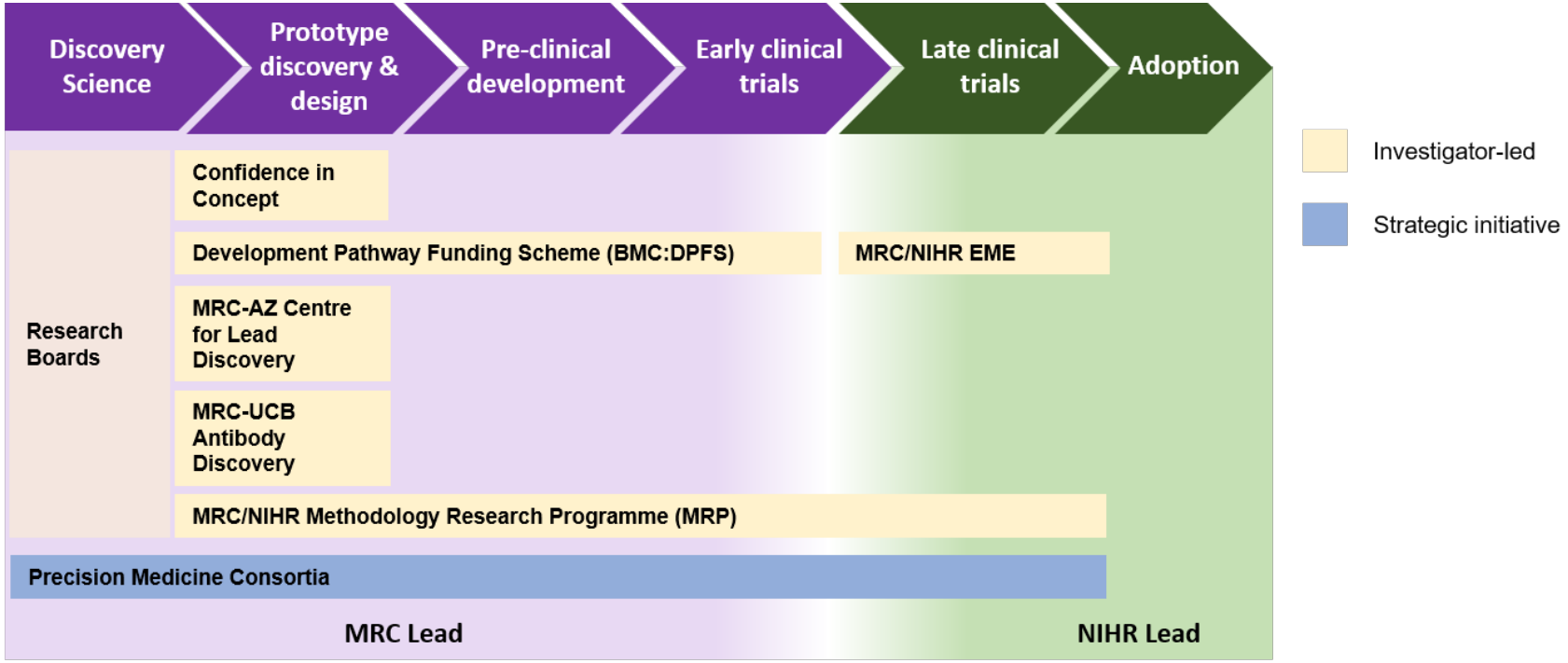
Translational Funding Opportunities



Future Opportunities:

- Co-Development Centres
- Target Validation
- AI for healthcare
- Advanced therapeutics
- Talent and capacity building

Confidence in Concept (CiC) 2018/19

- 24 devolved awards
- £10.9m commitment

DPFS Award Rates 2018/19:

- Overall 17/112 – 13%**

*** Normalised for the two stage assessment process*

MRC-Industry Collaboration Agreement (MICA)

6/19 DPFS awards

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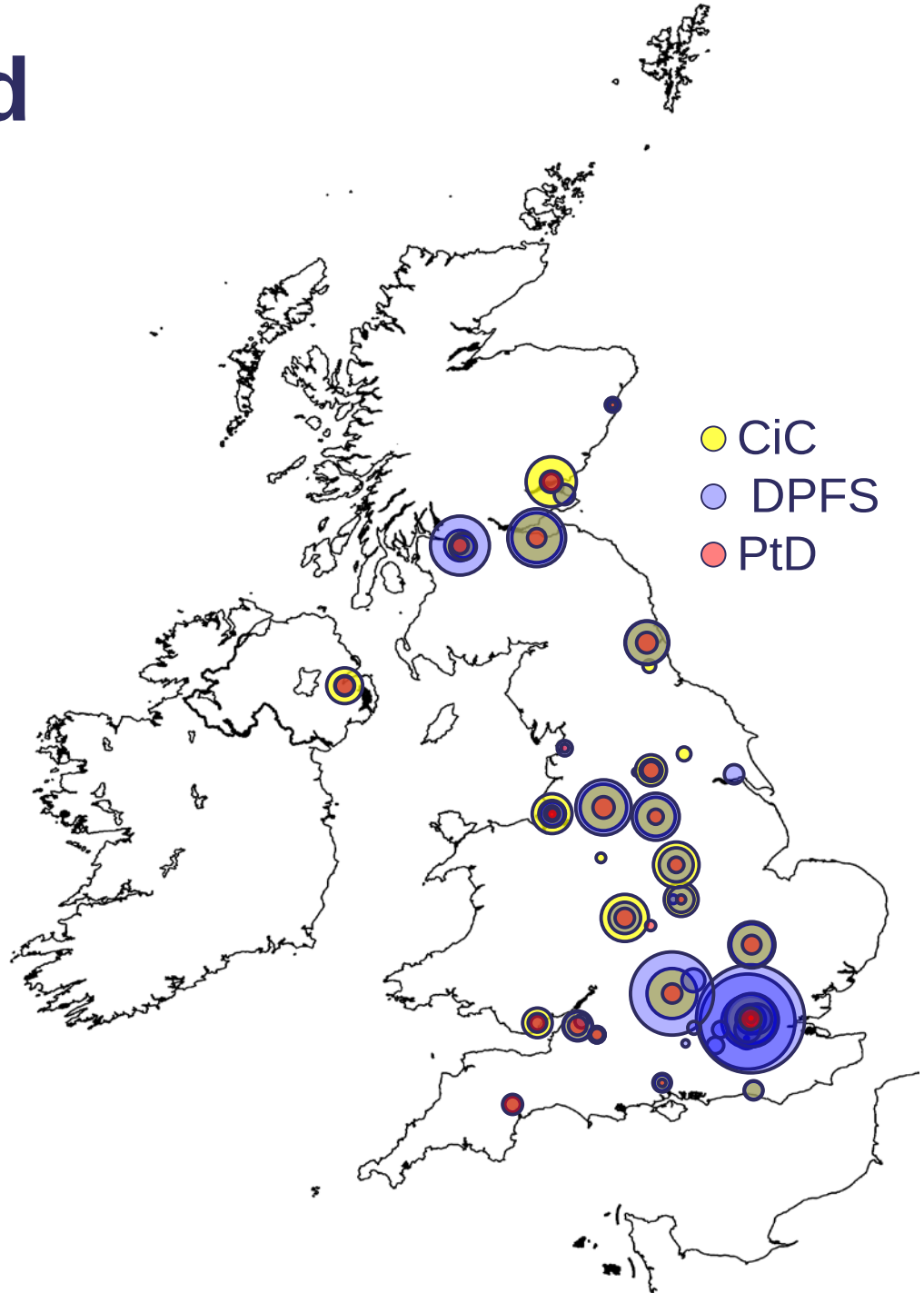
MRC Translational Spend

MRC annual research budget:

- 75% on underpinning science
- 25% on translation

Regional spread:

- DPFS, CiC and PtD are distributed across the UK



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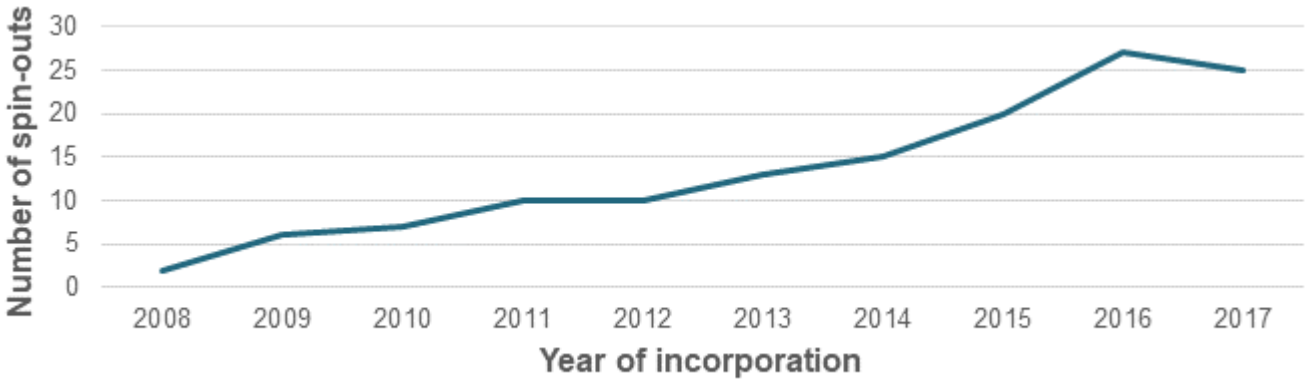
Bridging the Gap
10 years of MRC funded translational research

- What has resulted from the directed translation portfolio in contrast to the broader portfolio of translational research supported by the research boards?
- Can we understand the translational research landscape and MRC's place in it over the decade, and position MRC for future translational success?
- Can analysis of the progress of projects identify determinants of performance?

https://mrc.ukri.org/publications/browse/10-year-translation-research-evaluation-report-2019/

MRC Translational Research (2008-2018) Evaluation report



Source: MRC spin-out database, Companies House. The data excludes spin-outs established in 2018 as these were not yet captured in the monitoring information

Geographical reach across the UK

134 spin-out companies
78 arising from translational schemes (DPFS and CiC), raising £1.1bn of external equity investment.
These companies are valued at £2.7bn

41%
of total equity investment in pharmaceutical, biotechnology and medical technology sectors in 2018

59% of spin-outs emerged outside of London, Oxford and Cambridge

92%(117) of these companies remained active in 2018 with 92% incorporated in the UK

A Strengthened Translational Research Culture

The most important factors in enabling translational research highlighted by key stakeholders were skills, collaboration, the right mindset (attitudes and culture), and funding.

Key opinion leaders and researchers agreed that MRC funding schemes had:

- Helped change the culture of the academic research community, with more researchers engaged in translational research
- Led to increased understanding and collaboration between academia and the private sector
- Led to increased translational research skills within academia

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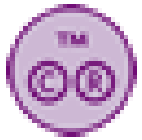
Confidence in Concept (CiC)

- Funding scheme to promote the development of a translational culture within the university.
- Awards of £250k to £1m provided directly to the university;
- Support for tightly defined projects designed to create proof of concept data (£50-100k & lasting a maximum of 12 months)
- Equivalent to seed funding – infrastructure and a pipeline of projects should already be in place

Since 2013 the Confidence in Concept scheme has

Supported **1533** projects
1699 interactions with industry on projects



191 patents awarded

£930M of follow on funding secured

81 spin-out companies created

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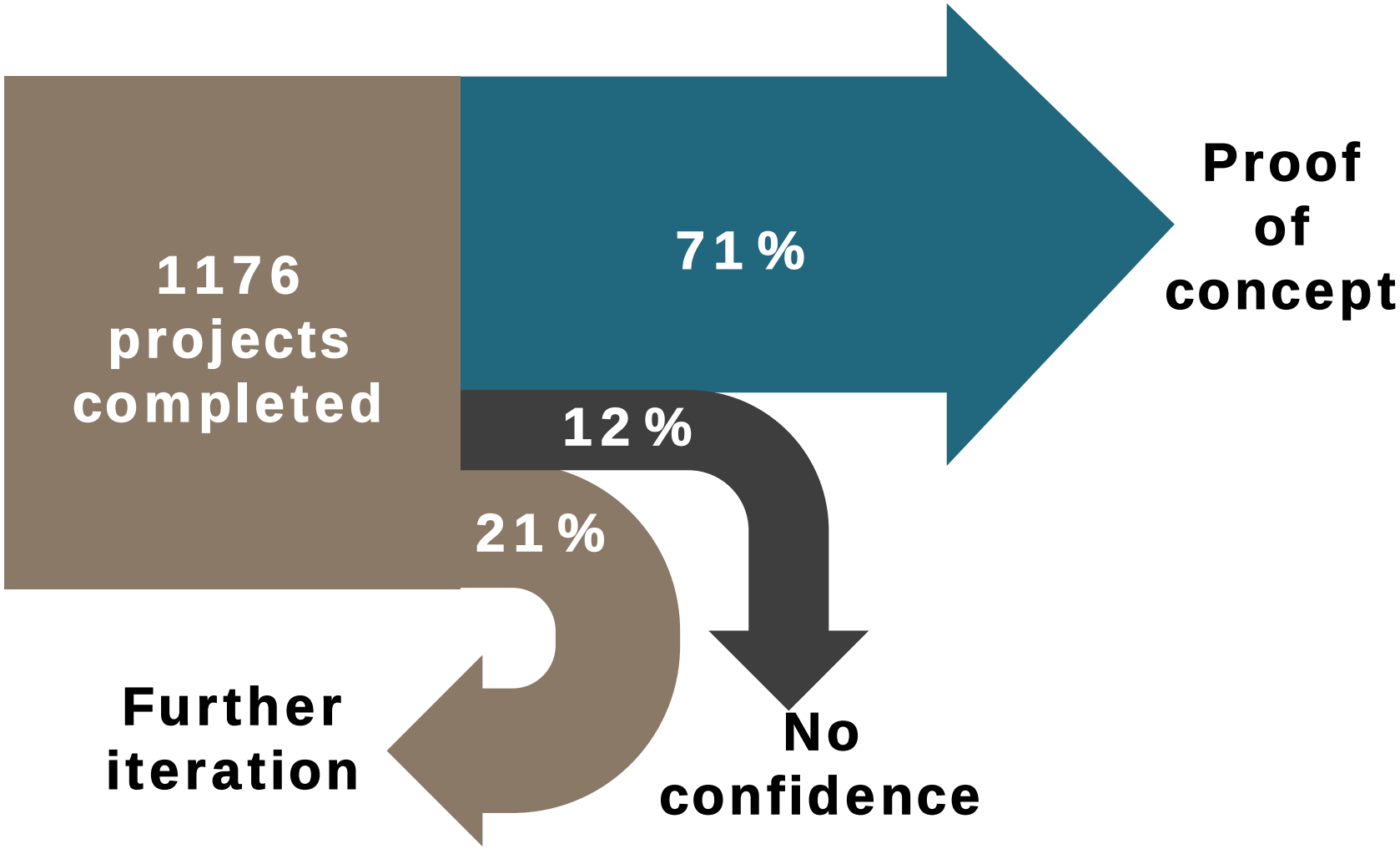
CiC projects – Early confidence for translation



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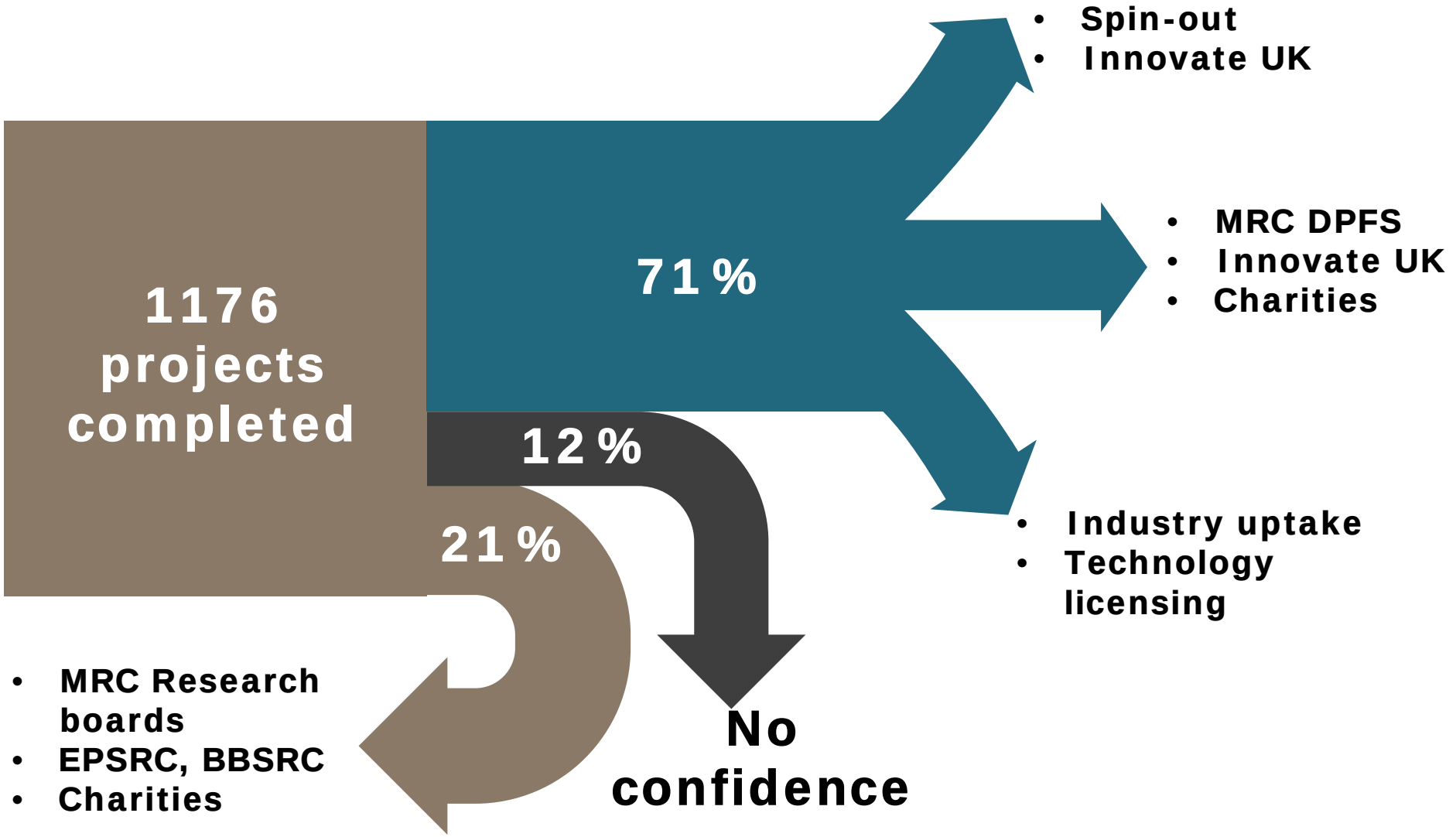
CiC projects – Follow-on funding pathways



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Developmental Pathway Funding Scheme (DPFS)

- The **cornerstone** of the MRC's Translational Strategy:
  - Progress academic-led research down the translational pathway.
  - ~£30m/year, rolling deadline every four months (March, July, November)
  - No restrictions on duration or value
- **Not just 'Translational Research Grants'**
  - Projects are goal oriented and milestone-based;
  - Allows MRC to provide a long-term commitment to inherently risky projects

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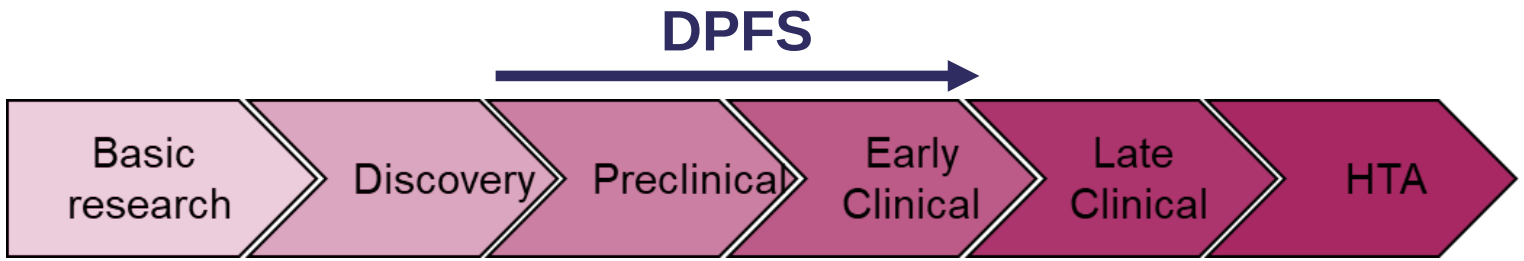
https://mrc.ukri.org/funding/browse/biomedical-catalyst-dpfs/biomedical-catalyst-developmental-pathway-funding-scheme-dpfs-outline-jul-2020/

Development Pathway Funding Scheme (DPFS)

In remit:

- Development and pre-clinical testing of novel therapeutic entities, devices and diagnostics through to early-phase clinical studies (Ph I to Ph IIa)



- "Repurposing" clinical studies – existing therapies in new indications
- Development of research tools that increase the efficiency of developing interventions

Out of remit:

- Discovery science including mechanistic studies and biomarker identification (MRC research boards)
- Technology development where not aligned to a medical/clinical developmental plan (likely BBSRC or EPSRC remit)
- Phase IIb and III clinical trials & trials of non-novel agent-disease combinations (NIHR)

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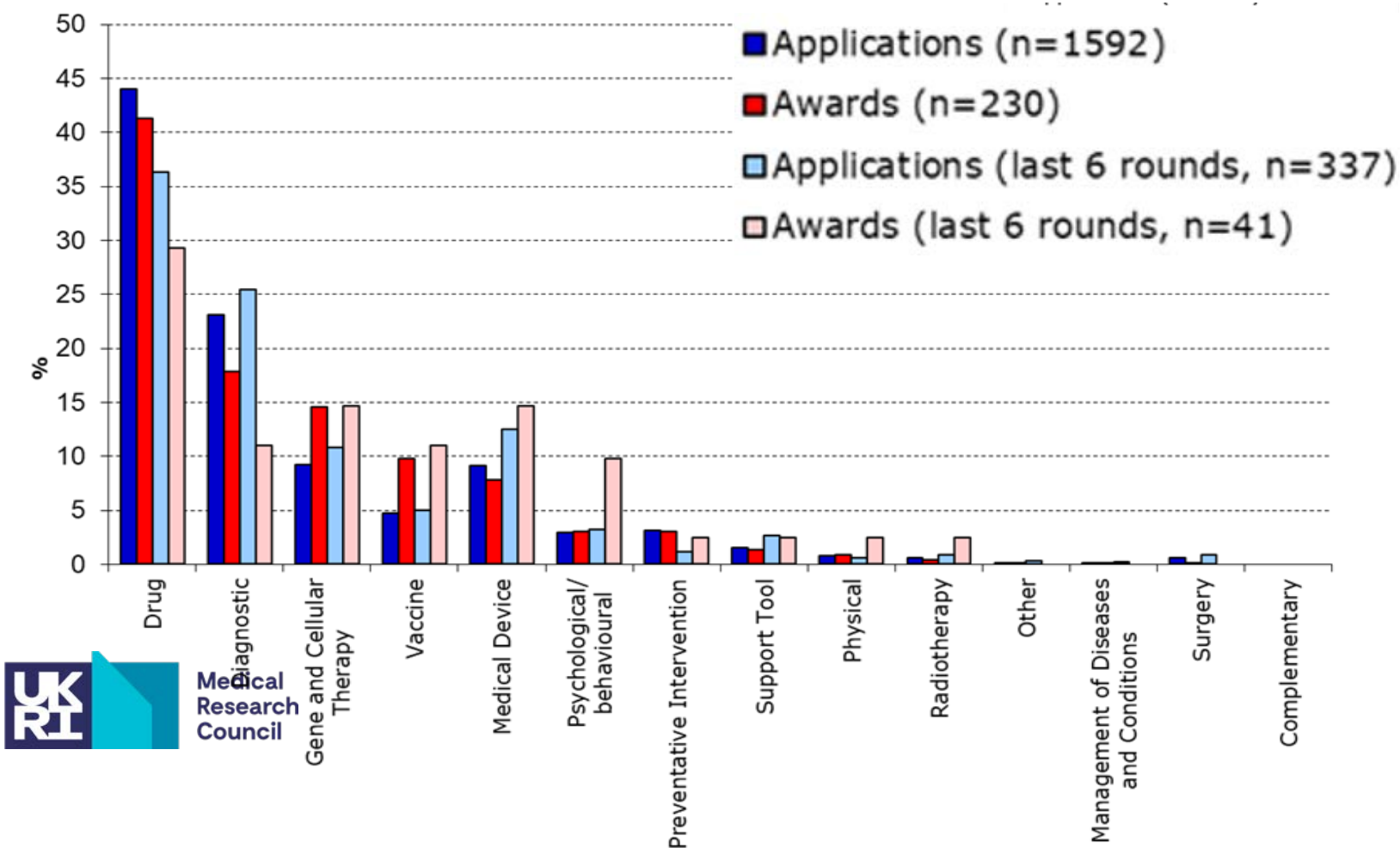
DPFS Portfolio

Applications by Modality

As of September 2018, 247 projects had been supported through DPFS, ranging from pre-clinical studies to early phase trials, with a total commitment of more than £250m: including



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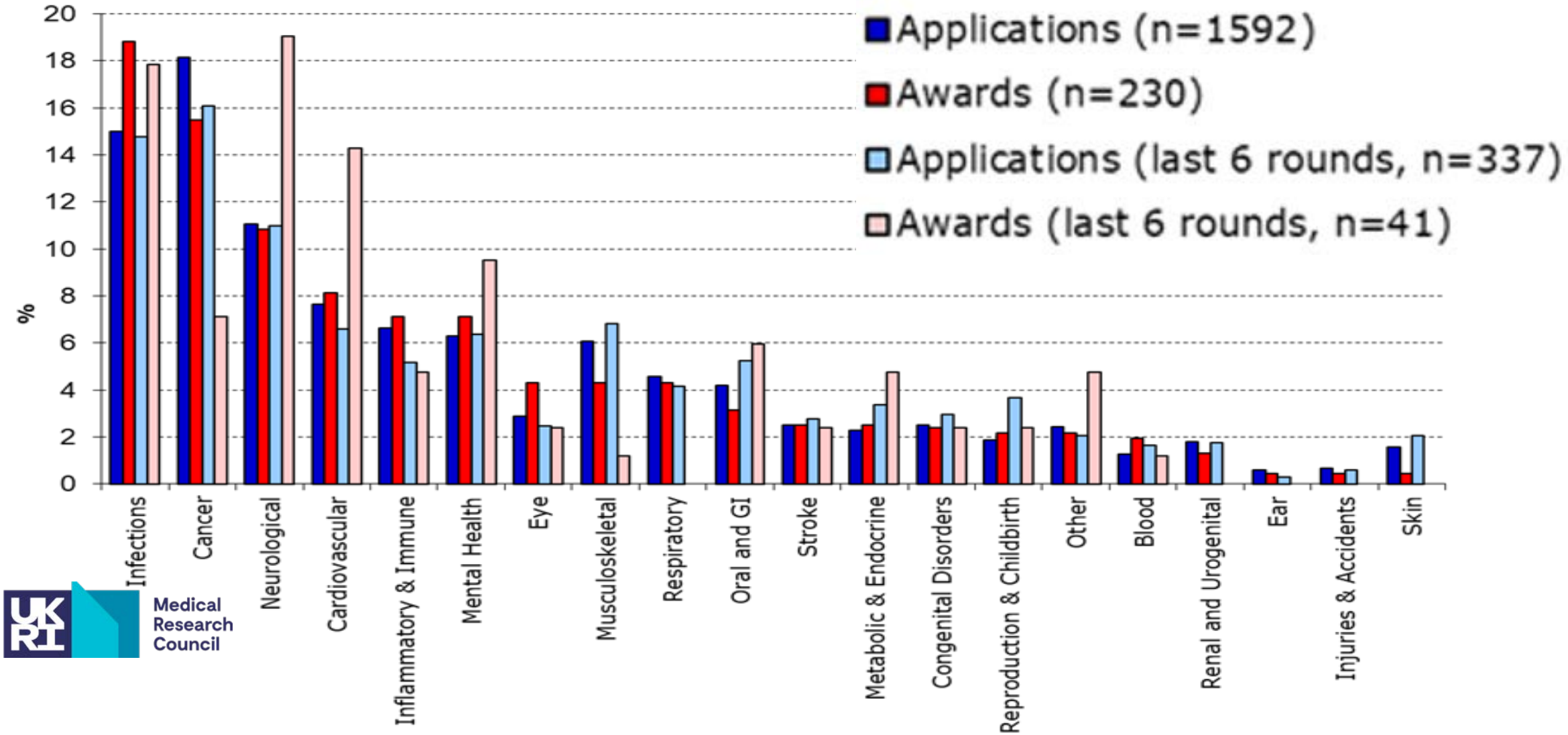
161 therapeutic interventions including:

- 40 small molecule
- 46 biologics (antibodies, proteins etc.)
- 14 drug other
- 23 genetic therapies
- 12 cell therapies
- 18 medical devices
- 7 psychological interventions
- 22 vaccines
- 40 diagnostics
- 13 others

DPFS Remit

Applications by Disease Area



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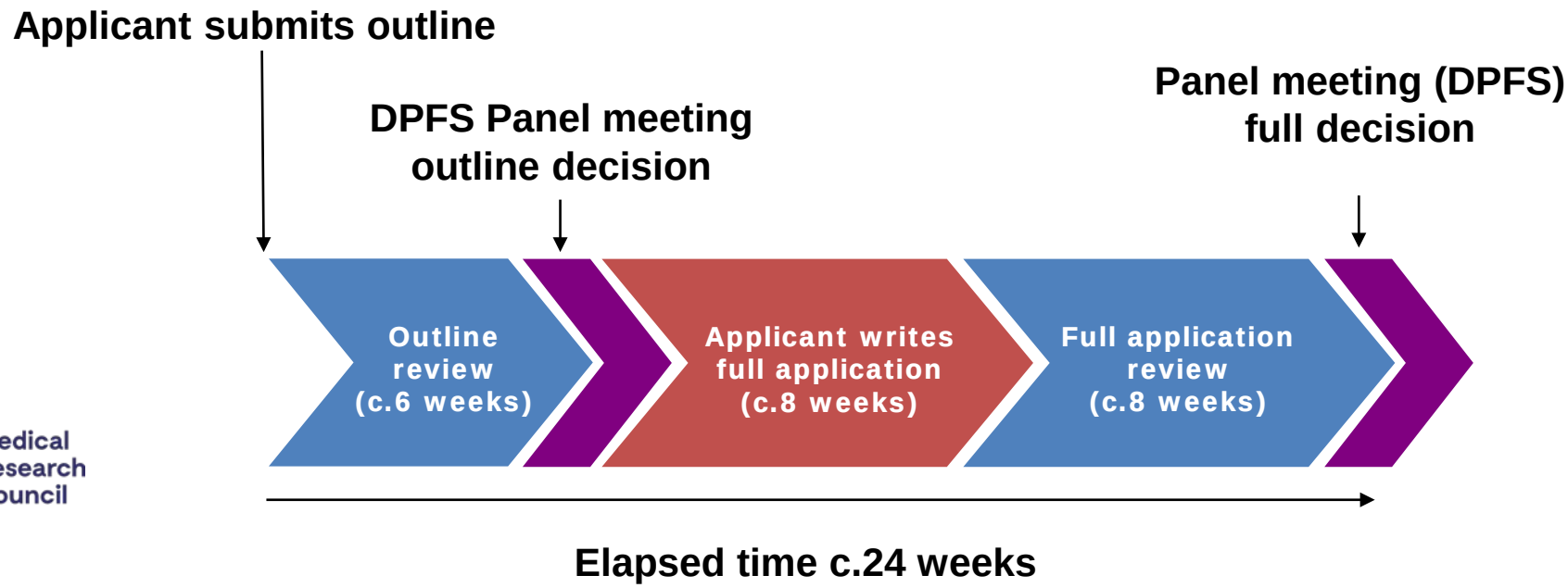
DPFS application process

- Two-step decision process
  - Outline application: DPFS Panel review
  - Full Application: Expert referee and Panel review
- Full stage applicants have six months in which to submit their application i.e. can skip a meeting



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Hints and Tips!
Writing a successful application

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Key elements of a great translational proposal

- Tailor your proposal to the audience
  - Outline: DPFS Panel
  - Full: Expert peer reviews and DPFS Panel

- Your proposal should answer these questions:
  - What is the underpinning problem or needs?
  - Where are you now?
  - What, specifically, will this project achieve? What is the next step?
  - What are the alternatives and why is your solution better?
  - What are the risks to the project and how will these be managed?
  - What is the long-term plan? How will your product impact care/clinical pathways?

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Need

- In addition to describing the clinical problem your work will address, you should indicate:
  - Where in the clinical pathway will your work be relevant?
  - What value will be added relative to current best practice?
  - Don’t forget to consider economics and feasibility
- Be specific and avoid catchy headline figures
- Focus on the need for your specific product/intervention

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Competition and market

- Clearly identify your competitions – why is your solution better?
  - Consider both related and unrelated avenues of work relevant to your condition of interest
  - Consider the potential impact of competitors doing well or poorly
  - Concentrate on benefits not features
  - Provide evidence or references to support your chosen approach
- Economics
  - In the long-term, will there be uptake of your work?
  - If the cost is higher than competing solutions, the need for extra spending will need to be justified
  - Consider the role of NICE where appropriate

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Rationale

- Why will your solution/approach work?

- Back up your argument with:
  - Robust scientific justification
  - Technical details - all our panels and reviewers are under CDA
  - Supporting data
  - If you are proposing a medicinal chemistry programme, provide structures
    - Medicinal chemistry supplement document should be included
  - Quantitative analysis where appropriate

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Deliverability: Objective and Approach

- What are the key objectives and deliverables?
- Support your approach:
  - Timeliness and innovation
  - The journey so far, capturing previous development and achievement
- Give details on your approach to achieving the objective:
  - Study design
    - Consult relevant experts, e.g. statisticians, CTU, methodology hubs, etc
    - For drug discovery programme, seek advice on the size of your screen and consider iterative development: SAR and PK/PD analysis to inform chemistry
  - Animal model
  - Patients/end-user involvements
  - Engagement with regulatory bodies and industry
  - End points and statistical analyses

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Deliverability: Project plan

- A good project plan will help you and your team to:
  - Identify critical path or rate-limiting activities
  - Allocate sufficient time and resources
  - Identify the key risks and put in place mitigation strategies
  - Measure success - Where are the key milestones?
- Use the **Gantt chart** to optimise and structure your work plans to deliver goal effectively
- Project plans are dynamic and evolve as a project develops
  - Active monitoring - **Project Management Group** should meet regularly to review progress
  - Timely response – Flag issues as they arise and put in place mitigation

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Milestones

- Major progress points that must be reached to achieve success
- Go/No-go decision points for your DPFS project
- A good milestone should describe:
  - Discrete packages of work to be carried out
  - Project schedule: The durations of each tasks and inform when is the right time for review
  - Measures for success:
    - Quantitative criteria - desirable and acceptable criteria
    - Probability of success
  - Risks and mitigation strategies

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Milestones

- Be specific and SMART
  - **S**pecific, **M**easurable, **A**ttainable, **R**elevant and **T**ime-Bound

Poor milestones	Effective milestones
MS1. Trial set up, recruitment of 200 patients in 8 centres in 24 months	MS1: Trial approvals obtained by month 6 MS2: First 4 sites open to recruitment and 50 patients recruited by month 12 MS3: All sites open by month 18 MS4: Recruitment completed by month 24

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Deliverability: Resources & Timelines

- Consider the resources and skills needed to deliver the project:
  - **Team** – Have you got all the expertise? Engineers, clinicians, statisticians, project manager, etc.
  - **Access** – Patients, samples, data, equipment, CRO time, etc.
  - **Costs** – Staff commitment, outsourcing, travel, regulatory advice, pharmacy, labelling, storage, etc.
  - **Time** – Tasks, approvals, staff recruitment, patient recruitment, clinical site set-up etc.

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Deliverability: Resources & Timelines

- Balance deliverability with resourcing
  - Over-costing will reduce value for money and the competitiveness of your proposal
  - Under-costing will reduce confidence that the work can be delivered

- For outsourced activities:
  - Recall that outsourced costs are largely met at 80% FEC
  - Spend time getting the right subcontractors and negotiate favourable terms
  - Scheduling - ensure their availability where needed
  - Due diligence to confirm their ability to deliver
  - Allocate sufficient time to fully execute agreements

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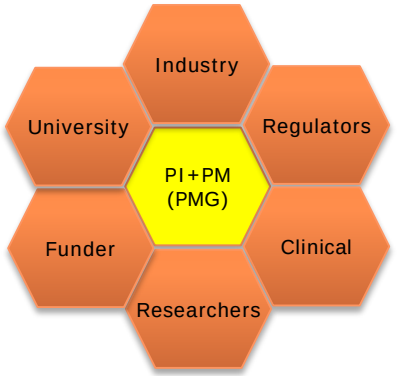
Deliverability: Project management

- The project team must be sufficiently broad to support all aspects of your project.
  - A trial proposal will require appropriate statistical expertise
  - A medical device proposal will typically require both clinicians and engineers
- All team members should have clear roles and their commitments justified
- For day-to-day project management – consider inclusion of a project manager
  - Multiple workstreams and outsourced work
  - Active monitoring and risk management is critical
  - DPFS has regular reporting requirement
  - MRC will meet appropriate project management costs



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Advantages of good project management

To investigator

- Enhanced opportunity for application success
- Better understanding of work to be done
- Improved control
- Easier reporting
- Clearer demarcation of work

To MRC

- Increased confidence in applicants' abilities to deliver
- Clearer reporting
- Clearer measures of progress

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Downstream Project Support and IP

- Downstream Project Support
  - Evidence of a well considered exit strategy provides confidence to the Panel that it is providing a bridge rather than a pier
  - Downstream manufacturing costs: although you may not bear these costs, you do design them in
  - Note that if you intend partnering with a company, please explain how the company will access necessary finance/collaborations to support the project's further development
- IP
  - Ensure that you provide details of the IP distribution agreements between academic and industrial parties

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Common pitfalls

- Insufficient justification on the medical need
- Development not aligned with clinical care pathway
- Insufficient technical details – all our panels and reviewers are under CDA
- Too far behind competitors
- Insufficiently differentiated from existing approaches
- Work too early for translation or insufficient evidence to support the investment
- Doubts about plan or its execution (milestones poorly aligned)
- Team does not have all the expertise
- Risk outweighs benefit
- No freedom to operate
- Trial design/Sample sizes and experimental power not fully justified

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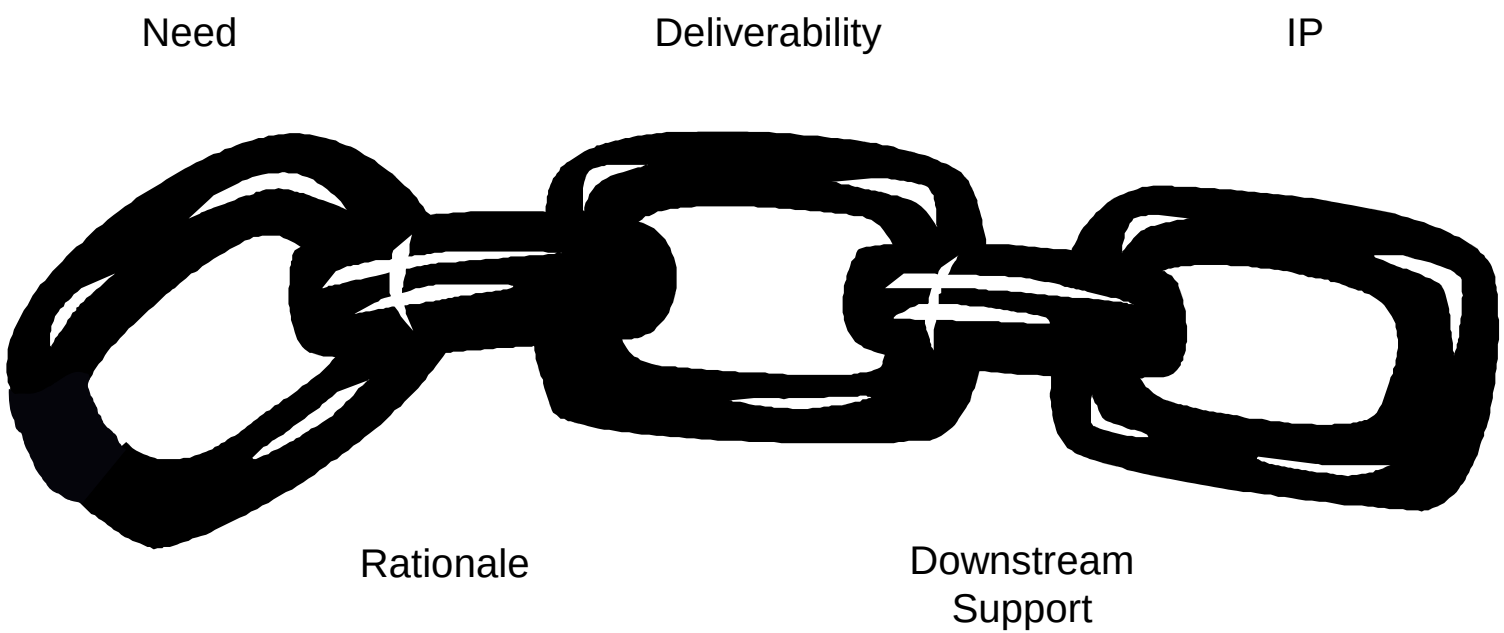
In conclusion

- Your application will only be as strong as its weakest link



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Contacts

If you have any specific queries about this funding scheme, please contact:

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Dr Charlotte Durkin	Charlotte.Durkin@mrc.ukri.org	Regenerative medicine
Dr Tim Ellis	Tim.Ellis@mrc.ukri.org	Biomarkers, diagnostics and psychological therapies
Dr Agnes Leong	Agnes.Leong@mrc.ukri.org	Medical devices, digital health (software development/AI tools), radiology and imaging
Dr Penny Morton	Penny.Morton@mrc.ukri.org	Advanced therapeutics: vectors, gene, nucleic acid and siRNA therapies
Dr Alex Phillips	Alexandra.Phillips@mrc.ukri.org	Antibodies, proteins and peptide therapeutics

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