

Submission

2016 National Research Infrastructure Roadmap Capability Issues Paper

Submission No: IP0022	
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Submission Questions

Question 1: Are there other capability areas that should be considered?

We contend that infrastructure to support the emerging landscape of regenerative medicine based therapies is an urgent addition to the national research infrastructure landscape. We are in full agreement with the statement within the NCRIS capability document surrounding regenerative medicine that suggests that “ a national capability providing researchers with advice and access to cell lines, protocols and training should be considered. This would assist Australia to develop regenerative medicine capability to significantly improve health outcomes.”

There is a requirement to develop a mechanism for ensuring Australia’s strong leadership in the Regenerative Medicine sector translates into a practical benefit for as many Australians as possible. The tantalising promise of this field of medical research is that it has the potential to impact on a nearly limitless range of diseases that afflict the human condition. In our opinion, no other area of medical science is poised to make such a broad clinical impact in the next decade. We wish to design and implement infrastructure that ensures we harness the potential of this sector to benefit the health of the Australian population and kick start innovation. Capital investment in high throughput & automated technologies for safety assessment of cells, for preclinical work and scale-up for drug screening and toxicology are required, in addition to investment in new technology for discovery. Reference laboratories will play a key future role in allowing access to technologies for a broader uptake. We urgently need to capitalise on the very strong basic science base in this discipline so as Australia can position itself to become a major international supplier of regenerative medicine technologies and therapeutics in a market that is expected to grow to \$50 billion by 2019.

The impediments to this occurring are twofold. A lack of an integrated pipeline of infrastructure and skill sets to facilitate movement of promising regenerative medicine based therapies into clinical trials and the paucity of local engaged commercial entities to promote their development. In attempting to develop a model of how these issues are best resolved we looked for examples of best practice internationally. A number of significant North America and European initiatives have been implemented in the last decade backed by dedicated government funding, that target diseases of considerable burden with well integrated pipelines of regenerative medicine based therapies. As a result, many sponsored clinical trials of cell and regenerative therapies are underway in these locations. They serve as different templates on how centralised government funding can unlock the therapeutic potential of a robust basic research pipeline, and bridge the gap between basic discovery science and clinical impact.

From an infrastructure capacity building, one of the most developed of these frameworks is UK Regenerative Medicine Platform. The UKRMP addresses the technical and scientific challenges associated with translating promising scientific discoveries in this area towards clinical impact.

Specific decentralised hubs have been funded to tackle specific issues that the sector has identified that impact on clinical delivery in the Regenerative Medicine sector. Collectively, the Hubs provide a world-leading program to promote the development of regenerative therapies. Each of the Hubs provides a UK centre of expertise/knowledge with the necessary critical mass to address key translational challenges and provide new tools, protocols and resources with broad applicability that can be utilised by other UK research groups in academia and industry. This is a different more focused approach than funding a competitive grant scheme and it tackles head on the infrastructure bottlenecks in translating particular technologies. It is a diversified model at different sites that draws on the UK's strengths at distinct research environments. In many ways, it fits well with the dispersed nature of Regenerative Medicine Research in this country, and such a model has been endorsed by the leadership of Stem Cells Australia. We call for the setting up of a network of reference laboratories for in stem cell and regenerative medicine to aid in translation of promising therapeutic approaches into the clinic

Question 2: Are these governance characteristics appropriate and are there other factors that should be considered for optimal governance for national research infrastructure.

Question 3: Should national research infrastructure investment assist with access to international facilities?

On a case by case basis

Question 4: What are the conditions or scenarios where access to international facilities should be prioritised over developing national facilities?

Where access to a similar facility is not possible in Australia and it strategically important to do so.

Question 5: Should research workforce skills be considered a research infrastructure issue?

Absolutely: There is little point having research enabling infrastructure without the know how to manage it.

Question 6: How can national research infrastructure assist in training and skills development?

Building relationships with international agencies and infrastructure where training can be achieved at world best practice.

Question 7: What responsibility should research institutions have in supporting the development of infrastructure ready researchers and technical specialists?

Partnerships with national funding should be developed between Institutions and NCRIS to develop infrastructure supporting individuals. In essence, this must be part of any plan to host and be funded for the development of national infrastructure.

Question 8: What principles should be applied for access to national research infrastructure, and are there situations when these should not apply?

Broadest access for the lowest access cost. There is simply no point in building such infrastructure if it is out of reach price wise for the average scientist.

Question 9: What should the criteria and funding arrangements for defunding or decommissioning look like?

Case by case as it will depend on each piece of infrastructure.

Question 10: What financing models should the Government consider to support investment in national research infrastructure?

Co-investment with State Government and institutions.

Question 11: When should capabilities be expected to address standard and accreditation requirements?

These should be built into operational plans from the start if they are critical to the success of the infrastructure involved.

Question 12: Are there international or global models that represent best practice for national research infrastructure that could be considered?

In Regenerative Medicine we are suggesting the UK Regenerative Medicine Platform represents such a paradigm.

Question 13: In considering whole of life investment including decommissioning or defunding for national research infrastructure are there examples domestic or international that should be examined?

It should be considered but rarely is. CERN perhaps is the institution with the most experience of decommissioning large infrastructure.

Question 14: Are there alternative financing options, including international models that the Government could consider to support investment in national research infrastructure?

None of which we are aware.

Health and Medical Sciences

Question 15: Are the identified emerging directions and research infrastructure capabilities for Health and Medical Sciences right? Are there any missing or additional needed?

As outlined above we suggest that infrastructure to support the emerging landscape of regenerative medicine based therapies is an urgent addition to the national research infrastructure landscape

Question 16: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Yes, we consider that for the Australian regenerative medicine sector a relationship with the UK Regenerative Medicine Platform would be desirable as well as with the key Canadian (Toronto) initiatives including the Medicine by Design Project and the Center for Commercialization of Regenerative Medicine (CCRM). The Canadian government has funded both of these key

regenerative medicine initiatives to create an unparalleled environment for innovation. The result has been spectacular for the sector producing a sustained global nexus for regenerative medicine commercialisation that unifies dynamic and focused business leadership with high value innovative translational technology platforms based on demonstrated excellence in fundamental stem cell and biomaterial science. We propose a similar investment in the Australian based regenerative medicine would be equally transformative, and overcome many of the gaps and challenges identified in creating clinical impact in this field. Furthermore, a considerable component of the Medicine by Design initiative is for co-investment in international collaboration, much of which will revolve around regenerative medicine infrastructure. NCRIS could play a critical role in providing the resource to co-invest in this infrastructure and collaboration.

Question 17: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Health and Medical Sciences capability area?

In 2008 Australia became an associate member of the European Molecular Biology Laboratory (EMBL), Europe's flagship research institution for the life sciences. Membership has given Australia the opportunity to internationalise Australian life science research and enabled Australia to create highly competitive research teams networked across the nation and with Europe. Membership activities, overseen by EMBL Australia and developed in conjunction with the EMBL focus on (i) internationalising Australian research (ii) empowering and training our best early career researchers and research leaders and (iii) embedding powerful new enabling tools such as bioinformatics and systems biology in Australian life science. The success of this initiative has seen the initial 7-year membership renewed on an ongoing basis (subject to Australian govt. approval).

The EMBL membership has proven a successful mechanism to provide access for Australian life science researchers to global expertise and increased international collaborations.

Moreover, the experience and expertise developed in the EMBL Australia initiative form a compelling template for progressing the proposed linkages with the UK and Canadian regenerative medicine initiatives.

On a smaller scale EMBL Australia has been an essential component of the success story of the formation of the Australian Regenerative Medicine Institute, which has housed the EMBL Australia administration and has been the largest node. Its further support and existence is essential for the continued success of the institute. Specifically, EMBL Australia is critical for the internationalisation of our science. It has been of particular importance in developing critical infrastructure such as high end imaging needs and the analysis of large datasets such instrumentation produces. Our ability to recruit future leaders, training (both in terms of PhD students but also with respect to new techniques and technologies) and access to major international resources (e.g. genomic-related, model organisms) have all been enhanced by this initiative.

Environment and Natural Resource Management N/A

Question 18: Are the identified emerging directions and research infrastructure capabilities for Environment and Natural Resource Management right? Are there any missing or additional needed?

Question 19: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 20: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Environment and Natural Resource Management capability area?

Advanced Physics, Chemistry, Mathematics and Materials N/A

Question 21: Are the identified emerging directions and research infrastructure capabilities for Advanced Physics, Chemistry, Mathematics and Materials right? Are there any missing or additional needed?

Question 22: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 23: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Advanced Physics, Chemistry, Mathematics and Materials capability area?

Understanding Cultures and Communities N/A

Question 24: Are the identified emerging directions and research infrastructure capabilities for Understanding Cultures and Communities right? Are there any missing or additional needed?

Question 25: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 26: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Understanding Cultures and Communities capability area?

National Security N/A

Question 27: Are the identified emerging directions and research infrastructure capabilities for National Security right? Are there any missing or additional needed?

Question 28: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 29: Is there anything else that needs to be included or considered in the 2016 Roadmap for the National Security capability area?

Underpinning Research Infrastructure

Question 30: Are the identified emerging directions and research infrastructure capabilities for Underpinning Research Infrastructure right? Are there any missing or additional needed?

As outlined above we suggest that infrastructure to support the emerging landscape of regenerative medicine based therapies is an urgent addition to the national research infrastructure landscape.

Question 31: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

As outlined above we think in the regenerative medicine space a relationship with the UK Regenerative Medicine Platform would be desirable as well as with the Medicine by Design and Center for Commercialization of Regenerative Medicine (CCRM) in Toronto.

Question 32: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Underpinning Research Infrastructure capability area?

Data for Research and Discoverability

Question 33 Are the identified emerging directions and research infrastructure capabilities for Data for Research and Discoverability right? Are there any missing or additional needed?

Question 34: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 35: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Data for Research and Discoverability capability area?

Other comments

If you believe that there are issues not addressed in this Issues Paper or the associated questions, please provide your comments under this heading noting the overall 20 page limit of submissions.